

Table of Contents

INTRODUCTION	2
PURPOSE.....	2
IMPORTANCE.....	3
METHODOLOGY	3
I. THE EMBODIMENT OF PRIVACY REGULATION WITHIN DOMESTIC LEGISLATION	3
Mental Health Act, 1987	5
Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994	5
Medical Termination of Pregnancy Act, 1971	6
Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002.....	6
(Code of Ethics Regulations, 2002)	6
Insurance Regulatory and Development Authority (Third Party Administrators) Health Services Regulations, 2001	8
EXCEPTIONS TO THE PROTECTION OF PRIVACY	8
Epidemic Diseases Act, 1897	8
POLICY AND REGULATIONS.....	9
National Policy for Persons with Disabilities, 2006	9
CASE LAW	10
II.REGULATION OF PRIVACY IN GOVERNMENT AND PRIVATE HOSPITALS AND DIAGNOSTIC LABORATORIES.....	16
III.INTERNATIONAL BEST PRACTISE AND RECOMMENDATIONS	20
KEY RECOMMENDATIONS.....	23
CONCLUSIONS.....	24

INTRODUCTION

To this date, there exists no universally acceptable definition of the right to privacy. It is a continuously evolving concept whose nature and extent is largely context driven. There are numerous aspects to the right to privacy, each different from the other in terms of the circumstance in which it is invoked. Bodily privacy however, is to date, the most guarded facet of this vastly expansive right. The privacy over one's own body including the organs, genetic material and biological functions that make up one's health is an inherent right that does not; as in the case of other forms of privacy such as communication or transactional privacy, emanate from the State. It is a right that has its foundations in the Natural Law conceptions of The Right to Life, which although regulated by the State can at no point be taken away by it except under extreme circumstances of a superseding Right to Life of a larger number of people.

The deliberation leading to the construction of a universally applicable Right to Privacy has up until now however only been in terms of its interpretation as an extension of the Fundamental Right to Life and Liberty as guaranteed under Article 21 as well as the freedom of expression and movement under Articles 19(1)(a) and (b) of the Constitution of India. While this may be a valid interpretation, it narrows the ambit of the right as one that can only be exercised against the State. The Right to privacy however has much larger implications in spheres that are often removed from the State. There is thus an impending need to create an efficient and durable structure of Law and policy that regulates the protection of privacy in Institutions that may not always be agents of the State.

It is in this regard that the following analysis studies the existing conceptions of privacy in the Healthcare sector. It aims to study the existing mechanisms of privacy protection and their pragmatic application in everyday practices. Further, it determines definitive policy gaps in the existing framework and endeavors to provide effective recommendations to not only redress these shortcomings but also create a system that is efficient in its fulfillment of the larger objective of the actualization of the Right to Privacy at an individual, state and institutional level.

PURPOSE

The purpose of this research study is to formulate a comprehensive guide that maps the synthesis, structure and implementation of privacy regulations within the healthcare sector in India. It traces the domestic legislation pertaining to various aspects of the healthcare sector and the specific provisions of the law that facilitate the protection of the privacy of individuals who furnish their personal information as well as genetic material to institutions of healthcare, either for the purpose of seeking treatment or to contribute to research studies. It is however imperative that the nature and extent of the information collected be restricted through the establishment of requisite safeguards at an institutional level that percolate down to everyday practices of data collection, handling and storage within healthcare institutions. The study thus aims to collate the existing systems of privacy protection in the form of laws, regulations and guidelines and compare these with actual practices in government and private hospitals and diagnostic laboratories to determine whether these laws are in fact effective in meeting the required standards of privacy protection. Further, the study also broadly looks at International practices of privacy protection and offers recommendations to better the existing mechanisms of delimiting unnecessary intrusions on the privacy of patients.

IMPORTANCE

The Indian Healthcare sector although at par with international standards in its methods of diagnosis, treatment and the use of contemporary technology, is still nascent in the nature and extent of its interaction with the Law. There are a number of aspects of healthcare that lie on the somewhat blurred line between the interest of the public and the sole right of the individual seeking treatment. One such aspect is the slowly evolving right to privacy. The numerous facets of this right have come to the fore largely through unique case laws that are reflective of a dynamic social structure, one that seeks to reconcile the socio economic rights that once governed society with individual interests that it has slowly come to realize. The right of an individual to disclose the nature of his disease, the liberty of a woman not to be compelled to undergo a blood test, the bodily autonomy to decide to bear children or not, the decisional privacy with regards to the termination of a pregnancy and the custodial rights of two individuals to their child are certain contentious aspects of healthcare that have constructed the porous interface between the right to privacy and the need for medical treatment. It is in this context that this study aims to delve into the existing basic structure of domestic legislation, case laws and regulations and their subsequent application in order to determine important gaps in the formulation of Law and Policy. The study thus aims to draw relevant conclusions to fill these gaps through recommendations sourced from international best practice in order to construct a broad framework upon which one can base future policy considerations and amendments to the existing law.

METHODOLOGY

This research study was undertaken in two major parts. The first part assesses domestic legislation and its efficacy in the current context. This is done through the determination of relevant provisions within the Act that are in consonance with the broader privacy principles as highlighted in the A.P Shah Committee report on Privacy Protection¹. This part of the research paper is based on secondary sources, both in terms of books as well as online resources. The second part of the paper analyses the actual practices with regard to the assimilation, organization, use and storage of personal data as practiced in Government and Private hospitals and Diagnostic laboratories. Three Private hospitals, a prominent Government hospital and a Diagnostic laboratory were taken into consideration for this study. The information was provided by the concerned personnel at the medical records department of these institutions of healthcare through a survey conducted on the condition of anonymity. The information provided was analyzed and collated in accordance with the compliance of the practices of these institutions with the Principles of privacy envisioned in the Report of the Group of Experts on Privacy.

I. THE EMBODIMENT OF PRIVACY REGULATION WITHIN DOMESTIC LEGISLATION

This section of the study analyses the viability of an approach that takes into account the efficacy of domestic legislation in regulating practices pertaining to the privacy of individuals in the healthcare sector. This approach perceives the letter and spirit of the law as the foundational structure upon which internal practices, self regulation and the effective implementation of policy

1. Report of the group of experts on Privacy chaired by Justice A.P Shah <http://planningcommission.nic.in/reports/genrep/rep_privacy.pdf> [Accessed on 14th May 2014]

considerations that aim to create an atmosphere of effective privacy regulation take shape, within institutions that offer healthcare services. To this effect, domestic legislation that provides for the protection of a patient's privacy has been examined. The law has been further studied with respect to its tendency to percolate into the everyday practices, regulations and guidelines that private and government hospitals adhere to. The extent of its permeation into actual practice; in light of its efficacy in fulfilling the perambulatory objectives of ensuring safe and unobtrusive practices, within the construct of which a patient is allowed to recover and seek treatment, has also been examined.

The term '**Privacy**' is used in a multitude of domestic legislations primarily in the **context of the foundation of the fiduciary relationship between a doctor and a patient**. This fiduciary relationship emanates from a reasonable expectation of mutual trust between the doctor and his patients and is established through the Indian Medical Council Act of 1952, specifically section 20(A) of the Act which lays down the code of ethics which a doctor must adhere to at all times. Privacy within the healthcare sector includes a number of aspects including but not limited to **informational privacy** (e.g., confidentiality, anonymity, secrecy and data security); **physical privacy** (e.g., modesty and bodily integrity); **associational privacy** (e.g. intimate sharing of death, illness and recovery); **proprietary privacy** (e.g., self-ownership and control over personal identifiers, genetic data, and body tissues); and **decisional privacy** (e.g., autonomy and choice in medical decision-making).

