Faculty Working Papers

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AN ANALYSIS OF LEGAL CONSIDERATIONS

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May 23, 1974

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The Use of Computers in Medical Decision-Making: An Analysis of Legal Considerations

This paper explores a series of legal issues arising from the introduction and use of computer-based information systems in medical decision-making. In addition to identifying legal precedents and legal trends, the analysis assumes that an understanding of the technology being introduced and the environment being examined should be developed for these factors, likewise, affect the ultimate analysis of legal problems. To provide this additional input a systems approach is utilized. The basic goal of the analysis is to examine the legal issues raised in a manner that insures the applicability of the discussion to a broad spectrum of potential factual situations.

In regard to its structure, this paper (1) discusses various types of computer-based medical information systems in terms of the functions they perform, their general characteristics, the environment within which they are being introduced, and the impact their introduction may have upon this environment; (2) identifies the individual and institutional parties that may have points of contact with various computer-based systems and briefly discusses the changing roles played by such parties; (3) identifies critical legal issues in generalizable categories; and (4) analyzes each legal issue in terms of existing law, the environment under discussion, and reasonable expectations as to the future direction of pertinent case law and its application to the questions under discussion.

Computer-Based Medical Information Systems

A prerequisite to analyzing the legal implications of using computers in the medical decision-making process is an understanding of the systems that are being used or have been proposed for use in this environment and the organizational implications of such usage. This initial section of the paper attempts to provide this background.

A Systems Perspective

Our mechanisms for health care delivery include a wide variety of individual and institutional providers and payers. A "systems" perspective can be employed as a framework for discussing the decision-making activities found within this complex environment.[1] When applying this concept to various types of human activity, systems can be thought of as existing in a hierarchy of complexity in terms of the organization of their basic unit of behavior Since the most encompassing system within this formation is the universal or "transcendental system," all physical and social phenomena can be described as being a system that is made up of sub-systems. Each system is in turn an element of a still larger system.[2]

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[1] The systems concept can be generally defined as a gestalt approach to analysis and inquiry. This implies a framework that examines the entire problematic universe rather than segmented portions of that universe, that recognizes the whole is often different from the sum of its parts, and that individual parts of the whole are frequently modified by their relationship to both the while and one another. Peter P. Schoderbek, Management Systems 1 (2nd ed. 1971) Operational definitions of the systems concept or the systems approach are normally in terms of the specialized methodological frameworks employing this conceptual tool. Among the more popular are general systems theory, cybernetics, information theory, and operations research. For further comment and observations concerning general aspects of the systems approach, see C. West Churchman, The Systems Approach 29 (1968) and Richard A. Johnson, Fremont E. Kast, and James E. Rosenzweig, The Theory and Management of Systems 3 (1973).

[2] Kenneth E. Boulding, "General Systems Theory - The Skeleton of Science," 2 Management Science 197, 200 (1956).

When speaking of the health care delivery system, we are referring to the vast collection of individuals and organizations who provide the broad range of health services consumed by our population. Among the multiple elements of this global health care delivery system, this paper is particularly concerned with the provision and use of information for medical decision-making. Decision-making occurs throughout the health care delivery system at all levels of organization and in many degrees of complexity. While the primary thrust of this discussion will be in terms of decision-making activity that takes place in an organizational or institutional context, the basic analysis is applicable whether a specific decision-making event or computer application occurs in an organizational context or not.

For the purpose of this analysis an organization is viewed as a system made up of numerous decision centers connected by a communications network providing information flows. The information flows associated with a given category of decisions constitute an information network or information system. Information flows represent the results of the efforts of the organization to relate and match information requirements with available sources of data for each major decision. Within the complex organization a number of interrelated information systems exist simultaneously. This theoretical framework assumes the use of computer-based systems as the primary tool for accumulating, storing, processing and transmitting information.[3]

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[3] This description of the organization is an element of the information systems approach, a systems methodology for describing, analyzing, and designing computer-based information systems. The material in the following four paragraphs in part represents various aspects of this methodological framework. For detailed discussion see Thomas R. Prince, Information Systems for Management Planning and Control (rev. ed. 1970).

When applying a systems framework, a number of analytical tools can be used to identify and discuss existing and proposed computer-based information systems. Among these is a continuum that places various computer-based systems within a hierarchy in terms of their relative sophistication. The breadth of this continuum can be demonstrated by outlining the systems described at its extreme points.

At the most elementary level is a simple computer program of which a basic computer-based perpetual inventory is an example. The most sophisticated system is described as an advanced information system. This may be defined as a large scale, online computer-based network that supports the major decision-making activities in two or more departments within the organization. While such a network may not encompass every information flow within a given organizational unit, there will eventually be an interface between manual and computer-based operations.[4]

A second viewpoint for examining computer-based information systems is to characterize the decision-making activities which they support in terms of their relative predictability and subjectivity and the time-frame of their use. Decisions described in this manner have either a planning or housekeeping focus. For the purposes of this anlysis, planning decisions can be more generally described as unstructured decisions.

Major information flows with a high degree of predictability form one integrated operation systems. In a health care delivery organization the housekeeping system includes a wide variety of information flows including those

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[4] In ascending order computer-based systems can be described as computer programs, activity programs, functional programs, operating systems, information systems, and advanced information systems.

involving the provision of personnel, supplies, and physical facilities, as well as certain medical information flows supporting decisions of a more routine and elementary nature. Information flows which are relatively more unpredictable support the unstructured decision system. This classification includes information flows supporting long-range planning activities as well as certain medical decision-making activities.

A third method for characterizing computer-based information systems is in terms of the functions they serve. In this regard the decision-making process found within the health care delivery system has often been divided between medical and administrative functions. Medical decisions are broadly classed as those decisions directly involving the medical well-being of the patients.[5] An empirical characteristic of this class of decisions is that they traditionally have been solely the responsibility of the physicians and other professional staff members. In general, all decisions involving diagnosis, treatment, and related procedures would clearly fall into the medical decision classification. Administrative decisions essentially include all other decision-making within the organization. This dichotomy is useful in this paper for the scope of the paper is limited to those computer-based information systems supporting medical decision-making.

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[5] Examples of administrative decisions might include non-professional personnel decisions, decisions relating to the operation of the physical plant including auxiliary services, the purchase of supplies, and decisions relating to financial planning and control. While useful in the context of this paper, the medical administrative decision-making dichotomy is not always appropriate. Several factors tend to blur the clarity of this distinction. These include the facts that certain personnel, particularly some members of the medical staff, have responsibility in both areas and that many decisions themselves have both medical and administrative factors.

Description of Computer-Based Systems and Applications

Medical decisions often involve a variety of variables and a complex decision-making process implying the need for a sophisticated system of supporting information flows. Examples of a number of computer-based medical information systems and analytical techniques are discussed in the following text. The discussion is presented in terms of the specific medical function served or supported by the system. While most of the systems and techniques described have great promise, few are fully operational and have seen widespread use.

The Diagnostic Function

Though there is significant dispute as to the decision-making process used to solve medical diagnostic problems, the potential for using computer-based systems in this area has great promise.[6] A computer-assisted diagnostic system might include a variety of aids for problem solving. Among the mathematical and operations research applications that have been explored are probability theory, multivariate analysis, numerical taxonomy, and simulation.

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[6] Medical diagnosis can be divided into the following three categories: (1) diagnosis of a condition when the doctor starts the process with no idea of what the final diagnosis will be, (2) diagnosis of a condition from a relatively small number of known alternatives, and (3) the interpretation of clinical diagnostic tests. See James A. Boyle, "Automated Diagnosis," 18 Computers and Automation 20 (June 1, 1969). The first two categories may also be described as "open ended and differential" clinical diagnosis, and in this paper will be jointly referred to as diagnostic decision-making. British Medical Association, Computers in Medicine 36 (1969). For further information concerning the dispute, among physicians, as to the decision-making process used to solve diagnostic problems and attempts to model this process, see Thomas R. Taylor, Principles of Medical Computing 82 (1967); G.A. Gorry, "Computer-Assisted Clinical Decision-Making," 12 Methods of Information in Medicine 45 (January 1973); and D. James Croft, "Is Computerized Diagnosis Possible?" 5 Computers and Biomedical Research 351 (1972).

Several studies have used Bayes theorem of conditional probability or its derivatives to calculate the likelihood that particular symptom clusters will occur, given an individual has a known set of symptoms. Though there are certain theoretical problems, this technique has appeal for further development before computers are potentially more capable of remembering probabilities learned from experience than is the individual physician.[7] Multivariant analysis has at least two basic applications in diagnostic practice. The first use is for isolation from a mass of data of the combination of factors having specific importance for determining the outcome of a given treatment or indicating the set of events common to various specified diseases. The second involves examining data concerning bodily functions with the intent of isolating patterns of chemical, electrical, or physical events that reflect various medical conditions.[8]

Numerical taxonomy is basically a pattern recognition or cluster analysis methodology in which groups of cases that most resemble one another are separated from a larger population of cases. The variables used to make the separation represent various symptoms and measurements of bodily functions. Simulation involves constructing a mathematical model that reflects, as accurately as possible, the relationships of various variables describing the system being modeled. Once a simulation model is developed, the value of its variables can be altered in various combinations to produce hypo-

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[7] Thomas R. Taylor, Principles of Medical Computing 84-85 (1967).

[8] T.D. Sterling and S.V. Pollack, (hereinafter cited as Sterling), "Automatic Data Screening: A Practical Solution to the Multivariate Problem in Clinical Data," 161 Annals of the New York Academy of Sciences 632, 633 (1969).

thetical results.[9]

Computer-based systems utilizing the methods described would involve a rather high level of sophistication. Initially, physicians and nurses having access to a computer through online, remote terminals may also be able to use specific computer programs capable of performing elementary calculations, statistical tests, and programmed anlyses. A more complex computer-based diagnostic system might allow a physician wide options as to the information he examines, the format in which the information is presented, and the statistical and analytical tools that he can apply to the information available. Such a system might provide the physician with the complete medical history of the patient in terms of numerous variables as well as information concerning both treatment and prognosis.

