Chapter 6

Governance of Healthcare Technology in Guwahati City
Drawing Lessons from the Ground

6.1: Introduction

Present Chapter endeavours to investigate the state of affairs concerning healthcare technology governance in Assam, with special focus on the emerging policies and the dominant public debates on health related issues followed by a microanalysis of field survey carried out amongst the high technology users in Guwahati city to understand the prevailing practices and challenges. Arguments are drawn from field experience, interactions with physicians and administrators in various healthcare facilities. It is the primary endeavour of the study to understand the challenging issues of technology driven healthcare that has a potential to undermine the benefits of advancement in knowledge in the local context.

Considering Assam in general and Guwahati City in particular, authentic and comprehensive studies have not yet been carried out on the issue of technological penetration in the domain of healthcare. However, it is easy to find availability of numerous appliances, equipments and bedside devices in almost any healthcare facilities in the state in general. Equipments like X-Ray machines, Ultra Sound Scanner, Computerized tomography (CT scan), Magnetic resonance Imaging (MRI), Electrocardiography (ECG), Endoscope, Computerized biochemistry analysers, electrolyte analyser, electrophoresis, Defibrillator Monitor, Holter Analyzer, Gas Analyzer, Echo Cardiography etc. have visible presence in the city, particularly in the private owned tertiary healthcare establishments and diagnostic centres.

It is to be noted that Guwahati has now emerged as one of the important health care destinations not only for the State of Assam or of the North Eastern Region alone but also for the neighbouring countries like Bhutan, Bangladesh and Myanmar etc. Guwahati has, however, been a centre of health care for more than half of century now as a few important public health care institutions- Government Ayurvedic College and Hospital (1948); Gauhati Medical College and Hospital- GMCH (1960) B. Borooah Cancer Institute- BBCI (1973) & Mahendra Mohan Choudhury Hospital- MMCH (1984) - were located in the city catering health care service to the region. But, Guwahati’s significance as a health care destination increased with the establishment of a good number of multi-specialty & super specialty
private hospitals and diagnostic centers in the city since late 1980s onwards. This coincides with the process of liberalization, privatization and globalization in the country. Today, there are around 80 big and small private hospitals with around 2000-hospital bed capacity and around 100 private diagnostic centers in Guwahati City. Apart from the leading private health care establishments like Gauhati Neurological Research Centre- GNRC (1987), Down Town Hospital (1988), Sri Sankardeva Netralaya (1994), International Hospital (1999), Hayat Hospital (2007) etc, there are the middle range private health establishments like Dispur Poly Clinic (1978), Goenka Nursing Home (1979), Advance Neuro Science Research Centre (1996), Good Health Hospital (1996), Swagat Endolaparocopic Research Centre (2000), Sanjevani Hospital (2004), etc.- to name only a few. Leading diagnostic Centres like Ecopath, Primus, Sahara Lab, Sky Lab etc. do posses very costly equipments mostly supplied by foreign companies. These establishments and centres have host of high end sophisticated imaging equipments like high field strength MRI, Multi detector CT scan, Dual X ray absorptiometry, Mammography, Image intensifying Television etc. Some of the leading manufacturer of this technological product are General Electric company, Siemens, Philips, Meditronics, etc.

Present study first constructs certain arguments that have contributed to the growth of technology in the health sector of the state, based on field experience of the researcher. Next section in the study includes discussion on the prevailing regulations or state of governance of healthcare facilities from the view point of health technologies. The subsequent section captures the dominant public view on issues related to health by reviewing available publications. Finally, a micro survey is presented to present a qualitative understanding of ongoing practices concerning the use of health technology and medical device in the city.

6.2: Technology Diffusion and Emerging Challenges: Recapturing some Critical Issues

It is generally believed that abundance of technological gadgets have made healthcare better and specially proliferation of diagnostic technologies like various scanners and blood chemistry analyzers have made diagnosing diseases and ailments easier. The stated objective of most healthcare facilities declare opening a world of better healthcare through cutting edge, sophisticated and world class technologies.
In spite of prevailing notion of technological superiority delivering better healthcare the pertinent question that a social scientist need to ask is: Where lies the patient and experience of sickness in this maze of technology and medicalization? Does technology driven healthcare bring in equitable benefit to all or does it bring in profit to some and sufferings and discrimination to most? These are uncomfortable questions with no easy answers. An enquiry to the meaning of technology diffusion in healthcare dissects and disputes the unwarranted romanticization about the power of technology to understand disease at microscopic level and offer its sometimes marvelous and often elusive solutions.

It can be argued that rather than facilitating healthcare, most healthcare establishment see technological power as a deterministic one to earn profit from sickness. The dimension of access and profiteering from healthcare technology is dealt with in earlier chapters of the present work. An expert of the US health sector informs that today the US has more MRIs and more CT scan machines and more dialysis machines than most other European countries do have. But, the heath security record of the US is relatively inferior in comparison to many European countries. Why is it so? Richard Levin suggests that it is due to the fact that medical decisions are not always taken on medical ground. For example, once a hospital buys an expensive machine it just cannot sit idle. “You cannot allow an MRI machine to sit idle in hospital, so doctors are encouraged to use it if only to amortize the institution’s investment.”

