

DRAFT

Health Privacy

INTRODUCTION

Confidentiality and privacy are essential to all trusting relationships, such as that between patients and doctors. Moreover, in a healthcare context, patient confidentiality and the protection of privacy is the foundation of the doctor-patient relationship. Patients must feel comfortable sharing private information about their bodily functions, physical and sexual activities, and medical history.¹ Healthcare personnel must acquire, process, store, retrieve and transfer clinical, administrative and financial health information as healthcare is an extremely information intensive and sensitive industry. The unfortunate aspect of the robust data flows is the inherent problem of the misuse of information, disclosure of confidential information and risk of privacy violations.

Medical confidentiality promotes the individual's medical autonomy, by sheltering those seeking morally controversial medical care from outside criticism and interference with decisions.² Medical privacy involves 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).³

Privacy violations in the healthcare sector that stem from policy and implementation gaps include: 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. Furthermore, various goods such as employment, life, and medical insurance, could be placed at risk if the flow of medical information were not restricted.⁴

However, there are certain situations where disclosure of personal health information is permitted, for example: 1) during referral, 2) when demanded by the court or by the

¹ Mishra, N., Parker, L., Nimgaonkar, V., & Deshpande, S. (2008). Privacy and the Right to Information Act, 2005. *Indian Journal of Medical Ethics*, 5(4), 158-161.

² Allen, A. (2011). Privacy and Medicine. in E. N. Zalta (Ed.), *The Stanford Encyclopedia of Philosophy* (2011st ed.). Retrieved from <http://plato.stanford.edu/archives/spr2011/entries/privacy-medicine/>

³ Allen, A. (2011). Privacy and Medicine. In E. N. Zalta (Ed.), *The Stanford Encyclopedia of Philosophy* (2011st ed.). Retrieved from <http://plato.stanford.edu/archives/spr2011/entries/privacy-medicine/>

⁴ Nissenbaum, H. (2004). Privacy as Contextual Integrity. *Washington Law Review*, 79(1), 101-139.

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

LEGISLATION

Epidemic Diseases Act, 1897

The Epidemic Diseases Act, 1897 brought into force for the purpose of preventing the spread of epidemic diseases. Implicit in the Epidemic Diseases Act, 1897 is the assumption that in the case of infectious diseases, the rights, including the right to privacy, of infected individuals must give way to the overriding interest of protecting public health.⁷ Because of the nature of the Act, the principles of access and correction, choice and consent, and notice do not apply to this Act.

Oversight

- *Inspection*: Under the Epidemic Diseases Act, 1897,⁸ if any part of the state is “visited by, or threatened with an outbreak of any dangerous epidemic disease”, the state government can enforce certain measures and prescribe regulations to prevent the outbreak or spread of a disease.⁹ Such measures may include “*inspection of persons travelling by railway or otherwise, and the segregation, in hospital, temporary accommodation or otherwise, of persons suspected by the inspecting officer of being infected with any such disease.*”¹⁰ Additionally, the Central Government may take measures including the inspection of any ship or vessel and detention of any person leaving or arriving at any port.

Missing Principles

- Accountability
- Openness
- Access and Correction
- Choice and Consent
- Notice
- Penalty/Offenses/Liability/ Remedy
- Quality/Verification
- Security

⁵ 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.

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

⁷ UNDP (2004) Law, Ethics and HIV/AIDS in South Asia. A Study of the Legal and Social Environment of the Epidemic in Bangladesh, India, Nepal and Sri Lanka.

⁸ *The Epidemic Diseases Act, 1897.*

⁹ *The Epidemic Diseases Act, 1897.* s. 2.1.

¹⁰ *The Epidemic Diseases Act, 1897,* s. 2.2(b).

- Disclosure
- Purpose Limitation
- Collection Limitation

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

The Medical Council of India (MCI) Code of Ethics Regulations¹¹ sets the professional standards for medical practice.

Security

- *Confidentiality*: Physicians are obliged to protect the confidentiality of patients including their personal and domestic lives¹², unless the law requires their revelation, or if there is a serious and identified risk to a specific person and / or community or notifiable disease.¹³
- *Digitization of records*: Efforts should be made to computerize medical records for quick retrieval.¹⁴

Disclosure

- *Disclosure of prognosis*: A contradictory clause requires physicians to ensure that the patient, his relatives or his responsible friends are aware of the patient's prognosis while serving the best interests of the patient and the family.¹⁵

Disclosure of a patient's prognosis should rest with the patient and not the medical attendant.

Purpose Limitation

- *Data Retention*: Physicians must maintain the medical records of their patients for a period of three years.¹⁶ Failure to maintain medical records for three years and/or refusal to provide medical records within 72 hours of the request constitutes professional misconduct rendering the Physician liable for disciplinary action.¹⁷

Access and Correction

- *Access to records*: Patients, authorized attendants or legal authorities can request for medical records, which have to be issued within 72 hours.¹⁸

¹¹ Code of Ethics Regulations, 2002 available at <http://www.mciindia.org/RulesandRegulations/CodeofMedicalEthicsRegulations2002.aspx>.

¹² Code of Ethics Regulations, 2002 Chapter 2, Section 2.2.

¹³ Code of Ethics Regulations, 2002 Chapter 7, Section 7.14.

¹⁴ Code of Ethics Regulations, 2002 Chapter 1, Section 1.3.4.

¹⁵ Code of Ethics Regulations, 2002 Chapter 2, Section 2.3.

¹⁶ Code of Ethics Regulations, 2002 Chapter 1, Section 1.3.1.

¹⁷ Code of Ethics Regulations, 2002 Chapter 7, Section 7.2.

¹⁸ Code of Ethics Regulations, 2002 Chapter 1, Section 1.3.2.

Records should not be made accessible to the attendants without the consent of the patient, except when the patient is not in a state to give consent and access to those records is imperative.

Choice and Consent

- *Informed Consent*: Physicians must obtain written consent from the husband or wife, parent or guardian in the case of a minor, or the patient himself, before performing an operation.¹⁹ When performing an operation, which may result in sterility, informed and written consent is required from both the husband and wife.²⁰
- *Consent for Research*: Publication of photographs or case studies without consent by patients is prohibited. If the identity of the patient cannot be discerned then consent is not needed.²¹

As a note, the method of consent, whether verbal or written, is not stated. This is peculiar as other clauses specifically state, whether verbal or written consent, is required.

Missing Principles

- Collection Limitation
- Notice
- Oversight Accountability
- Openness
- Collection Limitation
- Notice
- Penalty/Offenses/Liability/Remedy
- Quality/Verification

Case Law

Mr. Surupsingh Hrya Naik vs. State of Maharashtra,²² (2007)

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*,²³ 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. In this case health records of a convict were sought to be made public under the RTI Act to find out why he's been allowed to stay in hospital instead of jail. Dealing with the right to privacy in this context the Bombay High Court held that:

“The law as discussed may now be set out. The confidentiality required to be maintained of the medical records of a patient including a convict considering the

¹⁹ *Code of Ethics Regulations*, 2002 Chapter 7, Section 7.16.

²⁰ *Code of Ethics Regulations*, 2002 Chapter 7, Section 7.21.

²¹ *Code of Ethics Regulations*, 2002 Chapter 7, Section 7.17.

²² <http://www.indiankanoon.org/doc/570038/>

²³ <http://www.indiankanoon.org/doc/570038/>

Regulations framed by the Medical Council of India cannot override the provisions of the Right to Information Act. If there be inconsistency between the Regulations and the Right to Information Act, the provisions of the Act would prevail over the Regulations and the information will have to be made available in terms of the Act. The Act, however, carves out some exceptions, including the release of personal information, the disclosure of which has no relationship to any public activity or interest or which would cause unwarranted invasion of the right to privacy. In such cases a discretion has been conferred on the concerned Public Information Officer to make available the information, if satisfied, that the larger public interest justifies the disclosure. This discretion must be exercised, bearing in mind the facts of each case and the larger public interest. Normally 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.

In those cases where the information sought cannot be denied to either Parliament or State Legislature, as the case may be, then the information cannot be denied unless the third person satisfies the authority that Parliament/Legislature, is not entitled to the information. There is no discretion in such cases to be exercised by the concerned Information Officer. The information has to be either granted or rejected, as the case may be. Every public authority, whose expenditure is met partly or wholly from the funds voted by the Parliament/Legislature or Government funds are availed off is accountable to Parliament/Legislature, as they have interest to know that the funds are spent for the object for which they are released and the employees confirm to the Rules. The conduct of the employees of such an organisation subject to their statutory rights can also be gone into. If patients are to be admitted in hospital for treatment then those employees in the hospital are duty bound to admit only those who are eligible for admission and medical treatment. The records of such institution, therefore,, ought to be available to Parliament or the State Legislature. The Parliament/Legislature and/or its Committees are entitled to the records even if they be confidential or personal records of a patient. Once a patient admits himself to a hospital the records must be available to Parliament/Legislature, provided there is no legal bar. We find no legal bar, except the provisions of the Regulations framed under the Indian Medical Council Act. Those provisions, however, would be inconsistent with the proviso to Section 8(1)(j) of the Right to Information Act. The Right to Information Act would, therefore, prevail over the said Regulations.”

Case Highlights

- **The Right to Information Act, 2005 would prevail over an exercise in subordinate legislation such as the MCI Code of Ethics.**

- **The health records of a person in police or judicial custody, if admitted to a State or government hospital during the custody, should be made available under the RTI Act, and should be denied only in exceptional cases for good and valid reasons.**

Mental Health Act, 1987

In 1997, the National Human Rights Commission (NHRC) New Delhi carried out a survey of the 37 mental hospitals in the country. The survey revealed that physical infrastructure and living arrangements were inadequate in most hospitals. Patient's rights with respect to privacy and dignity were grossly violated. The Mental Health Act, 1987²⁴ was enacted to govern the law relating to the treatment and care of mentally ill persons. The Act allows the Central Government to establish an Authority for the regulation, development, direction, and co-ordination of mental health.²⁵

Oversight

- *Inspection of records:* Inspecting officers, who are authorized by the State Government to inspect any psychiatric hospital or psychiatric nursing home, may at any time, enter and inspect any psychiatric hospital and require the production of any records.²⁶ Additionally, they may interview in private any patient receiving treatment and care to inquire about a complaint or if there is reason to believe the patient is not receiving proper care and treatment.²⁷ If the inspecting officer is satisfied that the inpatient is not receiving proper treatment and care, he may report the matter to the licensing authority.²⁸

Collection Limitation

- *Inspection of living conditions:* 'Visitors' consisting of a medical officer, preferably a psychiatrist and two social workers are required to conduct a joint inspection on a monthly basis. They must analyze the living condition of every patient and the administrative processes of the psychiatric hospital and/or psychiatric nursing home.²⁹
- *Visitor log:* Visitors must maintain a book regarding their observations and remarks.³⁰

Standards governing the data retention, security and access regarding the book and its contents do not exist.

