Chapter 1

Introduction

1.1: Statement of the Problem

Health has received wider attention in the contemporary discourse on development. United Nations Development Programme (UNDP) in its own parameter of development defined as Human Development Index (HDI) considers issues related to health as a core determinant in human development. Millennium Development Goals (MDGs) also accepts health as significant priorities of development in the new millennium. Accordingly, the national governments around the world including India attempted to redirect its growth oriented development to more ‘inclusive development’ where health is getting significant priority. In case of India, the Economic Survey, the annual financial publication of GoI, now has a chapter on issues related to equity, environment and human development where health is a core issue. United Progressive Alliance (UPA) government which is in power in the country since 2004 has been publishing an Annual Report titled *UPA Government: Report to the People* in which too health is a core issue. National Health Policy 2002, National Rural Health Mission enacted in 2005 and presently in operation as well as the Draft National Health Bill 2009 project health as crucial determinant in the process of development. All these have focused on investment in public health, access and equity in health care system, issues like Infant Mortality Rate (IMR) and Maternal Mortality Rate (MMR) as well as gender equity in health etc.

The healthcare system, particularly at the secondary and tertiary level is taking a complex turn with technology penetrating into this domain. At tertiary level the healthcare system is gradually becoming dependent on technology. In other words, what is emerging is a technology-driven healthcare system. Generally, technology is perceived as instruments that facilitate universal empowerment. Technology is not believed to be biased i.e. an instrument that discriminates. However, in the contemporary world, technology is controlled both by the state and the corporate agencies. Accordingly, it is the state and the corporate agencies who decide how to use technology and also in whose interest. In other words, technology itself is an apparatus of influence, control and also accumulation of profit. This is true in case of health technology too. However, this dimension of health care technology is yet to draw
public attention. In development discourse too, these important issues of healthcare technology having implications on social equity are yet to capture important space.

Present study titled *Governance in Healthcare Technology: A Study on Policies & Practices of Safe use of Medical Devices* is an attempt to understand these challenges of technology penetration in modern healthcare system. The study is primarily a qualitative one which focuses on the emerging policies as well as policy deficit in governing healthcare technology. However, the study also has a micro level empirical study which is carried out in Guwahati city- the emerging centre of technology driven healthcare establishments in Northeast India.

1.2: Origin of the Research Problem

The present study originates in a researcher’s growing anxiety with phenomenal diffusion of healthcare technology without corresponding regulatory mechanism. For a practitioner of healthcare technology, as is the case with the present researcher, the anxieties invite thorough and comprehensive investigation into the relevant issues related to both diffusion and governance of healthcare technology. Growing assertions of people for rights and justice make a researcher bound to investigate these issues constantly referring to questions like who controls healthcare technology and whether it contributes towards equity in the healthcare system or not. Following issues were instrumental in determining the present study.

*Phenomenal Diffusion of Healthcare Technology*

Every day more than 50 000 different kinds of medical devices are estimated to be used in health care facilities and elsewhere all over the world\(^1\). In 2000, the estimated one and a half million different medical devices available on the market represented over US$145 billion and it is expected to exceed US$260 billion in 2006\(^2\).

Considering the impact of technology over medicine, World Health Organization (WHO) undertook several studies to assess the ground situation. WHO estimates that around 95% of the medical devices in developing countries are imported, much of which does not meet the needs of national health care systems and is not used effectively and efficiently.\(^3\) This has far-reaching implications for health care delivery and represents a deplorable waste of scarce resources. It is critical, therefore, that countries have a medical device management policy.
Of late use of CT scans has increased rapidly. According to a survey conducted in 1996, the number of CT scanners per 1 million population was 26 in the United States and 64 in Japan\(^4\). It is estimated that more than 62 million CT scans are currently obtained each year in the United States, as compared with about 3 million in 1980\(^5\).

At the national level, there is diffusion of various healthcare technology in India but there are very few statistics available on the quantum of technology diffusion in the Indian healthcare system and their regulations. As per 2011 Annual report of the Atomic Energy Regulatory Board India has close to 40,000 X ray facilities, 3000 CT scanners and more than 300 Radiotherapy equipments.\(^6\) Apart from radiographic, radio-therapeutic equipments one can look into the case of Dialysis machines. Dialysis is a technique of replacing & filtering body fluid in cases of terminally ill patients of kidney diseases. There are many types of dialysis and one of the most prevalent form is haemodialysis, where a sophisticated filtering equipment is connected to the patient’s blood circulation to filter it from the waste products. As per available market report number of dialysis machine in India has increased more than 100\% in a span of 5 years. The market estimate of dialysis equipment in 2006 was 4365 units which has increased to 8487 units in 2011.\(^7\)

**Private Sector dominated Healthcare Technology and the Profit Motive**

Emergence of private players as the dominant forces in the domain of healthcare technology under the present neo-liberal economic regime also invites critical investigation of healthcare technology. A cursory look at the dominance of private players in the healthcare technology in India may make the point clear.