In India too, the use of technology in the health sector has not been a very clean experience. In an investigative report, published in Nov 8, 2011 in the national daily The Hindu, the tacit understanding between diagnostic centres and a large pool of physicians for referring patients for a variety of diagnostic tests has been mentioned. It is reported that many medical practitioners themselves concede that many a time, tests which are not required are also prescribed to improve business of diagnostic centres, where doctors get hefty commissions. In yet another report titled ‘Shaming the Hippocratic oath’ in 4th July 12, edition of Times of India the condemnable practice of paying commission for writing up costly unwarranted tests, practice of paying kickbacks for referral by various health establishment is described.

One of the important reasons behind the huge inflow of patients to Guwahati city for health care has been the availability of world-class technology in the health care sector. It is not rare to encounter a patient disillusioned with the technological boom when these very technologies rob people of their valuable meager resources in the promise of marginally
longer life span. The dominant expression of apprehension concerning huge technology inflow into healthcare is already palpable and this is certainly not without substance.

Can technology be considered as the elusive solution to health problems or is it in itself the cause of ill-health at least in some instances? Concept of iatrogenesis is discussed in Chapter 3, with multiple statistical representations from authentic publications. The real danger of healthcare technology misuse has gathered some debate in recent past and there is worrisome publication by Andrew Kimbrell. In his book titled *Human Body Shop: Engineering and Marketing of the Human Life* (1993) that focuses on an ugly story of marketing and profiteering over human organs made possible by unprecedented development in science and technology, it is mentioned that “a whirlwind of advances in various biological technologies has created a boom market in the body organs and fetal transplantation, reproductive technologies, and genetic manipulation that have made body parts- even small amounts of our tissues- extremely valuable. Trade in human parts is becoming a worldwide industry.”

Why is there so much expressed skepticism surrounding healthcare technology? Healthcare technology in its essence is intended to be good. However the commercialization of healthcare in neoliberal era has brought out certain ugly issues concerning misuse of technology or cases of overuse of technology where simpler alternatives exist. There is ever present danger albeit small in proportion, of accidents concerning inappropriate use. Advertising the cutting edge technologies in a healthcare facility enhances a false sense of security, undermining the insecurities. It must be understood that most technological intervention in itself provides with fragmented pieces of information of the organic whole of the human body and soul. It is also to be asserted that human subjects cannot be considered in a medicalised setting bereft of its social context. Human beings are to be considered in its widest possible meaning of its physical organic body, elusive mind, socio-cultural context and interconnections. Technology does read the physical ailments, but the business of healthcare is not about producing an absence of disease in physical body, but also about healing the other components.

Another worrisome fact is that there is no guarantee of right course being chosen by technological up-gradation of health facilities. A campaign of technological abundance and superiority is advertised by most health facilities in an attempt to attract more patient to earn revenue. Induction of technology itself is seen as an opportunity for advertisement &
marketing tool. Advertisements listing equipments is a common sight in print or electronic media. Rarely advertisements are made about the human attributes of healthcare.

Healthcare facilities are marketed like other commodities. Innovative marketing ideas involve selling service of high technology through various promotions like “package deal”, “executive health check up”, “master check up” etc. Disease mongering as discussed earlier in Chapter 3, is not exclusive to pharmaceutical industry. In very subtle ways the idea of preventive healthcare or lifestyle modifications find place in modern corporate versions of healthcare. In its essence preventive health is much more that certain checkups, it’s about periodic assessment of general health, maintaining nutrition and healthy life style, maintaining standard of public health, immunization, so on and so forth. The question remains “Are many of the packaged health check ups in fact corporate gimmicks to sell health, for return on investment made on costly technologies?”

One of the reaction to consumerist approach to healthcare is increased investigation by physicians, for a more reliable evidence of suspected ailment. Breach of trust and introduction of new power equation of health consumption in the form of Consumer protection act is blamed by many of the physicians that have warranted increasing referral to diagnostic centers for battery of tests, where in most instances a good clinical examination would have sufficed.

Such equations have complex and multi-layered power relationships among the manufacturers of healthcare technology, the promoters and distributors, healthcare and diagnostic centres as well as the practitioners of healthcare technology. Growing evidences reveal that such a complex relationship give birth of a phenomena called profit from sickness. In such a situation the healthcare seekers are silent spectators of a process of victimization as the knowledge of good health is dominated and dictated by the producers, promoters, distributors and practitioners of health technology. Such a system can be questioned and altered only through a radical political process which is committed to values of equality, social justice and human dignity.

At the local level like in Guwahati city, both the penetration of healthcare technology as well as its inherent challenges is in operation today. In a federal set up like India, governance of such a phenomena lie primarily in the hands of the Union Government as it belongs to
different Ministries like health and technology etc. Besides, the health technology in India is primarily imported and the import is also regulated by the Union government. The regulatory mechanism or lack of it in the country has comprehensively been debated in the last chapter. However, ‘public health and sanitation; hospitals and dispensaries being the state subjects’, the state government has also a responsibility in this regard. Accordingly, this chapter intends to investigate the regulatory mechanism evolved by the state government of Assam in regard to governance of healthcare technology.

6.3: Policy Framework of Governance of Health and Health Technology in Assam

Present study attempts to understand the existing policy as well as practices related to healthcare technology in general and medical devices in particular, based on empirical observations in city of Guwahati, Assam. In the official website of the state government of Assam (http://assamgovt.nic.in/acts/index.asp), total of 316 Acts concerning all domains of life are tabulated for public viewing.

