CHAPTER 4
CONCEPTUALIZING THE RESEARCH PROBLEM AND METHODOLOGY

This chapter outlines a framework for our study of medical technology, in light of the limitations of the perspectives within the traditional sociology of medicine, or sociology/economics of technological innovations streams, and strengthens the social shaping of technology and social constructivist approaches. It ends with the statement of objectives and the method of information collection.

4.1 Limitations of the technological determinist approach

The 'impact'/effect' of medical technology has received a lot of attention in the industrialized countries of the West, especially the USA, since around the 1970s. These studies of medical technology so far have largely focused on the diffusion and cost aspects of several medical technologies. They are largely in the form of studies of adoption and diffusion, and evaluation of impact of several medical technologies in the 1970s and 1980s (after their widespread adoption).

For instance: there are:

- Studies and observations on the adoption of individual technologies (such as dialysis, ICUs, CT-scanners and coronary bypass surgery);
- Observations from a policy angle on the 'high' cost of medical technologies, and to devise ways to get around this and to make the technology available;
- Studies on the process of diffusion of several medical technologies among hospitals and doctors;
- Studies of impact of financing mechanisms, such as insurance, and policy mechanisms on development, and adoption/use of medical technologies
- There are also observations and studies by the medical professionals on specific technologies with respect to their usefulness, efficacy and effectiveness, as well as safety.
- Observations on the ethical and moral aspects of technologies such as the new reproductive technologies and life-extending technologies.

Hence, while there are descriptions of what happens when a technology gets adopted and used in medical practice, there has been no attempt to systematically address the issue of why there is widespread adoption and misuse, despite their supposed role in pushing up cost of medical care, and despite lack of formal evaluation of effectiveness of many technologies. There is hardly any attempt to put together such studies, to identify what is similar and different about these cases, and to get a general picture of the landscape of medical technology.
What one finds is a narrowness of analysis that tends to view the issue of expense and proliferation of technologies, especially of high technology, in medicine as separate from that of the practice and organization of medicine and medical care itself. Although not explicitly stated, the studies are within a broad technological determinism view – namely, that technological changes are an 'inevitable consequence of the inexorable progress of scientific research'. Given these notions of technological determinism (TD) and 'technological imperative' that form the assumptions of these studies, it has been taken for given that there will be 'advances' in medicine and medical technologies; and also that complex, advanced technologies will be expensive. Hence new technologies in medicine are taken as a given, as an independent factor and their 'high cost' is also accepted as given. It is as if a technology has somehow suddenly appeared and then gets adopted into medical practice, and starts having certain effects, desirable or undesirable. Irrespective of whether the studies and views are optimistic or pessimistic about the costs and benefits, it is the technological determinism model that provides the underpinnings.

Furthermore, given that the (TD) approach does not problematize or address the actual development and production of technologies, scant attention has been paid to these aspects of medical technology too. These studies do not address the question of how innovations actually develop; at why we have only these particular technologies and not something less expensive, or less complex, or free of the problems that have been identified. They do not also take into account the larger reality of the organization of healthcare, at the social circumstances of the use and deployment of medical technologies: namely, the nature of modern medical practice and of the healthcare system. They do not look at the relation to and the impact of the larger social context on the nature and development of the healthcare system, or on the technologies, nor on their use and distribution. This is so despite observations, such as the inadequacy of professional dominance theory in explaining adoption of medical technologies, references to influence of commercial forces in the manufacture, marketing and use of medical technologies, and observations on role of the State in development and promotion of technologies.

It is considered not necessary to examine the initial stages of research and origin/development of the technology, as it is assumed that these stages/processes are neutral, objective processes. The evaluation, usually of costs or of organizational changes to adapt to the technology or to make efficient use of it, is taken up well after the technologies have diffused into medical practice, and have become 'standard procedure'. In fact the dominant paradigm assumes that technological assessment can take place only after the prototype technology has been developed, and subsequently, after it has diffused in the health care system. In reality development of technologies
does not always follow such a neat, systematic process, where it is possible to distinguish clear stages of development, adoption and regular use. Earlier studies of medical technologies have found that some technologies were adopted even before they had been fully evaluated for their usefulness and effectiveness. Furthermore, the attempts to apply conventional cost-benefit/cost-effectiveness analysis to medical technologies have encountered several problems, such as in defining the effectiveness of a technology.

