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# Social and Legal Problems of Automation in Medicine

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In 1961 in this journal I wrote on electronic automation in medicine, pointing out some of its moral implications. Now I should like to highlight what has been accomplished and demonstrated as practical in this field, and to review some of the social and legal problems related to it.

## COMPUTERS IN CLINICAL MEDICINE

Since 1959 the computer's role in medicine has been investigated in: (1) medical diagnosis, (2) record keeping, (3) medical management, (4) laboratory analysis and functional testing, (5) patient monitoring, (6) hospital communication, and (7) utilization of hospital services and facilities.

Medical diagnosis by computer thus far is limited to specialized studies in hematology at Cornell University and in cardiology, especially in congenital heart diseases, at the University of Utah. In some instances the diagnostic acumen of the computer has been superior to that of experts in the specialty; but in conditions characterized by complex and overlapping groups of signs and symptoms the computer has been less useful. As a matter of fact, in order for the computer to act as an expert diagnostician it needs to know the precise incidence of each symptom and sign in a specific disease and the prevalence and incidence of the specific disease in a given population. Nevertheless, because it can store enormous amounts of medical information which can be processed accurately and recalled rapidly and efficiently, the computer can be an efficient diagnostic aid.

By and large, the automatic data processing of medical records has been restricted to specific parts of the medical record; for example, the face sheet, lists of diagnoses, clinic visits, and so on. At the present time, only a few hospitals and institutions use the computer to produce the total medical record. The process of transforming all clinical data into numbers acceptable for computer processing is too difficult. New developments at New York University and Roswell Park Hospital have proved that computer processing of English textual information is possible, although exceedingly costly. A system developed at the Texas Institute for Rehabilitation and Research for processing medical records, being revised continuously, clearly demonstrates the benefits of automatically processing clinical information, particularly in critically ill patients. For instance, it makes a comprehensive report during each nursing shift of patients' vital signs, intakes and outputs, medications, and clinical observations. Automatic recording of vital signs is plotted graphically and provides in perspective an account of the patient's course. Our experience, and that of others, has been such that we predict in the next decade most hospitals will adopt medical record data processing systems and that they may indeed evolve as a nationwide system for recording and filing medical data and information: useful not only to individual patients, physicians, and community health agencies but also to clinical and research studies.

It is well known that the computer can be utilized as an efficient medical clerk that facilitates the physician's calculations in treatment. For example, we have an automatic computer program that calculates the water and mineral needs of patients. It not only indicates the amounts of fluid and electrolytes to be administered and the number of fluid bottles and their composition needed, but it also determines the rate of administration. Such calculations are based on simple, logical decisions the physician makes often at considerable expense of his time.

Indeed, it is easy to give a computer simple logical criteria and have it produce an interpretation of the significance of laboratory data. In this regard, our computer program processes pulmonary function studies, calculates the results, and makes a diagnostic interpretation. Some hospitals (Grace-New Haven Medical Center) use computers to make the simple, but repetitive, calculations necessary in arriving at the results of chemical laboratory tests. As soon as costs become more reasonable this activity will doubtlessly be expanded; and in large medical centers it is likely that centralized, computerized facilities will serve the laboratory needs of all hospitals in the center.

Meanwhile, there is increasing use of physiological instrumentation that monitors patients at the bedside, in diagnostic procedures, and in the operating room. Most systems now used reveal in oscilloscopes the electrocardiogram, respiratory movement, blood pressure, and so on. Some monitoring systems also numerically indicate the vital signs. Thus, it is obvious that connecting the monitor to a computer increases the analytic capabilities of the system. For the computer can give not only the values of the vital signs of a patient at any given time but, in recalling the previous values, show any changes, or trends of change, that would indicate to the physician the need for specific treatment, or change in the treatment program. It may in the future be possible for computers to initiate treatment procedures automatically in order to correct promptly any changes in a patient's physiologic function.

In progress and continued development is the use of computers to

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expedite communications between the different and separate areas in large hospitals: administrative offices, patient wards, pharmacy, and central supply. Successful experiences at Massachusetts General Hospital and at Children's Hospital in Akron, Ohio, promise beneficial changes and improvements in many complex, inefficient systems currently used. Apart from utilizing data processing for keeping the accounts of patients' hospital charges, the same equipment is used to obtain information on admissions and releases, or the diagnostic characteristics of patients, and so on.

