I. Health and Health Research in India: An Overview

India has a population of about 1.24 billion and is a lower middle-income country under the World Bank classification. Urban population accounts for 31% of the population while the rest live in villages. Some states are more urbanized than others. Population under the age of 15 is 29% and above 60 is 8%, which means that India has a huge percentage of population between 15 and 60 years of age and the percentage of the population between 30 and 70 years of age is 40%. Total fertility rate (TFR) per woman is 2.5, but some states, such as Kerala and Tamil Nadu, have a TFR that is less than half of this. Life expectancy is 66 years. In terms of mortality, non-communicable diseases (NCD) account for 60%; injuries 12%; communicable, maternal, prenatal, and nutritional conditions account for 28%. Among the NCDs in terms of mortality, cardiovascular diseases account for 26%, followed by respiratory diseases 13%, cancer 7%, diabetes 2%, and other NCDs 12%.¹ The infant mortality rate has declined in the last two decades from 88.2 deaths per 1000 live births in 1990 to 43.8 deaths in 2012, but the variance across the states is significant.

With respect to Millennium Development Goals (MDGs), India’s record is a mixed one. The India country report on MDGs acknowledged that some targets have been achieved, like halving the poverty head count ratio and eliminating gender inequality in primary and secondary education. Also, internet and telephone connectivity improved significantly. For some targets, such as universal education, reduction in child mortality (infant mortality, under five mortality), and the fight against malaria and tuberculosis, the country was moderately on track. In tackling challenges in hunger and sanitation India lags behind. Another indicator of concern is that of maternal mortality.² Given the wide variance in health indicators across states and segments of society, India has to

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step up its efforts in achieving the targets set under MDGs, even as the Sustainable Development Goals (SDGs) are being negotiated. But there are challenges on other fronts too, such as patterns in diseases and the mortality and morbidity caused by them.

India is in the midst of a transition in the main causes of disease. While communicable diseases still account for a significant share of morbidity and mortality, non-communicable diseases are emerging as major causes.

Over time, with the modest decrease in the burden of communicable diseases, NCDs emerged as a major cause of death. The mortality burden attributed to NCDs has been increasing over time without replacing the burden attributed to communicable diseases. Among rural populations, the burden of NCDs increased from 12% in 1977 to 13% in 1982 and 28% in 1997. The decade of the 1990s witnessed a major rise in the burden of NCDs. Among urban populations, the share of NCDs increased from 29% in 1975 to 35% in 1985 and 36% in 1995. In general, the burden of NCDs among urban populations as compared to rural populations has been consistently higher.3

In India, until the 1960s, smallpox, plague, and malaria were the major communicable diseases, but by the 1990s, tuberculosis, gastroenteritis/dysentery, and pneumonia replaced them as major communicable diseases. Although communicable diseases are still a cause for major concern, the sharp increase in cases of NCDs calls for strategies to tackle them through better health care and other interventions. Most NCDs demand long-term medication/treatment and often the drugs/treatments are expensive. Moreover, in terms of morbidity and mortality they have a serious impact on public health.

Health spending in India is just 4% of GDP. The public sector contribution to health spending is 33% and out of pocket expenses constitute about 60% of health spending. The government spending on health is about 5% of government spending. India has 7 doctors per 1000 population. In terms of immunization coverage, 75% of the children are covered against diphtheria, tetanus, and pertussis (DTP) and measles.4

Although there are many methods to arrive at health spending in India, even after including water supply and sanitation the public sector spending is about 1.8% of the GDP. Many studies and reports have called for increasing this to 2-3% of GDP.5 However, it also has been suggested that this target is unrealistic.6

The central government allocates resources for various health-related missions, programs, and departments, and the state governments also allot resources for health. While the national policy and guidelines are developed by the central government, the state governments are free to decide on priorities and programs from their state budget for health. Generally, the state and central government work together; without working together on immunization, and HIV/AIDS, target-oriented projects and programs would not have succeeded.

The Indian Council for Medical Research (ICMR), Council for Scientific and Industrial Research (CSIR), and Department of Biotechnology (DBT) are the major agencies supporting research in health biotechnology, particularly in genomics and biosciences. CSIR funds research through centers and laboratories under its control, the ICMR and DBT fund research to institutions throughout the country including those under them, and the DBT also encourages research and development in the private sector. International collaboration in health and biosciences is also increasing and initiatives by the Wellcome Trust-DBT India Alliance promote research through fellowships. The Ministry of Health and Family Welfare and Department of Health Research are the two primary agencies in health care and health research in India.