The problems associated with a technology are viewed in relation to use of a specific technology and/or as arising from some aspect of the health care system, such as shortage of resources for healthcare or use of excess personnel or the mode of payment for healthcare, or inappropriate use, and so on. This is of limited use if at all; as it assumes that the technology is desirable and so has to be made available to the people. The problem is posed as: how should it be made available within the given resources, which are becoming scarce. The problems and dilemmas that arise are viewed as incapable of resolution, as a price that one has to pay for the putative advances or benefits from the technology. Sometimes the problems are linked to the manner in which the healthcare institutions using the technology are organised or managed, hence it is suggested that there is need for better management of hospitals, or resources, and so on. Hence they need to be managed or regulated by use of some economic or legal instruments, or by adjustments in society (impose limits on hospital budgets, laws to curb malpractice, or to prevent use of technology for a particular purpose, change in attitude/behaviour, limit population size, and so on). Questions such as whether there can be other technologies or other ways of treating diseases even within the biomedical model are either not posed at all or tend to be ignored.

The evaluation of medical technologies after they have diffused is of limited value. As pointed out by McKinlay: 'Many studies of the diffusion of innovations resemble those frustrating occasions when one arrives late at the theater, after a performance has commenced, and is forced to leave before the final curtain. One is never really on top of what occurs, finds it difficult to unravel the relationships between the various actors, and is left wondering how the whole thing ended anyway. Diffusion studies tend to cover what can be termed the midpoints in the career of some new procedure, drug, machine, or whatever. They provide useful information on the most publicly visible stages, but give inadequate attention to either their points of origin, or where they eventually end. By failing to trace innovations back to their points of origin in order to identify the interests and processes that launched them, such studies have limited utility for social policy. And without some understanding of the final stages, social policy upon the allocation of resources cannot be properly informed by the successes and failures of the past' (emphasis added) (McKinlay 1981).
Secondly, by the time evaluations are taken up the technology is found already completely frozen into particular moulds. *Serious problems arise with respect to evaluating medical technologies after they have been adopted in practice, and after there is widespread diffusion*. One is the clearly documented potential of medical technologies to cause long-term damage (for instance use of x-rays and certain pharmaceutical drugs). Secondly, it is seen that once a technology diffuses into practice, it sets off a chain of events, such as: attitudinal changes among doctors - changes in ways of thinking about a disease/health problem, effect on existing/previous ways of performing the tasks taken over by the by newer technology, institutional changes, changes among patients' attitudes. It becomes next to impossible to reverse these events, no matter what the results of the evaluations are or demand. In promoting their cause advocates of a new technology dwell on/highlight the defects or disadvantages of older or alternative methods, and it becomes difficult (if not impossible) to maintain earlier skills or even test out or refine the alternatives.

Another crucial fall-out of this deterministic approach to medical technology (to technology in general) is that *it implicitly denies any possibility of choice in technological development*. In this view therefore, the purpose and scope of study of technology, and of public policy is limited to forecasting and/or monitoring the progress of technology along its inevitable trajectory, to find ways of increasing the pace of innovations, their diffusion, etc., by making available the required resources and removing the obstacles, and promoting the smooth adaptation of concerned organizations and society, in general, to the changes it demands.

### 4.2 Limitations of the social constructivist approach

The review of literature on approaches to technology (chapter 1) has brought out the existence of studies of technology in the social shaping approach, which have addressed many issues regarding technology and its development, and its relation to science and to society. They indicate the range of issues that need to be kept in mind, to be addressed in study of technology. The social shaping of technology view (SST), and the social constructivist models, began to be articulated since the 1980s. *What defines studies in both these perspectives is the attempt to demonstrate and analyze social influence on the origins and development of technologies, on their use and deployment, and on the direction of technological change*. These studies indicate that the notion that scientific research leads to technology (technology as merely applied science) and the subsequent linear model of technology development/innovation are not very tenable. Technology does not possess some inner logic of its own, nor does it 'progress' in a uni-linear fashion. It does not simply come about as a result of its own 'inner logic', but is also a result of a series of social choices. The forms of technology one sees today are not the only options. There are other forms and ways in which it could have developed. This is not to say that there is infinite number of options in technology.
While there are limits imposed by the laws of nature, and questions of design, feasibility, etc., still the development and growth of technology has been intimately linked to the social system and the choice is shaped by many social factors. Thus, there are both social and technical aspects to technological innovation and its use.