Growth of private healthcare sector has been a phenomenon in Neoliberal era, and healthcare in India is not an exception. There is rise of large private sector healthcare organisation which is fuelling the market of healthcare technology adoption and subsequent diffusion across the country. In 1992-93 the private health sector accounted for 2.5\% of GDP and in 2004-05 it is estimated at 5.6\% of GDP. During the same period public health spending increased marginally from 0.74\% to 0.92\% of GDP but it was much lower than the 1.5\% of GDP it had peaked in 1986.\(^8\)
In India industry experts calculated that over 50% medical devices and equipments are imported\(^9\). The government has consistently worked towards reducing import duty on medical equipment and technology. As per Union budget of 2010-11, government had reduced customs duty of medical devices to a standard slab of 5%. Further benefit to the healthcare industry is given in the form of tax incentives. To facilitate financial flexibility to healthcare institutions, the Indian government increased the depreciation rates for essential equipments and consumables from 25% to 40%. This in turn allows considerable amount of tax savings while computing the tax returns for the hospitals and healthcare institutions.\(^{10}\)

Hospitals and Healthcare Institutions were conferred with Infrastructure Status, than an Industry status providing long term capital for private hospital projects. Medical tourism generated revenue of $ 600 million in 2006 with over 0.5 million international health travellers visiting India during the same year\(^{11}\).

It is a matter of concern that profit motive of privatised healthcare has precipitated the problem of unethical practices, such as medical practitioners receiving commissions of between 10-30 percent from private providers of diagnostic services in lieu of referrals\(^{12}\).

**Harmful Effects from Healthcare Technology**

Publication of the U.S. Institute of Medicine’s 1999 report *‘To Err is Human’*\(^{13}\) ignited concern about healthcare error and patient safety. Since publication of the report, much attention has been focused on adverse events (AEs), including medical error that compromises patient safety. Important factors contributing to patient safety problems include rapid changes in the health care system, increased use of technology, increasing complexity of modern healthcare technology and the quickening pace of work\(^{14}\). Data from the United States of America (USA) suggests that technology related complications accounted for 13% of adverse medical events\(^{15}\). A United Kingdom (UK) publication reported that 400 people die annually in the UK from adverse events related to medical devices\(^{16}\). That equipment failure was responsible for between one fifth and one half of all adverse events are supported by various reports\(^{17}\).

Estimates suggest that 5,000 to 8,000 new health technologies, the overwhelming majority being medical devices, come to market in the US each year\(^{18}\). There is considerable variability in how technologies come to market. In case of new medicines or drugs, there are
laid down standards of trial and new product must pass effectiveness and safety hurdles (at least as compared with placebo) before entering the market, whereas healthcare technologies such as ‘procedures’ emerge within the medical profession with little or no scrutiny. Medical devices fall somewhere between pharmaceuticals and procedures in terms of scrutiny, but in the USA, clinical data are rarely required for market approval with fewer than 100 devices undergoing full pre-market approval (i.e., safety and effectiveness) annually.

Concern for un-intended harm from use of technology may be better understood with an example. Computed Tomography scans or in short CT scans are very sophisticated modern diagnostic equipments which are used in various situations. At the heart of CT scanner lies a source of X Ray radiation. There are recent studies regarding CT imaging and risk of radiation exposures to patient in general and children in particular. Organ doses from CT scanning are considerably larger than in X rays. For example, a conventional abdominal x-ray examination results in a dose to the stomach which is at least 50 times smaller than the corresponding stomach dose from an abdominal CT scan. The radiation doses to particular organs from any given CT study depend on how the technologist uses the equipment. From our point of view this is where the element of ‘practice’ affects the security of patient.

A new term E-Iatrogenesis has been now coined by Weiner et al. to identify cases of perils brought about by computer uses in patient care. E-Iatrogenesis is termed as patient harm caused at least in part by the application of health information technology. These unintended errors originate from the healthcare information systems as users interact with systems differently than was anticipated.

Modern Computer based Order Entry system (CPOE) is seen as a key step toward slashing the sky-high rates of drug-related adverse events. Researchers at the University of Pennsylvania surveyed 261 interns, residents and other hospital staff who had used an old computer order-entry system at the University of Pennsylvania Hospital between 2002 and 2004. To their amazement, the researchers found 22 scenarios in which the computer system itself increased the prescription errors.

McConnell and Fletcher in a study of 323 registered nurses working in a 500-bed tertiary care hospital found that the most frequently identified methods of initial learning were trial and error (self-taught) and reading the user instruction manual. This study showed at least 90% of respondents indicated that their first encounter with a medical device was when they
simply learned its purpose, function, and operating concepts. Furthermore, 87.1% of the respondents indicated they had received instruction about a device from another staff member, typically another registered nurse. Another finding of the study was that medical device use causes more than 75% of staff nurses to feel stressed. In addition, this study showed that around 10% of nurses had used a medical device improperly, which had later harmed a patient. In response to these findings later in another study by McConnell and Murphy it was concluded that the introduction of sophisticated health-care technology does not guarantee high-quality patient care.