Privacy Violations stem from policy and information gaps: Violations in the healthcare sector that stem from policy formulation as well and implementation gaps² include the disclosure of personal health information to third parties without consent, inadequate notification to a patient of a data breach, unlimited or unnecessary collection of personal health data, collection of personal health data that is not accurate or relevant, the purpose of collecting data is not specified, refusal to provide medical records upon request by client, provision of personal health data to public health, research, and commercial uses without de-identification of data and improper security standards, storage and disposal. The disclosure of personal health information has the potential to be embarrassing, stigmatizing or discriminatory.³ Furthermore, various goods such as employment, life, and medical insurance, could be placed at risk ⁴if the flow of medical information were not restricted.⁵

Disclosure of personal health information is permitted and does not amount to a violation of privacy in the following situations: 1) during referral, 2) when demanded by the court or by the police on a written requisition, 3) when demanded by insurance companies as provided by the Insurance Act when the patient has relinquished his rights on taking the insurance, and 4) when required for specific provisions of workmen's compensation cases, consumer protection cases, or

2. Nissenbaum, H. (2004). Privacy as Contextual Integrity. *Washington Law Review*, 79(1), 101-139.

3. *Ibid*.

4. Thomas, J. (2009). Medical Records and Issues in Negligence, *Indian Journal of Urology : IJU : Journal of the Urological Society of India*, 25(3), 384-388. doi:10.4103/0970-1591.56208.

5. *Ibid*

for income tax authorities,⁶ 5) disease registration, 6) communicable disease investigations, 7) vaccination studies, or 8) drug adverse event reporting.⁷

The following domestic legislations have been studied and relevant provisions of the Act have been accentuated in order to analyse their compliance with the basic principles of privacy as laid out in the A.P Shah Committee report on Privacy.

Mental Health Act, 1987⁸

The Provisions under the Act pertaining to the protection of privacy of the patient have been examined. The principles embodied within the Act include aspects of the Law that determine the nature and extent of oversight exercised by the relevant authorities over the collection of information, the limitation on the collection of data and the restrictions on the disclosure of the data collected. The principle of oversight is embodied under the legislation within the provisions that allow for the inspection of records in psychiatric hospitals and nursing homes only by officers authorized by the State Government.⁹ The limitation on the Collection of information is imposed by the Inspection of living conditions by a psychiatrist and two social workers are on a monthly basis. This would include analyzing the living condition of every patient and the administrative processes of the psychiatric hospital and/or psychiatric nursing home.¹⁰ Additionally, Visitors must maintain a book regarding their observations and remarks.¹¹ Medical certificates may be issued by a doctor, containing information regarding the nature and degree of the mental disorder as reasons for the detention of a person in a psychiatric hospital or psychiatric nursing home.¹² Lastly, the disclosure of personal records of any facility under this Act by inspecting officers is prohibited¹³

Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994¹⁴

The Act was instituted in light of a prevalent public interest consideration of preventing female foeticide. However, it is imperative that the provision of the Act remain just shy of unnecessarily intrusive techniques and do not violate the basic human requirement of privacy in an inherently personal sphere. The procedure that a mother has to follow in order to avail of pre-natal diagnostic testing is mandatory consent of age, abortion history and family history. These conditions require a woman to reveal sensitive information concerning family history of mental retardation or

6. Plaza, J., & Fischbach, R. (n.d.). Current Issues in Research Ethics : Privacy and Confidentiality. Retrieved December 5, 2011, from <http://ccnmtl.columbia.edu/projects/cire/pac/foundation/index.html>.

7. *Ibid.*

8. The Mental Health Act, 1987 <<https://sadm.maharashtra.gov.in/sadm/GRs/Mental%20health%20act.pdf>> [Accessed on 14th May 2014]

9. The Mental Health Act, 1987, s. 13(1).

10. The Mental Health Act, 1987, s. 38.

11. The Mental Health Act, 1987, s. 40.

12. The Mental Health Act, 1987, s. 21(2).

13. The Mental Health Act, 1987, s. 13(1), *Proviso*.

14. Also see the: Pre-Conception and and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996.

physical deformities.¹⁵ **A special concern for privacy and confidentiality should be exercised with regards to disclosure of genetic information.**¹⁶

Medical Termination of Pregnancy Act, 1971¹⁷

Although, the right to an abortion is afforded to a woman within the construct of her inherent right to bodily privacy, decisional privacy (for e.g., autonomy and choice in medical decision-making) is not afforded to patients and their families with regards to determining the sex of the baby. The sections of the Act that have been examined lay down the provisions available within the Act to facilitate the protection of a woman's right to privacy during the possible termination of a pregnancy. These include the principles pertaining to the choice and consent of the patient to undergo the procedure, a limit on the amount of information that can be collected from the patient, the prevention of disclosure of sensitive information and the security measures in place to prevent the unauthorized access to this information. The Medical Termination of Pregnancy Regulations, 2003 supplement the Act and provide relevant restrictions within every day practices of data collection use and storage in order to protect the privacy of patients. The Act mandates *Written Consent* of the patient in order to facilitate an abortion. Consent implies that the patient is aware of all her options, has been counselled about the procedure, the risks and post-abortion care.¹⁸ The Act prohibits the disclosure of matters relating to treatment for termination of pregnancy to anyone other than the Chief Medical Officer of the State.¹⁹ The Register of women who have terminated their pregnancy, as maintained by the hospital, must be destroyed on the expiry of a period of five years from the date of the last entry.²⁰ The Act also emphasizes upon the security of information collected. The medical practitioner assigns a serial number for the woman terminating her pregnancy.²¹ Additionally, the admission register is stored in safe custody of the head of the hospital.²²

Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 (Code of Ethics Regulations, 2002)

The Medical Council of India (MCI) Code of Ethics Regulations²³ sets the professional standards for medical practice. These provisions regulate the nature and extent of doctor patient confidentiality. It also establishes universally recognized norms pertaining to consent to a

-
15. Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994, s. 4(3).
 16. Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994, s. 4(2). Pre-natal diagnostic techniques shall be conducted for the purposes of detection of: chromosomal abnormalities, genetic metabolic diseases, haemoglobinopathies, sex-linked genetic diseases, congenital anomalies any other abnormalities or diseases as may be specified by the Central Supervisory Board.
 17. Medical Termination of Pregnancy Amendment Act, 2002, Notification on Medical Termination of Pregnancy (Amendment) Act, Medical Termination of Pregnancy Regulations, 2003 and Medical Termination of Pregnancy Rules, 2003.
 18. Medical Termination of Pregnancy Act, 1971 (Amended in 2002), s. 2(4) and 4, and Medical Termination of Pregnancy Rules, 2003, Rule 8
 19. Medical Termination of Pregnancy Regulations, 2003, Regulation 4(5).
 20. Medical Termination of Pregnancy Regulations, 2003, Regulation 5.
 21. Medical Termination of Pregnancy Regulations, 2003, Regulation 4(2).
 22. Medical Termination of Pregnancy Regulations, 2003, Regulations 4(2) and 4(4).
 23. *Code of Ethics Regulations, 2002* available at <http://www.mciindia.org/RulesandRegulations/CodeofMedicalEthicsRegulations2002.aspx>.

particular medical procedure and sets the institutionally acceptable limit for intrusive procedure or gathering excessively personal information when it is not mandatorily required for the said procedure. The provisions addressed under these regulations pertain to the Security of the information collected by medical practitioners and the nature of doctor patient confidentiality.

Physicians are obliged to protect the confidentiality of patients⁵ during all stages of the procedure and with regard to all aspects of the information provided by the patient to the doctor, including information relating to their personal and domestic lives²⁴. The only exception to this mandate of confidentiality is if the law requires the revelation of certain information, or if there is a serious and identifiable risk to a specific person and / or community of a notifiable disease.