- *Medical certificates:* Medical certificates, issued by a doctor, and contain information regarding the nature and degree of the mental disorder that warrants

²⁴ The Mental Health Act, 1987.

²⁵ The Mental Health Act, 1987, s. 3(2).

²⁶ The Mental Health Act, 1987, s. 13(1).

²⁷ The Mental Health Act, 1987, s. 13(2).

²⁸ The Mental Health Act, 1987, s. 13(3).

²⁹ The Mental Health Act, 1987, s. 38.

³⁰ The Mental Health Act, 1987, s. 40.

- the detention of a person in a psychiatric hospital or psychiatric nursing home.³¹
- **Confidentiality:** Visitors are prohibited from inspecting any personal records of in-patients, which in the opinion of the medical officer-in-charge are confidential in nature.³² However, they may access medical certificates as well as the order of admission of mentally ill in-patients.ⁱ

There exist two privacy implications surrounding this provision. Firstly, the Act fails to define personal records. Therefore, it is conflicting as visitors can inspect medical certificates but not personal records. Secondly, the medical officer-in-charge has the power to determine which personal records are confidential in nature. Such a test appears to be too subjective; instead there should be a set of objective standards by which to adjudicate the inspection of personal records.

Disclosure

- Disclosure of personal records by inspecting officers: An officer inspecting health records of any possible facility under this act must not disclose the personal records and health information of a patient so inspected.³³

Penalty/Offenses/Redress/Liability

If any person who contravenes any provisions of the Act, for which no other penalty is provided	Imprisonment up to six months and/or a fine of rs.500 ⁱⁱ
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Missing Principles

- Security
- Access and Correction
- Purpose Limitation
- Choice and Consent
- Notice
- Accountability
- Openness
- Quality/Verification

Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994³⁴

The declining child sex ratio in India is so alarming that if the present trend continues it is going to result in a demographic and social disaster.³⁵ Consequently, the pre-natal

³¹ The Mental Health Act, 1987, s. 21(2).

³² The Mental Health Act, 1987, s. 40, *Proviso*.

³³ The Mental Health Act, 1987, s. 13(1), *Proviso*.

³⁴ Also see the: Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996.

³⁵ Josantony Joseph and Centre for Youth Development and Activities commissioned by UNFPA (2006). *Reflections on the Campaign against Sex Selection and Exploring Ways Forward*. Retrieved from <http://india.unfpa.org/drive/Reflections.pdf>

diagnostic legislation sanctions a blanket prohibition of sex selection, before and after conception, specifically it prohibits the determination and disclosure of sex of the foetus and prescribes criminal punishment for contravention.

Pre-natal diagnostic testing can be conducted only for the purpose of detecting any abnormalities or diseases,³⁶ however the person conducting the test must be satisfied that any of the following conditions:

- Over the age of thirty-five
- Undergone two or more spontaneous abortions or foetal loss
- Exposed to potentially teratogenic agents such as drugs, radiation, infection or chemicals
- Her or her spouse has a family history of mental retardation or physical deformities.³⁷

While the primary purpose of the Act is to prevent sex determination, the procedure that a mother has to follow in order to avail 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 physical deformities. This may provide grounds for a divorce or break up a family. A special concern for privacy and confidentiality should be exercised with regards to disclosure of genetic information.

Collection Limitation

- *Data Retention*: All records of pregnant women who have undergone an ultra sonography must be preserved for a period of two years. The Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996 (**PNDT Rules**) require that when the records are maintained on a computer, the person responsible for such record should preserve a printed copy of the record after authentication.³⁸

Oversight

- *Appropriate Authority*: The Act allows for the appointment of an Appropriate Authority by the State Government who, among other things, are responsible for supervising the implementation of the Act such as granting licenses, investigating complaints, enforcing standards, etc. They also have the power to summon persons, issue search warrants, order production of documents.³⁹

Penalty/Offenses/Redress/Liability

³⁶ 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.

³⁷ Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994, s. 4(3).

³⁸ 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.

³⁹ PNDT Act, s. 17 and 17A.

If any person who contravenes any provisions of the Act, for which no other penalty is provided	Imprisonment up to three months and/or a fine of rs.1,000. ⁱⁱⁱ
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Missing Principles

- Accountability
- Openness
- Security
- Notice
- Choice and Consent
- Purpose Limitation
- Access and Correction
- Disclosure
- Quality/verification

Case Law

Radiological & Imaging Association v. Union of India,⁴⁰ (2011)

On 14 January 2011 a circular was issued by the Collector and District Magistrate, Kolhapur requiring the Radiologists and Sonologists to submit on-line form “F” under the PNDT Rules. The Collector had also issued another circular dated 10 March 2010 in which reference was made to the workshop of doctors, sonologists and radiologists for installation of SIOB (silent observer) for all the sonography machines, as a part of ‘save the baby’ campaign for improving sex ratio in the district. Both these circulars were challenged by the Radiological and Imaging Association, *inter alia*, on the ground that it violates the privacy of their patients. Justifying that such a requirement would not violate the right to privacy of the patients. Deciding the above issue in *Radiological & Imaging Association v. Union of India*,⁴¹ Bombay High Court, 26-8-2011 the Court held as under:

“35. As regards the allegation of invasion of privacy rights, it is amply clear from the affidavit of the Collector and District Magistrate, that the images stored in the silent observer are not transmitted on-line to any server and thus they remain very much part of the ultra-sound machine on which the silent observer is embedded and that the silent observer is to be opened only in the presence of the concerned radiologist/sonologist/doctor incharge of the Ultra-sound Clinic.

Silent observer is an electronic device which is attached to Sonography machine. In the event of the appropriate authority needing to check the sonographies which have taken place through a particular machine, the appropriate authority i.e. the Collector/the civil surgeon may himself or his authorized officer will have to actually go to the site of the ultra-sound machine and it is only on the authorization of Collector that the silent observer can be removed from a

⁴⁰ <http://www.indiankanoon.org/doc/680703/>

⁴¹ <http://www.indiankanoon.org/doc/680703/>

particular ultra-sound machine and only on putting the user name and password under the control of Collector that the officer can actually see the sonographies done with the ultra-sound machine on a Computer. Moreover, mere seeing of these sonographies by lay person would be of no help and hence as per the protocol made by appropriate authority under the Act, whenever the silent observer is to be opened, presence of the concerned doctor at the sonography center as well as a third expert doctor would be necessary. The protocol made by the appropriate authority for seeing the results of the silent observer is annexed to the reply affidavit at exhibit `C'.

36. In view of the above factual backdrop, the submission that there will be violation of privacy rights is without any substance.

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40. Having regard to the aforesaid principles and considering the matter in the factual backdrop already highlighted hereinabove that the information contained in `F' form submitted on-line is submitted only to the Collector and District Magistrate and that except the authorized officer no third party can have access to it and that the information contained in the silent observer remains embedded on the ultrasound machine and that after analysis of the information contained in `F' form submitted on-line, the appropriate authority or the officer authorised by the authority has to access the information contained in the silent observer including the visual images, we are of the considered opinion that there is no violation of the doctor's duty of confidentiality or the patient's right to privacy. 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”

This case and the silent observer system is an excellent example of ‘privacy by design’, even though the issue of privacy by design was not discussed by the Court at all.

Case Highlights

- **The use of “Silent Observer” system on sonograph machines has enough safeguards to prevent any violations of the system and hence does not violate any privacy rights.**
- **The safeguards considered reasonable by the Court were i) information in `F' form is submitted only to the Collector and DM and only an authorized officer has access to it, ii) information in the silent observer remains embedded on the ultrasound machine, iii) after analysis of `F' form, the appropriate authority has to access the information contained in the silent observer including the visual images.**
- **Bringing the declining sex ratio of the country was considered as a compelling public interest with which to circumscribe the right to privacy.**

Medical Termination of Pregnancy Act, 1971⁴²

In India, a woman's right to abortion is not recognised under Indian law; instead, there are liberal grounds under which women can seek an abortion.⁴³ Therefore, decisional privacy (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 Medical Termination of Pregnancy Act, 1971⁴⁴ mandates abortion by a registered medical practitioner under stipulated conditions.⁴⁵

Choice & Consent

- *Written consent:* To facilitate an abortion under the existing laws, a medical practitioner must collect documents indicating consent. Consent assures the clinician performing the abortion that the patient has chosen the abortion on her own free will. Consent implies that the patient is aware of all her options, has been counselled about the procedure, the risks and post-abortion care. If married, the woman must provide written consent. The husband's consent is not required. Written consent of the guardian is required if the woman is below 18 years or is a lunatic within the meaning of the Indian Lunacy Act, 1912.⁴⁶

Disclosure

- *Disclosure to medical officer:* Medical practitioners are only allowed to disclose information of those who have terminated a pregnancy to the Chief Medical Officer of the State. Otherwise, the Act prohibits the disclosure of matters relating to treatment for termination of pregnancy.⁴⁷

Collection Limitation

- *Admission Register:* The Medical Termination of Pregnancy Regulations explicitly mandate data collection and processing. Hospitals have to maintain an Admission Register of women who have terminated their pregnancy. It must be destroyed on the expiry of a period of five years from the date of the last entry.⁴⁸

Security

- *Anonymization:* The Act stresses the importance of secrecy and security of information. The medical practitioner is required to assign a serial number for the

⁴² 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.

⁴³ <http://www.lawyerscollective.org/wri.html>

⁴⁴ *Medical Termination of Pregnancy Act (1971)* Retrieved from http://bhind.nic.in/Sparsh_MTP-Act-1971.pdf

⁴⁵ A pregnancy can be terminated if the continuance of the pregnancy would involve risk to the life or grave injury to the physical or mental health of the pregnant woman or if there is substantial risk that, if the child were born, it would suffer from such physical or mental abnormalities as to be seriously handicapped. In determining whether continuance of the pregnancy would involve a risk of injury to the health of the pregnant woman, additionally the Act accounts for the woman's actual or reasonably foreseeable environment. The Act also presumes that the anguish caused by a pregnancy resulting from the rape of any woman or from the failure of any contraceptive method used either by a married woman or her husband for the purpose of limiting the number of children constitutes grave injury to the mental health of the woman. A pregnancy may be terminated on these grounds within the first 12 weeks of pregnancy on the opinion of one registered medical practitioner. If the pregnancy has lasted more than 12 weeks, but fewer than 20 weeks, two registered medical practitioners must be of the opinion formed in good faith that the required grounds exist.

