Biomedical Engineering

This multidiscipline may revolutionize medical research and clinical practice.

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Distinctions between life sciences and engineering have become blurred during the past 20 years. Exciting and productive developments are emerging between the traditionally separate disciplines. In recent years basic medical sciences have become progressively more dependent upon the physical sciences, a trend which is now beginning in medical practice. Physicians and life scientists acted as independent entrepreneurs with supposed interrelations with sociology, political science, law, philosophy, and history (Fig. 1A). However, neither the training nor practice of medicine was rooted in any of these perimedical disciplines. Changes are now occurring as these disciplines overlap with medicine (Fig. 1B). Comparative physiology has provided simple models for study in lower forms of life (such as squid axon, hagfish heart, and oyster smooth muscle). Biochemistry has given rise to molecular biology and modern genetics. Biomathematics and biophysics have wrought fundamental changes in both basic medical sciences and certain aspects of the delivery of health care. Now, biomedical engineering is bringing new concepts, approaches, techniques, and technology to bear on the diverse problems in biology and medicine. Biomedical engineering has initiated a chain reaction affecting the economics of delivery of health care through new diagnostic and therapeutic techniques and technologies. The sociological implications are most obvious in the current inequalities in distribution of medical care. Innovations based on engineering applications (such as transplantation and artificial organs) have thrown into sharp relief many vexing problems of law, morality, ethics, and philosophy (Fig. 1B). Some specific examples of these problems are discussed below.

Biomedical engineering is destined to exert profound influence on the quest for knowledge of living creatures, on our capacity to analyze complex functional relations in animals and man, and on our abilities to detect and alleviate illness.

Operational Definition of Biomedical Engineering

Although groups devoted to the applications of engineering to biomedical problems have existed for many years, a great surge in activity began during the past decade. Most of the university programs emerged from departments of electrical engineering, presumably because of the obvious applications of systems analysis to complex living systems and because of the obvious requirements for new instrumentation. The most common affiliation of such groups has been with members of departments of physiology or biophysics, or with receptive clinical divisions, such as cardiology or surgery.

Many other types of collaborative relationships have developed between engineers and life scientists, combinations such as mechanical engineers working in collaboration with faculty in biological structure, orthopedics, or physical medicine. Chemical engineers and nephrologists have developed artificial kidneys. Cardiologists, cardiac surgeons, and engineers have cooperated on the problems of heart-lung machines for open heart surgery and artificial hearts for temporary assist or chronic implantation. Since engineers are most attracted to familiar problems, their efforts are concentrated on problems for which their particular training and experience seem most obviously appropriate.

In an attempt to identify objectively the areas of concentration and neglect, three tabulations of research projects have been made. Termed "Distribution of Effort Matrices," these are based on three different sources of data about current biomedical engineering research. The first is a summary of the (478) abstracts of papers presented at the 1968 Annual Conference on Engineering in Medicine and Biology (Table 1), which represents an inclusive biomedical engineering meeting held during the year. The abstracts have been placed in categories according to the apparent research objectives, as indicated on the left of the table and target groupings, across the top, which range from nonliving materials to whole man. A second matrix, based on 1067 abstracts of current research projects from the Science Information Exchange (SIE), is given in Fig. 2A. Requests were made to SIE for information in three broad categories: biomaterials, instrumentation, and radiation. These categories were chosen because they represent diverse aspects of engineering application and they can be identified directly in the SIE system. Based on the abstracts, the research projects have been tabulated according to subdivisions of the three major categories and the principal anatomical regions. The third matrix, shown in Fig. 2B, indicates the distribution of effort of the 255 biomedical engineering projects receiving financial support from the National Institutes of Health.

