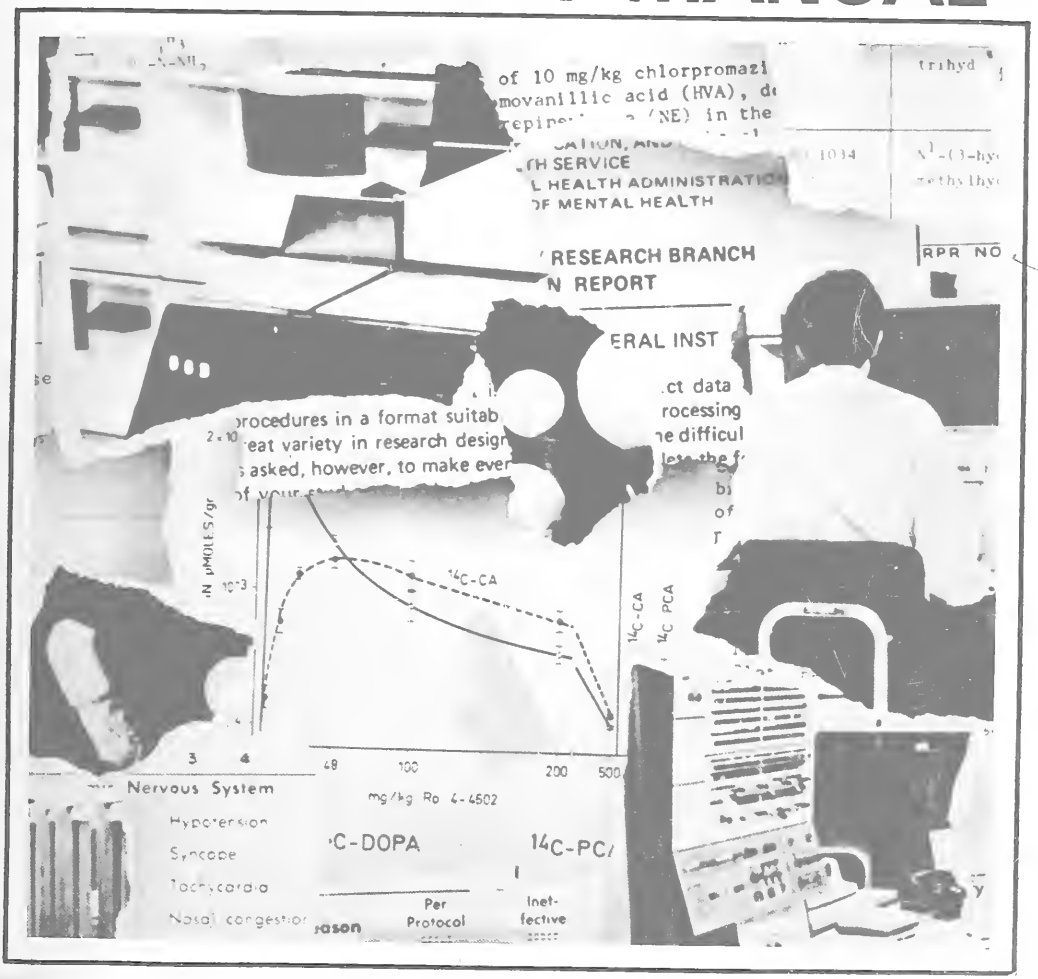
ECDEU ASSESSMENT MANUAL



U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE • Public Health Service
Alcohol, Drug Abuse, and Mental Health Administration

ECDEU ASSESSMENT MANUAL FOR PSYCHOPHARMACOLOGY Revised, 1976

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U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
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National Institute of Mental Health
Psychopharmacology Research Branch
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CONTENTS

INDEPENDENT ADULT SCALES

INDEPENDENT ADVERSE REACTION SCALES

MEDICAL SCALES

DOCUMENTATION (THE DATA PACKAGE)

APPENDICES

ACKNOWLEDGEMENTS

This revision of the 1970 ECDEU Assessment Manual represents the cooperative effort of many individuals whose comments and criticisms have served to sustain the ECDEU program as an evolving entity. The adult elements of the ECDEU Assessment Battery have been modified and expanded over the period of the last decade as a consequence of the interactions among those investigators employing the Battery in clinical drug trials, the pharmaceutical industry, the Psychopharmacology Research Branch of the National Institute of Mental Health and the Biometric Laboratory of The George Washington University. The size of this group makes it difficult to acknowledge every individual by name as I would wish, and, therefore, appreciation for their contributions is extended collectively but no less warmly.

The newer pediatric section of the ECDEU Assessment Battery is the culmination of several years of effort on the part of the Pediatric Psychopharmacology Conference which was organized under the auspices of the Psychopharmacology Research Branch. The contributions of this Conference have been summarized in a 1973 Special Issue of the Psychopharmacology Bulletin, entitled "Pharmacotherapy of Children" and are happily acknowledged here.

A number of individuals have been kind enough to provide special commentaries for sections of the Manual. A list of these contributing authors is given below. To them, and to the developers of all the assessment instruments cited in this Manual, deep appreciation is expressed.

The emergence of the present Assessment Battery has been accompanied by the development of a data processing system called the Biometric Laboratory Information Processing System (BLIPS). To the entire staff of the Biometric Laboratory - and particularly to those cited below - I want to extend special thanks for the ingenuity and patience they have shown during the several years of almost continuous designing and redesigning of BLIPS.

W.G.

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INTRODUCTION

This revision of the 1970 assessment manual describes the redesigned and expanded ECDEU Assessment Battery. Developed under the auspices of the Psychopharmacology Research Branch of the National Institute of Mental Health, the original and present assessment batteries have been an integral part of their Early Clinical Drug Evaluation program (ECDEU). The present product has evolved through a continuous interplay of interests among the participants in the ECDEU program - the investigators, the pharmaceutical industry, the Food and Drug Administration, Psychopharmacology Research Branch and the Biometric Laboratory of The George Washington University.

Intended for an audience with diverse interests, the general plan of the Manual mimics the usual order of events as they occur in a research study, i.e., from the planning phase to the analyses and interpretation of results. Individual instruments are presented in the order in which they are employed and are further categorized by purpose. Comments by their respective authors follow the description of the instruments. Being cognizant of the need for brevity, descriptions of the instruments, for the most part, have been kept to a minimum. For those who wish more detailed information about a particular scale and its psychometric properties, references have been provided and it is suggested that contact be made with the author/s.

Definitiveness is not implied in the choice of scales included in the Battery. A large number of scales with demonstrated utility in psychopharmacological assessment were discussed and evaluated by the ECDEU participants. The final selection was made by consensus. Thus, many scales of equal merit were omitted; but, through the versatility of the General Scoring Sheet, these scales may be processed and analyzed with almost equal facility. Several of the pediatric scales are frankly experimental. When the participants of the Pediatric Workshop felt that there were no completely satisfactory scales available for a particular assessment area, they set about to construct a new scale to serve the purpose. Necessarily, these new instruments have not yet undergone the degree of psychometric validation which characterizes the more venerable scales of the Battery. Recognizing the needs of the field, however, these new scales have been introduced with the understanding that psychometric analyses will be performed concurrently with their use.

In conjunction with the dissemination of the standard assessment battery, the Biometric Laboratory has provided processing and analytical services to the participants of the ECDEU program. The Biometric Laboratory Information Processing System (BLIPS) has been developed to generate standard documentation for the individual study. Consisting of a series of descriptive and statistical data displays as well as card output, the documentation provides the investigator with the fundamental analyses of his study based on an edited ("clean") data set. Given the uniqueness of a given study, standard documentation can not meet all specific needs. To the extent possible, however, requests for special analyses will be serviced. While the extent to which the investigator makes use of these services is at his discretion, both the Biometric Laboratory and Psychopharmacology Research Branch stand ready to provide assistance in the planning of the study; the selection and scheduling of assessments, the training of personnel in the use of the Battery and the choice of statistical techniques.

PARTICIPATION IN ECDEU PROGRAM

As originally conceived, the ECDEU program consisted primarily of grant-supported clinical investigators working in the common area of psychotropic drug evaluation (both new and established compounds). One of the problems they encountered, and task they accomplished, was the development of a uniform battery of clinical assessment instruments known as the ECDEU Standard Reporting System, first introduced for utilization in 1967. The rationale behind this effort was twofold. First, it was felt that such a system would enhance both the quality of early clinical drug research and allow greater generalizability of results across studies and investigating units. Second, data collected on common forms could be stored in a data bank for future study and research.

Since the implementation of this Standard Reporting System and the Biometric Laboratory Information Processing System (BLIPS), the ECDEU program has evolved into more than an extramural grant support program for psychotropic drug research teams. In collaboration with The George Washington University Biometric Laboratory, the ECDEU Standard Reporting System has been made available to any investigator interested in conducting clinical trials, whether federally grant supported or not. To utilize these services, the investigator is requested to:

1. Submit a Research Plan Report (021-RPR) and agree to send the study data to the Biometric Laboratory.

2. Collect sufficient information about the subjects in his study so that the data can be entered into the ECDEU data bank. This means, essentially, that a core of data must be collected for each patient. Such a core of data includes:

    a. Demographic information; e.g., The Adult Personal Data Inventory.

    b. At least one major rating scale of efficacy or psychopathology; e.g., the Brief Psychiatric Rating Scale.

    c. Information on dosage and toxicity; e.g., the Dosage Record and Treatment Emergent Symptoms Scale.

In return, he receives a sufficient number of assessment scales to conduct his research. Once the trial is completed, the forms are returned to the Biometric Laboratory for processing and data analyses, the results of which are sent to the investigator in the form of a standard data package. The rating scales and data processing services are provided at no charge - our sole "remuneration" being the opportunity to add the investigator's data to the data bank. It should be stressed that an investigator's data and/or results are never published or disseminated to others without his permission.

Along with extending participation in the ECDEU program to a larger group of investigators, greater latitude in the types of studies which are considered appropriate for the services is now permitted. Originally, only studies focussed on the investigation of drug effects were accepted. Now, studies in which the investigation of drug effects is peripheral may be submitted. This is particularly true in the pediatric area where the need for standardization data is great. Investigators who are uncertain about the appropriateness of their study are urged to contact the Biometric Laboratory or Psychopharmacology Research Branch.

GENERAL DESCRIPTION OF THE BATTERY

The most prominent feature of the new Battery - expansion aside - is the redesigned format of the scales. In the original Battery, the scales were self-contained with both items and their response positions preprinted on the form. While this format provided maximal rater legibility, the amount of data retrievable per page was low; and, since it was necessary to record identifying information on each page, the rater was faced with a great deal of redundant encoding. To offset these problems, items and response positions were separated. A universal answer sheet called the General Scoring Sheet was designed to serve as a means of encoding not only responses to the scales included in the Battery, but any type of data which an investigator might wish to encode.

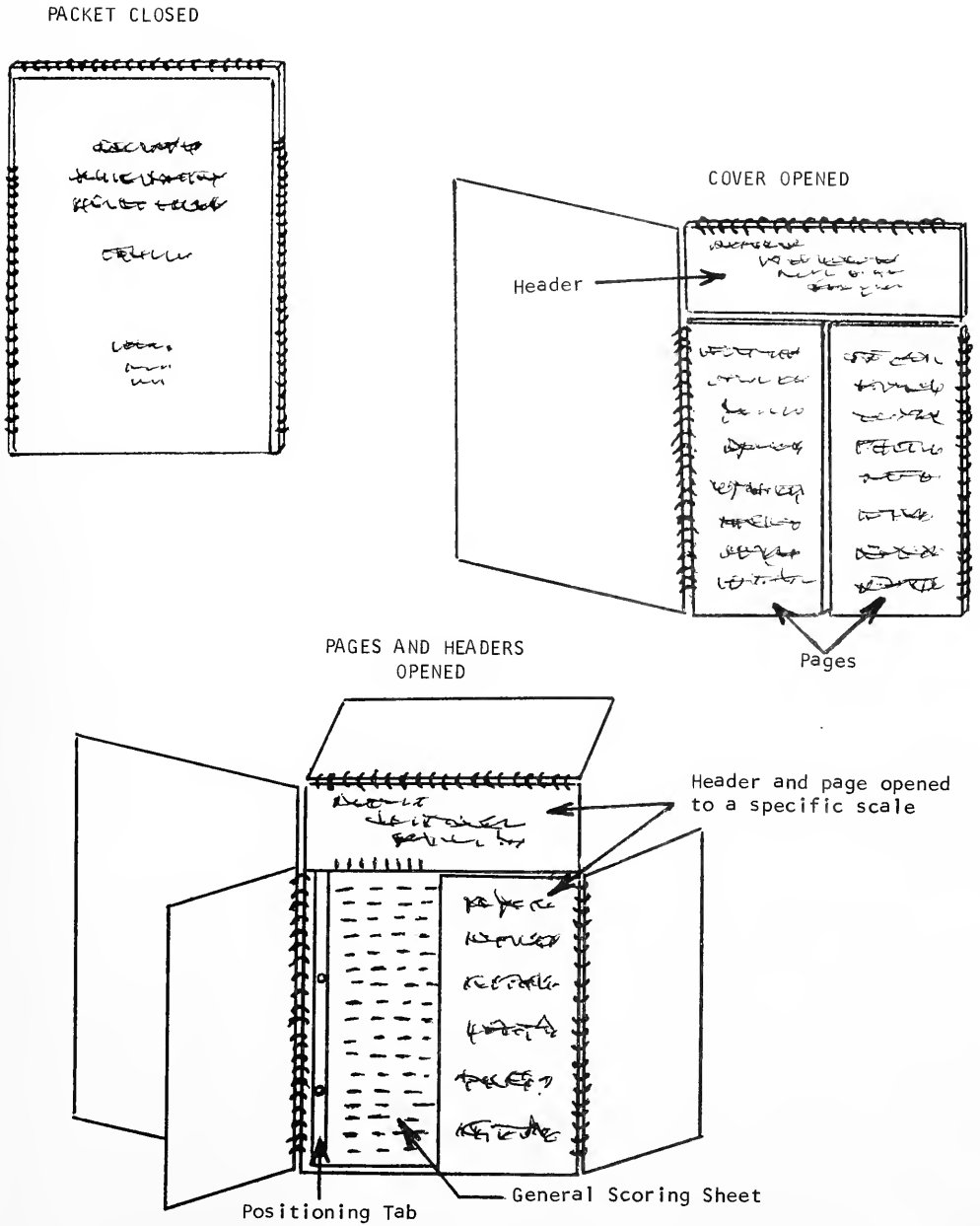
Coupled with the General Scoring Sheet, a number of assessment packets were developed. Each of these packets constructed of durable plastic contains the items of a set of related assessment instruments. Selecting the desired instruments from this set, a rater encodes responses on the General Scoring Sheet while retaining the packet for subsequent use.

Figure 1 illustrates the manner in which the packets are used. Spiral bindings appear on 3 sides of the packet. Upon opening the cover, there are 3 sections each attached to one of the spiral binders. Along the top are "headers", i.e., sections which contain instructions and scalepoints for a specific scale. The 2 lower sections open up from the middle and contain items for specific scales. The instructional header and the appropriate item pages for a specific scale are color-coded for the convenience of the rater. When all of the headers and pages are open, the back cover of the packet can be seen, and it is here that a General Scoring Sheet is placed - fixed by a positioning tab. With the General Scoring Sheet in place, the rater flips to the desired header and page; finds the appropriate area of the General Scoring Sheet exposed and is ready to encode. There are presently 5 packets in the Battery:

1. Demographic - containing 3 instruments for both pediatric and adult populations.
2. Pediatric - containing 6 instruments for rating psychopathology, diagnosis, adverse reactions and termination status.
3. Adult - containing 9 instruments - 3 of which are also contained in the Pediatric packet - for adult populations.
4. Nurse - containing 4 pediatric and adult behavioral scales for rating by ward or paraprofessional personnel.
5. Psychologist - containing 9 pediatric and adult psychometric scales.

FIGURE I

THE ASSESSMENT PACKET



In addition to the 28 scales contained within 5 packets, there are 15 independent (self-contained) instruments. Table 1 catalogues all of the scales which comprise the standard ECDEU Assessment Battery and classifies them by applicability, format, content and rater. Applicability refers to the population (s) for which a scale is appropriate. Format indicates whether a scale is designed for opscan or not and whether it is contained within a packet or is independent. The content areas are: demographic (Dem), efficacy (Eff), toxicity (Tox), medical (Med), psychometric (Psy) and administrative (Adm). Finally, the rater is designated. Fourteen of the 43 instruments are "universal" - reflecting the integration and compatibility of the Battery across diverse research populations.

TIME TABLE FOR USING THE ECDEU BATTERY

Table 2 depicts the usual order in which investigators employ various instruments in the ECDEU Assessment Battery during the 3 major phases of a research study - planning, data collection and analyses.

Planning phase - Having developed an hypothesis and a research design to test it, the investigator decides to utilize the assessment instruments and services of the ECDEU program. Generally, he will have prepared his own written protocol from which he can extract the information required on the Research Plan Report (RPR).

The RPR serves to notify the Biometric Laboratory and Psychopharmacology Research Branch that a study is contemplated and that it is expected to take a certain length of time for completion. Along with its intrinsic - and more important - value as a description of ongoing research, the RPR serves to alert the Laboratory to its future work load and, upon receipt of the data, to the nature of the study and the procedures employed. Along with the RPR, an ECDEU Order Form (EOF) requesting the quantities of forms necessary to carry out his study is completed and mailed to the Biometric Laboratory. Should problems be encountered in completing the RPR or EOF, assistance can be obtained from the Biometric Laboratory.

Data Collection Phase - With the availability of the General Scoring Sheet, the choice of assessment instruments is not limited to the standard ECDEU scales. The investigator may select those devices which he feels will best serve his needs - provided that he supplies the core of information required for ECDEU services. (p..11).

For new investigators unfamiliar with the instruments, the most frequent choice patterns of experienced ECDEU investigators working with adult populations may be helpful. The listing of these patterns should not be construed as obligatory but merely as a guide.

1. Neuroleptic Studies with Schizophrenic Populations
   a. Brief Psychiatric Rating Scale (BPRS)
   b. Clinical Global Impressions (CGI)
   c. Nurses' Observation Scale (NOSIE)

TABLE I

CATALOGUE OF ASSESSMENT INSTRUMENTS

	APPLICABILITY				FORMAT & CONTENT			RATER
	Child	Adult			Opscan		Non-Opscan	
		Inpt.	Outpt.	Ger.	Packet	Independ		
Research Plan Report	X	X	X	X			Adm	Princ.Inv.
ECDEU Order Form	X	X	X	X			Adm	" "
Children's Personal Data Inventory	X				Dem			S.W./Psychiat.
Children's Symptom History	X				Dem			" "
Adult Personal Data Inventory		X	X		Dem			" "
Prior Medication Record	X	X	X	X		Dem		Psychiat./Psychol.
Children's Psychiatric Scale	X				Eff			"
Children's Diagnostic Scale	X				Dem			"
Children's Diagnostic Classification	X				Dem			"
Brief Psychiatric Rating Scale		X	X	X	Eff			"
Depression Status Inventory		X	X	X	Eff			"
Hamilton Depression Scale		X	X	X	Eff			"
Hamilton Anxiety Scale			X		Eff			"
Anxiety Status Inventory		X	X		Eff			"
Wittenborn Rating Scale		X	X	X	Eff			"
Clinical Global Impressions	X	X	X	X	Eff			"
Dosage Record & Trmt.Emrgnt.Symp.	X	X	X	X	Tox			"
Patient Termination Record	X	X	X	X	Dem			"
Children's Behavior Inventory	X				Eff			Nurse
Nurses Observation Scale		X	X	X	Eff			"
Plutchik Geriatric Scale				X	Eff			"
Nurses Global Impressions	X	X	X	X	Eff			"
Teacher Questionnaire	X					Eff		Teacher
Parent Questionnaire	X					Eff		Parent
Parent-Teacher Quest.	X					Eff		Parent/Teacher
Self-Report Symptom Inventory		X	X			Eff		Self
TESS Write-In Scale	X	X	X	X		Tox		Psychiat.
Subject TESS	X					Tox		Self/Parent
Laboratory Data	X	X	X	X		Tox		Psychiat.
Phys & Neur. Exam.for Soft Signs	X					Med		Neurol.
Psychometric Scales								
for Children and Adults (7 scales)	X	X	X	X	Psy			Psychol.
Psychol.Exam.Behav. Profile	X				Psy			"
Friedhoff Task Behavior Scale		X	X	X	Psy			"
Self Rating Depression Scale		X	X	X		Eff		Self
Data Shipment	X	X	X	X			Adm	Princ.Inv.
Research Completion Report	X	X	X	X			Adm	" "

TABLE 2

TIME TABLE FOR USING THE ECDEU BATTERY

PLANNING PHASE	DATA COLLECTION PHASE: PRETREATMENT	DATA COLLECTION PHASE: POSTTREATMENT	ANALYTIC PHASE
Research Plan Report ECDEU Order Form			
	Demographic Packet Prior Medication Sheet		
	Psychiatrist Packet Psychologist Packet Nurse Packet Independent Behavioral Scales	---Repeated at least once	
		Patient Termination Record	
			Data Shipment-accompanying data sent to Biometric Laboratory Research Completion Report-following analyses of data

2. Antidepressant Studies
   a. Hamilton Depression Scale (HAMD)
   b. Clinical Global Impressions (CGI)
   c. Depression Status Inventory (DSI)
   d. Self Rating Depression Scale (SDS)

3. Anxiolytic Studies
   a. Hamilton Anxiety Scale (HAMA)
   b. Clinical Global Impressions (CGI)
   c. Anxiety Status Inventory (ASI)
   d. Self Rating Anxiety Scale (SAS)
   e. Self Report Symptom Inventory (SCL-90)

Along with appropriate demographic information, the assessment of side effects, and the recording of dosages through the use of an instrument such as the Dosage Record and Treatment Emergent Symptom Scale (DOTES) should be considered. Finally, information concerning the disposition of subjects; e.g., Patient Termination Record (PTR), should be gathered.

Analytic phase - Two administrative forms are completed at this phase. The new Data Shipment (071-DS) serves such a vital function in BLIPS II that processing of a study simply cannot proceed without an accompanying DS. The Research Completion Report (059-RCR) completes the transaction by documenting the investigator's overall conclusions and future plans as based on the results of his study.

GENERAL INSTRUCTIONS

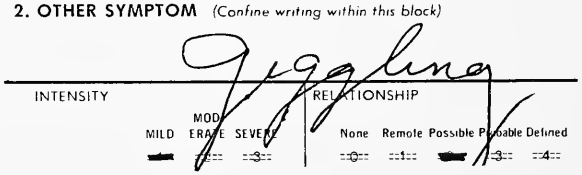
For the rater, the substantive judgments he makes are of paramount importance - not the way in which he records those judgments on a sheet of paper. These instructions, unfortunately, are concerned with the unavoidable mechanics of encoding those judgments on op-scan sheets. It has been our experience that encoding errors are - by far - the prime reason for delays and misinterpretations during data processing. It is important, therefore, that raters become familiar with the "do's" and "don't's" of op-scan encoding.

1. For those unfamiliar with it, the optical scan (op-scan) format can be frustrating, since it places strict constraints upon the rater. The op-scan reader is a sensitive machine which compulsively records intended as well as unintended marks. It should be remembered that an op-scan page is entirely covered with a field of response positions. Though not visible to the rater, these positions are "read" by the op-scan machine. With appropriate programming, many - but not all - of these extraneous positions can be suppressed. Consequently, some will be "triggered" by superfluous or incorrectly entered marks. Therefore, FOR ALL OP-SCAN SCALES, the following rules must be observed:

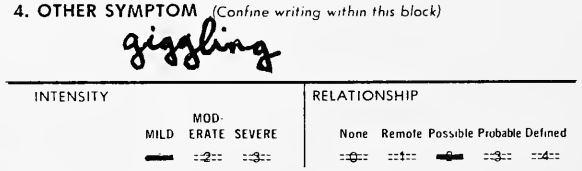
A. USE ONLY A #2 PENCIL. Ink, ball point, felt markers, etc. will not be "read" at all or will be read haphazardly.

B. DO NOT MAKE EXTRANEOUS MARKS ON THE GENERAL SCORING SHEET OR ANY OTHER FORM. Writing, when permissible, must be completely confined to the areas specified. Extra marks and/or writing in prohibited areas trigger multiple responses which will be rejected later during the editing process.

Example - On the TESS Write-In Scale (TWIS), the rater wishes to record the presence of the symptom "giggling" as mild and possibly related to the drug. He encodes as follows:



In this example, both INTENSITY and RELATIONSHIP may be rejected in the editing process because the lower part of the "g"s intrude into the "INTENSITY" and "RELATIONSHIP" areas and may be read by the op-scan reader as illegal multiple responses. The correct way to encode "giggling" is:

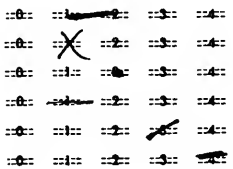


Here the rater has confined his writing completely within the specified area and no illegal multiple responses are evoked.

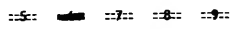
C. CONFINE YOUR MARK WITHIN THE TWO PARALLEL LINES. Slashes or flourishes which extend beyond the parallels result in multiple responses; i.e., 2 response positions being "read" by the op-scan machine. Marks which do not fill in all of the space between the parallels, on the other hand, may not be "read" at all.

Examples:

Incorrect



Correct



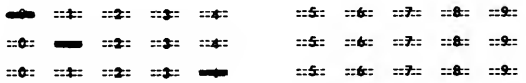
D. DO NOT USE STAPLES OR PAPER CLIPS to affix forms or pages together. Similarly, DO NOT PUNCH HOLES in the forms.

E. Please ERASE THOROUGHLY when changing a response. Failure to erase cleanly usually results in both the partially erased and corrected responses being "read".

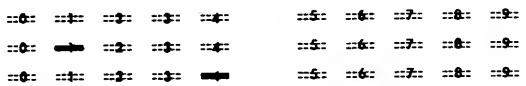
F. WHEN NUMERICAL VALUES ARE REQUIRED, ALL INDICATED DIGITS MUST BE MARKED including leading and following zeros.

Example: Given a 3-digit field, the rater wishes to record 14.

Correct



Incorrect



NOTE - Numerical values of more than one digit are always encoded vertically on 2 or more rows.

2. Generally, the scales require the rater to assess effects which are directly observable either in word or deed. Inferences should be minimized. While this restricts the rater, variability related to rater experience and theoretical orientation is reduced.

3. With some exceptions, the scales require a time-limited evaluation, i.e., the presence, absence and/or intensity of symptom at the time of the rating or within a specified time span prior to the rating. For example, on the Children's Psychiatric Rating Scale (CPRS) the subject reports feeling depressed "a couple of months ago, but not now". Since the time span for this item (35) is "now or within the past 7 days", the rater marks the item "Not Present". At the discretion of the principal investigator and with appropriate communication to the Biometric Laboratory, alternative time spans may be specified for a particular study objective. Suggested rating spans, where applicable, are given with each scale.

4. Raters often exhibit a tendency to remain in the conservative center of a scale. When undecided about two alternatives, the rater should choose the response nearer the extreme end of the scale. For example, if undecided whether to rate "mild" or "moderate" on an item in which there has been a positive change from "severe", the rater should choose "mild" - the alternative nearer the positive end of the scale. Similarly, the rater should choose the alternative representing the higher degree of pathology when he is undecided about the severity of illness. In essence, raters should choose the more "radical" response in either the direction of improvement or deterioration.

5. The style of interview is left to the discretion of the rater. Most raters quickly establish a method from which the material necessary for rating can be extracted. Generally, the method takes the form of a semi-structured interview in which target areas are explored in a more or less consistent sequential fashion. It is suggested, however, that raters not change interviewing techniques during the course of a study.

6. It is strongly urged that every effort be made to maintain the same rater for all assessments of a given subject on a given scale.

7. The processing system has been programmed to expect a response for all items. Raters are, therefore, urged to complete all items on all forms they use. When this is not possible, the rater should utilize the "Not Ascertained" or "Not Assessed" response positions. "Not Ascertained" should be interpreted as not available, not applicable, no answer, or in those instances where the information is considered specious or improbable. "Not Assessed" indicates that the rater made no effort to elicit the information.

8. While the investigator has complete freedom to employ any additional assessment techniques he wishes, the standard scales, their formats and items must not be modified or altered. It is imperative that data sent to the Biometric Laboratory be constituted under the contexts provided in this manual.

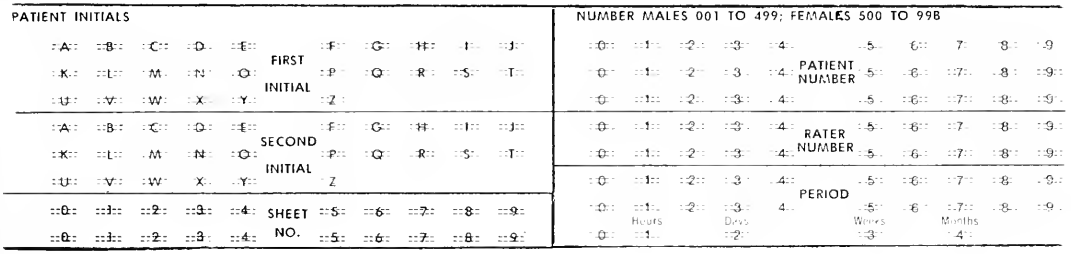
9. It is not possible to construct a manual which provides answers for all situations or contingencies. Should questions arise, feel free to contact either Biometric Laboratory or Psychopharmacology Research Branch by mail or telephone.

ENCODING THE IDENTIFICATION BLOCK

The identification (ID) block consists of 8 horizontal rows - 20 response positions (columns) to each row - and uniformly appears on all op-scan forms. The ID block provides response positions for the encoding of:

1. Patient Initials
2. Patient Number and Sex
3. Rater Number
4. Sheet Number
5. Period (Rating) Number

THE IDENTIFICATION (ID) BLOCK



Complete and accurate encoding of the ID block is of paramount importance. In BLIPS, errors and/or omissions within this block are regarded as "catastrophic errors"; i.e., errors which half any further processing of the data. Delays can be lengthy since ID problems may bring the entire data set under suspicion and, consequently, require extensive verification.

1. Patient Initials - First initial refers to given name; second to surname. Patient initials are utilized only during the editing phase; they never enter the data bank, thereby preserving patient anonymity.

2. Patient Number and Sex - Patient number requires a 3-digit code. Numbers between 001 and 499 designate male; 500 to 999 female. The investigator is required to assign numbers to his research sample. Any 3 digit numbers, within the stricture on sex - may be used; although it is the usual practice of investigators to assign numbers sequentially as subjects enter the study. In double-blind studies, care should be taken that the assigned Patient Numbers do not form a pattern which might reveal treatment assignment. ALL 3 DIGITS MUST BE ENCODED including leading and following zeros.

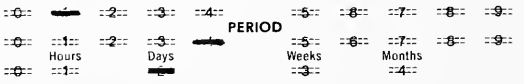
3. Rater Number - A 2-digit code assigned by the investigator is required. Wherever possible, it is suggested that investigators maintain the same numbers for their "permanent" raters, i.e., those who rate in a series of studies. Sections of some of the scales; e.g., CPDI, PMR, etc. may be completed by different individuals. In these cases, assign the number of that rater who has completed the greater portion of the scale.

4. Sheet Number - A 2-digit code which identifies, for computer processing, the data which is encoded on a specific General Scoring Sheet. Sheet Numbers for the scales within the various rater packets are given with the instructions for each scale and must be adhered to by raters. For non-standard scales or data sets, the investigator may assign any number from 80-99. Unlike PERIOD NUMBER which corresponds to the time when a particular rating is performed, SHEET NUMBER FOR A SPECIFIC SCALE OR DATA SET REMAINS CONSTANT THROUGHOUT THE STUDY. Thus, if a rating scale; e.g., Insipid Reaction Scale, is encoded on the GSS and assigned Sheet Number "80" at the initial rating; this number "80" must be assigned to all subsequent ratings of the Insipid Reaction Scale.

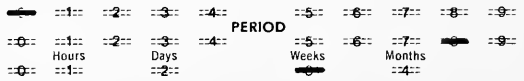
5. Period Number - a 3-digit code encoded by the investigator is required. The code designates the time when a specific rating is made. Two digits are provided for the numeric and one digit for the units of time - hours, days, weeks, months.

Examples:

1. To enter 14 days; code as follows:

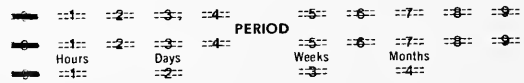


2. To enter 8 weeks;* code as follows:



*Note that the leading zero is encoded: 08 NOT blank 8.

3. To enter the initial rating; code as follows:



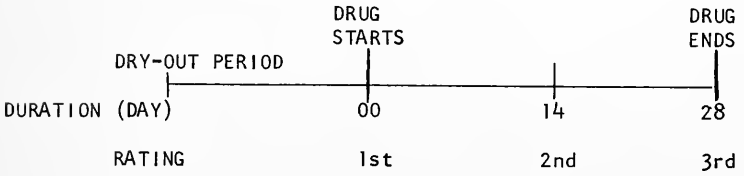
Time units should be consistent on all scales throughout a study, whenever possible. Code Week 01, Week 02, Week 04 or Day 01, Day 14, Day 28, NOT Week 01; Day 14, Month 01. While uniform use of any of the time units is acceptable, it is suggested that DAYS be used whenever possible.

In most studies, assessments are planned at regular intervals (Week 00, 02, 04, etc.) although the actual assessment may not be completed on the precise schedule. For uniformity, raters should encode PERIOD according to the study protocol. Example: Assessment is scheduled for Day 14 but the rater is unable to accomplish it until Day 15. Encode Day 14 - not 15 - as 15 would appear as an aberrant assessment in subsequent analyses and be deleted. Should a subject be prematurely terminated, however, and an assessment made at the time, encode the real time of the assessment even though it is "off schedule".

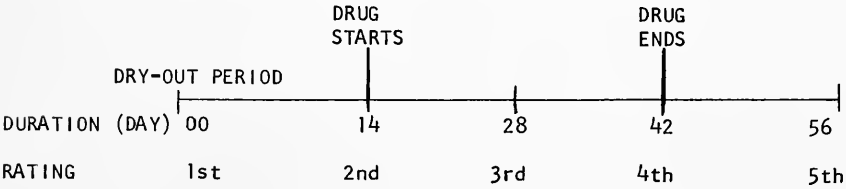
CODING DURATION OF STUDY - In order to achieve uniformity within a given study and across different studies, duration of study should - in all cases - be coded in the following manner. The initial rating should be encoded "000". Duration in the study for any subject is counted from the initial rating to the final rating whether or not this time period corresponds to the actual period of drug (treatment) administration. This method of counting is necessary to encompass those studies in which more than one pretreatment (pre-drug) assessments are made. Similarly, the cessation of treatment may or may not coincide with the final rating. Many studies employ more than one follow-up rating after the treatment (drug) has been stopped. In this coding system, both pretreatment and follow-up phases are included in determining total duration of the study IF assessments are made which span these pretreatment and followup phases.

Examples:

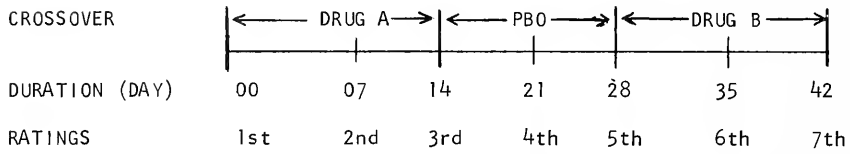
1. The investigator plans to have a 2-week drying out period following which the first ratings will be made. He then will administer his test drug for 4 weeks. He plans to make additional ratings 2 weeks and 4 weeks after the initiation of treatment. There will be no followup assessments. Duration of this study would be calculated and coded as follows:



2. The investigator plans a study exactly as before (1) but adds a rating at the beginning of the drying-out period and 2 weeks following the cessation of drug treatment. Duration in this study would now be calculated and coded as follows:



3. A crossover study is planned in which the sequence, Drug A - PBO - Drug B, will be employed. Each treatment will be of 2-week duration with assessments every week. Duration would be calculated and coded as follows:



SHADED AREAS - All independent scales; i.e., those with items printed directly upon them, will have one or more shaded areas in the identification block and possibly one or more within the text of the scale. The shaded areas with the ID are "prohibited areas" and NO MARKS OF ANY SORT are permitted. Similarly, shaded areas within the text of a scale are for coding only and writing should never be done here. This type of error has been so prevalent in the past that cautions are repeated throughout the Manual wherever there is the possibility of its occurrence.

CARD FORMAT - IDENTIFICATION BLOCK - (513, 212, 51x, 11, 15, 11, 13)

This format for identification is universal for all ECDEU card outputs.

Item	Col.	Item	Col.
Unit No.	1-3	Card No.	18-19
Study No.	4-6	Data Field	20-75
Subject No.	7-9	Treatment Assignment*	76-80
Form No.	10-12		
Assessment Period	13-15		
Rater No.	16-17		

*Treatment Assignment - This code will designate the specific treatment assignment for each individual subject. The information is obtained from Data Shipment (071-DS), Item V, Patient Identification. The coding is as follows:

Factor 1 Assignment - Col. 76
Factor 2 Assignment - Col. 77
Factor 3 Assignment - Col. 78
Special Assignment Coding - Col. 79-80.

021 RPR
RESEARCH
PLAN
REPORT

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

PSYCHOPHARMACOLOGY RESEARCH BRANCH

RESEARCH PLAN REPORT

DO NOT WRITE IN THIS BOX
UNIT NO.
STUDY NO.
RPR NO.

GENERAL INSTRUCTIONS

The Research Plan Report is designed to collect data concerning psychopharmacological research procedures in a format suitable for computer processing. The restrictions of such a format plus the great variety in research designs may create some difficulties in choosing a response. The investigator is asked, however, to make every effort to complete the form according to the instructions. If aspects of your study cannot be described appropriately under a given item or if the space provided is inadequate for your response, please describe the details on page 11 or on a separate sheet and attach to the form. Submission of the investigator's complete protocol would also be appreciated so that errors of interpretation can be avoided.

Specific instructions for this form (RPR) are given on pages 12 – 15 and should be read ***PRIOR TO COMPLETING THE FORM.*** This revision of the RPR, MH-9-21, Rev. 1-73 (Blue) supersedes all other versions. *Please discard all old forms, MH-9-13, Rev. 2-71 (Buff).*

I. IDENTIFICATION

NAME OF INVESTIGATOR/S	ADDRESS

TITLE OF STUDY

STARTING DATE	ANTICIPATED COMPLETION DATE
Month _____ Year _____	Month _____ Year _____

PURPOSE/S – Briefly state purpose/s and any specific hypotheses of the study

If you concur, the Research Plan Report which you submit can be released to the scientific community in the form of a short narrative description of the study. Chemical formulae may be held confidential even if other information is released.

Is this RPR a revision or modification of a previously submitted one? ☐ Yes ☐ No

If YES, give Unit and Study numbers assigned to original RPR: _____

May data on this form be given to the scientific community? ☐ Yes ☐ No

Should chemical formulae be held confidential? ☐ Yes ☐ No

Will ECDEU forms be used and data be sent to the Biometric Laboratory? ☐ Yes ☐ No

Mail this completed form to: ECDEU Data Analyses
Biometric Laboratory
George Washington University
11501 Huff Court
Kensington, Maryland 20795

ALL CARDS	DO NOT WRITE HERE – FOR BIOMETRIC LAB USE ONLY							
	UNIT NO.	STUDY NO.	YEAR COMPLETED	REVISION	FORM	RECEIPT Mo./Year	RPR NO.	STATUS
CODE:					21			
COL.:	2-4	5-7	8-9	10	11-12	13-16	75-78	79-80

II. DESCRIPTION OF DRUG/S EMPLOYED

DO NOT WRITE HERE

A. TEST DRUGS

COL. 17-18 — CODE CARD 01

1. Test Drug No. 1:

a. Name — Single Drug ☐ 1 / Combination Drug ☐ 2 — COL. 19-23 — INV NO. 1

b. Synonyms

c. Manufacturer — COL. 24-26 — MAN NO. 1

d. FDA *(or appropriate regulatory agency)* status — COL. 27 — FDA NO. 1

1. Approved for prescribing or sale and for the present indication or use ☐ 1
2. Approved for prescribing or sale but *NOT* for the present indication or use ☐ 2
3. Not approved for any use ☐ 3

2. Test Drug No. 2:

a. Name — COL. 28-32 — INV NO. 2

b. Synonyms

c. Manufacturer — COL. 33-35 — MAN NO. 2

d. FDA *(or appropriate regulatory agency)* status — COL. 36 — FDA NO. 2

1. Approved for prescribing or sale and for the present indication or use ☐ 1
2. Approved for prescribing or sale but *NOT* for the present indication or use ☐ 2
3. Not approved for any use ☐ 3

3. Presumed Clinical Action/s:

	TEST DRUG NO. 1	TEST DRUG NO. 2
01	Neuroleptic	Neuroleptic
02	Anxiolytic/Sedative	Anxiolytic/Sedative
03	Antidepressant	Antidepressant
04	Stimulant	Stimulant
05	Psychotomimetic	Psychotomimetic
06	Hypnotic	Hypnotic
99	Unknown	Unknown

COL. 37-40 — ACT NO. 1

COL. 41-44 — ACT NO. 2

Other Action *(Test Drug No. 1)*

Other Action *(Test Drug No. 2)*

4. For Investigations of New Uses For Established Drugs

Test Drug No. 1

The generally accepted action is:

The action to be tested in this study is:

COL. 45-48 — NEW NO. 1

Test Drug No. 2

The generally accepted action is:

The action to be tested in this study is:

COL. 49-52 — NEW NO. 2

5. Chemical Class/es *(If known)*

TEST DRUG NO. 1		TEST DRUG NO. 2	CHEMICAL CLASSES	TEST DRUG NO. 1		TEST DRUG NO. 2	CHEMICAL CLASSES
	101		Phenothiazines		401		Phenylethylamine derivatives
	102		Phenothiazine analogues & isosteres		402		Phenylacetic acid derivatives
	201		Lysergic acid derivatives		403		Diphenylmethane derivatives
	202		Reserpine & derivatives		404		Benzoic acid derivatives
	203		Harmine & derivatives		405		Other aromatic compounds
	204		Other indole derivatives		501		Glycols
	301		Cannabis derivatives		502		Carbamates
	302		Chromone derivatives		503		Carbinols
	303		Benzodiazepines		504		Amides & hydrazides
	305		Barbiturates		505		Amines & hydrazines
	306		Heterocyclic butyrophenones		506		Other aliphatic compounds
	307		Other nitrogen heterocycles		999		Unknown
	308		Benzodioxane derivatives				
	309		Other non-nitrogen heterocycles				

DO NOT WRITE HERE

COL.	CODE
63-68	CLASS NO. 1
59-64	CLASS NO. 2

6. For NEW DRUGS, draw chemical structure

COL.	CODE
65	FORMULAE
66	PUBLIC
67	SCALES
68-71	PURPOSE

B. COMPARISON DRUG/S

1. Does the study employ comparison drugs? ☐ Yes ☐ No *If Yes, which?* Standards ☐ 1; Active Placebo ☐ 2; Inert Placebo ☐ 3; Both Standard/s and Placebo/s ☐ 4

	COL.	CODE
	17-18	CARD 02
	19	COMPARE

2. Comparison Drug No. 1:
a. Name ____ Single Drug ☐ 1 Combination Drug ☐ 2 — 20-24 STD NO. 1
b. Manufacturer ____ — 25-27 MAN NO. 1

3. Comparison Drug No. 2:
a. Name ____ Single Drug ☐ 1 Combination Drug ☐ 2 — 28-32 STD NO. 2
b. Manufacturer ____ — 33-35 MAN NO. 2

4. Placebo:
a. Composition ____ — 36-40 PBO
b. Manufacturer ____ — 41-43 MAN-PBO

III. POPULATION

A. DEMOGRAPHY:

1. Total number of subjects in study: _____ — 44-46 NO. S
2. Sex: Males Only ☐ 1; Females Only ☐ 2; Both Sexes ☐ 3 — 47 SEX
3. Maturity: Children ☐ 1; Adolescents ☐ 2; Adults ☐ 3; Geriatric ☐ 4 — 48 MATUR
4. Age Range: From _____ To _____ — 49-50 AGE FROM; 51-52 AGE TO

		DO NOT WRITE HERE COL.	CODE
B. SUBJECT STATUS:	**1.** *(Check One)* Inpatient [1] Outpatient [2] Both [3] Not Applicable [9] **2.** *(Check One)* Acute [1] Chronic [2] Both [3] Not Applicable [9]	53	IN/OUT
		54	AC/CHRON
C. PRINCIPAL DIAGNOSTIC CATEGORIES:	**1. Adult** *Check all applicable* *(Omit if study involves children only)*	55-62	DSM DX
	Organic Brain Disorders [10] · Geriatric Disorders [11] · Alcoholism [13] · Manic-Depressive-Manic Phase [15] · Manic-Depressive-Depressive Phase [17] · Psychotic Depressions [20] · Schizophrenia [22] · Psychoneuroses-Anxiety States [40] · Psychoneuroses-Depressive States [42] · Personality Disorders [50] · Mental Deficiency [60] · Psychophysiological Disorders [70] · Varied Psychiatric Disorders [80] · Non-Psychiatric Population [88]		
	Other Categories *(WHO diagnoses may be given here)* _____ _____	63-71	WHO DX
	2. Children Childhood Schizophrenia [71] · Overanxious Reaction [72] · Unsocialized Aggressive Reaction [73] · Hyperactive Reaction [74] · Withdrawing Reaction [75] · Speech Disturbance* [76] · Learning Disturbance* [77] · Tic* [78] · Sleep Disorder* [79] · Feeding Disturbance* [81] · Enuresis* [82] · Encopresis* [83] · Varied Psychiatric Disorders [84] · Non-Psychiatric Population [85] **Special Symptom Disturbances*		
	Other Categories *(WHO diagnoses may be given here)* _____ _____		
D. BASIS FOR DIAGNOSIS:	**Check method/s for determining diagnoses of research sample:** Psychiatric Case Record [01] · Investigator's Clinical Judgment [02] · Independent Clinical Judgment [03] · Clinical Target Symptoms [04] · Psychometric (Cutoff) Score/s* [05] **If "Psychometric Score/s" checked, describe method:* _____	17-18	CARD 03
	_____	19-26	DX BASE
	Other Methods *(Specify):* _____		

E. EXCLUSION CRITERIA:

Check all conditions which would lead you to exclude (or remove) an individual from the study:

Acute or Chronic Brain Syndrome	☐ 27	Electroconvulsive Therapy	☐ 32		
History of Convulsive Disorder	☐ 28	Alcoholism	☐ 33		
History of CNS Disease	☐ 29	Drug Addiction	☐ 34		
Mental Deficiency	☐ 30	Pregnancy	☐ 35		
Psychosurgery	☐ 31	Females of Childbearing Age	☐ 36		
Medical Illnesses/Conditions:					
Allergic	☐ 37	Hepatic	☐ 39	Pulmonary	☐ 41
Cardiac	☐ 38	Hematologic	☐ 40	Renal	☐ 42

Other Medical Illness or Condition *(Specify)*: _____

_____

Any Other Exclusion Criteria *(Specify)*: _____

_____

DO NOT WRITE HERE	
COL.	CODE
27	EXCLUDE
28	
29	
30	
31	
32	
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41	
42	
43-50	

F. RESEARCH SETTING:

1. For inpatient studies - During the study, the population will reside:
(Check all applicable)

a.
ON: 1☐ One RESEARCH ward; 2☐ More than one RESEARCH ward
AT: 3☐ One Institution (hospital); 4☐ More than one institution (hospital); 5☐ *Under* administrative control of principal investigator; 6☐ *Not under* administrative control of principal investigator

51-53 — RES - 1a

b.
ON: 1☐ One CLINICAL ward; 2☐ More than one CLINICAL ward
AT: 3☐ One Institution (hospital); 4☐ More than one institution (hospital); 5☐ *Under* administrative control of principal investigator; 6☐ *Not under* administrative control of principal investigator

54-56 — CLIN - 1b

c. Describe, in detail, research settings which do not fit in the above categories:

57-60 — SET - 1c

2. For outpatient studies - During the study the population will be admitted:
(Check all applicable)

a.
FROM: 1☐ One catchment area; 2☐ More than one catchment area
TO: 3☐ One; 4☐ More than one
5☐ Community mental health center; 6☐ Other psychiatric clinic; 7☐ Child guidance center; 8☐ Psychiatric section (OPD) of a general hospital; 9☐ Office of private practitioner

61-67 — OUT - 2a

b. Describe, in detail, research settings which do not fit the above categories:

68-71 — SET - 2b

IV. PROTOCOL

DO NOT WRITE HERE

A. CLASS OF STUDY

			COL.	CODE
1. Clinical Pharmacology:	Phase I	*(Activity, toxicity, dose tolerance)*	1	17-18 CARD 04
	Early Phase II	*(Efficacy, dose range, small sample, non-blind)*	2	
2. Clinical Trial:	Late Phase II	*(Blind, efficacy, comparative agent)*	3	19 PHASE
	Phase III	*(Definitive efficacy trial, large sample size)*	4	
3. Special Drug Study:		*(EEG, metabolism, dose response, etc.)*	5	
4. Special Non-Drug Focussed Study:		*(Demographic, methodological, etc.)*	6	

B. EXPERIMENTAL DESIGN

1. Type:

				COL.	CODE
a.	Drug alone or compared with another drug/s:	Test Drug/s Only	01	20-21	TYPE-DES
		Test vs. Placebo	02		
		Test vs. Comparison Drug	03		
		Test vs. Comparison vs. Placebo	04		
b.	Two or more test conditions in the same drug:	2 or more Dose Levels	05		
		2 or more "Brands"	06		
		2 or more Dosage Forms	07		
c.	Drug in combination with or compared to non-drug treatment:	Drug vs. Individual Psychotherapy	08		
		Drug vs. Behavior Modification	09		
		Drug vs. Group Psychotherapy	10		
d.	Other type *(Specify):*				

2. Duration:

				COL.	CODE
		(Insert Number) LENGTH OF PERIOD	TIME UNIT		
a.	"Drying-out" period? ☐ Yes ☐ No	*If Yes, length will be:* _____	Days 1	22-24	ORY
		_____	Weeks 2		
		"Drying-out" period will employ:	No Treatment ☐ 1	25	TYPE-DRY
			Placebo ☐ 2		
b.	Drug administration period will be:	_____	Hours 1	26-28	RX-ADM
		_____	Days 2		
		_____	Weeks 3		
		_____	Months 4		
c.	Post treatment (follow-up) period will be:	_____	Hours 1	29-31	POST
		_____	Days 2		
		_____	Weeks 3		
		_____	Months 4		
		None	☐ 000		

3. For Cross-over Designs Only:

Describe duration and drug sequences to be employed. Duration should apply to the first sequence and will be adjusted for other sequences. Code drugs as follows:

Test Drug No. 1 = T1 Comparison Drug No. 1 = C1 Placebo = PBO
Test Drug No. 2 = T2 Comparison Drug No. 2 = C2

Duration coded in: 1☐Hours 2☐Days 3☐Weeks 4☐Months

	TREATMENT SEQUENCE				COL.	CODE
DURATION	No. 1	No. 2	No. 3	No. 4		
					17-18	CARD 05
					19	CROSSOVER UNIT
					20-25	
					26-31	
					32-37	
					38-43	
					44-49	
					50-55	

C. DOSAGE ADMINISTRATION

DO NOT WRITE HERE

COL. 17-18 — CODE CARD 04

1. Form:

TEST DRUG No. 1		TEST DRUG No. 2		COMPARISON DRUG No. 1		COMPARISON DRUG No. 2		PLACEBO	
1	Tablet	1		1	Tablet	1		Tablet	1
2	Capsule	2		2	Capsule	2		Capsule	2
3	"Spansule"	3		3	"Spansule"	3		"Spansule"	3
4	Liquid	4		4	Liquid	4		Liquid	4
5	I.V.	6		5	I.V.	5		I.V.	5
6	S.Q.	6		6	S.Q.	6		S.Q.	6
7	I.M.	7		7	I.M.	7		I.M.	7
8	Depot	8		8	Depot	8		Depot	8
Other:				Other:				Other:	

CODE: FORM — COL. 32-41

2. Dosage Schedule:

a. **Fixed/unchanging** — dosage fixed in protocol prior to study at a single level, e.g., 5 mg/day for 10 days ☐ 1

b. **Fixed/changing** — dosage fixed in protocol prior to study with increasing or decreasing levels; e.g., 100 mg. for first week; 200 for second; 300 for third, etc. ☐ 2

c. **Flexible** - dosage changed according to needs of subject ☐ 3

d. **Fixed/flexible** - dosage fixed in protocol for earlier dosages with option to "individualize" dosage according to needs of the subject later on ☐ 4

COL. 42 — CODE: SCHED

3. Dosage Protocol:

a. **Record Dosage Schedules Below**

If flexible dosage schedule, give initial and maximum dosage.
Enter TOTAL DAILY DOSE at each appropriate time period.
For combination drugs, use Test No. 1 for component A and Test No. 2 for component B.

Test 1 — CARD 06
Test 2 — CARD 07
Comp 1 — CARD 08
Comp 2 — CARD 09

DOSAGE LEVELS

TEST DRUG No. 1		TEST DRUG No. 2		COMPARISON DRUG No. 1		COMPARISON DRUG No. 2		COL.	CODE: PERIOD/DOSE
Time Period	Dosage	Time Period	Dosage	Time Period	Dosage	Time Period	Dosage		
								19-24	
								25-30	
								31-36	
								37-42	
								43-48	
								49-54	
								55-60	
								61-66	

b. **Dosages are recorded in:** *(Check appropriate unit for dosage)*

mcg ☐ 1
mg ☐ 2
gm ☐ 3
mg/kg ☐ 4

Other *(Specify)*: _____

COL. 67 — CODE: DOSE UNIT

c. **Time periods are recorded in:** *(Check appropriate unit for time)*

Hours ☐ 1
Days ☐ 2
Weeks ☐ 3
Months ☐ 4

Other *(Specify)*: _____

COL. 68 — CODE: TIME UNIT

D. CONTROL PROCEDURE

		DO NOT WRITE HERE COL.	CODE
		17-18	CARD 10
1. Procedure will be:	Nonblind ☐ 1		BLIND
	Double blind ☐ 2	19	
2. Subjects will be assigned to treatment by:	Strict Random Number ☐ 1		ASSIGN
	Sequential Assignment ☐ 2		
	Matching ☐ 3	20	
	Stratified-random *(Describe under "other")* ☐ 4		
Other: _____			
3. Will other concomitant non-drug therapies be permitted for the research population?			CON-THER
☐ Yes *If Yes, which therapies?*	Individual Psychotherapy ☐ 1		
☐ No	Group Psychotherapy ☐ 2		
	Behavior Modification ☐ 3	21	
	Varied Psychological Therapies ☐ 4		
	Other Therapies ☐ 5		
Specify Other: _____			
4. Will any other drug therapies be permitted? *(Check all applicable)*			ANCILL
No other drug therapies for any reason ☐ 1			
Only remedial medications, i.e., medications for the amelioration of adverse reactions ☐ 2			
Antiparkinson medication will be given prophylactically to all subjects ☐ 3		22-23	
Medication/s for medical conditions prescribed for subject prior to study will be permitted ☐ 4			
Non-study psychotropic medication may be administered in emergency (crisis) situation ☐ 5			
No restriction of use of other drug therapies ☐ 6			

Describe, in detail, other procedures which do not fit the above categories:

_____

_____

_____

_____

_____

E. ASSESSMENT INSTRUMENTS *(Check all applicable instruments)*

				DEMO
1. Demographic:	PDI ☐ 24	24		
	CPDI ☐ 25	25		
	Others: _____			
	_____			
				DIAG
2. Diagnostic:	CSH ☐ 26	26		
	CDC ☐ 27	27		
	CDS ☐ 28	28		
	Others: _____			DEMO/ DIAG
	_____	29-30		

E. ASSESSMENT INSTRUMENTS (Continued)

DO NOT WRITE HERE

		COL.	CODE
3. Efficacy:	Adult Behavioral Rating Scales		EFF-ADULT
	31 ☐CGI 38 ☐IMPS	31	
	32 ☐BPRS 39 ☐ZUNG Depression	32	
	33 ☐NOSIE 40 ☐SRSS	33	
	34 ☐HAM Depression 41 ☐SCL-90	34	
	35 ☐HAM Anxiety 42 ☐POMS	35	
	36 ☐WITT 43 ☐BECK	36	
	37 ☐PLUT 44 ☐DRI	37	
		38	
		39	
		40	
		41	
	Others: _____	42	
	_____	43	
		44	
		45-46	
	Children's Behavioral Rating Scales		EFF-CHILD
		47	
	47 ☐CGI 50 ☐PQ	48	
	48 ☐CPRS 51 ☐TQ	49	
	49 ☐CBI 52 ☐PEBP	50	
	Others: _____	51	
	_____	52	
		53-54	
4. Psychometric and Performance:			PSYCHO
	55 ☐WAIS/WISC 59 ☐GOOD	55	
	56 ☐MAZE 60 ☐RT	56	
	57 ☐BENDER 61 ☐CFF	57	
	58 ☐WRAT 62 ☐Continuous Performance	58	
	Others: _____	59	
	_____	60	
		61	
		62	
		63-64	
5. Adverse Reaction:			ADVERSE
	65 ☐DOTES 66 ☐TESS 67 ☐STESS	65	
	Others: _____	66	
	_____	67	
		68-69	
6. Laboratory Tests:		17-18	CARD 11
	Hematology		HEMAT
	19 ☐Hgb 23 ☐Differential	19	
	20 ☐Hct 24 ☐Sed. Rate	20	
	21 ☐RBC 25 ☐Platelet	21	
	22 ☐WBC 26 ☐Prothrombin Time	22	
	Other: _____	23	
	_____	24	
		25	
		26	
		27-28	
	Serum Chemistry		SERUM
	29 ☐Electrolytes 32 ☐Sugar Metabolism	29	
	30 ☐Liver function tests 33 ☐Blood fats	30	
	31 ☐Kidney function tests 34 ☐Thyroid function tests	31	
	Other: _____	32	
	_____	33	
		34	
		35-36	

		DO NOT WRITE HERE COL.	CODE
6. Laboratory Tests *(Continued)*	Urine 37 ☐ Sp. Gr. 40 ☐ Sugar 38 ☐ pH 41 ☐ Microscopic 39 ☐ Albumin 42 ☐ Electrolytes Other: _____	37	URINE
		38	
		39	
		40	
		41	
		42	
		43-44	
	Tests on Other Biological Specimens 45 ☐ Saliva 46 ☐ Feces 47 ☐ Cerebrospinal Fluid Other: _____	45	BIOL
		46	
		47	
		48-49	
7. Medical Assessment Procedures:	50 ☐ Physical Examination 53 ☐ EKG 51 ☐ Neurological Examination 54 ☐ EEG 52 ☐ PANESS 55 ☐ Slit Lamp Other: _____	50	MED
		51	
		52	
		53	
		54	
		55	
8. Any Other Procedures:	_____	56-57	
		58-60	MISC

F. RATERS

1.	How many different individuals (e.g., psychiatrists/psychologists) will perform the major behavioral ratings? No. _____	61-62	DIFF RATER
2.	Will "multiple raters" be used, i.e., 2 or more individuals performing simultaneous or concurrent ratings of the same subject? *(Check One)* No ☐ 0 Yes ☐ 1	63	MULT RATER

G. ASSESSMENT SCHEDULE

For Time Periods, check appropriate time units (days, weeks, etc.) and write in the assessment periods to be employed. In the four other columns, mark (X) in all rows where ratings will be made.
Circle the periods where drug treatment begins and ends. Designate initial (first) rating as "00".

For adverse reaction only

a. If symptoms are to be rated only if and when they occur; *check here* . . . . . ☐1

b. If symptoms are to be rated at each dosage change; *check here* . . . . . ☐2

c. If symptoms are to be rated on a fixed schedule, complete in manner described above.

Check whether time periods refer to: 1 ☐Hours 2 ☐Days 3 ☐Weeks 4 ☐Months

64	TIME UNIT
65-70	INITIAL PERIOD
17-18	CARD 12

TIME PERIOD	MAJOR BEHAVIORAL SCALE	MAJOR PSYCHOMETRIC/ PERFORMANCE	ADVERSE REACTION	LABORATORY TESTS		
					19-24	2nd
					25-30	3rd
					31-36	4th
					37-42	5th
					43-48	6th
					49-54	7th
					55-60	8th
					61-64	BEGIN-END
					65	ADa/b

H. TYPE OF DATA ANALYSIS		DO NOT WRITE HERE COL.	CODE ANALYSIS
1. **Pre (Middle) Post** – one way analyses of rating periods	☐ 1		
2. **Treatment (groups) Comparison** – e.g., drugs x periods	☐ 2	66	
3. **Factorial** – more than 2 factors, e.g., drugs x periods x diagnosis	☐ 3		
Describe factorial design: _____			
4. **Crossover** – two or more treatments in same subjects	☐ 4		
5. **Other:** _____			

REMARKS:

II. DESCRIPTION OF DRUG/S EMPLOYED

The term "Test Drug" refers to the investigational drug; while "Comparison Drug" refers to the control drug. As used here, these terms are not necessarily synonymous to the same ones used by FDA or other regulatory agencies. Space limitations allow a maximum of four drugs to be encoded — two Test Drugs under A and two Comparison Drugs under B of this section. In some instances, these space limitations may force arbitrary assignment of drugs to Test or Comparison categories; e.g., one test vs. three control drugs. Space is provided to encode a ***PLACEBO*** in addition to the maximum of four drugs.

The terms Test and Comparison may be used in various ways; not only as test versus ***control drugs*** but also to describe any test versus ***control situation*** (different brands of the same drug, different populations or age groups, high versus low doses, liquid versus tablet, etc.). In such cases, record the usual or standard medication as Comparison and the new or unusual form as Test.

A. TEST DRUGS

1a. Name — Give the generic name for the drug or, if none yet exists, give the code number.

Single/Combination — "Single drug" means a drug consisting of one compound. "Combination drug" refers to two or more compounds given as a single treatment, even if the components are not enclosed within a single "capsule" or "tablet". The drug Triavil, for example, is a combination of amitriptyline (Elavil) plus perphenazine (Trilafon). To record this drug, write in ***ONE*** space the generic name of each component — amitriptyline and perphenazine. Do ***NOT*** record the two components as Test Drug No. 1 and Test Drug No. 2.

b. Synonyms — Give only the more frequently used synonyms, trade names and/or code numbers.

c. FDA — Answer on the basis of the drug's FDA status for general use and for the use/indication being tested in the study. ***Example*** - A drug approved for use in general adult populations is to be tested for use in children. It is not approved for such a population by the appropriate regulatory agency. Check 2 - "Yes, approved for prescribing or sale but not for the present indication or "use" in this case.

3. **Presumed Clinical Action** — Two columns are provided for studies which involve two test drugs. In these studies be sure to mark the action for each drug in the correct column. For example, if thiothixene is Test Drug No. 1 and imipramine is Test Drug No. 2, check "neuroleptic" in column No. 1 and "anti-depressant" in column No. 2. When Combination drugs are present, mark the action of each component of the combination in the column. For example, if the combination drug, Triavil (amitriptyline + perphenazine) is Test Drug No. 1 check both "anti-depressant" and "neuroleptic" in column 1.

4. **New Uses For Established Drugs** — To be completed when a drug has an established psychotropic action, e.g., neuroleptic; and is being studied for some other presumed action, e.g., anti-depressant; or when a non-psychotropic drug, e.g., an analgesic is tested for psychotropic action, e.g., anxiolytic.

5. **Chemical Classes** — The classification is based on that of Usdin and Efron in their book "Psychotropic Drugs and Related Compounds". From the code numbers (101–506) choose the lowest number which is applicable to your Test Drug. If the drug, for instance, is both a heterocycle (307) and a carbamate (502), check only (307). For those drugs where chemical class is as yet unknown check (999). For studies involving 2 Test Drugs and/or Combination drugs, follow the procedure described under A3, "Presumed Clinical Action".

III. POPULATION

C. PRINCIPAL DIAGNOSTIC CATEGORIES

Complete either subsection 1 - Adult or 2 - Children. You may record a maximum of four categories. If the population is so heterogeneous that four of the categories can not account for the bulk of the sample, check "Varied Psychiatric Disorders". World Health Organization (WHO) diagnostic entities may be recorded under "Other Categories" if the investigator chooses.

D. BASIS FOR DIAGNOSIS

Psychiatric Case Record - refers to use of diagnosis contained in the subject's case (hospital) record as the determinant.
Investigator's Clinical Judgment - refers to the determination of diagnosis by the principal investigator or member of the research team.
Independent Clinical Judgment - indicates determination by an individual not directly involved in the study, e.g., a consultant - not a member of the research team - whose function is to ascertain or verify the appropriateness of the diagnosis.
Clinical Target Symptoms - refers to the clinical judgment of the presence or absence of specific synptoms or characteristics;
Psychometric Scores - refers to determination by the use of specific score/s on a psychometric assessment instrument/s; e.g., subjects rated below a specified severity (score) on a scale are ineligible (cutoff) for acceptance into the study sample.

F. RESEARCH SETTING

Research ward refers to a unit specifically organized for research purposes. Residents on a research ward are selected primarily on the basis of research requirements.

IV. PROTOCOL

A. CLASS OF STUDY

Check ***ONE*** of the six alternatives

B. EXPERIMENTAL DESIGN

1. **Type** — *Check ONE* of the ten alternatives listed under a, b, and c or write in a more appropriate description under d.

   Type of Drying-out — If a Placebo is used only during drying-out period and the design is not conceptualized as a crossover, *DO NOT* designate the study as Test versus Placebo.

2. **Duration** — For each of the subheadings a, b and c, insert numerals on the line before the appropriate time unit to indicate the length of the period. For example, an investigator plans to have a 2-week, no treatment drying-out period followed by 6 weeks of drug administration and no follow-up, Item 2a, 2b and 2c would be completed as follows:

   a. Drying-out period? ☑ Yes ____Days
   ☐ No 2 Weeks
   Drying-out period will employ: No Treatment ☑
   Placebo ☐

   b. Drug administration period will be: ____Hours
   ____Days
   6 Weeks
   ____Months

   c. Post treatment (follow-up) period will be: ____Hours
   ____Days
   ____Weeks
   ____Months
   None ☑

3. **Crossover** — *Example:* In a study involving a test drug, (T1) comparison drug (C1) and placebo (PBO), the investigator plans to vary the order in which the treatments are given. He plans to administer each of the drugs for 4 weeks and the placebo for 2 weeks. One half of the research sample will be placed on one sequence or the other. Coding is as follows:

   Duration is recorded in:
   ☐Days ☑Weeks ☐Months

TREATMENT		
Duration*	Sequence No. 1	Sequence No. 2
2	PBO	C1
4	T1	PBO
2	PBO	T1
4	C1	PBO

*Duration applies to Sequence No. 1. It is assumed that the durations for Sequence No. 2 would be shifted along with the treatments, e.g., 4, 2, 4, 2.

A Latin square design involving Test Drug No. 1, (T1), Comparison Drug No. 1 (C1), Comparison Drug No. 2 (C2) and Placebo (PBO) would be completed as follows:

Treatment Duration	Treatment Sequences			
	1	2	3	4
2	T1	C1	C2	PBO
2	C1	C2	PBO	T1
2	C2	PBO	T1	C1
2	PBO	T1	C1	C2

C. DOSAGE ADMINISTRATION

1. **Form** — Check *ONE* of the dosage forms for each group in the study. For example, in a study consisting of 2 drug groups — Test and Comparison — in which both groups receive their medication in tablet form, check "tablet" under both Test and Comparison columns. "Spansule" refers to a sustained release form. Depot refers to a drug contained in a vehicle for I.M. injection which allows for slow release and long action.

2. **Dosage Schedule** — Dose ranges rather than specific doses are often fixed in the protocol prior to the study and should be coded according to level; e.g., 3 to 7 mg/day for 10 days would be coded as **Fixed/unchanging;** 75 to 125 mg/day for the first week, 172—225 mg/day for the second week, etc. would be coded as **Fixed/changing.**

3. **Dosage Protocol**

   Example 1 — Test and comparison drugs with a Fixed/changing schedule. The total daily dose for the test drug will be 50 mg. for 1 week; 100 mg. for 1 week; 200 mg. for 1 week, etc. For the comparison drug, the total daily dose will be: 25 mg. for 1 week, 50 mg. for 1 week, 75 mg. for 1 week, etc.
   Code as follows:

   a.

Time Period	Test Drug No. 1	Time Period	Comparison Drug No. 1
1	50	1	25
1	100	1	50
1	200	1	75

   b. Dosages are recorded in:
   1☑mg 2☐mcg 3☐gm 4☐mg/kg

   c. Time periods are recorded in:
   1 ☐Hours 2☐ Days 3☑Weeks 4☐Months

   Example 2 — Test and comparison drugs with a flexible schedule. Over a 4 week period a range of 10—100 mg. of test drug is to be administered; 100-500 mg. for the comparison drug.
   Code as follows:

Time Period	Test Drug No. 1	Time Period	Comparison Drug No. 1
4	10-100	4	100-500

   (Units of dosage and time omitted for brevity)

   Example 3 — Combination test drug and 2 comparison drugs with a Fixed/changing schedule. Component A of combination is coded under Test No. 1 and Component B under Test No. 2. Dosage is changed as indicated.

Time Period	Test Drug No. 1	Time Period	Test Drug No. 2	Time Period	Comparison Drug No. 1	Time Period	Comparison Drug No. 2
1	50	1	5	1	50	1	5
2	100	2	10	2	100	2	10
2	150	2	15	2	150	2	15

3. Dosage Protocol (Continued)

Example 4 — Test drug in depot form and comparison drug in tablet form. Depot form (200 mg) is presumed to be effective for 4 weeks. Initial dose of comparison drug is 50 mg and it increased 50 mg each week to maximum of 200 mg.

Time Period	Test Drug No. 1	Time Period	Comparison Drug No. 1
4	200	1	50
		1	100
		1	150
		1	200

Example 5 — Test and comparison drug with a fixed/flexible schedule. Dosages for both test and comparidrugs are raised 100 mg each week for first 3 weeks of 6–week study. Dosages can then be "individualized" according to needs of subject. (Write in "open" to indicate "individualizing").

Time Period	Test Drug No. 1	Time Period	Comparison Drug No. 1
1	100	1	100
1	200	1	200
1	300	1	300
3	Open	3	Open

D. CONTROL PROCEDURE

1. Blindness — Single blind studies should be checked Nonblind.

2. Treatment Assignment — ***Strict random number*** refers to the use of a table of random numbers for assignment of subjects.

Matching refers to any attempt at specific matching of individuals. ***Sequential assignment*** refers to selection and/or assignment by order or sequence, i.e., alternating treatments to subjects as they are admitted; choosing every nth subject, etc. ***Stratified random*** — a variant of "matching" in which groups rather than individuals are selected on basis of a set of characteristics, e.g., sex, age, etc.

3. Concomitant Therapies — Refers to therapies which may be given to patients as part of their treatment but which are not a part of the research design.

G. ASSESSMENT SCHEDULE

Example 1 - Using the BPRS as his major behavioral rating scale, an investigator plans to make an assessment at pre-treatment, 2, 4, 6 and 8 weeks. Drug treatment will begin immediately following the initial rating and cease following the final rating. Ratings of adverse reactions and laboratory tests will be made at pre-treatment, 4 and 8 weeks. No psychometric/performance scales will be employed.

Time Period	Major Behavioral Scale	Major Psychometric Performance	Adverse Reaction	Basic Laboratory
(00)	X		X	X
02	X			
04	X		X	X
06	X			
(08)	X		X	X

Example 2 — On the major behavioral rating scale, the investigator plans to make assessments at the beginning and end of a 2 week drying-out period; the 1st, 3rd and 5th weeks of drug administration and 2 weeks after cessation of treatment. (Psychometric/performance tests, adverse reaction and laboratory tests are to be rated as marked).

Code as follows:

NOTE THAT THE TIME PERIODS ARE NUMBERED IN SEQUENCE REGARDLESS OF INITIATION/CESSATION OF DRUG ADMINISTRATION.

Time Period	Major Behavioral Scale	Major Psychometric Performance	Adverse Reaction	Basic Laboratory
00	X	X		
(02)	X	X	X	X
03	X	X		
05	X	X		
(07)	X	X	X	X
09	X	X		

1. Demographic:	PDI	Patient Data Inventory
	CPDI	Children's Patient Data Inventory
2. Diagnostic:	CDS	Children's Diagnostic Scale
	CDC	Children's Diagnostic Classification
	CSH	Children's Symptom History

3. Efficacy:	Adult Behavioral Rating Scales		Children's Behavioral Rating Scales	
	CGI	Clinical Global Impressions	CGI	Clinical Global Impressions
	BPRS	Brief Psychiatric Rating Scale	CPRS	Children's Psychiatric Rating Scale
	NOSIE	Nurses' Observation Scale for Inpatient Evaluation	CBI	Children's Behavior Inventory
	HAM Depression	Hamilton Depression Scale	PQ	Parents' Questionnaire
	HAM Anxiety	Hamilton Anxiety Scale	TQ	Teacher's Questionnaire
	WITT	Wittenborn Psychiatric Rating Scale	PEBP	Psychological Examination Behavior Profile
	PLUT	Plutchik Geriatric Rating Scale		
	IMPS	Inpatient Multidimensional Psychiatric Scale		
	ZUNG	Zung Self-Rating Depression Scale		
	SRSS	Self-Rating Symptom Scale		
	SCL–90	Symptom Check List		
	POMS	Profile of Mood States		
	BECK	Beck Depression Inventory		
	DRI	Discharge Readiness Inventory		

4. Psychometric and Performance Tests:	WAIS	Wechsler Adult Intelligence Scale
	WISC	Wechsler Intelligence Scale for Children
	MAZE	Porteus Mazes
	BENDER	Bender Gestalt Test
	WRAT	Wide Range Achievement Test
	GOOD	Goodenough-Harris Draw-A-Man Test
	RT	Reaction Time
	CFF	Critical Flicker Fusion
5. Adverse Reaction:	DOTES	Dosage Record and Treatment Emergent Symptoms
	TESS	Treatment Emergent Symptom Scale
	STESS	Self-Rating Treatment Emergent Symptom Scale
6. Laboratory Tests:	Hgb	Hemoglobin
	Hct	Hematocrit
	RBC	Red Blood Count
	WBC	White Blood Count
	Sp. Gr.	Specific Gravity
7. Medical:	PANESS	Physical and Neurological Examination for Soft Signs
	EKG	Electrocardiogram
	EEG	Electroencephalogram

Developed within the ECDEU program, the Research Plan Report (RPR) is a 43-item, self-contained scale for the recording of research procedures. The RPR is not formatted for optical scanning. It is, in essence, a summary protocol in which the purposes of the study are recorded, the size and nature of the population delineated, the investigational and comparative agents described, the duration and dosage set forth, the experimental conditions to be observed and the assessment procedures recorded. The value of the instrument extends beyond its usefulness for describing the design of a given study. As a data file, it can serve to describe the current status of research activities among a large group of investigators as well as provide an historical record of past activities. At this writing, data on over 1000 research protocols are on file.

APPLICABILITY - For all research populations

UTILIZATION - Once per study. Completed prior to the initiation of the study.

SPECIAL INSTRUCTIONS

The investigator should be familiar with the instructions printed on the form itself as well as those contained below. Since no one form or the items contained therein can possibly cover all eventualities, investigators are asked to include a copy of their research protocol along with the RPR. An extensive coding system has been developed for the RPR which contains many more categories for each item than those printed on the RPR itself. With the investigator's personal protocol at hand, it has been possible to categorize almost all research procedures within the general framework of the RPR.

Use of the RPR - Investigators may - and indeed are encouraged to - submit RPR's for their studies whether or not they intend to use ECDEU assessment instruments or Biometric Laboratory processing services.

Unit and Study Numbers - These numbers are assigned by the Biometric Laboratory. When an RPR is received, a notice will be sent to the investigator acknowledging receipt and will give the unit and study number assigned to that RPR. This 6-digit identification number should be referred to in all subsequent correspondence regarding that particular study so that misinterpretations can be minimized.

RPR Revision or Modification - If the investigator makes substantive changes in his study, a new RPR should be submitted. The original RPR can thus be "updated" in the ECDEU data bank.

Confidentiality - Investigators may request that all or part of the information on an RPR be held confidential. For many reasons, new chemical formulae may need to be confidential and data pertaining to this area can be withheld while disseminating the other RPR information to the scientific community.

ECDEU Forms - Indicates that ECDEU forms will be employed either wholly or in part.

II. Drug/s Employed - This section focuses on a description of the agents or conditions to be studied. "Test drug" can refer to ANY TEST CONDITION; "Comparison drug" to ANY COMPARISON CONDITION. Examples:

a. An atypical dosage of Drug A (test condition) vs. a typical dosage of Drug A (comparison condition) using the same drug in both instances.

b. "Brand X" (Test) vs. "Standard Brand" (Comparison).

c. Drug A given once a day (Test) vs. Drug A given 3 X a day (Comparison).

d. Drug A given in "depot" form (Test) vs. Drug A given in tablet form (Comparison).

e. Drug A given with a smile (Test) vs. Drug A given without a smile (Comparison).

f. Withdrawal of Drug A with PBO substitution (Test) vs. Withdrawal of Drug A without PBO (Comparison).

Space limitations allow recording of 2 "Tests", 2 "Comparisons" and a placebo. Which drugs or conditions are designated as "Test" or "Comparison" is left to the investigator and this decision may often be an arbitrary one.

Combination Drugs - This phrase seems to cause confusion. The intent here is to describe the condition in which 2 or more drugs are given simultaneously as ONE treatment; i.e., the investigator presumes that the combination has a different effect than either of the components used singly. Combination treatments may also consist of drug and non-drug components; e.g., Drug and ECT, Drug and Psychotherapy, Drug and Conditioning, etc.

Manufacturer - Should be interpreted as the SUPPLIER of the drug/s employed in the study. The supplier is not necessarily the actual manufacturer of the drug/s.

II,A,3. Presumed Clinical Action/s - The categories contained in this section are based on the classification developed by the International Reference Center for information on Psychotropic Drugs. Table 3 describes this classification in detail.

II,A,5. Chemical Class - Investigators may leave this section blank if they are uncertain of the classification of a drug. With very new drugs, a drawing of the chemical structure is most helpful in arriving at correct classification. When classifying a combination drug, check a class for each component - both in the appropriate column.

TABLE 3

PSYCHOTROPIC DRUG CLASSIFICATION – INTERNATIONAL REFERENCE CENTER NETWORK

DRUG GROUPS	SYNONYMS	WORKING DEFINITION	SUB-GROUPS	EXAMPLES
NEUROLEPTICS:	Major Tranquilizers Neuroplegics Psychoplegics Psycholeptics Antipsychotics	Non-hypnotic drugs with antipsychotic effects	Phenothiazine Derivatives . . . . Benzoquinolizine Derivatives . . . Thioxanthene Derivatives . . . . Butyrophenone Derivatives . . . Rauwolfia Alkaloids . . . . . . Other:	Chlorpromazine Thioridazine Fluphenazine Tetrabenazine Chlorprothixene Haloperidol Reserpine
ANXIOLYTICS:	Antianxiety Drugs Minor Tranquilizers Sedatives	Non-hypnotic drugs with antianxiety effects but without antipsychotic effects	Benzdiazepine Derivatives . . . . Glycol Derivatives . . . . . . Carbinols . . . . . . Diphenylmethane Derivatives . . . Barbiturates . . . . . . Other:	Chlordiazepoxide Oxazepam Meprobamate Phenaglycodol Phenprobamate Methaqualone Hydroxine Phenobarbital Amobarbital
ANTI-DEPRESSANTS:	Thymoleptics Thymoanaleptics Psychoanaleptics Psychic Energizers	Drugs which elevate mood and relieve depression	MAO-Inhibitors . . . . . . Tricyclics . . . . . . Other:	Isocarboxazid Nialamide Phenelzine Tranylcypromine Imipramine Desipramine Amitriptyline Protriptyline
STIMULANTS:	Psychoanaleptics Psychotonics Analeptics Psychomotor Stimulants	Drugs which accelerate psychomotor function and activity and improve performance under conditions of fatigue	Phenylethylamine Derivatives . . . Other:	Amphetamine Methamphetamine Phenmetrazine Methylphenidate Pipradol
PSYCHO-TOMIMETICS:	Psycholytics Psychodysleptics Hallucinogenics Psychedelics Eidetics	Drugs producing alteration in consciousness, characterized by perceptual and emotional changes without disorientation	Phenylethylamine Derivatives . . . Indole-alkaloids . . . . . . Piperidine Derivatives . . . . . Other:	Mescaline LSD Psilocybin Tryptamine Derivatives Ditran Phencyclidine
HYPNOTICS:	Soporifics Somnifacients	Psycholeptics with sleep-inducing and sleep-sustaining effects	Barbiturates . . . . . . Non-Barbiturates . . . . . . Other:	Secobarbital Pentobarbital Glutethimide Ethchlorvynol Ethinamate

Example 1 - Test Drug No. 1 is a combination of amitriptyline (Class - Phenothiazine analogue and isosteres) and perphenazine (Class - Phenothiazines). This combination of drugs will be administered as a single test condition. Code by checking both 101 and 102 under the column "Test Drug No. 1".

5. Chemical Class/es *(If known)*

TEST DRUG NO. 1		TEST DRUG NO. 2	CHEMICAL CLASSES	DR. NO.
X	101		Phenothiazines	
X	102		Phenothiazine analogues & isosteres	
	201		Lysergic acid derivatives	

Example 2 - Test Drug No. 1 is a single drug, amitriptyline, and Test Drug No. 2 is a single drug, perphenazine. Each is to be administered to one of two independent groups. Code Test Drug No. 1 in its appropriate column; Test Drug No. 2 in its appropriate column.

5. Chemical Class/es *(If known)*

TEST DRUG NO. 1		TEST DRUG NO. 2	CHEMICAL CLASSES	TE D
	101	X	Phenothiazines	
X	102		Phenothiazine analogues & isosteres	
			-ic acid derivatives	

II,B. Comparison Drug/s - Refers to any control or standard condition against which the test condition is to be compared. A frequent misinterpretation in completing the RPR occurs in studies where 2 drugs (conditions) are employed and, although the investigator is actually going to compare these conditions, he encodes both of them as "Test Drugs". For uniformity in the Data Bank, categorizing one drug as "Test" and one as "Comparison" is preferred - even though this may be arbitrary from the investigator's point of view.

III,A,1. Total Number of Subjects in Study - Give an estimate of the sample size you plan to achieve, even though it may be a tentative one.

III,C. Principal Diagnostic Categories - Up to 4 categories of diagnoses have been allotted in the coding system. Populations which exceed this limitation should be coded "Varied Psychiatric Disorders". The spaces labeled "Other Categories" may be used to record any additional diagnoses or to record the World Health Organization (WHO) diagnoses.

III,D. Basis for Diagnosis - When the response "Psychometric (Cut-Off) Score/s" is checked, specify the nature of the "cutoff score".

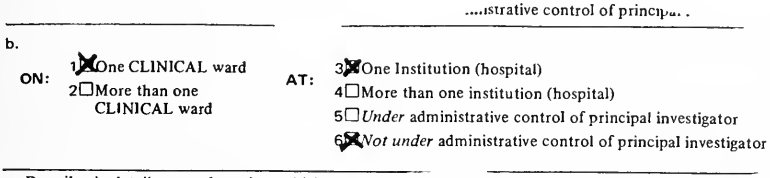
Examples:

BPRS Total Score of 30 or more
Hamilton Anxiety Scale Total Score of 25 or more
BPRS Thought Disorder Factor Score of 4 or more

III,F. Research Setting - For Items F,1,a and F,i,b, 3 MARKS are required.

Example:

The population will reside on one clinical ward in one hospital.
The ward is not under the investigator's administrative control.



For mixed inpatient/outpatient studies, fill in both sections of this item. The distinction between a research and clinical ward may be confusing. A clinical ward is one organized for treatment purposes. Patients residing on such a ward may be selected as research subjects but the ward itself is not organized as a research ward. Catchment area refers to a geographical subdivision of a larger area (metropolitan area, ward, city, county, state, province, etc.) from which a given agency receives its clients.

IV,B,2a. "Drying-out" period - In addition to checking the presence and length of a drying-out period, the investigator should indicate whether "no treatment" or PBO will be employed during this period. Should some other condition be maintained during the drying-out period, describe the nature of the condition.

IV,B,2c. Posttreatment (follow-up) period - Refers to the period immediately following the cessation of drug administration and during which assessment procedures will be conducted.

IV,C,2. Dosage Schedule - A single dose ("one-shot") would be coded as "Fixed-unchanging". When recording "Dosage Protocol" for a single dose, give the time period over which the dose is presumed effective and the amount of the dose. Single dose is coded the same way as "Depot" although its length of action may be considerably shorter.

E. Assessment instruments - When recording assessment instruments not printed on the RPR, give the FULL NAME of the instrument since there can be confusion in the interpretation of initials or partial titles. This is particularly important in describing laboratory tests or medical procedures. Citation of instruments here does NOT constitute an order for supplies. To obtain supplies, use the ECDEU Order Form (074-EOF). (See pp. 50-52).

IV,F Raters - Question 1 refers to the number of individuals performing the major behavioral ratings; e.g., the Children's Psychiatric Rating Scale and Clinical Global Impressions are selected by the investigator as his major instruments and he and 2 other colleagues will perform all of these ratings; enter "3" for the item.

DOCUMENTATION

Documentation for the RPR is both study-specific and general. For the study itself, the RPR provides the information for the "Description" paragraph contained in the Narrative Summary which accompanies each standard data analyses package and in the PRB Information Reporting and Retrieval System. For general documentation, the focus is on some selected subset of RPR's or RPR items contained in the ECDEU data bank, e.g., all studies reported in a given period of time; all Phase II studies; all double blind studies involving a given drug, etc. For the investigator, the PRB Information Reporting and Retrieval System is the primary source of general documentation of RPR information. A full description of this system and its use may be found in ECDEU Intercom, January, 1973, Vol. 2, No. 6. An offset of this Intercom issue may be obtained by writing to Program Head, ECDEU, Psychopharmacology Research Branch, NIMH, Room 9-101, 5600 Fishers' Lane, Rockville, Maryland, 20852.

074 EOF
ECDEU
ORDER
FORM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

ECDEU ORDER FORM (EOF)

FOR BIOMETRIC LABORATORY USE	
UNIT. NO.	
RECEIVED	SENT

INSTRUCTIONS: Please use ECDEU Order Form (EOF) when requesting supplies. Be sure to give COMPLETE mailing address. See reverse side for description of scales contained within packets. A *Research Plan Report* (21 - RPR) MUST be completed describing the study for which supplies are requested.

Has an RPR been completed? ☐ Yes - attached

☐ Yes - previously sent ECDEU Study No. _____

MAIL TO: Biometric Laboratory
ECDEU Data Analysis
The George Washington University
11501 Huff Court
Kensington, Maryland 20795

SUPPLIES REQUESTED BY:	NAME OF PRINCIPAL INVESTIGATOR	TO BE SENT TO: (Complete only if supplies to be sent to person other then principal investigator or to different address)
	INSTITUTION/AGENCY	NAME
	Number and Street	Number and Street
	City, State, Zip Code	City, State, Zip Code

Form No.		ITEM	No. Requested	No. Sent	Form No.		ITEM	No. Requested	No. Sent
807		Assessment Manual			38	STESS	Self Rating Treatment Emergent Symptom Scale		
801	Blue	Demographic Packet			41	PANESS	Physical and Neurological Examination for Soft Signs		
802	Green	Psychiatrist Packet – Child			46	PMR	Prior Medication Record		
803	Gold	Psychiatrist Packet – Adult			50	GSS	General Scoring Sheet		
804	Orange	Nurse Packet			53	SCL-90	Symptom Checklist – 90		
805	White	Psychologist Packet			54	SAS	Self Rating Anxiety Scale		
806	Red	Social Adjustment Packet			55	LAB	Laboratory Data		
21	RPR	Research Plan Report			59	RCR	Research Completion Report		
33	TWIS	Treatment Emergent Symptoms Write-in Scale			71	DS	Data Shipment		
35	TQ	Teacher Questionnaire			73	SDS	Self Rating Depression Scale		
36	PQ	Parent Questionnaire			74	EOF	ECDEU Order Form		
37	PTQ	Parent-Teacher Questionnaire			117	AIMS	Abnormal Involuntary Movement Scale		

MH-9–74
Rev. 2-75

NOTES ON FORMS

A full description of the ECDEU forms and their usage as well as the BLIPS processing system is given in the Assessment Manual. PACKETS refer to reusable, semi-permanent binders which contain sets of scales organized by professional discipline and/or specific population. A separate answer sheet – *General Scoring Sheet* – must be used in conjunction with the packets. In requesting packets, base your needs on the number of raters – NOT the number of subjects. Keep in mind that packets are reusable and need not be ordered anew for each study.

The contents of the packets are:

Demographic Packet (Blue)

43	CPDI	Children's Personal Data Inventory
44	CSH	Children's Symptom History
45	APDI	Adult Personal Data Inventory

Psychiatrist Packet – Child (Green)

27	CPRS	Children's Psychiatric Rating Scale
28	CGI	Clinical Global Impressions
29	DOTES	Dosage Record and Treatment Emergent Symptoms
30	CDS	Children's Diagnostic Scale
31	CDC	Children's Diagnostic Classification
32	PTR	Patient Termination Record

Psychiatrist Packet – Adult (Gold)

47	BPRS	Brief Psychiatric Rating Scale
72	DSI	Depression Status Inventory
49	HAMD	Hamilton Depression Scale
48	HAMA	Hamilton Anxiety Scale
51	ASI	Anxiety Status Inventory
52	WITT	Wittenborn Psychiatric Rating Scale
28	CGI	Clinical Global Impressions
29	DOTES	Dosage Record and Treatment Emergent Symptoms
32	PTR	Patient Termination Record

Nurse Packet (Orange)

34	CBI	Children's Behavior Inventory
39	NOSIE	Nurse's Observation Scale for Inpatient Observation
40	PLUT	Plutchik Geriatric Rating Scale
42	NGI	Nurse's Global Impressions

Psychologist Packet (White)

Children

60	WISC	Wechsler Intelligence Scale for Children
62	WRAT	Wide Range Achievement Test
61	MAZE	Porteus Mazes
63	GOOD	Goodenough–Harris Figure Drawing Test
64	BENDK	Bender Gestalt Test – Koppitz Scoring
66	PEBP	Psychological Examination Behavior Profile

Adult

67	WAIS	Wechsler Adult Intelligence Scale
61	MAZE	Porteus Mazes
68	BENDP	Bender Gestalt Test – Pascal-Suttell Scoring
69	WMEM	Wechsler Memory Scale
70	FTBS	Friedhoff Task Behavior Scale

Social Adjustment Packet (Red) – *In preparation, probable contents:*

58	DRI	Discharge Readiness Inventory
57	SADJ	Social Adjustment Scale

MH 9 –

21	RPR	Research Plan Report	Describes the clinical study. ***MANDATORY*** for all investigations
33	TWIS	Treatment Emergent Symptoms - Write-in Scale	Necessary for recording side effects not printed on the Dosage Record and Treatment Emergent Symptoms
37	PTQ	Parent-Teacher Questionnaire . .	Contains the ten items common to both the Teacher and Parent Questionnaires and usually employed in conjunction with them for repeated assessments
50	GSS	General Scoring Sheet	Necessary answer sheet for all packets. Also employed for the encoding of non-standard data
59	RCR	Research Completion Report . . .	Describe the investigator's conclusions of his study. Completed after data analysis
71	DS	Data Shipment	Supplies necessary information for BLIPS processing. ***MANDATORY*** for all data submissions to the Biometric Laboratory
54 73	SAS SDS	Self-Rating Anxiety Scale and Self-Rating Depression Scale . . .	Subject-rated versions of the clinician-rated Anxiety Status Inventory and Depression Status Inventory
117	AIMS	Abnormal Involuntary Movement Scale	Examination procedures and rating scale for dyskinetic movements

The ECDEU Order Form (EOF) is an administrative form for the distribution of ECDEU assessment material. It supersedes ECDEU Order Form (101-EOF).

UTILIZATION - Whenever supplies are requested from ECDEU Data Analyses of the Biometric Laboratory.

SPECIAL INSTRUCTIONS

1. Materials will be sent only upon receipt of a completed Research Plan Report, describing the study for which the supplies are requested. If additional supplies are needed for a study for which an RPR was previously submitted, be sure to include the assigned ECDEU Study Number.

2. Investigators are strongly urged to use the EOF when requesting supplies. Orders given by telephone or contained within letters primarily related to other matters are too easily misplaced - resulting in angry investigators and frustrated BLIPS bookkeepers. Emergencies do arise, however, and, under these circumstances, telephone orders will be accepted.

3. Investigators should restrict the quantity of supplies requested to that required for immediate use. "Stockpiling" of supplies is discouraged. It is suggested that investigators request only those supplies necessary to fulfill the assessment needs of the study or studies "ready to go" in the immediate future.

4. The new packets are expensive to produce and investigators should understand that they cannot be distributed with the largess we might wish. Since they are semi-permanent, packets should be serviceable for use in several studies or by several raters. Replacement of unserviceable packets will be made at reasonable intervals.

5. Since facsimiles of the Battery are contained within this Manual, copies of the Manual rather than the actual packets and instruments should be requested for training and educational purposes.

6. This form may be duplicated when originals are not available.

DOCUMENTATION

Documentation for the EOF is basically an "inhouse" bookkeeping operation.

050 GSS GENERAL SCORING SHEET

The General Scoring Sheet (GSS) is the basic ECDEU form for the encoding of data in op-scan format. It is the IBM Optical Scan Form No. 551 upon which the ECDEU identification block has been imprinted. The GSS replaces the General Purpose Scale (00-GP).

APPLICABILITY - All research populations and all types of numeric data.

UTILIZATION - The GSS may be used in 2 ways:

1. In conjunction with the various packets

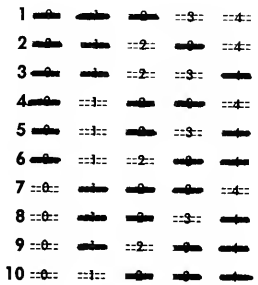
2. As a means for encoding non-standard data for BLIPS processing.

DATA FIELD FORMAT - The data matrix of the GSS (Figure 2) is bounded by the coordinates:

Rows (Horizontal)	1 - 41
Columns (Vertical)	1 - 20

There are 820 response positions within this matrix. Not all 820 positions can be encoded at any single time, however. Note that there are four "quadrants" of response positions: Cols. 1 - 5; 6 - 10; 11 - 15 and 16 - 20. On any given row within a "quadrant", any 3 of the 5 response positions can legally be marked at the same time.

Examples:



Thus, a maximum of 492 response positions can be utilized - legally - at any given time.

Four matrix coordinates are required to locate any data set:

Rows R_i to R_n

Columns C_i to C_n

MH-9-50
1-73

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HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB NO. 68-R965

ECDEU GENERAL SCORING SHEET (50-GSS)

FIGURE 2

PATIENT INITIALS

FIRST INITIAL

SECOND INITIAL

SHEET NO.

NUMBER MALES 001 TO 499

NUMBER FEMALES 500 TO 998

PATIENT IDENTIFICATION BLOCK

PERIOD

Hours 1

Days 2

Weeks 3

Months 4

ROW

DATA MATRIX

QUADRANT

HALF

COLUMN

Cols: 1 2 3 4 5 6 7 8 9 11 12 13 14 15 16 17 18 19 20

55

IBM H58269

SPECIAL INSTRUCTIONS

The GSS consists of an original and a carbon which are attached at the side of the set. Since only the original sheet can be processed by the opscan reader, carbons should be retained by the investigator for his files and NEVER be sent to the Biometric Laboratory for processing. Care should be exercised in detaching the carbon so that the original copy is not mutilated.

When the GSS is used in conjunction with the packets, the rater should follow the printed instructions carefully.

1. Encode ALL INFORMATION requested in the identification (ID) block for EACH GSS used.

   a. Patient Initials

   b. Patient Number

   c. Rater Number

   d. Period Number and Time Unit

   e. Sheet Number

2. Insert a new GSS when instructed to do so and again complete the ID block.

3. Use the Sheet Number specified in the packet instructions. Sheet Number - unlike Period Number - remains constant; i.e., it is always the same for a given scale or set of scales. Even when the investigator plans to use only a portion of the scales within a packet, he must adhere to the specified Sheet Numbers.

4. Follow the instructions for coding items carefully. Responses must be coded in precise locations or they will be rejected completely or decoded incorrectly in subsequent processing. Raters should not become confused by the numbers printed over each response position. Raters familiar with the NOSIE and its real scale points - 1,2,3,4,5 - may be disturbed by the GSS response position numbers - 5,6,7,8,9. Through programming, the 5-9 positions will be translated 1 - 5 in all output. The 0 to 9 labeling of GSS response positions is simply for rater orientation. The "number" is not "read" by the opscan reader - just the position.

5. If you wish to change a response, erase the incorrect response completely.

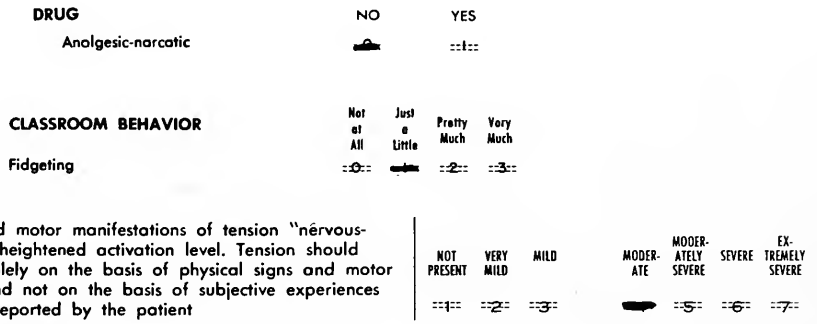
6. Finally, DO NOT FOLD, SPINDLE, STAPLE OR MUTILATE the GSS in any fashion. If, despite these prohibitions, you still feel an uncontrollable urge to use paper clips, PLEASE affix them to the BOTTOM EDGE of the GSS.

TYPES OF ENCODING

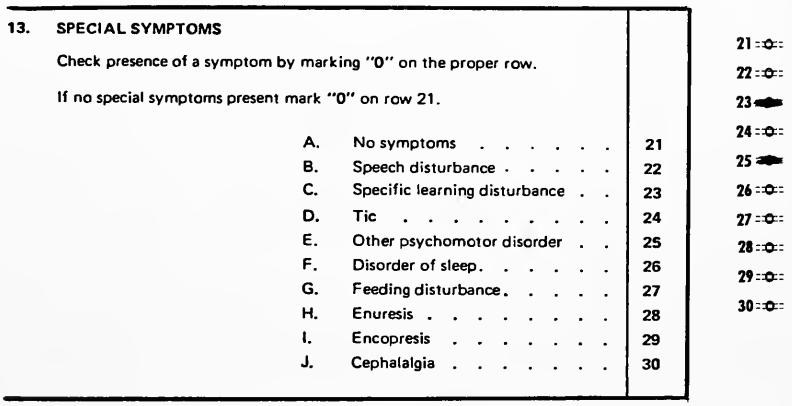
It might have been much less confusing for the rater if a single method of encoding a response had been adopted. To do this, however, the rater would have been faced with many more sheets of paper to complete - each with an identification block to fill. To avoid this, a variety of encoding techniques have been used to "pack" data on the fewest sheets possible. The type chosen in any given situation has been based primarily on specific space requirements. The response positions required to encode an item can be assigned in several ways.

Examples:

1. One item along a single row (horizontal). This is the most common type of encoding. Scale points may vary from 2 to 10.



2. In a single column (vertical) - For items where multiple responses are possible.



3. Two or more items in a single row - Used primarily on the demographic instruments where space is at a premium.

b.	Subject's Race is:	*Code both b and c on Row 4* 0 = Caucasoid 1 = Negroid 2 = Mongoloid 3 = Other	::0:: ::1:: ::2:: ::3:: ::4:: ::5:: ::6:: ::7:: ::8:: ::9::
c.	Has Subject's Residence Been:	5 = Primarily urban 6 = Primarily suburban 7 = Primarily rural	

4. Several items having a common code and requiring several rows and columns.

	Has either parent or present surrogate been: *Mark one response for each item using this code:* 0 = Neither parent 1 = Mother 2 = Father 3 = Both parents		
k.	Out of home *(3 months or longer)* due to physical or mental illness . .	22	::0:: ::1:: ::2:: ::3:: ::4::
l.	Separated *(3 months or longer)* due to marital difficulties	23	::0:: ::1:: ::2:: ::3:: ::4::
m.	Cruel or abusive *(to patient, spouse, siblings, etc.)*	24	::0:: ::1:: ::2:: ::3:: ::4::
n.	Not a steady worker or competent housewife	25	::0:: ::1:: ::2:: ::3:: ::4::

5. A single item requiring several rows - Used primarily for the encoding of numeric values of more than one digit.

::0:: ::1:: ::2:: ::3:: ::4:: ::5:: ::6:: ::7:: ::8:: ::9::
::0:: ::1:: ::2:: ::3:: ::4:: ::5:: ::6:: ::7:: ::8:: ::9::
::0:: ::1:: ::2:: ::3:: ::4:: ::5:: ::6:: ::7:: ::8:: ::9::
::X:: .00t .0t ::1:: ::10:: 100 1000

MAXIMUM TOTAL DAILY DOSE IN MILLIGRAMS

ENCODING NONSTANDARD DATA

The independent use of the GSS follows the procedures established for the now obsolete General Purpose Scale. Providing a larger data matrix, the GSS may be used for the encoding of a wide variety of numeric data in a format corresponding to the standard BLIPS identification and data fields. It enables investigators to submit non-standard assessment material in a format which will permit rapid processing and standard - as well as non-standard - analyses.

UTILIZATION - Dependent upon type of data

DATA FIELD MATRIX - The entire GSS matrix, or any part of it, may be used for non-standard data.

LOCATING DATA ON THE GSS MATRIX

A non-standard data set can be located within any portion of the GSS matrix. The choice of location depends on the size of the data set; i.e., the number of items, the number of scale points, the number of individual scales to be encoded, convenience in encoding and/or transcribing, etc. Generally, the investigator should try to "pack" data by encoding as much of his data set on one GSS as possible. Remember that more than one non-standard assessment instrument can be encoded on a single GSS provided that the data pertains to a single subject and a single rating period.

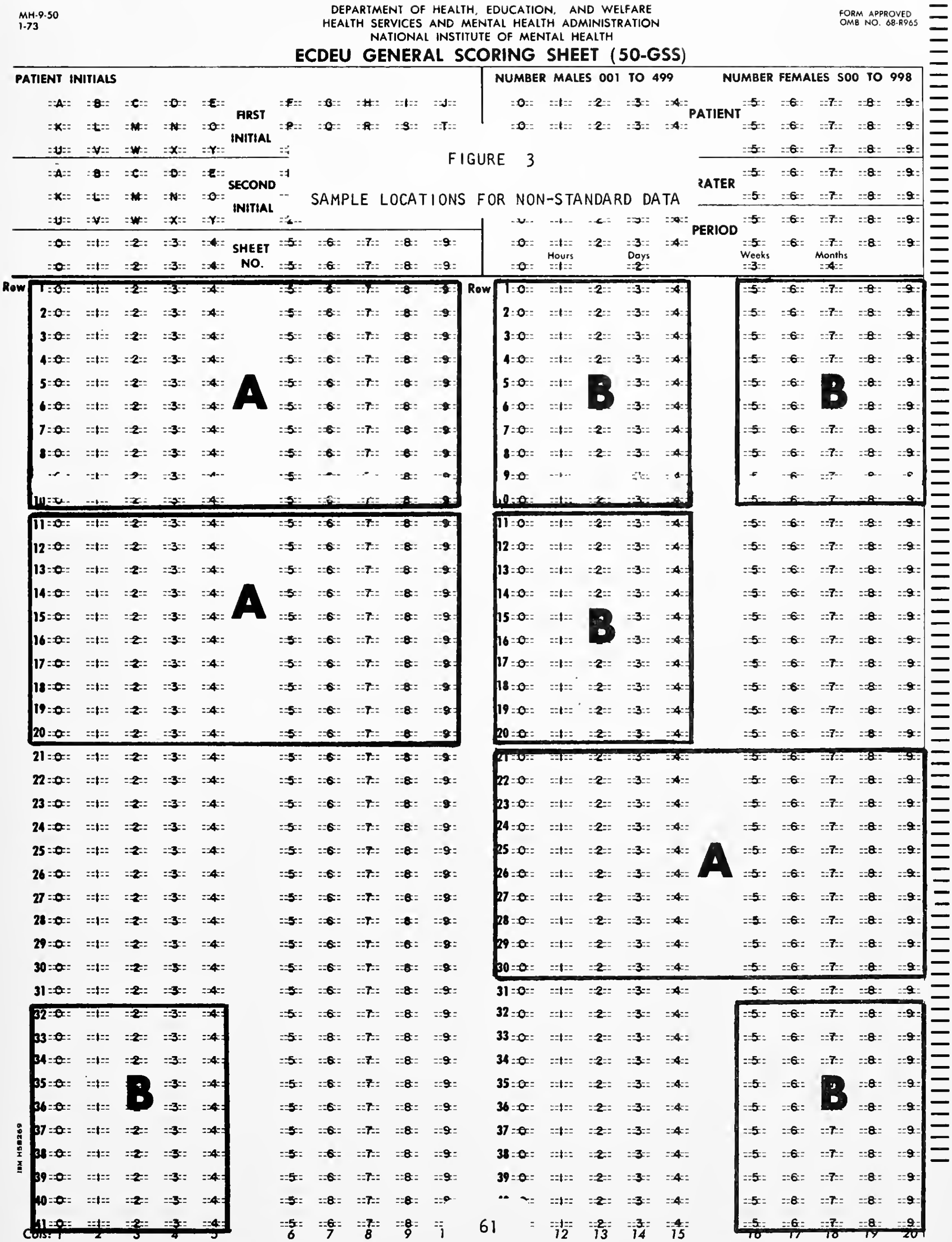
Figure 3 demonstrates some of the locations which might be used when encoding two non-standard scales. Scale A is a 10-item scale with 10 scale points; B is a scale with 10 items and 5 scale points. Note that only a few of the possible locations are illustrated. Also be aware that the numbers printed at each of the response positions are for the convenience of the rater and do not necessarily have to correspond to the actual scale points of given instrument. For example, Scale B's actual scale points are 0, 1, 2, 3, 4; but, the two extreme right locations of B utilize the response positions 5, 6, 6, 7, 9. This need not concern the investigator since the response positions will be "normalized"; i.e., changed to actual scale points, through computer programming.

ITEM FORMAT

Item format can vary according to the needs of the investigator EXCEPT THAT ONLY ROW CODING CAN BE EMPLOYED. The investigator cannot employ column-wise coding - either totally or partially - since this would require extensive and individualized programming. Items can have different size fields; i.e., number of rows, or different scale points and both can be interspersed. All data within an item, however, must be uniform. If an item varies from 1 to 125, all data must be encoded in 3 rows, e.g., 001, 014, 122, NOT blank blank 1, blank 14, etc.

SPECIAL INSTRUCTIONS

1. Data encoded on a single GSS MUST PERTAIN to a SINGLE subject. Do not encode data from different subjects on the same sheet.


MH-9-50
1-73
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH
ECDEU GENERAL SCORING SHEET (50-GSS)
FORM APPROVED
OMB NO. 68-R965
PATIENT INITIALS
FIRST INITIAL
SECOND INITIAL
SHEET NO.
NUMBER MALES 001 TO 499
NUMBER FEMALES 500 TO 998
PATIENT
RATER
PERIOD
Hours
Days
Weeks
Months
FIGURE 3
SAMPLE LOCATIONS FOR NON-STANDARD DATA
Row
A
A
A
B
B
B
B
B
Cols:

2. Similarly, do not encode data from different assessment periods on the same GSS.

3. Data pertaining to groups of subjects, e.g., summated data, means scores, may be encoded on the GSS. If you wish to compare these data with another group/s, the rules for the single subjects MUST be observed - only one group on one GSS: only one assessment period of the group on one GSS.

4. When encoding the identification block, follow the instructions exactly as you would when using a standard ECDEU assessment instrument.

5. SHEET NUMBERS from 80 to 99 MUST be used when encoding non-standard data. The Sheet Number - once assigned to a data set - must be used consistently throughout a given study.

6. Should the data set from a single assessment period for a given subject (group) be greater than the matrix of a single GSS, use another GSS and differentiate it from the first by assigning a different SHEET number to it; e.g., 80 for the first GSS; 81 for the second.

7. When an item is missing at a given rating period, leave ENTIRE field blank; i.e., use a field of blanks as a missing data code.

8. When a value for an item is recorded, there should be NO BLANKS within the field; e.g., encode 021, NOT blank 21.

9. It is not necessary to encode decimal points; but the placement of the decimal MUST be consistent within a SINGLE field. For example, the rater wishes to encode these four scores - 1.65, 10.41, 106.8, .37. They should be encoded in a field large enough to encompass all of them. For these 4 scores, the necessary field is xxx.xx; and the scores are coded as follows:

00165
01041
10680
00037

Note again that the decimal point is omitted in this example. It will appear in output when the proper format statement is inserted into programs; e.g., F6.2.

10. Items need not necessarily be encoded continuously, i.e., space may be left between items. The rater must, however, clearly indicate such "gaps".

11. Scale points may differ from item to item. Items may be continuous or discontinuous. The scale points may be given any name or designations. Examples of different scale possibilities are:

	0	1	2	3	
a)	Not present	Very mild	Mild	Moderate	---
b)	Never	Rarely	Occasionally		
c)	None	Once	Twice		
d)	0-.9	1.0-1.9	2.0-2.9	3.0-3.9	---
e)	Present	Absent			
f)	True	False			
g)	Yes	No			
h)	+	-			
i)	A	A + B	A + B + C		
j)	++	+ -	- +	--	

12. The investigator MUST send a copy of each scale or data set encoded on the GSS. In all instances, the investigator must identify clearly the positions in which he has encoded each item and, if it is not obvious from the actual scale, the scale points and/or range of scores of each item. For example:

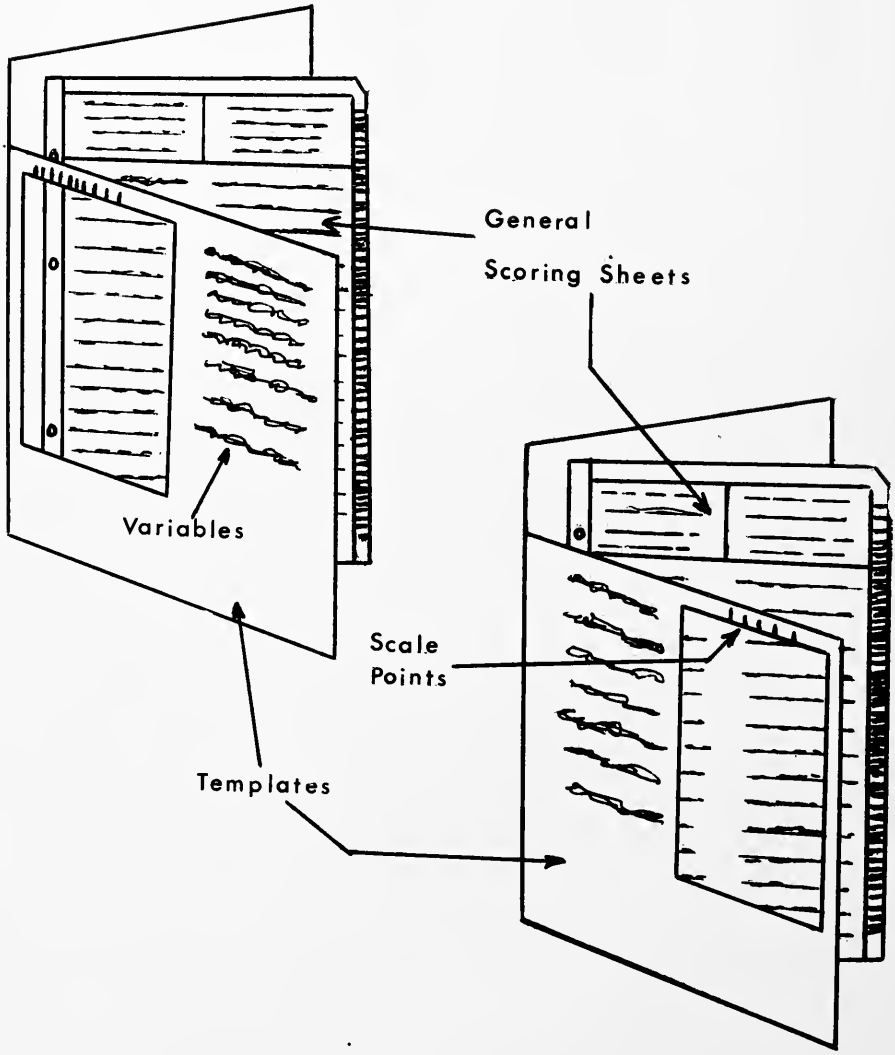
Rows	Name of Item	
1-3	Variable 1	050 to 500
4-5	Variable 2	01 to 20
6	Variable 3	0 to 9
7-8	Variable 4	10.00 to 99.99
9	Variable 5	True = 0; False = 1

13. More often than not, data will be transcribed from the original forms to GSS. The investigator may, however, wish to use GSS for direct encoding of observations. This may be accomplished by means of a template; e.g., a fold of paper covering 1/2 of a side upon which the items to be rated are typed so that they are aligned with response positions on the other half of GSS. (Figure 4). This home-made template, like the rater packets, can thus be reused and the problem of transcribing data eliminated.

14. It is ESSENTIAL that the location of all non-standard data be described in Item 11 of Data Shipment (071-DS). Without this information, BLIPS processing cannot be accomplished.

FIGURE 4

TEMPLATES FOR ENCODING NON-STANDARD DATA



THE DEMOGRAPHIC PACKET

The Demographic Packet contains three instruments - two for pediatric and one for adult populations. The demographic scales are:

Children	Adult
Children's Personal Data Inventory	Adult Personal Data Inventory
Children's Symptom History	

Figures 5 to 7 present data matrices for each of the scales. These matrices indicate the encoding location of each scale item as well as the GSS sheet number upon which it appears. These locations are FIXED and MAY NOT BE ALTERED. To do so will render the data non-processable.

Manipulating the sections of the packet and inserting the General Scoring Sheets may require some practice. The instructions on the back of the front cover of the packet should, however, provide the information needed to develop the necessary dexterity. It is important to state again, however, that the rater ALWAYS USE THE ASSIGNED SHEET NUMBERS for the scales - EACH AND EVERY TIME he uses them. Period Number changes, but Sheet Number never changes for a particular instrument.

Raters are cautioned that encoding for the Children's Personal Data Inventory (CPDI) is rather complicated. Since the CPDI acquires a large amount of information, "packing" of the data was necessary in order to encode everything on one GSS sheet. This was accomplished by formatting more than one item on a single row, thereby requiring the rater to make multiple marks in specific response positions. The rater must be particularly alert to follow the instructions carefully.

The Demographic Packet contains items which require varying degrees of professional "expertise" - from a clerical recording of a well-documented event to subtle judgments of development, motivation and veracity. A background in psychiatric social work would seem ideal for a rater of this packet, although such a background is not a requirement. What is paramount is the rater's ingenuity and persistence in acquiring complete and reliable information. The manner in which demographic data should be collected is succintly described by the following excerpt from Boothe, H. H.; and Schooler, N. R.; Instruction Manual for Brief Social History for Studies in Schizophrenia, Psychopharmacology Bulletin, 8, 1, 23-24, January, 1972.

> "Ideally the interviewer is so familiar with the content of the instrument that he can lead the discussion to each item in whatever way is most comfortable to the person interviewed, rather than by a rigid adherence to the word order of items in the form. He may not even want to have the form in sight, but may want to rely on his notes to complete the recording after the interview is finished. In any event it is good practice to check through the form before the informant leaves, to make sure that no items have been overlooked.

MH-9-50
9-75

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NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB NO. 68-R965

ECDEU GENERAL SCORING SHEET (50-GSS)

PATIENT INITIALS — FIRST INITIAL — SECOND INITIAL — SHEET NO.

NUMBER MALES 001 TO 499 — NUMBER FEMALES 500 TO 998

PATIENT — RATER — PERIOD (Hours, Days, Weeks, Months)

FIGURE 5
MATRIX FOR
CHILDREN'S PERSONAL
DATA INVENTORY

Row	Cols: 1	2	3	4	5	6	7	8	9	10
1										
2					4e					
3										
4										
5					4f					
6										
7										
8					4g					
9										
10		5a			5b		5c			
11					5d					
12										
13										
14					5e					
15										
16										
17					5f					
18										
19										
20					5g					
21										
22										
23					5h					
24										
25										
26					5i					
27										
28										
29					5j					
30										
31										
32					5k					
33										
34										
35					5l					
36										
37	5m				5n		5o			
38					6a					
39										
40					6b		6c			
41					7					

Row	Cols: 11	12	13	14	15	16	17	18	19	20
1		1								
2		1a								
3										
4		1b					1c			
5										
6					1d					
7										
8										
9		1e								
10					1f					
11		2a					2b			
12					2c					
13										
14					2d					
15										
16					2e					
17					2f					
18					2g					
19					2h					
20					2i					
21					2j					
22		2k								
23		2l								
24		2m								
25		2n								
26					3a					
27					3b					
28					3c					
29					2d					
30					2e					
31					2f					
32					2g					
33					2h					
34					2i					
35					2j					
36			4a				4b			
37					4c					
38										
39		1								
40					4d					
41										

MH-9-50
9-75

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB NO. 68-R965

ECDEU GENERAL SCORING SHEET (50-GSS)

PATIENT INITIALS — FIRST INITIAL — SECOND INITIAL — SHEET NO.

NUMBER MALES 001 TO 499 — NUMBER FEMALES 500 TO 998

PATIENT — RATER — PERIOD

FIGURE 6
MATRIX FOR
CHILDREN'S SYMPTOM HISTORY

Row	N	Y	N	Y	N	Y	N	Y
1	39a	17a	6a	1				
2	40	17b	6b	1a				
3	41	17c	6c	1b				
4	42	17d	6d1	2				
5	42a	17e	6d2	2a				
6	42b	17f	6d3	2b1				
7	43	18	6e	2b2				
8	44a	19	7	2b3				
9	44b	19a	7a	2b4				
10	44c	19b	7b	2b5				
11	45	19c	7c	2c				
12		19d	7d1	2d				
13		19e	7d2	3				
14		19f	7d3	3a				
15		19g	7e	3b1				
16		20	7f1	3b2				
17		20a	7f2	3b3				
18		21	7f3	3b4				
19		21a	7g	3b5				
20		21b	7h	3c				
21		21c	7i1	4				
22		22	7i2	4a1				
23		23	7i3	4a2				
24		23a	8	4a3				
25		23b	9	4b				
26		24	10	4c1				
27		25	10a1	4c2				
28		26	10a2	4c3				
29		27	10a3	4d1				
30		28	10b	4d2				
31		29	10c	4d3				
32		30	11	4e				
33		31	11a1	5				
34		32	11a2	5a				
35		33	11a3	5b				
36		34	12	5c				
37		35	13	5d1				
38		36	14	5d2				
39		37	15	5d3				
40		38	16	5e				
41		39	17	6				

Cols: 1 2 3 4 5 6 7 8 9 1 12 13 14 15 16 17 18 19 20

MH-9-50
9-75

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
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ECDEU GENERAL SCORING SHEET (50-GSS)

PATIENT INITIALS

FIRST INITIAL: A B C D E F G H / K L M N O P Q R / U V W X Y Z

SECOND INITIAL: A B C D E F G H / K L M N O P Q R / U V W X Y Z

SHEET NO.: 0 1 2 3 4 5 6 7 8 9 / 0 1 2 3 4 5 6 7 8 9

NUMBER MALES 001 TO 499 NUMBER FEMALES 500 TO 998

PATIENT: 0 1 2 3 4 5 6 7 8 9

RATER: 0 1 2 3 4 5 6 7 8 9

PERIOD: 0 1 2 3 4 5 6 7 8 9 / 0 Hours 1 Days 2 Weeks 3 Months 4

FIGURE 7
MATRIX FOR
ADULT PERSONAL
DATA INVENTORY

Row	Cols 1–9	Row	Cols 11–20
1	12c	1	1
2	12c	2	1
3	12c	3	2
4	12d	4	3
5	12d	5	4
6	12d	6	5a1
7	12e	7	5a2
8	12e	8	5b1
9	12e	9	5b2
10	12f	10	6a
11	1 (12g)	11	6b
12	2 (12g)	12	7
13	3 (12g)	13	7
14	4 (12g)	14	7
15	5 (12g)	15	8a
16	6 (12g)	16	8b
17	7 (12g)	17	8b
18	8 (12g)	18	8b
19	9 (12g)	19	8b
20	10 (12g)	20	8c
21	11 (12g)	21	8c
22	12 (12g)	22	8c
23	13a	23	8c
24	13b	24	9a
25	13c	25	9b
26	13d	26	9b
27	13e	27	9b
28	13f	28	9c
29	13g	29	9c
30	13h	30	9c
31	13i	31	10
32	13j	32	11a
33	13k	33	11b
34	14a	34	11c
35	14b	35	12a
36	15a	36	12a
37	15b	37	12b
38	15c	38	12b
39	15d	39	
40	15e	40	
41		41	

Cols: 1 2 3 4 5 6 7 8 9 12 13 14 15 16 17 18 19 20

The number and length of interviews needed to complete the form depend on a variety of factors, such as the personalities of the informants, their availability for interviews, the style of the interviewer, etc. Whenever possible, the interviewer should obtain a sufficient number of informants to cover the included items in the patient's life span adequately. For a married adult this ideally means a minimum of two people, a spouse and a parent. Available hospital records as well as additional knowledgeable informants are desirable. In fact, in dealing with schizophrenic patients who may be disconnected from any familial setting, an informant such as the landlady of the rooming-house, a neighbor, or such significant other person may be preferable as a source of reliable information about the patient's present circumstances to a relative who has had no real and recent contact with the patient. In each case, the objective is to acquire pertinent, reliable information, whatever the source.

Some of the information requested concerns straightforward, factual matters, such as those specified by the first few items in the form. On the other hand, a much larger body of material is not strictly "factual" but is subject to interpretation, and the interviewer must often probe for additional illuminating information. For example, the discussion about the patient's past may lead the interviewer to suspect that the patient had been psychiatrically sick before, despite the informant's earlier statement that the present illness was the first. By a skillful question, however, the interviewer may elicit information that confirms or eliminates his hunch.

Every interviewer has to contend with the empirical fact that there is no "one truth" about a mental illness. To reconcile fragments of historical data and to arrive at an interpretation which most closely resembles the "objective truth" is one of the interviewer's most challenging tasks. It requires knowledge, ingenuity, skill and time. There are circumstances, however, which make it impossible to obtain reliable information. In these rare instances, the interviewer is asked to mark "not ascertained" rather than to provide answers which are mainly guesses."

ERRATA - Raters should make the following corrections in their Demographic Packets:

1. Children's Personal Data Inventory (043-CPDI)
   Page R-2 - Item 6b. Should read "Mark both b and c on Row 40", NOT "Row 20".

2. Children's Symptom History (044-CSH)
   Page L-4 - Item 2b. The word "stomach-aches" is misspelled.
   Page L-5 - Item 7. Insert the letter "i" to the last question of this item "How do you deal with them?"
   Page L-5, Item 11a, Response No. 1 "Not at all" should read "Just a little".

3. Adult Personal Data Inventory (045-APDI)
   a) Page L-9 - Item 8a. Insert "15" for Row Number.
   b) Page L-9 - Item 8b. Text should read "Code diagnosis from those listed in ECDEU Manual using 4 digits for DSM II (Rows 16 - 19) or 4 digits for WHO (Rows 16 - 19)".
   c) Page R-3 - Item 12e. The Row Numbers for this item should read "7-9", NOT "5-9".

043 CPDI
CHILDRENS
PERSONAL DATA
INVENTORY

MH-9–43
6-73

CHILDREN'S PERSONAL DATA INVENTORY

C P D I

INSTRUCTIONS: *Insert General Scoring Sheet and Code 10 for Sheet Number. Code 000 for PERIOD.*

Raters are cautioned to be particularly careful in coding their responses since several items have sub parts which must be coded on the same row. Follow the coding instructions carefully. Complete once for each subject. Please answer all items.

If information is not ascertained, mark a field of "9"s, e.g., 9, 99, 999 etc.

Mark on right half of scoring sheet on row specified

1. IDENTIFICATION (Note: *Sex of subject is coded within Patient Number*)

a. Subject's Age: Mark time units — 1 = months; 2 = years on Row 1 and give numeric (2 digits) on Rows 2 - 3 — ROW NO. 1, 2-3

b. Subject's Race is: *Code both b and c on Row 4* — ROW NO. 4

0 = Caucasoid
1 = Negroid
2 = Mongoloid
3 = Other

c. Has Subject's Residence Been:

5 = Primarily urban
6 = Primarily suburban
7 = Primarily rural

d. Sibling Sequence: Subject is the *enter number (2 digits)* child . . of *enter number (2 digits)* children . . . . (Only child is coded "the 01 child of 01 children") — ROW NO. 5-6, 7-8

e. Is Subject One of Twins, Triplets, etc.? 0 = No; 1 = Yes, homozygous; 2 = Yes, heterozygous; 3 = Yes, unknown zygosity — ROW NO. 9

f. The Subject's Present Family Constellation Consists of: *(Mark all applicable on Row 10)* — ROW NO. 10

0 = Natural mother
1 = Natural father
2 = Step-parent
3 = Adoptive parent/s
4 = Paid foster parents
5 = Adult relative/s (grandparents, uncles, aunts, etc.)
6 = Siblings, step-siblings and/or other children
7 = Subject not living with family; is in non-psychiatric institution
8 = Subject not living with family; is in psychiatric institution/unit

2. PARENTS' DEMOGRAPHY

Is either NATURAL parent: *Code both a and b on Row 11* — ROW NO. 11

a. Dead? 0 = No; 1 = Yes, mother; 2 = Yes, father; 3 = Yes, both

b. Divorced or out of home? 5 = No; 6 = Yes, mother; 7 = Yes, father; 8 = Yes, both

c. Mother's Age: Mother or mother surrogate presently in the home *(2 digits)* 00 = Not applicable . . . . . — ROW NO. 12-13

d. Father's Age: Father or father surrogate presently in the home *(2 digits)* 00 = Not applicable . . . . . — ROW NO. 14-15

Continue marking on right half of scoring sheet on row specified

PARENTS' EDUCATION

e. Mother or Present Surrogate *Code highest level attained for MOTHER* — ROW NO. 16

f. Father or Present Surrogate *Code highest level attained for FATHER* — ROW NO. 17

0 = Not applicable
1 = Graduate professional training
2 = College graduate
3 = Some college or technical school
4 = High school graduate
5 = Some high school (10-11)
6 = Junior high school (7, 8, 9)
7 = Less than 7 years of school
9 = Not ascertained

PARENTS' OCCUPATION

g. Mother's or Female Surrogate's Present Occupational Status is: . . . — ROW NO. 18

h. Father or Male Surrogate's Present Occupational Status is: . . . . — ROW NO. 19

Use this code for g and h:
0 = Not applicable
1 = Full time gainful employment
2 = Part time gainful employment
3 = Unemployed
4 = Dependent spouse or student
5 = Recipient of public or private assistance

i. Mother's or Female Surrogate's Highest Occupational Attainment is: . — ROW NO. 20

j. Fathers or Male Surrogate's Highest Occupational Attainment is: . . — ROW NO. 21

Use this code for i and j. *See Manual for detailed list of occupations.*

1 = Higher executive, proprietor of large concern, major professional
2 = Business manager of large concern, proprietor of medium-sized business, lesser professional
3 = Administrative personnel, owner of small independent business, minor professional
4 = Clerical or sales worker, technician, owner of little business
5 = Skilled manual employee
6 = Machine operator, semi-skilled employee
7 = Unskilled employee
8 = Never worked in paid employment
9 = Not ascertained

Has either parent or present surrogate been:
Mark one response for each item using this code: 0 = Neither parent; 1 = Mother; 2 = Father; 3 = Both parents

k. Out of home *(3 months or longer)* **due to physical or mental illness** . . — ROW NO. 22

l. Separated *(3 months or longer)* **due to marital difficulties** . . . . — ROW NO. 23

m. Cruel or abusive *(to patient, spouse, siblings, etc.)* . . . . . — ROW NO. 24

n. Not a steady worker or competent housewife . . . . . — ROW NO. 25

Continue marking on right half of scoring sheet on row specified

3. FAMILY HISTORY OF PSYCHIATRIC ILLNESS

Has there been a history of psychiatric illness in family member/s?