⁴⁶ Medical Termination of Pregnancy Act, 1971, s. 4 and Medical Termination of Pregnancy Rules, 2003, Rule 8.

⁴⁷ Medical Termination of Pregnancy Regulations, 2003, Regulation 4(5).

⁴⁸ Medical Termination of Pregnancy Regulations, 2003, Regulation 5.

- woman undergoing an abortion.⁴⁹ Hospitals are prohibited from disclosing the information contained to anyone.
- *Storage of register:* The admission register is considered ‘secret’ and stored in safe custody of the head of the hospital.⁵⁰

Missing Principles

- Purpose Limitation
- Notice
- Access and Correction
- Accountability
- Openness
- Oversight
- Penalty/Offenses/Liability/Remedy
- Quality/Verification

POLICY AND REGULATIONS

Ethical Guidelines for Biomedical Research on Human Subjects

In 2006, Indian Council of Medical Research published the Ethical Guidelines for Biomedical Research on Human Subjects.⁵¹ The Guidelines outline general principles that should be followed when conducting research on human participants. Principles that protect patient privacy include: principle of informed consent, principle of privacy and confidentiality, principle of accountability and transparency and principle of compliance.

Choice & Consent

- *Principle of informed Consent:* For all biomedical research involving human participants, investigators must obtain informed consent in a document known as the Informed Consent Form with Participant/ Patient Information Sheet. Investigators must provide adequate information about the research in a simple and easily understandable form. 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.⁵²

Collection Limitation

⁴⁹ Medical Termination of Pregnancy Regulations, 2003, Regulation 4(2).

⁵⁰ Medical Termination of Pregnancy Regulations, 2003, Regulations 4(2) and 4(4).

⁵¹ Ethical Guidelines for Biomedical Research on Human Subjects. (2006) Indian Council of Medical Research New Delhi.

⁵² Informed Consent Process, Ethical Guidelines for Biomedical Research on Human Subjects (2006). Indian Council of Medical Research New Delhi.P. 21.

- *Research records:* Researchers must maintain full and complete records of the research inclusive of data and notes. Records should be retained for a reasonable period necessary for post-research monitoring, evaluation of the research, conducting further research (whether by the initial researcher or otherwise).⁵³
- *Confidentiality of Identity:* The protection of privacy and maintenance of confidentiality, specifically surrounding the identity and records, is explicitly mandated when researching participants.⁵⁴ The Guidelines delineate extra care to be taken to protect the privacy and confidentiality of the participants and communities in surveillance studies, disaster management studies, epidemiological studies and pedigree studies.
- *Collection for Surveillance Studies:* Surveillance studies require ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event or to measure the burden of a disease.⁵⁵ However, obtaining true disease burden rates requires the identification of populations at high risk and data dissemination. Investigators are required to take extra care in maintaining confidentiality, to prevent stigmatization.
- *Collection for Disaster Management Studies:* Special care is required during emergency or disaster situations as it is harder to ensure patient privacy and maintenance of confidentiality. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities. An abundance of data concerning those affected is created in disaster situations.
- *Collection for Epidemiological Studies:* The Guidelines require investigators to maintain confidentiality of epidemiological data due to the particular concern that some population based data may also have implications to issues like national security or public safety.⁵⁶ Investigators are also required to explain to participants if there is a risk of loss of privacy.
- *Collection for Pedigree Studies:* The Guidelines require special concern for privacy and confidentiality when conducting genetic family studies.⁵⁷ Because of the relationship between the participants, it emphasizes the right that within families each person is an individual, who has the right to keep the information about himself or herself confidential and that family members are not entitled to know each other's diagnosis. Investigators must establish secure safeguards to maintain confidentiality. Investigators are required to codify biological samples, delink genetic data, inform individuals of the limits of the investigator's ability to safeguard confidentiality and of the anticipated consequences of breach of confidentiality.
- *Collection for Cultural Sensitivity in Pedigree Studies:* The Guidelines are sensitive to the cultural background of India, in that, it recognizes the vulnerability of a woman as an exploited participant. It requires investigators to

⁵³ Statement of General Principles, Principle VII, Ethical Guidelines for Biomedical Research on Human Subjects (2006). Indian Council of Medical Research New Delhi.P. 6.

⁵⁴ General Ethical Issues. Ethical Guidelines for Biomedical Research on Human Subjects (2006). Indian Council of Medical Research New Delhi.P. 29.

⁵⁵ Updated Guidelines for Evaluating Public Health Surveillance Systems. (2001) Centre for Disease Control. 50(RR13);1-35.

⁵⁶ 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.

⁵⁷ 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.

exercise extra caution when conducting genetic counselling, so as to refrain from revealing information that may lead to or provide grounds for a divorce or break up a family. For example, revealing the fact that the wife is the carrier of balanced chromosomal translocation (leading to recurrent abortions or a genetic syndrome in her child) or that she is a carrier of a single gene causing 'X' linked or recessive disease may lead to grounds for a divorce despite the fact that the husband himself is a carrier of the autosomal recessive disorder.⁵⁸

- *Collection for DNA banking or Cell-line Banking:* DNA banking or cell-line banking⁵⁹ involves a biobank or repository of resources that can be accessed to retrieve human biological material and data, it consists of three components: (i) the collectors of tissue samples; (ii) the repository storage and data management center; and (iii) the recipient investigators. Specimens can be identified or unidentified. Research samples can be linked, unidentified, coded and identified. The sample collector must obtain informed consent of the donor, this includes: clearly stating the risks and benefits, the conditions under which samples from the Repository shall be provided to other researchers, how long the samples shall be preserved in the Repository and what will be the costs to individual researchers in obtaining samples from the Repository. Every donor reserves the right to order destruction of his sample from the Repository at any time.
- *Records Keeping of Institutional Ethics Committee (IEC):* All documentation and communication of the Institutional Ethics Committee (IEC) must be dated, filed and preserved according to the written procedures.⁶⁰ Strict confidentiality is to be maintained during access and retrieval procedures. All records are to be safely maintained after the completion and termination of the study for at least a period of 3 years.

Disclosure

- *Disclosure of participant information:* Investigators require written consent by the participant or someone authorized on their behalf, to disclose data of individual participants. However, researchers must ensure that the disclosure of the identity and records of the human participant does not cause hardship, discrimination or stigmatization as a consequence of having participated in the research or experiment.⁶¹
- *Disclosure of identity:* Disclosure of a participant's identity or records, without written consent, is permitted for scientific and legal reason, which may be essential for therapeutic purposes or other interventions. Data of individual participants can be disclosed under the following circumstances: 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

⁵⁸ 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.

⁵⁹ 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.

⁶⁰ Record Keeping, Ethical Guidelines for Biomedical Research on Human Subjects (2000). Indian Council of Medical Research, New Delhi.P. 19.

⁶¹ Statement of General Principles, Principle IV, Ethical Guidelines for Biomedical Research on Human Subjects (2006). Indian Council of Medical Research New Delhi.P. 5.

- public health.⁶²
- *Disclosure for scrutinization:* Records should be available for scrutiny by the appropriate legal and administrative authority, if necessary.
 - *Anonymization:* If the information is required to be placed in public domain it is recommended that anonymization be used, especially if applicable during disaster events, mental health and evaluation of health programs.

Security

- *Security of records from studies:* All records must be safely maintained after the completion/ termination of any medical study for a period of at least three years if it is not possible to maintain the same for more than that due to resource crunch and lack of infrastructure.

Missing Principles

- Access and Correction
- Purpose Limitation
- Notice
- Accountability
- Openness
- Penalty/Offences/Liability/Remedy
- Oversight
- Quality/Verification

National Policy for Persons with Disabilities, 2006⁶³

Although the policies of the government of India towards disabled persons has been reflected in a number of enactments such as the Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995 and the Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Rules, 1996 a need was felt for a comprehensive document in this regard and it was this need that gave birth to the National Policy for Persons with Disabilities, 2006. This policy relies on the framework and institutions set up under the legislations mentioned above for the implementation of its principles.

Collection Limitation

- *Medical Certificates:* The application for obtaining a disability certificate requires the person with disabilities to provide sensitive and personal information, including address, proof of residence (ration card, voter id card, driving license, bank passbook, PAN card, passport, passport photos etc.), educational status, occupation, diagnosis and nature of their disability.

⁶² 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 Research New Delhi.P. 29.

⁶³ 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

- *Purposes for Collection:* The National Policy for Persons with Disabilities requires regular collection, compilation and analysis of data relating to socio-economic conditions of persons with disabilities. For this purpose, the National Sample Survey Organization has been collecting information on socio-economic conditions of persons with disabilities on a regular basis once in ten years since 1981 and on persons with disabilities from the Census of 2001.⁶⁴ 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.⁶⁵ Data is collected by non-medical investigators.⁶⁶
- *Collection for Employment:* The Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995⁶⁷ mandates the reservation of job posts for persons with disabilities, thereby promoting equality and participation. The Special Employment Exchange, as established under the Act, collects and furnishes information in registers, regarding such jobs.⁶⁸ It permits 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.⁶⁹

Unlike the Mental Health Act, 1987 there is no mention of disclosure or protection of information.

Choice and Consent

- *Consent for Research:* When conducting research on persons with disabilities consent is required from the individual or their family members or caregivers.⁷⁰

The policy falls short in protecting the privacy rights and welfare of disabled persons. Informed consent including the method of consent, whether verbal or written, should be specified. Consent should only be accepted from the individual or their legally authorized representative/guardian. Retention, access and storage standards of records should be prescribed inclusive of provisions for employers, researchers and those inspecting the records to ensure the confidentiality and the security of records pertaining to persons with disabilities.

Missing Principles

- Accountability
- Openness

⁶⁴ Collection of regular information on Persons with Disabilities, National Policy for Persons with Disabilities, 1993.

⁶⁵ Research, National Policy for Persons with Disabilities, 1993.

⁶⁶ Survey of Disabled Persons in India. (December 2003) National Sample Survey Organization. Ministry of Statistics and Programme Implementation. Government of India.

⁶⁷ Persons With Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995.

⁶⁸ Persons With Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995, Section 2(x).

⁶⁹ Persons With Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act. 1995, Section 35.

⁷⁰ Research. National Policy for Persons with Disabilities, 2003.