All three matrices clearly indicate a sharply biased distribution of biomedical engineering effort. Much of the total effort seems directed toward the cardiovascular system (instruments, function, and therapy) and to the functional characteristics of the nervous system. Firm conclusions cannot be drawn with confidence from these samples of data, and more information is badly needed. Certainly, these data and particularly this method of presentation must be viewed with care. Some spaces in the matrices are not reasonable areas of effort, and a numerical summary gives no information as to the extent or quality of activity. The data represent only grant-supported research projects, and

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Table 1. The uneven distribution of biomedical engineering effort as indicated by the papers presented at the 21st Annual Conference on Engineering in Medicine and Biology held at Houston in 1968. The abstract for each paper was classified according to its apparent objective and anatomical region of interest. Each number indicates the total number of abstracts in that category.

	Materials	Cells	Tissues	Cardio-vascular	Nervous and sensory	Respi-ration	Gastro-intestinal	Genito-urinary	Musculo-skeletal	Skin	Whole man
Biomechanics	2	3	2	4	3	1			7	2	5
Instruments (R&D)	9	5	15	52	18	9	2	1	7		22
Function	14	2		58	42	16	2	2	8		10
Controls	5	1		10	1				1		1
Diagnostic technique		2	1	14	2	3			1		4
Therapeutic technique		2	5	33	3	4		8	11		3
Health care delivery	2	1	2								23
Environmental					1	1					9

does not include research and development in industrial organizations that do not rely on research grants. However, the disparities within each matrix, many of which are consistent for all three matrices, are sufficiently great to warrant attention. It seems clear that the contributions of engineering to gastroenterology, urology, dermatology, and neurology do not compare in amount or diversity to those easily visible in care of disease of the cardiovascular, respiratory, and skeletomuscular systems. A comprehensive analysis is needed to determine whether the distribution of effort across the country displays the same heavy concentration in certain discrete areas with little or no involvement in others, so that positive steps might be taken to bring the benefits of engineering to the problems not yet studied in this way.

The ultimate definition of biomedical engineering should include the effective applications of the concepts, approaches and technologies in the full range of engineering disciplines to the wide scope of problems involving living systems from single cells to human populations.

New Horizons and Opportunities for Biomedical Engineering

The broad definition stated above includes many new opportunities to use mathematics, physical sciences, and engineering for both basic medical research and clinical investigation. In basic medical sciences, subjective descriptions are being supplemented by quantitative measurements, dynamic responses, and systems analysis. These techniques and technologies are well established in hard sciences, but they are new and exciting in many aspects of the life sciences. Engineering techniques and technology have found greater acceptance in physiology than in most other basic medical sciences (such as pharmacology, pathology, anatomy, and embryology), and opportunities abound in all these disciplines.

In clinical medicine, the spectacular advances in transplantation and artificial organs has obscured the fact that medical practice outside the large centers has been little affected by modern technology. To test the accuracy of the foregoing statement, one might inquire of members of each medical specialty, "How many new quantitative diagnostic techniques or technical innovations in therapy have been added to your specialty in the past 10 years?" The answers might well be compared to the mechanization that has occurred in the average household, especially