Ethical Guidelines for Biomedical Research on Human Subjects²⁵

The provisions for the regulation of privacy pertaining to biomedical research include aspects of consent as well as a limitation on the information that may be collected and its subsequent use. The provisions of this act aim to regulate the protection of privacy during clinical trials and during other methods of research. The principal of informed consent is an integral part of this set of guidelines. The Privacy related information included in the participant/ patient information sheet includes: the choice to prevent the use of their biological sample, the extent to which confidentiality of records could be maintained and the consequences of breach of confidentiality, possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, the risk of discovery of biologically sensitive information and publications, including photographs and pedigree charts.²⁶ The Guidelines require special concern for privacy and confidentiality when conducting genetic family studies.²⁷ The protection of privacy and maintenance of confidentiality, specifically surrounding the identity and records, is maintained when using the information or genetic material provided by participants for research purposes.²⁸ The Guidelines require investigators to maintain confidentiality of epidemiological data due to the particular concern that some population based data may also have implications on issues like national security or public safety.²⁹ All documentation and communication of the Institutional Ethics Committee (IEC) must be dated, filed and preserved according to the written procedures. Data of individual participants can be disclosed in a court of law under the orders of the presiding judge, if there is a threat to a person's life, communication to the drug registration authority regarding cases of severe adverse reaction and communication to the health authority if there is risk to public health.³⁰

24. *Code of Ethics Regulations*, 2002 Chapter 2, Section 2.2.

25. *Ethical Guidelines for Biomedical Research on Human Subjects*. (2006) Indian Council of Medical Research New Delhi.

26. *Informed Consent Process*, *Ethical Guidelines for Biomedical Research on Human Subjects* (2006). Indian Council of Medical Research New Delhi. P. 21.

27. *Statement of Specific Principles for Human Genetics Research*, *Ethical Guidelines for Biomedical Research on Human Subjects* (2000). Indian Council of Medical Research New Delhi. P. 62.

28. *General Ethical Issues*. *Ethical Guidelines for Biomedical Research on Human Subjects* (2006). Indian Council of Medical Research New Delhi. P. 29.

29. *Statement of Specific Principles for Epidemiological Studies*, *Ethical Guidelines for Biomedical Research on Human Subjects* (2000). Indian Council of Medical Research New Delhi. P. 56.

30. *Statement of General Principles, Principle IV and Essential Information on Confidentiality for Prospective Research Participants*, *Ethical Guidelines for Biomedical Research on Human Subjects* (2006). Indian Council of Medical

Insurance Regulatory and Development Authority (Third Party Administrators) Health Services Regulations, 2001

The provisions of the Act that have been addressed within the scope of the study regulate the practices of third party administrators within the healthcare sector so as to ensure their compliance with the basic principles of privacy. An exception to the maintenance and confidentiality of information confidentiality clause in the code of conduct, requires TPAs to provide relevant information to any Court of Law/Tribunal, the Government, or the Authority in the case of any investigation carried out or proposed to be carried out by the Authority against the insurance company, TPA or any other person or for any other reason.³¹ In July 2010, the IRDA notified the Insurance Regulatory and Development Authority (Sharing of Database for Distribution of Insurance Products) Regulations³². These regulations restrict referral companies from providing details of their customers without their prior consent.³³ TPAs must maintain the confidentiality of the data collected by it in the course of its agreement and maintain proper records of all transactions carried out by it on behalf of an insurance company and are also required to refrain from trading information and the records of its business³⁴. TPA's must keep records for a period of not less than three years.³⁵

IDRA Guidelines on Outsourcing of Activities by Insurance Companies³⁶

These guidelines require the insurer to take appropriate steps that require third party service providers protect confidential information of both the Insurer and its clients from intentional or inadvertent disclosure to unauthorized persons.³⁷

EXCEPTIONS TO THE PROTECTION OF PRIVACY

The legal provisions with regard to privacy, confidentiality and secrecy are often superseded by Public Interest Considerations. The right to privacy, although recognized in the course of Indian jurisprudence and embodied within domestic legislation is often overruled prima facie when faced with situations or instances that involve a larger interest of a greater number of people. This policy is in keeping with India's policy goals as a social welfare state to aid in the effectuation of its utilitarian ideals. This does not allow individual interest to at any point surpass the interest of the masses.

Epidemic Diseases Act, 1897³⁸

Implicit within this formulation of this Act is the assumption that in the case of infectious diseases, the right to privacy, of infected individuals must give way to the overriding interest of protecting public health.³⁹ This can be ascertained not only from the black letter of the Law but also from its

Research New Delhi. P. 29.

31. The IRDA (Third Party Administrators - Health Services) Regulations 2001, (2001), Chapter 5. Section 2.

32. The IRDA (Sharing Of Database for Distribution of Insurance Products) Regulations 2010.

33. The IRDA (Sharing Of Database For Distribution Of Insurance Products) Regulations 2010.

34. The IRDA (Sharing Of Database For Distribution Of Insurance Products) Regulations 2010

35. List of TPAs Updated as on 19th December, 2011, Insurance Regulatory and Development Authority (2011), http://www.irda.gov.in/ADMINCMS/cms/NormalData_Layout.aspx?page=PageNo646 (last visited Dec 19, 2011).

36. The IRDA, Guideline on Outsourcing of Activities by Insurance Companies, (2011).

37. The IRDA, Guideline on Outsourcing of Activities by Insurance Companies, (2011), Section 9.11. P. 8.

38. *The Epidemic Diseases Act*, 1897.

39. *The Epidemic Diseases Act*, 1897. s. 2.1.

spirit. Thus, in the absolute positivist as well as a more liberal interpretation, at the crux of the legislation lies the undeniable fundamental covenant of the preservation of public health, even at the cost of the privacy of a select few individuals⁴⁰.

POLICY AND REGULATIONS

National Policy for Persons with Disabilities, 2006⁴¹

The following provisions of the Act provide for the incorporation of privacy considerations in prevalent practices with regard to persons with disabilities. The National Sample Survey Organization collects the **following information on persons with disabilities**: the socio-economic and cultural context, cause of disabilities, early childhood education methodologies and all matters connected with disabilities, at least once in five years.⁴²This data is collected by non-medical investigators.⁴³There is thus an inherent limit on the information collected. Additionally, this information is used only for the purpose for which it has been collected.

The Special Employment Exchange, as established under The Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995 Act, collects and furnishes information in registers, regarding provisions for employment. **Access to such data is limited to** any person who is authorized by the Special Employment Exchange as well as persons authorized by general or special order by the Government, to access, inspect, question and copy any relevant record, document or information in the possession of any establishment.⁴⁴ When conducting research on persons with disabilities consent is required from the individual or their family members or caregivers.⁴⁵

HIV Interventions

In 1992, the Government of India instituted the National AIDS Control Organization (NACO) for the prevention and control of AIDS. NACO aims to control the spread of HIV in India through the implementation of Targeted Interventions (TIs) for most at risk populations (MARPs) primarily, sex workers, men having sex with men and people who inject drugs.⁴⁶The Targeted Interventions (TIs) system of testing under this organization has however raised numerous concerns about relevant policy gaps in the maintenance of the confidentiality and privacy of persons living with HIV/ AIDS. The shortcomings in the existing policy framework include: The Lack of a limitation and subsequent confidentiality in the amount of Information collected. Project staff in TIs record the name, address and other contact information of MARPs and share this data with Technical Support Unit and State AIDS Control Societies.⁴⁷ Proof of address and identity

40. *The Epidemic Diseases Act*, 1897, s. 2.2(b).

41. The National Policy for Persons with Disabilities, 2006, Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995, Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Rules, 1996.

42. Research, National Policy for Persons with Disabilities, 1993.

43. Survey of Disabled Persons in India. (December 2003) National Sample Survey Organization. Ministry of Statistics and Programme Implementation. Government of India.