The need for rules or regulations have been felt in areas of patient safety world over and there are efforts at international levels to regulate norms and standards of practice in use of technology & delivering safe healthcare.

Guwahati being the nerve centre of NE, healthcare establishments in the city are catering to entire North East India. There is large number of high end healthcare technologies in the city and there is infusion of business capital in the private healthcare sector to earn profit from use of technology. Apart from Government medical institution, Guwahati is also home to corporate healthcare sector. Guwahati also is hosting multiple sophisticated high end diagnostic centres full of modern and expensive healthcare technologies.

These significant dimensions related to people’s right to health care invite a comprehensive research on it. The present work is an attempt towards understanding the policies and practices in technology use in modern healthcare from the view point of safety to peoples health.

**Deficit in Governance in Healthcare Technology**

Governance of healthcare technology in India is at best termed nascent in most instances. There are certain sectors like radiation related equipments or certain items termed medical devices that are being regulated to an extent. In India no proper definition of medical device has been formulated yet, and many items which are elsewhere classified as devices are termed as drugs for regulatory purpose. The basic demarcation of drug versus device being non existent the state of governance is taking a negative turn.
Practically almost no institutional mechanism of surveillance, adverse incidence reporting or market recall etc are firmly in place for medical devices. System of registration and licensing for medical device manufacturing or import in India is prevalent but the market is still flooded with poor quality spurious devices, repackaged units of disposable items.

There is barely any available practice standard or professional guidelines prepared by the various statutory professional bodies of physician, technologists or nurses. In absence of such standard guidelines, individual institutions are expected to formulate some tangible technology or medical device policy—which too is not very frequent, and most health facilities are still in the dark about such requirements.

1.3: Objectives of the Study

In conformity with the stated problems related to healthcare technology, the present work has the following objectives.

*General objective*
To map the alarming rise of high-end healthcare technology and emerging challenges with special focus on its impact on issues of global concern i.e. equity in access and distribution of benefits. The study attempts to capture the critical debates on the issue.

*Particular objectives*
To investigate the penetration of healthcare technology in India as well as its patterns of ownership and control, and to capture the corresponding regulatory and governance mechanisms.

To investigate penetration of healthcare technology and corresponding governance mechanisms in Assam with special focus on Guwahati city.

1.4: Research Questions

The present study is steered by the following research questions:

1. What are the determinant factors of penetration of high technology into the healthcare domain?
2. What are the patterns of ownership of healthcare technology?
3. How does technology emerge as a domain of knowledge and power?
4. What is the relationship between state and the health-technology industry?
5. What are the emerging concerns arising out of penetration of healthcare technology?
6. What have been the endeavours to regulate healthcare technology at different levels—global, national and local and how do they converge with each other?
7. What is the relationship between healthcare technology and profit vis-à-vis peoples’ rights?

1.5: Hypothesis

The present study started with the following hypotheses:

   a. Technology contributes towards universal empowerment in the domain of healthcare.

The hypothesis proved to be elusive as comprehensive investigations revealed that healthcare technology has wider implications and many instances hint on negative implications on social equity.

   b. Governance of healthcare technology brings in equitable benefit in healthcare.

Comparative analysis proved the hypothesis to be partially true as the developed countries have gained benefits out of emerging governance mechanisms whereas in a country like India non-existence of a governance mechanism is still a big concern. However, with critical theoretical inputs, it is understood that governance mechanism alone is not the solution unless the structures of control and dominance of healthcare technology is questioned.

1.6: Conceptual Categories

Healthcare Technology

Healthcare technologies are of many different types and serve a variety of functions in patient care. Commonly, medical or healthcare technology is classified based on its use as diagnostic or therapeutic technologies. Broad meaning of technology includes drugs, devices, appliances, procedures, supportive appliances like software etc. A more detailed concept is presented in chapter 2 of this work.
**Medical Devices**

Medical device is understood most commonly as a physical item, excluding drugs, used in medical care, and may range from a machine requiring large capital investment to a small instrument or implement. It can be understood that medical devices are everything from band aids to x-ray machines, contact lenses, hip implants, pacemakers, crutches, hospital beds and in vitro diagnostic devices. Considering the variety of items, medical devices are usually divided into subgroups, which is dealt with in chapter 4 of this work.

**Governance**

Contemporary discourse on governance is influenced by the parameters laid down by International Monetary Fund and World Bank, where importance is laid primarily on implementation. The shift of focus in the contemporary concept of governance is towards implementation, signifying that policies are beyond contest. Governance in this paradigm is a technocratic exercise which can deliver results expected if properly designed structure of decision makings are in place. In this framework issues of transparency, peoples’ participation as well as accountability are highlighted. Prevailing discourse on governance transcends government as well as national boundaries and includes the role played by private or non-governmental agencies. Issues of investment as well as procedures for ensuring transparency and accountability etc. also figures in the discourse. However, it excludes the policy debates.

