Chapter 7

Summing Up the Study and Recommendations

7.1: Introduction

Preceding Six Chapters have extensively debated theoretical and policy related issues concerning governance of healthcare technology in general and policies and practices related to safe use of medical devices. It started with the diffusion of technology into the health domain, debated the challenges emanating from the penetration of technology into the health domain, emerging global framework of governance of healthcare technology, policies and public debates on governance of healthcare technology in India and finally, policies, debates and practices concerning use of medical devices in Guwahati city. The study brought in critical issues and debates and attempted to focus on the danger in the free ride of technology in healthcare. It has also brought in the interest of the different forces in pushing technology into the healthcare domain and the nexus that has been built around technology by the manufacturers, promoters and distributors, user institutions and the practitioners. It is such a nexus that it cannot be challenged by piecemeal interventions. It needs comprehensive and consistent policy interventions.

7.2: Summing up the Important Arguments

a. The present work being a qualitative study, it developed the theoretical conceptions based on published works of host of authors, but primarily from Michel Foucault. Through the theoretical construction of power and dominance, healthcare technology is examined critically to understand how it exerts a form of power & control to the elite practitioner based on their specialised knowledge over human body, ailments and technology.

b. It has been argued that in the form of specialised knowledge, the healthcare professional in general and physicians in particular gather power over human population, to exert overt or covert influence. Physician by its power of ‘medical
gaze’ constructs the conceptual atlas of human body and allocates ‘spaces’ for known and unknown diseases. In doing so the physician attains a status of privilege and power. Infusion of technology in healthcare adds to the already existing pool of specialised knowledge body by further augmenting its potency. In modern healthcare, technology is seen as the driver of newer achievement in the form of newer drugs, devices and specialised procedures. What is to be noted is that healthcare technology being a large domain in itself, it is not possible to study entire gamut of healthcare technology at micro-level. Therefore, the present study concentrated on the issues related to medical devices which are used for diagnosis, treatment or rehabilitation of various sicknesses.

c. Following a review of earlier works by various researchers, present study arrived at a conceptual framework on diffusion of technology and the accompanying challenges. Technology being a product of applied research based on evolving new knowledge on basic sciences, it has brought in difficult challenges for regulation. As basic research is not regulated, the outcome based on new knowledge from basic research needs to be assessed later. On corollary it can be stated that regulations need to wait till after assessment of newer technology. Health technology assessment is seen as a new science that has to be given importance, for shaping regulation. Present study strengthens the prevailing legitimate view of giving health technology assessment an independent academic existence.

d. Diffusion and adoption of technology has changed healthcare in last few decades at a very fast pace. Introduction of technology centric healthcare has resulted in rising cost of healthcare, without desired parallel increase in health of the world population owing primarily to the issues of access. Access to healthcare technology in itself is a challenge for most people of the world. Apart from affordability, availability, health system architecture and other issues like adoption of technology are seen as challenging barriers to equal access of healthcare technology. Present research has summarised the problem of access to healthcare technology, which is a fertile breeding ground for health inequality and health insecurity. Problem of access to health technology has in fact become a primary challenge to modern technology driven healthcare.
e. On examining available evidences and reports, prior works by various researchers the next big challenge of technology centric healthcare is identified as ‘profit from sickness’. Acquisition of health technology by privatised or profit seeking healthcare facilities have posed a big threat to universal aspiration of ‘health for all’. Healthcare has become a domain of profit rather than service for most pharmaceutical companies, device industry and care delivery system that work for profit. Expression of profit motives are subtle and at times high healthcare costs are justified in the pretext of large research and development expense of innovation that leads to newer technological products.

f. The study highlights problems centering the primary ethics of healthcare, ‘primum non nocetum- first do no harm’. Technology dominated healthcare in itself has become a cause of ill health and physical harm, giving rise to the concept of Iatrogenesis. Present study has exhaustively reviewed the existing literature of iatrogenesis arising from technology use in healthcare. Based on the research, present study examines the issues of governance to develop a culture of safe use of medical devices in general.