44. Persons With Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act. 1995, Section 35.

45. **Research. National Policy for Persons with Disabilities, 2003.**

46. <http://www.lawyerscollective.org/files/Anti%20rights%20practices%20in%20Targetted%20Interventions.pdf>

47. <http://www.lawyerscollective.org/files/Anti%20rights%20practices%20in%20Targetted%20Interventions.pdf>

documents are required to get enrolled in government ART programs.⁴⁸ Peer-educators operate under a system known as line-listing, used to make referrals and conduct follow-ups. Peer-educators have to follow-up with those who have not gone at regular intervals for testing.⁴⁹ This practice can result in peer-educators noticing and concluding that the names missing are those who have tested positive.⁵⁰ Although voluntary in nature, the policy encourage the fulfillment of fulfilling of numerical targets, and in doing so supports unethical ways of testing.⁵¹

The right to privacy is an essential requirement for persons living with HIV/AIDS due to the potential stigmatizing and discriminatory impact of the revelation of this sensitive information, in any form.⁵² The lack of privacy rights often fuels the spread of the disease and exacerbates its impact on high risk communities of individuals. Fears emanating from a privacy breach or a disclosure of data often deter people from getting tested and seeking medical care. The impact of such disclosure of sensitive information including the revelation of tests results to individuals other than the person being tested include low self esteem, fear of loss of support from family/peers, loss of earnings especially for female and transgender sex workers, fear of incrimination for illicit sex/drug use and the insensitivity of counselors.⁵³ HIV positive individuals live in constant fear of their positive status being leaked. They also shy away from treatment as they fear people might see them taking their medicines and thereby guess their status. Thus breaches in confidentiality and policy gaps in privacy regulation, especially with respect to diseases such as HIV also prevents people from seeking out treatment.⁵⁴

CASE LAW

The following cases have been used to deliberate upon important points of contention within the ambit of the implementation and impact of Privacy Regulations in the healthcare sector. This includes the nature and extent of privacy enjoyed by the patient and instances where in the privacy of the patient can be compromised in light of public interest considerations.

Mr. Surupsingh Hrya Naik vs. State of Maharashtra,⁵⁵ (2007)

48. Aneka, Karnataka Sexual Minorities Forum. (2011) "Chasing Numbers, Betraying People: Relooking at HIV Services in Karnataka". P 22.

49. Aneka, Karnataka Sexual Minorities Forum. (2011) "Chasing Numbers, Betraying People: Relooking at HIV Services in Karnataka". P 16.

50. Aneka, Karnataka Sexual Minorities Forum. (2011) "Chasing Numbers, Betraying People: Relooking at HIV Services in Karnataka". P 16.

51. Aneka, Karnataka Sexual Minorities Forum. (2011) "Chasing Numbers, Betraying People: Relooking at HIV Services in Karnataka". P 14.

52. <http://www.hivaidsonline.in/index.php/HIV-Human-Rights/legal-issues-that-arise-in-the-hiv-context.html>

53. Chakrapani et al, (2008) 'HIV Testing Barriers and Facilitators among Populations at-risk in Chennai, India', INP, p 12.

54. Aneka, Karnataka Sexual Minorities Forum. (2011) "Chasing Numbers, Betraying People: Relooking at HIV Services in Karnataka". P 24.

55. <http://www.indiankanoon.org/doc/570038/>

Since the Code of Ethics Regulations are only delegated legislation, it was held in the case of *Mr. Surupsingh Hrya Naik v. State Of Maharashtra*,⁵⁶ that these would not prevail over the Right to Information Act, 2005 (**RTI Act**) unless the information sought falls under the exceptions contained in Section 8 of the RTI Act. This case dealt with the important point of contention of whether making the health records public under the RTI Act would constitute a violation of the right to privacy. These health records were required to determine why the convict in question was allowed to stay in a hospital as opposed to prison. In this context the Bombay High Court held that The Right to Information Act supersedes the regulation that mandate the confidentiality of a person, or in this case a convict's medical records. It was held that the medical records of a person sentenced or convicted or remanded to police or judicial custody, if during that period such person is admitted in hospital and nursing home, should be made available to the person asking the information provided such hospital nursing home is maintained by the State or Public Authority or any other Public Body. It is only in rare and in exceptional cases and for good and valid reasons recorded in writing can the information may be denied.

The decision in this case held that The RTI Act 2005 would supersede The Medical Council Code of Ethics. The health records of an individual in judicial custody should be made available under the Act and can only be denied in exceptional cases, for valid reasons.

Radiological & Imaging Association v. Union of India,⁵⁷ (2011)

On 14 January 2011 a circular was issued by the Collector and District Magistrate, Kolhapur requiring the Radiologists and Sonologists to submit an on-line form "F" under the PNDT Rules. This was challenged by the Radiological and Imaging Association, *inter alia*, on the ground that it violates the privacy of their patients. Deciding the above issue the Bombay High Court held that .The images stored in the silent observer are not transmitted on-line to any server and thus remain embedded in the ultra-sound machine. Further, the silent observer is to be opened only on request of the Collector/ the civil surgeon in the presence of the concerned radiologist/sonologist/doctor incharge of the Ultra-sound Clinic. In light of these considerations and the fact that the 'F' form submitted on-line is submitted only to the Collector and District Magistrate is no violation of the doctor's duty of confidentiality or the patient's right to privacy. It was further observed that The contours of the right to privacy must be circumscribed by the compelling public interest flowing through each and every provision of the PC&PNDT Act, when read in the background of the following figures of declining sex ratio in the last five decades.

Smt. Selvi and Ors. v. State of Karnataka (2010)

The use of a Silent Observer system on a sonograph has requisite safeguards and doesn't violate privacy rights. The declining sex ratio of the country was considered a compelling public Interest that could supersede the right to privacy.

The Supreme Court held that involuntary subjection of a person to narco analysis, polygraph test and brain-mapping violates the 'right against self-incrimination' which finds its place in Article

56. <http://www.indiankanoon.org/doc/570038/>

57. <http://www.indiankanoon.org/doc/680703/>

20(3)⁵⁸ of the Constitution.⁵⁹ The court also found that narco analysis violated individuals' right to privacy by intruding into a "subject's mental privacy," denying an opportunity to choose whether to speak or remain silent, and physically restraining a subject to the location of the tests and amounted to cruel, inhuman or degrading treatment.⁶⁰

The Supreme Court found that Narco-analysis violated an individuals' right to privacy by intruding into a "subject's mental privacy," denying an opportunity to choose whether to speak or remain silent.

Neera Mathur v. Life Insurance Corporation (LIC),⁶¹ (1991)

In this case the plaintiff contested a wrongful termination after she availed of maternity leave. LIC required women applicants to furnish personal details like their menstrual cycles, conceptions, pregnancies, etc. at the time of appointment. Such a requirement was held to go against the modesty and self respect of women. The Court held that termination was only because of disclosures in application, which was held to be intrusive, embarrassing and humiliating. LIC was directed to delete such questions.

The Court did not refer to the term privacy however it used the term personal details as well as modesty and self respect, but did not specifically link them to the right to life or any other fundamental right. These terms (modesty and self respect) are usually not connected to privacy but although they may be the harm which comes from an intrusion of one's privacy.

The Supreme Court held that Questions related to an individual's reproductive issues are personal details and should not be asked in the service application forms.