In addition to the foregoing, there is increasing use in clinical medicine and research of electronic instrumentation not of the computer type. Used to collect in electrical form a wide variety of medical information, it can be easily manipulated by a computer, thereby expanding its area of application in the medical field.

## MAN-MACHINE RELATIONSHIPS

The ecology of automation in medicine comprises in part the relationships of the computer to the patient, the patient's family, the physician, and the hospital. Our experience is too limited to identify significant trends and patterns in this regard, but these relationships require continuing evaluation.

### *(a) Computer-patient relationship*

Although the computer can substitute for some facets of the physician's work, it is not possible for a computer to understand, or to show, the kind of feeling that is part of the emotion of human l ngs. This often is the very heart, e core, of the physician-patient lationship that not only affects d nosis but also determines the eff iveness of treatment. A relations of this kind is not possible b en a patient and a computer. erefore, in order to preserve this l d of relationship, and in ord for the computer system in me ine to be significant and useful, only the physician but also role is essential.

Were a computer t screen the health history of a pers for insurance coverage or job placement, certain individuals wo d perhaps be reluctant to reveal a aspect of their past that would je ardize their securing a policy or a j . A similar problem exists now cause the applicant is evaluated y a physician, other than his , who can learn little of the patie 's past and must rely on his exa nation and laboratory findings. heoretically, the availability of an dequate and complete patient infor tion system would eliminate such eficits in a medical evaluation. Ind ed, were all the salient facts of the past history of any person readily available in the nation, assuming obviously that everybody procures pe odic medical checkups, one would not need to seek a medical examination at a time when it might be emotionally contraindicated. But even were a computer allowed to process all the patient's available medical information and make pronouncements on his fitness, the patient-computer relationship need not be a hostile one. The computer would only act as an objective outside monitor of the state of health and not be regarded any differently from a weight scale, or an electrocardiograph. That this is the case is suggested by experiences at the Mayo Clinic with a computer program that develops a patient's personality profile based on data received directly by the computer from the patient.

It is likely that computers will be accepted by patients so long as the perspective is proper, namely the computer is an automatic agent used by physicians to broaden the scope of their quest and learning about the patient. But the physician will interpret the computer's data because his humaneness is essential in evaluating the numerous dimensions, as well as the wide variety, of the signs and symptoms of patients.

### *(b) Computer-patient's family relationship*

Thus far our experiences in medical automation do not allow us to generalize; but we have not detected undue apprehension in any patient, or among a patient's family, who knows that computers are used in processing his clinical data. Obviously, when the computer produces "alarming" information based on spurious data, a patient's family regards it uneasily. This is apt to happen when a malfunctioning bedside monitor indicates a change in a patient's vital signs. Infrequent incidents, however, do not warrant condemnation of a system that mainly provides increased assistance in managing an individual patient's course, especially when it is a life-threatening situation. Nevertheless, engineers of medical monitoring and computer systems must realize that a patient's family, indeed a corps of physicians and related personnel, has almost no patience for equipment failure. Therefore, it is essential for artifacts to be minimized and for adequate backup systems to be made available to prevent and dispel fear of failure.

### *(c) Computer-physician relationships*

Since the introduction of computers to clinical medicine, apparently no physician has been very apprehensive that his own individual role would be replaced by a computer. However significant the job threat of automation in labor and industry, there is little chance it will affect adversely the medical profession. On the contrary, physicians analyzing the fundamental purpose of the computer regard it as a useful and valuable adjunct. But there are innumerable problems to be solved. One is the computer's inability to determine what data are clinically relevant. Another is the inadequacy of statistical and mathematical techniques to analyze most of the clinical data collected at the bedside. A third problem is that computer failures occur more often in the complex computer systems the kind that can be of greater usefulness to the physician. Solution of these problems requires the joint efforts of physicians, computer engineers, statisticians, and mathematicians. Only physicians can be responsible for providing the computer accurate clinical data and for developing ways that test the valid-

ity of the data entered. This will require increased study. But the physician is essential in order to evolve the maximum benefit of computers in medicine.