The ICMR is the national organization for developing ethical frameworks and guidelines and liaising with international organizations on these topics. In the last decade or so, the health sector in India has seen a rapid increase in Contract Research Organizations (CROs), companies conducting clinical trials, medical centers offering stem cell therapy, and commercial surrogacy. These developments include setting up biobanks in the public and private sectors. A major challenge is that of regulation and governance, including developing guidelines and frameworks, and enforcing them. In pharmacogenomics, India is emerging as an important market for diagnostic tests, and many private sector companies — several of which are start-ups — have begun offering different types of tests besides developing new diagnostic tests and treatment options.7

The Translational Health Science and Technology Institute (THSTI) at Gurgaon, Haryana, has been set up as a health biotech science consortium. The bio- and life sciences research in India is spread across different institutions, such as the National Center for Biological Sciences (NCBS), which is an offshoot of Tata Institute of Fundamental Research, National Institute of Immunology, Rajiv Gandhi Center for Biotechnology, and the National Center for Cell Science
To summarize, the evolving regulation and governance of biomedical research in India is influenced by many factors including globalization of science and technology; India’s focus on emerging technologies; the ethical conflicts and dilemmas in regulating R&D and clinical trials; the increased involvement of the private sector in biomedical R&D, including commercialization; and society’s high expectations from biomedical sciences and scientists.

II. Biobanks and Biobanking Framework in India

There is no universally accepted definition for biobank or what activities can be covered under biobanking. In the literature, biolibrary, biodepository, biorepository, and tissue bank are used. Depending upon the institutions like the Indian Institute of Science (IIISc, Bangalore) and Indian Institute(s) of Technology (IITs), and Jawaharlal Nehru Center for Advanced Scientific Research (JNCASR) continue to offer programs in life and biosciences and to conduct research, institutions that have a specific focus or specialized institutions such as NCCS, inSTEM, have also been established. In addition, the private sector is involved significantly in clinical research outsourcing and stem cell therapy.

ICMR, one of the oldest medical research bodies in the world, is the apex body in India for the formulation, coordination, and promotion of biomedical research. It has developed guidelines for research ethics (biobanks), stem cell research (stem cell/cell line banks), assisted reproductive technologies (sperm, ovum, and embryo banks), and guidelines framed by other ministries and laws enacted by parliament. For example, clinical trials are regulated by the Drugs and Cosmetics Act 1940, as amended in 2005 and its recent notifications during 2013. While ICMR’s Ethical Guidelines for Biomedical Research on Human Participants (2000/2006) have to be complied with, the Good Clinical Practices (GCP) 2001 guidelines framed by CDSCO, as well as the Ministry of Health regulations must be followed. Research proposals involving human subjects must be approved by an Institutional Ethics Committee (IEC) and consent from the human subjects should be obtained. IECs should abide by the Standard Operating Procedures developed by ICMR. The structure and function of these committees is usually based on the Policy Statement on Ethical issues involving humans in biomedical research issued by ICMR. The Drug Controller General of India (DCGI) is mandated to enforce the Drugs and Cosmetics Act, which covers clinical trials for new drugs. DCGI issued the GCP guidelines for establishment of institutional ethics committees that approve clinical trials in 2001 and has mandated registration of these committees since 2013. As a result, several institutions established IECs for clinical trials and to date more than 800 IECs are registered with CDSCO.

The accreditation of these committees is the next step planned by the Ministry of Health. Departments are free to impose additional conditions and restrictions while insisting that ICMR’s ethical guidelines have to be adhered to in projects funded by them. For example, DBT mandates that to conduct a pharmacogenomics study in India the following criteria have to be met:

1. The study should be of national relevance
2. The disease for which the study is conducted should have a high prevalence in India
3. The drug should be a widely used drug for treatment and
4. The proportion of patients who either do not elicit adverse reactions or patients who do not respond to the drug should be high.

To summarize, the evolving regulation and governance of biomedical research in India is influenced by many factors including globalization of science and technology; India’s focus on emerging technologies; the ethical conflicts and dilemmas in regulating R&D and clinical trials; the increased involvement of the private sector in biomedical R&D, including commercialization; and society’s high expectations from biomedical sciences and scientists.
tion, type of materials stored/collected, and purpose of collection, rules governing biobanks vary from country to country. Biobanking is evolving and as the diversity in biobanks and biobanking has increased there have been calls for global governance of biobanking. In the context of India, the ICMR guidelines of 2006 define biobank as “a collection of resources that can be accessed to retrieve human biological material and data.” As the scope of research on stored biological samples increases, the ICMR guidelines should include other “non-genetic uses” of biobanks. This will result in more clarity for researchers on the ethical guidelines to follow.

