

Instrumentation and the Delivery of Health Services

Instrumentation is playing an important role in the development of more adequate methods for health care.

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In a time of rising expectations and increasing demands, the delivery of health services is inadequate, and the promises of medical science are unfulfilled for too many people. Obviously, manpower, facilities, and organization will be major considerations in the evolution of more appropriate delivery systems. At the same time, in the coming decade a sufficient portion of our capabilities must also be directed toward elaborating the technologies called for by the changing patterns of medical care. A more extensive use of modern engineering science in the development of improved methods for the prevention, diagnosis, treatment, and management of disease is needed. More satisfactory forms of health-oriented instrumentation, automation, computation, communications, systems engineering, and operations research techniques must be developed. Not surprisingly, as the issue of technology and health care becomes of mounting national importance, the reasons for technology's successes and failures to date, criticisms of its current applications, and the outlook for the future are receiving increasing attention by the university (1), industry (2), and government (3).

Instrumentation plays an important role here. However, it is not the purpose of this article to pass judgment on the matter of technology and health care or the overall role of instrumentation in health care. Rather, the intention is to comment on some discrete topics in the area of instrumentation and the delivery of health services.

Automation of Clinical Laboratories

Ten years ago clinical laboratories had a battery of tests limited to 12 or so different biochemical determinations. Today these laboratories are being called on to perform any one of 50 to 350 different types of analyses. About half a billion of these tests are now performed annually, and it is likely that this number will double over the next 5 years, as it has every 5 years since 1946 (4).

The increasing number and complexity of these tests are generating serious problems with respect to their performance and the handling and storage of the data from individual patients. The reproducibility and reliability of the tests and the incidence of errors are often unacceptable. Moreover, methodology is only now being slowly improved, professional laboratory workers and technicians are in short supply or have inadequate training, and there are no universal standards of comparison of the normal with the sick individual. The one method of producing faster, cheaper, more reliable, and more accurate tests is the automation of the entire clinical laboratory process, from sample acquisition to computer printout of final results on the patient's chart.

After initial success in the automation of some biochemical tests, additional progress toward the total automation of the clinical laboratory is being made. As an outgrowth of work with zonal centrifuges in virology and in vaccine production, a series of analytical centrifuges is being produced which can measure samples, add and

mix reagents, and read the printout of up to 50 individual tests at a time. Clinical pathologists, in collaboration with industrial computer concerns, are developing unique data processing systems for the clinical laboratory that use conventional methods. These systems, housed in a small space, can process the laboratory data from a clinical laboratory in a 500-bed hospital. As a result of new computer interfaces, the number of tests that can be performed has increased threefold, while the average cost per test has decreased tenfold. A completely automated system for the bacteriology laboratory is being developed that will be able to plant, grow, identify, and isolate bacterial species. In the interest of improving the individual analytical procedures that will ultimately be part of a totally automated system, the highly sophisticated techniques of gas-liquid chromatography for mixture separation are being coupled with the mass spectrometer for sample identification and quantification in systems which are very accurate and are capable of computer control.

The complexities involved in developing an automated instrumental system that in the end will control the sample flow for various tests, perform analyses at various rates, and assemble the results into a single overall profile of the patient with the most important items flagged, are considerable. However, accomplishments to date are heartening and stand out in sharp contrast to the present-day operation of the average clinical laboratory.

Patient Monitoring

The patient-monitoring concept has evolved slowly over the past decade. Its purpose is to provide concentrated care in an effort to improve the survival of critically ill patients (5). Particular conditions requiring highly specialized surveillance and treatment include a variety of medical and surgical catastrophes such as pneumonia, drug overdose, bleeding from a gastric or intestinal ulcer, diabetic coma, burns, strokes, pulmonary and peripheral emboli, pulmonary edema, serious disorders of cardiac rhythm (particularly when they occur after a heart attack), and the postoperative stresses incident to major surgical procedures.

A variety of specialized intensive care facilities have been developed including trauma units, coronary care

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units, kidney dialysis units, postoperative intensive care wards, and resuscitation units for the treatment of drug overdosage, asphyxia, or poisoning. Patients in these units are maintained under intensive care for an average of 3 to 4 days. To date, it has been difficult to provide any quantitative documentation relative to an increase in survival as a result of the establishment of these units. However, there is little doubt but that they have been life-saving. Probably the most significant statistical information has come from the coronary care units, which have shown that the early recognition and treatment of arrhythmias in patients with heart attacks have definitely produced an increased rate of survival.