- Security
- Disclosure
- Access and Correction
- Purpose Limitation
- Notice
- Penalty/Offenses/Liability/Remedy
- Oversight
- Quality/Verification

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

The Insurance Regulatory Development Authority (Third Party Administrators - Health Services) Regulations⁷¹ issued in 2001, place regulatory guidelines on ‘third party administrators’ (TPAs). A TPA may be defined as “an insurance intermediary licensed by the Authority who, either directly or indirectly, solicits or effects coverage of, underwrite, collect, charge premium from an insured, or adjust or settle claims in connection with health insurance, except as an agent or broker or an insurer.”⁷² TPAs have to observe a code of conduct so as to obtain a license from the Insurance Regulatory Development Authority (IRDA). The salient features of the code of conduct in relation to health information privacy requires:

Disclosure

- *Trading*: TPAs are required to refrain from trading information and the records of its business.
- *Disclosure for legal purposes*: 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.⁷³
- *Sharing of databases*: In July 2010, the IRDA notified the insurance Regulatory and Development Authority (Sharing Of Database For Distribution Of Insurance Products) Regulations⁷⁴. These regulate the conditions under which insurance companies can purchase customer databases from referral companies. The regulations restrict referral companies from providing details of their customers without their prior consent, are forbidden from providing details of any person/firm/company with whom they have not had any recorded business transaction if they are bound by any confidentiality agreement in the matter of sharing the personal and financial databases of its customers. The IDRA (Insurance Advertisements and Disclosure) Regulations, 2000,⁷⁵ requires insurer or intermediary's to include disclosure statements on their web site or portal

⁷¹ The IRDA (Third Party Administrators - Health Services) Regulations 2001, (2001), <http://www.irdaindia.org/tpareg.htm> (last visited Oct 15, 2011).

⁷² The IRDA. Role of Third Party Administrators: An Approach Paper. (2001). <http://www.irdaindia.org/HTPA.htm>

⁷³ The IRDA (Third Party Administrators - Health Services) Regulations 2001, (2001), Chapter 5. Section 2.

⁷⁴ The IRDA (Sharing Of Database For Distribution Of Insurance Products) Regulations 2010.

⁷⁵ The IRDA (Insurance Advertisements and Disclosure) Regulations 2001.

outlining specific policies vis-à-vis the privacy of personal information.

Security

- *Confidentiality:* 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.

Collection Limitation

- *Data Retention:* TPA's must keep records for a period of not less than three years.⁷⁶

Missing Principles

- Accountability
- Openness
- Access and Correction
- Purpose Limitation
- Choice and Consent
- Notice
- Penalty/Offenses/Liability/Remedy
- Oversight
- Quality/Verification

IDRA Guidelines on Outsourcing of Activities by Insurance Companies⁷⁷

In February 2011, the IRDA issued guidelines permitting insurance companies to outsource their non-core functions which include claim processing for over overseas medical insurance, call centre, tele-marketing, data entry, printing and posting of reminders and other documents and pre employment medical checkups among others.

Security

- *Confidentiality:* The 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.⁷⁸
- *Standardized storage:* In addition, if insurers issue policies and data storage in electronic form, it is mandatory for them to do so with the repository service providers authorised by IRDA.⁷⁹

Oversight

- *Redressal Mechanism:* The guidelines require every Insurer to direct in house Grievance Redressal Machinery to deal with grievances relating to services provided by the outsourced agencies.⁸⁰

⁷⁶ As of this writing there are 29 licensed TPAs in India. See 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).

⁷⁷ The IRDA, Guideline on Outsourcing of Activities by Insurance Companies, (2011).

⁷⁸ The IRDA, Guideline on Outsourcing of Activities by Insurance Companies, (2011), Section 9.11. P. 8.

⁷⁹ The IRDA, Guideline on Outsourcing of Activities by Insurance Companies, (2011), P. 10.

⁸⁰ The IRDA, Guideline on Outsourcing of Activities by Insurance Companies, (2011), P. 10.

Missing Principles

- Accountability
- Openness
- Disclosure
- Access and Correction
- Purpose Limitation
- Collection Limitation
- Choice and Consent
- Notice
- Penalty/Offenses/Liability/Remedy
- Quality/Verification

IRDA Health Insurance Portability Guidelines⁸¹

In February 2011, the IRDA released the Health Insurance Portability Guidelines to enable and ensure that historical data on the policyholder's health related details of claims be available to insurers. This will ensure that portability is available in a smooth manner for the policyholders.

Collection Limitation

- *Databasing*: IRDA has provided a web based facility for the insurers to feed in all relevant details on health insurance policies issued by them to individuals which will be accessed by the new company to which a policyholder wishes to port his policy.⁸²

Missing Principles

- Accountability
- Openness
- Security
- Disclosure
- Access and Correction
- Purpose Limitation
- Choice and Consent
- Notice
- Penalty/Offenses/Liability/Remedy
- Oversight
- Quality/Verification

⁸¹ The IRDA, Health Insurance Portability Guidelines. (2011).

⁸² The IRDA, Press Release: Health Insurance Portability. (July 24, 2011).

PROJECTS AND PRACTICES

Investigative Techniques and Privacy

In India, investigative techniques such as brain mapping, narco analysis and polygraph tests have been administered under provisions of the Code of Criminal Procedure, 1973 and the Indian Evidence Act, 1872.⁸³ Specifically, narco analysis has been used in the investigation of a large number of high profile cases, including that of the Godhra train burning,⁸⁴ the Abdul Karim Telgi fake stamp paper scam,⁸⁵ the Nithari serial killings,⁸⁶ the Arun Bhatt kidnapping,⁸⁷ the ‘beer’ killer,⁸⁸ the Arushi-Hemraj double murder case⁸⁹ and the Mumbai blasts.

Narco analysis, popularly known as ‘Truth Serum Test’, is psychotherapy conducted while the patient is in sleep-like state induced by barbiturates or any other drug, especially as a means of releasing repressed feelings, thoughts, or memories.⁹⁰ A team comprising of an anaesthesiologist, a psychiatrist, a clinical or forensic psychologist, an audio-videographer, and supporting nursing staff conduct this test.⁹¹ The decision to conduct narco analysis is usually made by the Superintendent of Police or the Deputy Inspector-General handling a case.⁹²

Over the past decade, the constitutionality, reliability, ethics and validity of narco analysis has steadily been challenged in the Indian Courts. In 2004, the Bombay High Court ruled in the multi-crore fake stamp paper case that statements made under narco analysis are not admissible in evidence however; recoveries resulting from such drugged interviews are admissible as corroborative evidence.⁹³ Again in 2004, *Ramchandra Reddy and Ors. v. State of Maharashtra*, upheld the legality of the use of P300 or brain fingerprinting, lie-detector test and the use of truth serum or narco analysis, the admissibility of evidence procured under the effect of truth serum and that these tests involve minimal bodily harm.⁹⁴ In a 2006 judgment, *Dinesh Dalmia v. State*, the Madras High Court held

⁸³ Section 45 of the Indian Evidence Act, 1872 –“When the court has to form an opinion upon a point of foreign law, or of science, or art, or as to identity of handwriting or finger impression, the opinions upon that point or persons especially skilled in such foreign law, or of science, or art, or as to identity of handwriting or finger impressions are relevant.”

⁸⁴ In 2002, narco analysis was first used in to extract the truth from seven persons accused of setting a train coach on fire and subsequently killing 58 Hindus including 25 women and 15 children.

⁸⁵ The most infamous use of narco analysis was in connection with Abdul Karim Telgi and the multi crore fake stamp paper case.⁸⁵ In 2004, the Bombay High Court ruled that in the Telgi case subjecting an accused to certain tests like narco analysis does not violate the fundamental right against self-incrimination.

⁸⁶ In 2006, narco analysis was used on the two men accused of the Nithari serial killings of women and children in Nithari village, in Noida, Uttar Pradesh.

⁸⁷ In December 2003, the prime accused in the Arun Bhatt kidnapping case, Jeetu Patel moved the National Human Rights Commission and the Supreme Court against a Gujarat High Court directive to conduct a narco analysis on him. Patel objected on the grounds that he was a cardiac patient and was not in agreement to conducting the narco analysis on him and therefore it violates Article 20(3) of the Constitution.

⁸⁸ In 2007, Ravindra Kantrulu, nicknamed ‘beer’ killer, admitted to killing 15 people during a narco-analysis. He had earned the nickname ‘Beer man’ for leaving an empty beer can beside all his roadside victims, whom he killed by clubbing and stabbing.

⁸⁹ In 2008, the Central Bureau of Investigation extensively used narco analysis in the double murder case of Aarushi Talwar and Hemraj. The Supreme Court rejected a public interest litigation (PIL) case, which challenged the administration of narco analysis test on the accused in the case.

⁹⁰ <http://jurisonline.in/2010/08/narcoanalysis-r-h/>

⁹¹ <http://jurisonline.in/2010/08/narcoanalysis-r-h/>

⁹² <http://jurisonline.in/2009/03/constitutionality-of-narco-analysis/>

⁹³ <http://www.hindu.com/fline/fl2409/stories/20070518002109700.htm>

⁹⁴ <http://www.hindu.com/fline/fl2409/stories/20070518002109700.htm>

that subjecting an accused to narco analysis is not tantamount to testimony by compulsion. In 2007, a court in Kerala pronounced that no court order is required to do a narco analysis, disposing of a petition filed by the CBI seeking permission of the court. The magistrate said that filing this type of a plea would only delay the investigation.⁹⁵ The court said nobody could stand in the way of the investigating agency conducting tests recognized as effective investigation tools.⁹⁶

In 2010, *Smt. Selvi Ors. v. State of Karnataka*, the Supreme Court of India disagreed with various High Court judgments in three main areas: a) the reliability/unreliability of the tests; b) self-incrimination protections; and c) substantive due process rights. 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 20(3)⁹⁷ of the Constitution.⁹⁸ Additionally, even when a person volunteers to be subject to these tests, their result cannot be admitted as evidence in a court of law. However, the Court did say that any information or material that is subsequently discovered with the help of voluntarily administered test results can be admitted.⁹⁹

Lastly, the court 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.¹⁰⁰

Business Process Outsourcing

As leading markets such as the United States, Canada and Europe have growing healthcare information management sector, India has become a destination of choice for outsourcing in health information management. Outsourcing services such as medical transcription, coding and billing, pharmacy benefits management, electronic medical records solution, medical research, etc., exposes data holders to the threat of data theft, breach, and additional and unconsented use. Medical data is an important asset to the data holders who have collected and compiled the information as incentives to unauthorized data distribution arise from an increasingly thriving data industry where firms such as biotech companies collect, compile, share or sell (bio) medical data for profits.¹⁰¹ The proliferation of the (United States) Health Insurance Portability and Accountability Act (HIPPA) compliance training demonstrates the growing trend of Indian companies complying with (HIPPA) standards and the increased concern around transferring medical data to India.