Although there is no exact data on biobanks in India, the following are some of the biobanks in India: Bangalore Brain Bank, Narayana Hrudayalaya Tissue Bank and Stem Cell Research Center, Tata Memorial Hospital Tissue Bank, TCG Life Sciences Biobank, TranScell Biologics, and Dhruv Dental Stem Cell Bank. Of these, the Bangalore Brain Bank is housed in the National Institute of Mental Health and Neurological Sciences (NIMHANS, Bangalore). The biobanks in the public sector are the Bangalore Brain Bank, and the Tata Memorial Hospital Tumor Tissue Bank, and the rest are in the private sector. However, in our view there are many more biobanks that collect samples, including cord blood. In fact, in recent years cord blood banking has become popular and entities doing cord blood collection have to be registered with CDSCO, but no data are available on them. Given the diversity of medical and health research institutions in India, it is likely that there could be many more collections of all sorts of biomaterials including “waste” and many may qualify as biobanks. In recent years, the Department of Science and Technology has sponsored a cancer tissue biobank at IIT Madras in the Department of Biotechnology. This is not yet functioning, but considering the presence of the cancer institute and other hospitals offering oncology treatment in South India, particularly in Madras, this biobank can emerge as one of the specialized biobanks with many sample types relating to cancer.

Private sector involvement in biobanking is expanding its scope. For example, Sapien Biosciences is a joint venture between Apollo Hospitals and Saarum Innovations with the objective to create a “world class biobank.” It is also a personalized medicine company. This joint venture will combine the expertise of the Apollo Hospital Group and Saarum’s R&D expertise in novel clinical applications. The company will access the Apollo Network for its biobanking needs. In terms of ethical practices, the company claims that it follows ICMR guidelines: “We follow ICMR guidelines for sample acquisition (at par with all international guidelines). We follow high ethical norms with respect to transparency and patient privacy. Sapien’s Repository Ethics Committee (REC) is constituted to review projects internally. India’s 1st commercial Biobank with systematic archive of ethically consented, anonymized patient samples and associated data.”

The ICMR guidelines specify the following rules for 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.

The rules on collection for DNA banking or cell-line banking are as follows.

DNA banking or cell-line banking 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.
There are not many studies on privacy issues of biobanks in India, although privacy is referred to in some articles on biobanking in India. ICMR seems not to have done an audit of the biobanks on privacy issues. As a result, we have to presume that biobanks follow the guidelines on privacy, and that the IECs and IRBs take into account privacy issues.

The ICMR guidelines are necessary, but much has happened since 2006. It is time to revisit and revise them and ensure that they represent the best practices in addressing privacy and other issues in regulating biobanks. By now, there is enough literature and data from experiences elsewhere for ICMR to draw upon to revise the guidelines.

One important question is as follows: How should biobanks be regulated in India? Can they be regulated by guidelines framed by ICMR, or does India need legislation for this purpose? In 2006-2007, the Anthropological Survey of India convened a group of experts to develop a model law that could be converted into a draft bill for presentation before Parliament. The bill was to create a National Repository for Human Genetic Materials and frame rules for governing the repository. Further, it was envisaged that the National Repository will collect, share, and exchange such materials and also oversee similar repositories in India. The bill was drafted and submitted to the Anthropological Survey of India under the Ministry of Culture. It never saw the light of day and the current status of the bill is not known. In 2006, ICMR submitted a comprehensive bill for regulating biomedical research in the country to the Ministry of Health. It was revisited in 2010 and a revised Biomedical Ethics Bill was submitted once again in 2014. If this bill is passed, it is expected that a Biomedical Research Authority will be set up to implement this Act and regulate all aspects of biomedical research, including biobanks.

The reasons for drafting a bill and getting it enacted instead of regulating through guidelines are as follows:

1. An Act enacted by the Parliament has more legal authority than guidelines, which are considered as subordinate legislation. As discussed in the case law elsewhere when the provisions of an Act and subordinate legislation are in conflict or contradict each other, then the provisions of the Act will circumscribe the provisions of the guidelines.
2. An Act gives flexibility to frame rules, modify them, and implement them when an Authority is created through or empowered by law as the scope of the coverage through law can be comprehensive.
3. While ICMR has played an important role in biobank guidelines, an authority created through law with representatives from stakeholders and comprehensive powers can usher in better regulation. ICMR can be the nodal authority for regulation of biobanks.
4. Given the convergence of biobanking with many other activities, such as commercialization and development of treatments based on omics technologies, a comprehensive law is needed for regulating biobanking. Such a law can incorporate bioethical principles and key features of the guidelines within a regulatory structure. This will ensure that regulators can keep up with new demands and evolve new rules when required.