Though often discussed in the literature as a separate type of computer-based medical system, computer-based systems designed for use in laborato- and in automated multiphasic health screening would seem appropriate for inclusion under the basic diagnostic classification used in this study.

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9 Taylor, supra note 7, at 76-78, 86. For additional discussion of the application of computers in diagnostic medicine see Cesar A. Caceres and Arthur E. Rikli, Diagnostic Computers 11-65 (1969). For additional discussion of specific methodologies for computerized diagnosis, see Malcolm A. Gleser and Morris F. Coller, "Towards Automated Medical Decisions," 5 Computers and Biomedical Research 180 (April 1972); Joseph L. Fleiss, Robert L. Spitzer, Jacob Cohen, and Jean Endicott, "Three Computer Diagnosis Methods Compared," Archives of General Psychiatry 643 (November 1972); and David H. Gustafson, John J. Kestly, John H. Greist, a Norman M. Jensen, "Initial Evaluation of a Subjective Bayesion Diagnostic System," 6 Health Services Research 204 (Fall 1971).

Perhaps the most frequently encountered example of a computer-based diagnostic application is the analysis of electrocardiograms. While final diagnosis remains the responsibility of the physician, the computer analysis includes four significant types of data produced in a digital matrix format and accompanied by corresponding interpretive statements. See G.A. Kien, T.V. Balacek, L.L. Linka and W.V. Murphy (hereinafter cited as Kien), "Real-Time Analysis of Electrocardiograms by Computer," 19 Computers and Automation 16 (June 1970) and Cesar A. Caceres," Computer Electrocardiogra Processing," 44 Delemwar Medical Journal 218 (August 1972).

Presently the major application of computers in laboratories is for offline storage and transmission of data generated by the various tests performed. A most sophisticated laboratory system includes online data acquisition capabilities wherein the system acquires data directly from automated and semi-automated electronic laboratory testing equipment thus eliminating manual transcriptions and speeding the distribution of reports. This type of system can also minitor the laboratory instruments from which data are gathered.[10]

Automated health screening refers to procedures for examining a collection of variables and selecting for presentation to an investigator those combinations that may be of specific interest. Operationally, they include hospital admission health screening programs where a series of prescribed tests are administered to every patient entering a given institution and multiphasic health testing programs in which screening examinations are given to large numbers of people on a regular basis towards the end of preventing disabling disease.[11]

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10 For descriptions of computer-based applications within laboratories see J. Lloyd Johnson Associates, Clinical Laboratory Computer System (1971); National Institutes of Health, The Mechanization, Automation, and Increased Effectiveness of the Clinical Laboratory (DHEW Pub. No. (NIH) 72-145, 1971); and Clinical Oriented Documentation of Laboratory Data (E.R. Gabrieli ed. 1972).

11 For further information, see Sterline, supra note 8 at 634; 2 U.S. Dept. of Health, Education, and Welfare, Automated Multiphasic Health Testing and Services (1970); James L. Craig, "Automated Multiphasic Health Testing," 27 Archives of Environmental Health 264 (October 1973); and Ewen M. Clark and Mario Ariet, "Automated Health Testing and Medical Care," 59 Journal of the Florida Medical Association 34 (October 1972).

The systems discussed may be identified according to their relative sophistication. A system capable of performing a complete family of laboratory tests using previously established parameters and decision rules might be described as an operating system. A system that supports diagnostic decision-making activity and that is interfaced with operating systems performing the patient scheduling and pharmacy fulfillment functions might be described as a management information system. In such a system changes and responses dictated by basic diagnostic decisions would be automatically implemented. A diagnostic system that is integrated with a computer-based monitoring system or other computer-based system could attain the sophistication of an advanced information system.

The Monitoring Function

The second major class of computer-based medical information systems is those systems designed to assist and perform the monitoring function. For the purposes of this discussion, the monitoring function refers to the supervision accorded patients who have a disease or some diagnosed abnormality.[12] Computers can be used in two ways when performing this function. Utilizing the potential of computer-based information storage and retrieval, a computer-based system can be used for retrospective analysis of the condition and progress of various patients. The more fundamental use of computers in the monitoring process is for maintaining minute to minute surveillance of the

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12 For descriptions of monitoring applications see Harold G. Danford and others, "Remote Electrocardiographic Monitoring in Acute Myocardial Infraction," 223 Journal of the American Medical Association 998 (Feb. 26, 1973); Fred L. Farr and others, "Using a Dedicated Small Computer in Conjunction with a Time-Shared System in a Hospital Intensive Care Unit," 5 Computers and Biomedical Research 535 (1972); Herbert Shubin and others, "Monitoring the Critically Ill Patient with the Aid of a Digital Computer," 4 Computers and Biomedical Research 460 (1971).

condition of the patient.[13]

At their initial level patient monitoring systems may principally fulfill data handling and storage functions. Such systems are capable of collecting and retrieving data representing conventional variables of patient well-being. This type of system can greatly reduce the data collection and record keeping workload of the nursing staff and improve access of physiological data. More sophisticated systems can derive additional information from primary data, evaluate data over time to indicate significant changes in the condition of the patient, and provide clinical interpretation of the changes that are observed. Since computer systems can deal with a broad spectrum of variables with great speed, the real value of such systems lies in their potential for spotting dangerous conditions early enough in their developmental cycle to correct them and minimize their effect upon the patient.

In terms of relative sophistication, computer-based medical information systems performing the monitoring function likewise might vary from basic computer programs to systems that are a part of an advanced information system. Among other configurations, a monitoring system might ultimately be completely self-contained and be capable of (1) collecting and deriving pertinent data, (2) preparing periodic reports, (3) using programmed decision rules to evaluate changes in parameter values, and (4) alerting the hospital staff when its evaluation indicate abnormalities. Such a system undoubtedly would be real time and dynamic in that is decision rules would improve as the system is utilized on an increasing number of patients. In addition monitoring

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[13] The operating room represents an activity requiring almost continuous monitoring of many parameters. Post-operative recovery and intensive care situations represent monitoring applications where fewer parameters must be watched and periodic rather than continuous measurements may be sufficient.

systems might be interfaced with a number of manual and computer-based operating systems including automated medication systems and emergency care teams.

Computer-based information systems used in medicine will most likely vary across a wide continuum in terms of the housekeeping-unstructured decision dichotomy. While many of these systems will operate within the confines of well-defined constraints and carefully evolved decision rules, the more complex systems will tend to support decision-making activity that closely resembles the unstructured nature of decisions with a planning focus.

The Data Base

Regardless of the functions that computer-based information systems might assume in the medical decision-making process, the existence of a data base both is a prerequisite and is assumed. Particularly for the more sophisticated operating and management information systems, this data base is likely to be quite extensive.

Although the literature often discusses computerized "medical information systems" and computerized "medical records" as separate computer applications, in the framework of this analysis they are more properly seen as the underlying data bases for various operating and management information systems. The systems that have been referred to by these general characterizations have a wide variety of capabilities. They range from simple indexing systems for existing medical records to proposals to automate a significant part of the information flows within the hospital and the health care delivery system. Though the global use of these terms has left them somewhat meaningless, this fact does not reduce the appropriateness for general discussion of the data

base requirements for various computer-based medical information systems.

Among the significant data bases currently found in the health care delivery system are hospital medical records. Besides basic biographical data, the medical record includes the medical history of the patient, clinical findings, treatments, laboratory and other diagnostic test reports, and related clinical and non-clinical information. While some of this information may be coded, much will be in a narrative format. Though the data base required for computer-based medical information systems should not be viewed as a separate function, and may be structurally quite different from the traditional data bases,[14] it will contain a great deal of the information found in existing data bases plus additional information presently found in informal record systems or not currently accumulated.

In addition to the data bases discussed, there are several proposals to develop medical information data nets. Essentially a central medical record would be maintained within a computerized system for each individual within a defined population group.[15] This record would run from birth to death. Among the advantages cited for such an application is the fact that historical medical data would be available to any health care personnel treating the individual regardless of where he had previously received treatment and

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[14] For a proposed alternative to the present medical record, see Lawrence L. Weed, Medical Records, Medical Education, and Patient Care (1970).

[15] For discussion of proposals see Donald A.B. Lindberg, "A Statewide Medical Information System," in Proceedings of a Conference on Medical Information Systems, U.S. Dept. of Health, Education and Welfare, 73 (1970); Michael Davies, "Toward a Medical Data Bank for a Total Population," 15 Datamation 257 (November 1969); U.S. Dept. of Health, Education and Welfare, Records, Computers and the Rights of Citizens: Report of the Secretary's Advisory Committee on Automated Personal Data Systems (DHEW Pub. No. (OS) 73-94, July 1973).

care. A slight variation of the centralized medical record concept is a sys employing the interchange of data between various data banks. This might occur where the hospital and the personal physician of an individual maintai separate data bases but have access to each other's data files.

Identification of Parties

The parties having points of contact with different computer-based medical systems will vary significantly.[16] From a long-term view the two most significant events that occur in the life of most computer-based systems are (1) their design and testing phase and (2) their operational phase. Since most computer-based applications today are still in various stages of development, a given system may have been designed in the same institution at which it is now being used. In the future we might expect various health care providers desiring the use of a computer-based system to examine the different systems on the market and to select the one that best meets their requirements and needs. Therefore, the selection process may be viewed as the third phase in the life cycle of such systems.