The discourse on challenges of health technology in this study would indicate that the current situation of healthcare technology governance represent the interest of ‘capital’ represented by industry and elites. The interest of capital is the prime mover of emerging policies. In neoliberal era, increasing presence of capital in private healthcare has secured itself the status of industry and infrastructure to derive various benefits to augment its capital. Interest of capital coming before interest of public health is a fact that cannot be disregarded. The interest of professional groups of healthcare personals, drug & device industry, bureaucrats and political elite are converging to promote the interest of ‘capital’. The professional groups favor private healthcare facilities for enhancing their chances of economic benefits and elevating professional status through latest equipments and technology that the ‘capital’ can buy. The bureaucrats and political elite are benefitted by obtaining sophisticated healthcare service at par with the developed world. The ‘capital’ meanwhile forges its enormous power to penetrate the system of healthcare for its further expansion and ensure more profit. The
primary interest of the working class or poorer sections is weak forces at its best, to oppose the combined might of professional groups, industry capital & elite political class. This is the existing paradigm that illustrates the governance of technology dominated healthcare system.

Present study adopts the governance framework to include: Policies, Institutions, Infrastructure, Procedures & Practice.

Clinical gaze, medicalization & Iatrogenesis

There are few more concepts on modern medicine which are of relevance to biomedical advancements and contributes to the power perspective, they are- clinical gaze, medicalization and iatrogenesis.

With the innovations in modern medicine and development of technology the concept of clinical gaze started to develop. Physicians started developing knowledge based on technology at his disposal to gather insight into patients’ body. In Birth of clinic Foucault\(^\text{27}\) comments “The observing gaze refrains from intervening: it is silent and gestureless”. Development of modern sthetoscope in 19\(^\text{th}\) century enabled the physician to hear “sounds of disease” which is not heard by the patient.

Clinical gaze gives disciplinary power over patient to physician to control their behaviour in more than one ways. Doctors became less dependent on patients’ narratives of sickness and more reliant on scientific figures and information. Innovations in the sciences also created an intelligence gap between doctors and patients. While clinical gaze is criticised negatively as a dehumanising tool one can not discount the fact that the physician need to understand person's illness at the biological level at least to relive him from pain and symptoms.

While dealing with the phenomenon of diffusion of healthcare technology one needs to understand the concept of medicalization. Medicalization can be defined as the process by which some aspects of human life come to be considered as medical problems. Unlike the Foucauldian social constructionist approach medicalization thesis does not question the basis of medical knowledge but rather it seeks to challenge its application. Medicalization is seen as negative consequence in social science literature\(^\text{28}\). The power of a informed, elite community (the physicians) over dependent is the central dilemma of medicalization critics.
The physician yields power over the population due to their specialised knowledge and skill and can regulate their behaviour as a means of social control. Empowering people by preventive healthcare efforts, encouraging medical encounters armed with knowledge to challenge the physicians decision is seen as answers to the problem of medicalization in certain social frameworks.

Forty years ago Ivan Illich made an accurate analysis of the iatrogenesis of many illnesses. The word iatrogenesis comes from the ancient Greek and means "originating from a physician or treatment". According to Illich, social iatrogenesis is the proliferation of diseases caused by the extension of medical categories on everyday life. Illich expands the concept beyond doctors inflicting direct clinical harm. The expanded concept has a component of Cultural iatrogenesis that refers to the way in which medicine is seen to have undermined people's ability to manage their own health, and cope with pain, suffering, and death. Illich recognised modern hospitals run by professionals to be representing a facet of medicalization, where hospitals are emerging as ‘an intended place of containment’ of death and dying. The medical profession and the modern hospital is concerned with the management of the ‘technical aspects’ of symptom control thus depriving people of the experience of dying.

1.7: Theoretical Premises

The study is driven by theoretical premises of power and domination i.e. how health technology has emerged as a new tool of domination and accelerated inequality in the domain of healthcare. It has captured the debate centering medicalization and health technology from eminent social scientists and psychologists like Michel Foucault.

Foucault, in much of his writings have investigated into the tools and bases of power and also discussed how construction of knowledge itself is a power game. The growing dominance of technology in the health domain has power dimensions and it leads towards dominance versus marginalization and profit versus inequality of access to health.

Health and illness are biological descriptions of the state of our bodies. The Biomedical model of disease and health tends to identify disease as a temporary organic condition, treatable by medical intervention. In biomedical model of understanding, disease is experienced by a sick individual, and when symptoms appear, it is treated in a medical
environment. The biomedical model also underlies the official definition of health and disease adopted by state and international authorities.

Contrary to the narrow definition of disease in biomedical model, in a social science perspective medicine has a much wider meaning. The ever closer and more sophisticated inspection of the body has brought considerable power and prestige to the medical profession. It has also established a large and profitable market for major pharmaceutical companies.