There are basically two approaches to the monitoring of acutely ill patients. The first is to provide a more frequent, or, where possible, continuous presentation of the patient's condition by monitoring some fundamental physiological variables. The instrumentation involved must detect trends and changes which warn that prompt treatment is needed lest some irreversible catastrophe, such as stoppage of the heart, occur. The second is to develop more sophisticated types of monitoring designed to extend sensing capability by providing information that otherwise would not be available. To date, some electronic packages of the first type that are able to continuously and effectively monitor the basic data required have been provided by manufacturers. However, relatively few of the second type of monitoring device are available in the form of semiautomatic electronic devices. Clearly, the engineer has considerable to contribute here, both in the development of the instruments needed and in participation in the research studies.

Methods of patient monitoring are generally divisible into four main categories.

- 1) Staff surveillance. Hospital personnel, both professional and technical, must continuously observe the patient.

- 2) Conventional signs. The conventional vital signs usually include electrocardiogram, pulse rate, blood pressure, respiratory rate, and temperature. The tracing of the electrocardiogram is easily retrievable, and to date it has been the core of almost all electronic monitoring packages. A variety of automatic devices have been provided for blood pressure and pulse rate, but they are not entirely reliable. Respiratory rate

has been followed by a variety of means, including temperature sensors in the upper airway and the monitoring of chest-wall movement. Usually the tidal air volume, which may be a more important parameter, is neglected. Rectal temperature is commonly recorded, but it is probably the least useful of the conventional vital signs.

- 3) Additional signs. The measurement of central venous pressure is most important. It relates to the adequate replacement of circulating blood volume, and it reflects appropriate balances between peripheral arterial pressure and central resistance to venous return. The measurement of blood volume has also been helpful. The extent of perfusion of various parts of the body (renal, cerebral, and coronary circulations) is highly significant. Most of these methods are not yet highly developed or require extensive manipulation of the critically ill patient.

- 4) Physiological systems. There is dissatisfaction with continuous recording of the primary variables mentioned above because there is a limit to the information of importance that they actually provide. For example, the knowledge of flow is much more important than the knowledge of pressure per se, yet present methods do not permit ready measurement of organ perfusion. An assessment of the state of the body system as a whole is the ideal, but the piecemeal knowledge that must be integrated does not now exist.

A pertinent question is why have new monitoring devices and techniques not come into wider use? There are several reasons: (i) engineering problems have arisen in monitoring conventional vital signs; (ii) physicians are dissatisfied with monitoring the patient by such signs; and (iii) there is a limitation in the competence of medical personnel to operate complicated devices. Development of an adequate patient-monitoring system must include: (i) the development and validation of primary sensors; (ii) the automation of measuring and controlling devices; (iii) the development and testing of effectors such as pumps, pacemakers, and so forth; (iv) the development of data-acquisition systems that include analog data-filtering techniques; (v) the elaboration of special purpose data management techniques; (vi) the provision for informational output procedures concerned with the condensation of data in a form that can be presented to physicians and nurses in a functional fashion

for decision making, modeling of the decision-making processes of physicians and nurses, and techniques for the exchange of information between patient-monitoring units and other hospital units.

In summary, satisfactory patient monitoring requires reliable, easily applied sensing devices together with suitable mathematical models of patients in jeopardy. Many of the basic engineering, instrumentation, and analytic techniques required are available, and the beginning efforts suggest that a generally useful patient-monitoring system can be built.

Hospital Information Systems

Hospitals face a host of problems in a period of rapidly expanding health demands. They are, by and large, obsolete in terms of facilities, equipment, and most of all in the management of hospital information (6). The goal of a successful hospital information system is multifaceted. While it must collect, record, store, retrieve, summarize, and transmit information relative to the patient population of the hospital, it must also attend to payroll, patient billing, inventory, and so forth. For some time now, engineers, computer specialists, and physicians have been trying to bring the computer and its peripheral instrumentation more effectively into the hospital environment. To date, the results have been less than satisfactory. In an overview of current progress it is apparent that there has been a gross underestimation of the dimensions of the task at hand. The problems surrounding the satisfactory introduction of computing capabilities in a hospital include a lack of communication between the engineers and computer specialists on one hand and the physician and hospital administrators on the other. There has been failure to develop a mathematical and theoretical base adequate for the conceptual advances needed to deal with peculiarities of the problem. Also, a sequential series of studies demonstrating that hospital activities will be assisted and improved by computerization has not been conducted.