g. Governance models for medical devices of European Union, Japan & United states of America is studied considering the fact that the three geopolitical entity controlled development and dissipation of most medical device apart from the fact that they are the largest consumers of health technology in general and medical devices in particular. The learning from the three models can be summarised as –

- There is need base regulation depending on risk stratification of the devices,
- There is a prevailing mechanism of monitoring of certain medical devices with a mechanism of recall of such product,
- Premarket approval or licensing requirements are necessary for certain products
- There is provision of clinical data gathering, before approving medical devices in a phased manner
- There is recommendation of Good manufacturing practices for industry of medical devices Quality control and certification of quality exists.
h. Based on understanding of the internationally existing mechanisms of medical device regulations, the study examined the state of medical device regulation in national and local level. Policies, institutions and practices are examined at national and local level for state of Assam by the present study. The chief findings of the study on present state of medical device governance are:

- The process of medical device governance & regulations are still in evolution,
- Medical device definition and conceptual separation of device from drugs is yet to happen.
- Most devices being imported from abroad national policies regarding manufacturing, quality control or certification of product are yet to evolve in tune with international community,
- Certain interim measures are adopted by the central drugs standard control organisation, to govern few notified critical medical devices, but a more inclusive approach is lacking at present.
- There are pending bills in parliament concerning medical devices, which are yet to be debated and enacted.
- The infrastructure to oversee large number of device manufacturing unit, importers or users do not seem adequate both at national or local state level.

i. Present study intended to understand the public perception on healthcare technology considering the impact of technology on the basic issue of health. A review of all health related publications were made that appeared in most prestigious Economic and Political Weekly from 2008-12 and to the surprise of the researcher no debate or concern towards emerging threats of health technology in general or medical devices could be identified. This indifference towards health technology debate is significant considering the fact that there were two emerging bills submitted by department of science and technology and another by ministry of health and family welfare to regulate health technology. Similar conclusion is drawn based on review of The Assam Tribune, 2009-2013. Issues of health policy, universal health, rural health, National rural health mission, Various challenges of disease and public health found their mark in the pages of EPW as well as the Assam tribune, but health technology related issues, specially on its challenges and governance were conspicuously missing.
The researcher concludes that the specialised nature of the subject and lack of easy reference on healthcare technology centric debate is the primary reason of its great escape from mainstream socio-political debates. A meaningful debate on healthcare technology has to involve participation of social scientists, activists with active participation from healthcare practitioners, health policymakers, physician and finally the healthcare industry. An appropriate platform seems lacking for convergence of the various stakeholders on health technology issues.

Empirical survey work, done as a part of the research highlighted the state of non-uniform practices in high technology areas such as medical imaging. Though the safety climate of the surveyed facilities were good but whether a general inference can be drawn on safety climate of all medical device use in the state is questionable. The factors contributing to a positive trend can be identified as - in the city of Guwahati, presence of centres with some quality certifications like ISO by many surveyed facility, monitoring of certain radiation related equipments by a national body (Atomic energy regulatory board) and the fact that most of the equipment used by these areas are imported.

The researcher argues that in absence of quality certification (which is the case for most health facilities of government as well as private health sector) or in areas where devices are used without national regulatory mechanism (which is the state for many devices), or in sectors where locally manufactured devices are used or there is reuse of refurbished equipments the state of safety climate may not be same. This point needs to be further substantiated by further researches in the field.

7.3: Recommendations

Based on the current research work, the researcher is of the opinion that healthcare technology needs full attention by the discipline of social science, to bring in lively debates on various challenges of technology dominance of healthcare and also to suggest process of governance. Based on the present work researcher intends to place the following humble recommendations:

**Policies**

- The need of the hour is to adopt a more inclusive regulatory framework for medical devices. The pending bills need to be debated in the Parliament thoroughly. That
apart, all the pending Bills should also be made available to the public for debates and opinion;

- The policy on medical device must distinguish devices from drug, and separate classification, risk stratification; graded regulatory effort should find its place.