Hardware companies, software companies, systems designers (either corporation or individuals), research physicians, and programmers would seem to have the most significant points of contact with various systems in the design and testing stages of development. The systems selection process would seemingly involve the hospital administration and the medical staff in the case of hospitals, and one or more physicians in the case of the sole practitioner or group practices. Among those systems supporting medical

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16 A point of contact suggests a relationship on the part of a given party that gives rise to legal duties and responsibilities.

decision-making, physicians can be expected to have primary responsibility for the use of the output that is generated. A computer scientist and various technicians may be responsible for the actual operation of a given system. Nurses, laboratory technicians, and related personnel will play critical roles in the day-to-day operation of a system. Their responsibilities will include collecting and inputing data, responding to outputs involving critical time frames, performing tasks dictated by automated decision rules, and possibly performing some types of elementary analysis of outputs. It should be clear that the parties having points of contact in specific cases will vary significantly and will depend upon the function the system performs, the ownership of the system, and its relative sophistication.

Additional Considerations of Utilizing Computer-Based Medical Information Systems

A critical question exists as to physical location and ownership of various computer-based medical information systems. Since monitoring systems are expected to be primarily used in regard to the critically ill, these systems can be expected to be principally, if not totally, located within hospitals. Diagnostic systems and applications are expected to be used within multiple parts of the health care delivery system. Regardless of this fact, (1) their cost, (2) their complexity, (3) and their need for high utilization suggests that these systems will be hospital or institutionally based.[17]

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17 A number of alternative arrangements for ownership and location may exist within various communities. These include ownership and control by public and private institutions other than community hospitals, by public agencies, and by consortiums of corporate and individual providers.

Several additional considerations suggest that most computer-based medical information systems will be hospital or institutionally based. These include the facts that in most communities laboratory services for inpatients, outpatients, and office patients of individual practitioners are provided by the local hospital, that in most communities the hospital has been increasingly playing the pivotal role in overall community health care delivery, and that the Health Maintenance Organization program and related Federal programs encourage a hospital centered health care delivery system.[18]

Turning from the hospital and its role in the infusion of computer-based information systems into the health care delivery process, the role of the physician must be examined. As the role of the hospital is changing within the overall framework of the health care delivery system, the role of the physician is likewise changing. Among other things, the physician is increasingly becoming more closely associated with the hospital. Trends contributing to this changing relationship include the tendency for more doctors to become full time employees of hospitals or other delivery organizations, the construction of offices adjacent to hospitals, legal decisions making the hospital and the physician jointly responsible for the quality of medical care and service received by patients of the hospital, and various programs of the Federal government that encourage alternatives to the traditional fee for service practice of medicine.

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18 The Health Maintenance Organization program is a Federal program designed to encourage the development of prepaid health plans throughout the United States. Such plans are patterned upon the Kaiser-Permanente Medical Care Program. For descriptions of the Kaiser-Permanente Program, see Smith, Kline and French Laboratories, Report of a Symposium on Trends in Health Care 11-20 (1968). Though a hospital centered health care delivery system is not required in order to establish an HMO, this particular form of organizational arrangement is often used.

Another critical question in respect to the physician concerns the scope of his responsibility when a computer-based information system is in use. While the physician is generally said to be solely responsible for medical decisions, certain types of decisions are made by nurses and other personnel under the supervision of the physician while other decisions are sufficiently routine so as not to be treated as a medical decision. The question arises as to how the widescale use of computer-based systems might affect these relationships. Will some of the decision-making functions now at least nominally performed by the physician be assigned to the computer-based system or to other personnel? In the case of a monitoring system that uses predetermined decision-rules, to what extent must a physician supervise the operation of the system? Will the use of computer-based systems lead to a more careful examination to the nature of the medical decision-making process? Will this examination lead to some agreement as to the relative priority of various decisions and a determination of those decisions that clearly require the specialized training and experience of a physician? Has the concept of delegated authority been carried to an extreme? Should an individual physician be held responsible for the operation of a complex, computer-based system being used in regard to his patients or can be rely upon reasonably appearing output from the system?

Other significant problems face the designers of computerized medical information systems. Existing medical records vary in quality, are often in a narrative format, and may be incomplete, unstructured, irregularly posted, and include transcription errors. It is doubtful that any computerized system could meaningfully deal with the sheer volume of information that is currently accumulated within the health care delivery system. While coding procedures must be broad enough to provide the information needs of

many potential users, they must also deal with the problem of recording substantial amounts of narrative information and must limit the scope of possible variations among different observers. Since most physicians, nurses, technicians and other operating personnel have not had previous experience with computer-based systems, significant resistance to the introduction of this new technology may also be anticipated.

Legal Considerations

Of the important legal questions that arise when computers are used in large, complex organizations, several have been addressed and at least partially resolved. Issues of this nature include the admissibility of computerized records as evidence in judicial proceedings, the use of computerized records to fulfill record keeping requirements set by law, and the legal considerations of contracts for computer equipment and services. The purpose of this study is to discuss those issues that have not received adequate coverage elsewhere with special reference to problems involving systems designed for use in the medical decision-making process.

The Issue of Reliability

The principal legal consideration of this study has been characterized as the "issue of reliability." Essentially, the analysis of this issue deals with questions concerning the liability of various parties for injuries resulting from the use of computer-based medical information systems. Such injuries might result from faulty hardware, poorly designed or inadequate software, unreliable data inputs, equipment breakdowns and other operational problems, inappropriate application of the system or its outputs, and similar events. A short summary of applicable law is presented followed

by integrative analysis.

The Action of Negligence

A major portion of the existing civil litigation involving hospitals and the other individuals and organizations that make up our health care system is based upon various forms and derivatives of the tort action of negligence. Regardless of the innovations introduced by computers and their related technology, negligence will likely continue to be a primary cause of action in medical and health care tort suits. The applicability of the law of negligence in health care cases has been complicated by the fact that the judgements in various cases have been based upon a number of related, but to some extent, distinct principles. The first step in presenting the existing law is to consider the standard of conduct required of various potential defendants in more general circumstances.[19]

Though the minimum standard of care required by law generally assumes a man of average knowledge, skills, and ability, the rule for those individuals practicing a trade or profession is that they are required "to exercise the skill and knowledge normally possessed by members of that profession or trade in good standing in similar communities."[20] This element of law has particular importance for physicians, nurses, and other individuals in the health care or computer fields that hold themselves out as being specialists and as possessing special skills.

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19 In respect to physicians and other professionals, the term "malpractice" has often been used to refer to a variety of situations including those cases involving negligence. See Gregory v. McInnis, 140 S.C. 52, 59; 134 S.E. 527, 529 (1926); and 70 C.J.S. Negligence and Malpractice § 40 (1951). It has been suggested that in the case of the physician, malpractice should only refer to the negligent acts of these professions. Sidney Shindell, The Law in Medical Malpractice 53 (1966); and Arthur E. Southwick, "The Hospital's New Responsibility." 17 Clev.-Mar. L. Rev. 146, 149 (1968).

20 Restatement (second) of Torts § 299A (1965)

The standard of care required of a practicing physician is the degree of care that would be utilized by "(1) a reasonably prudent physician in the exercise of ordinary care applying that degree of skill and learning; (2) commonly possessed and exercised by members of the profession; (3) who are of the same school or system as the defendant physician; (4) who practice in the same or similar locality."[21] Though the locality rule has traditionally been a major consideration in formulating the standard of care for physicians, the restrictiveness of this rule is being eroded.[22] Since the easing of the locality requirements should make it less difficult to locate and qualify expert witnesses, the chances that a plaintiff will obtain a successful verdict in cases involving negligent acts of physicians can be said to be improving.

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[21] Practicing Law Institute, Medical and Dental Malpractice 11 (I.A. Cohen, ed. 1969).

[22] Id. at 11-14. For lists of cases and general comment see Elliot L. Segall and Barry C. Reed, The Law and Clinical Medicine 120 (1970). For a recent case espousing the minority position, see Murphy v. Little, 112 Ga. 517, 145 S.E.2nd 760 (1965). When the locality rule is operative, the standard of care within a community can only be established by expert witnesses familiar with the prevailing medical practice within the locality in question. The practical consequence of this requirement has generally been to require for the plaintiff the testimony of physicians practicing in the same community as the defendant. This fact has undoubtedly contributed to the widely discussed "conspiracy of silence" whereby many physicians are reluctant to testify in civil cases involving the negligence of a fellow physician. For further discussion of this problem see Agnew v. Parks, 172 Cal. App.2d 756, 343 P.2d 118 (1959). In this case a group of physicians were sued for conspiracy to obstruct prosecution of a group of civil cases by refusing to act as expert medical witnesses. See also William L. Prosser, Handbook of the Law of Torts 231 (1964).

As is the case for all individuals, hospital administrators and others serving in management positions are jointly and severally liable for their negligent acts and omissions that result in injury to another. Though this potential liability exists,[23] few cases have actually been reported where an administrator was found liable for negligence. While cases have held that the administrator is not protected by the charitable immunity doctrine,[24] it has also been held that employees are the agents of the hospital and not the administrator therefore the administrator is not liable under the doctrine of respondeat superior for the negligent acts of these individuals.[25]

A director, officer, or trustee may be liable for want of reasonable care giving appropriate consideration to the nature of the business, the duties of the individual at the time, and the circumstances under which the individual was expected to perform such responsibilities.[26] The practical

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[23]In Drefahl v. Connell, 85 Wis. 109, 55 N.W. 160 (1893), a patient sued a hospital superintendent for negligence in respect to his management of the hospital. Specifically, the complaint in the case stated the plaintiff was rightfully committed to the hospital, that the plaintiff had the right to proper care, treatment, and food, and that the superintendent had full control of the operations of the hospital and thus had the duty to provide proper care and treatment. The court found in this case that the complaint did state a good cause of action.

[24]Clark v. Ruidoso-Hondo Valley Hospital, 72 N.M. 9, 14; 380 P.2nd 168, 171 (1963)

[25]For lists of cases see Id. 72 N.M. at 14 n. 11, 380 P.2d at 171 n. 11. See also IIA Hospital Law Manual, Negligence Ch. 1, at 27-28 (1962).