**Medicine as Power**

The present study is based on theory of power and dominance as envisaged by Michel Foucault, but is not limited to Foucault’s perspective alone. Foucault insisted that in order to understand the role of medicine in society, it has to be seen as part of a wider social requirement for the regulation and surveillance of bodies. Foucault used the term bodies both in the physical sense of individuals’ bodies and in the more abstract sense of bodies of populations. Regulating mechanisms of single individual is termed ‘anatomo-politics’ and the regulation of a larger population is seen by Foucault as ‘bio-politics’. Bio-power emerges from control of larger population. In Foucault’s logic the demand for regulation grew as society became more complex – especially as it became urbanised and brought people together in one large mass. Urban areas have both public and private ‘spaces’ that dictate appropriate behaviour for the bodies that occupy them. Medicine, and public hygiene, has to be understood within this broader context of public control. Here the concept of ‘discipline’ is important. The emergence of ‘rational’ modern disciplines – such as economics, urban planning and notably medicine – was central to the disciplining of people as public and private bodies. In their different ways, each of these disciplines devised forms of social control and regulation over people.

Foucault was primarily interested in the way that power acts on individuals. Traditionally, exercitation of power is negative, by its prohibitions on what can not be done rather than what can be done. Traditional sovereign powers dictated the subjects regarding their right actions and behaviour by punishments, taxations or by other instruments.

It is worthwhile to observe that while power still operates negatively in society through laws and other juridical mechanisms, the importance of such mechanisms has been superseded by more productive forms of power. In the modern era, Foucault observed that modern era there
are diverse techniques rather than negative exercise of power to subjugate human bodies, and today juridical forms of power is in a subordinate role. Present day the instrument of control and power resides in knowledge –“knowledge is power”.

Michel Foucault’s idea of power is necessary to be understood in its essence. Power according to him is something that continually circulates through institutions like blood moving through veins\(^{32}\), It is never derived from a single source, nor can it be localized in a single body. Thus, for Foucault, power is not something that can be divorced from its points of application to study in some isolated environment.

Present work concerns itself with biomedical advancement that is at the heart of medical power. The specific focus of this study lies in healthcare technology and devices that has enabled modern medicine to extend its all pervading influence. The study examines technology driven healthcare from this perspective of power and control to understand how healthcare inequality & sufferings are converted into a domain of profit from sickness.

*Medicine in market metaphor*

Theoretical perspective of the present study also rests on understanding of medicine as a commodity in a market. The “market metaphor” has shown its impact over modern medical practice. In a review of the subject George Annas\(^{33}\), commented how in the language of insurance companies life of an individual become a ‘covered life’ or even "money-generating biological structures". Current language of market views healthcare plans, hospitals as a product to be sold to consumers of health who can purchase them on the basis of differential pricing. In the developed world and in neoliberal economies around the world medical care is a business that necessarily involves marketing through advertising and competition among suppliers who are primarily motivated by profit. In the domain of healthcare targets, turnover, mergers and acquisitions are the new buzz word that has replaced care delivery or compassion. Consumerist approach and choice of consumers becomes the central theme of the market metaphor. The role of physicians is radically reduced in this market driven model of healthcare where physicians are run by managers and corporate interests. Rather than defending right of health, physicians today advocate interest of the covered life, leading to a healthy income rather than a healthy population. It is very relevant to quote George Annas here for a lucid understanding of the crisis of medicine as a market metaphor: “The market
metaphor leads us to think about medicine in already familiar ways: emphasis is placed on efficiency, profit maximization, customer satisfaction, the ability to pay, planning, entrepreneurship, and competitive models. The ideology of medicine is displaced by the ideology of the marketplace. The corollary is that medical ethics is displaced by business ethics, and a management degree to run healthcare facility is at least as important as a medical degree.

Foucault commented in his essay of “crisis of medicine or crisis of antimedicine?” about certain vital challenges modern medicine is facing today. The crisis is a conflict resulting from evolution of a technologically driven triumph of modern medicine to fight diseases versus the political economy of medicine. The fact that large number of cattle death was responsible for a organized enquiry in south of France, that has finally culminated in the organized professional forum of Royal society of Medicine is a valid starting point, for understanding the economic interest of medicine. That disease of cattle and not men generate the political will and concern to organize medical enquiry is seen by Foucault as a reaffirmation of belief that economic problems were the chief impetus of modern medicine.

In the present context the Foucauldian viewpoint stresses the fact that the traditional link between economy and medicine has morphed into a sinister relationship. In the words of Foucault: “At present, medicine connects with the economy by another route. Not simply in so far as it is capable of reproducing the work force, but also in that it can directly produce wealth in that health is a need for some and a luxury for others. Health becomes a consumer object, which can be produced by pharmaceutical laboratories, doctors, etc., and consumed by both potential and actual patients. As such, it has acquired economic and market value.”