Mark all applicable for each item using this code:

0 = None of the members
1 = Natural mother
2 = Natural father
3 = Siblings
5 = Present mother surrogate
6 = Present father surrogate

		ROW NO.
e.	Non-psychotic psychiatric disturbance	26
b.	Manic-depressive disturbance	27
c.	Other major affective disturbance	28
d.	Schizophrenia	29
e.	Other psychotic disturbance	30
f.	Hospitalized for any psychiatric illness	31
g.	Mental deficiency	32
h.	Excessive use of alcohol	33
i.	Excessive use of drugs	34
j.	Imprisonment	35

4. SUBJECT'S HISTORY OF PSYCHIATRIC ILLNESS

Treatment Status *Code both a and b on Row 36* — 36

e. **Subject is presently:** *(Mark one)*
1 = Not in any type of psychiatric treatment
2 = In psychiatric treatment as an outpatient
3 = In partial hospitalization, e.g., day or night hospital, halfway house, etc.
4 = Hospitalized (24 hour)

b. **Prior to this episode, subject has:** *(Mark all applicable)*
5 = Never had any type of psychiatric treatment
6 = Received psychiatric outpatient treatment
7 = Received treatment in partial hospitalization setting
8 = Received treatment in 24-hour hospital

"Psychiatric treatment" should be interpreted broadly to include all forms of therapy whose basic function is the alleviation of emotional, behavioral or mental disturbance. "Partial hospitalization" and 24-hour hospitalization include all forms of treatment environments in which the subject spends a substantial part of the day or, in the latter case, the full day.

c. **Age** *(years)* **when first received treatment for psychiatric illness** *(2 digits)* — 37-38
00 = Never treated

d. **Estimate total duration of ALL outpatient psychiatric treatment — exclusive of present episode** — 39-41

Give time units *(0 = days; 1 = weeks; 2 = months; 3 = years)* and duration *(2 digits)*

EXAMPLE: Subject's total treatment amounts to 10 months.
Code 210. 000 = No outpatient treatment

ROW NO.	*Mark on left half of scoring sheet on row specified*
	4. *SUBJECT'S HISTORY OF PSYCHIATRIC ILLNESS — Continued*
1-3	**e. Estimate total duration of ALL partial hospitalization — exclusive of present episode** Give time units *(0 = days; 1 = weeks; 2 = months; 3 = years)* and duration *(2 digits)* 000 = No partial hospitalization
4-6	**f. Estimate total duration of ALL hospitalizations** *(24 hour)* **exclusive of present episode** Give time units *(0 = days; 1 = weeks; 2 = months; 3 = years)* and duration *(2 digits)* **EXAMPLE:** Subject's total hospitalization amounts to 4 years Code 304 000 = No hospitalizations
7-9	**g. Duration of present episode** Mark whether coded in 0 = days 1 = weeks 2 = months 3 = years and give duration *(2 digits)* 000 = Not applicable
	5. SUBJECT'S DEVELOPMENTAL HISTORY *Code a, b and c on Row 10*
10	**a. Pregnancy and Neonatal Course Were:** 0 = Normal 1 = Suspected abnormalities 2 = Definite abnormalities 3 = Not ascertained **b. Were there infant feeding problems?** 4 = YES 5 = NO 6 = Not ascertained **c. Colic?** 7 = YES 8 = NO 9 = Not ascertained
	For each of the following items d *through* k, *record months in 2 digits and judge rate of development on next row:*
11-12	**d. Age** *(months)* **first ate solids - not pureed or strained food**
13	Considered 0 = Slow; 1 = Normal 2 = Fast
14-15	**e. Age** *(months)* **first fed self with a spoon**
16	Considered 0 = Slow; 1 = Normal; 2 = Fast
17-18	**f. Age** *(months)* **sat unsupported**
19	Considered 0 = Slow; 1 = Normal; 2 = Fast
20-21	**g. Age** *(months)* **first walked by self without holding on**
22	Considered 0 = Slow; 1 = Normal; 2 = Fast
23-24	**h. Age** *(months)* **first words other than Mama and Dadda**
25	Considered 0 = Slow; 1 = Normal; 2 = Fast

ROW NO.	*Continue marking on left half of scoring sheet on row specified*
26-27 28	i. **Age** *(months)* **of speaking 3-word sentences** Considered 0 = Slow; 1 = Normal; 2 = Fast
29-30 31	j. **Age** *(months)* **trained bladder during day** Considered 0 = Slow; 1 = Normal; 2 = Fast
32-33 34	k. **Age** *(months)* **trained bowels** Considered 0 = Slow; 1 = Normal; 2 = Fast
35-36	l. **Age** *(year)* **began menstruating** *(2 digits)* 00 = Not applicable
37	*Mark m. n and o all on Row 37* m. **Masturbates?** 0 = NO 1 = YES 2 = Not ascertained n. **Does he/she dress in clothes or play with toys of opposite sex?** 3 = NO 4 = YES 5 = Not ascertained o. **Does he/she express a desire to grow up to be a member of opposite sex?** 6 = NO 7 = YES 9 = Not ascertained
	6. SUBJECT'S SCHOOL HISTORY
38-39	a. **Current Grade Placement** *(2 digits)* *Number grades 01 — 12* 20 = Preschool 21 = Nursery 22 = Kindergarten 23 = Special or Ungraded 24 = Not in school
40	*Mark both b and c on Row 20* b. **Child's School History is Best Characterized by:** 0 = Not applicable 1 = No significant problems at any time 2 = Minor problems or occasional difficulties 3 = Major problems seen only in current year 4 = Major problems throughout school history with periods of quiescence; "up and down" 5 = Major problems almost continually since entrance into school c. **In General Academic Achievement Has Been:** 6 = Above average 7 = Average 8 = Below average
41	**7. ATTITUDE TOWARD PRESENT TREATMENT** At pretreatment, the attitudes of the child and his parent/s were: *Make 2 marks (one for child, one for family) both on Row 41* 0 = Child positive 1 = Child indifferent 2 = Child ambivalent 3 = Child negative 4 = Child's attitude not ascertained 5 = Family positive 6 = Family indifferent 7 = Family ambivalent 8 = Family negative 9 = Family attitude not ascertained

The Children's Personal Data Inventory (CPDI) is a 55-item scale formatted for use with the General Scoring Sheet. Its purpose is to gather social and demographic data concerning the child and his family. The content of the CPDI was developed by members of the Pediatric Psychopharmacology Workshop. Wherever possible, items were made compatible with similar items contained in the Adult Personal Data Inventory (045-APDI).

APPLICABILITY - Children to age 15.

UTILIZATION - Once per subject

CARD FORMAT - ITEMS

CARD 01 = (19x, 211, 12, 211, 222, 11, 13, 211, 212, 1011, 1012, 211, 12)

Item	Column	Item	Column
Sex*	20	2k	46
1a	21 - 23	1	47
b	24	m	48
c	25	n	49
d	26 - 29	3a	50 - 51
e	30	b	52 - 53
f	31 - 33	c	54 - 55
2a	34	d	56 - 57
b	35	e	58 - 59
c	36 - 37	f	60 - 61
d	38 - 39	g	62 - 63
e	40	h	64 - 65
f	41	i	66 - 67
g	42	j	68 - 69
h	43	4a	70
i	44	b	71
j	45	c	72 - 73

* = This item is added to the card output.

CARD 02 = (19x, 413, 311, 813, 12, 311, 12, 211, 12, 211, 12)

Item	Column	Item	Column
4d	20 - 22	5j	53 - 55
e	23 - 25	k	56 - 58
f	26 - 28	l	59 - 60
g	29 - 31	m	61
5a	32	n	62
b	33	o	63
c	34	6a	64 - 65
d	35 - 37	b	66
e	38 - 40	c	67
f	41 - 43	7	68 - 69
g	44 - 46	Soc.Class M**	70
h	47 - 49	" " F**	71
i	50 - 52	Developmental Index**	72 - 73

**= These items are calculated and punched on the card via programming.

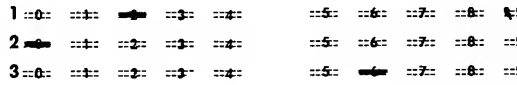
SPECIAL INSTRUCTIONS

All of the items on the CPDI can be encoded on one General Scoring Sheet. As a result of this "packing of data", raters are cautioned that the encoding procedures are intricate and that close attention should be paid to the instructions printed on the scale and given below.

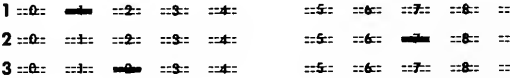
Item 1a. Age - Three marks are required for the encoding of this item: a designation of the time unit - month or year - in Row 1 and the numeric for age in Rows 2 and 3.

Examples:

Subject is 6 years old. Encode 206.



Subject is 72 months old. Encode 172.



Age encoded in years should be given to the nearest whole year; age in months to the nearest whole month.

Item 1b and 1c. Race and Residence - Both of these items are encoded on Row 4. Subjects of mixed racial heritage should be encoded "Other".

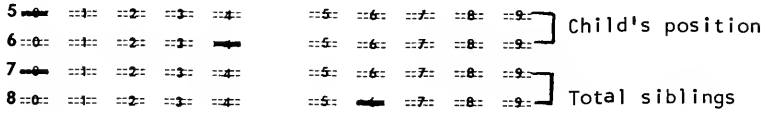
Example: Subject is negroid and her residence is primarily urban. Encode 1 and 5.

Where there is difficulty in deciding primacy of residence, encode the most recent residence.

Example: For approximately one-half of his life, a boy lived in an urban area. Since then, however, his residence has been suburban. Encode "Primarily suburban".

Item 1d. Sibling sequence - Consider only maternal natural siblings. Encode the child's position in the sibling sequence in Rows 5 - 6 and the total number of siblings in Rows 7 - 8.

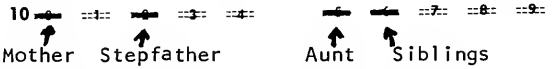
Example: The child is the fourth of six children. Do not leave any blank rows and encode as follows:



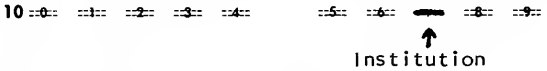
Item 1f. Present family constellation - The rater should mark all individuals living together as a family at the start of the study. All responses are encoded on Row 10.

Examples:

a. The child lives with his mother and stepfather. There are two natural siblings and one step-sibling living in the home along with a maiden aunt. Encode 0-2-5-6 on Row 10.



b. The child is a state ward. His family is unknown and he is currently residing at the state orphanage. Encode as follows:



To conserve space on card decks, a coding system has been developed which reduces the multiple entries of this item to a 2-digit field. The codes are given in Table 4. These codes should NOT be used by raters when recording (encoding) data. They are generated as output.

Example:

Output Code 33 = Response positions 0, 1 and 6; i.e., the rater coded mother, father and siblings as constituting the present family constellation.

TABLE 4

CODES FOR CPDI ITEM 1f - PRESENT FAMILY CONSTELLATION

Card Code	0 Mother	1 Father	2 Step-parent	3 Adoptive	4 Foster	5 Relative	6 Siblings	7 Non-Psychiatric	8 Psychiatric	9 Not Ascertained	Response Positions
00										X	9
01							X				6
02						X					5
03						X	X				5,6
04					X						4
05					X		X				4,6
06					X	X					4,5
07					X	X	X				4,5,6
08				X							3
09				X			X				3,6
10				X		X					3,5
11				X		X	X				3,5,6
12			X								2
13			X				X				2,6
14			X			X					2,5
15			X			X	X				2,5,6
16		X									1
17		X					X				1,6
18		X				X					1,5
19		X				X	X				1,5,6
20		X	X								1,2
21		X	X				X				1,2,6
22		X	X			X					1,2,5
23		X	X			X	X				1,2,5,6
24	X										0
25	X						X				0,6
26	X					X					0,5
27	X					X	X				0,5,6
28	X		X								0,2
29	X		X				X				0,2,6
30	X		X			X					0,2,5
31	X		X			X	X				0,2,5,6
32	X	X									0,1
33	X	X					X				0,1,6
34	X	X				X					0,1,5
35	X	X				X	X				0,1,5,6
36								X			7
37									X		8
88	Illegal or Improbable Family Constellation										

Item 2. Parents' Demography - Items 2a and 2b refer to NATURAL PARENTS. Subsequent items (2c through 2n) refer to natural parents or their surrogates - whichever are PRESENTLY part of the family constellation, i.e., at the beginning of the study.

Item 2a and 2b. These items are both encoded on Row 11.

Example: Neither of the child's natural parents are dead or divorced. Encode 0 - 5 on Row 11.

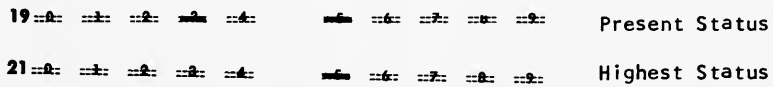
When information about the natural parents is not available, response position "4" may be used to indicate lack of information about death; position "9" to indicate lack of information about divorce.

Items 2g through 2j. Parents' occupational status - The parents' present occupational status (Items 2g and 2h) are encoded on Rows 18 (mother) and 19 (father) using the 5 categories given. More than one response may be encoded. Multiple entries will be recoded on card decks using the following 1-digit system.

Rater should Encode	If he wishes these Response/s	Description
6	2,5	Part-time employment and recipient of assistance
7	3,5	Unemployed and recipient of assistance
8	4,5	Dependent student/spouse and recipient of assistance

The parents' highest occupational status (Items i and j) are encoded on Rows 20 (mother) and 21 (father) using the 8 categories given. A list of occupations adapted from Hollingshead are given in Appendix I and should be used in classifying specific occupations.

Example: Father is a skilled machinist who is currently unemployed and receiving public assistance. Encode both "unemployed" (3) and "receiving public assistance" (5).on Row 19. Encode "skilled machinist" (5) on Row 21.



COMPUTATION OF SOCIAL CLASS

Social class for each parent is computed from their highest educational level and highest occupational level using the Hollingshead method. (Hollingshead, A.B., Two Factor Index of Social Position, 1965 Yale Station, New Haven, Connecticut, 1957).

The calculation of computed score for social class is as follows:

		Factor Weight	
Occupation Score (1-7)	X	7 =	Weighted score
Education Score (1-7)	X	4 =	Weighted score

Sum of weighted scores = Computed Score

Social Class is assigned on basis of Computed Score as follows:

Class	Computed Score
I	11 - 17
II	18 - 27
III	28 - 43
IV	44 - 60
V	61 - 77

Example: A graduate of a college nursing program is currently employed as an OR (Operating Room) supervisor. Her social class is calculated as follows:

Occupation = 2 x 7 = 14

Education = 2 x 4 = 8

22

Computed score = 22 Social Class = 2

Social class for each parent is calculated via programming and documented in the output.

Items 2k through 2n. Each of these 4 items requires a single response using the code provided:

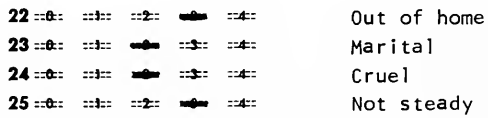
0 = Item applies to neither parent.

1 = Item applies to mother only.

2 = Item applies to father only.

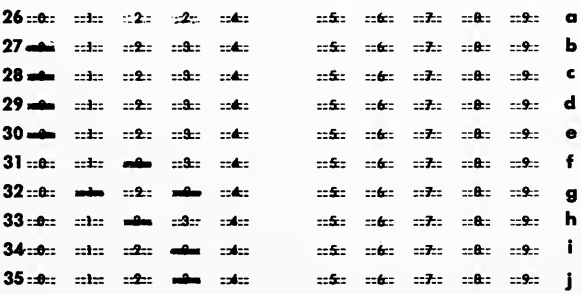
3 = Item applies to both parents.

Example: The father, a sporadic worker, left the home 6 months ago after assaulting his wife. The mother has been hospitalized for psychiatric illness for periods up to one year. She is considered a poor housekeeper but has never been abusive to the children. Encode as follows:



Item 3. Family History of Psychiatric Illness - For each of the 10 items (a through j), one to five positions may be encoded depending on the number of family members exhibiting the condition.

Example: While none of the members of this typical family are considered psychotic, the father has been hospitalized for alcoholism. The mother and youngest daughter are considered mentally retarded and an older brother is in prison for selling drugs to support his habit. Encode as follows:



The multiple entries possible on this item have been reduced to a 2-digit coding system which will appear on all card decks. (Table 5).

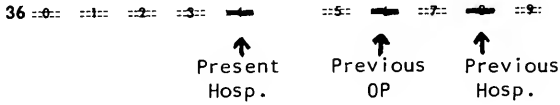
TABLE 5

CODES FOR CPDI ITEM 3a-3j - FAMILY PSYCHIATRIC ILLNESS

Card Code	None of Members 0	Natural Mother 1	Natural Father 2	Siblings 3	Surrogate Mother 5	Surrogate Father 6	Not Ascertained 9	Response Positions
00							X	9
01						X		6
02					X			5
03					X	X		5,6
04				X				3
05				X		X		3,6
06				X	X			3,5
07				X	X	X		3,5,6
08			X					2
09			X			X		2,6
10			X		X			2,5
11			X		X	X		2,5,6
12			X	X				2,3
13			X	X		X		2,3,6
14			X	X	X			2,3,5
15			X	X	X	X		2,3,5,6
16		X						1
17		X				X		1,6
18		X			X			1,5
19		X			X	X		1,5,6
20		X		X				1,3
21		X		X		X		1,3,6
22		X		X	X			1,3,5
23		X		X	X	X		1,3,5,6
24		X	X					1,2
25		X	X			X		1,2,6
26		X	X		X			1,2,5
27		X	X		X	X		1,2,5,6
28		X	X	X				1,2,3
29		X	X	X		X		1,2,3,6
30		X	X	X	X			1,2,3,5
31		X	X	X	X	X		1,2,3,5,6
32	X							0

Item 4. Subject's History of Psychiatric Illness - Item 4a, Treatment Status, and Item 4b, Prior History, are both encoded on Row 36. Only ONE Treatment Status may be marked; but as many marks as necessary (maximum of 3) may be used for Prior History.

Example: The child - currently hospitalized (24-hour) - has had previous outpatient treatment and previous 24-hour hospitalizations. Encode 4-6-8 on Row 36.



As noted within the Demographic Packet, "psychiatric treatment" should be interpreted broadly to include all forms of generally accepted therapies; e.g., chemotherapy, individual and group psychotherapies, behavior modification, counseling for behavioral or emotional problems, etc., provided by any of the professionally recognized disciplines; e.g., psychiatrist, pediatrician, physician, psychologist, social worker, supervised paraprofessionals, etc.

Since multiple entries are possible (maximum of 3) on 4b, a 1-digit coding system has been developed for card decks.

Code	Response Positions	Description
0	9	Not Ascertained
1	8	24-hour hospitalization
2	7	Partial hospitalization
3	7,8	Partial, 24-hour
4	6	Outpatient
5	6,8	Outpatient, 24-hour
6	6,7	Outpatient, partial hospitalization
7	6,7,8	Outpatient, partial, 24-hour
8	5	Never had treatment

Item 4c. First treated - Encode the age at which the subject first received any psychiatric treatment. To record the fact that the subject has never been "treated", the rater must encode "00" - leaving the item blank will be interpreted as missing data. The code "99" indicates Not Ascertained.

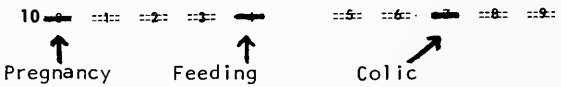
Items 4d through 4g. Duration of Treatments - Each of these 4 items requires a 3-digit entry: one digit indicating the time unit and 2 digits indicating the numeric for duration. Whichever time unit is employed, encode to the nearest whole unit.

Examples: If time unit is weeks: 11 days is encoded as 2 weeks.
If time unit is months: 11 weeks is encoded as 3 months.
If time unit is years: 13 months is encoded as 1 year.

"Outpatient psychiatric treatment" is to be interpreted broadly to include all forms of accepted therapy for behavioral or emotional disorders for which there are no "in-residence" requirements; e.g., outpatient hospital clinics, office visits to private practitioner, "the 50-minute hour", child guidance clinics, etc. "Partial hospitalization" refers to all therapies in which there is a "residency" requirement - either in terms of a certain portion of the day or in terms of a specific living situation; e.g., day hospitals, night hospitals, half-way houses, etc. "24 hour hospitalization" refers to therapies in which full time residency is a requirement; e.g., public or private psychiatric hospitals, psychiatric wards of general hospitals, schools for the emotionally disturbed, etc.

Item 5. Subject's Developmental History - Items 5a, b and c are all encoded on Row 10. Note that response positions 3 and 6 as well as 9 serve as "Not Ascertained" for this 3-part encoding.

Example: Pregnancy and neonatal course were considered normal, however, the child had feeding problems and colic. Encode 0-4-7 on Row 10.



Items 5d through 5k. Each of these items requires the recording of age in months and a judgment of developmental normality. If the information for one of the items is not available, CODE '999'.

The following table - supplied by Dr. Rachel Gittelman-Klein provides developmental norms for each of the 8 items. Other developmental inventories which may be of interest are:

1. Frankenburg, W. K. and Dodds, J. B., The Denver Developmental Screening Test, J. Pediatrics, 71, 2, 181-191, August, 1967.
2. Ireton, H. R. and Thwing, E. J., Minnesota Child Development Inventory, published by Interpretive Scoring Systems, 4401 W. 76th St., Minneapolis, Minnesota, 1972.

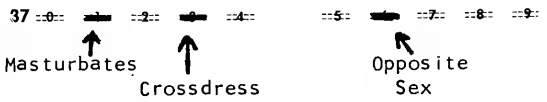
	Item	MONTHS Slow	Normal	Fast
5d.	First ate solids	13 or more	8-12	7 or less
e.	First fed self	24 or more	12-23	11 or less
f.	First sat alone	8 or more	5-7	4 or less
g.	First walked	14 or more	11-13	10 or less
h.	First words	21 or more	12-20	11 or less
i.	Speaking sentences	43 or more	24-42	23 or less
j.	Trained bladder	29 or more	18-28	17 or less
k.	Trained bowels	25 or more	15-24	14 or less

Developmental History Score - Items 5d through 5k are used to calculate a developmental score. Using the 3-point scale, the 8 items are added together and the sum is divided by the number of items minus "Not Ascertained". Five of the 8 items must be present, however, for a score to be computed. Developmental scores below 1 reflect slower development; those above 1 reflect accelerated development.

Item 5l. Age of Menstruation - This item requires the encoding of the YEAR of menarche. The code, "00" - NOT 2 blanks - indicates "Not applicable"; The code "99" indicates "Not Ascertained". No judgment of developmental normality is required.

Items 5m, 5n, and 5o. These 3 items are all coded on Row 37. Response positions 2 and 5 as well as 9 serve to indicate "Not Ascertained".

Example: A child who masturbates but does not crossdress or express a desire to be a member of the opposite sex should be encoded 1-3-6 on Row 37.



Item 6. Subject's School History

6a. Current grade placement - give 2-digit numeric code for grades 01 through 12 or use the following special codes:

20 - Preschool

21 - Nursery

22 - Kindergarten

23 - Special or ungraded

24 - Not in school

99 - Not ascertained

When child is in-between grades, e.g., has finished the fourth grade and is about to enter (promoted to) the fifth, encode the higher grade (05).

Item 6b and 6c. Note that both of these items should be encoded on Row 40 - NOT Row 20 as indicated on the packet. Both require a "global judgment"; i.e., an overall characterization of the child's behavior and academic achievement.

Example: The child has shown major problems only in the current year and his overall academic achievement is considered above average. Encode 3-6 on Row 40.

Item 7. Attitude toward Present Treatment - Judgments of both the child's and the family's attitudes are required and both are encoded on Row 41. Note that response position 4 as well as 9 are used to indicate "Not Ascertained".

Example: Although the child feels positive toward treatment, her family is decidedly negative. Encode 0-8 on Row 41.

Documentation

a. Raw score printout
b. Frequency Tables
c. Cross-tabulations

044 CSH
CHILDRENS
SYMPTOM
HISTORY

MH-9–44
6-73

CHILDREN'S SYMPTOM HISTORY

C
S
H

INSTRUCTIONS: *Insert New General Scoring Sheet and Code 11 for Sheet Number. Code 000 for PERIOD.*

Mark NO or YES for *ALL* items in **bold type.** All items in light type (a., b., c., etc.) mark only the YES responses.

EXAMPLE: 2b — What time of day does he/she have stomach-aches?

	NO	YES
1. Morning	:::::	:::::
2. Day	:::::	:::::
3. Evening	:::::	▬▬
4. Night	:::::	▬▬
5. Varies	:::::	:::::

USE A NO. 2 LEAD PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE.

Columns 12 13 | Columns 14 15 | Columns 16 17 | Columns 18 19

Mark each item on right half of scoring sheet on row specified
Mark NO or YES in columns 18 and 19

		ROW NO.
1.	**Does he/she ever have severe headaches?**	1
a.	Is he/she sick with them?	2
b.	Does it affect his/her sight at all?	3
2.	**Does he/she ever have stomach-aches?**	4
a.	Does he/she vomit when he/she has stomach-aches?	5
b	What time of day does he/she have stomaches? 1. Morning	6
	2. Day	7
	3. Evening	8
	4. Night	9
	5. Varies	10
c.	Are stomach-aches more on weekends than during the week?	11
d.	Does he/she get stomach-aches during school holidays?	12
3.	**Is he/she ever sick at his/her stomach *(Nauseated)*?**	13
a.	Does he/she vomit when he/she is nauseated?	14
b.	What time of day is he/she nauseated? 1. Morning	15
	2. Day	16
	3. Evening	17
	4. Night	18
	5. Varies	19
c.	Is he/she nauseated more on weekends?	20
4.	**Does he/she ever wet his/her bed?**	21
a.	How often does he/she wet the bed? 1. Occasionally	22
	2. Often	23
	3. Constantly	24
b.	Has he/she always wet the bed?	25
c.	When did he/she start? 1. 2–5 years old	26
	2. After 5	27
	3. After 10	28
d.	What is the longest period he/she has been dry? 1. Days	29
	2. Weeks	30
	3. Months	31
e.	Does he/she wet when away from home such as when with relatives or on holiday?	32
5.	**Does he/she ever wet his/her pants?**	33
a.	Does he/she wet his/her pants regularly?	34
b.	Has he/she always wet his/her pants?	35
c.	Did he/she start before he/she was 5 years old?	36
d.	What is the longest period he/she has been dry? 1. Days	37
	2. Weeks	38
	3. Months	39
e.	Does he/she wet when away from home such as with relatives or on holiday?	40
6.	**Does he/she ever soil him/herself?**	41

Continue marking NO or YES in columns 16 and 17 on row specified

		ROW NO.
6.	*Continued*	
a.	Does he/she soil him/herself regularly?	1
b.	Has he/she always soiled him/herself regularly?	2
c.	Did he/she start before he/she was 5 years old?	3
d.	What is the longest period he/she has been clean? 1. Days	4
	2. Weeks	5
	3. Months	6
e.	Does he/she soil him/herself when away from home such as with relatives or on holiday?	7
7.	**Does he/she ever have temper tantrums?**	8
a.	What are they like? Does he/she scream?	9
b.	Does he/she lie on the floor?	10
c.	Does he/she break things?	11
d.	How often? 1. Daily	12
	2. A few times per week	13
	3. A few times per month	14
e.	Do they last a long time?	15
f.	What seems to bring them on? 1. Spontaneous	16
	2. Frustration or stress	17
	3. Fatigue	18
g.	Does he/she have tantrums when at school?	19
h.	Does he/she have tantrums when with relatives or friends?	20
	How do you deal with them? 1. Ignore	21
	2. Restrain	22
	3. Punish	23
8.	**Has he/she in the last year ever cried or been tearful when going to school?**	24
9.	**Has he/she ever refused to go to school?**	25
10.	**Has he/she ever truanted from school?**	26
a.	How often? 1. Once only	27
	2. Occasionally	28
	3. Often	29
b.	Did he/she go home when he/she should have been at school?	30
c.	Did other children truant with him/her?	31
11.	**Does he/she get on with his/her brothers/sisters?**	32
a.	How much do they fight and squabble? 1. Not at all	33
	2. Quite a bit	34
	3. A lot	35
12.	**Does he/she get along with you?**	36
13.	**Does he/she get along with your husband/wife?**	37
14.	**Is he/she an affectionate child?**	38
15.	**Does he/she stutter or stammer?**	39
16.	**Has he/she any other difficulty with speech?**	40
17.	**Has he/she ever taken things that don't belong to him/her?**	41

CHILDREN'S SYMPTOM HISTORY

Continue marking NO or YES in columns 14 and 15 on row specified	ROW NO.
17. *Continued*	
a. Does he/she take things frequently?	1
b. Did he/she take things from home?	2
c. Did he/she take things at school?	3
d. Did he/she take things from shops?	4
e. Was he/she with others when he/she took things?	6
f. Any contact with police?	6
18. Is there any difficulty now with eating?	7
19. Is there any difficulty now with sleeping?	8
a. Does he/she heve any difficulty getting off to sleep?	9
b. Does he/she ever wake in the night?	10
c. Does he/she scream?	11
d. Does he/she come to your bed?	12
e. Does he/she ever have nightmares or wake up with bad dreams?	13
f. Does he/she ever walk in his/her sleep?	14
g. Does he/she wake early? *(More than normal for age)*	16
20. Is he/she a fidgety child?	16
a. Are there times when he/she doesn't fidget at all?	17
21. Is he/she a destructive child?	18
a. Does he/she break up his/her own things?	19
b. What about other people's things?	20
c. Does he/she break things frequently	21
22. Does he/she get into things that don't concern him/her?	22
23. Does he/she tend to get into a lot of fights?	23
a. Are they "friendly" fights?	24
b. Are they "real" fights?	25
24. Does he/she get on poorly with other children?	26
25. Has he/she got any particular friends?	27
26. Does he/she see them frequently outside school?	28
27. Does he/she get bullied or picked on at all?	29
28. Does he/she tend to pick on or bully other children?	30
29. Is he/she a good mixer?	31
30. Does he/she tend to do things on his/her own?	32
31. Does he/she worry a lot about things?	33
32. Does he/she get irritable or cross easily?	34
33. Is he/she generally unhappy or miserable?	35
34. Does he/she have any mannerisms or tics such as twitches of his/her face or shoulders?	36
35. Does he/she suck his/her thumb?	37
36. Does he/she suck anything else?	38
37. Does he/she bite his/her nails?	39
38. Does he/she bite pencils or anything else?	40
39. Is he/she disobedient a lot?	41

Continue marking NO or YES in columns 12 and 13 on row specified	ROW NO.
39. *Continued*	
a. Is he/she disobedient with other people?	1
40. Is his/her concentration poor?	2
41. Has he/she got anything he/she's afraid of — like dogs or cats — or the dark?	3
42. Does he/she tend to be over-fussy about things?	4
a. Are there things he/she insists on doing only in a special way — like getting dressed or washing?	5
b. Has he/she got any silly habits or rituals?	6
43. Does he/she tell lies?	7
44. Does he/she now, or at any time in the past, show the following signs of an unusual amount of activity?	
a. Wears out crib, toys, faster than other children?	8
b. Wears out bike, toys, faster than other children?	9
c. Wears out shoes, clothes, faster than other children?	10
45. Would you say he/she is very overactive or restless?	11

The Children's Symptom History (CSH) is a 104-item, 2-point scale formatted for the General Scoring Sheet. The CSH is an extension of the Children's Personal Data Inventory (CPDI) and is designed to record the occurrence of symptoms during the child's life as reported by the CPDI informant/s. The CSH was adapted by the Pediatric Psychopharmacology Conference from a medical and social history questionnaire developed by Satterfield.

APPLICABILITY — Children to 15

UTILIZATION — Once for each subject

TIME SPAN RATED — No specific time span for many of the items; others have clearly delineated time spans.

CARD FORMAT - ITEMS

CARD 01 = (19x, 5611)

Item	Column	Item	Column
1	20 - 22	4	40 - 51
2	23 - 31	5	52 - 59
3	32 - 39	6	60 - 67
		7-7e	68 - 75

CARD 02 = (19x, 5611)

Item	Column	Item	Column	Item	Column
7f-7i	20 - 27	15	43	22	67
8	28	16	44	23	68 - 70
9	29	17	45 - 51	24	71
10	30 - 35	18	52	25	72
11	36 - 39	19	53 - 60	26	73
12	40	20	61 - 62	27	74
13	41	21	63 - 66	28	75
14	42				

CARD 03 = (19x, 2211)

Item	Column	Item	Column
29	20	38	29
30	21	39	30 - 31
31	22	40	32
32	23	41	33
33	24	42	34 - 36
34	25	43	37
35	26	44	38 - 40
36	27	45	41
37	28	Total Score	42 - 44

COMPUTATION OF TOTAL SCORE - Total score for the CSH is calculated so as to reflect the degree of pathology; i.e., the higher the score the greater the number of symptoms reported as present in the child's history. Items encoded YES are scored as "1"; those encoded NO are scored as "0". The exceptions to this rule are as follows:

a. Items scored on a scale of 1 to 3

4a - Constantly = 3, Often = 2, Occasionally = 1
4c - After 10 = 3, After 5 = 2, 2 - 5 years = 1
4d - Days = 3, Weeks = 2, Months = 1
5d - Days = 3, Weeks = 2, Months = 1
6d - Days = 3, Weeks = 2, Months = 1
7d - Daily = 3, Few Times-week = 2, Few Times-month = 1
7f - Spontaneous = 3, Frustration = 2, Fatigue = 1
10a - Often = 3, Occasionally = 2, Once = 1
11a - A lot = 3, Quite a bit = 2, A little = 1

b. Items reflected in scoring; i.e., NO = "1"

12	25	
13	26	
14	29	
20a	30	
23a		

c. Items not included in total score

2b	7i
2c	10b
2d	10c
3b	17e
3c	

Total Score = Sum of Items Range = 0 - 115

SPECIAL INSTRUCTIONS

Time Span Rated - Note that the CSH contains some items which ask whether a symptom HAS EVER OCCURRED in the child's lifetime and others which ask whether a symptom occurs at a specific time or under specific conditions. Since most of the rating instruments in the Battery have a uniform, circumscribed time-span for all items, the rater is cautioned to be particularly alert to varying "time" conditions of the CSH items.

Obtaining Symptom History - While it is not necessary to follow the sequence of items, the rater is urged to make every effort to elicit responses to all items. Should the respondent be uncertain or ambiguous about the presence of a symptom or the rater question the validity of the response, the item should be left blank.

Encoding Dependent Items - The CSH has a quasi-Guttman quality to it in that series of items are dependent upon positive response/s to previous item/s. To reduce the encoding required of the rater, ONLY THE ITEMS IN BOLD TYPE MUST ALWAYS BE MARKED YES OR NO. These are the "numbered" items (1-45). The items in light type ("lettered" items) should be marked only when the response is positive, i.e., YES or present.

Example 1: A "NO" response to Item 5 automatically means that Items 5a, 5b, 5c, 5d, and 5e should ALL be encoded "NO". Encode "NO"(7) in Row 33, Column 18 and leave Rows 34 through 40, Columns 18 and 19 blank.

5.	**Does he/she ever wet his/her pants?**		33	33 7 8 **5**
a.	Does he/she wet his/her pants regularly?		34	34 7 8 **5a**
b.	Has he/she always wet his/her pants?		35	35 7 8 **b**
c.	Did he/she start before he/she was 5 years old?		36	36 7 8 **c**
d.	What is the longest period he/she has been dry? . .	1. Days	37	37 7 8 **d1**
		2. Weeks	38	38 7 8 **d2**
		3. Months	39	39 7 8 **d3**
e.	Does he/she wet when away from home such as with relatives or on holiday?		40	40 7 8 **e**

Example 2: If the response to Item 5 is YES, then one or more positive responses to 5a, 5b, 5c, 5d, and 5e should be encoded, as in the following:

> The child does wet her pants and has always done so since the age of 4. The longest dry period is estimated to be in weeks. She does not wet away from home.

5.	**Does he/she ever wet his/her pants?**		33	33 7 0 **5**
a.	Does he/she wet his/her pants regularly?		34	34 7 0 **5a**
b.	Has he/she always wet his/her pants?		35	35 7 0 **b**
c.	Did he/she start before he/she was 5 years old?		36	36 7 0 **c**
d.	What is the longest period he/she has been dry? . .	1. Days	37	37 7 8 **d1**
		2. Weeks	38	38 7 0 **d2**
		3. Months	39	39 7 8 **d3**
e.	Does he/she wet when away from home such as with relatives or on holiday?		40	40 7 8 **e**

Uses of the Scale - While the CSH is primarily for use as an adjunct to the CPDI at the initial assessment, it might also be considered for use as a criterion measure by making repeated ratings over the course of the study. There are hazards in employing the CSH in this manner. Since the CSH is primarily historical, symptoms may have been present in the "distant past" but not present immediately prior to the study. This may lead to distortions when attempting to use the instrument for the assessment of change.

Item IIa, page L-5 - Note that the first scale point should read "Just a little", NOT "Not at all".

DOCUMENTATION

a. Raw score printout
b. Total score printout
c. Variance analysis

045 APDI
ADULT
PERSONAL DATA
INVENTORY

MH-9—45
6-73

ADULT PERSONAL DATA INVENTORY

INSTRUCTIONS: *Insert General Scoring Sheet and Code 12 for Sheet Number.*
Items 1 through 10 are required for BLIPS processing and MUST BE COMPLETED FOR EACH SUBJECT.
PERIOD is coded as "000". Mark a field of 9's when data are "Not Ascertained".

A P D I

USE A NO. 2 LEAD PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE.

Mark on right half of scoring sheet on row specified

1. SUBJECT'S AGE: *(2 digits)* — ROW NO. 1-2

2. SUBJECT'S SEX: — ROW NO. 3
1 = Male
2 = Female

3. SUBJECT'S RACE: *(Mark one)* — ROW NO. 4
0 = Caucasoid
1 = Negroid
2 = Mongoloid
3 = Other

4. MARITAL STATUS: *(Mark one)* — ROW NO. 5
0 = Never married
1 = Presently married for first time
2 = Presently married with previous marriage/s
3 = Previously but not presently married (separated or divorced)
4 = Previously but not presently married (widowed)

5. SOCIOECONOMIC STATUS

a. **Occupation** *Use scale given below for 1 and 2. See Manual for detailed list of occupations*

1. Subject's highest occupational attainment is: . . . . . ROW NO. 6
2. Head of Household's highest occupational attainment is . . . ROW NO. 7

If subject is Head of Household, code "0" here (Row 7)

1 = Higher executive, proprietor of large concern, major professional
2 = Business manager of large concern, proprietor of medium-sized business, lesser professional
3 = Administrative personnel, owner of small independent business, minor professional
4 = Clerical or sales worker, technician, owner of little business
5 = Skilled manual employee
6 = Machine operator, semi-skilled employee
7 = Unskilled employee
8 = Never worked in paid employment
9 = Not ascertained

b. **Education**

1. Using scale provided, code highest level attained by the SUBJECT — ROW NO. 8
2. Code highest level attained by HEAD OF HOUSEHOLD . . . — ROW NO. 9

If subject is Head of Household, code "0" here (Row 9)

1 = Graduate or professional training *(Individuals who have completed or who have attended one year of a recognized professional course)*
2 = College or university graduate *(Individuals who have completed a four year college or university course leading to a recognized college or university degree)*
3 = Partial college training *(Individuals who have completed at least one year but not a full college course; individuals who have attended at least one year of, or who have completed a recognized junior college, technical school, nursing school, etc.)*
4 = High school graduate *(Private preparatory, public, parochial or trade school)*
5 = Partial high school *(Individuals who completed grades 10 or 11 but did not complete high school)*
6 = Junior high school *(Individuals who completed grades 7, 8 and 9)*
7 = Less than seven years of school
9 = Information not available

Continue marking on right half of scoring sheet on row specified

6. TREATMENT STATUS

a. **Subject is presently:** *(Mark one)* — ROW NO. 10
1 = Not in any type of psychiatric treatment
2 = In psychiatric treatment as an outpatient
3 = In partial hospitalization, e.g., day or night hospital, halfway house, etc.
4 = Hospitalized (24 hour)

b. **Prior to this episode, subject has:** *(Mark all applicable)* — ROW NO. 11
1 = Never had any type of psychiatric treatment
2 = Received psychiatric outpatient treatment
3 = Received treatment in partial hospitalization setting
4 = Received treatment in 24—hour hospital

"Psychiatric treatment" should be interpreted broadly to include all forms of therapy whose basic function is the alleviation of emotional, behavioral or mental disturbance. "Partial hospitalization" and "24—hour hospitalization" include all forms of treatment environments in which the subject spends a substantial part of the day or, in the latter case, the full day.

7. DURATION OF PRESENT EPISODE — ROW NO. 12-14

Code whether in: 0 = Days 1 = Weeks 2 = Months 3 = Years and give length *(2 digits)*

EXAMPLES:
Present episode = 11 Weeks Code 111
Present episode = 3 Months Code 203
Present episode = 4 Years Code 304

8. PRIMARY PSYCHIATRIC DIAGNOSIS

a. **Indicate nosological system used** 1 = DSM II 2 = WHO

b. **Code diagnosis from those listed in ECDEU Manual using 4 digits for DSM II** *(Rows 15—19)* **or 3 digits for WHO** *(Rows 16—18)* — ROW NO. 16-19

c. **Secondary psychiatric diagnosis** Use same nosological system as 8a — ROW NO. 20-23
If no secondary diagnosis, code field 0000

9. a. SIGNIFICANT CURRENT MEDICAL CONDITIONS? 1 = YES 2 = NO — ROW NO. 24
If NO, 9b and 9c may be left blank

b. **If YES, give ICD-8 code for illness** *(3 digits)* . . . . . — ROW NO. 25-27
See Manual for ICD-8 list of diseases. Maximum of 2 conditions may be entered at 9b and 9c

c. **Second medical condition** *(3 digits)* Code 000 if no 2nd condition — ROW NO. 28-30

10. ARE THE FOLLOWING ITEMS (11—15) TO BE COMPLETED FOR THIS SUBJECT? 1 = YES 2 = NO — ROW NO. 31

If YES, turn page and continue with item 11 on L—10

Continue marking on right half of scoring sheet on row specified	ROW NO.
11. CURRENT CONDITION *(Present Episode)*	
a. The current condition *(present episode)* **is best characterized as:** 1 = Indistinguishable from the past, continuation of long-standing condition 2 = Exacerbation of chronic condition 3 = Recurrence of similar previous condition 4 = Significantly different from any previous condition 5 = First occurrence with no previous psychiatric illness	32
b. Onset of current condition was: 1 = Sudden — less than 4 weeks 2 = Gradual — one to several months 3 = Very gradual — one to several years	33
c. Precipitating external stress was: 0 = Absent 1 = Probably present 2 = Definitely present	34
12. SUBJECT'S PSYCHIATRIC HISTORY	
a. Age when first received any treatment for psychiatric illness *(2 digits)* 00 = Never treated	35-36
b. Age when first hospitalized for psychiatric illness *(2 digits)* 00 = Never hospitalized	37-38

ROW NO.	*Mark on left half of scoring sheet on row specified*
	12. *SUBJECT'S PSYCHIATRIC HISTORY — Continued*
1-3	**c. Estimate total duration of ALL outpatient psychiatric treatment — exclusive of present episode** Give time units: 0 = Days 1 = Weeks 2 = Months 3 = Years and duration *(2 digits)* EXAMPLE: Subject's total treatment amounts to 10 months Code 210 000 = No outpatient treatment
4-6	**d. Estimate total duration of ALL partial hospitalization — exclusive of present episode** Give time units: 0 = Days 1 = Weeks 2 = Months 3 = Years and duration *(2 digits)* 000 = No partial hospitalization
5-9	**e. Estimate total duration of ALL hospitalizations** *(24 hour)* **— exclusive of present episode** Give time units: 0 = Days 1 = Weeks 2 = Months 3 = Years and duration *(2 digits)* EXAMPLE: Subject's total hospitalization amounts to 4 years Code 304 000 = No hospitalizations
10	**f. Number of hospitalizations** 0 = None, 1, 2, 3, 4, 5, 6, 7, 8 = 8 or more 9 = Not ascertained
	g. Does subject have a history of: 0 = No 2 = Yes, only within last year 1 = Yes, but not within last year 3 = Yes, both in past and last year
11	1. Excessive use of alcohol
12	2. Excessive use of Tobacco
13	3. Excessive use of Opiates
14	4. Excessive use of Marijuana
15	5. Excessive use of Sleeping pills or Sedatives
16	6. Excessive use of Amphetamines/Stimulants
17	7. Excessive use of Hallucinogens
18	8. Excessive use of Other Drugs
19	9. Imprisonment
20	10. Sexual deviation
21	11. Suicidal attempts
22	12. Contributory physical illness or injury

ROW NO.	*Continue marking on left half of scoring sheet on row specified*
	13. FAMILY PSYCHIATRIC HISTORY
	Among family members (lineal and conjugal), has there been a history of: *(Mark all applicable on the appropriate rows)*
	0 = No history in any lineal or conjugal family members

LINEAL	CONJUGAL
1 = No history in parents or siblings	5 = No history in spouse or children
2 = Mother	6 = Spouse
3 = Father	7 = Children
4 = Sibling/s	

23	a.	Non-psychotic psychiatric disturbance
24	b.	Manic-depressive disturbance
25	c.	Other major affective disturbance
26	d.	Schizophrenia
27	e.	Other psychotic disturbance
28	f.	Suicide
29	g.	Hospitalized for any psychiatric illness
30	h.	Mental deficiency
31	i.	Excessive use of alcohol
32	j.	Excessive use of drugs
33	k.	Imprisonment

14. LIVING SITUATION

34 **a. In the 3 years preceding the present episode, the subject's residence has been:**

1 = Primarily urban
2 = Primarily suburban
3 = Primarily rural

35 **b. Family type during this period has been:**

1 = Parental or lineal — Patient does not carry major responsibility for the home; it is either the home of his family of origin or of his children. Code foster home here.

2 = Conjugal — The patient or his spouse carries major responsibility for the home; the household may include his parents and/or children.

3 = Collateral — Home is not the responsibility of the patient, his parents or children, but of a sibling, aunt or some other non-linear relative

4 = Alone — Patient maintains – wholly or in part – his own quarters. Home may be shared with others not related to the patient, or he may live in a rooming house, dormitory, etc.

ROW NO.	*Continue marking on left half of scoring sheet on row specified*
	15. ROLE PERFORMANCE
36	**a. Subject's present occupational status is:**
	0 = Not applicable 1 = Full time gainful employment 2 = Part time gainful employment 3 = Unemployed 4 = Dependent spouse or student 5 = Recipient of public or private assistance 9 = Not ascertained
37	**b. In the past 3 years, subject has been gainfully employed:**
	1 = Briefly or not at all 2 = Less than 1/2 of the time 3 = Half of the time 4 = Most of the time 5 = Virtually all of the time 9 = Not ascertained
38	**c. His/her employment has been limited primarily by:**
	0 = Not limited 1 = Going to school 2 = Household responsibilities 3 = Job market 4 = Retirement 5 = Physical illness 6 = Psychopathology 7 = Institutionalization 9 = Not ascertained
39	**d. The subject's work performance** *(whether in job, in household or as student)* **during the past 3 years is best characterized as:**
	0 = Not applicable 1 = Marked decline in effectiveness 2 = Some decline in effectiveness 3 = Adequate with no change in effectiveness, static 4 = Some increase in effectiveness 5 = Variable, fluctuating in degree of effectiveness
40	**e. The subject's social functioning during the past 3 years is best characterized as:**
	1 = Marked decline in competence 2 = Some decline in competence 3 = Adequate with no change in competence, static 4 = Some increase in competence 5 = Marked increase in competence 6 = Variable, fluctuating in degree of competence

Developed within the ECDEU program, the Adult Personal Data Inventory (APDI) is a 55-item scale formatted for use with the General Scoring Sheet. Its purpose is to describe the social and demographic background of the subject. Evolving from the now obsolete Patient Personal Data Inventory, the APDI has been designed to cover a greater diversity of subject types than its forbear. Most of the items from the original inventory have been retained, although the majority have been modified to increase their universality. Items numbered 1 through 10 constitute the basic minimum of necessary demographic information. Items numbered 11 through 15 are considered supplemental, although they represent the types of information most investigators commonly collect.

APPLICABILITY - All adult populations

UTILIZATION - Once per subject

CARD FORMAT - ITEMS

CARD 01 = (19x, 12, 911, 13, 11, 214, 11, 213, 411, 212, 313, 911)

Item	Column
1	20 - 21
2	22
3	23
4	24
5a	25 - 26
5b	27 - 28
6a	29
b	30
7	31 - 33
8a	34
b	35 - 38
c	39 - 42
9a	43
b	44 - 46
c	47 - 49
10	50
11a	51
b	52
c	53
12a	54 - 55
b	56 - 57
c	58 - 60
d	61 - 63
e	64 - 66
f	67
12g-1	68
2	69
3	70
4	71
5	72
6	73
7	74
8	75

CARD 02 = (19x, 4I1, 1I2, 4I1, I3, 4I1)

Item	Column	Item	
12g-9	20	13h	38 - 39
10	21	i	40 - 41
11	22	j	42 - 43
12	23	k	44 - 45
13a	24 - 25	14a	46
b	26 - 27	b	47
c	28 - 29	15a	48
d	30 - 31	b	49
e	32 - 33	c	50 - 52
f	34 - 35	d	53
g	36 - 37	e	54
		Social class-Subject*	55
		Head/Household*	56

* - These items are calculated and punched on the card via programming.

SPECIAL INSTRUCTIONS

All items of the APDI are coded on one General Scoring Sheet. ITEMS NUMBERED 1 THROUGH 10 MUST BE COMPLETED. No data will be processed by the Biometric Laboratory without completion of these 10 items for each subject. While data will be processed without items numbered 11 through 15, investigators are strongly urged to complete the entire set of APDI items.

Item 1. Age - Encode the subject's age to the nearest whole year.

Examples: 25 years, 7 months. Encode as 26 years.
Exactly 25 years, 6 months. Encode as 25 years.
25 years, 4 months. Encode as 25 years.

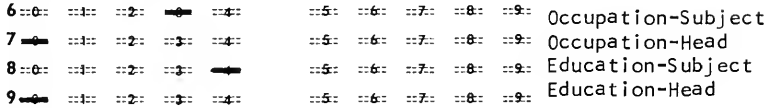
Since "99" is employed as a "missing" or "not ascertained" code, no subject can be 99 years of age - or, for that matter, any older - in this system. Any bias introduced by halting time at 98, however, would appear acceptable.

Item 2. Race - Subjects whose racial heritage is melanesoid, australoid or mixed should be encoded as "Other"(3). In geographical areas where these racial types are prevalent rater may encode melanesoid as 4; australoid as 5 and mixed as 6. "Unknown" racial heritage should be encoded as 9.

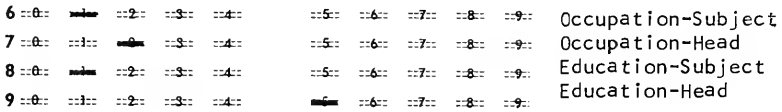
Item 4. Marital Status - The choice of categories is almost always straightforward. In the event that the subject could be classified as b oth "3" and "4", encode the most recent status, e.g., the subject's first marriage ended in divorce, the second in the death of the spouse. Encode as 4 (widowed). Code "5" may be used to designate common law relationships; i.e., living in a conjugal situation without legal status.

Items 5a and 5b — Occupation and Education - These 2 items require ratings of the subject AND/OR the Head of Household. If the subject is also the Head of Household, only one actual rating is required - "0" being encoded for both Head of Household's occupation (5a2) and education (5b2).

Example: The subject, owner of a small business and a high-school graduate, is also the Head of Household. Encode as follows:



The subject, a nuclear physicist prior to marriage, has a Ph.D. Her husband, the Head of Household, is a building contractor and has a 9th grade education.

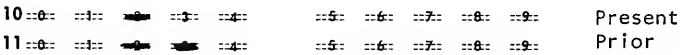


A list of occupations - adapted from Hollingshead - are given in Appendix I.

COMPUTATION OF SOCIAL CLASS - (See page 80).

Items 6a and 6b — Treatment Status - While only one response may be encoded for 6a, a maximum of 3 responses may be encoded for Item 6b. The terms - "psychiatric treatment", "Outpatient", "partial hospitalization", "24-hour hospitalization" - should be interpreted broadly. Definitions for these terms are given on p. 84.

Example: The subject is presently in outpatient treatment. In the past, she has received treatment as an outpatient and in a day hospital. Encode 2 on Row 10; 2 and 3 on Row 11.



A coding system has been developed to reduce the possible multiple entries in Item 6b to a 1-digit field for card decks.

Card Code	Response Position	Description
0	9	Not Ascertained
1	4	24-hour hospitalization
2	3	Partial hospitalization
3	3,4	Partial and 24-hour
4	2	Outpatient
5	2,4	Outpatient and 24-hour
6	2,3	Outpatient and partial
7	2,3,4	Outpatient,partial and 24-hour
8	1	Never had treatment

Item 7. Duration of present episode - A 3-digit entry is required: one digit to indicate the time unit; 2 digits for the numeric for duration. Whichever time unit is employed, encode to the nearest whole unit.

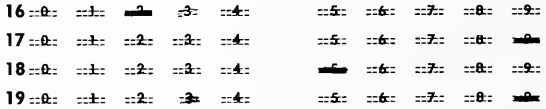
Examples: When time unit is months: 11 weeks and 2 days is encoded as 3 months.
When time unit is years: 1 year and 1 month is encoded as 1 year.

Item 8a. Nosological System - The rater may use one of two nosological systems, DSM II or ICD 8 (WHO), by the appropriate designation on Row 15. (Note that this Row Number has erroneously been omitted in the packet). Codes for both DSM II and WHO systems are listed in the Appendix 2. Certain 5-digit codes used in the official DSM II have been changed - for uniformity - to 4 digits.

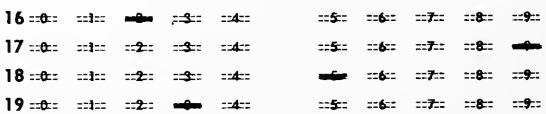
Item 8b. Primary psychiatric diagnosis - Rows 16 through 19 - NOT 15 - 19 as printed in the packet - are required for encoding a diagnosis under BOTH systems. Item 8b should read:

Encode diagnosis from those listed in Appendix 2 using 4 digits for both DSM II and WHO on Rows 16 - 19.

Examples: DSM II - Schizophrenia, chronic undifferentiated. Encode 2959.



WHO - Schizophrenia, paranoid type. Encode 2953.



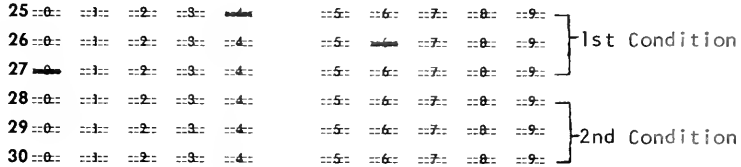
Item 8c. Secondary psychiatric diagnosis - This item MUST be encoded in the SAME NOSOLOGICAL SYSTEM as that used in Item 8b. Leaving the field blank or encoding "0000" will indicate no secondary diagnosis.

Item 9. Medical Conditions - If NO significant current medical conditions are present, Items 9b and 9c may be left blank. No error citations will occur since the "NO" response to Item 9a is a programming signal. A "YES" response to the item requires that the rater then MUST ENCODE RESPONSES FOR ITEMS 9a AND/OR 9b.

Item 9b. Medical Condition Number 1 - The rater selects the 3-digit code appropriate to his diagnosis and encodes it in Rows 25 - 27. For the comprehensive listing of diseases (and synonyms), refer to: Eighth Revision, International Classification of Diseases, (ICD-8) Public Health Service Publication No. 1693, Vol. 1 and 2, U.S.G.P.O., Washington, D. C. The ICD-8 codes may also be found in the Diagnostic and Statistical Manual of Mental Disorders, American Psychiatric Association, 1968, 3rd Edition.

Item 9c. Medical Condition Number 2 - Encoding a second significant current medical condition is at the option of the rater. Leaving Rows 28-30 blank will be interpreted as the absence of a second medical condition.

Example: Subject has acute nasopharyngitis but no second medical condition is rated. Encode 460 in Rows 25 - 27 and leave Rows 28 - 30 blank.



Item 10. This is a MANDATORY ITEM. It is a programming signal as well as a statement of fact. In responding "YES", the rater commits himself to respond to ALL of the remaining items (11 - 15).

Item 11a. Current condition - Only one response is permitted. Select the category which best describes the subject's current condition.

1. Indistinguishable from the past - refers to those conditions which have exhibited little - if any - variation in intensity or floridity from the previous status.

2. Exacerbation of chronic condition - refers to an intensification (flare-up) of a previously stable (static) condition.

3. Recurrence of similar previous condition - refers to recurrent episodes of illness. Differs from 2 in that there are symptom-free periods between episodes.

4. Significantly different from previous condition - refers to a present condition which can be clearly distinguished from any in the subject's past.

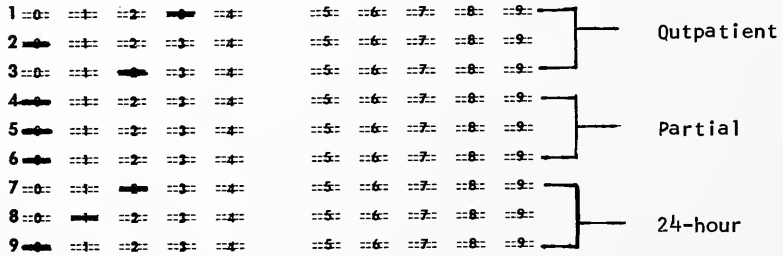
5. First occurrence - refers to the initial recognized episode of psychopathology. Differs from 4 in that there is no prior history of illness.

Item 12. Subject's Psychiatric History - The several parts of this item (12a - 12f) ask for the temporal aspects of some of the events in the subject's history. The information necessary to answer the items is not always complete or precise and the rater is urged to make the best estimates possible.

Items 12a and 12b. These 2 items require a 2-digit code for age in years. Encode age in the nearest whole year. Encode "99" if the subject is known to have been treated and/or hospitalized, but the age is "Not ascertained".

Items 12c-12e. Each of these items requires a 3-digit code: one digit to indicate the time unit and 2 digits to indicate the numeric for duration. To indicate that the subject has not received one or more of the treatments, the rater must encode "000". Do not leave blanks; rather encode "999" when data is "not ascertained".

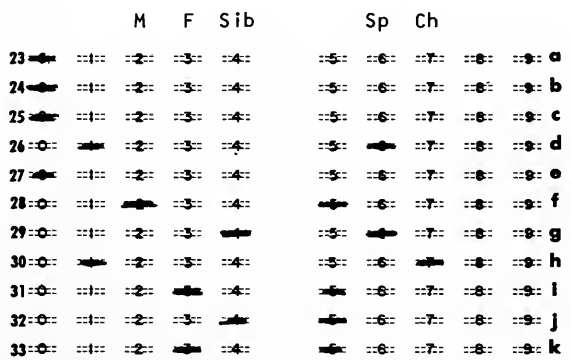
Example: The subject has received an aggregate of 2 years of outpatient treatment; has never received treatment in a partial hospitalization setting and has had a total of 10 months of 24-hour hospitalization.



Item 12g Each of the items asks whether the event has been present in the subject's recent (within the last year) and/or past (beyond the last year) history. Do not leave blanks. Encode 9 for "Not Ascertained".

Item 13. Family Psychiatric History - This item gathers information on the presence of a variety of psychiatric illnesses within both the subject's lineal and conjugal families. For each of the items (13a through 13k), record the presence or absence of the characteristics among family members by marking ALL appropriate response positions. The code "0" indicates the ABSENCE of the characteristic in BOTH lineal and conjugal family members. The code "1" indicates the absence of the characteristic among the subject's lineal family members ONLY, i.e., the subject's parents and/or his siblings. The code "5" indicates absence among the subject's conjugal family members ONLY, i.e., the subject's spouse and/or his children.

Example: The subject's mother committed suicide following the imprisonment of her alcoholic husband (the subject's father). One of the subject's sisters is hospitalized for heroin addiction. The subject's spouse, presently hospitalized, has been diagnosed as schizophrenic. The subject is presently taking care of the 10 children - one of whom has been diagnosed as mentally defective. Encode as follows:



To conserve space on card decks, the possible multiple entries on items 13a through 13k have been reduced to a 2-digit coding system - the first digit referring to lineal history and the second to conjugal.

Lineal History

Card Code	Response Positions	Description
1	4	Siblings
2	3	Father
3	3,4	Father, siblings
4	2	Mother
5	2,4	Mother, siblings
6	2,3	Mother, father
7	2,3,4	Mother, father, siblings
8	1	No lineal history
9	0	No lineal/conjugal

Conjugal History

Card Code	Response Positions	Description
1	7	Children
2	6	Spouse
3	6,7	Spouse, children
4	5	No conjugal history
9	0	No lineal/conjugal

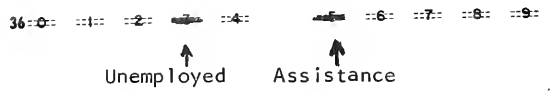
Examples: 99 = No lineal or conjugal history
62 = Illness in mother, father, spouse
83 = No lineal history, illness in spouse, children

Item 14a. Subject's residence - If the subject's residence has been split, approximately 50% between 2 of the categories, encode the most recent residence. Example: In the last 3 years, the subject lived on a farm for the first 18 months and in a large city thereafter. Encode the residence as "primarily urban" (1).

Item 14b. Family type - In circumstances analogous to those cited in Item 14a, encode the most recent family type.

Item 15a. Present occupational status - One or more responses may be encoded up to a maximum of 2.

Example: Subject is currently unemployed and receiving public assistance. Encode 3 and 5 on Row 36.

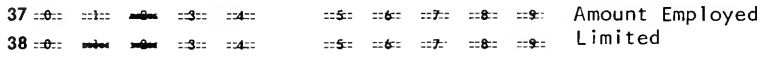


A 1-digit coding system has been developed for these multiple entries and is as follows:

Rater should encode	If he wishes these responses	Description
6	2,5	Part-time employment and recipient of assistance
7	3,5	Unemployed and recipient of assistance
8	4,5	Dependent student/spouse and recipient of assistance

Items 15b and 15c. While only one response is permitted for Item 15b; a maximum of 2 may be encoded for Item 15c.

Example: During the past 3 years, the subject has been gainfully employed for less than 1/2 the time. Her employment has been limited by attendance at school and household responsibilities. Encode 2 in Row 37; 1 and 2 in Row 38.



A 2-digit field is reserved for Item 15c on card decks. The codes are given in Table 6.

TABLE 6

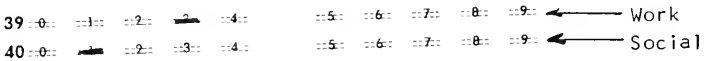
APDI (ITEM 15c - EMPLOYMENT LIMITATIONS)

Card Code	0 Not Limited	1 School	2 Household Responsibilities	3 Job Market	4 Retirement	5 Physical Ill	6 Psycho Ill	7 Institutionalized	9 Not Ascertained	Response Positions
00									X	9
01								X		7
02							X			6
03							X	X		6,7
04						X				5
05						X		X		5,7
06						X	X			5,6
07					X					4
08					X			X		4,7
09					X		X			4,6
10					X	X				4,5
11				X						3
12				X				X		3,7
13				X			X			3,6
14				X		X				3,5
15				X	X					3,4
16			X							2
17			X					X		2,7
18			X				X			2,6
19			X			X				2,5
20			X		X					2,4
21			X	X						2,3
22		X								1
23		X						X		1,7
24		X					X			1,6
25		X				X				1,5
26		X			X					1,4
27		X		X						1,3
28		X	X							1,2
29	X									0

Examples: 29 = Not limited
11 = Job Market
10 = Retirement, physical illness
01 = Institutionalization
00 = Not ascertained

Items 15d and 15e. These items attempt to characterize the course of work performance and social functioning during the past 3 years by a "global judgment". "Work performance" should be interpreted in a general way to include effectiveness as a housekeeper or student as well as effectiveness in gainful employment. For subjects who have been hospitalized for the 3-year period, rate their performance in industrial therapy, ward assignments, etc. Similarly, the social functioning of inpatients should be rated in the context of the hospital setting.

Example: The subject who has been hospitalized for the past 10 years has been a steady (unvarying) worker on the ward. He has become markedly more isolated and uncommunicative in relation to others, however. Encode 3 on Row 39; 1 on Row 40.



Documentation

a. Raw score printout
b. Frequency tables
c. Cross-tabulations

046 PMR
PRIOR
MEDICATION
RECORD

MH-9·46
1-73

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB NO 68-R965

PRIOR MEDICATION RECORD

PATIENT INITIALS

FIRST INITIAL: A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

SECOND INITIAL: A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

FORM NO. 4 5 6

NUMBER MALES 001-499 FEMALES 500-998

PATIENT: 0 1 2 3 4 5 6 7 8 9

RATER: 0 1 2 3 4 5 6 7 8 9

PERIOD: 0 1 2 3 4 5 6 7 8 9

0 Hours 1 2 Days 3 4 5 Weeks 6 7 8 Months 9

PLEASE USE A NO. 2 LEAD PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE.

1. PRIOR PSYCHOTROPIC MEDICATION

a. Record the name/s and maximum total daily dose/s of the drug/s which the subject received during the *MONTH PRECEDING THE STUDY (prior to any drying-out period).* If no drugs received, write "none". *DO NOT WRITE IN SHADED AREAS.*

1. Drug Name — *Confine writing within this block*

DRUG CODE: 0 1 2 3 4 5 6 7 8 9 (four rows)

MAXIMUM TOTAL DAILY DOSE IN MILLIGRAMS: 0 1 2 3 4 5 6 7 8 9; X .001 .01 .1 1 10 100 1000

2. Drug Name— *Confine writing within this block*

DRUG CODE: 0 1 2 3 4 5 6 7 8 9 (four rows)

MAXIMUM TOTAL DAILY DOSE IN MILLIGRAMS: 0 1 2 3 4 5 6 7 8 9; X .001 .01 .1 1 10 100 1000

b. Estimate length of time subject has been receiving psychotropic medications. Mark appropriate time units and enter number. If "never" or "not ascertained", leave number area blank.

	Never	Week	Month	Year	Not Ascertained
Neuroleptic		0 1 2 3 4 5 6 7 8 9			
Antidepressant		0 1 2 3 4 5 6 7 8 9			
Anxiolytic		0 1 2 3 4 5 6 7 8 9			
Other Psychotropic		0 1 2 3 4 5 6 7 8 9			

2. OTHER TREATMENTS RECEIVED PRIOR TO STUDY

Mark "YES" for all treatments which subject received in *MONTH PRECEDING THE STUDY (prior to any drying-out period).* Mark NO for those not received.

a. DRUG	NO	YES
Analgesic-narcotic	0	1
Analgesic-non-narcotic	0	1
Anesthesia-general	0	1
Anesthesia-local	0	1
Antiallergenic	0	1
Anticoagulant	0	1
Anticonvulsant	0	1
Antifertility	0	1
Antihypertensive	0	1
Antimicrobial	0	1
Antiparkinson	0	1
Antitumor	0	1
Blood tonic	0	1
Bronchodilator	0	1
Cardiac medication	0	1
Cough and cold preparation	0	1
Dermatological preparation	0	1
Diabetic medication	0	1
Diet medication	0	1
Diuretic	0	1
Gastraintestinal preparation	0	1
Harmonal medication	0	1
Muscle relaxant	0	1
Sedative/hypnotic	0	1
Stimulant	0	1
Thyroid medication	0	1
Vitamin	0	1

b. NON-DRUG	NO	YES
Behavior modification	0	1
Electroconvulsive therapy	0	1
Milieu therapy	0	1
Physical therapy	0	1
Psychotherapy-group	0	1
Psychotherapy-individual	0	1
Rehabilitation/occupational therapy	0	1
Remedial educational therapy	0	1

Developed with the ECDEU program, the Prior Medication Record (PMR) is a single-page, 8 item form designed to capture information concerning the subject's medication history prior to his entrance into the study. Responses are coded directly on the form and the General Scoring Sheet is not utilized. The PMR evolved from the now obsolete Drug Study Resume.

APPLICABILITY - All research populations.

UTILIZATION - Once for each subject.

TIME SPAN RATED - For Item 1a, 11a and 11b, one month prior to entrance into study. For Item 1b, time span is dependent on subject's psychotropic history.

CARD FORMAT ITEMS

CARD 01 = (19x, 2(15, 14), 413,2611)

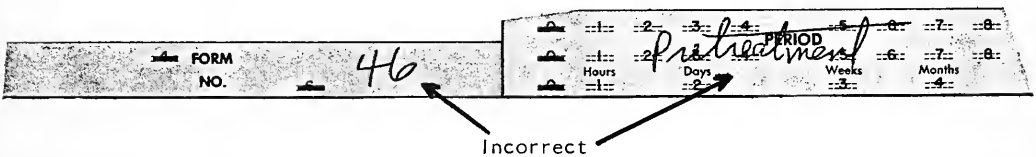
Item	Column
1a - Drug Name No. 1	20 - 24
Dose No. 1	25 - 28
Drug Name No. 2	29 - 33
Dose No. 2	34 - 37
1b - Neuroleptic	38 - 40
Antidepressant	41 - 43
Anxiolytic	44 - 46
Other psychotropic	47 - 49
2a - Other drug treatments (to Thyroid)	50 - 75

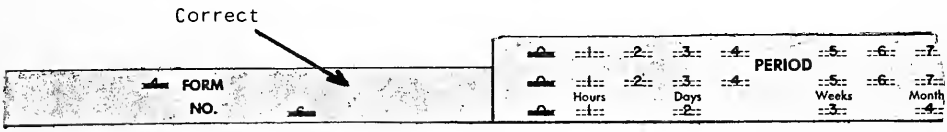
CARD 02 = (19x, 911)

2a - Other drug treatments (Vitamin)	20
2b - Other non-drug treatments	21 - 28

SPECIAL INSTRUCTIONS

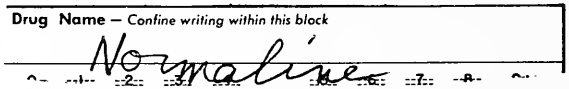
1. Do not write in the shaded areas of the ID block. Both Form Number and Period are pre-coded and need not be marked. (PERIOD for the PMR is always designated "000").



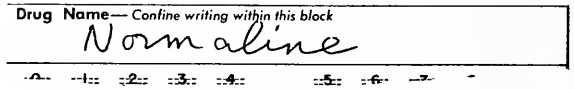


2. Item 1 - When writing in the names of drugs, the rater MUST CONFINE ALL WRITING WITHIN THE DESIGNATED AREAS. Failure to do so will result in processing difficulties. Needless to say, the writing should be legible.

Incorrect →



Correct →

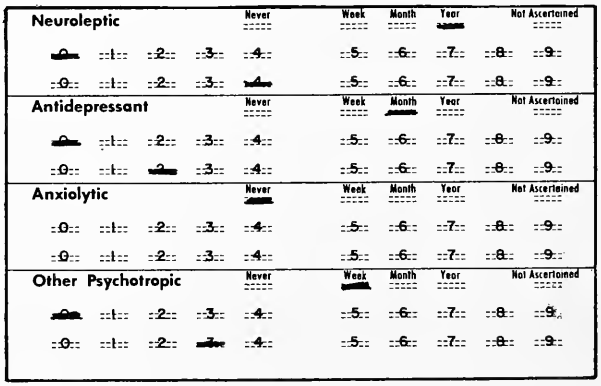


3. Item 1a - Note that "month preceding study" means prior to any drying-out period. Do not mark in the shaded area labeled DRUG CODE. Codes for drugs are assigned by the Biometric Laboratory. A list of the ECDEU drug codes may be obtained upon request from the Biometric Laboratory.

4. See pages 230-232 for instructions on encoding dosage. Note that all dosages should be coded in miligrams.

5. Item 1b - This item is NOT limited in time to the month prior to the study but encompasses the subject's entire prior drug history. Estimate duration as an aggregate total in those instances where intake has been intermittent. To encode this 4-part item, the rater must designate the time unit and then encode in the numerics for duration.

Example: Subject has received neuroleptics for 4 years; antidepressants only for 2 months; never received anxiolytics and received a stimulant for 3 weeks. These data should be encoded as follows:



6. Items 2a and 2b - Contrary to the instructions printed on the form, raters may mark positive responses (YES) and LEAVE NEGATIVE ONES (NO) BLANK.

DOCUMENTATION

a. Raw score printout
b. Frequency tables

THE PSYCHIATRIC PACKETS

There are two Psychiatrist Packets - one for pediatric and one for adult populations. Each packet contains scales specific for the particular population and three common or universal scales. The compositions of the packets are:

Children	Adult
Children's Psychiatric Rating Scale	Brief Psychiatric Rating Scale
Children's Diagnostic Scale	Depression Status Inventory
Children's Diagnostic Classification	Hamilton Depression Scale
	Hamilton Anxiety Scale
	Anxiety Status Inventory
	Wittenborn Psychiatric Rating Scale

Universal (Common to both packets)

Clinical Global Impressions
Dosage Record and Treatment Emergent Symptoms
Patient Termination Record

Manipulating the sections of the packet and inserting the General Scoring Sheets may require some practice. The instructions on the back of the front cover of the packets should, however, provide the information needed to develop the necessary dexterity. It is important to state again, however, that the rater ALWAYS USE THE ASSIGNED SHEET NUMBERS for the scales - EACH AND EVERY TIME he uses them. Period Number changes, but Sheet Number never changes for a particular instrument.

Although entitled "Psychiatrist Packets", these sets of scales may be rated by members of other professional disciplines as well; e.g., clinical psychologists, nonpsychiatric physicians, etc. The essential requirements for a rater are the appropriate clinical experience to make competent judgments and a thorough familiarity with these particular instruments and their uses. The selection of rating scales for a specific study is at the discretion of the investigator.

Figures 8 to 12 present data matrices for each of the scales. These matrices indicate the encoding location of each scale as well as the GSS sheet number upon which it appears. These locations are FIXED and MAY NOT BE ALTERED. To do so will render the data non-processable.

A maximum of 3 GSS is required at any given assessment with either packet. Figures 13 and 14 describe the manner in which Sheet Number is assigned to General Scoring Sheets and show a typical usage of the scales.

ERRATA - Raters should make the following corrections in their packets.

PSYCHIATRIST PACKET - CHILD (GREEN)

1. On the cover, the word "PSYCHOPHARMACOLOGY" is misspelled.
2. Dosage Record and Treatment Emergent Symptoms (29-DOTES)
   a) Page L-4, Item 3. Should read "(No. 0 through 6)", NOT "(No. 1 through 6)". Also on Adult (Gold) packet.
   b) Page R-5 - Item 5. The word "Tachycardia" is misspelled.
3. Clinical Global Impressions (28-CGI) - Page R-3. The word "GLOBAL" is misspelled. Also on Adult (Gold) packet.

PSYCHIATRIST PACKET - ADULT (GOLD)

1. Depression Status Inventory (072-DSI)
   a) All 20 items should be assessed using response positions 1 through 4. The "Not Assessed" category should NOT be used as it would change the scoring structure.
   b) Page L-3- Item 4. Under Interview Guide, the item should read: "Frequent and early AM wakings".
   c) Page L-3- Item 7. Under Interview Guide, the item should read: "Do you enjoy looking, talking or being with attractive men/women?"
2. Hamilton Depression Scale (049-HAMD)
   Item 9 - Agitation - This item should be rated on a 5-point scale as follows:

   0 = None
   1 = Fidgetiness
   2 = Playing with hands, hair, etc.
   3 = Moving about, can't sit still
   4 = Hand wringing, nail biting, hair-pulling, biting of lips

3. Anxiety Status Inventory (051-ASI)
   a) We regret that the author's name was inadvertently omitted from the ASI header page.
   b) The instructions given on the header page for the Depression Status Inventory should be applied to the Anxiety Status Inventory as follows:

MH-9-51

ANXIETY STATUS INVENTORY (ASI)
Wm. W. K. Zung

INSTRUCTIONS: *Code 01 under Sheet Number on General Scoring Sheet*

The data upon which the judgments are based come from the interview with the patient. The items in the scale are to be quantified by using all the information available to the rater. This includes both clinical observation and the material reported by the patient.

Use of the Interview Guide below assures coverage of all the areas on which judgments are required. However, the rater has the flexibility of modifying the questions or probing for details, which makes possible a smooth interview that does not sound like a question-answer examination. In rating the patient's current status, an arbitrary period of 1 week prior to the evalutaion is adopted in order to standardize the data. In order to reinforce this, the interviewer should occasionally precede questions with, "During the past week, have you. . . . ?"

MH-9-50
9-75

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB NO. 68-R965

ECDEU GENERAL SCORING SHEET (50-GSS)

PATIENT INITIALS — FIRST INITIAL — SECOND INITIAL — SHEET NO.

NUMBER MALES 001 TO 499 — NUMBER FEMALES 500 TO 998

PATIENT — RATER — PERIOD (Hours, Days, Weeks, Months)

FIGURE 8
MATRICES FOR
CHILDREN'S PSYCHIATRIC
ASSESSMENT SCALES

Row			
1	Compulsive	(42)	
2	Habits	(43)	
3	Obsessive	(44)	
4	Solitary	(45)	
5	Peer Interaction	(46)	
6	Gang	(47)	
7	Fighting	(48)	
8	Bully	(49)	
9	Temper	(50)	
10	Scapegoat	(51)	
11	Lying	(52)	
12	Exploitative	(53)	
13	Inability to fall asleep	(54)	
14	Sleep difficulties	(55)	
15	Bedwetting	(56)	
16	Reference	(57)	
17	Persecutory	(58)	
18	Thinking Disorders	(59)	
19	Delusions	(60)	
20	Hallucinations	(61)	
21	Fantasies	(62)	
22	Lack of insight	(63)	
23			
24			
25			
26			
27			
28			
29			
30			
31			
32			
33			
34			
35			
36			
37			
38	Severity	(1)	
39	Improvement	(2)	
40	Efficacy Index	(3)	
41	"		116

CGI

CPRS

Row		
1	Tension	
2	Underproductive Speech	
3	Fidgetness	
4	Hyperactivity	
5	Hypoactivity	
6	Distractibility	
7	Abnormal Relationships	
8	Withdrawal	
9	Overcompliant	
10	Negative	
11	Angry	
12	Silly	
13	Confusion	
14	Disorientation	
15	Clinging	
16	Unspontaneous	
17	Suspiciousness	
18	Depressed Demeanor	
19	Blunted Affect	
20	Lability	
21	Pressure of speech	
22	Speech development	
23	Stuttering	
24	Low voice	
25	Loud voice	
26	Mispronunciation	
27	Speech deviance	
28	Rhythmic motions	
29	Inferiority	
30	Grandiosity	
31	Physical complaints	
32	Obesity	
33	Eating problems	
34	Separation anxiety	
35	Depression	
36	Euphoria	
37	Lack of energy	
38	Anxiety topics	
39	Depressive topics	
40	Suicide	
41	Fears-Phobias	

Cols: 1 2 3 4 5 6 7 8 9 — Cols: 11 12 13 14 15 16 17 18 19 20

MH-9-50
9-75

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
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ECDEU GENERAL SCORING SHEET (50-GSS)

PATIENT INITIALS — FIRST INITIAL — SECOND INITIAL — SHEET NO.

NUMBER MALES 001 TO 499 — NUMBER FEMALES 500 TO 998

PATIENT — RATER — PERIOD (Hours, Days, Weeks, Months)

FIGURE 9
MATRICES FOR CHILDREN'S DIAGNOSTIC SCALES

Row		Row	
1		1	Psychotism
2		2	Anxiety reaction
3		3	Withdrawal
4		4	Unsocialized aggression
5		5	Socialized aggression
6		6	Explosive
7		7	Hyperactivity
8		8	Immature
9		9	Organic impairment
10		10	Delirium
11		11	Mental retardation
12		12	Diagnosis (a)
13		13	(b)
14		14	(b)
15		15	(b)
16		16	(b)
17		17	(c)
18		18	(c)
19		19	(c)
20		20	(c)
21		21	No special symptoms (A)
22		22	Speech disturbance (B)
23		23	Learning (C)
24		24	Tic (D)
25		25	Psychomotor (E)
26		26	Sleep (F)
27		27	Feeding (G)
28		28	Enuresis (H)
29		29	Encropresis (I)
30		30	Cephalalgia (J)
31		31	CDC
32		32	
33		33	
34		34	
35		35	
36		36	
37		37	
38		38	
39		39	
40			
41			

12

13

117

Cols: 1 2 3 4 5 6 7 8 9 1 — 12 13 14 15 16 17 18 19 20

MH-9-50
9-75

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
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ECDEU GENERAL SCORING SHEET (50-GSS)

PATIENT INITIALS — FIRST INITIAL — SECOND INITIAL — SHEET NO. (0 1 2 3 4)

NUMBER MALES 001 TO 499 — NUMBER FEMALES 500 TO 998

PATIENT — RATER — PERIOD (Hours, Days, Weeks, Months)

FIGURE 10
MATRICES FOR
ADULT PSYCHIATRIC
ASSESSMENT SCALES

Row	HAMD	ASI	BPRS
1	Depressed Mood	Anxious	Somatic Concern
2	Guilt	Fear	Anxiety
3	Suicide	Panic	Emotional Withdrawal
4	Early Insomnia	Disintegration	Conceptual Disorganization
5	Middle Insomnia	Apprehension	Guilt Feelings
6	Late Insomnia	Tremors	Tension
7	Work	Aches/Pains	Mannerisms & Posturing
8	Retardation	Fatigue	Grandiosity
9	Agitation	Restlessness	Depressive Mood
10	Anx. Psychic	Palpitation	Hostility
11	Anx. Somatic	Dizziness	Suspiciousness
12	Symptoms GI	Faintness	Hallucinatory Behavior
13	Symptoms Gener	Dyspnea	Motor Retardation
14	Symptoms Genit	Parathesias	Uncooperativeness
15	Hypochondriasis	Nausea	Unusual Thought Content
16	Wt. Loss - Hist	Urinary Freq	Blunted Affect
17	Wt. loss-Actual	Sweating	Excitement
18	Insight	Flushed Face	Disorientation
19	Diurnal-Pres	Insomnia	Depressed Mood (1)
20	Diurnal-Sev	Nightmares	Crying (2)
21	Depersonal	Threatened (1)	Diurnal (3)
22	Paranoid	Foreboding (2)	Sleep (4)
23	Obsess/Comp.	Guilt (3)	Appetite (5)
24	Anxious Mood (1)	Anxiety (4)	Weight Loss (6)
25	Tension (2)	Attention (5)	Libido (7)
26	Fears (3)	Symptoms (6)	Constipation (8)
27	Insomnia (4)	Organic (7)	Tachycardia (9)
28	Intellectual (5)	Phobic (8)	Fatigue (10)
29	Depressed (6)	Obsessive (9)	Agitation (11)
30	Somatic-Musc (7)	Compulsive (10)	Retardation (12)
31	Somatic-Sens (8)	Indecisive (11)	Confusion (13)
32	Symptoms-CV (9)	Avoidance (12)	Emptiness (14)
33	Symptoms-RE (10)	Retardation (13)	Hopelessness (15)
34	Symptoms-GI (11)	Overactive (14)	Indecisive (16)
35	Symptoms-GU (12)	Irrelevant (15)	Irritability (17)
36	Symptoms-AN (13)	Misinterprets (16)	Dissatisfact (18)
37	Behavior (14)	Influence (17)	Devaluation (19)
38			Suicidal (20)

HAMA — WIT — DSI

38 Severity (1)
39 Improvement (2) — CGI
40 Efficacy Index (3)
41 Efficacy Index

Cols: 1 2 3 4 5 6 7 8 9 10 — 2 13 14 15 16 17 18 19 20

MH-9-50
9-75

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
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ECDEU GENERAL SCORING SHEET (50-GSS)

PATIENT INITIALS — FIRST INITIAL — SECOND INITIAL — SHEET NO.

NUMBER MALES 001 TO 499 — NUMBER FEMALES 500 TO 998 — PATIENT — RATER — PERIOD (Hours, Days, Weeks, Months)

FIGURE 11
MATRIX FOR
DOSAGE RECORD AND
TREATMENT EMERGENT SYMPTOMS
SCALES

Row										
1	Akathisia									
2										
3	Dry Mouth									
4										
5	Nasal Congestion									
6										
7	Blurred Vision									
8										
9	Constipation									
10										
11	Increased Salivation									
12										
13	Sweating									
14										
15	Nausea/Vomiting									
16										
17	Diarrhea									
18										
19	Hypotension									
20										
21	Syncope/Dizziness									
22										
23	Tachycardia									
24										
25	Hypertension									
26										
27	EKG									
28										
29	Dermatologic									
30										
31	Weight Gain									
32										
33	Weight Loss									
34										
35	Anorexia/Decreased Appetite									
36										
37	Headache									
38										
39	Tardive Dyskinesia									
40										
41	Severity	Distress								

Row										
1	Reason									
2	Daily Dose (2a)									
3	(2a)									
4	(2a)									
5	(2a)									
6	(2b)									
7	(2b)									
8	(2b)									
9	(2b)									
10	Long Acting (2c)									
11	(2c)									
12	(2c)									
13	Prescription (3)									
14	Symptoms Present (4)									
15	Toxic Confusional State (5)									
16										
17	Excitement/Agitation									
18										
19	Depressive Affect									
20										
21	Increased Motor Activity									
22										
23	Decreased Motor Activity									
24										
25	Insomnia									
26										
27	Drowsiness									
28										
29	Abnormal Hematologic									
30										
31	Abnormal Liver									
32										
33	Abnormal Urine									
34										
35	Rigidity									
36										
37	Tremor									
38										
39	Dystonic Symptom									
40										

Cols: 1 2 3 4 5 6 7 8 9 10 — 119 — 12 13 14 15 16 17 18 19 20

MH-9-50
9-75

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB NO. 68-R965

ECDEU GENERAL SCORING SHEET (50-GSS)

PATIENT INITIALS — FIRST INITIAL — SECOND INITIAL — SHEET NO.

NUMBER MALES 001 TO 499 — NUMBER FEMALES 500 TO 998

PATIENT — RATER — PERIOD (Hours, Days, Weeks, Months)

FIGURE 12
MATRIX FOR
PATIENT TERMINATION
RECORD

Row		Cols: 1	2	3	4	5	6	7	8
1	Blood tonic	(6b)							
2	Bronchodilator	(6b)							
3	Cardiac	(6b)							
4	Cough	(6b)							
5	Dermatological	(6b)							
6	Diabetic	(6b)							
7	Diet	(6b)							
8	Diuretic	(6b)							
9	GI	(6b)							
10	Hormonal	(6b)							
11	Muscle relax.	(6b)							
12	Psychotropic	(6b)							
13	Sedative	(6b)							
14	Stimulant	(6b)							
15	Thyroid	(6b)							
16	Vitamin	(6b)							
17	Conformity	(7a)							
18	Cont. RX	(7b)							
19	Disp.-Inpt	(8a)							
20	Disp.-Outpt	(8b)							
21									
22									
23									
24									
25									
26									
27									
28									
29									
30									
31									
32									
33									
34									
35									
36									
37									
38									
39									
40									
41									120

Row		Cols: 11	12	13	14	15	16	17	18	19	20
1	Subject before	(1a)									
2	Data sent Lab	(1b)									
3	ECDEU	(1c)									
4		(1c)									
5	Study	(1c)									
6		(1c)									
7	and	(1c)									
8		(1c)									
9	Patient	(1c)									
10		(1c)									
11	Numbers	(1c)									
12	Duration	(2a)									
13	Days in	(2a)									
14	Study	(2a)									
15	Premat. Term.	(2b)									
16	Interval Hist	(3)									
17	Non-drug RX	(4a)									
18	Behavior Mod	(4b)									
19	ECT	(4b)									
20	Milieu	(4b)									
21	Physical	(4b)									
22	Psychother-grp	(4b)									
23	Psychother-ind	(4b)									
24	Rehabilitation	(4b)									
25	Educational	(4b)									
26	Family Inther	(4c)									
27	Efficacy	(4d)									
28	Drug-intake	(5)									
29	Ancillary Drug	(6a)									
30	Analgesic-narc	(6b)									
31	Analges-nonnarc	(6b)									
32	Anesthesia-gen	(6b)									
33	Anesthesia-loc	(6b)									
34	Antiallergenic	(6b)									
35	Anticoagulant	(6b)									
36	Anticonvulsant	(6b)									
37	Antifertility	(6b)									
38	Antihypertens	(6b)									
39	Antimicrobial	(6b)									
40	Antiparkinson	(6b)									
41	Antitumor	(6b)									

FIGURE 13

CHILDREN'S PSYCHIATRIST PACKET

Sequential Use of Scales and Assignment of

GSS Sheet Numbers

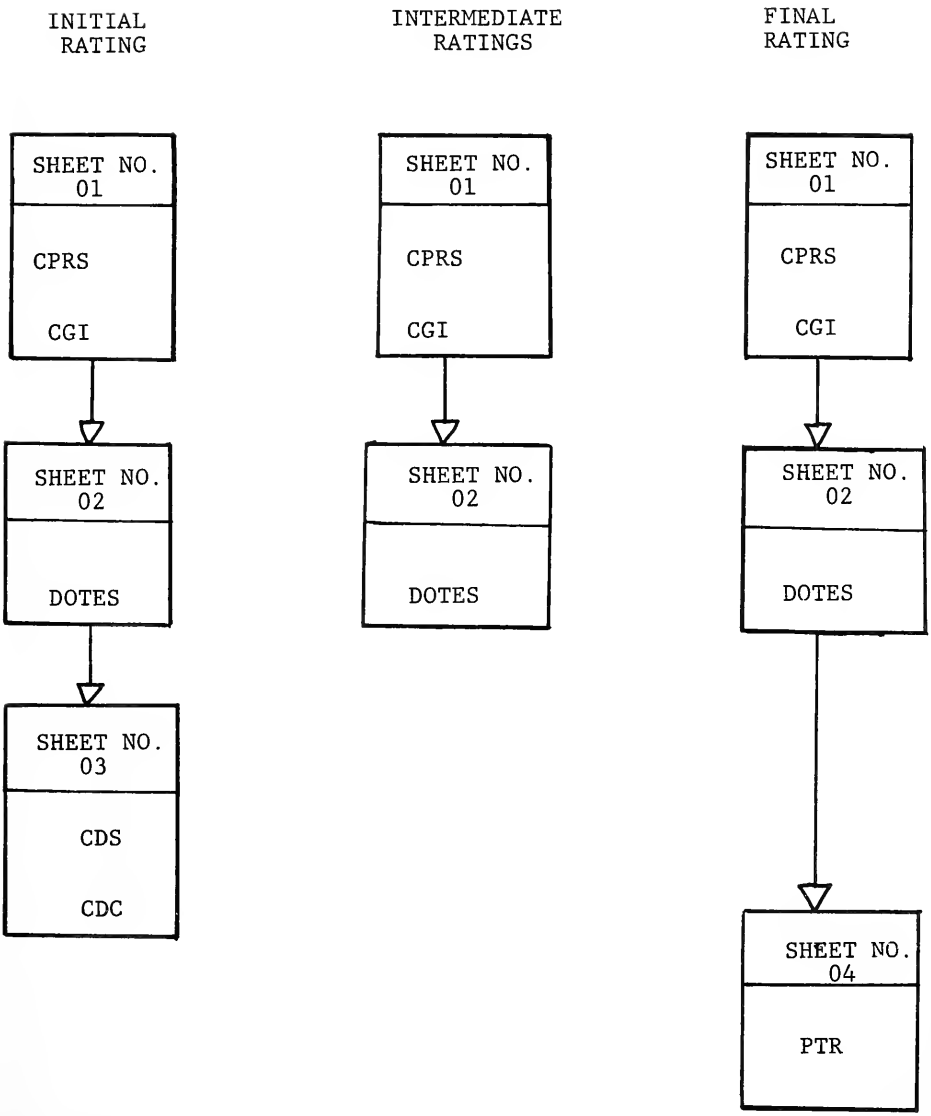
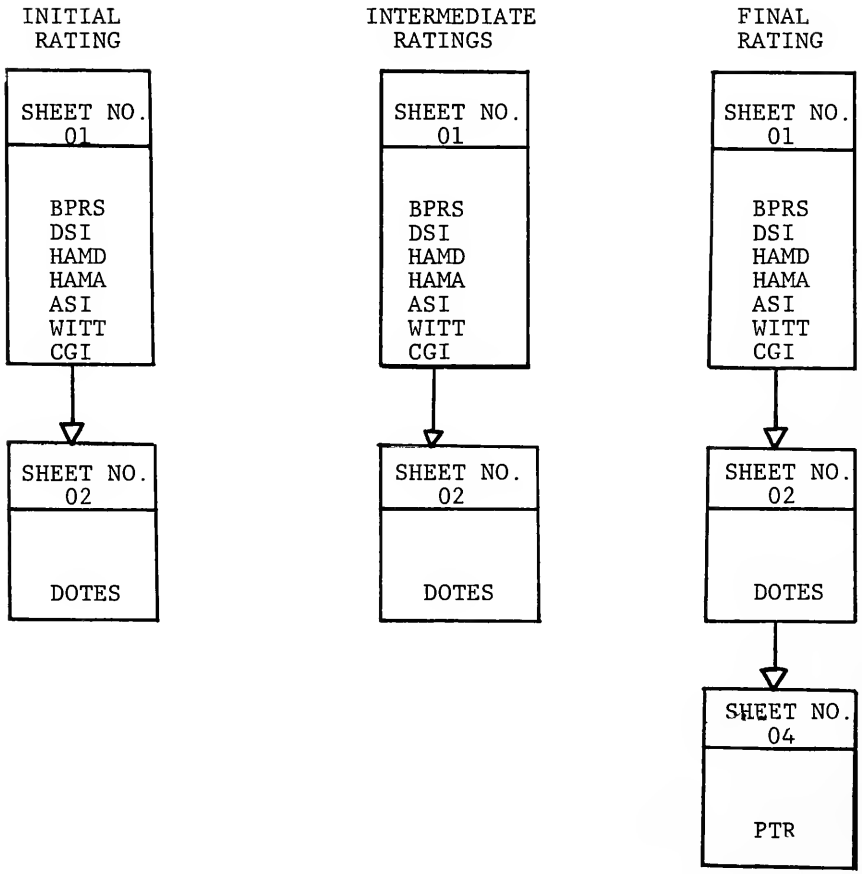


FIGURE 14

ADULT PSYCHIATRIST PACKET

Sequential Use of Scales and Assignment of

GSS Sheet Numbers



027 CPRS CHILDRENS PSYCHIATRIC RATING SCALE

MH-9–27
1-73

CHILDREN'S PSYCHIATRIC RATING SCALE

CPRS

INSTRUCTIONS: *Insert General Scoring Sheet, Form 50, and Code 01 under Sheet Number.*

Rate the first 28 items exclusively on the basis of direct observation during the interview.

Rate the last 34 items (29–63) on the basis of the child's verbal report of occurrence at the time of the interview or during the past seven days. Do not use any other data, but that obtained in the interview with the child.

Mark all rows consecutively – do not skip any rows. Each row is numbered on the scoring sheet and also on the page with the item to facilitate marking on the correct row.

USE A NO. 2 LEAD PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE.

NOT ASSESSED	NOT PRESENT	VERY MILD	MILD	MODERATE	MODERATELY SEVERE	SEVERE	EXTREMELY SEVERE

Mark on right half of scoring sheet on row specified	ROW NO.
1. TENSION *(Do not include fidgetiness)* Musculature appears taut, strained or tense. Fingers clothing, clenches jaws, grips arms of chair, hands tremulous.	1
2. UNDERPRODUCTIVE SPEECH *(Rate amount of speech only, not rate or relevance)* Fails to answer questions, monosyllabic, has to be pushed to get an answer, doesn't elaborate, blocked.	2
3. FIDGETINESS *(Do not include tics)* Wriggles, squirms, moves or shifts restlessly in chair	3
4. HYPERACTIVITY Has difficulty sitting in chair, gets up, moves fast, vigorously, impulsive bursts of locomotion. Exclude slow ambling even if constant. In rating degree of overactivity, consider the ease with which the hyperactivity can be controlled.	4
5. HYPOACTIVITY Few or no spontaneous movements. Sluggish. Movements are slowed, feeble or labored. Requires prompting for initiation of motor movements. Long latencies of appropriate motor behavior	5
6. DISTRACTIBILITY Distracted by usually minor, irrelevant stimuli. Shifts from one topic to another. Interrupts thought or action abruptly	6
7. ABNORMAL OBJECT RELATIONSHIPS Autistic use of objects with disregard for usual function. Stereotyped and repetitive sequences or fragments of play. Aimless behavior without organizing goal idea	7
8. WITHDRAWAL Oblivious of examiner, preoccupied. Facial expression and behavior do not respond directly to examiner. Attention focus is oblique and vague in direction, with avoidance of eye contact. Responses are very delayed and require forceful stimuli. *(The fact that the child may have peculiar interest in examiner, such as obsessive interest in parts of body or clothing does not preclude a rating of withdrawal).*	8
9. OVERCOMPLIANT Goes along with whatever examiner says in a passive fashion, even contradicting self. Does not assert self in a reasonable manner.	9
10. NEGATIVE, UNCOOPERATIVE Active opposition and resistance to examiner's initiative *(differs from withdrawal and oblique avoidance).* Guarded, evasive replies, teasing, manipulative or hostile refusal to cooperate. Child may remain silent in passive aggressive fashion.	10
11. ANGRY AFFECT Irritable, touchy, erupts easily – shouts angrily, screams at examiner, overtly and directly hostile.	11

Continue marking on right half of scoring sheet on row specified	ROW NO.
12. SILLY AFFECT Clowning, inappropriately giddy, playful, silly behavior.	12
13. CONFUSION Confused, bewildered, perplexed in behavior or verbal expression.	13
14. DISORIENTATION Child is unaware of identity of surroundings after being told where he is. Not aware of time discriminations. Doesn't know age or surname.	14
15. CLINGING BEHAVIOR Clinging, in physical and verbal behavior with the examiner. Seeks physical contact, demands constant direction.	15
16. UNSPONTANEOUS RELATION TO EXAMINER Responds to examiner, but does not initiate social or verbal overtures, nor sustain conversation once begun. Lacks spontaneity. Restricted.	16
17. SUSPICIOUS AFFECT Expresses concern about the intent of the examination. Questions instructions and good will of interviewer.	17
18. DEPRESSED DEMEANOR Exhibits a dejection, depression in mood. Looks sad. Seems to be in a state of painful dejection.	18
19. BLUNTED AFFECT Restricted range and intensity of emotional expressions; blank or fixed facial expression, monotonous voice	19
20. LABILITY OF AFFECT Can suddenly vary from calm or silly to sullen mood, to screaming, crying, loud complaining.	20
21. PRESSURE OF SPEECH Speech is hurried, accelerated, pushed, difficult to interrupt.	21
22. LEVEL OF SPEECH DEVELOPMENT *(Do not include diction, rate of speech, or relevance of speech)* From age-appropriate (1) to severely retarded (7) speech development. Using your clinical judgment of verbal I.Q., estimate the level of speech development (in percent) in relation to verbal I.Q. 1 = Over 90% 2 = 76 – 90% 3 = 61 – 75% 4 = 46 – 60% 5 = 31 – 45% 6 = 15 – 30% 7 = Less than 15%	22
23. STUTTERING	23
24. LOW VOICE Voice weak, mumbling, whispering, almost inaudible.	24
25. LOUD VOICE Voice loud, boisterous, shouting.	25

Continue marking on right half of scoring sheet on row specified	ROW NO.
26. MISPRONUNCIATIONS Lisping, mispronounces letters such as r, s, l, etc. Unclear speech	26
27. OTHER SPEECH DEVIANCE Echolalia, question-like melody, neologisms, sentences fragmented, unusual syntax.	27
28. RHYTHMIC MOTIONS (STEREOTYPE) Rocking, whirling, head banging, rolling, repetitive jumping, hand movements, athetoid, twiddling, arm flapping	28
RATE THE FOLLOWING 34 ITEMS ON THE BASIS OF THE CHILD'S VERBAL REPORT OF OCCURRENCE AT THE TIME OF THE INTERVIEW OR DURING THE PAST 7 DAYS. DO NOT USE ANY OTHER DATA BUT THAT OBTAINED IN INTERVIEW WITH THE CHILD.	
29. EXPRESSED FEELINGS OF INFERIORITY Describes feelings of inadequacy, inferiority, self-deprecating, self-belittling	29
30. EXPRESSED FEELINGS OF GRANDIOSITY Exaggerates own value, boasting. Unduly pleased with own achievement. Says he is much better than others. Distorted sense of own capacity.	30
31. PHYSICAL COMPLAINTS Somatic complaints of headaches, stomach aches, dizziness, not feeling well, etc. *(do not include fatigue).*	31
32. OBESITY Judge from child's appearance from normal physical appearance to severe obesity.	32
33. OTHER EATING PROBLEMS Picky, fussy, many dislikes, extremely restricted diet, peculiar food tastes.	33
34. SEPARATION ANXIETY Ease with which child separates from mother or other significant people. Extent of observed or reported anxiety (by child) experienced by child when separated from mother or other significant people.	34
35. DEPRESSION Admits feeling sad, lonely, feels like crying, expresses a despondent or despairing attitude. Difficulty in anticipating success and enjoyment.	35
36. EUPHORIA – ELATION States he feels terrific, great, elevation of mood, hypomanic state. "This is the best of all possible worlds." Feels elated and wonderful. Nothing is impossible.	36
37. LACK OF ENERGY States he feels sluggish, fatigued. Everything is too much. Weary and feels unable to make slightest effort. *(Do not infer from motor retardation or expressed indifference).*	37

	ROW NO.
When you have completed this page (item 41), turn all pages on this side and continue with text (item 42) on page R1	
38. PREOCCUPATION WITH TOPICS OF ANXIETY Says he has nervous or scary feelings, concerns, apprehension, fears. Says he worries about failure or other mishaps, thinks about something happening to self or parents- illness, injury, death, loss or separation.	38
39. PREOCCUPATION WITH DEPRESSIVE TOPICS Preoccupied with feelings of inadequacy and inferiority. Expresses feeling that nothing can turn out all right. Preoccupied with feelings of uselessness, futility, and possibly guilt. Suicidal preoccupation.	39
40. SUICIDAL ATTEMPTS 0 = Not assessed 1 = None 2 = Suicidal threat 3 = One minor gesture without danger 4 = A couple or several minor gestures without danger 5 = Dangerous gesture 6 = Infliction of life threatening damage to self 7 = Several life threatening attempts	40
41. FEARS AND PHOBIAS Irrational morbid fears of specific objects, person, or situations, which, if extreme, lead to avoidance behavior. Rate 6 or 7 only when fear is so severe it leads to phobic avoidance.	41

ROW NO.	*Mark on left half of scoring sheet on row specified*
1	**42. COMPULSIVE ACTS** Acts or "habits" which are regarded as unreasonable by the child, such as, counting, checking, rituals, excessive orderliness, and cleanliness.
2	**43. NERVOUS HABITS AND MANNERISMS** Stereotyped movements; rituals which are not perceived as irrational. Facial tics or mannerisms. Biting nails, fingers, cuticles. Sucking of objects or body parts *(thumb, fingers, hair, etc.);* Picking on skin, scabs, nose, twisting hair.
3	**44. OBSESSIVE THINKING** Inability to "turn off" repetitive thought. Preoccupation, ruminations about abstract problems or personal matters.
4	**45. SOLITARY INTERESTS** Interested in activities which require little if any peer interaction, such as stamp collecting, movie going, reading, school work, solitary activities.
5	**46. LACK OF PEER INTERACTION** Isolated from other children. Has no friends or cannot name current close friend nor describe participation in play with peers. Lacks interest in peers.
6	**47. GANG ACTIVITY** Joins in antisocial activities along with a group of children *(fighting, trouble making, stealing)* as a cooperating group against others.
7	**48. FIGHTING WITH PEERS** Says he frequently gets into fights — beats up other kids or gets beaten up. Says he has a bad temper.
8	**49. BULLY** Says he's always the leader, winner; or says he teases, bullies children; pushes children around; threatens them.
9	**50. TEMPER OUTBURSTS** Admits to feeling angry, irritable, touchy, admits he has a temper.
10	**51. SCAPEGOAT** Says he's picked on, teased, left out or pushed around, and bullied by other children. May be called "sissy" or "baby".
11	**52. LYING** Contradicts self in ways indicative of effort to hide the truth. Reports telling tall stories, fibs, or admits he's accused of telling lies.
12	**53. EXPLOITATIVE RELATIONSHIPS** Interested in other people insofar as he can get something out of it. Callous and calculating in interpersonal activities.

RDW NO.	*Continue marking on left half of scoring sheet on row specified*
13	**54. INABILITY TO FALL ASLEEP** Child reports a long time to fall asleep after going to bed. 1 = Not present 2 = 10 to 15 min. 3 = 16 to 30 min. 4 = 31 to 45 min. 5 = 46 to 60 min. 6 = 60 to 90 min. 7 = Over 90 min.
14	**55. OTHER SLEEP DIFFICULTIES** Nightmares, early morning awakening, sleep walking, interrupted sleep.
16	**56. BEDWETTING** Rating is for frequency of bedwetting for past 7 nights 1 = None 2 = One time 3 = 2 times 4 = 3 times 5 = 4 times 6 = 5 times 7 = 6 to 7 times
16	**57. IDEAS OF REFERENCE** People are looking at him, following him, staring, etc. Malevolent intent is not necessary but may occur.
17	**58. PERSECUTORY** Feels people have it in for him, try to hurt him. In the extreme rating, the thinking has a delusional quality in that the belief is impervious to change, rational arguments, or corrective experiences.
18	**59. OTHER THINKING DISORDERS** Irrelevant speech; or incoherent speech; or loose associations.
19	**60. DELUSIONS** Delusional beliefs or convictions besides paranoia (58), i.e. believes has introjected persons or objects in his body, has a mission; is some other person or character, has unusual powers; is guilty of some event.
20	**61. HALLUCINATIONS** The overall rating is a frequency rating reflecting the constancy of the experience: 1 = Not present 2 = Once 3 = 2 times 4 = 3 times 5 = 4 to 5 times 6 = 5 to 6 times 7 = Daily recurrent phenomenon
21	**62. PECULIAR FANTASIES** Morbid or bizarre fantasies and pre-occupations, peculiar body sensations, disturbances of body image experiences *(not figure drawings);* preoccupation with flying, supernatural influences, sadism, masochism.
22	**63. LACK OF INSIGHT** Is convinced of the reality of hallucinations or fantasies.

The Children's Psychiatric Rating Scale (CPRS) is an original scale constructed by members of the Pediatric Psychopharmacology Workshop. It is a comprehensive scale which endeavors to assess the broad spectrum of psychopathology within this age group. As a consequence, items of the CPRS will have varying degrees of relevance when assessing a circumscribed diagnostic group. The CPRS is formatted for use with the General Scoring Sheet and contains 63 items. A 7-point scale derived from the Adult Brief Psychiatric Rating Scale is employed. The CPRS should be regarded as experimental. Standardization procedures will be undertaken as soon as sufficient data are accumulated.

APPLICABILITY — For children to age 15.

UTILIZATION — Once at pretreatment; at least one posttreatment assessment. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED — The first 28 items are rated on the basis of direct observation of behavior during the interview. The last 34 items are rated on the basis of the child's report of occurrence during the interview or within the past week.

CARD FORMAT - ITEMS

CARD 01=(19x, 4111)

Item	Column	Item	Column	Item	Column	Item	Column
1	20	11	30	21	40	31	50
2	21	12	31	22	41	32	51
3	22	13	32	23	42	33	52
4	23	14	33	24	43	34	53
5	24	15	34	25	44	35	54
6	25	16	35	26	45	36	55
7	26	17	36	27	46	37	56
8	27	18	37	28	47	38	57
9	28	19	38	29	48	39	58
10	29	20	39	30	49	40	59
						41	60

CARD 02=(19x, 2211)

Item	Column	Item	Column	Item	Column	Item	Column
42	20	47	25	52	30	57	35
43	21	48	26	53	31	58	36
44	22	49	27	54	32	59	37
45	23	50	28	55	33	60	38
46	24	51	29	56	34	61	39
						62	40
						63	41

CARD FORMAT - CLUSTERS CARD 51 = (19x, 9F6.2)

(Code "5" in Column 18 indicates a card containing factors, clusters or other grouped scores).

Cluster	Column	Cluster	Column
I	20-25	VI	50-55
II	26-31	VII	56-61
III	32-37	VIII	62-67
IV	38-43	IX	68-73
V	44-49		

CARD 52 = (19x, 6F6.2,F4.0)

Cluster	Column	Cluster	Column
X	20-25	XIII	38-43
XI	26-31	XIV	44-49
XII	32-37	XV	50-55
		Total Score	56-59

$$\text{Cluster score} = \frac{\text{Sum of composite items}}{\text{Number of composite items}}$$ Cluster score range = 1 - 7

Total score = Sum of all items Total score range = 63 - 441

CLUSTER COMPOSITION - As a means of data reduction, the clusters have been empirically derived for use in statistical analyses. It is planned to undertake psychometric analyses of the CPRS when sufficient data are accumulated.

I. Psychotic

2. Underproductive speech
7. Abnormal object relationships
19. Blunted Affect
27. Other speech deviance
28. Rhythmic motions (stereotypic)
57. Ideas of reference

II. Hostile-Uncooperative

10. Negative, uncooperative
11. Angry affect
17. Suspicious affect
50. Temper outbursts

III. Hyperactive

3. Fidgetiness
4. Hyperactivity
6. Distractibility
20. Lability of affect

IV. Anxiety

1. Tension
15. Clinging behavior
34. Separation anxiety
38. Preoccupation - anxiety
41. Fears and phobias

V. Thought Disturbance

58. Persecutory ideation
59. Other thinking disturbances
60. Delusions
62. Peculiar fantasies
63. Lack of insight

VI. Neurotic

31. Physical complaints
42. Compulsive acts
43. Nervous habits
44. Obsessive thinking

CLUSTER COMPOSITION (cont'd.)

VII. Depression

5. Hypoactivity
18. Depressed demeanor
24. Low voice
29. Expressed feelings of inferiority
35. Depression
37. Lack of energy
39. Preoccupation with depressive topics
40. Suicidal attempts

VIII. Excited mood

12. Silly affect
21. Pressure of speech
25. Loud voice
30. Expressed feelings of grandiosity
36. Euphoria-elation

IX. Withdrawal

8. Withdrawal
9. Overcompliant
16. Unspontaneous relation to examiner
45. Solitary interests
46. Lack of peer interaction
51. Scapegoat

X. Antisocial

47. Gang activity
48. Fighting with peers
49. Bully
52. Lying
53. Exploitative relationships

XI. Organic

13. Confusion
14. Disorientation

XII. Speech disturbance

22. Level of speech development
23. Stuttering
26. Mispronunciations

XIII. Sleep disturbance

54. Inability to fall asleep
55. Other sleep difficulties

XIV. Eating disturbance

32. Obesity
33. Other eating problem

XV. Enuresis

56. Bedwetting

SPECIAL INSTRUCTIONS - Cues for rating as well as specific instructions for each item are printed on the scale. Strict adherence to these instructions is required of all raters.

Item 22 - Level of Speech Development - This item may be confusing. The rater is asked to judge whether the level of speech development is appropriate to the child's verbal IQ. For example, response position 4 is read as level of speech development is only 46 - 60% of Verbal IQ; position 2 as level of speech development is 76 to 90% of Verbal IQ.

Item 56 - Bedwetting and Item 61 - Hallucinations. Remember that these items (as with all items from 29 to 63) refer to the past 7 days.

DOCUMENTATION

a. Raw score printout
b. Cluster score printout
c. Means and standard deviations for cluster scores
d. Cross tabulations
e. Variance analyses

030 CDS
CHILDRENS
DIAGNOSTIC
SCALE

MH:9–30
1-73

CHILDREN'S DIAGNOSTIC SCALE

INSTRUCTIONS: *Insert New General Scoring Sheet and Code, 03 under Sheet Number.*

Responses should be based on overall psychiatric judgments utilizing all data sources integratively; e.g., school reports, mother's reports, interview data, etc.

Rate current status only. Be sure to answer all items.

Complete at pretreatment only.

Mark each item on right half of scoring sheet on row specified	ROW NO.
1. PSYCHOTICISM Gross impairment of relationship with people and environment, bizarre interaction, extreme preoccupation with internal stimuli; responses appear markedly inappropriate to external stimuli and/or displays distinct thinking disorders, neologisms, echolalia, incoherence, confused, irrelevant or tangential content, or confused about reality or morbid or bizarre ideation, delusions, hallucinations, or permeated by loosening of associations, illogical or contradictory statements.	1
2. ANXIETY REACTION *Expresses* feelings of nervousness, anxiety, unrealistic fears or worries; concern with feelings of inadequacy; inferiority, shyness, obsessions or compulsions.	2
3. WITHDRAWAL REACTION Isolation, seclusiveness, withdrawal, detachment, inability to form close relationships.	3
4. UNSOCIALIZED AGGRESSIVE BEHAVIOR *Overtly* negative, defiant, hostile, and/or manipulative, evasive, guarded. Attempts to control others; aggressive, antisocial, overwhelmingly selfish. Denial of anxiety and personal responsibility for feelings and acts. Is in hostile conflict with the environments in a variety of social settings (family, school) which do not involve group expression of hostility.	4
5. SOCIALIZED AGGRESSIVE BEHAVIOR Is in delinquent or hostile conflict with the environment, primarily in association with members of a gang, rarely on own.	5
6. EXPLOSIVE AGGRESSION Unable to control appropriately his responses towards peers and/or adults. Physically aggressive, impulsive, often reacts to others before understanding the meaning or motives of their words or actions. Gets into numerous fights. Physically disruptive particularly in classroom where he may hit out at others with little or no provocation.	6
7. CHRONIC HYPERACTIVITY High and conspicuous level of gross motor activity in a variety of settings such as school, home, stores, office, etc.	7
8. IMMATURE AND INADEQUATE BEHAVIOR Variable and poorly organized personality characteristics and coping techniques.	8
9. PRESENCE OF GROSS ORGANIC IMPAIRMENT 0 = NO 1 = YES Do not include impression of minimal brain damage, but use all available examinational data such as neurological tests, EEG, etc. Gross organic impairment refers to findings which lead to a strong inference of anatomical lesions or organic diagnosis, e.g., hemiparesis, cerebral palsy, epilepsy, etc. If YES, specify **PSYCHIATRIC** diagnosis (DSM II) in item 12b and/or 12c. Any neurologic diagnosis without associated psychopathology should be specified on the Physical and Neurological Examination form, form number 41.	9
10. DELIRIUM Gross acute impairment of orientation (time, place or person) and/or memory, with clouding of sensorium. Unlike item 9, delirium should imply reversable organic impairment. 0 = NO 1 = YES If YES, specify **PSYCHIATRIC** diagnosis (DSM II) in item 12b and/or 12c. Any neurologic diagnosis without associated psychopathology should be specified on the Physical and Neurological Examination form	10
11. PRESENCE OF GROSS MENTAL RETARDATION 0 = NO 1 = YES Obvious to the examiner and/or found on psychometric tests. If YES, specify diagnosis in item 12b and/or 12c.	11

NOT ASSESSED	NOT PRESENT	VERY MILD	MILD	MODERATE	MODERATELY SEVERE	SEVERE	EXTREMELY SEVERE

Continue marking on right half of scoring sheet on specified row	ROW NO.
12. DIAGNOSIS	12
(a) Specify ONE of the following diagnoses on row 12 OR record any other OSM II diagnosis under (b) and/or (c) below. 1 - Schizophrenia, childhood (295.8) 2 - Overanxious reaction (308.2) 3 - Unsocialized aggressive reaction (308.4) 4 - Hyperactive reaction (308.0) 5 - Withdrawal reaction (308.1) 6 - Diagnosis cannot be formulated but significant psychopathology is present 7 - No significant psychopathology (318.0)	
(b) Other diagnosis # 1 . . . . . Mark on 4 rows	13-16
(c) Other diagnosis # 2 . . . . . Mark on 4 rows	17-20
13. SPECIAL SYMPTOMS Check presence of a symptom by marking "0" on the proper row. If no special symptoms present mark "0" on row 21.	
A. No symptoms	21
B. Speech disturbance	22
C. Specific learning disturbance . .	23
D. Tic	24
E. Other psychomotor disorder . .	25
F. Disorder of sleep	26
G. Feeding disturbance	27
H. Enuresis	28
I. Encopresis	29
J. Cephalalgia	30

The Children's Diagnostic Scale (CDS) is a 13-item scale formatted for use with the General Scoring Sheet. It is an original scale developed by members of the Pediatric Psychopharmacology Workshop to explore and clarify some of the nosological problems within this age group. The first 8 items consist of behavioral syndromes to be evaluated on a 7-point scale derived from the adult Brief Psychiatric Rating Scale (BPRS). From the ratings obtained on the eight syndromes, construction of more precise typological entities may hopefully emerge. The remaining 5 items of the CDS are composed of specific diagnostic questions.

REFERENCE - Diagnostic and Statistical Manual of Mental Disorders, American Psychiatric Association, 1968, 3rd Edition.

APPLICABILITY - Children to 15

UTILIZATION - Once at pretreatment. May be used at termination at the discretion of the investigator.

TIME SPAN RATED - Current status only

CARD FORMAT - ITEMS (19x, 1211, 214, 1011)

Item	Column	Item	Column
1	20	12a	31
2	21	12b	32-35
3	22	12c	36-39
4	23	13A	40
5	24	13B	41
6	25	13C	42
7	26	13D	43
8	27	13E	44
9	28	13F	45
10	29	13G	46
11	30	13H	47
		13I	48
		13J	49

SPECIAL INSTRUCTIONS

Items 1 - 8 - Descriptions of each of the syndromes are printed on the CDS. Raters should make their judgments within these contexts.

Items 9,10,11-These 3 items require a present (YES) or absent (NO) judgment. Appropriate diagnoses should be encoded under Items 12b and/or 12c.

Item 12a - The 7 most frequent diagnoses are printed on the CDS. Criteria for these diagnoses are given in Table 7. To encode any one of them, the rater chooses the appropriate single-digit number and enters it on Row 12.

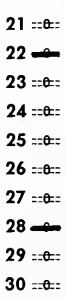
Example: The rater has decided that the diagnosis is Childhood Schizophrenia. She does NOT encode the DSM-II code-295.8; rather she encodes 1 in Row 12.

Items 12b- and 12c - Diagnoses other than the 7 listed in Item 12a are encoded here. Codes for these additional diagnoses (4 digits) should be obtained from Appendix 2. Some of the codes of the DSM-II have been modified so that all diagnoses may be entered with 4 digits. (The official DSM-II contains several 5 digit codes). Diagnoses associated with the presence of organic impairment, delirium or mental retardation (Items 9, 10, 11) should also be encoded here.

Item 13 - One or more of these Special Symptoms may be recorded as "Present" - regardless of the diagnosis - by encoding "0" in the appropriate row. The code "0" in Row 21 indicates that none of the 9 Special Symptoms are present.

Example: The child has both a speech disturbance and enuresis. Encode as follows:

A.	No symptoms	21
B.	Speech disturbance	22
C.	Specific learning disturbance . .	23
D.	Tic	24
E.	Other psychomotor disorder . .	25
F.	Disorder of sleep.	26
G.	Feeding disturbance.	27
H.	Enuresis	28
I.	Encopresis	29
J.	Cephalalgia	30



DOCUMENTATION

a. Raw score printout
b. Frequency tables
c. Means and standard deviations
d. Variance analyses

TABLE 7

DIAGNOSTIC CRITERIA - FORMULATED BY THE PEDIATRIC PSYCHOPHARMACOLOGY WORKSHOP

SCHIZOPHRENIA, CHILDHOOD TYPE

A. Necessary and Sufficient Symptoms

Autism - Gross impairment of relationships with people and the environment, consisting of:

1. Avoidance of, or bizarre, human interaction
2. Behavior reflects lack of comprehension of social or external situations, the ordinary meaning of words or even the uses of ordinary objects,

and/or Thought Disorder

Austic vocabulary, neologisms, stereotyped echolalia, incoherence, and/or disconnected, confused, irrelevant or tangential content, and/or permeated by bizarre fantasies which are ego-synotic, and/or lack of clear recognition of the unreality of bizarre or morbid preoccupations (such as introjected bodies, hallucinations, somatic delusions, persecutory delusions, delusions of special reference or purpose.

B. Symptoms Commonly Associated, but not sufficient for Diagnosis

1. Extreme preoccupation with internal stimuli.
2. Responses appear to be dictated by inner impulses and experiences, and appear inappropriate to external stimuli.
3. Treats other persons as interchangeable.
4. Rejects approaches or minimal initiative by other persons; remains isolated in group setting.
5. Excessively diminished responses to sensory stimuli or excessive responses to minor irrelevant stimuli.
6. Affect severely underresponsive, out of harmony with thought content, play or external context; exhibits inappropriate, acute and unmodulated shifts to undifferentiated excited, panicky or angry states, precipated by minimal change in the environment or arising without any apparent external stimulus.
7. Mutisim
8. Play is marked by one or more such features: stereotyped behavior; repetitive use of objects; fragmentary, disconnected and illogical sequences.
9. Motility usually dyskinetic; may show posturing, manneristic, choreo-athetotic or tic-like movements, catatonic rigidity, inert flaccid postures, or bursts of darting, tiptoeing and whirling hyperactivity.
10. Is seen as "different", "queer", "crazy" or "sick" by peers.
11. Scapegoated.

C. Disqualifiers

1. Organic psychosis
2. Delirious or toxic states (such as acute drug reaction)
3. Questionable or "borderline" psychotic features.

OVERANXIOUS REACTION

A. Necessary and Sufficient Symptoms

Generally well patterned, well organized behavior marked by expressed preoccupation with one or more of the following feelings of subjective distress: anxiety, "nervousness", worries, unrealistic fears, tension.

B. Symptoms Commonly Associated, but not Sufficient for Diagnosis

1. Overconcern with performance.
2. Compliant; attempt to conform to external demands or situations (including exam); dutiful, suggestible.
3. Seeks approval, protection and help from adults (including examiner) and usually elicits sympathetic responses as "nice child".
4. Expresses feelings of unmet/unsatisfied needs for approval, being cared for, helped, (which he/she may or may not see as unrealistic).
5. Expresses preoccupation with guilt for his/her own real or unreal demands on others, failures, misbehavior, imperfections.
6. Grossly self-conscious, lacking in self confidence, easily flustered, inhibited.
7. Usually apprehensive in new situations; readily moved to tears, upset or worried by inconsequential or imagined failure, rejection, disappointment or loss of support by others.

C. Disqualifiers

1. Psychosis - If shows generally well organized behavior and above preoccupation with anxiety, but language is so permeated by thought disorder, as defined under schizophrenia, as to necessitate a diagnosis of psychosis, then classify as Childhood Schizophrenia.

2. Denial of anxiety - Do not diagnose as overanxious, if anxiety is not openly expressed as a preoccupation by child on examination; e.g., if anxiety is only inferred from physiological signs (tremors, muscle tension, fidgeting, restlessness; sweating, vasomotor instability, irregular respiration); or if anxiety is only inferred from history of behavior which is interpreted as fearful by others (such as insomnia, feeding disorders, poor attention and perseverance in school or other activities); or if anxiety and fearfulness are diffuse and not fully articulated; or if unrealistic fears, anxiety or tension do not dominate the picture (upon exam or history) but are present only briefly.

UNSOCIALIZED AGGRESSIVE REACTION

A. Necessary and Sufficient Symptoms

Generally well patterned, organized behavior marked by: overt hostile disobedience, quarrelsomeness, physical and/or verbal aggressiveness, vengefulness and destructiveness in a variety of interpersonal contexts.

B. Symptoms Commonly Associated, but not Sufficient for Diagnosis

1. Tantrums, solitary stealing, lying and hostile teasing of other children. Usually has no consistent parental acceptance or discipline. Frequently rationalizes and construes feelings and actions in terms of external provocation. Denies anxiety and personal responsibility for feelings and acts.
2. Attempts to manipulate and control surroundings.
3. Expresses resentment at being controlled or placed in an inferior position, or being exposed as inadequate or helpless.
4. Overtly negative, defiant, hostile, suspicious, even belligerent with outbursts of anger and shouting.
5. Manipulative, obliquely negative and saucy; opportunistically placating and ingratiating when faced with superior strength or authority; bland, controlled affective facade, with bravado and even euphoria if feels in control of situation, becoming guarded, calculated, evasive, suspicious only if pressed in areas of personal concern.
6. Speech is guarded and calculated; capable of elaboration but content limited, noncommital and evasive about areas of personal concern.
7. Preoccupied with feeling restricted and threatened by the control of others and with the need to assert his/her own autonomy.
8. Denies feelings of needing support or approval from others.
9. Denies personal responsibility for feelings and difficulties.
10. Domineering or exploitative with peers; aggressive if challenged; respected, feared or resented by peers as "tough" leader, "bossy" or "bully".
11. Resentment at being controlled or placed in inferior position may lead to problems with authority figures and to antisocial behavior.
12. Despite superficially confident facade, may refuse to engage in any activity where unable to function adequately or compete successfully, including learning situations or peer group activity.

TABLE 7 (Continued)

C. Disqualifiers

1. Psychosis - If shows generally well organized behavior with denial of personal responsibility for feelings and acts with negativism, hostility, suspiciousness and projection, as described above, but language is so permeated by thought disorder, as defined under childhood schizophrenia, as to necessitate a diagnosis of psychosis, then classify as childhood schizophrenia.
2. Expressed preoccupation with anxiety and sadness which is pervasive, NOT transient.

HYPERACTIVE REACTION

A. Necessary and Sufficient Symptoms

Hyperactivity - with a high and conspicuous level of gross motor activity (locomotion; or "rump" hyperactivity when seated, i.e., squirming, changing position and getting up and down frequently; but not finger-hand twisting, picking or other small muscle activity) occurring across environments in situations in which sedentary or quiet behavior is appropriate for age;

and Disorder of attention - with higher distractability and shorter attention span than appropriate for chronological age (not mental age), especially in school or group situations.

B. Symptoms Commonly Associated but not Sufficient for Diagnosis

1. Poorly integrated and labile behavior, which gives the impression of immaturity and of uneven but generally inadequate abilities.
2. Extremely variable relation to adults (including examiner), with rapid fluctuation from attempts at compliance to silly clowning, boisterous; mischievous or impertinent behavior, clinging and demanding behavior and/or angry or sullen negativism.
3. Labile affect. Reacts with excessive irritability to any situation interpreted as rejecting, demanding or restricting, with angry, suspicious, anxious, unhappy and silly clowning responses, often associated with gross motor discharge, tantrums, destructive or aggressive behavior.
4. Speech is often sparse and unelaborated with a tendency to evade emotionally charged material.
5. Fantasy is usually expressed more clearly in play; concerned with movement and aggression, diffuse fears of retaliation and loss of love.
6. Motility usually variable, impulsive and poorly coordinated. Movements are relatively undifferentiated for age; has difficulty suppressing gross body movement when attempting isolated, finely coordinated finger-hand or arm movements. Body manipulation relatively uninhibited for age, chewing, sucking, nose picking, masturbation.

7. Unable to conform to demands of a group situation with peers; often becomes scapegoat and/or participates peripherally by provocative, wily, teasing, aggressive, quarrelsome behavior; usually considered "baby" and "pest" by peers.
8. Adults usually consider him/her immature, demanding, difficult to manage. Has chronic and recurring difficulties in adapting to age-appropriate social and educational demands.

C. Disqualifiers

1. Psychosis - If so permeated by autistic preoccupations or thought disorder, as defined under schizophrenia, as to necessitate a diagnosis of psychosis, then classify as Childhood Schizophrenia.
2. Expressed preoccupation with anxiety and sadness which is pervasive, NOT transient.
3. Unsocialized Aggressive Reaction with organized behavior pattern.

WITHDRAWAL REACTION

A. Necessary and Sufficient Symptoms

1. Generally well patterned; well organized behavior marked by shyness, seclusiveness, withdrawal, detachment, and general inability to form close interpersonal relationships.
2. Solitary "loner" or participant in group activities without zest, reticent, aloof in a variety of settings.

B. Symptoms Commonly Associated, but not Sufficient for Diagnosis

1. Compliant; attempt to conform to external demands or situations (including exam); dutiful, suggestible.
2. Expresses preoccupation with guilt for his/her own real or unreal demands on others, failures, misbehavior, imperfections.
3. Grossly self-conscious, lacking in self-confidence, easily flustered.
4. Apprehensive in new situations; may be moved to tears, upset or worried by inconsequential or imagined failure, rejection, disappointment or loss of support by others.

C. Disqualifiers

1. Psychosis - If shows generally well-organized behavior with above withdrawal but language is so permeated by thought disorder, as defined under schizophrenia so as to necessitate a diagnosis of psychosis, then classify as Childhood Schizophrenia.
2. Hostile - negative interaction with examiner.
3. Overtly expressed anxiety, worries and unrealistic fears.
4. Hyperactive Reaction.
5. Unsocialized Aggressive Reaction.

031 CDC CHILDRENS DIAGNOSTIC CLASSIFICATION

CHILDREN'S DIAGNOSTIC CLASSIFICATION

INSTRUCTIONS: *ONE RESPONSE and only ONE is permitted. Mark that response on ROW 31 in the column specified. Mark on General Scoring Sheet numbered 03.*

Rate current status only. Follow the items until you reach the most appropriate classification for the child. Mark that response and *STOP.*
Complete at pretreatment only.

MARK ON ROW 31 ONLY

Proceed through sequence of YES–NO choice points and choose ONE. Mark that response in specified RESPONSE POSITION.

31 ::0:: ::1:: ::2:: ::3:: ::4:: ::5:: ::6:: ::7:: ::8::

1. Is significant psychopathology present?

YES – Go to 2
NO – Diagnose as **NORMAL** . . . . . Mark and STOP **0**

2. Is delirium present?

YES – Diagnose as **ACUTE BRAIN SYNDROME** . . . . Mark and STOP **1**
NO – Go to 3

3. Is autism and/or thought disorder present?

YES – Diagnose as **SCHIZOPHRENIA CHILDHOOD TYPE** . Mark and STOP **2**
NO – Go to 4

4. Is subjective distress (anxiety, worries, etc.) expressed?

YES – Diagnose as **OVERANXIOUS REACTION** . . . . Mark and STOP **3**
NO – Go to 5

5. Is there deliberate antisocial behavior and/or hostile conflict with environment (not simply explosive reaction to frustration)?