The social constructivist approach focuses on social shaping at the micro-level, at negotiations and consensus building processes between the individuals (actors) concerned, and cultural aspects in the development and use of technology, and on aspects such as role of meanings and values attached to technologies, and shaping of knowledge in and about technology. The `thick description' characteristic of the social constructivist and social construction of technology (SCOT) studies tell us about how choices were made from a range of options, or about how certain kind of knowledge has been created, or about power relations between groups involved. While considering social influences on innovation the vision is restricted to individuals or small groups of individuals involved in the innovation process. The larger social influences on an individual or a group of individuals that shape the ideas about the technology and about the problems that it seeks to address remain out of the radar screen. These studies do not provide answers to why we have these technologies to begin with, or to the question of dominance of certain kinds of technologies in healthcare. The couple of studies of medical technology in this genre, respectively by Yoxen and Blume, look at the content of technology in a limited way, in terms of how images of the human body are created, and how they are to be interpreted – namely at creation of certain kinds of information/knowledge about the body by imaging technologies. The implications of such knowledge-constructs in real-life situations, where the technology is likely to diffuse widely in different social milieus, and is likely to be used on people are issues that are not considered.

However, the social aspects of technical innovation and development are not restricted to just individual agency and individual inclinations, motivations and aspirations, or even to just small groups of individuals and power relations between them, as the social constructivist models tend to convey. A major limitation therefore, of these micro-level studies is that by focusing on the immediate interests, actions and solutions of specific actors/groups, this approach disregards the possibility that there maybe deeper processes located elsewhere in society which may not always be visible. For instance: the influence of cultural values of capitalist societies, such as of technocracy and of consumption. Because of this limited vision, the studies in the social constructivist genre, like the TD studies, do not at all consider the field in which the technology is deployed – namely medicine and healthcare systems, and at whether they could have any influence on the technologies developed. Lastly, the limitations/problems of `relativism' and interpretative flexibility' advocated by this approach have already been discussed in a previous chapter.
A case for some realism derives from the far-reaching worldly implications and experiences of technology in the real world, and more so from the intentions to transform and extend human capabilities by material means and through technological innovations. A useful theory of the relationship between technology and society needs to address more directly the characteristics of the material world. It is also true that while technology may not determine human capability but it does constrain it; while it does not cause particular social changes, but does and can change the parameters on which humans interact.

4.3 Potential of Social Shaping of Technology

In contrast to the studies in the technological determinism (TD) and the social constructivist genre, those in the SST model show that modern technology is also linked to, and is an integral component of the larger industrial system. Hence technology cannot be located within an isolated trajectory of technological transformation alone, but needs to be also located in the context of the larger social structures of production, as well as deployment and use. In reality several actors are involved in development of technical innovations and their production – producers, consumers, universities, laboratories, government agencies, managers and several intermediaries – and the picture is pretty complex. Since the mid-twentieth century much technology, particularly the so-called advanced, 'high technology' (high-tech) has come to have an important public component as well as a private one. There has been considerable public involvement in inducing and supporting technological advances in industry, such as by imparting technological knowledge through scientific and engineering education in publicly funded universities, and conducting basic and applied scientific research. In areas such as agriculture and medicine there is a large component of government generic research focused on needs of industries (the recent support to biotechnology being the best example). Applied R&D, which has a significant chance of leading to proprietary production, has been left largely to the private industry. Industrial research laboratories have become important sites of creation of new technological products and processes, through the use of scientific and technological expertise, economic considerations and marketing skills. Several researchers have written about the need to incorporate these aspects into the SST approach. Furthermore, it has also been pointed out that it is not enough to look at how a technology is developed, but one needs to also look downstream of development, at how it is marketed/sold/promoted and used.

