Clinical Engineering—the Problems and the Promise

Clinical engineering may narrow the gap between basic biomedical research and health care delivery.

J. B. Oakes

Our national investment in health care has increased at a spectacular rate over the past several decades. From a total expenditure of $12 billion in 1950 [4.6 percent of the gross national product (GNP), or $78 per capita], health care costs rose to $83 billion in 1972 (7.6 percent of the GNP, or $394 per capita) (*1*, *2*). Various short-term projections made in the early 1970's indicated that this cost would rise to over $110 billion in 1975, and these projections could not anticipate those national and international events which have since added their impact to the spiral in medical care costs. The delivery of health care today involves nearly 5 million people, making it the nation's third largest industry in terms of manpower.

Yet, despite this huge expenditure on health, our system suffers by comparison to those of a number of other countries. The general reasons for this are often cited as a shortage of primary care facilities for timely treatment of less severe medical problems, uneven distribution of services, and poor use of manpower and other resources (*1*). However, if one examines a particular health care facility in detail, a wide range of more specific problems are found which contribute directly to the cost of medical care provided by that facility (*3*). The more important of these problems fall into several categories. Some of them are historical in nature. The medical care system has traditionally involved a one-to-one relationship between doctor and patient. While this approach provides the sympathy and individual concern which the patient desires, many health care organizations recognize it as costly, and are beginning to make more effective use of allied health professionals to reduce those burdens of the doctor not requiring his direct or full-time participation. Some of the problems are organizational in nature; the advantages of a lean, aggressive, and competitive organizational structure are not always as apparent to the cost-reimbursement health care delivery organizations as they are to the profit-oriented segments of private industry. Some of the problems are purely political in nature; the directors of every hospital, it seems, want the reputation for providing a full spectrum of services, no matter how specialized. For example, several of the larger hospitals in a given city may be equipped and staffed to carry out open heart surgery, even though maintenance of such parallel facilities may result in low usage, increased fees, and less than optimum care for patients requiring such major procedures. Work of the regional medical cost review commissions and planning councils is now beginning to have an impact on some facets of this problem area. Finally, some of the problems are technical in nature. As more advanced and sophisticated medical and engineering technology is applied to specific diseases, the cost of treatment tends to increase rapidly unless an effort has been made to evaluate and control the economic impact of such technology at the same time. In addition, special attention must be paid to the effectiveness with which highly technical devices and procedures are employed in medical diagnosis and therapy.

In the past several years, a new engineering specialty called clinical engineering has emerged which promises a means of solving some of the technologically based problems associated with health care delivery (*4*). The remainder of this article will examine the relation of clinical engineering to the biological and medical sciences, and will discuss the philosophical and organizational problems which must be overcome if clinical engineering is to contribute to improved health care.

The Interface

The interface between engineering science and technology and the biological and medical sciences is broad (*5*), spanning an area from highly mathematical biological theory to the practical problems of the health care system. Table 1 gives an example of the span and continuity of this interaction. In recent years, it has become increasingly common to label the two basic areas shown in Table 1 simply as biomedical engineering, defined as "the application of the tools of mathematics and the physical sciences to biological and medical problems," and to label the four applied areas as clinical engineering, defined as "the application of engineering principles for the improvement and delivery of health care" (*6*).

Graduate education in biomedical engineering has historically prepared its students to work in the basic, or research areas, rather than in the applied. Thus, with educational emphasis and government funding focused strongly on the research end of the spectrum, significant success has been achieved in the understanding of human disease, often by collaborative efforts between medical and engineering scientists. Relatively less attention has been given to those areas of applied biomedical engineering concerned with clinical science, patient care, and the health care system, with predictable results. First, a gap has developed between biomedical science—the discovery of new medical knowledge, and technology—the application of that science to the solution of patient care problems. Next, in those instances where attempts have been made to fill the gap—to solve problems of health care delivery—the impact of such attempts has often been limited (*7*).

Today, clinical engineers, working in the patient care environment, are helping to close this gap. Not all of their attempts are successful, but the record is improving. Many of the successful attempts have involved the evaluation, acquisition, and maintenance of highly technical equipment used to directly monitor the status, or temporarily support the lives, of critically ill patients. In the future, as our medical knowledge continues to expand, clinical engineering promises to increase the effectiveness with which this knowledge is applied to the solution of health care problems. Let us examine some of the problems which may be encountered as we realize this potential, and some suggestions which may be of value in solving them.

The author is Clinical-Engineer-in-Charge, The Johns Hopkins Hospital, 601 North Broadway, Baltimore, Maryland 21205.