YES – Diagnose as **UNSOCIALIZED AGGRESSIVE REACTION** . . . . Mark and STOP **4**
NO – Go to 6

6. Is antisocial behavior predominantly in peer group (gang) situation?

YES – Diagnose as **DYSSOCIAL REACTION** . . . . . Mark and STOP **5**
NO – Go to 7

7. Is hyperactivity/attention disorder present?

YES – Diagnose as **HYPERACTIVE REACTION** . . . . Mark and STOP **6**
NO – Go to 8

8. Is shyness-withdrawal the *predominant* behavior pattern?

YES – Diagnose as **WITHDRAWING REACTION** . . . . Mark **7**
NO – Diagnose as **UNDIAGNOSED** . . . . . Mark **8**

The Children's Diagnostic Classification (CDC) is an alternative method of arriving at a diagnosis. Developed by members of the Pediatric Psychopharmacology Workshop, the CDC differs from the Children's Diagnostic Scale in that it leads the rater through an ordered series of choice points until a diagnosis is made.

APPLICABILITY -	Children to 15.
UTILIZATION	Once at pretreatment. May be used at termination at the discretion of the investigator.
TIME SPAN RATED	Current status only
CARD FORMAT (19x, I1)	
CDC Item	Column 20

SPECIAL INSTRUCTIONS

Encoding the CDC is simple and direct. The rater proceeds through the sequence of YES-NO choice points until one of his choices results in the instruction to enter a number on the GSS. Having encoded this response on Row 31, the rater STOPS. No other method of rating is permitted. Detailed instructions for completing the CDC are given below.

DOCUMENTATION

The CDC item is displayed with the output of the Children's Diagnostic Scale (030-CDS).

a. Raw score
b. Frequency table

INSTRUCTIONS FOR THE CHILDREN'S DIAGNOSTIC CLASSIFICATION

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Like all diagnostic systems for children's psychiatric disorders, this one is a compromise and it has some unsatisfactory features. However, if it is to mean anything at all, it is important that the following rules be understood and adhered to strictly. It is also important to realize that the best prediction of drug action is likely to come from a multivariate analysis which includes measures additional to diagnosis such as neurological status, birth history, IQ and so on. Thus, any shortcomings of the present classification should be evaluated with the knowledge that such multivariate analyses will be done.

[1] Drs. B. Fish, R. Gittelman-Klein and D. Klein assisted in the development of this classification.

It will be seen that a section of the DSM II Diagnostic classification of the American Psychiatric Association (Behavior Disorders of Childhood and Adolescence (308) and Schizophrenia, childhood type (295.8)) form the basis of the terminology and symptomatological descriptions used since these appear to form the most parsimonious and the best cross-validated categories as judged by a wide variety of clinical and empirical-statistical studies. However, there are important differences from the DSM II classification, notably the exclusion of etiology, severity and mental deficiency as irrelevant to classification. The reason for so doing is that these three variables are included in other parts of the evaluative battery and it was felt, a) that they are more properly used in the context of a multivariate analysis, and b) that they are among the principal causes of obfuscation in present nosology. c) Their separation from clinical symptomatology is consistent with the proposed 9th revision of the International Classification of Diseases. It is important again to emphasize that the importance of these excluded variables is not denied in the present classification - it is simply felt that their contribution is better assessed by subsequent multivariate analyses on large numbers of subjects. The number of categories is few (7) but it was felt that this number could not only classify all children but would result in interjudge reliability of classification. Indeed it was also demonstrated in preliminary studies that assignment to these categories could be made reliably across investigators.

The diagnostic process has been specified and is designed on a systems analysis or pyramiding basis with each classification arranged in series and linked to the previous one by a binary (yes/No) decision. While this injects a certain artificiality it is designed to force a diagnostic decision and ensure comparability across investigators.

Rules of Procedure

1. Observe the stated data base from which to make the diagnosis. The format of the clinical examination should follow that of Rutter and Graham, the instructions for which are attached. Information not easily elicited in the examination and necessary for certain categories should be taken from the standard teacher and/or parent rating forms rather than based on each examiner's own rendering of these areas. This will ensure the use of a standard data base.

2. The diagnostic system must be purely symptomatological. Parent and teacher reports must be used only to establish the presence or absence of behavioral symptoms, their severity and their persistence across different environments (notably the school and peer group). The diagnostician must answer only two questions in classifying a child: 1) Is there clear evidence of abnormality? If so, 2) What is the symptomatological picture? Severity appears as a separate dimension and like CNS status is not denied to be important but is more properly entered separately.

The following are to be specifically excluded from use in making the diagnosis. a) Brain damage whether established by neurological tests, or inferred from pre or perinatal history and/or psychological tests. b) Severity (except to make the distinction of normal v. abnormal) and prognosis embodied in such distinctions as transient situational disturbance, behavior disorder, personality disorder or neurosis. c) Intellectual level (IQ) or cognitive function and all psychological test data (learning disorder, perceptual handicap, etc.). Of course, IQ or more properly, mental age is necessary for an accurate evaluation of the abnormality of behavior (such as activity level) within a developmental context.

3. Symptoms must be seen by the examiner, explicitly reported by the patient or detailed on the rating scales. Minimal inference must be made - in particular all psychodynamic formulations are specifically excluded. Extreme caution must be exercised in formulating affective states and only clear verbalizations and/or clear physiological evidence of such states may be used to make such inferences as "anxiety" or "depression". It will be seen that with the exception of overanxious-withdrawing disorder, all diagnoses are made on the basis of a necessary externally observable or reportable symptom complex.

4. Symptomatology must be evaluated within a developmental and sociological context; in particular, the peer group norm with reference to antisocial behavior. Thus, an appropriate question to ask is, what is the average child of his age in his neighborhood like? This will prevent classifying the average slum child as unsocialized aggressive.

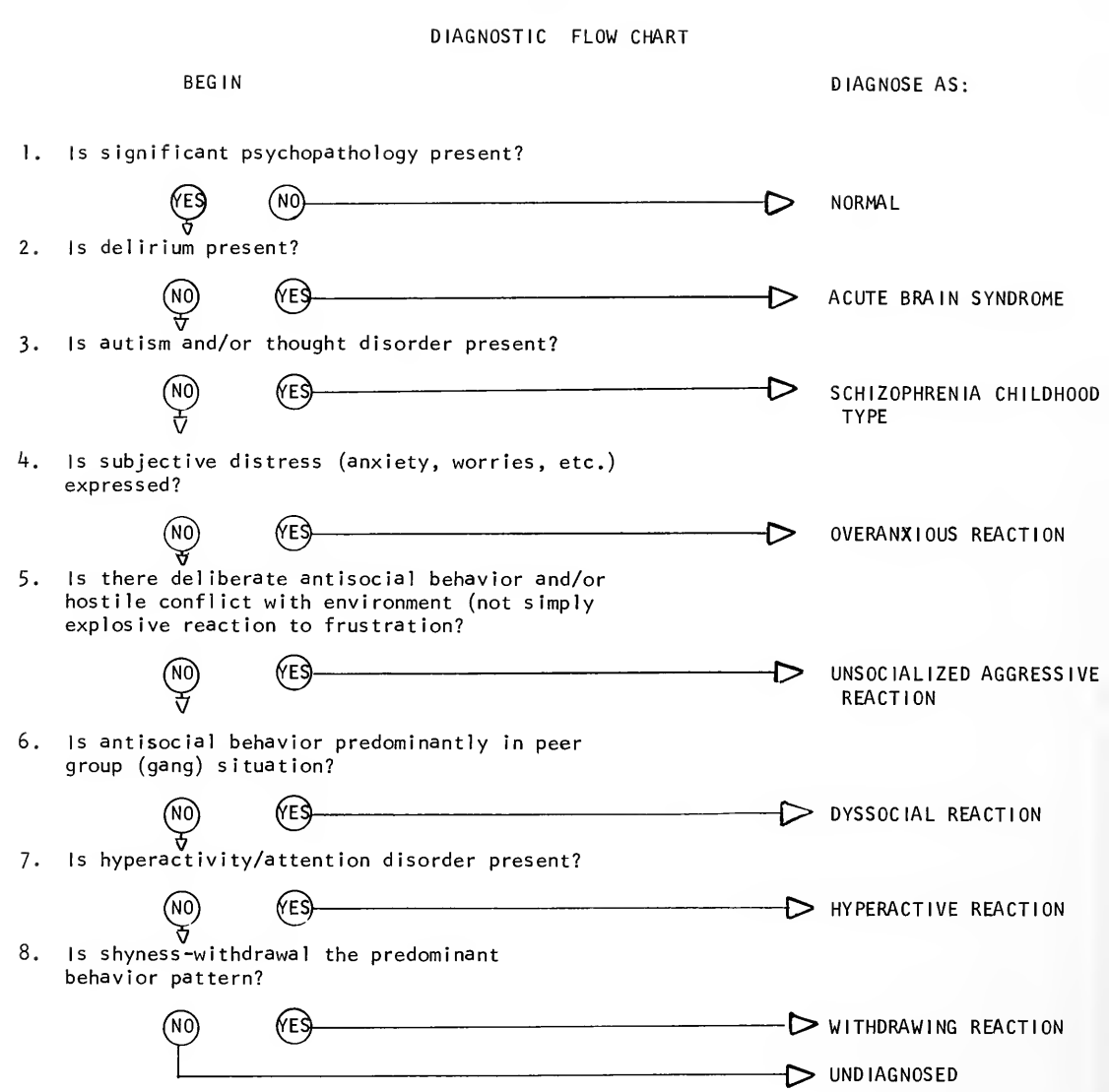
5. The diagnostic "flow sheet" (Figure 15) must be used with each case to ensure some minimal standardization across investigators. The diagnostician's job is primarily to establish the presence or absence of symptoms. Once this has been done the diagnostic flow sheet will make the diagnosis automatically.

6. Interjudge reliability of diagnosticians should be established by proper independent evaluations. Diagnosticians need not be psychiatrists, particularly when checking interjudge reliability. The categories are clear enough to be made by anyone with some clinical experience who follows the instructions. While it obviously is preferable to have every child independently diagnosed by two judges, once the reliability of a diagnostician has been established he may proceed to make unilateral diagnoses. Periodic checks of reliability should, however, be made (say every 20th case).

7. Use the Diagnostic Criteria of the Children's Diagnostic Scale (Table 7) for the interpretation of each diagnostic term.

FIGURE 15

DIAGNOSTIC FLOW CHART



DIAGNOSIS FOR PSYCHOPHARMACOLOGICAL STUDIES IN CHILDREN

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(Adapted from article appearing in Psychopharmacology Bulletin, Special Issue - Pharmacotherapy of Children, 89 - 96, 1973)

In 1969 the Psychopharmacology Research Branch of the National Institute of Mental Health brought together a group of clinicians and investigators interested in children to develop a battery of measures for pediatric psychopharmacological studies similar to those in the adult ECDEU test battery. The author was a member of a subcommittee on psychiatric examination and diagnosis. This paper describes the results of this subcommittee's deliberations but also provides some of the background concepts and literature on diagnosis in child psychiatry as well as some pilot work on the measures proposed.

Purposes of Diagnosis

We may arbitrarily draw a distinction between assessment and diagnosis: The former is concerned principally with the idiographic or unique features of the child; while the latter is an attempt to describe how this child resembles every other child with a similar condition - in short, it is a nomothetic concept. Diagnosis is a process in which a child is assigned to a nosological category in order to summarize statements about etiology, symptomatology, treatment, prognosis, and prevention. Unfortunately, because of the present state of knowledge in child psychiatry, this is likely to be less useful in dealing with the child as a patient than would be a detailed dissection of his inner and sociofamilial world.

However, as Dr. Fish (5) has argued, it is essential in psychopharmacological studies as opposed to patient needs that the type of child who is studied is clearly delineated so that others may interpret, replicate, and/or apply the findings In addition, there is also reason to believe from the history of medicine that improbable as it may seem at the moment, diagnosis may in the long run prove more heuristic than the idiographic approach (3).

It may also be noted that diagnosis alone cannot adequately describe the sample studied and that other identifying characteristics such as age, sex, socioeconomic, and ethnic status are also necessary.

Diagnosis takes two main forms, discontinuous and continuous. In the first, typical in medicine, the diagnostic condition (e.g., scarlet fever) is considered qualitatively distinct from health or some other disease. In the continuous concept, on the other hand, the condition is considered to be simply some arbitrary extreme point along a continuum, e.g., in obesity, two standard deviations from the age mean for triceps skin folds (9). There has been some debate in the mental health field whether the discontinuous or continuous position is more valid (17). As an example, some concepts of childhood psychosis, such as the Nine Points or Kanner's original description of autism, are discontinuous; while others, particularly psychoanalytic

[1] Drs. Barbara Fish, Rachel Gittelman-Klein and Donald Klein participated in the subcommittee, but the author is responsible for the opinions expressed herein.

views, reflect only a severe degree of psychopathology rather than anything qualitatively different from other conditions (19). The epidemiological approach (21), as typified in the works of Lapouse and Monk (8) and Rutter and Graham (14), which uses a statistical definition of abnormality but then treats the children so diagnosed as "sick", is nevertheless more discontinuous than continuous.

Allied but not identical to these two concepts of discontinuity and continuity of health and disease are those of nosological category and dimension. The first is a kind of "pigeon hole" into which a patient is fitted along with other children with similar disorders. The dimensional approach, on the other hand, assumes N dimensions of behavior or personality which like physical dimensions, such as height, weight, hemoglobin level, and skin hue, can be measured in any child. From this multidimensional space, diagnostic categories can be developed by defining upper limits of normality on any number (1 through N) of the dimensions; e.g., an albino could be described in terms of skin hue, while a dwarf could be described in terms of height and weight. These differences may appear pedantic but they tend to be associated with entirely different strategies in approaching a diagnosis.

The nosologist tends to employ the logical-intuitive or a priori technique - clinicians raise hypotheses which consider early infantile autism as a distinct disease entity and suggest symptoms which distinguish it. They then may or may not test the validity of their hypotheses. Depending on the prestige of the proponent and the degree of clinician concensus, these hypotheses are likely to become incorporated untested into the lore of the profession. The history of medicine and of psychiatry in particular shows that this technique may lead, as in nineteenth century European psychiatry, to a plethora of nonexistent syndromes. A modern day example is that of the symbiotic child (18) or the Gilles de la Tourette syndrome which is only a severe case of tics, as there is good reason to believe. However, in general, this strategy despite its haphazard nature has served medicine well, certainly in the pre-Vernard-Virchow era.

The second strategy is the empirical-statistical or, as some might less charitably call it, the serendipitous. Here the diagnostician makes few assumptions about classification. He concerns himself with only the data domain from which he believes classification will emerge. He then collects measurements on large numbers of children after which he tries, usually by means of multivariate statistical techniques, to group the children on a post hoc basis. The works of Jenkins, Lessing, Dreger, Patterson, and Quay (12) are examples of this approach. As might be expected, with the notable exception of Jenkins, the empirical-statistical technique is more favored by psychologists than by psychiatrists who tend to favour the a priori approach.

Diagnostic Examinations

Before a diagnostic category can be assigned, it is necessary to elicit the data (or signs and symptoms) by which diagnosis is made. The first concept germane to examination is the data domain of data base. This refers to the type and amount of information available to the "diagnoser" for processing into a diagnosis.

Data domains may be implicit or explicit. In psychiatry, a considerable number of invalid assumptions are made about the implicit data domain from which the diagnoser is operating. Thus, it is assumed that a competent child psychiatrist will cover all necessary points in the child's history and examination to arrive at a diagnosis. Though sporadic attempts have been made to systematize history and examination (15), they have never really become popular. In sharp contrast, psychologists have been almost obsessed with explicating the precise details of how to elicit information and then how to score it, e.g., in the standard intelligence tests. While this may inject some rigidity into the diagnostic examination, child psychiatrists could well take a lesson from their psychologist colleagues in the respect, since there is little doubt that the unreliability of current diagnostic systems in child psychiatry stems at least in part from the differing data domains of individual diagnosticians.

Diagnosis in child psychiatry is typically arrived at through a multifaceted data domain, including a history taken from the mother, buttressed by school psychometric reports, and confirmed by one or more psychiatric examinations of the child. Methods, except psychological tests, tend to be informal and verbal; but there is no good reason why they cannot be written, explicit (as in a questionnaire) and based on less inferential techniques of observation, such as time sampling of behavior (20) or measurement by electronic or other mechanical devices (16, 22). Obviously, the technique and the source of elicitation will affect the data domain sampled. It is also apparent that it will never be possible to sample the entire potential data domain but that accuracy will be improved by sampling across observers (or informants), environments, and techniques, i.e., in the case of psychopharmalogical studies, until the precise cellular or system locale of the drug action is known and can be measured. Even then its action is likely to be influenced by social and other variables.

In summary, in order to understand the accuracy of a diagnosis, we really need to know the scope and content of the techniques which elicit the information previous to the diagnosis.

Logical Processes in Formulating a Diagnosis

Once information has been elicited, it must be processed to form a diagnosis. The logical process can be judgmental or inexorable. Thus, once a psychologist has administered the test items in a WISC, the actual IQ score is inexorably fixed. On the other hand, a child psychiatrist in reviewing the data available to him from many sources and of many types will have to exercise a considerable degree of judgment in coming to a diagnosis. This is partly because different evidence is likely to be conflicting (e.g., mother and teacher ratings) but principally because the rules for assigning a child to one particular diagnostic category have never been spelled out in unambiguous fashion. Even the "Nine Points" for diagnosing childhood psychosis do not indicate which signs are necessary and how many are sufficient for a diagnosis. Thus as a starter, someone has to specify these rules, however arbitrary, so that assigning a diagnosis may become similar across different diagnosticians. Not only is it necessary to specify what a condition is in terms of necessary and

sufficient symptoms but also it must be indicated what it is not; in other words, disqualifiers must be determined. Thus, no two diagnostic categories should have the same set of necessary and sufficient signs or disqualifiers. There is only one way to decide whether a system is reliable. Construct a decision tree or flow chart, beloved of computer programmers, and then put the system to an empirical test with actual cases. No popular diagnostic system in child psychiatry presently meets these criteria. Even if one did, it is not always easy to get psychiatrists to abide by the logical rules as Overall and Hollister (10) have found. Their solution was to use the unquestioning and obsessively logical computer to make the diagnosis from the history and examination data.

Current Nosological Systems

One of the main obfuscating features of most current systems of nomenclature is that they are conceptually impure being based on a mixture of severity, etiology, intelligence, and behavioral symptomatology. This would be satisfactory if, as with Fish and Shapiro's (6) typology, it were a genuine multidimensional system where each cell or nomenclature is defined by its position along each dimension. Thus a true dimensional system would have the following possibilities: 1. Etiological - organic/nonorganic, 2. Intellectual - retarded/normal. 3. Severity - mild, moderate, and severe (replacing adjustment reaction, personality disorder, and psychosis). 4. Symptomatological - psychotic, antisocial, hyperkinetic, anxious, withdrawing, and mixed. Thus a child would then be scored on each of these dimensions. A child now described as psychotic, if one of Goldfarb's (7) organic group, could be described as organic, retarded, severe, psychotic, and not simply as of the schizophrenic-childhood type.

There are several popular systems available at the moment (12). The most widely used in North America is the APA's DSM II* which differs from the ICD 8** version only by the interpolation in the section on Children's Behavior Disorders (308.0) of a number of subcategories (such as, hyperkinetic reaction and withdrawing reaction) which are actually derived from Jenkins' empirical-statistical system (12). The GAP*** system is rather similar to the above except that in addition it categorizes by "developmental level." Other systems are (a) by Rutter (13) which is part traditional and part empirical-statistical and (b) a series of conceptually pure (i.e., behavioral only) empirical, statistical (mostly factor analytically derived), dimensional systems of which the best worked out is certainly the four dimensional one by Quay (12). Quay's dimensions are conduct problem, neurotic, immaturity-inadequacy, and socialized (gang) delinquency. Unlike most other systems, Quay's has a considerable amount of data on norms, reliability, predictive validity (e.g., outcome in delinquency), and discriminative power (normals vs. child guidance populations). A weakness of Quay's system is that his original samples included few psychotic children so that psychosis does not emerge. Dimensional systems like Quay's are theoretically dimensional but not categorical. Yet, in practice it is customary, as Quay does, to make categories by extreme scores, e.g., conduct-problem type (equals unsocialized aggressive reaction) for high scorers on that dimension,

*American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders-II
**World Health Organization's International Classification of Diseases-8
***Group for the Advancement of Psychiatry

low scorers on the other three dimensions.

We may note that the idea of an empirical-statistical classification as opposed to a logical intuitive one has won favor in the adult ECDEU battery in Overall's classification based on the Brief Psychiatric Rating Scale (BPRS) (11). What is remarkable about factor analytically derived systems is that many different investigators have derived virtually the same dimensions, certainly in so far as the more common ones are concerned (12), and it would, therefore, only be a matter of agreeing on the method of eliciting the information, the cutoff scores, and combinations of dimensional scores for diagnostic entities to have a good nosological system (in the scientific sense). The children's ECDEU battery will include, in sections other than the psychiatric examination, empirical statistical instruments and Conner's Teacher and Parent Rating Scales (1) which could be used nosologically. This would perhaps make the psychiatric examination and diagnosis unnecessary.

Characteristics of a Good System

When the committee came to consider its task, it had to define the characteristics of a good system. The following characteristics appear to have emerged not a priori but like termites out of the woodwork.

1. It should be acceptable to most investigators - simple, topical, comprehensible, accurate, and useful.

2. It should specify the data domain and the method of eliciting the data. This domain should be wide enough to cover all conditions, including uncommon ones like psychosis.

3. The decision flow from data to diagnosis should be explicated.

4. Diagnoses should be mutually exclusive. This does not preclude making a secondary diagnosis. It just means that one set of data should lead to a clear terminal diagnostic point distinct from all others.

5. Diagnosis should be reliable across investigators.

6. Diagnosis should be valid in predicting drug responders and meaningful in terms of current concepts and theory and in describing samples of children studied.

7. Diagnoses should be in a form suitable for statistical analysis, i.e., capable of being reduced to numbers or scales rather than a purely descriptive statement.

How far the committee achieved these goals is a matter for future verification.

The System of Examination

The system consists of three parts: 1) A system of psychiatric examination, 2) a rating scale to be completed by the psychiatrist, and 3) a diagnostic section.

1. Developed by Dr. Fish from Rutter and Graham's (15) method of examination, it describes the setting, conduct, and duration of the examination. While it is specified to a certain extent, it is only a semistructured examination and much is still assumed about the communality of operating assumptions, behavior, and the competence of child psychiatrists. This apparent weakness need not bother us at this time since reliability studies as well as other studies are planned. Furthermore, the complete children's ECDEU battery includes a number of other measures, such as Conner's Parent and Teacher Scales (1) against which it can be validated. Discrepancies will be difficult to interpret. Nevertheless, Conner's psychometrically developed instruments together with their proven usefulness in drug studies (4, 23) suggest that, opposed to the traditional position, the psychiatric rating must be regarded as "not proven" rather than as a standard. This is particularly the case since it is mainly based on a shorter sampling of the child's behavior and one taken in a most unusual situation for the child in a one-to-one interview. In the end, however, the acid test will come when its predictive ability to discriminate between drug responders and nonresponders is tested rather than its descriptive ability, important as the latter may be.

2. The Children's Psychiatric Rating Scale (CPRS) is a 63-item checklist to be completed by the psychiatrist from his own observations and the child's verbalizations to him. Each symptom is defined in a manual and rated on a 7-point scale of severity.

The reason for restricting it to interview material is so that it does not simply parrot mothers' or teachers' reports but offers something unique. There was a difference of opinion in the committee as to how valid the result is likely to be. The author was among those who felt that the yield from this restriction is not likely to be high, but in the end the proof of the pudding is in the eating and the usefulness of the checklist can be tested empirically by consumer reaction, data reduction, test construction, and other statistical analyses once sufficient numbers of observations have been accumulated in the ECDEU data bank.

Some initial work carried out by the author in the child psychiatry clinic of the Auckland Hospital shows that a number of the items are nonoccurring, and only 20 percent occurred with a frequency of 10 percent in the sample studied (N = 22). The reason may have been (as might be expected from Dr. Fish's participation) that the scale is overloaded with items reflecting severe psychopathology of the type found in psychosis. Also, items in which the child reports his own psychopathology were very infrequent, but this could reflect either the deficiencies of the Auckland examiners or the sample of children seen there (a preponderance of unsocialized, aggressive,and hyperkinetic reactions). If it should prove that many items are infrequent, a decision would have to be made as to their value in the occasional case - decide whether the instrument should remain wideranged or narrowed to a shortened version as Conner has done with his Parent and Teacher Scales. A more satisfactory alternative in the author's opinion would be to use a "gating" system whereby one key question, if positive, leads into a subset of related items (e.g., around psychotic behavior).

3. The diagnostic section consists of two scales - Children's Diagnostic Scale and Children's Diagnostic Classification. As might be expected the committee spent most of its time discussing this most contentious area. It was agreed that given the chaotic state of diagnosis in child psychiatry, some arbitrary decisions would have

to be made simply to achieve some standardization. Knowledge cannot progress until a common set of definitions and domains of study can be agreed upon. This does not mean that the definitions or their underlying assumptions are valid but that there can be no testing of their validity until this process has occurred. The system below is offered then - not as a definitive system - but as a starting point to be refined, extended, or even rejected - not a priori by armchair philosophers - but by systematic empirical study of its worth. Unlike the CPRS, this section is scored using information from all sources and informants. It is subdivided into four parts: (See Children's Diagnostic Scale)

a. Symptomatic Dimension Ratings (Items 1 - 8) - This section is a symptomatological or personality profile which is developed, as are all other parts of this section, on the basis of all information available (except factor scores on Conner's Parent and Teacher Scales). This is partly to see if psychiatrists can validate the basic personality dimensions revealed by empirical statistical studies (12) as Overall (11) has done with adult scales. It was mainly done though to provide a brief, readily comprehensible picture of the child's symptomatology or personality profile. The latter cannot be done either by the APA diagnosis, ignoring as it does all except the most prominent symptoms, nor by the 63-item Symptom Checklist which is too cumbersome for summary statements. It is important to realize that these are dimensions and not mutually exclusive diagnostic categories, and thus a child must be rated on all dimensions on a scale of severity from 1 (not present) through 7 (disabling). A preliminary test of the interexaminer reliability of both (23) showed that a satisfactory degree of reliability can be attained in both dimensional ratings and APA diagnoses.

b. Neurological and Intellectual Status (Items 9 - 11) - As discussed earlier, the mixed etiological, intellectual status, severity, and symptomatological nature of most diagnostic systems, such as the DSM II, presents insuperable difficulties. For this reason, the committee decided to separate out these areas, and all are scored separately except that severity is assumed to apply to behavioral psychopathology and scored there. There is provision elsewhere for inclusion of the actual IQ or estimate of severity of retardation. Only major neurological signs (not history, psychological tests, soft signs, etc.) permit a positive score for organic. This hard line position was decided upon in view of the elasticity with which the term organic is often used, making it virtually worthless.

c. Modified APA Diagnosis (Item 12) - It was decided that the Behavior Disorder section in the DSM II was the most suitable because it is purely symptomatological, is derived from empirical-statistical studies, and has been repeatedly validated in factor analytic (12) and clinical studies (6). It was of course necessary to add schizophrenia, childhood type to cover psychosis even though it has not emerged as a symptom complex, no doubt because of its infrequency in the patient samples of Jenkins, Peterson, Conners, and others. Some of Jenkins' categories which appear in this section of the DSM II were, however, rejected on the grounds that they have not appeared in other than his studies (e.g., runaway reaction). Also included are normal and undiagnosable categories, the latter largely as a test of consumer acceptance.

d. Special Symptoms (Item 13) - Provision is made for outstanding special symptoms, such as enuresis or learning disability, but these do not preclude making a modified APA diagnosis. Thus one could check enuresis and mark "normal" overanxious reaction or something else. Attention is drawn to the exclusion of juvenile delinquency of the gang-type which is considered to reflect social not individual pathology (12). Only the true psychopath (i.e., unsocialized aggressive reaction) of the gang would be included and not because of his belonging to a gang or because of severe antisocial behavior in accord with the gang's rules; but because of such behavior as cheating on friends, general impulsivity (most gangs require high degrees of discipline), exploitative relationships, and ultimately nearly always rejection by the peer group.

Conclusions

The above system is offered as a start to some degree of conformity in the areas of psychiatric examination and diagnosis for pediatric psychopharmacological studies. It is unlikely that it will become the definitive system, but it is hoped that changes will be based primarily on an empirical test of the reliability, validity, and predictive ability as far as the effects of medication are concerned. Only field testing of the instrument by many investigators making the results available to NIMH's ECDEU will provide the necessary data for this empirical analysis. Reliability studies require two independent examiners and thus more effort by the investigators, but hopefully this will be done, too, and the children's ECDEU battery will be off to a worthy start unusual for child psychiatry.

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047 BPRS
BRIEF
PSYCHIATRIC
RATING SCALE

MH-9—47
6-73

BRIEF PSYCHIATRIC RATING SCALE (Overall and Gorham)

BPRS

INSTRUCTIONS: *Insert General Scoring Sheet and Code 01 Under Sheet Number.*

This form consists of 18 symptom constructs, each to be rated on a 7—point scale of severity ranging from "not present" to "extremely severe". If a specific symptom is not rated, mark "0" = Not Assessed.

Mark the column headed by the term which best describes the patient's present condition.

USE A NO. 2 LEAD PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE.

Mark on right half of scoring sheet on row specified			ROW NO.
1.	SOMATIC CONCERN	Degree of concern over present bodily health. Rate the degree to which physical health is perceived as a problem by the patient, whether complaints have a realistic basis or not.	1
2.	ANXIETY	Worry, fear, or over-concern for present or future. Rate solely on the basis of verbal report of patient's own subjective experiences. Do not infer anxiety from physical signs or from neurotic defense mechanisms.	2
3.	EMOTIONAL WITHDRAWAL	Deficiency in relating to the interviewer and to the interview-er situation. Rate only the degree to which the patient gives the impression of failing to be in emotional contact with other people in the interview situation.	3
4.	CONCEPTUAL DISORGANI-ZATION	Degree to which the thought processes are confused, dis-connected or disorganized. Rate on the basis of integration of the verbal products of the patient; do not rate on the basis of patient's subjective impression of his own level of functioning.	4
5.	GUILT FEELINGS	Over-concern or remorse for past behavior. Rate on the basis of the patient's subjective experiences of guilt as evidenced by verbal report with appropriate affect; do not infer guilt feelings from depression, anxiety or neurotic defenses.	5
6.	TENSION	Physical and motor manifestations of tension,"nervousness," and heightened activation level. Tension should be rated solely on the basis of physical signs and motor behavior and not on the basis of subjective experiences of tension reported by the patient.	6
7.	MANNERISMS AND POSTURING	Unusual and unnatural motor behavior, the type of motor behavior which causes certain mental patients to stand out in a crowd of normal people. Rate only abnormality of movements; do not rate simple heightened motor activity here.	7
8.	GRANDIOSITY	Exaggerated self-opinion, conviction of unusual ability or powers. Rate only on the basis of patient's statements about himself or self-in-relation-to-others, not on the basis of his demeanor in the interview situation.	8
9.	DEPRESSIVE MOOD	Despondency in mood, sadness. Rate only degree of despondency; do not rate on the basis of inferences con-cerning depression based upon general retardation and somatic complaints.	9
10.	HOSTILITY	Animosity, contempt, belligerence, disdain for other people outside the interview situation. Rate solely on the basis of the verbal report of feelings and actions of the patient toward others; do not infer hostility from neurotic defenses, anxiety nor somatic complaints. *(Rate attitude toward interviewer under "uncooperativeness".)*	10
11.	SUSPICIOUS-NESS	Belief *(delusional or otherwise)* that others have now, or have had in the past, malicious or discriminatory intent toward the patient. On the basis of verbal report, rate only those suspicions which are currently held whether they concern past or present circumstances.	11

NOT ASSESSED	NOT PRESENT	VERY MILD	MILD	MODERATE	MODERATELY SEVERE	SEVERE	EXTREMELY SEVERE
0	1	2	3	4	5	6	7

Continue marking on right half of scoring sheet on row specified			ROW NO.
12.	HALLUCINA-TORY BEHAVIOR	Perceptions without normal external stimulus corre-spondence. Rate only those experiences which are reported to have occurred within the last week and which are described as distinctly different from the thought and imagery processes of normal people.	12
13.	MOTOR RETARDA-TION	Reduction in energy level evidenced in slowed movements. Rate on the basis of observed behavior of the patient only; do not rate on basis of patient's subjective impression of own energy level	13
14.	UNCO-OPERATIVE-NESS	Evidence of resistance, unfriendliness, resentment, and lack of readiness to cooperate with the interviewer. Rate only on the basis of the patient's attitude and responses to the interviewer and the interview situation; do not rate on basis of reported resentment or uncooperativeness outside the interview situation.	14
15.	UNUSUAL THOUGHT CONTENT	Unusual, odd, strange, or bizarre thought content. Rate here the degree of unusualness, not the degree of disorgan-ization of thought processes.	15
16.	BLUNTED AFFECT	Reduced emotional tone, apparent lack of normal feeling or involvement.	16
17.	EXCITEMENT	Heightened emotional tone, agitation, increased reactivity.	17
18.	DISORIENT-ATION	Confusion or lack of proper association for person, place or time.	18

Developed by Overall and Gorham, the Brief Psychiatric Rating Scale (BPRS) is formatted for use with the General Scoring Sheet and consists of the 18-item version of the scale. Developed from the longer Lorr Multidimensional Scale for Rating Psychiatric Patients (MSRPP) and Lorr Inpatient Multidimensional Psychiatric Scale (IMPS), the BPRS provides a rapid and efficient evaluation of treatment response in both clinical drug trials and routine clinical settings. Its focus is primarily inpatient psychopathology. It has been employed in outpatient settings to assess levels of anxiety and depression and to distinguish neurotic from more severely disturbed patients; but the authors caution that the BPRS was not designed to represent the fine distinctions between types of neurotic patients.

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APPLICABILITY — Primarily for adult inpatient populations.

UTILIZATION — Once at pretreatment; at least one post-treatment assessment. The number and spacing of post-treatment assessments are at the discretion of the investigator.

TIME SPAN RATED — At a maximum, the interval since the last assessment. At pretreatment, a span of one week is suggested.

CARD FORMAT - ITEMS CARD 01 = 19x, 1811)

Item	Column	Item	Column
1. Somatic Concern	20	10. Hostility	29
2. Anxiety	21	11. Suspiciousness	30
3. Emotional Withdrawal	22	12. Hallucinatory Behavior	31
4. Conceptual Disorganization	23	13. Motor Retardation	32
5. Guilt Feelings	24	14. Uncooperativeness	33
6. Tension	25	15. Unusual Thought Content	34
7. Mannerisms	26	16. Blunted Affect	35
8. Grandiosity	27	17. Excitement	36
9. Depressive Mood	28	18. Disorientation	37

CARD FORMAT - FACTORS CARD 51 = (19x, 5F6.2, F4.0)

Code "5" in Column 18 indicates card containing factor, cluster or derived scores.

Factor	Columns
I	20-25
II	26-31
III	32-37
IV	38-43
V	44-49
Total Score	50-53

Factor score = $\frac{\text{Sum of composite items}}{\text{No. of composite items}}$ Factor score range = 1 - 7

Total score = Sum of all items Total score range = 18 - 126

FACTOR COMPOSITION This factor structure is based on a 1974 analysis of the pretreatment scores of 3596 subjects with diagnoses of schizophrenia. (Table 8).

I. Anxiety-Depression (ANDP)

1. Somatic Concern
2. Anxiety
5. Guilt Feelings
9. Depressive Mood

II. Anergia (ANER)

3. Emotional Withdrawal
13. Motor Retardation
16. Blunted Affect
18. Disorientation

III. Thought Disturbance (THOT)

4. Conceptual Disorganization
8. Grandiosity
12. Hallucinatory Behavior
15. Unusual Thought Content

IV. Activitation (ACTV)

6. Tension
7. Mannerisms & Posturing
17. Excitement

V. Hostile-Suspiciousness (HOST)

10. Hostility
11. Suspiciousness
14. Uncooperativeness

TABLE 8

5-FACTOR VARIMAX SOLUTION OF 18-ITEM BRIEF PSYCHIATRIC RATING SCALE

Guy, W., Cleary, P. and Bonato, R. R., Methodological Implications of a Large Central Data System, published in Proceedings of IXth Congress, CINP, Excerpta Medica, Amsterdam, 1975.

ITEM	I	II	III	IV	V	Communalities
Somatic Concern	-627	066	-164	030	014	425
Anxiety	-746	115	-073	293	127	677
Emotional Withdrawal	156	-808	-139	157	073	726
Conceptual Disorganization	019	-344	-640	280	052	610
Guilt Feelings	-694	014	-055	013	074	491
Tensions	-381	-040	-064	732	161	712
Mannerisms	023	-463	-216	568	-082	591
Grandiosity	004	208	-536	-027	441	526
Depressive Mood	-784	-116	099	-008	124	653
Hostility	-208	036	-156	195	778	712
Suspiciousness	-346	078	-376	-020	650	689
Hallucinatory Behavior	-081	-147	-711	156	003	558
Motor Retardation	-337	-635	125	-198	039	573
Uncooperativeness	078	-451	044	301	641	713
Unusual Thought Content	159	-027	-797	049	286	745
Blunted Affect	015	-793	-094	-077	-032	645
Excitement	-030	172	-210	744	319	729
Disorientation	227	-475	-330	300	-208	519
Contribution of factor (V_p)	2.58	2.48	2.30	1.89	1.94	11.29
% Total Variance	14.3	13.8	12.8	10.5	10.8	62.7
% Common Variance	22.8	21.1	20.3	16.7	17.1	

SPECIAL INSTRUCTIONS

Brief instructions for rating each item are printed on the scale itself. To increase the degree of communality in interpretation, the items are defined below in greater detail by Overall and Gorham, and the rater is urged to confine his responses within these contexts.

A. Ratings Based Upon Observation of Patient

3. Emotional Withdrawal - This construct is defined solely in terms of the ability of the patient to relate in the interpersonal interview situation. Thus, an attempt is made to distinguish between motor aspects of general retardation, which are rated as "motor retardation" and the more mental-emotional aspects of withdrawal, even though ratings in the two areas may be expected to covary to some extent. In the factor analyses of change in psychiatric ratings, a "general retardation" factor has emerged in several different analyses, and this general retardation factor has included both emotional and motor retardation items. It is difficult to identify the basis for rating of "ability to relate"; however, initial work has indicated that raters achieve reasonably high agreement in rating this quality. Emotional withdrawal is represented by the feeling on the part of the rater that an invisible barrier exists between the patient and other persons in the interview situation. It is suspected that eyes, facial expression, voice quality and variability, and expressive movements all enter into the evaluation of this important, but nebulous, quality of the patients.

6. Tension - It should be noted that the construct "tension" is restricted in the Brief Scale to physical and motor signs commonly associated with anxiety. Tension does not involve the subjective experience or mental state of the patient. Although research psychologists in an effort to attain a high degree of objectivity frequently define anxiety in terms of physical signs, in the Brief Scale observable physical signs of tension and subjective experiences of anxiety are rated separately. Although anxiety and tension tend to vary together, developmental research with an earlier form of the Brief Scale indicated that the degree of pathology in the two areas may be quite different in specific patients. A patient, especially when under the influence of a drug, may report extreme apprehension but give no external evidence of tension whatsoever, or vice versa. In rating the degree of tension, the rater should attend to the number and nature of signs of abnormally heightened activation level such as nervousness, fidgeting, tremors, twitches, sweating, frequent changing of posture, hypertonicity of movements, and heightened muscle tone.

7. Mannerisms and posturing - This symptom area includes the unusual and bizarre motor behavior by which a mentally ill person can often be identified in a crowd of normal persons. The severity of manneristic behavior depends both upon the nature and number of unusual motor responses. However, it is the "unusualness", and not simply the amount of movement, which is to be rated. Odd, indirect, repetitive movements, or movements lacking normal coordination and integration, are rated on this scale. Strained, distorted, abnormal postures which are maintained for extended periods are rated. Grimaces and unusual movements of lips, tongue, or eyes are considered here also. Tics and twitches which are rated as signs of tension are not rated as manneristic behavior.

13. Motor retardation - Motor retardation involves the general slowing down and weakening of voluntary motor responses. Symptomatology in this area is represented by behavior which might be attributed to the loss of energy and vigor necessary to perform voluntary acts in a normal manner. Voluntary acts which are especially affected by reduced energy level include those related to speech as well as gross muscular behavior. With increased "motor retardation" speech is slowed, weakened in volume, and reduced in amount. Voluntary movements are slowed, weakened, and less frequent.

14. Uncooperativeness - This is the term adopted to represent signs of hostility and resistance to the interviewer and interview situation. It should be noted that "uncooperativeness" is judged on the basis of response of the patient to the interview situation while "hostility" is rated on the basis of verbal reports of hostile feelings or behavior toward others outside the interview situation. It was found necessary to separate the two areas because of an occasional patient who refrained from any reference to hostile feelings and who even denies them, while evidencing strong hostility toward the interviewer.

B. Ratings Based Primarily Upon Verbal Report

1. Somatic concern - The severity of physical complaints should be rated solely on the number and nature of complaints of bodily illness or malfunction, or suspiciousness of same, alleged during the interview period. The evaluation is of the degree to which the patient perceives or suspects physical ailments to play an important part in his total lack of well-being. No consideration of the probability of true organic basis for the complaints is required. Only the frequency and severity of complaints are rated.

2. Anxiety - Anxiety is a term restricted to the subjective experience of worry, overconcern, apprehension or fear. Rating of degree of anxiety should be based upon verbal responses reporting such subjective experiences on the part of the patient. Care should be taken to exclude from consideration in rating anxiety the physical signs which are included in the concept of tension, as defined in the scale. The sincerity of the report and the strength of the experience as indicated by the involvement of the patient may be important in evaluating degree of anxiety.

4. Conceptual disorganization - Conceptual disorganization involves the disruption of normal thought processes and is evidenced in confusion, irrelevance, inconsistency, disconnectedness, disjointedness, blocking, confabulation, autism, and unusual chain of associating. Ratings should be based upon the patient's spontaneous verbal products, especially those longer, spontaneous response sequences which are likely to be elicited during the initial, non-directive portion of the interview. Attention to the facial expression of the patient during the verbal response may be helpful in evaluating the degree of confusion or blocking.

5. Guilt feelings - The strength of guilt feelings should be judged from the frequency and intensity of reported experiences of remorse for past behavior. The strength of the guilt feelings must be judged in part from the involvement evidenced by the patient in reporting such experiences. Care should be exercised not to infer guilt feelings from signs of depression or generalized anxiety. Guilt feelings relate to specific past behavior which the patient now believes to have been wrong and the memory of which is a source of conscious concern.

8. Grandiosity - Grandiosity involves the reported feeling of unusual ability, power, wealth, importance, or superiority. The degree of pathology should be rated relative to the discrepancy between self-appraisal and reality. The verbal report of the patient and not his demeanor in the interview situation should provide the basis for evaluation of grandiosity. Care should be taken not to infer grandiosity from suspicions of persecution or other unfounded beliefs where no explicit reference to personal superiority as the basis for persecution has been elicited. Ratings should be based upon opinions currently held by the patient, even though the unfounded superiority may be claimed to have existed in the past.

9. Depressive mood - Depressive mood includes only the affective component of depression. It should be rated on the basis of expressions of discouragement, pessimism, sadness, hopelessness, helplessness, and gloomy thema. Facial expression, weeping, moaning and other modes of communicating mood should be considered, but motor retardation, guilt, and somatic complaints, which are commonly associated with the psychiatric syndrome of depression, should not be considered in rating depressive mood.

10. Hostility - Hostility is a term reserved for reported feelings of animosity, belligerence, contempt, or hatred toward other people outside the interview situation. The rater may attend to the sincerity and affect present in reporting of such experiences when he attempts to evaluate the severity of pathology in the symptom area. It should be noted that evidences of hostility toward the interviewer in the interview situation should be rated on the "Uncooperativeness" item and should not be considered in rating hostility as defined here.

11. Suspiciousness - Suspiciousness is a term which is used to designate a wide range of mental experience in which the patient believes himself to have been wronged by another person or believes that another person has, or has had, intent to wrong. Since no information is usually available as a basis for evaluating the objectivity of the more plausible suspicions, the term "accusations" might be a more appropriate characterization of this area. The rating should reflect the degree to which the patient tends to project blame and to accuse other people or forces of malicious or discriminatory intent. The pathology in this symptom area may range from mild suspiciousness through delusions of persecution or ideas of reference.

12. Hallucinatory behavior - The evaluation of hallucinatory experiences frequently requires judgment on the part of the rater as to whether the reported experience represents hallucination or merely vivid mental imagery. In general, unless the rater is quite convinced that the experiences reported represent true deviations from normal thought and imagery processes, hallucinatory behavior should be rated as "not present".

15. Unusual thought content - This symptom area is concerned solely with the CONTENT of the patient's verbalization; the extent to which it is unusual, odd, strange, or bizarre. Notice that a delusional or paranoid patient may present bizarre or unbelievable ideas in a perfectly straightforward, clear, and organized fashion. Rate only unusualness of content for this item, not degree of organization or disorganization.

16. Blunted affect - This symptom area is recognized by reduced emotional tone and apparent lack of normal feeling or involvement. Emotional expressions are apt to

be absent or of marked indifference and apathy. Attempted expressions of feeling may appear to be mimetic and without sincerity.

DOCUMENTATION:

a. Raw score printout
b. Factor score printout
c. Means and standard deviations
d. Cross tabulations
e. Variance analyses

COMMENTS OF THE AUTHOR

THE BRIEF PSYCHIATRIC RATING SCALE IN PSYCHOPHARMACOLOGIC RESEARCH

John E. Overall, Ph.D.

The Brief Psychiatric Rating Scale (BPRS) was originally developed to provide an efficient and clinically valid means of assessing efficacy in psychopharmacologic research.[1] Later research demonstrated its utility for descriptive classification of psychiatric patients according to profile pattern.[2,3] The BPRS consists of 18 (originally 16) symptom constructs, each to be rated on a 7-point scale of severity. The ratings are coded 0-6* for the 7 categories of severity ranging from "not present" to "extremely severe".

In most clinical research applications, the BPRS is completed immediately prior to the start of drug treatment and again after a fixed period of time, usually 4 to 6 weeks. Ratings are based on information obtained in a clinical interview of about 20 minutes duration. It is recommended that each patient be interviewed and rated independently by two professional observers to enhance the reliability of ratings, although the advantage gained from duplicate independent ratings is not now considered to be as great as it once was. A minimum of 35 to 40 patients in each treatment group should be included in any study in which the BPRS is used with two independent raters, or approximately 45 to 50 patients per group if a single rater is used.[4] These estimates of sample size do not appear restricted to the BPRS and can be readily calculated for any particular research setting.[5]

The BPRS pre-treatment ratings can be used to describe the patient sample and to classify patients into phenomenological homogeneous sub-types. Profile classification has been found useful in reducing within-treatment variability and in the study of specific indications of psychotherapeutic drugs. Although earlier efforts at profile classification using the BPRS were attempts to provide more objective methods for assigning patients among standard diagnostic categories,[6,7,8] more recent efforts have centered about the use of cluster analysis and related empirical methods to identify the most frequently occurring and thus most representative profile patterns.[9,10] The results of these studies have produced a classification system consisting of six types described as anxious depression, hostile depression, withdrawn-retarded depression, paranoid hostile-suspiciousness syndrome, withdrawn-disorganized thinking disturbance and florid thinking disorder.[11] Most psychiatric patients can be recognized as having symptom patterns fitting closely one of these six types. The six BPRS prototype patterns, which depend upon only the original 16 items, are as follows.

ANXIOUS DEPRESSION

2.6	2.8	1.1	0.5	0.8	0.2	0.2	2.5	0.8	0.4	0.1	1.0	0.3	0.4	1.0	

HOSTILE DEPRESSION

0.6	2.7	1.1	1.1	2.0	1.8	0.3	0.3	2.5	2.9	2.2	0.2	0.5	1.0	0.7	0.7

* The ECDEU version of the BPRS is coded 1 - 7 rather than 0 - 6.

WITHDRAWN-RETARDED DEPRESSION

1.4	1.7	3.0	1.2	0.7	1.1	0.6	0.1	3.4	0.5	0.5	0.3	2.2	0.8	0.4	2.7

PARANOID HOSTILE-SUSPICIOUSNESS SYNDROME

1.4	1.5	1.0	1.4	0.4	1.4	0.4	1.0	0.5	3.4	2.6	0.1	0.4	1.6	1.2	0.7

WITHDRAWN-DISORGANIZED THINKING DISTURBANCE

0.7	0.8	3.1	3.4	0.1	1.1	1.3	0.2	0.5	0.4	1.0	1.5	1.8	1.2	2.2	3.6

FLORID THINKING DISORDER

0.7	1.3	2.4	3.9	0.2	2.0	1.5	1.4	0.8	1.4	3.0	3.5	0.7	1.6	4.2	2.6

Patients can be classified among the six phenomenological sub-groups by simply calculating the sum of squared differences between individual profile elements (scored 0-6 for single rater or average of two raters) and the corresponding prototype values, with the patient then being assigned to the group for which the simple d^2 is smallest.[12] For studies involving only pre-screened clinically depressed patients, only the first three profile patterns need be considered. Several more complex profile analysis methods have been programmed for computer to classify patients among the six types and can be obtained from J. E. Overall (University of Texas Medical Branch, Galveston). Dr. Overall also has the facilities to process profiles sent to him in punched cards and has agreed to do so for any ECDEU investigator.

Several composite scores derived from the BPRS are frequently used in evaluating treatment effects. Numerous factor analyses of BPRS ratings have consistently revealed the presence of four major higher order factors which have been described as thinking disturbance, withdrawal-retardation, hostile-suspiciousness and anxious depression.[13] Factor scores are obtained by summing ratings on the three BPRS items most highly related to each factor.

THINKING DISTURBANCE - Conceptual Disorganization, Hallucinatory Behavior and Unusual Thought Content.

WITHDRAWAL-RETARDATION - Emotional Withdrawal, Motor Retardation and Blunted Affect.

HOSTILE-SUSPICIOUSNESS - Hostility, Suspiciousness and Uncooperativeness.

ANXIOUS DEPRESSION - Anxiety, Guilt Feelings, and Depressive Mood.

In addition to the four higher order factor scores, a "total pathology" score is used to represent the total deviation from normality and to evaluate total change during treatment. The total pathology score is the sum of ratings on all 18 rating constructs, each scored on a 0-6 scale. Where patients have been grouped into distinctively different profile types, the total pathology score is recommended for evaluation of treatment outcome because specific symptom factors tend to be too highly related to profile group.

Considerable effort has gone into the identification of extrinsic factors which influence BPRS ratings. It is considered that these non-drug factors produce variability in symptom patterns and treatment responses which should be controlled experimentally or statistically in order to improve the precision of clinical psychopharmacologic research. Differences in initial symptom patterns are significantly related to age, race, sex, age of onset, previous course of illness, marital status, education, work achievement and a variety of other less important factors.[14, 15, 16] Differences in treatment outcome have been found to depend significantly on pretreatment level and type of symptomatology, age of onset, previous hospitalizations and/or course of illness, marital status, presence of identifiable precipitating stress and race.[17, 18] Where several different raters are involved in a project, systematic rater differences are often very important.

While work is continuing along these lines, it appears obvious that a variety of factors do influence BPRS evaluations of symptom pattern and treatment outcome, and the above appear to be among the potentially most important. It is recommended that these extrinsic factors be carefully recorded and that their effects then should be removed by using somewhat more complex statistical analyses than have been used in the past.[17] Experimental control can be achieved by holding certain of the extrinsic factors constant, such as age or sex, but this tends to restrict the generality of conclusions that can be drawn.

A completely adequate experimental design involving BPRS evaluations should take into account (a) pre-treatment profile type, (b) pre-treatment level of severity, (c) demographic and sociocultural background characteristics of the patient which may influence outcome independently of drugs, (d) experimentally introduced systematic effects such as hospital differences, rater differences and the like, and (e) drug treatments. Where patients are classified into distinct profile groups, the broad measure of change in total pathology is recommended for evaluation of outcome with differences in pre-treatment level of severity partialled out. In this brief summary, an attempt has been made to provide the investigator with essential information concerning sample size, scoring, patient classification and control variables that will enable him to use the BPRS in as effective a manner as current methodology permits.

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072 DSI
DEPRESSION
STATUS
INVENTORY

MH-9–72
6-73

DEPRESSION STATUS INVENTORY (DSI)

Wm. W.K. Zung

INSTRUCTIONS: *Code 01 under Sheet Number on General Scoring Sheet*

The data upon which the judgments are based come from the interview with the patient. The items in the scale are to be quantified by using all the information available to the rater. This includes both clinical observation and the material reported by the patient.

Use of the Interview Guide below assures coverage of all the areas on which judgments are required. However, the rater has the flexibility of modifying the questions or probing for details, which makes possible a smooth interview that does not sound like a question-answer examination. In rating the patient's current status, an arbitrary period of 1 week prior to the evalutaion is adopted in order to standardize the data. In order to reinforce this, the interviewer should occasionally precede questions with, "During the past week, have you. . . . .?"

Mark on right half of scoring sheet on row specified

SIGNS AND SYMPTOMS OF DEPRESSION	INTERVIEW GUIDE	ROW NO.
1. Depressed Mood	Do you ever feel sad or depressed?	19
2. Crying Spells	Do you have crying spells or feel like it?	20
3. Diurnal Variation: symptoms worse in a.m.	Is there any part of the day when you feel worse? Best?	21
4. Sleep Disturbance	Frequent and early AM wakings	22
5. Decreased Appetite	How is your appetite?	23
6. Weight Loss	Have you lost any weight?	24
7. Decreased Libido	Do you enjoy looking, talking or being with attractive men/women?	25
8. Constipation	Do you have trouble with constipation?	26
9. Tachycardia	Have you had times when your heart was beating faster than usual?	27
10. Fatigue	How easily do you get tired?	28
11. Psychomotor Agitation	Do you find yourself restless and can't sit still?	29
12. Psychomotor Retardation	Do you feel slowed down in doing the the things you usually do?	30
13. Confusion	Do you ever feel confused and have trouble thinking?	31
14. Emptiness	Do you feel life is empty for you?	32
15. Hopelessness	How hopeful do you feel about the future?	33
16. Indecisiveness	How are you at making decisions?	34
17. Irritability	How easily do you get irritated?	35
18. Dissatisfaction	Do you still enjoy the things you used to?	36
19. Personal Devaluation	Do you ever feel useless and not wanted?	37
20. Suicidal Ruminations	Have you had thoughts about doing away with yourself?	38

	NONE 1	MILD 2	MODERATE 3	SEVERE 4
19	=1=	=2=	=3=	=4=
20	=1=	=2=	=3=	=4=
21	=1=	=2=	=3=	=4=
22	=1=	=2=	=3=	=4=
23	=1=	=2=	=3=	=4=
24	=1=	=2=	=3=	=4=
25	=1=	=2=	=3=	=4=
26	=1=	=2=	=3=	=4=
27	=1=	=2=	=3=	=4=
28	=1=	=2=	=3=	=4=
29	=1=	=2=	=3=	=4=
30	=1=	=2=	=3=	=4=
31	=1=	=2=	=3=	=4=
32	=1=	=2=	=3=	=4=
33	=1=	=2=	=3=	=4=
34	=1=	=2=	=3=	=4=
35	=1=	=2=	=3=	=4=
36	=1=	=2=	=3=	=4=
37	=1=	=2=	=3=	=4=
38	=1=	=2=	=3=	=4=
Cols:	*12*	*13*	*14*	*15*

The Depression Status Inventory (DSI), developed by Zung, has been designed as the professionally-rated analogue of the patient-rated Zung Depression Scale (SDS). With appropriate contextual changes, it consists of the same 20 items as the SDS; and, based on 209 cases, the author reports a Pearson product moment correlation of .87 between the 2 scales. The DSI provides a global measure of the intensity of depressive symptomatology.

REFERENCE — Zung, W. W. K., The Depression Status Inventory: An Adjunct to the Self-Rating Depression Scale, J. Clin. Psychol., 28: 539-543, 1972.

APPLICABILITY — Adults with depressive symptoms

UTILIZATION — Once at pretreatment; at least one posttreatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED — Now or in the last week

CARD FORMAT - ITEMS CARD 01 = (19x, 2011, 10x, 14)

Item	Column	Item	Column
1	20	11	30
2	21	12	31
3	22	13	32
4	23	14	33
5	24	15	34
6	25	16	35
7	26	17	36
8	27	18	37
9	28	19	38
10	29	20	39
		Z Score*	50-53

*The Z score is derived by dividing the sum of the raw item scores by the maximum possible score (80) multiplied by 100. See Table 9 for the Conversion of Interviewer-Rated Raw Scores to the DSI Z Scores. Zung has provided the following mean DSI "Z" scores for various diagnostic groups:

Diagnosis	N	Mean DSI Z Scores
Depressive disorders	96	61**
Schizophrenia	25	48
Anxiety disorder	22	51
Personality disorders	54	52
Transient situational disturbances	12	44

** = Significantly different from other diagnostic groups ($p. < .01$).

TABLE 9 (from Zung)

THE CONVERSION OF INTERVIEWER-RATED RAW SCORES TO THE DSI Z SCORES

Raw Score	DSI Z Scores	Raw Score	DSI Z Scores	Raw Score	DSI Z Scores
20	25	40	50	60	75
21	26	41	51	61	76
22	28	42	53	62	78
23	29	43	54	63	79
24	30	44	55	64	80
25	31	45	56	65	81
26	33	46	58	66	83
27	34	47	59	67	84
28	35	48	60	68	85
29	36	49	61	69	86
30	38	50	63	70	88
31	39	51	64	71	89
32	40	52	65	72	90
33	41	53	66	73	91
34	43	54	68	74	92
35	44	55	69	75	94
36	45	56	70	76	95
37	46	57	71	77	96
38	48	58	73	78	98
39	49	59	74	79	99
				80	100

SPECIAL INSTRUCTIONS

The following rules and guidelines should be used in rating the patient's psychopathology:

A. Each item should be rated independently as a unit in order to eliminate the "halo" effect.

B. Each score should be the average of the full range of responses observed or elicited, and not necessarily the extreme in severity.

C. The items are judged on a 4-point system that takes into account Severity in terms of: intensity, duration and frequency. These are defined as follows:

1 = none or insignificant in intensity or duration, present none or a little of the time in frequency

2 = mild in intensity or duration, present some of the time

3 = of moderate severity, present a good part of the time

4 = severe in intensity or duration, present most or all of the time in frequency

To help establish severity, the following questions may be necessary: Intensity: "How bad was it?", Duration: "How long did it last?", and Frequency: "How much of the time did you feel that way?"

D. An item is scored positive and present when (a) behavior is observed, (b) behavior was described by a patient as having occurred, and (c) patient admits that symptom is still a problem.

E. An item is scored negative and not present when (a) symptom has not occurred and not a problem or present, (b) response is ambiguous even after suitable probing, or (c) patient gives no information relevant to an item.

ERRATA

Rating of the items - The "Not Assessed" (0) position printed in the packet should NOT be used. Use scale points 1 through 4 only.

Item 4 - The printed instructions should read "Frequent and early AM wakings".
Item 7 - The printed instructions should read "Do you enjoy looking, talking or being with attractive men/women?"

DOCUMENTATION:

a. Raw score printout
b. Z score printout
c. Z score means and standard deviations
d. Variance analyses

10. Zung, W.W.K.: Depression in the normal adult population, Psychosom. 12: 164-167, 1971.

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049 HAMD HAMILTON DEPRESSION SCALE

MH-9—49
6-73

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION

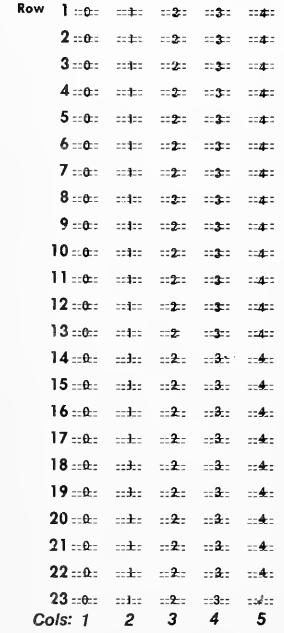
HAM D

INSTRUCTIONS: *Code 01 under Sheet Number on GSS.*

For each item select the one "cue" which best characterizes the patient.

Be sure to record your answers in the appropriate spaces (positions 0 through 4), Columns 1 — 5, on the left half of the General Scoring Sheet.

See *Special Instructions* in Manual for Items 7, 16, 18, and 20.



ROW NO.	Mark each item on left half of scoring sheet on row specified Use marking positions 0 — 4, columns 1 — 5
1	1. **DEPRESSED MOOD** *(Sadness, hopeless, helpless, worthless)* 0 = Absent 1 = These feeling states indicated only on questioning 2 = These feeling states spontaneously reported verbally 3 = Communicates feeling states non-verbally — i.e., through facial expression, posture, voice, and tendency to weep 4 = Patient reports VIRTUALLY ONLY these feeling states in his spontaneous verbal and non-verbal communication
2	2. **FEELINGS OF GUILT** 0 = Absent 1 = Self reproach, feels he has let people down 2 = Ideas of guilt or rumination over past errors or sinful deeds 3 = Present illness is a punishment. Delusions of guilt 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations
3	3. **SUICIDE** 0 = Absent 1 = Feels life is not worth living 2 = Wishes he were dead or any thoughts of possible death to self 3 = Suicide ideas or gesture 4 = Attempts at suicide *(any serious attempt rates 4)*
4	4. **INSOMNIA EARLY** 0 = No difficulty falling asleep 1 = Complains of occasional difficulty falling asleep — i.e., more than ½ hour 2 = Complains of nightly difficulty falling asleep
5	5. **INSOMNIA MIDDLE** 0 = No difficulty 1 = Patient complains of being restless and disturbed during the night 2 = Waking during the night — any getting out of bed rates 2 *(except for purposes of voiding)*
6	6. **INSOMNIA LATE** 0 = No difficulty 1 = Waking in early hours of the morning but goes back to sleep 2 = Unable to fall asleep again if he gets out of bed
7	7. **WORK AND ACTIVITIES** 0 = No difficulty 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies 2 = Loss of interest in activity; hobbies or work — either directly reported by patient, or indirect in listlessness, indecision and vacillation *(feels he has to push self to work or activities)* 3 = Decrease in actual time spent in activities or decrease in productivity. In hospital, rate 3 if patient does not spend at least three hours a day in activities *(hospital job or hobbies)* exclusive of ward chores 4 = Stopped working because of present illness. In hospital, rate 4 if patient engages in no activities except ward chores, or if patient fails to perform ward chores unassisted

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION

ROW NO.	Continue marking on left half of scoring sheet on row specified
8	**8. RETARDATION** *(Slowness of thought and speech; impaired ability to concentrate; decreased motor activity)* 0 = Normal speech and thought 1 = Slight retardation at interview 2 = Obvious retardation at interview 3 = Interview difficult 4 = Complete stupor
9	**9. AGITATION** 0 = None 1 = Fidgetiness 2 = Playing with hands, hair, etc. 3 = Moving about, can't sit still 4 = Hand wringing, nail biting, hair-pulling, biting of lips
10	**10. ANXIETY PSYCHIC** 0 = No difficulty 1 = Subjective tension and irritability 2 = Worrying about minor matters 3 = Apprehensive attitude apparent in face or speech 4 = Fears expressed without questioning
11	**11. ANXIETY SOMATIC** 0 = Absent 1 = Mild 2 = Moderate 3 = Severe 4 = Incapacitating Physiological concomitants of anxiety, such as: Gastro-intestinal – *dry mouth, wind, indigestion, diarrhea, cramps, belching* Cardio-vascular – *palpitations, headaches* Respiratory – *hyperventilation, sighing* Urinary frequency Sweating
12	**12. SOMATIC SYMPTOMS GASTROINTESTINAL** 0 = None 1 = Loss of appetite but eating without staff encouragement. Heavy feelings in abdomen 2 = Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms
13	**13. SOMATIC SYMPTOMS GENERAL** 0 = None 1 = Heaviness in limbs, back or head. Backaches, headache, muscle aches. Loss of energy and fatigability 2 = Any clear-cut symptom rates 2
14	**14. GENITAL SYMPTOMS** 0 = Absent 1 = Mild 2 = Severe Symptoms such as: *Loss of libido* *Menstrual disturbances*
15	**15. HYPOCHONDRIASIS** 0 = Not present 1 = Self-absorption (bodily) 2 = Preoccupation with health 3 = Frequent complaints, requests for help, etc. 4 = Hypochondriacal delusions

ROW NO.	Continue marking on left half of scoring sheet on row specified
16	**16. LOSS OF WEIGHT** *Rate either A or B* **A. When Rating By History:** 0 = No weight loss 1 = Probable weight loss associated with present illness 2 = Definite (according to patient) weight loss 3 = Not assessed
17	**B. On Weekly Ratings By Ward Psychiatrist, When Actual Weight Changes Are Measured:** 0 = Less than 1 lb. weight loss in week 1 = Greater than 1 lb. weight loss in week 2 = Greater than 2 lb. weight loss in week 3 = Not assessed
18	**17. INSIGHT** 0 = Acknowledges being depressed and ill 1 = Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc. 2 = Denies being ill at all
19	**18. DIURNAL VARIATION** **A. Note whether symptoms are worse in morning or evening. If NO diurnal variation, mark none** 0 = No variation 1 = Worse in A.M. 2 = Worse in P.M.
20	**B. When present, mark the severity of the variation. Mark "None" if NO variation** 0 = None 1 = Mild 2 = Severe
21	**19. DEPERSONALIZATION AND DEREALIZATION** 0 = Absent 1 = Mild 2 = Moderate 3 = Severe 4 = Incapacitating Such as: *Feelings of unreality* *Nihilistic ideas*
22	**20. PARANOID SYMPTOMS** 0 = None 1 = Suspicious 2 = Ideas of reference 3 = Delusions of reference and persecution
23	**21. OBSESSIONAL AND COMPULSIVE SYMPTOMS** 0 = Absent 1 = Mild 2 = Severe

Hamilton's Depression Scale (HAMD) is a 23-item (including two 2-part items) scale formatted for use with the General Scoring Sheet. The scale points vary from 3 to 5. The HAMD is one of the most widely used instruments for the clinical assessment of depressive states. Unfortunately, the scale has been employed in a number of different versions - creating considerable difficulty when attempting to compare published findings. The present version is, we believe, the author's version.

REFERENCE — Hamilton, M., Development of a Rating Scale for Primary Depressive Illness, Brit. J. Soc. Clin. Psychol., 1967, 6, 278-296.

APPLICABILITY — Adults with depressive symptomatology

UTILIZATION — Once at pretreatment; at least one posttreatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED — Now or within the last week

CARD FORMAT - ITEMS (19x, 2311)

Item		Column	Item		Column
1	Depressed Mood	20	13	Somatic-General	32
2	Guilt	21	14	Genital Symptoms	33
3	Suicide	22	15	Hypochondriasis	34
4	Insomnia - early	23	16A	Weight-History	35
5	Insomnia - middle	24	16B	Weight-Actual	36
6	Insomnia - late	25	17	Insight	37
7	Work	26	18A	Diurnal Variation-time	38
8	Retardation	27	18B	Diurnal Variation-severity	39
9	Agitation	28	19	Depersonalization	40
10	Anxiety-Psychic	29	20	Paranoid	41
11	Anxiety-Somatic	30	21	Obsess/Comp	42
12	Somatic-GI	31			

CARD FORMAT - FACTORS CARD 51 = (19x, 6F6.2, F4.0)
Code "5" in Col. 18 indicates card which contains factor, cluster or derived scores.

Factor	Columns	Factor	Columns
1	20-25	5	44-49
2	26-31	6	50-55
3	32-37	Total Score	56-59
4	38-43		

$$\text{Factor score} = \frac{\text{Sum of composite items}}{\text{No. of composite items}}$$ Factor Score Range = 0 - 4

Total Score = Sum of all items.* Total Score Range = 0 - 62.

* In calculating Total Score, Only Item 18B - not 18A - is included.

FACTOR COMPOSITION

This factor structure based on a 1975 analysis of the pretreatment ratings of 480 subjects with diagnoses of neurotic depression. (Table 10).

Factor I - Anxiety/Somatization

10. Anxiety, Psychic
11. Anxiety, Somatic
12. Somatic Symptoms, Gastro-Intestinal
13. Somatic Symptoms, General
15. Hypochondriasis
17. Insight

Factor II - Weight

16A. Loss of Weight (History)
16B. Loss of Weight (Actual

Factor III - Cognitive Disturbance

2. Feelings of Guilt
3. Suicide
9. Agitation
19. Depersonalization and Derealization
20. Paranoid Symptoms
21. Obsessional and Compulsive Symptoms

Factor IV - Diurnal Variation

18A. Diurnal Variation (Time)
B. Diurnal Variation (Severity)

Factor V - Retardation

1. Depressed Mood
7. Work and Activities
8. Retardation
14. Genital Symptoms

Factor VI - Sleep Disturbance

4. Insomnia, Early
5. Insomnia, Middle
6. Insomnia, Late

SPECIAL INSTRUCTIONS

Item 7. Work and Activities - Rater may seek information from relatives or ward personnel.

Item 9. Agitation - This item - printed in the packet as a 3-point scale - should be rated on a 5-point scale as follows:

0 = None
1 = Fidgetiness
2 = Playing with hands, hair, etc.
3 = Moving about, can't sit still
4 = Hand wringing, nail biting, hair pulling, biting of lips

Item 16. Loss of Weight - This is an "either/or" item requiring a response to only part of the item, i.e., 16A or 16B. Actual Weight Changes (16B) is the preferred choice - particularly during the course of a study. It is suggested that Weight by History (16A) be used only at the pretreatment rating.

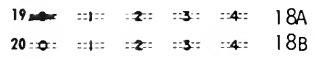
TABLE 10

6 - FACTOR VARIMAX SOLUTION OF 23-ITEM HAMILTON DEPRESSION SCALE

Cleary, P. and Guy, W., Factor Analyses of the Hamilton Depression Scale, presented at the International Symposium on the Evaluation of New Drugs in Clinical Psychopharmacology, Pisa, September, 1975.

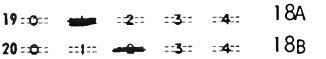
		F1	F2	F3	F4	F5	F6	Communalities
Depressed Mood	1	077	052	-213	043	709	100	57
Feelings of Guilt	2	012	006	-678	-068	152	090	50
Suicide	3	009	237	-429	163	366	157	43
Insomnia (Early)	4	091	367	-065	052	105	585	50
Insomnia (Middle)	5	058	109	-194	104	223	709	62
Insomnia (Late)	6	105	084	-102	119	244	708	60
Work & Activities	7	184	103	-167	-032	602	261	50
Retardation	8	167	000	-065	074	645	222	50
Agitation	9	420	144	-465	-196	-021	295	54
Anxiety Psychic	10	448	233	-393	117	201	030	46
Anxiety Somatic	11	720	155	-158	-030	156	109	60
Somatic Symptoms G.I.	12	462	293	-139	048	224	326	48
Somatic Symptoms - General	13	601	002	-211	116	338	284	61
Genital Symptoms	14	340	083	-117	325	531	004	52
Hypochondriasis	15	731	076	-070	048	167	-097	58
Loss of Weight A	16	086	746	025	167	136	269	68
Loss of Weight B	17	262	898	-101	054	-040	174	92
Insight	18	513	-417	054	094	-252	323	62
Diurnal A.M.	19	-015	109	-121	731	229	078	62
Diurnal P.M.	20	084	064	-082	814	-030	134	70
Depersonalization & Dualization	21	119	235	-556	140	223	146	47
Paranoid	22	173	-139	-678	229	-083	163	59
Obsessional-Compulsive Symptoms	23	162	-022	-626	076	205	-051	47
Contribution of factor (V_p)		2.63	2.05	2.45	1.56	2.33	2.09	13.11
% of Total Variance		11.43	8.91	10.65	6.78	10.13	9.08	56.9
% of Common Variance		20.06	15.63	18.68	11.89	17.77	15.94	

Item 18. Diurnal Variation - When no variation is present, encode "0" for Item A (Row 19) and leave 18B (Row 20) blank as follows:



When diurnal variation is present, encode the time of day when the symptoms are worse in 18A and indicate the severity of variation; i.e., the degree or amount of variation, in 18B. "Mild" should be interpreted as doubtful or slight variation: "Severe" as clear or marked variation.

Example: The patient's symptoms are clearly worse in the morning. Encode 1 in Row 19 and 2 in Row 20.



DOCUMENTATION

a. Raw score printout
b. Factor score printout
c. Means and standard deviations of factor scores
d. Crosstabulations
e. Variance analyses

COMMENTS OF THE AUTHOR - Adapted from "Development of a Rating Scale for Primary Depressive Illness"; Brit. J. of Soc. Clin. Psychol., 1967, 6, 278-296

Max Hamilton, M.D.

The scale provides a simple way of assessing the severity of a patient's condition quantitatively, and for showing changes in that condition. It should not be used as a diagnostic instrument. A set of items to be so used should include not only those which will show the presence of the symptoms that the patient has, but also those which the patient has not, for a diagnosis not only includes the patient within a certain category but also excludes him from others. It is possible that the scale may have other uses, e.g.: predicting outcome and selection of treatment, but these have not yet been worked out.

Ratings can be done in a number of ways, depending on the purpose, but whatever this may be it must never be forgotten that the scores are merely a particular way of recording the rater's judgment. Other things being equal, the value of the ratings therefore depends entirely on the skill and experience of the rater and on how adequate is the information available to him. This scale was devised for recording the severity of symptoms of a patient (apart from minor and temporary fluctuations) and therefore questioning should be directed to his condition in the last few days or week. It is desirable to obtain additional information from relatives, friends, nurses etc. and this should always be done whenever there is doubt about the accuracy of the patient's answers. A question frequently asked concerns the length of time required to make a rating, i.e. for how long should the patient be interviewed in order to obtain sufficient information on which to base a judgment. This will obviously depend on the skill of the rater and the condition of the patient. Sick patients cannot think quickly and they should never be hurried. An adequate interview will surely be not less than half an hour, for that gives an average time of about two minutes per item, which is not really sufficient.

The following points about interviewing will be obvious to the skilled interviewer, but it does no harm to emphasize them. The patient should not be pressed and should be allowed sufficient time to say what he wants to say; but he should not be allowed to wander too far from the point. The number of direct questions should be kept to a minimum and such questions should be asked in different ways and, in particular, both in positive and negative form, e.g. 'How badly do you sleep?' and 'How well do you sleep?' Questions should be asked in language which the patient understands and ordinary words should never be used in a technical sense. It must not be forgotten that patients sometimes misuse technical words. Patients should be helped and encouraged to admit to symptoms of which they are ashamed. Normal people do not talk freely about themselves to strangers, and this is true of patients; it is therefore helpful to delay a detailed assessment to a second interview.

When ratings are repeated they should be made independently. The interviewer should not have previous ratings in front of him and should use a new form on each occasion; this may seem a trivial matter but experience has shown that it is important. As far as possible he should avoid asking questions relating to changes since the previous interview. In order to increase the reliability of ratings, it is advisable for two interviewers to be present, one of them conducting the interview and the other asking supplementary questions at the end. The two raters should record scores independently and then sum them after the interview to give the rating for the patient. Discussion can take place after this. A discrepancy of one point on any

item is of no consequence, but a difference of two points requires careful consideration. Experience has shown that a preliminary training done on about a dozen patients should produce close agreement. A difference of 4 points on the total score is the maximum allowable, but in practice, the difference is rarely more than 2 points. There is a great practical gain from having two raters: occasionally one of them may not be available and then the other can do the rating (and double his scores). With increasing experience, a rater can learn to give half points, but summed scores from two raters should be converted into integers for each item.

Symptoms are rated finely or coarsely; the former are on a five-point scale (0-4) where the numbers are equivalent to absent, doubtful or trivial, mild, moderate and severe. The latter are on a three-point scale (0-2) equivalent to absent, doubtful or mild, and obvious, distinct or severe.

The Rating of Male Patients

1. Depression (0-4) - Depressed mood is not easy to assess. One looks for a gloomy attitude, pessimism about the future, feelings of hopelessness and a tendency to weep. As a guide, occasional weeping could count as 2, frequent weeping as 3, and severe symptoms alloted 4 points. When patients are severely depressed they may 'go beyond weeping'. It is important to remember that patients interpret the word 'depression' in all sorts of strange ways. A useful common phrase is 'lowering of spirits'.

2. Guilt (0-4) - This is fairly easy to assess but judgment is needed, for the rating is concerned with pathological guilt. From the patient's point of view, some action of his which precipitated a crisis may appear as a 'rational' basis for self-blame, which persists even after recovering from his illness. For example, he may have accepted a promotion, but the increased responsibility precipitated his breakdown. When he 'blames' himself for this, he is ascribing a cause and not necessarily expressing pathological guilt. As a guide to rating, feelings of self-reproach count 1, ideas of guilt 2, belief that the illness might be a punishment 3, and delusions of guilt, with or without hallucinations, 4 points.

3. Suicide (0-4) - The scoring ranges from feeling that life is not worth living 1, wishing he were dead 2, suicidal ideas and half-hearted attempts 3, serious attempts 4. Judgment must be used when the patient is considered to be concealing this symptom, or conversely, when he is using suicidal threats as a weapon, to intimidate others, obtain help and so on.

4, 5, 6 Insomnia (initial, middle and delayed) (0-2) - Mild, trivial and infrequent symptoms are given 1 point, obvious and severe symptoms are rated 2 points; both severity and frequency should be taken into account. Middle insomnia (disturbed sleep during the night) is the most difficult to assess, possibly because it is an artifact of the system of rating. When insomnia is severe, it generally affects all phases. Delayed insomnia (early morning wakening) tends not to be relieved by hypnotic drugs and is not often present without other forms of insomnia.

7. Work and Interests (0-4) - It could be argued that the patient's loss of interest in his work and activities should be rated separately from his decreased performance, but it has been found too difficult to do so in practice. Care should be taken not to include fatiguability and lack of energy here; the rating is concerned with loss of efficiency and the extra effort required to do anything. When the patient has to be

admitted to hospital because his symptoms render him unable to carry on, this should be rated 4 points, but not if he has been admitted for investigation or observation. When the patient improves he will eventually return to work, but when he does so may depend on the nature of his work; judgment must be used here.

8. Retardation (0-4) - Severe forms of this symptom are rare, and the mild forms are difficult to perceive. A slight flattening of affect and fixity of expression rate as 1, a monotonous voice, a delay in answering questions, a tendency to sit motionless count as 2. When retardation makes the interview extremely prolonged and almost impossible, it is rated 3, and 4 is given when an interview is impossible (and symptoms cannot be rated). Although some patients may say that their thinking is slowed or their emotional responsiveness has been diminished, questions about these manifestations usually produce misleading answers.

9. Agitation (0-4) - Severe agitation is extremely rare. Fidgetiness at interview rates as 1, obvious restlessness with picking at hands and clothes should count as 2. If the patient has to get up during the interview he is given 3, and 4 points are given when the interview has to be conducted 'on the run', with the patient pacing up and down, picking at his face and hair and tearing at his clothes. Although agitation and retardation may appear to be opposed forms of behavior, in mild form they can co-exist.

NOTE - The scale points printed on the original Adult packet are 0-2. Dr. Hamilton states that the original range (0-4) was abandoned when severer forms of agitation could not be found. He has since found that more severe cases of agitation do occur - particularly in countries other than Great Britain. The author prefers the 0-4 range, but the packet was printed before this instruction could be inserted. Subsequent editions of the Adult Packet will contain the 5-point scale and raters are urged to employ the 5-point scale for this item.

10. Anxiety (psychic symptoms) (0-4) - Many symptoms are included here, such as tension and difficulty in relaxing, irritability, worrying over trivial matters, apprehension and feelings of panic, fears, difficulty in concentration and forgetfulness, 'feeling jumpy'. The rating should be based on pathological changes that have occurred during the illness and an effort should be made to discount the features of a previous anxious disposition.

11. Anxiety (somatic symptoms) (0-4) - These consist of the well-recognized effects of autonomic over-activity in the respiratory, cardiovascular, gastro-intestinal and urinary systems. Patients may also complain of attacks of giddiness, blurring of vision and tinnitus.

12. Gastro-intestinal symptoms (0-2) - The characteristic symptom in depression is loss of appetite and this occurs very frequently. Constipation also occurs but is relatively uncommon. On rare occasions patients will complain of 'heavy feelings' in the abdomen. Symptoms of indigestion, wind and pain, etc. are rated under Anxiety.

13. General somatic symptoms (0-2) - These fall into two groups: the first is fatiguability, which may reach the point where the patients feel tired all the time. In addition, patients complain of 'loss of energy' which appears to be related to

difficulty in starting up an activity. The other type of symptom consists of diffuse muscular achings, ill-defined and often difficult to locate, but frequently in the back and sometimes in the limbs; these may also feel 'heavy'.

14. Loss of libido (1-2) - This is a common and characteristic symptom of depression, but it is difficult to assess in older men and especially those, e.g. unmarried, whose sexual activity is usually at a low level. The assessment is based on a pathological change, i.e. a deterioration obviously related to the patient's illness. Inadequate or no information should be rated as zero.

15. Hypochondriasis (0-4) - The severe states of this symptom, concerning delusions and hallucinations of rotting and blockages, etc., which are extremely uncommon in men, are rated as 4. Strong convictions of the presence of some organic disease which accounts for the patient's condition are rated 3. Much preoccupation with physical symptoms and with thoughts of organic disease are rated 2. Excessive preoccupation with bodily functions is the essence of a hypochondriacal attitude and trivial or doubtful symptoms count as 1 point.

16. Loss of insight (0-2) - This is not necessarily present when the patient denies that he is suffering from mental disorder. It may be that he is denying that he is insane and may willingly recognize that he has a 'nervous' illness. In case of doubt, enquiries should be directed to the patient's attitude to his symptoms of Guilt and Hypochondriasis.

17. Loss of weight (0-2) - The simplest way to rate this would be to record the amount of loss, but many patients do not know their normal weight. For this reason, an obvious or severe loss is rated as 2 and a slight or doubtful loss as 1 point.

18. Diurnal variation (0-2) - This symptom has been excluded from Hamilton's factors as it indicates the type of illness, rather than presenting an addition to the patient's disabilities. The commonest form consists of an increase of symptoms in the morning, but this is only slightly greater than worsening in the evening. A small number of patients insist that they feel worse in the afternoon. The clear presence of diurnal variation is rated as 2 and the doubtful presence is 1 point.

The following three symptoms were excluded from Hamilton's factors because they occur with insufficient frequency, but they are of interest in research.

19. Derealization and Depersonalization (0-4) - The patient who has this symptom quickly recognizes the questions asked of him; when he has difficulty in understanding the questions it usually signifies that the symptom is absent. When the patient asserts that he has this symptom it is necessary to question him closely; feelings of 'distance' usually mean nothing more than that the patient lacks concentration or interest in his surroundings. It would appear that the severe forms of this symptom are extremely rare in patients diagnosed as depressive.

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16. Loss of insight (0-2) - This is not necessarily present when the patient denies that he is suffering from mental disorder. It may be that he is denying that he is insane and may willingly recognize that he has a 'nervous' illness. In case of doubt, enquiries should be directed to the patient's attitude to his symptoms of Guilt and Hypochondriasis.

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18. Diurnal variation (0-2) - This symptom has been excluded from Hamilton's factors as it indicates the type of illness, rather than presenting an addition to the patient's disabilities. The commonest form consists of an increase of symptoms in the morning, but this is only slightly greater than worsening in the evening. A small number of patients insist that they feel worse in the afternoon. The clear presence of diurnal variation is rated as 2 and the doubtful presence is 1 point.

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20. Paranoid symptoms (0-4) - These are uncommon, and affirmative answers should always be checked carefully. It is of no significance if the patient says that others talk about him, since this is usually true. What is important in the mild symptom is the patient's attitude of suspicion, and the malevolence imputed to others. Doubtful or trivial suspicion rates as 1, thoughts that others wish him harm rates as 2, delusions that others wish him harm or are trying to do so rates as 3, and hallucinations are given 4 points. Care should be taken not to confuse this symptom with that of guilt, e.g. 'people are saying that I am wicked'.

21. Obsessional symptoms (0-2) - These should be differentiated from preoccupations with depressive thoughts, ideas of guilt, hypochondriacal preoccupations and paranoid thinking. Patients usually have to be encouraged to admit to these symptoms, but their statements should be checked carefully. True obsessional thoughts are recognized by the patient as coming from his own mind, as being alien to his normal outlook and feelings, and as causing great anxiety; he always struggles against them.

The Rating of Female Patients

The same general principles apply to the rating of women as of men, but there are special problems which need to be considered in detail.

1. Depression (0-4) - It is generally believed that women weep more readily than men, but there is little evidence that this is true in the case of depressive illness. There is no reason to believe, at the moment, that an assessment of the frequency of weeping could be misleading when rating the intensity of depression in women.

7. Work and interests (0-4) - Most women are housewives and therefore their work can be varied, both in quantity and intensity, to suit themselves. Women do not often complain of work being an effort, but they say they have to take things easily, or neglect some of their work. Other members of the family may have to increase the help they give. It is rare for a housewife to stop looking after her home completely. If she has an additional job outside the home she may have to change it to part-time, or reduce her hours of work or even give it up completely. Women engage in hobbies less frequently than men. Loss of interest, therefore, may not be as obvious. Patients may complain of inability to feel affection for their families. This could be rated here, but it could be rated under other symptoms, depending upon its meaning and setting. Care should be taken not to rate it in two places. It is a very valuable and important symptom if the patient mentions it spontaneously but could be very misleading as a reply to a question.

11. Anxiety (somatic) (0-4) - These last three symptoms appear to be more common in women than in men.

13. Somatic symptoms (general) (0-2) - It is not uncommon for women to complain of backache and to ascribe it to a pelvic disorder. This symptom requires careful questioning.

14. Loss of libido (0-2) - In women whose sexual experience is satisfactory, this symptom will appear as increasing frigidity, progressing to active dislike of sexual intercourse. Women who are partially or completely frigid find that their customary toleration of sex also changes to active dislike. It is difficult to rate this symptom in women who have had no sexual experience or, indeed, in widows since loss of libido in women tends to appear not so much as a loss of drive but as a loss of responsiveness. In the absence of adequate information of a pathological change a zero rating should be given. Disturbed menstruation and amenorrhea have been described in women suffering from severe depression, but they are very rare. Despite the difficulties in rating, it has been found that the mean score for women is negligibly less than men.

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048 HAMA
HAMILTON
ANXIETY
SCALE

MH-9-48
6-73

HAMILTON ANXIETY SCALE

INSTRUCTIONS: *Code 01 under Sheet Number.*
Be sure to record your answers in the appropriate spaces (positions 0 through 4), Columns 1 – 5, on the left half of the General Scoring Sheet.

USE A NO. 2 LEAD PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE.

	0 NOT PRESENT	1 MILD	2 MODERATE	3 SEVERE	4 VERY SEVERE
24	0	1	2	3	4
25	0	1	2	3	4
26	0	1	2	3	4
27	0	1	2	3	4
28	0	1	2	3	4
29	0	1	2	3	4
30	0	1	2	3	4
31	0	1	2	3	4
32	0	1	2	3	4
33	0	1	2	3	4
34	0	1	2	3	4
35	0	1	2	3	4
36	0	1	2	3	4
37	0	1	2	3	4
Cols:	*1*	*2*	*3*	*4*	*5*

ROW NO.	Mark on left half of scoring sheet on row specified Mark in response positions 0 – 4, columns 1 – 5. Follow rating scale on header template. 0 = Not Present 1 = Mild 2 = Moderate 3 = Severe 4 = Very Severe
24	**ANXIOUS MOOD** Worries, anticipation of the worst, fearful anticipation, irritability
25	**TENSION** Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax
26	**FEARS** Of dark, of strangers, of being left alone, of animals, of traffic, of crowds
27	**INSOMNIA** Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors
28	**INTELLECTUAL** Difficulty in concentration, poor memory
29	**DEPRESSED MOOD** Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing
30	**SOMATIC (Muscular)** Pains and aches, twitchings, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone
31	**SOMATIC (Sensory)** Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation
32	**CARDIOVASCULAR SYMPTOMS** Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, sighing, dyspnea
33	**RESPIRATORY SYMPTOMS** Pressure or constriction in chest, choking feelings, sighing, dyspnea
34	**GASTROINTESTINAL SYMPTOMS** Difficulty in swallowing, wind, abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation
35	**GENITOURINARY SYMPTOMS** Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence
36	**AUTONOMIC SYMPTOMS** Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair
37	**BEHAVIOR AT INTERVIEW** Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc.

The Hamilton Anxiety Scale (HAMA) is a 14-item scale formatted for use with the General Scoring Sheet. The HAMA was designed by Hamilton and intended for use with patients already diagnosed as suffering from neurotic anxiety states - not for assessing anxiety in patients suffering from other disorders. Until the contrary is proved, it must be regarded as invalid for the rating of anxiety in any other setting. This limits the range of usefulness of the scale but, within these limits, patients can be compared meaningfully. The scale places great emphasis on the patient's subjective state. This follows from the medical bias of the author. In treatment, the patient's subjective state takes first place both as a criterion of illness, which brings the patient for treatment and as a criterion of improvement.

REFERENCES

1. Hamilton, M., The Assessment of Anxiety States by Rating, Brit. J. Med. Psychol., 32, 50-55, 1959.
2. Hamilton, M., Diagnosis and Rating of Anxiety, in: Studies of Anxiety, Lader, M. H., Brit. J. Psychiat., Spec. Pub. 3, 76-79, 1969

APPLICABILITY — Adults with diagnosis of anxiety neurosis

UTILIZATION — Once at pretreatment; at least one posttreatment assessment. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED — Now or during the past week

CARD FORMAT - ITEMS — CARD 01 = (19x, 1411)

Item	Col.	Item	Col.
1	20	8	27
2	21	9	28
3	22	10	29
4	23	11	30
5	24	12	31
6	25	13	32
7	26	14	33

CARD FORMAT - FACTORS — CARD 51 = (19x, 2F6.2, F4.0)
(Code "5" in Column 18 indicates card containing factor, cluster or other derived scores).

FACTOR	COLUMN
I - Somatic Anxiety	20 - 25
II - Psychic Anxiety	26 - 31
Total Score	32 - 35

Factor Score = $\frac{\text{Sum of composite items}}{\text{No. of composite items}}$ — Factor score range = 0 - 5

Total Score = Sum of all items — Total score range = 0 - 70

FACTOR COMPOSITION

Hamilton has presented both centroid and orthogonal factor structures in his 1959 article. Since other ECDEU factors are orthogonal and unipolar, this structure - rather than the centroid one - will be employed for analyses. When a sufficient sample is accumulated, factor analysis will be performed on ECDEU data.

I. Somatic Anxiety
- 7 - Somatic, muscular
- 8 - Somatic, sensory
- 9 - Cardiovascular symptoms
- 10 - Respiratory symptoms
- 11 - Gastro-intestinal symptoms
- 12 - Genito-urinary symptoms
- 13 - Autonomic symptoms

II. Psychic Anxiety
- 1 - Anxious mood
- 2 - Tension
- 3 - Fears
- 4 - Insomnia
- 5 - Intellectual
- 6 - Depressed mood
- 14 - Behavior at interview

SPECIAL INSTRUCTIONS

1. Assessments are made on a 5-point scale. In practice, however, the last scale point (very severe, grossly disabling) is very rarely used for out-patients and serves more as a marker, a method of delimiting the range, rather than as a grade of practical use.

2. Each of the 14 items represents a set of symptoms grouped together according to their nature or where clinical experience indicates that they were associated. The symptom groups which serve as cues for the rater are:

1. Anxious mood

   Worries
   Anticipation of the worst
   Apprehension (fearful anticipation)
   Irritability

2. Tension

   Feelings of tension
   Fatiguability
   Inability to relax
   Startle response
   Moved to tears easily
   Trembling
   Feelings of restlessness

3. Fears

   Of Dark
   Strangers
   Being left alone
   Large animals, etc.
   Traffic
   Crowds

4. Insomnia

   Difficulty in falling asleep
   Broken sleep
   Unsatisfying sleep and fatigue on waking
   Dreams
   Nightmares
   Night terrors

5. Intellectual (cognitive)

Difficulty in concentration
Poor memory

6. Depressed mood

Loss of interest
Lack of pleasure in hobbies
Depression
Early waking
Diurnal swing

7. General somatic (muscular)

Muscular pains and aches
Muscular stiffness
Muscular twitchings
Clonic jerks
Grinding of teeth
Unsteady voice

8. General somatic (sensory)

Tinnitus
Blurring of vision
Hot and cold flushes
Feelings of weakness
Pricking sensations

9. Cardiovascular symptoms

Tachycardia
Palpitations
Pain in chest
Throbbing of vessels
Fainting feelings
Missing beat

10. Respiratory symptoms

Pressure or constriction in chest
Choking feelings
Sighings
Dyspnoea

11. Gastro-intestinal symptoms

Difficulty in swallowing
Wind
Dyspepsia:
- pain before and after means
- burning sensations
- fullness
- waterbrash
- nausea
- vomiting
- sinking feelings

'Working' in abdomen
Borborygmi
Looseness of bowels
Loss of weight
Constipation

12. Genito-urinary symptoms

Frequency of micturition
Urgency of micturition
Amenorrhea
Menorrhagia
Development of frigidity
Ejaculatio praecox
Loss of erection
Impotence

13. Autonomic symptoms

Dry mouth
Flushing
Pallor
Tendency to sweat
Giddiness
Tension headache
Raising of hair

14. Behavior at interview

a. General

Tense, not relaxed
Fidgeting: hands,
picking fingers,
clenching, tics
handkerchief
Restlessness: pacing
Tremor of hands
Furrowed brow
Strained face
Increased muscular tone
Sighing respirations
Facial pallor

b. Physiological

Swallowing
Belching
High resting pulse rate
Respiration rate over 20/min.
Brisk tendon jerks
Tremor
Dilated pupils
Exophthalmos
Sweating
Eye-lid twitching

DOCUMENTATION

a. Raw score printout
b. Factor score printout
c. Means and standard deviations of factor scores
d. Variance analyses

O51 ASI
ANXIETY
STATUS
INVENTORY

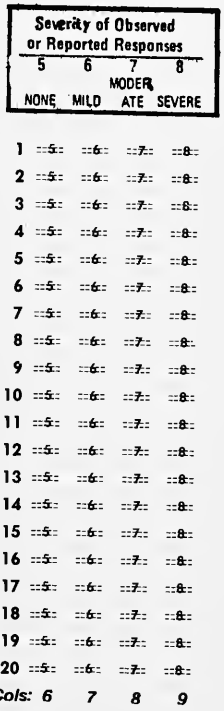
ANXIETY STATUS INVENTORY

Wm. W.K. Zung

INSTRUCTIONS: *Code 01 under Sheet Number on General Scoring Sheet*

The data upon which the judgments are based come from the interview with the patient. The items in the scale are to be quantified by using all the information available to the rater. This includes both clinical observation and the material reported by the patient.

Use of the Interview Guide below assures coverage of all the areas on which judgments are required. However, the rater has the flexibility of modifying the questions or probing for details, which makes possible a smooth interview that does not sound like a question-answer examination. In rating the patient's current status, an arbitrary period of 1 week prior to the evalutaion is adopted in order to standardize the data. In order to reinforce this, the interviewer should occasionally precede questions with, "During the past week, have you. . . . .?"



Mark each item on left half of scoring sheet on row specified.
Mark in response positions 5 – 8, columns 6 through 9.
Observe severity rating scale on header template

ROW NO.	AFFECTIVE AND SOMATIC SYMPTOMS OF ANXIETY	INTERVIEW GUIDE FOR ANXIETY STATUS INVENTORY (ASI)
1	Anxiousness	Do you ever feel nervous and anxious?
2	Fear	Have you ever felt afraid?
3	Panic	How easily do you get upset? Ever have panic spells or feel like it?
4	Mental disintegration	Do you ever feel like you re falling apart? Going to pieces?
5	Apprehension	Have you ever felt uneasy? Or that something terrible was going to happen?
6	Tremors	Have you had times when you felt yourself trembling? Shaking?
7	Body aches and pains	Do you have headaches? Neck or back pains?
8	Easy fatigability weakness	How easily do you get tired? Ever have spells of weakness?
9	Restlessness	Do you find yourself restless and can't sit still?
10	Palpitation	Have you ever felt that your heart was running away?
11	Dizziness	Do you ever have dizzy spells?
12	Faintness	Do you have fainting spells? Or feel like it?
13	Dyspnea	Evei have trouble with your breathing?
14	Paresthesias	Ever have feelings of numbness and tingling in your fingertips? Or around your mouth?
15	Nausea and vomiting	Do you ever feel sick to your stomach or feel like vomiting?
16	Urinary frequency	How often do you need to empty your bladder?
17	Sweating	Do you ever get wet, clammy hands?
18	Face flushing	Do you ever feel your face getting hot and blushing?
19	Insomnia	How have you been sleeping?
20	Nightmares	Do you have dreams that scare you?

Developed by Zung, the Anxiety Status Inventory (ASI) is a 20-item scale formatted for use with the General Scoring Sheet. Employing a 4-point scale, the ASI is the clinician-rated counterpart of the Self-Rating Anxiety Scale (SAS). The ASI along with the SAS were designed specifically for the assessment of anxiety as a clinical disorder rather than as a trait or feeling state. Zung reports a product-moment correlation of .74 between the ASI and SAS for patients with diagnoses of anxiety neurosis. (N = 22).

REFERENCE	Zung, Wm. W.K., A Rating Instrument for Anxiety Disorders, Psychosomatics, 12: 371-379, Nov.-Dec., 1971
APPLICABILITY	Adults with diagnoses of anxiety neurosis
UTILIZATION	Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.
TIME SPAN RATED	Now or in the week prior to evaluation
CARD FORMAT - ITEMS	CARD 01 = (19x, 2011, 10x, 14)

Item	Column	Item	Column
1	20	11	30
2	21	12	31
3	22	13	32
4	23	14	33
5	24	15	34
6	25	16	35
7	26	17	36
8	27	18	37
9	28	19	38
10	29	20	39
		Z Score *	50-53

*The Z score for the ASI is derived by dividing the sum of the raw item scores by the maximum possible score (80) multiplied by 100. See Table 11 for the conversion of raw scores to ASI and SAS indices. Zung has provided the following mean Z scores and standard deviations for 5 diagnostic groups:

Diagnosis	N	MN	
Anxiety Disorder	22	62.0	13.8**
Schizophrenia	25	49.4	15.9
Depressive Disorder	96	49.9	12.5
Personality Disorder	54	52.6	13.6
Transient Situational Disturbances	12	42.0	8.1

** Significantly different from other 4 groups (p = .05)

TABLE II

THE CONVERSION OF RAW SCORES TO ASI AND SAS INDICES

Raw Score	ASI & SAS Index	Raw Score	ASI & SAS Index	Raw Score	ASI & SAS Index
20	25	40	50	60	75
21	26	41	51	61	76
22	28	42	53	62	78
23	29	43	54	63	79
24	30	44	55	64	80
25	31	45	56	65	81
26	33	46	58	66	83
27	34	47	59	67	84
28	35	48	60	68	85
29	36	49	61	69	86
30	38	50	63	70	88
31	39	51	64	71	89
32	40	52	65	72	90
33	41	53	66	73	91
34	43	54	68	74	92
35	44	55	69	75	94
36	45	56	70	76	95
37	46	57	71	77	96
38	48	58	73	78	98
39	49	59	74	79	99
				80	100

SPECIAL INSTRUCTIONS

The Interview Guide is printed in the packet to assist the rater in eliciting the presence of a symptom. The items in the scale are to be quantified by using all of the information available to the rater. This includes both clinical observations and the material reported by the patient. Use of the Interview Guide assures coverage of all of the areas in which judgments are required. However, the rater has the flexibility of interposing other questions or probing for details which allow for a smooth interview without sounding like a question and answer examination.

In making judgments, the following rules should be observed:

1. Each item should be independently rated as a unit by itself in order to eliminate any "halo" effect.

2. Each score should be the average of the full range of responses observed or elicited, and not necessarily the extreme in severity.

3. The items are judged on a four-point system, taking into account Severity in terms of: intensity, duration, and frequency. These are defined as follows:

   1 = none or insignificant in intensity or duration, present none or a little of the time in frequency

   2 = mild in intensity or duration, present some of the time in frequency

   3 = of moderate severity, present a good part of the time in frequency

   4 = severe in intensity or duration, present most or all of the time in frequency

To help establish severity, the following questions may be necessary: Intensity - "How bad was it?" Duration - "How long did it last?" Frequency - "How much of the time did you feel that way?"

4. An item is scored positive and present when:

   a. Behavior is observed

   b. Behavior was described by the patient as having occurred

   c. Patient admits that symptom is still a problem

5. An item is scored negative and not present when:

   a. Symptom has not occurred and not a problem or present

   b. Patient gives no information relevant to an item

   c. Response is ambiguous even after suitable probing

ERRATA

The instructions printed on the "header" for the ASI should be identical to those printed on the "header" for the Depression Status Inventory. Raters are advised to duplicate these DSI instructions and paste them on the ASI "header".

Item 19 - Note that this item should be entitled "Insomnia-initial", NOT simply "Insomnia".

DOCUMENTATION

a. Raw score printout
b. Index score printout
c. Means and standard deviations of index scores
d. Variance analyses

ANXIETY STATUS INVENTORY

William W. K. Zung, M. D.

In the construction of the present rating instrument the symptoms of the illness were delineated by using the descriptive approach, since the basis of definition and classification in psychiatric nosology continues to be based upon presenting symptomatology. A review of the literature cited in the original publication describing the anxiety scale (1) will indicate that although anxiety as a disorder is discussed from several disparate frameworks of psychiatric orientation, the diagnostic criteria used by the various schools of thought are almost identical.

Anxiety Status Inventory (ASI)

As with the Depression Status Inventory (DSI) described elsewhere in this manual, (p. 174), the data upon which the judgments are based for the ASI come from the interview with the patients. Thus, the following discussion is applicable to both interviewer rated scales.

The items in the scale are to be quantified by using all of the information available to the rater. This includes both clinical observations and the material reported by the patient.

Use of the Interview Guide assures coverage of all of the areas in which judgments are required. However, the rater has the flexibility of interposing other questions or probing for details which allow for a smooth interview without sounding like a question-answer examination. In rating the patient's current status, an arbitrary period of one week prior to the evaluation is adopted in order to standardize the data.

REFERENCES

1. Zung, W.W.K. and Green, R. L., Jr.: Detection of affective disorders in the aged, in Eisdorfer, C. and Fann, W.E. (Editors): Psychopharmacology and Aging, Plenum Press, New York, 1973.

2. Zung, W.W.K.: The differentiation of anxiety and depressive disorders: A psychopharmacological approach, Psychosom. 15, 1974.

3. Zung, W.W.K.: The measurement of affects: Depression and anxiety, in Pichot, P. (Editor): Psychological Measurements in Psychopharmacology, Karger, Basel, 1974.

052 WITT
WITTENBORN
PSYCHIATRIC
RATING SCALE

MH-9–52
6-73

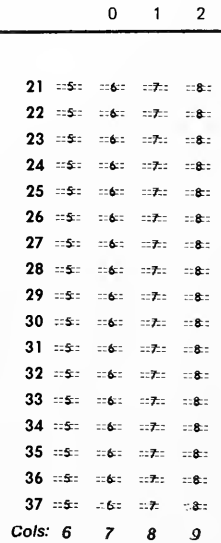
WITTENBORN PSYCHIATRIC RATING SCALES (Short Survey)

INSTRUCTIONS: *Code 01 under Sheet Number.*

1. The statements in the Rating Scales are arranged in steps from 0 (no pathology) through 3 (extreme pathology).
2. For each scale, select the one statement which best describes the most extreme manifestation during the past week.
3. If the behavior is doubtful or variable, select the alternative which is nearer to 3.
4. Rate every item, but base the rating on the specified period of observation only.
5. Record your rating by marking the appropriate response position on the answer sheet.

   Be sure to record your answers in the appropriate spaces *(positions 5 – 8), columns 6 – 9,* on the left half of the General Scoring Sheet.

USE A NO. 2 LEAD PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE.



Mark each item on left half of scoring sheet on row specified.
Mark in response positions 5 – 8, columns 6 – 9.
See rating instructions on header template.

ROW NO.		
	I. ANXIETY	
21	Threatened by Task	0 = Does not express any feeling of anxiety when confronted with a task, a test or a new situation
		1 = When confronted with a task, a test or a new situation, the patient admits anxiety experiences
		2 = When confronted with a task, a test or a new situation, the patient admits anxiety experiences, and quality of performance is adversely affected
		3 = Feels threatened by a task, or new situation, and shows failure and blocking
22	Sense of Foreboding	0 = Does not complain of premonitory experiences or any sense of foreboding
		1 = Has vague feelings of foreboding or misfortune
		2 = Has definite feeling that something bad is going to happen which will involve him or his family (but there is no evidence upon which to base a prediction)
		3 = Definite feelings of impending, inescapable, personal doom or catastrophe (but there is no apparent basis for this strong fear)
23	Guilt	0 = No evidence that patient considers himself to be particularly unworthy or blameworthy
		1 = Patient tends to blame himself or refer to his unworthiness
		2 = Patient blames and criticizes self to an unrealistic and inappropriate degree
		3 = Patient appears to have a delusional belief that he is an extraordinarily evil, unworthy or guilty person
24	Subjective Anxiety	0 = No complaint of subjectively experienced anxiety
		1 = Experiences at least minor feelings of anxiety
		2 = Experiences anxiety which is strong enough to make him express acutely uncomfortable feelings
		3 = Is desperately distressed by his anxiety and considers it to be intolerable
	II. SOMATIC-HYSTERICAL	
25	Attention Demanding	0 = Does not appear to be attention-demanding
		1 = In conversation, usually brings attention of others to his own role
		2 = Engages insistently in description of own role or difficulties
		3 = Dramatically attention-demanding

ROW NO.	Continue marking on left half of scoring sheet on row specified	
26	Uses Symptoms	0 = No discernible psychological use made of physical disease symptoms
		1 = Use is made of physical disease symptoms to gain attention or to dramatize self
		2 = Use is made of physical disease symptoms for evading responsibilities, justifying failures, etc.
27	Organic Involvement	0 = Presents no complaint or symptoms of organic pathology or malfunctioning
		1 = Presents symptoms of organic pathology or malfunctioning which was not caused by emotional factors
		2 = Presents organic pathology or malfunctioning which may be caused in part or greatly aggravated by emotional factors
		3 = Presents organic pathology or malfunctioning which probably was caused by emotional factors
	III. OBSESSIVE-COMPULSIVE-PHOBIC	
28	Phobic	0 = No complaint of phobias or phobic reactions (i.e., specific isolated, inappropriate fears)
		1 = Patient experiences phobic reactions in certain situations
		2 = Phobic reactions have affected patient's current behavior
		3 = Patient's behavior is greatly disrupted or delimited by his phobias
29	Obsessive	0 = No evidence for obsessional (repetitive, stereotyped) thinking
		1 = Obsessive thoughts recur but can be banished without difficulty
		2 = Patient is able to banish obsessive thoughts, but only with difficulty
		3 = Cannot banish or control obsessive thoughts
30	Compulsive	0 = No evidence of compulsive (repetitive, nonadaptive, uneconomical) behavior
		1 = Acts judged to be compulsive are performed from time to time but not every day
		2 = Compulsive acts occur daily
		3 = Compulsive acts are practically continuous
	IV. DEPRESSIVE RETARDATION	
31	Indecisive	0 = No evidence of difficulty in making decisions
		1 = Reports uncertainty and postponement of decisions
		2 = Cannot make decisions without advice or pressure
		3 = Cannot make decisions

ROW NO.	Continue marking on left half of scoring sheet on row specified	
32	Avoids People	0 = No evidence of social withdrawal
		1 = Does not appear to seek out the company of other people
		2 = Avoids many people
		3 = Attempts to avoid almost all people
33	Motoric Retardation	0 = No evidence of slowing of responses
		1 = Actions have a deliberate quality. No evidence of haste
		2 = Overt responses are slow and may appear to be delayed
		3 = All overt activity is at a minimum. Patient loath to move and all motions tend to be tediously slow
	V. EXCITEMENT	
34	Overactive	0 = Is not particularly overactive
		1 = Moderately overactive, e.g., toys with objects, frequently changes his sitting position
		2 = Noticeably restless
		3 = In almost constant movement
35	Irrelevant Words	0 = Does not use words in an obscure or irrelevant manner
		1 = Words not always clearly relevant to recognizable idea
		2 = Words used in such a manner that ideas seem unclear and confused
		3 = Words not relevant to any recognizable, logical idea
	VI. PARANOIA	
36	Misinterprets Others	0 = No evidence that he misconstrues the intentions of others
		1 = May exaggerate the intentions of others
		2 = May seriously misinterpret the intentions of others
		3 = Arbitrarily misinterprets the intentions of others, apparently to conform with his delusional beliefs
37	Ideas of Influence	0 = No evidence that patient feels that others seek to spy upon or control his behavior or thought
		1 = Wonders if others have a particular interest in or desire to know about his thoughts or behavior
		2 = Wonders if others attempt to influence his behavior in some unknown manner or attempt to control his thoughts
		3 = Believes that others influence his behavior in some strange manner or control his thoughts

Wittenborn's Psychiatric Rating Scale (WITT) is a 17-item scale formatted for use with the General Scoring Sheet. The present ECDEU version was developed from the longer 72-item Wittenborn scale in response to the need for a brief assessment procedure to ascertain the rate and nature of symptomatic change. With one exception, items are rated on a 4-point scale.

REFERENCE — Wittenborn, J. R., Manual: Wittenborn Psychiatric Rating Scales, 1955, Psychological Corporation, New York.

APPLICABILITY — Inpatient and outpatient adult populations

UTILIZATION — Once at pretreatment; at least one posttreatment rating. Additional ratings are at the discretion of the principal investigator.

TIME SPAN RATED — Now or during the past week

CARD FORMAT - ITEMS CARD 01 (19x, 1711)

Item	Column	Item	Column
1	20	10	29
2	21	11	30
3	22	12	31
4	23	13	32
5	24	14	33
6	25	15	34
7	26	16	35
8	27	17	36
9	28		

CARD FORMAT - FACTORS CARD 51 (19x, 6F6.2, F4.0)

(Code "5" in Column 18 indicates card containing factor, cluster or derived score.)

Factor	Column	Factor	Column
I	20-25	V	44-49
II	26-31	VI	50-55
III	32-37	Total Score	56-59
IV	38-43		

$$\text{Factor Score} = \frac{\text{Sum of composite items}}{\text{No. of composite items}}$$ Factor score range = 0 - 4

Total Score = Sum of all items Total score range = 0 - 68

FACTOR COMPOSITION:

FACTOR I ANXIETY
1. Threatened by task
2. Sense of foreboding
3. Guilt
4. Subjective anxiety

FACTOR II SOMATIC - HYSTERICAL
5. Attention demanding
6. Uses symptoms
7. Organic involvement

FACTOR III OBSESSIVE - COMPULSIVE - PHOBIC
8. Phobic
9. Obsessive
10. Compulsive

FACTOR IV DEPRESSIVE RETARDATION
11. Indecisive
12. Avoids people
13. Motoric Retardation

FACTOR V EXCITEMENT
14. Overactive
15. Irrelevant words

FACTOR VI PARANOIA
16. Misinterprets others
17. Ideas of influence

SPECIAL INSTRUCTIONS

See "Comments of the Author" (pp. 210-216) for detailed instructions.

DOCUMENTATION

a. Raw score printout
b. Factor score printout
c. Means and standard deviations for factor scores
d. Cross Tabulations
e. Variance analyses

Manual for Wittenborn Psychiatric Rating Scales

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I. CHARACTERISTICS OF SYMPTOM RATING SCALES

The development of research in psychiatry, clinical psychology, and clinical psychopharmacology has been accompanied by the appearance of several psychiatric symptom rating scales. Although these rating scales may all be used as criteria for therapeutic efficacy, they may differ in several fundamental respects.

A. Content

There are many different patient characteristics which may be sampled by rating scales. For example, it is possible for scales to reflect the strength of certain aspects of the patient's personality. It is possible also for rating scales to include aspects of the patient's clinical history. Some rating scales include only currently discernible symptoms of psychopathology, and such scales can be most sensitive to any change in the patient's status. Symptom rating scales can be restricted to represent only certain limited psychopathological deviations, such as depression, anxiety, or somatization, or they can attempt to sample a broad spectrum of psychopathology so that change in target symptoms may be seen in the context of a total symptom complex.

The WPRS samples a broad spectrum of commonly encountered psychopathology and is restricted to currently discernible symptoms. It is not a diagnostic device in any fundamental sense. Instead, it is intended to be sensitive to change and to be sufficiently comprehensive to provide a common basis for comparing a wide diversity of patients.

B. Referents

Many rating scales provide distinctions between patients on the basis of the rater's general impression of the patient. Such scales do not refer directly to the observational or factual basis for the judgments. As a consequence, a rating based on such a judgmental scale may be as sensitive to rater characteristics as it is to patient characteristics. A few other scales refer explicitly to verifiable observations or other factual situations or events directly descriptive of the patient and in this way minimize evaluative and interpretive judgments of the rater. It is never possible to eliminate the influence of the rater's judgment or to correct completely for the selective nature of his observation. Rating scales do vary greatly, however, in the extent to which they involve the screening, evaluative, and judgmental characteristics of the individual rater.

The WPRS emphasizes the use of verifiable observations as the basis for rating and attempts to minimize the rater's judgmental involvement. For this reason, the WPRS requires thorough and meticulous observation of the patient and does not rely upon the interpretive acumen of the rater.

C. Observational basis

The observational requirements for the proper use of a rating scale must be related to its content. If historical considerations or aspects of the premorbid personality are included in the ratings, the observational period cannot be rigidly defined. Despite their possible diagnostic interest, ratings based on enduring personal qualities or referring to indefinite time periods cannot be most sensitive to the changes which are pertinent to current therapeutic effects.

Since the WPRS is designed to reveal changes, the observational period on which the ratings are based must be carefully defined. This period can be of any duration, but it is necessary that firm limits be set so that old observations do not bias current ratings and so that comparisons may be made between definite periods or phases in the illness. Obviously, the selected rating period must be standard within any sample of data submitted to common analysis.

For a sample of data submitted to common analysis, the observational setting should be specified also. For the Long Form, the diversity of content requires an in-patient setting. For the Short Form, however, the outpatient interview situation (including the substance of the patient's verbalization) can provide an adequate setting.

The provocative qualities of the observational setting remain an uncontrolled factor in the ordinary use of rating scales. Certain settings, because of the personnel or because of the qualities of the interview situation, can admittedly be most provocative of psychopathological reactions. For this reason, it is important for comparative purposes that the setting for a given patient remain constant, otherwise the effect of any changes in the setting would be confounded with effects due to treatment. In order to keep the "error variance" as small as possible, it is desirable also that the settings be as uniform as possible among patients generating data for a common analysis. Nevertheless, it is not recommended that ratings be based on a standardized question and answer type of inquiry which is little more than a tour de force of the items comprising the rating scale. Instead, it is recommended that the observations and the interview be thorough and evocative with reasonable opportunity for the expression of thoughts, sentiments, and reactions which are pertinent to the patient's disorder and to the content of the rating scale.

The rater may either restrict the ratings to his own observations or decide to incorporate the reports and observations of reliable informants, such as ward personnel, family associates, etc. If ratings are to include the reports of informants, it is obviously necessary that the informant be used in a consistent and standard manner throughout any set of ratings required by an investigation. In many outpatient situations, particularly in work with juveniles and with character disorders, it may be most helpful for the rater to have recourse to reliable informants.

The behavior of patients is ordinarily episodic and variable in its pathologic quality. Accordingly, the interview itself provides, at best, a meager and, at worst, a misleading sample of the patient's reactions. All other things equal,

the longer the observational period the greater the opportunities for pertinent observation. For example, if the assessment period for which the rating is to be descriptive is one week, the inadequate, untoward, or deviant behaviors during that week are probably much more pertinent to the quality of the patient's current functioning than are the qualities of behavior manifested during the period of one interview. The limitation inherent in ratings based on the interview apply to any rating scale, particularly any symptom rating scale which, by its nature, is concerned with current manifestations of psychopathology and not merely with those qualities of behavior which may emerge in the course of one interview. Accordingly, in the outpatient situation, the rater is particularly dependent on self-reports and must rely on the patient's ability to recognize and willingness to describe difficulties and deviations which have occurred during the period covered by the assessment. This means, of course, that the rater must have excellent evocative rapport with his outpatients.

In the evaluation of outpatient rating data based primarily on the interview, it is important to recognize the special vulnerabilities of such data and to remember that they are much more dependent upon both the rater's skill as an interviewer and his interpretive acumen than are data which have a broader observational basis, e.g., data gathered in an inpatient situation.

D. Scaling continua

The purpose of the rating scale is to record and systematize distinctions which may be observed in the behavior of patients and which may be used to distinguish between patients. These distinguishable qualities can be placed on continua to indicate increasing levels of pathology or severity of disorder. The arrangement of behavior qualities on such a continuum implies that a quality placed at any given level of severity is more pathologically significant in its deviance than a quality placed on the continuum at any lesser level of severity. The pertinence of such an arrangement or continuum of behavior rests upon the consensual acceptance of experts and is obviously dependent upon conventional concepts of pathological deviance. Some arrangements or gradients which reflect increasing severity of pathological deviation in our society may not be accepted as representing a gradient of deviation in all other societies. It is possible also that certain individuals within our society will challenge and perhaps reject an arrangement of items accepted by the majority as an indication of progressing deviance.

Within any such a graded arrangement of behaviors, the distinctions between successive behavioral qualities or conditions represent no uniform quantity. Regardless of their substance or format, behavior rating scales, like other measures of behavior, do not offer a standard, equal unit (and are not based on an absolute zero). Thus the increasing scores given to the successive rating scale positions represent only the direction of the difference and not successive magnitudes in any standard sense.

In some instances, behavioral qualities have been conceived to range from one extreme through a point of indifference to some other extreme, e.g., from happiness through a point of indifference to sadness, extroversion to introversion, love to hate, honesty to dishonesty, etc. Unfortunately, human behavior seems not to

arrange itself according to the antonyms of the English language. In pathological states particularly, it is possible to observe extremes of happiness and sadness or love and hate concurrently, if not simultaneously, in the same individual. For this reason, in bipolar continua which range from one extreme to another, a given level of severity has no necessary implications for other levels of severity, i.e., a person might or might not be given an extreme position at both ends of the scale. As a consequence, most symptom rating scales are now restricted to a unipolar format which begins with a point of indifference and proceeds in one direction through a series of graded observations or circumstances to some one pathological extreme.

It must be acknowledged that rating scales which comprise an explicit arrangement of verifiable behavior qualities or events require specific information for their proper use. In addition, such scales place only minimal reliance on the rater's own judgment of the severity of the symptomatic quality in question. Accordingly, a set of rating scales, such as the WPRS, which relies on a graded series of verifiable behaviors, may not be preferred by raters who have no specific information about their patients. The use of the WPRS may be questioned also by raters who prefer to indicate their own estimates of the severity of the disorder and do not feel satisfied in expressing their evaluation in terms of a fixed series of graded qualities. For this reason, most professionals will appreciate an opportunity to supplement their standard objective ratings with a statement of their own estimate of the patient.

E. The Model of Psychopathology

Psychopathology can be assessed from the etiological, prognostic, dynamic, or descriptive standpoint. The WPRS is a strictly descriptive instrument. It represents no particular a priori dynamic or conceptual model. The separate scales comprising the set represent the symptomatic facets which occur commonly and are sensitive to the changing quality of psychopathology. These scales, each constructed to reflect increasing levels of severity, may be combined to provide cluster scores which represent the general severity of groups of interrelated symptoms. These groups of interrelated symptoms do not necessarily reflect a priori considerations. Instead, they indicate the natural symptom groupings which were found repeatedly by factor analyses of data from samples of patients in the northeastern portion of the United States. It is reassuring to find that these empirically determined groups of symptoms tend to reflect familiar syndromes and are reminiscent of the traditional descriptive concepts which have been in common usage since the days of Kraepelin.

II. THE RATING SCALE FORMS

The 1955 Form

The form copyrighted by the Psychological Corporation in 1955 was generated in the course of a program of investigation initiated in 1947. The symptom rating scales that this form comprises were based on interviews with New England psychiatrists, and the 52 items represent a consensual agreement concerning the tangible psychiatric symptoms which, at that time, were considered to be important in newly admitted mental hospital patients. This was a period prior to modern tranquilizers and one in which a primary emphasis was placed on the newly admitted patient. Accordingly, the 1955 version includes florid symptomatic qualities which are not conspicuous in tranquilized patients or in chronic patients.

The 1964 Form

After 1955, patients appearing at psychiatric hospitals were usually to some degree tranquilized, and as a consequence florid unmodulated symptomatic manifestations became unusual. In addition, the availability of tranquilizers generated a substantial research and therapeutic interest in chronic patients. (As a matter of fact, chronic patients appear to have been the subjects for most studies of the effects of tranquilizers.) In order to accomodate to this shift in interest, the original rating scales were extended and revised, and in 1964, a set of 72 symptom rating scales was made available. Many of these scales were included for the explicit purpose of revealing differences in and distinctions among chronic patients and other patients whose manifestations were somewhat subdued in consequence of tranquilization. In addition to the supplemental items, some of the original scales were deleted, and others were revised. The 1964 form has been applied to several samples. Factor analyses of these data revealed distinctions in symptomatic patterns not apparent in the factor analyses of the untranquilized, newly admitted patients rated with the 1955 form.

The 1964 form is more versatile than the 1955 form in the sense that, in addition to being descriptive of newly admitted patients, it reveals distinctions among chronic patients. It should be noted that the 1964 form attempts to place a minimal reliance on inferences of the rater. For example, there are no scales which rate the hallucinatory experience per se, but there are several scales which rate observable response qualities that tend to accompany hallucinations.

The short form provides scores for six major factors or symptom clusters: anxiety, somatic-hysterical, obsessive-compulsive-phobic, depressive retardation, excitement, and paranoia. The scales which contribute to these respective cluster scores were selected on the basis of their appropriateness for outpatient use, their pertinence to the factor to which they contribute, and their proven sensitivity to changes accompanying treatment.

III. DIRECTIONS FOR USE

A. The Rating Procedure

1. It is necessary that the observational period on which the ratings are based be scrupulously defined and that the limits of this observational period be recorded in the appropriate space on the face sheet.

2. It is necessary that a rating be indicated for <u>every scale</u>. If there is no information on which to base a rating, the initial or least severe level is the appropriate rating.

3. The rating should always be the <u>most pathological extreme</u> observed during the rating period. Ratings should <u>not</u> be based on an average or general condition of the patient.

4. When informants are consulted as a basis for rating, the identity or the role of the informant should be recorded.

5. Wherever possible, a diagnosis should be indicated in the appropriate space. Because of the episodic and variable nature of psychopathological manifestations, it is understood that the diagnosis of the patient and the symptoms which are rated as currently descriptive may not always be consistent.

B. The Rater

1. Familiarity with the rating scales is an important determiner of the speed and ease with which ratings may be made. The rater should anticipate that his initial experiences with the rating scales will seem tedious and time-consuming.

2. Most professionally trained raters, particularly psychiatrists, psychologists, and social workers, will be able to use the rating scales without personal instruction. In a research team, where standardization can be critical, it is useful for beginners to review their initial ratings with other members of the group.

3. Raters not professionally trained in psychopathology, e.g., occupational therapists, nursing personnel, or other ward personnel, should have at least their first six rating forms reviewed by a professionally trained person who shares their knowledge of the patient. Although the language of the scales is simple, it involves conceptual and terminological usages which may be unfamiliar to nonprofessional raters, or at best only partially understood by them.

4. Almost any careful observer can be trained to make satisfactory ratings based on inpatient situations. Ordinarily, outpatient ratings should be provided only by professionally trained persons who are well acquainted with the patient.

C. The Observational Setting

Almost any standard observational setting can provide a useful basis for symptom ratings. For interpretive purposes, however, it is important that the observational setting be recorded on the face sheet of the form.

The observational setting which provides the most useful ratings will depend upon the manner in which the setting is used and the purposes of the assessment. In general, the ratings of psychiatrists and psychologists show very slight average differences. The ratings of nurses tend to be consistently different from those of psychiatrists, particularly in the sense that nurses' ratings will contain fewer indications of affective or conceptual deviation, but will emphasize matters relevant to ward routine, particularly matters concerning the patient's cooperation and participation.

Ratings by different personnel will differ according to the observational basis for the rating. Thus, ratings of the same patient by two different raters should be expected to differ somewhat unless the two raters are observing at the same time. Accordingly, differences between raters describing the same patient have no necessary implications for either the validity or the reliability of the scales and may reflect differences in the behavior sample on which the ratings are based.

Where a fully comprehensive description is imperative, independent ratings by the psychiatrist, the psychologist, and the nurse should be sought. Scale by scale the different ratings from these persons may then be reconciled and combined by selecting as most valid the one rating which shows the greatest pathological extreme. The appropriateness of this procedure is based on the assumption that the most pathological manifestation is the most pertinent basis for the rating and on the further assumption that an observation of an extreme pathological manifestation is a valid basis for a descriptive rating regardless of whether the observation was made by the nurse, the psychologist, or the psychiatrist.

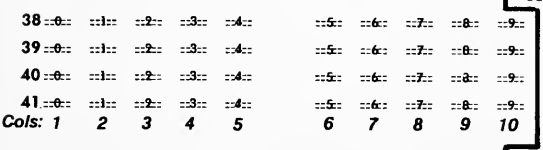
028 CGI CLINICAL GLOBAL IMPRESSIONS

CLINICAL GLOBAL IMPRESSIONS

INSTRUCTIONS: *Mark these items on General Scoring Sheet coded 01.*

Complete Item 1 — **SEVERITY OF ILLNESS** at the initial and subsequent assessments.
Items 2 and 3 may be omitted at the initial assessment by marking 0 — "Not Assessed".

Mark on the left half of the scoring sheet on rows 38 — 41.



ROW NO.	CLINICAL GLOBAL IMPRESSIONS
38	**1. SEVERITY OF ILLNESS** Considering your total clinical experience with this particular population, how mentally ill is the patient at this time? 0 = Not assessed 1 = Normal, not at all ill 2 = Borderline mentally ill 3 = Mildly ill 4 = Moderately ill 5 = Markedly ill 6 = Severely ill 7 = Among the most extremely ill patients
	THE NEXT TWO ITEMS MAY BE OMITTED AT THE INITIAL ASSESSMENT BY MARKING "NOT ASSESSED" FOR BOTH ITEMS
39	**2. GLOBAL IMPROVEMENT** — Rate total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his condition at admission to the project, how much has he changed? 0 = Not assessed 1 = Very much improved 2 = Much improved 3 = Minimally improved 4 = No change 5 = Minimally worse 6 = Much worse 7 = Very much worse
40 & 41	**3. EFFICACY INDEX** — Rate this item on the basis of **DRUG EFFECT ONLY.** Select the terms which best describe the degrees of therapeutic effect and side effects and record the number in the box where the two items intersect. EXAMPLE: Therapeutic effect is rated as "Moderate" and side effects are judged "Do not significantly interfere with patient's functioning". Record 06 in rows 40 and 41.

THERAPEUTIC EFFECT	SIDE EFFECTS: None	Do not significantly interfere with patient's functioning	Significantly interferes with patient's functioning	Outweighs therapeutic effect
MARKED — Vast improvement. Complete or nearly complete remission of all symptoms	01	02	03	04
MODERATE — Decided improvement. Partial remission of symptoms	05	06	07	08
MINIMAL — Slight improvement which doesn't alter status of care of patient	09	10	11	12
UNCHANGED OR WORSE	13	14	15	16
Not Assessed = 00				

Clinical Global Impressions (CGI), developed during the PRB collaborative schizophrenic studies, consists of 3 global scales (items) formatted for use with the General Scoring Sheet. Since the items are "universal", the CGI is included in both the Pediatric and Adult packets. Two of the items, Severity of Illness and Global Improvement, are rated on a 7-point scale; while the third, Efficacy Index, requires a rating of the interaction of therapeutic effectiveness and adverse reactions.

APPLICABILITY — For all research populations

UTILIZATION — For Severity of Illness: Once at pretreatment and at least one post-treatment assessment. Additional ratings are at the discretion of the investigator. For Global Improvement and Efficacy Index: No pretreatment (baseline) assessment is required. At least one post-treatment assessment should be made. Additional post-treatment ratings are at the discretion of the investigator.

TIME SPAN RATED — For Severity of Illness: Now or within the last week. For Global Improvement: Since admission to the study. For Efficacy Index: Now or within the last week.

CARD FORMAT - ITEMS CARD 01 = (19x, 2I1, I2)

Item	Column
Severity of Illness	20
Global Improvement	21
Efficacy Index	22 - 23

SPECIAL INSTRUCTIONS

The contexts under which the 3 CGI items are to be rated have been modified to increase the reliability and precision of the items. Veteran ECDEU raters should be alert to these new contexts.