Technically, biobanks deal with biological materials, but the boundary between materials and data/information is permeable. As technological developments facilitate transfer and storage of data through various modes, there are privacy issues to be addressed. Thus, whether it is an issue of access to health data stored in digital form or accessing biological materials in biobanks, there are many common issues. Moreover, with the convergence of technologies new opportunities and threats will emerge relating to privacy. Technology can play an important role in safeguarding privacy if the systems are technically designed to protect privacy. Therefore, from the perspective of addressing privacy issues in biobanks in India we suggest the following:

1. Study the best practices in privacy regulation in biobanks elsewhere and see how best they can be applied in India.
2. Address privacy issues in India through surveys on user perception, user needs, how different stakeholders address privacy issues, and what values are driving their perceptions.
3. Understand the linkage between the emerging legal landscape in India on privacy and examine how this will impact upon addressing privacy issues in biobanks.
4. Based on the above, develop suitable guidelines for privacy regulation in biobanks.

III. Privacy and Legal Principles in India

Privacy is a fundamental right in India, but this is due more to interpretation of Article 21 of the Constitution of India than any specific provision on privacy. Article 21 of the Constitution of India states that “No person shall be deprived of his life or personal liberty except according to procedure established by law.” In many
judgments the highest court of India, the Supreme Court, has interpreted that the term “life” to include all those aspects of life that are essential to make a person's life meaningful, complete, and worth living. In interpreting the right to privacy as a fundamental right, the Court has taken into account Article 12 of the Universal Declaration on Human Rights and Article 17 of the International Covenant on Civil and Political Rights, 1966.

In the absence of a specific law on privacy, the decisions of the Supreme Court in significant cases form the basis for deciding on privacy rights and their violation. In Kharak Singh v. State of UP, the Supreme Court held that the right to privacy is one of the penumbral rights of Article 21 of the Constitution. Article 19, which guarantees the right of freedom of expression and Article 21, which upholds the right to life, are the key articles invoked in these cases. Over the years, the Court has expanded the scope of Article 21 through its judgments. In R. Rajagopal v. State of T.N., it was held that a right to privacy was implicit in Article 21 and through this, the Court recognized that prisoners are entitled to the right to privacy. The core issue was what rights were available to citizens when the rules or action taken by the state were considered as violation of privacy. The Court took the position that actions like tapping telephonic conversations are violations of privacy and the power conferred under Section 5 of the Indian Telegraph Act for the purpose of telephone tapping and interception of other messages has to be exercised under a procedure that is “just, fair and reasonable” and laid down guidelines for this.

In India, freedom of speech is a fundamental right, but not an absolute right. The First Amendment to the Indian Constitution qualified this right. None of the leading privacy cases in India involve access to tissues or biobanks, nor are they about informed consent and privacy in giving and collecting samples. The applications to biobanks must be extrapolated from more general principles.

Due to issues relating to state surveillance, collection of data for government-sponsored programs, outsourcing, and handling of data including personal and financial information and press freedom, privacy issues have received attention in recent years. Privacy issues in health or research, however, have not received much attention. Regarding privacy in health matters, courts have interpreted that although privacy is a fundamental right, it cannot be enforced as an absolute fundamental right without any restriction and in some contexts public good or public welfare can override the right to privacy. Thus, courts have tried to strike a position that balances private right with public welfare. When provisions of two acts are contradictory or when more than one act and guideline is applicable the general interpretations of guidelines are subordinate to acts enacted by Parliament or legislatures. Important cases on health privacy in India are given here to illustrate how courts have handled such cases and the principles invoked therein.

In Mr. Surupsingh Hrya Naik v. State of Maharashtra, the key issue was whether the provisions of the Right to Information Act would prevail over the rules under the Code of Ethics of the Medical Council of India. The Bombay High Court took the view that as the Code of Ethics and regulatory guidelines are subordinate legislation, the provisions of an Act of Parliament would override such regulation if there are conflicts in applying them. In this case, the question was whether the health records of a person in custody and when admitted to a state hospital while in custody can be sought under the Right to Information Act or could they be denied as furnishing them would violate the Code of Ethics. The Court took the position that

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.

Had the patient been admitted in a private hospital for which the Right to Information Act is not applicable, the outcome would have been different. In such cases, the rules of the hospital and/or the Code of Ethics would prevail. The need to balance the privacy interests and the demands under the Right to Information Act are obvious as the right to information can be misused to seek information that affects both the privacy and the confidentiality maintained by hospitals and diagnostic centers. There is no need to conclude that demands under RTI can circumscribe privacy. There are other means of finding facts and verifying truth including appointment of commissioners and if privacy has to be circumscribed the breach should be minimal.