The Outward Symptoms

A clue as to why the full potential of clinical engineering is not being realized today is found in the following remarks, made by dedicated clinicians involved in the daily rigors of caring for real patients in the real health care environment:

> All that complicated equipment just detracts from real personal contact with my patients.
>
> You engineers can't even keep my simple instruments working—why should I buy any new ones?
>
> I bought this new equipment, but it doesn't do what the salesman said it would.
>
> Technology is always too expensive, and often ineffective.
>
> Biomedical research is too far removed from the reality of patient care.

Similarly, the following remarks, made by engineers working for industry, also illustrate the gap between biomedical science and technology:

> We can't get the doctors to tell us what they really want—they don't even agree among themselves.
>
> We spent a lot of our own money developing an instrument for Dr. X., but we can't interest any other users.
>
> Doctor, we developed this great little sensor for the space program, and we figured you might like to try it out on your patients.

If one examines these remarks, all of which have a certain ring of familiarity, one can deduce a set of symptoms that form the basis for these outward manifestations of frustration (*8*).

First, a technology gap certainly exists between biomedical science and the technology of health care. Many valuable research methodologies are never clinically evaluated, either because of lack of funds or lack of interest on the part of the researchers or the clinicians. Conversely, many doctors struggle with real patient care problems without realizing that a technological solution already exists. It is unrealistic to expect academic biomedical research programs to have a direct impact on health care delivery unless an overt attempt is made to bridge the gap.

Technological overkill is another symptom which reduces the impact of engineering technology on health care delivery. An elegant solution to a simple problem is often proposed by the technologist and accepted by the clinician, without any evaluation of the real problem or of the economic impact of the proposed solution. One must be particularly alert to the possibility of technological overkill when existing technology from another field is proposed to solve a specific patient care problem. The difference between what can be done and what should be done must be kept clearly in mind.

Table 1. The spectrum of engineering in medicine and biology (*14*).

Area	Example
Basic biomedical engineering	
Theoretical	Use of Walsh functions to represent cardiovascular waveforms
Experimental	Study of the neuroendocrine control of blood volume
Applied biomedical engineering	
Basic science	Development of microflow probe for pituitary blood flow measurement
Clinical science	Computation of beat-by-beat stroke volume in man
Patient care	Monitoring cardiac function in the intensive care unit
Health care systems	Technologic support of emergency care

The historical concept of health care as a cottage industry is responsible for certain restrictions in applying engineering technology to health care delivery. Although today's medical student is exposed to the concept that engineering technology can broaden his effectiveness, the concept of a one-to-one relationship between doctor and patient is also growing stronger. Thus, one must introduce technological improvement in such a way that these personal relationships are not disrupted.

The vacuous systems approach is a common mistake of the unwary. It is easy for an experienced engineer, on being confronted with a problem in patient care technology, to mentally review his experience and choose an approach before he really understands the problem. This substitution of extrapolated past experience for a detailed understanding of the problem is an easy trap for the uninitiated but experienced engineer, and also for his organization.

Another symptom, the technological language barrier, is a source of concern to the clinician, the engineering technologist, and the entire health care system. There is, of course, a very real language barrier, since medicine and engineering each has its own specialized technical jargon. Repeated translation is usually required to convert medical system requirements into meaningful technical specifications. Frustration with this process can lead the clinician to unquestioned acceptance or rejection of whatever industry has to offer, and leads industry to offer what it appears that the clinician wants. Consequently, hospitals are filled with devices which meet the manufacturers' specifications but which do not meet the users' requirements.

Finally, basic biomedical engineering research occasionally loses touch with the real world. While physiological models and mathematical modeling are keys to the understanding of many medical phenomena, all too often "open loop" refinement of such models replaces true experimental verification. Such an open loop approach widens the gap between theory and reality and thus dooms attempts at clinical application.