*(d) Computer-hospital and computer-allied professional relationships*

Not uncommonly the introduction of computers in hospitals is met with resistance, perhaps even animosity, among hospital personnel. In part, some professional persons regard the computer as a source of job displacement, similar to what has occurred in industry. Obviously any skepticism is increased, and a belief that automation has no place in a hospital is enhanced, when attempts to substitute automatic programs for existing communication systems are unsuccessful and when equipment failures are frequent. But the anxiety of job threat is unfounded. In addition, the ever-increasing complexity of medical care makes it essential that patient care be highly individualized in accordance with individual patient needs. Although it may some day be possible for a computer to be programmed to consider the needs of the patient, it is unlikely that it can also cope with all the human contingencies arising from a patient's wishes, feelings, and so on. The fulfillment of the latter is extraordinarily important and can be met only with the understanding of human hospital personnel.

Thus, the use of computers in hospitals offers real possibilities in laboratory analyses, procuring and dispensing medicines, medical record keeping, bed allocatio: personnel distribution, and so Indeed, plans for restructuring ital facilities in the country a eared to providing centralized co uter facilities that will fulfill se needs. The object is not to dec se current hospital expenses by bstituting machines for human be gs; it is to curb the spiraling cost hospitalization by increasing the ality and the efficiency of patier ervice. As a matter of fact, the hea field may provide increased chall es to personnel displaced from onmedical jobs by automation; the ed to provide increasingly com x medical services to patients wil equire the participation of innume ble professionals and clerical wo rs.

**SHARING CONFIDENTIAL INFORMATION**

At the present time increasing amount of patient medical information is being entered into punch cards, processed by computers, and preserved in computer files scattered throughout the country. As regional computer facilities in large medical centers are developed and established the opportunity for the widespread sharing of medical information will become a reality. It is essential that safety measures be programmed into computers in order not to release any patient information to unauthorized personnel nor to release and use any confidential records without a patient's specific permission. Such provisions can be made. Indeed, it is necessary because secrecy of private and personal information will even be more vulnerable when it is stored in a computerized network of communications. The right of privileged communications *must* be guaranteed!

But there are special advantages in a system that can facilitate providing and sharing nonpersonal medical data, e.g. diagnosis, laboratory values, and so on. The Professional Activities Study (PAS) of Michigan offers to hospitals throughout the nation a computer service that collects, stores, and processes all the medical information recorded on the face sheet of hospital medical records — thus statistical reports at a minimal cost. Information received from each hospital may be compared with that of the others. In this connection one study revealed that in one hospital the hemoglobin values of patients were consistently low. Furthermore, the incidence of blood transfusions in that hospital was much greater than in the other hospitals participating in the collaborative study. Detection of discrepancy led to the discovery that the low blood values were due not to an endemic blood disorder but to a faulty laboratory technique in the hospital. Correction of the latter resulted in proper laboratory procedures and a significant decrease in the number of blood transfusions administered.

But relative to an individual patient's data, who is the proprietor of the data? Is it the patient, or is it the physician who collected it, or the institution where the data was collected? These questions may not seem pertinent at present but they will be as soon as a computer shared national system is available. In addition to having a record in the hospital file, should a patient also not want his data kept in the kind of general file that would assure for his own personal good its quick and easy availability when needed by physicians elsewhere? Or, can a hospital require that all its clinical data be entered in a national network of stored information to be shared with other hospitals and physicians? An investigator may claim special rights relative to the data that are part of his accumulative experience for a scientific report. Once data are entered in a large electronic file it would be possible without special preventive measures for investigators to scoop the data and write a report before the original investigator did. While acknowledging the potential risk of electronic snooping one should, of course, consider what the likelihood is that one investigator's data would be used by another without consent and for exactly the same purpose. Use without permission would be an overt violation of an investigator's privilege to participate in such a program. But an investigator, assuming some probability of this occurrence, could decide either to withhold his information from the shared system or to take the risk of being scooped. Fortunately, the computerized system would allow him to retrieve his investigational data quickly and to establish their significance. All this should be possible while respecting the patient's rights and complying with the hospital requirements. The choice of not entering the data would be in defiance of the rights and regulations agreed upon by the patient and hospital and it would penalize him

also by depriving him of an opportunity to test his original hypotheses quickly and comprehensively.