In Arjesh Kumar Madhok v. Centre for Fingerprinting & Diagnostics (CDFD), the Central Information Commissioner held that the information regarding the results and objective of medical testing was exempted
from disclosure under RTI and when the personal information has no relationship or is not relevant for public interest disclosure of personal information it would cause invasion of privacy of the individual. The Commissioner also took into account the fact the information sought by the petitioner was disclosed to another person within the doctor-patient fiduciary relationship which was exempt from public disclosure on that ground. Although the cases under RTI illustrate the challenges to privacy, how to interpret “public interest” in such cases is a big question that is not yet answered.

Whether or not the introduction of a silent observer and on-line submission of information would be a violation of privacy was considered in *Radiological & Imaging Association v. Union of India.* To prevent the misuse of prenatal diagnostic tests for identifying the sex of the fetus and subsequent abortion if the child were to be a girl, the Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 was enacted. The Act includes implementation guidelines for undergoing prenatal tests, sharing of information, and storing data. Despite the Act, selective abortions continued unabated and as a solution it was decided to install a silent observer in each sonogram and make submission of Form F online under the rules. This was challenged by the plaintiffs on grounds of violation of privacy of the patients. However, the High Court did not agree with this view. The High Court took the view that installation and functioning of silent observer in the ultrasound machine and online submission of 'F' Form to the collector and district magistrate do not violate the doctor’s duty of confidentiality or the patient’s right to privacy. It observed that the contours of the right to privacy must be circumscribed by the compelling public interest found in the provisions of the PC&PNDT Act, and this can be seen in the context of the declining sex ratio over the last five decades. Reversing the decline in sex ratio through application of provisions of the Act serves the public interest. The Court took the position that the compelling public interest, in this case the skewed male-female ratio among the children, could limit the right to privacy. Further, the Court took into account the fact that the system has enough safeguards to ensure that access to data / information is restricted to selected public authorities. The Court observed:

> While the Court cannot close its eyes to these depressing figures, the assertion of Collector and District Magistrate, Kolhapur that after introduction of the impugned innovative measures, the sex ratio in the district has gone up from 839 in May 2010 to 876 in January 2011- is certainly a heart warming eye opener.

In the above view of the matter, it is not necessary to consider the further submission on behalf of the respondents that the right of the unborn child to be born would also be a fundamental right, and therefore, when there is a conflict of fundamental rights of two parties, that right which advances public morality will prevail.

In this case, the installation of a silent observer was an example of privacy by design.

Although the court did not address the privacy by design issues in the judgment and instead took the position that public interest legislation's rules and provisions could circumscribe the privacy of a patient, sooner or later such issues will have to be addressed. This is because the privacy by design principle is fine, but there could be provisions in a system that violates privacy unknown to the patient or to the doctor or both. Given the rapid advances in health care technology and informatics, medical devices with embedded facilities for transmission of health data of a patient could be developed, and they may violate the privacy of the patient. In case of biobanks, privacy by design is a good principle to follow.

In *Smt. Selvi Ors. v. State of Karnataka,* the Supreme Court addressed the issue of whether investigative techniques such as narco analysis violate the privacy of the accused. The Court stated that these tests, even if they are taken voluntarily, their result could not be considered as evidence. The involuntary use of such a test violates the right against self-incrimination, which is a fundamental right under Article 20(3) of the Constitution. But the important point is that such tests violate the individual’s right to privacy as they intrude into the “subject’s mental privacy.” Moreover, they deny the option to speak or remain silent. The Supreme Court observed: “There are several ways in which the involuntary administration of either of the impugned tests could be viewed as a restraint on ‘personal liberty’... the drug induced revelations or the substantive inferences drawn from the measurement of the subject’s physiological responses can be described as an intrusion into the subject’s mental privacy.” These points are significant from the perspective of privacy of a citizen as they underscore the importance of the right against self incrimination and the Court’s inclusion of mental privacy indicates that the Court looks at privacy in a holistic manner.

In *Neera Mathur v. Life Insurance Corporation,* the question was whether an employer can seek personal details, such as menstrual cycles, conceptions,
and pregnancies from female employees and whether termination on the basis of the information furnished would be valid. Life Insurance Corporation of India (LIC) collected such information at the time of appointment. In this case, the petitioner contended that her employment was terminated when she took maternity leave. The court held that providing such information was “embarrassing if not humiliating” for a woman and it went against her modesty and self-respect. The court ordered that LIC should not collect such information from employees. The court did not directly invoke the concept of privacy and its violation by LIC by seeking such information. Instead, it invoked principles of modesty and self-respect to hold such collection illegal. This information is too personal to be disclosed to an employer. If employers want to deny maternity leave and other benefits to employees who are joining the service, the option would be to subject them to a medical examination including a pregnancy test.