There have been some scattered serious efforts to make inroads into this problem. Governmental agencies, hospitals, computer manufacturers, and individual researchers have been involved in a variety of studies designed

to develop satisfactory automated and computer-assisted hospital information systems. Most attempts in this direction, particularly those concentrating on total on-line systems arrangements, have been experimental. In some instances plans have evolved for the establishment of community-wide, computer-based physiological measurement and patient-monitoring capabilities. Remote stations would be installed in outlying hospitals, various transmission links would be set up to central computing facilities, and teletypewriter connections would be possible at all remote stations. The embedding of these kinds of computer systems in patient-care environments will be a unique and interesting experiment in that the intention is to make available to a nonlaboratory-oriented clinician the power of a large laboratory. In other instances, self-administered patient history taking is being automated. Here multiple-choice responses, branching, and other techniques are being used in a manner that appears readily acceptable and that requires very little explanation or training of patients.

It will likely prove best in the long run to proceed in stepwise fashion toward total hospital information systems, changing the system as new problems are encountered. Interestingly enough, the problem is an almost equal blend of technology and sociology. Technology probably does not exist for a hospital information system in its entirety, and present methods of physician procedure, nursing procedure, record-keeping, and information handling will require considerable reworking if the most is to be made of newly developing instrumentation and technology.

Multiphasic Screening

The purpose of screening for disease is to discover people who appear to be well but who are in fact suffering from disease. Such people can then be given treatment, and steps can be taken to prevent spread of the disease. Thus, screening is a way of combating disease because it can help detect disease in its early stages and allow it to be treated adequately before it secures a firm hold.

A few centers equipped to perform comprehensive screening examinations are presently in operation. For example, the Permanente Medical Group in Oakland and San Francisco, California, provides a multiphasic health checkup

for plan subscribers (7). The Kaiser Foundation Hospitals and Permanente Medical Group, through a system of 9 hospitals and 19 clinics, provide a comprehensive medical care program to 760,000 health-plan members in the San Francisco Bay area.

Tests in this screening procedure include the medical history, analysis of blood and urine constituents, x-rays, blood pressure, height and weight, visual studies, evaluations of the vascular system, electrocardiogram, mammography, Papanicolaou cervical smear, spirometry, audiometry, and so forth. Data for all parts of the examination except the cardiological, radiological, and retinalogical interpretation are fed to a computer, analyzed, and returned in preliminary reports prior to the patient's leaving the clinic. The computer checks for completeness, realistic values, "normal" ranges for age and sex, and cross-checks on other related information to determine consistency or contradictions. When an abnormal response or combination of responses is obtained, the computer advises the performance of additional, more specialized tests which are not part of the routine. Such screening centers are intended to provide an efficient means for the detection of abnormalities or indications of disease but not to replace full examinations. Their purpose is to place in the hands of the examining physician a summary of basic data and to refer to the physician's care a person with indications of disease.

Multiphasic screening does result in a reduction in unit cost per test. In fact, it is estimated that the same tests taken under traditional conditions would cost four times as much. Unit cost is directly related to the patient load, and if health examinations are made in large numbers, automated multiphasic screening represents an economical and efficient method.

The technique has been criticized because in the past only test-positive patients were referred and the tests used were of poor quality; there has been a lack of real evidence that periodic examinations have a salutary effect on morbidity or mortality; methods for bringing screening into the health-care system have been unavailable; and scientifically based evaluations of the effectiveness of multiphasic screening and of long-term cost benefit have not been available.

However, multiphasic screening does allow for economies when large num-

bers are involved, and it is probable that in the decade ahead communities of 150,000 or more will have screening centers. Unquestionably, multiphasic screening has been undergoing rapid changes in concept as tests are becoming better instrumented, more sophisticated, and more quantitative and diagnostic. It is also likely that once these programs become more widely available the practicing physician will more readily accept them. However, the explicit role of multiphasic screening in health-care systems of the future still remains a question.

Future needs include: (i) improved diagnostic instrumentation, (ii) automated equipment to conserve physicians' time, (iii) improved instruments, devices, and systems for modern automated clinical laboratories, and (iv) improved data-processing capabilities (particularly input and output devices). Special efforts must be directed toward stimulating industrial interest in producing the mechanical and electronic components needed for such screening systems.