To understand the local environment of medical device governance a careful search for existing healthcare regulation enacted by the Assam State Legislative Assembly is enumerated in Table 6.1 which is gathered from Assam government website, and also with inputs from websites of Assam health authority and National Rural Health Mission (NRHM).

Table 6.1 Assam’s Healthcare related Acts and Bills till 2012

<table>
<thead>
<tr>
<th>No</th>
<th>Title of Act/Bill</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Indian Medical Degrees Act (Assam amendment)</td>
<td>1916</td>
</tr>
<tr>
<td>2</td>
<td>Assam Drugs Control Act</td>
<td>1950</td>
</tr>
<tr>
<td>4</td>
<td>Assam Medical Council Act</td>
<td>1999</td>
</tr>
<tr>
<td>5</td>
<td>Assam Rural Health Regulatory Authority Act</td>
<td>2004</td>
</tr>
<tr>
<td>6</td>
<td>Assam Public Health Act</td>
<td>2010</td>
</tr>
</tbody>
</table>

The relevant Acts in regard to governance of medical devices in particular and governance of health technology in general are Assam Health Establishment Act 1993 & Assam Public Health Act 2010. The salient features of the 1993 Act are enumerated in Table 6.2.

**Table 6.2 Salient Features of Assam Health Establishment Act, 1993**

<table>
<thead>
<tr>
<th>Domain</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory &amp; licensing body</td>
<td>Establishment of Assam Health Authority for licensing healthcare establishments &amp; clinical laboratories</td>
</tr>
<tr>
<td>Main regulatory function</td>
<td>Licensing, ensuring minimum prescribed standard in terms of manpower, facility, sanitation &amp; amenities. Gathering data on disease conditions &amp; notifiable disease.</td>
</tr>
<tr>
<td>Medical device &amp; equipment</td>
<td><em>Under section 26 (2, e)</em> government is empowered to prescribe the basic amenities and related healthcare equipments that should be made available for operating a particular type of health facility. Same section also provides for adequate qualified paramedical &amp; qualified staff.</td>
</tr>
<tr>
<td></td>
<td><em>Schedule VI states</em>, “Equipments for Diagnostic Laboratory and other Health Institutions must be provided with all necessary instruments and appliances which are of high quality standard and preferably having latest developed techniques. The Instrument requirements will be as per the nature of the institutions. The addition to the equipments of the institutions must have high quality glass, wares and chemicals of high quality.”</td>
</tr>
<tr>
<td>Safety of environment</td>
<td>Stress on appropriate biomedical waste disposal, specifically of disposable syringes, needles.</td>
</tr>
<tr>
<td>Inspection &amp; enforcement</td>
<td>Entrusts the chief medical &amp; health officer for all inspections of health establishments, for maintenance of stated objectives of standardisation.</td>
</tr>
<tr>
<td>Penalty provision</td>
<td>Imprisonment up to 1 year fine up to 10000/-</td>
</tr>
</tbody>
</table>
Despite the adoption of various legislations for regulating clinical establishments, the common public perception is of apathy & ineffective governance. The working group on Clinical Establishments, Professional Services Regulation and Accreditation of Health Care Infrastructure report\(^6\) contains critical analysis of existing clinical establishment Acts and enumerates the following deficiencies and weaknesses (Summarized in table 6.3), which are found to be of relevance also in the state of Assam.

**Table 6.3 General Deficiencies of Health Establishment Act,\(^7\)**

<table>
<thead>
<tr>
<th>Area</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ineffective rules</td>
<td>The rules merely cover registration of nursing homes/private hospitals. Minimum standards have not been developed, nor are issues relating to accountability of quality and price been addressed.</td>
</tr>
<tr>
<td>Non-uniform standard</td>
<td>Prescribed norms for facilities across state are different. Private sector accuses the govt. of observing double standards in prescribing minimum standards for private establishments and doing nothing to improve the pathetic conditions in public health institutions. This issue would need to be addressed in the right spirit by the government.</td>
</tr>
<tr>
<td>Outdated regulation</td>
<td>Fails to address contemporary issues arising out of recent developments in medicine and technology. Newer challenges are not covered, example: Present regulation has no recommendation on issue of appropriate qualification of operators, in areas such as endoscopy. No regulation for healthcare software use, nor there is proper regulation in areas of record keeping &amp; digital archiving.</td>
</tr>
<tr>
<td>Implementation</td>
<td>Mostly seen as ineffective owing to limited resource of the state \</td>
</tr>
</tbody>
</table>

Source: The table is based on the - Report on the Working Group on Clinical Establishments, Professional Services Regulation and Accreditation of Health Care Infrastructure For the 11th Five-Year Plan

The Assam Health Establishment Act, 1993 is a general instrument to ensure uniform standards in healthcare establishment. There is no specific directive or provision, to govern medical device or equipments separately in this Act. However the Act has enabled the
government to bring about further rules and notifications to ensure safe use of medical equipments by qualified personnel in all clinical establishments. The Assam Health Establishment Act, 1993 proposes to regulate healthcare through the authority of licensing the care delivery facilities, but there is no provision in this Act to include the medical device manufacturer or the sellers. There is no specific focus on regulating potentially hazardous technologies nor there is any evidence of intention towards setting up of regulatory controls to enlist adverse consequence arising out of device use.