Item 1 - Severity of Illness - For this item, the modification for rating context is:

OLD **Considering your total clinical experience, how mentally ill is the patient at this time?**

NEW Considering your total clinical experience with this particular population, how mentally ill is the patient at this time?

The old version asked the rater to judge the severity of illness of a given subject in the context of that rater's total experience with all types of patients; i.e., regardless of diagnosis, chronicity, age, etc. The present version restricts the judgment within the range of the specific population under study. Thus, an anxious neurotic subject is judged in the context of the rater's experience with anxious

neurotics - not, as was the case in the past - against a clinical background which may have included schizophrenics, brain damaged, and depressive subjects as well as anxious ones.

Item 2 - Global Improvement - The modification here involves the relationship between this item and Efficacy Index (Item 3). In the past, no distinction between TOTAL clinical improvement and that portion of the TOTAL which, in the opinion of the rater, is the direct result of the drug administered. The present contexts are:

Global Improvement

GLOBAL IMPROVEMENT — Rate total improvement whether or not, in your judgment, it is due entirely to drug treatment.

Efficacy Index

EFFICACY INDEX — Rate this item on the basis of DRUG EFFECT ONLY.

In many studies, of course, TOTAL improvement and improvement due to drug will be one and the same; nevertheless, the new contexts allow a distinction to be made when it is present.

Raters are cautioned to observe the unique time span rated for Global Improvement. For most other ECDEU items, the time span to be rated is either a specified number of days or since the last rating. The time span for Global Improvement - at each and every rating - is "since admission to the project (study)" - NOT from the last rating period.

Item 3 - Efficacy Index - In addition to the contextual modification mentioned above, the matrix of therapeutic vs. side effects has been changed as follows:

THERAPEUTIC EFFECT	SIDE EFFECTS			
	None	Do not significantly interfere with patient's functioning	Significantly interferes with patient's functioning	Outweighs therapeutic effect
MARKED — Vast improvement. Complete or nearly complete remission of all symptoms	01	02	03	04
MODERATE — Decided improvement. Partial remission of symptoms	05	06	07	08
MINIMAL — Slight improvement which doesn't alter status of care of patient	09	10	11	12
UNCHANGED OR WORSE	13	14	15	16
Not Assessed = 00				

The new matrix has been made symmetrical (4 x 4) by combining 2 therapeutic categories, "Unchanged" and "Worse" into one category. Category 4 of Side Effects has also been reworded.

Efficacy Index is an attempt to relate therapeutic effects and side effects. Therapeutic effect is regarded as gross profit; side effects as cost. The Index, then, is analogous to net profit. The Index is derived by dividing therapeutic effect score by side effect score as follows:

	Side Effects			
Therapeutic Effect	None 1	No Significant Interference 2	Significant Interference 3	Outweighs 4
4 Marked	4.00*	2.00	1.33	1.00
3 Moderate	3.00	1.50	1.00	0.75
2 Minimal	2.00	1.00	0.67	0.50
1 Unchanged or Worse	1.00	0.50	0.33	0.25

* Example: $\frac{\text{Therapeutic Score (4)}}{\text{Side Effect Score (1)}}$ = Efficacy Index (4.00)

The transformation procedure for Efficacy Index (EI) is:

Number Encoded	= Transformed Score	= EI
01	41	4.00
02	42	2.00
03	43	1.33
04	44	1.00
05	31	3.00
06	32	1.50
07	33	1.00
08	34	0.75
09	21	2.00
10	22	1.00
11	23	0.67
12	24	0.50
13	11	1.00
14	12	0.50
15	13	0.33
16	14	0.25
00	00	0.00

Employing the cross tabulation scheme (page 478) to interpret EI, indices falling on the diagonal CB would indicate that the therapeutic and toxic effects of a treatment are equivalent. Those in the upper left quadrant would indicate some degree of "profit" - the profit increasing as pole A is approached. The converse is true of indices falling in the lower right quadrant and, in fact, in all of the last column. The treatment with the greatest efficacy fills the cell at Pole A; the worst at Pole D. The cell at Pole C contains the "inert" treatment. Pole B represents a paradoxical and "theoretical" cell - not one likely to be encountered in the real world.

DOCUMENTATION

a. Raw score printout
b. Means and standard deviations
c. Frequencies and crosstabulations
d. Variance analyses

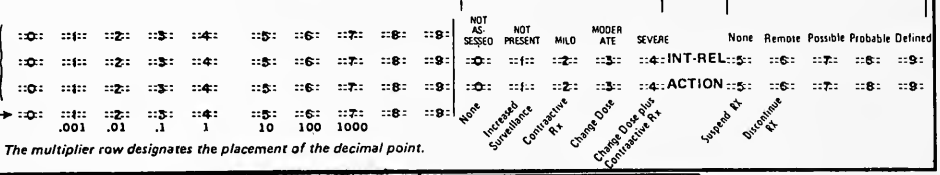
029 DOTES
DOSAGE RECORD AND TREATMENT EMERGENT SYMPTOM SCALE

DOSAGE RECORD AND TREATMENT EMERGENT SYMPTOM SCALE

INSTRUCTIONS: *Insert New General Scoring Sheet and Code 02 for Sheet Number*

Coding Dosage: Three rows are provided for the coding of the numeric value and one row for the multiplier

Coding Symptom Judgments: The 3 judgments are coded on 2 rows as follows:



The multiplier row designates the placement of the decimal point.

INSTRUCTIONS

TOTAL DAILY DOSE: To permit the coding of the widest range of dosages and, at the same time, minimize the number of "marks" required of the rater, the following 4—row schema has been constructed.

Examples:

2500 mg. = 250 x 10;	code 2505		25 x 100:	code 0256
250 mg. = 250 x 1;	code 2504		25 x 10:	code 0255
25 mg. = 250 x .1;	code 2503	OR	25 x 1:	code 0254
2.5 mg. = 250 x .01;	code 2502		25 x .1:	code 0253
0.25 mg. = 250 x .001;	code 2501		25 x .01:	code 0252

CATALOGUE OF SYMPTOMS — For each symptom cited (present), three (3) judgments are required — intensity of the symptom, its relationship to the drug and the action undertaken as a consequence of its presence.

a. **INTENSITY** — Generally, the levels of intensity are defined as follows:

0 = Not Assessed — Mark this category when NO assessment (rating) of a specific symptom is made. Leave Relationship and Actions sections blank.

1 = Not Present — Mark this category if symptom is assessed and is found absent.

2 = Mild — The symptom does not hinder the subject's normal functioning level, i.e., his level at pretreatment. An annoyance to the subject.

3 = Moderate — The symptom produces some degree of impairment to functioning but is not hazardous to health. Uncomfortable and/or embarrassing to the subject.

4 = Severe — The symptom is a definite hazard to well being. Significant impairment of functioning or incapacitation.

b. **RELATIONSHIP** — A judgment of the degree of relationship between the occurrence of the symptom and the drug rated on a 5—point scale.

5 = None — No relationship between symptom and drug

6 = Remote — Less than a 10% probability that symptom occurrence is related to drug employed

7 = Possible — Probability between 10% and 50%

8 = Probable — Probability between 50% and 90%

9 = Defined — Greater than 90% probability that symptom is related to drug employed

c. **ACTION TAKEN** — Refers to action taken as a consequence of the symptom's appearance. Actions are arranged in order of increasing stringency. Only ONE action — the most stringent — should be recorded as it is assumed that less stringent actions may also be employed.

ACTION CODE:

0 = None

1 = Increased Surveillance

2 = Contraactive Rx

3 = Change Dose

4 = Change Dose plus Contraactive Rx

5 = Suspend Rx

6 = Discontinue Rx

DOSAGE RECORD AND TREATMENT EMERGENT SYMPTOM SCALE

Mark each item on right half of scoring sheet on row specified	ROW NO.
1 REASON FOR COMPLETING SCALE On the *DAY* recorded under *PERIOD*, dosage was: *(Mark ONE only)* 0 = Initiated (First Dose) 1 = Changed per protocol 2 = Changed due to ineffectiveness 3 = Changed due to toxicity 4 = Changed for titration (Test Dose) 5 = Discontinued/suspended 6 = Reinitiated following suspension 7 = Changeover point of crossover design 8 = Not changed but treatment emergent symptom/s occurred 9 = Regular (fixed) TESS assessment	1
2. TOTAL DAILY DOSE a. Component *(Use for all single component drugs)*	2-5
b. Component *(For combination drugs only)*	6-9
c. *FOR STUDIES IN WHICH RECORDING "TOTAL DAILY DOSE" IS INAPPROPRIATE, E.G., LONG-ACTING DRUGS, DEPOT DRUGS, VERY SHORT-ACTING DRUGS, ETC.*, enter amount of drug in 2 a (b) and mark the length of time and time units over which the drug is presumed to be effective. (See Manual for instructions) Drug is presumed to be effective for (Code number)	10-11
Time Unit: 1 = Hours 2 = Days 3 = Weeks 4 = Months (Code one)	12
3. PRESCRIPTION Mark 2 responses — one for prescription (No. 0 through 6) and one for proportions (No. 7 or 8) Dosage is to be given: 0 = hs 1 = qd 2 = bid 3 = tid 4 = qid 5 = prn 6 = depot 7 = equal 8 = unequal proportions	13
4. TREATMENT EMERGENT SYMPTOMS At the previous dosage level *(or since the last assessment)*, were any significant physical signs, laboratory findings or symptoms present? *(For initial assessment, record presence or absence of symptoms for that day only)* *Mark one:* 0 = NO *(If NO, and ALL SYMPTOMS WERE ASSESSED, no further responses necessary)* 1 = YES, printed symptoms present but no "write-ins" 2 = YES, both printed and "write-in" symptoms present 3 = YES, only "write-ins" present. *(Do not forget to complete Item 6 before proceeding to TWIS, TESS Write-In Scale)*	14
5. CATALOGUE OF SYMPTOMS *(See Instructions on page R — 4)*	
Behavioral Toxicity: Toxic confusional state . . .	15-16
Excitement/agitation . . .	17-18
Depressive affect	19-20
Increased motor activity . .	21-22
Decreased motor activity . .	23-24
Insomnia	25-26
Drowsiness	27-28
Abnormal Laboratory Findings: Abnormal hematologic . . .	29-30
Abnormal liver	31-32
Abnormal urine	33-34
Neurologic: Rigidity	35-36
Tremor	37-38
Dystonic symptoms	39-40

ROW NO.	*Mark each item on left half of sheet on row specified*
	5. CATALOGUE OF SYMPTOMS (Continued)
1-2	Neurologic: Akathisia
3-4	Autonomic: Dry Mouth
5-6	Nasal Congestion
7-8	Blurred Vision
9-10	Constipation
11-12	Increased Salivation
13-14	Sweating
15-16	Nausea/Vomiting
17-18	Diarrhea
19-20	Cardiovascular: Hypotension
21-22	Syncope/Dizziness
23-24	Tachycardia
25-26	Hypertension
27-28	EKG Abnormality
29-30	Other: Dermatologic
31-32	Weight Gain
33-34	Weight Loss
35-36	Anorexia/Decreased Appetite
37-38	Headache
39-40	Tardive Dyskinesia
	6. GLOBAL JUDGMENTS *(Omit at Pretreatment)*
	a. Compared to other subjects in this study, how serious have his/her treatment emergent symptoms been? 0 = Not at all 1 = Minimal 2 = Moderate 3 = Marked 4 = Not Ascertained
41	b. Compared to other subjects in this study, how much distress has this subject expressed or attributed to his symptoms? 5 = Not at all 6 = Minimal 7 = Moderate 8 = Marked 9 = Not Ascertained

The Dosage Record and Treatment Emergent Symptom Scales (DOTES) is a 41-item scale formatted for use with the General Scoring Sheet. Processing experience with the separate Dosage Record (DR) and Treatment Emergent Symptoms Scale (TESS) revealed that subsequent collation of the data was frequently fraught with errors. By combining the two scales, the rater is spared the tedium of redundant coding; and, more importantly, the emergent symptoms can be related to a specific dosage. Further, the combined scale is designed to capture judgments on the relationship of a symptom to the drug and the action undertaken as well as the intensity of that symptom. These three judgments - linked to a specific dosage - allow for a more precise documentation of the adverse event. DOTES supersedes both 02-DR Dosage Record and 03-TESS Treatment Emergent Symptom Scale. The scale is contained in both the Children's and Adults' Psychiatrist Packets.

APPLICABILITY — All populations

UTILIZATION — Completed for every dosage change. A pretreatment and terminal DOTES should always be completed.

ITEM FORMAT

CARD 01 (19x, I1, 2I4, I3, 3I1, 1313, I2) - Each symptom requires a 3-column field. 1st column - Intensity; 2nd column = Relationship; 3rd column = Action.

Item	Column	Item	Column
1	20	Dec.motor	47 - 49
2a	21 - 24	Insom.	50 - 52
2b	25 - 28	Drowsi.	53 - 55
2c	29 - 31	Abn.hemat.	56 - 58
3a	32	Abn.liver	59 - 61
3b	33	Abn.urine	62 - 64
4	34	Rigid	65 - 67
5 Toxic	35 - 37	Tremor	68 - 70
Excite.	38 - 40	Dyston.	71 - 73
Depress.	41 - 43	Akath.(Intens/Rel)	74 - 75
Inc.Motor	44 - 46		

CARD 02 (19x, I1, 1813, I1)

Item	Column	Item	Column
Akath (Action)	20	Diarrhea	42 - 44
Mouth	21 - 23	Hypoten.	45 - 47
Nasal	24 - 26	Syncope	48 - 50
Bl.Vis.	27 - 29	Tachycard.	51 - 53
Constip.	30 - 32	Hyperten.	54 - 56
Inc.Sal.	33 - 35	EKG	57 - 59
Sweating	36 - 38	Dermat.	60 - 62
Nausea	39 - 41	Wt.Gain	63 - 65
		Wt.Loss	66 - 68
		Anorexia	69 - 71
		Headache	72 - 74
		Tardive (Intensity)	75

CARD 03 (19x, I2, 2I1)

Item	Column
Tardive (Rel/Action)	20 - 21
6a Severity	22
6b Distress	23

FACTOR FORMAT - CARD 51 = (19x, 7F6.2, F4.0)

Code "5" in Column 18 indicates factor, cluster or other derived scores.

Factor	Column	Factor	Column
I	20 - 25	V	44 - 49
II	26 - 31	VI	50 - 55
III	32 - 37	VII	56 - 61
IV	38 - 43	Total Score	62 - 65

Total Score = Sum of all symptoms (including TWIS)

FACTOR COMPOSITION

Six factors have been derived from a 1974 BLIPS analysis of 1963 pretreatment TESS records. (Table 12). A seventh "factor" - actually an empirical cluster - is composed of the 3 Abnormal Laboratory Findings.

I. Anti-cholinergic (ANT)
- Drowsiness
- Nasal Congestion
- Dry Mouth
- Blurred Vision

II. Central Nervous System (CNS)
- Rigidity
- Tremor
- Dystonic
- Akathisia
- Increased Salivation

III. Neurotic (NEU)
- Insomnia
- Depression
- Constipation
- Headache
- Weight Loss

IV. Autonomic Nervous System (ANS)
- Hypotension
- Syncope/Dizziness*
- Tachycardia
- Nausea/Vomiting
- Diarrhea

V. Miscellaneous (MIS)
- Dermatologic
- Weight Gain

VI. Delirium (DEL)
- Excitement
- Toxic Confusion

VII. Abnormal Laboratory Findings (LAB)
- Abnormal Hematologic
- Abnormal Liver
- Abnormal Urine

Symptoms not included in any factor
- Increased motor activity
- Decreased motor activity
- Sweating
- EKG Abnormality
- Anorexia/Decreased Appetite
- Tardive Dyskinesia

* Dizziness now combined with syncope

TABLE 12

6-FACTOR VARIMAX SOLUTION OF PRETREATMENT TESS

SCORES OF 1963 SCHIZOPHRENIC SUBJECTS (Guy and Cleary)

Item	I	II	III	IV	V	VI	Communalities
Insomnia	-011	032	-685	-094	106	242	549
Drowsiness	-482	018	-031	-025	-092	171	272
Excitement	-134	045	-040	-100	-100	528	320
Depression	007	-040	-733	-201	073	123	600
Toxic Confusion	038	059	-107	036	-007	612	392
Rigidity	-062	660	059	143	-039	033	466
Tremor	-171	574	-121	049	-075	118	395
Dystonia	162	578	073	-191	124	002	418
Akathisia	-019	708	-030	-003	-035	-099	514
Hypotension	059	187	098	-556	-050	-304	452
Syncope	-021	005	-029	-653	-015	041	430
Tachycardia	-234	005	-220	-530	-076	040	391
Nasal Congestion	-713	014	083	-072	081	055	530
Dry Mouth	-629	196	-251	-073	007	-123	517
Incr. Salivation	-217	328	128	-109	182	206	259
Blurred Vision	-612	089	-105	-199	-012	-008	434
Nausea	-261	-102	-095	-358	164	092	251
Diarrhea	-129	-059	-145	-470	-059	189	301
Constipation	-307	172	-517	060	090	-301	493
Dermatitis	-060	-078	047	054	743	-058	570
Headache	-187	-116	-467	-295	178	327	493
Dizziness	-282	-022	-454	-278	-018	279	442
Wt. Gain	065	070	-138	035	521	-036	302
Wt. Loss	010	-088	-498	100	-216	-301	402
V_p	1.99	1.88	2.19	1.73	1.05	1.35	10.19
Percent Total Variance	19.5	18.4	21.5	16.9	10.3	13.2	42.5
Percent Common Variance	8.3	7.8	9.1	7.2	4.4	5.6	

SPECIAL INSTRUCTIONS

DOTES is the most difficult form to encode since the data are not as "fixed in time" as are efficacy measures. The advent of side effects and the need for dosage manipulations are much more idiosyncratic and not readily scheduled in a pre-determined protocol. Raters should, therefore, pay particular attention to the following instructions.

PERIOD - Whenever feasible, encode period in days since it will permit the more precise delineation of effects.

Item 1. Reason for completing scale - Preferably DOTES should be completed for each dosage change and/or occurrence of treatment emergent symptoms. The first 6 response positions are related directly to changes in dosage; while the last three (7, 8, 9) are to be employed for unique situations. Only one response is permitted for each DOTES.

1. "Per protocol" refers to all planned dosage changes established prior to the study. The final (terminal) dose should be encoded under "Per Protocol" and Total Daily Dose encoded as "0000".

2. Ineffectiveness - includes instances of increased psychopathology (worsening) as well as instances where psychopathological condition is unchanged, unimproved or static.

3. Toxicity - refers to changes which in the judgment of the clinician are the result of an untoward effect of the medication; i.e., to be distinguished from ineffectiveness (2).

4. Titration - refers to changes which are made to enhance therapeutic response in the individual subject; i.e., "test doses".

5. Discontinued/suspended - refers to unplanned interruptions in dosage schedule. Encode "5" here and "0000" for Total Daily Dose.

6. Reinitiated - use this category when restarting medication following suspensions. (5)

7. "Changeover point" refers to planned switches of medication and is for use only in crossover designs. Encode the dosage of the new medication as usual.

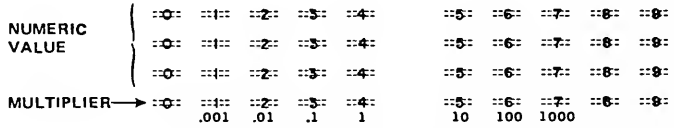
8. "Not changed but treatment emergent symptom/s occurred" - Although the dosage is unchanged from previous one, it should nevertheless be encoded again rather than left blank.

9. "Regular TESS assessment" - Enter dosage whether or not the regular TESS assessment coincides with an actual dosage change. "Regular TESS assessment" refers to the use of the scale independent of dosage change, i.e., using the DOTES in the manner of the original TESS, e.g., fixed periods of assessment which are scheduled prior to the start of the study.

Item 11. Total Daily Dose - DOTES' time perspective requires the rater to be like Janus - looking simultaneously in two directions, forward for dosage; backward for symptoms. The dosage which he encodes is the dosage which he is going to give - not the dosage which has been given. Conversely, the symptoms which he cites have occurred under the previous dosage - not the one actually encoded on the form.

Example: For the first 6 days of the study, the patient received a total daily dose of 100 mg. of drug. On Day 007 - on which the patient is still receiving 100 mg - the physician increases the dosage to 150 mg and records this new dosage on DOTES. He then encodes nasal congestion and headache - two symptoms which have occurred under the old (100 mg) dosage.

To permit the coding of the widest range of dosages and, at the same time, minimize the number of "marks" required of the rater, the following 4-row schema has been constructed. Three rows are provided for the coding of the numeric value and one row for the multiplier.

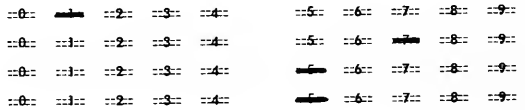


The multiplier row designates the placement of the decimal point.

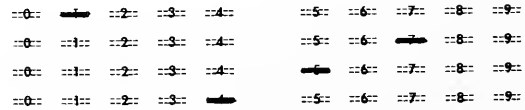
1 = .001; 2 = .01; 3 = .1; 4 = 1; 5 = 10; 6 = 100; 7 = 1000.

Examples:

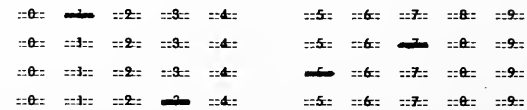
1. To enter 1750 mg; translate as 175 x 10
   Encode 1755



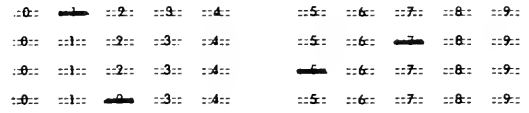
2. To enter 175 mg; translate as 175 x 1
   Encode 1754



3. To enter 17.5 mg; translate as 175 x .1
   Encode 1753



4. To enter 1.75 mg; translate as 175 x .01
Encode 1752



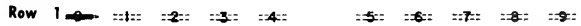
ALL FOUR ROWS MUST CONTAIN AN ENTRY. Blanks are not permitted and will be "read" by the computer as missing data. Therefore, all leading and following zeros must be marked. For 1 mg., code 0014, NOT __ __ 14; for 100 mg., code 1004, NOT 1 __ __ 4.

For single drugs, i.e., drugs with one chemical component, complete Item IIa only. For combination drugs, encode Component A in IIa and Component B in IIb. Even if the dosage for only one component of the combination is being changed, encode BOTH the "changed" and "unchanged" components. In a given study, always encode the components in a consistent fashion, i.e., A in IIa, B in IIb.

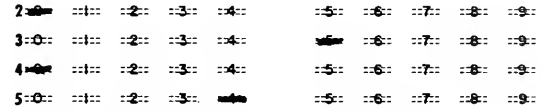
Item IIc. The sole purpose of this item is to record dosage regimes which can not be adequately described by Total Daily Dose. In all other circumstances, it should be left blank.

Examples: A depot drug is presumed to be effective for 2 weeks. The investigator plans to administer an initial dose of 50 mg. He encodes as follows:

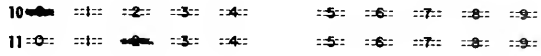
I. REASON FOR COMPLETING SCALE (0 = initiated)



II. TOTAL DAILY DOSE (50 mg)
a. Component



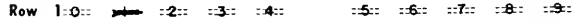
b. Component Rows 6-9 omitted; i.e., left blank.
c. Drug is presumed to be effective for: (2 weeks)



1 = hours; 2 = days; 3 = weeks; 4 = months

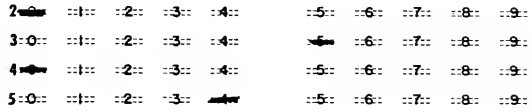
At the end of 2 weeks, the investigator plans to administer another 50 mg dose. He encodes as follows:

I. REASON (Marked as "1" - changed per protocol)



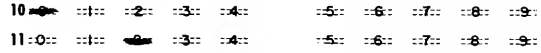
II. TOTAL DAILY DOSE (50 mg)

a. Component



b. Component - Rows 6 - 9 omitted; i.e., left blank

c. Drug is presumed to be effective: (2 weeks)



1 = hours; 2 = days; 3 = weeks; 4 = months

NOTE - For double-blind studies in which the rater is unaware of the actual dosage administered, the number of capsules or other units may be encoded rather than dosage. Later, when the data are processed, actual dosages can be calculated via computer.

Example: In a double-blind trial, the rater does not know the actual dosage contained in identical capsules (one capsule contains 100 mg of Investigational Drug; the other capsule contains 10 mg of Control Drug). The rater changes dosage by adding or subtracting the number of capsules given per day. To encode this information, he encodes the number of capsules in the 3-digit field for numeric value and encodes "8" in the multiplier. This will signal the computer that number of capsules - not dosage - has been encoded.

III. Prescription - ERRATA: The phrase within the parentheses following the word "prescription" should read "(No. 0 through 6)" NOT (No. 1 through 6). This item requires 2 responses - one for prescription (0-6) and one for proportions (7 and 8).

Example: The total daily dose of 300 mg is to be given "tid" in equal proportions of 100 mg. each. Code as follows:

"Depot", which refers to a drug contained in a vehicle allowing for slow release and long action, should always be coded as equal proportions. Similarly, QD, HS and PRN are coded as equal proportions.

Example: The drug is prescribed "QD". Encode "1" AND "7"

13 ::0:: ::1:: ::2:: ::3:: ::4:: ::5:: ::6:: ::7:: ::8:: ::9::

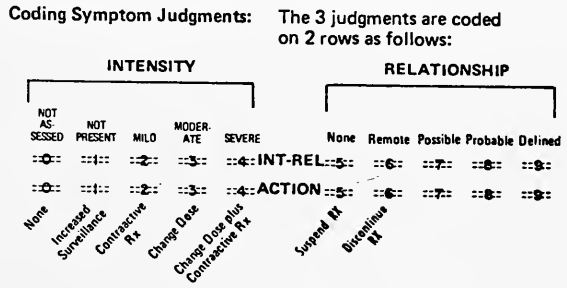
IV. Presence/absence of symptoms - Since symptoms other than those printed on the scale can occur and should be recorded, a separate "write-in" form has been provided (033-TWIS). on DOTES, three "YES" positions are necessary as signals to instruct the computer in its search for data. In the case where only write-in symptoms are present, encode response 3 - leave all the catalogue of symptoms blank (Item 5) - but be sure to answer Item 6, Global Judgments.

V. Catalogue of Symptoms - Originally it was thought desirable to have raters encode some response for each and every symptom whether present or absent. Whatever the merits of insisting on positive responses, the notion has been troublesome for raters - as reflected in the high incidence of errors. Therefore, raters need ENCODE ONLY THOSE SYMPTOMS PRESENT OR NOT ASSESSED. Leave the rest of the catalogue blank. Be extra careful, however, that you are encoding data on the appropriate rows.

The rater should endeavor to make an assessment of all symptoms printed on the scale as well as an inquiry into the occurrence of any other "non-printed" symptoms. The extent to which symptoms may be monitored is - in part - dependent upon the setting of the study, the sources of observation and the capacity of the subject to report their occurrence. In making judgments, it is suggested that the rater make use of all available sources of information, (nurses' observations, family comments, subject's complaints, etc.) Whenever possible, objective verification of the symptom should be attempted. General questions such as "How have you been feeling physically?"; "How does the drug make you feel?" may be utilized to elicit the occurrence of symptoms which are not directly observable or which have not been brought to light from other sources.

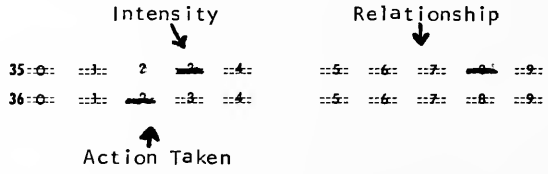
NOTE - Raters may find it helpful to duplicate the "Instructions - Catalogue of Symptoms" on page R-10 and paste copies on the backs of pages L-3 and R-11 where they will be more accessible during rating.

For each symptom cited (present), three (3) judgments are required - intensity of the symptom, its relationship to the drug and the action undertaken as a consequence of its presence. The 3 judgments are coded on 2 rows as follows:



On the row labeled INT-REL, the rater makes a judgment of intensity - using response positions 0 through 4 and a judgment of relationship - using 5 through 9. On the row labeled ACTION, the rater records the action (if any) undertaken - using 0 through 6.

Example: The symptom "Rigidity" emerges and the rater judges it to be moderate in intensity and probably related to the drug employed. She prescribes an antiparkinson drug. Encoding is as follows:



a. Intensity - Precise definition of the levels of intensity is complicated. Many symptoms are subjective; i.e., not directly observable; and, further, no established standards exist for rating intensity. (See NOTE below). Generally, however, the 3 levels may be defined as:

2 = Mild — the symptom does not hinder the subject's normal functioning level, i.e., his level at pretreatment. An annoyance to the subject. Evidence for the presence of the symptom may be equivocal or based entirely on subjective report.

3 = Moderate - the symptom produces some degree of impairment to functioning but is not a hazard to life. Uncomfortable and/or embarrassing to the subject. Evidence for the presence of the symptom is clear-cut, i.e., directly observable and/or deduced from the subject's behavior.

4 = Severe — Symptom is a definite hazard to well being. Significant impairment of functioning or incapacitation. Again, evidence is clearcut.

Intensity should be rated independently without regard to its relationship to drug. Since there is a high degree of correlation between intensity and the action undertaken as a consequence of a symptom, however, raters may find that they differentiate intensity levels partially on the basis of action.

b. Relationship - a judgment of the degree of relationship between the occurrence of the symptom and the drug rated on a 5-point scale.

5 = None - no relationship.
6 = Remote - less than a 10% probability that symptom occurrence is related to drug employed.
7 = Possible - probability between 10% and 50%.
8 - Probable - probability between 50% and 90%.
9 = Defined - greater than 90% probability that symptom occurrence is related to drug employed.

c. Action Taken - refers to action taken as a consequence of the symptom's appearance. Actions are arranged in order of increasing stringency. Only ONE action - the most stringent - should be recorded as it is assumed that less stringent actions may also be employed.

0 = None - no action is taken; the symptom is simply cited as present by the investigator.
1 = Increased surveillance - Increased alertness over and above routine observation is required by the professional staff, the subject's relatives and/or the subject himself.
2 = Contraactive Rx - Remedial medication or treatment is prescribed. Include all medications and treatments which, in the opinion of the physician, are administered in response to the presence of an adverse reaction/s.
3 = Change dose - Any non-protocol change (increase or decrease) ordered as a consequence of adverse reaction/s.
4 = Change plus Contraactive Rx - A combination of actions 2 and 3 undertaken simultaneously.
5 = Suspend Rx - Cessation of treatment for a period of time as a consequence of an adverse reaction. Be sure to encode response 6 (Item 1) when reinitiating medication.
6 = Discontinue Rx - A decision to stop medication completely as a consequence of adverse reaction/s. Do not rate the termination of treatment as planned in the protocol here. Such "planned" termination is considered "Per Protocol".

Item VI. a. Global Severity. An overall judgment - similar to the widely used efficacy judgment - of the extent to which treatment emergent symptoms have affected the subject in comparison to all other subjects in the study. Omit the item at the pre-treatment rating.

b. Degree of distress. An overall judgment of the subject's degree of distress attributed by him to "adverse reactions" in comparison to all other subjects in the study. The subject's degree of distress is judged here - not the accuracy of his attributions. Omit the item at pretreatment.

NOTE ON DEFINING INTENSITY

In the near future, it is planned to distribute a questionnaire among ECDEU participants in an attempt to derive objective standards for the rating of intensity levels of treatment emergent symptoms. This technique has been successful in the past in obtaining consensual definitions - the new DOTES itself being a prime example. In the interim, the following list of definitions is presented as guidelines for rating the intensity of symptoms in adults. The sources for these definitions are:

1. Vinar, O., Scale for Rating Side Effects during Psychiatric Psychopharmacology, Activ. Nerv. Super. 8, 4, 411-412, 1966.
2. Schiele, B., Parkinson's Disease Rating Scale
3. McGlashan, T., Personal Communication

CATALOGUE OF SYMPTOMS

1. Toxic Confusional State (Vinar)

   Moderate - Transitory toxic confusion during night
   Severe - Toxic confusion lasting during daytime

2. Excitement/Agitation (McGlashan)

   Mild - Expressed fear and anxiety
   Moderate - Expressed fear and anxiety and frequent - but not constant - agitated motor movements
   Severe - Expressed fear and anxiety with constant agitated motor movements; e.g., pacing, wringing of hands, etc.

3. Depressive Affect (McGlashan)

   Mild - Complains of depressed mood when questioned
   Moderate - Volunteers feelings of depression and hopelessness. Cries easily.
   Severe - Mimics full blown depressive episode with psychomotor retardation, etc.

4. Increased Motor Activity (McGlashan)

   Mild - Increased - but not constant - activity which can be self controlled
   Moderate - Constant activity but no external controls needed
   Severe - Constant activity; external controls needed

5. Insomnia (McGlashan)

   Mild - Loss of 2 hours from regular sleep pattern
   Moderate - Loss of 3 - 6 hours
   Severe - Loss of more than 6 hours

6. Drowsiness (McGlashan)

   Mild - Dozing or sleeping the equivalent of 2 hours during daytime
   Moderate - The equivalent of 2 - 8 hours/day
   Severe - More than 8 hours; asleep most of the time but not comatose

7. Liver Functions (Vinar)

   Moderate - Changes in the liver tests
   Severe - Jaundice

8. Rigidity (Schiele)

Mild - Detectable rigidity in neck and shoulders. Activation phenomenon is present. One or both arms show mild, negative, resting rigidity.
Moderate - Moderate rigidity in neck and shoulders. Resting rigidity is positive when patient not on medication.
Severe - Severe rigidity in neck and shoulders. Resting rigidity cannot be reversed by medication.

9a. Tremor (Schiele)

Mild - Less than one inch of peak-to-peak tremor movement observed in limbs or head at rest or in either hand while walking or during finger to nose testing.
Moderate - Maximum tremor envelope fails to exceed 4 inches. Tremor is severe but not constant and patient retains some control of hands.
Severe - Tremor envelope exceeds 4 inches. Tremor is constant and severe. Patient cannot get free of tremor while awake unless it is a pure cerebellar type. Writing and feeding himself are impossible.

9b. Tremor (Vinar)

Mild - A feeling of inner tremble or tremor, which is not objectively visible, unless a little when the arms are stretched in front of the body and the eyes are closed.
Moderate - Clear, objectively visible tremor, not preventing the patient from work (not even a fine work or writing)
Severe - Greater tremor, preventing the patient from precise manual work. Big tremor, the patient cannot even eat.

10. Dystonic Symptoms (McGlashan)

Mild - Rigidity without impaired mobility
Moderate - Interferes with mobility but not incapacitating
Severe - Incapacitated (motoric mobility)

11. Akathisia (Vinar)

Mild - Subjectively felt "inner agitation", lack of patience; the patient resists it.
Moderate - Lack of patience makes the patient stand up during conversation; when working, he stands up now and then and walks a little. The conversation, however, is not interrupted and the work is finished in due time.
Severe - The patient cannot keep sitting even when consulting the doctor, must walk along the room; his rate of work is substantially reduced, cannot read even one page of a book without break. Impatience and agitation prevent the patient completely from any useful activity; he must be walking continuously, cannot master himself.

12. Dry Mouth (Vinar)

Mild	Mucuous membranes are dry; the patient complains of it.
Moderate or Severe	Mucuous membranes are so dry that it can be seen by the observer clearly.

13. Nasal Congestion (Vinar)

Mild	Feeling of stopped-up nose - or a very disagreeable feeling of completely dry membrane in the nose.
Moderate or Severe	A stopped-up nose - it may be observed and proved (as the patient speaks, etc.)

14. Blurred Vision (McGlashan)

Mild	Complaints of blurriness but little if any sensory impairment
Moderate -	Interferes with acuity
Severe	Interferes with acuity and motor movements, e.g., bumps into things

15. Constipation (Vinar)

Mild	Constipation for more than 36 hours
Moderate -	Constipation for more than 4 days
Severe	The patient needs to be given clysma

16. Increased Salivation (Vinar)

Moderate -	More saliva, the patient manages to swallow it.
Severe -	Saliva flows out of the mouth.

17. Sweating (Vinar)

Mild or Moderate	He sweats more than usually or in fits
Severe	Facies oleosa

18. Nausea/Vomiting (Vinar)

Moderate -	Nausea
Severe -	Vomiting

19. Diarrhea (McGlashan)

Mild	Two loose bowel movements per day
Moderate -	5 loose bowel movements/day
Severe -	Over 5/day

20. Hypotension (Vinar)

Mild Blood pressure one tenth lower than before treatment
Moderate - Blood pressure two tenths lower
Severe - Blood pressure scarcely measurable

Note: This evaluation does not refer to subjective troubles that may be in connection with hypotension. There is only the question of objectively measured values of blood pressure with mobile patients in sitting and immobile patients in lying.

21. Syncope/Dizziness (McGlashan)

Mild Transient feelings of dizziness either standing or sitting with no interference with equilibrium.
Moderate - Dizziness with disequilibrium. No unconsciousness.
Severe - Unconsciousness

22. Tachycardia (Vinar)

Mild The heart rate is between 90 and 100/min. in subjects where it was under 80/min. before treatment.
Moderate - The heart rate is between 100 and 120/min.
Severe - The heart rate is over 120/min.

Note: The heart rate is recorded in the morning before the patient leaves his bed.

23. Hypertension McGlashan)

Mild Blood pressure 140/90
Moderate - 160/100
Severe - 200/120

24. Dermatologic (Vinar)

Mild Photosensitivity (the patient complains and/or is more sunburnt than usual).
Moderate - Itch, rash, transitory
Severe - Dermatitis

25. Weight Gain (McGlashan)

Mild Gain of 5 pounds in one month
Moderate - Gain of 6 - 10 pounds/month
Severe - Over 10 pounds gain in one month

26. Weight Loss (McGlashan)

Mild - Loss of 5 pounds in one month
Moderate - Loss of 6 - 10 pounds/month
Severe - Over 10 pounds/month

27. Anorexia/Decreased Appetite (McGlashan)

Mild - Subject consumes the equivalent of 2 meals/day
Moderate - The equivalent of 1 meal/day
Severe - Does not eat

28. Headache (McGlashan)

Mild - Subjective complaint with no impairment
Moderate - Sensory input painful but not incapacitating
Severe - Incapacitating

DOCUMENTATION

Since DOTES is a crucial element in the documentation, the data displays provided for it are extensive and, to a large extent, unique - requiring discussion in detail.

a. Raw score printout - Follows the schema given in the Documentation section. (p.474).
b. Cumulative factor scores - Factor scores along with total score are the variables employed in the quantitative analysis of DOTES. Unlike most efficacy measures, however, DOTES is not necessarily completed on a fixed schedule since differences in treatment response and/or the emergence of adverse reactions among subjects are to be expected. These individual differences produce variations in temporal order which make nomothetic analyses extremely difficult. By restructuring the DOTES data set, however, a temporal uniformity - necessary for analysis - can be achieved. The method chosen involves accumulating individual DOTES by time spans which correspond to those designated in the protocol for the major efficacy measure/s. Factor scores along with total score are first computed for each DOTES and then all DOTES within the specified time span are added together to produce cumulative scores. The display of these scores follows the schema for such data given in the Documentation section. (p.474).
c. Individual summary - This display (Table 13) provides a detailed record of events on an idiographic level. Emergent symptoms and their attributes are linked directly to a given dosage level (total daily dose and cumulative dose) so that the investigator can follow the treatment course within the individual subject.

d. Dosage by groups - This display summarizes dosage events by group and is organized by uniform time spans (Table 14). Treatment groups are juxtaposed so that the investigator can make direct comparisons.
e. All symptoms by group - A group summary of symptom events by uniform time spans (Table 15).
f. Drug-related emergent symptoms - This group display enumerates ONLY those symptoms which meet the following criteria:
    1. The symptom is not present in a subject at pretreatment.
    2. Relationship is judged to be either "Probable" or "Defined".
    3. Some action - excluding "None" - is recorded.

    The display follows the schema given in Table 15.
g. Variance analyses - The format for these displays follows the schema given in the Documentation section (p. 490).

TABLE 13

STUDY NO. INVESTIGATOR'S NAME STUDY TITLE

DOSAGE RECORD AND TREATMENT EMERGENT SYMPTOMS (DOTES AND TWIS) INDIVIDUAL SUMMARY

GP 1 DOSAGE UNITS = MG;

PAT 001

PAT	PER	REAS	DOSAGE AMOUNT PER DAY	CUM(%)	PRESC	PROP	SYMPTOM	INT	REL	ACT	GLOBAL SEV	GLOBAL DIST
001	001	PROT	100	100 (5)	BID	E	AKATHISIA	MI	NO	NON		
							HEADACHE	MI	POS	CON	NOT	MIN
001	007	PROT	200	700(20)	TID	U	RIGIDITY	MI	PRO	SUR		

N

CUM = CUMULATIVE DOSAGE
PRESC=PRESCRIPTION
PROP =PROPORTIONS
INT =INTENSITY
MI = MILD
REL =RELATIONSHIP
NO = NONE
POS= POSSIBLE
PRO= PROBABLE
ACT =ACTION
NON = NONE
CON = CONTRAACTIVE RX
SUR = INCREASED SURVEILLANCE
SEV = GLOBAL SEVERITY
DIST= SUBJECT DISTRESS
NOT = NOT AT ALL
MIN = MINIMAL

TABLE 14

STUDY NO. INVESTIGATOR NAME STUDY TITLE

DOSAGE RECORD AND TREATMENT EMERGENT SYMPTOMS (DOTES AND TWIS) DOSAGE BY GROUP

DAYS	N	MIN	MAX	DAILY	CUMU	(%)	PRO	INF	TOX	TIT	DIS	REN
PRETREAT*												
GP 1	XX	-	-	XXX	-		XX(%)	XX(%)	XX(%)	XX(%)	XX(%)	XX(%)
GP 2	XX	-	-	XXX	-		XX(%)	XX(%)	-	-		
-		-	-	-	-							
-		-	-									
001-007**												
GP 1		XXX	XXX	XXX	XXXX	(XX)						
GP 2		XXX	XXX	XXX	XXXX	(XX)						
-		-	-	-								
-		-	-									
008-014												
GP 1		XXX	XXX									
GP 2		XXX	-									
-												
ALL PERIODS												
GP 1		XXX	XXX	XXX								
GP 2		XXX	XXX	XXX								
-												

PRETREAT = INITIAL TOTAL DAILY DOSE GIVEN UNDER "DAILY"

001-007** = TIME SPAN IN DAYS FOR WHICH MEANS AND REASON APPLY: TIME SPAN DETERMINED BY ASSESSMENT INTERVALS OF MAJOR PSYCHIATRIC RATING SCALE

MIN = MEAN MINIMUM DOSAGE (LOWEST DOSAGE DURING TIME SPAN)
MAX = MEAN MAXIMUM DOSAGE (HIGHEST DOSAGE DURING TIME SPAN)
DAILY = MEAN TOTAL DAILY DOSAGE DURING TIME SPAN
CUMU (%) = MEAN CUMULATIVE DOSAGE AND CUMULATIVE PERCENT AT END OF TIME SPAN
PRO = PROTOCOL (INCLUDES INITIATED, CROSSOVER AND REGULAR TESS)
INF = INEFFECTIVENESS DIS = DISCONT/SUSPEND
TOX = TOXICITY REN = REINITIATE
TIT = TITRATION

TABLE 15

STUDY NO. INVESTIGATOR NAME STUDY TITLE

DOSAGE RECORD AND TREATMENT EMERGENT SYMPTOMS - SYMPTOMS BY GROUP
GROUP I

	TOT		INTENS			RELAT					ACTION						
DAY 000	SUB	OCC	MI	MO	SV	NO	RE	PO	PR	DE	NO	SR	CO	CH	C+C	SU	DE
AKATH	XX	XX	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
RIGID	XX	XX	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
INSOM	XX	XX	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
DAY 001-007																	
AKATH	XX	XX	XX	X	X	X	X	X	X	XX	X	X	XX	X	X	X	X
RIGID	XX	XX	XX	X	X	X	X	X	X	XX	X	X	X	XX	X	X	X
DAY 008-014																	
AKATH	XX	XX	XX	X	X	X	X	X	X	X	X	X	X	X	X	X	X
RIGID	XX	XX	XX	X	X	X	X	X	X	X	X	X	X	X	X	X	X
HYPO	XX	XX	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
ALL PERIODS																	
AKATH	XX	XX	XX	XX	XX	-	-	-	-	-	-	-	-	-	-	-	-
RIGID																	

032 PTR
PATIENT
TERMINATION
RECORD

MH-9–32
1-73

PATIENT TERMINATION RECORD

INSTRUCTIONS: *Insert New General Scoring Sheet and Code 04 for Sheet Number*

To be completed at the termination of the subject from the study.

P
T
R

Mark on right half of scoring sheet on row specified

1. REPEATER

a. Has the patient ever been a research subject before? 0 = No; 1 = Yes; 9 = Not Ascertained — ROW NO. 1

b. If YES, was the patient a subject in a study in which the data was sent to the Biometric Laboratory? 0 = No; 1 = Yes; 9 = Not Ascertained — ROW NO. 2

c. If YES, for the most recent previous study, give:

1. ECDEU study number 3-8
2. Patient's number in that study . . . 9-11

2. DURATION

a. Total number of days in this study 12-14

b. Was patient prematurely terminated? *(Give major reason):* — ROW NO. 15

0 = Not prematurely terminated
1 = Did not return for treatment or refused treatment
2 = Adverse reaction
3 = Ineffectiveness or deterioration
4 = Improvement
5 = Intercurrent illness
6 = Found not to meet study criteria
7 = Dosage/Medication error or violation
8 = Administrative

3. INTERVAL HISTORY

During the course of the study, were there any significant events or changes — external to treatment situation — in the subject's life situation? — ROW NO. 16

0 = No significant events or changes
1 = Catastrophic event — fire, flood, financial disaster, accident, etc.
2 = Death of significant other
3 = Physical/mental illness of significant other
4 = Difficulties in relationships with relatives or peers — spouse, children, family, lover, friends, fellow employees, etc.
5 = Decrease in status and/or responsibility — layoff, dismissal, demotion or retirement from employment, school failure, loss of hospital privileges, rejection by or dissolution of family unit by divorce, separation or inability to perform household responsibilities
6 = Improvement in relationships with relatives or peers
7 = Increase in status and/or responsibility — promotion in school or employment, new employment, marriage or reuniting of family unit, increased hospital privileges
8 = Pregnancy of subject (spouse or parents) and/or birth of child/sibling

Continue marking on right half of scoring sheet on row specified

4. NON-DRUG TREATMENT

a. Did the subject receive any non-drug treatments during the course of the study? 0 = No; 1 = Yes — ROW NO. 17

b. If YES, rate the effectiveness of all treatments received: *Mark row in appropriate column*

Treatment	Efficacy Unknown	Unsatisfactory	Equivocal	Satisfactory	ROW NO.
Behavior modification	0	1	2	3	18
Electroconvulsive therapy					19
Milieu therapy					20
Physical therapy					21
Psychotherapy — group					22
Psychotherapy — individual					23
Rehabilitation/occupational therapy					24
Remedial educational therapy					25

c. Did the subject's spouse/family receive therapy/counseling as part of the subject's overall treatment regime? 0 = No; 1 = Yes — ROW NO. 26

d. If YES, rate the effectiveness of the therapy/counseling: — ROW NO. 27

0 = Efficacy unknown
1 = Unsatisfactory
2 = Equivocal
3 = Satisfactory

5. DRUG INTAKE

How well did the patient follow his drug regime? — ROW NO. 28

0 = Not applicable, did not receive drugs
1 = Took study medication as prescribed
2 = Some irregularities but primarily took study medication as prescribed
3 = Suspected significant irregularities
4 = Confirmed significant irregularities
5 = Took additional medication in violation
9 = Not ascertained

6. ANCILLARY MEDICATION

a. During the course of the study, did the subject receive any ancillary medication/s other than test/control drug/s? 0 = No; 1 = Yes — ROW NO. 29

b. If YES, rate the effectiveness of all ancillary medication received:

Ancillary Medication	Efficacy Unknown	Unsatisfactory	Equivocal	Satisfactory	ROW NO.
Analgesic-narcotic	0	1	2	3	30
Analgesic-non-narcotic					31
Anesthesia-general					32
Anesthesia-local					33
Antiallergenic					34
Anticoagulant					35
Anticonvulsant					36
Antifertility					37
Antihypertensive					38
Antimicrobial					39
Antiparkinson					40
Antitumor					41

PATIENT TERMINATION RECORD

ROW NO.	6. ANCILLARY MEDICATION (Continued)				
	Mark on left half of scoring sheet on row specified	Efficacy Unknown	Unsatis-factory	Equivocal	Satis-factory
1	. . Blood tonic	0	1	2	3
2	. . Bronchodilator				
3	. . Cardiac medication				
4	. . Cough & cold preparation				
5	. . Dermatological preparation				
6	. . Diabetic medication				
7	. . Diet medication				
8	. . Diuretic				
9	. . Gastrointestinal preparation				
10	. . Hormonal medication				
11	. . Muscle relaxant				
12	. . Psychotropic medication *(other than test or control drug)*				
13	. . Sedative/hypnotic				
14	. . Stimulant				
15	. . Thyroid medication				
16	. . Vitamin				

7. GLOBAL ITEMS

17 — a. Compared to other subjects, how well did this subject conform to study requirements?

- 0 = Much below average
- 1 = Below average
- 2 = Average
- 3 = Above average
- 4 = Much above average

18 — b. Given the choice, would you continue this subject on his study medication?

- 0 = Definitely no
- 1 = Inclined to say no
- 2 = Undecided
- 3 = Inclined to say yes
- 4 = Definitely yes

8. DISPOSITION AT TERMINATION *Answer either "a" or "b"*

19 — a. **Inpatients**

- 0 = Elopement or discharge against medical advice
- 1 = Remains hospitalized and has lost privileges and/or work assignments previously held; e.g., loss or decrease in passes, or freedom of movement within hospital, loss of or decrease in industrial therapy assignments, transfer to more closely supervised wards
- 2 = Remains hospitalized and status is unchanged from pretreatment
- 3 = Remains hospitalized and has earned greater privileges and/or work assignments, e.g., formal industrial therapy assignments, day or night passes, transfers to wards with less supervision

Continue "Inpatients" on next page — **R–13**

ROW NO.	*Continue marking on left half of scoring sheet on row specified*
19 Cont.	a. Inpatients *(continued)* 4 = Paroled or discharged to a supervised living situation in community, e.g., foster home, halfway house, day hospital, community mental health clinic, etc. 5 = Paroled or discharged to own custody or own family. Include patients discharged with recommendation to continue treatment with family physician; on OPD basis, etc. 6 = Transferred or discharged for reasons unrelated to present treatment, e.g., intercurrent illness or accident, administrative reasons, etc.
20	b. **Outpatients** 0 = Discharged against medical advice, e.g., refused treatment, did not return for treatment, family uncooperative, etc. 1 = Hospitalized (transferred to inpatient status) because of exacerbation or deterioration of psychiatric condition 2 = Remains on outpatient status and treatment is intensified because of exacerbation or deterioration of psychiatric condition, e.g., greater psychiatric supervision, partial hospitalization such as day or night hospital, etc. 3 = Remains on outpatient status and status is unchanged from pretreatment 4 = Remains on outpatient status and treatment is reduced because of improvement of psychiatric condition; e.g., less supervision, more widely spaced visits, etc. 5 = Discharged to own custody or own family. Include patients discharged with recommendation to continue treatment with family physician or to seek treatment independently. 6 = Transferred or discharged for reasons unrelated to present treatment, e.g., intercurrent illness or accident, administrative reasons, geographical relocation, etc.

Developed within the ECDEU program, the Patient Termination Record (PTR) consists of 8 items and is formatted for use with the General Scoring Sheet. The items of the PTR focus on the historical events of the study itself; e.g., the course and length of treatment, ancillary treatments, disposition of termination, etc. The information elicited by the PTR is essential for the complete documentation and evaluation of a study. The PTR evolved from and now replaces the Drug Study Resume (04-DSR).

APPLICABILITY — All research populations

UTILIZATION — Once per subject. Completed at the time of the subject's termination from the study.

TIME SPAN RATED — The length of the study; from entrance to termination.

CARD FORMAT - ITEMS — CARD 01 = (19x, 211, 19, 13, 11, 12, 3911)

Item	Column	Item	Column
1a	20	4a	37
1b	21	4b 1 - 8	38 - 45
1c	22 - 30	4c	46
2a	31 - 33	4d	47
2b	34	5	48
3	35 - 36	6a	49
		6b 1 - 26	50 - 75

CARD 02 = (19x, 611)

Item	Column	Item	Column
6b27	20	7b	23
6b28	21	8a	24
7a	22	8b	25

SPECIAL INSTRUCTIONS

Item 1. Repeater - This item has been included on the PTR for technical reasons rather than for its pertinence to termination status. (Translation - It didn't fit no place else!) The item enables BLIPS to identify all individuals who have been participants in more than one study and, further, to identify those who have multiple data sets in the ECDEU data bank. If the subject has participated in several previous studies, the rater should encode the identification data from the most recent study. Identification of a repeater requires 9-digit code as follows:

X X X	X X X	X X X
Unit #	Study #	Pat. #
Rows 3-5	6-8	9-11

If the subject has never been a repeater, leave items 1b and 1c blank. If the subject has been a repeater but does not have data in the ECDEU bank, leave Item 1c blank.

Item 2a. Duration - Duration is defined as the number of days from a subject's entrance into a study to his termination. Entrance into a study is defined as the day of the initial assessment; termination as the day of the final assessment. Total number of days in the study may or may not coincide with total number of days under medication. Duration in studies in which a pretreatment drying-out period and/or a follow-up period are encompassed (bracketed) by assessments, for example, will exceed the actual duration of medication. (For detailed instructions, see "Coding Duration, p. 25). Notice that duration MUST BE CODED IN DAYS.

Example: The subject was in the study for 4 weeks. Encode 0, 2, 8 in Rows 12 - 14. Note that 28 days - NOT 4 weeks - is encoded and that the leading zero is included.

Item 2b. Premature Termination - Only ONE reason should be given. Definitions for the categories are as follows:

1 = Did not return for treatment or refused treatment - includes elopement; unauthorized leaves; rescinding of treatment permission by parents, relatives or legal guardian; sporadic or insufficient attendance of treatment appointments; refusal to cooperate with assessment and/or other research procedures.

2 = Adverse reaction - Any reaction, side effect or treatment emergent symptom which, in the opinion of the investigator, requires termination of drug treatment.

3 = Ineffectiveness or deterioration - Refers to lack of change or exacerbation of psychiatric symptomatology which, in the opinion of the investigator, is ethically unacceptable and, therefore, requires termination.

4 = Improvement - Refers to a degree of positive change (improvement) in psychiatric symptomatology which, in the opinion of the investigator, ethically requires release from treatment situation, e.g., discharge or parole from hospital; discharge from clinic or other agency.

5 = Intercurrent Illness - Refers to any non-treatment related illness or medical condition requiring termination of treatment. Pregnancy should be included here.

6 = Found not to meet study criteria - Refers to subjects erroneously admitted to study, e.g., lacks required target symptoms; does not fit age group; has a history incompatible with inclusion criteria.

7 = Dosage/medication error or violation - Includes errors or violations by either the subject or the staff which necessitate termination, e.g., "over" or "under dosing" by subject himself or by his relatives; intake of medications prohibited by protocol; dispensing errors in dosage and/or medication.

8 = Administrative - Includes transfers to other wards or hospitals; subject moving from area; drug withdrawn by company; personnel defections; protocol violations such as accidental revelation of treatment assignment codes, improper assessment procedures, introduction of services or activities prohibited by protocol.

Item 3. Interval History - This item (and Item 8) is written in general terms so that it might serve as wide a population as possible. Rather than specifying the exact nature of the event, the rater is asked to judge the effect of the event upon the subject. An external event or change is considered significant if, in the opinion of the investigator, it has had a substantial effect on the course of treatment.

1 = Catastrophic event - refers to any natural disaster, economic event, "act of God", etc.

4 = Difficulties in relationship with relatives or peers - refers to detrimental events or changes in the subject's emotional or social interactions which do not appear to be primarily related to treatment.

5 = Decrease in status and/or responsibility - includes any significant event or change which reflects a diminution in the subject's status or responsibility.

6 = Improvement in relationships with relatives or peers - non-treatment related events or changes which reflect facilitation of relationships.

7 = Increase in status and/or responsibility - any events or changes which enhance the subject's status or reflect increased responsibilities.

A MAXIMUM OF 2 ENTRIES may be made for this item. On card decks, the entries will be coded by a 2-digit code. The legal codes are given in Table 16.

Examples: 00 = No significant events
10 = Difficulties in relationships
31 = Catastrophic event and decrease in status

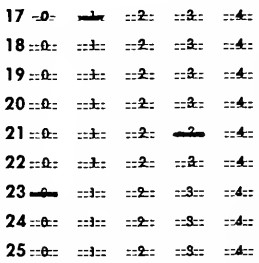
TABLE 16

PTR - ITEM 3 INTERVAL HISTORY

Card Code	NONE 0	EVENT 1	DEATH 2	ILLNESS 3	DIFFICULTY 4	DECREASE 5	IMPROVEMENT 6	INCREASE 7	PREGNANCY 8	Response Positions
00	X									0
01									X	8
02								X		7
03								X	X	7,8
04							X			6
05							X		X	6,8
06							X	X		6,7
07						X				5
08						X			X	5,8
09						X	X			5,6
10					X					4
11					X				X	4,8
12					X			X		4,7
13					X	X				4,5
14				X						3
15				X					X	3,8
16				X				X		3,7
17				X			X			3,6
18				X		X				3,5
19				X	X					3,4
20			X							2
21			X						X	2,8
22			X					X		2,7
23			X				X			2,6
24			X			X				2,5
25			X		X					2,4
26			X	X						2,3
27		X								1
28		X							X	1,8
29		X						X		1,7
30		X					X			1,6
31		X				X				1,5
32		X			X					1,4
33		X		X						1,3
34		X	X							1,2
88	ILLEGAL OR IMPROBABLE CODES									

Item 4a and 4b. Non-drug Treatments - If the answer to Item 4a is "NO", Item 4b may be left blank. A "YES" response to 4a requires that EACH TREATMENT RECEIVED must be evaluated.

Example: The subject did receive non-drug treatments. (Encode 1 in Row 17). Her response to physical therapy was satisfactory (Encode 3 in Row 21) while her response to individual psychotherapy was unknown. (Encode 0 in Row 23). Leave the other non-drug treatments blank.



Note: Items 4c, 4d, 6a and 6b are encoded in the same fashion.

Item 5. Drug Intake - Only one response is permitted.

Item 7a. This item requires a judgment of the behavior of the subject qua subject; i.e., how well did he follow the "rules" of the study; did he miss appointments; require surveillance; rebel against procedure; act as "guard-house lawyer"; etc.

Item 7b. In double blind studies, it is crucial that this item be completed prior to breaking the blind; i.e., revealing the exact nature of the treatment to the rater.

Item 8. Disposition at termination - As in Item 3, this item endeavors to be universa by stating the responses in general terms. The investigator must judge whether the subject's treatment regime - as it existed at the beginning of the study - has been re duced, intensified or altered substantially.

DOCUMENTATION

a. Raw score printout
b. Frequency tables

THE NURSE PACKET

Unlike the Psychiatrist packets which are focussed on specific populations, the Nurse packet is "discipline oriented"; i.e., it contains all of the scales which are rated by this profession. Spanning age from pediatric to geriatric, the scales are:

Childrens Behavior Inventory (034-CBI) - Pediatric
Nurses Observation Scale for Inpatient Evaluation (039-NOSIE) - Adult and Geriatric
Plutchik Geriatric Rating Scale (040-PLUT) - Geriatric
Nurses Global Impressions (042-NGI) - Universal

Although entitled "Nurse Packet", this set of scales may be rated by ward personnel other than registered nurses (RN); e.g., licensed practical nurses (LPN) psychiatric aides, attendants, orderlies, etc. The essential requirements are that raters have appropriate clinical experience and that they be thoroughly familiar with the rating instructions for each scale.

The selection of scales for any given study is at the discretion of the investigator. Depending on the population involved, the most frequent selection is one of the major scales - CBI, NOSIE or PLUT - in combination with the NGI.

Figure 16 shows the data matrices for each of the scales. These matrices describe the encoding locations of the scales. Since all - or any combination - of scales may be encoded on one GSS, the raters ALWAYS encodes Sheet Number as 10 - each and every time he or she rates. Period number changes; but Sheet Number always remains the same.

ERRATA - The authors' names were inadvertently omitted from the header for 039-NOSIE. The authors are:

Honigfeld, G., Gillis, R. D. and Klett, C. J.

MH-9-50
9-75

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB NO. 68-R965

ECDEU GENERAL SCORING SHEET (50-GSS)

PATIENT INITIALS — FIRST INITIAL — SECOND INITIAL — SHEET NO.

NUMBER MALES 001 TO 499 — NUMBER FEMALES 500 TO 998 — PATIENT — RATER — PERIOD

FIGURE 16
MATRICES FOR
NURSES' ASSESSMENT
SCALES

Row		1	2	3	4	5		6	7	8		11	12	13	14	15		16	17	18	19	20
												Y	N	Y	N			Y	N	Y	N	
1	Eating						Sloppy			(1)	1			(40)				(79)		(118)		
2	Incontinent						Impatient			(2)	2			(41)				(80)		(119)		
3	Bathing						Cries			(3)	3			(42)				STOP		(120)		
4	Falling						Activities			(4)	4			(43)				(81)		(121)		
5	Walking						Sits			(5)	5			(44)				(82)		(122)		
6	Vision						Angry			(6)	6			(45)				(83)		(123)		
7	Hearing						Hears Things			(7)	7			(46)				(84)		(124)		
8	Sleep-Night						Heat			(8)	8			(47)				(85)		(125)		
9	Sleep-Day						Friendly			(9)	9			(48)				(86)		(126)		
10	Restless						Upset			(10)	10			(49)				(87)		(127)		
11	Worse Night						Refuses do			(11)	11			(50)				(88)		(128)		
12	Appearance						Irritable			(12)	12			STOP				(89)		STOP		
13	Masturbates						Remembering			(13)	13			(52)				(90)		(129)		
14	Confused						Refus. speak			(14)	14			(53)				(91)		(130)		
15	Names						Laughs			(15)	15			(54)				(92)		(131)		
16	Communicates						Eating			(16)	16			(55)				(93)		(132)		
17	Reacts						Converses			(17)	17			(56)				(94)		(133)		
18	Plays						Blue			(18)	18			(57)				(95)		(134)		
19	Reads						Interests			(19)	19			(58)				(96)		(135)		
20	Initiates						Sees things			(20)	20			(59)				(97)		(136)		
21	Willing						Reminder			(21)	21			(60)				(98)		(137)		
22	Helps - chores						Sleeps			(22)	22			(61)				(99)		(138)		
23	" - others						No Good			(23)	23			(62)				(100)		(139)		
24	Friends						Follow			(24)	24			(63)				(101)				
25	Talks						Comp. Task			(25)	25			(64)				(102)				
26	Works						Mumbles			(26)	26			(65)				(103)				
27	Destructive						Sluggish			(27)	27			(66)				(104)				
28	Shouts						Giggles			(28)	28			(67)				(105)				
29	Steals						Fly Off			(29)	29			(68)				(106)				
30	Threatens						Clean			(30)	30			(69)				(107)				
31	Tries Harm										31			(70)				(108)				
32											32			(71)				(109)				
33											33			(72)				(110)				
34											34			(73)				(111)				
35											35			(74)				(112)				
36											36			(75)				(113)				
37											37			(76)				(114)				
38											38			(77)				(115)				
39											39			(78)				STOP				
40	Severity										40			STOP				(116)				
41	Improvement										41							(117)				
	Cols:	1	2	3	4	5		6	7	8		11	12	13	14	15		16	17	18	19	20

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034 CBI CHILDRENS BEHAVIOR INVENTORY

MH 9-34
1-73

CHILDREN'S BEHAVIOR INVENTORY

Eugene I. Burdock and Anne S. Hardesty

C
B
I

INSTRUCTIONS: *Code 20 under sheet number on general scoring sheet.* This inventory is applicable to children from 1 to 15 years of age. The items have been grouped according to the ages at which the corresponding behaviors first become significant of departure from developmental norms. The behavior recorded should have occurred during a specified interval of the observation day. Always start at the beginning of the inventory and proceed through the level corresponding to the child's last birthday. A STOP signal is given at the end of each age grouping. Mark "yes" when you reach the level corresponding to the child's last birthday; "no" if you are continuing to the next level.

For each item record your judgment by marking "yes" or "no." All items within appropriate age groupings should be answered.

USE A NO. 2 LEAD PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE.

Mark all items on this page in columns 11 & 12	YES	NO	ROW NO.
AGES ONE TO THREE:			
1. Responds to social stimulation *(by talking, smiling, or reaching, etc.)*			1
2. Is slow in his movements			2
3. Maintains a rigid posture when standing, sitting, lying or being held			3
4. Grinds teeth			4
5. Voice is flat and monotonous			5
6. Ignores toys or other objects around him			6
7. Repeatedly falls asleep			7
8. Bangs head on wall or other hard surface			8
9. Holds breath until face changes color			9
10. Responds to physical contact with limpness			10
11. Utters no sounds			11
STOP (mark "yes" or "no")			12
AGES THREE TO FIVE:			
12. Soils bed or clothing with excrement			13
13. Acts apprehensive and afraid			14
14. Engages in rhythmic motions *(swaying, head rolling, etc.)*			15
15. Says that he had a bad dream			16
16. Eats or drinks strange substance *(plaster, ink, etc.)*			17
17. Has attack of panic			18
18. Remains in one place unless directed into some activity			19
19. Has momentary lapse of consciousness			20
20. Complains of aches and pains or of physical distress			21
21. Picks at self *(pulls out hair, picks at skin, face, buttocks, genitals, etc.)*			22
22. Talks and talks or babbles and babbles *(pressure of speech)*			23
23. Refuses to eat			24
24. Lisps			25
25. Has tic or twitch *(distorts face, turns neck, blinks, etc.)*			26
26. Gets angry or annoyed when addressed by adult			27
27. Has recurrent spells of nausea or vomiting			28
28. Appears listless and apathetic			29
29. Responds to own antisocial act with no sign of sorrow or remorse			30
30. Shows incongruous emotional response			31
31. Smears self and surroundings with food or feces			32
32. Acts perplexed or confused			33
33. Repeatedly gets irritated			34
34. Repeats some act over and over again as though driven			35
35. Wets bed or clothing *(incontinent)*			36
36. Is tense and anxious			37
37. Has a fixed grin			38
38. Speech is inarticulate			39
STOP (mark "yes" or "no")			40
AGES FIVE TO SEVEN:			
39. Clings to adult			41

(Continue this age group on next page)

Mark all items on this page in columns 13 & 14	YES	NO	ROW NO.
AGES FIVE TO SEVEN (Continued):			
40. Keeps drooling			1
41. Has temper tantrum			2
42. Slurs his speech			3
43. Uses baby talk			4
44. Keeps feeling the contours of objects within reach			5
45. Shifts attention in a restless manner			6
46. Becomes anxious when he cannot make things neat and orderly			7
47. Has a dull expression			8
48. Maltreats younger child with deliberate cruelty			9
49. Complains of insomnia			10
50. Gets angry when interrupted at play by adult			11
51. Displays excessive self-control and composure			12
52. Cries or looks hurt when criticized			13
53. Takes part in ongoing activity without being urged			14
54. Does not play with other children			15
55. Protests or resists directions of adult			16
56. Keeps asking for help in whatever he is doing			17
57. Utterances consist of monosyllables or single words			18
58. Says he is going to kill himself			19
59. Shows understanding when given directions			20
60. Sucks thumb			21
61. Acts nervous or agitated			22
62. Uses no gestures			23
63. Plays with genitals or masturbates			24
64. Has a tight-lipped expression			25
65. Swears or uses bad language			26
66. Speaks in a faint voice			27
67. Bites lip			28
68. Keeps slopping food on self or table			29
69. Twists mouth			30
70. Has a mournful and downcast expression			31
71. Bites nails			32
72. Walks on tiptoe			33
73. Stays by himself			34
74. Speech is slow and full of pauses			35
75. Is hesitant and uncertain in making up his mind			36
76. Gives excuse for breaking the rules			37
77. Spills something or bumps into something			38
78. Talks about death and killing			39

(Continue this age group on next page)

Mark all items on this page in columns 16 & 17	ROW NO.
AGES FIVE TO SEVEN (Continued):	
79. Whines or whimpers	1
80. Deliberately hurts himself	2
STOP (mark "yes" or "no")	3
AGES SEVEN TO NINE:	
81. Snatches food from others	4
82. Pinches, slaps or spits at others	5
83. Does not play at all	6
84. Joins in competitive game	7
85. Forgets detail, task or event	8
86. Twists or turns hands	9
87. Speech is sensible and connected	10
88. Starts talking about sex	11
89. Keeps moving about	12
90. Eggs on other child to complain or rebel	13
91. Says that he is bad, that he is in the wrong, or that he is ashamed of himself	14
92. Looks obese	15
93. Does the opposite of what he is asked to do	16
94. Eyes keep shifting	17
95. Acts as if he has a vision or talks about his vision	18
96. Pouts	19
97. Talks to his voices or acts as if he hears voices	20
98. Says there are many people he hates	21
99. Is impatient *(will not wait for something to be given to him or to be done for him)*	22
100. Is overcome by frenzied excitement	23
101. Runs away or plays truant	24
102. Keeps eyes closed or averted or head bowed down	25
103. Has an angry expression	26
104. Walks with a cautious tread *(as if stepping on eggs)*	27
105. Shows suspicion or complains of unfair treatment	28
106. Deliberately tears or breaks something	29
107. Tries to kill himself	30
108. Screams again and again	31
109. Squirms or moves limbs restlessly	32
110. Curses or sneers at other child	33
111. Attacks adult	34
112. Sets a fire	35
113. Jumps up and walks about restlessly	36
114. Keeps smiling	37
115. Shows cringing submissiveness	38
STOP (mark "yes" or "no")	39
AGES NINE TO ELEVEN:	
116. Assumes clownish posture and expression	40
117. Talks, mutters, or mumbles to himself	41
(Continue this age group on next page)	

Mark all items on this page in columns 18 & 19	ROW NO.
AGES NINE TO ELEVEN (Continued):	
118. Giggles inappropriately	1
119. Weeps under slight provocation	2
120. Keeps demanding to be the leader	3
121. Says he feels sad	4
122. Has a scornful expression	5
123. Attention wanders	6
124. Gets angry when something does not suit him	7
125. Hits or attacks other child	8
126. Takes part in conversation	9
127. Runs around or throws himself about in a wild and uncontrollable manner	10
128. Grimaces or gestures grotesquely	11
STOP (mark "yes" or "no")	12
AGES ELEVEN TO THIRTEEN:	
129. Bullies younger child	13
130. Has a dirty appearance	14
131. Speaks in a jerky, uneven fashion	15
132. Acts friendly with another child	16
133. Shows pleasure at being talked to	17
134. Behaves in a sullen or argumentative manner	18
STOP (mark "yes" or "no")	19
AGES THIRTEEN TO FIFTEEN:	
135. Shows difficulty in concentrating	20
136. Shows interest in the opposite sex *(positive or negative feelings)*	21
137. Expresses feelings of inferiority	22
138. Expresses a pessimistic outlook toward his future accomplishments	23
139. Complains that an adult wants to kill him	24

Burdock and Hardesty's Children's Behavior Inventory (CBI) is a 139-item, 2-point scale formatted for use with the General Scoring Sheet. The scale is a technique for recording maladaptive behavior of children. The absence of professional or technical jargon makes it possible for members of different professions to carry out and record the relevant observations after brief training. Experience with the method to date has demonstrated that with proper selection and adequate training the CBI is equally reliable in the hands of nurses, teachers, psychologists, psychiatrists and graduate students in psychology or special education.

REFERENCES

1. Burdock, E. I. and Hardesty, A. S., A Children's Behavior Diagnostic Inventory, Ann. New York Academy of Sciences, 105: 890-896, 1964.
2. Burdock, E. I., and Hardesty, A. S., Contrasting Behavior Patterns of Mentally Retarded Children and Emotionally Disturbed Children, in Psychopathology of Mental Development, p. 370-386, Grune and Stratton, New York, 1967.

APPLICABILITY — Children aged 1 to 15

UTILIZATION — Once at pretreatment, at least one posttreatment assessment. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED — Restricted to the period of observation

CARD FORMAT - ITEMS

CARD 01 = (19x, 5611)

Item	Column	Item	Column	Item	Column	Item	Column	Item	Column
1	20	11-stop	31	22	42	33	53	43	64
2	21	12	32	23	43	34	54	44	65
3	22	13	33	24	44	35	55	45	66
4	23	14	34	25	45	36	56	46	67
5	24	15	35	26	46	37	57	47	68
6	25	16	36	27	47	38	58	48	69
7	26	17	37	28	48	38-stop	59	49	70
8	27	18	38	29	49	39	60	50	71
9	28	19	39	30	50	40	61	51	72
10	29	20	40	31	51	41	62	52	73
11	30	21	41	32	52	42	63	53	74
								54	75

CARD 02 = (19x, 5611)

Item	Column	Item	Column	Item	Column	Item	Column	Item	Column
55	20	66	31	77	42	87	53	98	64
56	21	67	32	78	43	88	54	99	65
57	22	68	33	79	44	89	55	100	66
58	23	69	34	80	45	90	56	101	67
59	24	70	35	80-stop	46	91	57	102	68
60	25	71	36	81	47	92	58	103	69
61	26	72	37	82	48	93	59	104	70
62	27	73	38	83	49	94	60	105	71
63	28	74	39	84	50	95	61	106	72
64	29	75	40	85	51	96	62	107	73
65	30	76	41	86	52	97	63	108	74
								109	75

CARD 03 = (19x, 3311)

Item	Column	Item	Column	Item	Column
110	20	120	31	130	42
111	21	121	32	131	43
112	22	122	33	132	44
113	23	123	34	133	45
114	24	124	35	134	46
115	25	125	36	134-stop	47
115-stop	26	126	37	135	48
116	27	127	38	136	49
117	28	128	39	137	50
118	29	128-stop	40	138	51
119	30	129	41	139	52

Blanks on CBI cards indicate missing data only if they occur on items which are at or below the child's age. Blanks on items over the child's age should be interpreted as "not applicable".

CARD FORMAT - SUBTESTS CARD 51 = (19x, 9F5.2, F3.0)

(Code "5" in column 18 indicates card containing factor, cluster or other grouped scores).

Subtest	Column	Subtest	Column
I	20 - 24	VI	45 - 49
II	25 - 29	VII	50 - 54
III	30 - 34	VIII	55 - 59
IV	35 - 39	IX	60 - 64
V	40 - 44	Total Score	65 - 67

Subtest Score - Sum of Composite Items
Total Score = Sum of all Items

Total Score Range = 0-139

SUBTEST COMPOSITION

1. Anger-Hostility - Contains items describing verbal behavior, attitudes and actions of an angry or hostile nature.

26	50	90	103	120
29	55	93	106	122
33	65	96	110	124
41	76	98	111	125
48	82	99	112	129
				134

II. Conceptual Dysfunctioning - Contains items reflecting disturbances of speech, memory, or orientation.

11	42	85
19	43	87*
22	45	117
24	56	123
32	59*	131
38	75	135

* = Items reflecting in scoring

III. Fear and Worry - Contains items describing verbal behavior or actions reflecting fear and worry.

13	52
15	61
17	79
36	119
46	121

IV. Incongruous Behavior. Indicates modes of behavior which are either inconsistent with one another or with age norms, or which are anomalous and unusual ways of doing things: head banging, incontinence, walking on tiptoes, etc. The more visual characteristics of psychological deviance are grouped here.

4	35	69	104
8	37	71	108
9	39	72	109
12	40	77	113
14	44	81	114
16	60	86	115
21	63	89	116
25	64	94	118
31	67	100	127
34	68	101	128
			130

V. Incongruous Ideation - Contains items indicative of bizarre emotional and cognitive behaviors.

30	105
78	139
88	

VI. Lethargy-Dejection - Is reflected in both physical and emotional behavior. A child may be reported to be slow in his movements, to fall asleep repeatedly, or to have a voice that is flat or monotonous; on the other hand, he may detach himself from his environment by staying by himself, or by ignoring toys or other objects around him.

1*	28	62	84*
2	47	66	102
5	51	70	126*
6	53*	73	132*
7	54	74	133*
18	57	83	136*

* = Items reflected in scoring

VII. Perceptual Dysfunctioning - Items related to hallucinatory experiences.

95 97

VIII. Physical Complaints - Is concerned with such indicators as refusal to eat, recurrent spells of vomiting, or responding to physical contact with limpness.

3	27
10	49
20	92
23	

IX. Self-Depreciation - is more dependent on verbal report than the other subareas. However, deliberately hurting himself and trying to kill himself are behavioral items included here in addition to expressions of feeling of inferiority.

58	107
80	137
91	138

SPECIAL INSTRUCTIONS

1. Conduct of Observers - Whenever a study is to be undertaken in a new setting the observer should arrange to let himself be seen in the situation and by the subjects before the beginning of the formal observations in order that his presence lose its novelty. It is best when the child who is the focus of interest does not perceive himself as such. The observer should give an impression of being interested in the activities of the whole group. If a child inquires about the observer's role or purpose, the observer may tell him, "I am watching because I am interested in

what children do here." There are two requirements which are essential if quantitative or even only qualitative use is to be made of the instrument:

a. The observer must be able to maintain a friendly detachment from the situation so that he neither manipulates nor purposely evokes behavior that would not have occurred in his absence.

b. The observer must be closely attentive to the appearance, verbalizations, movements and gestures of the child.

2. Recording Observations - The CBI has 139 dichotomous items. The observer should always start with the first item and proceed through all the items listed for the age group of the child under observation. When the child's age "overlaps" two age groupings, answer all items of the OLDER groupings and stop. (Example - if a child is 5, complete age group "Five to Seven". If child is 7, complete group "Seven to Nine".) The observer should mark "YES" when the child has displayed the behavior noted and "NO" if he has not seen the relevant behaviors. The observer must be able to set aside what he remembers or has heard from others about the child. His judgments must be based solely on what he sees or hears from the child during the observation period. He must be sure to read every item carefully. Some items call for a judgment of the presence of a behavior; other items require judgment that a particular behavior is absent. Certain items describe behaviors which can be judged unequivocally from a single event; others describe complex qualities whose presence may only be inferred toward the end of the observational interval.

3. Time Interval - The most effective use of the CBI is achieved when it is possible to observe an individual child in his normal activities over several behavioral settings. When the observer can give his undivided attention to the actions and reactions of a single child, a period of two hours has been found to produce enough behavioral diversity to be of discriminative significance. On the other hand, should service obligations preclude such highly focussed observation, the behavior displayed over the usual working shift of approximately eight hours will offer a reliable basis for judgments provided observations are carried out consistently.

DOCUMENTATION

a. Raw score printout - item listings will end at each individual subject's appropriate age group.
b. Subtest scores.
c. Means and standard deviations for subtests.
d. Crosstabulations of subtest scores.
e. Variance analyses.

039 NOSIE
NURSES OBSERVATION SCALE FOR INPATIENT EVALUATION

MH 9-39
1-73

NURSES' OBSERVATION SCALE FOR INPATIENT EVALUATION

Honigfeld, G., Gillis, R. D. and Klett, C. J.

INSTRUCTIONS: *Code 20 under sheet number on general scoring sheet.*
For each of the 30 items below you are to rate this patient's behavior during the last THREE DAYS ONLY. Indicate your choice by marking one response position for each item.

USE A NO. 2 LEAD PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE.

Row	NEVER	SOME-TIMES	OFTEN	USU-ALLY	ALWAYS
1	5	6	7	8	9
2	5	6	7	8	9
3	5	6	7	8	9
4	5	6	7	8	9
5	5	6	7	8	9
6	5	6	7	8	9
7	5	6	7	8	9
8	5	6	7	8	9
9	5	6	7	8	9
10	5	6	7	8	9
11	5	6	7	8	9
12	5	6	7	8	9
13	5	6	7	8	9
14	5	6	7	8	9
15	5	6	7	8	9
16	5	6	7	8	9
17	5	6	7	8	9
18	5	6	7	8	9
19	5	6	7	8	9
20	5	6	7	8	9
21	5	6	7	8	9
22	5	6	7	8	9
23	5	6	7	8	9
24	5	6	7	8	9
25	5	6	7	8	9
26	5	6	7	8	9
27	5	6	7	8	9
28	5	6	7	8	9
29	5	6	7	8	9
30	5	6	7	8	9
Cols	*6*	*7*	*8*	*9*	*10*

ROW NO.	*Mark each item on row designated in columns 6 – 10*
1	Is sloppy
2	Is impatient
3	Cries
4	Shows interest in activities around him
5	Sits, unless directed into activity
6	Gets angry or annoyed easily
7	Hears things that are not there
8	Keeps his clothes neat
9	Tries to be friendly with others
10	Becomes easily upset if something doesn't suit him
11	Refuses to do the ordinary things expected of him
12	Is irritable and grouchy
13	Has trouble remembering
14	Refuses to speak
15	Laughs or smiles at funny comments or events
16	Is messy in his eating habits
17	Starts up a conversation with others
18	Says he feels blue or depressed
19	Talks about his interests
20	Sees things that are not there
21	Has to be reminded what to do
22	Sleeps, unless directed into activity
23	Says that he is no good
24	Has to be told to follow hospital routine
25	Has difficulty completing even simple tasks on his own
26	Talks, mutters, or mumbles to himself
27	Is slow moving and sluggish
28	Giggles or smiles to himself without any apparent reason
29	Quick to fly off the handle
30	Keeps himself clean

Developed by Honigfeld, Gillis and Klett, the Nurses' Observation Scale (NOSIE) is a 30-item scale formatted for use with the General Scoring Sheet. Designed for the assessment of ward behavior by nursing personnel, the NOSIE provides measures of the patients' strengths as well as pathology. Employing a 5-point scale, the items are written in simple language and ask for ratings based on the direct observation of behavior. Since its introduction in 1965, the scale has been widely used and has demonstrated its sensitivity to change.

REFERENCES

1. Honigfeld, G. and Klett, C., The Nurses' Observation Scale for Inpatient Evaluation (NOSIE): A New Scale for Measuring Improvement in Chronic Schizophrenia, J. Clin. Psychol., 1965, 21: 65-71.

2. Honigfeld, G., NOSIE-30: History and Current Status of Its Use in Pharmacopsychiatric Research, published in Modern Problems in Pharmacopsychiatry: Psychological Measurement, P. Pichot (Ed), Karger, Basle, 1973.

3. Guy, W. and Cleary, P., Factor Analyses of the NOSIE, to be published.

APPLICABILITY — Adult and geriatric inpatients

UTILIZATION — Once at pretreatment; at least one post-treatment assessment. Additional rating periods are at the discretion of the investigator.

TIME SPAN RATED — The span has been established by the author as "the last three days only".

CARD FORMAT - ITEMS CARD 01 = (19x, 30I1)

Item	Column	Item	Column
1	20	16	35
2	21	17	36
3	22	18	37
4	23	19	38
5	24	20	39
6	25	21	40
7	26	22	41
8	27	23	42
9	28	24	43
10	29	25	44
11	30	26	45
12	31	27	46
13	32	28	47
14	33	29	48
15	34	30	49

CARD FORMAT - FACTORS CARD 51 = (19x, 8F4.0)

(Code "5" in Column 18 indicates card containing factor, cluster or devised score.)

Factor	Column	Factor	Column
I	20 - 23	V	36 - 39
II	24 - 27	VI	40 - 43
III	28 - 31	VII	44 - 47
IV	32 - 35	Total Assets	48 - 51

Factor Score = 2 X Sum of Composite Items

Total assets = 150 + total POSITIVE (I, II, III) - total NEGATIVE factors (IV,V,VI,VII).

FACTOR COMPOSITION

This factor structure is based on a 1975 analyses of the pretreatment ratings of 2415 subjects with diagnoses of schizophrenia. The factors derived are identical with the original Honigfeld factors except for addition of Factor VII - Depression. (Table 17).

POSITIVE FACTORS

I. Social Competence
- *13 - Has trouble remembering
- *14 - Refuses to speak
- *21 - Has to be reminded what to do
- *24 - Has to be told to follow hospital routine
- *25 - Has difficulty completing even simple tasks on his own

II. Social Interest
- 4 - Shows interest in activities around him
- 9 - Tries to be friendly with others
- 15 - Laughs or smiles at funny comments or events
- 17 - Starts up conversation with others
- 19 - Talks about his interests

III. Personal Neatness
- *1 - Is sloppy
- 8 - Keeps his clothes neat
- *16 - Is messy in his eating habits
- 30 - Keeps himself clean

NEGATIVE FACTORS

IV. Irritability
- 2 - Is impatient
- 6 - Gets angry or annoyed easily
- 10 - Becomes easily upset if something doesn't suit him
- 11 - Refuses to do ordinary things expected of him
- 12 - Is irritable and grouchy
- 29 - Quick to fly off the handle

V. Manifest Psychosis

7 - Hears things that are not there
20 - Sees things that are not there
26 - Talks, mutters or mumbles to himself
28 - Giggles or smiles to himself without any apparent reason

VI. Retardation

5 - Sits, unless directed into activity
22 - Sleeps, unless directed into activity
27 - Is slow moving and sluggish

VII. Depression

3 - Cries
18 - Says he feels blue or depressed
23 - Says he is no good

* = Items reflected in scoring

SPECIAL INSTRUCTIONS

Although most raters find it relatively easy to arrive at agreement on the meaning of the items, confusions and misinterpretations do occur. It would be prudent, therefore, to conduct training sessions for neophyte raters to reduce any confusion which may exist.

DOCUMENTATION

a. Raw score printout
b. Factor score printout
c. Means and standard deviations for factor scores
d. Cross-tabulation of factor scores
e. Variance Analyses

TABLE 17

7-FACTOR VARIMAX SOLUTION OF THE NURSES' OBSERVATION SCALE FOR INPATIENT EVALUATION

Item	I	II	III	IV	V	VI	VII	Communalities
1	-161	190	002	802	018	188	-257	807
2	052	780	-032	208	-087	140	-089	690
3	089	167	-059	-043	-612	032	-129	433
4	655	-116	-217	-273	-028	-160	160	616
5	-383	043	575	024	-047	-005	-255	547
6	-062	905	-045	076	-053	124	-096	858
7	-247	163	-150	135	-027	768	-155	743
8	230	-148	-023	-864	-024	-101	143	853
9	823	-115	-089	-116	-032	-087	137	739
10	004	893	-029	081	-120	091	-085	835
11	-087	567	128	226	-032	127	-441	608
12	-083	829	027	130	-090	124	-142	756
13	-106	024	115	259	008	251	-686	627
14	-312	167	013	029	010	035	-636	532
15	743	-025	201	-131	-037	110	189	660
16	-032	119	114	567	029	263	-324	525
17	849	047	-094	-075	-078	-107	149	777
18	154	067	147	-070	-797	-087	062	701
19	704	032	-175	-140	-222	-123	049	614
20	-234	192	-159	116	-042	725	-223	708
21	-195	256	185	400	011	192	-660	770
22	-014	024	862	076	-037	-027	020	752
23	032	036	084	050	-804	025	068	663
24	-141	342	153	381	010	161	-617	712
25	-205	241	060	366	-028	235	-654	721
26	-076	263	-014	238	-013	760	-111	722
27	-107	-141	562	092	-174	-158	-324	516
28	126	093	093	131	081	787	-094	685
29	-042	882	-011	058	-025	155	-098	817
30	245	-173	-073	-816	-025	-138	196	819
Contribution of factor (V_p)	3.57	4.61	1.73	3.27	1.79	2.83	2.99	20.80
% Total Variance	11.9	15.4	5.8	10.9	6.0	9.4	9.9	69.3
% Common Variance	17.1	22.2	8.3	15.7	8.6	13.6	14.3	

COMMENTS OF THE AUTHOR

The Nurses' Observation Scale for Inpatient Evaluation

Gilbert Honigfeld, Ph.D.

As a result of continued research with the NOSIE over the past several years we have developed a revised scoring system based on a subset of 30 items from the original 80-item scale. Our analyses show that this new version, the NOSIE-30, is as reliable and valid as the parent scale and will be considered the definitive scoring system in our future work. This research was based on an expanded normative sample of over 600 chronic schizophrenic patients aged 26 to 74.

Five of the original 7 factors held up well under repeated factor analyses of both pre-treatment and change score data. One factor, Cooperation, became obscured because of its strong relationship with Social Competence and has since been dropped as a separate factor.

Although potentially useful for describing patient status in a small number of chronic schizophrenic men and of some usefulness in describing changes in behavior over long time spans, Paranoid Depression has been dropped from the general scoring system since it is of relatively little use in measuring patient change over customary experimental time spans. However, a new factor, Retardation, has been added which is related to observable aspects of Depression, and which is quite sensitive to changes over short time periods. Depression can still be scored using the NOSIE-30, but for general purposes its use is not encouraged.

In addition a composite or overall score, Total Patient Assets, has been added for the use of investigators who want a global estimate of patient status or change. This score is simply the algebraic sum of the positive factors minus the negative factors, with the addition of a constant to adjust the scale to a true zero-point.

A further addition to the scoring system involves the conversion of raw scores to normalized T-scores. Similar to the MMPI a conversion table will be used to provide a rapid way of profiling patient scores, as well as giving immediate normative comparisons. T-scores involve the conversion of raw scores to an adjusted mean of 50 and standard deviation of 10. Thus a patient's normalized T-score can be easily interpreted as a centile rank by reference to a normal-curve table.

Regarding the validity of the scale, favorable evidence has been reported independently by Lentz et al., (1971). Although based on a sample significantly younger than the original norm group these authors reported (p. 75), "when compared to Honigfeld's older, chronic geriatric group, the current sample was essentially at the mean for Total Assets (T score=52), and for all subscales (T score=49 or 50) except Social Interest. On the latter subscale females were significantly higher than males in the norm groups (T score=56), and males in the current sample (T score(T score=51)). For Irritability, the other subscale on which sex differences were found, males were slightly below the norm group (T=47) and females were slightly above (T=52)."

In comparing the NOSIE with other scales, Ludwig and Marx (1969) reported a correlation of +.90 between NOSIE Total Assets and a ward behavior form. Kish (1970) reported that patients high on "sensation-seeking" (a measure of "Interest in seeking stimulating activities") exhibited on the NOSIE-30 significantly less retardation than patients low on "sensation-seeking".

Svensborg and Willenson (1969) compared NOSIE-30 scores for mentally retarded as well as mentally ill patients of both sexes. Very comparable scores obtained across both diagnostic groups and both sexes with one major discrepancy - mentally ill males scored significantly lower than all other groups on Social Interest. A specific relationship was found between high scores on the irritability factor and clinical categorizations of "hyperactive" classification.

Concerning the reliability of these scores, the report by Lentz et al, (1971), showed high inter-rater reliabilities, as follows:

Factor		Inter-rater Reliability
Total Assets	(TOT)	.95
Social Competence	(COM)	.86
Social Interest	(INT)	.95
Personal Neatness	(NEA)	.95
Irritability	(IRR)	.83
Manifest Psychosis	(PSY)	.82
Retardation	(RET)	.83

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O4O PLUT
PLUTCHIK
GERIATRIC
RATING SCALE

MH 9-40
1-73

PLUTCHIK GERIATRIC RATING SCALE

INSTRUCTIONS: *Code 20 under sheet number on general scoring sheet.*
Choose one response for each item and record in the appropriate spaces.

Row	1	2	3
1	0	1	2
2	0	1	2
3	0	1	2
4	0	1	2
5	0	1	2
6	0	1	2
7	0	1	2
8	0	1	2
9	0	1	2
10	0	1	2
11	0	1	2
12	0	1	2
13	0	1	2
14	0	1	2
15	0	1	2
16	0	1	2
17	0	1	2
18	0	1	2
19	0	1	2
20	0	1	2
21	0	1	2
22	0	1	2
23	0	1	2
24	0	1	2
25	0	1	2
26	0	1	2
27	0	1	2
28	0	1	2
29	0	1	2
30	0	1	2
31	0	1	2
Cols:	*1*	*2*	*3*

ROW NO.	*Mark each item on row designated in columns 1 – 3*
1	**1. When eating, the patient requires:** 0 = No assistance *(feeds himself)* 1 = A little assistance *(needs encouragement)* 2 = Considerable assistance *(spoon feeding, etc.)*
2	**2. The patient is incontinent:** 0 = Never 1 = Sometimes *(once or twice per week)* 2 = Often *(three times per week or more)*
3	**3. When bathing or dressing, the patient needs:** 0 = No assistance 1 = Some assistance 2 = Maximum assistance
4	**4. The patient will fall from his bed or chair unless protected by side rail:** 0 = Never 1 = Sometimes 2 = Often
5	**5. With regard to walking the patient:** 0 = Has no difficulty 1 = Needs assistance in walking 2 = Does not walk
6	**6. The patient's vision, with or without glasses, is:** 0 = Apparently normal 1 = Somewhat impaired 2 = Extremely poor
7	**7. The patient's hearing is:** 0 = Apparently normal 1 = Somewhat impaired 2 = Extremely poor
8	**8. With regard to sleep, the patient:** 0 = Sleeps most of the night 1 = Is sometimes awake 2 = Is often awake
9	**9. During the day, the patient sleeps:** 0 = Sometimes 1 = Often 2 = Most of the day
10	**10. With regard to restless behavior at night, the patient is:** 0 = Seldom restless 1 = Sometimes restless 2 = Often restless
11	**11. The patient's behavior is worse at night than in the daytime:** 0 = Never 1 = Sometimes 2 = Often

PLUTCHIK GERIATRIC RATING SCALE

ROW NO.	*Mark each item on row designated in columns 1 – 3*
12	**12. When not helped by other people, the patient's appearance is:** 0 = Almost never sloppy 1 = Sometimes sloppy 2 = Almost always sloppy
13	**13. The patient masturbates or exposes himself publicly:** 0 = Never 1 = Sometimes 2 = Often
14	**14. The patient is confused** *(unable to find his way around the ward, loses his possessions, etc.)*: 0 = Almost never 1 = Sometimes 2 = Often
15	**15. The patient knows the names of:** 0 = More than one member of the staff 1 = Only one member of the staff 2 = None of the staff
16	**16. The patient communicates in any manner** *(by speaking, writing, or gestering)* **well enough to make himself easily understood:** 0 = Almost always 1 = Sometimes 2 = Almost never
17	**17. The patient reacts to his own name:** 0 = Almost always 1 = Sometimes 2 = Almost never
18	**18. The patient plays games, has hobbies, etc.:** 0 = Often 1 = Sometimes 2 = Almost never
19	**19. The patient reads books or magazines on the ward:** 0 = Often 1 = Sometimes 2 = Almost never
20	**20. The patient will begin conversations with others:** 0 = Often 1 = Sometimes 2 = Almost never
21	**21. The patient is willing to do things asked of him:** 0 = Often 1 = Sometimes 2 = Almost never
22	**22. The patient helps with chores on the ward:** 0 = Often 1 = Sometimes 2 = Almost never

ROW NO.	*Mark each item on row designated in columns 1 – 3*
23	**23. Without being asked, the patient physically helps other patients:** 0 = Often 1 = Sometimes 2 = Almost never
24	**24. With regard to friends on the ward, the patient:** 0 = Has several friends 1 = Has just one friend 2 = Has no friends
25	**25. The patient talks with other people on the ward:** 0 = Often 1 = Sometimes 2 = Almost never
26	**26. The patient has a regular work assignment:** 0 = Away from the ward 1 = On the ward 2 = No regular assignment
27	**27. The patient is destructive of materials around him** *(breaks furniture, tears up magazines, etc.)* 0 = Never 1 = Sometimes 2 = Often
28	**28. The patient disturbs other patients or staff by shouting or yelling:** 0 = Never 1 = Sometimes 2 = Often
29	**29. The patient steals from other patients or staff members:** 0 = Never 1 = Sometimes 2 = Often
30	**30. The patient** *verbally* **threatens to herm other petients or staff:** 0 = Never 1 = Sometimes 2 = Often
31	**31. The patient** *physically* **tries to harm other patients or staff:** 0 = Never 1 = Sometimes 2 = Often

Developed by Plutchik, Conte, Lieverman, Bakur, Grossman and Lehrman, the Plutchik Geriatric Rating Scale (PLUT) is a 31-item scale formatted for use with the General Scoring Sheet. The scale was designed to measure the degree to which geriatric patients are able to function, both physically and socially, in an intact, integrated manner. The items are rated on a 3-point scale and the ratings are based on the direct observation of the patient's behavior.

REFERENCE

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APPLICABILITY

Geriatric inpatients

UTILIZATION

Once at pretreatment; at least one post-treatment assessment. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED

None specified by authors; but it is suggested that the time span be limited to now or within past week.

CARD FORMAT - ITEMS

CARD 01 = (19x, 3I1I)

Item	Column	Item	Column
1	20	17	36
2	21	18	37
3	22	19	38
4	23	20	39
5	24	21	40
6	25	22	41
7	26	23	42
8	27	24	43
9	28	25	44
10	29	26	45
11	30	27	46
12	31	28	47
13	32	29	48
14	33	30	49
15	34	31	50
16	35		

CARD FORMAT - FACTORS CARD 51 = (19x, 7F6.2, F4.0)

(Code "5" in Column 18 indicates card containing factor, cluster or derived score.)

Factor	Column	Factor	Column
I	20-25	V	44-49
II	26-31	VI	50-55
III	32-37	VII	56-61
IV	38-43	Total Score	62-65

Factor Score = $\frac{\text{Sum of Composite Items}}{\text{No. of Composite Items}}$ Factor Score Range = 0 - 2

Total Score = Sum of all items Total Score Range = 0 - 62

FACTOR COMPOSITION

This factor structure is based on a 1975 analysis of pretreatment scores from 260 geriatric subjects. (Table 18).

I. Overall Dysfunction
- 1 - Eating
- 2 - Incontinent
- 3 - Bathing and dressing
- 12 - Appearance
- 14 - Confusion
- 16 - Communicates easily
- 17 - Reacts to name
- 21 - Willing to do things

II. Aggressive Behavior
- 27 - Destructive
- 28 - Disturbs others
- 29 - Steals
- 30 - Verbally threatens
- 31 - Physically tries to harm

III. Sleep Disturbance
- 8 - Sleeps at night
- 10 - Restless at night
- 11 - Behavior worse at night

IV. Social Isolation
- 20 - Begins conversations
- 24 - Friends
- 25 - Talks with others

V. Sensory Impairment
- 6 - Vision
- 7 - Hearing

VI. Work and Activities
- 18 - Games and hobbies
- 22 - Helps with chores
- 23 - Helps other patients
- 26 - Regular work assignment

VII. Motor Impairment
- 4 - Falls
- 5 - Walking

Items not included in any factor
- 9 - Sleep during day
- 13 - Masturbates
- 15 - Knows names of staff
- 19 - Reads

TABLE 18

7-FACTOR VARIMAX SOLUTION OF PLUTCHIK GERIATRIC RATING SCALE

Items	I	II	III	IV	V	VI	VII	Communalities
1	589	-069	-024	-151	-076	-163	-333	518
2	692	103	-077	-166	-051	-264	-246	655
3	683	071	-026	-103	026	-294	-245	631
4	269	-007	-008	-038	-144	-199	-640	544
5	305	-049	054	004	-150	-237	-654	604
6	-051	-026	-041	110	-547	-097	-245	387
7	-022	-031	023	-109	-768	018	-008	605
8	-103	010	-815	035	011	013	014	677
9	249	-010	-013	-044	-394	318	-025	321
10	-064	154	-809	091	031	-068	090	705
11	082	073	-770	003	-054	062	-073	618
12	706	130	-097	-140	134	-033	-133	581
13	033	289	-142	-371	-074	026	-104	260
14	702	-011	045	-042	-088	-320	006	607
15	234	033	-039	-301	-268	-413	246	451
16	690	-023	105	-269	-054	-103	066	578
17	604	-061	187	-245	029	-114	-068	482
18	260	058	014	-244	-127	-482	-032	380
19	273	044	042	-223	-108	-403	-064	306
20	331	-086	143	-719	014	-218	-042	703
21	460	044	085	-328	098	-416	-169	540
22	295	-021	-043	-153	085	-686	-269	663
23	170	-079	057	-477	047	-518	-181	570
24	225	025	-053	-653	-052	-219	135	549
25	242	-048	186	-790	049	-202	-056	767
26	222	044	-014	-054	073	-590	-174	439
27	187	555	086	-182	273	143	-196	517
28	137	513	194	-141	-037	-031	-174	372
29	144	503	-072	088	193	092	158	358
30	-144	780	-096	079	-086	-109	054	667
31	-116	755	022	066	-048	-119	126	621
Contribution of factor (V_p)	4.28	2.19	2.14	2.59	1.39	2.54	1.55	16.67
% Total Variance	13.8	7.1	6.9	8.4	4.5	8.2	5.0	53.8
% Common Variance	25.7	13.1	12.8	15.5	8.3	15.2	9.3	

SPECIAL NOTE

Plutchik et al have also provided percentile scores for geriatric subjects. The following table "provides a frame of reference against which future patients may be evaluated for purposes of placement, selection, treatment, and research".

PERCENTILE DISTRIBUTION OF INDIVIDUAL PLUTCHIK SCORES OF GERIATRIC PATIENTS

Score	Percentile	Score	Percentile
0-4	1	25	55
5-6	2	26	59
7	3	27	62
8	5	28	65
9	8	29	68
10	10	30	71
11	12	31	73
12	15	32	76
13	19	33	80
14	22	34	83
15	25	35	86
16	27	36	88
17	30	37	91
18	32	38	93
19	34	39	95
20	38	40	96
21	41	41	97
22	45	42-43	98
23	48	44-48	99
24	52	49-51	100

DOCUMENTATION:

a. Raw score printout
b. Factor score printout
c. Means and standard deviations of factor scores
d. Variance Analyses

042 NGI
NURSES
GLOBAL
IMPRESSIONS

MH 9-42
1-73

NURSES' GLOBAL IMPRESSIONS

INSTRUCTIONS: *Code 20 under sheet number on general scoring sheet.*
Choose one response for each item.

USE A NO. 2 LEAD PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE.

40	::0::	::1::	::2::	::3::	::4::	::5::	::6::	::7::
41	::0::	::1::	::2::	::3::	::4::	::5::	::6::	::7::
Cols:	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*

ROW NO.	*Mark each item on row designated in columns 1 – 8*
40	**1. SEVERITY OF ILLNESS** Considering your total clinical experience with this particular population, how mentally ill is the patient at this time? 0 = Not assessed 1 = Normal, not at all 2 = Borderline mentally ill 3 = Mildly ill 4 = Moderately ill 5 = Markedly ill 6 = Severely ill 7 = Among the most extremely ill patients
41	**2. GLOBAL IMPROVEMENT** Compared to his condition at admission to the study, how much has he changed? *(this item may be omitted at the initial evaluation by marking "0" - Not assessed)* 0 = Not assessed 1 = Very much improved 2 = Much improved 3 = Minimally improved 4 = No change 5 = Minimally worse 6 = Much worse 7 = Very much worse

The Nurses' Global Impressions (NGI) was developed during the PRB collaborative schizophrenia studies and is a 2-item scale for the assessment of global clinical judgments and is formatted for use with the General Scoring Sheet. These two items correspond to the first 2 items of the Clinical Global Impressions. They were previously attached as Items 31 and 32 to the NOSIE but have now been formatted independently so that they may be used with any combination of scales in the Nurses' Packet.

APPLICABILITY	All populations
UTILIZATION	Generally rated simultaneously with other Nurses' scales. If used alone, the NGI should be rated once at pretreatment and at least once at post-treatment. Additional ratings of the NGI are at the discretion of the investigator.
TIME SPAN RATED	Now or within the past week
CARD FORMAT - ITEMS	CARD 01 = (19x, 2I1)
	Severity of Illness Column 20
	Global Improvement Column 21

SPECIAL INSTRUCTIONS

Severity of Illness - It should be noted that this item is rated in the context of the particular population under study, e.g., in a study involving schizophrenic subjects, the degree of illness should be assessed against the rater's clinical experience with this type of subject. This represents a contextual change from the original item in which the rater was asked to judge severity in the context of total clinical experience with ALL populations. (See page 219).

Global Improvement - Change at any given rating should be compared to the subject's condition at pretreatment - NOT to his condition at the preceding rating. This item should be rated in the same context as CGI Global Improvement; i.e., "Rate total improvement whether or not, in your judgment, it is due entirely to drug treatment."

DOCUMENTATION

a. Raw score printout
b. Means and standard deviations
c. Frequencies
d. Crosstabulation
e. Variance analysis

O35 TQ
TEACHER
QUESTIONNAIRE

MH-9-35
1-73

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE–PUBLIC HEALTH SERVICE
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB NO. 68-R965

CONNERS TEACHER QUESTIONNAIRE

PATIENT INITIALS

FIRST INITIAL

SECOND INITIAL

FOR NIMH USE ONLY

NUMBER MALES 001 TO 499; FEMALES 500 TO 998

PATIENT

RATER

PERIOD

Hours | Days | Weeks | Months

PLEASE USE A NO. 2 LEAD PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE.

Listed below are descriptive terms of behavior. Mark in the column which best describes this child. ANSWER ALL ITEMS.

CLASSROOM BEHAVIOR	Not at All	Just a Little	Pretty Much	Very Much
1. Fidgeting	0	1	2	3
2. Hums and makes other odd noises	0	1	2	3
3. Demands must be met immediately; gets frustrated	0	1	2	3
4. Coordination poor	0	1	2	3
5. Restless (overactive)	0	1	2	3
6. Excitable, impulsive	0	1	2	3
7. Inattentive, distractable	0	1	2	3
8. Fails to finish things he starts (short attention span)	0	1	2	3
9. Sensitive to criticism	0	1	2	3
10. Serious or sad	0	1	2	3
11. Daydreams	0	1	2	3
12. Sullen or sulky	0	1	2	3
13. Cries	0	1	2	3
14. Disturbs other children	0	1	2	3
15. Quarrelsome	0	1	2	3
16. Mood changes quickly	0	1	2	3
17. Acts "smart"	0	1	2	3
18. Destructive	0	1	2	3
19. Steals	0	1	2	3
20. Lies	0	1	2	3
21. Temper outbursts (explosive and unpredictable behavior)	0	1	2	3

GROUP PARTICIPATION	Not at All	Just a Little	Pretty Much	Very Much
22. Isolates himself from other children	0	1	2	3
23. Appears to be unaccepted by group	0	1	2	3
24. Appears to be easily led	0	1	2	3
25. No sense of fair play	0	1	2	3
26. Appears to lack leadership	0	1	2	3
27. Does not get along with opposite sex	0	1	2	3
28. Does not get along with same sex	0	1	2	3
29. Teases other children or interferes with their activities	0	1	2	3

ATTITUDE TOWARD AUTHORITY	Not at All	Just a Little	Pretty Much	Very Much
30. Submissive	0	1	2	3
31. Defiant	0	1	2	3
32. Impudent	0	1	2	3
33. Shy	0	1	2	3
34. Fearful	0	1	2	3
35. Excessive demands for teachers attention	0	1	2	3
36. Stubborn	0	1	2	3
37. Anxious to please	0	1	2	3
38. Uncooperative	0	1	2	3
39. Attendance problem	0	1	2	3

	None	Mild	Moderate	Severe
40. Considering your total teaching experience with children of this age, how much of a problem is the child at this time?	0	1	2	3

41. What changes have you observed in this child since the start of the study? *(Omit this item at the initial rating)*

	Much Improved	Minimally Improved	No Change	Minimally Worse	Much Worse
Academic Achievement	1	2	3	4	5
Overall Behavior	1	2	3	4	5
Group Participation	1	2	3	4	5
Attitude Toward Authority	1	2	3	4	5

IBM H88581

Developed by Conners, the Teacher Questionnaire (TQ) is a single-page, 41-item scale to be completed by the child's home-room teacher. It is an independent form in that responses are coded directly on the form and the General Scoring Sheet is not utilized. The first 39 4-point items are divided into 3 large groups: classroom behavior, group participation, attitude toward authority. Item 40 is a 4-point global judgment of the severity of the child's problem. Item 41 consists of four 5-point global judgments of improvement in the following areas: academic achievement, overall behavior, group participation, attitude toward authority. The TQ was designed to tap the teacher's evaluations of the child's ability to cope with his peers and with the demands of the school curriculum.

REFERENCE — Conners, C. K., A teacher rating scale for use in drug studies with children. American Journal of Psychiatry, 1969, 126, 152-156.

APPLICABILITY — Children to 15 years of age

UTILIZATION — Once at pretreatment. The 41-item TQ may be used for repeated assessments; but frequently the 10-item Parent-Teacher Questionnaire (PTQ) is substituted for ratings subsequent to the initial rating. The number of assessments is at the discretion of the investigator.

TIME SPAN RATED — Now or within the past month.

CARD FORMAT - ITEMS CARD 01 = (19x, 4411)

Item	Column	Item	Column	Item	Column	Item	Column
1	20	12	31	23	42	34	53
2	21	13	32	24	43	35	54
3	22	14	33	25	44	36	55
4	23	15	34	26	45	37	56
5	24	16	35	27	46	38	57
6	25	17	36	28	47	39	58
7	26	18	37	29	48	Severity	59
8	27	19	38	30	49	Improvement	
9	28	20	39	31	50	Academic	60
10	29	21	40	32	51	Overall	61
11	30	22	41	33	52	Participation	62
						Attitude	63

CARD FORMAT - FACTORS CARD 51 = (19x, 5F6.2, F2.0, F4.0, 4F2.0)

(Code "5" in column 18 indicates card containing factor, cluster or other grouped scores).

Factor	Columns
I	20 - 25
II	26 - 31
III	32 - 37
IV	38 - 43
V	44 - 49

Item	Columns
Severity	50 - 51
Total Score	52 - 55
Improvement, Academic	56 - 57
" Overall	58 - 59
" Participation	60 - 61
" Attitude	62 - 63

Factor score = $\frac{\text{Sum of composite items}}{\text{No. of composite items}}$

Factor Score Range = 0 - 3

Total Score = Sum of all items

Total Score Range = 0 - 117

FACTOR COMPOSITION

I. Conduct Problem
- 12 - Sullen or sulky
- 14 - Disturbs other children
- 15 - Quarrelsome
- 17 - Acts "smart"
- 18 - Destructive
- 19 - Steals
- 20 - Lies
- 21 - Temper outbursts
- 25 - No sense of fair play
- 29 - Teases other children
- *30 - Submissive
- 31 - Defiant
- 32 - Impudent
- 36 - Stubborn
- 38 - Uncooperative

II. Inattentive-Passive
- 4 - Coordination poor
- 7 - Inattentive
- 8 - Fails to finish things
- 11 - Daydreams
- 24 - Appears to be easily led
- 26 - Appears to lack leadership

III. Tension-Anxiety
- 9 - Sensitive
- 10 - Serious or sad
- 30 - Submissive
- 33 - Shy
- 34 - Fearful
- 37 - Anxious to please
- *39 - Attendance problem

IV. Hyperactivity
- 1 - Fidgeting
- 2 - Hums and makes other odd noises
- 5 - Restless
- 6 - Excitable
- 14 - Disturbs other children
- 29 - Teases other children
- 35 - Excessive demands
- 37 - Anxious to please

V. Social Ability
- 22 - Isolates himself
- 23 - Unaccepted by group
- 27 - Does not get along with opposite sex
- 28 - Does not get along with same sex

Items not included in any factor: 3, 12, 16.

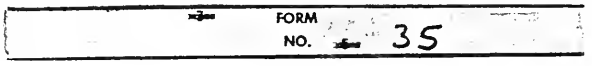
* = Items subtracted from factor score

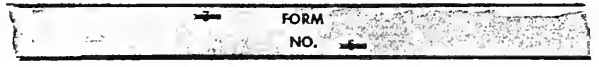
This factor analysis of the TQ (Conners, 1969) was based on a slightly reworded version of the scale. The sample consisted of 82 boys and 21 girls (Mean age - 117.5 months; SD - 21.5 months) characterized by behavior disorders, hyperactivity and poor attention spans associated with learning disorders. Only children for whom drug therapy seemed specifically indicated were included. Factor I accounts for 39 percent of the variance; Factor II for 16 percent; Factor III for 12 percent; Factor IV for 19.6 percent and Factor V for 13.7 percent. The factors have some degree of intercorrelation, especially between Factors I and IV.

SPECIAL INSTRUCTIONS

1. The investigator should make certain that teachers fully understand how to complete the scale - particularly how to properly mark their responses. In checking the completed scale, make sure that the encoded initials are the patient's, NOT the teacher's. If the investigator wishes, teachers may complete the ID block. To do so, however, they must be given patient numbers, their rating number and thorough grounding in the encoding of PERIOD.

2. Do not write in the shaded area of the ID block. Form Number has been precoded.

Incorrect → 

Correct → 

DOCUMENTATION

a. Raw score printout
b. Factor score printout - including global items
c. Means and standard deviations for factor scores and global items. Ten-item totals, in lieu of factor scores, will be displayed when the PTQ is substituted for repeated assessments.
d. Crosstabulation of factor scores - Displayed only when TQ is used for repeated assessments.
e. Variance analyses.

036 PQ
PARENT
QUESTIONNAIRE

MH 9-36
1-73

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

CONNERS PARENT QUESTIONNAIRE

INSTRUCTIONS: Listed below are items concerning children's behavior or the problems they sometimes have. Read each item carefully and decide how much you think your child has been bothered by this problem during the last month: NOT AT ALL, JUST A LITTLE, PRETTY MUCH, or VERY MUCH.

Indicate your choice by filling in the space (▬) in the appropriate column to the right of each item.

OBSERVATION		Not at all	Just a little	Pretty much	Very much
		0	1	2	3
PROBLEMS OF EATING:	1. Picky and finicky				
	2. Will not eat enough				
	3. Overweight				
PROBLEMS OF SLEEP:	4. Restless				
	5. Nightmares				
	6. Awakens at night				
	7. Cannot fall asleep				
FEAR AND WORRIES:	8. Afraid of new situations				
	9. Afraid of people				
	10. Afraid of being alone				
	11. Worries about illness and death				
MUSCULAR TENSION:	12. Gets stiff and rigid				
	13. Twitches, jerks, etc.				
	14. Shakes				
SPEECH PROBLEMS:	15. Stuttering				
	16. Hard to understand				
WETTING:	17. Bed wetting				
	18. Runs to bathroom				
BOWEL PROBLEMS:	19. Soiling self				
	20. Holds back bowel movements				
COMPLAINS OF FOLLOWING SYMPTOMS EVEN THOUGH DOCTOR CAN FIND NOTHING WRONG:	21. Headaches				
	22. Stomachaches				
	23. Vomiting				
	24. Aches and pains				
	25. Loose bowels				
PROBLEMS OF SUCKING, CHEWING or PICKING:	26. Sucks thumb				
	27. Bites or picks nails				
	28. Chews on clothes, blankets, or others				
	29. Picks at things such as hair, clothing, etc.				
CHILDISH OR IMMATURE:	30. Does not act his age				
	31. Cries				
	32. Wants help doing things he should do alone				
	33. Clings to parents or other adults				
	34. Baby talk				
TROUBLE WITH FEELINGS:	35. Keeps anger to himself				
	36. Lets himself get pushed around by other children.				
	37. Unhappy				
	38. Carries a chip on his shoulder				

MH-9-36
1-73

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB NO. 68-R965

CONNERS PARENT QUESTIONNAIRE

PATIENT INITIALS

FIRST INITIAL: A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

SECOND INITIAL: A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

FORM NO.

NUMBER MALES 001 TO 499; FEMALES 500 TO 998

PATIENT: 0 1 2 3 4 5 6 7 8 9

RATER: 0 1 M 2 F 3 4 5 6 7 8 9

PERIOD: 0 1 Hours 2 Days 3 Weeks 4 Months 5 6 7 8 9

	OBSERVATION	
OVER-ASSERTS HIMSELF:	39.	Bullying
	40.	Bragging and boasting
	41.	Sassy to grown-ups
PROBLEMS MAKING FRIENDS:	42.	Shy
	43.	Afraid they do not like him
	44.	Feelings easily hurt
	45.	Has no friends
PROBLEMS WITH BROTHERS AND SISTERS:	46.	Feels cheated
	47.	Mean
	48.	Fights
PROBLEMS KEEPING FRIENDS:	49.	Disturbs other children
	50.	Wants to run things
	51.	Picks on other children
RESTLESS:	52.	Restless *(overactive)*
	53.	Excitable, impulsive
	54.	Fails to finish things he starts *(short attention span)*
TEMPER:	55.	Temper outbursts, explosive and unpredictable behavior
	56.	Throws himself around
	57.	Throws and breaks things
	58.	Pouts and sulks
SEX:	59.	Plays with own sex organs
	60.	Involved in sex play with others
	61.	Modest about his body
PROBLEMS IN SCHOOL:	62.	Learning is a problem
	63.	Does not like to go to school
	64.	Is afraid to go to school
	65.	Daydreams
	66.	Truancy
	67.	Will not obey school rules
LYING:	68.	Denies having done wrong
	69.	Blames others for his mistakes
	70.	Tells stories which did not happen
STEALING:	71.	From parents
	72.	At school
	73.	From stores and other places
FIRE-SETTING:	74.	Sets fires
TROUBLE WITH POLICE:	75.	Gets into trouble with police

	OBSERVATION	
PERFECTIONISM:	76.	Everything must be just so
	77.	Things must be done same way every time
	78.	Sets goals too high
ADDITIONAL PROBLEMS:	79.	Inattentive, easily distracted
	80.	Fidgeting
	81.	Cannot be left alone
	82.	Climbing; gets into things
	83.	A very early riser
	84.	Will run around between mouthfuls at meals
	85.	Demands must be met immediately —easily frustrated
	86.	Cannot stand too much excitement
	87.	Laces and zippers are open
	88.	Cries
	89.	Unable to stop a repetitive activity
	90.	Acts as if driven by a motor
	91.	Mood changes quickly
	92.	Poorly aware of surroundings or time of day
	93.	Clumsy

94. How serious a problem do you think your child has at this time?

The Parent Questionnaire (PQ), developed by Conners, is a 93-item check list of symptoms most commonly associated with behavior disorders of childhood. The 94th item is a global judgment of the severity of the child's problem. Symptoms are rated on a 4-point scale by either or both parents of the child. The PQ is an independent form and does not require a General Scoring Sheet.

REFERENCE — Conners, C. K. Symptom patterns in hyperkinetic, neurotic and normal children, Child Development, 1970, 41, 667-682.

APPLICABILITY — Children to 15 years of age

UTILIZATION — Once at pretreatment. The 94-item PQ may be used for repeated assessments; but frequently the 10-item Parent-Teacher Questionnaire (PTQ) is substituted for ratings subsequent to the initial rating. The number of assessments is at the discretion of the principal investigator.

TIME SPAN RATED — Now or within the last week.

CARD FORMAT - ITEMS — CARD 01 - (19x, 5611)

Item	Column	Item	Column	Item	Column	Item	Column
1	20	15	34	29	48	43	62
2	21	16	35	30	49	44	63
3	22	17	36	31	50	45	64
4	23	18	37	32	51	46	65
5	24	19	38	33	52	47	66
6	25	20	39	34	53	48	67
7	26	21	40	35	54	49	68
8	27	22	41	36	55	50	69
9	28	23	42	37	56	51	70
10	29	24	43	38	57	52	71
11	30	25	44	39	58	53	72
12	31	26	45	40	59	54	73
13	32	27	46	41	60	55	74
14	33	28	47	42	61	56	75

CARD 02 - (19x, 3811)

Item	Column	Item	Column	Item	Column	Item	Column
57	20	66	29	75	38	84	47
58	21	67	30	76	39	85	48
59	22	68	31	77	40	86	49
60	23	69	32	78	41	87	50
61	24	70	33	79	42	88	51
62	25	71	34	80	43	89	52
63	26	72	35	81	44	90	53
64	27	73	36	82	45	91	54
65	28	74	37	83	46	92	55
						93	56
						Severity	57

CARD FORMAT - FACTORS CARD 51 = 19x, 8F6.2, F2.0, F4.0)

(Code "5" in Column 18 indicates card containing factor, cluster or other derived scores.)

Factor	Column	Factor	Column
I	20 - 25	VI	50 - 55
II	26 - 31	VII	56 - 61
III	32 - 37	VIII	62 - 67
IV	38 - 43	Severity	68 - 69
V	44 - 49	Total Score	70 - 73

Factor score = $\frac{\text{Sum of composite items}}{\text{No. of composite items}}$ Factor Score Range = 0 - 3

Total Score - Sum of 93 items Total Score Range = 0 - 279

FACTOR COMPOSITION

I. Conduct Problem
- 39 - Bullying
- 40 - Bragging and boasting
- 41 - Sassy to grown-ups
- 47 - Mean
- 48 - Fights constantly
- 51 - Picks on other children
- 69 - Blames others for his mistakes

II. Anxiety
- 8 - Afraid of new situations
- 9 - Afraid of people
- 10 - Afraid of being alone
- 11 - Worries about illness and death
- 42 - Shy
- 43 - Afraid they (children) do not like him
- 64 - Is afraid to go to school

III. Impulsive-Hyperactive
- 79 - Inattentive, easily distracted
- 80 - Constantly fidgeting
- 81 - Cannot be left alone
- 82 - Always climbing
- 83 - A very early riser
- 84 - Will run around between mouthfuls
- 89 - Unable to stop a repetitive activity
- 90 - Acts as if driven by a motor

IV. Learning Problem
- 45 - Has no friends
- 62 - Is not learning
- 63 - Does not like to go to school
- 67 - Will not obey school rules

V. Psychosomatic
- 6 - Awakens at night
- 21 - Headaches
- 22 - Stomach aches
- 23 - Vomiting
- 24 - Aches and pains

VI. Perfectionism
- 76 - Everything must be just so
- 77 - Things must be done same way
- 78 - Sets goals too high

VII. Antisocial
- 71 - (Stealing) from parents
- 72 - (Stealing) at school
- 73 - (Stealing) from stores
- 75 - Gets into trouble with police

VIII. Muscular Tension
- 12 - Gets stiff and rigid
- 13 - Twitches, jerks, etc.
- 14 - Shakes
- 36 - Lets himself get pushed around

Only 42 items are subsumed under the 8 factors; the other 52 items are not utilized in the factor scoring.

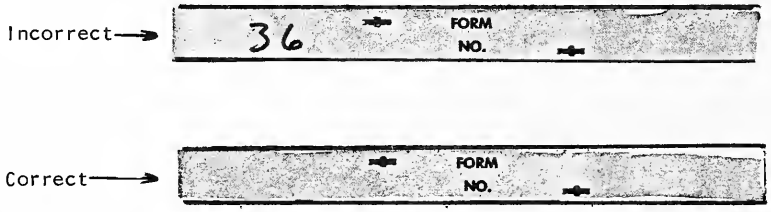
This factor analysis is based on a sample of clinic outpatients and normal children (N=683) and has been shown to give relatively stable factor structure across ages and a wide social class range (Conners, 1970). These factor scores will be relatively independent since items were selected so as to have minimal overlap in loadings on other factors. However, some correlation among scales can be expected since only factor scores derived by using actual loadings will be orthogonal to other factors. Although similar patterns of symptomatology appear in normals and outpatients, the severity of symptomatology is higher among the patient groups.

SPECIAL INSTRUCTIONS

1. For any scales which are filled out by "lay raters" (patient, parent, etc.) an observer should be present, whenever possible, to make sure that the instructions are understood and that the rater knows how to properly mark his/her responses. Following completion of the scale, check to make certain that all items are completed and that only one answer is given to each item. With the PQ, make certain that the rater realizes that there are additional items under the first fly leaf. If the parent fills in the initials, check to see that they are the patient's initials, NOT the parent's. The rest of the ID block is best completed by the observer.

2. Coding Rater - Code 11(M) when mother or mother surrogate completes the scale; code 22(F) when father or father surrogate completes the scale. Use any other 2 digits for other rater.

3. Do not write in the shaded area of the ID block. Form Number has been precoded.



DOCUMENTATION

a. Raw score printout
b. Factor score printout - including global item
c. Means and standard deviations for factor scores and severity. Ten item totals, in lieu of factor scores, will be displayed when the PTQ is employed for repeated assessments.
d. Crosstabulation of factor scores - Displayed only when PQ is used for repeated assessments.
e. Variance analyses - When the PTQ is employed for ratings subsequent to the initial one, the 10 comparable items extracted from the PQ will be used as for the initial rating.

O37 PTQ
PARENT-TEACHER QUESTIONNAIRE

MH-9-37
1-73

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB NO. 68-R965

CONNERS PARENT–TEACHER QUESTIONNAIRE

PATIENT INITIALS

FIRST INITIAL: A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

SECOND INITIAL: A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

FORM NO.

NUMBER MALES 001 TO 499; FEMALES 500 TO 998

PATIENT: 0 1 2 3 4 5 6 7 8 9

RATER: M 0 1 2 3 4 5 6 7 8 9 / F 0 1 2 3 4 5 6 7 8 9

PERIOD: 0 Hours 1 2 Days 3 4 Weeks 5 6 7 Months 8 9

PLEASE USE A NO. 2 LEAD PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE.

INSTRUCTIONS: Listed below are items concerning children's behavior or the problems they sometimes have. Read each item carefully and decide how much you think this child has been bothered by this problem *at this time:* NOT AT ALL, JUST A LITTLE, PRETTY MUCH, or VERY MUCH. Indicate your choice by filling in the space (▬) in the appropriate column to the right of each item.

ANSWER ALL ITEMS

	Not at All	Just a Little	Pretty Much	Very Much
1. Restless (overactive)	0	1	2	3
2. Excitable, impulsive	0	1	2	3
3. Disturbs other children	0	1	2	3
4. Fails to finish things he starts (short attention span)	0	1	2	3
5. Fidgeting	0	1	2	3
6. Inattentive, distractable	0	1	2	3
7. Demands must be met immediately; frustrated	0	1	2	3
8. Cries	0	1	2	3
9. Mood changes quickly	0	1	2	3
10. Temper outbursts (explosive and unpredictable behavior)	0	1	2	3
	None	**Minor**	**Moderate**	**Severe**
How serious a problem do you think this child has at this time?	0	1	2	3

The Conners Parent-Teacher Questionnaire (PTQ) is an independently formatted scale containing 11 items common to both the Parent Questionnaire and Teacher Questionnaire. The PTQ per se is not so much an independent scale as it is a device which reduces - by abbreviation - the burden of repeated assessments for teachers and parents. The correspondence of items across the 3 scales is as follows:

PTQ	PQ	TQ
1	52	5
2	53	6
3	49	14
4	54	8
5	80	1
6	79	7
7	85	3
8	88	13
9	91	16
10	55	21
Severity (11)	94	40

APPLICABILITY — Children to 15 years of age

UTILIZATION — The PTQ must be used in conjunction with either the Parent Questionnaire or Teacher Questionnaire.

TIME SPAN RATED — Now or within the last week.

CARD FORMAT - ITEMS — CARD 01 = (19x, 1011, 12, 11)

Item	Column	Item	Column
1	20	7	26
2	21	8	27
3	22	9	28
4	23	10	29
5	24	Total Score	30 - 31
6	25	Severity	32

Total Score = Sum of Items 1 through 10. Total Score Range = 0 - 30

SPECIAL INSTRUCTIONS

Either the full PQ or full TQ must be used for the initial assessment, even though the investigator plans to use the abbreviated PTQ for subsequent ratings. This is strongly recommended since a more detailed description of the subject prior to treatment can be obtained by use of these longer scales. Although the brevity of the PTQ is a decided advantage for repeated ratings, it yields only a total score.

Both the PQ and TQ provide factors which may permit scrutiny of specific drug effects within circumscribed behavior areas. For investigators who wish a more detailed measure of drug effect, it is suggested that the full PQ or full TQ be used for all ratings.

Encoding Rater - Encode 11 (M) if mother completes the PTQ; encode 22 (F) for father. Use any other number for teacher; but, of course, use the same number for a given rater throughout the study.

Shaded Area - Do not write in the shaded area of the ID block. Form Number is pre-coded.

Incorrect → 

Correct → 

Monitoring - As with all forms used by lay raters, be sure that the rater fully understands the instructions and how to properly mark his/her responses. Whenever possible, the completed scale should be reviewed immediately for omissions or multiple entries (more than one mark for an item). The ID block should also be checked for accuracy if the lay rater has completed it. Make sure that the patient's (child's) initials - NOT the rater's - are encoded.

DOCUMENTATION

a. Raw score printout
b. Total score means and standard deviations.
c. Variance analyses - When the longer PQ and TQ are used at the initial rating, the 10 PTQ items will be extracted from them for use in the variance model.

RATING SCALES FOR USE IN DRUG STUDIES WITH CHILDREN*

C. Keith Conners, Ph.D.

The purpose of this report is to describe some rating scales for use in children's drug studies. It seems eminently clear that no single choice of scales is likely to meet the needs for the variety of populations, designs, facilities and purposes of various research problems, and though I have chosen to recommend certain scales for consideration, I have also presented alternatives that may enrich the discussion and possibly be of use to investigators unfamiliar with these alternatives.

A number of good sources are available regarding the technology of scale construction and methodologic issues (1, 2, 3), and reviews of rating scales in psychiatric settings are available (4, 5). While there is indeed an elaborate technology for producing "pure" psychometric instruments, most evidence seems to indicate that the practical gains from elaborate and sophisticated scaling procedures is minimal (1), and I do not propose to deal with the many methodologic issues raised in the use and construction of rating scales. Certain basic attributes of reliability and validity need, of course, to be considered, and for the most part I have not included a number of scales that look interesting but which have no published reliability or validity data.

