"Made in India": How's that for an indigenous medical device?

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ABSTRACT

With increasing costs of imported equipment, there is a need for Indigenization of medical devices in India. The resources including skilled manpower to develop equipment of a good standard are available in the country. What plagues the developmental process is the lack of adequate interaction between the medical profession and the technologists and reluctance of the industry to venture into the medical device manufacturing. A much bigger and more serious road-block is the lack of formal certification and regulatory processes for these devices. Medical practitioners should be open to evaluating and accepting indigenous equipment that pass the requisite standards. Formal mechanisms should be developed to orient both physicians and engineers to the technical and commercial issues of device development.

Key words: Equipment, health-care economics, indigenization, medical devices, regulation

INTRODUCTION

Medical devices account for a significant proportion of the rising health-care costs in recent years. Public sector, which is a major health-care provider, is finding it increasingly difficult to meet this expenditure. It is a big paradox that a nation that has achieved excellence in space technology and atomic energy is unable to produce medical devices, which are several-fold less complex.

Medical devices form a $200 billion global industry every year. In 2011, India's medical devices market was worth $3 billion (Rs. 16,200 crores) and is expected to grow at 15% annually during 2010-2015[1] to reach $6 billion by 2015.[2] Currently, over 75% of medical devices used in India are imported.[1]

OUR EXPERIENCE WITH INDIGENIZATION OF A CRITICAL CARE VENTILATOR

The travails and tribulations that we have gone through, in developing a critical care ventilator, typify the process involved in indigenization of major medical equipment in India.

In the year 1999, National Institute of Mental Health and Neurosciences (NIMHANS) and Defense Bio-engineering and Electro-medical Laboratory (DEBEL) entered into a memorandum of understanding for technical collaboration. The potential for development of several medical devices was explored of which action on critical care ventilator started immediately. Initially, the scientists planned for a pneumatic design that was unlikely to have met the requirements of an intensive care unit (ICU) ventilator to be used on very sick patients. A new set of specifications were made for a microprocessor-based ventilator with a wider range of functions. The funding was provided by the Society for Biomedical Technology (SBT), an inter-ministerial organization that promotes health-care by providing indigenous solutions in the field of equipment and devices using the spin off technologies from Defense Research and Development and other scientific organizations. PSG College of Engineering at Coimbatore was chosen as the center for developing the technology.

The initial exercise was for the medical professionals to understand the engineering details and engineers to understand medicine. Several rounds of discussions took place among the participating institutions namely, NIMHANS, DEBEL and PSG College of Engineering. A bench model was made through collaboration between professionals from several branches of engineering – mechanical, electrical, electronics and computer sciences.

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Incorporating the complex physiology into an engineering design was not easy. After several months of deliberation, breakthrough came in when a senior scientist from the Defence Metallurgical Research Laboratory, Hyderabad pitched in as a team member. After spending some time observing the ventilators in the ICU and having discussions with the medical members of the team, he brought out a manual that accurately translated physiology of mechanical ventilation into pneumatic, electrical and electronic systems.

The initial stumble block in fabrication was non-availability of some crucial electronic components in our country. Understanding the specifications of these components was easy, but finding a source for their supply was not. Some of them had to be imported and the vendors were not willing to supply the small numbers required for our work. Fabricating them in India was not practical at this stage as each one of them would be an independent project by itself. Many of them were, of course, indigenized later. Perseverance of two young engineers finally, paid-up and active work resumed again. About a year was lost! The initial design was made on a windows-based platform.

Implementing basic air flow patterns for apneic patients was not difficult. But to adapt the flows to patients with different ventilatory patterns, through several modes of ventilation, was tough. Several combinations of flow deliveries were tried. They all worked only within certain limits. The infinitely dynamic flow requirements of the real patient were tough to achieve. More than a year was spent addressing these challenges.

With the key members of the team located in three different cities, communications was heavily dependent on E-mails and telephonic discussions. The gestation was proving itself to be too long. For about a month, the engineering team moved to NIMHANS along with the prototype-in-fabrication. Work during this phase led to some major break-through solutions.

It is a well-known fact that any product will not see the light of the day as long as it is in the laboratories and in the hands of the academicians. Only industry feels the pressure to covert the concept model to a salable product. Realizing this, technology was transferred to a reputed industry with a proven record of manufacturing precision instrumentation for both Indian and imported automobiles.

Transfer of Technology quickened the pace of development. Designs and features were refined. The platform changed form a personal computer-base to an embedded system. Some indigenous components were fabricated. A designing agency was hired for esthetic and practical designing of the product. The members from the agency made observations for several hours at a stretch sitting silently in the ICU and finally provided a user-friendly and esthetic design.