Cultural values like modesty and self-respect can be invoked to ensure privacy when the right to privacy is not explicitly protected by law. But in such cases the problem is that these values may prioritize societal norms and values over a person’s right to privacy, particularly the right not to disclose information or the right to prevent unnecessary intrusion into privacy. Hence, the use of such values for protecting privacy also could go against privacy.

What are the rights available under the right to privacy and can a woman extend the right of her privacy to an aborted fetus? These were addressed in Ms. X v. Mr. Z & Anr. The court reasoned that the right to privacy was not an absolute right and cannot be extended to an aborted fetus. In this case, the couple had filed for divorce and the husband alleged that the wife had become pregnant out of an adulterous affair. To prove this, he wanted a DNA test to be conducted on the tissue of the aborted fetus. Opposing this plea, the wife argued that it would be a violation of her privacy and asserted that his plea should be dismissed. The court reasoned that she was entitled to her right of privacy, but it was not an absolute right. According to the court, as the fetus had been aborted it cannot be claimed that testing would amount to a violation of her privacy. The court differentiated between an act that would violate her privacy, such as requiring her to undergo tests or provide samples, and an act that would result in testing the samples from a fetus. It stated that the husband could not demand that she should undergo a test or provide samples in cases where the allegation of adultery is made. The court stated that if she were compelled to subject herself to some tests, she could raise the defense that she could not be compelled to be a witness against herself in a criminal case or compelled to give evidence against herself even in a civil case. This judgment sets the boundary of privacy by refusing to consider an aborted fetus as an object over which the right to privacy of a woman would extend. Nevertheless, she cannot be compelled to undergo tests or provide samples as that would violate her right to privacy. This ruling made it clear that the right to privacy is not an absolute fundamental right. It can arise from a contract or a specific relationship, such as a marital relationship.

But what exactly is the nature of the tissue: is it private property, or is it public property that can be subjected to tests on orders of courts? This is an unresolved issue. The logic that the right to privacy does not apply to aborted fetuses addresses one part of the question, the limits of the right to privacy, but it ignores access rights to such fetuses. There are many grey areas in the cases involving biological specimens that have to be addressed and these include access and benefit sharing, the right to use and appropriate, and the right of a woman over the fetus. This case raises issues in the famous U.S. case of Moore v. Regents of the University of California. There have been no biobank cases in India so far, but regulation of biobanking will have to take account of such privacy questions.

Another important issue is whether a court can direct a person to undergo genetic testing to determine whether that person is the biological father. Can that person refuse to undergo the test by arguing that it would be a violation of privacy? In Rohit Shekhar v. Shri Narayan Dutta Tiwari, the Delhi High Court directed the putative father to undergo a DNA test despite his objection. According to the court:

There is of course the vital interest of child to not be branded illegitimate; yet the conclusiveness of the presumption created by the law in this regard must not act detriment to the interests of the child. If the interests of the child are best subserved by establishing paternity of someone who is not the husband of her (or his) mother, the court should not shut that consideration altogether. The protective cocoon of legitimacy, in such case, should not entomb the child’s aspiration to learn the truth of her or his paternity.

The court took the position that the “right of the child to know of her (or his) biological antecedents” is affirmed by international covenants. But the court also ruled that such tests could be ordered to be conducted if the petitioner could establish a prima facie case and produce evidence that his legal father is not his biological father. The Supreme Court upheld this
judgment. The claims of the right to privacy were circumscribed by the rights of the child to know his biological parents. Although this judgment and the judgment given in Ms. X v. Mr. Z & Anr may seem to be contradictory, the facts and the contexts vary. In the case of Ms. X v. Mr. Z and Anr, the court allowed tests on the samples from the fetus and took the position that no person could be compelled to undergo tests or provide samples as that would be a violation of privacy. But in the latter case, the issue was the right of the child to know his biological father versus the right to privacy of a person. The court, after deliberating on the issues of legitimacy and paternity, decided in favor of the right of the child to know.

Another question is whether courts can mandate DNA testing to determine the paternity of an unborn child. This issue arose in Bhabani Prasad Jena v. Convenor Secretary, Orissa State Commission for Women & Anr. In this case, the Supreme Court overturned the high court’s order for a DNA test to determine paternity. The Supreme Court took into account the best interests of the unborn child and the need to balance the interests of the parties and for a just decision.