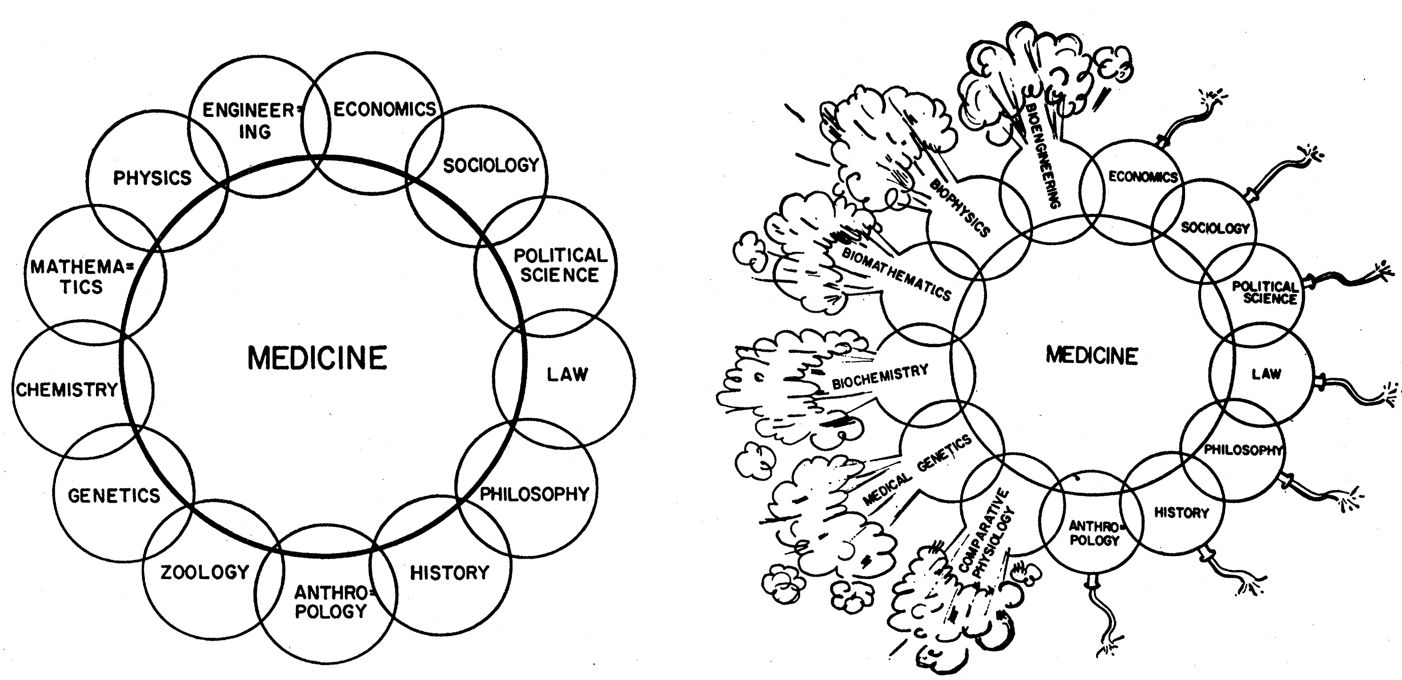

Fig. 1. (Left) The overlapping of many established physical, biological, and social sciences with the "sphere" of medicine. (Right) The explosive changes which have been occurring at these interfaces in the past two decades.

in the kitchen. Physicians routinely recognize disease states largely on the basis of subjective impressions supplemented by the few objective measurements most of which have been available without change for many years. The average practitioner uses only a small number of clinical tests to provide actual numbers in the course of physical examinations, or in the diagnosis of maladies of the gastrointestinal system, the genitourinary system, the skeletomuscular system, or the skin. More rigorous diagnosis has become available for certain organic systems (such as the heart and lungs) through new techniques such as cardiac catheterization and pulmonary function testing. Modern technology can be applied to other organ systems to improve the accuracy of diagnosis, therapy, to eval-

A

		MATERIALS	CELLS: Plant, Micro	TISSUES: Animal	CNS	CVS: Heart	CVS: Arteries	CVS: Microcirculation Lymphatic	CVS: Veins	RESP: Gas Exchange	RESP: Airways	GI: Mouth, Teeth	GI: Gut	GU: Kidney	GU: Urinary Tracts	GU: Reproductive System	MUS-SKEL: Bones, Joints	MUS-SKEL: Muscle	MUS-SKEL: Prosthetics	SKIN	WHOLE MAN
BIOMATERIALS	Structure	30	1	2	7			3									3			1	
	Mechanics	5	2		2	2	6	1		1		20				1	17	1		1	2
	Compatibility, Usefulness	18			5	6	28	1				39	2		1		5		2	5	
INSTRUMENTATION	Research	7	5	30	17	6	11	2		1	3	3	1					1		4	
	Diagnostic	5		9	7	31	11	1	1	4	1	3	1			3		2		1	9
	Therapeutic	8		8	23	145	24		7	28	4	10	4	22	4		3	1	31	15	
RADIATION	EM: Long wave	1	3	7	3	1	1	1										1		2	1
	EM: Visible	28	25	22	48			2												16	2
	Ionizing – Short wave	35	49	24	6													1		7	4
	Sound	1	2	2	9	1															1
	Ultrasound			6	2		1				2	2					2				