The equipment was ready. The next phase was an ordeal! It was a surprise to realize that there are no statutory processes for certification of the product in our country. Correspondence with some regulatory agencies did not help. Finally, the equipment was subjected to testing as per the IEC 60601 norms, which are a series of standards for the safety and effectiveness of medical equipment.

LESSONS LEARNT

Ultimately, the equipment was ready for use. The journey was long and wayward punctuated from time to time by spells of total loss of sense of direction. However, it enhanced our confidence that indigenization of equipment is possible. The lessons learnt were valuable:

1. With the highly talented technical manpower in the country, development of indigenous medical equipment of a good standard is feasible
2. Indigenization does not mean compromising on the standards
3. There is no dearth for funding of biomedical device development. Technically sound projects do attract funding from governmental sources. Prototypes with a high probability of commercialization attract participation by potential manufacturers; though, the process is not easy
4. Involving an industrial partner early and an early transfer of technology to the industry helps to fast-track the development.

WHAT AILS THE PROCESS THEN?

1. Lack of interaction between the medical professionals and technologists: Very few physicians evince interest in the development of the devices that they need. Technologists believe that the standards of medical equipment are so high that they may not be able to meet the precision and the safety demands. A close interaction between the two would reveal that the design demands of medical devices are several-fold less stringent than those of several non-medical equipments. Medical profession must lead the way to facilitate such interaction
2. All technical knowhow and skills required for development of a device may not be available in a single institution. Inter-institutional coordination and synchronization of the activities is laborious, time-consuming and requires great perseverance

3. Prejudice against Indian product: In general, the Indian medical community prefers imported to indigenous devices. This conviction has been reinforced over years by the bad experiences of some users with substandard equipment marketed by some fly-by-night operators. Participation by the academicians in the developmental process helps to bring out good equipment and augments the user-confidence
4. Attracting the industrial partners with the right skills and motivation: Industry will not be interested in entering the medical field unless adequate business is assured. Marketing skills required for medical devices are different from those required for other equipment, which is an additional demand on the manufacturer. It needs a highly motivated manufacturer to take on all these burdens
5. Inadequate understanding of the technical and commercial issues at the beginning of the project: At times, time and resources are wasted in projects that are ill-conceived at the beginning and therefore, reach a dead-end at some point, with the prototypes remaining museum pieces
6. Lack of certification processes: Certification of the standards by regulatory authorities boosts the confidence of the end-user. The Indian Medical Devices Regulatory Authority Act is in the pipeline, but its time lines seem to be uncertain.[3]

THE NEUROSURGICAL SCENARIO

Neurosurgery is heavily dependent on sophisticated equipment such as microscopes, specialized surgical instruments, endoscopic instruments, neuronavigators, equipment for stereotaxy and deep brain stimulation, not to mention general purpose equipment such as bipolar cautery machines, drills and imaging devices such as intraoperative computed tomography scanners and magnetic resonance imaging equipment etc., Indigenization of at least some of these devices is highly desirable.

ROLE OF INDIAN ACADEMIA AND INDUSTRY IN INDIGENIZATION OF NEUROSURGICAL EQUIPEMNT

The contribution made by some of the Indian organizations is commendable. Sri Chitra Thirunal Institute for Medical Sciences and Technology made Chitra Ventriculo-peritonel shunt tubes and Chitra blood bags that have been major commercial and medical successes.[4] Several private concerns are manufacturing surgical drills, spinal implants, surgical instruments etc., at prices several fold less than the imported equipment. Projects for development of devices such as intracranial pressure monitors, deep-brain stimulators, electrocorticographic electrode grids etc., are going on in several institutions. With a stringent quality control in development and manufacturing, there is a great scope for these devices to become import-substitutes in future.

THE WAY AHEAD

Indigenization of devices is imperative if health-care has to reach the masses in our country. Clinicians with a flair for technology should collaborate with technologists. Interest groups should be formed that comprise technologists, medical professionals and potential industrial partners. Funding agencies must set aside finances for technology development.

Academic institutions should start medical instrumentation courses for medical and engineering graduates. Job opportunities should be created for these professionals. The government should bring in acts for medical device regulation. Facilities must be established for testing the indigenously developed equipment to international standards such that the products would find their way into the international market too, encouraging the industry to take up medical device manufacturing. Clinicians should be willing to accept an Indian product that passes such international standards. Import of devices may be discouraged where an equivalent Indian substitute is available.

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