Ms. X vs. Mr. Z & Anr,⁶² (2001)

In this case, the Delhi High Court held that an aborted foetus was not a part of the body of a woman and allowed the DNA test of the aborted foetus at the instance of the husband. The application for a DNA test of the foetus was contested by the wife on the ground of "Right to Privacy".⁷In this regard the court held that The Supreme Court had previously decided that a party may be directed to provide blood as a DNA sample but cannot be compelled to do so. The Court may only draw an adverse interference against such party who refuses to follow the direction of the Court in this respect. The position of the court in this case was that the claim that the preservation of a foetus in the laboratory of the All India Institute of Medical Science, violates the petitioner's right to privacy, cannot be entertained as the foetus had been voluntarily discharged from her body

58. No person accused of any offence shall be compelled to be a witness against himself, (the 'right to silence').

59. <http://indiankanoon.org/doc/338008/>

60. <http://www.hrdc.net/sahrdc/hrfeatures/HRF205.pdf>

61. AIR 1992 SC 392.

62. 96 (2002) DLT 354.

previously, with her consent. The foetus, that she herself has discharged is claimed to be subjected to DNA test. Thus, in light of the particular facts and the context of the case, it was held that petitioner does not have any right of privacy.

It is important to note here that the fact that the Court is relying upon the principles laid down in the case of *R. Rajagopal* seems to suggest that the Court is treating organic tissue preserved in a public hospital in the same manner as it would treat a public document, insofar as the exception to the right to privacy is concerned.

A woman's right to privacy does not extend to a foetus, which is no longer a part of her body. The right to privacy may arise from a contract as well as a specific relationship, including a marital relationship. The principle in this case has been laid down in broad enough terms that it may be applied to other body parts which have been disassociated from the body of the individual.

B.K Parthasarathi vs. Government of Andhra Pradesh,⁶³ (1999)

In this case, the Andhra Pradesh High Court was to decide the validity of a provision in the Andhra Pradesh Panchayat Raj Act, 1994 which stipulated that any person having more than two children should be disqualified from contesting elections. This clause was challenged on a number of grounds including the ground that it violated the right to privacy. The Court, in deciding upon the right to privacy and the right to reproductive autonomy, held that The impugned provision, i.e. Section 19(3) of the said Act does not compel directly anyone to stop procreation, but only disqualifies any person who is otherwise eligible to seek election to various public offices coming within the ambit of the Andhra Pradesh Panchayat Raj Act, 1994 or declares such persons who have already been holding such offices to be disqualified from continuing in such offices if they procreate more than two children. Therefore, the submission made on behalf of the petitioners 'right to privacy' is infringed, is untenable and must be rejected."

Mr. X v. Hospital Z, Supreme Court of India,⁶⁴ (1998 and 2002)

The petitioner was engaged to be married and thereafter during tests for some other illness in the hospital it was found that the petitioner was HIV positive. This information was released by the doctor to the petitioner's family and through them to the family of the girl to whom the petitioner was engaged, all without the consent of the petitioner. The Court held that:

"The Right to privacy is not treated as absolute and is subject to such action as may be lawfully taken for the prevention of crime or disorder or protection of health or morals or protection of rights and freedoms of others."

This decision of this case could be interpreted to extend the principle, of disclosure to the person at risk, to other communicable and life threatening diseases as well. However, a positivist interpretation would render these principle applicable to only to HIV+ cases.

Right to privacy and is subject to such action as may be lawfully taken for the prevention of crime or disorder or protection of health or morals or protection of rights and freedoms of others.

63. AIR 2000 A.P 156.

64. <http://indiankanoon.org/doc/382721/>

*M. Vijaya v. Chairman and Managing Director, Singareni Collieries Co. Ltd.*⁶⁵ (2001)

The petitioner alleged that she had contracted the HIV virus due to the negligence of the authorities of Maternity and Family Welfare Hospital, Godavarikhani, a hospital under the control of Singareni Collieries Company Ltd., (SCCL), in conducting relevant precautionary blood tests before transfusion of blood of her brother (donor) into her body when she was operated for hysterectomy (Chronic Cervicitis) at the hospital. The petition was initially filed as a Public Interest Litigation, which the court duly expanded in order to address the problem of the lack of adequate precautionary measures in hospitals, thereby also dealing with issues of medical confidentiality and privacy of HIV patients. The court thus deliberated upon the conflict between the right to privacy of an HIV infected person and the duty of the state to prevent further transmission and held:

In the interests of the general public, it is necessary for the State to identify HIV positive cases and any action taken in that regard cannot be termed as unconstitutional. As under Article 47 of the Constitution, the State was under an obligation to take all steps for the improvement of the public health. A law designed to achieve this object, if fair and reasonable, in our opinion, will not be in breach of Article 21 of the Constitution of India

However, another aspect of the matter is whether compelling a person to take HIV test amounts to denying the right to privacy? The Court analyzed the existing domestic legislation to arrive at the conclusion that there is no general law that can compel a person to undergo an HIV-AIDS test. However, specific provisions under the Prison Laws⁶⁶ provide that as soon as a prisoner is admitted to prison, he is required to be examined medically and the record of prisoner's health is to be maintained in a register. Further, Under the ITP Act, the sex workers can also be compelled to undergo HIV/ AIDS test.⁶⁷ Additionally, under Sections 269 and 270 of the Indian Penal Code,

The right of reproductive autonomy is a component of the right to privacy .A provision disqualifying a person from standing for elections due to the number of children had, does not violate the right to privacy as the object of the legislation is not to violate the autonomy of an individual but to mitigate the population growth in the country. Measures to control population growth shall be considered legal unless they impermissibly violate a fundamental right.

1860, a person can be punished for negligent act of spreading infectious diseases.

After mapping legislation that permit the invasion of bodily privacy, the Court concluded that they are not comprehensive enough to enable the State to collect information regarding patients of HIV/AIDS and devise appropriate strategies and therefore the State should draft a new legislation

The right to privacy of a person suspected to be HIV+ would be subordinate to the power and duty of the state to identify HIV+ patients in order to protect public interest and improve public health. However any law designed to achieve this object must be fair and reasonable. In a conflict between the individual's privacy right and the public's right in dealing with the cases of HIV-AIDS, the Roman Law principle 'SalusPopuliEstSuprema' (regard for the public wealth is the highest law) applies when there is a necessity.

65. <http://indiankanoon.org/doc/859256/>

66. See Sections 24, 37, 38 and 39 of The Prisons Act, 1894 (Central Act 9 of 1894) Rules 583 to 653 (Chapter XXXV) and Rules 1007 to 1014 (Chapter LVII) of Andhra Pradesh Prisons Rules, 1979

67. Section 10-A, 17(4), 19(2) Immoral Traffic (Prevention) Act 1956

in this regard. Further the Court gave certain directions to the state regarding how to handle the epidemic of HIV/AIDS and one of those directions was that the “Identity of patients who come for treatment of HIV+/AIDS should not be disclosed so that other patients will also come forward for taking treatment.”

Sharda v. Dharmpal,⁶⁸ (2003)

The basic question in this case was whether a party to a divorce proceeding can be compelled to a medical examination. The wife in the divorce proceeding refused to submit herself to medical examination to determine whether she was of unsound mind on the ground that such an act would violate her right to personal liberty. Discussing the balance between protecting the right to privacy and other principles that may be involved in matrimonial cases such as the ‘best interest of the child’ in case child custody is also in issue, the Court held:

"Privacy" is defined as "the state of being free from intrusion or disturbance in one's private life or affairs". However, the right to privacy in India, is only conferred through an extensive interpretation of Article 21 and cannot therefore in any circumstance be considered an absolute right. Mental health treatment involves disclosure of one's most private feelings. However, like any other privilege the psychotherapist-patient privilege is not absolute and may only be recognized if the benefit to society outweighs the costs of keeping the information private. Thus if a child's best interest is jeopardized by maintaining confidentiality the privilege may be limited." Thus, the power of a court to direct medical examination of a party to a matrimonial litigation in a case of this nature cannot be held to violate the petitioner's right to privacy.