[26]3 Fletcher Cyclopedia of the Law of Private Corporations, Directors, Other Officers and Agents § 1029 (rev. vol. 1965).

effect of this type of liability is greatly diluted by the "business judgment rule."[27] The position of the board as a policy maker acting upon the recommendation of the managers and the professional staff suggests their potential for liability in cases involving computer-based information systems is somewhat remote.

Unlike the ambiguous organizational and legal status of the physician, nurses are normally employees of the hospital and are liable for injuries resulting from their torts.[28] The hospital is liable for the negligence of nurses in its employment by virtue of the doctrine of respondeat superior. While the standard of care required of the nurse is generally higher than that of other individuals because of her special training and skill, this standard varies according to the classification of the nurse[29] and is increasingly being determined on a national scope.[30]

Most hospitals and related health care institutions in the United States are organized as not-for-profit corporations operated by governmental bodies, private charitable organizations, or groups of private citizens. A smaller number of health care delivery organizations are organized as profit making corporations. In general corporations are liable for the torts committed

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[27]This rule states "that ordinarily neither directors nor the other officers of a corporation are liable for mere mistakes or errors of judgment, either of law or fact." Id. §1039. Although the business judgment rule gives wide latitude to the board of directors in their policy and decision making position, liability will exist if it can be shown that the individual in question acted recklessly, failed to use ordinary knowledge and skill, or acted in want of ordinary prudence. Id. §1040.

[28]Benjamin Werne, Law for Doctors 78 (1969).

[29]Eric W. Springer, Nursing and the Law 61 (1970).

[30]Werne, supra note 28.

by officers, agents, or employees acting within their actual or implied scope of authority, or in the furtherance of corporate business. This is true whether the cause of action is based upon negligence or other tort theories.[31] Though this general statement of the law applies to hospitals, other health care delivery organizations, and the multitude of corporations that may be involved in the introduction of computer-based, medical information systems, important caveats exist in respect to not-for-profit hospitals and related institutions.

The doctrines of governmental and charitable immunity have in the past, and to a lesser extent continued to preclude recovery in tort cases against many of these not-for-profit organizations. Historically, a physician using hospital facilities for his patients has been treated as an independent contractor, a free agent no more than marginally subject to the control of the organization. These two concepts working in tandem have had the effect of making the physician assume primary liability for torts committed within the hospital.

In cases where hospitals and other non-profit health care organizations have been found liable for negligence, the courts have applied either the theory of corporate negligence or the theory of respondeat superior.
Corporate negligence has been defined as "the failure of those entrusted with the task of providing the accommodations and facilities necessary to carry out the charitable purposes of the corporation to follow, in a given situation, the established standard of conduct to which the corporation

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[31]Garafano v. Neshohe Beach Club, Inc., 126 Vt. 566, 569; 238 A.2d 70, 73 (1968).

should conform."[32] The doctrine of corporate liability is comprised of three types of non-delegable duties directly owed the patient by the hospital. These include the duty to provide proper, adequate, and non-defective equipment;[33] those duties owed by an owner or occupier of land or buildings to those individuals entering his premises;[34] and the duty to exercise reasonable care in the selection and retention of non-professional employees.[35]

Darling v. Charleston Community Memorial Hospital[36] is the most important case among those in which the concept of corporate liability has been dramatically expanded. Among other holdings the court concluded that custom should not be conclusive in determining the standard of care required by law and allowed admitted into evidence hospital regulations, national hospital accreditation standards, and the bylaws of the hospital to aid the jury in establishing the standard of care required of the hospital.

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[32]Bader v. United Orthodox Synagogue, 148 Conn. 449, 452; 172 A.2d 192, 194 (1961).

[33]South Highlands Infirmary v. Camp, 279 Ala. 1, 180 So.2d 904 (1965). This duty of the hospital does not require that the latest or best equipment be furnished or that existing equipment must incorporate the latest inventions or improvements, though such improvements may make the equipment safer. It must, however, be "reasonably suited to the uses intended and such are in general use under the same or similar circumstances in the area." Emory Univ. v. Porter, 103 Ga. App. 752, 755; 120 S.E.2d 668, 670 (1961). A hospital and its physicians may also be liable for attempting to treat a patient for which it is not equipped. Carrasco v. Benkoff, 220 Cal. App.2d 230, 239; 33 Cal. Rptr. 673, 678 (Dist. Ct. App. 1963).

[34]For further discussion see Wheeler v. Monadnock Community Hospital, 103 N.H. 306, 171 A. 2d 23 (1961); and Ackerberg v. Muskegon Osteopathic Hospital, 366 Mich. 596, 115 N.W.2d 290 (1962).

[35]Hipp v. Hospital Authority of the City of Marietta, 104 Ga. App. 174, 121 S.E.2d 273 (Ga. Ct. App. 1961).

[36]33 Ill.2d 326, 211 N.E.2d 253 (1965), cert. denied, 383 U.S. 946 (1966).

In explaining its reasoning the court found that the traditional view that hospitals do not undertake to treat patients or undertake to act through its doctors and nurses is no longer appropriate. The court recognized that modern hospitals have hired large staffs of physicians and other professionals; developed large, complex health care delivery organizations; are expected by the public to provide health care services; and have in fact assumed certain patient care responsibilities.[37] In this specific case the court found that the hospital had a duty to provide trained nurses for all patients at all times capable of recognizing a progressive gangrenous condition, to require consultation with or examination by members of the hospital surgical staff skilled in the treatment of the plaintiff's condition, to review the treatment received by the plaintiff, and to require that consultants be called in when they are needed.[38] The effect of this reasoning is to make the treatment rendered a patient by the professional staff a shared responsibility between the hospital and that staff.

Respondeat superior is the second theory applied by the courts in negligence

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[37] Id. at 257.

[38] Id. at 258. For additional comment see Raymond L. Hanson and Ross E. Stromberg (hereinafter cited as Hanson), "Hospital Liability for Negligence," 21 Hastings Law Journal 1, 13 (1969), and Practicing Law Institute, Hospital Liability Litigation 2d 8 (1970). Darling has been interpreted in Illinois as imposing potential liability upon the hospital for imprudent or careless selection of its staff members regardless of the amount of insurance carried. Mauer v. Highland Park Hospital Foundation, 90 Ill. App.2d 409, 415; 232 N.E.2d 776, 779 (App. Ct. 1967). A hospital may be liable for allowing a dentist to operate on a patient under general anesthetic without the presence and supervision of a physician in violation of the rules of the hospital. Pederson v. Dumouchel, 72 Wash. 73, 80;431 P.2d 973, 978 (1967). The reasoning of Darling has been adopted in Foley v. Bishop Clarkson Memorial Hospital, 185 Neb. 89, 95; 173 N.W.2d 881, 884 (1970).

cases involving hospitals and other institutional health care providers. Respondeat superior is a form of vicarious liability that imposes responsibility upon the health care delivery institution for the torts of its employees. The two crucial factors necessary for the operation of the theory are that there be an employer-employee relationship and that the employee was acting within the scope of his employment when the conduct or act in question occurred. Unlike other corporations, hospitals and other non-profit organizations have traditionally avoided the full impact of the doctrine of respondeat superior both because of the defenses of governmental and charitable immunity and because of the ambiguous legal and organizational relationship that exists between the physician, other professional employees, the hospital, and the patient. Specifically, if a physician were found to be an independent contractor, the theory of respondeat superior would not be operative.[39]

When professional personnel are salaried it can generally be said that the doctrine of respondeat superior is applicable and that the hospital or other health care delivery organization is liable for the torts of such employees.[40] This consideration can be expected to have growing importance

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[39]Arthur E. Southwick, "The Hospital's New Responsibility." 17 Clev.-Mar. L. Rev. 146, 155 (1968).

[40]For physicians see Klema v. St. Elizabeth's Hospital of Youngstown, 170 Ohio St. 519, 166 N.E.2d 765 (1960) and Guisti v. C.H. Weston Co., 165 Ore. 525, 108 P.2d 1010 (1941). For residents see Waynick v. Rearden, 236 N.C. 116, 72 S.E.2d 4 (1952); for contra. decision see Moon v. Mercy Hospital, 150 Colo. 430, 373 P.2d 944 (1962). For interns see City of Miami v. Oates, 152 Fla. 21, 10 S.2d 721 (1942). For nurses see Arnold v. James B. Haggin Memorial Hospital, 415 S.W.2d 844, 845 (Ky. 1967). This last case is of particular interest for the court found the hospital liable for damages resulting from the negligent acts of the nurses it employed even though the nurses were acting in accordance with the orders of the patient's physician. A similar holding is found in Norton v. Argonaut Ins. Co., 144 So.2d 249, 260 (La. Ct. App. 1962).

for there is a definite trend for physicians and other professional employees to be full-time employees of these organizations. The concept of apparent or ostensible agency is yet another inroad to the independent contractors exception to the doctrine of respondeat superior. In the leading case upon this point, Seneris v. Haas,[41] the court predicated the liability of the hospital for damages resulting from an act by a physician upon the fact that the hospital had held the patient to believe the physician was its employee.

Res Ipsa Loquitur

In addition to the difficulty of securing qualified, expert witnesses, the plaintiff in many medical liability cases is faced with the problem that the only people other than the plaintiff present at the time an alleged tort occurred were the defendants or the employees of defendants. In partial response to this difficulty of proof, the doctrine of res ipsa loquitur, a latin phrase meaning "the thing speaks for itself," has seen increasing application in medical liability cases.[42] The effect of the doctrine can vary

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[41] 45 Cal.2d 811, 291 P.2d 915 (1955). Additional applications of this doctrine include Kober v. Stewart, 148 Mont. 117, 417 P.2d 476 (1966) and Brown v. Moore 247 F.2d 711 (3d Cir. 1957), cert. denied, 355 U.S. 882 (1957).