Consumption of healthcare do not necessarily result in improvement of the health status of an individual. Foucault summarizes his observation, “When medical consumption is placed in a real setting, it can be observed that environmental variables, in particular food consumption, education and family income, are factors that have more influence than medical consumption on the rate of mortality. ......It follows that, in order to live longer, a higher level of education is preferable to the consumption of medicine.”

Foucault has pointedly observed that the profit from the politics and economics of medicine goes to the rich, making it a bigger divide between the haves and have not. The plight of medical profession is realised by the observation that physicians no matter how much they are paid receive only the tiniest part of the profit generated by medicine. Physicians serve as an intermediary through which the power flows. “ ..who profits from the social financing of
medicine, the profits derived from health? Apparently doctors, but this is not in fact the case. The remuneration that doctors receive, however elevated it might be in certain countries, represents only a minor proportion of the economic benefits derived from illness and health. Those who make the biggest profits from health are the major pharmaceutical companies”\(^38\).

### 1.8: Review of Literature

It is a great concern for researchers in health policy or healthcare governance that no definite framework is recommended for poor and middle income countries. Most studies related to healthcare governance, health economics & policy are actually carried out in the developed countries and their methodology might not be wholly appropriate to be applied in developing world. Researchers in developing countries are mostly concerned with focussed or funded research in the field of policy evaluation or outcome analysis only. In a recent work, Walt et al \(^39\) elaborates the problem of reductionalism in policy research in developing countries. Most of health policy research is motivated (and attracts funding) by practical concerns such as the evaluation of existing programmes, and policy analysts are expected to deliver easily implementable recommendations within relatively short time horizons. The author has discussed the positionality of researcher to effect research outcome. Researcher positionality has important implications for data access and knowledge construction. It is feasible to label the researcher as ‘insiders’ or ‘outsiders’ in case of health policy research, where insiders may be both participants and researchers (participant-observers) of the policy process. Walt et al pointed out that attributes like Class, caste, gender, age, ethnicity and profession may also be highly relevant to insider/outsider status in some health policy research contexts. In seeking to unravel complex policy dynamics, insiders may see things quite differently than the outsiders, with implications for the data collected and the interpretation of research findings. Naturally being an insider means easy access, the ability to ask more meaningful questions and read non-verbal cues, and most importantly, to be able to project a more truthful, authentic understanding of the culture under study. In contrast the negativism surrounding insider is that her/his viewpoints are inherently biased. It is also agreed by the authors that in reality health policy analysis is only emerging and has yet to establish its legitimacy as a field within developing countries, ‘insider’ policy researchers are hard to recruit and ‘outsider’ researchers may be expensive and time-constrained.

Siddiqui et al\(^40\) has researched on the selection of appropriate framework for health service governance evaluation. Their study analysed multiple models of governance analysis for
health services of developing country, with special reference to Pakistan. After careful considerations the researchers commented that United Nations Development Programmes principle of good governance are most suitable for analysing healthcare governance issues. The chief criticism for World Health Organization model of healthcare stewardship was that there is difficulties in empirically measuring stewardship function of state. Siddique et al identified the problem of rapid market development for healthcare services which has outgrown the domain of policy evolution in developing world. The result is that many health market transactions take place outside of a legal regulatory framework, and are not supportive of public policy priorities. The looming danger of stronger market entities controlling healthcare and making state regulations ineffective is considered as a real threat by the researchers. The researchers suggest governance of health service should involve the state and non-state actors together to deliver the greater good from public health perspective. The study suggests reassessment of coercive regulations and expects that participatory form of regulation and governance can deliver better results.

Balka et al, has researched extensively on the issues of technology governance and patient safety from a health system perspective. The study has critically reviewed methodology of such research and identified the problems of research in those areas. There is in general a tendency to under report technological error or errors emanating from use of health care devices due to prevailing culture of blame game. One of the important difficulty concerns different classification systems adopted for the same technological products across different contexts or country. Other emerging problem as identified by the researcher is repeat use of disposable items and circulation or refurbished medical devices. The researchers have pointed out that governance of medical technology involves a number of stakeholders like the device manufacturer, device vendors, device users, the public (beneficiaries of medical devices), the government and a number of other stakeholders ranging from insurance companies to equipment resellers that constitute the domain of governance of Medical technology. Responsibility for governance is dispersed between multiple actors, most of whom are hidden from the end user’s view.

Though the facet of healthcare technology is diverse, there are researchers delving deep into certain aspects of cutting edge technologies. Certain technologies, like Nanomedicine has been generating debates regarding its safety and policy researchers from around the world has
dissected the issues. One notable research emanating from Europe by Christa Altenstetter et al \cite{42} has addressed policy issues specifically from a patient safety perspective. The researcher brings out the divergence between the implied motivation of device makers and regulators to cooperate at the global level. The next important issue identified by the researcher is that law and regulation are good at specifying what needs to be done. But law cannot explain nor can predict how implementation will actually work. International or global policy agreements can not predict its stringent implications at local level. The paper suggested that further researches is needed to bring in governance perspective to domestic implementation of global policies to help identify pitfalls and erroneous assumptions about what is feasible. While device manufacturers or large corporations can be expected to comply with laid down state regulations, since continued access to the market is in their interest the physicians may follow practice recommended by peers that is accepted as legitimate. The researcher ultimately mentions that it is the public that face the real challenge to decide what is an acceptable risk in using certain health technology.