<p>If the best interest of a child is in issue in the case then the patient's right to privacy and confidentiality would get limited. The right to privacy of an individual would be subordinate to the power of a court to arrive at a conclusion in a matrimonial dispute and the right of a party to protect his/her rights in a Court of law would trump the right to privacy of the other.</p>

68. <http://www.indiankanoon.org/doc/1309207/>

II. REGULATION OF PRIVACY IN GOVERNMENT AND PRIVATE HOSPITALS AND DIAGNOSTIC LABORATORIES

A. FIELD STUDY

The Hospitals that have been chosen for the analysis of the efficacy of these legislations include prominent Government Hospitals, Private Hospitals and Diagnostic Centers. These Institutes were chosen because of their widely accredited status as centers of medical research and cutting edge treatment. They have also had a long standing reputation due to their staff of experienced and skilled on call doctors and surgeons. The Private Hospitals chosen had patient welfare centers that addressed the concerns of patients including questions and doubts relating to but not limited to confidentiality and consent. The Government hospitals had a public relations office that addressed the concerns of discharged patients. They also provided counseling services to patients to aid them in addressing concerns relate to the treatment that they might want to be kept confidential. Diagnostic laboratories also have an HR department that addresses similar concerns. The laboratory also has a patient welfare manager who addresses the concerns and queries of the patient prior to and during the procedure.

The following section describes the practices promulgated by Government and Private Hospitals, as well as Diagnostic Laboratories in their endeavor to comply with the basic principles of privacy as laid down in the A.P Shah Committee report on Privacy.

(i) Notice

Through an analysis of the information provided by Government and Private hospitals and diagnostic laboratories, relevant conclusions were drawn with regard to the nature, process and method in which the patient information is recorded. Through interviews of various medical personnel including administrative staff in the patient welfare and medical records departments we observed an environment of openness and accountability within the structure of the patient registration system.

In Government Hospitals, the patient is notified of all types of information that is collected, in terms of both personal information as well as medical history. The Patient admission as well as the patient consent form is filled out by the patient or the attending relative accompanying the patient and assistance for the same is provided by the attending staff members, who explain the required details that need to be filled in a language that the patient is able to understand. The patient is notified of the purpose for which such information is collected and the procedure that he/ she might have to undergo depending on his injury or illness. The patient is not however, notified of the method in which he/she may correct or withdraw the information that is provided. There is no protocol provided for the correction or withdrawal of information, once provided. The patient is, at all times notified of the extent and nature of doctor patient confidentiality including the fact that his/her personal information would not be shared even with his/her immediate relatives , insurance companies, consulting doctors who are not directly involved with his/her treatment or any unauthorized third party without requisite consent from the patient. The patient is informed of the fact that in some cases the medical records of the patient will have to be shared with consulting doctors and that all the patient's medical records would be provided to insurance companies, but this will only be done with the consent of the patient.

The same system of transparency and accountability transcends across private hospitals and diagnostic laboratories as well. In private hospitals, the patient is informed of all the information that is collected and the purpose for which such information may be collected. Diagnostic

laboratories have specific patient consent forms for specific types of procedures which the patient will have to fill out depending on the required tests. These forms contain provisions with regard to the confidential nature of all the information provided. This information can only be accessed by the patient and the consulting doctor with the consent of the patient. Both private hospitals and diagnostic laboratories have a specific protocol and procedure in place to correct or withdraw information that has been provided. In order to do so the patient would have to contact the medical records department with requisite proof of the correct information. Private hospitals inform patients of the nature and extent of doctor patient confidentiality at every stage of the registration process. Some private hospitals contain patient safety brochures which inform patients about the nature and extent of consent and confidentiality, even with regard to consulting doctors and insurance agencies. If the patient does not want certain information revealed to insurance agencies the hospital will retain such records and refraining from providing them to third party insurance agencies. Thus, all information provided by the patient remains confidential at the behest of the patient.

(ii) Choice and Consent

Choice and consent are two integral aspects of the regulation of privacy within the healthcare sector. Government and Private hospitals as well as diagnostic laboratories have specific protocols in place to ensure that the consent of the patient is taken at every stage of the procedure. The consent of the patient can also be withdrawn just prior to the procedure even if this consent has already been given by the patient in writing, previously. The choice of the patient is also given ample importance at all stages of the procedure. The patient can refuse to provide any information that may not mandatorily required for the treatment provided basic information regarding his identity and contact information in case of emergency correspondence has been given.

(iii) Collection Limitation

The information collected from the patient in both government and private hospitals is used solely for the purpose that the patient has been informed of. In case this information is used for purposes other than for the purpose that the patient has been informed of, the patient is informed of this new purpose as well. Patient records in both Government and Private hospitals are stored in the Medical Records Department as hard copies and in some cases as scanned soft copies of the hard copy as well. These Medical Records are all stored within the facility. The duration for which the records are stored range from a minimum of two years to a maximum of ten years in most private hospitals. Some private hospitals store these records for life. Government hospitals store these records for a term of thirty years only as hard copies after which the records are discarded. Private hospitals make medical records accessible to any medical personnel who may ask for it provided the requisite proof of identity and reasons for accessing the same are provided, along with an attested letter of authorization of the doctor who is currently involved or had been involved in the treatment of the patient. Government hospitals however do not let any medical personnel access these records except for the doctor involved in the treatment of that particular patient. Both private and government hospitals are required to share the medical records of the patient with the insurance companies. Government Hospitals only share patient records with nationalized insurance agencies such as The Life Insurance Corporation of India (LIC) but not with private insurance agencies. The insurance claims forms that are required prior to providing medical records to the insurance companies mandatorily require the signature of the patient. The patient is thus informed that his records will be shared with the insurance agencies and his signature is a proof of his implied consent to the sharing of these records with the company with which he has filed a health insurance claim.

Diagnostic laboratories collect patient information solely for the purpose of the particular test that they have been asked to conduct by the treating or consulting doctor. Genetic samples (Blood, Semen, Urine etc) are collected at one time and the various tests required are conducted on these samples. In case of any additional testing that is required to be conducted on these samples, the patient is informed. Additional testing is conducted only in critical cases and in cases where the referral doctor requests for the same to be conducted on the collected samples. In critical cases, where immediate testing is required and the patient is unreachable, the testing is conducted without informing the patient. The patient is mandatorily informed after the test that such additional testing was conducted. The patient sample is stored for one week within the same facility. The Patient records are digitized. They can only be accessed by the patient, who is provided with a particular username and password using which he can access only his records. The information is stored for a minimum of two years. This information can be made available to a medical personnel only if such medical personnel has the required lab no, the patients name, and reason for which it needs to be accessed. He thus requires the permission of the authorities at the facility as well as the permission and consent of the patient to access such records. The Medical test records of a patient are kept completely confidential. Even insurance companies cannot access such records unless they are provided to the company by the patient himself. In critical cases however, the patient information and tests results are shared with the treating or referral doctor without the consent of the patient.

(iv) Purpose Limitation

In Government and Private Hospitals, the information is only used for the purpose for which it is collected. There is thus a direct and relevant connection between the information collected and the purpose for which it used. Additional information is collected to gauge the medical history of the patient that may be relevant to the disease that has to be treated. The information is never deleted after it has been used for the purpose for which it had been collected. The Medical Records of the patient are kept for extended periods in hard copy as well as soft copy versions. There is a provision for informing the patient in case the information is used for any purpose other than the purpose for which it was collected. Consent of the patient is taken at all stages of collecting and utilizing the information provided by him.

Diagnostic Laboratories have a database of all the information collected which is saved in the server. The information is mandatorily deleted after it has been used for the purpose for which it was collected after a period of two years. In case the information is used for any purpose other than the purpose for which it was collected, for example, in critical cases where additional tests have to be conducted the patient is\ always informed of the same.