[42] This doctrine has been stated as follows:

(1) It may be inferred that harm suffered by the plaintiff is caused by negligence of the defendant when (a) the event is of a kind which ordinarily does not occur in the absence of negligence; (b) other responsible causes, including the conduct of the plaintiff and third persons, are sufficiently eliminated by the evidence; and (c) the indicated negligence is within the scope of the defendant's duty to the plaintiff
(2) It is the function of the court to determine whether the inference may reasonably be drawn by the jury, or whether it must necessarily be drawn.
(3) It is the function of the jury to determine whether the inference is to be drawn in any case where different conclusions may reasonably be reached.

Rudolf F. Binder, "Res Ipsa Loquitur in Medical Malpractice," 17 Clev.-Mar L. Rev. 218, 219 (1968).

from merely allowing the jury to draw an inference of negligence from the circumstances of the case without shifting the burden of proof or the burden of introducing evidence to actually shifting the burden of proof to the plaintiff.[43]

The doctrine of res ipsa loquitur has recently seen significant expansion as a legal concept in cases involving both hospitals and health care personnel. At the same time the use of the doctrine has been significantly expanded. This expanded use has been particularly true in surgical cases.[44] While physicians have been relatively successful in defending themselves in cases involving the doctrine, it increasingly is being used in cases involving hospitals and other providers and it has been suggested that such parties may not have as favorable an experience as physicians for these institutions may be held accountable for the tortious acts of their non-professional staff.[45]

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[43]Prosser, supra note 22, at 232-34.

[44]Several trends underscore the expanding applicability of this doctrine. Among these are (1) the weakening of the requirement that an injury cannot be attributed to one of several causes, some of which are not in the control of the defendant; (2) the interpretation of the "instrumentalities" causing the injury as applying to people as well as objects or equipment; (3) the application of the doctrine in surgical cases in situations involving rare and unexplainable accidents; and (4) the finding of consecutive joint control among various defendants and the requirement that such defendants then come forward and explain what occurred. For an outline of cases and citations see Raymond L. Hanson and Ross E. Stromberg (hereinafter cited as Hanson), "Hospital Liability for Negligence," 21 Hastings Law Journal 1, 17 (1969); and Practicing Law Institute, Hospital Liability Litigation 20, 233-34 (1970).

[45]Practicing Law Institute, supra note 44, at 240.

Strict Liability

In addition to the tort theory of negligence, several other tort theories may have application in the areas of concern to this study. Among the more prominent is the concept of strict liability, a special type of liability by which a person engaged in a particular type of activity is made liable for the harm caused by that activity regardless of whether negligence is present or not. While this concept has been applied to a wide variety of situations, the most applicable use of this theory to the subject in question is in the area of product liability.[46]

Strict liability in product liability cases makes the seller of a product responsible for all the physical harms caused by that product regardless of the care exercised by the seller in its preparation and sale or of the existence of a direct contractual relationship between the buyer and seller.[47] The scope of its application has rapidly been expanded to cases involving the "sale of any product which, if it should prove to be defective, may be expected to cause physical harm to the consumer or his property."[48] The most

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[46]For general discussion see Prosser, supra note 22, at 506.

[47]The following is the text of Restatement (Second) of Torts §402A (1965).

> §402A Special Liability of Seller of Product for Physical Harm to User or Consumer.
> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liabiltiy for physical harm thereby caused to the ultimate user or consumer, or to his property, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
> (2) The rule stated in Subsection (1) applied although (a) the seller has exercised all possible care in the preparation and sale of his product, and (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

[48]For detailed listing of cases and products where strict liability has been found applicable see Restatement (Second) of Torts §402A, at 349 (1965).

important application of this doctrine in the medical liability cases, has been in cases involving the sale of blood allegedly contaminated by serum hepatitis.

Among other findings in the leading case, Cunningham v. MacNeal,[49] involving serum hepatitis the court found that human blood is a "product" regardless of the fact that it does not undergo intermediate processing before sale,[50] that the argument that the transfusion of whole blood for a fee is a service rather than a "sale" is "unrealistic,"[51] and that the blood bank and the hospital were in the "business of selling" human blood.[52] These findings were rendered in spite of the arguments that there is at the time no way to detect the presence of serum hepatitis virus in whole blood,[53] that blood was an unavoidably unsafe product,[54] and that this decision would drain the resources of hospitals and "thwart the fulfillment of their" worthy mission.[55] While it is impossible to predict whether this case foretells a growing application of the strict liability concept in medical liability cases, it underscores three observations: (1) There is a trend towards

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[49]Cunningham v. MacNeal Memorial Hospital, 47 Ill.2d 433, 266 N.W.2d 897 (1970). The effect of this decision has been reversed by statute, however, the statute includes a provision for its own repeal effective July 1, 1976. Ill. Rev. Stat. Ch. 91, §181-184 (West 1973).

[50]Id. at 899.

[51]Id. at 901.

[52]Id.

[53]Id. at 903.

[54]Id.

[55]Id. at 904. Various cases involving the liability of a hospital for contaminated blood are reviewed in 9 Duquesne L. Rev. 286 (1970).

expanded applicability of the strict liability concept in product liability cases; (2) the courts are rocognizing that hospitals have become large, complex organizations doing great volumes of business; and most critically, (3) while the individual consumer may desperately need the services provided by the hospital, he is essentially helpless in protecting himself from the harms that might exist in the delivery of such services.

The Law of Contracts

In addition to the strict liability theory of tort law, recent developments in product liability litigation suggest that the contract concept of liability for the breach of the implied warranty of merchantability[56] or the implied warranty of fitness for a particular purpose[57] in respect to the sale of a product could eventually have significant impact and application within the health care field. The application of the doctrine can be seen in Hoffman v. Misoricordia Hospital of Philadelphia,[58] another case involving damages allegedly resulting from serum hepatitis. Of particular significance in this case is the finding of the court that implied warranties might still exist even if no sale existed and if Sections 2-314 and 2-315 of the Uniform Commercial code were not applicable to the transaction. A final significant aspect of this case lies in the implication that warranties of merchantability and fitness for a particular use should be implied by the law to services as well as products when such services are rendered as a result of a market transaction.

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[56]Uniform Commercial Code §2-314.

[57]Uniform Commercial Code §2-315.

[58]439 Pa. 501, 267 A.2d 867 (1970).

Legal Defenses

Though previously mentioned elsewhere, the legal defences applicable to the issues being discussed will be briefly outlined. From its inception nearly one hundred years ago in McDonald v. Massachusetts General Hospital,[59] the doctrine of charitable immunity has been widely applied to preclude recovery in tort cases involving hospitals. While the doctrine has been vigorously attacked, most jurisdictions within the United States have recognized it at one time or another.[60] The landmark case altering the general trend towards applying this doctrine was President and Directors of Georgetown College v. Hughes.[61] Among the observations in his opinion, Judge Rutledge recognized that the "doctrine reverses the general trend of responsibility in a risk-sharing and distributing age."[62] He further stated that:

> "The rule of immunity is out of step with the general trend of legislative and judicial policy in distributing losses incurred by individuals through the operation of an enterprise among all who benefit by it rather than in leaving them wholly to be borne by those who sustain them."[63]

While obviously critical in those states where it is still applicable, it is sufficient for the purposes of this discussion to point out that it has

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[59]120 Mass. 432 (1876). The ruling in this case was erroneously based upon an earlier English case that had already been overruled. See Case Note, "Charitable Immunity," 1 St. Mary's Law Journal 275, 276 (1969). For further explanation of the theory, see Comment, "Vicarious Liability of Hospitals," 6 Williamette L.J. 299, 301 (1970).

[60]Hanson, supra note 44, at 1.

[61]130 F.2d 810 (D.C. Cir. 1942).

[62]Id. at 814.

[63]Id. at 827.

been abrogated in at least twenty-five states.[64] Governmental immunity is essentially akin to charitable immunity. It applies to hospitals and institutions operated by states and to a lesser extent their political subdivisions.[65] Though this type of immunity has been abondoned by many courts and waived in other jurisdictions by statue, it has proven more resilient than charitable immunity and remains the rule in a majority of the states.[66]

In general terms the doctrine of independent contractors states that an employer will not be held liable "for the physical harm caused to another by the act or omission of an independent contractor."[67] In the medical setting it has often most been applied in cases involving torts committed by physicians or those under his direction. The resulting effect of such applications has been to allow hospitals to escape the liability normally imposed upon corporations by virtue of the doctrine of respondeat superior. The traditional analysis in such cases is that professional staff members, physicians and in some cases nurses, are independent contractors, for the hospital does not have the right to control their professional actions.[68]

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[64] Case Note, supra note 59, at 277.

[65] Immunity from suit for federal institutions is generally waived by the Federal Tort Claims Act, 28 U.S.C.

[66] Hanson, supra note 44, at 4.

[67] Restatement (Second) of Torts, Explanatory Notes §409, comment b at 370 (1965). As early as 1937 it was observed "that the rule is now primarily important as a preamble to the catalogue of its exceptions." It has been further observed "that it can now be said to be 'general' only in the sense that it is applied where no good reason is found for departing from it." Restatement (Second) of Torts, Exploatory Notes §409, comment b at 370 (1965).

[68] Comment, supra note 59, at 307.

While the doctrine of independent contractors continues to have some importance in determining the liability of physicians not directly employed by the hospital,[69] it has been said "that the independent contractors doctrine as a defense for the hospital is dying."[70] The trend reversing the effect of an independent contractor's doctrine may be further accentuated by the cases establishing responsibility on the part of the hospital for the quality of care received by the patient.[71]

The Allocation of Legal Responsibility

Regardless of the legal theory applied, the critical question arising when assessing the consequences of a reliability failure within a computer-based medical information system is to determine prospectively what legal duties and responsibilities will exist. In our discussion of computer-based systems and applications that may be utilized in the medical decision-making process, two critical phases in the life cycle of most systems were outlined. These were identified as the design and testing phase and the operational phase. In addition, we may consider the selection process as a third important phase in the life of most computer-based systems. In each phase different parties will play the dominant role. Among the characterisitcs to be considered when analyzing a specific legal question are the identity of the parties organizationally responsible for the activities in question,

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[69]Practicing Law Institute, Business and Legal Problems of Hospitals 53 (D. Goldrich ed. 1969).