The choice of children's rating scales needs to be based on certain criteria and working assumptions which will eliminate some scales from further consideration.

First, there is the source of the rating data. If the source of data is the parent or teacher, then the scale must be non-technical, brief and easily filled out. A clinician or trained observer on the other hand, may use much more detailed and theoretically-oriented instruments. Since parent, teacher, and clinician have different (though overlapping) behavior samples, the scales for different observers almost certainly need to be different in content, though an overlap in some areas would be desirable.

Secondly, there is the question of level of observation. This can be very molecular--where specific behavioral acts or sequences can be observed and time-sampled--or the categories can be quite global, abstract or inferential. Most people are agreed that ratings which require a great deal of inference about underlying processes tend to be unreliable; but descriptive global ratings that use "middle level" inferences are often the most reliable. Unless the observer is highly trained there is likely to be a loss of reliability for rating of molecular events. We have, therefore, tended to assume that some middle level of abstraction, requiring a minimum of inference, is preferable unless highly trained observers are available.

*This material was written by Dr. Conners for presentation to the Pediatric Psychopharmacology Workshop. It reflects the processes by which assessment instruments were chosen for the ECDEU Pediatric Battery.

A related issue is whether one is interested in rating current behaviors, symptoms or states; or whether the intent is to describe basic traits, dispositions, or personality characteristics. While not mutually exclusive, these approaches lead to somewhat different types of scales. I have assumed that a symptom focus is most appropriate for our purposes, though the difference between a symptom and a trait is probably more a question of values as to whether the behavior in question is normative or undesirable.

Whether one uses state or trait methods depends to some extent on the purpose of using the ratings in the first place. A use for prediction might well require more trait-disposition items, while symptoms would seem to be more appropriate for measuring change. Both types of items are appropriate for questions of taxonomic classification. It is conceivable to me that all three purposes--prediction, measurement of change, and classification--might be meaningfully applied in drug studies. In general, I have recommended the use of behavior items that are susceptible to short term change, but which can also be used in conjunction with statistical techniques for prediction and classification.

The population under study clearly makes a difference in the type of scale to be employed. It has seemed reasonable that separate instruments should be employed for severe psychiatric disturbances (psychosis, retardation, autism, etc.) as contrasted with the more frequent and typical patients found in outpatient settings. Institutionalized children are usually more severely affected by their illness, and many of their symptoms are of low frequency in outpatients (e.g., hallucinations, autistic aloofness).

Finally, the format of the scale needs consideration. For most purposes a scale with specific anchor points describing the behavior in question is most likely to be reliable and valid. But such scales are also more cumbersome and time-consuming to use. If the range of behavior to be sampled is broad, (as it is likely to be in the screening phase of a study) then the items should be brief and the rating procedure as simple as possible. This consideration has led me to recommend the "check-list" type of scale, especially for parent ratings.

Teacher Rating Scales

1. Cattell and Coan (6) administered a 38-item trait list of bipolar items to teachers of 198 first and second grade pupils. This list was compiled to include the major "markers" from other personality research, as well as "useful indicators of personality disturbance." Many of the items are probably irrelevant for symptom-oriented studies (e.g., "aesthetically sensitive, aesthetically fastidious, vs. lacking in artistic feeling"), but for those investigators interested in predicting drug effect from personality traits, this might be a useful scale. They identified some 15 factors by Cattell's methods (oblique rotations), but the reliability of factor scores is not given, and the non-independence of the factors probably makes them of little use as independent predictors in regression equations.

2. Peterson (7) used the referral problems of 427 cases at a guidance clinic to select the 58 most common symptoms. The list was given to teachers of 831 kindergarten through sixth grade pupils for ratings. Two major factors (conduct problem and personality problem) emerged with considerable consistency across the whole age range. Interrater reliabilities (for the Kg sample) were .77 and .75 for factor

scores for the two factors. Quite similar factors have emerged in a number of studies by Quay and associates (8) for various populations, from sources as disparate as case history ratings, questionnaires, standard ratings, and by a variety of factor extraction methods.

However, several questions can be raised about these results. The presence of only two (sometimes three) factors suggests that either the repertoire of items is so restricted as to guarantee a small number of independent factors or the method of analysis produces few factors. Secondly, the two factors appear to subsume some very disparate behaviors which intuitively seem distinct. Thirdly, many of the items, particularly conduct problem items, are essentially synonyms, guaranteeing that a strong factor will emerge. Some of the items are symptomatic (e.g. fighting), while some are essentially trait names (e.g. nervousness, aloofness). Nevertheless, similar factors emerge in some form or other in many other studies, and it is probably safe to assume that there are at least two important dimensions, or causally independent factors, that could be extremely useful in basic classification, prediction, and possibly measurement of change in drug studies.

3. A comprehensive classroom behavior and personality instrument has been developed by Shaeffer and colleagues at the Laboratory of Psychology of NIMH. The items were selected from a theoretical model of child behavior, have been extensively analyzed for factor structure and reliability, and tested in the U.S. and Scandinavia. Specific classroom behaviors are organized into traits, and the traits are organized into factors and arranged in a "circumplex" model. Figure 17 shows the conceptualization of the item-trait-factor derivation, and Figure 18 is an example of the ordering of traits on a circumplex.[1] The major difficulty with this instrument seems to be its length. The 320 items in the scale seem prohibitively time-consuming for volunteer reporting by teachers. However, the excellent pool of items, and the extensive analytic work on sub-scales might be useful in some settings.

4. The Devereux Elementary School Behavior Rating Scale (9) is a 47-item anchored scale for teachers, with items easily grouped into 11 behavior factors. Normative data is available on 809 normal children in kindergarten through 6th grades. Test-retest factor scale reliabilities range from .71 to .91, with small standard errors of measurement, and median reliability of .87. The factor structure is quite similar across grade levels. In general the scale meets most of the requirements for an instrument in drug studies, though I know of no demonstration that it is "drug-sensitive". This scale has a high priority for use as a standardized data-gathering instrument.

5. A 39-item Teacher Symptom Checklist originally developed by Eisenberg and colleagues has been used in several drug studies and recently factor analyzed by Conners (10). The five factors are highly reliable on test-retest, and appear to be quite sensitive to changes due to drug, with relatively little placebo influence. Test-retest reliabilities over a one-month period ranged from .72 to .91. The five

[1] These data are from an unpublished manuscript by Shaeffer, Droppelman, and Kalverboer. Unfortunately, at the time of this preparation I did not have available Dr. Shaeffer's more recent extensive work.

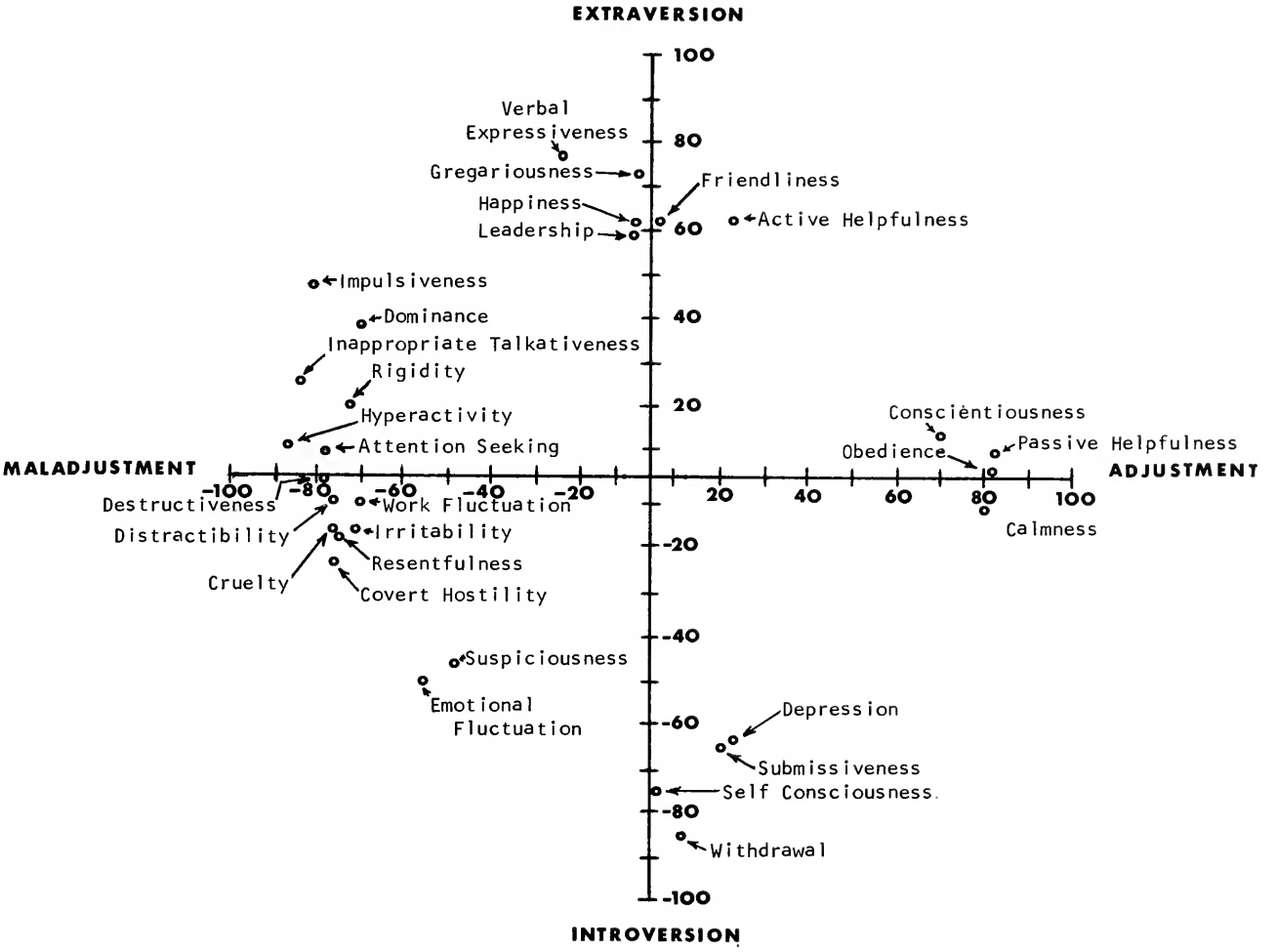
FIGURE 17

HIERARCHIAL STRUCTURE OF THE CLASSROOM BEHAVIOR INVENTORY
(Form for Preschool to Early Primary)

Molar, abstract → Concrete, specific

	Dimensions (3 Factors)	Traits (12 Scales)	Specific Behaviors (60 Items)
Classroom Adjustment	Extraversion vs. Introversion	Verbal Expressiveness Gregariousness	Always has something to say in group discussions.
		Social Withdrawal Self-Consciousness	Rarely joins in activities with others of his own accord.
	Love vs. Hostility	Considerateness Kindness	Is careful not to disturb an activity of another.
		Resentfulness Irritability	Sits and sulks if he has been reproved.
	Positive Task-Oriented vs. Negative Task-Oriented	Perseverance Concentration	Nearly always sticks to tasks until they are finished.
		Hyperactivity Distractibility	Frequently is twisting, turning or getting up from his chair.

FIGURE 18


EXTRAVERSION
INTROVERSION
MALADJUSTMENT
ADJUSTMENT
100
80
60
40
20
-20
-40
-60
-80
-100
-100
-80
-60
-40
-20
20
40
60
80
100
Verbal Expressiveness
Gregariousness
Friendliness
Happiness
Leadership
Active Helpfulness
Impulsiveness
Dominance
Inappropriate Talkativeness
Rigidity
Hyperactivity
Attention Seeking
Conscientiousness
Obedience
Passive Helpfulness
Destructiveness
Work Fluctuation
Distractibility
Irritability
Resentfulness
Cruelty
Covert Hostility
Calmness
Suspiciousness
Emotional Fluctuation
Depression
Submissiveness
Self Consciousness
Withdrawal

factors were labeled "aggressive conduct", "day-dreaming-inattentive", "anxious-fearful", "hyperactivity", "sociable-cooperative". (A newer, slightly modified form has been developed which contains 10 items that overlap with the symptom checklist for parents, described below. This allows one to compare ratings from both sources on a common core of items.)

6. Two excellent teacher scales should be mentioned. Both are more appropriate for identification of learning disorders and children with developmental deviations than for measuring change, but in view of the likelihood of increased interest in drug studies of learning disorders, the scales are important to keep in mind where large scale screening may be needed to identify potential candidates for drug studies. The first is a 24-item anchored scale by Myklebust (11). The items are grouped into five areas: auditory comprehension and learning, spoken language, orientation (time, space, relationship), behavior, and motor. The scale was used to identify children with minimal cerebral dysfunction in a sample of 2767 third and fourth graders. Excellent discriminative power and validity were shown with the scale, though reliabilities are not reported.

The Classroom Screening Inventory developed by the Rocky Mountain Educational Laboratory (12) is an 80-item scale that is divided into 14 sub-scales focused on classroom learning and behavior. A very thorough item analysis, factor analysis, reliability and validity studies are reported. The instrument was used in a study of a stratified random sample of 2400 children in the Rocky Mountain area. Inter-rater reliability was .85. A validity study showed that the screening produced no false positives and very few false negatives. This instrument though still being developed is the best of its kind known to this writer.

In summary, the Devereux Elementary School Behavior Rating Scale appears to meet most of the requisites for a brief, reliable scale for children's drug studies. As an alternative, the Conners scale is probably easier to use and less likely to be resisted by the busy teacher because of its checklist format. However, the more extensive published research on the Devereux Scale makes it appear as the best bet at this time.

Parent Rating Scales

A number of studies of the dimensions of symptom behavior in young children have been made during the past several years. Jenkins and Hewitt (13) described three clusters of traits identified from case records of 500 children rated on 90 symptoms. More recently, Jenkins (14) identified 5 clusters which he labelled "shy-seclusive", "overanxious-neurotic", "hyperactivity with poor concentration", "undomesticated", and "socialized delinquent". These clusters fell into two broad categories of inhibited and aggressive children. Peterson (15) identified two dimensions from parent and teacher ratings which he labelled "conduct disorder" and "personality disorder". These patterns have emerged in several other studies by Quay (16), Dreger, et al. (17), and Borgatta and Fanshel (18). The latter study produced 12 factors: defiance, unsocialized, tension-anxiety, lack of affection, infantilism, overcleanliness, sex precociousness, sex inhibition, learning difficulty, (a and b), likeability, responsibility. A second-order factor analysis

produced six factors including an "acting-out" factor, developmental immaturity, inhibited behavior, learning disorder, and sociable-responsible. Reliabilities of factor scales are not given, but individual item reliability ranges from .60 to .77, suggesting that factor scales are likely to be highly reliable. These studies and others mentioned below provide a substantial base of knowledge for purposes of prediction and classification.

An anchored rating scale for nonprofessionals was developed by Spivack and Spotts (19) at the Devereux Foundation. Good norms are available for the 17 subscales of the 97-item scale. Like the teacher's version, this scale is thoroughly researched, easy to use and score, and covers a broad range of psychopathology.

The Missouri Children's Behavior Checklist (20) is a similar 70-item yes-no checklist of symptoms. The factors of aggression, inhibition, activity level, sleep disturbance, somatization and sociability have odd-even reliabilities ranging from .67 to .86. Inter-parent agreement on individual items ranged from 53% to 94%. Validity studies of clinic versus controls showed significant discrimination of all factors except somatization and sleep disturbance.

Conners (21) has described a 93-item parent symptom checklist that was factor-analyzed on 316 clinic patients between the ages of 6 and 14, and 367 normal controls of the same age. Twenty-four categories of symptoms (sleep, learning, sociability, etc.) were factor analyzed. Six factors were identified by principal components analysis and labelled aggressive conduct disorder, anxious-inhibited, antisocial, enuresis-encopresis, psychosomatic, and anxious-immature. Discriminant function analysis showed that 83% of controls and 70% of clinic patients could be correctly classified from factor scores. Neurotic and hyperkinetic children were also correctly identified in 77% and 74% of the cases, respectively. Mother-father agreement averaged .85 on total scores, but factor scale agreement is not reported as yet. The first two factors (conduct disorder and anxious-inhibited) have been used in drug studies and show significant drug-placebo interactions. A recently modified version employs a 10-item scale to overlap with teacher ratings for repeated measures in drug studies.

A factor analysis was also completed on individual items for the total sample of 683 subjects (previous analyses had shown close similarity in factor structure for different social classes, different age ranges, and for the sexes). Factor loadings on each of the seven factors are very similar to the factors reported by Achenbach, Borgatta and Fanshel (18), and several others.

One drawback of the scales described here is that none includes symptoms of severe psychopathology such as psychotic manifestations. A rather extensive study on children's psychiatric symptoms by Achenbach (22) includes more of such symptoms. The large, first principal component factor appeared to be a bipolar "internalizing vs. externalizing" factor, and the second large component was identified as a unipolar "diffuse psychopathology" factor. Eight rotated factors were identified as: somatic complaints, delinquent behavior, obsessions, compulsions and phobias; sexual problems; schizoid thinking; unsocialized aggression; hyperactivity; and one minor factor. The main problem with this scale is that it is designed for professionals

or semi-professionals, so that various items would be difficult for parents to use (such as diplopia, compulsions, etc.). This is an excellent list, however, for rating of case records or other symptom rating in a clinical context.

In summary, both the Conners and Devereux scales appear to be feasible in drug studies, with the latter scale being more thoroughly standardized.

Clinician's Ratings

1. Very few standardized child-psychiatry rating scales are available. The brief standardized rating procedure described by Rutter and Graham (23) appears to have both good inter-examiner reliability and validity. A somewhat more comprehensive rating scale for psychiatrists has been provided by Drs. Klein from the Hillside Hospital but standardization procedures are not available at this time.

2. A valuable source of observation, particularly for measuring change in drug studies, is a behavior rating by the psychologist on the basis of observations made during psychological testing. I am unaware of any standardized forms for this purpose, but the rating scale used by the NINDS Collaborative Perinatal project appears to be excellent for most purposes.

Inpatients and Retarded

The Children's Behavior Inventory by Burdock and Hardesty (24) is a 139-item yes-no scale with items grouped by age-appropriateness. Extensive reliability and validity studies have been done, and the results indicate sufficient discriminative power and stability to warrant using the inventory in settings where a moderate amount of training of observers is possible. The items are rationally grouped into categories of vegetative function, appearance and mannerisms, speech and voice, emotional display, socialization and thought processes. Drug studies have not yet been reported with this instrument.

A much briefer scale has been reported by Davis, Sprague and Werry (25) for time-sampling measurement of stereotyped behavior in retardates. Interjudge reliabilities ranged from .61 to .88 for the 7 categories. The scale showed sensitivity to drug treatment, and would appear to be an excellent measure for this relatively restricted (but common) set of behaviors in retardates or other severely disturbed inpatients.

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O53 SCL-90
SELF-REPORT
SYMPTOM
INVENTORY

SCL–90

Below is a list of problems and complaints that people sometimes have. Please read each one carefully. After you have done so, please fill in one of the numbered spaces to the right that best describes HOW MUCH THAT PROBLEM HAS BOTHERED OR DISTRESSED YOU DURING THE PAST WEEK INCLUDING TODAY. Mark only one numbered space for each problem and do not skip any items. Make your marks carefully using a No. 2 pencil. DO NOT USE A BALLPOINT PEN. If you change your mind, erase your first mark carefully. Please do not make any extra marks on the sheet. Please read the example below before beginning.

EXAMPLE:

HOW MUCH WERE YOU BOTHERED BY:	NOT AT ALL	A LITTLE BIT	MODERATELY	QUITE A BIT	EXTREMLY
1. Backaches	:::::	■	:::::	:::::	:::::

HOW MUCH WERE YOU BOTHERED BY:

1. Headaches
2. Nervousness or shakiness inside
3. Unwanted thoughts, words, or ideas that won't leave your mind
4. Faintness or dizziness
5. Loss of sexual interest or pleasure
6. Feeling critical of others
7. The idea that someone else can control your thoughts
8. Feeling others are to blame for most of your troubles
9. Trouble remembering things
10. Worried about sloppiness or carelessness
11. Feeling easily annoyed or irritated
12. Pains in heart or chest
13. Feeling afraid in open spaces or on the streets
14. Feeling low in energy or slowed down
15. Thoughts of ending your life
16. Hearing voices that other people do not hear
17. Trembling
18. Feeling that most people cannot be trusted
19. Poor appetite
20. Crying easily
21. Feeling shy or uneasy with the opposite sex
22. Feeling of being trapped or caught
23. Suddenly scared for no reason
24. Temper outbursts that you could not control
25. Feeling afraid to go out of your house alone
26. Blaming yourself for things
27. Pains in lower back
28. Feeling blocked in getting things done
29. Feeling lonely
30. Feeling blue
31. Worrying too much about things
32. Feeling no interest in things
33. Feeling fearful
34. Your feelings being easily hurt
35. Other people being aware of your private thoughts
36. Feeling others do not understand you or are unsympathetic
37. Feeling that people are unfriendly or dislike you
38. Having to do things very slowly to insure correctness

MH 9-53
5-73

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB NO. 68-R555

SCL - 90

PATIENT INITIALS

FIRST INITIAL: A B C D E F G H I J / K L M N O P Q R S T / U V W X Y Z

SECOND INITIAL: A B C D E F G H I J / K L M N O P Q R S T / U V W X Y Z

FORM [redacted]

NUMBER MALES 001 to 499; FEMALES 500 to 998

PATIENT: 0 1 2 3 4 5 6 7 8 9

RATER: 0 S 1 2 3 4 5 6 7 8 9

PERIOD: 0 1 2 3 4 5 6 7 8 9
0 Hours 1 Days 2 Weeks 3 Months 4

AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE

HOW MUCH WERE YOU BOTHERED BY:

39. Heart pounding or racing
40. Nausea or upset stomach
41. Feeling inferior to others
42. Soreness of your muscles
43. Feeling that you are watched or talked about by others
44. Trouble falling asleep
45. Having to check and double-check what you do
46. Difficulty making decisions
47. Feeling afraid to travel on buses, subways, or trains
48. Trouble getting your breath
49. Hot or cold spells
50. Having to avoid certain things, places, or activities because they frighten you
51. Your mind going blank
52. Numbness or tingling in parts of your body
53. A lump in your throat
54. Feeling hopeless about the future
55. Trouble concentrating
56. Feeling weak in parts of your body
57. Feeling tense or keyed up
58. Heavy feelings in your arms or legs
59. Thoughts of death or dying
60. Overeating
61. Feeling uneasy when people are watching or talking about you
62. Having thoughts that are not your own
63. Having urges to beat, injure, or harm someone
64. Awakening in the early morning
65. Having to repeat the same actions such as touching, counting, washing
66. Sleep that is restless or disturbed
67. Having urges to break or smash things
68. Having ideas or beliefs that others do not share
69. Feeling very self-conscious with others
70. Feeling uneasy in crowds, such as shopping or at a movie
71. Feeling everything is an effort
72. Spells of terror or panic
73. Feeling uncomfortable about eating or drinking in public

HOW MUCH WERE YOU BOTHERED BY:

74. Getting into frequent arguments
75. Feeling nervous when you are left alone
76. Others not giving you proper credit for your achievements
77. Feeling lonely even when you are with people
78. Feeling so restless you couldn't sit still
79. Feelings of worthlessness
80. Feeling that familiar things are strange or unreal
81. Shouting or throwing things
82. Feeling afraid you will faint in public
83. Feeling that people will take advantage of you if you let them
84. Having thoughts about sex that bother you a lot
85. The idea that you should be punished for your sins
86. Feeling pushed to get things done
87. The idea that something serious is wrong with your body
88. Never feeling close to another person
89. Feelings of guilt
90. The idea that something is wrong with your mind

Developed by Derogatis, Lipman and Covi, the Self-Report Symptom Inventory (SCL-90) is an independently formatted form and does not require a General Scoring Sheet. The SCL-90 is composed of 90 items - each rated on a 5-point scale of distress. Evolving from the earlier Hopkins Symptom Checklist, the SCL-90 was designed primarily as a general measure of psychiatric outpatient symptomatology in both clinical and research situations.

APPLICABILITY	Adults in psychiatric and nonpsychiatric outpatient settings.
UTILIZATION	Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.
TIME SPAN RATED	Now or in the last week.

CARD FORMAT - ITEMS CARD 01 = (19x, 5611)

Item	Column	Item	Column	Item	Column
1	20	20	39	39	58
2	21	21	40	40	59
3	22	22	41	41	60
4	23	23	42	42	61
5	24	24	43	43	62
6	25	25	44	44	63
7	26	26	45	45	64
8	27	27	46	46	65
9	28	28	47	47	66
10	29	29	48	48	67
11	30	30	49	49	68
12	31	31	50	50	69
13	32	32	51	51	70
14	33	33	52	52	71
15	34	34	53	53	72
16	35	35	54	54	73
17	36	36	55	55	74
18	37	37	56	56	75
19	38	38	57		

CARD 02 = (19x, 3411)

Item	Column	Item	Column	Item	Column	Item	Column
57	20	66	29	75	38	84	47
58	21	67	30	76	39	85	48
59	22	68	31	77	40	86	49
60	23	69	32	78	41	87	50
61	24	70	33	79	42	88	51
62	25	71	34	80	43	89	52
63	26	72	35	81	44	90	53
64	27	73	36	82	45		
65	28	74	37	83	46		

CARD FORMAT - DIMENSIONS CARD 51* = (19x, 9F6.2)

Dimension	Column	Dimension	Column
I	20 - 25	VI	50 - 55
II	26 - 31	VII	56 - 61
III	32 - 37	VIII	62 - 67
IV	38 - 43	IX	68 - 73
V	44 - 49		

CARD 52* = (19x, 3F6.2)

Global Scores	Column
GSI	20 - 25
PSI	26 - 31
PSDI	32 - 37

General Symptomatic Index (GSI) = $\frac{\text{Sum of all Items}}{\text{No. of Items}}$

Positive Symptom Total (PSI) = No. of items rated positively; i.e., rated 1, 2, 3 or 4.

Positive Symptom Distress Index (PSDI) = $\frac{\text{Sum of all items}}{\text{PST}}$

* Code "5" in Column 18 indicates card containing factor, cluster or derived scores.

DIMENSION COMPOSITION - Dimensions I - V have been validated on samples involving over 2500 patients. Dimensions VI - IX are presently assigned provisional status since validation studies for them are still in progress.

I. Somatization

1	48
4	49
12	52
27	53
40	56
42	58

II. Obsessive-Compulsive

3	45
9	46
10	51
28	55
38	65

III. Interpersonal Sensitivity

6	41
21	61
34	69
36	73
37	

IV. Depression

5	30
14	31
15	32
20	54
22	71
26	79
29	

V. Anxiety

2 57
17 72
23 78
33 80
39 86

VI. Anger-Hostility

11 67
24 74
63 81

VII. Phobic Anxiety

13 70
25 75
47 82
50

VIII. Paranoid Ideation

8 68
18 76
43 83

IX. Psychoticism

7 84
16 85
35 87
62 88
77 90

Items Not Included in any Factor

19 64
44 66
59 89
60

SPECIAL INSTRUCTIONS

The SCL-90 is normally completed by the patient, with administration and monitoring being performed by a technician familiar with the procedure. Usually about 15 minutes of patient time and about 5 minutes of technician time are required. In instances where someone other than the patient is doing the rating, (e.g., doctor, nurse, etc.) the technician's primary involvement is in verifying the accuracy for identifying information. The SCL-90 may be introduced to the patient as part of the facility's attempt to understand the problems of the patient, or it may be explained directly as part of a research project for which the patient's assistance is requested. Both methods have proven quite successful. Stress completion of ALL items as quickly as possible. The patient should also work independently without discussing the items with spouse, family members, etc. The instructions should be read and carefully explained to the patient by the technician/administrator, with particular attention being given to an explanation of the Example printed on the form and the definitions of the scale points given below.

Definition of Scale Points - To be explained to the subject and to be used by raters other than the subject.

0 - Not At All — Patient reports no distress associated with the particular symptom.

1 - A Little Bit = Patient is aware of some distress associated with the symptom, but it is infrequent and of low intensity.

2 - Moderately = Patient experiences distress associated with the symptom in a somewhat regular manner and it is of mild or moderate intensity.

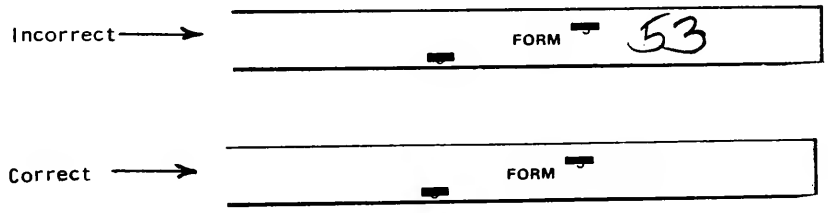
3 - Quite A Bit = Patient experiences distress associated with the symptom with regularity, and it is of moderate to high intensity.

4 - Extremely = Patient experiences extreme distress associated with the symptom, due to frequency, intensity, or a combination of both.

RATER CODE - The code "00" is reserved for the subject; i.e., it indicates that the scale has been self-rated. Any other number may be used to designate a rater other than the subject.

FORM NUMBER - The SCL-90 has the Form Number preprinted and it is not necessary - in fact it is prohibited - to encode this number.

Example: Writing in the form number may trigger multiple opscan punches.



DOCUMENTATION

a. Raw score printout
b. Dimension printout
c. Means and standard deviations of dimensions and global scores
d. Cross-tabulation of dimensions
e. Variance analyses

SCL-90: An Outpatient Psychiatric Rating Scale: Preliminary Report

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The SCL-90 is a self-report clinical rating scale oriented toward the symptomatic behavior of psychiatric outpatients. It is comprised of 90 items which reflect 9 primary symptom dimensions believed to underly the large majority of symptom behaviors observed in this class of patients. A number of additional scales are included outside the principal dimensional framework to assess disturbances in appetite and sleep. The primary symptom dimensions are:

I. Somatization	VI. Hostility
II. Obsessive-Compulsive	VII. Phobic Anxiety
III. Interpersonal Sensitivity	VIII. Paranoid Ideation
IV. Depression	IX. Psychoticism
V. Anxiety	

Dimensions I-V have been empirically established and validated in the context of the Hopkins Symptom Checklist on samples involving over 2,500 patients. Major studies in this series are listed in the Bibliography. Assessments of the various forms of reliability, validity and factorial invariance of these dimensions have been presented in Derogatis et al. (1) (24). Dimensions VI-IX represent "new" dimensions that have been integrated with the five previous measures to provide a more complete representation of the outpatient symptomatic domain.

A brief description of the symptom constructs defined by these dimensions and, in several cases, a short synopsis of the development and rationale basic to each follow below. This is given so that the user may gain a better appreciation of the range and meaning of the SCL-90 clinical profile.

I. Somatization - Reflects distress arising from perceptions of bodily dysfunction. Complaints focused on cardiovascular, gastro-intestinal, respiratory, and other systems with strong autonomic mediation are included. Headaches, backaches, and pain and discomfort localized in the gross musculature are also components, as are other somatic equivalents of anxiety.

II. Obsessive-Compulsive - Reflects behaviors that are closely identified with the clinical syndrome of the same name. The focus of this measure is on thoughts, impulses and actions that are experienced as unremitting and irresistible by the individual but are of an ego-alien or unwanted nature. Behaviors indicative of a more general cognitive difficulty (e.g., "mind going blank", "trouble remembering") also load on this dimension.

III. Interpersonal Sensitivity - Focuses on feelings of personal inadequacy and inferiority, particularly in comparison with other individuals. Self-deprecation, feelings of uneasiness, and marked discomfort during interpersonal interactions are characteristic of persons showing high levels of

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I.S. Feelings of self-consciousness and negative expectancies regarding interpersonal communications are also typical sources of distress.

IV. Depression - Reflects a broad range of the concomitants of the clinical depressive syndrome. Symptoms of dysphoric affect and mood are represented, as are signs of withdrawal of interest in life events, lack of motivation, and loss of vital energy. The dimension mirrors feelings of hopelessness and futility as well as other cognitive and somatic correlates of depression. Several items are included concerning thoughts of death and suicidal ideation.

V. Anxiety - Subsumes a set of symptoms and experiences usually associated clinically with high manifest anxiety. General indicators such as restlessness, nervousness, and tension are included here as are additional somatic signs (e.g. "trembling"). Scales measuring free floating anxiety and panic attacks are an integral aspect of this dimension, and an item on feelings of dissociation is included. The SCL-90 Anxiety dimension has been augmented beyond the item set used with the previous HSCL.

VI. Hostility - The consistent observation that the presence of anger and hostile behavior function as important determinants in a variety of clinical decisions with psychiatric outpatients (e.g. diagnosis, treatment assignment, disposition, etc.) has led to the development of a formal Hostility dimension. This dimension is organized around three categories of hostile behavior: thoughts, feelings, and actions. Items range from feelings of annoyance and urges to break things, through arguments and uncontrollable temper outbursts.

VII. Phobic Anxiety - Reflects symptoms that have been observed with high incidence in conditions termed phobic anxiety state or agoraphobia (Marks 2,3). Fears of a phobic nature oriented towards travel away from home, open spaces, crowds, or public places and conveyances are represented by this measure. In addition, several scales representing social phobic behavior have been included.

VIII. Paranoid Ideation - Derives from the notion that paranoid behavior is best considered from a syndromal point of view. The authors have adopted the position put forth by Swanson, Bohnert, & Smith (4) that paranoid phenomena are most effectively conceived as a mode of thinking. Accordingly, scales have been developed around the primary characteristics of paranoid thought. Swanson, et al. (4) list projective thinking, hostility, suspiciousness, centrality, delusions, loss of autonomy, and grandiosity as cardinal paranoid characteristics. Within the limitations imposed by a self-report format, scales were designed to reflect these manifestations.

IX. Psychoticism - Since psychotic behaviors are observed in the out-patient setting, and play a critical role in administrative and treatment decisions when manifest, a psychoticism dimension was integrated into the SCL-90. The approach taken in building this scale involved sampling from the full

continuum of psychotic behaviors. Thus, florid, acute symptomatology, as well as behaviors typically viewed as more oblique, less definitive, indicators of psychotic process are represented. Four items reflect Schneiderian first-rank symptoms of schizophrenia: auditory hallucinations, thought broadcasting, external thought control, and external thought insertion (Schneider, (5); Mellor, (6); Taylor, (7)). In addition secondary signs of psychotic behavior, as well as indications of a schizoid life style, are also represented. This combination approach is believed to have the greatest potential validity within the self-report format of the instrument.

Areas of Utilization - Due to the ease of administration and broad range of symptoms reviewed in the SCL-90, it should find ideal utilization as a clinical screening instrument in numerous outpatient psychiatric settings. Outpatient departments, emergency services, acute treatment centers, and like facilities are potential primary users. The graphic presentation of the SCL-90 Symptomatic Profile, coupled with the 9 dimensional symptom scores and the three global indices, provides a concise, relevant statement of the patient's immediate symptom status (Figures 19 and 20). A brief clinical narrative may also be appended to the SCL-90 Symptomatic Profile to provide a verbal description of the symptom picture in greater depth. Clinical utilization may be found particularly effective in situations where the patient/professional staff ratio is high and para-medical staff are employed in a screening role.

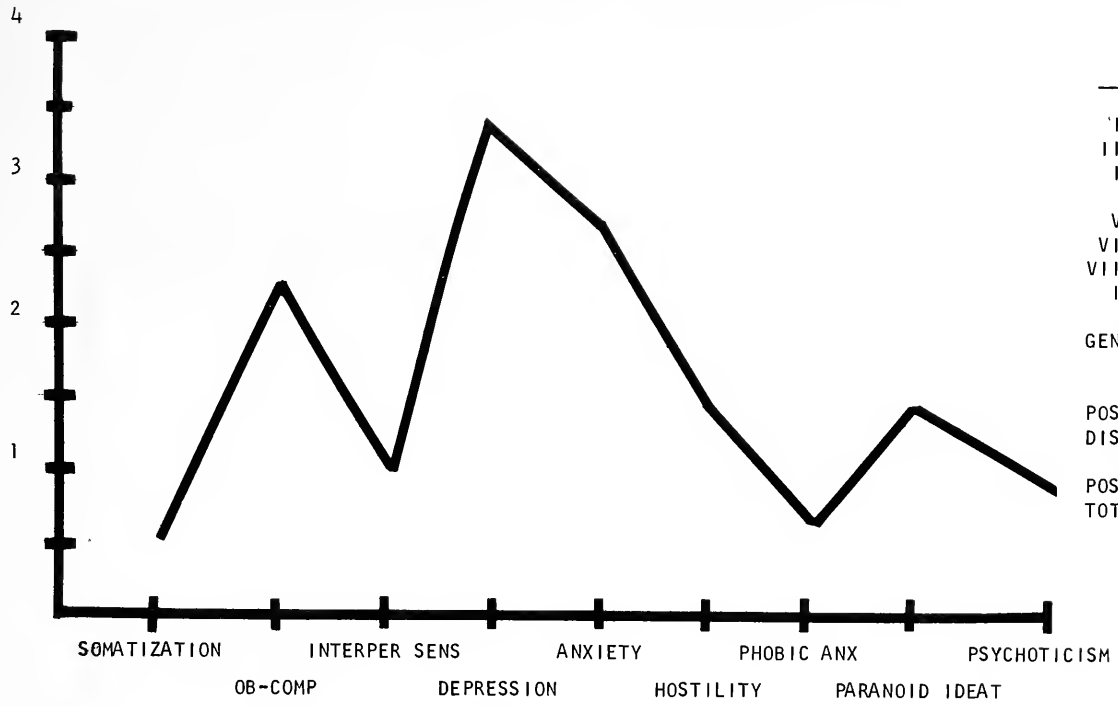
The SCL-90 should also find effective utilization as an efficient means of obtaining symptomatic information in non-psychiatric settings: Counseling centers, student health facilities and medical clinics with a primary orientation toward psychosomatic conditions should find the scales highly relevant. In addition, general medical and surgical facilities are increasingly incorporating information on the psychological status and psychiatric symptomatology of their patients to aid in making decisions about adequate treatment regimens and case dispositions. The scale provides a ready means of evaluating the interactive potential that the psychological status of the individual may have on both primary physical conditions, and on the outcome of procedures designed to alleviate or treat those conditions.

Although designed primarily for use with outpatients, the SCL-90 may also be found valid and useful in certain specified inpatient settings. Raskin et al. (8) found a modified version of the HSCL to be a sensitive indicator in the NIMH-PRB inpatient studies of depression. Validation studies with inpatients are presently examining its feasibility in this regard. Modified administrative formats (e.g. interview presentation) are being assessed concomitantly.

In research contexts, the SCL-90 is an excellent instrument for inclusion in protocols where the major criterion of interest involves assessment of an outpatient symptomatic configuration. Relative brevity and ease of administration allow the SCL-90 to be efficiently utilized in treatment studies which involve repeated assessments of the symptom picture across time. The high test-retest and inter-rater reliabilities of Dimensions I-V (1), (24) are expected to extend to the new dimensions, thereby providing the clinical investigator with a consistent basis for evaluating treatment differences.

FIGURE 19

SCL-90 SYMPTOMATIC PROFILE



RAW SCORE DATA

I. SOMATIZATION	.5
II. OB-COMP	2.3
III. INTERP. SENS.	1.0
IV. DEPRESSION	3.4
V. ANXIETY	2.7
VI. HOSTILITY	1.5
VII. PHOBIC ANX.	.7
VIII. PARAN. IDEAT.	1.5
IX. PSYCHOTICISM	.9

GENERAL SYMPTOMATIC INDEX= 1.7

POSITIVE SYMPTOM DISTRESS INDEX = 2.5

POSITIVE SYMPTOM TOTAL = 68

NAME:

DATE: 3/7/72

LOCATION: HOPKINS OPD

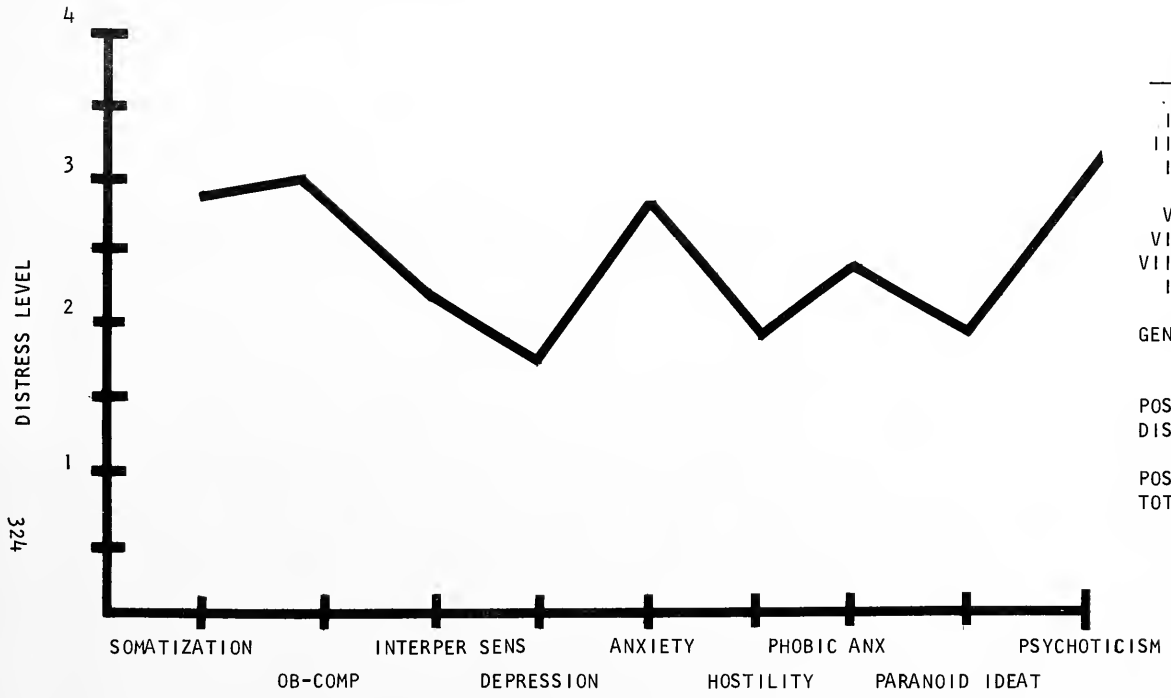
DIAGNOSIS: DEPRESSIVE NEUROSIS

CLINICAL NARRATIVE:

This 26 yr. old, white female was referred from another service where she was seen initially for a physical condition. Although interview suggests a depressive "style of life" for this patient, the present episode is described as relatively acute. Primary symptoms involve dysphoric affect with marked feelings of hopelessness, suicidal thoughts, and manifest resentment. Panic attacks and generally high anxiety levels are also in evidence.

FIGURE 20

SCL-90 SYMPTOMATIC PROFILE



RAW SCORE DATA

I. SOMATIZATION	2.9
II. OB-COMP	3.0
III. INTERP. SENS.	2.2
IV. DEPRESSION	1.8
V. ANXIETY	2.9
VI. HOSTILITY	2.0
VII. PHOBIC ANX.	2.5
VIII. PARAN. IDEAT.	2.0
IX. PSYCHOTICISM	3.2

GENERAL SYMPTOMATIC INDEX= 2.4

POSITIVE SYMPTOM DISTRESS INDEX = 3.1

POSITIVE SYMPTOM TOTAL = 82

NAME:

DATE: 3/7/72

LOCATION: HOPKINS OPD

DIAGNOSIS: CHRONIC UNDIFFERENTIATED SCHIZOPHRENIC

CLINICAL NARRATIVE:
This 24 yr. old, black female presents with notable disturbances in cognitive functioning and associative processes. In addition, there are indications of hallucinations with delusional thought patterns. Somatic concern is high and probably incorporated into the delusions, with suggestions of both free floating and phobic anxiety at elevated levels. Paranoid ideation is present to a moderate degree.

More specifically, the SCL-90 is expected to be particularly valid as a criterion measure in clinical drug trials where the principal focus is on the relative efficacy of psychoactive agents. Dimensions I-V have been repeatedly shown to be sensitive indicators of treatment effects with a wide range of psychoactive drugs (1), (24). The refinements in these scales, coupled with the supplementation provided by Dimensions VI-IX, results in a marked extension of the instrument's sensitivity to drug effects. Beyond the validity revealed for this specific utilization, Dimensions I-V have been shown to be sensitive to a wide variety of non-pharmacologic factors in the treatment setting (1), (24). It is expected that the methodological revisions and substantive extensions incorporated into the SCL-90 will function to enhance this sensitivity to drug-extrinsic influences as well.

Scale Characteristics - The SCL-90 is comprised of 90 distinct items each of which is rated on a 5-point scale of distress ranging from "not-at-all" to "extremely". Under conditions of typical administration, the patient is instructed by the technician as to how to fill out the form. Questions concerning procedure or interpretation are resolved by the technician; however, the technician in no way interferes with the self-rating characteristics of the procedure.

In those instances when the rater is other than the patient, (e.g. doctor, social worker, psychiatric nurse, etc.) ratings should be made in terms of manifest behaviors and/or complaints. Inferences about symptoms or distress, where there is no explicit behavioral or verbal referent on the part of the patient, should be minimized.

The SCL-90 has been provided with a flexible time context so that different temporal limits may be utilized with the instrument. This feature also greatly facilitates research on the effects of different temporal referents on the nature of the symptomatic picture. Normally, however, the time context used with the SCL-90 is 7 days. Numerous other rating scales use the one-week rating period as standard, and a more extensive rationale for selection of this period is given by Hamilton (9).

In developing the items, care was taken to use very fundamental phrasing; an attempt was made to select the most basic word levels possible that would still be consistent with the meaning of the item. Toward this end, the Thorndike-Lorge Word Book of 30,000 Words (10) was employed to equate the vocabulary levels of the 9 dimensions and the overall verbal level of the instrument. Even with this consideration, some patients' literacy levels will be insufficient to allow them to validly complete the SCL-90. In cases of marginal literacy, care must be taken in making interpretations; profiles developed under such conditions are probably best assigned a tentative status.

The selection of 5-point rating scales for each symptom reflect the well-documented observation - from both psychometric theory (11) and information theory (12) - that the reliability of rating scales tends to be proportional to the number of scale points provided (within certain limits). Also, the minimum number of items subsumed under any one of the primary dimensions is six, in keeping with recent observations about the relationship between factorial invariance and the number of items per factor (13).

Developmental History - The immediate precursor to the SCL-90 was a rating scale termed the Hopkins Symptom Checklist (HSCL). This rating scale is comprised of 58 items which tend to focus on conventional neurotic symptoms, and are rated on a 4-point scale of distress. A series of factor-analytic studies of both psychiatrist's ratings (14) and patient self-ratings (15) on the HSCL isolated five primary symptom dimensions underlying the scale. Construct validity has been demonstrated for these dimensions (16), and factorial invariance has been shown for this dimensional set regarding patient social status, doctor rating versus patient rating, and diagnostic class (see Bibliography).

The SCL was developed principally as a criterion measure in psychoactive drug trials. It has been shown to have high sensitivity and predictive validity in this regard (17, 18, 19). In addition, numerous "extrinsic" factors (e.g. doctor medication attitude, patient perception of doctor warmth, etc.) have been reflected by scores on the primary HSCL dimensions (see Bibliography). A consistent typology of "anxious neurotic" patients (20) has also been developed in terms of the HSCL symptom scales.

Slight variations in the number and content of the scales have resulted in several similar versions of the HSCL (8, 21). These scales have very similar formats and tend to be highly compatible regarding the underlying dimensions they reflect. Also, there is a brief version (35-item) of the HSCL that has been utilized primarily by investigators in the Early Clinical Drug Evaluation Units (ECDEU) sponsored by Psychopharmacology Research Branch of NIMH. Most of these alternate versions may be traced back to a prototype "Discomfort Scale" developed by Parloff (22), and further elaborated by Frank (23). The Discomfort Scale was based to an appreciable extent on symptoms taken from the Cornell Medical Index, and has been used as a criterion measure in studies of psychotherapy.

A bibliography documenting much of the recent research done with the Hopkins Symptom Checklist (HSCL) has been appended. In addition several thorough reviews of this work have recently become available (1), (24).

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073 SDS
SELF-RATING
DEPRESSION
SCALE

MH 9-73
6-73

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB NO. 68-R955

ZUNG SDS

PATIENT INITIALS

FIRST INITIAL: A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

SECOND INITIAL: A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

FORM NO.: 9

NUMBER MALES 001 to 499; FEMALES 500 to 998

PATIENT: 0 1 2 3 4 5 6 7 8 9

RATER: 0 1 2 3 4 5 6 7 8 9

PERIOD: 0 1 Hours 2 Days 3 Weeks 4 Months

PLEASE USE A NO. 2 LEAD PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE.

INSTRUCTIONS

Listed below are 20 statements. Please read each one carefully and decide how much of the statement describes how you have been feeling during the past week. Decide whether the statement applies to you for NONE OR A LITTLE OF THE TIME, SOME OF THE TIME, A GOOD PART OF THE TIME, OR MOST OR ALL OF THE TIME. Mark the appropriate column for each statement.

EXAMPLE

STATEMENT	NONE OR A LITTLE OF THE TIME	SOME OF THE TIME	A GOOD PART OF THE TIME	MOST OR ALL OF THE TIME
I feel nervous	1	2	3	4

If the statement "I feel nervous" describes the way you have felt "A GOOD PART OF THE TIME", you would mark column 3 "A GOOD PART OF THE TIME" as shown.

	STATEMENT	NONE OR A LITTLE OF THE TIME	SOME OF THE TIME	A GOOD PART OF THE TIME	MOST OR ALL OF THE TIME
1.	I feel downhearted and blue	1	2	3	4
2.	Morning is when I feel the best	1	2	3	4
3.	I have crying spells or feel like it	1	2	3	4
4.	I have trouble sleeping at night	1	2	3	4
5.	I eat as much as I used to	1	2	3	4
6.	I still enjoy sex	1	2	3	4
7.	I notice that I am losing weight	1	2	3	4
8.	I have trouble with constipation	1	2	3	4
9.	My heart beats faster than usual	1	2	3	4
10.	I get tired for no reason	1	2	3	4
11.	My mind is as clear as it used to be	1	2	3	4
12.	I find it easy to do the things I used to do	1	2	3	4
13.	I am restless and can't keep still	1	2	3	4
14.	I feel hopeful about the future	1	2	3	4
15.	I am more irritable than usual	1	2	3	4
16.	I find it easy to make decisions	1	2	3	4
17.	I feel that I am useful and needed	1	2	3	4
18.	My life is pretty full	1	2	3	4
19.	I feel that others would be better off if I were dead	1	2	3	4
20.	I still enjoy the things I used to do	1	2	3	4

Zung's Self-Rating Depression Scale (SDS) is a 20-item independently formatted scale in which the subject rates his symptomatology on a 4-point scale of severity. This version of the SDS replaces the original Zung Depression Scale (Form 09). The identification block has been changed and the wording of 2 of the scale points has been altered in the present version. The SDS is the patient-rated version of the Depression Status Inventory.

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APPLICABILITY — Adults with depressive symptoms

UTILIZATION — Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED — Now or within the past week

CARD FORMAT - ITEMS — CARD 01 = (19x, 2011, 10x, I4)

Item	Column	Item	Column
1	20	11*	30
2*	21	12*	31
3	22	13	32
4	23	14*	33
5*	24	15	34
6*	25	16*	35
7	26	17*	36
8	27	18*	37
9	28	19	38
10	29	20*	39
		Index Score	50 - 53

* Items reflected in scoring.

Table 9 gives the conversion of SDS raw scores into Index scores, (p. 174). The following table from Zung presents mean index scores for 5 diagnostic groups:

Diagnosis	N	Mean SDS Index
Depressive disorders	96	65*
Schizophrenia	25	51
Anxiety disorder	22	53
Personality disorders	54	56
Transient situational disturbances	12	48

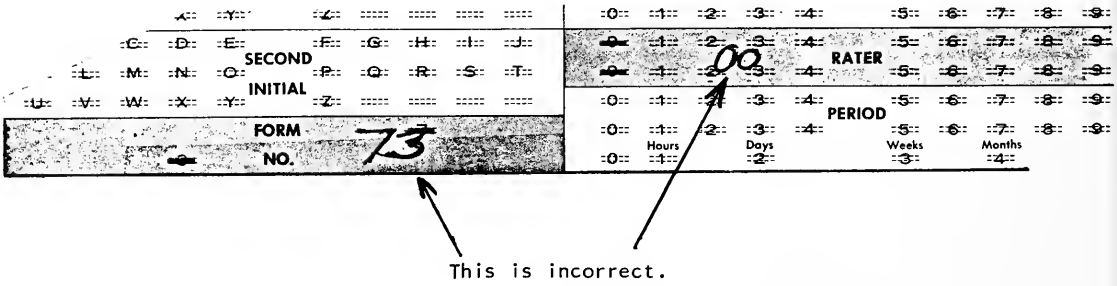
* Significantly different from other 4 groups ($p < .01$).

SPECIAL INSTRUCTIONS

The rater should make certain that the subject fully understands the task and the correct method of recording his responses. When the subject finishes, the rater should check all items for omissions or multiple marks. Unless clinically inadvisable, the rater should urge subject to complete all items. The rater should also encode patient and period numbers within the identification block. Rater number is precoded and need not be filled in. The patient's initials may be encoded by either the subject or rater.

Both Form and Rater Numbers are precoded and no entries are required - or indeed permitted - in these shaded areas.

Example: Writing in Form and/or Rater Number is incorrect and may trigger multiple opscan punches.



DOCUMENTATION:

a. Raw score printout
b. Index score printout
c. Means and standard deviations for index scores
d. Variance analyses

054 SAS
SELF-RATING
ANXIETY
SCALE

MH-9—54
4-73

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB No. 68-R955

S A S

William W.K. Zung, M.D.

PATIENT INITIALS

FIRST INITIAL: A B C D E F G H I J / K L M N O P Q R S T / U V W X Y Z

SECOND INITIAL: A B C D E F G H I J / K L M N O P Q R S T / U V W X Y Z

FORM NO.

NUMBER MALES 001 TO 499 NUMBER FEMALES 500 TO 998

PATIENT: 0 1 2 3 4 5 6 7 8 9 / 0 1 2 3 4 5 6 7 8 9 / 0 1 2 3 4 5 6 7 8 9

RATER: 0 1 2 3 4 5 6 7 8 9 / 0 1 2 3 4 5 6 7 8 9

PERIOD: 0 1 2 3 4 5 6 7 8 9 / 0 Hours 1 Days 2 Weeks 3 Months 4

INSTRUCTIONS: Listed below are 20 statements. Please read each one carefully and decide how much of the statement describes how you have been feeling during the past week. Decide whether the statement applies to you NONE OR A LITTLE OF THE TIME, SOME OF THE TIME, A GOOD PART OF THE TIME, OR MOST OR ALL OF THE TIME. Mark the appropriate column for each statement.

PLEASE USE A NO.2 PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE.

		None or a little of the time	Some of the time	A good part of the time	Most or ALL of the time
1.	I feel more nervous and anxious than usual	1	2	3	4
2.	I feel afraid for no reason at all	1	2	3	4
3.	I get upset easily or feel panicky	1	2	3	4
4.	I feel like I'm falling apart and going to pieces	1	2	3	4
5.	I feel that everything is all right and nothing bad will happen	1	2	3	4
6.	My arms and legs shake and tremble	1	2	3	4
7.	I am bothered by headaches, neck and back pains	1	2	3	4
8.	I feel weak and get tired easily	1	2	3	4
9.	I feel calm and can sit still easily	1	2	3	4
10.	I can feel my heart beating fast	1	2	3	4
11.	I am bothered by dizzy spells	1	2	3	4
12.	I have fainting spells or feel like it	1	2	3	4
13.	I can breathe in and out easily	1	2	3	4
14.	I get feelings of numbness and tingling in my fingers, toes	1	2	3	4
15.	I am bothered by stomachaches or indigestion	1	2	3	4
16.	I have to empty my bladder often	1	2	3	4
17.	My hands are usually dry and warm	1	2	3	4
18.	My face gets hot and blushes	1	2	3	4
19.	I fall asleep easily and get a good night's rest	1	2	3	4
20.	I have nightmares	1	2	3	4

☆ U.S. GOVERNMENT PRINTING OFFICE: 1973—503-088

Zung's Self-Rating Anxiety Scale (SAS) is a 20-item scale in which the subject rates his symptomatology on a 4-point scale of severity. The SAS is self-contained and does not utilize the General Scoring Sheet. The comparable clinician-rated version (ASI) is described on pages

REFERENCE — Zung, Wm. W. K., A Rating Instrument for Anxiety Disorders, Psychosomatics, 12, 371-379, Nov./Dec.1971.

APPLICABILITY — Adults with symptoms of anxiety

UTILIZATION — Once at pretreatment; at least one post-treatment assessment. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED — One week prior to rating

CARD FORMAT - ITEMS — CARD 01 = (19x, 2011, 11x, 14).

Item	Column	Item	Column
1	20	11	30
2	21	12	31
3	22	13*	32
4	23	14	33
5*	24	15	34
6	25	16	35
7	26	17*	36
8	27	18	37
9*	28	19*	38
10	29	20	39
		Index Score	50 - 53

* = Scores on these items are reflected when computing total raw score.

Table 11 gives the conversion of SAS raw scores into Index scores, (p. 202). The following table from Zung presents mean index scores and standard deviations for 5 diagnostic groups:

Diagnosis	N	SAS Index Mean	S.D.
Anxiety Disorder	22	58.7	13.5*
Schizophrenia	25	46.4	12.9
Depressive Disorder	96	50.7	13.4
Personality Disorder	54	51.2	13.2
Transient Situational Disturbances	12	45.8	11.9
Controls (Normals)	100	33.8	5.9**

* = Significantly different from other 4 diagnostic groups (p = .05)
** = Significantly different from all diagnostic groups (p = .01)

SPECIAL INSTRUCTIONS:

The rater should make certain that the subject fully understands the task and the correct method of recording his responses. When the subject finishes, the rater should check all items for omissions or multiple marks. Unless clinically inadvisable, the rater should urge subject to complete all items. The rater should also encode patient and period numbers within the identification block. Rater number is precoded and need not be filled in. The patient's initials may be encoded by either the subject or rater.

Both Form and Rater Numbers are precoded and no entries are required - or indeed permitted - in these shaded areas. (See page 336).

DOCUMENTATION:

a. Raw score printout
b. Index score printout
c. Means and standard deviations for Index scores
d. Variance analyses

COMMENTS OF THE AUTHOR

William W. K. Zung, M.D.

The SAS is based on the same 20 diagnostic criteria as the observer rated Anxiety Status Inventory. So that the patient is less able to discern a trend in his answers, the scale was devised so that of the 20 items used, some of the items were worded symptomatically positive, and others symptomatically negative, depending upon their suitability and usage. In addition, an even-number of columns were used to eliminate the possibility of a patient checking middle and extreme columns.

Cumulative data on the SAS from several completed studies of psychiatric and normal subjects indicate that a morbidity cut-off score on this scale would be at 45. Thus, patients with scores of 45 and above on the SAS would be considered by most clinicians to have anxiety symptoms of significant severity. Complete correlation with clinical global impressions and the SAS indices and other anxiety scales will be available at a later date.

033 TWIS
TESS
WRITE-IN
SCALE

MH-9-33
1-73

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB NO. 68-R965

TREATMENT EMERGENT SYMPTOMS SCALE—WRITE-IN

PATIENT INITIALS

FIRST INITIAL: A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

SECOND INITIAL: A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

FORM NO.

NUMBER MALES 001 TO 499; FEMALES 500 TO 998

PATIENT NUMBER: 0 1 2 3 4 5 6 7 8 9

RATER NUMBER: 0 1 2 3 4 5 6 7 8 9

PERIOD: 0 Hours; 1 Days; 2 Weeks; 3 Months

PLEASE USE A NO. 2 LEAD PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE.

INSTRUCTIONS: This scale MUST be used in conjunction with the DOTES. Be sure that the PERIOD designation matches the proper DOTES. Make three judgments for each symptom and confine all writing within the box provided.

DO NOT MARK IN SHADED AREAS

1. OTHER SYMPTOM *(Confine writing within this block)*

INTENSITY: MILD 1 | MODERATE 2 | SEVERE 3

RELATIONSHIP: None 0 | Remote 1 | Possible 2 | Probable 3 | Defined 4

ACTION TAKEN: None 0 | Increased Surveillance 1 | Contractive Ex 2 | Change Dose 3 | Change Dose plus Contractive Ex 4 | Suspend Ex 5 | Discontinue Ex 6

2. OTHER SYMPTOM *(Confine writing within this block)*

INTENSITY: MILD 1 | MODERATE 2 | SEVERE 3

RELATIONSHIP: None 0 | Remote 1 | Possible 2 | Probable 3 | Defined 4

ACTION TAKEN: None 0 | Increased Surveillance 1 | Contractive Ex 2 | Change Dose 3 | Change Dose plus Contractive Ex 4 | Suspend Ex 5 | Discontinue Ex 6

3. OTHER SYMPTOM *(Confine writing within this block)*

INTENSITY: MILD 1 | MODERATE 2 | SEVERE 3

RELATIONSHIP: None 0 | Remote 1 | Possible 2 | Probable 3 | Defined 4

ACTION TAKEN: None 0 | Increased Surveillance 1 | Contractive Ex 2 | Change Dose 3 | Change Dose plus Contractive Ex 4 | Suspend Ex 5 | Discontinue Ex 6

4. OTHER SYMPTOM *(Confine writing within this block)*

INTENSITY: MILD 1 | MODERATE 2 | SEVERE 3

RELATIONSHIP: None 0 | Remote 1 | Possible 2 | Probable 3 | Defined 4

ACTION TAKEN: None 0 | Increased Surveillance 1 | Contractive Ex 2 | Change Dose 3 | Change Dose plus Contractive Ex 4 | Suspend Ex 5 | Discontinue Ex 6

5. OTHER SYMPTOM *(Confine writing within this block)*

INTENSITY: MILD 1 | MODERATE 2 | SEVERE 3

RELATIONSHIP: None 0 | Remote 1 | Possible 2 | Probable 3 | Defined 4

ACTION TAKEN: None 0 | Increased Surveillance 1 | Contractive Ex 2 | Change Dose 3 | Change Dose plus Contractive Ex 4 | Suspend Ex 5 | Discontinue Ex 6

6. OTHER SYMPTOM *(Confine writing within this block)*

INTENSITY: MILD 1 | MODERATE 2 | SEVERE 3

RELATIONSHIP: None 0 | Remote 1 | Possible 2 | Probable 3 | Defined 4

ACTION TAKEN: None 0 | Increased Surveillance 1 | Contractive Ex 2 | Change Dose 3 | Change Dose plus Contractive Ex 4 | Suspend Ex 5 | Discontinue Ex 6

Developed within the ECDEU program, the TESS Write-In Scale (TWIS) is an independently formatted 6-item scale to be used in conjunction with the Dosage Record and Treatment Emergent Symptoms (DOTES). Since writing of any sort is absolutely prohibited on the General Scoring Sheet, a separate scale had to be designed to allow the rater to record the presence of any treatment emergent symptoms whose names were not printed on DOTES.

APPLICABILITY — For all research populations

UTILIZATION — Used in conjunction with DOTES whenever it is necessary to record the presence of a symptom not printed on DOTES

TIME SPAN RATED — Same as the referent DOTES

CARD FORMAT - ITEMS CARD 01 = (19x, 6(13, 311))

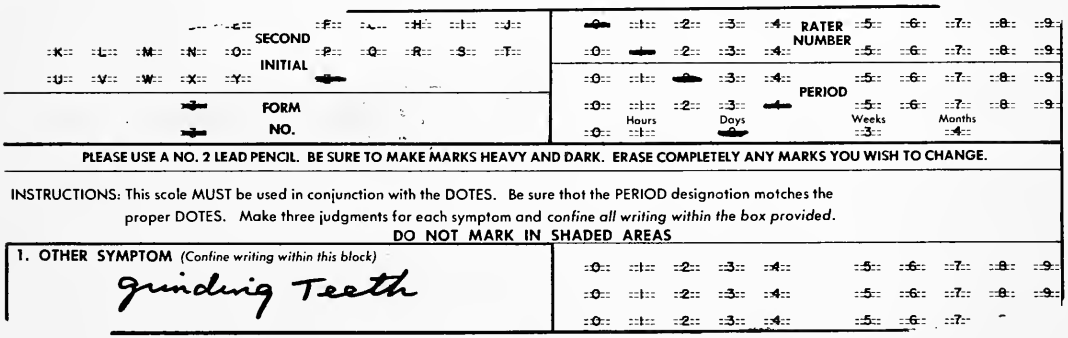
Symptom	Columns	Symptom	Columns
1	20 - 25	4	38 - 43
2	26 - 31	5	44 - 49
3	32 - 37	6	50 - 55

The length of the data field will vary with the number of "write-ins". The field for each "write-in" is 16 and is coded as follows:

Symptom code	First 3 columns
Intensity	4th column
Relationship	5th column
Action	6th column

SPECIAL INSTRUCTIONS

Identification Block (ID) - It is essential that the ENTIRE ID BLOCK coded on TWIS MATCH EXACTLY the ID block of the corresponding DOTES. Example - While rating the DOTES at Day 24, the rater observes that - in addition to tremor and increased salivation (printed symptoms) - the subject is grinding his teeth. On Item 4 of DOTES, he codes "2 = yes, both printed and write-ins present" and then proceeds to code his judgments of "tremor" and "increased salivation". He next fills out the TWIS by completing the ID block exactly as it appears on DOTES. Finally, he writes in "grinding teeth" and makes his 3 judgments of the symptom.

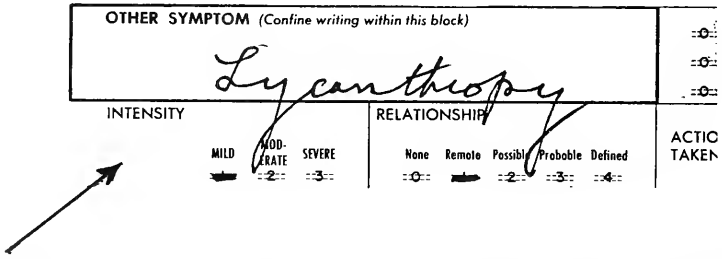


Notice in the above example that NO marks have been made in the shaded areas of either the ID block or text of the scale. The code for "grinding teeth" will be inserted by BLIPS editors.

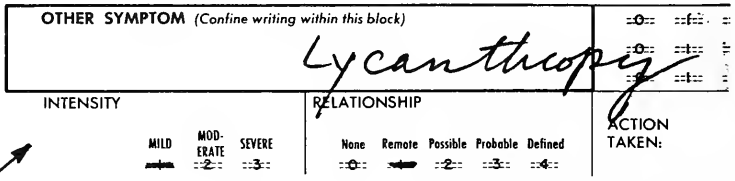
Form Number - This number is preprinted on the form and need not - indeed must not - be encoded again. (See page 336).

Items 1 - 6. Other Symptom - When writing in a symptom, the rater must make judgments of intensity, relationship and action undertaken exactly as he does for DOTES. He must also confine his writing ENTIRELY within the blocks provided. Failure to do so may cause the optical reader to misinterpret signals and cause processing delays.

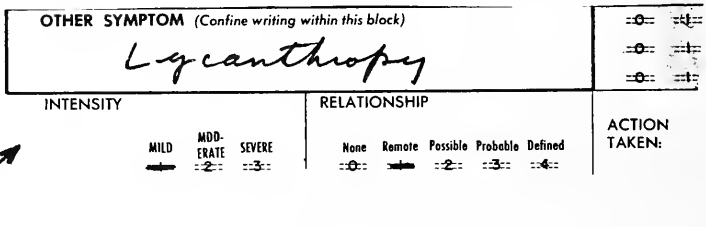
Examples:



INCORRECT - May cause multiple codes in Intensity and/or Relationship.



INCORRECT - Requires erasure before symptom code can be inserted.



CORRECT - No opscan problems.

Symptom Code - A 3-digit numeric code for the "write-in" permits documentation of "write-ins" by name. A list of these treatment emergent symptom codes will be provided upon request to the Biometric Laboratory.

Intensity, Relationship, Action - These 3 judgments are rated in the same manner as described in DOTES.

DOCUMENTATION

a. Raw score printout
b. "Write-ins" will be incorporated within the documentation provided for DOTES.

038 STESS
SUBJECTS
TREATMENT EMERGENT
SYMPTOM SCALE

MH-9-38
1-73

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB NO. 68-R65

STESS

PATIENT INITIALS

FIRST INITIAL

SECOND INITIAL

FORM NO.

NUMBER MALES 001 TO 499; FEMALES 500 TO 998

PATIENT

RATER (S / M / F)

PERIOD (Hours / Days / Weeks / Months)

PLEASE USE A NO. 2 LEAD PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE.

INSTRUCTIONS: Since the last time here, have you been bothered with or had trouble with any of the items listed below? If this is your first visit, have you been bothered by any of these items in the last week? Mark the number which best tells how much you were bothered. When filling out form for the child, mark on the basis of what you have seen or what the child has complained about. If you are unsure, mark "Don't know".

EXAMPLE	Not at All	Just a Little	Pretty Much	Very Much	Don't Know
Cramps?	0	1	●	3	4

Have you had trouble with:

ITEM	Not at All	Just a Little	Pretty Much	Very Much	Don't Know
1. Eating?	0	1	2	3	4
2. Drinking?	0	1	2	3	4
3. Dry mouth and lips?	0	1	2	3	4
4. Wetness in mouth?	0	1	2	3	4
5. Fewer bowel movements (constipation)?	0	1	2	3	4
6. More bowel movements (diorrhea)?	0	1	2	3	4
7. Stomach aches?	0	1	2	3	4
8. Muscle cramps?	0	1	2	3	4
9. Being sick to your stomach?	0	1	2	3	4
10. Wetting the bed?	0	1	2	3	4
11. Urinating?	0	1	2	3	4
12. Itchy or scratchy skin?	0	1	2	3	4
13. Rashes?	0	1	2	3	4
14. Colds or sniffles?	0	1	2	3	4
15. Headache?	0	1	2	3	4
16. Dizziness?	0	1	2	3	4
17. Playing sports?	0	1	2	3	4
18. Shakiness?	0	1	2	3	4
19. Pronouncing words?	0	1	2	3	4
20. Doing things with your hands?	0	1	2	3	4
21. Sitting still?	0	1	2	3	4
22. Tiredness?	0	1	2	3	4
23. Feeling sleepy?	0	1	2	3	4
24. Trouble getting or staying asleep?	0	1	2	3	4
25. Bad dreams?	0	1	2	3	4
26. Getting along with parents?	0	1	2	3	4
27. Getting along with other kids?	0	1	2	3	4
28. Crying?	0	1	2	3	4
29. Getting mad?	0	1	2	3	4
30. Not being happy?	0	1	2	3	4
31. Being sad?	0	1	2	3	4
32. Paying attention?	0	1	2	3	4

IBM H68283

The Subject's Treatment Emergent Symptom Scale (STESS) was developed within the ECDEU program and is an independently formatted 32-item scale designed to elicit information on the presence and degree of physical complaints. It may be completed by the child, parent or other knowledgeable adult. Although focussed on possible treatment emergent symptoms, STESS does not ask the rater to judge the relationship of his "symptoms" to the drug he is taking. A 4-point scale of severity is used with an additional response position for "Don't Know".

APPLICABILITY — Children to the age of 15

UTILIZATION — Once at pretreatment; at least one post-treatment assessment. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED — Now or within the past week.

CARD FORMAT - ITEMS CARD 01 = (19x, 32I1, I2)

Item	Column	Item	Column	Item	Column	Item	Column
1	20	9	28	17	36	25	44
2	21	10	29	18	37	26	45
3	22	11	30	19	38	27	46
4	23	12	31	20	39	28	47
5	24	13	32	21	40	29	48
6	25	14	33	22	41	30	49
7	26	15	34	23	42	31	50
8	27	16	35	24	43	32	51
						Total Score*	52-53

* Total Score = Sum of all items. Total Score Range = 0 - 96

SPECIAL INSTRUCTIONS

1. Coding Rater - When the child completes STESS, Code 00 (S); for mother or mother surrogate, encode 11; for father or father surrogate, encode 22. Use any other numbers for other adult raters. Do not intermix raters for a given subject; e.g., mother at one rating; father at the next; self at the next. Use the same rater throughout the study; e.g., self at every rating; mother at every rating, etc. Concurrent ratings may, of course, be used; e.g., self ratings along with mother and/or father.

2. Do not write in the shaded area of the ID block. Form Number has been precoded.

3. STESS may be used as an independent scale for the periodic evaluation of treatment emergent symptoms (physical complaints) as:

a. perceived by the subject

b. observed by one or both parents or parent surrogates

c. observed by other raters, e.g., nurses, counselors, aides, etc.

Along with its use as an independent measure, the completed scale may also be referred to by the physician as a screening device in his assessments of treatment emergent symptoms.

4. As with all scales filled in by lay raters (patient, parent, etc.) be certain that the rater understands the instructions and knows how to mark his responses. Immediate monitoring of the completed form is suggested whenever possible to check that each item has been marked properly and that there are no multiple answers.

DOCUMENTATION

a. Raw score printout including total score
b. Total score means and standard deviations by period and rater where applicable.
c. Symptom frequencies by period and rater where applicable
d. Variance analyses - Rater may be included as a factor if the investigator chooses. When sufficient sample is available, factor analysis will be performed on the STESS.

055 LAB
LABORATORY
DATA

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH
PSYCHOPHARMACOLOGY RESEARCH BRANCH

LABORATORY DATA

INSTRUCTIONS

LABORATORY STANDARDS – If Laboratory Standards (normal limits) are not already established for your unit, i.e., in the ECDEU Data File or if you wish to employ different standards for analyses, please include such Standards with data.

PERIOD – Laboratory tests MUST be encoded PERIOD BY PERIOD, i.e., do not encode laboratory data from different assessment periods on the same General Scoring Sheet (GSS).

Record PERIOD in DAYS from initial (first) rating regardless of initiation of medication. For example, if ratings are made at the start and end of a 2-week drying out period; every week during a 4-week course of medication and finally 2 weeks after the cessation of medication, PERIOD would be recorded as follows:

Rating	1	2	3	4	5	6	7
Day	00	14	21	28	35	42	56
	|	Dry |		Drug		|	Followup |

While a set of laboratory tests may actually be collected in 2 days, code the entire set under one PERIOD if they were meant to constitute a single assessment. When a test requires verification, i.e., repeated to check result, ONLY THE VERIFIED VALUE should be encoded.

For each laboratory test encoded, the rater must make 4 entries:

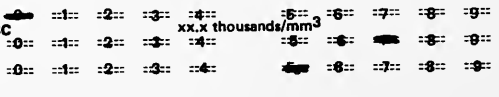
1. The numeric value
2. A clinical judgment of abnormality
3. A clinical judgment of relationship to drug
4. The action undertaken as a consequence of the finding

VALUE – Refers to the numeric value obtained from the test.

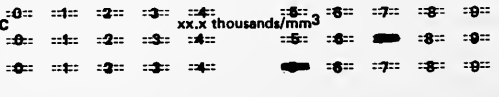
For the preprinted tests, the number of "x's" indicates the number of digits required. Raters must fill in ALL required rows - including leading and following zeros.

EXAMPLE - Obtained White Blood Count (WBC) was 7,500/mm^3.

Correct coding =



Incorrect =



CLINICAL

JUDGMENTS – For each laboratory test, 3 clinical judgments are made: abnormality (ABN), relationship (REL) and ACTION.

a. ABNORMAL — Abnormal refers to a clinical judgment of abnormality - regardless of numerical value.

N = No, Not abnormal
? = Questionably abnormal
Y = Yes, Clinically abnormal
A = Alert, an extreme abnormality

b. RELATIONSHIP - a judgment of the degree of relationship between the test abnormality and the drug rated on a 5-point scale.

N	= None,	- no relationship
R	= Remote,	- less than a 10% probability that symptom occurrence is related to drug employed.
PO	= Possible,	- probability between 10% and 50%.
PR	= Probable,	- probability between 50% and 90%.
D	= Defined,	- greater than 90% probability that symptom occurrence is related to drug employed.

c. ACTION TAKEN - refers to action taken as a consequence of the symptom's appearance.

Actions are arranged in order of increasing stringency. Only ONE action - the most stringent - should be recorded as it is assumed that less stringent actions may also be employed.

ACTION CODE:

NO	= None	CH+	= Change plus Contraactive Rx
SR	= Increased Surveillance		
CO	= Contraactive Rx	SU	= Suspend Rx
CH	= Change Dose	DI	= Discontinue Rx

EXAMPLE: A BUN value of 42mg/100 ml is obtained on a young schizophrenic male. The investigator considers the result abnormal; feels it is probably due to drug and suspends medication. Coding is as follows:

Unlisted tests may be encoded on pages 3 and 4 - either in conjunction with listed tests or by themselves by using Page 4 as an "independent scale." See Manual for instructions.

If you obtain data from a laboratory test using units other than those preprinted on the form, do not encode the data in the preprinted section. Record the data in one of the sections under "Additional Laboratory Tests."

IMPORTANT – PLEASE READ CAREFULLY BEFORE MARKING THIS FORM.

INSTRUCTIONS FOR COMPLETION OF MULTIPLE PAGE FORMS

1. Complete page 1.
2. Following completion of page 1 carefully tear out and remove the pink protective sheet lying between the carbon and your copy of page 2. Follow this procedure for each subsequent page. You must do this to obtain a copy of the data for your files.

   CAUTION: DO NOT REMOVE PINK PROTECTIVE SHEETS OTHER THAN THE ONE LYING BETWEEN CARBON AND COPY OF THE PAGE YOU ARE ABOUT TO COMPLETE.
3. When you have completed all pages of the form, carefully tear out and remove carbon papers and your copy pages. The machine scannable pages should be left in booklet form for shipment to the Biometric Laboratory in packages prepared according to instructions received from the Biometric Laboratory.

MH-9-55
6-73

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB NO. 68-R955

LABORATORY DATA

PATIENT INITIALS — FIRST INITIAL — SECOND INITIAL

FORM NO.

NUMBER MALES 001 TO 499 — NUMBER FEMALES 500 TO 998

PATIENT

RATER

PERIOD — Hours / Days / Weeks / Months

PLEASE USE A NO. 2 PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE.

HGB	xx.x gm/100 ml
HCT	xx %
RBC	x.x millions/mm3
WBC	xx.x thousand/mm3
Neutrophiles	xx%
Lymphocytes	xx%
Eosinophiles	xx%
Monocytes	xx%
Basophiles	x.x%
Sedimentation Rate	xx mm/hr
NA+	xxx meq/L
K+	x.x meq/L
CL−	xxx meq/L
CA++	xx mg/100 ml
PO_4 ≡	x.x mg/100 ml
MG++	x.x meq/L
LI+	x.x meq/L
SGOT	xx Karmen U./100 ml

LABORATORY DATA

BE SURE TO MARK IN PATIENT, RATER AND PERIOD NUMBERS ON THIS PAGE EXACTLY AS YOU DID ON PAGE 1. ⟶

NUMBER MALES 001 to 499 NUMBER FEMALES 500 to 998

PATIENT	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
RATER	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
PERIOD	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1 Hours	2 Days	3 Weeks	4 Months					

Test	Units	Value positions (each 0 1 2 3 4 5 6 7 8 9)	Codes
SGPT	xx units/100 ml	2 rows	N ? Y A N R PO PR D / NO SR CO CH CH* SU DI
LDH	xxx units/100 ml	3 rows	N ? Y A N R PO PR D / NO SR CO CH CH* SU DI
Amylase	xxx Somogyi units/100 ml	3 rows	N ? Y A N R PO PR D / NO SR CO CH CH* SU DI
Alkaline P'tase	xx.x King-Armstrong units/100 ml	3 rows	N ? Y A N R PO PR D / NO SR CO CH CH* SU DI
BUN	xx mg/100 ml	2 rows	N ? Y A N R PO PR D / NO SR CO CH CH* SU DI
Creatinine	x.x mg/100 ml	2 rows	N ? Y A N R PO PR D / NO SR CO CH CH* SU DI
Uric Acid	x.x mg/100 ml	2 rows	N ? Y A N R PO PR D / NO SR CO CH CH* SU DI
Total Bilirubin	x.x mg/100 ml	2 rows	N ? Y A N R PO PR D / NO SR CO CH CH* SU DI
Direct Bilirubin	x.xx mg/100 ml	3 rows	N ? Y A N R PO PR D / NO SR CO CH CH* SU DI
Total Protein	x.x gm/100 ml	2 rows	N ? Y A N R PO PR D / NO SR CO CH CH* SU DI
Blood Albumin	x.x gm/100 ml	2 rows	N ? Y A N R PO PR D / NO SR CO CH CH* SU DI
FBS	xxx mg/100 ml	3 rows	N ? Y A N R PO PR D / NO SR CO CH CH* SU DI
Cholesterol	xxx mg/100 ml	3 rows	N ? Y A N R PO PR D / NO SR CO CH CH* SU DI
PBI	x.x mcg/100 ml	2 rows	N ? Y A N R PO PR D / NO SR CO CH CH* SU DI
Triglycerides	xxx mg/100 ml	3 rows	N ? Y A N R PO PR D / NO SR CO CH CH* SU DI
Specific Gravity (Urine)	1.xxx	3 rows	N ? Y A N R PO PR D / NO SR CO CH CH* SU DI

LABORATORY DATA

BE SURE TO MARK IN PATIENT, RATER AND PERIOD NUMBERS ON THIS PAGE EXACTLY AS YOU DID ON PAGE 1. →

NUMBER MALES 001 to 499 FEMALES 500 to 998

PATIENT
0 1 2 3 4 5 6 7 8 9
0 1 2 3 4 5 6 7 8 9
0 1 2 3 4 5 6 7 8 9

RATER
0 1 2 3 4 5 6 7 8 9
0 1 2 3 4 5 6 7 8 9

PERIOD
0 1 2 3 4 5 6 7 8 9
0 1 2 3 4 5 6 7 8 9
0 1 2 3 4
Hours Days Weeks Months

Test	Value		Judgments
Albumin (Urine)	(None or trace) 0 1 2 3 4 (4 or 4+)		N ? Y A N R PO PR D / NO SR CO CH CH* SU DI
Sugar (Urine)	(None or trace) 0 1 2 3 4 (4 or 4+)		N ? Y A N R PO PR D / NO SR CO CH CH* SU DI
RBC (Urine)	0 1 2 3 4 5 6 7 8 9 / 0 1 2 3 4 5 6 7 8 9	xx/HPF	N ? Y A N R PO PR D / NO SR CO CH CH* SU DI
WBC (Urine)	0 1 2 3 4 5 6 7 8 9 / 0 1 2 3 4 5 6 7 8 9 / 0 1 2 3 4 5 6 7 8 9	xxx/HPF	N ? Y A N R PO PR D / NO SR CO CH CH* SU DI

ADDITIONAL LABORATORY TESTS

Spaces are provided below for the encoding and rating of laboratory tests not printed above. Write in the name of test in the space provided *(PLEASE CONFINE WRITING TO THAT SPACE)* and then code in value and make the clinical judgments as usual. As they serve as essential processing signals, ALWAYS BE SURE TO ANSWER THE FOLLOWING TWO QUESTIONS:

	NO	YES
Have you encoded non-listed tests on page 3?	-----	-----
Have you encoded non-listed tests on page 4?	-----	-----

Name of Test and Units

0 1 2 3 4 5 6 7 8 9 (three rows, test code)

0 1 2 3 4 5 6 7 8 9
0 1 2 3 4 VALUE 5 6 7 8 9
0 1 2 3 4 5 6 7 8 9

N ? Y A N R PO PR D
NO SR CO CH CH* SU DI

Name of Test and Units

0 1 2 3 4 5 6 7 8 9 (three rows, test code)

0 1 2 3 4 5 6 7 8 9
0 1 2 3 4 VALUE 5 6 7 8 9
0 1 2 3 4 5 6 7 8 9

N ? Y A N R PO PR D
NO SR CO CH CH* SU DI

Name of Test and Units

0 1 2 3 4 5 6 7 8 9 (three rows, test code)

0 1 2 3 4 5 6 7 8 9
0 1 2 3 4 VALUE 5 6 7 8 9
0 1 2 3 4 5 6 7 8 9

N ? Y A N R PO PR D
NO SR CO CH CH* SU DI

Name of Test and Units

0 1 2 3 4 5 6 7 8 9 (three rows, test code)

0 1 2 3 4 5 6 7 8 9
0 1 2 3 4 VALUE 5 6 7 8 9
0 1 2 3 4 5 6 7 8 9

N ? Y A N R PO PR D
NO SR CO CH CH* SU DI

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB NO. 68-R955

LABORATORY DATA

PATIENT INITIALS — FIRST INITIAL / SECOND INITIAL

NUMBER MALES 001 to 499 — NUMBER FEMALES 500 to 998 — PATIENT

RATER

PERIOD — Hours / Days / Weeks / Months

If the laboratory data you wish to encode consist ONLY OF TESTS NOT PRINTED ON PAGES 1-3, this page (4) may be used independently, i.e., by itself.
Fill in patient's initials, potient, rater and period numbers and MARK HERE ⟶
Discord pages 1-3.

Name of Test and Units

VALUE

NI PI YI AI — NI RI PO PR DI — NO SR CO CH CH* — SU DI

Name of Test and Units

VALUE

NI PI YI AI — NI RI PO PR DI — NO SR CO CH CH* — SU DI

Name of Test and Units

VALUE

NI PI YI AI — NI RI PO PR DI — NO SR CO CH CH* — SU DI

Name of Test and Units

VALUE

NI PI YI AI — NI RI PO PR DI — NO SR CO CH CH* — SU DI

NOTE THAT 4 ROWS ARE PROVIDED FOR VALUE IN THE NEXT 2 BLOCKS.

Name of Test and Units

VALUE

NI PI YI AI — NI RI PO PR DI — NO SR CO CH CH* — SU DI

Name of Test and Units

VALUE

NI PI YI AI — NI RI PO PR DI — NO SR CO CH CH* — SU DI

Developed within the ECDEU program, Laboratory Data (LAB) is an independently formatted 52-item form for the recording of results from clinical laboratory tests. It is in op-scan format and replaces the earlier key-punch versions of Laboratory Data (05-LD Regular, 05-LD Special).

APPLICABILITY	All populations
UTILIZATION	Once at pretreatment; at least once at posttreatment. Additional assessments are at the discretion of the investigator.
TIME SPAN RATED	By their nature, laboratory tests are "point in time" assessments.

CARD FORMAT - ITEMS

CARD 01 = (19x, 16, 215, 16, 615, 13, 11)

Item	Col.	Item	Col.
Hgb*	20-25	Lymph	47-51
Hct	26-30	Eosin	52-56
RBC	31-35	Mono	57-61
WBC	36-41	Baso	62-66
Neut	42-46	Sed.Rate	67-71
		Na (Value)	72-74
		Na (Abn)	75

* The format for each "printed" test is:

Value	=	up to 3 columns
Abnormal	=	1 column
Action	=	1 column
Relation	=	1 column

CARD 02 = (19x, 12, 715)

Item	Col.	Item	Col.
Na (Act)	20	Mg	43-47
Na (Rel)	21	Li	48-52
K	22-26	SGOT	53-57
Cl	27-32		
Ca	33-37		
PO4	38-42		

CARD 03 = (19x, 15, 316, 415, 16, 15, 12)

Item	Col.	Item	Col.
SGPT	20-24	Tot.Bili	58-62
LDH	25-30	Dir.Bili	63-68
Amal	31-36	Tot.Prot.	69-73
Alk.Phosp.	37-42	Bl.Alb.(Value)	74-75
BUN	43-47		
Creat	48-52		
Uric	53-57		

CARD 04 = (19x, 13, 216, 15, 216)

Item	Col.	Item	Col.
Bl.Album.(Abn.)	20	Chol.	29-34
Bl.Album.(Act.)	21	PBI	35-39
Bl.Album.(Rel.)	22	Tri.	40-45
FBS	23-28	S.G.(Urine)	46-51

CARD 05 = (19x, 214,15,16,12, 319, 18)

Item	Col.	Item	Col.
Alb.(Urine)	20-23	Page 3 Used	39-40
Sugar (Urine)	24-27	Write-in 1	41-49
RBC (Urine)	28-32	Write-in 2	50-58
WBC (Urine)	33-38	Write-in 3	59-67
		Write-in 4	68-75

CARD 06 = (19x, 11)

Item	Col.
Write-in 4(Rel)	20

CARD 07 = (19x, 11, 419, 110, 19)

Item	Col.	Item	Col.
Page 4 (Used)	20	Write-in 8	48-56
Write-in 5	21-29	Write-in 9	57-66
Write-in 6	30-38	Write-in 10	67-75
Write-in 7	39-47		

CARD 08 = (19x, 11)

Item	Col.
Write-in 10(Rel)	20

"Write-in" tests have the following format:

Test Code No.*	3 columns
Value	3 columns (4 for No. 4 and 5, p.4)
Abnorm	1 column
Action	1 column
Relation	1 column

*Three-digit codes for "write-in" LAB tests are assigned by the Biometric Laboratory. A list of LAB codes will be provided upon request.

SPECIAL INSTRUCTIONS

Detailed instructions are printed directly upon the form and should be read carefully by the rater.

1. STANDARDS refer to the limits of normality set by the investigator for his laboratory data. These standards MUST be sent to the Biometric Laboratory - otherwise processing cannot proceed. In subsequent BLIPS processing, each investigator's standards will be used as the basis of analyses for his data. Investigators may utilize more than one set of standards if they desire. For a given study, however, the investigator must specify which set of standards is to be used in the analyses.

2. The new LAB form differs from the older key-punch version in one major way. ONLY DATA FROM A SINGLE PERIOD CAN BE ENCODED ON A SINGLE FORM. The older version permitted the encoding of data from several periods (assessments) on a single form. While this feature was popular among investigators, it created significant processing problems. Error rates for both the investigator and BLIPS staff were excessive and, consequently, much valuable data were lost.

3. In assigning PERIOD to a set of LAB tests, ALWAYS encode the day on which the set of tests was actually obtained - not the day the report of results was obtained. Since the LAB usually requires transcription from hospital laboratory slips, this post-dating should not be any great problem.

4. When a given test value requires verification (repeating the test), ENCODE THE "VERIFIED" VALUE ONLY: i.e., the value the investigator considers correct.

5. If one of the LAB tests printed on the form employs UNITS OTHER THAN THOSE INDICATED, the test must be encoded as a write-in and the units indicated; e.g., SGOT values are obtained in Frankel units - not Karmen units. The investigator codes SGOT in one of the "write-in" blocks - not in the SGOT block printed on the form.

6. In instances where the obtained value of a test exceeds the number of rows provided for that test, use one of the "write-in" blocks; e.g., a BUN value of 100 is obtained and, as this exceeds the 2 rows provided, the investigator uses one of the "write-in" blocks.

ENCODING TESTS NOT LISTED ON THE SCALE

1. Encoding non-listed tests in conjunction with listed tests - When the investigator wishes to encode both listed and unlisted tests at a given assessment period, he MUST so indicate by answering the 2 questions on page 3. He then may encode a maximum of 10 additional tests on pages 3 and 4.

2. Encoding non-listed tests only - When the investigator's data consist ONLY of unlisted tests, he MUST use page 4 - NOT page 3 - and so indicate by marking the specified location on page 4. In this case, Page 4 becomes an "independent scale" - the first 3 pages can be discarded. When using Page 4 as an independent scale, the investigator MUST COMPLETE THE ENTIRE IDENTIFICATION BLOCK ON PAGE 4.

3. Note that the last 2 sections of Page 4 contain 4 rows of digits under VALUE rather than 3 rows. This provides for the encoding of test values which may require the extra digit.

DOCUMENTATION

a. Standards printout - it is the investigator's prerogative as to the set of standards employed.
b. Intra-subject display of test values and judgments. (Figure 21).
c. Group summaries by test. (Figure 22).
d. Cross-tabulation of tests/actions. (Figure 23).
e. Variance analyses

For each subject, the events occurring throughout the study are described test by test. The daily and cumulative dosages, the actual value and its position in regard to limits and judgments of abnormality and drug relatedness are given. Similar data are summarized by treatment group. Finally, a cross-tabulation of actions undertaken by test are displayed for each treatment group.

FIGURE 21

LABORATORY DATA - BY SUBJECT

STUDY #	INVESTIGATOR - STUDY - DATE					
GROUP	DRUG X					
SUBJECT #	001					
TEST A	DAY	000	014	028	042	045
	DOSE DAILY	000	100	200	150	100
	DOSE CUMULATIVE	000	1400	4200	6300	6600
	LIMITS ABOVE					
	LIMITS WITHIN	XXX		XXX		
	LIMITS BELOW		XXX		XXX	XXX
	CLINICAL ABNORM.	N	Y	Y	RED	DIS
	CLINICAL RELAT.	NO	POSS	PROB	DEF	DEF
TEST B	(REPEAT "LIMITS" AND "CLINICAL)					
TEST n	(REPEAT "LIMITS" AND "CLINICAL")					

FIGURE 22

LABORATORY DATA - BY GROUP

STUDY # - INVESTIGATOR - STUDY - DATE

GROUP - DRUG X

TEST A	RX DAY		000	014	028	042	045	TOTAL
	MEAN DOSE	DAILY	000	100	187	-	-	
		CUMULATIVE	000	1387	4104	-	-	
	LIMITS	ABOVE	0	1	1	-	-	
		WITHIN	20	15	12	-	-	
		BELOW	0	4	6	-	-	
	CLINICAL ABNORM.	N	20	15	-	-	-	-
		Y	00	04	-	-	-	-
		ALERT	00	01	-	-	-	-
		NA	00	00	-	-	-	-
	ACTION		00	04	-	-	-	-
	RELAT.	DEF	00	00	-	-	-	-
		POSS	00	00	-	-	-	-
		PROB	00	03	-	-	-	-
		REM	00	01	-	-	-	-
		NO	20	16	-	-	-	-
TEST B		(REPEAT)						
TEST n		(REPEAT)						

FIGURE 23

LABORATORY DATA - BY GROUP (CONT.)

ACTIONS UNDERTAKEN BY TEST (ALL RATINGS)

TEST	NONE	SURV	CONT	RED	R + CON	SUS	DIS	OTH	NA	TOTAL
A	-	-	-	-	-	-	-	-	-	-
B	-	-	-	-	-	-	-	-	-	-
C	-	-	-	-	-	-	-	-	-	-
⋮										
n										
TOTAL	-	-	-	-	-	-	-	-	-	-

* TOTAL WOULD EXCLUDE "NONE" AND "NA".

CLINICAL LABORATORY STANDARDS IN PEDIATRIC PSYCHOPHARMACOLOGY*

Samuel Gershon, M.D., NYU Medical Center

Clinical laboratory data at baseline and changes with treatment are an integral part of the assessment of the effects of new drugs. Former speakers have presented certain problems in this area in regard to studies in adults and to the applicability of textbook normative data for psychiatric populations (3).

Whatever the magnitude of the problem with adults, the situation in regard to children is far worse. First, the same problems, as mentioned above, will certainly arise, i.e., in the applicability of medical textbook norms to a population of mentally ill children. Second, they will arise also in regard to the vagueness of some of the child norms, i.e., when an adult normative figure is given and is followed by the statement: "higher in children" or "lower in children" without additional qualifications (1). Third, another problem which arises with children is the distinction between child and adult. This distinction is in itself somewhat arbitrary and still inadequate. More particulate divisions ought to be made in grouping children by age, e.g., norms for three years may not be applicable to norms for six years. In addition to such age subdivisions, another parameter of maturational, physical, and mental levels may cut across such age levels. This issue of physical and mental levels of maturation may be even more marked in child psychiatric populations. Fourth, there is the problem of the effect of manifest or covert intercurrent infection or physical disease on the clinical chemistry data. Admittedly, such situations can and do occur in studies with adult psychiatric populations, but they are more frequent and prevalent in institutions housing child psychiatric populations. The influence of such a variable may be of much greater magnitude than the possible effect of the drug under investigation. Fifth, laboratory measurements may indeed be the greatest source of error under adverse conditions.

In this discussion, we will present some of the norms currently available in the literature, a brief analysis of some of the laboratory data obtained from the child psychiatric studies at New York University, and then conclude with a review of this material and proposals for consideration by this group.

NORMS FROM REFERENCE SOURCES

It can readily be seen that most of the information available is on hematology and that the normative data show variance at the different age levels. Also, there are differences in these values from one source to another. Other areas are not that well covered, e.g., liver function tests.

* Presented at the Pediatric Psychopharmacology Conference, November 13-14, 1969, Washington, D. C. Sponsored by the Psychopharmacology Research Branch, Division of Extramural Research Programs, National Institute of Mental Health.

* Reprinted from Psychopharmacology Bulletin, Special Issue, Pharmacotherapy of Children, 1973.

DISCUSSION

This review of laboratory findings was undertaken to explore the possibility that such data might show variation from recognized normal values derived from a nonpsychiatric population. Recognition of this problem in adult psychiatric populations has resulted in exploratory studies which have tended to confirm the divergence of findings from textbook norms in this special population.

The report by Gonzales et al. (3), Table 22, on hemogram studies in a psychiatric population showed that in the case of white blood cell (WBC) counts and if an upper normal limit of 7,000/cu mm is used as proposed by some reference sources, then 50.2 percent of the values fell above 7,000 and 14 percent above 8,500. In regard to hemoglobin values in males, 14 percent fell below the normal range of 14-18 grams.

The findings for hematocrit were: 26.2 percent of determinations fell below and 11.0 percent above the normal range of 42 to 50. When broken down by sex, 44.1 percent of hematocrit determinations in males fell outside these limits and for females 42 percent were abnormal.

Sedimentation rate determinations for males showed that 77.2 percent were above the normal range of 0 to 9.

These findings would strongly suggest that it may be necessary to redefine limits of normal values for specialized patient groups.

Hollister et al. (5) have commented on this same problem in adult psychiatric populations. These workers reported that 97 of 475 patients prior to treatment exhibited counts greater than 10,000/cu mm. There were 19 instances of serum glutamate oxalecetate transaminase (SGOT) estimations over 40 units in 154 patients in the same study. A study by Holden et al. (4) in a similar population produced similar findings and corroborated the previous reports that clinical laboratory data in adult chronic psychiatric populations exceed established textbook standards. Here again the greatest discrepancies were: 31 percent of erythrocyte sedimentation rate (ESR) in males and 70 percent in females were beyond the normal range, almost 30 percent of WBC were beyond the normal range and 15 percent of the differential counts.

To date we do not have any such studies to compare results in a child psychiatric population with textbook norms.

Looking at the very limited data obtained to date at New York University (2) on Dr. Fish's* nursery children (to six years), it is exceedingly likely that a similar discrepancy will result as has been observed in the adult psychiatric population.

The laboratories themselves may contribute markedly to errors. Variation in the methods or the time of day for the collection of blood can account for differences in results greater than those produced by standard laboratory methods. There are also variations which can be attributed to laboratory personnel. Clinical laboratory estimations of hemoglobin by two observers differed by more than 10 percent in 17 percent of measurements using the same laboratory facilities and methods. In a special study (10) of errors in measurement of serum electrolytes, it was found that for the same sample of blood the serum sodium, potassium, and chloride values varied widely among four

*Now at: Department of Psychiatry, University of California (UCLA), Los Angeles, California.

hospital laboratories. The standard deviations of the results in three of the laboratories are approximately twice those obtained by the authors. The hospital results on normal sera were frequently outside the quoted normal ranges. This occurred for 48 percent of the sodium results from one laboratory and 55 percent of the chloride results from another.

Thus, there is enough evidence to suggest that new normative clinical chemistry data will need to be obtained for a child psychiatric population. This issue is further compounded when the investigation of an experimental pharmacological compound is added. The question then becomes: How much deviation from normal laboratory norms is allowed before attributing the "abnormal" findings to the experimental medication?

PROPOSALS

1. It will be necessary to establish new norms for laboratory data in this population and ranges for each age level. In few of the evaluations of new psychotropic compounds have parallel clinical and laboratory studies in control populations living under similar environmental conditions been reported. Reliance is most often placed on published standards of normality. It is most fortunate that the Biometric Laboratory of The George Washington University, Kensington, Maryland, now has procedures available for the collection of such data and the provision of such norms. This should provide the sorely needed normative lab data for this special population and enable the better interpretation of drug effects in regard to clinical chemistry.

2. Special care will be required in regard to quality control in each laboratory to avoid the possibility that laboratory errors alone may obliterate drug-induced changes.

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Table 19

Childrens
Laboratory Norms

Hemoglobin (7)

5 yrs. 12 1/2-15 gms. (Aver. 13 1/2)
8-13 yrs. 13-15 1/2 gms. (Aver. 14)
RBC 3,800,000–5,400,000

Hematocrit

A. (11)
4 yrs. – 33-37
6 " – 34-38
8 " – 35-39
12 " – 35-40

B. (7)
4-10 yrs. – 37% ± 6%

WBC Count (11)

4 yrs.	5,500-15,500	(Aver. 9,100)
6 "	5,000-14,500	" 8,500
8 "	4,500-13,500	" 8,300
10 "	4,500-13,500	" 8,100
12 "	4,500-13,500	" 8,000

WBC Differential (11)

Age	Segmented Neut.	Band Neut.	Lymphos	Monos	Eos	Basos
4 yrs.	29-49%	1-5%	35-65%	5% (Av.)	2.8% (Av.)	.6% (Aver.)
6 "	38-58%	1-5%	28-57%	4.7% "	2.7% "	.6% "
8 "	40-60%	1-5%	24-54%	4.2% "	2.4% "	.6% "
10 "	36-66%	1-5%	28-48%	4.3% "	2.4% "	.5% "
12 "	37-67%	1-5%	28-48%	4.4% "	2.5% "	.5% "

Table 20*

					Differential					
	Hgb[3]	Hct[3]	RBC[3]	WBC[4]	Neutros	Lymphos	Monos	Eos	Basos	Platelets
1 yr.		36%	4.6 mil	12,000	30%	60%	5%	2-3%	0.5%	250,000
2 yrs.	10-12.5				↓	↓	↓	↓	↓	350,000
3 yrs.		40%								↓
4 yrs.				8,000-10,000	40%	50%				
5 yrs.	13-13.5									
6 yrs.				7,500	55-60%	40%	↓	↓	↓	↓

*Relevant data extracted from text (9).
[3] Hemoglobin.
[3] Hematocrit.
[3] Red Blood Cells.
[4] White Blood Cells.

Table 21*

Laboratory Test Values and Textbook Standards for Children (Ages 4–9)

Test	Text Standard Range: Children	Text Standard Range: Adult	Number of Estimations	Study Range	Mean	Total Percent "Abnormal"
Hemoglobin on: Gm%	12.5-15	14-18	121	7.7–17.2	11.27	67
Hemoglobin on**: Gm%			31	9–13.5	11.26	93
Hemoglobin off			132	8.5–16.9	11.92	84
Hemoglobin off**			32	9.4–15.5	12.68	44
Hematocrit on	34-38	44-54	116	30.5–48	37.39	68
on**			39	31–48	37.69	36
off			131	29–48	38.09	69
off**			33	31.5–44	37.11	51
Neutrophils: WBC% on	5,000-14,500	5,000-10,000	118	3500–21,800	2043.30	17
on**			37	4100–17,800	10,222.70	19
off			130	3150–19,400	9757.69	21
off**			36	4850–26,500	12,041.67	25
Poly% on	29-58	50-80	118	23–79	45.80	
on**			37	27–75	49.81	
off			129	17–86	43.40	
off**			36	25–73	53.83	
Band% on	1-5	3-5	15	1–3	1.4	
on**			8	1–3	2.12	
off			21	1–8	2.05	
off**			9	1–8	4.0	
Lymph% on	35-54	25-33	116	16–74	49.51	
on**			38	16–69	43.76	
off			130	17–77	51.52	
off**			35	20–70	42.23	
Mono% on	4.7 (Aver.)	3-7	75	1–10	2.84	
on**			26	1–6	2.61	
off			92	1–8	2.90	
off**			21	1–5	2.38	

*New York University Lab Data.

**Test administered during fever or other infection.

Table 22 Summary of Laboratory Findings for 65 Chronic Schizophrenics on Placebo (3)

Test	Normal limits*	Number of Determination	Mean	S.D.	Percent below normal	Percent above normal	Total Percent "abnormal"
Red blood count	4.2-5.5 mill.	244	4.6 mill.	0.3 mill.	6.4	1.6	8.0
White blood count	5,000-10,000	342	7,090	1,200	2.0	1.8	3.8
Hemoglobin:							
(Males)	14-18 grams	178	14.9	1.6	14.0	0.0	14.0
(Females)	12-16 grams	134	13.9	1.5	1.5	2.2	3.7
Hematocrit**	42-50	345	45.8	5.2	26.2	11.0	37.2
(Males)	47±7%	195	47.0	4.1	26.7	17.4	44.1
(Females)	42±5%	150	43.8	4.5	10.7	31.3	42.0
Sed. Rate (Wintrobe):							
(Males)	0-9	145	12.3	7.6	—	77.2	77.2
(Females)	0-20	134	21.4	7.7	—	49.2	49.2

* From Sunderman, F. W. and Boerner, F. Normal Values in Clinical Medicine. Philadelphia: W. B. Saunders Co., 1949.

** Normal limits of 42-50 for hematocrit from reference above. Additional separate norms for males and females from *Merck Manual of Diagnosis and Therapy*, 10th Edition, 1961.

NORMAL BLOOD VALUES

TABLE 23 CHEMICAL CONSTITUENTS OF BLOOD

ACID-BASE CONSTITUENTS		
Total fixed cations (Na + K + Ca + Mg)	(serum)	150–155 mEq./liter
By methods of Hald and Sunderman, normal values tend to be lower		143–150 mEq./liter
Sodium*	(serum)	136–143 mEq./liter
Potassium*	(serum)	4.1–5.6 mEq./liter
Calcium*	(serum)	10–12 mg./100 ml.
		5–6 mEq./liter
Calcium,* diffusible (ionized Ca)	(serum)	5–5.5 mg./100 ml.
Magnesium*	(serum)	2–3 mg./100 ml.
In the newborn a value as low as 1.3 mEq./liter would be considered normal		1.65–2.5 mEq./liter
Chlorides* (Cl)	(serum)	98–106 mEq./liter
At birth and during early infancy the plasma (serum) chloride is 6–10 m.Eq./liter higher than that of older infants and children		585–620 mg./100 ml.
Phosphorus, inorganic, as P	(serum)	4.0–6.5 mg./100 ml.
Slightly higher in the newborn (in infants, up to 8 mg./100 ml. considered normal)		1.29–2.1 mM./liter
$HPO_4^{--}/H_2PO_4^-$ (average valence 1.8 at pH 7.4)		2.3–3.8 mEq./liter
Serum protein cation-binding power	(serum)	15.5–18.0 mEq./liter
Bicarbonate cation-binding power	(serum)	19–30 mEq./liter
The above two constitute a major portion of the buffer base (Hastings and Singer) of serum		
Standard bicarbonate (Astrup)†	(plasma)	21–25 mEq./liter
Buffer base, $[BB]_b$	(blood)	46–52 mEq./liter
Base excess $[BE]_b$	(blood)	−2.3 to +2.3 mEq./liter
Sulfates, inorganic, as SO_4^{--}	(serum)	0.5–1.0 mEq./liter
		2.5–5.0 mg./100 ml.
Sulfates, ethereal	(serum)	0.1–1.0 mg./100 ml.
Sulfur, neutral	(serum)	1.7–3.5 mg./100 ml.
Lactic acid	(serum)	10–20 mg./100 ml.
pH at 38° C.	(blood, plasma or serum)	7.3–7.45
The sample must be protected against loss of CO_2 and determination made as soon as possible. Arterial blood in a resting person is about 0.03 pH unit higher than venous blood.		
pH at 38° C.	(serum from arterial blood)	
(Data from Cassels and Morse)		
1.5– 3.4 years		7.30–7.40
3.5– 5.4 years		7.35–7.43
5.5–12.4 years		7.37–7.43
12.5–17.4 years		7.35–7.41

* In human red blood cells an average concentration of sodium would be about 21 mEq./liter of red blood cells; of potassium about 86 mEq./liter.

The level of calcium in serum is influenced by the concentration of serum protein because part of the calcium is associated with or bound to the protein. Practically all the calcium in blood is in the plasma.

The chloride concentration of whole blood depends largely on the cell volume, since the erythrocyte contains approximately half as much chloride as serum.

† Concentration of bicarbonate in plasma which is separated from the cells with the hemoglobin completely oxygenated, at a $pCO_2 = 40$ mm. Hg and at a temperature of 38° C.

TABLE 23 *(Continued)*

ACID BASE CONSTITUENTS

Carbon dioxide content	(serum from venous blood)	45–70 vol. per cent 20.3–31.5 mM./liter
The CO_2 content is lower at birth and rises slightly during the first 4 days of life		
Carbon dioxide content	(whole venous blood)	40–60 vol. per cent 18–27 mM./liter
Carbon dioxide content	(arterial blood)	
(Data from Cassels and Morse)		
1.5– 3.4 years		15.5–20.5 mM./liter
3.5– 6.4 years		18.7–21.2 mM./liter
6.5–11.4 years		19.3–21.6 mM./liter
11.5–14.4 years		19.9–22.2 mM./liter
14.5–17.4 years		20.4–22.4 mM./liter
Carbon dioxide tension	(arterial blood)	
(Data from Cassels and Morse)		
1.5– 6.4 years		33.5–41.1 mm. Hg
6.5–12.4 years		35.4–40.6 mm. Hg
12.5–17.4 years		38.3–44.4 mm. Hg
Oxygen tension P_{O_2}	(arterial blood)	85–100 mm. Hg
Oxygen capacity*	(whole blood)	19–22 vol. per cent
Oxygen saturation	(whole venous blood)	60–85 per cent
Blood of newborn		30–80 per cent
Hemoglobin		
At birth	(whole blood)	17–20 gm./100 ml.
3 months		10.5–12 gm./100 ml.
1 year		11–12.5 gm./100 ml.
5 years		12–13 gm./100 ml.
10 years		13–14 gm./100 ml.
Above 10 years		14–16 gm./100 ml.
Methemoglobin	(whole blood)	0.0–0.3 gm./100 ml.
Premature infants at higher level		(0.4)
Carbon monoxide hemoglobin	(whole blood)	up to 5% of total hemoglobin
Haptoglobin	(serum)	40–170 mg. % as hemoglobin-binding capacity
Water	(whole blood)	79–81 gm./100 ml.
	(serum)	91–92 gm./100 ml.
	(red blood cells)	64–65 gm./100 ml.

* The oxygen capacity and iron content of blood are directly related to the hemoglobin content of the blood (1.335 ml. O_2/gm. of hemoglobin).

CARBOHYDRATES, LIPIDS AND PIGMENTS

Sugar, fasting		
(Somogyi-Nelson)	(blood)	60–90 mg./100 ml.
Under fasting conditions capillary or arterial blood and venous blood are nearly the same		
Sugar, fasting arterial (Folin-Wu)	(blood)	80–120 mg./100 ml.
fasting venous (Folin-Wu)	(blood)	70–100 mg./100 ml.
Lactic acid. See *Acid-Base Constituents*		
Pyruvic acid, fasting	(blood)	0.7–1.2 mg./100 ml.
Citric acid	(blood)	1.3–2.3 mg./100 ml.
Citric acid	(plasma)	1.6–2.7 mg./100 ml.
α-Ketoglutaric acid	(blood)	8–10 mg./100 ml.
Acetone bodies (as acetone)	(serum)	1–6 mg./100 ml.
Total cholesterol (over 6 yr.)	(serum)	150–250 mg./100 ml.
Infants		70–125 mg./100 ml.
Newborn		50–100 mg./100 ml.
Cholesterol esters		125–180 mg./100 ml.
17-Hydroxycorticosteroids	(plasma)	10–13.5 microgm./100 ml.
Total lipids		
(Rafsted) 2–14 years	(serum)	490–1000 mg./100 ml.
3 days–1 year		240–800 mg./100 ml.

TABLE 23 *(Continued)*

CARBOHYDRATES, LIPIDS AND PIGMENTS

3 days–10 days		430–760 mg./100 ml.
Newborn		170–450 mg./100 ml.
Free fatty acids	(serum)	230–380 microgm./ml.
More variable in young children		
Phosphatides (lipid P × 25)	(plasma)	
Children		180–295 mg./100 ml.
Up to 1 year		100–275 mg./100 ml.
Newborn		75–170 mg./100 ml.
Bilirubin (total)	(serum)	0.2–0.8 mg./100 ml.
Higher in newborn		1.0 or more
Conjugated bilirubin (direct)		0–0.3 mg./100 ml.
Icterus index		4–6 units

PROTEINS

Total protein (from nitrogen determination)	(serum)	6.5–7.5 gm./100 ml.
At birth the protein is slightly lower		
Albumin* [globulins precipitated by Na_2SO_4-Na_2SO_3 mixture (20.8% Na_2SO_4 + 7.0% Na_2SO_3)]	(serum)	3.9–4.5 gm./100 ml.
Globulins (by difference)		2.3–3.5 gm./100 ml.
A/G ratio		1.2–1.9 gm./100 ml.
Protein values vary slightly with age. The following values for plasma are adapted from the paper of Metcoff and Stare (*New England J. Med.*, 1947)		
Total protein (plasma)		
Premature infant		4.55 ± 0.59 gm./100 ml.
Full-term infant		5.11–5.70 gm./100 ml.
Birth to 1 year		6.10 ± 0.29 gm./100 ml.
1–4 years		6.94 ± 0.47 gm./100 ml.
5–12 years		7.30 ± 0.59 gm./100 ml.
12 years and above		7.16 gm./100 ml.
Albumin (plasma) (globulin precipitation by 22% Na_2SO_4; Howe)		
Premature infant		3.55 ± 0.65 gm./100 ml.
Full-term infant		3.76–3.79 gm./100 ml.
Birth to 1 year		4.97 ± 0.73 gm./100 ml.
1–4 years		4.59–4.83 gm./100 ml.
5–12 years		5.0 ± 0.78 gm./100 ml.
12–15 years		4.72 gm./100 ml.
Globulin (plasma)		
Premature infant		1.01 ± 0.45 gm./100 ml.
Full-term infant		1.34–1.66 gm./100 ml.
Birth to 1 year		1.38 ± 0.68 gm./100 ml.
1–4 years		2.03 ± 0.34 gm./100 ml.
5–12 years		2.4 ± 0.74 gm./100 ml.
12–15 years		2.49 gm./100 ml.
Fibrinogen	(plasma)	0.2–0.4 gm./100 ml.
Gamma globulin		10–15% of total protein
		0.7–1.2 gm./100 ml.
At birth values approximate adult levels, owing to passive transfer from the mother; during the ensuing weeks there is a decrease, the "low point" being reached between the second and fourth months. After this there is a gradual increase to the "adult level" by about the second year of life.		
Ceruloplasmin	(serum)	16–33 mg./100 ml.
Mucoprotein	(serum)	45–105 mg./100 ml.
Mucoprotein tyrosine	(serum)	2–4.5 mg./100 ml.
Serum protein partition by paper electrophoresis (Durrum)		
% of total protein		
Albumin		50–60%
α_1-globulin		5–8%
α_2-globulin		8–13%
β-globulin		11–17%
γ-globulin		15–25%

* When the globulin is precipitated with the Na_2SO_4-Na_2SO_3 mixture, the albumin values agree with those obtained by electrophoresis.

TABLE 23 *Continued)*

NITROGEN CONSTITUENTS		
Nonprotein nitrogen	(whole blood)	25–40 mg./100 ml.
(Tungstic acid filtrate; zinc hydroxide filtrates give lower values because more small molecule nitrogenous compounds are precipitated)	(plasma)	18–30 mg./100 ml.
Urea nitrogen	(whole blood)	7–15 mg./100 ml.
	(plasma)	10–17 mg./100 ml.
Creatinine	(serum)	0.4–1.2 mg./100 ml.
Absorption by Lloyd's reagent	(whole blood)	0.5–2.0 mg./100 ml.
Creatine + creatinine	(whole blood)	5–8 mg./100 ml.
Concentration of creatine is low in plasma		
Uric acid	(serum)	2–6 mg./100 ml.
At birth the uric acid concentration of the blood of the infant is identical with that of the mother		
Ammonia	(whole blood)	0.1–0.3 mg./100 ml.
Amino acid nitrogen	(plasma)	3.5–5.5 mg./100 ml.
Serum gives slightly lower value than plasma		
Phenylalanine	(serum)	0.7–4.0 mg./100 ml.
Proline (fasting)	(plasma)	13.8–32.5 microgm./liter
Glutamine	(plasma)	6–12 mg./100 ml.
Citrulline	(plasma)	0.3–1 mg./100 ml.
ENZYMES		
Amylase	(plasma or serum)	70–200 Somogyi units
		6–33 Close-Street units
Aldolase	(serum)	0.15–0.8 units (micromoles of fructose diphosphate split/per ml. serum/hour)
Alkaline phosphatase		
Infants	(serum)	5–10 Bodansky units
Children (2–15 years)		3–13 Bodansky units
The values by the Shinowara Jones and Reinhardt method are about ⅓ higher, owing to incubation at pH 9.3 instead of 8.6		
Infants		4–14 Bessey-Lowry-Brock units (substrate p-nitrophenol-phosphate) (Sigma units)
Children		3.4–9 B.L.B. units
Children		10–20 King-Armstrong units (Substrate disodium phenyl-phosphate)
Infants		3.8–11 Klein-Babson-Reed units
Children		2–15 (Substrate buffered sodium phenolphthalein phosphate); 1 unit of activity liberates 1.0 mg. phenolphthalein in 30 minutes at 37° C.
Phosphatase, acid	(serum)	1–5 King-Armstrong units
Creatine phosphokinase (CPK)	(serum)	to —0.72 milliunits (Bergmeyer)
Lactic acid dehydrogenase (Snodgrass method)	(serum)	30–120 units
Copper oxidase (Ravin method) (ceruloplasmin)	(serum)	0.14–0.57 O.D. units
Lipase	(serum)	< 1 unit/ml. Sigma-Tietz unit (ml. of 0.05 *N* NaOH to neutralize free fatty acid during 6-hr. incubation period)
Transaminase (children)	(serum-glutamate-oxalacetate)	
SGO, spectrophotometric method		4–40 units (higher in infants)
Serum glutamate pyruvate		1–45 units
MISCELLANEOUS		
Ascorbic acid	(serum)	0.4–1.5 mg./100 ml.
Vitamin A	(serum)	15–60 microgm./100 ml.
Carotenoids	(serum)	40–400 microgm./100 ml.
Iron		0.04–0.18 mg./100 ml.

TABLE 23 *(Continued)*

MISCELLANEOUS		
Iron-binding capacity	(serum)	0.187–0.65 mg./100 ml.
Transferrin	(serum)	0.2–0.3 gm./100 ml.
Copper	(serum)	0.08–0.235 mg./100 ml.
Lead	(serum)	0.001–0.003 mg./100 ml.
Lead	(blood)	0.01–0.06 mg./100 ml.
Bromine	(serum)	0.7–1 microgm./100 ml.
Iodine, protein-bound	(serum)	0.003–0.008 mg./100 ml.
Iodine, butanol extractable		0.003–0.0065 mg./100 ml.
Potassium	(erythrocytes)	86–104 mEq./liter of red blood cells
Thiamine	(blood)	5.5–9.5 microgm./100 ml.
Tocopherols	(serum)	0.6–1.2 mg./100 ml.
Lower in the newborn		
PHYSICAL MEASUREMENTS		
Specific gravity	(whole blood)	1.048–1.05
Newborn infants: falls rapidly during first 2 weeks and continues to decrease until second or third year		1.06 – 1.085
	(plasma)	1.025–1.03
Prothrombin time (Quick)	(plasma)	12–15 seconds
This determination should always be controlled by a determination on a normal blood, since the activity of the thromboplastin preparations may vary greatly		
Bleeding time		1–3 minutes
Coagulation time (test tube method)		3–9 minutes
Cephalin flocculation	(serum)	0–1+ units
During first 6 months of life this test may be negative in the presence of liver disease		
Thymol turbidity	(serum)	0–4 Maclagan units
Zinc sulfate turbidity	(serum)	2–8 Maclagan units
Viscosity, compared to water as unity	(whole blood)	4.5–5.5
	(serum)	1.7–2.1
Corrected erythrocyte sedimentation rate		
(Rourke-Ernstene)		0.1–0.35 mm./min.
Cutler method		2–10 mm./hr.
The rate is slower in the neonatal period		
Freezing point depression	(serum)	−0.535°–(−0.555°) C.
Osmolality	(plasma)	270–285 milliosmoles/liter plasma water
Refractive index, 20° C.		1.3485–1.3505

NORMAL CEREBROSPINAL FLUID VALUES

TABLE 24

Amount in the newborn	Up to 5 ml.
Increases with age to adult figure	100–150 ml.
Initial pressure	70–200 mm. H_2O
Cell count	
Under 1 year	Up to 10 cells/mm.^{3}
1–4 years	Up to 8 cells/mm.^{3}
5 years to puberty	0–5 cells/mm.^{3}
Specific gravity	1.005–1.009
Freezing point depression	−0.56–(−0.60)°C.
Refractive index at 20°C.	1.33554
pH 38°C. (protected against loss of CO_2)	7.33–7.42
Fluid exposed to air becomes alkaline	
Carbon dioxide-combining power	40–70 vol. per cent 18–31 m.Eq./liter
Chloride	
7 days–3 months	108.8–122.5 mEq./liter
4–12 months	112.7–128.5 mEq./liter
13 months–12 years	116.8–130.5 mEq./liter
Cholesterol	Trace–0.22 mg./100 ml.
Glucose, 6 months–10 years	71–90 mg./100 ml.
over 10 years	50–80 mg./100 ml.
The glucose level is less than, and varies proportionally with, the rise and fall of the plasma glucose level	
Total fixed cations	About 155 mEq./liter
Sodium	130–165 mEq./liter
Potassium	2.8–4.1 mEq./liter
Calcium	4.5–5.5 mg./100 ml.
Magnesium	2.8–3.3 mg./100 ml.
Phosphorus, inorganic	1.5–3.0 mg./100 ml.
3 mg. first day of life	
Lactic acid	Trace
Fluid on standing may increase in concentration with disappearance of glucose	
Protein	15–40 mg./100 ml.
The ventricular fluid contains much less protein than does lumbar fluid. Fluid from the cisterna magna contains more protein than that from the ventricle and less than that from lumbar region. The range is greater in the newborn and during the first month of life (20–120 mg./100 ml.)	
Albumin	80% of total protein
Globulin	20% of total protein
Fibrinogen	None
Pandy reaction	No precipitate
Urea nitrogen	7–15 mg./100 ml.
Nonprotein nitrogen	8.5–20 mg./100 ml.
Creatinine	0.45–1.9 mg./100 ml.
Uric acid	0.3–1.5 mg./100 ml.
Amino acid nitrogen	1.5–3 mg./100 ml.
Ammonia nitrogen	0–0.015 mg./100 ml.
Bilirubin	None
Iodine	Trace
Transaminase (GOT)	2–20 units (about ½ the value of SGOT)
Colloidal gold number (Wuth and Faupel)	0000000000
Dilutions 1–10 to 1–5120 with 0.4% NaCl solution	

TABLE 25

Normal Laboratory Data

Blood:	
Nonprotein nitrogen	25–40 mg/100 ml
Urea nitrogen	10–15 mg/100 ml
Uric acid	2–3 mg/100 ml
Creatinine	1–2 mg/100 ml
Creatine	5–7 mg/100 ml
Glucose	60–120 mg/100 ml
Cholesterol	120–250 mg/100 ml
Esters	100–150 mg/100 ml
Free	50–100 mg/100 ml
Bilirubin	0.2–1.0 mg/100 ml
Icterus index	3–5 units
Chlorides (expressed as NaCl):	
Whole blood	450–500 mg/100 ml (70–85 mEq/liter)
Serum	585–620 mg/100 ml (100–106 mEq/liter)
Sodium—serum	310–330 mg/100 ml (133–143 mEq/liter)
Potassium—serum	16–22 mg/100 ml (4.0–5.5 mEq/liter)
Phosphorus—serum	3.5–5.0 mg/100 ml (2.0–3.0 mEq/liter)
Calcium—serum	9–12 mg/100 ml (4.5–6 mEq/liter)
CO_2 content—serum	45–70 vol % (20.3–31.5 mEq/liter)
Serum albumin	4.5–5.5 gm/100 ml
Serum globulin	1.8–2.7 gm/100 ml
Sedimentation rate:	
Micro	4–10 mm/hr
Westergren	5–20 mm/hr
Coagulation time:	
Capillary	3–4 min
Venous	4–10 min
Bleeding time	1–3 min
Fragility test	0.46–0.30% saline
Prothrombin time (Quick test):	
Plasma	12–15 sec
Urine:	
Albumin	Negative (trace is often of no significance)
Sugar	Negative
Acetone bodies	Negative
Specific gravity	1.005–1.030
Urobilinogen	Positive in dilution 1:20
Bilirubin	Negative
Red blood cells	Absent (centrifuged)
White blood cells	0–2 HPF* (centrifuged)
Casts	Absent (few hyaline casts are often not significant)
Spinal fluid:†	
Pressure	70–200 mm water
Cell count	0–10 (chiefly lymphocytes)
Protein	20–40 mg/100 ml
Sugar	50–90 mg/100 ml
Chlorides (expressed as NaCl)	650–750 mg/100 ml (111–128 mEq/liter)

* HPF: high-power field.

† Amount in newborn infants ranges from 30 to 60 ml; in a child of 10 yr, there may be up to 200 ml

TABLE 26 Average Blood Cell Values during Infancy and Childhood*

Cells	Birth	2 days	2 weeks	3 months	1 year	5 years	10 years
Red blood cells, millions per cu mm	4.9–5.5	5.3–6.5	4.5–5.5	3.9–4.8	4.5–5.0	4.7–5.3	4.8–5.5
Hemoglobin, gm per 100 ml	16–20	18–22	14–17	10.5–11.5	12–13	12.5–13.5	12.5–14.5
Reticulocytes, %	3–5	1–5	1–2	0.2–1.0	0.1–1.5	0.1–1.5	0.1–1.5
Nucleated red blood cells, per 100 white cells	2–10	0–5	0–2	0	0	0	0
White blood cells, thousands per cu mm	10–20	12–22	8–12	5–9	6–10	6–10	6–10
Neutrophils, %	45–55	50–65	30–45	30–40	35–45	40–50	45–55
Lymphocytes, %	45–30	40–20	55–45	65–50	60–50	55–45	50–45
Others, %—monocytes, eosinophils, bosophils	10–15 Occasional myelocytes	10–15	15–10	5–10	5	5	5
Platelets, thousands per cu mm	350	450	350	200–300	250–350	250–350	250–350

* Determination of the peripheral red cell count or hemoglobin reflects the true size of the circulating red blood cell mass only when the blood volume is normal. In dehydration, for example, when the plasma volume is greatly reduced, peripheral measurements give falsely high values. In brisk hemorrhage, on the other hand, while plasma and red blood cell volumes are being proportionately reduced, peripheral measurements early do not reflect the true reduction of total red blood cell mass. After the bleeding has slowed or stopped and plasma volume has been restored from the extravascular fluids, red cell and hemoglobin concentrations indicate the change in size of the circulating red blood cell mass. In chronic anemia, the total blood volume is usually unchanged; the total circulating red blood cell mass is reflected by the peripheral values. Several hours after birth, the total erythrocyte, plasma, and blood volume increases by as much as 20 per cent and remains elevated for about 2 weeks.

TABLE 27 Normal blood values significant in diagnosis of anemias in infancy and childhood*

Hemoglobin	
First day	20 gm. (18 to 22 gm.)
2 weeks	17 gm.
First and second years	11 gm. (10 to 12.5 gm.)
3 to 5 years	12.5 to 13 gm.
5 to 10 years	13 to 13.5 gm.
10 years	14.5 gm.
Red blood cells	
First day	5,500,000 (5 to 6 million)
Second week	5,000,000
Older infant and child	4,000,000 per cubic millimeter lower limit of normal
Nucleated red cells	
Average—3 to 10 per 100 white cells (birth to 4 days of life)	
Reticulocytes	
0.5 to 1.5% (6% upper limit of normal—from birth to 4 days of life) (Below 0.5% in aplastic and hypoplastic anemia; increased in hemolytic anemia; in deficiency anemia rise from low to high levels with treatment)	
Volume of packed red cells (hematocrit)	
Infants 1 month to 2 years	34%
Children 2 years to 12 years	36%
Older children	40%
Serum bilirubin	
Newborn full-term infants	2 to 8 mg.%
Newborn premature infants	1 to 15 mg.%
(Values given for both full-term and premature newborn infants are the low values at birth rising to maximum during first week of life)	
Normal infants and children	Under 1 mg.%
(Hemolytic anemias—elevated total bilirubin predominantly indirect fraction)	
Fragility test	
Normal range	0.425 to 0.325% sodium chloride
(Increased fragility in hereditary spherocytosis and in some cases of acute hemolytic anemia; decreased fragility in sickle cell anemia, thalassemia [major and minor], and in iron-deficiency anemia)	

*From Smith, C. H.: Anemias in infancy and childhood; diagnostic and therapeutic considerations, Bull. New York Acad. Med. 30:155, 1954.