Medical technology related research is a very nascent field for Indian researcher. As the advent of technological medicine is still a emerging phenomenon in India, there are only few researches that are already published. The Government of India is yet to define a comprehensive policy for medical technology in an appropriate manner. In a recent work by Ajay Mahal \cite{43}, the problem of certain medical technology from an Indian perspective is evaluated. The research has attempted to understand the spread of new medical device technology in India and what are the main factors underlying this diffusion. The research has attempted to understand cost burden brought in by healthcare technology diffusion. The research also tends to explore the domain of inequalities in access to health care technology. The study holds a strong view regarding regulations governing second hand as well as new medical devices entering the country. The author argues that a strong institution which is lacking at this moment needs to be built to regulate import, manufacture and monitor technology diffusion. The researchers felt that there is a huge need for comprehensive analysis of threat to health security of people arising out of unregulated technology. The chief limitation of this research is that considering multitude of health technology the author has done the empirical work only on high value diagnostic equipment, but nevertheless this is an eye opener to the proverbial tip of the iceberg. A very pertinent recommendation made by the researcher is regarding inevitability of Health Technology Assessment (HTA) research in India. In a resource constrained setting such as India’s, relying on an unregulated market to
guide the growth of medical technologies may lead to a lot of wastage and inequity. The situation demands national institutions to undertake “Healthcare technology assessment”, which currently do not exist in India.

One of the most recent investigational research titled ‘Unholy Alliances in Healthcare Services, Collusive Behaviour in Healthcare and Impact on Consumers: Evidence from Assam and Chhattisgarh’ had identified three main issues jeopardising health security of people. The paper identifies three important factors - lack of appropriate regulation, possibility of collusion among the different players at different levels and consumer ignorance to endanger healthcare. The study concerns mainly the domain of medicines & pharmaceutical industry but nevertheless it is one of the most relevant study done in Assam to bring out the salient issues of healthcare insecurities. The study is limited in scope as it has surveyed only few district head quarters and Guwahati city. The study did not identify other important areas of healthcare like infrastructure and technology etc but nevertheless the attempt to unmask the ugly state of non-governance is creditable. Researchers have argued that existing framework to regulate the healthcare sector is ambiguous and hence often ineffective. Several institutions are empowered to intervene on matters having public interest implications, yet such actions are often few and far in between. The possibility of collusion is yet another area that no doubt needs investigation. This study has proposed possibility of multiple levels and layers for collusions and calls for more careful delineation of the specific areas in light of ambiguous regulation.

1.9: Methodology

a. It is primarily a qualitative study.

b. Policy analysis constitutes the core of the study. The study has comprehensively debated the policies towards regulating healthcare technology at three levels - international, national and local.

c. Used information generated by authentic studies/websites of the respective ministries and departments to substantiate the arguments.

d. Surveyed EPW (Economic and political Weekly) for five years to capture the debate on governance of health technology in India.

e. Surveyed The Assam Tribune for four years to capture the debate on governance of health technology in Assam.
f. Conducted a field survey to understand both diffusion of health technology at the local level and also the issue of governance. It was a more qualitative than quantitative and oriented towards policy debates.

g. Used end notes for the chapters and *EPW style sheet* for references.

1.10: Scope of the Study

Governance of health may be viewed as pluralistic authority spheres and networks. Multitude of forces interacts in a complex adaptive system of healthcare to generate the outcome. Health care technology governance aptly fits to the concept of plurality of participation. The stakeholders for health technology issues now extend far beyond any government. It includes: private or commercial entities (multinational corporations); academia; non-governmental organizations such as private foundations, humanitarian groups, and advocacy organizations; multilateral organizations such as the World Health Organization (WHO), the World Bank, and the U.N. development agencies; and bilateral aid structures such as the U.S. Agency for International Development, the Swedish International Development Agency, and the Japan International Cooperation Agency etc. Owing to multitude of players, a state-centric approach to regulation of health care delivery is inadequate for today’s public health challenges.45

For penetration into the domains of governance of healthcare technologies, one has to review globally prevailing standards of regulation and practices as health technology in itself is a globalised issue. Global governance is a highly contested idea. The 1995 "Report of the Commission on Global Governance" took governance to be "the sum of the many ways in which individuals and institutions, public and private, manage their common affairs."46 While developing our concept of power, we need to view governance as "polyarchy" wherein a multiplicity of agencies with authority and influence now co-exists. Though the political sovereign authority of any single state is never absolute, in general terms the authority of state is prioritised over non-state actors. The processes of globalisation and a plurality of actors have led to certain changes where various stakeholders share the table, in deciding how decisions will be made.
1.11: Significance and Relevance

The significance and relevance of the study lie in the fact that in India despite enormous presence and growing penetration of technology in the healthcare sector, health technology and its governance are yet to capture attention from the policy makers and policy analysts. Social science research is concerned on health security which, however, is confined to health investments and socio-economic determinants of health. Health insecurity manifestations have, of course, received wider attentions and accordingly ambitious projects including National Rural Health Mission (NRHM) have been launched. However, emergence of technology as a determining force having implications both on privatization of healthcare, particularly at the tertiary level and also on technology determining the health discourse have not found adequate space in social science research. It has helped the government to evade its responsibility of developing a regulatory mechanism on healthcare technology.