The Assam Public Health Act of 2010 contains very little relevant elements on health technology & medical devices. The few elements that are having any relation to these two subject are presented in the next Table 6.4

Table 6.4 Relevant Features Related to Health Technology in Assam Public Health Act 2010

<table>
<thead>
<tr>
<th>Area</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutional structure</td>
<td>Establishment of public health authority board</td>
</tr>
<tr>
<td>Monitoring mechanism</td>
<td>Health information system, government mechanism &amp; public monitoring</td>
</tr>
<tr>
<td>Health research definition</td>
<td>Includes development and new use of technology</td>
</tr>
<tr>
<td>Access to health care service</td>
<td>Provide healthcare service of minimum standard to all</td>
</tr>
<tr>
<td>Standardisation</td>
<td>Act mentions laying down of standards &amp; norms of safety for healthcare process, treatment protocol, and also includes equipment</td>
</tr>
<tr>
<td>Users right</td>
<td>To information &amp; access to healthcare technologies</td>
</tr>
<tr>
<td></td>
<td>To be free from:”health nuisance”, defined as situation or a state of affairs that endangers life or health of a person or community.</td>
</tr>
<tr>
<td></td>
<td>Information on cost and benefit, risk of harm for each options in healthcare</td>
</tr>
<tr>
<td></td>
<td>Right to informed consent, for health procedures</td>
</tr>
</tbody>
</table>
The act proposes monitoring of public health activity by yet another authority. The Act echoes what has been already contained in different words in the prior Health Establishment Act of 1993.

The 2010 Act clearly mentions prescribing standard of healthcare process, protocol and equipment. There is mention of intent and scope in this regard but no actual rules for developing a set of governing principles for healthcare technology is seen in the act.

The 2010 Act defines various users right and mentions necessary informed consent process for providing healthcare. This process of informed consent in uneducated population itself is a matter of debate. Providing complicated health technology related information in a manner understood by lay person is not easy, even obtaining a informed consent from legal representative is not easy, in its true spirit.

Defining health nuisance is a welcome step in this Act, and sincerely pursuing to reduce health nuisance from technology misuse by further relevant Acts is an open option. A reference to clinical trial & experimental medicine is made in this Act, which is another relevant feature in any discussion on medical devise safety. New medical device or a programme of improvisation on existing device must follow laid down norms of safety and medical research. This particular feature indirectly opens further scope to bring about regulations in use of under trial medical devices.

6.4: The Dominant Public Discourse on Health Related Issues in Assam

In the current study an attempt is made to understand the public awareness and debate on health related issues in Assam, from mass media reports and publications. Present study selected the *The Assam Tribune* for survey of its content based on its eminent stature and circulation figure as the dominant English daily of the region. *The Assam Tribune* is published since 1939. Current editor is T G Baruah and founder editor was RG Baruah.
Current estimated daily circulation of the Guwahati Edition is 94000 and the Dibrugarh edition is 15500 copies. The Assam Tribune is third most popular newspaper of Assam. Its readership has been recorded 2.52 lakh in 2011.

For the purpose of the study, a review of the contents in the editorial page of all the issues of *The Assam Tribune* (1st January 2009 to 28th Feb 2013) is carried out from the library. All editorials, letters to the editor or editorial page articles were included in the content analysis and a total of 57 editorials, 106 articles & 17 letters to the editor concerning healthcare is selected. The detailed list of titles and their chronological order of appearance in the publication can be seen in the Appendix III.

In the present study to analyse the data, the selected publications were assigned to thirteen broad groups under nomenclature of health policy, universal health, public health, rural health & NRHM, Drug & drug policy, disease, women’s health, health finance & insurance, health law, health ethics, healthcare quality, life style disease, medical hazard, nutrition and whatever remained out were considered in the heading - unclassified. Some entries made to multiple categories of domains. Table 6.5 is presenting the information in a concise manner, to apprise the researcher of the qualitative trend of the prevailing healthcare discourse in the state. The ideal of classifying the articles into domain is for convenience of understanding and reference, and this classification scheme is based on key concepts or attributes enlisted in the table itself. It is possible to reclassify the same published materials into various other groupings depending on frame of analysis.

Table 6.5 The Dominant Public Discourse on Health, as per *The Assam Tribune* (1st January 2009 to 28th February 2013).