Medical Termination of Pregnancy and Quality of Care

⁹⁵ <http://www.issuesinmedicaethics.org/151co09.html>

⁹⁶ <http://www.issuesinmedicaethics.org/151co09.html>

⁹⁷ 'No person accused of any offence shall be compelled to be a witness against himself', (the 'right to silence').

⁹⁸ <http://indiankanoon.org/doc/338008/>

⁹⁹ Please see the discussion on case law in the National Security chapter

¹⁰⁰ <http://www.hrdc.net/sahrdc/hrfeatures/HRF205.pdf>

¹⁰¹ Elisa Bertino and Yanjiang Yang, "Privacy and ownership preserving of outsourced medical data," *IN ICDE* (2005): 521--532.

Implementation of the Medical Termination of Pregnancy Act, 1971 has been slow and geographically uneven; abortion services are often inaccessible and women are reluctant to utilize those services because of the lack of anonymity and confidentiality.¹⁰² Privacy and anonymity on which the practice of abortion fundamentally depends on is non-existent. Patients need anonymity and privacy to be safe from community stigma or retaliation and free from the unwanted influence of friends, family members, and acquaintances.¹⁰³ In a study in Pune, India, women seeking an abortion outside of marriage ranked confidentiality, discreetness and distant location of abortion services as the most important indicators of quality of services.¹⁰⁴ Studies show that providers often disregard the need to respect the privacy and confidentiality of women seeking abortion: “privacy and confidentiality is not an issue with women. After all where can you get more anonymity than at a public hospital where thousands are milling around in the outpatient department?”¹⁰⁵

‘Save The Baby Girl’ Project

Launched on March 8, 2009, the Save The Baby Girl (STBG) Project was created to implement the Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (**PCPNDT Act**), with the objective of curbing female foeticide and enhancing sex ratio.¹⁰⁶ The STBG system is implemented in two phases, an online portal called www.savethebabygirl.com¹⁰⁷ and fitting a video capture device called Silent Observer (SIOB) to the ultra sound machine.

The SIOB now called the ‘active tracker’ (an improved version of SIOB) monitors ultrasound tests and records sonography images of each sonography conducted and stores it in the local hard drive of the SIOB.¹⁰⁸ The sonography video “is accessible to doctors and a few government and company officials,” said Girish Lad, CEO of Magnum Opus, the company which has pioneered the technology.¹⁰⁹ The SIOB is sealed in presence of the concerned doctor/radiologist with his signature and the appropriate authority, whenever it deems fit, may request the concerned doctor/radiologist and his authorized person go to the centre and access the selected data on pen drive, it is then viewed by a member of Radiologist Association after which they offer their observation.¹¹⁰

The online portal was created for filling the ‘F’ form, which is mandatory and contains

¹⁰² *Abortion Policy: India*. Population Policy Data Bank maintained by the Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat. Retrieved From www.un.org/esa/population/publications/abortion/doc/india.doc
103 Clapman, A. (2003). Privacy Rights and Abortion Outing: A Proposal for Using Common-Law Torts to Protect Abortion Patients and Staff. *The Yale Law Journal*, 112(6), 1545-1576. doi:10.2307/3657452.

¹⁰⁴ Santhya, K.G. and Verma, S. (2004) *Induced Abortion: The Current Scenario in India*. Regional Health Forum. Volume 8, Number 2. Pg. 9.

¹⁰⁵ Santhya, K.G. and Verma, S. (2004) *Induced Abortion: The Current Scenario in India*. Regional Health Forum. Volume 8, Number 2. Pg. 8.

¹⁰⁶ One World Foundation India, “Save the Baby Girl - Mitigating Female Foeticide through ICT”, March 2011, <http://indiagovernance.gov.in/bestpractices.php?id=746>.

¹⁰⁷ www.savethebabygirl.com

¹⁰⁸ http://www.dnaindia.com/mumbai/report_exclusive-maharashtra-government-s-silent-observer-can-do-little-to-save-girl-child_1588899

¹⁰⁹ http://articles.timesofindia.indiatimes.com/2011-01-30/mumbai/28370095_1_sonography-machines-kolhapur-model

¹¹⁰ Radiological & Imaging ... vs Union of India on 26 August, 2011. (n.d.). Retrieved November 15, 2011, from <http://www.indiankanoon.org/doc/680703/>

the case history and details of pregnant women.¹¹¹ The appropriate authorities get the reports of the each USG immediately through an online system which they can cross check and monitor and track easily and from anywhere with the use of PC with internet connection.¹¹² The portal is developed in such a way that it automatically creates various reports such as pregnant females with two or more previous girl child, etc. So suspected cases can be identified and tracked on a single click. Users are created as per the authority levels such as district user with access of all district level data, tehsil level users, rural and urban level users, etc.¹¹³ So each appropriate authority as per the region can access and monitor the USGs performed in their respected areas.

A high level committee, headed by Dr. PP Doke, Director of Health Services reported that in Kolhapur, the SIOB has failed to have any significant impact on the district's sex ratio and labelled it "useless" as it can be easily detached from a sonography machine.¹¹⁴ Dr. Jignesh Thakker, Maharashtra head of Radiological and Imaging Association, said they had pointed out the flaws of SIOB right at the beginning. "Sex determination tests can be done easily even with SIOB attached to machines, one just needs to remove a thin tape seal and carry on. There will be no record," Thakker said.

The Secretary General of IRIA, Dr. Jignesh Thakker has stated that, "the privacy of the individual was most important, and we feel that the SIOB breaches it, as male patients and non-pregnant patients do not fall under the purview of the PCPNDT Act, and hence, their images at least should not be recorded. By doing so, the doctors who are using this program may be at risk of being sued by the patient whose images have been recorded, as it goes against Clause 72 of the Information Technology Act 2000". Another radiologist said, "installing silent observers only benefit private manufacturers as it costs about Rs. 30,000".¹¹⁵

Officials admit that the PNDT Act is difficult to implement because sex selection happens within the confines of doctor-patient confidentiality.¹¹⁶ Aside from the civil-society-inspired way of ensuring implementation of the PNDT Act through sting/decoy operations, almost the entire 'success' of the implementation of the PMDT Act depends on the maintenance of the records and the monitoring of the same sometimes through sudden inspections.¹¹⁷ Demonstrating the difficulty of enforcement, a United States patent introduced a "back-door" sex determination kit called 'Baby Gender Mentor Home DNA Gender Testing Kit'. The kit, priced at \$275 was popularly known as 'Jantar Mantar' in rural Punjab. It had a built-in-equipment for collecting and sending a finger-prick blood sample to a Massachusetts laboratory from where confidential results were

¹¹¹ One World Foundation India. (2011, March). Save the Baby Girl - Mitigating Female Feticide Through ICT. Retrieved December 6, 2011, from <http://indiagovernance.gov.in/bestpractices.php?id=746>

¹¹² <http://savethebabygirl.in/readmore.aspx>

¹¹³ <http://savethebabygirl.in/readmore.aspx>

¹¹⁴ http://www.dnaindia.com/mumbai/report_exclusive-maharashtra-government-s-silent-observer-can-do-little-to-save-girl-child_1588899

¹¹⁵ http://www.dnaindia.com/mumbai/report_exclusive-maharashtra-government-s-silent-observer-can-do-little-to-save-girl-child_1588899

¹¹⁶ National Population Stabilization Fund. (2007). *Jansankhya Sthirata Kosh*. Retrieved December 5, 2011, from http://jsk.gov.in/sexratio_and_population.asp

¹¹⁷ Josantony Joseph and Centre for Youth Development and Activities commissioned by UNFPA (2006). *Reflections on the Campaign against Sex Selection and Exploring Ways Forward*. Retrieved from <http://india.unfpa.org/drive/Reflections.pdf>

sent via e-mail within 48 hours. Legislation surrounding such other methods of sex determination does not exist.

UID Project and Health

UID is becoming ubiquitous and is a prerequisite identifier for access to a wide variety of welfare schemes and services such as public health. The Unique Identification Authority of India (**UIDAI**) identified health and health related development schemes as a “killer application” for UID in the form of a unique health identification number. It is envisioned that health related transactions and the associated identifying information will be aggregated by a wide variety of health care providers, including family physicians, consultants, pathology laboratories, radiology clinics, hospitals, primary health centres etc.

In August 2009, Apollo Hospitals had written to the UIDAI and to the Knowledge Commission to link the UID number with health records of those provided with the ID number, and offered to manage the health records. The Apollo Hospital group has already created “HealthHiway” a cloud-based health information network that allows hospitals, doctors, clinics, and insurance providers to access and share personal health records of patients.¹¹⁸ However, it is unclear whether or not the HealthHiway will be used within the UID system.

The Ministry of Health and Family Welfare, alongside the National Knowledge Commission, Centre For Development Of Advanced Computing have constituted an EHR Standards committee. The sub-committee on inter-operability of health data recommended the UID number as the most feasible method of digitizing health records for the entire country.¹¹⁹ Recommending that everyone associated in the treatment process should be identified not by name but by the UID number to ensure accuracy and transferability of the data.

Mohan Rao, a professor at the Centre of Social Medicine and Community Health (JNU, New Delhi) had this to say in a critique: “Given that many diseases continue to bear a stigma in this country, the UID scheme has the unique potential of increasing stigma by breaching the anonymity of health data collected.¹²⁰ It thus violates the heart of the medical encounter, namely confidentiality.¹²¹ By making this information potentially available to employers and insurance companies, the scheme bodes further gross violations of health rights.¹²²

Sangita Reddy, executive director (operations) at Apollo Hospitals, cites the hypothetical case of a car accident victim being rushed to a hospital emergency room.

“You could physically identify who that person is but you wouldn’t know his blood

¹¹⁸ <http://www.business-standard.com/india/news/apollo-begins-project-to-connect-health-players/21/15/368246/>

¹¹⁹ <http://www.indianexpress.com/news/ministry-panel-for-uid-as-basis-for-digitised-health-records/880760/0>

¹²⁰ <http://www.frontlineonnet.com/stories/20111202282401900.htm>

¹²¹ <http://www.frontlineonnet.com/stories/20111202282401900.htm>

¹²² <http://www.frontlineonnet.com/stories/20111202282401900.htm>

group, his allergies or anything about his health,” Reddy says. “Whereas, if his UID number was linked to a UHID (unique healthcare identification number), and there was something called emergency access, you could go into that and identify his complete record. So, there are all kinds of instances as to how we could use this to help save lives and improve quality of care and reduce cost.”¹²³

However it must be pointed out that error rates for biometric technology are high. Considering the fact that people can be wrongly identified (false-positives), not detected at all (false-negative) or other system errors relying on biometrics and the UHID is not infallible, especially when people are in an unconscious state. Relying on biometric technology could potentially cause more harm if someone is falsely identified, as the health-care providers could be misinformed.

