# The reign of technology in contemporary medicine

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*Technology has cast its mantle on every aspect of medicine and health care during the last few decades and accounted for a major industry for medical and health care products. In Western countries, the development of medical technology is facilitated by industrial funding of R&D, close linkage between industry and universities and the regulatory role of the Government. Since these conditions do not exist in India and the demand for medical products is soaring, it is necessary to devise a new mechanism which will bring together industry, universities and research laboratories for a joint effort in developing medical instruments, devices and other health care products. The initiative for this move should preferably emerge from industry. This will open a new vista in industrial growth which will have a salutary effect on our standards of health care.*

IF a patient with effort angina approached a good hospital in the 1950s, the physician would take a careful history, conduct physical examination, order laboratory tests, evaluate the chest X-ray and electrocardiogram and conclude that the patient had coronary artery disease. There was little more he could do to confirm the diagnosis – he could do even less for treatment. The prescription, in fact, consisted of rest, nitrates and plenty of reassurance. The patient's expectations were small and the physician's resources, even smaller.

Today, the management of effort angina has changed beyond recognition. History taking and physical examination have faded into the background. Apart from a battery of biochemical tests done by an autoanalyser, the patient will now have a stress electrocardiogram to uncover latent angina or to assess its severity; the stress test will often be augmented by scanning of the distribution of labelled thallium in the heart muscle. The pumping function of the heart chambers will be computed by two-dimensional echocardiography or by radionuclide scanning. If the stress test is positive, the patient will undergo coronary angiography in a catheterization laboratory, complete with X-ray generators, image intensifier chain, motorized table, multichannel recorders, anaesthetic machines and resuscitation console. If the angiography shows the blocks in the coronary arteries to be suitable for balloon dilatation or for bypass surgery, these procedures will then be performed promptly. They will in turn involve the use of a variety of specialized equipment, but all procedures will get over soon and restore the patient to work in less than two months.

The remarkable change in the management of effort angina is typical of what has happened in the management of patients over the last few decades. At every level of diagnosis and treatment, the prospects for the patient have been totally transformed by the whirlwind of technology.

Table 1 gives a summarized classification of the technologies which have recast contemporary medical practice. The list is by no means exhaustive; it excludes, for example, surgical instruments, vaccines and drugs. It does, however, illustrate the pervasive applications of technology from the primary health centre to the tertiary-level hospital. What is no less striking is the fact that the equipment, for the most part, entered medical practice no earlier than four decades ago. In fact, few of the technologies were developed primarily for medical applications; they came as by-products of some other endeavour. Ultrasound, which revolutionized medical diagnosis, for example, owes its origin to the work on sonar during the Second World War and the defence scientists could hardly have imagined that sonar technology, which dealt with submarines, would be applied to scan the foetus floating in the amniotic fluid! Another example is the development of polyamide by Carrothers. An initial application of the first man-made fibre related to parachutes; but a surgeon, Vorhees, visualized its application as a fabric tube for replacing diseased arteries. This was the beginning of vascular surgery, which saved many thousands of lives and limbs over the years.

Not all developments in medical technology were, however, accidental or concerned solely with equipment. A notable exception, for example, was that of William Kouwenhoeven – an electrical engineer – who developed the current method for cardiac resuscitation when he was in his sixties![1] The credit for developing an AC defibrillator belongs to him.

## Development of medical technology abroad

If the western initiative in medical technology was instrumental in revolutionizing health care, it was equally

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**Table 1.** Technology for medical applications

| Instrumentation | Category Examples |
|---|---|
| *Diagnostic* | |
| BP apparatus<br>Doppler blood flow monitor | Fluid dynamics |
| ECG<br>EEG<br>EMG | Bioelectricity |
| Autoanalysers | Analytical biochemistry/ computer |
| *Imaging* | |
| CT Scan | X-ray |
| Endoscopy | Optical |
| MRI<br>Magnetoencephalography<br>Radionuclide | Nuclear |
| Echocardiography | Ultrasound |
| *Therapeutic* | |
| Defibrillators<br>Pacemakers | Biostimulators |
| Medical lasers<br>Radiotherapy units | Radiation |
| Heart assist devices | Hybrid technologies |
| *Devices* | |
| Implants | Hip joint<br>Heart valve<br>Lens<br>Vascular graft |
| Disposables | Oxygenators<br>Blood bag<br>Blood dialyser |
| External prosthesis | Artificial limbs<br>Dentures |
| *Biotechnology applications* | |
| Diagnostic kits<br>Hormones, enzymes by recombinant DNA technique<br>Cryopreserved organs, tissues for transplant | |

successful in commercial terms. According to the 1994 edition of the *US industrial outlook*, published by the US Department of Commerce, computers and semiconductors, which were the fastest-growing manufacturing sectors between 1973 and 1988, gave way to health care equipment industries for the 1987–1994 economic cycle. The medical devices industry reported the value of shipments in 1993 to be more than $44 billion, which was estimated[2] to touch $51 billion in 1994. What made medical technology so successful in the US and other industrialized countries?