B

		MATERIALS	CELLS: Plant, Micro	TISSUES: Animal	CNS	CVS: Heart	CVS: Arteries	CVS: Microcirculation Lymphatic	CVS: Veins	RESP: Gas Exchange	RESP: Airways	GI: Mouth, Teeth	GI: Gut	GU: Kidney	GU: Urinary Tracts	GU: Reproductive System	MUS-SKEL: Bones, Joints	MUS-SKEL: Muscle	MUS-SKEL: Prosthetics	SKIN	WHOLE MAN
INSTRUMENTATION	General	29		6	1	7		3	7				3			1		1		1	
	Clinical	11			5	1					1	1				1			5		1
	X-ray, Radioisotope	3									1						1				1
FLUID DYNAMICS		1		2			11	5							1	1					
BIOMATHEMATICS	General	1		1	4	1								1							
	Computer Techniques			4	7	14						1									
	Modeling: Control Systems	1	1	1	9	7	9			1	1	1									
	Patient Monitoring Diagnosis				1	2					1				1						3
BIOMATERIALS		7			1						1		1							2	1

Fig. 2. The distribution of current biomedical engineering research effort, as indicated by two sets of data. (A) Samples of funded research projects listed by the Science Information Exchange in the three categories of biomaterials, instrumentation, and radiation. (B) Samples of research projects funded by the National Institutes of Health and classified by that agency as biomedical engineering and into the subcategories indicated on the left of the figure. For each set of data, the projects have been assigned to appropriate subcategories of effort and anatomical interest, as indicated by their abstracts. Anatomical categories have been abbreviated as follows: *CNS*, central nervous system; *CVS*, cardiovascular system; *RESP*, respiratory system; *GI*, gastrointestinal system; *GU*, genitourinary system; *MUS-SKEL*, musculoskeletal system. Data regarding projects were made available through the courtesy of Drs. T. Kennedy and P. Chen (NIH).

uate therapy, and ultimately to prevent disease.

In providing services, the medical profession is being challenged to consider the cost of their delivery of health care, whether to individuals or to groups. This challenge, in turn, is a stimulus for increased activity in biomedical engineering and clinical medicine. Operations analysis, cost-benefit analysis, and other proven industrial techniques should be applied in an effort to prevent continuing increases of medical costs. The new tools required for efficient multiphasic screening to detect diseases early have not yet fully emerged. New types of allied health professionals and technicians must be equipped with new tools and equipment to increase their effectiveness so that they can relieve physicians of routines and free them for the decision-making process for which they were uniquely trained.

Industry stands to profit from the potential market being created by demands for new equipment and processes in both basic medical science and health care. A few companies, large and small, are meeting these demands; most stand watchfully on the sidelines of the third largest category of expenditures in our country's gross national product. At present the major item of cost of medical care is for personnel and our greatest hope to restrain the rising costs must lie in improved organization with supplement of high-priced personnel with machines. The reduction in costs of health care by new technology will require volume production of materials and equipment which are not now available. The impediments to such a major effort must be analyzed and countered.

Obstacles to Progress in Biomedical Engineering

The potential offered by biomedical engineering can be realized by individual initiative and private enterprise, but the advance would be halting and spotty. Widespread applications of engineering to life sciences would be accelerated by judicious federal support of the enterprise. The extent of the financial support tends to determine the net amount of activity, but the effective distribution of the effort depends on farsighted leadership, selection of appropriate goals and priorities, comprehensive analysis, and long-range planning. The current biomedical engineering effort is dispersed under many different auspices and headings. The attention of the entire world was focused for a while on a succession of emotionally appealing suspenseful dramas (open-heart surgery, heart and kidney transplants, artificial organs). There is danger that owing to the pressures of public opinion, physicians are concentrating unduly on dramatic and newsworthy developments which benefit small numbers of patients through advanced technology at enormous cost, while medical care available to the general public remains essentially unaffected by technical progress.