<table>
<thead>
<tr>
<th>Domain</th>
<th>Key Issues Included in the Domain</th>
<th>No of Publications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy</td>
<td>Health policy in general, criticism of existing policy, basic healthcare challenges and solution</td>
<td>20</td>
</tr>
<tr>
<td>Universal health</td>
<td>Universal health, health for all, Infant mortality, maternal mortality, suggestions &amp; policy prescriptions for removing health challenges and disparity</td>
<td>32</td>
</tr>
<tr>
<td>Category</td>
<td>Description</td>
<td>Count</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Public health</td>
<td>Issues of public health, sanitation, environment</td>
<td>22</td>
</tr>
<tr>
<td>Rural health and NRHM</td>
<td>Rural healthcare at national or state level, rural health issues, policies, NRHM debates</td>
<td>9</td>
</tr>
<tr>
<td>Drugs and policy</td>
<td>Drug policy, drug pricing, drug patenting, spurious drug, generic drug</td>
<td>8</td>
</tr>
<tr>
<td>Life style disease</td>
<td>Stress, Coronary heart disease, tobacco, addiction</td>
<td>6</td>
</tr>
<tr>
<td>Specific diseases</td>
<td>Malaria, TB, Dengue, Encephalitis, Swine flue, HIV &amp; AIDS, HIV-AIDS, Cancer, rare disease report</td>
<td>79</td>
</tr>
<tr>
<td>Women’s health</td>
<td>Gender equity in health care, women health, maternal mortality, antenatal services, institutional deliveries</td>
<td>6</td>
</tr>
<tr>
<td>Nutrition</td>
<td>Nutrition of child, malnutrition, healthy food, diet, disease of nutrition</td>
<td>3</td>
</tr>
<tr>
<td>Health finance</td>
<td>Finance of health care, funding, health insurance, Public private partnership, healthcare budget</td>
<td>3</td>
</tr>
<tr>
<td>Health law</td>
<td>Legal provisions for health care</td>
<td>1</td>
</tr>
<tr>
<td>Ethics</td>
<td>Ethical questions in disease to health, physicians conduct, dilemmas of medical research, doctor patient relation</td>
<td>2</td>
</tr>
<tr>
<td>Healthcare quality</td>
<td>Index of quality, clinical audit, ensuring standard, Patient receiving harm, safety concern, iatrogenesis</td>
<td>2</td>
</tr>
<tr>
<td>Others</td>
<td>Everything else related to health issues,</td>
<td>19</td>
</tr>
</tbody>
</table>

It is of great concern that during the review of the published items, no direct reference to healthcare technology governance is made. There were write-ups related to certain new drugs & technologies, there were few publications related to medical adverse events, healthcare quality control but specific concept of medical device or technology governance were absent in the available write ups. Considering the fact that health technology centred debates are still uncommon and no proper debate has started in the most important & respected News paper of NE India, researcher concludes that the state of health technology regulation at regional level is at best in its infancy.
There were occasional reflections on issues pertaining to clinical establishments and problems associated with them. The following may be illustrative in this regard.

1. On 6th Jan 2013, the editorial expressed its concern over unethical clinical trials of drugs in human subject, following a relevant Supreme Court debate. The editorial tends to raise the ethical dilemma of experimentation on human body.

2. On 7th December 2012, in a letter to the editor, the director of health service comments about legal provisions for regulating healthcare establishments. The author acknowledged presence of non-uniform or unjustified pricing of service in private health facilities.

3. On 6th Nov 2012, in an editorial page Article on medical hazard by DR D C Mahanta made an introduction to the subject of medical hazard and patient safety etc. The author asked the policy maker to bring in regulations and healthcare guidelines to protect public.

4. Dr D Goswami, on 29th Jan 2012 argued that healthcare quality assurance is a necessary component of health care. Clinical audit is suggested as the main approach to healthcare quality. Author concluded that in the health care system, public health is a major issue and unless clinical audit is done the standard of healthcare system cannot be improved.

5. D N Bezbaruah, in an article on 20th October 2011 commented that healthcare scenario in India not befitting its claim of welfare state. Economic hardship is not accepted by the author as an excuse for prevailing pathetic conditions of the public hospitals, with shortage of medical and paramedical. Author lamented on lack of proper healthcare technologies in public hospitals.

Though there is need and ample scope to debate out issues related to hazard and benefit of health technology in general and medical devices in particular, present exercise of content analysis could not gather much material on these lines.

Finally, a graphical representation of dominant public discourse is created in Fig 6.1 by assigning the values based on number of publications in the classified domains as per table 6.5. It is worth stating that some write ups are counted in more than one domain, and the
graphical representation is made for representing a visual picture of the qualitative arguments only.

**Fig 6.1: The graphical chart detailing relative importance given to each domain in public healthcare debate in *The Assam Tribune*, (2009-13).**

The presentation reveals that the public debate on health in Assam did not capture issues related to governance of healthcare technology in general and of medical devices in particular. The issues like the growing penetration of health technology, the emerging alliance between international manufacturers of health technology, national distributors, local health establishments and practitioners etc. escaped public attention. The potentially hazardous healthcare technologies is yet to get any public attention till date.

### 6.5: Governance of Healthcare Technology at the Ground: Capturing the Understanding of the Users

Present study as a part of critical conceptualisation of prevailing practice related to health technology use, included a small survey based on interview schedule (Appendix 1). The interview was carried out in the identified healthcare facilities within city of Guwahati.
Sampling methodology & justification

The present survey is based on a preliminary data collection from healthcare service provider and vendors selling consumables to various facilities. A comprehensive list of healthcare providers within city of Guwahati (List 6.1) is prepared by the researcher considering CT scan installation as criteria of inclusion. The reason of choosing this particular device or technology is its immediate visibility owing to large size and traceability of its use to certain consumable items like films, while performing the scan.