Sometimes the result of such scientific test may bastardise an innocent child even though his mother and her spouse were living together during the time of conception. In our view, when there is apparent conflict between the right to privacy of a person not to submit himself forcibly to medical examination and duty of the court to reach the truth, the court must exercise its discretion only after balancing the interests of the parties and on due consideration whether, for a just decision in the matter, DNA is eminently needed.

Thus, when the right of privacy and the interests of the child are in conflict, the courts seem to give more importance to the interests of the child and depending upon the context it may order a DNA test.

In Mr. X v. Hospital Z, the right to privacy of one party and the right to health of another party were in conflict. Another issue was whether a doctor can disclose information in violation of the duty of confidentiality if that information is critical for another party in decision making. The petitioner was engaged to be married and during testing for some other disease from which he was suffering, it was found that he was HIV positive. The doctor, without the consent of the petitioner, shared this information with his family who shared it with the family of the girl who was engaged to the petitioner. The Supreme Court took into account the fact that the girl was saved from the prospect of getting infected since the petitioner’s health status was made known before the wedding. The Court ruled that privacy is not an absolute right and there are grounds to circumscribe it. Similarly, it held that when the right of one person to be left alone is in conflict with the right of another to know, the latter would prevail over the former. According to the Court:

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. 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.

Subsequently, the Supreme Court clarified that if a person is informed that the potential spouse is HIV positive and still consents to marriage, then that disclosure is permissible as information has been provided to the other party. The judgment in M. Vijaya v. Chairman and Managing Director, Singareni Collieries Co. Ltd., laid down norms for HIV. The Andhra Pradesh High Court took into account the conflict between the right of the person suspected to be HIV positive and the duty of the state to identify those infected by HIV for the sake of public interest. Considering public interest and applying the legal principle of “Salus Populi est Suprema” (regard for the public health is the highest law), the Court opined:

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. Further, the court directed that the identity of persons who come forward for treatment of HIV/AIDS should not be disclosed.

In *Sharda v. Dharmpal,* the wife in a divorce case refused to undergo tests to determine whether she was of sound mind on the grounds that such a test would violate her right to personal liberty. The Supreme Court observed:

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.

Thus, a court can order medical examination if such an examination is necessary to arrive at facts in a dispute and that will override the right to privacy. In cases of two competing rights or when there is a conflict, the right of one person to protect his or her interest will circumscribe the right of privacy of the other party.

The above-cited cases highlight the tension between competing rights and the reasoning by the courts in addressing the tension. In all of these cases, the right to privacy has been circumscribed by another right or in the public interest or in the best interests of a child. Moreover, although courts have recognized the right to privacy as a fundamental right, they have also noted the limits of applying this right as an absolute, fundamental right. The courts have also taken the position that in many instances besides the right of privacy, the duty of not disclosing information to a third party, based on a code of ethics or ethical guidelines, cannot be invoked as a defense that should always be accepted by the court. These reveal a serious lacunae in the jurisprudence over the right to privacy in India. The lacunae arises from the fact that although the right to privacy is considered a fundamental right that flows from Article 21, which is the right to life, courts have been reluctant to stretch its limits and have rather circumscribed its reach by invoking different reasons.

This position gives ample room for courts to issue orders for undergoing medical tests and to invoke the best interests of the child argument in cases where the right to privacy of a parent is pitted against another parent’s or third party’s right. Moreover, as the courts have not discussed the dimensions of the right to privacy in detail nor laid down guiding principles in determining the scope of the right to privacy, there are many unaddressed issues and grey areas. They range from access and ownership over fetus/tissues removed from the body to relationships between informed consent and the right to privacy. In one sense, this is a paradox because the highest court has expanded the scope of the Right to Life under Article 21 by including the right to privacy, but in cases cited in this article the scope of this right is limited through invoking reasons such as the ones cited above.

Between 2009 and 2014 some initiatives were taken to enact new laws on privacy, but after 2014 nothing much has happened. The Right to Privacy Bill of 2014 has yet to be tabled in the Parliament and despite many positive features, it is not clear if or when it will be enacted. In the absence of a statutory or regulatory framework, the decisions by the courts serve as legal guidance on privacy issues. Often courts have interpreted existing laws when privacy issues, such as tapping of telephones, were raised. But as dimensions of privacy undergo change, the old definition of “right to be left alone” will not be sufficient.