Without questioning the advisability of supporting research and development of artificial hearts, lungs, or kidneys, the magnitude of the effort should bear some reasonable relation to the total requirements for both fundamental research and "adequate" health care delivery for all. The manpower pool of competent life scientists and engineers individually and in combination is not sufficient for our requirements. The situation in medicine is reminiscent of the high concentration of talent and money on space spectaculars when our immediate environment is threatened by overwhelming problems. The dramatic medical spectaculars should not be allowed to jeopardize essential support of basic science and health care delivery in general.

Hazards to Health and Welfare from Technological Success

The technology that has provided us with the good life spews out wastes and toxic products that pollute our air, poison our water, and even threaten our future climatic conditions. The creative power that has produced these deleterious changes must be reoriented to provide constructive solutions to the problems it has produced. Threats to health stemming directly from technological successes are not a recent development; they began at the very outset of the industrial revolution. In the early 1800's, water was still obtained from individual wells or springs; water-borne diseases were scattered and relatively rare. With the advent of pumps adequate to supply whole cities from a single source, disastrous epidemics of cholera wiped out as much as 10 percent of a city's population (for example, London), every few years. Purification of water supplies largely controlled the cholera epidemics, but the poliovirus was also killed in the process. Immunity to poliomyelitis was not achieved during infancy when paralysis rarely occurs, and the disease began to spread to older children and adults. Thus began yearly epidemics of paralytic poliomyelitis, only recently controlled by the Salk vaccine. The current specter of a population explosion apparently was triggered by successful control of infectious diseases, which resulted in lengthening of life; at the same time there was no provision for restraining birth rates. Now the most common cause of death and disability among citizens under 35 years of age in "civilized Western nations" is accidental trauma from automobile accidents. Evidence has been widely disseminated to the effect that the high incidence of atherosclerosis in affluent societies may be due in part to our rich diets with high intake of fats. The self-imposed risks to health from smoking are well advertised. Even more threatening is the overuse of many different therapeutic agents sold ubiquitously by the billions and without prescription. This overuse constitutes a hazard even more widespread than the illegitimate use of narcotics or hallucinogens. The fact that any technological advance may induce health hazards must be recognized and analyzed in each case. For example, the long-range effects of organ transplants or artificial organs (heart and kidneys), on patients, the family groups, the community can be partially predicted in medical, economic, psychological, and legal terms.

In this regard, kidney transplants and artificial kidneys can serve as prototypes for substitution of hearts and other internal organs. Kidney transplants have a greater prospect of success than other internal organs for several reasons: one normal kidney is functionally adequate to serve the entire body, donors survive, patients can survive cessation of kidney function for days, and artificial kidneys have proved fully effective for long periods (for example, 10 years). Patients with successful transplants may live normal lives. At present, kidney transplantation costs range between $5,000 and $40,000 each, and only small numbers of individuals can be accommodated in existing kidney centers (usually, 30 to 50 patients per year in each). Patients sustained on periodic dialysis may engage in varied activities, including gainful employment. Their lives are far from "normal" because of the restraints, namely, threatened or actual complications and constant emotional and financial stress. Cost of dialysis has progressively diminished and now runs about $12,000 to $14,000 for the first year and to about $4,000 per year thereafter, if home dialysis is instituted. An estimated 5000 patients develop kidney failure per year. With increasing federal support of health care delivery, we must consider the extent to which these expensive procedures can be made available to others than the few who can pay for them. When the federal government supports such a major therapeutic effort, should all citizens have equal access without discrimination? In that case, the total cost per year could increase at a rate between $20 to $60 million per year to reach amounts in excess of $200 million per year in 10 years.