The studies on production of pharmaceuticals, and Blume’s work on the role of radiologists and the industry in development of imaging technologies, indicate patterns and relationships that are instructive. They point to an organic link between the professionals/experts’ in the medical
and industrial system respectively, in which the state plays an important role. One can discern certain common characteristics between the production of pharmaceuticals and that of the 'hard technologies', namely medical equipment. The two are 'knowledge-intensive' manufacturing industries, based on 'science', and, as earlier mentioned, the creation of this knowledge has an important public component; the products of both are intimately connected to the human body; both are dependent on the medical profession for creation, manufacture, distribution and consumption. Finally, these technologies are exclusively developed and manufactured by private parties, for whom profit is the major consideration.

Studies in the SST perspective have, so far, largely looked at social influences in consumer, military and industrial production technologies, and in recent times at information and communication technologies (ICTs). Not much attention has been paid to medical technologies.

As pointed out by Russell, to understand the specificities of technologies there is need to understand the nature of the domain, the field, in which the technology is used and adopted. For our purpose therefore, an important dimension to understanding and evaluating medical technology is to locate it in the context of the overall medical and healthcare system. Insofar as the medical technologies that we see and experience today are the major component of contemporary healthcare systems (the modern hospital as the center of healthcare as well as of medical technology), and their producers, users and promoters all profess to be concerned with the health of the people, we need to view them against these complexities it is entangled in. McKinlay has pointed this out in another way in his studies of healthcare systems. According to him, as long as the medical-industrial complex is viewed in terms of its own internal logic, it would appear 'inexplicable' and 'unmanageable'. It is necessary to understand what is happening in healthcare and the logic that the organization of healthcare imposes on all medical care activities. In McKinlay's view the possibility of a competing external logic and the potential offered by its use must be considered. As he suggests, in the specific context of proliferation of unevaluated high technology anywhere in the world, it is necessary to trace it to its principal source: which is the worldwide invasion of the medical care sector by large-scale financial and industrial capital (McKinlay 1980).

In an earlier chapter we have reviewed some of the social-historical processes that have shaped the genesis of modern public health and medical care systems, and how they have developed over time, and the place assigned to technology within this system. Public health has got reduced to 'the application of scientific and medical knowledge to the protection and improvement of the health of populations'. In this notion of public health, technology holds the solution for most disease and ill-health, and public health itself has become a sub-discipline of
medicine, which in turn is organized around use of technology. There is conflation of 'health care' with 'medical care' and clinical services. Despite the pervasiveness and the increasing role of technology and technical solutions, they are not given adequate and critical attention in public health. There is no scrutiny of the kind of technologies that are adopted and promoted. Essentially, there is a spill-over of the TD and the 'technological imperative' approach from modern medicine into public health. Within this biomedical and clinical notion of public health, there is a pre-occupation with medical/healthcare services, and what is called health systems research (HSR). The focus of inquiry of HSR happens to be organization and financing of medical/health services, on improving their efficiency and effectiveness, on specific sub-systemic tasks (such as immunization, disease control programmes, improving working of a hospital), on controlling costs, on community and regional resources, on disease profiles, on priorities among disease control, programme evaluation, on generating new knowledge and technology for diseases such as hypertension, cancer, etc. The health services are analyzed as an autonomous sector, and the macro political, social and economic forces that underpin and could explain their policies, organization, and financing are rarely taken into account. However, the organization of medical care/health care cannot be understood solely with reference to medicine, or to the relation between doctors and patients, or even all of the forces internal to the healthcare sector. The development of medical care, like other institutions in society, takes place within the larger framework of social and economic forces (Banerjee 1985). Developments in the social medicine perspective look at how social conditions affect health, disease and the practice of medicine. The political economy perspective questions the biomedical model for its narrow focus on single causative factors, and focuses on the political, economic and social factors that shape health, disease, and ways of treatment (Navarro 2004).

Recognition of these larger structural forces that influence medical technology, medical care and health care systems then has a profound influence on the very issues selected for investigation, and the concepts and levels of analysis adopted to explain them.

4.4 Framework for this study

Any attempt to conceptualize technology in medical care must be able to encompass the social dimensions of that technology, rather than a narrow conception solely in terms of procedures and machines that are used by the medical professionals on sick individuals. As opposed to the prevailing TD model, this thesis adopts a social shaping of technology approach. Furthermore, the framework adopts a social medicine approach, which emphasizes that social and historical processes are determinants of the relationship between health, disease and healthcare systems.
Thus, our understanding is that both, the development and diffusion of medical technology and the development of systems of public health are related, and that both are determined by historical and structural elements internal and external to them. The thesis adopts a methodology wherein a historical perspective is used to enrich qualitative research on medical technology. The study of development and diffusion of medical technology in India is situated in the context of the developments in the larger public healthcare system, and both are examined in a historical framework that incorporates social dimensions, namely economic & political, and also devotes attention to the actual technology itself.