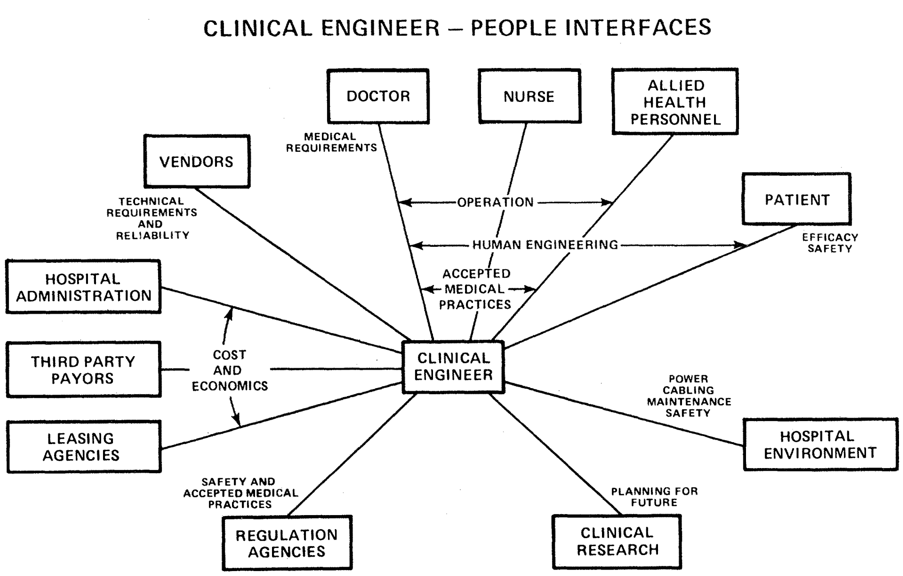

Fig. 1. Typical interaction involved in procuring a patient monitoring system for an intensive care unit (*9*). [Courtesy of I.E.E.E.]

Diagnosis of the Real Problems

A diagnosis based on the general symptoms described above makes it possible to state in a relatively simple manner why engineering technology has not had a greater impact on patient care, and can thereby provide guidance for the future. One could certainly attribute the symptoms to faulty communication, or insufficient interaction, but these are diffuse terms which do not suggest specific therapy. A more specific approach reveals that several major and interrelated factors appear to be involved in the symptoms described above. (i) Superficial understanding of the problem and its ramifications. This is often fostered by industrial organizations, whose engineers do not take time to understand the real problem they are being asked to solve. (ii) Narrow engineering expertise. This problem is usually encountered in the health care organization, which often has little or no internal expertise in engineering technology, and which often makes no attempt to obtain such help even as a temporary expedient. (iii) Failure to recognize constraints on the solution. The clinician and the organization he represents are often ignorant of the technical constraints which pertain to their problem. In a similar manner, the industrial representatives may not be aware of the administrative and political climate which constrains the solution as far as the health care organization is concerned. The benefit of making these constraints plain may not be realized by either participant. (iv) Insufficiently organized interaction. Limitations on time and money, and language difficulties, often militate against just that repeated interaction which may be required to cope with the first three factors. These four factors, then, describe a framework of pitfalls which must be avoided if engineering science and technology are to have full impact on health care delivery. Competent clinical engineers, working in the proper organizational environment, can help assure that these mistakes are avoided.

Therapy

Five safeguards against the mistakes described above are proper problem selection, identification of the real problem, recognition of constraints on the solution, provision for appropriate interaction, and objective evaluation of the outcome.

Proper problem selection requires more serious attention than it often receives from all facets of the health care delivery system. Technology is no panacea. This is a difficult concept to grasp for the engineer, especially the inexperienced one, and for the administrator, who is frequently sure that money can purchase a technological solution to any problem. The result is that, all too often, attempts are made to automate processes which simply needed to be organized.

Pinpointing the real problem is another necessary step in avoiding pitfalls. Unquestioning acceptance of the problem as described by its owner is often a precursor to failure, although neither the problem owner nor its erstwhile solver may realize it until the proffered solution doesn't really work.

Recognition of the constraints on the solution—living with reality—is another mandatory requirement for success. The difference between the possible and the acceptable must be kept continually in mind. For example, it is technically feasible to generate clinical laboratory and radiology test requests in machinable form at the source, or in fact to enter such data into a hospital-wide information system in real time. However, any such system which requires the physician to become a teletype operator is probably doomed in today's health care environment. Similarly, economic constraints are often neglected by the system designer. Claims of cost saving through technological improvement are dimly heard by the management of most cost-reimbursement industries, and instant deafness occurs if developmental funds are requested.

Appropriate interaction is also required if the problem-solving process is to be effective. The form of interaction required depends on the problem at hand. Traditionally, biomedical engineers have been trained to understand the medical problem and devise its engineering solution. When such people pursue long-term, open-ended problems, such as the understanding of the cardiovascular control system, their programs have been both successful and effective. On the other hand, many of the problems in today's hospital are both discrete and definable, with solutions aimed at specific facets of patient care. Monitoring of the critically ill patient is an excellent example of such a problem. Here, experience indicates that a true collaborative approach is most successful; an equally capable clinician and engineer interact, with consultative expertise available to each in the solution of system problems. The clinical engineer often provides the engineering collaboration in such discrete and definable projects, and he will find that multiple interactions with all the people who will be involved with the system are required to arrive at an acceptable solution. Ensuring that this interaction does occur must become the single most important objective for any clinical engineer. As an example of the extent to which this involvement may be carried, Fig. 1 illustrates the actual liaison required in the specification, acquisition, and installation of a patient monitoring system for a new 40-bed intensive care unit (*9*). Much of the success of the monitoring system which resulted can be attributed to that early liaison, where all participants expressed their initial requirements, and then saw the system take shape by a refinement process in which they were included. At an even higher level, in solving multifaceted problems impacting the overall management of the hospital (implementation of a hospital information system, or revision of its role in health care delivery), no specific approach appears to be universally effective. However, broad collaboration between interested groups of biomedical scientists and engineers, with enlightened administrative leadership, have achieved success in certain cases. An experienced clinical engineer may be particularly valuable in such multifaceted problems, and may in fact find himself in a leadership position because of his breadth of knowledge.