The number of patients requiring and requesting mechanical hearts is not known, but it could easily amount to hundreds of thousands per year, and the cost could become astronomical unless the scope of the effort can be limited by judicious and reasonable selection criteria based on study and analysis. Transplantation and artificial substitutes for various organs have many similar features and may be regarded as components of a single problem, with the kidney as a prototype, for judging the ultimate magnitude of the federal commitment to providing and supporting the cost of artificial organs individually or collectively.

If it is determined that artificial organs or transplants will not be available to all who need them, we must be prepared with acceptable criteria and guidelines for distinguishing which patients benefit and which are denied. We must take advantage of our opportunity to establish a balance sheet of overall benefits and expenditures for the patient, the family unit, the local community, and society as a whole by studying groups of patients receiving transplants and artificial organs. Such an estimate of cost effectiveness is new to medicine, but may become essential. The scientific community must consider the consequences of its technological advances to avoid unpredicted catastrophic effects.

Deterrents to Improved Health Care Delivery Systems

A sense of urgency has developed regarding the need for arresting the upward spiral of medical costs. Biomedical engineering can help to defend the continuing investment in basic research by accelerating the conversion of innovations and concepts for application to clinical medicine. Unfortunately, a serious obstacle to applications of new technology to medical practice is the resistance of the practicing physician to new techniques.

Many physicians regard technicological innovation as (i) unnecessary or noncontributory, (ii) potential hazards, (iii) intrusions between the physician and his patient, (iv) professional threats, or (v) potential economic competition, along with other real and imagined sources of concern. The most important requirement for physician and patient acceptance is the ability to demonstrate that effectiveness can be achieved without these difficulties. This will require availability of prototypes for clinical evaluation and demonstrations. If prototypes prove successful, the next barrier to progress would be the threat to accreditation of hospitals which accept innovations in spite of universal legal liability assumed. The constant threat of lawsuits instituted by patients imposes serious restraint in both medical practice and industrial production of equipment, particularly in view of the recent trend toward very large settlements in medicolegal cases. One factor which may discourage hospitals from using new types of medical equipment is concern for lawsuits which may result from malfunction of the equipment. The highest standards of safety, reliability, and accuracy must be developed and maintained for all forms of medical equipment.

A reluctant consumer with high sales resistance is an effective deterrent to commercial production by industry. Medical equipment has long been regarded as having small and uncertain markets with very high economic risks for any industry. The individuality of physicians militates against the economics of mass production. Stringent requirements for reliability, safety, and consistency of performance in the hands of personnel poorly trained in technical matters elevate costs and complicate maintenance. The threat of large legal settlements together with other sources of uncertainty has been enough to dissuade many industrialists from entering the field to a significant depth. Producers of consumer goods with established and lucrative markets have little incentive to divert highly competent engineering staff (always in short supply) to medical equipment with attendant economic hazards. Until more manufacturers are willing to invest in the production of biomedical equipment, the prospects of utilizing new technologies to help stem the upward spiral of medical costs seems remote. An analysis of the deterrents to industrial involvement and of mechanisms for circumventing them is a prime necessity of immediate importance. One essential ingredient must be the grant and contract support by federal government of prototype development to the stage where evaluations and demonstrations can provide convincing evidence of effectiveness and marketability. Unequivocal demonstration of effectiveness is an essential step toward dissipating impediments to industrial involvement. Biomedical engineering is a costly process which will succeed only with rather massive allocation of wisely administered federal funds. It cannot flourish and attain full maturity through the uncoordinated efforts of individuals. A comprehensive overview of biomedical engineering effort is needed to achieve balance between basic and applied research, for adequate funding with balanced distribution, for training of manpower, and for long-range planning.

Summary

Activities reasonably labeled biomedical engineering are widely dispersed throughout universities, research foundations, industry, and the federal government. The current status of research, development, and support of these activities is obscured by the fact that they lack identity and visibility in many institutions and organizations. The potential opportunities for contributions by biomedical engineering need to be identified so that a more balanced distribution of effort might be achieved. In addition, the obstacles to progress should be recognized and analyzed to dispel or circumvent them.