(v) Access and Correction

In private hospitals, the patient is allowed to access his own records during his stay at the hospital. He is given a copy of his file upon his discharge from the hospital in the form of a discharge summary. However, if he needs to access the original records at a later stage, he can do so by filing a request for the same at the Medical Records Department of the hospital. A patient can make amendments or corrections to his records by providing requisite proof to substantiate the amended information. The patient however at no stage can confirm if the hospital is holding or processing personal information about him or her with the exception of the provisions provided for the amendment or correction to the information held.

The Medical records of a patient in a government hospital are completely sealed. A patient has no access to his own records. Only the concerned doctor who was treating the patient during his stay

at the hospital can access the records of the patient. This doctor has to be necessarily associated with the hospital and had to have been directly involved in the patient's treatment in order to access the records. The patient is allowed to amend information in his medical records but only generic information such as the spelling of his name, his address, telephone number etc. The patient is at no point allowed to access his own records and therefore cannot confirm if the hospital is holding or processing any information about him/her. The patient is only provided with a discharge summary that includes his personal information, the details of his disease and the treatment provided in simple language.

Diagnostic laboratories have an online database of patient records. The patient is given a username and a password and can access the information at any point. The patient may also amend or correct any information provided by contacting the Medical records department for the same. The patient can at any time view the status of his record and confirm if it is being held or processed by the hospital. A copy of such information can be obtained by the patient at any time.

(vi) Disclosure of Information

Private Hospitals are extremely cautious with regard to the disclosure of patient information. Medical records of patients cannot be accessed by anyone except the doctor treating that particular patient or consulting on the case. The patient is informed whenever his records are disclosed even to doctors. Usually, even immediate relatives of the patient cannot access the patient's records without the consent of the patient except in cases where the condition of the patient is critical. The patient is always informed about the type and extent of information that may be disclosed whenever it is disclosed. No information of the patient is made available publicly at any stage. The patient can refuse to consent to sharing of information collected from him/her with non-authorized agencies. However, in no circumstance is the information collected from him/her shared with non authorized agencies. Some private hospitals also provide the patient with patient's safety brochures highlighting the extent of doctor patient confidentiality, the patient's rights including the right to withdraw consent at any stage and refuse access of records by unauthorized agencies.

In government hospitals, the medical records of the patient can only be disclosed to authorized agencies with the prior approval of patient. The patient is made aware of the type and extent of information that is collected from him/her and is mandatorily shared with authorized bodies such as insurance agencies or the treating doctor. No information of the patient is made publicly available. In cases where the information is shared with insurance agencies or any such authorized body the patient gives an undertaking via a letter of his consent to such disclosure. The insurance companies only use medical records for verification purposes and have to do so at the facility. They cannot take any original documents or make copies of the records without the consent of the patient as provided in the undertaking.

Diagnostic Laboratories provide information regarding the patient's medical records only to the concerned or referred doctor. The patient is always informed of any instance where his information may be disclosed and the consent of the patient is always taken for the same. No information is made available publicly or shared with unauthorized agencies at any stage. Information regarding the patient's medical records is not even shared with insurance companies.

Government and Private Hospitals provide medical records of patients to the police only when a summons for the same has been issued by a judge. Diagnostic laboratories however do not provide information regarding a patient's records at any stage to any law enforcement agencies unless there is summons from a judge specifying exactly the nature and extent of information required.

Patients are not made aware of laws which may govern the disclosure of information in private and government hospitals as well as in diagnostic laboratories. The patient is merely informed that the information provided by him to the medical personnel will remain confidential.

(vii) Security

The security measures that are put in place to ensure the safety of the collected information is not adequately specified in the forms or during the collection of information from the patient in Government or Private Hospitals. Diagnostic laboratories however do provide the patient with information regarding the security measures put in place to ensure the confidentiality of the information.

(viii) Openness

The information made available to the patient at government and private hospital and diagnostic laboratories is easily intelligible. At every stage of the procedure the explicit consent of the patient is obtained. In government and private hospitals the signature of the patient is obtained on consent forms at every stage of the procedure and the nature and extent of the procedure is explained to the patient in a language that he understands and is comfortable speaking. The information provided is detailed and is provided in simplistic terms so that the patient does at all stages understand the nature of any procedure he is consenting to undergo.

(ix) Accountability

Private hospitals and Diagnostic laboratories have internal and external audit mechanisms in place to check the efficacy of privacy measures. They both have grievance redress mechanisms in the form of patient welfare cells and complaint cells. There is an assigned officer in place to take patient feedback and address and manage the privacy concerns of the patient.

Government hospitals do not have an internal or external audit mechanism in place to check the efficacy of privacy measures. There is however a grievance redressal mechanism in government hospitals in the form of a Public Relations Office that addresses the concerns, complaints, feedback and suggestions of the patients. There is an officer in charge of addressing and managing the privacy concerns of patients. This officer also offers counseling to the patients in case of privacy concerns regarding sensitive information.

III. INTERNATIONAL BEST PRACTISE AND RECOMMENDATIONS

A. European Union

An official EU data protection regulation⁶⁹ was issued in January 2012. A key objective of this was to introduce a uniform policy directive across all member states. The regulation, once implemented was to be applicable in all member states and left no room for alteration or amendments.

The regulation calls for **Privacy Impact Assessments**⁷⁰ when there are specific risks to privacy which would include profiling, sensitive data related to health, genetic material or biometric information. This is an important step towards evaluating the nature and extent of privacy regulation required for various procedures and would be effective in the creation of a systematic

69. http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf

70. Article 33, Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) < http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf> [Accessed on 14th May, 2014]

structure for the implementation of these regulations. The regulation also established the need for explicit consent for sensitive personal data. The basis for this is an inherent imbalance in the positions of the data subject and the data controller, or in simpler terms the patient and the hospital or the life sciences company conducting the research. Thus, implied consent is not enough ⁷¹ and a need arises to proceed with the testing only when there is **explicit informed consent**.

Embedded within the regulation is the **right to be forgotten** ⁷² wherein patients can request for their data to be deleted after they have been discharged or the clinical trial has been concluded. In the Indian scenario, patient information is kept for extended periods of time. This can be subject to unauthorized access and misuse. The deletion of patient information once it has been used for the purpose for which it was collected is thus imperative towards the creation of an environment of privacy protection.

Article 81 of the regulation specifies that health data may be processed only for three major processes⁷³:

- a) In cases of Preventative or occupational medicine, medical diagnosis, the care, treatment or management of healthcare services, and in cases where the data is processed by the healthcare professionals, the data is subject to the obligation of professional secrecy;
- b) Considerations of public interest bearing a direct nexus to public health, for example, the protection of legitimate cross border threats to health or ensuring a high standard of quality and safety for medicinal products or services;
- c) Or other reasons of public interest such as social protection.

An added concern is the nature and extent of consent. The consent obtained during a clinical trial may not always be sufficient to cover additional research even in instances of data being coded adequately. Thus, it may not be possible to anticipate additional research while carrying out initial research. Article 83⁷⁴ of the regulation prohibits the use of data collected for an additional purpose, other than the purpose for which it was collected.

Lastly, the regulation covers data that may be transferred outside the EEA, unless there is an additional level of data protection. If a court located outside the EU makes a request for the disclosure of personal data, prior authorization must be obtained from the local data protection

71. Article 4 (Definition of “Data Subject’s Consent”), Article 7, Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) < http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf > [Accessed on 14th May, 2014].

72. Article 17, “Safeguarding Privacy in a Connected World – A European Data Protection Framework for the 21st Century” COM(2012) 9 final. Based on, Article 12(b), EU Directive 95/46/EC – The Data Protection Directive at <<http://www.dataprotection.ie/docs/EU-Directive-95-46-EC-Chapter-2/93.htm>> [Accessed on 14th May, 2014]

73. Article 81, Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) < http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf > [Accessed on 14th May, 2014]

74. Article 83, Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) < http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf > [Accessed on 14th May, 2014]

authority before such transfer is made. It is imperative that this be implemented within Indian legislation as currently there is no mechanism to regulate the cross border transfer of personal data.