In the first place, the universities, research institutions and industry in the West enjoy a working relationship which is marked by pragmatism and complementarity of interests. This is vastly different from the picture in India, where a variant of the caste hierarchy operates in relation to scientific work and industrial initiative. An example from the Western context will illustrate the contrasting situations. In the 1960s, I was a research fellow in Dr Gott's surgical laboratory at the Johns Hopkins Hospital, Baltimore. We had then done a good deal of work on developing and characterizing a surface with wall-bonded heparin[3,4]. Though the bonding of heparin was ionic and lasted no more than a few hours, it was a novel development which found applications in cardiovascular surgery[5]. We had recognized the defects of the new surface insofar as it could be applied only to rigid materials; it would bar the diffusion of solutes because of the graphite layer between the heparin and the substrate and so on. Within a few weeks of the publication of our papers, Dr Leininger of the Battelle Laboratories discussed with us his ideas about grafting heparin directly to the surface without the intermediacy of graphite. Soon he produced a new surface which grafted heparin molecule on plastic materials through a cationic surfactant[6,7]. This was an obvious improvement on what we had developed and became the basis for the celebrated Gott shunt, which continues to be in vogue in cardiovascular surgery. For our team at the Hopkins and Dr Leininger's group at the Battelle, the collaboration came as a spontaneous and enjoyable exercise. While Hopkins received the credit for introducing the concept of wall-bonded heparin, the credit for its conversion into a technology went to Battelle. This pattern of development is quite common abroad.

Secondly, industry provides the main engine for progress in the developed countries because it invests substantially in R&D. Large companies like Dupont and General Electric, whose main interests are anything but medical, support R&D in medical products and instrumentation because of their social value and corresponding gain for the image of the company. But the majority of instruments and devices are developed by 'start-up' or small companies, which bears testimony to the entrepreneurial spirit of the Western technologists. The smaller companies, in fact, spend more on R&D than their larger counterparts and the percentage may be as high as 15–30% of their turnover. Once a product is conceptualized and the market shown to be promising, the companies carry out much of the developmental work in-house and contract out the remainder to other laboratories or universities, while retaining overall control and responsibility for production and marketing. This is as true for a computerized treadmill as for a pacemaker. Thanks to the participation of many laboratories and groups, medical instruments and devices are often the products of a truly national effort. Indeed, the recent trend is to extend R&D and production transnationally to save on costs and to improve global marketability.

Thirdly, the Government supports the enterprise in medical technology in two ways. It makes itself absent

in the University – industry interactions and does not interfere in R&D activities. It does, however, ensure that the products of medical technology conform to rigid standards. Elaborate regulations are made and implemented to ensure the safety and efficacy of what is introduced in the market. There are also provisions to recall defective products, which the industry promptly complies with.

Whether one looks at University–industry linkage, industrial support for R&D or the role of the Government, the Western model for the development of medical technology is clearly inapplicable nearer home.

## The Indian scenario

In India, one looks in vain for close linkages between industry and university science departments. Industry does not spend enough on R&D, preferring the security of manufacture under licence, and Government hardly wakes up to the problems in medical technology or health care unless something as terrible as plague sweeps across the country. In this highly unpromising climate, why worry about technology development? Why reinvent the wheel when the writing of the MNCs is on the wall? Why cannot we import whatever we need? The trouble with this approach is that a prescription for blind imports spells nothing short of disaster. A survey carried out by the Sree Chitra Tirunal Institute, Trivandrum, in 1985 showed that the demand for medical devices – excluding instruments, vaccines, drugs and so on – exceeded Rs. 350 crores, which was estimated to reach Rs 1000 crores by 2000 AD[8]. Following the devaluation of the rupee and the acquisition of more recent data, industry sources estimate that the actual demand may be far greater by the turn of the century. It is unthinkable that India can import equipment and devices at such cost, or produce them under licence, to run its hospital services. There will be no appeal from the harsh judgment that will befall those who advise the perpetual borrowal of technology as a policy. It is no one's case that we should develop everything we need by ourselves: I do, however, claim that our technological capacity should be such that, while our time scales and priorities may bar the development of a given technology, we could definitely accomplish any job and build a base which would be self-generating.