Dr. Kamlesh Bajaj, points out that since the UID database has to be accessible over networks in real time, if networks fail or become unavailable, the entire identification system may collapse, this can have fatal effects in the healthcare industry.

The UID system is prone to function creep, whereby information can be used for a secondary purpose that goes beyond the primary purpose of collection. In addition, using the UID, intelligence agencies can profile individuals by analyzing patterns of behaviours across various datasets (health records, bank records, air travel records etc.). Significant security risks include insider abuse, spoofing, tampering, hacking, possibility of easy manipulation without detection and access control.

HIV Interventions

In 1992, the Government of India formulated the National AIDS Control Organisation (NACO) for the prevention and control of AIDS. NACO considers the most effective means of controlling the spread of HIV in India is through the implementation of Targeted Interventions (TIs) for most at risk populations (MARPs) namely, sex workers, men having sex with men and people who inject drugs.

TIs are implemented at the community-level through a peer-group approach. Peer educators and outreach workers promote and link MARPs to HIV related services like testing, counselling etc., in a “buddy support” fashion.

This target-based system of testing has raised many concerns surrounding violations of confidentiality and privacy of persons living with HIV/ AIDS. In an interview with Subha Chacko, she outlined the various loopholes in the current system that results in an invasion of privacy.

Collection of Personal Information: Project staff in TIs are mandated to record the name, address and other contact information of MARPs and share this data with Technical Support Unit and State AIDS Control Societies.¹²⁴ Proof of address and

¹²³ <http://www.livemint.com/2009/12/29203506/Healthcare-sites-may-see-a-fun.html>

¹²⁴ <http://www.lawyerscollective.org/files/Anti%20rights%20practices%20in%20Targetted%20Interventions.pdf>

identity documents were required to get enrolled in government ART programmes.¹²⁵

Line-listing: 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.¹²⁶ This practice can result in peer-educators noticing and concluding that the names missing are those who have tested positive.¹²⁷

Involuntary nature: While the policy states that testing has to be voluntary, in practice the model places at its centre the fulfilling of numerical targets, and thereby inherently supports unethical ways of testing.¹²⁸

Undue pressure: Fear of a cut in salary, loss of work and a negative performance assessment has reportedly resulted in peer staff pressurizing their contacts to get tested.¹²⁹ In addition, they are under pressure to meet unrealistic targets vis-à-vis testing.¹³⁰ Peer-educators get MARPs to use different names and addresses to access testing and treatment centres, so as to ensure their quota is met.

The right to privacy is considerably essential for persons living with HIV/AIDS due to the potential stigmatizing and discriminatory impact.¹³¹ Consequently, lack of privacy rights fuels the spread and exacerbates the impact of the disease. Fears emanating from a privacy breach or of disclosure that deter people from getting tested, seeking medical care and treatment 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, inflexibility of ICTC timings and insensitivity of counsellors.¹³² People living with HIV fear their positive status being leaked if they visit the ART centre or when they are on treatment (i.e. people see them taking their medicines and thereby guess their status) also prevents people from seeking out treatment.¹³³

Mother and Child Tracking System

The Ministry of Health and Family Welfare has registered more than 10 million pregnant women in an e-governance initiative known as ‘The Mother and Child Tracking System (MCTS)’.¹³⁴ MCTS is a name-base tracking system that generates date-wise details to keep track of pregnant women and children. Pregnant women are tracked from

¹²⁵ Aneka, Karnataka Sexual Minorities Forum. (2011)“Chasing Numbers, Betraying People: Relooking at HIV Services in Karnataka”. P 22.

¹²⁶ Aneka, Karnataka Sexual Minorities Forum. (2011)“Chasing Numbers, Betraying People: Relooking at HIV Services in Karnataka”. P 16.

¹²⁷ Aneka, Karnataka Sexual Minorities Forum. (2011)“Chasing Numbers, Betraying People: Relooking at HIV Services in Karnataka”. P 16.

¹²⁸ Aneka, Karnataka Sexual Minorities Forum. (2011)“Chasing Numbers, Betraying People: Relooking at HIV Services in Karnataka”. P 14.

¹²⁹ <http://www.lawyerscollective.org/files/Anti%20rights%20practices%20in%20Targetted%20Interventions.pdf>

¹³⁰ Aneka, Karnataka Sexual Minorities Forum. (2011)“Chasing Numbers, Betraying People: Relooking at HIV Services in Karnataka”. P 14.

¹³¹ <http://www.hivaidsonline.in/index.php/HIV-Human-Rights/legal-issues-that-arise-in-the-hiv-context.html>

¹³² Chakrapani et al, (2008) ‘HIV Testing Barriers and Facilitators among Populations at-risk in Chennai, India’, INP, p 12.

¹³³ Aneka, Karnataka Sexual Minorities Forum. (2011)“Chasing Numbers, Betraying People: Relooking at HIV Services in Karnataka”. P 24.

¹³⁴ <http://www.medindia.net/news/Mother-and-Child-Tracking-SystemMCTSRegisters-One-Crore-Pregnant-Women-92684-1.htm#ixzz1cd01jfbT>

registration to Ante-Natal Care Check-ups (ANCs) to delivery till post-natal care (PNCs) for complete service delivery, timely identification of risk, irrespective of place of registration. Whereas, tracking of children takes place from birth to the end of immunization, irrespective of place of registration. MCTS has a feedback system that conveys date-wise details to auxiliary midwife nurses (ANM) or accredited social health activist (ASHA) workers to ensure that all pregnant women receive their ANCs and PNCs; and further children receive their full immunization. Additionally, every expectant mother receives cell phone messages with regard to their next immunization and check up dates.¹³⁵

Information required to track pregnant women include identification details (name, husband's name, phone number, date of birth, JSY beneficiary, caste), location details, health provider details, ANC details, pregnancy outcome (place of delivery, complications, abortion), PNC details, infant details, and immunization details. Information is collected and accessed in the following manner:

1. Data is collected under the National Rural Health Mission and is fed on the MCTS software.
2. The software is installed in the taluk hospitals across the state.
3. The taluk hospitals get the data from primary health centres which in turn obtain information from ANM or ASHA workers.
4. The ANM and ASHA workers issue a 'thayi' card to pregnant women and register them for ante-natal check-up.
5. The details are SMSed to taluk hospitals where the data operators feed the information into the software.
6. The software generates date-wise details of deliverance of services which are conveyed to the ANMs and ANCs and the expectant mothers.
7. Supervisory checks are carried out to ensure correctness of primary data and services delivered.

The Health Ministry is planning to set up a central monitoring call centre to monitor progress under the National Universal Immunization Program.

Although it is a management tool to reduce maternal mortality rates, infant mortality rates and total mortality rates and track the health service delivery at the individual level, there are many concerns surrounding the ethical use of information, privacy and data sharing issues. Specific guidelines should mandate data collection, storage, and shared according to specific guidelines. The MCTS system involves data sharing with various parties and means, however, the lack of access and security standards could potentially result in a data breach and privacy violation. ANMs and ANCs are required to SMS the details of pregnant women and children. This method of data sharing should detail restrictions on disclosure and safeguarding of transferring health information.

Health Insurance Schemes

¹³⁵ <http://www.deccanherald.com/content/189872/mother-child-tracking-system-suffers.html>

Four important initiatives by the central government (through Rashtriya Swasthya Bima Yojana - RSBY) and state-sponsored schemes, as in Andhra Pradesh, Tamil Nadu, and Karnataka seek to provide medical insurance to a large number of the population. Three of the giant schemes (RSBY, Rajiv Aarogyasri and Kalaingar) in a span of three years have covered roughly 247 million, over one-fifth of India's population.¹³⁶ This is due to the fact that Andhra Pradesh and Tamil Nadu models provide care for high-end, low-frequency, rare diseases, while RSBY provides largely secondary care of high-frequency and common diseases.¹³⁷

The National Health Insurance Scheme: Rashtriya Swasthya Bima Yojana (RSBY)

In 2008, the Rashtriya Swasthya Bima Yojana (RSBY) was launched by Ministry of Labour and Employment, Government of India to provide health insurance coverage for Below Poverty Line (BPL) families. The objective of RSBY is to provide protection to BPL households from financial liabilities arising out of health shocks that involve hospitalization. Beneficiaries under RSBY are entitled to hospitalization coverage up to Rs. 30,000/- for most of the diseases that require hospitalization.¹³⁸

One of the hallmarks of the scheme is its heavy reliance on smart cards to ensure delivery of services.¹³⁹ Around 25 million smart cards have been issued benefitting more than 75 million individuals from BPL families.¹⁴⁰ Smart cards enable cashless transaction as well as inter-operability in network hospitals throughout the country.¹⁴¹ Every beneficiary family is issued a biometric enabled smart card containing their fingerprints and photographs. All the hospitals empanelled under RSBY are IT enabled and are connected to the server at the district level.¹⁴²

Under the scheme, each state selects an insurance company to fulfill the mandate of the scheme within the territory of the state.¹⁴³ The insurance company in turn enters into agreements with hospitals, which will be the sites of service delivery.¹⁴⁴ The state supplies the insurance company with a full list of BPL households enumerated according to the previous census.¹⁴⁵ It is the insurance company which is responsible for enrolling beneficiaries by obtaining their biometric data (fingerprints and photographs) and issuing them a smart card.¹⁴⁶ The list is posted in each village prior to the enrollment and the date and location is publicized in advance.

Currently, the various insurance companies in each state have their own software and

¹³⁶ Public Health Foundation of India. (Jan 2011) *A Critical Assessment of the Existing Health Insurance Models in India*. P. 10.

¹³⁷ Public Health Foundation of India. (Jan 2011) *A Critical Assessment of the Existing Health Insurance Models in India*. P. 12.

¹³⁸ *About the Scheme*, RASHTRIYA SWASTHYA BIMA YOJANA (2009), http://www.rsby.gov.in/about_rsby.html (last visited Oct 15, 2011).

¹³⁹ Iyengar, P. (2011) Country Report: Privacy in India. P. 105.

¹⁴⁰ <http://www.business-standard.com/india/news/qa-dr-k-seeta-prabhu-undp-india-senior-advisor/454648/>

¹⁴¹ Swarup, Anil. (2008). Country Paper: India (Rashtriya Swasthya Bima Yojana). Asia-Pacific Regional High-Level Meeting on Socially-Inclusive Strategies to Extend Social Security Coverage.

¹⁴² *How it Works*, RASHTRIYA SWASTHYA BIMA YOJANA (2009), http://www.rsby.gov.in/about_rsby.html (last visited Oct 15, 2011).

¹⁴³ Iyengar, P. (2011) Country Report: Privacy in India. P. 105.