Computers

Better diagnostic testing, treatment of individual diseases, and total patient care will depend upon an improved interface between the physician, the hospital system, and the computer. Presently, a language gap continues to impede the satisfactory introduction of computers into clinical medicine and to delay an optimum delivery of health services. Mathematicians and engineers have discovered that programming a computer for fundamental biomedical research is one thing, but that using it for decision-making and problem-solving tasks in clinical medicine is quite another matter. The disappointments to date have been largely due to the oversimplification of medical problems in order to make use of the computer's present language capabilities. Too often mathematical solutions have been attempted on problems in the clinical area where sufficient hard data do not exist. On the other hand, physicians have not made the most of the present potential of the computer. They must become more intimately acquainted with what the computer can and cannot do. Their data must be assembled in a different format if the most is to be made of the capabilities inherent in present-day computer systems.

An important general problem of physician-computer interaction is the need for a natural language input to these machines. The difficulty, of course, is that natural language depends on context, which the computer is simply not able to handle in its present stage of development. This means that terms in medicine should become more formalized. To date, terms in medicine have grown helter-skelter and there is no real logic to medical terminology. We should get on with an arrangement of terms in a more logical fashion, but this will be difficult because there are many features of medicine as an art that cannot be formalized. We should consider whether more effective types of standardization and classification of disease processes could be developed.

Despite these problems, the computer does continue to make inroads into medicine. It is a key to control and operation in many instrument-oriented areas and its capability for making accumulated knowledge and experience more generally available in the delivery of health services has begun to be exploited. As indicated, examination techniques are being developed for automated and computerized multiphasic health programs. Computerized health centers are providing medical care for residents in low-income housing developments. Scattered private and industrial efforts are engaged in the development of hospital information systems. The President's Commission on Technology, Automation, and Economic Progress (8) has indicated the desirability of evaluating the establishment of regional health computer facilities providing medical record storage for 15 to 20 million people in a geographic region. Such a facility could in time give hospitals and doctors in the area access to screening, disease detection, and other capabilities via telephone line connections.

Artificial Organs

The area of artificial organs, which has generated a good deal of scientific and popular interest in the past 10 years, presents a number of mechanical and biological problems whose solutions are particularly dependent on advances in instrumentation and engineering development.

The artificial kidney, an instrument of considerable importance for the delivery of health services, is the subject

of much attention at this time due to its high cost to patients. Recently, some inroads of significance have been made in the development of lower-cost units for home dialysis to the extent that total costs to the patient for the first year are being halved and subsequent maintenance costs are being cut by two-thirds. Clearly, ingenuity and simplicity in instrumentation design are needed much more than complex automatic devices. It is important to recognize, however, that preventable kidney disease is still the major reason that dialysis machines are necessary. In this light it is difficult to overstate the importance of the use of technology to prevent disease across the entire medical front.

While total success with the artificial heart is some time away, the work to date has been rather remarkable. Currently, it is a focus for an expanding instrumentation effort in materials development, oxygenators, valves, pumps, assist devices, biological fuel cells, implantable energy systems, and a variety of other peripheral instrumentation such as implantable transducers which continuously measure blood and oxygen pressure. A particularly intriguing and elusive problem is the matter of appropriate feedback control mechanisms when the patient is completely dependent on a prosthesis that has totally replaced his heart. Pumps have been designed which simulate flow and pressure wave forms of the intact heart to a reasonable degree. However, the development of a reliable automatic control mechanism for these artificial pumps is a different and more difficult type of design problem. This is not surprising when one considers that the normal heart is controlled through nervous and humoral channels that are responsive to a variety of body actions and functions.

Instrumentation Development and Production

In recent years, ideas for a variety of instruments and devices useful in the delivery of health care have emerged, and in some instances successful prototype development, production, and marketing have followed. At the same time many problems inherent in medical engineering development have become visible.