[70]Southwick, supra note 39, at 156.

[71]The leading case on this point is Darling v. Charleston Community Memorial Hospital, 33 Ill.2d 326, 211 N.E.2d 253 (1965), cert. denied, 383 U.S. 946 (1966).

the organizational relationship existing between various parties performing a given set of tasks, the legal duties and responsibilities of these parties, and the ultimate allocation of legal responsibility.

The computer-based systems being discussed utilize complex technology. Their implementation and operation often involve the participation of multiple corporate and individual parties. Though the final result of a computer assisted medical decision process may resemble the outcome achieved today by a physician supported by a manual information system, the process for obtaining this outcome is quite dissimilar. In regard to the medical decision-making process, legal responsibility today is relatively well defined. So long as a decision is identified as being medical, it is generally said to be the ultimate responsibility of the physician. Although others may provide certain of the inputs that the physician uses in his decision-making process, it is his responsibility to assess and analyze those inputs. Using his training, experience, and own observations, the physician must make the ultimate decision for which he is both organizationally and legally responsible. Though this present model of responsibility allocation may contain certain elements of fiction, such as the cases in which the physician may lack the degree of control that we attribute to him, the model does have at least argumentable basis.[72]

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[72]It should also be recognized that this legal treatment historically has been encouraged by the charitable immunity of the hospital. If the physician were not viewed as having a status independent of the hospital, an injured patient might be hard-pressed to receive any recovery in view of the hurdle of charitable immunity.

As compared with the traditional legal analysis, two significant differences arise when computer-based information systems are introduced into the medical decision-making process. First, at any point in time a number of parties will have points of contact with the system and can thus be viewed as potential defendants, and, second, responsibility for a given error may exist anywhere along the entire life cycle of the system. In regard to these points we should first look at the design and testing phase.

A prerequisite to the successful introduction of computer-based medical information systems is the need for the adequate standards in design and testing.[73] In this stage hardware companies, software companies, systems designers, programmers, and technical consultants will be the parties with the most significant points of contact. The physicians who are actually going to use a given system may have a minimal involvement. This participation will probably be limited to suggestions as to how the system might be altered to fit the particular needs of specific users.

While individuals will always have joint and severable liability, the major legal responsibility in the design and testing phase will probably be corporate in nature. This is true whether we are discussing a hospital, a university, or a for-profit corporation. An individual consultant may remain a

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[73]Although a general statement as to the desirability of high standards of reliability in the design and testing phase may be accepted, there is a practical difficulty in operationalizing this concept. A reliability standard lower than existing manual systems cannot be tolerated. Beyond such minimal levels, significantly improved reliabiltiy might be expected. To establish objective reliability standards we might examine computer-based applications in areas such as in air traffic control where, as in health care, the existence of an unreliable system can directly result in the loss of human life.

viable party though the complexity of large, complicated undertakings tends to blur individual contributions or omissions. In respect to the use of an experimental system on patients, the recurring problems of experimental treatments and informed consent naturally exist. A critical question in some situations will be identifying the point in time at which a system ceases to be experimental and becomes operational.

In the case of an institutionally designed system, there may be a direct passage from the design and testing phase to the operational phase. If systems are ever to see widespread use, it is assumed they will tend to have general application and adaptability, thus implying the need for some type of selection process. Although this event may be relatively immaterial in terms of the overall reliability question, the selection process poses certain special problems. In respect to institutions such as hospitals both the administration and the medical staff can be expected to play critical roles in the selection process. Presumedly the administration will be primarily concerned with questions such as the capital outlay required, the operating cost of the system, and the compatibility of the proposed system with existing computer-based and manual systems.

From the point of view of this analysis, the critical decisions in the selection process, such as the appropriateness of the system for the purposes intended and the adequateness of the system in terms of its reliability, will probably be made by the medical staff. This raises the question as to who on the hospital staff is qualified to make the selection decisions required. In the absence of standards set by a Federal agency or a trade association,

delivery organizations may be forced to rely on the claims of the vendors and the opinion of outside consultants. Although the selection of an unreliable or inappropriate system can adversely affect patient well-being, it is doubtful that most hospitals and delivery organizations have the internal expertise to make the decisions with which they will be faced in the systems selection process. This statement can only be amplified in the case of the individual practitioner.

Though an institutional board of directors or trustees may ultimately approve the decision to purchase a particular computer-based system they will undoubtedly rely upon the judgment of the administrator and the medical staff when making this decision. While the trustees may potentially be liable for want of care in selecting competent staff to make this decision, this liability is probably more theoretical than real.

While the potential for liability in the developmental stage and in the selection process are substantial, the complexity of the systems under discussion suggest that it is in the operational phase that the most serious problems will arise. Though hospitals and other organizational providers are increasingly being found to have secondary liability for torteous acts committed within their institutions, the physician has traditionally been held responsible for all decisions made in the medical decision-making process.[74] This is true even when the physician must rely on informational inputs such as laboratory test results and nursing reports over which he has only limited or theoretical control.

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[74]For discussion, see this paper at p. 26.

The use of computer-based medical information systems in an operational mode may require a marked departure from traditional legal analysis. This is suggested by the complexity of the systems that have been proposed. Such systems will involve many people to input information, operate the hardware and software, and maintain the system. Clearly the physician will be responsible for the actual decision he makes. The critical questions will be the extent to which the physician can rely on the outputs from the system. If this line of reasoning is sustained, the individuals that input information and operate the system will probably be employees of the corporate party owning the system. In this case the corporation would normally assume primary liability for the errors of its employees by operation of the legal doctrine of respondeat superior. If computer-assisted medical decision-making is treated as a single process or event, even the decision of the physician may over time be viewed as a corporate activity for which the corporation has primary responsibility. Increasing corporate responsibility may not be easily avoided in any case, for it becomes quite difficult to identify the individuals responsible for a given tort as the decision-making process and its underlying information system becomes more complex and involves a greater number of people. In a similar vein, the fact that most systems will be owned by corporate parties may, from a practical viewpoint, encourage a greater allocation of legal responsibility to the corporate parties.

The foregoing discussion leads to the conclusion that physicians employed by the parties owning and operating a given system might in the future be treated in a manner similar to that of other employees thought they may continue to

have a degree of liability owing to their education, their identification as a professional, and their relative socio-economic status.

When a physician in private practice uses a computer-based system in the institution that owns and operates it, there will likely be some type of joint liability depending upon the exact factual circumstances of each case. The general thrust of the law towards making the hospital secondarily liable for the torts of physicians occurring within the hospital, the difficulty in separating the activities of the physician from that of the organization providing the computer-based system, and the fiction of assuming that the physician actually controls inputs and other aspects of the operation of the system all suggest a growing secondary, if not primary, liability for the corporate party in these situations.

This leaves only the situation where the individual practitioner uses a hospital or institutionally-based computerized system in his private practice outside the hospital. In this instance any control on the part of the system operator over the practitioner becomes rather difficult to argue. It is, therefore, assumed that the provider of the system will assume primary liability for the consequences of systems failures, improperly coded inputs, and related matters while the physician would assume liability for his use of the information and analyses provided.

Legal responsibilities are operationally defined in terms of the standard of care required in a given situation. The question arises as to what standard of care will be required of those who design, select, and operate computer-based medical information systems. It would seem obvious that the minimum

standard of care required of a new, alternative technology is that standard of care required for the old technology. A second possibility is that the standard of care required will increase. It is assumed that no direct cost benefits are envisioned from the use of the computer-based systems discussed, but rather the use of such systems is expected to improve the quality of medical decision-making and improve the overall quality of patient care. Thus the goals of the systems themselves suggest that the minimum standard of care required in the design and operation of these systems might exceed that of the existing system that they replace.

At a more practical level several additional considerations arise. It has been suggested that the existing medical decision-making process is not well-understood.[75] It can also be stated that existing success/failure ratios for various classes of decisions presently involve significant degrees of conjecture. Though the nature of various medical decision-making activities will have to be much more precisely defined before their supporting information flows can be computerized, physicians, the hospitals, and other parties involved in tort suits concerning computer-based systems may have difficulty proving the relative reliability of new systems versus the systems that were replaced unless the potential legal significance of this step of the design phase is anticipated. In more simplified terms this problem represents the perpetual problem that exists in health care research of defining relative changes in the quality of care.

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[75]For discussion, see this paper at p. 6.

Other considerations may also affect the standard of care imposed under the law. Though bordering upon speculation, it is possible that the complexity, the promise, and the technical sophistication of various computer-based systems may raise expectations upon the part of juries, courts, as well as physicians, administrators and others that are beyond the capabilities of the systems in use. Should high expectations exist for a given system, it is reasonable that such expectations will affect the legal standard of care imposed for such a system. Still another consideration is the "deep pocket" effect that might arise in given cases. Specifically, this is the effect upon the jury and the court when a plaintiff alleges an injury was the result of the malfunction or misuse of an extremely complicated, costly, and complex computerized system owned by a large "corporate" delivery organization. The injury ceases to be the result of a mistake made by a personal physician, but rather the result of an impersonal technology utilized by an impersonal bureaucracy.

A final matter that must be considered is the potential liability of various parties for failure to use a given computer-based system. While the significance of this matter may be somewhat in the future, it is elementary that at some point in time the type of technological innovation discussed will become accepted medical practice.[76] At that point in time the failure to use it will raise a question of potential liability. Since we expect the systems and applications discussed to give results superior to those that we now have, this

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[76] For a short comment on the process of presently acceptable practice changing to substandard and negligent practice, see American Hospital Association, 4 Society of Hospital Attorneys Newsletter 5 (August 1971).

issue has special significance.