¹⁴⁴ Iyengar, P. (2011) Country Report: Privacy in India. P. 105.

¹⁴⁵ It is unclear to what extent this transfer is legal.

¹⁴⁶ Iyengar, P. (2011) Country Report: Privacy in India. P. 105.

databases.¹⁴⁷ According to one account, “A central server has been established wherein participating insurers (or TPAs on behalf of insurer) push/upload data in batches.¹⁴⁸ Original bio-metric data containing finger prints, photographs etc is submitted in CD/hard disk separately”.¹⁴⁹ However owing to inconsistencies in storage formats between insurers, a Central Data Management Agency is envisaged which would consolidate the data held by the various insurers and be “a comprehensive, uniform system” to operate the scheme.¹⁵⁰ Once installed, this CDMA would have the potential to become a National Health Record system.¹⁵¹

Judicial Interventions

The jurisprudence in India on medical privacy has primarily evolved, like many other areas of privacy law, through judicial pronouncements given in specific circumstances. Therefore, no discussion of this issue in the context of Indian law would be complete without a discussion of some of the important judgments which not only talk about privacy rights in the medical arena but also juxtapose this right with others, such as the right to privacy of infected individuals vis-a-vis the right to protect non infected persons.

Neera Mathur v. Life Insurance Corporation,¹⁵² (1991)

In this case Ms. Mathur contested wrongful termination after she availed of maternity leave. LIC required the 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.

“We have examined the matter carefully. We have nothing on record to indicate that the petitioner's work during the period of probation was not satisfactory. Indeed, the reason for termination seems to be different. It was the declaration given by her at the stage of entering the service. It is said that she gave a false declaration regarding the last menstruation period with a view to suppress her pregnancy. It seems to us that the petitioner cannot be blamed in this case. She was medically examined by the Doctor who was in the panel approved by the Corporation. She was found medically fit to join the post. The real mischief though, unintended is about the nature of the declaration required from a lady candidate. The particulars to be furnished under columns (iii) to (viii) in the declaration are indeed embarrassing if not humiliating. The modesty and self respect may perhaps preclude the disclosure of such personal problems like whether her menstrual period is regular or painless, the number of conceptions

¹⁴⁷ Iyengar, P. (2011) Country Report: Privacy in India. P. 105.

¹⁴⁸ Iyengar, P. (2011) Country Report: Privacy in India. P. 105.

¹⁴⁹ Malti Jaiswal, *Insuring Health of Millions*, 8 IRDA JOURNAL 25-28 (2010), http://www.rsby.gov.in/how_works.aspx (last visited Dec 16, 2011).

¹⁵⁰ Central Data Management Agency Concept Note, (2010), <http://www.rsby.gov.in/Documents.aspx?ID=16> (last visited Oct 16, 2011).

¹⁵¹ Iyengar, P. (2011) Country Report: Privacy in India. P. 105.

¹⁵² AIR 1992 SC 392.

taken place; how many have gone full term etc. The Corporation would do well to delete such columns in the declaration. If the purpose of the declaration is to deny the maternity leave and benefits to a lady candidate who is pregnant at the time of entering the service (the legality of which we express no opinion since not challenged), the Corporation could subject her to medical examination including the pregnancy test. In the circumstances the interim order already issued is made absolute. We however, direct that the appellant is not entitled to the salary from the date of discharge till her reinstatement. With this direction the appeal stands disposed of but no order as to costs.”

Although 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.

Case Highlights

- **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,¹⁵³ (2001)

In *Ms. X vs. Mr. Z & Anr*,¹⁵⁴ 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 though the application was opposed by the wife on the ground of “Right to Privacy”.⁷ The couple were in the midst of divorce litigation and the husband had alleged that the wife had an adulterous affair with another person due to which she had become pregnant. In order to prove this charge the husband wanted a DNA test to be conducted on the tissues of the foetus (which had been preserved by the hospital upon termination of the pregnancy). This plea of the husband was opposed by the wife on the ground that this would violate her right to privacy.

“9. Bombay High Court in the case of *Sadashiv Malikarjun Kheradkar v. Smt. Nandini Sadashiv Kheradkar and Another*, 1995 CrL. L.J. 4090, the Court relied upon the decision of the Supreme Court in the case of [Goutam Kundu v. State of West Bengal](#), and held that the Court has power to direct blood examination but it should not be done as a matter of course or to have a roving inquiry. The Bombay High Court even felt that there should be a suitable amendment by the Legislature and after noting that nobody can be compelled to give blood sample, it was held that the Court can give a direction but cannot compel giving of blood sample. The findings in this regard are:

“.....There was be some strong prima facie case to be established by the husband to show non-access in order to get over the legal presumption under Section 112 of the Evidence Act and Supreme Court has also observed that nobody can be compelled to give blood sample. Therefore,

¹⁵³ 96 (2002) DLT 354.

¹⁵⁴ 96 (2002) DLT 354.

the position is that the Court has power to give a direction to a party to give blood sample for the purpose of examination of the same but the party cannot be compelled to give blood for testing purpose. In other words, the Court can direct a party and if the party fails to obey the direction, the Court cannot compel the party to give blood sample. In such circumstances, when there is a direction and non-compliance by a party, the only thing is that the Court may draw an adverse inference against the party who fails to give blood samples in spite of the direction of the Court."

11. The conclusions are obvious that nobody can be compelled without his consent to submit to DNA test. A direction can be issued. Such direction should not be done in the ordinary course, in routine or as a roving inquiry. A strong prima-facie case should be made out.

12. In the facts of the present case, at this stage, the foetus is not a part of the body of the petitioner. It had already been discharged. It is true that the carrying of the foetus would depend upon the mother but the bond between them came to an end when it was discharged. It cannot thereafter be treated as a part of the mother, but was a unique organism. When the foetus has already been discharged from the body of the petitioner there is no question of compelling her to submit to any test. It is an organism, which has been preserved and, therefore, once the organism is preserved, the petitioner cannot claim that it should not be put to any test. The question of compelling her to do any particular act does not arise. This argument, therefore, so much thought of by the learned Counsel for the petitioner, must fail.

19. From the aforesaid, the conclusion can conveniently be drawn, viz., that right of privacy though a fundamental right, forming part of her constitutional right of her life enshrined under Article 21 cannot be taken to be an absolute right. The right of privacy may arise from contract and also may arise from a particular specific relationship including matrimonial but when the right to privacy has become a part of public document, in that event a person concerned, indeed cannot insist that any such test would infringe his/her right of privacy.

20. The position herein can again be taken note of. As already referred to above, the foetus is no more a part of the body of the petitioner. The petitioner indeed has a right of privacy but is being not an absolute right, therefore, when a foetus has been preserved in All India Institute of Medical Science, the petitioner, who has already discharged the same cannot claim that it affects her right of privacy. Adultery has been alleged to be one of the grounds of divorce. At this stage, the Court is not expressing any opinion on merits of the matter, but the petitioner indeed cannot resist the request of respondent No. 1. However, if the petitioner was being compelled to subject herself to blood test or otherwise, she indeed could raise a defense that she cannot be compelled to be a witness against herself in a criminal case or compelled to give evidence against her own even in a civil case but the position herein is different. The petitioner is not being compelled to do any such act. Something that she herself has discharged, probably with her

consent, is claimed to be subjected to DNA test. In that view of the matter, in the peculiar facts, it cannot be termed that the petitioner has any right of privacy.”

It is very important to note here that although it was held that the Court can give a direction to a party in a litigation to give a blood sample, it cannot compel that party to give its blood, i.e. if the party fails to comply with the order of the Court, the Court cannot compel the party to give a blood sample but can only draw an adverse inference from the party’s conduct.

Further, 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.

Case Highlights: Ms. X vs. Mr. Z & Anr

- **The right to privacy is not absolute and a women’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 Parthasarthi vs. Government of Andhra Pradesh,¹⁵⁵ (1999)

In *B. K. Parthasarthi vs. Government of Andhra Pradesh*,¹⁵⁶ the Andhra Pradesh High Court had 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. While discussing the right to privacy and the right to reproductive autonomy, the Court held:

“14. The personal decisions of the individual about the birth and babies called 'the right of reproductive autonomy' is a facet of a 'right of privacy.' The American Supreme Court in *Skinner v. Oklahoma*, 316 US 535, characterised the right to reproduce as a "one of the basic civil rights of man."

15. The right to make a decision about reproduction is essentially a very personal decision either on the part of the man or woman. Necessarily, such a right includes the right not to reproduce. The intrusion of the State into such a decision making process of the individual is scrutinised by the constitutional Courts both in this country and in America with great care.

¹⁵⁵ AIR 2000 A.P 156.

¹⁵⁶ AIR 2000 A.P 156.

22. The impugned provision, viz., subsection (3) of Section 19 of the said Act does not directly curtail or directly interfere with the right of any citizen to take a decision in the matter of procreation. It only creates a legal disability on the part of any person who has procreated more than two children as on the relevant date of seeking an elected office under the Act. The substance of the provision is that it 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.

25. Whether creation of a restriction such as the one created in this case, would in fact achieve the object sought to be achieved, cannot be demonstrated in proceedings like this, but however, the legislative measure is reasonably be connected with the object sought to be achieved. In our considered view, the inquiry must stop there and this Court would not be justified in making a further inquiry as to what extent such a purpose would be achieved. The fact remains that the population growth is one of the major problems facing this country and any measure to control the population growth unless it impermissibly violates some constitutionally protected right, must be upheld as a legally permissible exercise of legislative power.....

27. This has been the consistent view of the Supreme Court till today. Therefore, the submission made on behalf of the petitioners 'right to privacy' is infringed, is untenable and must be rejected.”

Case Highlights

- **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.**
- **Measures to control population growth shall be considered legal unless they impermissibly violate a fundamental right.**

Mr. X v. Hospital Z, Supreme Court of India,¹⁵⁷ (1998 and 2002)

This was a very interesting case regarding the right to privacy in the realm of the health of an individual. 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 Supreme Court initially held that a person could not invoke his “right to privacy” to prevent a doctor from disclosing his HIV-positive status to others. It was

¹⁵⁷ <http://indiankanoon.org/doc/382721/>

ruled that in respect of HIV-positive persons, the duty of confidentiality between the doctor and patient could be compromised in order to protect the health of other individuals. The Court held that in such a case disclosure by the Doctor could not be violative of either the rule of confidentiality or the patient's right of privacy as the person with whom the patient was likely to be married was saved in time by such disclosure. The Court held that:

“25. As one of the basic Human Rights, the right of 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.