Present study intends to capture the dominant discourse on healthcare at national level reviewing the health related publications in Economic and Political Weekly for last five years (2008-12). The Economic and Political Weekly, published from Mumbai, India, enjoys global reputation for excellence in independent scholarship and critical inquiry. The online EPW archive (http://www.epw.in/epw-archive.html) is used for the survey of health related literature with enlisting of the write-ups. A total of 72 publications appeared in the domain of healthcare in general in last five years out of which there were 7 editorials, 16 special articles & 28 nos of commentaries. There were further 10 letters to editors and few other write ups under different headings on health related issues. The full list of health related publications of EPW from 2008-2012 is presented in Appendix II. Surprisingly, out of those 72 publications, almost none have dealt with the issue of health technology, despite the fact that a few important legislations related to regulation of health technology are pending in the Parliament. This may itself explain the significance and relevance of the present study.

1.12: Chapter Outlines

The present work has seven chapters including introduction and conclusion.

The First Chapter i.e. Introduction, as the preceding section reveals, outlines the basic research problem and tends to constructs the theoretical framework. This chapter presents the objectives of the study as well as refers to the research and development in the area of the study. The basic proposition of this chapter is that little work is done to assess safety
concerns of healthcare related technology in India and Assam in particular though the subject has been alive worldwide and literature search reveals a huge volume of writing on the subject of patient safety issues, healthcare technology assessment etc.

The Second Chapter, titled *Healthcare Technologies A Brief History on Diffusion and Debates* comprehensively analyzes the historical development of medicine, technology development and adoption in healthcare. This chapter present the various theories related technology diffusion and the course healthcare technology chooses depending on social, moral, political & economic factors.

The Third Chapter, titled *Political Economy of Healthcare technology: Issues of Inequality, Profit and Hazards* investigates the emerging challenges healthcare technology has created. The chapter outlines the problem of access and inequality in a technology driven model of healthcare. The subsequent section depicts the case of profiteering from sickness by technologically driven healthcare market. Finally, this chapter unearths the world of iatrogenesis – the case of bodily harm brought in by health technology to patients. This chapter is the main basis of research problem of the entire work.

Fourth Chapter, titled *Governance of Healthcare technology: Emerging Global Policy Discourse* explores the governance question related to medical device. The chapter presents broad definitions and illustrates governance concepts as applicable to medical devices and proceeds to explore the prevailing policies and current practices in the European Union, Japan and United States of America, considering the preeminent position of these three countries in the healthcare field. Comparison of the systems is done with critical arguments concerning the Indian national scenario.

The Fifth Chapter, titled *Governance of Healthcare Technology in India: Emerging Policies and Public Debate* deals with the in depth analysis of Indian regulatory system considering Medical devices. It dissects and debates the various healthcare bills, policies and intended reforms from a view point of generating benefits of technology to patients. The chapter includes the pertinent section on survey of EPW for health related issues.
The Sixth Chapter, titled *Governance of Healthcare technology in Guwahati City: Drawing Lessons from the Ground* presents the state level scenario concerning healthcare technology regulation. The chapter reviews the existing healthcare regulatory mechanism, reviews the scope of state healthcare bills for provisions of technology governance and finally presents the empirical reality drawn from surveying the technology users in city of Guwahati. The chapter includes the facets of dominant public discourse based on survey of *The Assam Tribune* for four years to critically understand the state centric issues.

The concluding Seventh Chapter titled *Summing up the Debates and Recommendations* presents a brief summary of finding of present research as detailed in previous two chapters and reflects on the necessity of exploring remedies and alternatives to the current state of insecure health care system.

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23 Dark side of wired hospital, Viewed on 11th April, 2013 (www.forbes.com)


29 Ibid


34 Ibid
35 Foucault, M (2004) *Crisis of Medicine or Crisis of Antimedicine?*, Foucault studies no 1, pp1-15, 2004
36 Ibid
37 Ibid
38 Ibid
44 CUTS Centre for Competition Investment & Economic Regulation, Viewed on 11th April 2013 (www.cuts-international.org)
45 Novotny, T E, Global Governance and Public Health Security in 21st Century, Viewed on 11th April 2013 (www.cwsl.edu/content/journals/Novotny)