The Applicability of Legal Theories

The tort of negligence will likely remain the primary legal theory in cases arising under the circumstances described in this paper. As an analytical model, negligence is highly adaptable to cases involving technological advances and altered organizational relationships. It has been observed that the liability of individual parties may be reallocated with greater liability being assumed by the various corporate parties. Though other legal theories can likewise be applied, the flexibility of negligence makes its use appealing in this reallocation process.

Among the critical questions arising in cases utilizing the negligence theory is that of evidence and proof. This consideration has several elements including the determination of what actually occurred, the determination of how this resulted in the injury of the patient, and the identification of the parties involved. If the entire information provision and decision-making activity is treated as a unitary activity with the corporation having primary responsibility for its direction and operation, the difficulties mentioned will tend to be diluted. The selection phase would almost have to be treated as a corporate activity thus making one or more corporate parties primarily liable for any negligence occurring in the course of this activity.

In regard to both the developmental and operational phases, the doctrine of res ipsa loquitur may have special significance when viewing the information-provision function and the resulting decision-making process as a single activity under the control of one organization. This is particularly appropriate

in situations where the exact cause of system failure and the parties specifically responsible cannot be readily identified. An additional consideration in such cases is the possibility that the data bank of the system itself may contain a great deal of information concerning the events leading to a medical liability case. Much of this information will be of a nature that is traditionally unavailable.

While not arguing the extent to which it should be applied, the strict liability concept would seem to have certain logical applications in cases involving computer-based systems used to support the medical decision-making process.[77] The position of the consumer using the health care delivery system is similar to that when he uses a manufactured product. He has no rational alternative to the services offered him. Except for the limited involvement required by the rules of informed consent, he must largely rely on the good judgment of the physician. This is particularly true in emergency situations. In respect to electronic and other types of medical instrumentation, the patient basically has no say as to which equipment will be used upon him and would not be capable of making a rational judgment if he did. In large measure the patient is a captive of the system. In this situation the designers and manufacturers of computer-based information systems are providing a product to the extent that any reasonable definition of this term can be given. Beyond the application of the strict liability concept to the hardware and software of the system, arguments exist for applying the strict liability concept to all situations involving computer-based medical

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[77] For discussion see Hanson, supra note 44, at 25.

applications. This is particularly so when such systems become complex. These arguments include the difficulty of identifying the specific parties involved, the inability of the individual to protect himself, the lack of any alternative except for refusing care, the recognition that the total process which utilizes a computer-based information system should be recognized as a product, and the realization that the product-service distinction is simply not appropriate.

Beyond definitional arguments such as the distinction between services and products, the arguments against applying strict liability in the situation discussed would seem to be basically of a policy nature involving the relative ability and appropriateness of various parties to absorb the losses anticipated. One clear distinction must be made. It is not suggested that a strict liability theory would be applied to the decision-making activity supported by the computerized system. Such an application would amount to insuring the patient against the possibility that the medical procedure or decision dictated under the circumstances of the case is unsuccessful. Strict liability would only be applicable to failures occurring in the underlying computerized information system.

Contractual theories of liability would seem to be particularly appropriate in cases involving the provision of hardward and software. In regard to contractual theories as well as strict liability theories, their application in cases involving unreliable computer-based information systems would seem to be stronger than in cases involving serum hepatitis. Systems failures will normally be of the nature that could have been avoided had proper care been used, whereas, the application of the most advanced technology will not prevent

the occurrence of at least some hepatitus.[78]

The use of complex computer-based information systems suggests an environment in which medical decisions involve many parties acting in multiple roles. In this situation the use of the independent contractors doctrine is even more inappropriate than it is today.[79]

Final Comments in Respect to the Reliability Issue

The impact of introducing computer-based medical information systems will tend to re-enforce existing trends in the law towards shifting primary legal responsibility away from individual parties and toward corporate parties. In order to insure that reasonable standards of care are adopted, it is necessary that the relative reliability factors of alternative computer-based systems be known as well as the reliable factors of those systems they replace and that the distinction between the reliability of the information system and the reliability of the resulting decision be clearly maintained. It is also apparent that information found within the data bank may subsequently help explain what has occurred in medical liability cases. Finally, it is observed that some type of standard setting and testing for the various systems proposed for use in the medical decision-making process would be extremely helpful in aiding institutions and individuals in their selection process. Such standards could also be used as evidence in cases in which the minimum standards of care for various systems are set.

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[78] For discussion of the application of the strict liability theory in cases involving serum hepatitis, see this paper at p. 30.

[79] A possible exception to this statement is in the situation where a court is bound by the charitable immunity doctrine. In this circumstance the doctrine may be required if the plaintiff is to receive any recovery.

Additional Legal Issues Relating to the Data Base

The relevance of the reliability issue extends not only to computer-based medical information systems serving operating and planning functions, but to the data base as well. In respect to the data base, two additional issues arise.[80] First, the question of what information should be included within given data bases and the legal rights relating to such decisions, and second, the legal rights and duties that exist or should exist in respect to the storage, access, and disclosure of the information that is contained within various data bases. Since these issues represent general problems that arise in regard to computer-based information systems, this discussion will focus upon these issues in context of the medical decision-making environment.[81]

The Problem

The capacity of computer-based systems to process, store, and retrieve large quantities of data has led to their increasing use by private, governmental and quasi-public organizations. In applications where "sensitive" personal data is processed and therefore included in the resulting data base, a basic problem of individual privacy arises. In the area of medicine, individual physiological and psychological data have traditionally been collected in separate records maintained by institutional health care providers, physicians, schools, university health services, public health agencies, public and private counseling services, and by other individuals and groups. Though sensitive

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[80] Medical data bases are discussed in this study at 12-14, 17-18.

[81] For in depth discussion of the impact of computer-based information systems and their resulting effect upon human rights see Arthur R. Miller, The Assault on Privacy (1971); Information Technology in a Democracy (A. Westin ed. 1971); National Academy of Sciences, Data Banks in a Free Society (1972).

personal information may be disclosed in the existing system, the risk of such disclosure is minimized by the dispersion of information among many record keepers, the difficulty of retrieving information in the manual systems normally employed, and the informal manner in which much of the information is coded and maintained. Since computers combine the capabilities of integrating diverse data bases, substancially increasing retrieval ability, and allowing access to such data bases by a multitude of users at diverse locations, a substantially increased risk to the right of personal privacy is presented. The law having yet to adequately define the concept, the issue of privacy involves considerations of an ethical and philosophical nature as well as of a legal nature.[82] Conceptually two issues exist, the questions of inclusion and disclosure. In a legal context the disclosure issue can be further partitioned between judicial and non-judicial disclosures. In regard to both issues distincions can be made between intentional and unintentional disclosures as well as between truthful and untruthful disclosures. In examining these issues the applicability of contemporary substantivive law will first be considered.

The Law as It Exists Today

The doctrine of privilege applies to exchanges of information for which there exists a statutory right allowing one party to prevent disclosure by the second party of the information communicated. The application of this

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[82]The right of privacy has seemed to elude succinct definition in either law or philosophy. Among the classic explanations of this concept are Samuel D. Warren and Louis D. Brandeis, "The Right to Privacy," 4 Harv. L. Rev. 193 (1890); and Brandeis' dissent in the case of Olmstead v. United States, 277 U.S. 438 (1928). Among the works of a more recent nature dealing with this concept, from both a legal and philosophical standpoint, are Oscar M. Ruebhausen and Orville G. Brim, Jr., "Privacy and Behavioral Research," 21 American Psychologist 423 (May, 1966); Michael F. Mayer, Rights of Privacy (1972); and M.C. Slough, Privacy Freedom and Responsibility (1969).

doctrine is limited to judicial proceedings. In the context of medicine, privilege normally arises in respect to the physicial-patient relationship, though some statutes extend the doctrine to nurses, dentists, and other professional personnel.[83]

The right of privacy has three distinct legal foundations. These arise in common law, statutory law, and constitutional law. Though no right of privacy existed in common law, the development of photography, photographic reproductions in newspapers, and other technological advancements in the latter part of the nineteenth centruy presented substantial temptations to invade personal privacy. In the course of providing relief for the aggrieved parties, courts dealing with such problems utilized either a property rights analysis or recognized privacy as a personal right. The result has been the development of a cause of action in the law of torts, a personal right for which damages are compensated in the form of monetary awards.[84]

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[83]For example see N.M. Stats. § 20-1-12 (1953), which applies to physicians, surgeons, and nurses. Though the physician-patient privilege exists in a majority of the states, this rule is purely a statutory creation and did not exist at common law. For a listing of the scope of privilege statutes, see Emanuel and Jonathon Hayt, Legal Aspects of Medical Records 75 (1964).

[84]One of the earliest reported cures basing recovery squarely upon the right of privacy was DeMay v. Roberts, 46 Mich. 160, 9 N.W. 146 (1881). This case involved a physician who took a young man with him while he delivered a child. It later developed that the young man was neither a physician, nor a medical student, nor an assistant. In its formative stages the right of privacy in tort developed in four areas: "(1) protection against intrusion on the seclusion or solitude, or the private affairs of an individual; (2) protection against public disclosure of embarrassing private facts of an individual; (3) protection against publicity which places an individual in a false light; and (4) protection against the appropriation of an individual's name and likeness (e.g. photograph) for monetary advantage." Jeffrey A. Meldman, "Centralized Information Systems and the Legal Right to Privacy," 52 Marq. L. Rev. 335, 341 (1969).