26. Right of Privacy may, apart from contract, also arise out of a particular specific relationship which may be commercial, matrimonial, or even political. As already discussed above, Doctor-patient relationship, though basically commercial, is, professionally, a matter of confidence and, therefore, Doctors are morally and ethically bound to maintain confidentiality. In such a situation, public disclosure of even true private facts may amount to an invasion of the Right of Privacy which may sometimes lead to the clash of person's "right to be let alone" with another person's right to be informed.

28. Having regard to the fact that the appellant was found to be HIV(+), its disclosure would not be violative of either the rule of confidentiality or the appellant's Right of Privacy as Ms. Akali with whom the appellant was likely to be married was saved in time by such disclosure, or else, she too would have been infected with the dreadful disease if marriage had taken place and consummated.”

However, upon a separate petition filed later, the Supreme Court in *Mr. X v. Hospital Z*¹⁵⁸ dated 10-12-2003, had to decide whether a person suffering from HIV (+) contracting marriage with a willing partner after disclosing the fact of disease to that partner will be committing an offence of negligently spreading infection or disease¹⁵⁹. In substance, the petitioner wanted the Court to clarify that there is no bar for the marriage, if the healthy spouse consents to marry in spite of being made aware of the fact that the other spouse is suffering from the said disease. The three Judge Bench of the Supreme Court held that if an HIV-positive person contracted marriage with a willing partner, then the same would not constitute the offences defined by the Indian Penal Code. However even the revised judgment did not touch upon the original conclusion that the 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.

From a reading of this case, it could be argued that this principle of disclosure to the person at risk may be applicable to other communicable and life threatening diseases as well, while a conservative opinion would be that this principle should only be applied to HIV+ cases. It may also be noted that the Court in this case did not discuss whether disclosure of such a disease may be made to only the persons at risk or to the public in

¹⁵⁸ <http://www.indiankanoon.org/doc/1826342/>

¹⁵⁹ Sections 269 and 270 of the IPC.

general, although it would be safe to say that since most cases as well as medical ethics require the doctors to keep the patient's health records private, it is highly unlikely that 'disclosure' can be made to the public in general.

Case Highlights

- **A disclosure can be made regarding the HIV+ status of a person if such disclosure would prevent another person from contracting the same disease.**
- **There is no bar on an HIV+ person to marry someone provided the fact that the person is HIV+ has been disclosed to the potential spouse.**
- **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**

*M. Vijaya v. Chairman and Managing Director, Singareni Collieries Co. Ltd.*¹⁶⁰ (2001)

In *M. Vijaya v. Chairman and Managing Director, Singareni Collieries Co. Ltd.*¹⁶¹ the petitioner alleged that she was infected with AIDS on account of the negligence on the part 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 lady wrote to the Court asking it to treat the letter as a Public Interest Litigation and give a direction to SCCL to provide sufficient financial assistance. The Court however expanded the scope of the case having regard to the importance and magnitude of the problem, thereby also dealing with issues of medical confidentiality and privacy of HIV patients. While discussing the conflict between the right to privacy of an HIV infected person and the duty of the state to prevent further transmission the High Court held as follows:

“54. There is an apparent conflict between the right to privacy of a person suspected of HIV not to submit himself forcibly for medical examination and the power and duty of the State to identify HIV infected persons for the purpose of stopping further transmission of the virus. 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

¹⁶⁰ <http://indiankanoon.org/doc/859256/>

¹⁶¹ <http://indiankanoon.org/doc/859256/>

Constitution of India.

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58. In the event of conflict between the individual right and public right which more often occurs while dealing with the cases of HIV-AIDS, the Roman Law principle 'Salus Populi est Suprema' (regard for the public health (welfare) is the highest law) -must apply. This maxim is based on the implied agreement of a member of the society that his own individual interest and welfare shall in cases of necessity yield to that of the community and that his life and liberty under certain circumstances be placed in jeopardy or even sacrificed for the public good See Broom's Legal Maxims-10th Edn, 1989 - Sweet and Maxwell.

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62. Yet another aspect of the matter is whether compelling a person to take HIV test amounts to denying the right to privacy? In *Kharak Singh v. State of UP.*, *Govind v. State of M.P.* and other cases, the Supreme Court held that right to privacy is one of the penumbral rights of Article 21 of the Constitution. In all situations, a person can be asked to undergo HIV test with informed consent. If a person declines to take a test, is it permissible to compel such person to take the test? The question is whether right to privacy is violated if a person is subjected to such test by force without his consent? By the end of 1991, 36 Federal States in USA enacted legislations regarding informed consent for HIV test. These legislations intended to promote voluntary test and risk reduction counselling. In USA, law also applies for involuntary tests and disclosure of information about the people in prisons, mental hospitals, juvenile facilities and residential homes for mentally disabled persons. (See AIDS Law Today - Scott Burry and others published by Yale University- 1993).

63. In India there is no general law as such compelling a person to undergo HIV-AIDS test. Indeed, Article 20 of the Constitution states that no person accused of any offence shall be compelled to be a witness against himself. Be that as it may, under Prison Laws, 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, 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. Women prisoners can only be examined by the matron under the general or special powers of the Medical Officer. As per Section 37 of the Prisons Act, any prisoner wanting to be medically examined or appearing to be sick has to be reported before the Jailor who in turn is liable to call the attention of the Medical Officer in that behalf and all the directions issued by the Medical Officer are to be recorded.

64. Under the ITP Act, the sex workers can also be compelled to undergo HIV/AIDS test. When sex workers are detained in corrective institutions or welfare homes either under Section 10-A or under Section 17(4) or 19(2) of the Act, there are adequate provisions for medical examination. There are also provisions in segregating rescued women who are suffering from venereal diseases. We may

also notice that Section 2 of Dissolution of Muslim Marriage Act, 1939, Section 32 of Parsi Marriage and Divorce Act, 1936, Section 10 of Indian Divorce Act, 1869, Section 13 of Hindu Marriage Act, 1956 and Section 27 of the Special Marriage Act, 1955 make incurable venereal diseases of either of spouses a ground for divorce. Further under Sections 269 and 270 of the Indian Penal Code, 1860, a person can be punished for negligent act of spreading infectious diseases.

65. In cases of divorce on the ground that the other spouse is suffering from HIV/AIDS or in case under Sections 269 and 270 I.P.C., can the person be compelled to give blood specimen for HIV test. The immunity under Article 20 does not extend to compulsion of giving of blood specimens.”

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 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.”

Case Highlights

- **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 'Salus Populi est Suprema' (regard for the public wealth is the highest law) applies when there is a necessity.**
- **The Court has acknowledged that in all situations, a person can be asked to undergo HIV test with “informed consent”.**
- **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,¹⁶² (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

¹⁶² <http://www.indiankanoon.org/doc/1309207/>

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:

“75. If the nature of the information relates directly to the well-being of the child or to the parent's ability to adequately care for child, and the court believes the child is potentially in danger, courts are likely to admit the information despite a patient's expectation of confidentiality. There are two competing interests involved when a court determines whether to compel discovery of a patient-litigant's mental health records over his objection in a child custody dispute. The first involves the privacy, confidentiality and privilege expectation of both the patient and the treating mental health professional in those communications. The second involves the application of the best interests of the child(ren) standard. Virtually every jurisdiction in the United States makes a child custody determination based upon the "best interest of the child".

76. "Privacy" is defined as "the state of being free from intrusion or disturbance in one's private life or affairs". Mental health treatment involves disclosure of one's most private feelings. In sessions, therapists often encourage patients to identify "thoughts, fantasies, dreams, terrors, embarrassments, and wishes". To allow these private communications to be publicly disclosed abrogates the very fibre of an individual's right to privacy, the therapist-patient relationship and its rehabilitative goals. However, like any other privilege the psychotherapist-patient privilege is not absolute and may only be recognized if the benefit to society outweigh the costs of keeping the information private. Thus if a child's best interest is jeopardized by maintaining confidentiality the privilege may be limited.”

The Court further held that:

“81. The matter may be considered from another angle. In all such matrimonial cases where divorce is sought, say on the ground of impotency, schizophrenia...etc. normally without there being medical examination, it would be difficult to arrive at a conclusion as to whether the allegation made by his spouse against the other spouses seeking divorce on such a ground, is correct or not. In order to substantiate such allegation, the petitioner would always insist on medical examination. If respondent avoids such medical examination on the ground that it violates his/her right to privacy or for a matter right to personal liberty as enshrined under Article 21 of the Constitution of India, then it may in most of such cases become impossible to arrive at a conclusion. It may render the very grounds on which divorce is permissible nugatory. Therefore, when there is no right to privacy specifically conferred by Article 21 of the Constitution of India and with the extensive interpretation of the phrase "personal liberty" this right has been read into Article 21, it cannot be treated as absolute right. What is emphasized is that some limitations on this right have to be imposed and particularly where two competing interests clash. In matters of aforesaid nature where the legislature has conferred a right upon his spouse to seek divorce on

such grounds, it would be the right of that spouse which comes in conflict with the so-called right to privacy of the respondent. Thus the Court has to reconcile these competing interests by balancing the interests involved.

82. If for arriving at the satisfaction of the Court and to protect the right of a party to the *lis* who may otherwise be found to be incapable of protecting his own interest, the Court passes an appropriate order, the question of such action being violative of Article 21 of the Constitution of India would not arise. The Court having regard to Article 21 of the Constitution of India must also see to it that the right of a person to defend himself must be adequately protected.

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85. So viewed, the implicit power of a court to direct medical examination of a party to a matrimonial litigation in a case of this nature cannot beheld to be violative of one's right of privacy.”

It is interesting to note that in the previous cases it was a balance between the competing rights of two people, whereas in this case it was more about the right of one person vis-a-vis the best interest of a child.

Case Highlights

- **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.**
- **In a number of matrimonial cases the relief is based on medical facts (impotency, mental illness, etc. of the spouse) and these can only be decided after a medical examination. Thus 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 individual**

Conclusion

	Principle	# represented
1	Openness	
2	Accountability	
3	Oversight	***
4	Access and Correction	*
5	Purpose Limitation	*
6	Choice and Consent	*****
7	Notice	
8	Collection Limitation	*****
9	Security	*****
10	Quality/Verification	
11	Disclosure	*****

When analyzing the relevant legislation for the Indian Health sector, there are a number of provisions that speak to the principles of collection limitation, security, and disclosure. Surprisingly, the principles of choice and consent are not strongly represented in present legislation. Similarly other principles like notice and quality and verification are also not recommended. On the whole the legislations and regulations governing the health sector in India are fairly well aware of privacy issues and do try to address them at a policy level even though implementation is still playing catch up.

ⁱ Ibid section 38

ⁱⁱ Ibid section 85

ⁱⁱⁱ PMDT Act section 25