Currently industry finds itself with a shortage of engineering talent and a

number of identifiable promising markets. When this is coupled with the fact that the medical engineering high-need, low-volume market has failed to crystallize predictably, it is not surprising to find that industry is reluctant to enter the field (9). Industry has highly organized distribution systems and people trained to manipulate these systems. In the health field, similar distribution systems do not exist, and there is difficulty supplying the needed services. Further, industry faces the problem of the high cost of medical engineering development, and it is unable to control consumer acceptance as it does in other fields. Also, there are long-term problems in financing because in the medical field products often cannot be gotten out fast enough to provide an adequate return. At the same time it is obvious that unbridled enthusiasm for technology per se is not appropriate. There is increasing criticism of current attempts to apply technology to medical care largely due to gadgeteering introduced for its own sake, to faulty knowledge, premises, and engineering, and to those few irresponsible individuals who continue to promote fraudulent devices.

Concluding Comments

The medical profession is several years behind in assimilating the advances of modern technology. The satisfactory introduction of sophisticated instrumentation into our health-care system cannot take place without adequately prepared and trained manpower. This presupposes in some instances special training over and above that usually accepted. The clinical pathologist must become acquainted with physical methods of data handling. The nurse must learn new forms of record-keeping and interpretation of such records and must understand the new instrumentation. Finally, highly skilled technical staffs must be developed to install, operate, and repair these often complicated systems. To date, bioinstrumentation has largely been neglected in biomedical engineering training programs. Accordingly, in the future it will be important to train bioinstrumentation technologists in increased numbers at the bachelor's and master's levels.

The development of basic instrumentation, some of which will prove to be applicable to the health-care field, must

be stressed. The current use of the gas chromatograph or mass spectrometer, or both, for clinical laboratory analyses, the use of the scanning electron microscope for the study of pathological specimens, and the application of ultrasound are cases in point. The design of new transducers, of new measurements of health and disease, and of new approaches to the study of physiological functions are urgently needed, and a closer coupling between the theoretical analysis of physiological systems and

the development and production of instrumentation is an absolute essential. To these ends, the necessity to establish centers where research, teaching, and engineering can be done on instruments and where scientists and technicians can learn to use them continues as an urgent and top-priority matter.

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Identification of a Speaker by Speech Spectrograms

How do scientists view its reliability
for use as legal evidence?

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The sound spectrograph is an instrument that finds widespread use in current research on speech sounds. It portrays, in graphical form, the time variations of the short-term spectrum of the speech wave (1). Examples of such speech spectrograms are shown in Fig. 1 for four instances of the word "science." In each spectrogram the horizontal dimension is time, the vertical dimension represents frequency, and the darkness represents intensity on a compressed scale. This representation of the sound patterns of speech has proved to be extremely powerful in research on the phonetic aspects of speech because the spectrogram gives valuable information about speech ar-

ticulation. In the examples of Fig. 1, the middle portions of the patterns show effects of the articulations corresponding to the vowels of "science." The initial and final portions of each spectrogram show sudden changes in the frequency pattern where consonants and vowels join.

When two persons speak the same word, their articulation is similar but not identical; therefore, spectrograms of these words will be similar but not identical. There are also similarities and differences even when the same speaker repeats the same word. These facts are apparent in the spectrograms of Fig. 1. The two spectrograms at the top were made by the same speaker on two different occasions; the two spectrograms at the bottom were made by two other speakers.

Speech scientists have found spectrograms very useful in studying how people pronounce different words. Can spectrograms also be applied to distinguishing one person from another?

In several recent court hearings, evidence has been presented both for and against the use of speech spectrograms, or "voiceprints," for personal identification. Scientists in speech research have been concerned, for reasons of social importance and scientific credibility, about such use of speech spectrograms; the Technical Committee on Speech Communication of the Acoustical Society of America asked six members of the Society (the authors of this article) to study and report on this issue (2). In considering the problem, we asked questions such as the following: When two voice spectrograms look alike, do the similarities mean "same speaker" or merely "same word spoken?" Are the irrelevant similarities likely to mislead a lay jury in assessing conflicting testimony from opposing experts? How permanent are voice patterns? How distinctive are they for the individual? Can they be successfully disguised or faked?

Whatever the future may hold for voiceprinting as a method of identification, expert witnesses at the present time do not agree as to its reliability, and various courts of law have ruled both for and against the admission of such evidence (3). These differences of opinion are, however, only the surface reflections of deep-lying difficulties, inherent in the nature of spoken language, that serve to make voice identification equivocal for the expert and confusing to the layman.

It is against this background that we have undertaken to point up the difficulties inherent in voice identification, to review and assess the relevant scientific knowledge available today, and to examine the problem of scientific validation for the use of voiceprint identification as legal evidence (4).

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