While it is important to look at the social context of technologies, in our view an important element in study of medical technologies is to also pay attention to the actual technologies themselves, to their content, the attributes/specific features of the technologies, to how they are developed and produced. This study tries to develop an understanding of the technology at two levels:

(i) The development and production of medical technologies. Herein innovation, development and production are looked upon as including stages of adoption, diffusion and utilization.

(ii) Understanding the technology in terms of safety, efficacy and effectiveness, and their need, desirability and ease of usability, as far as health systems are concerned. These are, features that are neglected/systematically overlooked in studies of technology, but should be actually accorded priority at all stages of development and use of medical technologies. Rather, they should be an integral part of development and assessment of medical technologies.

Our review of public health and healthcare also covers the healthcare system in India that has emerged out of its colonial past. It indicates that developing countries such as India have, by and large, adopted the patterns and values of modern, western medicine and the corresponding models of healthcare. Medical care and healthcare, and medical education are all oriented to the standards of the West. The significance of medical technology for developing countries, particularly India is an area of particular interest and concern. Unfortunately, there has been very little work on medical technologies in India, an exception being the manufacture and trade of therapeutic drugs and pharmaceuticals. There has been no attempt in India so far to systematically study medical technology, of the nature and spread of technology, their relative place in the health-care system, on the need and desirability, usefulness, reliability, patterns of utilization and costs of these technologies. References to medical technology are incidental to studies and discussions on privatization and specialization of medical care, and in context 'of overuse/misuse'. There is paucity of primary data on the kind of medical equipment and techniques being introduced, on their procurement, diffusion, costs, distribution, and accessibility.
Given the nature of the healthcare system in India - marked by increased pace of commercialization of health services, increasing and deepening inroads into it of corporate interests and withdrawal of the State - and given the current processes of liberalization and privatization, the subject of development, manufacture, adoption and international trade of medical technology assume greater relevance and importance. Given the need to consider processes downstream of production of technologies as part of the production process itself, the thesis looks at processes of acquisition and utilization of medical technology in specific contexts. The situation prevailing in India vis-à-vis the nature of medical care and growth of private sector provides an opportunity to address issues of effect of nature of medical services and of socio-economic factors on diffusion and utilization of technology. One can develop a detailed case study of the considerations underlying commercialization of technology and their implications for public health and for society at large.

4.5 Objectives

The following were the objectives of this study of medical technology:

A. To study the elements of development and production of medical technologies. In this regard there were certain specific issues in mind. One was to get a general picture of how medical innovations have come about so far, the considerations/criteria used in development of innovations; the historical development of the medical equipment industry, its involvement in development and production of medical technology, structure and activities of the medical equipment industry; its relation with the medical profession, and how it influences medical work and practice; arrangements for distribution of technology: pricing issues.

B. To examine the features of some specific technologies that are considered to be advanced, sophisticated technologies, currently highly 'visible' and being widely promoted in India. This study examines the efficacy and safety of imaging technologies of X-ray, CT-scanning (computerized tomography), ultrasound and MRI (magnetic resonance imaging), and some others used in cardiology – the intensive care unit and bypass surgeries.

C. To study procurement of medical technologies and the structure of the medical equipment industry in India, as well as their diffusion and provisioning, to look at the nature and spread of technologies, forms in which it is being commercialized, price of technology, policy issues and role of government in these processes. The specific areas of study were: (a) activities, behaviour and role of medical equipment industry, in general, its relation with the medical profession. (b) Role of State, State policies relating to medical technology and factors shaping them since Independence. (c) Provision of technology to the public in the present health care system.
The expected outcome was to identify issues of significance for public health in the development and production of medical technologies.