Table 6.6 Healthcare Facilities in Guwahati City housing CT Scan Facility

(Alphabetic order):

1. Advance Neuroscince Hospital, Ganeshguri
2. Alcare, Bhangagarh
3. Apolo Clinic, Lachitnagar
4. Ayursundara One stop Centre, Lachitnagar
5. B Barooah Cancer Institute, Birubari
6. Base Hospital, Basistha
7. Dispur Hospital, Ganeshguri
8. Dispur Polyclinic, Ganeshguri
9. Down Town Hospital, Dispur
10. Gauhati Medical College Hospital, Bhangagarh
11. GNRC Hospital, Dispur
12. GNRC Hospital, Sixth Mile
13. Hayyat Hospital, Lalgaon
14. International Hospital, GS Road, Christian Basti
15. Mahendra Mohan Chaudhury Hospital
16. Matrix, Bhangagarh
17. Marwari Hospital, Athgaon
18. Nemcare Hospital, Bhangagarh
19. Primus, Bhangagharh
20. Rahman Hospital, Sixth mile
21. Sanjivani Hospital, Maligaon
22. Skylab, Ulubari
Source: Prepared from industry data & based on interview with the Secretary, Guwahati City Chapter of Indian Radiological & Imaging Association (2013).

Next important justification of choosing CT scan is that owing to large capital investment and operational cost of these equipments, they are expected to be under certain regulatory control by the authorities and also by the housing facilities. Present survey, identified medical imaging as its specific domain to understand issues related to safety of medical device.

In the course of research, it is learned that elsewhere in the world owing to use of radiation by CT Scan, their diffusion and use are regulated strictly. CT scan is identified as an intermediate risk device (Class II, under FDA of United States of America). The researcher’s assumption is that the users of CT Scan can give valuable inputs towards developing an understanding of actual practices concerning medical device in state of Assam.

The survey is conducted in the medical imaging divisions of various health facilities, from Guwahati city only. Medical imaging field has seen huge technology inflow in the last couple of decades. A typical medical imaging unit concerns itself with use of equipments like X Ray machines & Ultrasonography equipment for various body parts. Larger facilities use CT scanner & MRI (Magnetic resonance imaging), Dual energy X ray absorptiometry scan (DEXA), Mammography etc for developing advance understanding on internal organs to formulate treatment. Based on primary data collection as presented in Chapter 2, on status of technology diffusion in entire NE India, it is realised that Guwahati city houses the highest concentration of sophisticated medical imaging devices. In 2011 Entire NE India was having total of 92 nos of CT scanner, currently Guwahati city alone has 26 nos of functioning CT scanner, 2 nos of unused scanner and according to market source few more are being installed in the city in next few months. The study is carried out based on a rational assumption of mapping existing policies and practices by Imaging technologist, in Guwahati city that is truly representing the entire state of Assam.

**Sampling**

The chief technologist or the senior most technologist in each facility was interviewed personally and the interview schedule is filled up based on input received. The survey was carried out in the month of March 2013. Based on the list of healthcare facility, the survey respondents were chosen. Out of 22 healthcare facilities, respondent were taken from 21 facility (response rate 95.4%). One facility, the 151 base hospital Guwahati did not participate owing to absence of the respondent at the time of survey.
Findings and Observations

The findings of present work are presented in four sub-headings

a. General information

b. Findings related to technology infusion

c. Current practice concerning medical device use

d. Safety attitude

A. General information

This section presents the data to develop a general understanding on the facilities housing CT scan and other imaging equipments.

Years in operation

Out of the 21 surveyed facilities 8 (38%) are less than 10 years old, 8 (38%) are between 10-15 years old and the rest 5 (24%) are over 15 years old.

Management

The bulk of health facilities are privately operated. In the sample 18 (86%) belonged to private sector, 3 (14%) belonged to Government sector.

Number of full time technologist in the facility

Most facilities of the sample were having up to 5 technologists manning the imaging facility. 15 (71%) facilities reported having up to 5 technologist. 5 (23%) facilities were having between 5-10 technologists and rest 1 facility had much larger number of technologists numbering at more than 10.

Equipment availability

A total of 68 X Ray machines in various, combinations and 58 ultrasonography equipments are available at these facilities. There were total 23 CT scanner and 10 MRI equipments. Rest of the equipments are much less in number, that comprises of 2 DEXA units, 3 mammography units & 4 cardiac cathlab equipment. Fig 6.2 shows the relative number of medical imaging equipment based on data collected from 21 facilities in Guwahati City.
B. Technology infusion

This section intends to understand the quantum of technology infusion over a period of time. The answers to Q1 & Q2 are compiled to arrive at the following result. In the sample of 21 facilities 6 (28%) facilities went for some new equipment in last 1 year, 10 (48%) facility had new equipment within last 2-3 years and only 5 (24%) facility did not have any new induction within last 3 years. Thus 70% of the facilities introduced some technology import to their facilities, the data is converted into pi chart in fig 6.3 for easy representation.

![New medical technology infusion](chart)

**Fig 6.3:** Technology Infusion in Health Facilities, 76% Facility Introduced Some Form of Equipment in Last 3 Years.
A further enquiry into the nature of technology upgradation, related to specific device revealed the following statistics. In last 5 years 13 new CT equipments were installed in these facilities either replacing older equipment or as starting facility. 9 MRI equipment were installed in this same time.

Accurate data on installation of X Ray or Ultrasound equipment were not forthcoming owing to larger number of these equipment, also probably lesser value assigned to them by the respondents.

**Technology trend**

Question no 3 & 5 were put in an attempt to understand the trend of technology use. The 19 out of 21(90%) respondents agreed to increased trend of imaging procedures. Specifically, the case of CT use was probed and 15(71%) respondent answered in the affirmative, confirming rise in use of this device.