CLINICAL LABORATORY TEST STANDARDS FOR SCHIZOPHRENIC RESEARCH SUBJECTS

T. H. McGlashan, M.D. and P. Cleary, M.S.

Standards for 15 clinical laboratory tests have been developed from data obtained from pretreatment blood samples of subjects who were participants in 22 clinical psychotropic drug trials conducted in collaboration with the ECDEU Program at nine different research centers in the United States and Canada between 1969 and 1972. A final sample of 325 research subjects was selected on the criteria:

a) Diagnosis of schizophrenia (regardless of subtype)

b) Adult (18 years or more)

c) No significant concurrent medical conditions

d) Non-repeating research subject (i.e., if a patient participated in more than one research project in which laboratory values were recorded, only his first test results were included in the final sample).

e) Complete data on age, sex, and race (i.e., if any of this demographic information was missing, the subject was excluded).

Demographic characteristics of the sample are given in Table 28. Both parametric means and ranges (mean $\pm$ 2 standard deviations) and non-parametric medians and percentile ranges (2.5 and 97.5 percentiles) are reported in Tables 29 and 30. The results generally confirm the finding of increased variability in schizophrenic laboratory test data noted in the past. This, and implications of the method, are discussed more fully in a paper entitled "Clinical Laboratory Test Standards for a Sample of Schizophrenics", Psychopharmacologia, 44, 281-285, 1975.

TABLE 28
POPULATION DEMOGRAPHIC CHARACTERISTICS
N=325*

CHARACTERISTIC	FREQUENCY	PERCENT
Sex		
Male	170	52
Female	155	48
Race		
White	271	83
Black	47	14
Other	7	3
Marital Status		
Ever married	138	43
Never married	185	57
Previous Treatment for Mental Illness (total time)		
None	28	9
Less than two years	72	23
More than two years	212	68
Duration of Present Hospitalization		
Outpatient	45	14
Less than one month	113	32
One month to two years	33	10
More than two years	143	44
Schizoid Life Style		
Definitely characteristic	128	44
Somewhat characteristic	112	38
Not characteristic	51	18
Occupational - Role Adjustment		
Adequate	44	14
Marginal	134	43
Inadequate	136	43

	MEAN	S.D.	RANGE
Present Age	40	11	18 - 77
Age First Hospitalization	25	8	11 - 56

*Missing data existed for many of the demographic characteristics other than age, sex and race. Therefore, the N's listed under Frequency do not always sum to 325.

TABLE 29
PARAMETRIC NORMAL RANGE ESTIMATES
FOR 15 CLINICAL LABORATORY TESTS:
SCHIZOPHRENIC SAMPLE AND TEXTBOOK NORMALS*

TEST	SCHIZOPHRENICS				TEXTBOOK NORMAL RANGE
	Sample	N	Mean	Range (Mean ± 2 SD)	
Hemoglobin gm/100 ml	male	149	15.2	12.8 - 17.6	14 - 18
	female	153	13.8	11.6 - 16.0	12 - 16
Hematocrit %	male	166	46	40 - 52	40 - 54
	female	150	41	35 - 47	37 - 47
Red Blood Count millions/cumm	male	51	5.0	4.0 - 6.0	4.6 - 6.2
	female	56	4.5	3.7 - 5.3	4.2 - 5.4
Sedimentation Rate mm/hr	male	22	17	1 - 33	0 - 20
	female	31	28	0 - 60	0 - 30
White Blood Count thousands/cumm	total	320	8.4	3.2 - 13.6	5 - 10
Differential Count	total	268			
% neutrophiles			61	41 - 81	
% lymphocytes			33	13 - 53	
% eosinophiles			3	0 - 9	
% monocytes			4	0 - 8	
% basophiles			0.4	0 - 1.8	
Blood Urea Nitrogen mg/100 ml	total	274	12	2 - 22	8 - 20
Sodium meq/liter	total	65	139	131 - 147	136 - 142
Potassium meq/liter	total	64	4.3	3.1 - 5.5	4.0 - 4.8
Creatinine mg/100 ml	total	53	1.0	0.6 - 1.4	0.5 - 1.2
Direct Bilirubin mg/100 ml	total	124	0.2	0 - 0.4	0 - 0.4
Total Bilirubin mg/100 ml	total	196	0.6	0 - 1.2	0.5 - 1.4
Total Protein gm/100	total	58	7.5	6.5 - 8.5	6.0 - 7.8
Blood Albumin gm/100 ml	total	49	4.8	3.8 - 5.8	3.2 - 4.5
Fasting Blood Sugar mg/100 ml	total	103	98	62 - 134	60 - 100
Cholesterol mg/100 ml	total	131	207	113 - 301	150 - 250

*Taken from: Clinical Diagnosis By Laboratory Methods
Davidsohn and Henry, 1969
14th Edition, W. B. Saunders Co.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

PHYSICAL AND NEUROLOGICAL EXAMINATION FOR SOFT SIGNS

The Physical and Neurological Examination for Soft Signs (MH-9-41 PANESS) is a 4-page form for the assessment of physical status (pages 1 and 2) and soft neurological signs (pages 3 and 4) in pediatric populations. ***BEFORE ATTEMPTING TO COMPLETE THE FORMS, RATERS SHOULD BE FAMILIAR WITH THE INSTRUCTIONS GIVEN IN THE ECDEU ASSESSMENT MANUAL. THIS IS PARTICULARLY CRUCIAL FOR THE EXAMINATION OF SOFT NEUROLOGICAL SIGNS.***

The neurological examination for soft signs has been developed and copyrighted by Abbott Laboratories and their permission to use it is gratefully acknowledged.

IMPORTANT – PLEASE READ CAREFULLY BEFORE MARKING THIS FORM.

INSTRUCTIONS FOR COMPLETION OF MULTIPLE PAGE FORMS

1. Complete page 1.

2. Following completion of page 1 carefully tear out and remove the pink protective sheet lying between the carbon and your copy of page 2. Follow this procedure for each subsequent page. You must do this to obtain a copy of the data for your files.

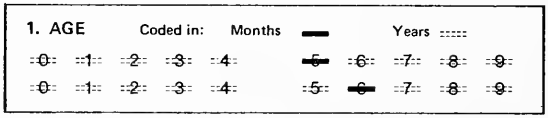
   CAUTION: DO NOT REMOVE PINK PROTECTIVE SHEETS OTHER THAN THE ONE LYING BETWEEN CARBON AND COPY OF THE PAGE YOU ARE ABOUT TO COMPLETE.

3. When you have completed all pages of the form, carefully tear out and remove carbon papers and your copy pages. The machine scannable pages should be left in booklet form for shipment to the Biometric Laboratory in packages prepared according to instructions received from the Biometric Laboratory.

MARKING INSTRUCTIONS

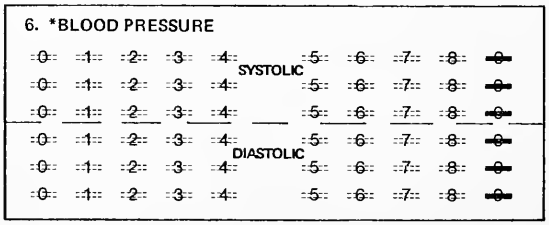
Read each item and its numbered responses. When you have decided which response is correct, blacken the corresponding space on the page with a No. 2 pencil. Do not use a ball point pen. Make your mark as long as the pair of lines, and completely fill the area between the pair of lines. If you change your mind, erase your first mark COMPLETELY.

EXAMPLE: The child is 56 months old. Code as follows:



Mark a field of 9's if an item is unanswered or Not Ascertained.

EXAMPLE: Blood pressure was not taken; the rater codes as follows:



NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
BUDGET BUREAU NO. 68-R955

PHYSICAL AND NEUROLOGIC EXAMINATION FOR SOFT SIGNS

PATIENT INITIALS

FIRST INITIAL

SECOND INITIAL

FORM NUMBER

NUMBER MALES 001-499 FEMALES 500-998

PATIENT

RATER

PERIOD

Hours Days Weeks Months

PLEASE USE A NO. 2 PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE.

1. AGE — Coded in Months / Years

2. *HEIGHT — Coded in Inches / Centimeters

3. *WEIGHT — Coded in Lbs / Kg

4. *HEAD CIRCUMFERENCE — Inches / Cm

5. *PULSE — Code Per minute — Regular / Irregular

6. *BLOOD PRESSURE — SYSTOLIC / DIASTOLIC

7. *VISUAL ACUITY — Code numerator only — RIGHT / LEFT

8. *OPHTHALMOSCOPIC — Normal / Abnormal / NA

9. *AUDIOGRAM — Normal / Abnormal / NA

*HANDEDNESS — Right / Left / Mixed / NA

*Specify abnormalities under Item 14

11. PHYSICAL EXAMINATION — *Specify any abnormal findings under Item 14*

		Normal	Abnormal	NA
A	HEENT			
B	NECK			
C	CARDIOVASCULAR			
D	PULMONARY			
E	LIVER			
F	KIDNEY			
G	SPLEEN			
H	OTHER ABDOMINAL			
I	MUSCULOSKELETAL			
J	GROSS NEUROLOGIC			
K	SKIN			
L	LYMPHATICS			
M	G.U.			

12. Was the neurological examination for soft signs conducted and coded on pages 3 and 4 of this form?

NO YES

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

PHYSICAL AND NEUROLOGICAL EXAMINATION FOR SOFT SIGNS

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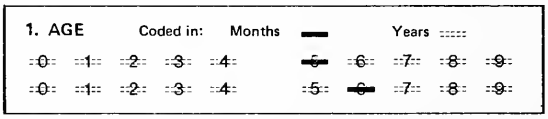
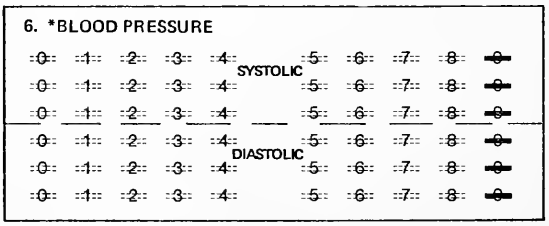
EXAMPLE: The child is 56 months old. Code as follows:



Mark a field of 9's if an item is unanswered or Not Ascertained.

EXAMPLE: Blood pressure was not taken; the rater codes as follows:



NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
BUDGET BUREAU NO. 68-R955

PHYSICAL AND NEUROLOGIC EXAMINATION FOR SOFT SIGNS

PATIENT INITIALS — FIRST INITIAL / SECOND INITIAL

FORM NUMBER

NUMBER MALES 001-499 FEMALES 500-998

PATIENT

RATER

PERIOD: Hours, Days, Weeks, Months

PLEASE USE A NO. 2 PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE.

1. AGE — Coded in Months / Years

2. *HEIGHT — Coded in. Inches / Centimeters

3. *WEIGHT — Coded in Lbs / Kg

4. *HEAD CIRCUMFERENCE — Inches / Cm

5. *PULSE — Code "Per minute"
Regular / Irregular

6. *BLOOD PRESSURE
SYSTOLIC
DIASTOLIC

7. *VISUAL ACUITY — Code numerator only
RIGHT
LEFT

8. *OPHTHALMOSCOPIC — Normal / Abnormal / NA

9. *AUDIOGRAM — Normal / Abnormal / NA

*HANDEDNESS — Right / Left / Mixed / NA

*Specify abnormalities under Item 14

11. PHYSICAL EXAMINATION — *Specify any abnormal findings under Item 14*

		Normal	Abnormal	NA
A	HEENT	0	1	9
B	NECK	0	1	9
C.	CARDIOVASCULAR	0	1	9
D	PULMONARY	0	1	9
E.	LIVER	0	1	9
F	KIDNEY	0	1	9
G.	SPLEEN	0	1	9
H	OTHER ABDOMINAL	0	1	9
I.	MUSCULOSKELETAL	0	1	9
J.	GROSS NEUROLOGIC	0	1	9
K.	SKIN	0	1	9
L.	LYMPHATICS	0	1	9
M.	G U.	0	1	9

12. Was the neurological examination for soft signs conducted and coded on pages 3 and 4 of this form?

NO 0 YES 1

PHYSICAL AND NEUROLOGIC EXAMINATION FOR SOFT SIGNS (PANESS)

BE SURE TO MARK IN PATIENT, RATER AND PERIOD NUMBERS ON THIS PAGE EXACTLY AS YOU DID ON PAGE 1

FORM NUMBER

NUMBER MALES 001-499 FEMALES 500-998

PATIENT

RATER

PERIOD

Hours Days Weeks Months

13 **PAST MEDICAL HISTORY** — Describe only CONTRIBUTORY illness, accidents, operations, etc

14. **ABNORMAL PHYSICAL FINDINGS** — Specify all abnormalities noted on physical and GROSS neurologic examination (Item 11) *(Soft signs are coded on page 3 and 4.)*

15. **DIAGNOSIS** — Specify all physical and neurological diagnoses here Please use ICD-8 classifications

DO NOT MARK OR WRITE IN THIS AREA

PHYSICAL AND NEUROLOGIC EXAMINATION FOR SOFT SIGNS (PANESS)

BE SURE TO MARK IN PATIENT, RATER AND PERIOD NUMBERS ON THIS PAGE EXACTLY AS YOU DID ON PAGE 1 →

FORM NUMBER

NUMBER MALES 001-499 FEMALES 500-998

PATIENT

RATER

PERIOD

Hours Days Weeks Months

USE THIS CODE FOR ITEMS 1-20 • SEE INSTRUCTIONS IN ASSESSMENT MANUAL FOR DETAILS

1 — Performed correctly
2 — Performed but not well
3 — Performed poorly or only after repeated instruction and demonstration
4 — Unsuccessful even after repeated demonstration
9 — Not done or not ascertained

1. Touch your finger to your nose
2. Touch your other finger to your nose
3. Close your eyes and touch your finger to your nose
4. Close your eyes and touch your other finger to your nose
5. Touch one heel to your other leg
6. Do the same with your other heel
7. Close your eyes and do it again
8. Now the other heel

Child writes name at the top of separate sheet of paper. Trace a "6" in each palm and identify it for the child. Figure is drawn in palm as child would see it. "Close your eyes and I will draw a mark on your hand. Now open your eyes and draw it on paper."

9. □ Right Hand
10. × Left Hand
11. O Right Hand
12. □ Left Hand
13. × Right Hand
14. 3 Left Hand
15. O Right Hand
16. 3 Left Hand

"Close your eyes and tell me what I'm putting in your hand."

17. Coin Right Hand
18. Ring Left Hand
19. Safety Pin Right Hand
20. Key Left Hand

SCORING: Count number of errors (more than 3 scored as three). An error is definite deviation from the line or steps incorrectly done

21. Walk the line to the end on your toes
22. Walk back on your heels
23. Hop on one foot to the end of the line
24. Now hop back on the other foot
25. Walk to the end this way (show tandem)
26. Now walk backwards the same way (6 steps)
27. FACE—HAND Brush face and/or hand gently with equal stroke (patient's eyes closed)
28. FACE—NOISE Brush face and/or click toy cricket ipsilateral ear (patient's eyes closed)
29. Two point discrimination. 1 cm. separation, dorsum of digiti minimi.

PERSISTENCE MEASUREMENTS — Period of uninterrupted success (stopwatch)

	SECONDS 20	15-19	10-14	0-9
30. Stick out your tongue until I tell you to stop				
31. Raise your arms out in front of you until I tell you to stop				
32. Close your eyes until I tell you to open them				
33. Stand on one foot until I tell you to stop				
34. Now stand on the other				

	SECONDS 20	15-19	10-14	0-9
35. Close your eyes and stand still until I tell you to stop				
Tendency to fall?		NO		YES
36. Now do it again like this (Demonstrate tandem)				
Tendency to fall?		NO		YES

PHYSICAL AND NEUROLOGIC EXAMINATION FOR SOFT SIGNS (PANESS)

BE SURE TO MARK IN PATIENT, RATER AND PERIOD NUMBERS ON THIS PAGE EXACTLY AS YOU DID ON PAGES 1, 2, 3 →

FORM NUMBER

NUMBER MALES 001-499 FEMALES 500-998

PATIENT

RATER

PERIOD

Hours Days Weeks Months

USE THIS CODE FOR THE QUALITY SECTION OF ITEMS 37 – 42 • SEE INSTRUCTIONS IN ASSESSMENT MANUAL FOR DETAILS

1 – Performed correctly
2 – Performed but not well
3 – Performed poorly or only after repeated instruction and demonstration
4 – Unsuccessful even after repeated demonstration
9 – Not done or not ascertained

SCORING: These are 5 second tests. Always demonstrate with a 4/second beat. Three scores are recorded for each test.

TEST		NUMBER OF TAPS (20 / 15-19 / 10-14 / 0-9)	NUMBER OF MOVEMENTS (If greater than 4, mark 4)	QUALITY
37 Tap this fast with your finger	Left			
38	Right			
39 Tap this fast with your foot	Left			
40	Right			
41 Tap with your finger and foot	Left			
42	Right			

43 **STRING TEST**

Mark the number of times child successfully followed the five motions

To the left

To the right

NYSTAGMUS: Not Present / Right / Left

44 **GLOBAL IMPROVEMENT** Rate degree of improvement since admission to the study

	Much Improved	Minimally Improved	No Change	Minimally Worse	Much Worse	Not Assessed
(At initial rating, mark "Not Assessed")	1	2	3	4	5	9

45. **The conditions of the examination were:** Satisfactory 1 Unsatisfactory 2

The Physical and Neurological Examination for Soft Signs (PANESS) is a multipage form which is independently formatted and does not require the use of a General Scoring Sheet. The first 2 pages contain the section relating to the physical examination; while the last 2 pages contain the scored neurological examination for soft signs. Investigators may employ one or both sections of PANESS in their studies. The content of the physical examination section - though new to the ECDEU battery - should be very familiar to physicians. The neurological section, on the other hand, attempts to "quantify" a number of standard clinical procedures and may require additional training. The physical examination section has been developed within the ECDEU program; while the neurological section has been developed by Abbott Laboratories and Dr. Close.

APPLICABILITY	Children to Age 15
UTILIZATION	Once at pretreatment; at least one post-treatment assessment. Additional ratings are at the discretion of the investigator.
TIME SPAN RATED	Present status

CARD FORMAT - ITEMS

CARD 01 = (19x, I3, 2I4, I3, I4, 4I3, I7I1)

Item	Column	Item	Column
Age	20 - 22	Neck	54
Height	23 - 26	Cardiovascular	55
Weight	27 - 30	Pulmonary	56
Circumference	31 - 33	Liver	57
Pulse	34 - 37	Kidney	58
Systolic BP	38 - 40	Spleen	59
Diastolic BP	41 - 43	Other Abdom.	60
Visual acuity-R	44 - 46	Musculoskeletal	61
Visual acuity-L	47 - 49	Gross Neur.	62
Opthal	50	Skin	63
Audiogram	51	Lymphatic	64
Handedness	52	GU	65
HEENT	53	Neuro. Exam	66

CARD 02 - Open-ended. Dependent upon number of "write-ins" under Items 13, 14 and 15. Using 3-digit ICD-8 codes, "write-ins" will be encoded by the Biometric Laboratory as follows:

13.	Past Medical History	Columns 20 - 31
14.	Abnormal Findings	Columns 32 - 43
15.	Diagnoses	Columns 44 - 55

CARD 03 = (19x, 3811)

Item	Column	Item	Column	Item	Column
1	20	13	32	24	43
2	21	14	33	25	44
3	22	15	34	26	45
4	23	16	35	27	46
5	24	17	36	28	47
6	25	18	37	29	48
7	26	19	38	30	49
8	27	20	39	31	50
9	28	21	40	32	51
10	29	22	41	33	52
11	30	23	42	34	53
12	31			35 (Sec)	54
				35 (Fall)	55
				36 (Sec)	56
				36 (Fall)	57

CARD 04 = (19x, 613, 212, 211)

Item	Column	Item	Column
37 (Tap)	20	43 Left String	38 - 39
37 (Move)	21	43 Right String	40 - 41
37 (Qual)	22	44 Glob.Imp.	42
38	23 - 25	45 Exam	43
39	26 - 28		
40	29 - 31		
41	32 - 34		
42	35 - 37		

CARD FORMAT - CLUSTERS

CARD 51 = (19x, 1512, 13)

Code "5" in Column 18 indicates card with factor, cluster or other derived score

Cluster	Column	Cluster	Column
1	20 - 21	9	36 - 37
2	22 - 23	10	38 - 39
3	24 - 25	11	40 - 41
4	26 - 27	12	42 - 43
5	28 - 29	13	44 - 45
6	30 - 31	14	46 - 47
7	32 - 33	15	48 - 49
8	34 - 35	Total Score	50 - 52

CLUSTER COMPOSITION

CLUSTER	ITEMS	CLUSTER SCORE RANGE
1 - Synergy	1-8	8 - 32
2 - Graphesthesia (Right)	9,11,13,15	4 - 16
3 - Graphesthesia (Left)	10,12,14,16	4 - 16
4 - Graphesthesia (Both	9 - 16	8 - 32
5 - Stereognosis (Right)	17,19	2 - 8
6 - Stereognosis (Left)	18,20	2 - 8
7 - Stereognosis (Both	17 - 20	4 - 16
8 - Gait	21 - 26	0 - 18
9 - Topognosis	27 - 29	0 - 9
10 - Persistence	30 - 36	7 - 30*
11 - Rapid Movements (Left)	37,39,41	9 - 36
12 - Rapid Movements (Right)	38,40,42	9 - 36
13 - Rapid Movements (Both)	37 - 42	18 - 72
14 - String (Left)	43a	2 - 5**
15 - String (Right)	43b	2 - 5**
Total Score	All	

*Score = Sum of Items 30 - 36 + 35b + 36b
**Score = No. of Movements + (Absence (1) or Presence (2,3) of Nystagmus)

SPECIAL INSTRUCTIONS

Identification block (ID) - Patient, rater and period numbers MUST be encoded on ALL pages used. Form and Page Numbers are precoded and no marks are required - indeed none are permitted - in these shaded areas.

Multipage forms - The pink sheets inserted after the carbons of pages 2, 3 and 4 prevent marks from passing through to the sheets below. Each pink sheet must be removed before you complete the page before it; e.g., remove the pink sheet between white page 2 and yellow page 2 BEFORE filling in page 2. Exercise care in tearing out pink sheets so as not to mutilate white sheets.

Physical Examination - This section of PANESS comprises pages 1 and 2. It may be used independently or in conjunction with the neurological examination for soft signs. All items should be "filled in" - whether or not all items (examinations), were conducted. For those examinations not done, code a field of "9"s". (See example on face sheet of PANESS).

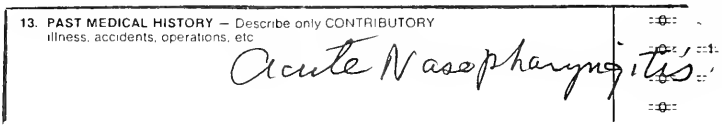
NOTE - Although the physical examination section was designed specifically for children, the items - with the exception of Item 4, perhaps, are applicable for all populations. Investigators with adult populations may use this section of PANESS to submit medical data for BLIPS processing.

Item 12 - This item MUST BE COMPLETED. It is a necessary signal - the absence of which will produce "severe perseveritis" in the computer; i.e., the computer will search endlessly for further data.

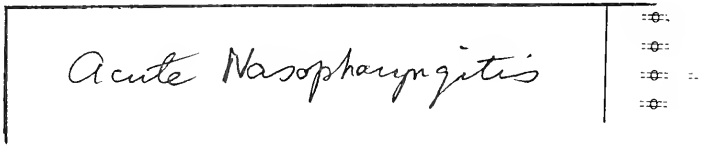
Page 2 - ONLY the left side of this page is for "write-ins"; the right side for encoding of "write-ins".

EXAMPLE

INCORRECT



CORRECT



Page 2 should always contain written entries if any abnormalities are cited on page 1. If the physical examination is completely "normal" and there are no "write-ins" to enter, page 2 may be omitted. The omission of page 2 under these circumstances may occur whether or not the neurological examination (pages 3 and 4) is completed.

Items 13, 14 and 15 - Write-ins must be legible. Use ICD-8 terminology whenever possible to describe illness. The ICD-8 List of Major Disease Categories is given in the Diagnostic and Statistical Manual of Mental Disorders, American Psychiatric Association, 1968, 3rd Edition. Raters may write in the appropriate 3-digit codes in lieu of the written words.

Pages 3 and 4 - Neurological Examination for Soft Signs - EXAMINERS MUST BE THOROUGHLY FAMILIAR WITH THE PROCEDURES FOR CONDUCTING THIS EXAMINATION GIVEN IN THE SECTION "SCORED NEUROLOGICAL EXAMINATION". DO NOT ALTER OR MODIFY THE MANNER IN WHICH THE TESTS ARE TO BE GIVEN.

Item 17 - The child need not name the correct denomination of the coin - merely recognize it as a coin.

Item 18 - The response "circle" is acceptable for "ring".

Items 27 and 28 - These tests are performed only ipsilaterally.

Items 30 and 34 - The scale points for these items are in time intervals rather than quality of performance. No second chances are given with these items.

Item 32 - Use clinical judgment as to whether eyes are closed tightly.

Items 35 - 36 - These 2 items require judgments on the subject's tendency to fall in addition to recording time intervals. No second chances are given with these items.

Items 37 - 42 - Each of these items requires 3 judgments: number of taps, number of adventitious movements and quality of performance.

Example - Subject taps 12 times; makes 2 adventitious movements and the quality is judged as poor. Code as follows:

SCORING: These are 5 second tests Always demonstrate with a 4/second beat Three scores are recorded for each test

TEST	NUMBER OF TAPS (20 / 15-19 / 10-14 / 0-9)	NUMBER OF MOVEMENTS (If greater than 4, mark 4)	QUALITY
37 Tap this fast with your finger Left	1 / 2 / **3** / 4 / 5	1 / **2** / 3 / 4 / 5	1 / 2 / **3** / 4 / 5

Item 39 - Do not downgrade scores if amplitudes are increasing.

Item 43 - This 2-part item (left and right) requires 2 judgments: one for quality of performance and one for presence and direction of nystagmus.

Example - Subject is able to follow the target to the left 2 out of 5 times and exhibits nystagmus with a fast component to the right. Code as follows:

43 STRING TEST Mark the number of times child successfully followed the five motions		NYSTAGMUS 1 Not Present / **2** Right / 3 Left / 9
	To the left 1 / **2** / 3 / 4 / 5	

DOCUMENTATION

a. Raw score printout
b. Cluster score printout
c. Frequency tables
d. Means and standard deviations of cluster scores
e. Variance analyses

MANUAL FOR THE NEUROLOGICAL EXAMINATION FOR SOFT SIGNS

Abbott Laboratories and John H. Close, M.D.

I. Introduction

This scored neurological examination is designed to assist the observer in determining whether neurological soft signs are present in a child. Because this is not a test of learning, it is important that the patient fully understand what is expected of him. The examiner (who need not necessarily be a physician) should demonstrate every task to be performed while giving the verbal instructions in the test description. Prefacing instructions should be used in an identical manner from one child to the next, utilizing a set routine of presentation. The time usually required to perform this test is 15 to 20 minutes.

At the beginning of testing, the child's attention should be obtained by making the statement, "Pay attention and watch what I do because you will have to do it after me." Since many items require stopwatch timing, the caution must be given, "Don't start until I say NOW, Okay?" immediately after the description and demonstration of each task. Proper instruction and clear demonstration are important contributors to the effectiveness of this scored examination.

A positive atmosphere should be maintained throughout the examination, accompanied by verbal praise and reinforcement. Incentive, such as the promise of a choice of a toy upon completion of testing from a box of inexpensive toys, may also be used.

II. Materials and Equipment

The room used for the test should be adequately lit, have a minimum noise level and be as free as possible for extraneous materials. One wall should be darkened by a black felt cloth or blackboard to provide a black background for the test of opticokinesia. Other needed items include the examiner's chair (facing away from the dark wall), a chair for the patient which faces a table or desk, and a convenient drawer for examining materials. Adhesive tape, 1 1/2 inches in width should be used to make a six-foot long, straight line on the floor, away from any nearby obstructions.

The following materials are needed:

a. A standard-lined 8 1/2 inch by 11 inch writing tablet. On the cardboard back, clearly ink geometrically attractive figures of a square, a six, a circle, a three, and an X, approximately one inch high.

b. Three or four sharp, soft lead pencils.

c. A ball point pen.

d. A toy cricket or other hand-held device for making clicking noises.

e. A stop watch (expensive models are unnecessary).

f. A two-point discriminator with one-centimeter separation.

g. A ring (simple wedding band type).

h. A car key.

i. A coin (nickel).

j. A standard two-inch safety pin.

k. Box of small, cheap toys.

III. Administration and Scoring

Rapport should be established by a few minutes of conversation. Acclimatization to test circumstances may then be phased in by one or two simple unscored tasks, such as, "Can you show me your right foot? Good! Now point to your left ear." (Gentle correction is used with an incorrect gesture, and then the gesture repeated). Above all, a completely encouraging, nonpunitive atmosphere is required. In all the directions that follow, quotation marks indicate verbal instructions; parentheses enclose a physical description of the demonstration. Right or left handedness should be recorded before the test begins. (Item 10, PANESS - Page 1).

NOTE - WHEN THE CHILD SIMPLY DOES NOT DO A TEST, MARK "9" = NOT ASCERTAINED.

A. Tests 1 - 20

1. Finger to Nose

"I want you to touch a finger to your nose. Begin with your arm out here." (Extend the arm laterally with the hand in a loose fist, index finger extended as pointer.)

"Now do like this." (Make a wide sweep medially to touch the nose.)

Score: 1 - Smoothly and accurately performed.
2 - Slowly, jerkily, and missing the target, then correcting. (If 10 seconds pass with no attempt, instruct and demonstrate again.)
3 - Same as 2; but done only after encouragement or a repeat instruction and demonstration.
4 - Same as 3: but without correcting target error.

2. Contralateral Finger to Nose

"Now do the other hand." (Demonstrate again.)

Score as in Test No. 1

3. Finger to Nose, Eyes Closed

"Now close your eyes and do that again." (No demonstration necessary.)

Score as in Test No. 1

4. Contralateral Finger to Nose, with Eyes Closed

"Close your eyes again and do it with the other hand." (No demonstration necessary.)

Score as in Test No. 1.

5. Heel to Shin

"Touch your heel against the front of your other leg, up high like this." (Demonstrate the heel touching just beneath the patella.)

Score as in Test No. 1. Either foot may be used acceptably.

6. Contralateral Heel to Shin

"Now do it with the other heel." (Demonstrate again.)

Score as in Test No. 1

7. Heel to Shin, Eyes Closed

"Now close your eyes and do that last one again." (No demonstration necessary.)

Score as in Test No. 1

8. Contralateral Heel to Shin, Eyes Closed

"Now close your eyes and try it with the other heel." (No demonstration necessary.)

Score as in Test No. 1

For questions 9 - 16, the child is told to turn to the table, where a sheet of paper is taken from the pad and placed in front of the child and the date written in the upper right-hand margin. Tape or thumbtacks may be

used to fix the page in front of the child securely. The child is then given a pencil and told to write or print his name at the upper left. No matter how poorly this is performed, the child should be told that it is well done.

For drawing on the child's hand, one should try to imagine a frame that consists of a line bordering one-half inch within the proximal, distal, and lateral margins of the hand. All numbers and figures should be drawn in the palm in the same aspect that the child would look at it when reading. All figures should be drawn with the nonwriting end of the ball point pen. On all graphesthesia and stereognostic samples, the child should be told, "Now turn your face up toward the ceiling and close your eyes." One must be certain that the demonstration cannot be visualized. Having been told this, take the palm of the child's hand in your hand and slowly (about three seconds) and smoothly draw a number or figure, the base of which should be at the thenar and hypothenar portions of the palm. The child should then be told, "Open your eyes and draw the figure on the paper." Practice one or more times with each hand until the child understands the procedure. The actual examinations are then initiated.

The child is told, "Draw on the paper each of the things I draw in your hands while your eyes are closed. I may draw another number, or I may draw figures, like a circle or square."

9. - 16. Graphesthesia

"Now turn your face up and close your eyes while I draw. There. Now open your eyes and see if you can draw it."

These verbal instructions are used prior to each of the tasks listed to the right.

9. Draw a square - right hand
10. Draw an x - left hand
11. Draw a circle - right hand
12. Draw a square - left hand
13. Draw an x - right hand
14. Draw a 3 - left hand
15. Draw a circle - right hand
16. Draw a 3 - left hand

If the child is unsuccessful after the first tracing, make the remark, "That's fine, close your eyes and let me do it again." If after the second time the child is still unable to draw the figure, raise the pad off the table so that the figures drawn on the back are visible. "Can you pick out the one I drew? Fine, draw it." The child is allowed to draw the figure while still visualizing the example on the back of the pad.

Scoring: "1" is marked if the child does the figure correctly after the first trial.

"2" is marked if the child does it successfully after the second example.

"3" is marked if the child picks it from those drawn on the pad.

"4" is marked if the child is still unsuccessful after two examples and the visualization of the figure on the pad.

Questions 17-20 involve stereognosis. Different objects are placed in the hands without bilateral repetition of the same object. The method of testing and of scoring here is similar to that in the preceding description. The child's face should be directed toward the ceiling with eyes closed at all times when the objects might be in sight. The box of objects is kept beneath the table out of sight. Each object is placed in the child's hand in the order described on the examination form for a period of approximately five seconds, and then the child is told, "Now give it back. Without looking, tell me what it is." If at that point the child is unable to identify the object, it is replaced in the hand with the remark, "Feel it and think what it could be." After five seconds, it is removed and replaced in the box with the other objects. If the child is still unable to identify it, the box is brought into sight with the question, "Can you pick it out of here?"

Scoring: "1" is marked if the child names the object successfully on the first trial.

"2" is marked if the child names the object after the second placement in the hand.

"3" is marked if the child is successful only after seeing the object.

"4" is marked if the child is unable to pick the object out of the box.

B. Questions 21 - 29

Here, the straight line taped on the floor is used for testing. As long as the patient's foot is touching the tape in any way, it is not considered a miss.

21. Walking Tiptoe

"Walk this line to the end up on your toes." (Demonstrate while up on the balls of the feet; arms hanging naturally, carefully walk the line.)

"Be sure you stay on the line."

The examiner should wait at the end of the line. This serves two purposes; first, he remains close to the child to protect against falling; and secondly, he will be positioned for the next demonstration, the return trip. An error count is made for each time the child misses the line or puts a foot down flatfooted. This actual count, 0, 1, 2, or 3, is scored. If a greater number of misses occurs, score as "3".

22. Heel Walking

"Now go back on your heels like this." (Arms at side, walk on heels on the line.)

Score: The same method as in Test No. 21 is used.

23. Hopping on One Foot

"Can you hop all the way without missing the line? Be sure not to put the other foot down." (Demonstrate a hop on the line.)

The examiner should again remain at the end of the line.

Scoring: An error occurs if the child misses the line or if the elevated foot is allowed to touch the floor.

24. Hopping on the Other Foot

"Now hop back on the other foot." (Demonstrate accordingly.)

Score as in Test No. 23

25. Tandem Walking Forward

"Now be sure you put your heel against your toe and walk to the end staying on the line." (Demonstrate heel-toe walking on line and remain at the end.)

Score: An error consists of not placing the heel to toe or missing the line completely.

26. Tandem Walking Backward

"Now do the same thing backwards." (Demonstrate accordingly.)

Score as in Test No. 25

In test Nos. 27, 28, and 29 the child is seated at the side of the table with hands on knees. Three (3) clear examples are given in each case before actual counting begins. The examples should always be given exactly the same way. The test should be performed on the dominant side; in a right-handed child the right cheek and right hand should be employed. Again, the child's face is directed upward with the eyes tightly closed.

27. Face-Hand Test

"I am going to brush your hand and face at the same time." (With a light fluff of cotton in each hand, the dorsum of the hand and the cheek beneath the malar eminence should be brushed simultaneously and softly with as nearly equal pressure as is possible.)

27. Face-Hand Test (Continued)

"Did you feel it?"

"Now I'm going to brush only your face." (This is then performed.)

"Did you feel it?"

On the third example, the hand only is brushed, and again with the forewarning:

"Now I'm going to brush only your hand." (This is then performed.)

Begin actual test -

"Now I'm going to do this some more and I want you to tell me what I do each time." (First, hand only; Second, face only; Third, face-hand combination; each time asking the child: "There, what did I do?")

Scoring: If the child misses none of these, "0" is marked; if he misses one, "1" is marked; and so on, up to a total of missing all three.

28. Face-Noise Test

This test is similar, except that the face is brushed at the same time a cricket toy is clicked in the ipsilateral ear. Again, three variations are performed as examples. First, the cricket only is clicked; second, the cricket is clicked and the face is brushed; third, the cricket is clicked without brushing the face. Note that the cricket is clicked in every example.

Begin actual test --

(First, the cricket is clicked and face simultaneously brushed; "Can you tell me what I did?"

Second, the cricket is clicked without brushing; "Can you tell me what I did?"

Third, the cricket is clicked and face brushed again.) "Can you tell me what I did?"

Scoring: As in the case of Test No. 27, the number of errors is counted; if the child misses none of the trials, "0" is marked; if 1 of the examples is missed, "1" is marked; if two are missed, "2" is marked; and if all three are missed, "3" is marked.

29. Two-Point Discrimination

Again, three examples are given utilizing the one-centimeter separation, two-point discriminator on the dorsum of the digiti minimi.

"You see, I have only touched you with one point." (Only one point is touched.)

"I used two points on you that time, could you tell it?" (Both points are used.)

"Now only one point again." (One point only is again used.)

Begin actual test --

"What did I do that time?" (Using two points.)

"What did I do that time?" (Using one point.)

"What did I do that time?" (Using two points.)

Scoring: Same as in Tests 27 and 28, appropriate number is marked for 0 through 3 errors.

C. Questions 30 - 36

These tests require the use of a stopwatch and accurate timing of the child's performance. It is necessary that the child know clearly when the test starts, and that he is told to keep doing the task until the examiner tells him to stop. For scoring purposes, if the child persists in the task for 20 seconds or more "1" is marked; 15 to 19 seconds, "2" is marked; 10 to 14 seconds, "3" is marked; and 0 to 9 seconds, "4" is marked. At the outset of these tests the child is told, "Now I am going to tell you some things to do; be sure that you don't start doing each one of them until I say 'begin'. Do you understand? Also, be sure you continue doing them until I tell you to stop."

30. Tongue Extrusion

"Watch me now." (The examiner should stick out his tongue for a period of three to four seconds.)

"Did you see that I did? All right, now when I tell you to start do it a long time until I tell you to stop. Ready - begin!"

31. Arms Extended

"Hold your arms in front of you like this until I tell you to stop."

(The arms should be extended directly in front of the examiner, palms down.)

"Could you see how I did that? Are you ready to start? All right - begin!"

Presence of drift does not alter the timed nature of scoring in this task.

32. Eyes Closed

"Watch how tightly I can close my eyes.

Now you do it when I tell you to. Ready - begin!"

(Close the eyes very tightly.)

33. Stand on One Foot

"Now I'm going to stand on one foot without moving it."

"It doesn't matter which foot you stand on. Did you see how I did that? Are you ready? Begin!"

(Stand up on either foot with the arms hanging naturally down at the sides.)

34. Stand on the Other Foot

"Now do the same thing when I tell you to start, standing on the other foot. Are you ready? Begin!"

(No demonstration necessary.)

35. Romberg

"Now stand up like this on both feet but keep your eyes closed."

"Are you ready to do that? All right, begin!"

(The examiner stands in front of the child on both feet, erectly, with his hands at his sides and his eyes tightly closed.)

36. Tandem Romberg

"Now put one heel against the other toe and stand with your eyes closed until I tell you to stop. Either foot may be in front."

(Demonstrate eyes closed, tandem stance, arms at sides.)

D. Questions 37 - 43

In these tests, the examiner should assure himself of exactly what constitutes a four-per-second beat. A general tendency is to make this beat faster than it should be. The examiner should appraise his own sense of rhythm by listening to a four-per-second example; either with a clock or, if available, a metronome. A typical alarm clock or wrist watch (but not a stopwatch) ticks at a four-per-second rate.

Each test is of five seconds duration. The child is seated at the table facing the dark background wall, and the examiner's demonstrations should be clear and perhaps exaggerated. The child should be allowed three or four seconds practice at Nos. 37, 39, 41, and 43. If a mistake is seen for which the child would be downgraded, such as a lack of smooth delivery, the child should be informed. He should also be told at the outset not to move the rest of his body, but rather just the part that is supposed to be moving.

Adventitious movement will be considered any movement unnecessary to the task at hand, whether it be a jerk, twitch, grimace, body contortion, sticking out of the tongue, etc. Contralateral rigidity is not considered adventitious. The starting point of each of these tasks for the purpose of timing should be a clear-cut signal.

37. Finger Tapping

"Now watch how I tap only my finger just this fast. Notice that I leave my other arm down at my side."

(Demonstrate sitting erectly with the tapping motion mainly comprised of finger action not hand motion.)

'You see that I am just moving my finger and not my hand and arm? Would you like to practice that quickly before we start?"

At this point, if the child is going too slowly he should be told, "Go a little faster", and allowed to practice again.

"That looks good. Are you ready now? All right, begin."

Scoring: The examiner is actually grading three things at once. A brief familiarization and practice is needed to accomplish this. The first type of scoring is the actual count of the number of taps performed in the five-second period. The child must be shown the proper rate of tapping at the beginning. The number of taps is scored in the proper position. Simultaneously, one is making mental note of adventitious movements. Their number represents a separate score and is indicated by a mark in the proper position.

"Quality" is also scored 1 through 4; the examiner marks the appropriate number based on his best judgment of performance. This evaluation is not meant to reflect absolutely correct rhythmicity, but rather the smoothness of delivery overall. Points should not be taken away if the child ends the task at a more rapid or more slow tapping rate than that with which he began, as long as he phases in and out of such changes smoothly. We downgrade the child for sporadicism, or for the appearance of "bursts" in his sequencing. If the child only makes one such change in rhythm, he will receive a score of 1 in the quality position; if he makes this error twice, he will receive a score of 2; three times, a score of 3; and a score of 4 could represent a completely arrhythmic performance.

38. Finger Tapping - Other Hand

"Now we are going to do it with the other hand; why don't you practice that for a moment?"

(No repeat demonstration necessary.)

"That's fine. Are you ready now? Begin."

Scoring as in Test No. 37

39. Foot Tapping

"Now watch how I sit and tap only my foot just this fast. Would you like to practice that for a moment?"

(Demonstrate accordingly. The heel remains on the floor. Assure that there is moderate extension at the knee or the resultant angle on the foot makes the task difficult.)

"That's fine. Are you ready now? Begin."

Scoring as in Test No. 37

40. Foot Tapping - Other Foot

"Now let's do it with the other foot; you may practice for a moment."

(No repeat demonstration necessary.)

Scoring as in Test No. 37

41. Finger and Foot Synchronization

"Now we are going to try the finger and the foot at the same time. You must tap them together at the same rate you have been tapping them separately. Watch how I do it."

(Examiner must be careful to synchronize finger and foot tapping through several repetitions at an adequately fast rate. Like sides are always paired; right hand with right foot; left hand with left foot.)

"Do you want to practice that now?"

"That's fine, do you think you are ready to start? All right. Begin."

Scoring: The scoring of tap count and adventitious movement count is the same here as in previous examples. However, the "Quality" score now reflects the actual number of times the child deviates from synchronized tapping. A complication of this scoring immediately becomes obvious; that is, if the child is unsynchronized from the start. In such a circumstance one must grade quality according to the amount of time during the test asynchrony is apparent. A quality score of 1 is well synchronized, hand and foot, through the entire study. If the child is not well-synchronized for some portion of the test, divide total test time into thirds. If the child's tapping is not synchronized for one-third of the time, a quality score of 2 is recorded; if two-thirds of the time asynchrony is demonstrated, a score of 3 is received; and a quality score of 4 is recorded for gross asynchrony throughout.

42. Synchronous Finger and Foot Tapping - the Opposite Side

"Now I want you to tap your foot and finger on the other side together. Do you want to practice that? All right, begin."

(No repeat demonstration necessary.)

Scoring as in Test No. 41.

43. String Test

This is an opticokinetic test performed with a rapid and a slow component. An object on the examiner's hand should serve as a target on which the child may fix his gaze; a ring on a finger or a piece of chalk between fingers is adequate. The motion is made against the dark background, and through a distance of about two feet. The test hand is moved away from the body rather quickly, then brought back to the examiner's side more slowly. It is performed approximately two feet from the child with first the right and then the left hand. The examiner should step to the right or left far enough so that the demonstrating hand will be directly in front of the child's face. The child's head must remain still, following only with the eyes.

"Now I'm going to pretend that I am pulling on a piece of string several times that is hooked to my belt. I want you to follow my hand with your eyes everywhere it moves. But you can't move your head. It may help you if you watch this ring on my finger."

(The hand is moved away from the body in a quick motion and then more slowly brought back medially. This is done five consecutive times rhythmically.)

"Now I'm going to do it on the other side."

It is permissible for the examiner to place a hand on the child's head, if it would help to stabilize him. The number of times the patient successfully follows the target movement out of the possible five is scored. If nystagmus is present, the direction of the fast component should be noted.

THE PSYCHOLOGIST PACKET

The Psychologist Packet consists of a series of formats upon which data from psychological tests may be transcribed. Unlike the other packets, the Psychologist Packet does not contain the actual scales - merely locations where scores may be encoded. There are two sets of scales - one for children and one for adults. Wherever possible, scales were selected which had applicability to both populations. Two measures of test behavior per se have also been included. The inventory of scales is:

CHILDREN	ADULTS
Wechsler Intelligence Scale for Children	Wechsler Adult Intelligence Scale
Porteus Mazes	Porteus Mazes
Wide Range Achievement Test	
Goodenough-Harris Draw-a-Man Test	
Bender Gestalt Test - Koppitz Scoring	Bender Gestalt - Pascal-Suttell Scoring
	Wechsler Memory Scale
Psychological Examination Behavior Profile	Friedhoff Task Behavior Scale

All of the scales in each set are formatted to fit on one General Scoring Sheet. Matrices for the Children's and Adult Psychometric Scales are given in Figures 24 and 25. It is essential that the rater ALWAYS USE THE ASSIGNED SHEET NUMBER for the packet - Sheet Number 15 for both the Children's and the Adult sections. Remember that PERIOD number changes; but Sheet Number remains constant regardless of the time of assessment.

Should an investigator wish to encode other psychometric or psychological information, he must follow the procedures outlined for the encoding of non-standard data. (pp 59-64). Modifications of any of the standard scales are considered "non standard instruments"; e.g., the Canter scoring of the Bender Gestalt.

While entitled "Psychologist Packet", psychometrists or other individuals with appropriate testing experience may administer the scales. Supervision by a professional psychologist is suggested when non-professional test administrators are employed.

PSYCHOMETRIC SCALES - CHILDREN

MH-9-50
9-75

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB NO. 68-R965

ECDEU GENERAL SCORING SHEET (50-GSS)

PATIENT INITIALS: FIRST INITIAL / SECOND INITIAL

SHEET NO.

NUMBER MALES 001 TO 499 — NUMBER FEMALES 500 TO 998

PATIENT / RATER / PERIOD (Hours, Days, Weeks, Months)

FIGURE 24
MATRICES FOR CHILDREN'S PSYCHOMETRIC SCALES

Row	Cols 1–10	Row	Cols 11–20
1	Maze Quotient (MAZE)	1	Information (WISC)
4	Quantitative Score (MAZE)	3	Comprehension
7	Standard Score (GOOD)	5	Arithmetic
10	Quality Score (GOOD)	7	Similarities
12	Fig A (BENDK)	9	Vocabulary
13	Fig 1	11	Digit Span
14	Fig 2	13	Picture Comple.
15	Fig 3	15	Picture Arrange
16	Fig 4	17	Block Design
17	Fig 5	19	Object Assembly
18	Fig 6	21	Coding
19	Fig 7	23	Verbal IQ
20	Fig 8	26	Performance IQ
21	Total Score	29	Full IQ
23	Separation (1) (PEBP)	32	Reading (1) (WRAT)
24	Fearfulness (2)	35	Spelling (2)
25	Rapport (3)	38	Arithmetic (3)
26	Confidence (4)		
27	Reactivity (5)		
28	Cooperation (6)		
29	Frustration (7)		
30	Dependency (8)		
31	Attention Span (9)		
32	Goal (10)		
33	Activ. Level (11)		
34	Nat. Activ. (12)		
35	Communication (13)		
36	Assertiveness (14)		
37	Hostility (15)		

MAZE — GOOD — BENDK — PEBP — WISC — WRAT

Cols: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20

MH-9-50
9-75

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
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FORM APPROVED
OMB NO. 68-R965

ECDEU GENERAL SCORING SHEET (50-GSS)

PATIENT INITIALS — FIRST INITIAL — SECOND INITIAL — SHEET NO.

NUMBER MALES 001 TO 499 — NUMBER FEMALES 500 TO 998 — PATIENT — RATER — PERIOD (Hours, Days, Weeks, Months)

FIGURE 25
MATRICES FOR
ADULT PSYCHOMETRIC
SCALES

Row	MAZE	BENDPS	WMEM	WAIS
1	Maze Quotient			Information
2				
3				Comprehension
4	Quantitative Score			
5				Arithmetic
6				
7		Fig 1		Similarities
8				
9		Fig 2		Vocabulary
10				
11		Fig 3		Digit Span
12				
13		Fig 4		Picture Completion
14				
15		Fig 5		Picture Arrangement
16				
17		Fig 6		Block Design
18				
19		Fig 7		Object Assembly
20				
21		Fig 8		Digit Symbol
22				
23	Configuration Score			Verbal IQ
24				
25	Total Score			
26				Performance IQ
27				
28	Information			
29	Orientation			Full IQ
30	Control			
31	Logical Memory			
32				Cooperation (1)
33	Digits Forward			Grasp (2)
34	Digits Backward			Annoyance (3)
35	Reproduction			Withdrawn (4) ← FTBS
36				Agitation (5)
37	Learning			Apprehensive (6)
38				Attention (7)
39	Memory Quotient			Relation (8)
40				
41				

Cols: 1 2 3 4 5 6 7 8 9 10 — 411 — 1 12 13 14 15 16 17 18 19 20

MH-9 Series
10-73

PSYCHOMETRIC SCALES

CHILDREN

Code 15 for Sheet Number when encoding any or all of the standard Children's Psychometric Scales.

The texts for all children's scales are printed on *PINK* templates.

MH-9–60	(WISC)	Wechsler Intelligence Scale for Children
62	(WRAT)	Wide Range Achievement Test
61	(MAZE)	Porteus Mazes
63	(GOOD)	Goodenough-Harris Drawing Test
64	(BENDK)	Bender Gestalt Test – Koppitz Scoring
66	(PEBP)	Psychological Examination Behavior Profile

Mark on right half of scoring sheet on row specified (Cols. 11–20)

WECHSLER INTELLIGENCE SCALE FOR CHILDREN

(60-WISC) *(Code 15 for Sheet Number)*

INSTRUCTIONS: Code scaled scores, NOT raw scores, in 2 digits; code IQ's in 3 digits. When using "short forms" or abbreviated versions of WISC, be sure to encode subtests and IQ's on the proper rows. Leave blank all unused rows.

	ROW NO.
Information	1-2
Comprehension	3-4
Arithmetic	5-6
Similarities	7-8
Vocabulary	9-10
Digit Span	11-12
Picture Completion . . .	13-14
Picture Arrangement . .	15-16
Block Design	17-18
Object Assembly	19-20
Coding or Mazes	21-22
Verbal IQ	23-25
Performance IQ	26-28
Full IQ	29-31

WIDE RANGE ACHIEVEMENT TEST

(62-WRAT) *(Code 15 for Sheet Number*

Code Standard Scores in 3 digits

	ROW NO.
Reading	32-34
Spelling	35-37
Arithmetic	38-40

Mark on left half of scoring sheet on rows specified

PORTEUS MAZES

(Code 15 for Sheet Number) (61-MAZE)

Code 3 digits for each of the two scores

ROW NO.	
1-3	. . . Maze Quotient
4-6	. . . Qualitative Score

GOODENOUGH-HARRIS DRAWING TEST

(Code 15 for Sheet Number) (63-GOOD)

Code 3 digits for Standard Score; 2 digits for Quality Scale

ROW NO.	
7-9	. . . Standard Score
10-11	. . . Quality Scale

BENDER GESTALT TEST – Koppitz Scoring

(Code 15 for Sheet Number) (64-BENDK)

For each figure, record the errors by encoding all appropriate numbers on the ROW designated. Encode "0" for no errors. Encode Total Score in 2 digits.

ROW NO.		
12	Figure A	0 = No errors 1 = Distortion of Shape 3 = Disproportion 5 = Rotation 7 = Integration
13	Figure 1	0 = No errors 1 = Circles for Dots 3 = Rotation 5 = Perseveration
14	Figure 2	0 = No errors 1 = Rotation 3 = Row added, omitted 5 = Perseveration
15	Figure 3	0 = No errors 1 = Circles for Dots 3 = Rotation 5 = Shape Lost 7 = Lines for Dots

ROW NO.	*Continue marking on left half of scoring sheet on row specified*	
	BENDER GESTALT TEST—Koppitz Scoring *(Continued)*	
16	Figure 4	0 = No errors 1 = Rotation 3 = Integration
17	Figure 5	0 = No errors 1 = Circles for Dots 3 = Rotation 5 = Shape Lost 7 = Line for Dots
18	Figure 6	0 = No errors 1 = Angles in Curves 3 = Straight Line 5 = Integration 7 = Perseveration
19	Figure 7	0 = No errors 1 = Disproportion 3 = Incorrect Angles 5 = Rotation 7 = Integration
20	Figure 8	0 = No errors 1 = Incorrect Angles 3 = Rotation
21-22	Total Bender Score	

ROW NO.	*Mark on left half of scoring sheet on row specified. (Cols. 1–5)*
	PSYCHOLOGICAL EXAMINATION BEHAVIOR PROFILE *(Code 15 for Sheet Number)* (66-PEBP)
	Adapted from the Collaborative Study on Cerebral Palsy, Mental Retardation and Other Neurological and Sensory Disorders of Infancy and Childhood, Perinatal Research Branch, National Institute of Neurological Diseases and Stroke, National Institutes of Health. INSTRUCTIONS: Rate each item on the basis of behavior observed or elicited during the psychological examination.
23	1. **SEPARATION FROM MOTHER** 0 = Shows no concern; eager to leave mother and go with examiner 1 = Shows very little concern 2 = May show some initial reticence, which is felt to be entirely appropriate 3 = More than usual amount of concern 4 = Very upset, cries, clings to mother
24	2. **FEARFULNESS** 0 = No apparent awareness of strange situation 1 = Very little fear evidenced 2 = Normal amount of caution in the situation 3 = Inhibited and uneasy throughout with some slowing of responses 4 = Very fearful and apprehensive
25	3. **RAPPORT WITH EXAMINER** 0 = Exceptionally shy; withdrawn 1 = Shy; waits for friendly gestures 2 = Perhaps some initial shyness; feels at ease 3 = Very friendly and at ease 4 = extreme friendliness
26	4. **SELF-CONFIDENCE** 0 = Lacks self-confidence; extremely self-critical 1 = Distrusts own ability 2 = Adequately self-confident 3 = More than usual amount of self-confidence 4 = Very self-confident

ROW NO.	*Continue marking on left half of scoring sheet on row specified*
	Psychological Examination Behavior Profile – *Continued*
27	**5. EMOTIONAL REACTIVITY** 0 = Extremely flat; no change in facial expression 1 = Somewhat flat; little change in emotional tone 2 = Normal responsiveness; affect appropriate to situation 3 = Mood more variable than average 4 = Extreme instability of emotional responses, marked emotional lability
28	**6. DEGREE OF COOPERATION** 0 = Extreme negativism 1 = Resistive to demands or directions a good deal of the time 2 = Cooperative with reasonable amount of discomfort and anxiety 3 = Accepts direction or demands more easily 4 = Extremely suggestible and conforming
29	**7. LEVEL OF FRUSTRATION TOLERANCE** 0 = Withdraws completely 1 = Occasionally withdraws from task where difficulty is encountered 2 = Attempts to cope with difficult situations 3 = Becomes quite upset by difficulty 4 = Extreme acting out behavior and/or crying
30	**8. DEGREE OF DEPENDENCY** 0 = Very self-reliant; refuses help 1 = Rarely needs reassurance 2 = Dependent in appropriate situations 3 = Demands more attention than average 4 = Constant need for attention or help
31	**9. DURATION OF ATTENTION SPAN** 0 = Attends to tasks very briefly 1 = Spends short time with tasks 2 = Spends adequate amount of time on tasks 3 = Spends more than average time on tasks 4 = Highly perseverative

ROW NO.	PEBP–*Continued* *Mark on left half of scoring sheet*
32	**10. GOAL ORIENTATION** 0 = No effort to reach a goal 1 = Briefly attempts to achieve goal 2 = Able to keep goal or direction in mind 3 = Keeps goal and questions in mind 4 = Compulsive absorption with task
33	**11. LEVEL OF ACTIVITY** 0 = Extreme inactivity and passivity; placid, sluggish 1 = Little activity; content to sit still most of the time 2 = Normal amount of activity 3 = Unusual amount of activity and restlessness 4 = Extreme overactivity and restlessness; can't sit still
34	**12. NATURE OF ACTIVITY** 0 = Extreme rigidity; unable to shift activity or approach to task 1 = Some rigidity 2 = Flexible behavioral patterns; activity appropriate to different situations 3 = Behavior frequently impulsive 4 = Extremely impulsive; explosive and uncontrolled behavior
35	**13. NATURE OF COMMUNICATION** 0 = Little or no verbal communication 1 = Verbal or non-verbal responses confined to answering directed questions 2 = Readily answers questions; may elaborate 3 = Answers questions freely 4 = Difficult to follow child's thinking
36	**14. ASSERTIVENESS** 0 = Extremely assertive, willful personality 1 = Quite forceful, unnecessarily rough and careless in handling materials 2 = Self-assertive but accepting of the situation and capable of control 3 = Passive acceptance; permits self to be somewhat controlled by examiner and situation 4 = Extreme passivity; malleability and acquiescence to everything
37	**15. HOSTILITY** 0 = Very hostile, obstructive 1 = Unusual amount of hostility present 2 = No unusual amount of hostility evidenced 3 = Very agreeable child who rarely shows hostility even where it might be 4 = Ingratiating child

WECHSLER INTELLIGENCE SCALE FOR CHILDREN (060-WISC)

The Wechsler Scales (WISC and WISC-R) are widely used standardized measures of intelligence, or, in Wechsler's words, "for assessing an individual's potential for purposive and useful behavior". The 1949 WISC was a logical outgrowth of the original Wechsler-Bellevue Scales. An extensive revision of the WISC - designated as the WISC-R - was published in 1974 and it is this version which is recommended for use. The WISC-R - like its predecessor - consists of 12 subtests - 10 of which are considered mandatory. Wechsler strongly urges the inclusion of Digit Span and Mazes in clinical situations because of the diagnostic information they add.

REFERENCES

1. Wechsler, D., Manual for the Wechsler Intelligence Scale for Children, Psychological Corporation, New York, 1949.

2. Wechsler, D., Wechsler Intelligence Scale for Children - Revised, Psychological Corporation, New York, 1974.

3. Wechsler, D., Wechsler Preschool and Primary Scale of Intelligence, Psychological Corporation, New York, 1967.

Manuals and materials for the WISC, WISC-R and WPPSI may be obtained from the publisher

APPLICABILITY WISC - 5 to 15 years. WISC-R - 6 to 16 years

UTILIZATION At the discretion of the investigator. May be used at the initial assessment only or as a change measure.

CARD FORMAT - ITEMS

CARD 01 = (19x, 1112, 313)

Item	Column	Item	Column
Information	20 - 21	Picture Arrangement	34 - 35
Comprehension	22 - 23	Block Design	36 - 37
Arithmetic	24 - 25	Object Assembly	38 - 39
Similarities	26 - 27	Coding or Mazes	40 - 41
Vocabulary	28 - 29	Verbal IQ	42 - 44
Digit Span	30 - 31	Performance IQ	45 - 47
Picture Completion	32 - 33	Full IQ	48 - 50

SPECIAL INSTRUCTIONS

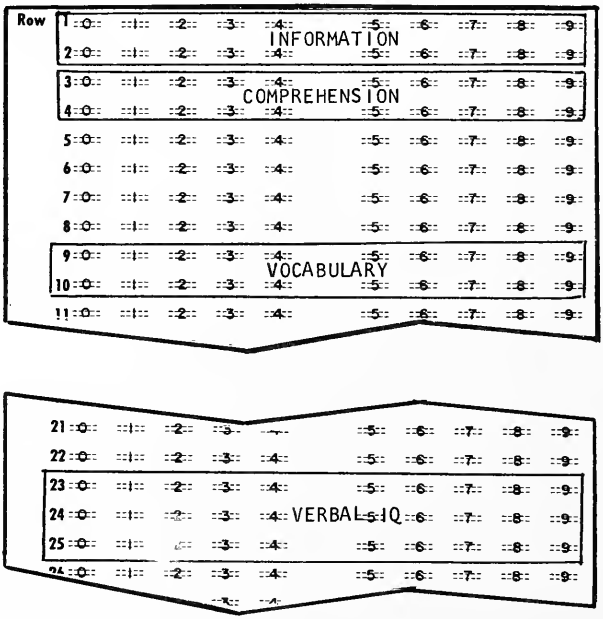
1. The instructions given in the WISC or WISC-R Manuals on the scoring of items should be followed by the test administrator. Be sure to encode SCALED SCORES, not raw scores. When using an abbreviated WISC encode each of the subtests used and the pro-rated IQ's in their appropriate data fields. When the WISC-R is employed the investigator should note the part by adding the letter R to 60-WISC on page 4 of the Data Shipment (071-DS); i.e., 60-WISC-R.

2. Abbreviated Versions - Many investigators employ "short" versions of the Wechsler scales; i.e., a selected number of subtests rather than the full set. These versions may be encoded according to the procedures for non-standard scales or may be encoded directly in the matrix for the full WISC as follows:

   1) Each subtest and/or prorated IQ must be encoded in its standard location.

   2) The investigator MUST make note of the fact on the Data Shipment form and give the composition of his abbreviated version.

   Example: The abbreviated WISC consists of Information, Comprehension, Vocabulary and a prorated Verbal IQ. Encode as follows:



3. NOTE - WECHSLER PRESCHOOL AND PRIMARY SCALE OF INTELLIGENCE - This scale may also be employed for the appropriate age group (4 - $6\frac{1}{2}$ years) and may be encoded in the same data field as the WISC or WISC-R. The investigator should note the fact that the WPSSI was used by crossing out "60-WISC" on page 4 of

the Data Shipment (071-DS) and inserting "WPPSI". The format for encoding scaled scores is:

Item	Column	Item	Column
Information	20 - 21	Animal House	34 - 35
Comprehension	22 - 23	Block Design	36 - 37
Arithmetic	24 - 25	Geometric Design	38 - 39
Similarities	26 - 27	Mazes	40 - 41
Vocabulary	28 - 29	Verbal IQ	42 - 44
Sentences	30 - 31	Performance IQ	45 - 47
Picture Completion	32 - 33	Full IQ	48 - 50

DOCUMENTATION

a. Scaled score printout
b. Means and standard deviations
c. Variance analyses - when appropriate

WIDE RANGE ACHIEVEMENT TEST (062-WRAT)

The Wide Range Achievement Test (WRAT) is a relatively brief test which assesses the level of skill in 3 areas - Reading, Spelling and Arithmetic. Its content is concerned primarily with the mastery of the mechanics of the basic subjects rather than their comprehension. As its name implies, it is applicable from kindergarten to college.

REFERENCES

1. Jastak, J. F., and Jastak, S. R., WRAT Manual, Guidance Associates, Wilmington, Delaware, 1965. Materials may be purchased from Psychological Corporation, 304 E. 45th Street, New York, New York. 10017

2. National Health Survey, School Achievement of Children 6 - 11 years as Measured by the Reading and Arithmetic Subtests of the Wide Range Achievement Test, PHS Publication No. 1000 - Series 11 - No. 103, U. S. Government Printing Office, Washington, D. C. June, 1970.

APPLICABILITY: 5 years old to adulthood

UTILIZATION: Once at pretreatment; at least one posttreatment assessment. Additional ratings are at the discretion of the investigator.

CARD FORMAT - ITEMS: CARD 01 = (19x, 3I3)

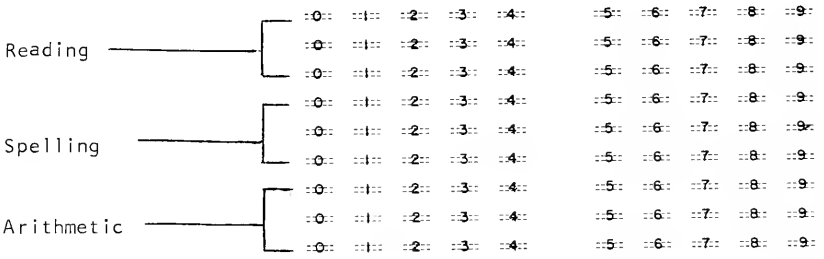
Item	Column
Reading	20 - 22
Spelling	23 - 25
Arithmetic	26 - 28

SPECIAL INSTRUCTIONS

1. Test administrators should follow the instructions given in the WRAT Manual.

2. Standard scores for the Reading and Arithmetic subtests should be obtained from Tables 31 and 32 rather than from Jastak's manual. These tables have been reproduced from the National Health Survey. (Reference 2 above) and are based on a much larger probability sample of 7100 children aged 6 to 11 years. Unfortunately, the Spelling subtest was not employed in the National Health Survey so the standard scores given in the Jastak manual should be used for this subtest.

USE OF WRAT FOR ADULTS - Investigators wishing to use the WRAT with adult populations must encode the scale as a non-standard instrument. (See instructions (p. 59). A 9 x 10 matrix (9 rows and 10 columns) is required and should be encoded as follows:



The standard scores given in the Jastak manual (Reference 1 above) should be encoded. Be sure to describe the matrix location and the Sheet Number in Item 11 of the Data Shipment (071-DS).

DOCUMENTATION

a. Standard score printout
b. Means and standard deviations
c. Variance analyses

PORTEUS MAZES (061-MAZE)

Introduced about 60 years ago, the Porteus Maze Test is a nonverbal test which has been used in a wide diversity of settings and has been shown to be sensitive to drug effects in both children and adults. There are 3 series of mazes - the Original series of 12, an Extension series of 8 and a Supplement series of 8. The latter two series have been developed to reduce practice effects when retesting subjects and the author considers them to be equivalent tests.

TABLE 31

Table for converting raw scores on the Reading subtest of the Wide Range Achievement Test to standard scores, for children, 6-11 years, by 6-month-age intervals: United States, 1963-65

Raw score	Age in months											
	72-77	78-83	84-89	90-95	96-101	102-107	108-113	114-119	120-125	126-131	132-137	138-143
	Standard score											
000	069	063	056	049	*	*	*	*	*	*	*	*
001	071	064	057	050	*	*	*	*	*	*	*	*
002	072	065	058	051	*	*	*	*	*	*	*	*
003	074	067	059	052	*	*	*	*	*	*	*	*
004	075	068	060	053	*	*	*	*	*	*	*	*
005	077	069	062	055	051	042	042	043	038	039	*	*
006	078	070	063	056	052	043	043	044	040	040	*	*
007	079	072	064	057	053	044	044	045	041	041	*	*
008	081	073	065	058	054	045	045	046	042	042	037	033
009	082	074	066	059	055	047	046	047	043	043	038	034
010	084	075	067	060	057	048	048	048	044	044	039	035
011	085	077	069	061	058	049	049	049	045	045	040	036
012	087	078	070	063	059	050	050	050	046	046	041	037
013	088	079	071	064	060	051	051	051	047	047	042	038
014	089	080	072	065	061	053	052	052	048	048	043	039
015	091	082	073	066	062	054	053	053	049	049	045	040
016	092	083	074	067	063	055	054	054	050	050	046	041
017	094	084	076	068	064	056	055	055	051	051	047	043
018	095	085	077	069	065	057	056	056	052	052	048	044
019	097	086	078	071	066	058	058	057	053	053	049	045
020	098	088	079	072	067	060	059	058	054	054	050	046
021	100	089	080	073	068	061	060	060	055	055	051	047
022	101	090	081	074	069	062	061	061	056	056	052	048
023	102	091	083	075	070	063	062	062	057	057	053	049
024	104	093	084	076	072	064	063	063	058	058	054	050
025	105	094	085	077	073	066	064	064	059	059	055	051
026	107	095	086	079	074	067	065	065	061	060	056	052
027	108	096	087	080	075	068	066	066	062	061	057	053
028	110	098	088	081	076	069	067	067	063	062	058	054
029	111	099	089	082	077	070	069	068	064	063	059	055
030	112	100	091	083	078	072	070	069	065	064	060	056
031	114	101	092	084	079	073	071	070	066	065	061	058
032	115	103	093	085	080	074	072	071	067	066	062	059
033	117	104	094	087	081	075	073	072	068	067	063	060
034	118	105	095	088	082	076	074	073	069	068	064	061
035	120	106	096	089	083	077	075	074	070	069	066	062
036	121	107	098	090	084	079	076	075	071	070	067	063
037	123	109	099	091	085	080	077	076	072	071	068	064
038	124	110	100	092	086	081	079	077	073	072	069	065
039	125	111	101	093	088	082	080	078	074	073	070	066
040	127	112	102	095	089	083	081	079	075	074	071	067
041	128	114	103	096	090	085	082	080	076	075	072	068
042	130	115	105	097	091	086	083	081	077	076	073	069
043	131	116	106	098	092	087	084	083	078	077	074	070
044	133	117	107	099	093	088	085	084	079	078	075	071
045	134	119	108	100	094	089	086	085	081	080	076	073
046	136	120	109	101	095	091	087	086	082	081	077	074
047	137	121	110	103	096	092	088	087	083	082	078	075
048	138	122	112	104	097	093	090	088	084	083	079	076
049	140	124	113	105	098	094	091	089	085	084	080	077
050	141	125	114	106	099	095	092	090	086	085	081	078

Table for converting raw scores on the Reading subtest of the Wide Range Achievement Test to standard scores, for children, 6-11 years, by 6-month-age intervals: United States, 1963-65—Con.

Raw score	Age in months											
	72-77	78-83	84-89	90-95	96-101	102-107	108-113	114-119	120-125	126-131	132-137	138-143
	Standard score											
051	143	126	115	107	101	096	093	091	087	086	082	079
052	144	127	116	108	102	098	094	092	088	087	083	080
053	146	128	117	109	103	099	095	093	089	088	084	081
054	147	130	119	111	104	100	096	094	090	089	085	082
055	148	131	120	112	105	101	097	095	091	090	086	083
056	150	132	121	113	106	102	098	096	092	091	088	084
057	151	133	122	114	107	104	099	097	093	092	089	085
058	153	135	123	115	108	105	101	098	094	093	090	086
059	154	136	124	116	109	106	102	099	095	094	091	088
060	156	137	126	117	110	107	103	100	096	095	092	089
061	157	138	127	119	111	108	104	101	097	096	093	090
062	159	140	128	120	112	110	105	102	098	097	094	091
063	160	141	129	121	113	111	106	103	099	098	095	092
064	161	142	130	122	114	112	107	104	100	099	096	093
065	163	143	131	123	116	113	108	106	102	100	097	094
066	164	145	133	124	117	114	109	107	103	101	098	095
067	166	146	134	125	118	115	111	108	104	102	099	096
068	167	147	135	127	119	117	112	109	105	103	100	097
069	169	148	136	128	120	118	113	110	106	104	101	098
070	170	149	137	129	121	119	114	111	107	105	102	099
071	*	*	138	130	122	120	115	112	108	106	103	100
072	*	*	139	131	123	121	116	113	109	107	104	101
073	*	*	141	132	124	123	117	114	110	108	105	102
074	*	*	142	133	125	124	118	115	111	109	106	104
075	*	*	143	135	126	125	119	116	112	110	107	105
076	*	*	144	136	127	126	120	117	113	111	109	106
077	*	*	145	137	128	127	122	118	114	112	110	107
078	*	*	146	138	129	128	123	119	115	113	111	108
079	*	*	148	139	131	130	124	120	116	114	112	109
080	*	*	149	140	132	131	125	121	117	115	113	110
081	*	*	150	141	133	132	126	122	118	116	114	111
082	*	*	151	143	134	133	127	123	119	117	115	112
083	*	*	152	144	135	134	128	124	120	118	116	113
084	*	*	153	145	136	136	129	125	121	119	117	114
085	*	*	155	146	137	137	130	126	123	120	118	115
086	*	*	*	*	138	138	132	127	124	121	119	116
087	*	*	*	*	139	139	133	129	125	122	120	117
088	*	*	*	*	140	140	134	130	126	123	121	119
089	*	*	*	*	141	142	135	131	127	125	122	120
090	*	*	*	*	142	143	136	132	128	126	123	121
091	*	*	*	*	143	144	137	133	129	127	124	122
092	*	*	*	*	144	145	138	134	130	128	125	123
093	*	*	*	*	146	146	139	135	131	129	126	124
094	*	*	*	*	147	147	140	136	132	130	127	125
095	*	*	*	*	148	149	141	137	133	131	128	126
096	*	*	*	*	*	*	143	138	134	132	129	127
097	*	*	*	*	*	*	144	139	135	133	131	128
098	*	*	*	*	*	*	145	140	136	134	132	129
099	*	*	*	*	*	*	146	141	137	135	133	130
100	*	*	*	*	*	*	147	142	138	136	134	131

TABLE 32

Table for converting raw scores on the Arithmetic subtest of the Wide Range Achievement Test to standard scores, for children, 6-11 years, by 6-month-age intervals: United States, 1963-65

Raw score	Age in months											
	72-77	78-83	84-89	90-95	96-101	102-107	108-113	114-119	120-125	126-131	132-137	138-143
	Standard score											
00	050	041	*	*	*	*	*	*	*	*	*	*
01	053	045	*	*	*	*	*	*	*	*	*	*
02	056	048	*	*	*	*	*	*	*	*	*	*
03	060	051	*	*	*	*	*	*	*	*	*	*
04	063	054	*	*	*	*	*	*	*	*	*	*
05	066	057	050	032	*	*	*	*	*	*	*	*
06	070	060	053	036	*	*	*	*	*	*	*	*
07	073	064	056	040	*	*	*	*	*	*	*	*
08	076	067	059	043	039	028	*	*	*	*	*	*
09	079	070	063	047	043	032	*	*	*	*	*	*
10	083	073	066	051	046	035	035	035	036	038	041	040
11	086	076	069	054	050	039	038	038	039	041	043	042
12	089	080	072	058	053	043	042	041	042	043	045	044
13	093	083	075	062	057	047	045	044	045	046	047	046
14	096	086	078	065	061	051	049	048	048	048	050	048
15	099	089	082	069	064	054	052	051	051	051	052	051
16	102	092	085	073	068	058	055	054	054	054	054	053
17	106	095	088	076	071	062	059	057	057	056	057	055
18	109	099	091	080	075	066	062	061	060	059	059	057
19	112	102	094	084	078	069	066	064	063	061	061	059
20	116	105	098	088	082	073	069	067	066	064	063	061
21	119	108	101	091	085	077	073	070	068	066	066	063
22	122	111	104	095	089	081	076	074	071	069	068	065
23	125	115	107	099	092	085	080	077	074	072	070	067
24	129	118	110	102	096	088	083	080	077	074	072	069
25	132	121	114	106	100	092	087	083	080	077	075	072
26	135	124	117	110	103	096	090	087	083	079	077	074
27	139	127	120	113	107	100	094	090	086	082	079	076
28	142	130	123	117	110	104	097	093	089	085	081	078
29	145	134	126	121	114	107	101	097	092	087	084	080
30	148	137	130	124	117	111	104	100	095	090	086	082
31	152	140	133	128	121	115	108	103	098	092	088	084
32	155	143	136	132	124	119	111	106	101	095	091	086
33	158	146	139	135	128	123	115	110	104	097	093	088
34	162	149	142	139	131	126	118	113	106	100	095	090
35	165	153	146	143	135	130	122	116	109	103	097	092
36	168	156	149	146	138	134	125	119	112	105	100	095
37	171	159	152	150	142	138	128	123	115	108	102	097
38	175	162	155	154	146	141	132	126	118	110	104	099
39	178	165	158	157	149	145	135	129	121	113	106	101
40	181	169	162	161	153	149	139	132	124	116	109	103
41	*	*	165	165	156	153	142	136	127	118	111	105
42	*	*	168	169	160	157	146	139	130	121	113	107
43	*	*	*	*	163	160	149	142	133	123	115	109
44	*	*	*	*	167	164	153	145	136	126	118	111
45	*	*	*	*	170	168	156	149	139	128	120	113
46	*	*	*	*	*	*	160	152	141	131	122	116
47	*	*	*	*	*	*	163	155	144	134	125	118
48	*	*	*	*	*	*	167	158	147	136	127	120
49	*	*	*	*	*	*	170	162	150	139	129	122
50	*	*	*	*	*	*	174	165	153	141	131	124
51	*	*	*	*	*	*	*	*	156	144	134	126
52	*	*	*	*	*	*	*	*	159	147	136	128
53	*	*	*	*	*	*	*	*	162	149	138	130
54	*	*	*	*	*	*	*	*	165	152	140	132
55	*	*	*	*	*	*	*	*	168	154	143	134
56	*	*	*	*	*	*	*	*	171	157	145	136
57	*	*	*	*	*	*	*	*	174	159	147	139
58	*	*	*	*	*	*	*	*	176	162	150	141
59	*	*	*	*	*	*	*	*	179	165	152	143
60	*	*	*	*	*	*	*	*	182	167	154	145
61	*	*	*	*	*	*	*	*	*	*	156	147
62	*	*	*	*	*	*	*	*	*	*	159	149
63	*	*	*	*	*	*	*	*	*	*	161	151

REFERENCE — Porteus, S. D., Porteus Maze Tests: Fifty Years Application, Pacific Books, Palo Alto, California, 1965. Materials for the Porteus Maze Tests may be purchased from the Psychological Corporation, 304 E. 45th Street, New York, New York, 10017.

APPLICABILITY — Children - 3 to 14 years through Adult

UTILIZATION — Once at pretreatment; at least one posttreatment assessment. Additional ratings are at the discretion of the investigator.

CARD FORMAT CARD 01 = (19x, 2I3)

Item	Column
Maze Quotient	20 - 22
Qualitative Score	23 - 25

SPECIAL INSTRUCTIONS

Instructions for the test are given in Porteus Maze Tests (see Reference) and should be followed by the test administrator.

DOCUMENTATION

a. Raw score printout
b. Means and standard deviations
c. Variance analyses

GOODENOUGH-HARRIS FIGURE DRAWING TEST (063-GOOD)

The Goodenough-Harris Figure Drawing Test (GOOD) - often referred to as the "Draw a Man" test - is a brief, convenient, non-language measure of intellectual or conceptual maturity. The original 1926 scoring and norms have been revised and extended by Harris.

REFERENCES

1. Harris, D. B., Children's Drawings as Measures of Intellectual Maturity. Harcourt, Brace and World, New York, 1963.

2. National Health Survey, Intellectual Maturity of Children as Measured by the Goodenough-Harris Drawing Test, PHS Publication No. 1000-Series 11-No. 105, U. S. Government Printing Office, Washington, D. C., December, 1970.

APPLICABILITY — Optimum usage - 6 - 11 years

UTILIZATION	Once at pretreatment; at least one post-treatment rating; additional ratings are at the discretion of the investigator.
CARD FORMAT	CARD 01 = (19x, I3, I2)

Item	Column
Standard Score	20 - 22
Quality Score	23 - 24

SPECIAL INSTRUCTIONS

1. Instructions for the administration and scoring of the test are contained in Harris' book; (See Reference No. 1) and should be followed by the test examiner with the exception that only the score for the first figure drawn by the child should be encoded.

2. Standard scores as given in Tables 33 to 36 should be encoded in Rows 7 - 9, Columns 1 - 10. These standard scores are based on a probability sample of approximately 7400 non-institutionalized children aged 6 through 11 years. (See Reference No. 2). Be sure to use the appropriate table when converting raw scores into standard scores; e.g., use Table 28 when a man figure is drawn first by a boy.

DOCUMENTATION

a. Standard score printout
b. Means and standard deviations of standard scores and quality scores
c. Variance analyses

BENDER GESTALT TEST - Koppitz Scoring (064-BENDK)

The Bender Gestalt Test is a non-verbal perceptual test and was originally introduced in 1938. A developmental scoring system was published by Koppitz in 1963 to provide a means to measure perceptual maturity, possible neurological impairment and emotional adjustment in children. The scoring system was standardized on more than 1200 public school children.

REFERENCE	Koppitz, E. M., The Bender Gestalt Test for Young Children, Grune and Stratton, New York, 1964.
APPLICABILITY	5 to 11 years
UTILIZATION	Once at pretreatment, at least one posttreatment rating. Additional ratings are at the discretion of the investigator.

TABLE 33

Goodenough-Harris Figure Drawing Test Standard Scores for Man Figure Drawn by Boy (National Health Survey)

Raw score	Age (years) 6	7	8	9	10	11
	Standard score					
00	54	52	48	46	46	46
01	57	54	50	48	47	48
02	59	57	53	50	49	50
03	62	59	55	52	51	51
04	64	61	57	54	53	53
05	67	64	59	56	55	55
06	69	66	61	58	57	56
07	72	68	64	60	58	58
08	74	71	66	62	60	60
09	76	73	68	64	62	62
10	79	76	70	66	64	63
11	81	78	72	68	66	65
12	84	80	75	70	68	67
13	86	83	77	72	70	69
14	89	85	79	74	71	70
15	91	88	81	76	73	72
16	94	90	83	78	75	74
17	96	92	85	81	77	76
18	99	95	88	83	79	77
19	101	97	90	85	81	79
20	104	99	92	87	82	81
21	106	102	94	89	84	83
22	109	104	96	91	86	84
23	111	107	99	93	88	86
24	113	109	101	95	90	88
25	116	111	103	97	92	89
26	119	114	105	99	93	91
27	121	116	107	101	95	93
28	124	118	110	103	97	95
29	126	121	112	105	99	96
30	129	123	114	107	101	98
31	131	126	116	109	103	100
32	134	128	118	111	105	102
33	136	130	120	113	106	103
34	139	133	123	115	108	105
35	141	135	125	117	110	107
36	144	138	127	119	112	109
37	146	140	129	121	114	110
38	149	142	131	123	116	112
39	151	145	134	125	117	114
40	154	147	136	127	119	116
41	156	149	138	129	121	117
42	158	152	140	131	123	119
43	161	154	142	133	125	121
44	163	157	145	135	127	122
45	166	159	147	137	128	124
46	168	161	149	139	130	126
47	171	164	151	141	132	128
48	173	166	153	143	134	129
49	176	168	156	145	136	131
50	178	171	158	147	138	133
51	*	173	160	149	140	135
52	*	176	162	151	141	136
53	*	178	164	153	143	138
54	*	180	166	155	145	140
55	*	183	169	157	147	142
56	*	*	171	159	149	143
57	*	*	173	161	151	145
58	*	*	175	163	152	147
59	*	*	177	165	154	149
60	*	*	180	167	156	150
61	*	*	*	169	158	152
62	*	*	*	171	160	154
63	*	*	*	173	162	155
64	*	*	*	175	163	157
65	*	*	*	177	165	159
66	*	*	*	*	167	161
67	*	*	*	*	169	162
68	*	*	*	*	171	164
69	*	*	*	*	173	166
70	*	*	*	*	175	168
71	*	*	*	*	*	169
72	*	*	*	*	*	171
73	*	*	*	*	*	173

TABLE 34

Goodenough-Harris Figure Drawing Test Standard Scores for Woman Figure Drawn by Boy (National Health Survey)

Raw Score	Age (years)					
	6	7	8	9	10	11
	Standard score					
00	48	46	47	46	47	46
01	51	48	49	48	48	48
02	53	51	51	50	50	50
03	56	53	53	52	52	51
04	59	56	55	54	54	53
05	62	58	58	56	56	55
06	64	61	60	58	58	57
07	67	63	62	60	60	59
08	70	66	64	62	62	61
09	72	68	66	64	63	62
10	75	71	69	66	65	64
11	78	73	71	68	67	66
12	80	76	73	70	69	68
13	83	79	75	72	71	70
14	86	81	77	74	73	71
15	88	84	79	76	75	73
16	91	86	82	78	77	75
17	94	89	84	80	78	77
18	96	91	86	82	80	79
19	99	94	88	84	82	81
20	102	96	90	86	84	82
21	104	99	93	88	86	84
22	107	101	95	90	88	86
23	110	104	97	92	90	88
24	112	107	99	94	92	90
25	115	109	101	96	93	92
26	118	112	104	98	95	93
27	120	114	106	100	97	95
28	123	117	108	102	99	97
29	126	119	110	104	101	99
30	128	122	112	106	103	101
31	131	124	114	108	105	103
32	134	127	117	110	106	104
33	136	129	119	112	108	106
34	139	132	121	114	110	108
35	142	135	123	116	112	110
36	145	137	125	118	114	112
37	147	140	128	120	116	114
38	150	142	130	122	118	115
39	153	145	132	124	120	117
40	155	147	134	126	121	119
41	158	150	136	128	123	121
42	161	152	139	130	125	123
43	163	155	141	132	127	125
44	166	157	143	134	129	126
45	169	160	145	136	131	128
46	171	162	147	138	133	130
47	174	165	149	140	135	132
48	177	168	152	142	136	134
49	179	170	154	144	138	136
50	182	173	156	146	140	137
51	*	175	158	148	142	139
52	*	178	160	150	144	141
53	*	180	163	152	146	143
54	*	183	165	154	148	145
55	*	185	167	156	150	147
56	*	*	169	158	151	148
57	*	*	171	160	153	150
58	*	*	174	162	155	152
59	*	*	176	164	157	154
60	*	*	178	165	159	156
61	*	*	*	167	161	157
62	*	*	*	169	163	159
63	*	*	*	171	165	161
64	*	*	*	173	166	163
65	*	*	*	175	168	165
66	*	*	*	*	170	167
67	*	*	*	*	172	168
68	*	*	*	*	174	170
69	*	*	*	*	176	172
70	*	*	*	*	178	174
71	*	*	*	*	*	176
72	*	*	*	*	*	178
73	*	*	*	*	*	179

TABLE 35

Goodenough-Harris Figure Drawing Test Standard Scores for Man Figure Drawn by Girl (National Health Survey)

Raw score	Age (years)					
	6	7	8	9	10	11
	Standard score					
00	61	61	56	53	50	51
01	63	63	58	55	52	53
02	65	65	60	56	53	54
03	67	66	61	58	55	56
04	69	68	63	60	57	57
05	72	70	65	62	58	59
06	74	72	67	63	60	60
07	76	74	69	65	62	62
08	78	76	71	67	63	64
09	80	78	73	69	65	65
10	82	80	74	70	67	66
11	84	82	76	72	68	68
12	86	84	78	74	70	70
13	88	86	80	75	72	71
14	90	88	82	77	73	73
15	92	90	84	79	75	74
16	94	92	86	81	77	76
17	96	93	87	82	78	77
18	98	95	89	84	80	79
19	100	97	91	86	81	80
20	103	99	93	88	83	82
21	105	101	95	89	85	83
22	107	103	97	91	86	85
23	109	105	99	93	88	87
24	111	107	100	95	90	88
25	113	109	102	96	91	90
26	115	111	104	98	93	91
27	117	113	106	100	94	93
28	119	115	108	102	96	94
29	121	117	110	103	98	96
30	123	119	111	105	100	97
31	125	120	113	107	101	99
32	127	122	115	109	103	100
33	129	124	117	110	105	102
34	132	126	119	112	106	104
35	134	128	121	114	108	105
36	136	130	123	116	110	107
37	138	132	124	117	111	108
38	140	134	126	119	113	110
39	142	136	128	121	115	111
40	144	138	130	122	116	113
41	146	140	132	124	118	114
42	148	142	134	126	119	116
43	150	144	136	128	121	117
44	152	145	137	129	123	119
45	154	147	139	131	124	121
46	156	149	141	133	126	122
47	158	151	143	135	128	124
48	160	153	145	136	129	125
49	163	155	147	138	131	127
50	165	157	149	140	133	128
51	*	159	150	142	134	130
52	*	161	152	143	136	131
53	*	163	154	145	138	133
54	*	165	156	147	139	134
55	*	167	158	149	141	136
56	*	*	160	150	143	138
57	*	*	162	152	144	139
58	*	*	163	154	146	141
59	*	*	165	156	148	142
60	*	*	167	157	149	144
61	*	*	*	159	151	145
62	*	*	*	161	152	147
63	*	*	*	163	154	148
64	*	*	*	164	156	150
65	*	*	*	166	157	151
66	*	*	*	*	159	153
67	*	*	*	*	161	154
68	*	*	*	*	162	156
69	*	*	*	*	164	158
70	*	*	*	*	166	159
71	*	*	*	*	*	161
72	*	*	*	*	*	162
73	*	*	*	*	*	164

TABLE 36

Goodenough-Harris Figure Drawing Test Standard Scores for Woman Figure Drawn by Girl (National Health Survey)

Raw score	Age (years)					
	6	7	8	9	10	11
	Standard score					
00	49	46	42	40	38	37
01	51	49	44	41	39	39
02	53	51	46	43	41	41
03	55	53	48	45	43	42
04	57	55	50	47	45	44
05	60	57	52	49	47	46
06	62	59	54	51	48	48
07	64	62	56	53	50	49
08	66	64	58	55	52	51
09	69	66	60	57	54	53
10	71	68	63	59	56	55
11	73	70	65	61	58	56
12	75	72	67	63	59	58
13	78	74	69	64	61	60
14	80	77	71	66	63	62
15	82	79	73	68	65	63
16	84	81	75	70	67	65
17	87	83	77	72	68	67
18	89	85	79	74	70	69
19	91	87	81	76	72	70
20	93	90	83	78	74	72
21	96	92	85	80	76	74
22	98	94	87	82	77	76
23	100	96	89	84	79	77
24	102	98	91	85	81	79
25	105	100	93	87	83	81
26	107	102	95	89	85	82
27	109	105	97	91	86	84
28	111	107	99	93	88	86
29	114	109	101	95	90	88
30	116	111	103	97	92	89
31	118	113	105	99	94	91
32	120	115	107	101	95	93
33	123	118	109	103	97	95
34	125	120	111	105	99	96
35	127	122	113	107	101	98
36	129	124	115	108	103	100
37	132	126	117	110	105	102
38	134	128	119	112	106	103
39	136	130	122	114	108	105
40	138	133	124	116	110	107
41	141	135	126	118	112	109
42	143	137	128	120	114	110
43	145	139	130	122	115	112
44	147	141	132	124	117	114
45	150	143	134	126	119	116
46	152	146	136	128	121	117
47	154	148	138	130	123	119
48	156	150	140	131	124	121
49	159	152	142	133	126	123
50	161	154	144	135	128	124
51	*	156	146	137	130	126
52	*	158	148	139	132	128
53	*	161	150	141	133	130
54	*	163	152	143	135	131
55	*	165	154	145	137	133
56	*	*	156	147	139	135
57	*	*	158	149	141	137
58	*	*	160	151	143	138
59	*	*	162	153	144	140
60	*	*	164	154	146	142
61	*	*	*	156	148	144
62	*	*	*	158	150	145
63	*	*	*	160	152	147
64	*	*	*	162	153	149
65	*	*	*	164	155	151
66	*	*	*	*	157	152
67	*	*	*	*	159	154
68	*	*	*	*	161	156
69	*	*	*	*	162	158
70	*	*	*	*	164	159
71	*	*	*	*	*	161
72		*	*	*	*	163
73		*	*	*	*	165

CARD FORMAT CARD 01 = (19x, 1012)

Item	Column	Item	Column
Fig. A	20 - 21	Fig. 5	30 - 31
Fig. 1	22 - 23	Fig. 6	32 - 33
Fig. 2	24 - 25	Fig. 7	34 - 35
Fig. 3	26 - 27	Fig. 8	36 - 37
Fig. 4	28 - 29	Total Score	38 - 39

SPECIAL INSTRUCTIONS

Follow the instructions given in the Koppitz Manual (See Reference).

On data decks, a 2-digit coding system has been designed to record the types of errors made by the subject. The codes are:

	Response Positions						
Code	0	1	3	5	7	Designs for which code is legal	Score
01					X	All	1
02				X		All	1
03				X	X	All	2
04			X			A,1,2,3,5,6,7	1
05			X		X	A,1,2,3,5,6,7	2
06			X	X		A,1,2,3,5,6,7	2
07			X	X	X	A,1,2,3,5,6,7	3
08		X				A,3,5,6,7	1
09		X			X	A,3,5,6,7	2
10		X		X		A,3,5,6,7	2
11		X		X	X	A,3,5,6,7	3
12		X	X			A,3,5,6,7	2
13		X	X		X	A,3,5,6,7	3
14		X	X	X		A,3,5,6,7	3
15		X	X	X	X	A,3,5,6,7	4
16	X					All	0

Examples: 07 in Cols. 24-25 = 3 errors on Des. 2: rotation, rows added and perseveration
08 in Cols. 32-35 = 1 error on Des. 6: perseveration
16 in any column pair = no errors on the particular design

DOCUMENTATION

a. Raw score printout
b. Means and standard deviations
c. Variance analyses

PSYCHOLOGICAL EXAMINATION BEHAVIOR PROFILE (066-PEBP)

The Psychological Examination Behavior Profile (PEBP) is a 15-item scale formatted for use with the General Scoring Sheet. The scale is designed to assess the behavior of the subject during the administration of psychological tests. The PEBP was developed as part of a collaborative study conducted by the Perinatal Research Branch, National Institute of Health.

REFERENCE — Manual for the Collaborative Study on Cerebral Palsy Mental Retardation and Other Neurological and Sensory Disorders of Infancy and Childhood, Perinatal Research Branch, National Institute of Neurological Diseases and Stroke, National Institute of Health, Public Health Service, Department of Health, Education and Welfare, Part III-E, April, 1970.

APPLICABILITY — For children, 5 - 15 years old.

UTILIZATION — To be used in conjunction with each psychological examination.

TIME SPAN RATED — The duration of the psychological examination.

CARD FORMAT — CARD 01 = (19x, 1511, 12)

Item	Column	Item	Column
1	20	8*	27
2	21	9	28
3	22	10	29
4	23	11	30
5	24	12	31
6	25	13	32
7	26	14*	33
		15*	34
		Total Score	35 - 36

* = Items reflected in scoring

Total Score = Sum of Items 1 through 15 Total Score Range = 0 - 60

SPECIAL INSTRUCTIONS

A. On the PEBP form itself, only cue words are provided for each scale point. A more detailed description of each scale point is given below to aid the rater in making his judgments.

1. Separation from Mother - The range is from "shows no concern" to "very upset".

0 = Shows no concern; eager to leave mother and go with examiner.
1 = Shows very little concern; shows little cautiousness and comes with examiner without preamble, needs little or no explanations.
2 = May show some initial reticence, which is felt to be entirely appropriate; separates from mother after some minimal reassurances and explanations.
3 = More than usual amount of concern; more disturbed than most, but finally is able to separate; may need continuing reassurances.
4 = Very upset, cries, clings to mother, may have tantrum or withdraw, refusing to look at or talk to the examiner; mother's presence may be required in the test room.

2. Fearfulness - The range is from "no apparent awareness of strange situation" to "very fearful and apprehensive".

0 = No apparent awareness of strange situation; completely unafraid, and behavior uninhibited.
1 = Very little fear evidenced; quickly at ease in the situation.
2 = Normal amount of caution in the situation but able to cope with it.
3 = Inhibited and uneasy throughout with some slowing of responses.
4 = Very fearful and apprehensive; acute discomfort interferes significantly with test performance.

3. Rapport with Examiner - The range is from "exceptionally shy" to "extreme friendliness".

0 = Exceptionally shy; withdrawn; unresponsive or ignores any friendly overtures.
1 = Shy; waits for friendly gestures; very little social interaction or social contact on his own initiative.
2 = Perhaps some initial shyness; feels at ease; relates in a friendly manner.
3 = Very friendly; and at ease.
4 = Extreme friendliness; focuses on social interaction with little or no interest in test materials.

4. Self-Confidence - The range is from "lacks self-confidence" to "very self-confident".

0 = Lacks self-confidence; extremely self-critical; may refuse to attempt many tasks because they seem too difficult.
1 = Distrusts own ability; tends to minimize his performance and often points out what is wrong.
2 = Adequately self-confident; usually sure of himself but recognizes difficulty of certain tasks and may be a little hesitant with them.

3 = More than usual amount of self-confidence; works easily without tensions and is usually satisfied with his performance.
4 = Very self-confident; child extremely proud of performance and acts as if he can tackle anything.

5. Emotional Reactivity - The range is from "extremely flat" to "extreme instability of emotional responses".

0 = Extremely flat; no change in facial expression; responds to all activities in same manner.
1 = Somewhat flat; little change in emotional tone, some slight variations at times.
2 = Normal responsiveness; affect appropriate to situation.
3 = Mood more variable than average; may be motivated internally or exaggerated responsiveness to situation.
4 = Extreme instability of emotional responses; marked emotional lability; either overreactive to external situations or to undetermined stimuli.

6. Degree of Cooperation - The range is from "extreme negativism" to "extremely suggestible and conforming".

0 = Extreme negativism; continually resistant to directions or demands of the situation; examiner's suggestions or directions have little obvious effect on child.
1 = Resistive to demands or directions a good deal of the time; willing to comply only when faced with success, or requires considerable prompting to elicit response.
2 = Cooperative with reasonable amount of discomfort and anxiety when faced with difficulty or failure, responds well to directions most of the time.
3 = Accepts direction or demands more easily; eager to conform even when faced with failure; rarely attempts to do anything unless examiner has explicitly stated it.
4 = Extremely suggestible and conforming; no apparent discomfort when faced with failure, completely dependent upon specific directions from examiner.

7. Level of Frustration Tolerance - The range is from "withdraws completely" to "extreme acting out behavior and/or crying".

0 = Withdraws completely; refuses to continue or attempt any task which appears too difficult for him.
1 = Occasionally withdraws from task where difficulty is encountered or appears too difficult for success.
2 = Attempts to cope with difficult situations; does not become unduly upset if task is too difficult.
3 = Becomes quite upset by difficulty; may react with some disorganized behavior; some anger may be displayed against the test materials or examiner; may resort to crying.
4 = Extreme acting out behavior and/or crying; considerable anger displayed; behavior becomes uncontrolled and continuation of examination may become impossible or very difficult.

8. Degree of Dependence - The range is from "very self-reliant to "constant need for attention or help".

   0 = Very self-reliant; refuses help; extreme overt confidence.
   1 = Rarely needs reassurance; primarily absorbed with test materials; little attention demanded.
   2 = Dependent in appropriate situations; enjoys attention but can function easily without it; adequately confident.
   3 = Demands more attention than average; needs frequent help, reassurance, approval and encouragement.
   4 = Constant need for attention or help; cannot function without continual approval or support.

9. Duration of Attention Span - The range is from "attends to tasks very briefly" to "highly perseverative".

   0 = Attends to tasks very briefly; highly distractible, fleeting and sporadic attention; lack of concentration interferes significantly with test performance.
   1 = Spends short time with tasks; easily distractible; frequently needs help in maintaining attention; brief attention may interfere somewhat with test performance.
   2 = Spends adequate amount of time on tasks; able to concentrate until successful or until failure is clear.
   3 = Spends more than average time on tasks; eventually is able to turn to new activity.
   4 = Highly perseverative; unable to shift attention; fixated at one task; requires examiner's intervention in order to change activity.

10. Goal Orientation - The range is from "no effort to reach a goal" to "compulsive absorption with task".

   0 = No effort to reach a goal; extremely lacking in persistence or unable to keep goal or questions in mind.
   1 = Briefly attempts to achieve goal; easily forgets goal or question, or fails to persist; less than average ability to continue to completion.
   2 = Able to keep goal or directions in mind; able to persist until completion; able to "give up" when appropriate.
   3 = Keeps goal and questions in mind; persists for more than usual amount of time; continues effort beyond necessary point.
   4 = Compulsive absorption with task; unwilling or unable to "give up"; resists or ignores examiner's attempts to change activity.

11. Level of Activity - The range is from "extreme inactivity and passivity" to "extreme overactivity and restlessness".

   0 = Extreme inactivity and passivity; placid, sluggish; posture adjustments in chair may be slow and infrequent.
   1 = Little activity; content to sit still most of the time.
   2 = Normal amount of activity; able to sit quietly when interested; may fidget and become restless at times.
   3 = Unusual amount of activity and restlessness; very seldom able to sit quietly.
   4 = Extreme overactivity and restlessness; can't sit still; constantly in motion; activities not in response to specific external stimulation.

12. Nature of Activity - The range is from "extreme rigidity" to "extremely impulsive".

    0 = Extreme rigidity; unable to shift activity or approach to task; cannot vary or adapt responses; stays with one aspect of task.
    1 = Some rigidity; tends to be inflexible in most situations but does shift approach in some instances; at times can change to appropriate response to task.
    2 = Flexible behavioral patterns; activity appropriate to different situations.
    3 = Behavior frequently impulsive; fluid and sometimes uncontrollable.
    4 = Extremely impulsive; explosive and uncontrolled behavior.

13. Nature of Communication - The range is from "little or no verbal communication" to "difficult to follow child's thinking".

    0 = Little or no verbal communication; uses gestures and/or pantomime; verbal communication limited to "yes" and "no", or one or two words.
    1 = Verbal or non-verbal responses confined to answering directed questions; communication generally elicited rather than initiated by child.
    2 = Readily answers questions; may elaborate responses; may initiate conversation; content generally appropriate and easily followed.
    3 = Answers questions freely, initially appropriate but tends to lose main idea by elaborations or free associations; at times content seems inappropriate or illogical.
    4 = Difficult to follow child's thinking; content usually irrelevant and inappropriate; at times bizarre.

14. Assertiveness - The range is from "extremely assertive, wilful personality" to "extreme passivity".

    0 = Extremely assertive, wilful personality; approach dominating, aggressive and lacking in reserve; attempts to manipulate session, and resists externally imposed limitations.
    1 = Quite forceful, unnecessarily rough and careless in handling materials; little inhibited by examiner's presence from doing exactly what he wants; often ignores imposed limits.
    2 = Self-assertive but accepting of the situation and capable of control and reserve when demanded; looks for feedback and becomes less assertive; more pliant, when this is indicated.
    3 = Passive acceptance; permits self to be somewhat controlled by examiner and situation; rarely shows inclination to want to do something different from what examiner suggests.
    4 = Extreme passivity; malleability, and acquiescence to everything, with no trace of resistance; seems extremely overcompliant.

15. Hostility - The range is from "very hostile, obstructive" to "ingratiating child".

    0 = Very hostile, obstructive; engages in overt physical or verbal attacks on examiner, test materials or testing room objects. May have tantrums.
    1 = Unusual amount of hostility present; very uncooperative and/or becomes angry when restrictions are imposed; may introduce frequent aggressive themes into verbal productions. May want to engage in irrelevant conversation and games, thus indirectly refusing or hindering progress in testing.
    2 = No unusual amount of hostility evidenced; negative behavior or affect is generally appropriate and controlled.
    3 = Very agreeable child who rarely shows hostility, even where it might be appropriate; never seems to balk at any imposed limitations or react in displeased manner to them.
    4 = Ingratiating child. Desire to please examiner seems to be the main determinant of behavior.

B. Interpretation of Scores - The items of the PEBP are bipolar. Scale point "2" is a neutral or zero point between the poles and represents "normal" or appropriate behavior. Item scores at the lower end (0.1) tend to reflect low levels of arousal or interaction; while higher scores (3.4) indicate high arousal and interaction. Similarly, a total score of 30 represents "normal" or appropriate behavior. Total scores below 30 indicate lower levels of arousal; while total scores above 30 represent higher levels of arousal.

DOCUMENTATION

a. Raw score printout
b. Means and standard deviations
c. Variance analyses

PERFORMANCE TESTS FOR MEASURING PSYCHOPHARMACOLOGICAL EFFECTS ON CHILDREN

Robert L. Sprague
Children's Research Center
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The following recommendations have used a few basic assumptions about experimentation in the area of psychopharmacology. One, if the area of research interest is psychotropic drugs, then it seems that one of the target areas of measurement should be the behavior of the child. Two, in measuring behavior of the child, one should measure this behavior as precisely as can be done within the limits of the methods available today. This means that the test used should have high reliability, i.e., it should give the same results when repeated if there has been no change in the child. The test should also have validity, which means that the tests actually are measuring what they purport to measure and furthermore, the test should be related in a logical fashion to a theoretical system. Three, since one of the primary characteristics of children is development, then the behavioral tests should measure what is thought to be important in developmental processes.

Listed below are major subdivisions of important developmental processes in children.

The cognitive area of development is one of the most important for children. Children have learning as their main occupation: both formally in school and informally in the family. It is almost trite to say that what they learn shapes their life for the future. For these obvious reasons, tests which measure the effects of psychotropic drugs on learning should be included in the battery of tests. The development of standardized tests in this area is quite uneven in that there has been heavy emphasis on the creation of psychological tests to assess intellectual development with relatively little emphasis on tests to measure current learning efficiency and current memory ability of the children. Recent theoretical developments in the area of attention should not be ignored because often psychotropic drugs are administered to improve the attention of the distractable child. These theoretical foundations give a foothold for beginning of sound experimentation in this area.

Motor development is another major area which should be investigated. Unfortunately, there has been relatively little emphasis on the development of standardized tests to assess the development of motor ability in children. Consequently, only one test which measures one aspect of motor development has been suggested.

Social development is extremely important for the child, but again, unfortunately, relatively few standardized tests have been developed to measure the social ability of the child. Most of this information must then necessarily be taken from rating scales which attempt to assess the social behavior of the child in a variety of situations. Dr. Conners has prepared material in this area.

Finally, the academic achievement of the child or what he learns from formalized instruction in the public school is of prime interest. Most problem children who receive psychotropic drugs also have problems with academic performance, therefore it is felt that academic achievement should be evaluated.

Recommended Performance Tests

1. Intellectual Tests

   A. Draw-A-Person

      This test is listed first because clinicians often give it to start a testing session with the child by using something that is easy and understandable. It can give information both about the child's intellectual level and his motor ability.

   B. Porteus Mazes

      This test has repeatedly been shown to be sensitive to drug effects. It is relatively quick and with some practice easy to administer.

   Optional Tests

   C. Wechsler Intelligence Scale for Children

      Since this IQ test is so commonly given in clinics across the nation, it is also listed. It is suggested as an optional test because it requires about 1 - 1 1/2 hours to administer, and many research projects might not have the necessary personnel nor the time.

   D. Peabody Picture Vocabulary Test

      This is a fairly reliable, very quick intelligence test that can be given in cases where an intellectual estimate is needed but not enough time is available to administer the WISC.

2. Learning Tests - Optional

It is quite difficult to satisfactorily measure learning without using some equipment. Equipment is needed to obtain a precise measurement, e.g., latency of responding, which is the length of time (usually in tenths of a second) from the onset of a stimulus until the child responds. Although the equipment is somewhat expensive and requires some technical knowledge to operate, it is felt that the precision which comes with the use of this kind of apparatus warrants its inclusion. It should be also pointed out that in other areas, such as clinical chemistry, laboratory apparatus is accepted as absolutely necessary to conduct the investigations.

Commercial equipment available from three companies has been listed in the back of this report. This is only a sample of the equipment available and is not intended to be exhaustive, although the companies probably represent the best equipment that is available today for the type of behavioral assessment suggested herein. Experimenters planning to use these learning measures should be warned that some minimum amount of knowledge about this equipment is needed. Most of these firms offer extensive manuals in the use of their equipment and some of the firms even offer short workshops to teach the unsophisticated how to use their equipment. Most psychologists, particularly those with training in experimental psychology, can readily utilize such equipment. Thus, any project that has the services of a psychologist probably can benefit from this kind of equipment.

A. Continuous Performance Task
This task has been used extensively in assessing the effects of psychotropic drugs on human behavior. This type of task is within the ability of a wide range of children, and it is relatively easy to program.

B. Paired Associate Learning
This is one of the oldest techniques to evaluate learning ability in both adults and children. A variety of stimuli and responses can be utilized that are appropriate with children. For example, pictures from the picture vocabulary subtest of the Stanford Binet or pictures from the Peabody Picture Vocabulary Test can be paired with numbers or letters to form an acceptable paired associate task.

C. Recognition Memory
Recognition tests are generally enjoyable for the child. They can be used to measure the attention of the child and also to investigate both short-term and long-term memory of the child. Some of the most useful data coming from this test is the latency data.

3. Motor Performance

The motor test of the Kløve-Matthews modified version of the Halsted Battery would provide a useful measure of motor performance. These tests include tapping speed, steadiness task, and finger mazes. All of the tests give reliable quantitative information. The tests can be purchased from Dr. Halgrim Kløve, Neuropsychology Laboratory, Department of Neurology, University of Wisconsin Medical Center, 1300 University Avenue, Madison, Wisconsin 53706.

A. Stabilimetric Cushion
The stabilimetric cushion developed and used by Sprague might be of use in situations where the child is seated at a school desk or seated at a table while performing psychological or behavioral tasks. It measures rather accurately the amount of wiggling, and it has been shown to be sensitive to drug effects. Anyone interested in this device should contact Robert Sprague, Children's Research Center, University of Illinois, Champaign, Illinois 61820.

4. Achievement Tests
A. Wide Range Achievement Test
There are a variety of achievement tests on the market, but most of them are lengthy and difficult to administer. For these reasons, the WRAT has been suggested because it is simple and easy to administer.

5. Apparatus to Measure Learning Performance

Listed below are sets of apparatus from three different companies which could be utilized to measure the effects of psychotropic drugs on learning performance of children. Each of the sets have some advantages and some disadvantages, but it is thought that they are representative samples of the kind of equipment that can

be purchased commercially to measure learning performance in children. These lists have been developed with four types of performance measures in view: (1) the continuous performance task, (2) paired-associates learning task, (3) recognition and memory task, and (4) match to sample task.

A. Behavioral Controls, Inc.
1506 West Pierce Street
Milwaukee, Wisconsin 53246
Telephone: 414-671-1255

The advantage of equipment manufactured by Behavior Controls is that it is small and compact, it is self contained, and it requires relatively little skill or equipment to make the stimulus material.

The disadvantages of this equipment (as listed below) are that it provides no printout of the responses and latency. To obtain a printout, additional equipment must be purchased. Further disadvantages are that it permits less precise control of the time intervals between the presentation of the stimuli which are of some considerable importance if one measures latency of responding accurately, and the changing of the stimulus material is somewhat more difficult than the other two sets of apparatus in that the machine must be opened up and a length of fan folded material changed.

Quantity	Item
1	SR-400 Stimulus Programmer with press panel cover
1	Standard 400 cover
5M	Fan folded program paper
1	4 hole indexing punch
1	4 choice auxilliary control console
2	Dual 4-digit reset response counters
1	Timing control module
1	Continuous loop attachment
1	Continuous performance/delayed response module
1	Component mounting and display console
1	Function control network
1	Set-sample programs and operating instructions for each mode of use
	FOB Milwaukee $3,450

B. Behavior Apparatus Builders
305 Water Street
St. Joseph, Illinois
Telephone: 217-469-7108

The advantage of the equipment built by Behavior Apparatus Builders is that it automatically provides a printout on a roll of paper of the number of correct responses, the number of the trial, and the latency in tenths of a second; one can program as many stimuli as needed; the stimuli can easily be changed by simply placing on or removing a Kodak slide tray; and the equipment is automatically programmed with a paper tape reader.

The disadvantages of the equipment are that it consists of three major units which are a projection tunnel, a Kodak projector and base, and a relay rack of equipment which means that it is somewhat bulky in comparison with the Behavior Controls equipment. In order to make the stimuli, some photography is necessary because the stimuli are on 35mm slides which are projected by the Kodak projector. Some knowledge of programming equipment is essential to use the equipment satisfactorily.

Quantity	Item
1	Projection tunnel
1	Reinforcement-dispensing system
1	Shutter-projector control
1	Paper tape reader
1	Manual paper tape punch
2	Dual relays
3	Pulse formers
1	Adjustable timer
2	Power panels
1	24 VDC power supply
1	Automatic printer with 6 channels of data printout

TOTAL @ $3,463

The above price does not include the Kodak Carousel projector, a relay rack for the programming equipment, and cross patch cords for interconnecting the programming equipment.

C. Lehigh Valley Electronics, Inc.
Box 125
Fogelsville, Pennsylvania 18051
Telephone: 215-285-4211

The advantages of the Human Test System built by Lehigh Valley is that there are a great number of other types of modules available for the system and a great variety of programming equipment including a computer system which could be attached to the Human Test System.

The disadvantages of the apparatus as currently listed are considerable in that it will only handle one of the four tests listed in the introduction, namely the recognition memory task. It would be possible to buy equipment from Lehigh Valley which would handle all four tests, but this would require more expense and more equipment or a special order. The apparatus as it now stands would require extensive knowledge of programming equipment to operate it satisfactorily.

Quantity	Part #	Item
1	111-10	Projector with slide reader and control panel
1	520-13	Two-rail console for projector
1	520-22	Connector harness
3	521-41	Rear screen projection key
1	521-74	Coin dispenser
2	1357	Pulse formers
6	1360	Dual relays
3	1419	Timers
1	1660	Printer
1	1384	Timing pulse generator

TOTAL @ $3,149

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PSYCHOMETRIC SCALES-ADULT

PSYCHOMETRIC SCALES

ADULT

Code 15 for Sheet Number when encoding any or all of the standard Adult Psychometric Scales.

The texts for all adult scales are printed on *GREEN* templates.

MH-9–67	(WAIS)	Wechsler Adult Intelligence Scale
70	(FTBS)	Friedhoff Task Behavior Scale
61	(MAZE)	Porteus Mazes
68	(BENDPS)	Bender Gestalt Test – Pascal Suttell Scoring
69	(WMEM)	Wechsler Memory Scale

Mark on right half of scoring sheet on row specified (Cols. 11–20) — ROW NO.

WECHSLER ADULT INTELLIGENCE SCALE

(67-WAIS) *(Code 15 for Sheet Number)*

INSTRUCTIONS: Code scaled scores, NOT raw scores, in 2 digits; code IQ's in 3 digits. When using "short forms" or abbreviated versions of WAIS, be sure to encode subtests and IQ's on the proper rows. Leave blank all unused rows.

	ROW NO.
Information	1-2
Comprehension	3-4
Arithmetic	5-6
Similarities	7-8
Vocabulary	9-10
Digit Span	11-12
Picture Completion . . .	13-14
Picture Arrangement . .	15-16
Block Design	17-18
Object Assembly	19-20
Digit Symbol	21-22
Verbal IQ	23-25
Performance IQ	26-28
Full IQ	29-31

FRIEDHOFF TASK BEHAVIOR SCALE

(70-FTBS) *(Code 15 for Sheet Number)*

INSTRUCTIONS: At the close of the testing session please rate the patient on the following aspects of his behavior and performance.

1. COOPERATION — ROW NO. 32

1 = Good	No urging needed
2 = Fair	Little urging
3 = Poor	Much urging
4 = Very poor	Refuses completely

Continue marking on right half of scoring sheet on row specified — ROW NO.

FRIEDHOFF TASK BEHAVIOR SCALE – *Continued*

2. GRASP INSTRUCTIONS — 33

1 = Good	Understands quickly
2 = Fair	Occasional repetition and correction required
3 = Poor	Constant repetition and correction required
4 = Very poor	Unable to understand

3. SHOWS ANNOYANCE OR HOSTILITY — 34

1 = Not at all
2 = A little
3 = Quite a bit
4 = Extremely

4. WITHDRAWN — 35

1 = Not at all
2 = A little
3 = Quite a bit
4 = Extremely

5. SHOWS AGITATION OR EXCITEMENT — 36

1 = Not at all
2 = A little
3 = Quite a bit
4 = Extremely

6. APPEARS APPREHENSIVE OR TENSE — 37

1 = Not at all
2 = A little
3 = Quite a bit
4 = Extremely

7. ATTENTION TO TASK — 38

1 = Good	Complete attention
2 = Fair	Usually attentive
3 = Poor	Attention limited and wandering
4 = Very poor	Complete inattention

8. RELATIONSHIP WITH TEST ADMINISTRATOR — 39

1 = Good	Friendly, at ease
2 = Fair	Reserved, took a while before warming up
3 = Poor	Ill at ease, uncomfortable
4 = Very poor	Preoccupied; ignored me; acted as if I weren't present; practically no interpersonal contact

ROW NO.	*Mark on left half of scoring sheet on rows specified*
	PORTEUS MAZES *(Code 15 for Sheet Number)* (61-MAZE)
	Code 3 digits for each of the 2 scores
1-3	. . . Maze Quotient
4-6	. . . Qualitative Score
	BENDER GESTALT TEST — Pascal.Suttell Scoring *(Code 15 for Sheet Number)* (68-BENDPS)
	Code score for each design in 2 digits; code total score in 3 digits
7-8	. . . Figure 1 *(Record total score for design)*
9-10	. . . Figure 2
11-12	. . . Figure 3
13-14	. . . Figure 4
15-16	. . . Figure 5
17-18	. . . Figure 6
19-20	. . . Figure 7
21-22	. . . Figure 8
23-24	. . . Configuration Score
25-27	. . . Total Test Score
	WECHSLER MEMORY SCALE *(Code 15 for Sheet Number)* (69-WMEM)
	Unless otherwise indicated, code scores in 1 digit
28	. . . Personal and Current Information
29	. . . Orientation
30	. . . Mental Control
31-32	. . . Logical Memory *(Code in 2 digits)*
33	. . . Digits Forward
34	. . . Digits Backward
35-36	. . . Visual Reproduction *(Code in 2 digits)*
37-38	. . . Associate Learning *(Code in 2 digits)*
39-41	. . . MEMORY QUOTIENT *(Code in 3 digits)*

This section is formatted to encode five psychological scales on a single General Scoring Sheet. Other psychometric data may be encoded according to the instructions given in the section "Encoding of Non-Standard Data". (pp. 59-64).

WECHSLER ADULT INTELLIGENCE SCALE (067-WAIS)

Introduced by Wechsler in 1955, the WAIS is a revision and restandardization of the original Wechsler scales. As with its precursor, the WAIS is composed of verbal and performance subtests yielding a total score which is converted into an age-related IQ.

REFERENCES

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APPLICABILITY

Adults 16 to 75 years

UTILIZATION

At the discretion of the investigator. May be used at initial assessment only or as a change measure.

CARD FORMAT

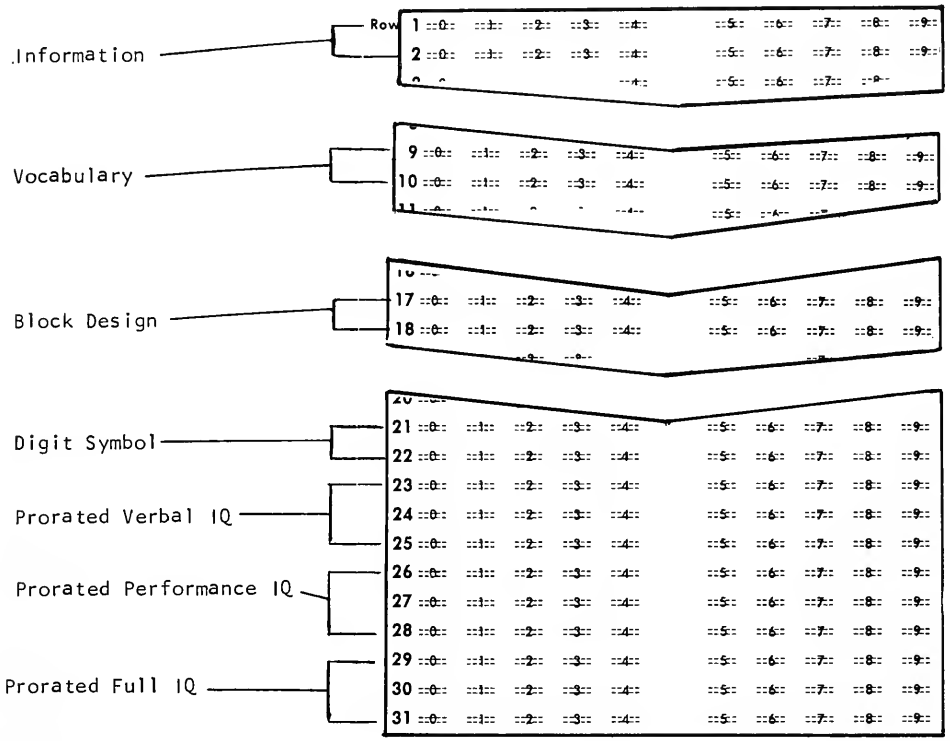
CARD 01 = (19x, 1112, 313)

Item	Column	Item	Column
Information	20 - 21	Picture Arrangement	34 - 35
Comprehension	22 - 23	Block Design	36 - 37
Arithmetic	24 - 25	Object Assembly	38 - 39
Similarities	26 - 27	Digit Symbol	40 - 41
Vocabulary	28 - 29	Verbal IQ	42 - 44
Digit Span	30 - 31	Performance IQ	45 - 47
Picture Completion	32 - 33	Full IQ	48 - 50

SPECIAL INSTRUCTIONS

The instructions given in the WAIS Manual (Reference 1) should be followed by the test administrator. Be sure to encode SCALED SCORES, not raw scores. When using any abbreviated WAIS, encode the scaled scores of the subjects used and the prorated IQ's in their appropriate rows and columns.

Example: The psychologist plans to employ only 4 WAIS subtests: Information, Vocabulary, Block Design and Digit Symbol. She should encode these subtests - and the prorated IQ's as follows:



DOCUMENTATION

a. Scaled score printout
b. Means and standard deviations
c. Variance analyses

BENDER GESTALT TEST (068-BENDPS) - Pascal-Suttell Scoring

In wide use since its introduction by Bender, the BENDPS is a nonverbal visual-motor test which has been employed for the estimation of maturation, intelligence, psychological disturbance and cortical impairment. Pascal and Suttell published their scoring system in 1951 and have attempted to differentiate cortical deficit ("organicity") from psychogenic disorders.

REFERENCES

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Test material may be obtained from the Psychological Corporation, New York.

APPLICABILITY — 15 years to adult

UTILIZATION — Once at pretreatment; at least one posttreatment rating. Additional ratings are at the discretion of the investigator.

CARD FORMAT — CARD 01 = (19x, 912, 13)

Item	Column	Item	Column
Fig. 1	20 - 21	Fig. 6	30 - 31
Fig. 2	22 - 23	Fig. 7	32 - 33
Fig. 3	24 - 25	Fig. 8	34 - 35
Fig. 4	26 - 27	Config. Score	36 - 37
Fig. 5	28 - 29	Total Score	38 - 40

SPECIAL INSTRUCTIONS

Instructions for scoring the test are contained in the Pascall-Suttell volume. (See Reference 1). Investigators wishing to employ other scoring systems should encode the data according to the instructions for "Encoding Non-Standard Data" (pp.59-64).

DOCUMENTATION

a. Raw score printout
b. Means and standard deviations
c. Variance analyses

WECHSLER MEMORY SCALE (069-WMEM)

The Wechsler Memory Scale (WMEM), is a brief, widely used measure of memory deficit. It consists of 7 subtests whose raw scores are summated to obtain a memory quotient. Two forms of the scale are available and are considered to be equivalent. It is suggested that investigators alternate the 2 forms to reduce practice effects.

REFERENCE

Wechsler, D., and Stone, C. P., Manual for Wechsler Memory Scale, Psychological Corporation, New York. (Originally published in J. of Psychol., 19, 87-95, 1945). Materials for the WMEM may be obtained from the Psychological Corporation.

APPLICABILITY

Adults

UTILIZATION

Once at pretreatment; at least one posttreatment rating. Additional ratings are at the discretion of the investigator.

CARD FORMAT

CARD 01 = (19x, 311, 12, 211, 212, 13)

Item	Column	Item	Column
Information	20	Digits Backward	26
Orientation	21	Reproduction	27 - 28
Control	22	Assoc. Learning	29 - 30
Logical	23 - 24	Memory Quotient	31 - 33
Digits Forward	25		

SPECIAL INSTRUCTIONS

Instructions for scoring the items are contained in the manual (see Reference).

DOCUMENTATION

a. Raw score printout
b. Means and standard deviations
c. Variance analyses

FRIEDHOFF TASK BEHAVIOR SCALE (070-FTBS)

The Friedhoff Task Behavior Scale (FTBS) is an 8-item, 4-point scale for the assessment of the subject's behavior during the administration of psychological tests. It is the adult analogue of the Psychological Examination Behavior Profile and, like the PEBP, is formatted for use with the GSS.

REFERENCE — Friedhoff, A. J. and Alpert, M., The Effect of Chlorpromazine on the Variability of Motor Task Performance in Schizophrenics, J. Nerv. Ment. Dis., 130, 110-116, 1960.

APPLICABILITY — Adult Populations

UTILIZATION — To be used in conjunction with each psychological examination.

TIME SPAN RATED — The duration of the psychological examination.

CARD FORMAT — CARD 01 = (19x, 811, 12)

Item	Column	Item	Column
1. Cooperation	20	5. Agitation	24
2. Grasp	21	6. Apprehensive	25
3. Annoyance	22	7. Attention	26
4. Withdrawn	23	8. Relationship	27
		Total Score	28 - 29

Total Score = Sum of items 1 through 8. Total Score Range = 8 - 32.

SPECIAL INSTRUCTIONS

Clues for each scale point are given on the scale itself.

DOCUMENTATION

a. Raw score printout
b. Means and standard deviations
c. Variance analyses

ASSEMBLING DATA FOR SHIPMENT

Perhaps the least exhilarating aspect of research is the data collection phase since it demands close and constant attention to a myriad of details. However, the care expended here is subsequently justified in the analytic phase. Since the greatest amount of processing time is spent in creating an error-free data set, it is as much in the interest of the Biometric Laboratory to campaign for strict data control as it is in the investigator's interest.

Experience has shown that processing time is reduced substantially when an investigator establishes his own control procedures prior to sending data for computer processing. This is best accomplished when the responsibilities for data control and coordination are assigned to some member of his research staff. The data coordinator has the task of seeing that the requirements of the protocol - particularly the data collection aspects - are carried out. By constructing an overall assessment table showing rater assignment and required rating instruments, the coordinator can drastically reduce subsequent "missing data" problems. By monitoring each set of ratings as they are obtained, the coordinator can ensure the completeness and correctness of the encoding. To accomplish this, the coordinator must be thoroughly familiar with the proper encoding procedures for all the instruments used in a study. In the past, the Biometric Laboratory has conducted several group workshops for coordinators in the use of the ECDEU Battery and has found the resultant interchange of information most rewarding. Consultation with coordinators on the problems of data collection continues to be a function of the Laboratory and investigators are welcome to make use of this service.

ASSEMBLING DATA FOR SHIPMENT

Predominantly, input data has been received at the Biometric Laboratory in the form of completed op-scan sheets which represent the data collection for an entire study. In preparing a data set for shipment, the following instructions should be noted:

1. Check all forms for completeness both in the ID block and in the data matrix. Erase extraneous marks or writing. Check to see that a #2 pencil was used. Above all, do not use staples or clips: do not punch holes in the forms, etc.

2. Only the original copy (white) should be sent as it alone can be op-scanned. The yellow copy should be retained by the investigator. Xeroxed copies cannot be op-scanned and therefore should not be sent. If a form is mutilated, recopy the data on another form.

3. Sorting data in a uniform manner serves to alert the unit coordinator to missing ratings or other errors and, later, aids BLIPS editors to locate a specific form during their editing procedures. Two of the most frequently-used sorting arrangements are:

a. Subjects and periods ordered within Sheet and/or Form as follows:

Treatment Group A

Sheet or Form Number (In numeric order)
Subject 001 Period 00
Subject 001 Period 01
Subject 001 Period 02
Subject 001 Period k

Subject 002 Period 00
Subject 002 Period 01
Subject 002 Period 02
Subject 002 Period k

Subject n Period 00
Sheet or Form Number

(as above)

Treatment Group B (Repeat as in "A")

b. Sheets, forms and periods ordered by subject as follows:

Treatment Group A

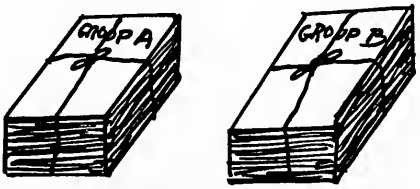
Subject 001
Sheet 01 Period 00
Sheet 01 Period 01
Sheet 01 Period 02
Sheet 01 Period k

Sheet 03 Period 00
Sheet 03 Period 01
Form n Period 00

Treatment Group B (Repeat as in "A")

4. Note in the above sorting examples (3a and 3b) that data is always separated into treatment groups. Identify each treatment group by writing its name on a sheet of paper and placing it on top of the data and tie the data together to make a bundle of each group's data.

Example:



5. Make sure that you've enclosed the completed Data Shipment (071-DS). If you have additional special requests or comments, state them in a letter even though you may have discussed them previously by telephone.

6. Place all the data into a stout box and wrap securely. Please enclose ONLY ONE STUDY TO A BOX. More than one box may, of course, be used for large studies. To avoid mistakes, however, we urge that you do not enclose 2 or more different studies in a single box.

7. Mail to: ECDEU DATA ANALYSES
BIOMETRIC LABORATORY
11501 HUFF COURT
KENSINGTON, MARYLAND 20795

When data is received at the Laboratory, a notice will be sent acknowledging its receipt and giving an estimate of turnaround time. If, after a reasonable time, you do not receive this notice, notify the Laboratory so that tracing can begin.