Statutory enactments have aided both in the formulation of the right of privacy as a concept and in the development of the substantive law to enforce this right, though such statutes are generally somewhat limited in scope and do not directly address problems discussed in this paper. Examples include an early New York law prohibiting the unauthorized use of the name, portrait, or picture of any living person in advertising or for the purpose of trade[85] and Section 605 of the Federal Communications Act of 1934.[86]

A clear recognition of a Federal constitutional right of privacy did not occur until the decision of Griswold v. Connecticut[87] in 1965. In this case, involving criminal convictions for giving information and advice concerning the prevention of conception and for prescribing contraceptive devices to married women, Justice Douglas examined a number of specific guarantees of the Bill of Rights, and noted they often involve elements of a more general right of privacy. This suggests "that specific guarantees in the Bill of Rights have penumbras, formed by emanation from those guarantees that help give them life and substance." The situation arising in this case "concerns a relationship lying within the zone of privacy created by several constitutional guarantees."[88] Beyond the developing Federal constitutional law in this area,

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[85]N.Y. Civil Rights Law § 50 (McKinney 1948).

[86]Among other provisions this statute (1) makes it unlawful for any person involved in the reception or transmission of interstate or foreign communication by wire or radio to divulge or publish the contents of the message to any person other than the addressee or his authorized representative and (2) makes it unlawful to intercept such messages and divulge or publish their contents without the authorization of the sender. Federal Communications Act, 47 U.S.C. § 605 (1964).

[87]381 U.S. 479 (1965).

[88]Id. at 484.

there are instances where state courts have recognized a right of privacy based upon state constitutions.[89]

A final legal concept having some application to the issues raised is the tort action of defamation. Defamation involves a written or oral communication, to someone other than the person defamed, of false reports concerning a living person that tend to injure his good name and reputation. Traditionally libel is a written defamation, and while slander is a spoken defamation.[90]

Of the legal doctrines outlined, the constitutionally based right of privacy appears to be the most significant in the context of the problems discussed in this paper. It is a potentially broad legal concept in the developmental stages of definition and application. It applies to both the questions of inclusion and disclosure and is not limited to situations involving untruthful disclosures. The tort cause of action of privacy has application to the problems raised though its utility is limited by its ex post application and the limitation of its remedy to monetary damages. The application of privilege doctrine is basically restricted to disclosures by physicians in judicial proceedings. Defamation is of relatively less importance, for it is applicable only when a disclosure is untruthful.

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[89]Melvin v. Reid, 112 Cal. App. 285, 297 P. 91 (Dist. Ct. App. 1931), represents one of the clearer formulations of a right of privacy based upon state constitutional guarantees. The court noted the state constitution guaranteed the "right to pursue and obtain happiness," and concluded that this guarantee "by its very nature includes the right to live free from the unwarranted attack of others upon one's liberty, property, and reputation," The court further stated that this right includes a freedom from unnecessary attacks on ones character, social standing, or reputation. The application of this case to the broader questions raised by this study is limited for the unauthorized dissemination of truthful information was in the form of a movie bringing this fact situation within the public and non-oral communication qualification of the tort action of right to privacy. The holding itself was clearly upon the constitutional basis.

[90]Deen v. Snyder 57 S.W.2d 338 (Tex. Dist. Ct. Civ. App. 1932).

The Application of Existing Law to the Issue of Inclusion

The issue of inclusion seeks to establish what rights an individual has in regard to preventing or controlling the inclusion of personal data in computer-based data bases operated by others regardless of the desirability of including such data. Although the right of privacy may potentially define the limits presented by this issue, its present articulation does not offer a substantive answer to the problems posed, for this right has yet to be defined to an extent that the limits of its applicability can be identified. Other than the potential application of the right of privacy, itself an inadequate remedy, there is little, if any, existing law pertaining to the issue of inclusion as it relates to medical data bases.

The Application of Existing Law to the Issue of Disclosure

The issue of disclosure relates to the revelation of information once it has been included in a data base. Disclosure may be judicial or non-judicial, truthful or untruthful, authorized or non-authorized. Since authorized disclosures do not present substancial questions, this discussion is limited to unauthorized disclosures.

Privilege Statutes.

Within that limited set of cases involving judicial disclosures by physicians and other personnel, privilege statutes would generally be applicable in respect to computerize data bases; however, the extent of the protection afforded is in doubt. Unlike the present situation where records containing information representing an outgrowth of the patient-physician relationship

are generally maintained by the physician himself, integrated data bases imply the inclusion of a wide variety information in a single base or a series of integrated bases with access capability, total or partial, for a variety of professional and non-professional personnel. Although privilege statutes may apply to information obtained through a physician-patient relationship regardless of the location of its storage, differentiation of that data protected by privilege as against that data that is not may be difficult. Further, there is a question of the extent privilege statutes would prevent the use of a suponena seeking information from integrated data bases or centralized data files or prevent the disclosure of such information by individuals, other than physicians, having access to them.

The Action for Defamation

Though the tort theory of defamation would seem to apply to untruthful disclosures from computerized data bases just as it applies to manual data bases, the legal practition afforded by this action is limited. First, truthfulness is a defense to this action, and second, it must be shown that the disclosure diminished the esteem, respectability and good name of the individual within his community.[91]

The Right of Privacy

Aside from the rather limited applicability and protection afforded by privilege statutes and the theory of defamation, the principal legal remedy for unauthorized disclosure of information contained within computerized medical data bases is the tort theory of the right of privacy. The extent

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[91]For additional comment see Eric W. Springer, Automated Medical Records and the Law 88 (1971).

to which this theory is applicable to non-judicial, truthful disclosures of medical information is somewhat conjectual. There is some agreement that civil liability would exist if the unauthorized disclosure is by the physician, though this conclusion is not based upon the legal concept of the right of privacy.[92]

The right of privacy action in tort may have general applicability in cases of unauthorized disclosures of information from medical data bases but with important qualifications. These include the exclusion of oral communications and the requirement that the dissemination be of the nature of a mass communication. Further, certain private parties including attorneys, insurance company representatives, and family members may, in a given circumstance, be viewed as having a legitimate interest to material in the medical data base.[93] This raises two problems. First, the limits placed upon unauthorized disclosure of information to parties having a legitimate interest in the information in question and applicability of the law in respect to disclosures to single individuals or small groups of individuals having no legitimate interest to any of the information invloved. Under present formulations of the concept, there would seem to be little applicability in either of these latter cases.[94]

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[92]Note, "Extrajudicial Truthful Disclosures of Medical Confidences: A Physician's Civil Liability," 44 Denver L.J. 463 (1967).

[93]Springer, supra note 90, at 90.

[94]Extensive recommendations concerning possible legal safeguards for computer-based information systems, particularly those operated by governmental agencies are found in the report of the Advisory Committee on Automated Personal Data Systems. U.S. Dep't of Health, Education & Welfare, Records, Computers and the Rights of Citizens (1973).

Additional Considerations

In addition to the problems discussed, it is possible that accidental disclosure of information might occur. Since existing law would not seem to apply in this situation, this possibility would be best remedied through controls built into the system particularly those controls limiting access to the system.

In addition to the points previously made, there is a basic question as to the extent to which sensitive personal data need be maintained. Viewed from a time oriented continuum only a limited amount of information reflecting current diagnosis, treatment, and condition need be maintained over the longer term. Even data that becomes a part of the medical history loses its applicability over time. Though not practical within existing manual systems, a potential of computerized systems is the design of edit and screening routines which would automatically purge aged data from various data files. Assuming data coding is standardized and appropriate, such an application is quite practical. From another standpoint data can be viewed in terms of its relative sensitivity should it be disclosed in an unauthorized fashion. One clear implication that should arise from this discussion is the desirability of severely limiting both the amount of sensitive data included in various data bases and the access to such data bases.

Additional questions arise concerning the use of data contained in computerized medical data bases by researchers, physician peer review committees, and related governmental and non-governmental regulatory efforts. While recognizing the justification and desirability of such uses, several observations

are called for. First, it would seem desirable that some reputable group, either governmental or otherwise, prepare uniform guidelines for the use of data from established data bases by researchers. Legal questions that arise include the possibility that both the underlying data gathered by researchers as well as their work product might be suponenaed in legal proceedings. In the case of a peer review committee, there is the additional question of the applicability of privilege statutes particularly in regard to the work product of the group as distinguished from the underlying data base, for no direct physician-patient relationship can be said to exist.

Data contained in an integrated computerized data bases should include a comprehensive data set representing both diagnostic and monitoring information relative to a particular medical event, present this information in a context of the medical history of the individual concerned, and be capable of comparing this profile with data reflecting segments of the general population and norms of medical practice. Such information combined with information from peer review committees might prove invaluable as evidence in liability litigation.

Final Comments in Respect to Data Base Issues

Though this segment of the study does not purport to definitively assess the inclusion and disclosure problems, the following general observations are in order: (1) the applicability of the law to such data bases is not well defined and serious questions arise as to whether the law as it presently exists adequately protects individual rights in respect to these data bases; (2) the need for legal standards and safeguards against unwarranted disclosure and use of information contained in such data bases is significantly greater

in respect to computerized data bases than in the case for traditional medical records for more information is likely to be included, it will be significantly more accessible, and information from multiple collection points will be integrated into central data files; (3) the law is basically unequipped to deal with the question of exclusion and only marginally applicable to the question of disclosure; (4) the law is particularly lacking in its applicability and adequateness in regard to the problems raised by medical data nets and data exchanges. The final irony in regard to the questions discussed in this section of this paper is our reliance on the inefficiency of the present medical record keeping system as the principal protector of our privacy.

Conclusion

This paper has examined the legal issues of reliability, the inclusion of data, and the disclosure of data in the context of computer-based information systems used in medical decision-making. It is hoped that this study will provide a framework for analyzing problems in this area, will be found applicable to a wide variety of factual situations that might arise, will answer at least some of the questions that have arisen among those facing these problems, and will aid in the solution of those questions that remain unresolved.