4.6 Design and Tools

Design

While medical technology was of central interest in this study, however, the study itself has been motivated primarily by public health concerns about the development, place, and use of such technology; the larger context was that of public health issues and policy. At the outset it was not very clear as to what aspect of medical technology should be focused upon. No conceptual tools were readily available from within public health for this purpose. During the initial exploratory phase of literature review, semi-structured discussions were also held with some doctors associated with leading hospitals in Delhi (Sir Ganga Ram Hospital, St Stephens' Hospital; All India Institute of Medical Sciences and Ram Manohar Lohia Hospital), to be able to identify possible focus areas, and to also explore the feasibility of undertaking hospital-based study of utilization of medical technology. Based on the discussions with them it emerged that the latter would be a difficult proposition, since medical equipment was distributed across different departments in a hospital, getting information and even permission for a study would be a hurdle. In addition, it emerged from these discussions that equipments were expensive, that there was the practice of commissions among doctors for referral for use of technologies, that imported equipment were better than locally made ones ('it is like the difference between driving an Ambassador car and a Honda City car'), that maintenance of equipment was a problem. As one doctor, with experience of working in both a reputed tertiary public hospital as well a reputed private one pointed out, 'there are a lot of opinions and views, but no concrete information' regarding acquisition and utilization of medical equipment. It was not very clear how, and whether, hospital-based study would adequately answer the kind of issues that were gradually coming into focus. From the literature work too the area of development of medical innovations, production and diffusion of medical technologies emerged as an area that was inadequately studied, especially in the Indian context. In light of such considerations the objectives of this study were formulated as stated above. Namely – to study the elements of development and production of medical technologies, with the specific case-study of India.

Tools

Qualitative, observational and descriptive information from studies, published in medical and other journals, and primary information from several sources has been collected, as detailed below.
Objectives stated in A and B above—namely, study of development and diffusion of medical technologies and of some features of medical equipment, were undertaken through study of existing case studies and other published work on medical technologies, which are available in sociological and medical literature. Primary data on the medical equipment industry at the international level was collected from medical business intelligence journals, such as Clinica, Medical Device Business News, Medical Imaging, Medical Device and Diagnostic Industry, International Journal of Medical Marketing, routinely available primary data from government and industry (statistics of industrial production and of foreign trade), observation of specific real conditions from newspaper reports; from advertisements and websites of various companies as well as of business journals. Substantial information on the international medical equipment industry was collected from University of Cambridge Library, Cambridge, between March-September 2002, where several medical business journals were freely available. A word is needed here about access to information on the industry. Information about demand, growth trends, trade, in the 'healthcare industry' and medical equipment industry, is available largely in the form of exorbitantly-priced market research/market intelligence reports. It has not been possible to get these reports in Delhi. Relevant portions have been accessed from summaries of these reports, posted on the respective websites and/or carried in the medical business journals named above. Hence, there are gaps in the information on time-trends in production, markets, etc.

Objective C—study of the medical equipment industry in India, utilization and status, was done by—Semi-structured discussions with government officials (in the Ministry of Health and Delhi government Department of Health) to get information about government role vis-à-vis equipment procurement and regulations; with some business executives (from Philips Medical Systems and Agilent Technologies, the medical equipment wing then of Hewlett-Packard), and suppliers at exhibitions; with industry associations, specifically the Medical Equipment Division of the Confederation of Indian Industry-CII, Delhi. Primary information has been collected from statistics, information and/or reports put out by the industry and government, by looking at advertisements and business newspaper reports, and attending exhibitions of medical equipment suppliers in Delhi. Tender/bid documents have proved to be a useful source of information on procurement of medical equipment for government hospitals. Reports of the Comptroller and Auditor General of India were another valuable source of information on both, the procurement as well status of medical equipment in the government hospitals.

It emerged that government statistics on production of medical equipment in India is riddled with problems. In the course of our information collection we found that information on production of 'medical electronic equipment' was available with the Department of Electronics; whereas
information on production of 'medical instruments and appliances' was available in the Annual Survey of Industries compiled by the Ministry of Statistics and Programme Implementation. The latter source also covered some items of medical equipment such as ultrasound scanners and X-rays that were also covered by the Department of Electronics. However, the figures from these two sources did not match. Furthermore, systematic, disaggregated data on individual items within the category of medical instruments and appliances was not being compiled regularly by the Annual Survey of Industries. Given such constraints, information on the medical equipment production in India should be considered to be indicative of overall trends rather than a detailed compilation of production figures.

REFERENCES