One could go about the task in different ways. A recent approach was that of the Sree Chitra Tirunal Institute, Trivandrum, which demonstrated that medical technology can be developed quite successfully within the country by creating a joint institutional framework for medical science and technology. The example of the blood bag – the first technology to be developed by the Institute – is instructive. In commercial production for over four years, it has captured 70% of the domestic market; it is exported to countries, including those in Europe; apart from Penpol in the joint sector, which produces over two million bags annually, a second unit under Hindustan Latex Limited will produce them shortly and a third unit will open in Calcutta in two years. From all accounts, it is a success story.

## The blood bag story

Soon after the technology development programme of the Sree Chitra Institute got underway in the early 1980s, we took up the development of an oxygenator, which is a disposable device used in open-heart operations. The device, in our design, consisted of two PVC sheets welded together in such a manner that it provided, in sequence, a bubble chimney wherein oxygen was bubbled through a rising column of venous blood, a defoaming chamber and an arterial column from which blood was pumped back to the patient. As we had no calendaring machine and the commercially available PVC sheets lacked biosafety, my colleague, Pal, developed a PVC compound which was specially extruded for us by the Bhor Industries. The difficulties in the development of the oxygenator were aggravated by our concern that no industry would care to produce the oxygenator since its demand was unlikely to exceed three or four thousand a year. We then hit upon the idea that the same PVC sheet could be welded to make a blood bag, which could have a large market. Even though several blood transfusion experts were sceptical, the Health Ministry figures indicated that a national blood transfusion service would need two million bags a year. We also knew that blood bags had replaced bottles abroad, thanks to their many advantages, the facility to separate blood components being foremost among them. Our initial samples were easily made with the PVC sheets obtained from the Bhor Industries, but the samples cracked on centrifugation – one of the crucial tests for a candidate bag. We realized that a new PVC compound had to be developed which would release minimal quantities of phthalate during storage and would withstand rigorous mechanical tests. It took nearly three years to produce a prototype blood bag which fulfilled the standards recommended by the DHSS in Britain.

After the prototype bag was developed and tested successfully, no manufacturer could be found for the device in spite of efforts to persuade several companies in the public and private sectors. Two years passed, when a science reporter who covered one of our symposia wrote about the blood bag; this elicited a few enquiries from entrepreneurs. As we had no expertise in selecting an entrepreneur, Dr Varadarajan, who was then Secretary, DST, arranged for two consultants from the IPCL to assist us. Their choice fell upon an IAS officer who was keen to leave the service and set up Penpol – a new company to manufacture blood bags. He had no industrial experience or background, but we felt that he had

the drive, knowledge and tenacity to succeed. We assigned the technology to the NRDC, who transferred it in turn to Penpol and promoted the company with the Kerala State Industrial Development Corporation. The transfer of technology posed its own problems, but the involvement of the Institute in setting up the Penpol factory in Trivandrum was total. Preparing a detailed project report, training the Penpol technicians during the pilot production of blood bags in the Chitra laboratories, deputing of engineers for the selection and erection of equipment, and many other things were done in a truly cooperative spirit as neither side could afford the risk of failure. It was fortunate for the project that Prof Ramaseshan agreed to be its Chairman.

But troubles continued. When the production of blood bags began, pamphlets and articles appeared from nowhere to condemn the product as carcinogenic! Since vinyl chloride had been known to produce cancer among the workers who were exposed to the gas, it was claimed that the PVC pellets and sheets would also be similarly deadly! Since the pamphlets had the air of spurious authenticity, the Chitra Institute was called upon to prove that its blood bag did not contain vinyl chloride residues despite the fact that the DHSS standards did not demand the test. As the analysis for vinyl chloride residues could not be done in India, the Institute was obliged to get the job done in a laboratory in the US. The exercise to kill the disinformation campaign cost the Institute Rs 35,000, not to speak of all the vexation in the bargain.

Hardly had the slander campaign died when a fresh crisis gripped the project. A foreign manufacturer of blood bags, who had dominated the Indian market, reduced the price by half overnight even as they continued to sell their product at the old price in the neighbouring countries. It was an example of unfair trade practice by a multinational company whose target was an infant industry which was struggling to survive in India. It took the effort of several influential men of goodwill to overcome the crisis by having customs duty imposed on the foreign bag. The Indian industry never looked back thereafter and steadily increased their production and market share. The demand for blood bags grew dramatically, thanks to the public awareness of blood-transmitted diseases. Recently, MOUs were signed by the National Research Development Corporation for the transfer of the blood bag technology to Egypt and Indonesia.

In a decade, the Chitra Institute replicated the blood bag story for a series of medical devices, including the oxygenator, cardiotomy reservoir, hydrocephalus shunt, tilting disc heart valve and a polyester vascular graft, and each had a story to tell. Can the Chitra model provide inputs for the formulation of a national strategy for meeting the demand for skilled manpower, for support to R&D and for regulatory control in the field of medical technology?