- The new policy should be harmonised with international regulatory principles.

- For promoting growth of home grown medical device industry the quality approval process of United States, European Union, Japan etc may also be considered. However, the Indian context, considering the diversity and interest in indigenous practices, quality approved process must address the local issues too.

Institution & Infrastructure

- India being a large country in terms of population and geographic expanse it is imperative that a decentralised effort at governance is the need of the hour. It can be argued that a central body or authority for governing medical device may be inappropriate unless it also has number of regional arms and ramifications.

- Building multiple state level infrastructures, testing laboratories and regional regulatory centres for medical device with uniform standard is seen as an effective tool of building a uniform regulatory environment by various committees, including the Committee led by Dr Mashlekar which is already discussed.

- The state level regulatory agencies may be entrusted with the enforcement and data gathering functions on medical device manufacturing, post market surveillance etc. Licensing of medical device manufacturer & import licensing of medical devices can be delegated to regional level only for Class I & II medical devices, but all class III devices need to be controlled at the central level.
• Device classifications, hearing of appeal, formulation of policies and establishment of sophisticated training centres for regulatory manpower generation needs to be given high priority at central level.

**Defining Standard of Practice**

• It is necessary to bring in healthcare accreditation concepts to the country encompassing both government as well as private healthcare facilities. Accreditation of healthcare facilities can work towards harmonizing practices concerning various healthcare technologies based on recommendation of physician, nursing & technologist national councils or bodies.

• Healthcare facilities based on accreditation status should be allowed access to sophisticated technology.

**Defining Health Care Cost & Pricing**

• To rationalise profit seeking motive of the large private healthcare industry, expert panels, physician bodies need to be created for a framework on pricing of various medical services that used different device or consumables.

• The present government rates of reimbursement, is insufficient as many of the services do not find mention. Moreover government recommendations do not consider rising inflation, cost of technology ownership and rising manpower cost. The cost calculation by stakeholders should be periodic and done in a transparent manner, leaving room for examination by auditors. Based on recommended base line pricing, accredited health facilities should be allowed to charge for services. It may be necessary to take into considerations regional taxes and levies, nature of geographic location however a base line recommendation by expert panel can go a long way to rationalise unhealthy pricing.
**Health Technology Assessment**

- Health technology assessment (HTA) should be given a status of emerging academic discipline and graduate –postgraduate level courses should be introduced in Indian universities.

- A national authority on health technology, with advisory power to the government can be constituted for settling all technical debates concerning newer issues.

**Stake Holder Participation**

- All health facilities should be directed to follow prescribed ‘standard operating procedures’ prepared by concerned physician bodies.

- Healthcare industry should be directed on compulsory user training to device users.

- Health industry should be subjected to strict compliance for maintaining of database on adverse events arising out of device uses, that can be accessed by Health technology researcher for long term research on technology outcome for proper evaluation.

- Mandatory documentation of training on sophisticated health technology before clinical use by technologist or physician should be considered. Training and accreditation of such programmes may be locally done by academic arm of the concerned specialities.

- Finally governance of medical device needs to be accomplished through a concerted effort of professional bodies of physician, nurses, other healthcare workers and technologists and involvement of these organisations for prescribing best practise on various technological products must be accomplished.
7.4: Conclusion

It is evident from the study that health technology has also given birth to newer power relationship, a relationship of inequality and also domination and subjugation. Profiteering over health distress is a dominant feature in the technology driven healthcare. Therefore, paradigm of governance given by pro-profiteering institutions may not solve the problem. Accordingly, the study has extensively argued for enactment of policies. However, the policies themselves have to have a philosophy of ensuring peoples’ right to health. In other words the policies have to be people-centric. Such an argument is easier said than done. Current politics reveal that change in policy has to be linked up with peoples’ movements that asserts for liberation from multiple forms of domination. In the present healthcare system, people need liberation from technology driven profiteering and subjugation. The policies on health technology have to address this important political question.