ALTERNATIVE TYPES OF DATA SUBMISSIONS

In the majority of cases, submission of "complete study" data is logistically the preferred one since much of BLIPS has been predicated on this kind of input. Increasingly, however, investigators have made inquiries concerning alternative ways of submitting data. Consequently, the following types of data submissions are acceptable:

1. Partial submissions - Often, there is a need to examine data before a study is completed; e.g., multi-phase studies where one phase of the design is dependent upon the results of a preceding one. Given the need, investigators should inform the Biometric Laboratory of their requirements in detail - giving as much "lead-time" as possible.

2. Card Input - Data submitted in this manner is acceptable as long as it conforms to the standard ECDEU card formats. (p. 26). Investigators should recognize the need to undertake their own editing of the source documents; since BLIPS editing will necessarily be limited to the cards themselves. When absolutely necessary, card input with formats other than ECDEU will be accepted - provided the precise "non-standard" formats are stated.

3. Tape Input - Tapes may be submitted provided the following specifications are met:
   Tape Restrictions
   a. 9 track
   b. 1600 bits per inch
   c. Maximum block size = 32,000
   d. IBM mode
   Information Required
   a. Blocking factor
   b. Number of records
   c. Label information
   As noted with card formats, BLIPS editing is limited to the tape.

071 DS
DATA
SHIPMENT

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

DATA SHIPMENT (DS)

FOR BIOMETRIC LABORATORY USE

ECDEU NUMBER

DATE RECEIVED

PRINCIPAL INVESTIGATOR/S

TITLE OF STUDY

1. Have you previously submitted a Research Plan Report (21-RPR) for this study?

   ☐ Yes

   ☐ No *(If "No," please complete an RPR and enclose along with data. Studies can not be processed without an RPR.)*

2. Were there any revisions from the original protocol as described on the RPR which you have submitted?

   ☐ Yes *(If "Yes," please submit revised RPR)*

   ☐ No

INSTRUCTIONS

The Data Shipment form has been designed to facilitate processing of studies and to involve the investigator in the decision process regarding analyses to a greater extent than heretofore possible. In completing the form, the investigator can select or delete ratings and/or raters for analyses; construct a factorial design and request special analyses. For the Biometric Laboratory, the Data Shipment will serve as a "master control form" - selecting the appropriate programs for use in processing and analyses. Errors of patient assignment and/or period (rating) utilization can be minimized. Further, output displays can be labeled by drug name and/or other factor names. Since the form serves such a crucial role, *A DATA SHIPMENT FORM MUST ACCOMPANY THE DATA WHEN IT IS MAILED TO THE BIOMETRIC LABORATORY.* Answer all items as completely as possible. Should the form be inappropriate for your data or should you be uncertain about its completion, please contact the Laboratory.

ITEM I - INVENTORY OF FORMS

1. **New and Old Scales**
   For each scale, check whether new or old versions of the scales have been used in the study. The use of both the old and new versions of a single scale in a single study is discouraged since it complicates processing and increases the probability of error.

2. **Sheet Number**
   Sheet numbers routinely assigned to the standard scales are preprinted on the DS. When non-standard scales are employed, the investigator must assign the same Sheet number to a given data set throughout the study. Any 2-digit number not already assigned may be used.

3. **Time Unit**
   Indicate whether the time units are hours = H; days = D; weeks = W or months = M.

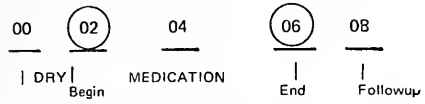
4. **Periods**
   For each scale, record all time periods (ratings) which were made during the study. The initial (first) rating should be designated "00"; others by the week (or other time unit) when they were made. *CIRCLE* the ratings where drug medication began and ended. *UNDERLINE* those periods (ratings) you wish to employ in subsequent analyses.

   EXAMPLES:

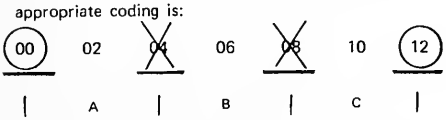
   a. A pretreatment rating is obtained following which medication is begun. Ratings are then made at 2 weeks and 4 weeks when medication is stopped. The investigator wishes to use only the first and last ratings in analyses. The correct coding is:

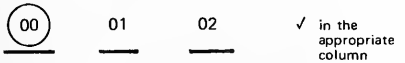
b. Ratings are made at the beginning and end of a 2-week drying out period following which medication begins. Ratings are also made at 4 and 6 weeks when medication is stopped. A final rating is made 2 weeks later. The investigator wishes to use all ratings in analyses. The appropriate coding is:



c. For CROSSOVER designs, designate the medication changeover points by x's. For example, three drugs A, B and C are alternated every 4 weeks and ratings are made every 2 weeks. Only ratings at the beginning and end of medications are to be used in analyses. The appropriate coding is:



5. Last Available Rating
A check in this box signifies that there was an uneven end point in the study, i.e., patients were terminated after different durations of treatment. For example; in a 4-week study with weekly ratings, the investigator found that all subjects completed at least 2 weeks of treatment and were rated at weeks 00, 01 and 02. However, some subjects were so improved that they could be terminated prior to the 4th week. He wishes to use all subjects in a repeated model design. He wishes to use the first 3 ratings (00, 01, 02) and the final rating for each subject whether it is the 03 or 04 week rating. The appropriate coding is:



6. Rater
For each scale, give the number/s of the rater/s. Circle those rater numbers which you wish used in analyses.

ITEM II - NON-ECDEU FORMS

This item is to be completed in the same manner as Item I with the exceptions of the columns named "Form" and "Matrix". Under Form, give the title of the scale or data set. For Sheet Number use any number not already assigned. Use the same Sheet Number for the same data set for all assessment periods. Under Matrix, give the numbers of the rows which encompass the items of the scale; e.g., a 25 item scale coded in Rows 1 to 25; give the numbers of the columns which encompass the scale points, e.g., a 5 point scale coded in Column 16 to 20. If the scale contains items with different number of scale points, e.g., some 3 point, 4 point and 5 point items, give the dimensions of the largest set of scale points, e.g., 5 points.

ITEM III - RATER IDENTIFICATION

This item becomes crucial if investigators contemplate conducting reliability studies across a number of trials. It is suggested that investigators try to use the same number for a rater who participates in a series of trials as this will simplify identification for both the investigator and the Biometric Laboratory. Do NOT use duplicate numbers in a single study.

ITEM IV - VARIANCE ANALYSES

The present analyses of variance/covariance (AVACOV) program used in BLIPS allows for a 4-factor design. RESERVING ONE FACTOR FOR PERIOD EFFECT, the investigator may designate the number of additional factors (maximum of 3) he wishes to employ in his statistical design. In the usual clinical trial, Factor 1 would be named "DRUG" and the drug/s employed in the study labeled as Group A, B, C, etc. Factors 2 and 3 can be any designated effect that the investigator wishes to study, e.g., age, diagnosis, hospital, chronicity, dosage, experimental manipulation, etc. A maximum of 10 groups may be categorized under any one factor. Part 2 of Item 4 asks for a choice of the standard variance models; while Part 3 provides for requests for special analyses.

EXAMPLES:

a. For a study in which only one drug (UGH) was employed; the coding is:

FACTOR 1.	Name	Drug
Group A		Ugh

This, in essence, would indicate a one-way analyses of periods.

b. Two drugs - WOW and GEE - were employed in the study, in addition, and the investigator wishes to test the effect of diagnosis - schizophrenic vs. nonschizophrenic. The coding is:

FACTOR 1	Name	Drug
Group A		Wow
Group B		Gee
FACTOR 2	Name	Diagnosis
Group A		Schizophrenic
Group B		Non-Schizophrenic

ITEM V - PATIENT IDENTIFICATION

This listing will be used for editing and processing procedures. In addition to the patient's number, sex and initials, the investigator is asked to categorize the factorial assignment of the patient. By specifically categorizing each subject, subsequent analyses can be checked for misassignment. Males are numbered 001 to 499; females 500 to 998.

EXAMPLE:

Patient 507, a female whose initials are ZZ, received the drug WOW during the study and she is not schizophrenic. *(See Item IV, example b. above).* The coding is:

Patient Number	Sex	Initials	Factor Assignment 1	2	3
507	F	ZZ	A	B	

ITEM VI - OUTPUT

Check whether one or two copies of the data package and one or two decks of cards are desired.

ITEM VII - DOSAGE DATA

This information is requested ONCE on this form rather than asking raters to complete it at every dosage change.

I. INVENTORY OF FORMS

SCALES New	Check	SHEET NUMBER	SCALES Old	Check	TIME UNIT	PERIODS	CHECK IF LAST AVAILABLE RATING TO BE USED	GIVE RATER NUMBER/S TO BE USED IN ANALYSES
27-CPRS		01						
28-CGI		01	12-CGI					
29-DOTES		02	03-TESS					
30-CDS		03						
31-CDC		03						
32-PTR		04	04-DSR					
33-TWIS								
34-CBI		20						
35-TQ								
36-PQ								
37-PTQ								
38-STESS								
39-NOSIE		20	07-NOSIE					
40-PLUT		20						
41-PANESS								
42-NGI		20	07-NOSIE					
43-CPDI		10						
44-CSH		11						
45 -APDI		12	01-PDI					
45 -TRAITS		13						
46-PMR								
47-BPRS		01	06-BPRS					
48-HAMA		01						
49-HAMD		01	08-HAM					
51-ASI		01						
52-WITT		01	11-WITT					
53-SCL90			10-SRSS					
54-SAS								

MH 9-71
4-73

I. INVENTORY OF FORMS

SCALES New	SCALES Check	SHEET NUMBER	SCALES Old	SCALES Check	TIME UNIT	PERIODS	CHECK IF LAST AVAILABLE RATING TO BE USED	GIVE RATER NUMBER/S TO BE USED IN ANALYSES
55-LAB			05-LD					
56-POMS								
57-SADJ		14						
58-DRI		14						
59-RCR								
60-WISC		15						
61-MAZE		15						
62-WRAT		15						
63-GOOD		15						
64-BENDK		15						
65-FROST		15						
66-PEBP		16						
67-WAIS		15						
68-BENDPS		15						
69-WMEM		15						
70-FTBS		16						

MH 9-71
4-73

II. NON-ECDEU FORMS

Complete this section only if you are submitting data from scales which are not part of the ECDEU Assessment battery. Copies of the scales and any relevant material would be appreciated and would aid in processing.

TITLE OF FORM	SHEET NUMBER	MATRIX - Coded in the following location				TIME UNIT	PERIODS	CHECK IF LAST AVAILABLE RATING TO BE USED	RATER NUMBER/S TO BE USED
		ROW		COLUMN					
		From	To	From	To				

III. RATER IDENTIFICATION

Complete items for all raters utilized in the study.

RATER NUMBER	RATER'S NAME *(First initial and last name)*	RATER NUMBER	RATER'S NAME *(First initial and last name)*

NOTE: When "multiple raters" are used; i.e., 2 or more individuals performing simultaneous or concurrent ratings of the same subject, and the investigator wishes to include this dimension in analyses, the raters should be identified under a factor entitled "Rater" (Item IV).

IV. VARIANCE ANALYSES

1. FACTOR IDENTIFICATION:

FACTOR 1:

Give Name _____

Group A _____

Group B _____

Group C _____

Group D _____

Group E _____

Group F _____

FACTOR 2:

Give Name _____

Group A _____

Group B _____

Group C _____

Group D _____

Group E _____

Group F _____

FACTOR 3:

Give Name _____

Group A _____

Group B _____

Group C _____

Group D _____

Group E _____

Group F _____

2. VARIANCE MODEL DESIRED:

Analyses of Variance - Regular Model _____

Analyses of Variance - Repeated Model _____

Analyses of Covariance - Regular Model _____

Analyses of Covariance - Repeated Model _____

3. SPECIAL ANALYSES: *(Describe)*

V. PATIENT IDENTIFICATION

Please complete all items. Use additional sheets if necessary. Males are numbered 001 to 499; females 500 to 998.

PATIENT NUMBER	SEX (M or F)	INITIALS (First - last)	FACTOR ASSIGNMENT			PATIENT NUMBER	SEX (M or F)	INITIALS (First - last)	FACTOR ASSIGNMENT		
			1	2	3				1	2	3

VI. OUTPUT

A. Number of Data packages requested: 1_____ 2 _____

B. Number of Card decks requested: 1_____ 2 _____

C. If two data packages/card decks are requested, should both sets be sent to you?

☐ YES
☐ NO If NO, give name and address of other recipient:

_____

_____

_____

D. Do you want the original data forms returned to you? ☐ YES ☐ NO

To another address? ☐ YES ☐ NO

If YES, give name and address of recipient:

_____

_____

_____

VII. DOSAGE DATA

Check appropriate units for dosages coded on Dosage Record and Treatment Emergent Symptoms (DOTES) for each treatment group.

DRUG GROUP	UNITS *(Check)*				
	mg	mcg	gm	mg/kg	Other *(Specify):*
A					
B					
C					
D					
E					
F					

FOR BIOMETRIC LABORATORY USE ONLY

	Start	Finish	Comments
CODE:			
OPSCAN:			
EDIT:			
ANALYSES:			

Date mailed: _____ Editor: _____

Developed within the ECDEU program, the Data Shipment contains 7 items and is designed to supply information necessary for BLIPS processing. Not in opscan format, the data from DS are key-punched and serve as control cards to select the appropriate programs for processing.

APPLICABILITY - All research populations

UTILIZATION - Once per study - when shipping data to the Biometric Laboratory

CARD FORMATS - Cards generated from the DS are used internally by the Biometric Laboratory for data processing.

SPECIAL INSTRUCTIONS

Instructions are printed directly on the form. Since DS information is essential to BLIPS processing, this form is MANDATORY and must be submitted with shipments of data. If uncertain about completing the DS or any of its items, the investigator is urged to contact the Biometric Laboratory.

Item 1. Inventory of Forms - The shaded areas within the item indicate that no entries are required. These data are used to:

a. Identify and locate each scale used in a study.

b. Record the total number of assessment periods as well as those to be used in subsequent analyses.

c. Call forth the appropriate programs for the editing and routine displaying of the data.

CDS - While the Children's Diagnostic Scale (CDS) is usually employed only at pretreatment, some investigators may want to use the first 8 items for repeated assessment. Encoding of these two usages is as follows:

At pretreatment only

As repeated measures (pre-post)

PQ and TQ - Since the Parent Questionnaire and Teacher Questionnaire can be used for repeated assessments by themselves or in conjunction with the Parent-Teacher Questionnaire, (PTQ), investigators may have difficulty in describing their usage

of these scales. Examples - In a 6-week study, the investigator makes an initial rating and 3 subsequent ratings at 2-week intervals using the PQ and TQ at each rating. Encode as follows:

35-TQ	✓				W	00, 02, 04, 06		25
36-PQ	✓				W	00, 02, 04, 06		11
37-PTQ								

The investigator, using the same assessment schedule as above, uses the PQ and TQ only at the initial rating - substituting the PTQ at the 3 subsequent ratings. Encode as follows:

35-TQ	✓				W	00,		25
36-PQ	✓				W	00,		11
37-PTQ	✓				W	02, 04, 06		11, 25

STESS - This scale may be rated by the subject and/or a parent or other knowledgeable adult. If the investigator wishes to indicate that he has used concurrent ratings - the subject (S = 00) rating each week for 4 weeks and his mother (M = 11) rating every 2 weeks for 4 weeks, he would encode as follows:

38-STESS	✓				W	00, 01, 02, 03, 04 00, 02, 04		00 11

PMR - No recording of PERIODS is necessary for Prior Medication Record. The lack of shading on the form is an error and it should have been printed as follows:

46-PMR								

Item 11. Non-ECDEU Forms - This item serves the same purpose as Item 1, but requires an alternative set of programs for processing. Location of the data matrices for each non-standard scale is particularly crucial. To insure precise labeling and correct interpretation in data displays, it is strongly

suggested that a copy of the instrument - showing items and scale points - be sent to the Biometric Laboratory. If the data is composed of factor or cluster scores, their names, the data fields they occupy and the range of the scale points should be given. Should the investigator wish to have the Biometric Laboratory "factor score" the items on the basis of his own factor analysis, inclusion of the item composition of each factor is required. The more information an investigator can supply about a non-standard data set; the less likely it will be that BLIPS makes an error.

Item IV-3. Special Analyses - The investigator can describe additional analyses here. It should be kept in mind that special analyses requests will have a lower priority than routine (standard) analyses. An investigator requesting special in addition to standard analyses will receive lower priority ONLY for the special requests.

Item V. Patient Identification - This item provides both a clerical and a computer check of patient identity and treatment assignment. The item conveys the necessary information for the identification of data while maintaining the anonynimity of the subject. Only the principal investigator will know the identity of the subjects and this identity cannot be ascertained from the data package or, later, when the data are entered into the data bank. By asking for treatment assignment once, the rater's task will be reduced, i.e., he need not encode treatment assignment for each subject on several scales as the earlier BLIPS required.

Item VI. Output - Here the investigator can specify how many copies of the data package and card decks he desires as well as to whom they should be sent. It is necessary to state the number at this time, since a later request for an additional package would require a complete "rerun" of the study. By requesting here that a copy of the data package be sent to another part, e.g., a drug firm, the investigator is assumed to be giving his formal consent for such transmission of data.

Item VII. Dosage Data - By asking for this information here and only once, raters will be spared the task of marking "units" ad nauseum throughout a study. Computer programming will insert "units" in the appropriate data displays.

DOCUMENTATION
(The Data Package)

Documentation refers to the presentation of data in a manner which describes what happened during a study and permits inferences to be drawn from it. It is vital, therefore, that the documentation depict the events of the trial as accurately and comprehensibly as possible. All too frequently, failure to document a trial properly has led to incomplete or ambiguous findings which make it impossible to arrive at a substantive judgment of the trial itself or to compare its results with other similar trials. The effects of the drug cannot be assessed under these conditions and its true merits may be obscured.

For many, the first exposure to computer output can be bewildering. The neophyte finds himself lost in the bulk of the package; and, even upon finding the location he desires, he is confused by the way in which the data is presented. He must learn to "decipher" the output before he can begin to interpret the findings of his study. Experience with the adult standard package has shown that there are almost as many inquiries relating to "deciphering" as there are regarding the interpretation of results. In the majority of these instances, more elaborate labeling - in English - would have avoided the need for "deciphering".

In the 10 years of its existence, the BLIPS data package has undergone repeated changes in an attempt to increase its clarity and comprehensiveness. The pressure of service requirements necessitated the introduction of changes in the package one by one - rather than by a systematic overhaul. Coincident with the introduction of the new Battery, major revision of the Biometric Laboratory Information Processing System has been undertaken. The major goals of this revision (called BLIPS II) are to increase the efficiency and generalizability of processing and to enhance the clarity of documentation. The concept of a standard data package remains; since, in concert with a standard assessment battery, it has proven advantageous as a method of documenting the single trial and for facilitating comparisons across several trials. In order that the uniqueness of a trial is not lost, however, a greater degree of variation within the standard package has been introduced in the form of increased display and analytic options.

THE PROCESSING SYSTEM (BLIPS II)

The Biometric Laboratory Information Processing System (BLIPS) is a fully operational, integrated series of computer programs that produce documentation for a variety of scientific data inputs. Since 1967, BLIPS has produced documentation for over 500 clinical drug trials conducted by 80 different investigators and involving approximately 17,000 patients. Based on a common assessment battery and standard documentation, BLIPS, nevertheless, attempts to minimize the constraints placed upon the investigator.

In its original version, BLIPS consists of numerous programs which were each designed to process a particular form. This created processing and analytic weaknesses whenever deviations from preprogrammed designs occurred. In 1972, BLIPS was extensively modified - and designated as BLIPS II - with the following objectives in mind:

1. Flexibility to process any scientific data which may be converted to computer readable form.

2. Exhaustive verification of data validity.

3. Simplification of external controls to a level at which non-technical personnel can manage routine system operations.

4. Capability to produce a final documentation report tailored to the investigator's needs.

Acceptable input data may be any type which can be converted into computer readable form. At the present, however, most data are recorded on assessment instruments designed to be processed by an optical scan reader device. Through use of the universal answer sheet and certain control information, any non-standard assessment instrument may also be entered into the system. The merits of such non-standard instruments can be analyzed and, if warranted, added to the standard Battery, thereby increasing its capability.

The verification of data validity is executed by an error detection and correction subsystem which is called the preprocessor. The preprocessor consists of basic and specialized functions which detect missing information, duplicate identification fields, invalid entries and the logical consistency of interrelated items either within a single form or across several forms; e.g., the natural mother's age should not be less than or equal to her children's ages. When errors are detected, they are corrected via punched cards. These cards contain all the necessary information to locate the exact field within the data file where the correction is to be inserted and correspond in format to an error listing which is produced as a visual aid. The correction cards are resubmitted to the system. The preprocessor will then make the corrections and reprocess the data set. This process is repeated until no further errors are detected.

To maintain the external control at a level which non-technical personnel can manage, the transformation and analysis of the data is done via a semi-automated subsystem called DATRAN. Fixed control information needed to process the data is stored permanently on disk, while the variable control information, e.g., the number of patients, the number of assessment periods, etc., is generated via a series of programs which examine the data as well as the Data Shipment form, completed by the investigator. In addition to self-generating complex control information, the subsystem will select the appropriate combination of procedures necessary to fully analyze the data. This selection is performed by testing criterion variables such as forms used in the drug trial, number of patients in the study, analysis desired, etc. The subsystem will run fully automated until new assessment instruments are introduced. Then additional control information must be generated to process the new entries.

To obtain a final documentation report tailored to meet most of the needs of the investigator, an output generator subsystem transforms the output obtained from existing analysis programs. This subsystem provides extensive labeling information; merges several data sets, and combines the results to facilitate comparisons and make interpretation an easier task for the investigator. An indexed, paginated document is the final product.

CONTENTS OF STANDARD DATA PACKAGE

The bulkiness of a data package necessarily varies from study to study depending upon the number of subjects, scales, and rating periods. The output for a given scale, however, is standardized regardless of the size of a study. For small studies, this may give the package the appearance of overelaborateness; while, for larger studies, the output may seem pedestrian. This lack of precise tailoring is inevitable, however, in a system which attempts to cover the diversity which exists among psychotropic drug trials. The usual order of presentation in the data package is as follows:

1. Table of Contents
2. Narrative Summary
3. Patient Listing
4. Data Inventory
5. Demographic Data
    a. Adult or Children's Personal Data Inventory
    b. Prior Medication Record
    c. Children's Symptom History
    d. Children's Diagnostic Scale and Children's Diagnostic Classification
    e. Patient Termination Record
6. Efficacy Data
    a. Psychiatric Rating Scales; *e.g., 028-CGI, 047-BPRS, 049-HAMD, etc.
    b. Paraprofessional Rating Scales; e.g., 035-TQ, 039-NOSIE, etc.
    c. Self-Rating Scales; e.g., 054-SAS, 073-SDS, etc.
    d. Psychological Tests; e.g., 060-WISC, 062-WRAT, etc.
    e. Social Adjustment Scales; e.g., 057-SADJ

*Within each subgroup, scales are ordered by number.

7. Adverse Reaction Data
    a. Dosage Record and Treatment Emergent Symptoms (Including 033-TWIS)
    b. Laboratory Data
    c. Subject's Treatment Emergent Symptom Scale
8. Medical Data
    Physical and Neurological Examination for Soft Signs
9. Non-standard Data
    Scales are ordered by number
10. Multi-instrument displays
    Presentations of data from two or more scales
11. Error Diagnostics

Data displays for the individual assessment instrument are arranged as follows:

1. Legend
2. Raw score printout
3. Computed score printout
4. Means and standard deviations
5. Frequency tables
6. Cross tabulations
7. Graphic displays
8. Variance analyses

While not every display is present for each and every instrument, the order of the displays is maintained throughout.

The standard package has evolved through the continual exchange of ideas among investigators, Biometric Laboratory and Psychopharmacology Research Branch. Data displays have been designed to provide maximal acuity and relevance to the clinician. Information regarding the individual subject as well as the various treatment groups has been provided in a variety of displays to increase the utility of the analyses and to provide meaningful clinical comparisons. In the design of the standard data package, a basic objective has been the utilization of all items in the assessment battery. Considering the great expenditure in time, effort and resources which goes into the collection of data, it is obligatory to generate an output which maximally utilizes the available material. Output has been therefore universally generated on an idiographic and a nomothetic level - enabling the investigator to follow the progress of individual subjects as well as to compare various treatment groups.

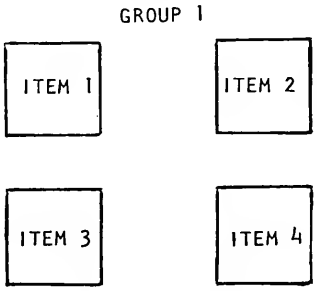
There are a number of general features in the new package which should increase its utility.

1. Consistent with legibility, the bulkiness of the package has been reduced by conserving space whenever possible.

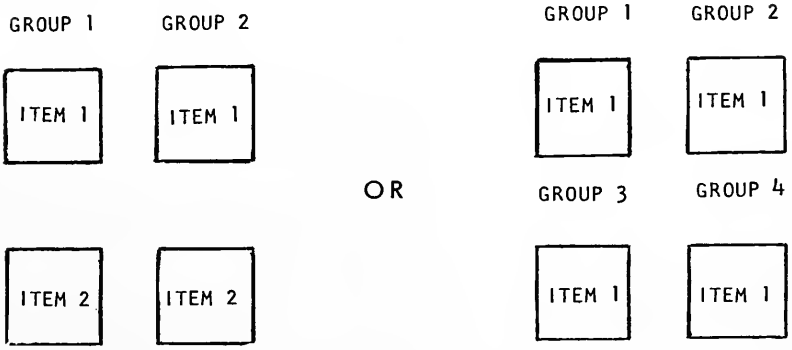
2. Since study protocols and the number of scales used are not fixed by BLIPS, pagination of the package has been difficult to routinize. These problems, however, have been overcome, and pagination is now a standard part of the data package.

3. Preceding each data subset, i.e., all the data relating to one assessment instrument, a legend - defining all terms used in the subsequent displays - is provided.

4. For convenience in comparing treatment groups, equivalent data displays are juxtaposed on the same page. In earlier data packages, all displays relating to a treatment group were located together - making direct comparisons between groups difficult. Using the crosstabulative display as an example, the earlier package had the following alignment on a single page:



The new alignment juxtaposes treatment groups as follows:



EDITING AND ERROR DIAGNOSTICS

The editing of data has been, by far, the most time-consuming element in BLIPS. The procedure has been complicated by the fact that errors can enter the system by three avenues: the rater, BLIPS editors and machine (op-scan) malfunctions. Errors by BLIPS editors have been substantially reduced by shifting the responsibility for coding the identification block to the investigator. While experience with the system has reduced errors from all sources, the preparation of data for analyses remains most vulnerable to delays. In dealing with the problem, the central premise has been to transfer human effort to computer operations insofar as possible. Thus, there has been a continuous development of editing programs especially designed to prepare diverse data sets for standard BLIPS analyses.

The frequency of errors attributable to the rater seems inversely proportional to the length of his experience with the forms. Neophyte raters tend to make a higher proportion of errors of commission in comparison to errors of omission. These consist primarily of illegal marks and enscribers, mutilated forms and unidentifiable subjects or assessment periods. With experience, these commission errors diminish and errors of omission remain the primary problem.

The major portion of error detection is carried out by computer programs. An error is first specifically located, then defined and space provided for correction in an error diagnostics listing. Any and all errors are cited even though, in a specific study, certain items may have been purposely deleted by the investigator. Number and frequency of errors is summarized for each form and a table of this summary comprises part of the error diagnostics listing. (Table 37). Both the quality and quantity of errors serve as bases for the decision whether to proceed with analyses. A significant proportion of errors in any given study can be corrected by BLIPS personnel. For example, poorly erased changes or extraneous marks within the response areas of the forms will often produce multiple op-scan punches. Such errors are usually readily detectable and can be corrected without recourse to the investigator. However, BLIPS editors never presume what an ambiguous response should or might represent. In all cases, resolution of the ambiguity resides with the investigator.

The error citations employed in error diagnostics are defined as follows:

CITATION	DEFINITION
Missing	Item or part of item is missing, e.g., item requiring 3 digits is encoded with two.
Illegal	Item requiring only one entry contains two or more entries or the entry is out of range; e.g., a 4 is encoded for a 3-point item.
Logical	Two or more items are logically inconsistent; e.g., one cannot be the 5th child of a cohort of 3, diarrhea and constipation are present simultaneously.
Identification	Error occurs within the identification block.
Data	Error occurs within the data matrix.

TABLE 37

SCHEMA FOR ERROR DIAGNOSTICS

STUDY NO.	INVESTIGATOR NAME	STUDY TITLE	DATE	PAGE NO.

SCALE NAME

PAT	PER	RAT	ITEM	ERROR	STATUS
XXX	XXX	XX	XX	-----	C
XXX	XXX	XX	XX	-----	(BLANK)

C = CORRECTED BY BLIPS

(BLANK) = NOT CORRECTED

LOGICAL = TWO OR MORE ITEMS ARE INCONSISTENT

MISSING = RESPONSE OR PART OF RESPONSE IS MISSING

ILLEGAL = RESPONSE IS UNACCEPTABLE: E.G., MULTIPLE ENTRIES, OUT OF RANGE

IDEN = IDENTIFICATION FIELD

DATA = DATA FIELD

ERROR SUMMARY

FORM	ORIGINAL IDEN	ORIGINAL DATA	TOTAL BEFORE EDIT	TOTAL AFTER EDIT
XXX	XX(%)	XX(%)	XX(%)	XX(%)
ALL	XX(%)	XX(%)	XX(%)	XX(%)

BEFORE EDIT = FREQUENCY AND PERCENT OF ERRORS IN ORIGINAL DATA SET
AFTER EDIT = FREQUENCY AND PERCENT OF RESIDUAL ERRORS FOLLOWING EDITING

RAW AND COMPUTED SCORE LISTINGS

When the editing process is completed and retrieval of erroneous data accomplished, raw and computed scores are generated in tabular form. Descriptive headings; e.g., patient, period and rater numbers, are given along the top of the table: data are displayed in columns. (Table 38). When possible, items are labeled, but for lengthy scales, item numbers are used. Spacing between sets of items, e.g., every 5, every 10, etc., aids in locating a specific item.

Computed scores are obtained by combining raw item scores according to some rule or set of operations. Most common are factor scores in which item scores are statistically combined on the basis of a factor analysis. Empirical clusters; i.e., combinations on the basis of logical decisions developed from clinical experience, are another example. Since many of the scales used in the Pediatric Battery are newly developed, cluster scores will be employed until sufficient data are collected for factor analytic procedures. Displays for computed scores follow the same format as raw scores.

MEANS AND STANDARD DEVIATIONS

These displays differ from raw and derived score printouts in that they present nomothetic (group) rather than idiographic (individual) data. Means, standard deviations and number of subjects involved in their calculations are displayed by period along the vertical; items by group(s) and total sample appear as headings along the horizontal. (Table 39). Grand item means and standard deviations for each group and the total sample are displayed following the last assessment period.

FREQUENCY TABLES

This display is used primarily for categorical data such as demographic items, descriptive events, etc. Items and their response positions are listed vertically; frequency and percent of occurrence by group and total sample along the horizontal. (Table 40). Means and standard deviations are also supplied where relevant. Because of their complexity, some items, e.g., Family Psychiatric History, require special formatting or computation; e.g., Social Class.

CROSS-TABULATION

The purpose of cross-tabulation is to condense and organize data so that directional changes can be readily detected. The usual comparison is between pre and post-treatment data although any two sets of data may be compared. The schema below illustrates some general principles of interpretation. The diagonal (AD) contains those cells in which patients exhibit no pre/post changes in rating. The upper triangle, ABD, contains cells in which some degree of improvement is rated. As cells approach pole B, greater degrees of improvement are implied. Conversely, the lower triangle, ACD, reflects degrees of exacerbation - greater degrees as pole C

TABLE 38

SCHEMA FOR RAW, FACTOR OR OTHER COMPUTED SCORES

STUDY NO. INVESTIGATOR'S NAME STUDY TITLE DATE

ITEMS GP

RAT	PER	RAT	1	2	3	4	5 ——— N	GP
001	000	02	X	X	X	XX	XXX	1
001	012	02	X	X	X	XX	XXX	1
002	000	02	X			XX	XXX	
020	012	02						2
021	000	03						2
021	012	03						

PAT = PATIENT NUMBER
PER = PERIOD NUMBER: 3RD DIGIT REPRESENTS TIME UNIT
RAT = RATER NUMBER
ITEMS = ITEM NAMES (ABBREVIATED) WILL BE USED INSTEAD OF NUMBERS WHERE SPACE PERMITS
GP = GROUP ASSIGNMENT
1,2 = TREATMENT GROUPS WILL FOLLOW ONE ANOTHER: TEST DRUG NO. 1; TEST NO. 2; COMPARISON NO. 1; ETC.

PAGE NO.

TABLE 39

SCHEMA FOR MEANS AND STANDARD DEVIATIONS

STUDY NO. INVESTIGATOR'S NAME STUDY TITLE

SCALE NAME

PERIOD		GP 1	GP 2	GPn	SAMPLE
00	N	XXX	XXX	XXX	XXX
	MN	XXX	XXX	XXX	XXX
	SD	XXX	XXX	XXX	XXX
07	N	XXX	XXX	XXX	XXX
	MN	XXX	XXX	XXX	XXX
	SD	XXX	XXX	XXX	XXX
TOTAL	N	XXX	XXX	XXX	XXX
	MN	XXX	XXX	XXX	XXX
	SD	XXX	XXX	XXX	XXX

GROUP MEANS (MN) AND STANDARD DEVIATIONS (SD) ARE CALCULATED FOR RAW OR COMPUTED SCORES (WHICHEVER IS APPROPRIATE) FOR EACH RATING PERIOD. SAMPLE MEANS (ROW MEAN) PROVIDE DATA FOR THE ENTIRE POPULATION AT EACH PERIOD. GRAND MEANS (COLUMN MEAN) FOR ALL PERIODS ARE GIVEN FOR EACH GROUP AND FOR THE ENTIRE SAMPLE.

ITEM 2

PAGE NO.

TABLE 40

SCHEMA FOR FREQUENCY TABLES

STUDY NO. INVESTIGATOR'S NAME STUDY TITLE

SCALE NAME

VARIABLE	GP 1	GP 2	GP_n	SAMPLE
NO SUBJECTS	XX	XX	XX	XX
VARIABLE 1				
RESPONSE 1	XX(XX)	XX(XX)	XX(XX)	XX(XX)
RESPONSE 2	XX(XX)	XX(XX)		
RESPONSE 3	XX(XX)			
MISSING	XX(XX)			
MEAN	XXX			
SD	XXX			
VARIABLE 2				

XX(XX) = FREQUENCY (PERCENT)
GP = GROUP
SAMPLE = FREQUENCY AND PERCENT FOR ENTIRE POPULATION
MEANS AND SD ARE GIVEN ONLY WHEN APPROPRIATE.

PAGE NO.

is approached. The cell at pole A contains patients who are asymptomatic; pole B, the zenith of treatment success; pole C, the nadir of treatment failure and pole D, the "untouchables" - sickest at pretreatment and sickest at posttreatment.

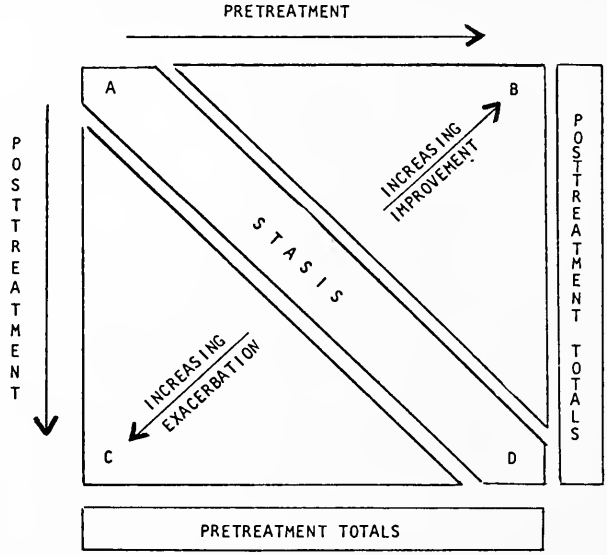


Table 41 represents a cross-tabulation of the BPRS symptom, Somatic Concern. The distribution of 15 pre and posttreatment ratings on a 7-point scale ranging from NOT PRESENT to EXTREMELY SEVERE is shown. Pretreatment scores (presum) are read horizontally; (7 = Not Present; 2 = Very Mild; 4 = Mild, etc.); posttreatment scores (postsum) vertically (8 = Not Present; 4 = Very Mild, etc.). The diagonal of the matrix is emphasized by underlining. Scores which fall here reflect static scores, i.e., scores which remain at the same intensity level at both ratings. When both pre and posttreatment scores are "NOT PRESENT", this is designated as asymptomatic. Asymptomatic is, of course, a variant of a static score and, in the example, there are 4 asymptomatic subjects. Any scores above the diagonal represent improvement; any below represent worsening (increased severity). Three subjects, for example, changed from "Mild" at pretreatment to "Very Mild" at posttreatment. One subject changed from "Not Present" at pretreatment to "Moderately Severe" at posttreatment - a change of 4 points in a negative direction.

TABLE 41

SCHEMA FOR CROSS TABULATIONS

STUDY NO. INVESTIGATOR'S NAME STUDY TITLE DATE
047-BPRS BRIEF PSYCHIATRIC RATING SCALE

GP 1

GP 2

SOMATIC CONCERN

POST TREATMENT		NP	VM	MI	MO	MS	SV	ES	NA	POST SUM
	NP	4	1	1	2	0	0	0	0	8
	VM	0	1	3	0	0	0	0	0	4
	MI	1	0	0	0	0	0	0	0	1
	MO	1	0	0	0	0	0	0	0	1
	MS	1	0	0	0	0	0	0	0	1
	SV	0	0	0	0	0	0	0	0	0
	ES	0	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0	0
PRESUM		7	2	4	2	0	0	0	0	

TOT N = TN-NA = ASYMPT = 4(27)

STAT = 1 (7) + CHANGE = 7(47); - CHANGE = 3(20)

VARIABLE 2

4 CROSSTABS CAN BE PLACED ON A PAGE. IF MORE THAN 2 GROUPS, GROUP 3 AND 4 WILL BE PLACED IN LOWER LEFT AND RIGHT POSITIONS. WITH ONE OR TWO GROUPS, NEXT VARIABLE WILL APPEAR IN LOWER ROW.

NP	NOT PRESENT	POSTSUM	POSTTREATMENT SUM
VM	VERY MILD	PRESUM	PRETREATMENT SUM
MI	MILD	TOT N	TOTAL NO. OF SUBJECTS
MO	MODERATE		
MS	MODERATELY SEVERE	TN-NA	TOTAL NUMBER-NOT ASCERTAINED
SV	SEVERE	ASYMPT	NO.(%) SUBJECTS RATED NP AT BOTH PERIODS
ES	EXTREMELY SEVERE	STATIC	NO.(%) SUBJECTS RATED AT SAME INTENSITY AT BOTH PER. (NO CHANGE)
NA	NOT ASCERTAINED AND/OR NOT ASSESSED	+ CHANGE	NO.(%) SUBJECTS SHOWING POSITIVE CHANGE (IMPROV'MT)
		- CHANGE	NO.(%) SUBJECTS SHOWING NEGATIVE CHANGE (WORSENING)

PAGE NO.

Cross-tabulation accomplishes data reduction and facilitates interpretation of group results without losing sight of the individual patient. The exact nature of changes between two ratings can be followed in detail irrespective of sample size or tests of significance. Cross-tabulations can be examined to ascertain whether the result is due to modest unidirectional changes in a large proportion of the sample or to dramatic changes in a few individuals. Noting bipolar changes, the investigator may find that specific subgroups are responding differentially under the same drug condition. It should be remembered, however, that cross-tabulation involves comparison between only two ratings. Investigators are cautioned that changes may have occurred at other points in the course of the study, e.g., pre vs. posttreatment ratings will not reveal changes which occur at the midpoint of a study. Perusal of other data sets; e.g., means and SD, variance analyses, will alert the investigator to the possibility of change not revealed in the cross-tabulations.

GRAPHIC DISPLAYS

These displays are of two types. The first presents data derived from a single assessment instrument in unaltered raw form. Only the format is changed to facilitate rapid assimilation of results. In Figure 26 pre and posttreatment factor means obtained from a hypothetical scale are shown and, further, data for 2 treatment groups are juxtaposed - greatly increasing the usefulness of the display. Graphics of this type will be employed in BLIPS II to a much greater extent to present, in addition to the traditional pre-post differences, data from diagnostic instruments; e.g., Children's Diagnostic Scale and from analogous instruments; e.g., Depression Status Inventory vs. Self-Rating Depression Scale; Parent vs. Teacher Questionnaires, the 10 common items from each, as rated by the parent vs. the teacher.

The second type of graphic involves the conversion of data from several assessment instruments into standard scores and their presentation in one composite display. Conversion into standard scores, of course, does not alter the relative magnitude of data while permitting instruments with differing scale points to be plotted together for rapid comparison. (Figure 27). Routinely, standard scores will be based on sample parameters. For each variable, the sample mean and standard deviation will be calculated and a standard score, for each treatment group derived on that basis. The formula for conversion is:

$$\text{Group Standard Score} = 50 + \frac{10\ (\text{Group Mn} - \text{Sample Mn})}{\text{Sample SD}}$$

Norms for various research populations are currently being constructed for most of the standard ECDEU assessment instruments and will be employed in future BLIPS documentation.

FIGURE 26

SCHEMA FOR GRAPHIC DISPLAY FOR SINGLE ASSESSMENT INSTRUMENT

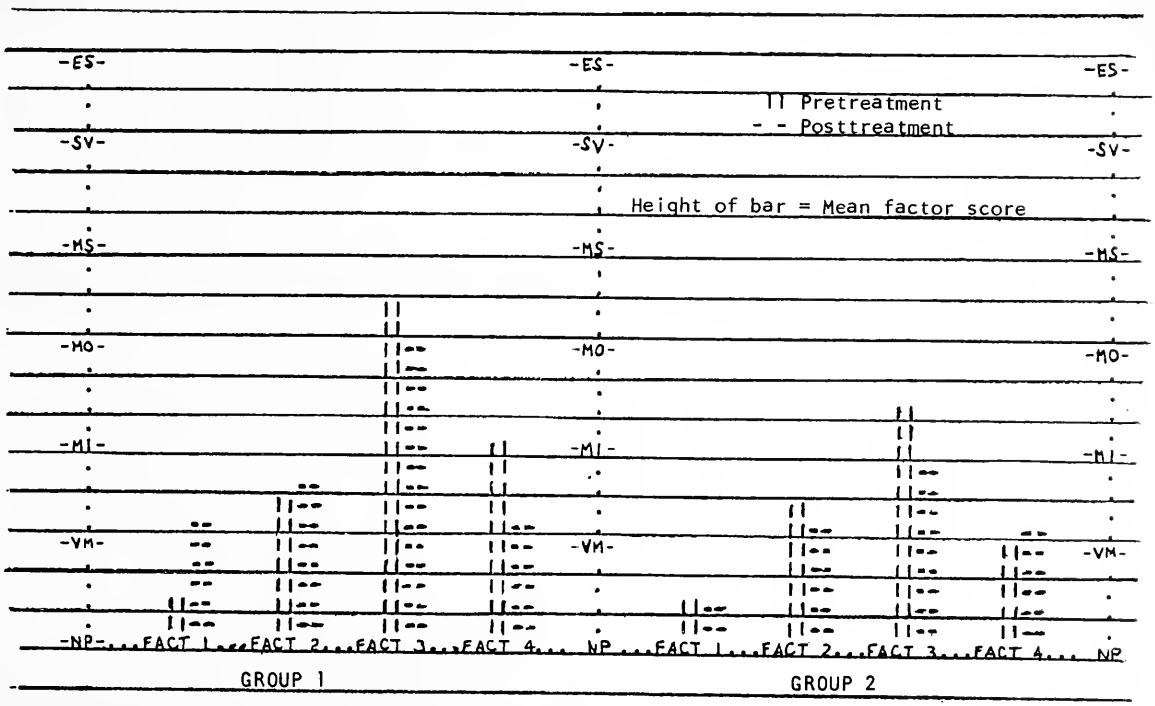
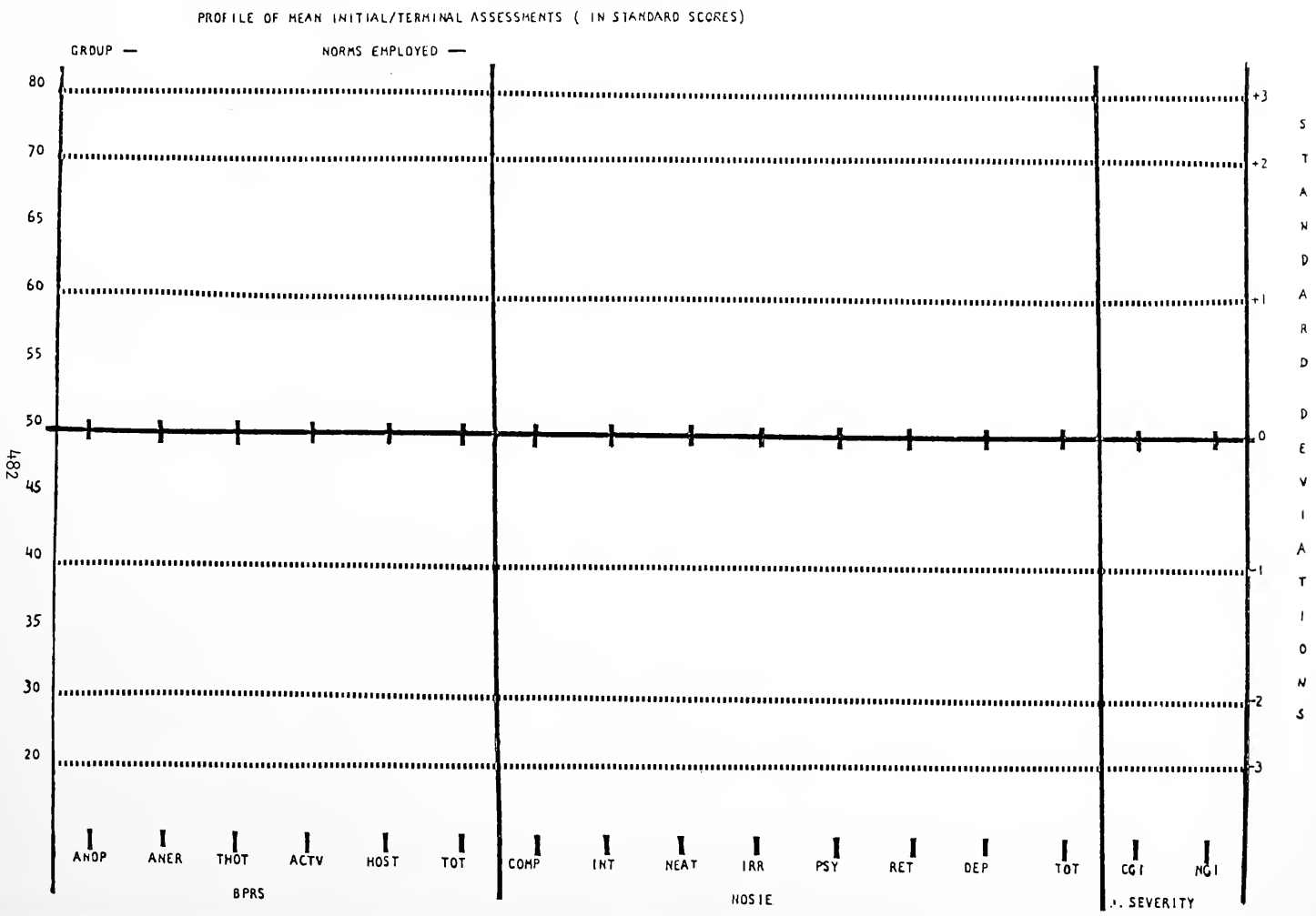


FIGURE 27

SCHEMA FOR GRAPHIC DISPLAY FOR COMBINED INSTRUMENTS



DATA INVENTORY

The Data Inventory serves two purposes:

1. For an individual study, a subject by subject itemization of each form present in the data matrix.

2. Across studies, the source material for a cumulative inventory of the contents of the ECDEU data bank.

Table 42 illustrates the display provided for the individual study. The dots indicate "present" - the crosses "absent". Totals are provided for each form by subject, assessment period and grand sum. The inventory gives the investigator an accurate picture of the magnitude and distribution of his data matrix and provides a basis for decisions on further data transformations or analyses.

Cumulative inventories are generated across all studies in the ECDEU data bank. The number of forms, subjects, studies and items is summed for each rating scale as well as across all scales. This display - while not part of the standard data package - provides periodic information to members of the ECDEU program regarding the magnitude and distribution of the total data bank at a given time and, in conjunction with preceding inventories, an estimate of the rate of growth of the bank. It also provides a general estimate of the amount of data available for any particular research purpose.

THE ANALYTIC COHORT

Preceding each statistical analyses, a listing of subjects excluded from that analysis along with the reason for exclusion is given. (Table 43). The display continues with a listing of all subjects included in the analysis as well as the periods and raters used. Specification of the analytic cohort has proved to be highly desirable for interpreting the results of any statistical analyses performed.

NARRATIVE SUMMARY

The Narrative Summary provides the investigator or reviewer with an overview of the study. Though brief, it contains sufficient detail to enable the reader to grasp the essential nature of the study and its results. As with all other segments of the standard package, the Narrative Summary is non-judgmental and contains only statements based directly on the data received and the analyses performed. Final judgment as to the clinical meaningfulness of the data or the efficacy of the drugs involved remains entirely with the investigator. Narrative summaries consist of four paragraphs:

1. Description - Data are derived from the Research Plan Report and consist of details of the research design, the drugs and dosages employed and the research procedures.

2. Efficacy - derived primarily from variance analyses. All statistically significant findings - or their absence - are cited for each of the psychopathological rating scales employed.

3. Toxicity - Derived primarily from Dosage Record and Treatment Emergent Symptom Scales. Toxicity is described in terms of the number and kinds of symptoms evolving under each treatment condition, as well as the clinical actions necessitated by the emergence of such symptoms.

4. Demography - Derived primarily from the Adult or Children's Personal Data Inventory. Distributions for a number of pertinent demographic variables are given for each treatment group.

TABLE 42

SCHEMA FOR DATA INVENTORY

STUDY NO. INVESTIGATOR NAME STUDY TITLE

FORM NAME

	PERIOD				
SUBJ	0	1	2	N	TOT
1	•	•	•	•	10
2	•	X	•	•	10
N					
TOT	10	10	10	10	100

THE INVENTORY TOTALS EACH FORM BY SUBJECT (ROW TOTAL) AND BY SAMPLE (COLUMN TOTAL).

• = FORM PRESENT FOR THAT PERIOD

X = FORM MISSING FOR THAT PERIOD

FORM NAME

	PERIOD		
SUBJ	0	2	TOT
1	•	•	10
2	•	X	10
N			

THE SUMMARY TABLES PRESENT THE TOTAL NUMBER OF FORMS FOR EACH PERIOD.

SUMMARY TABLES

	PERIOD			
FORM	0	1	2	N
27	20	20	20	20
28	20			
N	50	50	50	50

TABLE 43

SCALE NAME

SCHEMA FOR ANALYTIC COHORT

STUDY NO. INVESTIGATOR NAME STUDY TITLE
SCALE NAME

SUBJECTS EXCLUDED FROM (FORM X) ANALYTIC COHORT

PAT	GROUP	REASON FOR EXCLUSION
XXX	1	MISSING PERIOD
XXX	1	MISSING PERIOD

IF NO SUBJECTS ARE EXCLUDED FROM AN ANALYSES, THE DOCUMENTATION WILL SO STATE. THE LISTING OF EXCLUSIONS IS FOLLOWED BY A SEPARATE LISTING GIVING THE SUBJECTS INCLUDED IN THE ANALYSES.

PAT	PER	RTR	CARD	GROUP
001	000	01	51	1
001	063	01	51	1
002	000	01	51	1
002	063	01	51	
017	000	01	51	2

COMMENTS ON STATISTICAL PROCEDURES

P. A. Cleary and K. Yang

This discussion is divided into three areas. The first deals with the repeated measures analysis of variance and the use of stricter criteria in detecting significance for the within-subject variables. The second part concerns the multiple comparisons problem. By focusing on two methods it is expected that the decision to use a particular technique will be made clearer to our audience. The last section is an explanation of the displays of the statistical methods just discussed.

Those statistical techniques previously introduced in BLIPS I[10] are not discussed here. These comments are not intended as definitive but only as guidance.

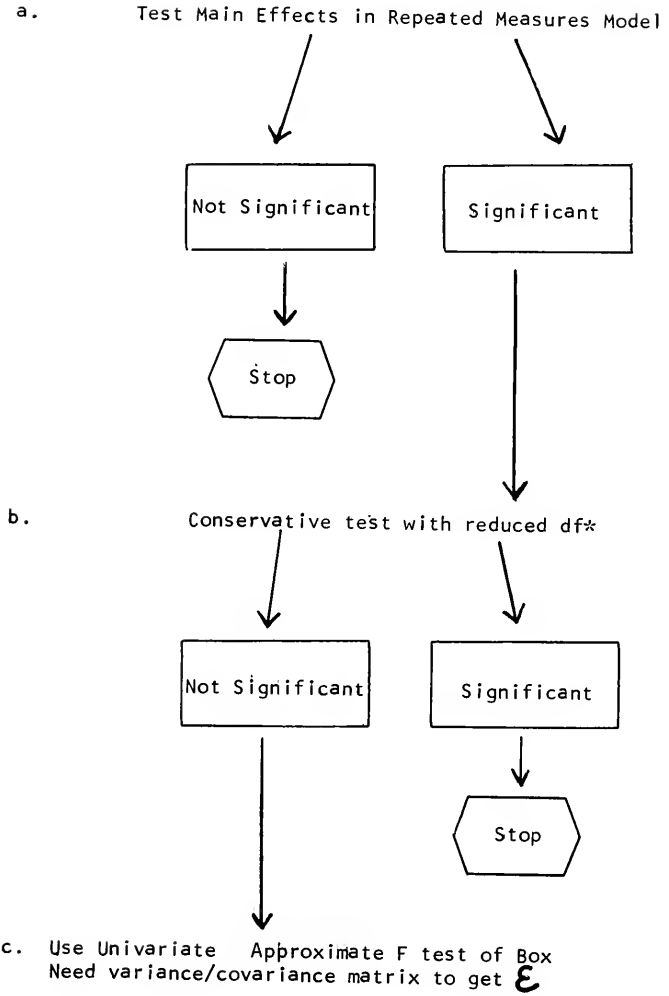
Repeated Measures Model

A popular research design in psychopharmacological research is the analysis of variance model in which a single dependent variable is measured on more than one occasion on the same subjects. This is often called a repeated measures analysis of variance. Several authors (1, 2, 3, 4) have discussed the problems which arise when this type of analysis is performed. One of the more serious problems is the distortions of p levels and confidence levels caused by the heterogeneity of covariance. The conclusions drawn are that multivariate tests are exact with repeated measurements but in many instances the n is too small. It is suggested that the Greenhouse-Geisser three step procedure might be most useful.[1] However, even this approach is discouraged if ρ (population correlation) is not constant or relatively constant over treatments. That is, the assumption of homogeneity of covariances between repeated measurements must be met. When the design involves more than one factor the covariance assumptions are more stringent. For example, in a two-factor experiment in which factor A with levels a_1 and a_2 is not repeated but factor B with occasions b_1, b_2, b_3, and b_4 is repeated, two covariance assumptions must be made. First, the matrix of variances and covariances among the several repeated assessments (b_1 through b_4) must be the same within each level of the nonrepeated factor (the matrix must be the same within a_1 as within a_2). Second, the covariances pooled across levels of the independent factor must be homogeneous. Procedures for testing these assumptions are given by Winer (1971, pp. 594-599).

Figure 28 outlines the Greenhouse-Geisser procedure when employing univariate analyses of repeated measures; (a) Use the regular degrees of freedom for the F tests on the repeated factors. If the result is not significant the analysis is completed. Clearly, if the obtained F value using the conventional degrees of freedom is not significant then there is no need to examine the effect further using the more conservative test. (b) If the result of (a) is significant the most stringent test is employed. The degrees of freedom for the numerator and denominator of the obtained F are multiplied by the inverse of the degrees of freedom for the within-subjects variable. If the obtained F is still significant the analysis can stop at this point.

FIGURE 28

GREENHOUSE-GEISSER PROCEDURE



(c) If step (b) indicates a lack of significance the researcher may try the Box approximate F test in which ε, a function of the heterogeneity of the variance and covariances, must be calculated. The degrees of freedom for the numerator and the denominator for the obtained F are then each multiplied by this function. These degrees of freedom will lie in the middle of the most liberal and the most conservative sets of degrees of freedom.

The Greenhouse-Geisser procedure is routinely applied in the analysis of Variance-covariance program (AVACOV) used in ECDEU analyses with the modification that the Box approximate test is not used. When an obtained F is significant at the .05 level, main effects and interactions using repeated measures are further tested using the reduced degrees of freedom. If they still indicate a significant result a (*) is printed. A ( ) indicates significance was not reached using the conservative degrees of freedom. At this point the procedure stops.

When a two-factor experiment in which factor A with levels a_1 and a_2 is repeated as is factor B with occasions b_1, b_2, b_3, and b_4 AVACOV cannot be employed. In this type of design the Statistical Analysis System (SAS)[8] procedure entitled Analysis of Variance and Covariance is employed.[9] The model includes a subject by factor A interaction, as well as a subject by factor B interaction, and also a subject by factor A by factor B. These interactions are employed to test the main effects A and B and the AB interaction. In the last section the output from the AVACOV and the SAS procedure will be explained in more detail.

Multiple Comparisons Techniques

When an analysis of variance indicates a significant difference among two or more means, paired comparisons aid the researcher in determining which differences contribute to the overall significance. It is generally agreed that the use of t-tests to carry out all possible two-group comparison produces a high rate of erroneous conclusions. Aside from this there is no consensus among statisticians about the multiple comparisons methods most appropriate. Any single test of a comparison has probability of a type 1 error. However, as the number of comparison increases the probability of at least one type 1 error increases. The usual α level, the probability that a single comparison results in a type 1 error is referred to as the error rate per comparison (EC). The probability that an entire set of comparisons contains at least one type 1 error is called the error rate experimentwise (EW). What is needed is a technique to adjust the EC downwards as the total number of comparisons increases and adjusting in such a way that the change in the number of comparisons does not alter EW. The literature is replete with proposals for dealing with the multiple comparison-error rate problem. However, only the Scheffé and the Tukey A or HSD (honestly significant difference) techniques hold the EW as α for the entire possible set of contrasts. The Scheffé method is very conservative and it is possible that a significant test of main effects will not be followed by at least one significant contrast. The power of the Scheffé test is equal to that of the overall F test only when detection of the maximum possible contrast is at issue. Scheffé recommends use of Tukey's B method where sample sizes are equal and only paired comparisons are made. The Tukey B method fixes experimentwise error rates at conventional levels. This method is affected by those violations such as unequal sample size, unequal variances, nonnormal populations to the degree that they also influence the obtained F value.

Tukey B method is based on the distribution of Q, the studentized range statistic. It is a compromise between the Tukey A which like the Scheffe yields too few significances and the Newman-Keuls which can give too many erroneous results. Briefly the procedure followed is:

$$\text{Critical Value} = \left[Q_{(K,df)} + Q_{(r,df)} \right] / 2$$

K = number of means in entire set
r = number of steps between the two means being compared
df = degrees of freedom for appropriate error term

$$Qr = M_i - M_j \Big/ \sqrt{MS_{error} / n}$$

if n_i are not equal use the harmonic means of the n_i's in the set

Qr is the test statistic and is known to have a distribution known as the studentized range. Qr must be greater than the critical value for significance to be indicated

M_i and M_j are means for the two levels being compared

MS_{error} is the mean square for the error term used in testing the effect

The treatment means are ordered from the lowest to the highest. In BLIPS II output, these differences are given in the lower half of a matrix on the right in which the upper half is occupied by the Qr statistics. Table 40 of the sample output display shows the treatment's means differences and the Qr statistics for the study effect. The number 4.05 is the ratio of

$$1.8333 - 1.3351 \Big/ \sqrt{\frac{1.1358}{\tilde{n}}}$$

where $\tilde{n}$ = harmonic mean = 75.0750

The critical value for means two steps apart is 3.31 which is the average of the critical values for means 2 steps apart and 5 means in a set

$$\text{Critical Value} = (2.77 + 3.86) / 2 = 3.31$$

These values are given in the lower half of the matrix on the left of page 485. The top half of matrix consists of * for those Qr's which are greater than the corresponding critical value. In our sample output on page 485, 5 studies are compared. The first comparison is treatment 1 versus treatment 4. Since the obtained Q of 5.96 is greater than the critical value of 3.86 an asterisk is placed in the upper portion of this matrix. In reading the significances we can discover that study 1 is significantly different from the other four but they are not different from one another.

AVACOV

AVACOV (Analysis of Variance-Covariance) is a modification of MANOVA. This program can perform analyses of variance on models consisting of four factors each with ten levels. It has the ability to analyze repeated measures on one factor only. Analysis of covariance can also be performed.

Additional features consist of:

1. Detection of F-Ratio's significant at the .05 probability level - with asterisks indicating significance.

2. Multiple Comparisons - Tukey B Method - run when main effects are significant at .05 level.

3. Means, standard deviations, and variances are output options for main effects and for interactions.

4. For the repeated measures designs when the main effects and/or interactions are significant they are tested again against the Greenhouse-Geisser conservative criterion. If they are still significant an (*) is assigned.

Tables 44 , 45 , and 46 are sample outputs of AVACOV. The variable is the depression factor of the BPRS scale. (The design is 5 studies by 2 drugs by 3 periods) - where the 3 periods represent repeated measures. The source table is displayed in Table 44. Df represent degrees of freedom. The letters placed next to the appropriate df are there to illustrate which df are used to form which Mean Squares and which Mean Squares form which tests or F-Ratios. The * under Sig (.05) are significant using the table df. The (*) under the Sig (.05) - GG Column where GG means Greenhouse-Geisser are indications that the effect is still significant using the stricter criteria of fewer degrees of freedom. We can see that three significant effects were obtained and that two of these three were still significant after testing with the stricter criteria. The df for this design are defined below the source table.

The significant main effects, that is, studies and periods, are reexamined via multiple comparisons in Table 45 . The mean and standard deviation are presented for each study - they represent the cumulation across both drug groups and all three periods in the first study. The matrices which contain the multiple comparison statistics were explained earlier. The means and standard deviations for the two drugs represent 213 different entries for the INV group and 210 for the Kontrol group; 213 represents the summing across the five studies and three rating periods; 210 represents the summing across the five studies and three rating periods for all the control subjects. The means and standard deviations for the period levels cumulate across drug and study. The multiple comparison for the significant period effects indicates that periods 2 and 3 are different from period 1 but not from each other.

Table 41 displays the last page of the AVACOV output which is the cell means and standard deviations. Cell 111 represents study 1, INV drug period 00; cell 523 represents study 5, Kontrol drug and period 02.

SAS Output

When the design of the study calls for a repeated measures across two factors - as in a rater by period design - then AVACOV cannot be used. A special analysis has to be performed and as an example of special analyses, the ANOVA procedure of the SAS, Statistical Analysis System will be given. The program allows the researcher to specify his own model and also the error terms he wishes to use to test various effects. In our example, a two factor repeated measurements design - rater by period - we wish to use a subject by rater to test rater effect, a subject by period to test period effect and a subject by rater by period to test a rater by period interaction. Table 47 displays the source table for ANOVA. Again we are looking at BPRS factor, depression, whose mean is 1.81. The differences in this table from the source table of AVACOV are:

1. Corrected total is listed under source - its df and sum of squares are the sum of source items 1-7 df and sum of squares.

2. LSD .01 - least significant difference at .01 and LSD .05 - least significant difference at .05 level. Any two means whose difference exceed this value are declared significantly different. This is another approach to the problem of regulating and apportioning the type 1 error rate.[6]

3. The tests of interest can be isolated in such a way that there is no confusion as to which error term was used. The probability associated with each F-Ratio is given. In our example we see that a significant rater effect is present with the probability of obtaining a F-value as large or larger of only .04.

This program expands the analytic facility of BLIPS II. In the future new statistical techniques which are routinely used in the output package will be reviewed and explained in a similar manner.

TABLE 44

THE BIOMETRIC LABORATORY, GWU - AVACOV - UP TO 4 WAY CLASSIFICATION
BPRS REPEATED MEASURES
PROBLEM NUMBER 1
VARIABLE 1 BPRS REPEATED MEASURES FIVE STUDY COMPARISON

ANALYSIS OF VARIANCE
DEPRESSION

	DF	SUM OF SQUARES	MEAN SQUARES	F-RATIO	SIG (.05)	SIG (.05) -GG
ANOVA ERROR 1 - BETWEEN	131 (A)	148.7892 (J)	1.1358 J/A=1			
ANOVA ERROR 2 - WITHIN	262 (B)	78.2368 (K)	0.2986 K/B=2			
STUDY DRUG PERIODS	8 (C)	2.7663 (L)	0.3458 L/C=3	3/2= 1.1580		
STUDY DRUG	4 (D)	3.2878 (M)	0.8219 M/D=4	4/1= 0.7237		
STUDY PERIODS	8 (E)	10.5166 (N)	1.3146 N/E=5	5/2= 4.4023	*	(*)
DRUG PERIODS	2 (F)	0.0653 (O)	0.0326 O/F=6	6/2= 0.1093		
STUDY	4 (G)	35.7133 (P)	8.9283 P/G=7	7/1= 7.8609	*	
DRUG	1 (H)	1.0273 (Q)	1.0273 Q/H=8	8/1= 0.9044		
PERIODS	2 (I)	5.8043 (R)	2.9022 R/I=9	9/2= 9.7188	*	(*)

$$A = \sum_{i=1}^{5} \sum_{j=1}^{2} (n_{ij} - 1)$$

B = A X 1
C = I X H X G
D = H X G
E = I X G
F = H X I

G = # of Studies - 1
H = # of Drugs - 1
I = # of Periods - 1

TABLE 45

VARIABLE 1 BPRS REPEATED MEASURES FIVE STUDY COMPARISON

LEVEL MEANS OF TREATMENT COMBINATION

	"N"	"MEAN	"STD.DEV."
STUDY			
LEVEL 1	144	1.3351	0.65
LEVEL 2	78	1.8333	0.70
LEVEL 3	48	1.8594	0.62
LEVEL 4	75	2.0689	1.06
LEVEL 5	78	1.9231	0.81

MULTIPLE COMPARISONS ON RANK ORDERED MEANS - (TUKEY-B METHOD)

LEVEL	1	2	3	5	4
1		*	*	*	*
2	3.31				
3	3.58	3.31			
5	3.74	3.58	3.31		
4	3.86	3.74	3.58	3.31	

SIGNIFICANCE(*) IN UPPER HALF MATRIX
CRITICAL VALUES IN LOWER HALF MATRIX

LEVEL	1	2	3	5	4
1		4.05	4.26	4.78	5.96
2	0.50				1.91
3	0.52	0.03			1.70
5	0.59	0.09	0.06		1.18
4	0.73	0.24	0.21	0.15	

Q-STATISTICS IN UPPER HALF MATRIX
DIFFERENCES IN LOWER HALF MATRIX

DRUG			
LEVEL 1	213	1.6761	0.80
LEVEL 2	210	1.7746	0.84
PERIODS			
LEVEL 1	141	1.8895	0.95
LEVEL 2	141	1.6596	0.76
LEVEL 3	141	1.6259	0.72

MULTIPLE COMPARISONS ON RANK ORDERED MEANS - (TUKEY-B METHOD)

LEVEL	3	2	1
3			*
2	3.04		*
1	3.31	3.04	

SIGNIFICANCE(*) IN UPPER HALF MATRIX
CRITICAL VALUES IN LOWER HALF MATRIX

LEVEL	3	2	1
3		0.73	5.73
2	0.03		5.00
1	0.26	0.23	

Q-STATISTICS IN UPPER HALF MATRIX
DIFFERENCES IN LOWER HALF MATRIX

TABLE 46

VARIABLE 1 BPRS REPEATED MEASURES FIVE STUDY COMPARISON

THE MEANS FOR EACH CELL CELL ID		"MEAN"	"STD.DEV."
1 1 1	24 OBSERVATIONS	1.6979	1.01
1 1 2	24 OBSERVATIONS	1.1667	0.24
1 1 3	24 OBSERVATIONS	1.0729	0.17
1 2 1	24 OBSERVATIONS	1.7500	0.88
1 2 2	24 OBSERVATIONS	1.2396	0.48
1 2 3	24 OBSERVATIONS	1.0833	0.19
2 1 1	13 OBSERVATIONS	1.7692	0.77
2 1 2	13 OBSERVATIONS	1.6923	0.56
2 1 3	13 OBSERVATIONS	1.7115	0.64
2 2 1	13 OBSERVATIONS	2.0962	0.87
2 2 2	13 OBSERVATIONS	1.9615	0.65
2 2 3	13 OBSERVATIONS	1.7692	0.73
3 1 1	8 OBSERVATIONS	1.4063	0.55
3 1 2	8 OBSERVATIONS	1.7813	0.39
3 1 3	8 OBSERVATIONS	2.1875	0.56
3 2 1	8 OBSERVATIONS	1.7500	0.42
3 2 2	8 OBSERVATIONS	1.9375	0.58
3 2 3	8 OBSERVATIONS	2.0938	0.91
4 1 1	13 OBSERVATIONS	2.1731	1.28
4 1 2	13 OBSERVATIONS	1.8654	1.11
4 1 3	13 OBSERVATIONS	1.6346	0.60
4 2 1	12 OBSERVATIONS	2.0975	1.21
4 2 2	12 OBSERVATIONS	2.3958	1.13
4 2 3	12 OBSERVATIONS	2.2917	0.90
5 1 1	13 OBSERVATIONS	2.1154	0.87
5 1 2	13 OBSERVATIONS	1.9038	0.77
5 1 3	13 OBSERVATIONS	2.0192	0.85
5 2 1	13 OBSERVATIONS	2.0962	1.10
5 2 2	13 OBSERVATIONS	1.6346	0.72
5 2 3	13 OBSERVATIONS	1.7692	0.50

TABLE 47

BPRS (FORM 047) ANOVA REP. MEASURES PERIOD X RATER (ITEMS)

ANALYSIS OF VARIANCE FOR VARIABLE DEPRESSION MEAN 1.81111111

	SOURCE	DF	SUM OF SQUARES	MEAN SQUARE	LSD .01	LSD .05	DIVISOR
1	SUB	8	24.8888889	3.1111111			
2	PERIOD	4	1.1777778	0.2944444			
3	RATER	1	10.6777778	10.6777778			
4	PERIOD*RATER	4	3.9333333	0.9833333			
5	SUB*PERIOD	32	21.2222222	0.6631944			
6	SUB*RATER	8	14.6222222	1.8277778			
7	SUB*PERIOD*RATER	32	17.2666667	0.5395833			
	ERROR PERIOD	32	21.2222222	0.6631944	0.743380070	0.552933633	18
	ERROR RATER	8	14.6222222	1.8277778	0.956328452	0.657255113	45
	ERROR PERIOD X RATER	32	17.2666667	0.5395833	0.948275983	0.705337286	9
	CORRECTED TOTAL	89	93.7888889	1.0538077			

TESTS	SOURCE	DF	SUM OF SQUARES	MEAN SQUARE	F VALUE	PROB F
NUMERATOR:	PERIOD	4	1.1777778	0.2944444	0.44398	0.7780
DENOMINATOR:	ERROR PERIOD	32	21.2222222	0.6631944		
NUMERATOR	RATER	1	10.6777778	10.6777778	5.84195	0.0406
DENOMINATOR:	ERROR RATER	8	14.6222222	1.8277778		
NUMERATOR:	PERIOD* RATER	4	3.9333333	0.9833333	1.82239	0.1480
DENOMINATOR:	ERROR PERIOD X RATER	32	17.2666667	0.5395833		

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059 RCR RESEARCH COMPLETION REPORT

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

PSYCHOPHARMACOLOGY RESEARCH BRANCH

RESEARCH COMPLETION REPORT (RCR)

DO NOT WRITE IN THIS BOX
UNIT/STUDY NO.
RPR NO.
RCR NO.

GENERAL INSTRUCTIONS

The Research Completion Report (RCR) is a companion form of the Research Plan Report (RPR). In contrast to the RPR's emphasis on the planning phase of research, the RCR is designed to collect data on the results of the study and the investigator's interpretations and conclusions in a format suitable for computer processing. The two forms – in concert – will provide a better understanding of the research process qua process as well as document the specific study. The investigator is asked to make every effort to complete the form according to the instructions. If aspects of the study cannot be described appropriately under a given item or if the space provided is inadequate for your response, please describe the details on a separate sheet and attach to the form. Specific instructions for this form (RCR) are given on pages 13, 14, and 15 and should be read PRIOR TO COMPLETING THE FORM.

I. IDENTIFICATION

NAME OF INVESTIGATOR/S	ADDRESS

TITLE OF STUDY

PLANNING PHASE		DATA COLLECTION PHASE		ANALYTIC PHASE	
Initiated	Completed	Initiated	Completed	Initiated	Completed
Mo.____ Yr.____	Mo.____ Yr.____	Mo.____ Yr.____	Mo.____ Yr.____	Mo.____ Yr.____	Mo.____ Yr.____

1. Has a Research Plan Report (21-RPR) for this study been submitted? . . . . 1 ☐ Yes 2 ☐ No

2. If YES, give Unit and Study numbers assigned_____
   If NO, please complete an RPR for the study.

3. Is this RCR a revision or modification of a previously submitted one? . . . . 1 ☐ Yes 2 ☐ No

   If you concur, the Research Completion Report which you submit - in conjunction with the Research Plan Report - may be released to the scientific community in the form of a short narrative description of the study. Chemical formulae may be held confidential even if other information is released.

4. May data on this form be given to the scientific community? . . . . . 1 ☐ Yes 2 ☐ No

5. Should chemical formulae be held confidential? . . . . . 1 ☐ Yes 2 ☐ No

6. Have data from this study been sent to the Biometric Laboratory? . . . . . 1 ☐ Yes 2 ☐ No

7. If NO, will data be sent? . . . . . 1 ☐ Yes 2 ☐ No

Mail this completed form to: ECDEU Data Analyses
Biometric Laboratory
George Washington University
11501 Huff Court
Kensington, Maryland 20795

ALL CARDS	DO NOT WRITE HERE – FOR BIOMETRIC LABORATORY USE ONLY								DO NOT WRITE HERE	
	UNIT NO.	STUDY NO.		REVISION	FORM	RECEIPT Mo./Year	RPR NO.	STATUS	Col.	Code
CODE:					59					CARD 01
COLUMN:	2-4	5-7	8-9	10	11-12	13-16	75-78	79-80	17-18	

II. DISPOSITION OF STUDY

1. Was the study (as a whole) discontinued before its planned completion? 1 ☐ YES 2 ☐ NO — 19 — 1

2. Abbreviated? 1 ☐ YES 2 ☐ NO — 20 — 2

3. Significantly modified from original protocol (other than by abbreviation)? 1 ☐ YES 2 ☐ NO — 21 — 3

If answers to 1, 2, and 3 are all "NO", go to Item 7.

4. If YES to any of the above, was the decision to discontinue/abbreviate/modify made by: *(Check all applicable)* — 22-23, 24-25, 26-27 — 4

01 ☐ Investigator
02 ☐ Pharmaceutical Firm
03 ☐ Government regulatory agency
04 ☐ Other *(Specify)*: _____

5. What was/were the reason/s for the disposition? *(Check most important. Maximum of 3)*: — 28-29, 30-31, 32-33 — 5

01 ☐ Ineffectiveness of drug/s
02 ☐ Occurrence of adverse reactions
03 ☐ Withdrawal or reduction of financial support
04 ☐ Loss of key personnel
05 ☐ Problems in obtaining population
06 ☐ Other *(Specify)*: _____

6. If the study was abbreviated or modified, what was/were the procedure/s? *(Check most important. Maximum of 3)*: — 34-35, 36-37, 38-39 — 6

01 ☐ INCREASE	or	07 ☐ DECREASE	in sample size
02 ☐ INCREASE	or	08 ☐ DECREASE	in dosage
03 ☐ EXTENSION	or	09 ☐ REDUCTION	of duration of treatment
04 ☐ ADDITION	or	10 ☐ REDUCTION	of frequency of assessment
05 ☐ ADDITION	or	11 ☐ DELETION	of assessment instruments
06 ☐ EXPANSION	or	12 ☐ CONSTRICTION	of population (by diagnosis, age, symptoms, etc.)

13 ☐ Other *(Specify)*: _____

III. RESEARCH PLAN

	Not Applicable	Definitely NO	Inclined to say NO	Undecided	Inclined to say YES	Definitely YES		
7. Was the research plan satisfactory to test the study hypothesis/es?	0	1	2	3	4	5	40	7
DURATION								
8. Was the duration of the drying out period satisfactory?	0	1	2	3	4	5	41	8
9. If NO drying out period was employed in the study, do you, in retrospect, believe one should have been employed?	0	1	2	3	4	5	42	9
10. Was the duration of the drug administration period sufficient?	0	1	2	3	4	5	43	10
11. Was the duration of the followup period sufficient?	0	1	2	3	4	5	44	11
12. If NO followup period was employed, do you, in retrospect, believe one should have been employed?	0	1	2	3	4	5	45	12
13. For crossover designs, were any of the treatment sequences of insufficient duration?	0	1	2	3	4	5	46	13
14. For crossover designs, were there significant "carry-over effects"; i.e., one treatment affecting the subsequent treatment?	0	1	2	3	4	5	47	14

DOSAGE Do you feel that optimal dose levels for the test drug/s were attained in this study?	Not Applicable	Definitely NO	Inclined to say NO	Undecided	Inclined to say YES	Definitely YES	Col.	Code
15. Test Drug No. 1	0	1	2	3	4	5	48	15
16. Test Drug No. 2	0	1	2	3	4	5	49	16

If the answer to Item 15 or 16 is box 1, 2, or 3 check reason/s for your judgment. *(Check most important. Maximum of 3):* — 17

17. TEST DRUG NO. 1

- 01 ☐ Initial dosage too low
- 02 ☐ Dosage increased too slowly
- 03 ☐ Effective level never reached
- 04 ☐ Dosage increased too rapidly
- 05 ☐ Initial dosage too high
- 06 ☐ Effective level exceeded
- 07 ☐ Other *(Specify below):*

18. TEST DRUG NO. 2

- 01 ☐ Initial dosage too low
- 02 ☐ Dosage increased too slowly
- 03 ☐ Effective level never reached
- 04 ☐ Dosage increased too rapidly
- 05 ☐ Initial dosage too high
- 06 ☐ Effective level exceeded
- 07 ☐ Other *(Specify below):*

50-51 52-53 54-55 — 18

56-57 58-59 60-61

FOR TEST vs. COMPARISON DRUG STUDIES: Was the comparison drug/s utilized in the study aptly chosen; i.e., did it closely resemble the test drug in clinical action?	Not Applicable	Definitely NO	Inclined to say NO	Undecided	Inclined to say YES	Definitely YES		
19. Comparison Drug No. 1	0	1	2	3	4	5	62	19
20. Comparison Drug No. 2	0	1	2	3	4	5	63	20
21. For Test vs. Comparison drug/s: Was dosage equivalence among the drugs achieved?	0	1	2	3	4	5	64	21

22. If the answers to items 19, 20, or 21 were box 1, 2, or 3, please describe difficulties: — 65-66 67-68 69-70 — 22

IV. RESEARCH EXECUTION

	Not Applicable	Definitely NO	Inclined to say NO	Undecided	Inclined to say YES	Definitely YES	17-18	CARD 02
23. Were there problems in the execution of the study, i.e., in the conduct of the trial and collection of the data?	0	1	2	3	4	5	19	23
DOSAGE ADMINISTRATION								24
24. As a consequence of its form; i.e., tablet, capsule, etc., were there significant problems in dispensing the Test Drug medication?	0	1	2	3	4	5	20	
25. Were there significant dosage violations by the subjects or their families, i.e., not taking specified amounts, taking prohibited medications, lapses in medication, etc.?	0	1	2	3	4	5	21	25
26. Were there significant dosage deviations by staff in violation of the protocol?	0	1	2	3	4	5	22	26
CONTROL PROCEDURES								27
27. Were there significant violations of blind conditions by the subjects/families?	0	1	2	3	4	5	23	
28. By the staff?	0	1	2	3	4	5	24	28
29. Was there significant introduction by staff of other drug therapies in violation of the protocol?	0	1	2	3	4	5	25	29
30. Non-drug therapies?	0	1	2	3	4	5	26	30

ASSESSMENT PROCEDURES	Adequate ?						Col.	Code
For the assessment areas listed, rate whether the frequency of assessment and/or sensitivity of the instruments were sufficient to provide an adequate test of your hypotheses	Not Applicable	Definitely NO	Inclined to say NO	Undecided	Inclined to say YES	Definitely YES		31
31. Demographic	0	1	2	3	4	5	27	
32. Diagnostic	0	1	2	3	4	5	28	32
33. Therapeutic Efficacy	0	1	2	3	4	5	29	33
34. Psychometric/Performance	0	1	2	3	4	5	30	34
35. Adverse Reactions	0	1	2	3	4	5	31	35
36. Laboratory Tests	0	1	2	3	4	5	32	36
37. Medical Assessment Procedures	0	1	2	3	4	5	33	37
Other *(Specify)*: 38.	0	1	2	3	4	5	34-36	38
39.	0	1	2	3	4	5	37-39	39
40. If the answers to any of the above (items 31 – 39) were box 1, 2, or 3, please describe difficulties:							40-41 42-43 44-45	40

STATISTICS	Not Applicable	Definitely NO	Inclined to say NO	Undecided	Inclined to say YES	Definitely YES		41
41. In multidrug studies, were there significant demographic differences among the groups (treatments)?	0	1	2	3	4	5	46	
42. Were there significant pretreatment differences in severity and/or type of psychopathology among the groups (treatments)?	0	1	2	3	4	5	47	42
43. Was there differential utilization of permissible concurrent drug therapies; i.e., significantly greater use in one group than another?	0	1	2	3	4	5	48	43
44. Differential utilization of permissible non-drug therapies?	0	1	2	3	4	5	49	44
45. If BIOMETRIC LABORATORY ANALYSES were performed, were the routine BLIPS analyses complete and free from significant error?	0	1	2	3	4	5	50	45

V. RESEARCH RESULTS

46. How many subjects were screened (evaluated) for the study?	Total Number _____	51-53	46
47. How many subjects were accepted into the study?	Total Number _____	54-56	47

	What was/were the reason/s for rejection?		CARD 02 Col.	Code
	Number of Subjects			
48.		Subject refusal	57-59	48
49.		Family member (guardian) refusal	60-62	49
50.		Psychiatric exclusion criteria	63-65	50
51.		Medical exclusion criteria	66-68	51
52.		Failure to meet target symptom/diagnostic criteria	69-71	52
53.		Other *(Specify):* _____	72-76	53
54.	Of the subjects accepted into the study, how many completed the protocol requirements; i.e., completed the planned treatment regime? Total Number _____		17-18	CARD 03
			19-21	54
	What was/were the reason/s for premature termination; i.e., failure to complete the protocol?			55
	Number of Subjects			
55.		Subject withdrawal from treatment; i.e., refused continued participation	22-24	
56.		Family (guardian) withdrawal from treatment	25-27	56
57.		Protocol violation by subject/family	28-30	57
58.		Protocol violation by staff	31-33	58
59.		Ineffectiveness of treatment; i.e., deterioration of clinical course	34-36	59
60.		Occurrence of adverse reaction	37-39	60
61.		Intercurrent medical illness	40-42	61
62.		Other *(Specify):* _____	43-47	62
63.	Of the protocol completers, how many were utilized in major statistical analyses? Total Number _____		48-50	63
	What was/were the reason/s for exclusion from analyses?			64
	Number of Subjects			
64.		Missed assessments (due to subject)	51-53	
65.		Missed assessments (due to staff)	54-56	65
66.		Missing data on assessment instrument/s	57-59	66
67		Incorrect rating procedures	60-62	67
68.		Other *(Specify):* _____	63-67	68

		Col.	Code
69.	Do you consider the rate of attrition: 1 ☐ Unusually low 2 ☐ Usual or expected 3 ☐ Excessive 4 ☐ Uncertain	68	69
70.	Did the pattern of attrition seem to be: *(Check one):* 1 ☐ Random 2 ☐ Systematic 3 ☐ Uncertain	69	70
	If bias is suspected, in which subset/s (group) of the sample did it occur? *(Check all applicable and designate subset by name)*	17-18	CARD 04
71.	Specific drug (treatment) group Test: No. 1 (01), No. 2 (02); Comparison: No. 1 (03), No. 2 (04); Placebo (05) Other Treatment Group *(Specify):*	19-22	71
72.	Specific sex ☐ Male ☐ Female	23-24	72
73.	Specific age group *(Specify):* _____	25-28	73
74.	Specific diagnostic group *(Specify):* _____	29-32	74
75.	Specific treatment period – including pretreatment *(Specify):* _____	33-36	75
76.	Specific treatment agency (ward, hospital, clinic, school, etc.) *(Specify):* _____	37-40	76
77.	Other subset/s *(Specify):* _____	41-46	77

ADVERSE REACTIONS

What were the clinically important DRUG-RELATED adverse reactions which emerged under the Test Drug and Comparison Drug conditions and what was the MOST STRINGENT ACTION required as a consequence of their emergence? Under column labeled "Drug", indicate under which drug condition/s the symptom emerged (T1, T2, C1, C2, PBO) and then check the most stringent action.

NAME OF ADVERSE REACTION	DRUG	ACTION TAKEN							Col.	Code
		None	Increased Surveillance	Contraactive RX	Change Dose	Change Dose Plus Contraactiva RX	Suspend RX	Discontinue RX	17-18	CARD 05
		0	1	2	3	4	5	6		
78.									19-28	78
79.									29-38	79
80.									39-48	80
81.									49-58	81
82.									59-68	82
									17-18	CARD 06
83.									19-28	83
84.									29-38	84
85.									39-48	85
86.									49-58	86
87.									59-68	87

VI. STATISTICAL RESULTS

Report all assessment instruments employed — whether or not statistically significant results were obtained on the instrument. In this latter case, give the name of the scale and write "N.S." under Interpretation of Results.

If BIOMETRIC LABORATORY ANALYSES have been performed:

Do you wish all BLIPS results incorporated in this section? 1 ☐ YES 2 ☐ NO

(If YES, you need not enter those results here. They will be entered automatically by Biometric Laboratory.)

NAME OF SCALE	NAME OF VARIABLE	TYPE OF VARIABLE	TYPE OF STATISTIC	SIGNIFICANCE LEVEL	TYPE OF EFFECT	INTERPRETATION OF RESULTS

VI. STATISTICAL RESULTS (Continued)

NAME OF SCALE	NAME OF VARIABLE	TYPE OF VARIABLE	TYPE OF STATISTIC	SIGNIFICANCE LEVEL	TYPE OF EFFECT	INTERPRETATION OF RESULTS

VII. RESEARCH CONCLUSIONS

88. What was/were the hypothesis/es of this study?

47-52 | CARD 04 | 88

	Not Applicable	Definitely NO	Inclined to say NO	Undecided	Inclined to say YES	Definitely YES		
	0	1	2	3	4	5		
89. Do you feel that the study provided a valid test of the hypothesis/es?							53	89
90. On balance, do the results support the major hypothesis/es of the study?							54	90

91. *Please describe your conclusions regarding the hypothesis/es:*

55-60 | 91

CLINICAL ACTION — CARD 04

92. FOR SINGLE TEST DRUG/S — was the clinical action of the test drug/s as presumed; i.e., as anticipated or hypothesized? — Col. 61-65 — Code 92

(Check one):

1 ☐ Clinical action as presumed with NO unexpected or secondary therapeutic action

2 ☐ Clinical action as presumed WITH unexpected or secondary therapeutic action

Specify secondary action _____

_____

3 ☐ Presumed clinical action NOT apparent BUT unexpected secondary action noted

Specify secondary action _____

_____

4 ☐ Presumed clinical action NOT apparent and NO unexpected or secondary action noted

5 ☐ Other — for responses which cannot be categorized above — please specify:

_____

93. FOR COMBINATION TEST DRUG/S — were the clinical actions of ALL the components as anticipated? — 66 — 93

1 ☐ Yes 2 ☐ No 3 ☐ Undecided

94. COMMENTS _____ — 67-72 — 94

_____

_____

CLINICAL COMPARISONS — 17-18 — CARD 07

95. For Test Drug Only Studies; i.e., studies in which no comparison (control) drug is employed, which standard drug/s do you feel it most resembles in clinical action? — 19-28 — 95

_____

_____

96. In your judgment, what is the dose equivalent of the test drug to the standard/s given in the item above? — 29-33 — 96

97. Comparative Index — This item is analogous to the Efficacy Index which appears on the ECDEU scale, Clinical Global Impressions. The investigator is asked to judge the overall efficacy and toxicity of the *test drug* in comparison to the standard drug. Check the ONE single box which best reflects your clinical judgment. *(For Test Drug Only Studies, compare test drug with standard named in item 95)* — 34-35 — 97

EFFICACY	TOXICITY			
	Less Toxic	Equally Toxic	More Toxic	Much More Toxic
	1	2	3	4
4 Greatly Superior				
3 Superior				
2 Equivalent				
1 Inferior				

98. How do the statistical results compare with clinical judgments? 36-37 | 98

(Check one):

01 ☐ No statistical analyses performed
02 ☐ Statistical results strongly confirm and coincide with clinical judgment
03 ☐ Statistically, results generally confirm with some exceptions
04 ☐ Positive statistical findings are not clinically meaningful
05 ☐ Negative or equivocal statistical findings do not confirm clinical judgment
06 ☐ Not possible to answer
07 ☐ Other *(Specify):* _____

99. Comments _____ 38-43 | 99

_____

VIII. FUTURE PLANS

100. What priority would you assign to any further investigation of this test drug (or hypothesis)? | 100

(Check one): HIGHEST 1 ☐ | HIGH 2 ☐ | MODERATE 3 ☐ | LOW 4 ☐ | LOWEST 5 ☐ 44

High Priority ⟵ ⟶ Low Priority

101. What recommendation/s would you make for further research? | 101
Rank your recommendations (maximum of 3) on the basis of priority: 45-50

_____ Replication of study/hypothesis
_____ Comparison trial against PBO
_____ Comparison trial against standard
_____ Comparison trial against both
_____ Crossover design
_____ Larger sample
_____ Other *(Specify)* _____
_____ Other *(Specify)* _____
_____ Other *(Specify)* _____
_____ Dosage alteration
_____ Different dosage regime
_____ Duration alteration
_____ Different population
_____ No further investigation

102. Do you plan to conduct further studies of this drug (or hypothesis) at your research unit? 1 ☐ YES 2 ☐ NO 3 ☐ UNDECIDED 51 | 102

103. What are your plans to publish (disseminate) the results of this study? | 103
(Check all applicable): 52-55

01 ☐ No plans to publish
02 ☐ Article to be submitted for publication but no decision as to specific journal
03 ☐ Article submitted to specific journal or book
Name of journal/book _____
04 ☐ Oral presentation of results at professional meeting
Specify meeting _____
05 ☐ Other *(Specify):* _____

_____

SPECIAL INSTRUCTIONS

The primary purpose of the Research Completion Report (RCR) is to obtain from the investigator a summary of his study and its results. As such, the RCR attempts to document conclusions pertinent to a single drug trial and, simultaneously, assemble a data base for the methodological examination of psychotropic drug trials as a generic process. Investigators are encouraged to amplify any of their responses by the insertion of additional pages. When there are several such "insertions," please label each separate comment with the appropriate Item Number. To facilitate reference, items are numbered consecutively regardless of headings and subheadings.

I. IDENTIFICATION

Phases of Study — The separation into three phases may be artificial for some studies; e.g., aspects of the analytic phase may be carried out concurrent with data collection. Since the purpose of the item is to obtain estimates of the times required to complete various aspects of clinical trials, investigators are asked to make the best estimates possible within the context of these categories.

Research Plan Report (RPR) — Together, the RPR and RCR constitute a detailed description of a given trial. It is necessary, therefore, to request that investigators complete both of these forms - whether or not they submit the actual data of the trial to the Biometric Laboratory.

II. DISPOSITION OF STUDY

Disposition refers to the abandonment, abbreviation or significant modification of the entire study rather than the disposition of individual subjects. Abbreviation refers to reduction in data collection phase from that planned in the original protocol.

III. RESEARCH PLAN and
IV. RESEARCH EXECUTION

These sections contain items to be rated on a five-point scale. A sixth response position "Not Applicable" is provided for those items which are not relevant to a given study. For some items, space is provided for 2 test drugs and/or 2 comparison drugs. Be sure to encode your responses in the appropriate boxes.

V. RESEARCH RESULTS

Items in this section describe the course of events from the initial screening pool to the final analytic cohort.

Items 46 through 69 — The investigator is asked to record the numbers of subjects and their dispositions at each step.

Example:

Item		Response
46.	Number Screened	25
47.	Number Accepted	20
48.	Subject Refusal	1
50.	Psychiatric Exclusion	2
51.	Medical Exclusion	2
54.	Number Completers	18
56.	Family Withdrawal	1
61.	Intercurrent Illness	1
63.	Number Used in Analysis	16
66.	Missing Data	2

Note that the investigator omits those items (reasons) which are not pertinent.

Items 71 through 77 — Bias here refers to systematic differences among the treatment groups or other subsets of the sample which tend to distort, restrict or confound the interpretation of the results.

Examples:

72. **Specific Sex** — A trial in which only males are prematurely terminated.

73. **Specific Age Group** — Only older subjects show response to treatment.

74. **Specific Diagnostic Group** — In a trial utilizing subjects with heterogeneous depressive diagnoses, only involutional melancholics show positive change.

75. **Specific Treatment Period** — Significant pretreatment differences exist among the groups.

76. **Specific Treatment Agency** — Subjects residing on one of the three wards utilized in a trial show a set of adverse reactions not observed on the other wards.

Items 78 through 87 — Adverse Reactions — Complete this item for all appropriate studies; i.e., Test Drug Only or Test vs. Comparison Drug. Clinically important adverse reactions should include those judged to be drug-related and clinically important on the basis of the stringency of the action undertaken as a consequence of their emergence. "Actions" are aligned in order of stringency; i.e., from "None" to "Discontinue RX"

VI. STATISTICAL RESULTS

This section permits the investigator to record all statistical results — BLIPS and/or his own — that he wishes. The interpretation of all results — including BLIPS — is the prerogative of the investigator.

Non-significant Results — For those assessment instruments used in the study which do not yield any statistically significant results, record the name of the instrument and write "n.s." or "no significance" under the column "Interpretation of Results."

Type of Variable — Refers to composition of the variable; e.g., I = Item C = Cluster F = Factor T = Total Score

Type of Statistic — Refers to statistical operation performed; e.g.,

VAR = Analyses of variance - regular model
VAR-R = Analyses of variance - repeated measures
COV = Analyses of covariance - regular
COV-R = Analyses of covariance - repeated measures
T = "t" test
X^2 = Chi square

Significance Level — Refers to the probability level to be exceeded if support of the hypothesis being tested is warranted. While the p = .05 level is the "establishment level," investigators may select the level which is considered best to reflect their conclusions.

Type of Effect — Refers to effect in the statistical sense; e.g.
G = Group (treatment) effect
P = Period (time) effect
G x P = Interaction (Group x Period)

Interpretation of Effect — Refers to the direction of change, magnitude of effect, differential change, etc.

BLIPS Results — If the investigator checks "YES", all significant BLIPS results will be encoded automatically for him. If he wishes to select only part of the BLIPS interpretation, the investigator should record the appropriate results and check "NO" to the question. The investigator may, of course, enter other statistical results in addition to "automatic" BLIPS results. Examples of encoding are given in Table 1.

VII. RESEARCH CONCLUSIONS

Items 88 through 91 — Hypotheses, in many cases, may correspond to the "Purpose/s" recorded on the RPR. Item 90 refers to the clinical hypothesis rather than the statistical one. Example: The null hypothesis states that there is no significant difference between the two treatments; while the clinical hypothesis states that the test drug is more efficacious than the placebo.

Items 92 through 94 — Clinical Action — Complete only the pertinent section/s. Presumed clinical action refers to the verification of the presumed or anticipated main therapeutic action of the drug; i.e., if the drug was presumed to be a neuroleptic, did it indeed exhibit this action during the study. Secondary clinical action refers to the observation of a clinical action other than the presumed one: e.g. drug which is presumed a neuroleptic exhibits an antidepressant action. A drug may exhibit both its main presumed action and a secondary one or it may not exhibit the presumed action but demonstrate an unexpected one.

Item 95 — Clinical Comparisons — Test Drug Only — If the Test Drug is unique and does not closely resemble any standard drugs in its clinical action, state this fact.

Item 96 — Dose Equivalent — Make the best estimate of equivalence.
Example: The Test Drug most resembles chlorpromazine. The investigator might state the equivalence as: 200 mg of Test Drug = 100 mg of CPZ Test Drug to CPZ = 2:1.

Item 97 — Comparative Index — Only ONE box should be checked.

Example: The Test Drug is judged to be equally efficacious to the Comparison Drug but more toxic. Code as follows:

	TOXICITY			
	Less Toxic	Equally Toxic	More Toxic	Much More Toxic
	1	2	3	4
4 Greatly Superior				
3 Superior				
2 Equivalent			X	
1 Inferior				

For Test Drug Only studies, compare the Test Drug to the standard drug you feel it most resembles; i.e., the one given in Item 95.

Item 98 — Clinical Inference — The purpose of this section is to obtain from the investigator a judgment relating the statistical results to clinically meaningful changes. Essentially, the investigator is asked to judge whether the magnitude and/or direction of the changes obtained by statistical methods — be they significant or not — have clinical relevance.

VIII. FUTURE PLANS

Item 100 — Priority — Refers to the general priority you would set for your OWN RESEARCH UNIT taking into consideration the merits of the study itself in the context of your other research activities. "1" = highest priority; "5" = lowest.

Item 101 — Recommendations — This item requires the RANKING rather than mere checking of items. The rankings should reflect the order in which you feel further research might proceed — whether or not you intend to carry our the recommendations at our research unit.

Example: Based on the results of a small Test Drug Only study, the investigator recommends that a trial using a standard drug should be undertaken as the next step. He also has a hunch that the drug, a neuroleptic, might have antidepressant effects. He marks a "1" beside "Comparison trial against standard" and a "2" beside one of the "Others" and specifies that he wishes to examine "antidepressant action."

TABLE I

EXAMPLES OF ENCODING STATISTICAL RESULTS

NAME OF SCALE	NAME OF VARIABLE	TYPE OF VARIABLE	TYPE OF STATISTIC	SIGINIFICANCE LEVEL	TYPE OF EFFECT	INTERPRETATION OF RESULTS
BPRS	Anxiety	I	VAR-R	.01	P	TEST DRUG - greater improvement across time
	Anergia	F	VAR-R	.05	G x P	TEST DRUG - improved at 4th week; PBO - worse at 4th week
NOSIE	Total Assets	T	COV	.05	G	COMPARISON DRUG - greater improvement at termination
Children's Psychiatric Rating Scale	Hyperactive	C	VAR-R	.01	POP	POPULATION A - greater improvement than POP B
Self Esteem Scale	Downtrodden	I	T	.05	G	PSYCHOLOGISTS - more downtrodden than Psychiatrists
CGI	Global Improvement	I	X^2	.05	AGE	YOUNGER SUBJECTS - greater improvement than older subjects
Attila Hostility Scale	Total Score	T	Wilcoxon Sign Test	.01	SEX	FEMALES - greater increase in hostility than MALES
O'Reilly Sobriety Scale	Total Score	T	VAR-R			n.s.

Developed within the ECDEU program, the Research Completion Report is a 103-item instrument designed to collect information on the execution, results and conclusions of a clinical trial in computer-compatible form. Together with the Research Plan Report, the RCR permits a detailed historical reconstruction of the individual trial as well as providing data for subsequent collation with other trials. The Research Completion Report replaces the Evaluation Summary Form (22-ESF).

APPLICABILITY - For all research populations

UTILIZATION - Once per study. To be completed after the completion of the trial and the analyses of the data.

SPECIAL INSTRUCTIONS

Investigators should be thoroughly familiar with the instructions printed on the form itself. Since it is impossible to construct a form which will be adequate in all circumstances, investigators are urged to augment their responses - through the use of additional sheets - whenever the constraints of the RCR format make explanations difficult.

At first glance, the RCR looks long and formidable. Investigators should keep in mind, however, that the majority of items require only a checkmark and, in any given trial, not all items are relevant - hence can be omitted. The potential usefulness of this type of data is such that we feel the time and effort involved will be justified.

Use of the RCR - When data analyses are performed by the Biometric Laboratory, an RCR will be sent to the investigator along with his data package. After reviewing the BLIPS analyses and any additional analyses that he may have performed, the investigator completes the RCR and returns it to the Biometric Laboratory. The form will then be coded and a computer printout of the data will be mailed to the investigator.

NOTE - Investigators are urged, however, to complete an RCR - along with a Research Plan Report - whether or not data are sent to the Laboratory.

DOCUMENTATION

Like its counterpart - the RPR - documentation for the Research Completion Report is two-fold. For the individual study, printouts will be generated - utilizing both RPR and RCR data - to provide an historical narrative. For general documentation, RPR and RCR data will be assembled in a data file for methodological research.

APPENDICES

APPENDIX 1

OCCUPATIONAL CATEGORIES

(from Hollingshead, Two-Factor Index of Social Position)

Code 1. Higher Executives, Proprietors of Large Concerns or Major Professionals

a. Higher Executives

Bank Presidents; Vice-Presidents
Judges (Superior Courts)
Large Businesses, e.g., Director, Presidents, Vice-Presidents, Assistant Vice-Presidents, Executive Secretary, Treasurer.
Military, Comm. Officers, Major & above, Officials of the Executive Branch of Government, Federal, State, Local, e.g., Mayor; City Manager, City Plan Director, Internal Revenue Directors.
Research Directors, Large Firms

b. Proprietors of Large Concerns

Brokers
Contractors
Dairy Owners
Lumber Dealers

b. Major Professionals

Accountants (C.P.A.)
Actuaries
Agronomists
Architects
Artists, Portrait
Astronomers
Auditors
Bacteriologists
Chemical Engineers
Chemists
Clergymen (Professionally Trained)
Dentists
Economists
Engineers (College Grad.)
Foresters
Geologists
Lawyers
Metallurgists
Physicians
Physicists, Research
Psychologists, Practicing
Symphony Conductor
Teachers, University, College
Veterinarians (Veterinary Surgeons)

Code 2. Business Managers in Large Concerns Proprietors Of Medium-Sized Businesses, and Lesser Professionals

a. Business Managers in Large Concerns

Advertising Directors
Branch Managers
Brokerage Salesmen
District Managers
Executive Assistants
Export Managers, Int. Concern
Govt. Officials, minor, e.g., Internal Revenue Agents
Farm Managers
Office Managers
Personnel Managers
Police Chief; Sheriff
Postmaster
Production Managers
Sales Engineers
Sales Managers, National Concerns
Store Managers

b. Proprietors of Medium-Sized Businesses

Advertising Owners
Clothing Store Owners
Manufacturer's Representatives
Poultry Business
Contractors
Express Company Owners
Fruits, Wholesale
Furniture Business
Jewelers
Labor Relations Consultants
Purchasing Managers
Real Estate Brokers
Rug Business
Store Owners
Theater Owners

c. Lesser Professionals

Accountants (Not CPA)
Chiropodists
Chiropractors
Correction Officers
Director of Community House
Engineers (Not College Grad.)
Finance Writers
Health Educators
Librarians
Military, Comm. Officers, Lts., Captains
Musicians (Symphony Orchestra)
Nurses
Opticians
Pharmacists
Public Health Officer (M.P.H.)
Research Assistants, University (Full-time)
Social Workers
Teachers, Elementary and High

Code 3. Administrative Personnel, Owners of Small Independent Businesses, Minor Professionals and Farmers

a. Administrative Personnel

Advertising Agents
Chief Clerks
Credit Managers
Insurance Agents
Managers, Dept. Stores
Passenger Agents--R.R.
Private Secretaries
Sales Representatives
Purchasing Agents
Section Heads, Federal, State, and Local Govt. Offices
Section Heads, Large Businesses and Industries
Service Managers
Shop Managers
Store Managers (Chain)
Traffic Managers

b. Owners of Small Independent Businesses

Art Gallery
Auto Accessories
Awnings
Bakery
Beauty Shop
Boatyard
Brokerage, Insurance
Car Dealers
Cattle Dealers
Cigarette Machines
Cleaning Shops
5 cents & 10 cents Stores
Florist
Food Equipment
Food Products
Foundry
Funeral Directors
Furniture
Garage
Gas Station
Glassware
Clothing
Coal Businesses
Contracting Businesses
Convalescent Homes
Decorating
Dog Supplies
Dry Goods
Engraving Business
Feed
Finance Co., Local
Fire Extinguishers
Painting Contracting
Plumbing
Poultry Producers
Publicity & Public Relations
Real Estate
Records and Radio
Restaurant
Roofing Contractor
Shoe
Signs
Grocery-General
Hotel Proprietors
Inst. of Music
Jewelry
Machinery Brokers
Manufacturing
Monuments
Package Store (Liquor)
Tavern
Taxi Company
Tire Shop
Trucking
Trucks and Tractors
Upholstery
Wholesale Outlets
Window Shades

c. Minor Professionals

Actors and Showmen
Army M/Sgt.; Navy, C.P.O.
Artists, Commercial
Appraisers (Estimators)
Clergymen (Not professionally trained)
Concern Managers
Deputy Sheriffs
Dispatchers, R.R. Train
Interior Decorators
Interpreters, Court
Laboratory Assistants
Landscape Planners
Morticians
Oral Hygienists
Photographers
Physio-therapists
Piano Teachers
Radio, T.V. Announcers
Reporters, Court
Reporters, Newspapers
Surveyors
Title Searchers
Tool Designers
Travel Agents
Yard Masters, R.R.

d. Farmers

Owners of large farms

Code 4. Clerical and Sales Workers, Technicians, Owners of Little Businesses, and Farmers

a. Clerical and Sales Workers

Bank Clerks and Tellers
Bill Collectors
Bookkeepers
Business Machine Operators, Office
Claims Examiners
Clerical or Stenographic
Conductors, R.R.
Employment Interviewers
Factory Storekeeper
Factory Supervisor
Post Office Clerks
Route Managers
Sales Clerks
Shipping Clerks
Supervisors, Utilities, Factories
Toll Station Supervisors
Warehouse Clerks

b. Technicians

Dental Technicians
Draftsmen
Driving Teachers
Expeditor, Factory
Experimental Tester
Instructors, Telephone Co., Factory
Inspectors, Weights, Sanitary Inspectors, R.R.; Factory
Investigators
Laboratory Technicians
Locomotive Engineers
Operators, P.B.X.
Proofreaders
Safety Supervisors
Supervisors of Maintenance
Technical Assistants
Telephone Company Supervisors
Timekeepers
Tower Operators, R.R.
Truck Dispatchers
Window Trimmers (store)

c. Owners of Little Bisinesses

Flower Stand
Newsstand
Tailor Shop

d. Farmers

Owners of Medium-Sized Farms

Code 5. Skilled Manual Employees and Farmers

a. Skilled Manual Employees

Auto Body Repairers
Bakers
Barbers
Blacksmiths
Bookbinders
Boilermakers
Brakeman, R.R.
Brewers
Bulldozer Operators
Butchers
Cabinet Makers
Cable Splicers
Carpenters
Casters (Founders)
Cement Finishers

a. Skilled Manual Employees (cont'd)

Cheese Makers
Chefs
Compositors
Diemakers
Diesel Engine Repair & Maintenance (Trained)
Diesel Shovel Operators
Machinists (Trained)
Maintenance Foremen
Installers, Electrical Appliances
Masons
Masseurs
Mechanics (Trained)
Millwrights
Moulders (Trained)
Painters
Paperhangers
Patrolmen, R.R.
Pattern and Model Makers
Piano Builders
Piano Tuners
Plumbers
Policemen, City
Postmen
Printers
Radio T.V., Maintenance
Electricians
Electrotypers
Exterminators
Engravers
Fitters, Gas, Steam
Fireman, City
Firemen, R.R.
Foremen, Construction, Dairy
Gardeners, Landscape (Trained)
Glassblowers
Glaziers
Gunsmiths
Gauge Makers
Hair Stylists
Heat Treaters
Horticulturists
Lineman, Utility
Linoleum Layers (Trained)
Linotype Operators
Lithographers
Locksmiths
Loom Fixers
Repairmen, Home Appliances
Rope Splicers
Sheetmetal Workers (Trained)
Shipsmiths
Shoe Repairmen (Trained)
Stationary Engineers (Licensed)
Stewards, Club
Switchman, R. R.
Tailors (Trained)
Teletype Operators
Toolmakers
Track Supervisors, R.R.
Tractor-Trailor Trans.
Typographers
Upholsterers (Trained)
Watchmakers
Weavers
Welders
Yard Supervisors, R.R.

b. Farmers

Owners of Little Farms
Tenant Farmers Who Own Farm Equipment

Code 6. Machine Operators, Semi-skilled Employees and Farmers

a. Machine Operators

Aides, Hospital
Apprentices, Electricians, Printers, Steamfitters, Toolmakers
Assembly Line Workers
Bartenders
Bingo Tenders
Bridge Tenders
Building Superintendents (Cust.)
Bus Drivers
Checkers
Coin Machine Fillers
Cooks, Short Order
Delivery Men
Dressmakers, Machine
Elevator Operators
Enlisted Men, Military Services
Filers, Benders, Buffers
Foundry Workers
Garage and Gas Station Assistants
Greenhouse Workers
Guards, Doorkeepers, Watchmen
Timers
Tire Moulders
Trainmen, R.R.
Truck Drivers, General
Waiters-Waitresses
Weighers

b. Semi-skilled Employees

Hairdressers
Housekeepers
Meat Cutters and Packers
Meter Readers
Operators, Factory Machines
Oilers, R.R.
Practical Nurses
Pressers, Clothing
Pump Operators
Receivers and Checkers
Roofers
Set-up Men, Factories
Shapers
Signalmen, R.R.
Solderers, Factory
Sprayers, Paint
Steelworkers (Not skilled)
Stranders, Wire Machines
Strippers, Rubber Factory
Taxi Drivers
Testers
Welders, Spot
Winders, Machine
Wiredrawers, Machine
Wine Bottlers
Wood Workers, Machine
Wrappers, Stores and Factories

c. Farmers

Tenant Farmers Who Own Little Equipment

Code 7. Unskilled Employees and Farmers

a. Unskilled Employees

Amusement Park Workers (Bowling Alleys, Pool Rooms)
Ash Removers
Attendants, Parking Lots
Cafeteria Workers
Car Cleaners, R.R.
Car Helpers, R.R.
Carriers, Coal
Countermen
Dairy Workers
Deck Hands
Domestics
Farm Helpers
Fishermen (Clam Diggers)
Freight Handlers
Garbage Collectors
Grave Diggers
Hod Carriers
Hog Killers
Hospital Workers, Unspecified
Hostlers, R.R.
Janitors (Sweepers)
Laborers, Construction
Laborers, Unspecified
Laundry Workers
Messengers
Platform Men, R.R.
Peddlers
Porters
Roofer's Helpers
Shirt Folders
Shoe Shiners
Sorters, Rag & Salvage
Stagehands
Stevedores
Stock Handlers
Street Cleaners
Unskilled Factory workers
Truckman, R.R.
Waitress - "Hash Houses"
Washers, Cars
Window Cleaners

b. Farmers

Share Cropper

APPENDIX 2

LIST OF DSM-II AND ICD-8 DIAGNOSES

These two lists of diagnoses have been juxtaposed for your convenience. For detailed explanations of the diagnoses please refer to:

DSM-II - Diagnostic and Statistical Manual of Mental Disorders
American Psychiatric Association
3rd Edition
Washington, D. C., 1968

ICDA-8 - Eighth Revision
International Classification of Diseases
Volume 1,
Public Health Publication No. 1693,
U.S. Dept. HEW, Public Health Service
U. S. Government Printing Office,
Washington, D. C. 20402

NOTE - For uniformity in coding, some code numbers have been changed to a 4-digit number. Such changes have been noted by asterisks (*). (The original 5-digit DSM-II code number is given in parentheses following the diagnostic name.) For encoding diagnosis on ECDEU forms, always use the 4-digit BLIPS number which precedes each diagnosis. Decimal points are omitted in BLIPS coding.

To encode one of the diagnoses under the heading of "Mental Retardation", use the first 3 digits plus one of the 10 qualifiers.

Example - Moderate mental retardation associated with chromosomal abnormality is coded as follows: 312 + 5 = 3125.

DSM-II

I. MENTAL RETARDATION

310 - Borderline
311 - Mild
312 - Moderate
313 - Severe
314 - Profound
315 - Unspecified

Code with above: Following or associated with
0 - Infection or intoxication
1 - Trauma or physical agent
2 - Disorders of metabolism, growth, or nutrition
3 - Gross Brain Disease (postnatal)
4 - Unknown prenatal influence
5 - Chromosomal abnormality
6 - Prematurity
7 - Major psychiatric disorder
8 - Psycho-social (environmental) deprivation
9 - Other condition

II. ORGANIC BRAIN SYNDROMES (OBS)

A. PSYCHOSES

Senile and pre-senile dementia
2900 - Senile dementia
2901 - Pre-senile dementia

Alcoholic psychosis
2910 - Delirium tremens
2911 - Korsakov's psychosis
2912 - Other alcoholic hallucinosis
2913 - Alcohol paranoid state
2914 - Acute alcohol intoxication
2915 - Alcoholic deterioration
2916 - Pathological intoxication
2919 - Other alcoholic psychosis

Psychosis associated with intracranial infection
2920 - General paralysis
2921 - Other Syphilis of CNS
2922 - Epidemic encephalitis
2923 - Other and unspecified encephalitis
2929 - Other intracranial infection

WHO (ICD -8)
MENTAL DISORDERS (290-315)

MENTAL RETARDATION (310-315)

310 - Borderline
311 - Mild
312 - Moderate
313 - Severe
314 - Profound
315 - Unspecified

Code with above: Following or associated with
0 - Infection or intoxication
1 - Trauma or physical agent
2 - Disorders of metabolism, growth, or nutrition
3 - Gross Brain Disease (postnatal)
4 - Unknown prenatal influence
5 - Chromosomal abnormality
6 - Prematurity
7 - Major psychiatric disorder
8 - Psycho-social (environmental) deprivation
9 - Other condition

PSYCHOSES (290-299)

290 Senile and pre-senile dementia
2900 - Senile dementia
2901 - Pre-senile dementia

291 Alcoholic psychosis
2910 - Delirium tremens
2911 - Korsakov's psychosis
2912 - Other alcoholic hallucinosis
2913 - Alcoholic paranoia
2914 - Acute alcohol intoxication

2919 - Other and unspecified alcoholic psychosis

292 Psychosis associated with intracranial infection
2920 - General paralysis
2921 - Other syphilis of CNS
2922 - Epidemic encephalitis
2923 - Other and unspecified encephalitis
2929 - Other and unspecified intracranial infection

DSM-II

II. ORGANIC BRAIN SYNDROMES (OBS) continued

Psychosis associated with other cerebral condition
- 2930 - Cerebral arteriosclerosis
- 2931 - Other cerebrovascular disturbance
- 2932 - Epilepsy
- 2933 - Intracranial neoplasm
- 2934 - Degenerative disease of the CNS
- 2935 - Brain trauma
- 2939 - Other cerebral condition

Psychosis associated with other physical condition
- 2940 - Endocrine disorder
- 2941 - Metabolic and nutritional disorder
- 2942 - Systemic infection
- 2943 - Drug or poison intoxication (other than alcohol)
- 2944 - Childbirth
- 2948 - Other and unspecified physical condition

B. NON-PSYCHOTIC OBS

- 3090 - Intracranial infection
- 3201*- Alcohol* (simple drunkenness) (309.13)
- 3202*- Other drug, poison or systemic intoxication* (309.14)
- 3092 - Brain trauma
- 3093 - Circulatory disturbance
- 3094 - Epilepsy
- 3095 - Disturbance of metabolism, growth or nutrition
- 3096 - Senile or presenile brain disease
- 3097 - Intracranial neoplasm
- 3098 - Degenerative disease of the CNS
- 3099 - Other physical condition

WHO (ICD -8)
MENTAL DISORDERS (290-315)

293 Psychosis associated with other cerebral condition
- 2930 - Cerebral arteriosclerosis
- 2931 - Other cerebrovascular disturbances
- 2932 - Epilepsy
- 2933 - Intracranial neoplasm
- 2934 - Degenerative disease of the CNS
- 2935 - Brain trauma
- 2939 - Other cerebral condition

294 Psychosis associated with other physical condition
- 2940 - Endocrine disorder
- 2941 - Metabolic and nutritional disorder
- 2942 - Systemic infection
- 2943 - Drug or poison intoxication (other than alcohol)
- 2944 - Childbirth
- 2948 - Other physical condition
- 2949 - Unspecified physical condition

309 Mental disorders not specified as psychotic associated with physical conditions.
- 3090 - Intracranial infection
- 3091 - Drug, poison or systemic intoxication
- 3092 - Brain trauma
- 3093 - Circulatory disturbance
- 3094 - Epilepsy
- 3095 - Disturbance of metabolism, growth or nutrition
- 3096 - Senile or presenile brain disease
- 3097 - Intracranial neoplasm
- 3098 - Degenerative disease of the CNS
- 3099 - Other or unspecified physical condition

DSM-II	WHO (ICD -8) MENTAL DISORDERS (290-315)
III. PSYCHOSES NOT ATTRIBUTED TO PHYSICAL CONDITIONS LISTED PREVIOUSLY	
Schizophrenia	295 Schizophrenia
2950 - Simple	2950 - Simple
2951 - Hebephrenic	2951 - Hebephrenic
2952 - Catatonic	2952 - Catatonic
3301*- Catatonic type, excited (295.23)	
3302*- Catatonic type, withdrawn (295.24)	
2953 - Paranoid	2953 - Paranoid
2954 - Acute schizophrenic episode	2954 - Acute schizophrenic episode
2955 - Latent	2955 - Latent
2956 - Residual	2956 - Residual
2957 - Schizo-affective	2957 - Schizo-affective
3303*- Schizo-affective, excited (295.73)	
3304*- Schizo-affective, depressed (295.74)	
2958 - Childhood	2958 - Other
2959 - Chronic undifferentiated (295.90)	2959 - Unspecified type
3306*- Other schizophrenia (295.99)	
Major affective disorders	296 Affective Psychoses
2960 - Involutional melancholia	2960 - Involutional melancholia
2961 - Manic-depressive illness, manic	2961 - Manic-depressive psychosis, manic
2962 - Manic-depressive illness, depressed	2962 - Manic-depressive psychosis, depressed
2963 - Manic-depressive illness, circular	2963 - Manic-depressive psychosis,circular
3401*- Manic-depressive, circular, manic, (296.33)	
3402*- Manic-depressive, circular, depressed (296.34)	
2968 - Other major affective disorder	2968 - Other major affective disorder
	2969 - Unspecified
Paranoid states	297 Paranoid states
2970 - Paranoia	2970 - Paranoia
2971 - Involutional paranoid state	2971 - Involutional paraphrenia
2979 - Other paranoid state	2979 - Other
Other psychoses	298 Other psychoses
2980 - Psychotic depressive reaction	2980 - Psychotic depressive reaction
2990*- Psychotic reaction without clearly defined structural change other than above	
	2981 - Reactive excitation
	2982 - Reactive confusion
	2983 - Acute paranoid reaction
	2989 - Reactive psychosis, unspecified
	299 Unspecified psychosis (encode 2990)

DSM-II	WHO (ICD -8) MENTAL DISORDERS (290-315)
V. NEUROSES	300 NEUROSES
3000 - Anxiety	3000 - Anxiety
3001 - Hysterical	3001 - Hysterical
3501*- Hysterical, conversion type (300.13)	
3502*- Hysterical, dissociative type (300.14)	
3002 - Phobic	3002 - Phobic
3003 - Obsessive compulsive	3003 - Obsessive compulsive
3004 - Depressive	3004 - Depressive
3005 - Neurasthenic	3005 - Neurasthenic
3006 - Depersonalization	3006 - Depersonalization syndrome
3007 - Hypochondriacal	3007 - Hypochondriacal
3008 - Other neurosis	3008 - Other neurosis
	3009 - Unspecified neurosis
V. PERSONALITY DISORDERS AND CERTAIN OTHER NON-PSYCHOTIC MENTAL DISORDERS	
Personality disorders	301 Personality disorders
3010 - Paranoid	3010 - Paranoid
3011 - Cyclothymic	3011 - Affective
3012 - Schizoid	3012 - Schizoid
3013 - Explosive	3013 - Explosive
3014 - Obsessive compulsive	3014 - Anankastic
3015 - Hysterical	3015 - Hysterical
3016 - Asthenic	3016 - Asthenic
3017 - Antisocial	3017 - Antisocial
3601*- Passive-aggresive (301.81)	
3602*- Inadequate (301.82)	
3603*- Other specified types (301.89)	
	3018 - Other
	3019 - Unspecified
Sexual deviation	302 Sexual deviation
3020 - Homosexuality	3020 - Homosexuality
3021 - Fetishism	3021 - Fetishism
3022 - Pedophilia	3022 - Pedophilia
3023 - Transvestitism	3023 - Transvestitism
3024 - Exhibitionism	3024 - Exhibitionism
3025 - Voyeurism	3025 - Voyeurism
3026 - Sadism	3026 - Sadism
3027 - Masochism	3027 - Masochism
3028 - Other sexual deviation	3028 - Other
	3029 - Unspecified

DSM-II

Alcoholism
- 3030 - Episodic excsssive drinking
- 3031 - Habitual excessive drinking
- 3032 - Alcohol addiction
- 3039 - Other alcoholism

Drug Dependence
- 3040 - Opium, opium alkaloids and their derivatives
- 3041 - Synthetic analgesics with morphine-like effects
- 3042 - Barbiturates
- 3043 - Other hypnotics and sedatives or "tranquilizers"
- 3044 - Cocaine
- 3045 - Cannabis sativa (hashish, marihuana)
- 3046 - Other psycho-stimulants
- 3047 - Hallucinogens
- 3048 - Other drug dependence

VI. PSYCHOPHYSIOLOGIC DISORDERS
- 3050 - Skin
- 3051 - Musculoskeletal
- 3052 - Respiratory
- 3053 - Cardiovascular
- 3054 - Hemic and lymphatic
- 3055 - Gastro-intestinal
- 3056 - Genito-urinary
- 3057 - Endocrine
- 3058 - Organ of special sense
- 3059 - Other type

VII. SPECIAL SYMPTOMS
- 3060 - Speech disturbance
- 3061 - Specific learning disturbance
- 3062 - Tic
- 3063 - Other psychomotor disorder
- 3064 - Disorders of sleep
- 3065 - Feeding disturbance
- 3066 - Enuresis
- 3067 - Encopresis
- 3068 - Cephalalgia
- 3069 - Other special symptom

WHO (ICD -8)
MENTAL DISORDERS (290-315)

303 Alcoholism
- 3030 - Episodic excessive drinking
- 3031 - Habitual excessive drinking
- 3032 - Alcohol addiction
- 3039 - Other and unspecified alcoholism

304 Drug Dependence
- 3040 - Opium, opium alkaloids and their derivatives
- 3041 - Synthetic analgesics with morphine-like effects
- 3042 - Barbiturates
- 3043 - Other hypnotics and sedatives or "tranquilizers"
- 3044 - Cocaine
- 3045 - Cannabis sativa (hashish, marihuana)
- 3046 - Other psycho-stimulants
- 3047 - Hallucinogens
- 3048 - Other
- 3049 - Unspecified

305 Physical disorders of presumably psychogenic origin
- 3050 - Skin
- 3051 - Musculoskeletal
- 3052 - Respiratory
- 3053 - Cardiovascular
- 3054 - Hemic and lymphatic
- 3055 - Gastro-intestinal
- 3056 - Genito-urinary
- 3057 - Endocrine
- 3058 - Organ of special sense
- 3059 - Other

306 Special symptoms not classified elsewhere
- 3060 - Stammering and stuttering
- 3061 - Specific learning disturbance
- 3062 - Tics
- 3063 - Other psychomotor disorders
- 3064 - Specific disorders of sleep
- 3065 - Feeding disturbances
- 3066 - Enuresis
- 3067 - Encopresis
- 3068 - Cephalalgia
- 3069 - Other

DSM-II	WHO (ICD -8) MENTAL DISORDERS (290-315)
VIII. TRANSIENT SITUATIONAL DISTURBANCES	3070* Transient situational disturbances (307)
3070 - Adjustment reaction of infancy	
3071 - Adjustment reaction of childhood	
3072 - Adjustment reaction of adolescence	
3073 - Adjustment reaction of adult life	
3074 - Adjustment reaction of late life	
IX. BEHAVIOR DISORDERS OF CHILDHOOD AND ADOLESCENCE	3080* Behavior disorders of childhood (308)
3080 - Hyperkinetic reaction	
3081 - Withdrawing reaction	
3082 - Overanxious reaction	
3083 - Runaway reaction	
3084 - Unsocialized aggressive reaction	
3085 - Group delinquent reaction	
3089 - Other reaction	
X. CONDITIONS WITHOUT MANIFEST PSYCHIATRIC DISORDER AND NON-SPECIFIC CONDITIONS	
Social maladjustment without manifest psychiatric disorder	
3160 - Marital maladjustment	
3161 - Social maladjustment	
3162 - Occupational maladjustment	
3163 - Dyssocial behavior	
3169 - Other social maladjustment	
Non-specific conditions	
3170 - Non-specific conditions	
No Mental Disorder	
3180 - No mental disorder	
XI. NON-DIAGNOSTIC TERMS FOR ADMINISTRATIVE USE	
3190 - Diagnosis deferred	
3191 - Boarder	
3192 - Experiment only	
3193 - Other	

APPENDIX 3

FORMATS FOR NON-STANDARD INSTRUMENTS

The following group of assessment instruments reflect the variety of input which can be processed by BLIPS and, at the same time, suggest alternative means for the assessment of treatment effects. The selection is not meant to be definitive. Rather, it is a pot-pourri of devices: some new - some venerable; some self-rated - some physician rated; some sharply focussed - some quite general. The instruments are presented in the same style as the standard ECDEU scales though with a greater emphasis on encoding.

Here are some general instructions which apply to all non-standard instruments. (Also see "Encoding Non-Standard Data, pp. 59-64).

1. While the precise location on the General Scoring Sheet for a scale can vary from study to study, the location must remain constant within a study.

2. Similarly, the Sheet Number assigned - any number between 80 and 99 - must be constant within a study.

3. All non-standard data must be described in Item II of The Data Shipment (071-DS).

4. Several instruments and/or data sets can be encoded on a single GSS, but - again - the location pattern must be constant throughout a study.

5. As an alternative to transcribing data onto the GSS, investigators may submit card decks. Should the card format differ from the standard ECDEU format, its description must accompany the data.

PROFILE OF MOOD STATES (056 - POMS)

McNair, Lorr and Droppleman

0 Not at all
1 A little
2 Moderately
3 Quite a bit
4 Extremely

1. Friendly
2. Tense
3. Angry
4. Worn out
5. Unhappy
6. Clear-headed
7. Lively
8. Confused
9. Sorry for things done
10. Shaky
11. Listless
12. Peeved
13. Considerate
14. Sad
15. Active
16. On edge
17. Grouchy
18. Blue
19. Energetic
20. Panicky
21. Hopeless
22. Relaxed
23. Unworthy
24. Spiteful
25. Sympathetic
26. Uneasy
27. Restless
28. Unable to concentrate
29. Fatigued
30. Helpful
31. Annoyed
32. Discouraged
33. Resentful
34. Nervous
35. Lonely
36. Miserable
37. Muddled
38. Cheerful
39. Bitter
40. Exhausted
41. Anxious
42. Ready to fight
43. Good natured
44. Gloomy
45. Desperate
46. Sluggish
47. Rebellious
48. Helpless
49. Weary
50. Bewildered
51. Alert
52. Deceived
53. Furious
54. Efficient
55. Trusting
56. Full of pep
57. Bad-tempered
58. Worthless
59. Forgetful
60. Carefree
61. Terrified
62. Guilty
63. Vigorous
64. Uncertain about things
65. Bushed

The POMS is a self-rated scale consisting of 65 adjectives and has been designed to assess feelings, affect and mood and their changes under therapeutic intervention or experimental manipulation. The POMS has been extensively evaluated and normative samples for psychiatric and normal subjects are available.

REFERENCE — McNair, D. M., Lorr, M., and Droppleman, L. F., Manual for the Profile of Mood States, Educational and Industrial Testing Service, San Diego, California, 1971.

APPLICABILITY — Psychiatric outpatients and normal subjects

UTILIZATION — Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED — During the past week including today.

ENCODING INSTRUCTIONS — POMS rating forms and instruction manual must be obtained from the publisher. (See Reference). Scoring is also available from the publisher. Investigators who desire BLIPS processing may find it more convenient to punch data directly on cards using the formats given below.