## The task ahead

Since medical technology involves medicine and engineering, the first desideratum is an interdisciplinary dialogue which must begin early in one's training. It is a waste of time to try and interest medical and engineering students in the 'other culture' because they are too set in their way of thinking and too preoccupied with their own subjects to really care. What is preferable is to begin at the beginning and impart a medical or engineering orientation to subjects, wherever appropriate, at the school level. A lesson in sanitation can touch upon incinerators; a course on fish heart physiology can refer to finger pumps, and the neural connections in the brain can recapture the design of computers. Conversely, the teaching of dynamics, mechanics, electricity, etc., can draw upon the infinite variety of examples in the human body and sensitize the potential students of medicine and engineering to the form and function of the human machine. A reorientation along these lines will not only enliven the school curricula but will also facilitate interdisciplinary dialogue when the school children become physicians, engineers and scientists. Obviously, the same philosophy and approach to teaching must prevail in the professional colleges.

At the postgraduate level, there is a case for expanding the training programmes in biomedical engineering provided the generation of manpower is tailored to meet the changing needs of health care in the country. Manpower requirements currently fall into three categories. The largest demand relates to the category of clinical engineers, who are responsible for keeping the hospital equipment in operating condition. Given the enormous volume of the documented disuse of hospital equipment in India and the fact that every hospital with over 200 beds will have sufficient equipment to keep an engineer busy, the increasing demand for clinical engineers is understandable. Secondly, industry and R&D organizations have begun to look for talented biomedical engineers who can develop new products and processes for the domestic and international market. The third category relates to the few who work at the conceptual level or with mathematical models and find their niche in research institutions. A two-year programme of postgraduate training for all the three categories could offer a common curriculum which covers basic sciences, basic medical subjects, engineering principles, biostatistics, etc., during the first year and leave the second year free for the candidates to do an 'internship' under supervision in large hospitals, R&D laboratories or a university to gain practical experience in any of the three areas. If the training programme is well-structured and the facilities and teachers are competent, hospitals and industries will readily depute engineers for training, thanks to the growing realization that trained staff hold the key to the success of organizations. This will make a major contribution to the growth of biomedical technology.

Regarding support to R&D, the Indian industry has a choice. It could either stick to production under licence and become marginalized in the world, or it could develop a technologic base and be counted as a global player. For a start, a given industry could identify a family of devices which share a common base such as computers or material science and resolve to produce them over a specified period of time as part of corporate planning. While opting to import some of the technologies, they could fund a laboratory or university with proven ability in India to develop the remaining products on a contractual basis. This would give assured funding to the laboratories or universities and free them from the constant anxiety regarding resources. It would also enable the industry to own the technology, plan and control pilot production, manufacture and marketing. This calls for awareness of global market trends, superior managerial skills and societal concern. Whether our industrial and scientific communities will rise to the occasion is a big question at this time.

Where does the Government come in? Given the present realities in the national economy, public funding can play only a marginal role in the development of medical technology. But marginal need not be insignificant. Government funding of the universities or laboratories for research projects in computer science, tissue–material interactions, materials toxicology and so on may create a valuable reservoir of knowledge which the R&D teams can draw upon for given tasks. But the main role of the Government is regulatory, where the picture is unsatisfactory. The Lentin report told us about the Drug Act and the poor state of its implementation. For medical devices, we do not even have a legislation! Unless a devices legislation is enacted speedily and implemented effectively, a rapid expansion in production can create avoidable problems, including the violation of consumer protection laws.

## Conclusion

Technology has cast its mantle on all aspects of health care, which will continue to evolve in the years ahead. This has serious implications for the economics of health care, quality of treatment, generation of skilled manpower and the development of a health care industry in the country. The present institutional mechanisms are neither suited nor competent to study these issues and formulate a policy because medical technology covers as many disciplines as different areas of scientific and economic activity. Unless a new initiative is taken, Indian industry and health care will stand to lose heavily in the new economic climate. What we have achieved in the growth of pharmaceuticals can be replicated, if not excelled, in the field of medical equipment and devices if we act with wisdom and speed. The time has come for the Indian industry to set up a Bureau for Medical Technology which will watch global trends and the nature of domestic demands, assess the capabilities of the industries and research laboratories in India, advise industry on productive tie-ups with laboratories or universities, liaise with similar organizations abroad and work with the Government on framing workable and fair laws on regulation. Since the health care industries belong to the medium- or small-scale sector, the Bureau can assist them in engineering consultancy and a variety of other services which a start-up firm will need. It can provide support in crises when a foreign manufacturer threatens the existence of a small company. Instead of looking to the Government perpetually, industry and the scientific community will do well to create a self-reliant mechanism for the development of medical technology through the Bureau. To invest in its creation and promotion will be an act of prudence and a vote for our self-confidence.


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