B. The United States of America

The Health Maintenance Organizations Act, 1973⁷⁵ was enacted with a view to keep up with the rapid development in the Information Technology sector. The digitization of personal information led to new forms of threats with regard to the privacy of a patient. In the face of this threat, the overarching goal of providing effective and yet unobtrusive healthcare still remains paramount.

To this effect, several important federal regulations have been implemented. These include the Privacy and Security Ruled under the Health Insurance Portability and Accountability Act (HIPAA) 1996⁷⁶ and the State Alliance for eHealth (2007)⁷⁷. The HIPAA privacy rules addressed the use and subsequent disclosure of a patient's personal information under various healthcare plans, medical providers, and clearinghouses. These insurance agencies were the primary agents involved in obtaining a patients information for purposes such as treatment, payment, managing healthcare operations, medical research and subcontracting. Under the HIPAA it is required of insurance agencies to ensure the implementation of various administrative safeguards such as policies, guidelines, regulations or rules to monitor and control inter as well as intra organizational access.

Apart from the HIPAA, approximately 60 laws related to privacy in the healthcare sector have been enacted in more than 34 states. These legislations have been instrumental in creating awareness about privacy requirements in the healthcare sector and improving the efficiency of data collection and transfer. Similar legislative initiative is required in the Indian context to aid in the creation of a regulated and secure atmosphere pertaining to the protection of privacy within the healthcare sector.

C. Australia

Australia has a comprehensive law that deals with sectoral regulations of the right to privacy. An amendment to the Privacy Act 1988⁷⁸ applies to all healthcare providers and was made applicable from 21st December 2001. The privacy Act includes the following practices:

- a. A stringent requirement for informed consent prior to the collection of health related information
- b. A provision regarding the information that needs to be provided to individuals before information is collected from them
- c. The considerations that have to be taken into account before the transfer of information to third parties such as insurance agencies, including the specific instances wherein this information can be passed on
- d. The details that must be included in the Privacy policy of the healthcare service providers' Privacy Policy

75. Health Maintenance and Organization Act 1973, Notes and Brief Reports available at <http://www.ssa.gov/policy/docs/ssb/v37n3/v37n3p35.pdf> [Accessed on 14th May 2014].

76. Health Insurance Portability and Accountability Act, 1996 available at <http://www.hhs.gov/ocr/privacy/hipaa/administrative/statute/hipaastatute.pdf> [Accessed on 14th May 2014]

77. Illinois Alliance for Health Innovation plan available at <http://www2.illinois.gov/gov/healthcarereform/Documents/Alliance/Alliance%20011614.pdf> [Accessed on 14th May 2014]

78. The Privacy Act 1988 available at <http://www.comlaw.gov.au/Series/C2004A03712> [Accessed on 14th May 2014]

- e. The securing and storing of information; and
- f. Providing individuals with a right to access their health records.

These provisions are in keeping with the 13 National Privacy ⁷⁹Principles that represent the minimum standards of privacy regulation with respect to the handling of personal information in the healthcare sector. These guidelines are advisory in nature and have been issued by the Privacy Commissioner in exercise of his power under Section 27(1)(e) ⁸⁰of the Privacy Act.

The Act also embodies similar privacy principles which include a collection limitation, a definitive use and purpose for the information collected, a specific set of circumstance and an established protocol for the disclosure of information to third parties including the nature and extent of such disclosure, maintenance accuracy of the data collected, requisite security measures to ensure the data collected is at all times protected, a sense of transparency, accountability and openness in the administrative functioning of the healthcare provider and accessibility of the patient to his own records for the purpose of viewing, corroboration or correction.

Additionally, the Act includes the system of identifiers which includes a number assigned by the organization to an individual to identify the purpose of that person's data for the operation of the organization. Further, the Act provides for anonymity wherein individuals have the option not to identify themselves while entering into transactions with an organization. The Act also provides for restrictions on the transfer of personal data outside Australia and establishes conclusive and stringent barriers to the extent of collection of personal and sensitive data. These principles although vaguely similar to those highlighted in the A.P. Shah Committee report can be used to streamline the regulations pertaining to privacy in the healthcare sector and make them more efficient.

KEY RECOMMENDATIONS

It is imperative that Privacy concerns relating to the transnational flow of Private data be addressed in the most efficient way possible. This would involve international cooperation and collaboration to address privacy concerns including clear provisions and the development of coherent minimum standards pertaining to international data transfer agreements. This exchange of ideas and multilateral deliberation would result in creating more efficient methods of applying the provisions of privacy legislation even within domestic jurisdictions.

There is a universal need for the development of a foundational structure for the physical collection, use and storage of human biological specimens (in contrast to the personal information that may be derived from those specimens) as these are extremely important aspects of biomedical research and clinical trials. The need for Privacy Impact Assessments would also arise in the context of clinical trials, research studies and the gathering of biomedical data.

Further, there also arises the need for patients to be allowed to request for the deletion of their personal information once it has served the purpose for which it was obtained. The keeping of records for extended periods of time by hospitals and laboratories is unnecessary and can often result in the unauthorized access to and subsequent misuse of such data.

There is a definitive need to ensure the incorporation of safeguards to regulate the protection of patient's data once accessed by third parties, such as insurance companies. In the Indian Context as well as insurance agencies often have unrestricted access to a patient's medical records however

79. Schedule 1, Privacy Act 1988 [Accessed on 14th May 2014]

80. Section 27(e), Privacy Act 1988 [Accessed on 14th May 2014]

there is a definitive lack of sufficient safeguards to ensure that this information is not released to or access by unauthorized persons either within these insurance agencies or outsourced consultants

The system of identifiers which allocate specific numbers to an individual's data which can only be accessed using that specific number or series of numbers can be incorporated into the Indian system as well and can simplify the administrative process thus increasing its efficacy. This would afford individuals the privilege of anonymity while entering into transactions with specific healthcare institutions.

An important means of responding to public concerns over potential unauthorized use of personal information gathered for research, could be through the issuing of Certificates of confidentiality as issued in the United States to protect sensitive information on research participants from forced disclosure.⁸¹

Additionally, it is imperative that frequent discussions, deliberations, conferences and roundtables take place involving multiple stakeholders from the healthcare sector, insurance companies, patient's rights advocacy groups and the government. This would aid in evolving a comprehensive policy that would aid in the protection of privacy in the healthcare sector in an efficient and collusive manner.

CONCLUSIONS

The Right to Privacy has been embodied in a multitude of domestic legislations pertaining to the healthcare sector. The privacy principles envisioned in the A.P Shah Committee report have also been incorporated into the everyday practices of healthcare institutions to the greatest possible extent. There are however significant gaps in the policy formulation that essentially do not account for the data once it has been collected or its subsequent transfer. There is thus an imminent need for institutional collaboration in order to redress these gaps. Recommendations for the same have been made in the report. However, for an effective framework to be laid down there is still a need for the State to play an active role in enabling the engagement between different institutions both in the private and public domain across a multitude of sectors including insurance companies, online servers that are used to harbour a data base of patient records and civil action groups that demand patient privacy while at the same time seek to access records under the Right to Information Act. The collaborative efforts of these multiple stakeholders will ensure the creation of a strong foundational framework upon which the Right to Privacy can be efficiently constructed.

81. Guidance on Certificates of Confidentiality, Office of Human Research Protections, U.S Department of Health and Human Services available at <http://www.hhs.gov/ohrp/policy/certconf.pdf> [Accessed on 14th May, 2014].