It was further examined by asking about the trend of X ray equipment use (Question 4) whether it’s use has gone down in light of use of higher or sophisticated devices. 18 (86%) of the respondents answered in the negative, thus ruling out decrease use of less sophisticated devices of imaging.

Based on Inputs received, the increased use of both basic & advance form of imaging device can be confirmed, without compromising the scope of the other.

**Motive of technology induction**

Question 6, 8 and 9 were reflecting on the relevance of technology in healthcare setting. In reply to the question 6, whether modern equipment increases level of patient care 20(95%) out of 21 respondents answered in the affirmative.

The role of sophisticated technology in organisational growth was agreed by 20 (95%) respondent, in answering question 8.

Overwhelming 19, (90%) number of technologist believed that it is not possible to improve healthcare without installing modern equipment.
Present survey work gives powerful data to understand motive of technology induction and the dominant views of technology induction states that they are of great benefit to improve healthcare standard, it is also a driver of organisational growth in terms of hierarchy in the market.

*Technologists’ role in selecting device*

The role of the technologists in selecting new equipment was examined by asking a direct question (Question 7), and in response there is no clear answer. 10 (48%) respondents felt their opinion was important, equal 10(48%) respondent believed it was not important to have any opinion in the matter of technology selection as they are not consulted.

![Perceived drivers of new technology diffusion](image)

**Fig 6.4 : Drivers of Technology Diffusion**

Finally based on various exchanges of opinions, driver of technology diffusion is attempted to be identified. Based on the technologist’s feed backs six groups of drivers were identified and the data is tabulated. Technologists’ were asked to rate any number of factors as important to increased technology use. A total of 60 responses were divided over these six domains.

Highest number of technologist identified dependence of physician on new imaging devices as the chief driver of technology use followed by the fact of availability.

Financial incentive and affordability were chosen as the least important cause. Fig 6.4 graphically represents the identified drivers of technology diffusion.
C. Practices concerning Medical Imaging Devices

This section contained 10 questions which can be sub-grouped for analysis of the responses. The question no 1, 2, 3, 4, 5 and 10 were related to governance mechanism, while question 5 and 7 were for Equipment maintenance issues & finally question 6, 7, 8, 9 to gauge depth of prevailing ‘safety culture’.

Device governance issues

Overwhelming majority 9 (43%) respondent identified no informal or formal structure for clinical audit in the imaging department. Only 4(19%) had informed of existence of a board or proper committee to audit the department, and 6(29%) respondent informed of existence of staff meeting for the same function, the rest 2 (9%) respondent cited head of facility meeting as the only audit mechanism in existence. The data is graphically represented in Fig 6.5.

Fig 6.5: Presence of Departmental Clinical Audit Structure

14 (67%) respondent agreed that there is a formal structure to manage all equipment related issues. Rest 7 (33%) refrained from identifying any formal structure, neither did they comment on absence of such mechanism. Possibly in these situation no fix structure exists, but all malfunction, accidents, repairs are handled case to case basis on an a common sense approach.
Fig 6.6: Agreement Vs Disagreement on Existence of Formal Structure for Equipment Governance.

Chief technologist is identified as the key person in both cases of maintenance and information for breakdown. In 20 (95%) of the facilities chief technologist is made responsible for all issues of repair and device maintenance and malfunction.

In 12 facilities (57%) chief technologist gets the first news of equipment malfunction, and they state the process of correction by informing the proper people. In 7 (33%) facilities the facility head like the radiologist or medical superintendent gets first information of equipment malfunction from the on duty technologist or worker and in 2 (10%) facilities the owner gets the first information.

17 or 80% facilities have some arrangement with service provider or third party to manage equipment failure and repair.

19 facilities (90%) do have error reporting or adverse event reporting system to the in charge in place, which is a welcome sign of safety culture.

In summary, though in most instances no clear structure of governance exists in most medical imaging units, the chief technologist is the key person for most issues of maintenance and device administration, followed by the physician in charge of the facility. There is presence of a mechanism for equipment repair and also a clear system of error reporting and adverse event reporting to the facility in charge.
Equipment malfunction

On the issue of periodic checks and calibration of equipment the response is divided. There is somewhat agreement on regular calibration in 13 (62%) respondents, 3 (14%) respondents did not recall any such calibration or periodic checks and 5 (24%) respondents did not reply clearly.

The divided feedback on equipment calibration is reflected in Fig. 6.7.

![Calibration of X ray & CT equipment](image)

**Fig 6.7 : Calibration of Equipment**

Possibly there is poor understanding between the difference of preventive maintenance and calibration. As most of facilities are under arrangement with third party to provide annual service there are at least 2-3 preventive cleaning and maintenance call in almost all imaging devices. There is however a different calibration requirement for the Radiation related devices like CT, X Ray units are which are more specialised in nature and done irregularly.

Safety perspective

13 (62%) respondent agreed on existence of evacuation protocol for patients in times of emergencies. 8 (38%) respondents could not provide a definite response, and their view is counted as neutral on this subject as they did not out rightly rejected the presence of such protocol.
A very large number 12 (57%) of respondent answered poorly the question no 7, asking about frequency of checks maintained for emergency stock of drugs. They stated that only occasional checks were done. 7 (33%) respondent stated daily checks & remaining 2 (10%) stated about weekly checks. Fig 6.8 depicts the frequency of Periodic checks for emergency drugs, in medical imaging suites.