CARD FORMAT - ITEMS — CARD 01 = (19x, 56I1)

Item	Column	Item	Column	Item	Column
1	20	20	29	39	58
2	21	21	40	40	59
3	22	22	41	41	60
4	23	23	42	42	61
5	24	24	43	43	62
6	25	25	44	44	63
7	26	26	45	45	64
8	27	27	46	46	65
9	28	28	47	47	66
10	29	29	48	48	67
11	30	30	49	49	68
12	31	31	50	50	69
13	32	32	51	51	70
14	33	33	52	52	71
15	34	34	53	53	72
16	35	35	54	54	73
17	36	36	55	55	74
18	37	37	56	56	75
19	38	38	57		

CARD 02 = (19x, 911)

Item	Column	Item	Column
57	20	61	24
58	21	62	25
59	22	63	26
60	23	64	27
		65	28

CARD FORMAT - FACTORS (CARD 51 = (19x,6F6.2, F4.0)

Factor	Column	Factor	Column
I	20 - 25	IV	38 - 43
II	26 - 31	V	44 - 49
III	32 - 37	VI	50 - 55
		Total	56 - 59

FACTOR COMPOSITION

1. Tension-Anxiety
   - 2 Tense
   - 10 Shaky
   - 16 On edge
   - 20 Panicky
   - 22 Relaxed
   - 26 Uneasy
   - 27 Restless
   - 34 Nervous
   - 41 Anxious

2. Depression-Dejection
   - 5 Unhappy
   - 9 Sorry
   - 14 Sad
   - 18 Blue
   - 21 Hopeless
   - 23 Unworthy
   - 32 Discouraged
   - 35 Lonely
   - 36 Miserable
   - 44 Gloomy
   - 45 Desperate
   - 48 Helpless
   - 58 Worthless
   - 61 Terrified
   - 62 Guilty

3. Anxiety-Hostility
   - 3 Angry
   - 12 Peeved
   - 17 Grouchy
   - 24 Spiteful
   - 31 Annoyed
   - 39 Bitter
   - 42 Ready to fight
   - 47 Rebellious
   - 52 Deceived
   - 53 Furious
   - 57 Bad-tempered

4. Vigor
   - 7 Lively
   - 15 Active
   - 19 Energetic
   - 38 Cheerful
   - 51 Alert
   - 56 Full of pep
   - 60 Carefree
   - 64 Vigorous

5. Fatigue
   - 4 Worn-out
   - 11 Listless
   - 29 Fatigued
   - 40 Exhausted
   - 46 Sluggish
   - 49 Weary
   - 65 Bushed

6. Confusion
   - 8 Confused
   - 28 Unable to concentrate
   - 37 Muddled
   - 50 Bewildered
   - 54 Efficient
   - 59 Forgetful
   - 64 Uncertain about things

SPECIAL INSTRUCTIONS

For a detailed description of the POMS, its validity, reliability and normative data, the reader is referred to author's Manual.

DOCUMENTATION

a. Raw score printout
b. Factor score printout
c. Factor means and standard deviations
d. Variance analyses

FROSTIG DEVELOPMENTAL TEST OF VISUAL PERCEPTION (065 - FROST)

The FROST is designed to measure the development of perceptual skills in children and to obtain a Perceptual Quotient which reflects expected development for given age levels. The test contains 5 subtests - each possessing relatively distinct functions. It may be administered either individually or to groups.

REFERENCES -

1. Frostig, M., Maslow, P., Lefever, D. W., and Whittlesey, J. R. B., The Marianne Frostig Developmental Test of Visual Perception, 1963, Standardization, Consulting Psychologist's Press, 577 College Avenue, Palo Alto, California 1963.

2. Frostig, M., Lefever, W., and Whittlesey, J. R. B., Administration and Scoring Manual, Consulting Psychologist's Press, Palo Alto, California, revised 1966.

Test materials and manuals can be obtained from the publishers.

APPLICABILITY

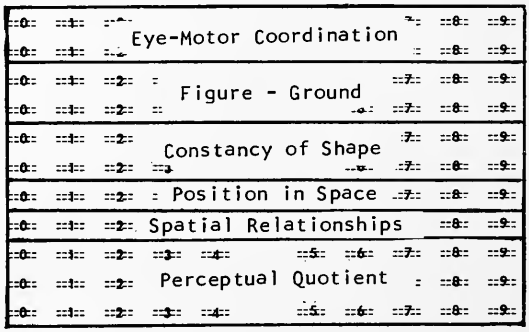
Norms available for children 4 to 8 years old. Test applicable to older children with learning difficulties. May also be useful for assessing perceptual difficulties in brain-injured adults.

UTILIZATION

Once at pretreatment; at least one posttreatment rating. Additional ratings are at the discretion of the investigator.

ENCODING FORMAT

SCALED SCORES - not raw scores - must be encoded. The test requires an 11 x 10 matrix, i.e., 11 rows and 10 columns. It may be encoded on either the left or right half of the General Scoring Sheet. The matrix is as follows:



CARD FORMAT - (19x, 312, 211, 13)

Subtest	Column
1	20 - 21
2	22 - 23
3	24 - 25
4	26
5	27
Perceptual Quotient	28 - 30

SPECIAL INSTRUCTIONS - Raters should familiarize themselves with the manuals referred to under References.

DOCUMENTATION

a. Scaled score printout
b. Means and standard deviations
c. Variance analyses

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

ABNORMAL INVOLUNTARY MOVEMENT SCALE (AIMS)

STUDY	PATIENT	FORM	PERIOD	RATER	HOSPITAL
		117			
(1-6)	(7-9)	(10-12)	(13-15)	(16-17)	(79-80)

PATIENT'S NAME

RATER

DATE

INSTRUCTIONS: Complete Examination Procedure (reverse side) before making ratings.
MOVEMENT RATINGS: Rate highest severity observed. Rate movements that occur upon activation one *less* than those observed spontaneously.

Code: 0 = None
1 = Minimal, may be extreme normal
2 = Mild
3 = Moderate
4 = Severe

			(Circle One)					CARD 01 (18-19)
FACIAL AND ORAL MOVEMENTS:	1.	Muscles of Facial Expression e.g., movements of forehead, eyebrows, periorbital area, cheeks; include frowning, blinking, smiling, grimacing	0	1	2	3	4	(20)
	2.	Lips and Perioral Area e.g., puckering, pouting, smacking	0	1	2	3	4	(21)
	3.	Jaw e.g., biting, clenching, chewing, mouth opening, lateral movement	0	1	2	3	4	(22)
	4.	Tongue Rate only increase in movement both in and out of mouth, NOT inability to sustain movement	0	1	2	3	4	(23)
EXTREMITY MOVEMENTS:	5.	Upper *(arms, wrists, hands, fingers)* Include choreic movements, (i.e., rapid, objectively purposeless, irregular, spontaneous), athetoid movements (i.e., slow, irregular, complex, serpentine). Do NOT include tremor (i.e., repetitive, regular, rhythmic)	0	1	2	3	4	(24)
	6.	Lower *(legs, knees, ankles, toes)* e.g., lateral knee movement, foot tapping, heel dropping, foot squirming, inversion and eversion of foot	0	1	2	3	4	(25)
TRUNK MOVEMENTS:	7.	Neck, shoulders, hips e.g., rocking, twisting, squirming, pelvic gyrations	0	1	2	3	4	(26)
GLOBAL JUDGMENTS:	8.	Severity of abnormal movements	None, normal 0 Minimal 1 Mild 2 Moderate 3 Severe 4					(27)
	9.	Incapacitation due to abnormal movements	None, normal 0 Minimal 1 Mild 2 Moderate 3 Severe 4					(28)
	10.	Patient's awareness of abnormal movements Rate only patient's report	No awareness 0 Aware, no distress 1 Aware, mild distress 2 Aware, moderate distress 3 Aware, severe distress 4					(29)
DENTAL STATUS:	11.	Current problems with teeth and/or dentures	No 0 Yes 1					(30)
	12.	Does patient usually wear dentures?	No 0 Yes 1					(31)

EXAMINATION PROCEDURE

Either before or after completing the Examination Procedure observe the patient unobtrusively, at rest (e.g., in waiting room).

The chair to be used in this examination should be a hard, firm one without arms.

---

1. Ask patient whether there is anything in his/her mouth (i.e., gum, candy, etc.) and if there is, to remove it.

2. Ask patient about the current condition of his/her teeth. Ask patient if he/she wears dentures. Do teeth or dentures bother patient now?

3. Ask patient whether he/she notices any movements in mouth, face, hands, or feet. If yes, ask to describe and to what extent they currently bother patient or interfere with his/her activities

4. Have patient sit in chair with hands on knees, legs slightly apart, and feet flat on floor. (Look at entire body for movements while in this position).

5. Ask patient to sit with hands hanging unsupported. If male, between legs, if female and wearing a dress, hanging over knees. (Observe hands and other body areas.)

6. Ask patient to open mouth. (Observe tongue at rest within mouth.) Do this twice.

7. Ask patient to protrude tongue. (Observe abnormalities of tongue movement.) Do this twice.

- 8. Ask patient to tap thumb, with each finger, as rapidly as possible for 10—15 seconds; separately with right hand, then with left hand. (Observe facial and leg movements.)

9. Flex and extend patient's left and right arms (one at a time.) (Note any rigidity and rate on DOTES.)

10. Ask patient to stand up. (Observe in profile. Observe all body areas again, hips included.)

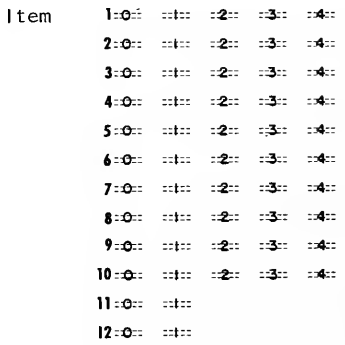
- 11. Ask patient to extend both arms outstretched in front with palms down. (Observe trunk, legs, and mouth.)

- 12. Have patient walk a few paces, turn, and walk back to chair. (Observe hands and gait.) Do this twice.

- Activated movements

The AIMS is a 12-item scale designed to record in detail the occurrence of dyskinetic movements. In the development of this scale, the Psychopharmacology Research Branch has had the benefit of consulting with many of the scientists who have previously devised rating scales for dyskinetic movements and the continuing advice of a formal consultant neurologist (Dr. Roger Duvoisin). One of the units in a PRB collaborative study (St. Paul Ramsey Hospital) had separately undertaken the development of a rating scale and had actively carried out studies with patients showing dyskinetic movements utilizing video-recording techniques. Preliminary versions of the AIMS were used to rate video recordings of patients with dyskinetic movements and although no formal interrater reliability studies have been conducted there was relatively good consensus among the group doing the ratings. Because of the great need for an assessment instrument in this field, the scale is being made available to the larger scientific community through the ECDEU Battery despite the fact that it has not been validated using psychometric procedures.

APPLICABILITY	Patients receiving neuroleptic drugs.
UTILIZATION	Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.
TIME SPAN RATED	Period of the examination only.
ENCODING FORMAT	Available in non-opscan format, the AIMS can also be transcribed to the General Scoring Sheet should the investigator desire BLIPS processing. A 12 x 5 matrix is required; i.e., 12 rows and 5 columns, as follows:



CARD FORMAT - (19x, I2I, I2)

Item	Column	Item	Column
1	20	7	26
2	21	8	27
3	22	9	28
4	23	10	29
5	24	11	30
6	25	12	31
		Total	32-33

Total Score = Sum of the items. Total Score Range = 0 - 42.

DOCUMENTATION:

a. Raw score printout
b. Means and standard deviations
c. Variance analyses

ITEMS

Score	1 Mobility	2 Orientation	3 Communication	4 Co-operation	5 Restlessness	6 Dressing	7 Feeding	8 Continence	9 Sleep	10 Mood: Objective	11 Mood: Subjective
1	Fully ambulant (including stairs)	Complete	Always clear and retains information	Actively co-operative	None	Dresses correctly - unaided	Feeds correctly unaided at appropriate times	Fully continent	Normal (Hypnotic not required)	Normal and stable affective response and appearance	Well-being or euphoria
2	Usually independent (not stairs)	Orientated in ward and identifies persons correctly	Can indicate needs. Can understand simple verbal directions. Can deal with simple information	Passively co-operative	Intermittent	Dressing imperfect but adequate	Feeds adequately with minimum supervision	Nocturnal incontinence unless toileted. Occasional accidents (urine or faeces)	Requires occasional hypnotic; or occasionally restless	Fair affective response; or not always appropriate or stable	Self-reproachful, listless, dejected, indecisive, lacks interest. (Not completely well though no specific complaints)
3	Walks with supervision	Misidentifies persons and surroundings but can find way about	Understands simple verbal and non-verbal information but does not indicate needs	Requires frequent encouragement and/or persuasion	Persistent by day	Dressing adequate with minimum supervision	Does not feed adequately unless continually supervised	Continent by day if regularly toileted	Sleeps well with regular hypnotic; or usually restless for a period every night	Marked blunting or impairment of mood or inappropriateness of affect	Marked somatic or hypochondriacal concern. Preoccupation
4	Walks with artificial aids or under careful supervision	Cannot find way to bed or to toilet without assistance	Cannot understand simple verbal or non-verbal information but retains some expressive ability	Rejects assistance and shows some independent but poorly directed activity	Persistent by day with frequent nocturnal restlessness	Dressing inadequate unless continually supervised	Defective feeding because of physical handicap or poor appetite	Urinary incontinence in spite of regular toileting	Occasionally disturbed in spite of regular standard hypnotic	Emotional lability or incontinence of affect. Retarded, lacks spontaneity but can respond	Severe retardation or agitation. Marked withdrawal though responds to questioning
5	Bedfast or mainly so. Chairfast	Lost	No effective contact	Completely resistive or withdrawn	Constant	Unable to dress or retain clothing because of mental impairment	Unable to feed because of mental impairment	Regularly/ frequently doubly incontinent	Disturbed even with heavier sedation	Hallucinations or nihilistic delusions of guilt or somatic dysfunction	Suicidal or death wishes. Mute, or agitated to the point of incoherence

The 11-item CRICHT was developed as part of a geriatric treatment program and was designed to assess the level of behavioral functioning. Derived from clinical observation, the items are rated on a 5-point scale - ranging from normality (1) to complete failure of function (5).

REFERENCE

Robinson, R. A., The Diagnosis and Prognosis of Dementia, Current Achievements in Geriatrics, W. F. Anderson, Ed., Cassell 1964, 190-203.

APPLICABILITY

Elderly psychiatric patients.

UTILIZATION

Once at pretreatment; at least one posttreatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN TO BE RATED

None stated by author. Now or within the past week is suggested.

ENCODING FORMAT

The 201 - CRICHT requires a 11 x 5 matrix; i.e., 11 rows and 5 columns. The matrix may be located in any one of the 4 quadrants of the General Scoring Sheet. Either of the following formats can be used for encoding:

SCALE POINTS

Item	1	2	3	4	5		1	2	3	4	5
1	0	1	2	3	4		5	6	7	8	9
2	0	1	2	3	4		5	6	7	8	9
3	0	1	2	3	4		5	6	7	8	9
4	0	1	2	3	4		5	6	7	8	9
5	0	1	2	3	4		5	6	7	8	9
6	0	1	2	3	4	OR	5	6	7	8	9
7	0	1	2	3	4		5	6	7	8	9
8	0	1	2	3	4		5	6	7	8	9
9	0	1	2	3	4		5	6	7	8	9
10	0	1	2	3	4		5	6	7	8	9
11	0	1	2	3	4		5	6	7	8	9

Total score need not be encoded as it will be derived by computer programming.

CARD FORMAT - (19x, 1111, 12)

Item	Column	Item	Column
1	20	7	26
2	21	8	27
3	22	9	28
4	23	10	29
5	24	11	30
6	25	Total	31 - 32

Total Score = Sum of the 10 items. Total Score provides a useful index of deterioration according to the author:

Total Score	Deterioration
10 - 20	Mild
21 - 30	Moderate
31 +	Severe

DOCUMENTATION

a. Raw score printout
b. Means and standard deviations
c. Variance analyses

Beck Depression Inventory 203-BECK

Instructions

This is a questionnaire. On the questionnaire are groups of statements. Please read the entire group of statements in each category. Then pick out the one statement in that group which best describes the way you feel today, that is, *right now!* Circle the number beside the statement you have chosen. If several statements in the group seem to apply equally well, circle each one.

Be sure to read all the statements in each group before making your choice.

1. (Sadness)
   - 0 I do not feel sad
   - 1 I feel sad or blue
   - 2 I am blue or sad all the time and I can't snap out of it
   - 3 I am so sad or unhappy that I can't stand it
2. (Pessimism)
   - 0 I am not particularly pessimistic or discouraged about the future
   - 1 I feel discouraged about the future
   - 2 I feel I have nothing to look forward to
   - 3 I feel that the future is hopeless and that things cannot improve
3. (Sense of Failure)
   - 0 I do not feel like a failure
   - 1 I feel I have failed more than the average person
   - 2 As I look back on my life, all I can see is a lot of failures
   - 3 I feel I am a complete failure as a person (parent, husband, wife)
4. (Dissatisfaction)
   - 0 I am not particularly dissatisfied
   - 1 I don't enjoy things the way I used to
   - 2 I don't get satisfaction out of anything anymore
   - 3 I am dissatisfied with everything
5. (Guilt)
   - 0 I don't feel particularly guilty
   - 1 I feel bad or unworthy a good part of the time
   - 2 I feel quite guilty
   - 3 I feel as though I am very bad or worthless
6. (Self-Dislike)
   - 0 I don't feel disappointed in myself
   - 1 I am disappointed in myself
   - 2 I am disgusted with myself
   - 3 I hate myself
7. (Self-Harm)
   - 0 I don't have any thoughts of harming myself
   - 1 I feel I would be better off dead
   - 2 I have definite plans about committing suicide
   - 3 I would kill myself if I had the chance
8. (Social Withdrawal)
   - 0 I have not lost interest in other people
   - 1 I am less interested in other people than I used to be
   - 2 I have lost most of my interest in other people and have little feeling for them
   - 3 I have lost all of my interest in other people and don't care about them at all
9. (Indecisiveness)
   - 0 I make decisions about as well as ever
   - 1 I try to put off making decisions
   - 2 I have great difficulty in making decisions
   - 3 I can't make any decisions at all any more
10. (Self-Image Change)
    - 0 I don't feel I look any worse than I used to
    - 1 I am worried that I am looking old or unattractive
    - 2 I feel that there are permanent changes in my appearance and they make me look unattractive
    - 3 I feel that I am ugly or repulsive looking
11. (Work Difficulty)
    - 0 I can work about as well as before
    - 1 It takes extra effort to get started at doing something
    - 2 I have to push myself very hard to do anything
    - 3 I can't do any work at all
12. (Fatigability)
    - 0 I don't get any more tired than usual
    - 1 I get tired more easily than I used to
    - 2 I get tired from doing anything
    - 3 I get too tired to do anything
13. (Anorexia)
    - 0 My appetite is no worse than usual
    - 1 My appetite is not as good as it used to be
    - 2 My appetite is much worse now
    - 3 I have no appetite at all any more

Note: The item titles should be omitted from the subject's copy of the scale.

The short form of the BECK consists of 13 items from the original 21-item scale and has been developed to measure the depth of depression as well as for the rapid screening of depressed patients. A self-rating instrument, the clinically derived items are rated on a 4-point scale (0 - 3). The authors state that the 13-item version correlates 0.96 with the longer 21-item scale and 0.61 with clinician's ratings of depression.

REFERENCES

1. Beck, A. T., Depression: Clinical, Experimental and Theoretical Aspects, Hoeber Medical Division, Harper and Row, New York, 1967.

2. Beck, A. T. and Beamesderfer, A., Assessment of Depression: The Depression Inventory in Psychological Measurements in Psychopharmacology, Vol. 7, 151-169, Ed. P. Pichot, Karger, Basel, 1974.

APPLICABILITY

Psychiatric and medical patients with depressive illness

UTILIZATION

Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED

"Right now", i.e., at the time of the rating

ENCODING FORMAT

A 13 x 4 matrix, i.e., 13 rows and 4 columns are required to encode the BECK on the General Scoring Sheet. This matrix may be located in any one of the four GSS quadrants. EITHER of following matrices may be used:

Scale Points

Item	0	1	2	3
1	0	1	2	3
2	0	1	2	3
3	0	1	2	3
4	0	1	2	3
5	0	1	2	3
6	0	1	2	3
7	0	1	2	3
8	0	1	2	3
9	0	1	2	3
10	0	1	2	3
11	0	1	2	3
12	0	1	2	3
13	0	1	2	3

OR

	0	1	2	3
	5	6	7	8
	5	6	7	8
	5	6	7	8
	5	6	7	8
	5	6	7	8
	5	6	7	8
	5	6	7	8
	5	6	7	8
	5	6	7	8
	5	6	7	8
	5	6	7	8
	5	6	7	8
	5	6	7	8

CARD FORMAT - (19x, 1311, 12)

Item	Column	Item	Column
1	20	8	27
2	21	9	28
3	22	10	29
4	23	11	30
5	24	12	31
6	25	13	32
7	26	Total	33 - 34

Total Score = Sum of all items

Total Score Range = 0 - 39

The authors have provided the following estimates of the severity of depression based on Total Score:

Score	Severity
0 - 4	None or minimal
5 - 7	Mild
8 - 15	Moderate
16+	Severe

SPECIAL INSTRUCTIONS

Raters are urged to familiarize themselves with the volume cited in Reference 1. As with all self-rating instruments, the examiner should make certain that the patient fully understands the instructions and that the scale is properly and - as far as possible - completely filled out.

DOCUMENTATION:

a. Raw score printout
b. Total score means and standard deviations
c. Variance analyses

GUILD MEMORY TEST (205-GUILD)

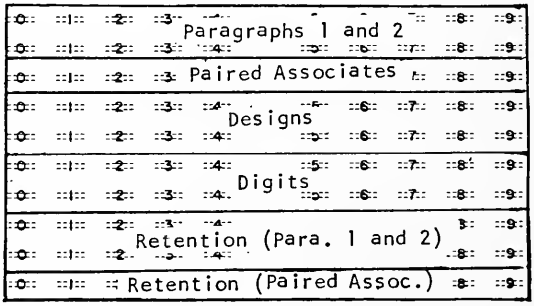
The GUILD was designed to be used in conjunction with and as an adjunct to the Wechsler Adult Intelligence Scale. It consists of 6 subtests designed to measure different facets of memory. There are 2 forms of the test (A and B) which are considered equivalent and which may be used interchangeably for repeated testing.

REFERENCE — Gilbert, Jeanne G., Guild Memory Test Manual, Unico National Mental Health Research Center, 17 Mulberry Street, Newark, New Jersey 07102 The Manual contains the test items.

APPLICABILITY — Same population range as WAIS; 16 to adult

UTILIZATION — Once at pretreatment; at least one posttreatment rating. Additional ratings are at the discretion of the investigator.

ENCODING — To encode the test on the General Scoring Sheet a 10 x 10 matrix, i.e., 10 rows and 10 columns is required. This matrix may be located on either half of the GSS. Specifically, the SCALED SCORES are encoded as follows:



CARD FORMAT (19x, I2, I1, 2I2, I2, I1)

Item	
Paragraphs 1 and 2	20 - 21
Paired Associates	22
Designs	23 - 24
Digits	25 - 26
Retention (Para. 1 and 2)	27 - 28
Retention (Period Assoc.)	29

SPECIAL INSTRUCTIONS

Instructions for administration and scoring are contained in Manual cited above. Remember that scaled scores - NOT RAW SCORES - must be encoded. To convert from raw to scaled scores, use the following table:

SCALED SCORES

RAW SCORE	Paragraph 1 and 2	Paired Assoc.	Designs	Digits	Retention Paragraph 1 and 2	Retention Paired Assoc.
19		8	10		18	9
18	15			15	17	
17	14		09		16	
16	13	7		14		8
15	12		08	13	15	
14	11				14	7
13		6	07	12	13	
12	10				12	
11	09	5	06	11	11	6
10	08				10	
9	07		05	10	09	
8	06	4		09	08	5
7			04		07	
6	05			08	06	4
5	04	3	03			
4	03			07	05	
3	02			06	04	3
2	01	2	02		03	
1				05	02	
0	00	1	01	04	01	2

DOCUMENTATION:

a. Scaled score printout
b. Means and standard deviations
c. Variance analyses

Physician Questionnaire 208 - PHYS

Rickels and Howard

	Not Present	Very Mild	Mild	Moderate	Moderately Severe	Severe	Ext. Severe
1. Anxiety (Apprehensive, tense, worried, frightened, anxious, nervous)	1	2	3	4	5	6	7
2. Depressive Mood (Feelings of depression, unhappiness; sorrow, pessimism, sadness; hopelessness, tearfulness)	1	2	3	4	5	6	7
3. Irritability (Easily annoyed or angered)	1	2	3	4	5	6	7
4. Hostility (Expression of anger toward others)	1	2	3	4	5	6	7
5. Phobia—Obsession—Compulsion (Unrealistic fears, repetitive unwanted thoughts or actions)	1	2	3	4	5	6	7
6. Hypochondriasis (Preoccupation with physical health)	1	2	3	4	5	6	7
7. Somatization (Number and intensity of somatic & autonomic symptoms, [excluding headaches], backache, G.I., sweating, trembling, dizziness, heart palpitations, etc.)	1	2	3	4	5	6	7
8. Insomnia	1	2	3	4	5	6	7
9. Appetite Disturbance Decreased ☐ 1 Increased ☐ 2	1	2	3	4	5	6	7
10. Headaches (Frequency and intensity)	1	2	3	4	5	6	7
11. Psychomotor retardation (Slowness of thought, speech, motor activity)	1	2	3	4	5	6	7
12. Fatigue, tiredness, lethargy	1	2	3	4	5	6	7
13. Impairment of interpersonal relationships (Home, work, social)	1	2	3	4	5	6	7

	Not Ill	Very Mild	Mild	Moderate	Moderately Severe	Severe	Extremely Severe
14.* Degree of Global Psychopathology (OJP): How ill is this patient now, compared to your experience with other neurotic patients?	1	2	3	4	5	6	7

The revised PHYS consists of 13 items plus a global rating of psychopathology. The original version of the scale consisted of the first 10 items and the "global". The PHYS was developed by Rickels and Howard as a simple measure of neurotic symptomatology and focussed on commonly observed symptoms familiar to non-psychiatric physicians. The scale has proved sensitive to changes occurring under drug treatment.

REFERENCE

Rickels, K. and Howard, K., The Physician Questionnaire: A Useful Tool in Psychiatric Drug Research, Psychopharmacologia, 17, 338-344, 1970.

APPLICABILITY

Neurotic outpatients

UTILIZATION

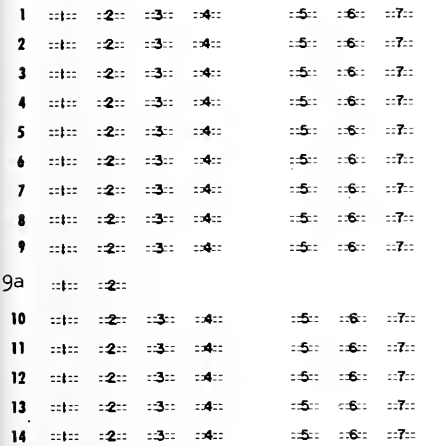
Once at pretreatment; at least once at post-treatment. Additional assessments are at the investigator's discretion.

TIME SPAN RATED

Now or within the last week

ENCODING FORMAT

To encode the PHYS on the General Scoring Sheet, a 15 x 7 matrix, i.e., 15 rows and 7 columns, is required. The matrix may be located in either half of the GSS.



CARD FORMAT - ITEMS CARD 01 = (19x, 1511,312)

Item	Column	Item	Column
1	20	9	28
2	21	9a	29
3	22	10	30
4	23	11	31
5	24	12	32
6	25	13	33
7	26	14	34
8	27	*Emotional	35 - 36
		*Somatic	37 - 38
		*Total	39 - 40

* Emotional Cluster = Sum of Items 1 - 5 Range=5 - 35
* Somatic Cluster = Sum of Items 6 - 10 Range=5 - 35
* Total Score = Sum of Items 1 - 13 (except 9a) Range= 13 - 91

CARD FORMAT - FACTORS CARD 51 = (19x, 3F6.2)

Factor	Column
1	20 - 25
2	26 - 31
3	32 - 37

FACTOR COMPOSITION

Factor 1 - Anxiety

1. Anxiety
3. Irritability
4. Hostility
5. Phobia

Factor 2 - Somatic Concern

6. Hypochondriasis
7. Somatization

Factor 3 - Depression

2. Depressive Mood
8. Insomnia
9. Appetite Disturbance
10. Headaches

DOCUMENTATION

a. Raw score printout
b. Factor and cluster score printout
c. Factor means and standard deviations
d. Variance analyses

INPATIENT MULTIDIMENSIONAL PSYCHIATRIC SCALE (210-IMPS)

Lorr, McNair, Klett and Lasky

COMPARED TO THE NORMAL PERSON TO WHAT DEGREE DOES HE...

Not At All
Very Slightly
A Little
Mildly
Moderately
Quite A Bit
Distinctly
Markedly
Extremely

0 1 2 3 4 5 6 7 8

1. Manifest speech that is slowed, deliberate, or labored?

2. Give answers that are irrelevant or unrelated in any immediately conceivable way to the question asked or topic discussed?
   CUES: Do not rate here wandering or rambling conversation which veers away from the topic at issue (see Item 4). Also do not rate the coherence of the answer.

3. Give answers that are grammatically disconnected, incoherent, or scattered, i.e., not sensible or not understandable?
   CUES: Judge the grammatical structure of his speech, not the content which may or may not be bizarre.

4. Tend to ramble, wander, or drift off the subject or away from the point at issue in responding to questions or topics discussed?
   CUES: Do not rate here responses that are obviously unrelated to the question asked (see Item 2)

5. Verbally express feelings of hostility, ill will, or dislike of others?
   CUES: Makes hostile comments regarding others such as attendants, other patients, his family, or persons in authority. Reports conflicts on the ward.

6. Exhibit postures that are peculiar, unnatural, rigid, or bizarre?
   CUES: Head twisted to one side; or arm and hand held oddly. Judge the degree of peculiarity of the posture.

7. Express or exhibit feelings and emotions openly, impulsively, or without apparent restraint or control?
   CUES: Shows temper outbursts; weeps or wrings hands in loud complaint; jokes or talks boisterously; gestures excitedly.

8. Exhibit indifference or apathy towards such matters as his treatment, his release from the hospital, or plans for the future?
   CUES: Content to stay. Willing to "leave it to the doctor." Sees no need for treatment. Seems to have no goals or expectations.

9. Manifest speech that is hurried, accelerated, or pushed?
   CUES: Pressure of speech.

10. Manifest overt signs of tension?
    CUES: Moves or shifts restlessly; body musculature appears taut, strained or tense; fingers clothing; scratches, drums or fiddles with objects; face or neck muscles twitch; exhibits startle reactions; palms feel sweaty.

11. Express a feeling or attitude of contempt, disdain, or scorn towards other people as unworthy or beneath him?
    CUES: Derogatory or snide comments about others; sarcasm or ridicule of others; condescending.

12. Exhibit an elevation in mood, a sense of well-being or euphoria, or an optimistic and hopeful attitude towards himself and others?
    CUES: Everything is wonderful and this is the best of all possible worlds.

COMPARED TO THE NORMAL PERSON TO WHAT DEGREE DOES HE...

Not At All
Very Slightly
A Little
Mildly
Moderately
Quite A Bit
Distinctly
Markedly
Extremely

0 1 2 3 4 5 6 7 8

13. Exhibit a facial expression that is fixed, immobile, and without discernible play of feeling or expression.

14. Tend to blame, criticize, condemn, or otherwise hold himself responsible for past or present, real or fancied, thought or actions?

    CUES: Blames self for failure, difficulties, and frustrations in family relations, work, or finances.

15. Exhibit in demeanor and/or in verbalizations an attitude of self-importance, superiority, or conceit?

    CUES: Speech is pompous or stilted; boasts of his accomplishments; demands and expects special privileges.

16. Manifest movements or gestures that are slowed, deliberate, labored, or delayed?

    CUES: Acts as if he is fatigued; walking and moving seem to require special effort.

17. Dramatize or seek to attract the attention of others to himself or his symptoms?

    CUES: Seems to enjoy being observed by others; histrionic in his gestures; affected or artificial; a "show-off."

18. Manifest a hostile, sullen, or morose attitude towards others, by tone of voice, demeanor, or facial expression?

    CUES: Seems to have a chip on his shoulder; slams door or bangs chair; sarcastic tone. Try not to judge on the basis of content of remarks.

19. Exhibit a deficit in his memory for events of the last week?

    CUES: Does not know what he had for supper last night, what he did yesterday, or what treatments he received the past week.

20. Manifest speech that is loud, boisterous, and/or intense in tone?

21. Report or admit being uneasy or anxious in anticipation of specific future difficulties or problems?

    CUES: Worried about his symptoms, his family, or his finances.

22. Manifest blocking, halting, or irregular interruptions in his speech?

    CUES: Stuttering or stammering should not be rated here.

23. Exhibit apathy, indifference, or lack of response in feeling to a discussion of his own problems, of his family, or to his surroundings?

    CUES: Doesn't laugh, smile, or react when kidded; neither sad nor angry; doesn't seem to care what goes on; discusses emotional matters in a flat, detached manner.

COMPARED TO THE NORMAL PERSON TO WHAT DEGREE DOES HE...

Not At All
Very Slightly
A Little
Mildly
Moderately
Quite A Bit
Distinctly
Markedly
Extremely

0 1 2 3 4 5 6 7 8

24. Report or admit feeling anxious, apprehensive, or worried in anticipation of vague indefinable future misfortunes or outcomes?

CUES: Feels worried about coming events but doesn't know why.

25. Manifest irritability, grouchiness annoyance, or anger?

CUES: Tone of voice; sharpness of response; explosiveness of retorts; use of profane or obscene language resulting from irritation.

26. Exhibit overactivity, restlessness, and/or acceleration in body movements?

CUES: Paces or shifts about restessly. Bearing, posture and gestures suggest excitement or agitation.

27. Exhibit in his general demeanor or in his verbalizations an attitude of self-depreciation, inadequacy, or inferiority?

CUES: Talks about his faults and lack of accomplishment. Underrates his skills.

28. Tend to blame, criticize, or hold other people, objects or circumstances responsible for his difficulties, failures, or frustrations?

29. Manitest verbally or in demeanor a dejection or depression in mood and a despondent or despairing attitude?

CUES: Says he doesn't want to talk; complains of loss of interest and enjoyment, lack of energy; discouraged about being helped; expresses lack of hope; may wish he were dead; reports crying spells or tearfulness; expects the worst, everything seems flat and stale.

30. Exhibit a slovenly, unkempt, or disordered appearance and/or asocial manners?

31. Express feelings of guilt, sorrow or remorse for having done wrong, that are accompanied by a desire to make amends?

CUES: Says he has been a terrible father or husband: claims sexual misdeeds; recounts past "sins"; has let people down and brought suffering upon others; has neglected his friends, family or work, wants to atone for his sins or misdeeds.

32. Express feelings of bitterness and resentment because he feels others have wronged, cheated, injured, or slighted him?

33. Manifest speech that is low, weak, whispered, or difficult to hear?

34. Manifest in facial expression, posture, voice, and manner, a mood of dejection and sadness?

CUES: Rate only on the basis of external appearance and manifest behavior.

COMPARED TO THE NORMAL PERSON TO WHAT DEGREE DOES HE...

Not At All 0
Very Slightly 1
A Little 2
Mildly 3
Moderately 4
Quite A Bit 5
Distinctly 6
Markedly 7
Extremely 8

35. Express feelings of dejection, sadness, and unhappiness?

CUES: Rate only on the basis of what the patient spontaneously reports or admits to on questioning. Do not rate external appearance here.

36. Complain, criticize, gripe, or find fault with people and conditions in or out of the hospital?

CUES: Complains about everything and anything: The medical care, the food, the aides, fellow patients, the routine, the hospital, people in general.

37. Exhibit an excess of speech?

CUES: Difficult to stop flow of speech once started or to get a word in edgewise. Judge the amount of speech and not its rate or relevance.

38. Express suspicion of people or their motives?

CUES: Expresses lack of trust in others; feels or suspects others are hostile towards him; questions motives of examiner; questions fidelity of wife.

39. Express feelings of discouragement, loss of hope, or despair about the future.

CUES: Doubts things will improve. Discouraged about being helped. Despairs of finding solutions. Feels hopeless and "at the end of the rope." Says: "I'll never get well" or its equivalent.

40. Try to dominate, control, or direct the conduct of the interview?

CUES: Number of times he interrupts, or "talks down" the interviewer. Tries to control or dominate the conversation.

41. Fail to respond to questions, answer in monosyllables, or give only minimal responses?

CUES: Answers "yes" or "no"; stares blankly; has to be pushed to get an answer. Judge amount, not rate or relevance of speech.

42. Express attitudes and feelings indicative of reduced self-esteem?

CUES: Says he has failed as a person (friend, husband, parent, etc.) Says he is useless, worthless, a failure.

43. Show a lack of insight regarding himself or an inability to recognize that he has problems?

CUES: Offers physical illness as an explanation. Believes he is in a rest home or prison. Asks to be sent home immediately. Denies illness or need for treatment.

44. Show outer signs of inner agitation and anxiety?

CUES: Wrings hands, pulls on hair or skin, bites nails, purses or bites lips; moans and sighs.

45. Express sense of personal helplessness and powerlessness to alter or remedy his condition.

Answer the following on the basis of the patient's reports or admissions.
If a symptom is not present, rate "not at all."

Not at all
Once or Twice
A Few Times
Fairly Often
Very Often
0 2 4 6 8

TO WHAT EXTENT DOES HE APPEAR PREOCCUPIED WITH...

46. Suicidal thoughts or impulses? (Says life is not worth living. Wishes he were dead. Threatens or plans suicide.)

47. Unwanted thoughts that recur persistently and are difficult to control? (He must recognize these ideas as irrational.)

48. Specific morbid fears of objects, persons or situations? (e.g., crowds, enclosed spaces, catching a disease.)

49. Urges or compulsions to perform a repetitive act or ritual which he recognizes to be unnecessary or illogical, but difficult to control? (e.g., counting, handwashing.)

50. Delusional beliefs or convictions? (e.g., ideas of persecution, reference, control, etc.)

51. Hallucinatory sounds or voices? (e.g., singing, buzzing, laughing, blaming voices.)

HOW OFTEN DURING THE INTERVIEW DID HE...

52. Grin or giggle inappropriately? (Exclude reactions resulting from embarrassment.)

53. Grimace peculiarly or otherwise exhibit unusual or bizarre frowns or other facial expressions?

54. Exhibit peculiar, inappropriate, or bizarre repetitive gestures and/or manneristic body movements (e.g., rhythmic neck twisting, lip smacking, odd gestures)?

55. Use phrases or coin words not found in the ordinary language or the dictionary (neologisms)?

56. Mechanically repeat certain words or fixed phrases in a seemingly meaningless way (stereotypy)?

57. Talk, mutter, or mumble to himself without an apparent provoking stimulus?

58. Glance around at and/or appear to be startled as if hearing voices?

Inquire about the patient's view of his cognitive functioning, ability to make decisions, level of interest in people, work and sex, energy level, and ease of sleeping for the past week. If, and only if, he admits or complains of disturbances, ask how frequently these occur.

HOW OFTEN DURING THE PAST WEEK DID HE...

Not at all
Once or Twice
A Few Times
Fairly Often
Very Often
0 2 4 6 8

59. Experience difficulty in making decisions, even about little things, without help?

60. Observe a decrease in, or loss of, ability to concentrate, remember things, or solve problems?

61. Feel tired, worn out, or lacking in energy?

62. Observe a reduction or loss of interest or enjoyment in people, social activities or hobbies?

63. Experience a difficulty or inability to get started, to work at, or to keep interest up in anything?

64. Experience a decrease in, or loss of, sexual interest, pleasure or potency?

65. Experience difficulty in falling asleep or remaining asleep without sedatives?

Answer on the basis of evidence obtained in the interview that the patient NOW has or during the past week had hallucinatory experiences or delusional beliefs.

HOW OFTEN DID HE...

66. Hear voices that accused, blamed, or said "bad" things about him? (e.g., he is a spy, homosexual, murderer.)

67. Hear voices that praised, extolled, or spoke to him about divine missions?

68. Hear voices that threatened punishment, torture, or death?

69. Hear voices that ordered him to carry out or perform certain tasks?

70. See actual visions? (Note: Check carefully as this is infrequent except in organic cases.)

71. Have other hallucinatory experiences: Tactual, gustatory, olfactory? (e.g., sensations of crawling on the skin, smells queer or foul odors, food or drink tastes peculiar or "bad.")

72. Experience self-estrangement, i.e., feel or think he is no longer same person; feel changed, unreal, unfamiliar, or detached? (e.g., feel numb, dead, like a corpse, or without feeling; as though floating in space.)

DOES HE BELIEVE THAT. . .

No 0 Yes 8

73. Some people talk about, refer to, or watch him?

74. He is being blocked, cheated, deprived, discriminated against, or persecuted?

75. Certain people are plotting or conspiring against him? (e.g., secret police, criminals, international spies.)

76. Certain people are trying to or now do control his actions or thinking?

77. Certain external forces (e.g., machines, electronic devices) are influencing or controlling his behavior and thinking?

78. He has unusual or extraordinary abilities, powers, or knowledge? (e.g., scientific or religious.)

79. He is a well-known present day or historical personality? (e.g., president, Christ.)

80. He is unworthy, sinful, evil, and/or guilty of unpardonable sins and crimes?

81. Familiar things, people, or surroundings have changed and are unreal?

82. His body is diseased, distorted, or that his internal organs are rotted or missing?

83. He has a distinct divine mission, that he received commands from God, or that he has other religious "calls" ?

DOES HE KNOW. . .

No 1 Yes 0

84. That he is in a hospital?

85. In what state the hospital is located or the nearest large city?

86. The name of at least one person in the hospital?

87. The season of the year? (Allow for transitional periods.)

88. The calendar year?

89. His own age?

Extensively revised in 1966, the IMPS consists of 89 items rated on the basis of observations made during a psychiatric interview. The scale has been designed to measure psychotic syndromes and has undergone extensive psychometric analysis.

REFERENCES -

1. Lorr, M., Klett, C. J., McNair, D.M. and Lasky, J. J., Manual: Inpatient Multidimensional Psychiatric Scale, Consulting Psychologists Press, Palo Alto, California, 1963.

2. Lorr, M. and Klett, C. J., Inpatient Multidimensional Psychiatric Scale, (Revised Edition), Consulting Psychologists Press, 577 College Avenue, Palo Alto, California, 1966.

APPLICABILITY

Functional psychotic or severely neurotic adults who can be interviewed.

UTILIZATION

Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED

Observations based on behavior during the interview.

ENCODING INSTRUCTIONS -

IMPS rating forms and instruction manual must be obtained from the publisher. (See Reference 2). Investigators who desire BLIPS processing may find it more convenient to have the data punched directly on cards rather than transcribing the data to General Scoring Sheets. Instructions for transcribing, however, may be obtained from the Biometric Laboratory. Card formats are given below.

CARD FORMAT - ITEMS

CARD 01 = (19x, 5611)

Item	Column	Item	Column	Item	Column	Item	Column
1	20	15	34	29	48	43	62
2	21	16	35	30	49	44	63
3	22	17	36	31	50	45	64
4	23	18	37	32	51	46	65
5	24	19	38	33	52	47	66
6	25	20	39	34	53	48	67
7	26	21	40	35	54	49	68
8	27	22	41	36	55	50	69
9	28	23	42	37	56	51	70
10	29	24	43	38	57	52	71
11	30	25	44	39	58	53	72
12	31	26	45	40	59	54	73
13	32	27	46	41	60	55	74
14	33	28	47	42	61	56	75

CARD 02 = (19x, 33I1)

Item	Column	Item	Column	Item	Column
57	20	68	31	79	42
58	21	69	32	80	43
59	22	70	33	81	44
60	23	71	34	82	45
61	24	72	35	83	46
62	25	73	36	84	47
63	26	74	37	85	48
64	27	75	38	86	49
65	28	76	39	87	50
66	29	77	40	88	51
67	30	78	41	89	52

CARD FORMAT - FACTORS CARD 51 = (19x, 9F6.2)

Factor	Column	Factor	Column
1	20 - 25	5	44 - 49
2	26 - 31	6	50 - 55
3	32 - 37	7	56 - 61
4	38 - 43	8	62 - 67
		9	68 - 73

CARD 52 = (19x, F6.2)

Factor	Column
10	36 - 41

FACTOR COMPOSITION

1. Excitement
   7. Unrestrained
   9. Hurried speech
   12. Elevated mood
   17. Dramatization
   20. Loud
   26. Overactive
   37. Excess speech
   40. Dominates

2. Hostile and Belligerence
   5. Verbal
   11. Contempt
   18. Attitude
   25. Irritability
   28. Blames others
   32. Bitter
   36. Complaints
   38. Suspicious

3. Paranoid Projection
   50. Delusional
   73. Reference
   74. Persecution
   75. Conspiracy
   76. People controlling
   77. External controlling
   82. Body destruction

4. Grandiose Expansiveness
   15. Superiority
   67. Voices extoll
   78. Unusual powers
   79. Great personality
   83. Divine mission

FACTOR COMPOSITION (Continued)

5. Perceptual Distortion
   51. Hears voices
   66. Voices accuse
   68. Voices threaten
   69. Voices order
   70. Visions
   71. Other hallucinations
   81. Ideas of change

6. Anxious Intropunitiveness
   14. Blames self
   21. Anxiety (specific)
   24. Apprehensive
   27. Self depreciating
   29. Depressed
   31. Guilt
   43. Insight
   46. Suicidal
   47. Obsessive
   48. Phobic
   80. Sinfulness

7. Retardation and Apathy
   1. Slowed speech
   8. Lack of goals
   13. Fixed facies
   16. Slowed movements
   19. Memory deficit
   22. Speech blocking
   23. Apathy
   30. Slovenly
   33. Whispered speech
   41. Failure to answer

8. Disorientation
   84. Hospital
   85. State
   86. Knows no one
   87. Season
   88. Year
   89. Age

9. Motor Disturbances
   6. Posturing
   10. Tension
   52. Giggling
   53. Grimacing
   54. Repetitive movements
   57. Talks to self
   58. Startled glances

10. Conceptual Disorganization
   2. Irrelevant
   3. Incoherent
   4. Rambling
   55. Neologisms
   56. Stereotypy

Items not included in any factor:

34	44	60	65
35	45	61	72
39	49	63	
42	59	64	

SPECIAL INSTRUCTIONS - Detailed descriptions on administration, statistical analyses and norms are provided in Lorr and Klett's Manual (See Reference), and raters are advised to familiarize themselves with its contents.

DOCUMENTATION

a. Raw score printout
b. Factor score printout
c. Factor means and standard deviations
d. Variance analyses

PHYSICIAN'S OUTPATIENT PSYCHOPATHOLOGY SCALE

(211-POPS)

PATIENT: _____ DATE: _____

RATER: _____ ☐ PRE DRUG ☐ ON DRUG ☐ POST DRUG

The symptoms below are described by physical signs observed and/or discomforts expressed by patients. Please use individual descriptions to orient your ratings. Rate every symptom using these terms:

0 = Absent, 1 = Very Mild, 2 = Mild, 3 = Moderate, 4 = Severe, 5 = Disabling

	RATING	
1	☐	ANXIETY - experiencing subjective feelings such as worry, fears of surroundings, apprehension of the future.
2	☐	DEPRESSIVE MOOD - sadness, despondence, feeling helpless and/or hopeless.
3	☐	HYPERACTIVITY - energy spent excessively in rapid, frequent movements.
4	☐	PSYCHOPHYSIOLOGIC DISTURBANCES - headaches, gastrointestinal upset, respiratory effects, cardiovascular effects.
5	☐	TENSION - subjective feeling of being wound up, taut, energy pressing for release, sensing explosive potential.
6	☐	UNEASINESS - ill at ease, sensitive to criticism, emotionally upset.
7	☐	GUILT FEELINGS - concern, distress or remorse for personal activities in the past.
8	☐	FEELING OF INFERIORITY - feelings of inadequacy, negative self-image, loss of confidence.
9	☐	LOSS OF INTEREST - reduced desire to work or to participate in activities.
10	☐	AGITATION - restlessness, fidgetting, shifting, pacing.
11	☐	MOTOR DISTURBANCE - involuntary muscular movements, tremor, or other manifestations of nervousness that interfere with purposeful activity.
12	☐	FATIGUE - constantly feeling tired, washed out, lacking energy.
13	☐	HYPOCHONDRIASIS - vague somatic complaints, malaise, unsupported complaints of physical illness.
14	☐	SKELETAL MUSCULAR DISCOMFORT - complaints of aches and pains of muscles and joints.
15	☐	SLEEP DISTURBANCE - insomnia, cannot go to sleep, irregular sleep pattern, or early awakening.

Revised from the Physician's Rating List and renamed, the POPS has been designed to assess the primary symptom dimensions of outpatient psychopathology. Consisting of 15 items which were clinically derived from the factors of several standard rating scales, the POPS employs generally familiar concepts and is suitable for rating by persons who are not specifically mental health professionals.

REFERENCES

1. Free, S. M., and Guthrie, M. B., A Rating Scale for Evaluating Clinical Response in Psychoneurotic Outpatients, J. Clin. Pharmacol., 9, 3, 187-194, May-June, 1969.

2. Free, S. M., Factor Analysis of Outpatient Clinical Data, J. Clin. Pharmacol., 9, 3, 195-199, May-June, 1969.

3. Overall, J., Psychometric Characteristics of the Physicians Rating List, Psychometric Laboratory Reports, University of Texas Medical Branch, Galveston, June, 1971.

APPLICABILITY

Psychoneurotic outpatient adults

UTILIZATION

Once at pretreatment; at least one posttreatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED

None specified by authors. Suggest "now or within last week."

ENCODING FORMAT

The POPS requires a 15 x 6 matrix; i.e., 15 rows and 6 columns. This matrix may be located in either half of the GSS as follows:

Item						
	1	0	1	2	3	4	5
	2	0	1	2	3	4	5
	3	0	1	2	3	4	5
	4	0	1	2	3	4	5
	5	0	1	2	3	4	5
	6	0	1	2	3	4	5
	7	0	1	2	3	4	5
	8	0	1	2	3	4	5
	9	0	1	2	3	4	5
	10	0	1	2	3	4	5
	11	0	1	2	3	4	5
	12	0	1	2	3	4	5
	13	0	1	2	3	4	5
	14	0	1	2	3	4	5
	15	0	1	2	3	4	5

CARD FORMAT - ITEMS (19x, 1511)

Item	Column	Item	Column
1	20	8	27
2	21	9	28
3	22	10	29
4	23	11	30
5	24	12	31
6	25	13	32
7	26	14	33
		15	34

CARD FORMAT - FACTORS CARD 51 = (19x, 4F6.2, F4.0)

Factor	Column
1	20 - 25
2	26 - 31
3	32 - 37
4	38 - 43
Total	44 - 47

Total Score = Sum of 15 items Total Score Range = 0 - 75

FACTOR COMPOSITION - This factor composition is based on a recent analysis of the ratings obtained from 328 outpatients. (Overall and Free, Personal Communication, 1976, to be published).

1. ANXIETY

1 Anxiety
5 Tension
6 Uneasiness

2. DEPRESSION

2 Depressive Mood
7 Guilt Feelings
8 Feeling of Inferiority
9 Loss of Interest

3 PSYCHOMOTOR ACTIVITY

3 Hyperactivity
10 Agitation
11 Motor Disturbance

4 SOMATIZATION

4 Psychophysiological Disturbances
13 Hypochondriasis
14 Skeletal Muscular Discomfort

Items not included in factor structure: 12, 15

DOCUMENTATION

a. Raw score printout
b. Factor score printout
c. Factor means and standard deviations
d. Variance analyses

MEMORY FOR DESIGNS TEST (212 - MFD)
F. K. Graham and B. S. Kendall

The MFD Test consists of 15 geometric designs which the subject is required to reproduce from memory. It has proved useful as an adjunct in a test battery for the assessment of brain damage in a wide variety of settings. The time required for administration is short and the test has been effective in differentiating functional behavior disorders from brain injury.

REFERENCE

Graham, F. K., and Kendall, B. S., Memory for Designs Test: General Revised Manual, Perceptual and Motor Skills, Monograph Supplement 2-VII, 11, 147-188, 1960. Materials for MFD may be obtained from Psychological Test Specialists, Box 1441, Missoula, Montana 59801

APPLICABILITY

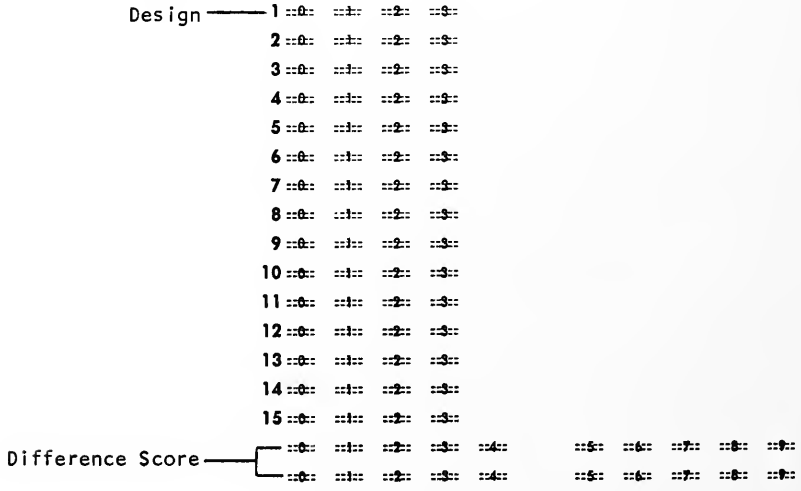
Children (8.5 years and up) and adults

UTILIZATION

Once at pretreatment; at least one posttreatment rating. Additional ratings are at the discretion of the investigator.

ENCODING FORMAT

The MFD requires a 15 x 4 matrix; i.e., 15 rows and 4 columns, to encode the raw design scores and a 2 x 10 matrix; i.e., 2 rows and 10 columns, to encode the difference score. The matrix may be located in either half of the General Scoring Sheet.



DATA FIELD FORMAT (19x, 1511, 12)

Design	Column
1	20
2	21
3	22
4	23
5	24
6	25
7	26
8	27
9	28
10	29
11	30
12	31
13	32
14	33
15	34
Difference Score	35 - 36

Calculation of Difference Score (from Graham-Kendall Manual)

Predicted Score = Vocabulary value - Chronological age value

Total Raw Score = Sum of 15 designs

Difference Score = Total raw score - predicted score

SPECIAL INSTRUCTIONS - Raters should consult the manual for administration and scoring procedures. According to the authors, total raw scores may be interpreted as follows:

0 - 4	Normal
5 -11	Borderline
12 +	Brain damage

Difference Scores may be interpreted:

0 - 1	Normal
2 - 6	Borderline
7 +	Brain damage

DOCUMENTATION

a. Raw score printout
b. Total raw and difference score means and standard deviations
c. Variance analyses

Phillips Scale of Premorbid Adjustment in Schizophrenia 213-PHIL

Farina and Garmezy Modification

A. Recent Sexual Adjustment

(Note.—Score as sexual contact; when information is not explicitly given, use inference to get at this actual sexual behavior.)

1. Stable heterosexual relation and marriage 0
2. Continued heterosexual relation and marriage but unable to establish home 1
3. Continued heterosexual relation and marriage broken by permanent separation 2
4. (a) Continued heterosexual relation and marriage but with low sexual drive 3
   (Note.—If only informant is mother, don't score sexual adjustment. Prorate from rest of Premorbid History section. Look here for evidences of frigidity, distaste, avoidance, infrequency. Don't score on matters of technique.)
   (b) Continued heterosexual relation with deep emotional meaning but emotionally unable to develop it into marriage 3
   (Note.—This must involve actual physical contact. Petting behavior is acceptable here. *Mutuality* of feeling is not necessary, but sexual behavior is, i.e., no adoration from afar.)
5. (a) Casual but continued heterosexual relations, i.e., "affairs" but nothing more 4
   (Note.—"Casual" here implies lack of emotional meaning, although sexual behavior is consistent and regular.)
   (b) Homosexual contacts with lack of or chronic failure in heterosexual experiences 4
6. (a) Occasional casual heterosexual or homosexual experiences with no deep emotional bond 5
   (Note.—This differs from 5(a) on the dimension of frequency. Contacts less often here.)
   (b) Solitary masturbation with no active attempt at homosexual or heterosexual experiences 5
7. No sexual interest in either men or women 6

B. Social Aspects of Sexual Life During Adolescence and Immediately Beyond

1. Always showed a healthy interest in the opposite sex—with a "steady" during adolescence 0
   (Note.—"Steady" implies the exclusiveness of the dating relationship [neither partner dates anyone else] as well as frequency and emotional attachment.)
2. Started dating regularly in adolescence 1
   (Note.—This implies twosomeness, pairing off into couples, as distinguished from 3, below.)
3. Always mixed closely with boys and girls 2
   (Note.—This involved membership in a "crowd"—interest in and attachment to others, but without the initiative factor for males, the selection factor for females.)
4. Consistent deep interest in same sex attachments with restricted or no interest in opposite sex 3
5. (a) Casual same sex attachments with inadequate attempts at adjustments to going out with opposite sex 4
   (Note.—This differs from 4 on the basis of the consistency and meaningfulness of the same sex attachment.)
   (b) Casual contacts with boys and girls 4
   (Note.—This differs from 3 in that the person was not a regular member of a crowd and just associated with others on occasion.)
6. (a) Casual contacts with same sex, with lack of interest in the opposite sex 5
   (b) Occasional contacts with opposite sex 5
7. No desire to be with boys and girls; never went out with opposite sex 6

(Scale points are at the right of the items.)

C. *Social Aspects of Recent Sexual Life—30 Years of Age and Above*

1. Married and has children, living as a family unit 0
2. Married and has children but unable to establish or maintain a family home 1
3. Has been married and had children but permanently separated 2
4. (a) Married, but considerable marital discord 3
   (b) Single—has had engagement or deep heterosexual relationship but was emotionally unable to carry it through to marriage 3
5. Single, with short engagements or relationships with the opposite sex which do not appear to have had much emotional depth for both partners, i.e., affairs 4
6. (a) Single, has dated some, but without other indications of a continuous interest in the opposite sex 5
   (Note.—Implication here is that person has dates every once in awhile but that this behavior is not habitual—doesn't play an important part of his/her life, i.e., take-or-leave attitude.)
   (b) Single, consistent deep interest in same sex attachments, no interest in opposite sex 5
7. (a) Single, occasional same sex contacts, no interest in opposite sex 6
   (b) Single, interested in neither men nor women 6

C. *(continued) Social Aspects of Recent Sexual Life—Below 30 Years of Age*

1. Married, living as a family unit, with or without children 0
2. (a) Married, with or without children, but unable to establish or maintain a family home 1
   (b) Single, but engaged or in a deep heterosexual relationship (presumably leading toward marriage) 1
3. Single, has had engagement or deep heterosexual relationship but has been emotionally unable to carry it through to marriage 2
4. Single, consistent deep interest in attachments to persons of either sex 3
   (Note.—This implies a habitual interest in object relations, a consistent desire for human intimacy, but has never settled into a meaningful, continued relationship with one partner in particular.)
5. Single, casual relationships with persons of either sex 4
   (Note.—Has dated more often than implied by 6 below, less often than implied by 4 above. Differentiate on the basis of frequency, regularity of social-sexual activity.)
6. Single, has dated a few persons casually, but without other indications of a continuous interest in object relationships 5
   (Note.—Dating here the exception rather than the rule. Person has had occasional social-sexual contact, but doesn't actively seek out other persons. This behavior not consistent, nor an important part of his life. His contacts have been solely casual, i.e., with prostitutes to satisfy sex drive; no warmth or capacity to establish human relationships.)
7. (a) Single, never interested in or never associated with either men or women; asocial 6
   (b) Antisocial; destructive, belligerent acting out against others 6

D. Personal Relations: History

(Note.—Score here is determined by the time of life at which person withdraws, narrows his range of social contacts. The earlier this occurs, the higher the score will be.)

1. Always has been a leader, and has always had many close friends 0
   (Note.—Score for "closeness" if record states close friends, or describes frequent contact, shared activity.)
2. Always has had a number of close friends but did not habitually play a leading role 1
   (Note.—From childhood until breakdown, person had extensive social contacts.)
3. (a) From adolescence on had a few close friends 3
   (Note.—This may involve a drop in the number of close friends after adolescence, but person has retained relationships involving mutual give-and-take with several people through this period.)
   (b) From adolescence on had a few casual friends 3
   (Note.—Person maintains relationships with several persons, even though these relationships may lack real emotional depth. Throughout life he has kept up contact with others.)
4. From adolescence on stopped having friends 4
   (Note.—Cultivated human relationships during childhood, but has withdrawn since puberty.)
5. (a) No intimate friends after childhood 5
   (Note.—Withdrawal began earlier—before puberty.)
   (b) Casual, but never any deep, intimate, mutual friendships 5
   (Note.—Implies no close friends, even during childhood, but *did* maintain contacts on a superficial level, as distinguished from 6 below.)
6. Never worried about boys or girls; no desire to be with boys and girls 6

E. Recent Adjustment in Personal Relations

(Note.—Score here the period prior to the noticeable change in behavior which *preceded* symptoms and hospitalization. Any changes noted within 6 months to a year prior to hospitalization will constitute a "change" by this definition. Score period *prior* to these changes.)

1. Habitually mixed with others, was usually a leader 0
   (Note.—Again, this involves extensive social contacts.)
2. Habitually mixed with others, but not a leader 1
3. Mixed only with a close friend or group of friends 3
   (Note.—Distinguished from 4 below on the basis of consistency and frequency of contacts.)
4. No close friends or very few friends or had friends but never quite accepted by them 4
5. Quiet or aloof or seclusive or preferred to be by self 5
6. Antisocial, actively avoided contact, acted out against others 6

The PHIL is designed as a prognostic instrument for schizophrenic patients. The scale consists of 5 items which are rated on the basis of historical data obtained from case records or interviews with the subject or other knowledgeable respondents. A number of reliability and validity studies have demonstrated the sensitivity of the scale.

REFERENCES

1. Phillips, L., Case History Data and Prognosis in Schizophrenia, J. Nerv. Ment. Dis., 117, 515-525, 1953.

2. Garmezy, N., Process and Reactive Schizophrenia: Some Conceptions and Issues, The Role and Methodology of Classification in Psychiatry and Psychopathology, Katz, M. M., Cole, J. O., and Barton, W. E., eds., Public Health Service Publication No. 1584, U.S. Government Printing Office, Washington, D. C. 1968.

APPLICABILITY

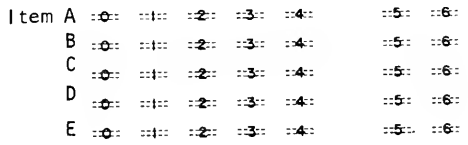
Schizophrenic subjects

UTILIZATION

Once at pretreatment

ENCODING FORMAT

The PHIL requires a 5 x 7 matrix, i.e., 5 rows and 7 columns. The matrix may be located on either half of the General Scoring Sheet. PERIOD for the scale should be designated as 000. The format is as follows:



CARD FORMAT - CARD 01 = (19x, 511, 12)

Item	Column	Item	Column
A	20	D	23
B	21	E	24
C	22	Total	25 - 26

Total Score = Sum of the items. Total Score Range = 0 - 30

Total scores may be categorized as follows:

Poor Premorbid		17 and up
Ambiguous		13 - 16
Good Premorbid	=	12 and below

DOCUMENTATION

a. Raw score printout
b. Total score means and standard deviations
c. Variance analyses

1.MOOD DEPRESSION	Dejected, despondent, helpless, hopeless, preoccupation with defeat or neglect by family or friends, hypochondriacal concern, functional somatic complaints, early waking. Rate on patient's statements, attitude and behavior.
2.CONFUSION	Lack of proper association for surroundings, persons and time - "not with it." Slowing of thought processes and impaired comprehension, recognition and performance; disorganization. Rate on patient response and behavior at interview and on reported episodes since last interview.
3.MENTAL ALERTNESS	Reduction of attentiveness, concentration, responsiveness, alacrity and clarity of thought, impairment of judgment and ability to make decisions. Rate on structured questions and response at interview.
4.MOTIVATION INITIATIVE	Lack of spontaneous interest in initiating or completing tasks, routine duties and even attending to individual needs. Rate on observed behavior rather than patient's statements.
5.IRRITABILITY (Cantankerousness)	Edgy, testy, easily frustrated, low tolerance threshold to aggravation and stress or challenging situations. Rate on patient's response and general attitude at interview.
6.HOSTILITY	Verbal aggressiveness, animosity, contempt, quarrelsome, assaultive. Rate on impression at interview and patient's observed attitude and behavior towards others.
7.BOTHERSOME	Frequent unnecessary requests for advice or assistance, interference with others, restlessness. Rate on behavior at and outside the interview situation.
8. INDIFFERENCE TO SURROUNDINGS	Lack of interest in everyday events, pastimes and environment where interest previously existed, e.g. news, TV, heat, cold, noise. Rate on patient's statements and observed behavior at and outside interview.
9.UNSOCIABILITY	Poor relationships with others, unfriendly, negative reaction to social and communal recreational activities, aloof. Rate on observed behavior and not on patient's own impressions.
12.FATIGUE	Sluggish, listless, tired, weary, worn out, bushed. Rate on patient's statements and observed response to normal daily activities outside interview situation.

NOT PRESENT	VERY MILD	MILD	MODERATE	MODERATELY SEVERE	SEVERE	EXTREMELY SEVERE
1	2	3	4	5	6	7

SANDOZ CLINICAL ASSESSMENT-GERIATRIC 238-SCAG

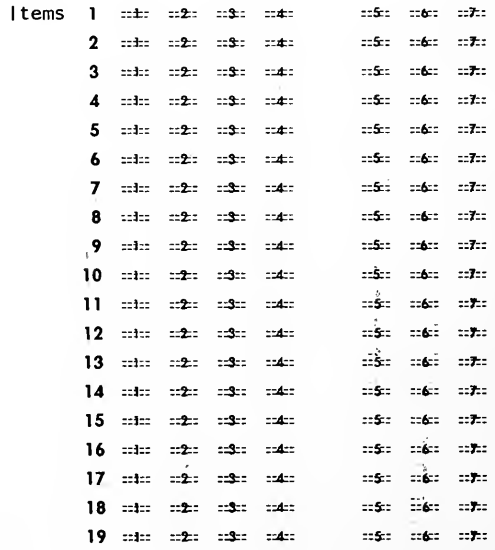
10. UNCOOPERATIVENESS	Poor compliance with instructions or requests for participation. Performance with ill grace, resentment or lack of consideration for others. Rate on attitude and responses at interview and observed behavior outside interview situation.
11. EMOTIONAL LABILITY	Instability and inappropriateness of emotional response, e.g. laughing or crying or other undue positive or negative response to non-provoking situations as the interviewer sees them.
13. SELF-CARE	Impairment of ability to attend to personal hygiene, dressing, grooming, eating and getting about. Rate on observation of patient at and outside interview situation and not on statements of patient.
14. APPETITE (Anorexia)	Disinclination for food, inadequate intake, necessity for dietary supplements, loss of weight. Rate on observed attitude towards eating, food intake encouragement required and loss of weight.
15. DIZZINESS	In addition to true vertigo, dizziness in this context includes spells of uncertainty of movement and balance, subjective sensations in the head apart from pain, e.g. lightheadedness. Rate on physical examination as well as patient's subjective experience.
16. ANXIETY	Worry, apprehension, overconcern for present or future, fears, complaints of functional somatic symptoms, e.g. headache, dry mouth, etc. Rate on patient's own subjective experience and on physical signs, e.g. trembling, sighing, sweating, etc., if present.
17. IMPAIRMENT OF RECENT MEMORY	Reduction in ability to recall recent events and actions of importance to the patient, e.g. visits by members of family, content of meals, notable environmental changes, personal activities. Rate on structured pertinent questions and not on reported performance.
18. DISORIENTATION	Reduced awareness of place and time, identification of persons, including self. Rate on response to questions at interview only.
19. OVERALL IMPRESSION OF PATIENT	Considering your total clinical experience and knowledge of the patient, indicate the patient's status at this time, taking into account physical, psychic and mental functioning.

NOT PRESENT	VERY MILD	MILD	MODERATE	MODERATELY SEVERE	SEVERE	EXTREMELY SEVERE
1	2	3	4	5	6	7

238-SCAG
(CONT'D)

The SCAG was recently developed by Sandoz Pharmaceuticals for the rating of geriatric patients. The scale consists of 18 symptoms plus a global rating. The scale points (7) are similar to those employed on the Brief Psychiatric Rating Scale. The SCAG appears to differentiate among subjects of various degrees of impairment.

REFERENCE	Shader, R. I., Harmatz, J. S., and Salzman, C., A New Scale for Clinical Assessment in Geriatric Populations: Sandoz Clinical Assessment - Geriatric (SCAG), J. of Amer.Geriat.Soc., XXII, 3, 107-113, March, 1974.
APPLICABILITY	Geriatric populations
UTILIZATION	Once at pretreatment; at least one posttreatment assessment. Additional ratings are at the discretion of the investigator
TIME SPAN RATED	Now or within the past week
ENCODING FORMAT	To encode the SCAG on the General Scoring Sheet, a matrix of 19 x 7 is required; i.e., 19 rows and 7 columns. The matrix may be located in either half of the GSS. The matrix is as follows:



CARD FORMAT - CARD 01 = (19x, 19I1, I4)

Item	Column	Item	Column	Item	Column	Item	Column
1	20	6	25	11	30	16	35
2	21	7	26	12	31	17	36
3	22	8	27	13	32	18	37
4	23	9	28	14	33	19	38
5	24	10	29	15	34	Total	39 - 42

Total Score = Sum of Items 1 - 18 Total Score Range = 19 - 126

SPECIAL INSTRUCTIONS - The cues printed on the scale for each of the items indicate the context to be used by the rater.

DOCUMENTATION

a. Raw score printout
b. Means and standard deviations
c. Variance analyses

CLYDE MOOD SCALE (239-CLYDE)

Dean J. Clyde

	1 Not at all	2 A little	3 Quite a bit	4 Extremely
1. good-natured	☐	☐	☐	☐
2. troubled	☐	☐	☐	☐
3. efficient	☐	☐	☐	☐
4. dependable	☐	☐	☐	☐
5. clearthinking	☐	☐	☐	☐
6. lonely	☐	☐	☐	☐
7. humorous	☐	☐	☐	☐
8. rude	☐	☐	☐	☐
9. kind	☐	☐	☐	☐
10. daring	☐	☐	☐	☐
11. considerate	☐	☐	☐	☐
12. boastful	☐	☐	☐	☐
13. defiant	☐	☐	☐	☐
14. fatigued	☐	☐	☐	☐
15. unhappy	☐	☐	☐	☐
16. businesslike	☐	☐	☐	☐
17. friendly	☐	☐	☐	☐
18. grouchy	☐	☐	☐	☐
19. sleepy	☐	☐	☐	☐
20. sad	☐	☐	☐	☐
21. bossy	☐	☐	☐	☐
22. impulsive	☐	☐	☐	☐
23. jittery	☐	☐	☐	☐
24. bold	☐	☐	☐	☐
25. playful	☐	☐	☐	☐
26. afraid	☐	☐	☐	☐
27. able to work hard	☐	☐	☐	☐
28. warm-hearted	☐	☐	☐	☐
29. sick to the stomach	☐	☐	☐	☐
30. alert	☐	☐	☐	☐
31. tired	☐	☐	☐	☐
32. shaky	☐	☐	☐	☐
33. demanding	☐	☐	☐	☐
34. sociable	☐	☐	☐	☐
35. nagging	☐	☐	☐	☐
36. sarcastic	☐	☐	☐	☐
37. pleasant	☐	☐	☐	☐
38. quarrelsome	☐	☐	☐	☐
39. independent	☐	☐	☐	☐
40. depressed	☐	☐	☐	☐
41. drowsy	☐	☐	☐	☐
42. able to concentrate	☐	☐	☐	☐
43. dizzy	☐	☐	☐	☐
44. reckless	☐	☐	☐	☐
45. downhearted	☐	☐	☐	☐
46. worried	☐	☐	☐	☐
47. forceful	☐	☐	☐	☐
48. polite	☐	☐	☐	☐

The CLYDE is a 48-item scale for measuring aspects of mood that may be influenced by drugs and may be employed as a self-rating as well as an observer-rated instrument. The scale has been shown to be sensitive to drug effects.

REFERENCE

Clyde, D. J., Manual for the Clyde Mood Scale
Clyde Computing Service,
Box 166, Coconut Grove Station
Miami, Florida 33133
1963
This manual may be obtained from the author.

APPLICABILITY

Wide range of patients and normals

UTILIZATION

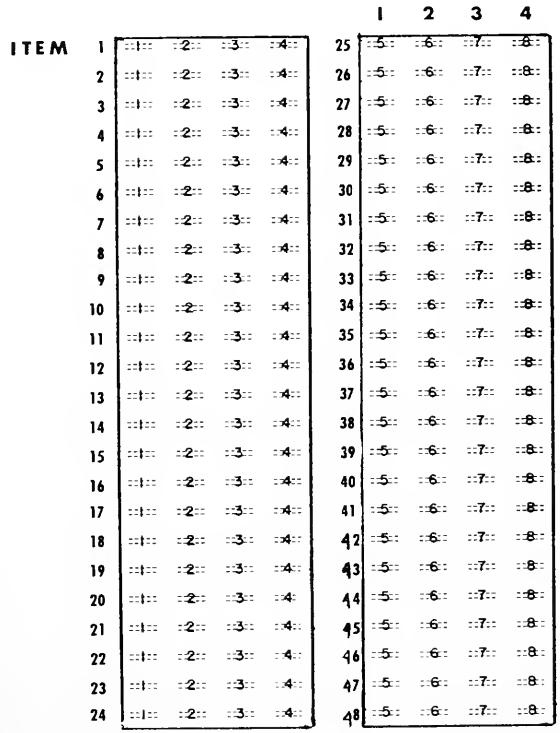
Once at pretreatment; at least one posttreatment assessment. Additional assessments are at the discretion of the investigator.

TIME SPAN RATED

"Now"; at the time of the rating.

ENCODING FORMAT

To encode the scale on the General Scoring Sheet, a 24 x 8 matrix; i.e., 24 rows and 8 columns are required. The matrix may be located in the 2 quadrants of either half of the GSS. The following format should be used:



CARD FORMAT - ITEMS CARD 01 = (19x, 48I1)

Item	Column	Item	Column	Item	Column	Item	Column
1	20	13	32	25	44	37	56
2	21	14	33	26	45	38	57
3	22	15	34	27	46	39	58
4	23	15	35	28	47	40	59
5	24	17	36	29	48	41	60
6	25	18	37	30	49	42	61
7	26	19	38	31	50	43	62
8	27	20	39	32	51	44	63
9	28	21	40	33	52	45	64
10	29	22	41	34	53	46	65
11	30	23	42	35	54	47	66
12	31	24	43	36	55	48	67

CARD FORMAT - FACTORS CARD 51 = (19x, 6F6.2)

Factor	Column	Factor	Column
1	20 - 25	4	38 - 43
2	26 - 31	5	44 - 49
3	32 - 37	6	50 - 55

FACTOR COMPOSITION

1. Friendly
   1. good-natured
   9. kind
   28. warm-hearted
   37. pleasant

2. Aggressive
   8. rude
   12. boastful
   36. sarcastic
   47. forceful

3. Clear thinking
   3. efficient
   5. clear thinking
   30. alert
   42. able to concentrate

4. Sleepy
   14. fatigued
   19. sleepy
   31. tired
   41. drowsy

5. Unhappy
   2. troubled
   20. sad
   45. downhearted
   46. worried

6. Dizzy
   23. jittery
   29. sick to the stomach
   32. shaky
   43. dizzy

NOTE - Higher scores reflect greater "pathology" for all factors except Factors 1 and 3.

DOCUMENTATION:

a. Raw score printout
b. Factor score printout
c. Factor means and standard deviations
d. Variance analyses

Hopkins Symptom Checklist (240-HSCL)

Derogatis, Lipman, Rickels, Uhlenhuth and Covi

NOT AT ALL	A LITTLE	QUITE A BIT	EXTREMELY
1	2	3	4

1. Headaches
2. Nervousness or shakiness inside
3. Being unable to get rid of bad thoughts or ideas
4. Faintness or dizziness
5. Loss of sexual interest or pleasure
6. Feeling critical of others
7. Bad dreams
8. Difficulty in speaking when you are excited
9. Trouble remembering things
10. Worried about sloppiness or carelessness
11. Feeling easily annoyed or irritated
12. Pains in the heart or chest
13. Itching
14. Feeling low in energy or slowed down
15. Thoughts of ending your life
16. Sweating
17. Trembling
18. Feeling confused
19. Poor appetite
20. Crying easily
21. Feeling shy or uneasy with the opposite sex
22. A feeling of being trapped or caught
23. Suddenly scared for no reason
24. Temper outbursts you could not control
25. Constipation
26. Blaming yourself for things
27. Pains in the lower part of your back
28. Feeling blocked or stymied in getting things done
29. Feeling lonely
30. Feeling blue
31. Worrying or stewing about things
32. Feeling no interest in things
33. Feeling fearful
34. Your feelings being easily hurt
35. Having to ask others what you should do
36. Feeling others do not understand you or are unsympathetic
37. Feeling that people are unfriendly or dislike you
38. Having to do things very slowly in order to be sure you are doing them right
39. Heart pounding or racing
40. Nausea or upset stomach
41. Feeling inferior to others
42. Soreness of your muscles
43. Loose bowel movements
44. Difficulty in falling asleep or staying asleep
45. Having to check and double-check what you do
46. Difficulty making decisions
47. Wanting to be alone
48. Trouble getting your breath
49. Hot or cold spells
50. Having to avoid certain places or activities because they frighten you
51. Your mind going blank
52. Numbness or tingling in parts of your body
53. A lump in your throat
54. Feeling hopeless about the future
55. Trouble concentrating
56. Weakness in parts of your body
57. Feeling tense or keyed up
58. Heaving feelings in your arms or legs

Precursor of the SCL-90, the HSCL is a 58-item, self-rated scale designed to measure the presence and intensity of symptomatology in a wide variety of subjects. Normative data has been established for the scale and its sensitivity to change has also been demonstrated.

REFERENCES -

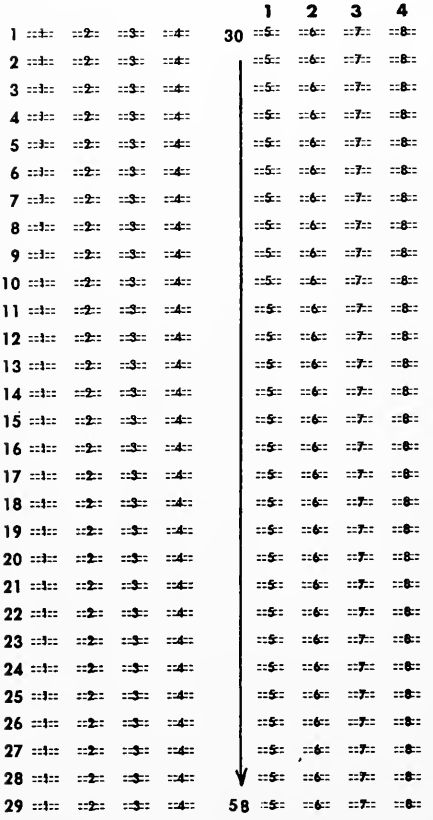
1. Derogatis, L. R., Lipman, R. S., Rickels, K., Uhlenhuth, E. H. and Covi, L., The Hopkins Symptom Checklist (HSCL): A Measure of Primary Symptom Dimensions, in Psychological Measurement: Modern Problems in Pharmacotherapy, P. Pichot, Ed., S. Karger, Basel, 1973.
2. Derogatis, L. R., Lipman, R. S., Rickels, K., Uhlenhuth, E. H., and Covi, L., The Hopkins Symptom Checklist (HSCL): A Self-Report Symptom Inventory, Behavioral Science, 19, 1, 1-15, January 1974.

APPLICABILITY - Outpatient neurotics

UTILIZATION - Once at pretreatment; at least one post-treatment assessment. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - During the past week.

ENCODING FORMAT - To encode the HSCL on the General Scoring Sheet, a 58 x 4 matrix is required. The matrix may be located on either half of the GSS as is shown on the left.



CARD FORMAT - ITEMS CARD 01 = (19x, 5611)

Item	Column	Item	Column	Item	Column
1	20	23	42	45	64
2	21	24	43	46	65
3	22	25	44	47	66
4	23	26	45	48	67
5	24	27	46	49	68
6	25	28	47	50	69
7	26	29	48	51	70
8	27	30	49	52	71
9	28	31	50	53	72
10	29	32	51	54	73
11	30	33	52	55	74
12	31	34	53	56	75
13	32	35	54		
14	33	36	55		
15	34	37	56		
16	35	38	57		
17	36	39	58		
18	37	40	59		
19	38	41	60		
20	39	42	61		
21	40	43	62		
22	41	44	63		

CARD 02 = (19x, 2I1)

Item	Column
57	20
58	21

CARD FORMAT - FACTORS CARD 51 = (19x, 56F6.2)

Factor	Column	Factor	Column
1	20 - 25	4	38 - 43
2	26 - 31	5	44 - 49
3	32 - 37		

FACTOR COMPOSITION - The composition of the factors (called symptom dimensions) is given in Table 48 . Factor means and standard deviations for 3 normative groups - anxious and depressed neurotics and a sample of non-institutionalized residents of Oakland, California - are as follows:

FACTOR	NEUROTIC Anxious (1435 MN	SD	Depressed (367) MN	SD	OAKLAND "Normals" (735) MN	SD
1. Somatization	1.91	.59	1.89	.53	1.15	.27
2. Obsessive-Compulsive	1.95	.67	2.30	.68	1.16	.27
3. Interpersonal Sensitivity	2.00	.68	2.33	.67	1.12	.24
4. Depression	2.04	.63	2.62	.63	1.14	.28
5. Anxiety	2.22	.67	2.45	.68	1.13	.26

Items not included in any factor are:
3, 7, 8, 13, 16, 18, 21, 25, 35, 40, 43, 44, 47

ITEM COMPATIBILITY - The first 58 items of the SCL-90 are the same as those contained in the HSCL with these nine exceptions: 7, 8, 13, 16, 18, 25, 35, 43, 47. However, the SCL-90 utilizes a 5-point scale in contrast to the HSCL's 4-point scale.

INSTRUCTIONS - The instructions to the subject are as follows:

> Below is a list of problems and complaints that people sometimes have. Please read each one carefully. After you have done so, please darken one of the four spaces to the right that best describes HOW MUCH THAT PROBLEM HAS BOTHERED OR DISTRESSED YOU DURING THE PAST WEEK, INCLUDING TODAY.
>
> Mark only one space for each problem and do not skip any items. Make your marks carefully. If you change your mind, erase your first mark completely.
>
> It is wise to observe the subject as he proceeds to make sure he understands the task.

DOCUMENTATION

a. Raw score printout
b. Factor score printout
c. Factor means and standard deviation
d. Variance analyses

TABLE 48

DEFINITIONS AND CONTRIBUTING ITEMS OF THE HSCL SYMPTOM DIMENSIONS

Symptom Dimension	Contributing Items	Dimension Definition
1. Somatization	1,4,12,14,27,42, 48,49,52,53,56,58	The items comprising this dimension reflect distress arising from perceptions of bodily dysfunction. Complaints focused on cardiovascular, gastrointestinal, respiratory, and other systems with marked autonomic medication are included. Headaches, pain and discomfort localized in the gross musculature and other somatic equivalents of anxiety are also represented.
2. Obsessive-Compulsive	9,10,28,38, 45,46,51,55	The items that form this dimension reflect symptoms that are closely identified with the clinical syndrome of this name. This dimension focuses on thoughts, impulses, and actions that are experienced as unremitting and irresistible by the individual, but are of an ego-alien or unwanted nature. Behaviors indicative of a more general cognitive difficulty also load on this measure.
3. Interpersonal Sensitivity	6,11,24,34, 36,37,41	The symptoms that are fundamental to I.S. focus on feelings of personal inadequacy and inferiority, particularly in comparison to other persons. Self-deprecation, feelings of uneasiness, and marked discomfort during interpersonal interactions are characteristic manifestations, as are acute self-consciousness and negative expectancies regarding interpersonal communications.
4. Depression	5,15,19,20,22, 26,29,30,31,32,54	Scales subsumed under the depression dimension reflect a broad range of the concomitants of a clinical depressive syndrome. Symptoms of dysphoric mood and affect are represented as are signs of withdrawal of life interest, lack of motivation, and loss of vital energy. Feelings of hopelessness and futility as well as other cognitive and somatic correlates are also included.
5. Anxiety	2,17,23,33,39,50, 57	This dimension is comprised of a set of symptoms and behaviors associated clinically with high manifest anxiety. General indicators such as restlessness, nervousness, and tension are represented, as are additional somatic signs, e.g. "trembling". Items touching on free-floating anxiety and panic attacks are also included.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE - PUBLIC HEALTH SERVICE
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED,
BUDGET BUREAU NO 68-R953

PATIENT RECORD FOR DRUG STUDY

SELF-RATING SYMPTOM SCALE

DO NOT MARK IN THIS AREA

NAME OF HOSPITAL AND STUDY		PATIENT
PATIENT'S NAME (First, Middle Initial, Last)	HOSPITAL NO.	
RATER	DATE FORM COMPLETED	RATER
FORM NO.		PERIOD

INSTRUCTIONS

Listed below are 35 symptoms or problems that people sometimes have. Please read each one carefully and decide how much the symptom bothered or distressed you during the past week, NOT AT ALL, A LITTLE, QUITE A BIT, or EXTREMELY. Mark the column that applies to you. Do not skip any items.

EXAMPLE

HOW MUCH WERE YOU BOTHERED BY:	NOT AT ALL	A LITTLE	QUITE A BIT	EXTREMELY
Noise	1	2	3	4

If "noise" bothered you "A LITTLE," you would mark the space to the right under "A LITTLE" as shown.

HOW MUCH WERE YOU BOTHERED BY:	NOT AT ALL	A LITTLE	QUITE A BIT	EXTREMELY
1 Sweating	1	2	3	4
2 Trouble getting your breath	1	2	3	4
3 Suddenly scared for no reason	1	2	3	4
4 Difficulty in speaking when you are excited	1	2	3	4
5 Feeling low in energy or slowed down	1	2	3	4
6 Pains in the heart or chest	1	2	3	4
7 Trouble remembering things	1	2	3	4
8 Hot or cold spells	1	2	3	4
9 Blaming yourself for things	1	2	3	4
10 A lump in your throat	1	2	3	4
11 Feeling fearful	1	2	3	4
12 Numbness or tingling of parts of your body	1	2	3	4
13 Feeling critical of others	1	2	3	4
14 Having to avoid certain things, places, or activities because they frighten you	1	2	3	4
15 Having to do things very slowly in order to be sure you were doing them right	1	2	3	4
16 Heavy feelings in your arms and legs	1	2	3	4
17 Faintness or dizziness	1	2	3	4
18 Crying easily	1	2	3	4
19 Nervousness or shakiness inside	1	2	3	4
20 Your feelings being easily hurt	1	2	3	4
21 Constipation	1	2	3	4
22 Loss of sexual interest or pleasure	1	2	3	4
23 Feeling easily annoyed or irritated	1	2	3	4
24 Poor appetite	1	2	3	4
25 Difficulty making decisions	1	2	3	4
26 Difficulty in falling asleep or staying asleep	1	2	3	4
27 Feeling hopeless about the future	1	2	3	4
28 Feeling blue	1	2	3	4
29 Feeling lonely	1	2	3	4
30 Temper outbursts you could not control	1	2	3	4
31 Headaches	1	2	3	4
32 Heart pounding or racing	1	2	3	4
33 Trouble concentrating	1	2	3	4
34 Your mind going blank	1	2	3	4
35 Thoughts of ending your life	1	2	3	4

MH-9-10 (3-67)

The SRSS consists of 35 items selected from the 58-item HSCL on the basis of factor saturation, proportional frequency of occurrence and clinical relevance in drug trials. Part of the original ECDEU Battery, the SRSS was superceded by the SCL-90.

REFERENCE - Lipman, R. S., et al, Sensitivity of Symptom and Nonsymptom-Focused Criteria of Outpatient Drug Efficacy, Amer. J. Psychiat., 1965, 122: 24-27.

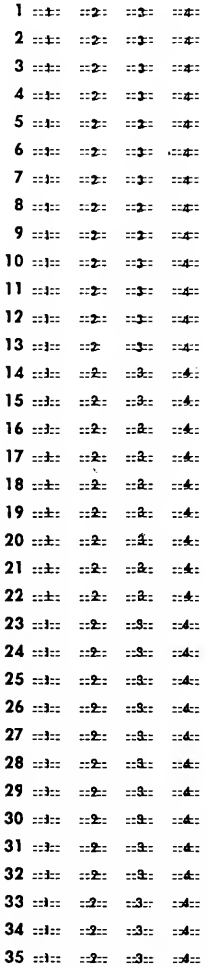
APPLICABILITY - Neurotic outpatients primarily. Has also been employed with inpatient populations.

UTILIZATION - Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - During the past week.

ENCODING FORMAT

A limited supply of the opscan SRSS are still available. When these supplies are exhausted, investigators may encode the SRSS on the General Scoring Sheet by using a 35 x 4 matrix; i.e., 35 rows and 4 columns. This matrix may be encoded in any quadrant of the GSS, as is shown on the left.



CARD FORMAT - ITEMS CARD 01 = (19x, 3511)

Item	Column	Item	Column
1	20	19	38
2	21	20	39
3	22	21	40
4	23	22	41
5	24	23	42
6	25	24	43
7	26	25	44
8	27	26	45
9	28	27	46
10	29	28	47
11	30	29	48
12	31	30	49
13	32	31	50
14	33	32	51
15	34	33	52
16	35	34	53
17	36	35	54
18	37		

CARD FORMAT - FACTORS CARD 51 = (19x, 5F6.2, F4.0)

Factor	Column	Factor	Column
1	20-25	4	38-43
2	26-31	5	44-49
3	32-37	Total	50-53

Total Score = Sum of 35 Items Total Score Range = 35 - 140

FACTOR COMPOSITION

These factors were derived from a factor analysis performed by Lipman et al on a sample of 1519 neurotic subjects.

FACTOR 1 GENERAL NEUROTIC FEELINGS

9. Blaming yourself for things
13. Feeling critical of others
20. Your feelings being easily hurt
23. Feeling easily annoyed or irritated
27. Feeling hopeless about the future
28. Feeling blue
29. Feeling lonely
30. Temper outbursts you could not control
35. Thoughts of ending your life

FACTOR 2 SOMATIZATION

1. Sweating
2. Trouble getting your breath
6. Pains in the heart or chest
8. Hot or cold spells
10. A lump in your throat
12. Numbness or tingling
16. Heavy feelings in your arms and legs
17. Faintness or dizziness
26. Difficulty in falling asleep
31. Headaches
32. Heart pounding or racing

FACTOR 3 COGNITIVE PERFORMANCE-DIFFICULTY

4. Difficulty in speaking
7. Trouble remembering things
15. Having to do things very slowly
25. Difficulty making decisions
33. Trouble concentrating
34. Your mind going blank

FACTOR 4 DEPRESSION

18. Crying easily
22. Loss of sexual interest or pleasure
24. Poor appetite

FACTOR 5 FEAR/ANXIETY

3. Suddenly scared for no reason
11. Feeling fearful
14. Having to avoid certain things
19. Nervousness or shakiness inside

Items omitted
5
21

Two sets of means and standard deviations are provided for the investigator. The anxious neurotic outpatients provided the sample upon which the factor analysis was performed. The ECDEU sample employed the same factor structure to derive its means and standard deviations.

	Anxious Neurotic Outpatients (n = 1519)		ECDEU Population (n = 238)	
	Mean	Stan. Dev.	Mean	Stan. Dev.
General Neurotic Feelings	2.06	1.14	2.21	0.76
Somatization	1.96	1.08	1.89	0.54
Cognitive Performance	1.93	1.16	2.02	0.75
Fear-Anxiety	1.96	1.37	1.97	0.85
Depression	2.07	1.28	2.18	0.81

ITEM COMPARABILITY - The SRSS items and their counterparts in the Hopkins Symptom Checklist (HSCL) are:

SRSS	HSCL	SRSS	HSCL	SRSS	HSCL
1	16	13	6	25	46
2	48	14	50	26	44
3	23	15	38	27	54
4	8	16	58	28	30
5	14	17	4	29	29
6	12	18	20	30	24
7	9	19	2	31	1
8	49	20	34	32	39
9	26	21	25	33	55
10	53	22	5	34	51
11	33	23	11	35	15
12	52	24	19		

DOCUMENTATION

a. Raw score printout
b. Factor score printout
c. Factor means and standard deviations
d. Variance analyses

GLOBAL ASSESSMENT SCALE (241-GAS)
R. L. Spitzer, M. Gibbon and J. Endicott

Rate the subject's lowest level of functioning in the last week by selecting the lowest range which describes his functioning on a hypothetical continuum of mental health-illness. For example, a subject whose "behavior is considerably influenced by delusions" (range 21-30) should be given a rating in that range even though he has "major impairment in several areas" (range 31-40). Use intermediary levels when appropriate (e.g., 35, 58, 63). Rate actual functioning independent of whether or not subject is receiving and may be helped by medication or some other form of treatment.

100 | 91 — No symptoms, superior functioning in a wide range of activities, life's problems never seem to get out of hand, is sought out by others because of his warmth and integrity.

90 | 81 — Transient symptoms may occur, but good functioning in all areas, interested and involved in a wide range of activities, socially effective, generally satisfied with life, "everyday" worries that only occasionally get out of hand.

80 | 71 — Minimal symptoms may be present but no more than slight impairment in functioning, varying degrees of "everyday" worries and problems that sometimes get out of hand.

70 | 61 — Some mild symptoms (e.g., depressive mood and mild insomnia) OR some difficulty in several areas of functioning, but generally functioning pretty well, has some meaningful interpersonal relationships and most untrained people would not consider him "sick".

60 | 51 — Moderate symptoms OR generally functioning with some difficulty (e.g., few friends and flat affect, depressed mood, and pathological self-doubt, euphoric mood and pressure of speech, moderately severe antisocial behavior).

50 | 41 — Any serious symptomatology or impairment in functioning that most clinicians would think obviously requires treatment or attention (e.g., suicidal preoccupation or gesture, severe obsessional rituals, frequent anxiety attacks, serious antisocial behavior, compulsive drinking).

40 | 31 — Major impairment in several areas, such as work, family relations, judgment, thinking, or mood (e.g., depressed woman avoids friends, neglects family, unable to do housework), OR some impairment in reality testing or communication (e.g., speech is at times obscure, illogical, or irrelevant), OR single serious suicide attempt.

30 | 21 — Unable to function in almost all areas (e.g., stays in bed all day), OR behavior is considerably influenced by either delusions or hallucinations, OR serious impairment in communication (e.g., sometimes incoherent or unresponsive) or judgment (e.g., acts grossly inappropriately).

20 | 11 — Needs some supervision to prevent hurting self or others, or to maintain minimal personal hygiene (e.g., repeated suicide attempts, frequently violent, manic excitement, smears feces), OR gross impairment in communication (e.g., largely incoherent or mute).

10 | 01 — Needs constant supervision for several days to prevent hurting self or others, or makes no attempt to maintain minimal personal hygiene.

The GAS consists of a single scale (item) for evaluating the overall functioning of a subject on a continuum from psychological or psychiatric illness to health. The GAS has been shown to be sensitive to change in a variety of clinical situations.

REFERENCE — Endicott, J., Spitzer, R. L., Fliess, J. L. and Cohen, J. The Global Assessment Scale: A Procedure for Measuring Overall Severity of Psychiatric Disturbance, Personal Communication, 1976.

APPLICABILITY — Adult populations

UTILIZATION — Once at pretreatment; at least one post-treatment assessment. Additional ratings are at the discretion of the investigator

TIME SPAN RATED — Within the last week

ENCODING FORMAT — To encode GAS on the General Scoring Sheet, a 2 x 10 matrix; i.e., 2 rows and 10 columns, is required and may be located in either half of the GSS. The matrix is as follows:

0	1	2	3	4	5	6	7	8	9
0	1	2	3	4	5	6	7	8	9

NOTE - 100 is encoded as 00.

CARD FORMAT — CARD 01 = (19x, I2)

SPECIAL INSTRUCTIONS (Adapted from the authors)

The scale values range from 01, which represents the hypothetically sickest possible individual, to 100, the hypothetically healthiest. The scale is divided into ten equal intervals: 01 - 10, 11 - 20, and so on to 81 - 90 and 91-100. The defining characteristics of each 10 point interval comprise the scale. The two highest intervals, 81 - 90 and 91 - 100, are for those unusually fortunate individuals who not only are without significant psychopathology but also exhibit many traits often referred to as "positive mental health", such as superior functioning, a wide range of interests, social effectiveness, warmth and integrity. The next interval, 71 - 80, is for individuals with no or only minimal psychopathology but who do not possess the positive mental health features noted above. Although some individuals rated above 70 may seek some form of assistance for psychological problems, the vast majority of individuals in treatment will be rated between 1 and 70. Most outpatients will be rated 31 to 70, and most inpatients between 1 and 40.

In making a rating one first selects the lowest interval which describes the subject's functioning during the preceding week. For example, a subject whose "behavior is considerably influenced by delusions" (range 21 - 30) should be given a rating in that range even though he has "marked impairment in several areas" (ranges 31 - 40). In order to determine the scale point within the ten point interval, the defining characteristics of the two adjacent intervals are examined to determine whether the subject is closer to one or the other. For example, a subject in the range 21 - 30 who is much closer to the 11 - 20 range than the 31 - 40 range would be given a specific rating of 21, 22, or 23. A subject who seems to be equidistant from the two adjoining ranges is given a rating of 24, 25, 26, or 27.

Since the ratings are for overall functioning during a specific time period; it is important that the rating be based on functioning and symptomatology during that time period and not be influenced by considerations of prognosis, previous diagnosis, or the presumed nature of the underlying disorder. In a similar fashion, the rating should not be influenced by whether or not the patient is receiving medication or some other form of help.

The information needed to make the rating can come from any source: direct interview of the patient, a reliable informant, or a case record. Little information may be needed to make a rating at the low end of the scale. For example, knowledge that the individual makes repeated suicidal attempts and thus requires constant supervision is sufficient, by itself, to warrant rating a patient in the 1 - 10 range. On the other hand, before an individual can be given a very high rating it is necessary not only to determine the absence of psychopathology and any serious impairment in functioning, but also to ascertain the presence of signs of "positive mental health".

Because the scale covers the entire range of severity it can be used in any situation or study where an overall assessment of severity of illness or degree of health is needed. In most studies only a portion of the scale will be actually used. For example, community studies will rarely have individuals in the lowest range, whereas studies involving newly admitted psychiatric patients will rarely have individuals in the highest intervals. However, many individuals who may have been rated in a very low range on admission may be sufficiently recovered at follow-up and warrant a rating in one of the higher intervals.

DOCUMENTATION:

a. Raw score printout
b. Means and standard deviations
c. Variance analyses

242 - TARTU
TARTU PSYCHOMETRIC BATTERY

1. OPERANT MEMORY TEST
2. LEARNING TEST
3. WORD ASSOCIATION TEST
4. CALCULATION TEST
5. PROOF-READING TEST
6. MOTOR REFLEX TEST

TABLE 49

OPERANT MEMORY TEST

NAME _____

HOSPITAL NO _____

DATE _____

	Immediate reply		Delayed reply	
	response	time	response	time
BOOK				
HORSE				
CHIMNEY				
SNOW				
TABLE				
SPARROW				
INK				
SHOE				
MAPLE				
FISH				
CEILING				
WIND				

total correct: _____ Mn. Time _____ _____ Mn. Time _____

total incorrect: _____ _____

difference correct immediate and correct delayed responses: _____

Tested by: _____

TABLE 50

LEARNING TEST

NAME _____

HOSPITAL NO _____

DATE _____

	TRIALS									
	1	2	3	4	5	6	7	8	9	10
BED										
SPOON										
CAT										
ANCHOR										
NEWS										
SURFACE										
PILLOW										
NUT										
LAKE										
NOSE										
Incorrect resppnses:										
time: (sec)										
no. correct:										
time/no. corr:										
no. incorrect:										
deviation:										

totals: no. corr.: _____ mean: time/corr. resp.: _____ LI _____

no. incorr: _____ CI _____

time: _____

Tested by: _____

TABLE 51

WORD ASSOCIATION TEST

NAME: _____

HOSPITAL NO. _____

DATE _____

SIGNAL	RESPONSE	LATENCY(sec)	DEVIATION
CHAIR			
BOOK			
SUMMER			
FLOOR			
WIFE			
ARM			
CIRCLE			
SPOON			
ROSE			
ANIMAL			
BELT			
DOCTOR			
METAL			
HILL			
CHANCE			
SHAPE			
WATER			
SPIRIT			
PICTURE			
ROAD			

No. adq: _____	total:		
No. inadq: _____	mean:		

Tested by: _____

TABLE 52

CALCULATION TEST

8	3	2	4	8	6	9	5	6	2	6	8	7	1	4	9	3	5	2	6	8	3	5	1	7
6	8	4	2	5	7	2	3	4	8	1	6	3	5	3	9	6	4	3	3	2	7	5	6	6
1	5	8	5	2	7	3	6	2	8	9	4	6	2	4	1	7	3	6	4	8	7	2	3	7
6	5	8	3	5	2	5	1	8	4	3	6	7	2	5	1	3	5	8	6	4	4	2	1	2
6	9	4	2	3	8	1	7	5	8	3	8	4	1	7	2	9	4	8	6	3	4	2	5	3
7	2	4	8	6	8	3	5	2	6	5	8	1	2	9	5	8	3	5	2	4	2	7	8	9
2	5	8	7	4	7	2	5	1	4	8	6	9	4	6	3	4	2	6	1	7	4	5	7	3
8	1	5	3	2	5	6	2	7	5	3	8	9	3	8	2	8	3	4	6	5	4	8	2	4
3	5	1	4	8	5	3	9	8	5	3	2	2	7	6	9	3	4	6	2	6	3	4	5	2
6	4	2	9	6	3	5	7	7	2	3	7	6	8	9	7	2	6	4	8	2	5	7	5	9
3	6	5	8	2	9	3	2	1	4	2	6	7	4	9	4	3	8	5	2	1	8	5	3	7
2	6	8	6	9	4	1	6	8	9	4	9	8	8	5	3	8	6	3	7	5	8	7	4	6

ROWS

	1	2	3	4	5	6	t	m
cal								
dev								
err								

Name _____

Hospital No. _____

Date _____

TABLE 53

PROOF-READING TEST

R	N	U	A	K	V	R	E	A	M
U	K	A	O	N	E	M	U	R	V
M	V	N	E	S	A	O	N	S	K
O	R	M	S	E	O	V	S	O	U
E	A	O	V	R	O	U	M	S	N
N	S	K	U	A	M	K	V	E	R
V	N	E	K	S	U	A	R	A	M
K	M	R	N	S	V	E	U	K	O
U	K	V	S	M	R	O	E	N	A
A	U	M	E	O	N	S	R	V	K

t:

e:

Name _____

Hospital No. _____

Date _____

TABLE 54

MOTOR REFLEX TEST

PART 1

NAME _____

HOSPITAL NO._____

DATE _____

Stim.	Interv. (sec)	Stimulus	Resp. positive stim.	
			latency (sec)	deviation
1	-	Y		
2	20	Y		
3	15	Y		
4	25	Y		
5	10	Y		
6	30	Y		
7	15	Y		
8	25	Y		
9	25	Y		
10	20	Y		
11	30	Y		
12	15	Y		
13	20	Y		
14	10	Y		
15	25	Y		
		total:		
		mean:		

No. absent responses:_____

Tested by:_____

TABLE 55

MOTOR REFLEX TEST

PART 2

NAME _____

HOSPITAL NO _____

DATE _____

Stim.	Interstim. interval	Stimulus	Resp. pos. stim.		Resp. diff. stim. latency (sec)
			latency (sec)	deviation	
1	30	R	---	---	
2	10	Y			
3	25	Y			
4	15	G	---	---	
5	15	Y			
6	25	G	---	---	
7	15	R	---	---	
8	20	Y			
9	10	Y			
10	15	G	---	---	
11	25	Y			
12	15	R	---	---	
13	20	R	---	---	
14	30	Y			
15	10	Y			
16	10	G	---	---	
17	20	Y			
18	15	R	---	---	
19	30	Y			
20	10	G	---	---	
	total				
	mean				

Diff. latency Part 2: - Part 1: _____ no. disinhibitions: _____

Tested by: _____

The TARTU is presented as one example of the way in which multiple psychometric/psychophysiological tests may be encoded on the GSS. Developed by Juri Saarma, M.D., of Tartu State University, Estonia SSR, USSR, this battery has been employed in a number of drug trials - particularly by Thomas Ban, M.D., McGill University, Montreal. Consisting of six familiar and frequently used tests presented to the subject in a standardized manner, the TARTU is representative of assessment and encoding procedures in this area. The entire TARTU requires approximately 1 hour to administer.

APPLICABILITY	Adult populations
UTILIZATION	Once at pretreatment; at least one posttreatment rating. Additional assessments are at the discretion of the investigator.
ENCODING FORMAT	The locations for each of the tests are given in Figure 28. The locations of specific variables are given within the descriptive sections for each test.

CARD FORMATS - When entire battery is employed

CARD 01 = (19x, F4.1, 2F2.0, F4.1, 3F2.0, 2F3.0, 4F4.1, 2F2.0, 3F3.0)

Test	Column
Operant Memory	
1. Mn. Time-Immediate	20 - 23
2. Total Correct-Immediate	24 - 25
3. Total-Incorrect-Immediate	26 - 27
4. Mn.Time-Delayed	28 - 31
5. Total Correct-Delayed	32 - 33
6. Total Incorrect-Delayed	34 - 35
7. Difference between 2 and 5	36 - 37
Learning	
1. Learning Index	38 - 40
2. Confabulation Index	41 - 43
3. Mn. Learning Time	44 - 47
4. Mn. Deviation	48 - 51
Word Association	
1. Mean Latency	52 - 55
2. Mn. Deviation	56 - 59
3. Number Adequate	60 - 61
4. Number Inadequate	62 - 63
Calculation	
1. Mn. Additions	64 - 66
2. Mn. Deviation	67 - 69
3. Mn. Error	70 - 72

MH 9 50
9 75

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB NO. 68 R965

ECDEU GENERAL SCORING SHEET (50-GSS)

FIGURE 28

DATA MATRIX FOR TARTU PSYCHOMETRIC BATTERY

PATIENT INITIALS

FIRST INITIAL: A B C D E F G H / K L M N O P Q R / U V W X Y Z

SECOND INITIAL: A B C D E F G H / K L M N O P Q R / U V W X Y Z

SHEET NO. 0 1 2 3 4 5 6 7 8 9

NUMBER MALES 001 TO 499

NUMBER FEMALES 500 TO 998

PATIENT 1 2 3 4 5 6 7 8 9

RATER 1 2 3 4 5 6 7 8 9

PERIOD 1 2 3 4 5 6 7 8 9

Hours 0 1 2 3 4 5 6 7 8 9

Days 0 1 2 3 4 5 6 7 8 9

Weeks 0 1 2 3 4 5 6 7 8 9

Months 0 1 2 3 4 5 6 7 8 9

Row

1 0 1 2 3 4 5 6 7 8 9

2 0 1 2 3 4 5 6 7 8 9

3 0 1 2 3 4 5 6 7 8 9

4 0 1 2 3 4 5 6 7 8 9

5 0 1 2 3 4 5 6 7 8 9

6 0 1 2 3 4 5 6 7 8 9

7 0 1 2 3 4 5 6 7 8 9

8 0 1 2 3 4 5 6 7 8 9

9 0 1 OPERANT MEMORY TEST 8 9

10 0 1 2 3 4 5 6 7 8 9

11 0 1 2 3 4 5 6 7 8 9

12 0 1 2 3 4 5 6 7 8 9

13 0 1 2 3 4 5 6 7 8 9

14 0 1 2 3 4 5 6 7 8 9

15 0 1 2 3 4 5 6 7 8 9

16 0 1 2 3 4 5 6 7 8 9

17 0 1 2 3 4 5 6 7 8 9

18 0 1 2 3 4 5 6 7 8 9

19 0 1 2 3 4 5 6 7 8 9

20 0 1 2 3 4 5 6 7 8 9

21 0 1 2 3 4 5 6 7 8 9

22 0 1 2 3 4 5 6 7 8 9

23 0 1 2 3 4 5 6 7 8 9

24 0 1 2 3 4 5 6 7 8 9

25 0 1 2 3 4 5 6 7 8 9

26 0 1 2 LEARNING TEST 7 8 9

27 0 1 2 3 4 5 6 7 8 9

28 0 1 2 3 4 5 6 7 8 9

29 0 1 2 3 4 5 6 7 8 9

30 0 1 2 3 4 5 6 7 8 9

31 0 1 2 3 4 5 6 7 8 9

32 0 1 2 3 4 5 6 7 8 9

33 0 1 2 3 4 5 6 7 8 9

34 0 1 2 3 4 5 6 7 8 9

35 0 1 2 3 4 5 6 7 8 9

36 0 1 WORD ASSOCIATION TEST 8 9

37 0 1 8 9

38 0 1 2 3 4 5 6 7 8 9

39 0 1 2 3 4 5 6 7 8 9

40 0 1 2 3 4 5 6 7 8 9

41 0 1 2 3 4 5 6 7 8 9

Cols: 1 2 3 4 5 6 7 8 9 10

Row

1 0 1 2 3 4 5 6 7 8 9

2 0 1 WORD ASSOCIATION TEST 8 9

3 0 1 8 9

4 0 1 2 3 4 5 6 7 8 9

5 0 1 2 3 4 5 6 7 8 9

6 0 1 2 3 4 5 6 7 8 9

7 0 1 2 3 4 5 6 7 8 9

8 0 1 2 3 4 5 6 7 8 9

9 0 1 CALCULATION TEST 7 8 9

10 0 1 2 3 4 5 6 7 8 9

11 0 1 2 3 4 5 6 7 8 9

12 0 1 2 3 4 5 6 7 8 9

13 0 1 2 3 4 5 6 7 8 9

14 0 1 2 3 4 5 6 7 8 9

15 0 1 2 3 4 5 6 7 8 9

16 0 1 2 7 8 9

17 0 1 2 PROOF-READING 7 8 9

18 0 1 2 3 4 5 6 7 8 9

19 0 1 2 3 4 5 6 7 8 9

20 0 1 2 3 4 5 6 7 8 9

21 0 1 2 3 4 5 6 7 8 9

22 0 1 2 3 4 5 6 7 8 9

23 0 1 2 3 4 5 6 7 8 9

24 0 1 2 3 4 5 6 7 8 9

25 0 1 2 3 4 5 6 7 8 9

26 0 1 2 3 4 5 6 7 8 9

27 0 1 2 3 4 5 6 7 8 9

28 0 1 2 3 4 5 6 7 8 9

29 0 1 7 8 9

30 0 1 MOTOR REFLEX TEST 7 8 9

31 0 1 2 3 4 5 6 7 8 9

32 0 1 2 3 4 5 6 7 8 9

33 0 1 2 3 4 5 6 7 8 9

34 0 1 2 3 4 5 6 7 8 9

35 0 1 2 3 4 5 6 7 8 9

36 0 1 2 3 4 5 6 7 8 9

37 0 1 2 3 4 5 6 7 8 9

38 0 1 2 3 4 5 6 7 8 9

39 0 1 2 3 4 5 6 7 8 9

595 0 1 2 3 4 5 6 7 8 9

Cols: 11 12 13 14 15 16 17 18 19 20

CARD 02 = (19x, F4.1, 2F2.0, 4F3.1, F4.1, F2.0)

Test	Column
Proof Reading	
1. Completion Time	20 - 23
2. No. Errors	24 - 25
Motor Reflex	
1. No. Absent	26 - 27
2. Latency-Part I	28 - 30
3. Deviation-Part I	31 - 33
4. Latency-Part II	34 - 36
5. Deviation-Part II	37 - 39
6. Difference-Latency	40 - 43
7. No. Negative Stimuli	44 - 45

GENERAL INSTRUCTIONS

The TARTU should be administered under standardized conditions. The testing room should be quiet and free from distracting stimuli. It should be furnished with a table and 2 chairs. The subject should be seated across from the experimenter in such a way that he is not able to see the presentation material. Additional apparatus include:

1. Pencils
2. Stop watch
3. Recording sheets for each of the tests
4. Motor reflex apparatus

SPECIFIC TEST INSTRUCTIONS

Operant Memory Test

Experimental Design - The subject is given two groups of three words and asked to recall them immediately after presentation of the words and again after a slight delay. The procedure is then repeated with two other groups of three words. The scores are the number of seconds for the immediate and delayed responses; the number of correct and incorrect responses.

Time for Administration - 5 minutes

Procedure - Before starting the test, the following instructions are given to the subject (S) by the experimenter (E):

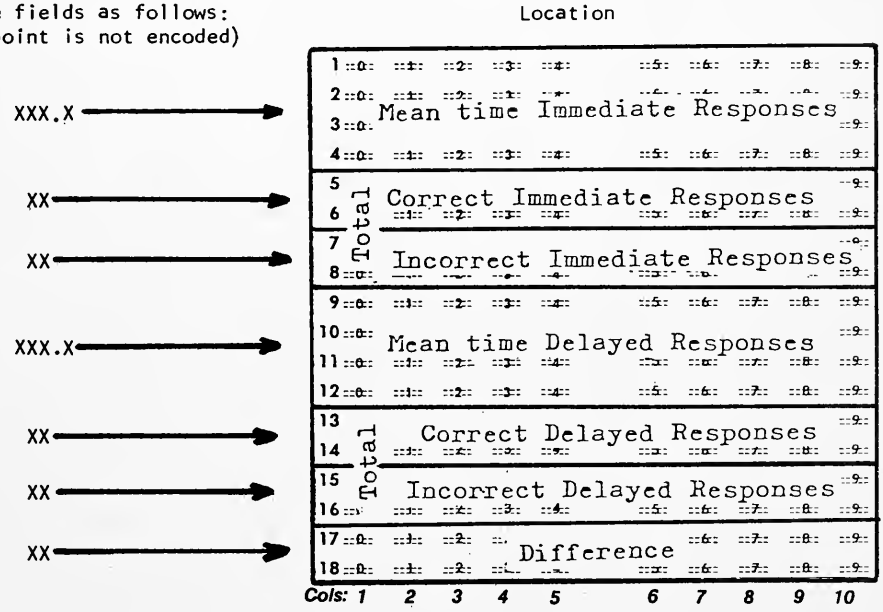
"I am going to give you a simple memory test. I shall read three words to you and will ask you to repeat them. Then I shall read you another three words, and I shall ask you to repeat them also. Then, I shall ask you to recall the first three words, and then the second group of three words. We shall then repeat the whole procedure for a second time again with different words. Any questions?"

The first three words on the recording sheet (Table 49) are read to S, then S is immediately asked to repeat them. The time taken from the command until the end of last word repeated by S is measured by means of a stop watch. The second group of three words is read to S by E according to the same procedure. Then E asks S to recall the first group of three words, after which S is asked to recall the second group of three words. The words repeated by S and the time taken for each group of three words are recorded by E. The entire procedure is repeated in the same way with the third and fourth groups of three words.

Variables

1. Mean time for immediate response. It is calculated by dividing the sum of the times for the 4 (immediate) groups of three words by 4.
2. Total number of correct immediate responses.
3. Total number of incorrect immediate responses.
4. Mean time for delayed response. It is calculated by dividing the sum of the times of the 4 (delayed) groups of three words by 4.
5. Total number of correct delayed responses.
6. Total number of incorrect delayed responses.
7. The difference between the number of correctly recalled immediate responses (measurement 2) and the number of correctly recalled delayed responses. (measurement 5).

ENCODING FORMAT - The Operant Memory Test should be encoded as follows:



Experimental Design - The subject is told that his (her) task is to learn ten words. Then the words are read to subject by the experimenter ten consecutive times. After each reading, the subject is asked to repeat them. The scores are expressed in terms of time, i.e., number of seconds required for repeating the words each time and the number of correct and incorrect responses.

Time for Administration - 15 minutes

Procedure - Before starting the test, the following instructions are given to S:

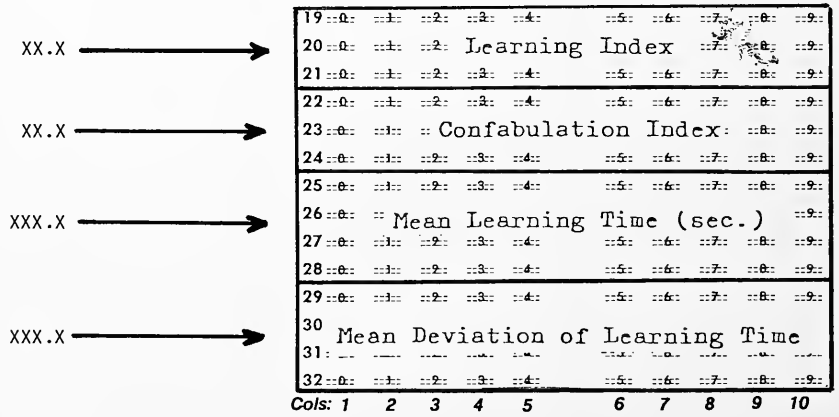
"We will now do another memory task. I am going to read ten words which I would like you to learn by heart. Please listen carefully. When I have read you all ten words, I will ask you to repeat all the words you can remember. Please tell me when you have recalled all the words you can. Then I will read all ten words to you again and you will try to recall once again as many words as you can. We will continue in the same way until you can easily recall all ten words. I am going to read the words to you in the same order each time, but you can repeat them in any sequence. Do you have any questions?"

Ten words are read slowly (with 2 second intervals) by E to S. Upon completion E asks S to repeat the words he (she) has just heard. E records the total time spent in repeating the recalled words and the number of correctly and incorrectly recalled words on the recording sheet (Table 50). The same procedure is repeated ten times. Different words are used for each trial with the same S.

Variables

1. Learning Index, (LI), i.e., mean number of correct responses for the 10 presentations. It is calculated by dividing the total number of correct responses by 10.
2. Confabulation Index, (CI), i.e., mean number of incorrect responses for the 10 presentations. It is calculated by dividing the total number of incorrect responses by 10.
3. Learning Time, i.e., mean time for learning one word correctly. It is calculated by dividing the total learning time for the 10 presentations by the total number of correct responses (measurement 1).
4. Deviation of Learning Time, i.e., mean deviation of learning time for each particular word from the mean learning time of the whole test. It is calculated by dividing the total of all the differences between the mean learning time for <u>each</u> of the 10 words and the mean learning time (measurement 3) by 10.

ENCODING FORMAT - The Learning Test should be encoded as follows:



Experimental Design - The subject is instructed to respond to each of the 20 words with the very first word which comes to his (her) mind. The score is the mean latency time, the mean deviation about this mean latency time, and number of adequate and inadequate responses.

Time for Administration - 7 minutes

Procedure - Before starting the test the following instructions are given to S:

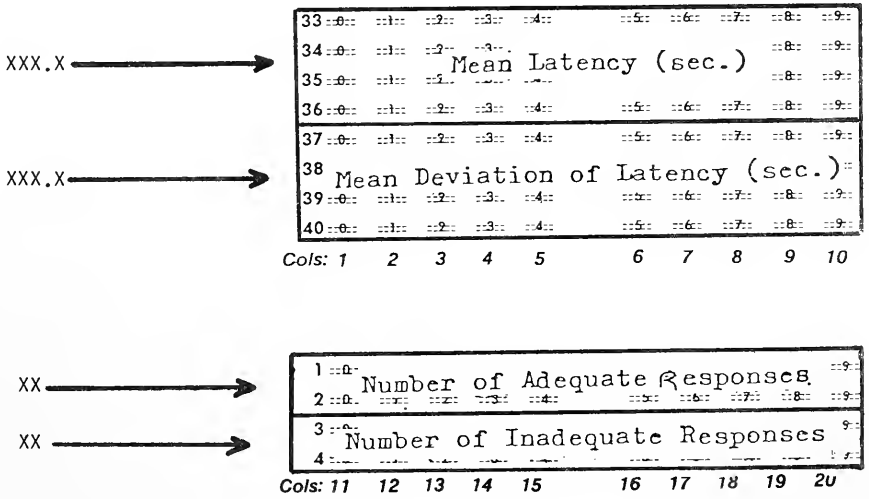
"I am now going to see how you respond to words. I am going to give you a word and I would like you to say the very first word which comes to your mind in connection with the word which I say. Try to answer as quickly as you can. The answer should be only one single word. Any questions?"

E presents the 20 words to S - one by one. The latency times and the responses are recorded on the sheet. (Table 51). Different words are used for each trial with the same S.

Variables

1. Mean latency time. It is calculated by dividing the sum of the individual latency times by 20.
2. Mean deviation of latency time. It is calculated by dividing the sum of the deviations of each individual latency time from the mean latency time (measurement 1) by 20.
3. Number of adequate responses. The total number of word responses which are connected with the stimulus word by content.
4. Number of inadequate responses. The total number of word responses which are not connected with the stimulus word by content.

ENCODING FORMAT - The Word Association Test is encoded as follows:



Calculation Test

Experimental Design - The subject is given a sheet of paper with six rows of two digits, 25 digit-pairs in each row. He (she) is asked to add the digit-pairs and write the answer underneath as quickly as he (she) can. S is given a time limit of 15 seconds per row. The scores comprise the mean number of digit-pairs added, the mean deviation about this mean, and the mean number of errors.

Time for Administration - 5 minutes

Procedure - Before starting the test, the following instructions are given to s:

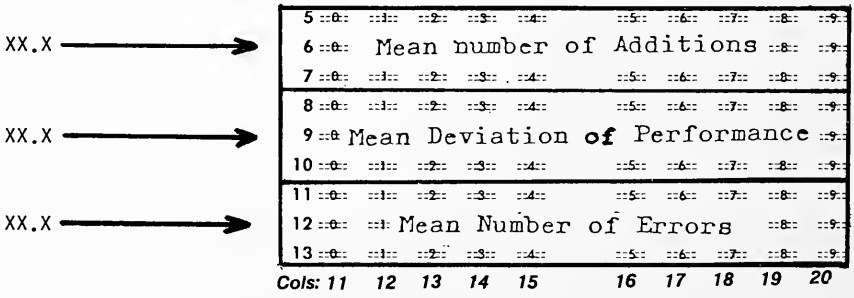
"The next task will be simple addition. I am going to give you a sheet of paper with six rows of digits on it. You have to add each digit-pair in the row and write your answer beneath the row in the free space. You will start when I say "Ready - Start" and continue adding the digit-pairs in the row until I say "Start next row". Complete as many additions in each row in the given time as you can. Any questions?"

E places the test sheet (Table 52.) in front of S and gives the command "Ready - Start". Fifteen seconds measured by means of a stop-watch are given for each row and S is instructed "Start next row" at that time. The same test sheet is used for all trials with the same S.

Variables

1. Mean number of additions performed. It is calculated by dividing the sum of all completed additions by 6.
2. Mean deviation of performances. It is calculated by dividing the sum of the deviations of the number of additions of each row from the mean number of additions (measurement 1) by 6.
3. Mean number of errors. It is calculated by dividing the sum of all the additions incorrectly performed by 6.

ENCODING FORMAT - The Calculation Test is encoded as follows:



Proof-Reading Test

Experimental Design - The subject is given a sheet of paper with 100 letters, i.e., ten rows with ten letters in each, and is requested to cross out a particular letter as many times as it occurs. The scores are expressed in terms of time, i.e., the number of seconds required to complete the task, and the number of errors made.

Time for Administration - 5 minutes

Procedure - Before starting the test, the following instructions are given to S:

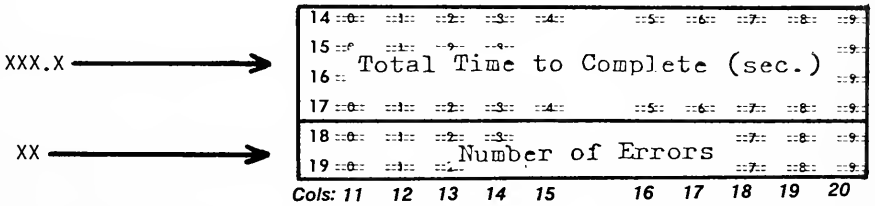
"The next task will be very simple. I am going to give you a sheet of paper, with letters typed on it. Your task will be to cross out the letter ... (in each particular testing a different letter is used) as many times as you see it. Please try to complete this test as quickly as you can. Do you have any questions?"

The sheet of paper with 100 letters (Table 53) is placed in front of S. Then E calls "Ready - Start". Time to complete the task is measured by means of a stop watch.

Variables

1. Time to complete the task
2. Number of errors (both omissions and commissions).

ENCODING FORMAT - The Proof-Reading Test is encoded as follows:



Motor Reflex Test

Experimental Design - The subject is instructed to press a button as quickly as possible at the onset of a positive conditional stimulus (a particular coloured light) and not to react to negative conditional stimuli (other coloured lights, different from the particular colour used as the positive conditional stimulus).

Part 1 consists of the presentation of fifteen positive conditional stimuli. Part 2 consists of the presentation of a mixture of ten positive and ten negative conditional stimuli.

The scores are the mean latency time upon the positive conditional stimuli of Part 1; the mean latency time upon the positive conditional stimuli of Part 2; the mean deviations about the mean latency times upon the positive conditional stimuli of Part 1 and Part 2; the number of no responses upon the positive conditional stimuli; and the number of responses upon the negative conditional stimuli of Part 2.

Time for Administration - 20 minutes

Apparatus - Motor Reflex Test Apparatus: screen upon which four different coloured lights, i.e., green (G), red (R), yellow (Y) and blue (B), can be presented; electric timer to the accuracy of 1/100th of a second. S is seated at the table across from E facing the "stimulator screen". The reaction time button is in front of S. The switches of the light - stimuli and the timer are facing E, not visible to S.

Procedure - Before starting the test, the following instructions are given to S:

"We will now do a reaction time test. Place your finger on the button in front of you. Every time you see the .....(one of the four colours is named, according to a schedule) light come on, press the button down as quickly as you can. If any other light comes on, do not push the button. Any questions?"

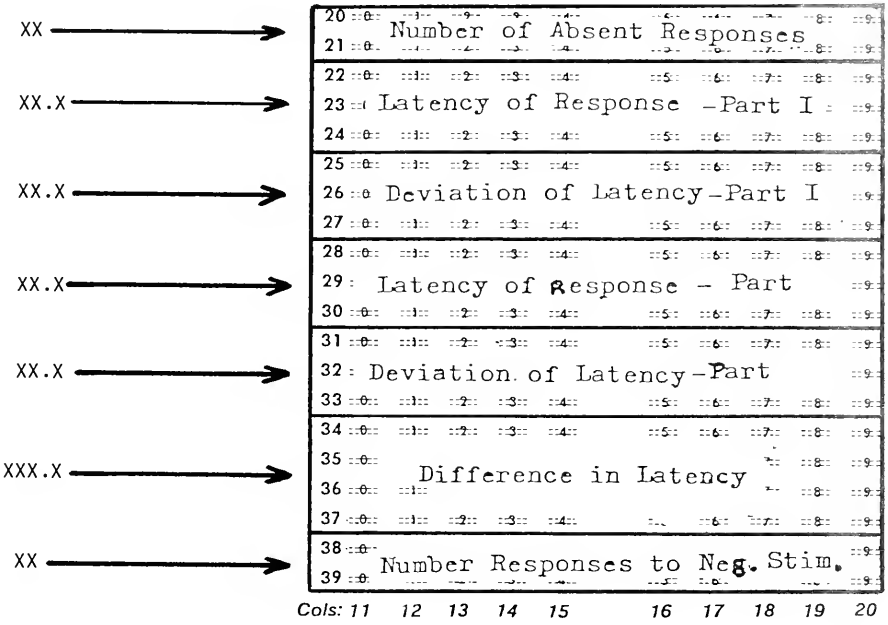
In Part 1 of the test, 15 positive conditional light stimuli are administered. In Part 2 of the test, a random mixture of 10 positive and 10 negative conditional stimuli are given. Different positive and negative conditional stimuli are used for each trial with the same S.

Variables

1. Number of absent responses to the presentation of the 25 positive conditional stimuli.
2. Latency time upon the positive conditional stimuli of Part 1. It is calculated by dividing the sum of the last 10 latency times to the positive conditional stimuli of Part 1 by 10. The first 5 latency periods of Part 1 are excluded.
3. Deviation of latency time about the positive conditional stimuli of Part 1. It is calculated by dividing the sum of the deviations of the latency times to the last 10 positive conditional stimuli from the mean latency time of Part 1 (measurement 2) by 10.
4. Latency time upon the positive conditional stimuli of Part 2. It is calculated by dividing the sum of the latency times to the positive conditional stimuli of Part 2 by 10.
5. Deviation of latency time about the positive conditional stimuli of Part 2. It is calculated by dividing the sum of the deviations of the latency times to the positive conditional stimuli from the mean latency time of Part 2 (measurement 4) by 10.

6. Difference of latency times upon the positive conditional stimuli of Part 1 and Part 2. It is calculated by subtracting measurement 2 from measurement 4.
7. Number of reactions to negative conditional stimuli.

ENCODING FORMAT - The Motor Reflex Test is encoded as follows:



DOCUMENTATION:

a. Raw score printout
b. Means and standard deviations
c. Variance analysis

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