If large networks of shared information ever become a reality, the acceptance of a code of ethics relative to use of medical information will doubtlessly depend on specific criteria that can consider data as "confidential" or "classified." Furthermore, it is obvious that there will be need to build in safety provisions to prevent stored data from becoming available to unauthorized persons. Programming provisions such as these offer no difficulties. Reaching agreements on what constitutes these provisions, however, may be difficult and set up some major roadblocks.

### LEGAL CONSIDERATIONS

As experience is gained in the use of computers in medical record keeping, it becomes essential to establish the legal validity of medical documents prepared by computers. It would be an ordeal to require that a physician sign each report attesting to their accuracy, validity, and reliability. Therefore, this kind of problem is being analyzed by a joint group of the American Hospital Association, the American Medical Association, and the American Bar Association.

Another legal implication pertains to a physician's decision to overrule computer judgments and warnings. For example, the Massachusetts General Hospital computer project led to the development of a system warning when a physician prescribes an excessive dose of a medication. The physician must then indicate his decision – to overrule the computer's warning before the medication is dispensed – to adjust the dosage. Should something happen to the patient would the physician be held legally responsible? The potential incriminatory effect of the "I-told-you-so" computer may restrain the physician's desire to take a bold action in specific cases and go against the computer. The situation presumably is not different now because a physician's actions are judged according to the standards of practice in a community and in a hospital. But the situation is different: each treatment decision is a judgment according to which ranges of treatment dose have been programmed into the computer. Yet, how judge the rate of drug utilization and excretion, or the individuality of patient effect and response. Thus, there always is need to consider how any standards apply to an individual person. Nor can the computer's statements be infallible for they are predicated merely on limits of data established by other physicians. Therefore their criteria no matter how authoritative, must be revised often and cannot be taken differently than warnings in textbooks. A long held legal opinion is that textbook information is to be considered "hearsay."

### LIFE OR DEATH DECISIONS BY COMPUTER

Although computer measurement of survival probability may be possible in the light of a patient's condition, innumerable years will pass before it will have the power to suggest when a patient should die and when he should live. Indeed, would a computer ever have the kind of information to arrive at such a decision? It even is questionable how a computer's prognosis could alter a patient's management except perhaps in difficult logistic situations resulting from war or civil disaster. In ordinary circumstances, a physician's decision to marshall all available means to assist a critically ill patient should never be subordinated to a computer's pronouncements.

Any patient critically ill, or in a terminal state, has right to be considered in all his dimensions: the extent of physiological deterioration, treatment resources, expected survival, likelihood of permanent sequelae, his contribution to society, cost of treatment — but above all, his inalienable right to survive. In this regard, there is a growing controversy on the wisdom of affording life sustaining treatment to persons suffering from a hopeless and terminal pathophysiological condition. Most situations are easily recognized — terminal cancer, a massive stroke in an elder person, and so on. But others are more difficult to assess and often impose tremendous dilemmas in management and treatment.

The continuous development of techniques for life sustainment and their successful application "against all odds" have permitted physicians to gain further insight into the attitudes of patients and their families confronted with a profoundly serious threat to life. In our experience in treating severely and permanently disabled persons, the patient and his family often have expressed in times of impending death, even after years of total disability and suffering, with very few exceptions, an unqualified desire to be spared no effort in trying to preserve their life. On the other hand a "realistic" and cold "objective" analysis of some cases would have resulted in stout evidence against the worthiness of therapeutic efforts. Yet, realistic and objective analyses are precluded at the moment of despair unless the sentiments and rights of all the persons involved are considered. Although a person's rights are immutable, his sentiments may fluctuate considerably. It is up to the physician finally to assess the sentiments as they had been, as they are, and as they will be after the crisis. Let us not live in utopia and think that these assessments can ever be done equally well by a computer.