Fig 6.8: Different Standards for Emergency Trolley Checks

In response to education need fulfilment of the technologist 13 (62%) informed absence of training in facility regarding safe use of consumable (contrast). 7 (33%) stated sometimes training was available and 1 (5%) stated rare occasional training was available. The response is depicted in pi chart, in Fig 6.9.
Fig 6.9: Different Training Frequency for Technologists

D. Safety Perspective among Medical Imaging Device Users

This section contained a set of 20 questions, based on a standard safety attitude questionnaire. These questions are grouped as safety climate (1-7), working condition (8-11), management perception (12-15) and team work (16-20).

All these questions are given weightage of 5, 4, 3, 2, 1 based on agreement or disagreement on a 5 point scale (Agree strongly, agree, neutral, disagree & disagree strongly). For question 4 the marking is in reverse scale (Disagree strongly gets 5). The responses are given numerical value for each subgroup and then added and divided by the number of respondents in this case (21) than again by the number of questions for each group to arrive at a final score. Highest possible score is 5 in each domain, and score above 4 are considered acceptable. The present study scores are depicted graphically in Fig 6.10.

From the total 21 respondent’s score in safety climate section a total point of 681 was calculated which was divided by 21 (no of respondents). The obtained value is further divided by 7 (no of question was 7 in this section) to give a safety climate score for the population at 4.6.
Similarly working condition score was calculated at 4.8 from a total score of 411, divided by 21 (respondent) and then by 4 (question). The management perception was calculated at 4.5 and team work climate is assessed at 3.6.

**Fig 6.10: Graphic Representation of Scores in Different Safety Domains**

The overall safety perspective in the device users are good, but there needs to be better governance to increase management perception among the workers. There is reduced team work score in this population, which can be explained by the fact that the entire population is drawn from across different facility, and in some facilities team performance might be low.

The finding of high score in safety climate in medical imaging device use, needs explanation. Medical imaging devices are sophisticated equipments and they are governed by regulatory controls from Atomic Energy Regulatory Board. The health facilities housing sophisticated and costly equipments too are very concerned with their appropriate use and in most facilities the general rule is to let it run by experienced and trained personnel only. The equipments are mostly imported and these imported Class II equipment do have stringent control in their country of origin. Irrespective of the high score of safety climate, there are other empirical data to look at medical imaging.
Severe to moderate adverse events were recorded in many of these health facilities according to inputs obtained from the consumable supplier. There are at least 3-4 severe adverse events compromising health in imaging suites every year in North East India. These events are chiefly related to use of Iodinated intravenous injections, while putting patient in the X Ray or CT scanner. Considering number of facilities scattered in NE India, and the relative smaller number of events present study may not be mapping certain safety lapses. The study is also done among technologists, who are subordinate employees and actual adverse event data may not be communicated to the researcher. Table 6.6 presents the compiled data on adverse events for last three years based on industry sources. Three manufacturers provided the sales figure and reported events with use of product in NE India. All these adverse events were mild to moderate, no death resulted. The patients had to be admitted for medical attention as a result of these events. To understand the tabulated data one need to consider that in more than half of the CT scan one unit of such consumable is used, which points out that for every 6000-7000 scan a facility is going to face one incident of such Adverse event. Our data size being small it is difficult to infer much but considering reported volume of work (10-30 scan/ day ) in the CT facilities, it is expected that at least one adverse event might be occurring every 2-3 years in such facilities.

**Table 6.7 Adverse events from Iodinated contrast use**

<table>
<thead>
<tr>
<th>Year</th>
<th>Company 1: total sales in Units &amp; no of AE</th>
<th>Company 2: total units sold &amp; no of AE</th>
<th>Company 3: total units sold &amp; No of AE</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>21600 units, No AE</td>
<td>5565 Units, No AE</td>
<td>----</td>
</tr>
<tr>
<td>2011</td>
<td>19500 units, No AE</td>
<td>6311 Units, AE 1</td>
<td>----</td>
</tr>
<tr>
<td>2012</td>
<td>25200 units, 3 AE</td>
<td>6700 Units, AE 1</td>
<td>8400 units, AE 2</td>
</tr>
</tbody>
</table>

Source: Confidential business communication to researcher by Tyco, Bayer, GE, 2013

Present survey did not get a positive response in this regard, and possibly the technologist are instructed to communicate sensitive data only to the facility administration or statutory bodies.
6.6: Conclusion

In Northeast India in general and in the state of Assam in particular, governance of health technology is yet to draw attention either from legislators or the concerned public. The review of the legislative attempts and public discourse endorse this statement. Whereas technological penetration in the health domain has been high, particularly in the private health establishments and diagnostic centres, there is no corresponding regulatory mechanism either for safe use or to prevent any excess use of it for profiteering. Considering the scope of the study, it has not addressed issues like nexus among various stakeholders of the healthcare technology and also the profit motives. However, the input drawn from the users of technology which reveal a worrisome state of affairs in regulation of healthcare technology, it could reasonably be argued that in Guwahati city too technology has emerged as important driving force in healthcare particularly in the tertiary sector. Such penetration has created dominance of technology in deciding the state of health and also opened avenues of profiteering from sickness.


7 Ibid

8 http://www.myadcorner.com/assam-tribune-newspaper/cities.htm

9 Ibid

10 Confidential communication to researcher (2013) from GE, Tyco & Bayer healthcare, 2013