Finally, one must objectively evaluate the outcome of each attempted solution. While the comment "never look back" may have validity in a track meet, a clinical engineer's track record will suffer from such an attitude. Documented evaluation of both successes and failures may well play a key role in assuring continued support for the clinical engineering program.

The Hospital's Role

Allusion has already been made to the importance of organizational environment in realizing the potential of clinical engineering. Establishing and maintaining a receptive environment within a health care facility is not always an easy task (*10*), but it is one which must be successfully accomplished. Effective clinical engineering programs have been organized in a number of ways (*11*); one method (*12*) will be outlined briefly here. It represents a straightforward and overt approach by the administration of a large teaching hospital to the establishment of a clinical engineering group with broad support of the hospital staff. The approach appears to be transferable to other health care facilities.

1) Evaluate and organize existing resources. Every hospital has both human and material resources available to it in carrying out an assessment of the state of its patient care technology. Initially, establish an informal committee or task force, with members representing the hospital administration and the clinical and nursing units who have insight into the real problems of patient care delivery. Some members of the clinical laboratory, radiology department, and plant engineering department are usually technically current with

and perceptive of the various technological possibilities available, and should be asked to join the committee. As an alternative, or in addition, outside technical consultants from universities or other hospitals might be considered. All members should be chosen with an aim toward promoting effective interaction, and the support of the committee's efforts by top level hospital administration should be made formally evident on a hospital-wide basis.

2) Define the present status of engineering technology at the hospital. With a properly constituted task force committee, it is feasible to examine the existing status of engineering technology insofar as it affects patient care. Such areas as technical equipment and instruments (procurement, operation, safety, maintenance, and standards), ensembles of such equipment, and logistical systems such as communication, transportation, and materials handling, should be examined.

3) Identify problems amenable to technological solution. The fact-finding process described above will prompt both realization and discussion of problems which need attention; it is probable that steps 2 and 3 will, in fact, be carried out in parallel. In identifying problem areas, special attention should be directed to busy areas having a high flow of patients, personnel, information, or goods; bottlenecks to this flow; activities having a high cost per unit operation; activities which are out of control, due either to lack of information or its communication; and activities involving high degrees of technology. It may well be that certain of these problems, upon organized reflection, have a quick and feasible solution, and these should be categorized and separated from the rest.

4) Develop explicit solutions, or approaches to a solution, for the problems so identified. A time table, personnel requirements, cost, and possible source of support for each solution should be worked out.

5) Assign priorities to the solutions, in concert with the hospital management. It is probable that a number of those problems whose solutions were both feasible and quick will occupy high positions on the priority list. By all means, opt for approval to work on these problems, and give small subcommittees of the task force the opportunity to implement their solutions.

6) Propose an organizational and administrative structure to implement the remaining tasks. The organizational structure can take several forms, depending on the resources of the hospital. Large hospitals may well be able to support a clinical engineering group whose initial task is the implementation of specific problem solutions as determined by the steps above, but with the ability to be flexibly responsive to future needs of the hospital. Another structure, possibly more attractive to smaller hospitals, is a shared clinical engineering facility, which is owned and supported by a group of such hospitals. Alternatively, a hospital may choose to avail itself of the services of a nonprofit or profit-making clinical engineering organization, and direct it toward specific problem areas (*13*).

As a result of this action-oriented program for locating problems amenable to an engineering solution, the need for, and advantages of, a permanent clinical engineering capability should be clear at both the administrative and clinical levels of the hospital. The effort of the task force should also be a case study in the avoidance of those conceptual errors described earlier.

Summary

Despite the nation's massive investment in health care, a variety of problems constrains the effectiveness of health care delivery. These problems may be generally categorized as historical, organizational, political, and technical in nature. An emerging technical specialty, clinical engineering, which involves the application of engineering principles to the delivery of health care, shows promise for solving some of the technologically based problems of the system.

Clinical engineers working in the health care environment are beginning to have an impact on the quality of patient care. Not all such attempts are successful, however, and an analysis of the successes and failures provides insight into ways in which the effectiveness of clinical engineering can be increased. The clinical engineer himself can contribute to success by properly identifying the real problem, by recognizing possible constraints on the solution, and by interacting effectively with the clinical staff. The hospital administration can contribute to the success of its clinical engineering organization by establishing and maintaining a receptive environment for such interaction.

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