There have been a few articles on data privacy and patient information, but there too the focus has been more on processing of personal information under the Information Technology Act 2000. In 2013, the Electronic Medical Records Standard Committee constituted by the Ministry of Health and Family Welfare submitted its recommendations for the Electronic Medical Records Standard and analyzed the issues on data ownership, privacy, and access to patient health data.

It has been pointed out that Indian jurisprudence on privacy has been heavily influenced by American jurisprudence, but more serious problems remain.

To use a litigator’s yardstick, there is no test for privacy; no Indian judge has fashioned a judicial model of privacy that is logical, predictable, and supported by reason, not even the inimitable Justice Subba Rao whose contribution to privacy law continues to tower over the field. On the other hand, as long as India’s law and polity remain ambivalent about the rights of the individual against the community, privacy law will suffer.

India follows the common law tradition, but there is no specific tort law for violation of privacy. The issue of extending breach of confidence to protect privacy is
largely an unattended issue, although the judgments and decisions discussed in the earlier sections have highlighted the views of the courts.

A tort of invasion of privacy has not been established in Indian law, though there is some slight judicial support for it. The distinction between a common law right and a constitutional right is still important in India, both because the scope of the two rights may differ, and because (as discussed earlier) Indian courts are unlikely to allow horizontal enforcement of the constitutional implied right of privacy. Nor have Indian courts yet adopted the extension of the law of breach of confidence to protect privacy interests as has occurred in the UK over the past decade, although there are only limited dicta to that effect. Supreme Court decisions are needed to clarify both matters.\textsuperscript{37}

This is all the more relevant in health law and privacy, where courts have taken recourse to factors like “public interest,” “best interests of the child,” and “public good” without giving sound legal reasoning or principles of privacy. But what is lacking is a holistic understanding of the issues and development of principles to address privacy concerns. Similarly, if interests of different parties have to be compromised, which principles should govern such decision making is not clear.

To conclude, privacy issues related to health law have not received the attention they deserve in India. As a result, instead of a law or a set of coherent guidelines, the judgments and interpretations by courts prevail.

This state of the law applies to privacy issues in biobanks, even though there have not been any cases involving biobanking in India. In one sense, this is a blessing as it provides an opportunity to enact a law on biobanking that covers privacy issues. The lawmakers, policymakers, and regulators should use the lacunae to initiate new action to develop well defined principles and guidelines to address privacy issues in biobanking.

\textbf{IV. Legal Analysis of Six Aspects of Privacy in Biobanks}

There are six key aspects of privacy that we summarize below.

\textbf{a. Governance and oversight:} The current guidelines cover governance and oversight in a limited way as the guidelines mandate setting up IECs and following the provisions of guidelines. But they do not cover the core issues relating to governance and oversight, such governance structure, conflict of interest, or dealing with benefit sharing of different types, nor issues involving oversight, particularly when the biobank is operated on a commercial basis or is part of a commercial venture.

\textbf{b. De-identification policies:} At present there are no specific guidelines on this for biobanking.

\textbf{c. Security policies:} The guidelines do not address this in the context of biobanking.

\textbf{d. Databases open/controlled access policies:} The guidelines have some provisions on this, but not in the context of biobanking.

\textbf{e. Role of informed consent in the privacy frameworks:} Informed consent is mandated in the case of identified samples. According to the guidelines:

\begin{quote}
The sample collector must obtain informed consent of the donor for DNA banking or for cell-line transformation and banking. The process of seeking informed consent for purposes of banking must clearly be stated in addition to possible 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. The sample collector must also clearly inform every donor that he reserves the right to order destruction of his sample from the Repository at any time.
\end{quote}

The current framework takes into account some issues like use of samples for research, but it can be revised taking into account all aspects relating to prior informed consent and privacy.

\textbf{f. Other restrictions to data sharing for the protection of the privacy of research participants:} the current regulations on this seem to be adequate, but they may be evaluated on the basis of evolving norms in this.

Our brief analysis shows that while the current regulations address privacy issues, the rules in the guidelines can be revisited and revised to meet the norms of international genomic research. In the absence of a comprehensive law or framework on privacy in India, however, mere revision of the guidelines is not sufficient. The then-Planning Commission in 2012 appointed a group of experts on privacy and the group...
was headed by Justice A.P. Shah. The group submitted a report suggesting a conceptual framework for regulation of privacy in India. The key points are:

1. The privacy act should not focus on any specific technology and should be generic enough with flexibility. It should be technologically neutral and interoperable with global standards so that it helps in building trust of global clients and users;

2. The multi-dimensions of privacy should be taken in account and the act should cover physical privacy, DNA, audio, video etc.;

3. The legislation should apply to the government and private sector;

4. The data controller should guarantee privacy and be made accountable; and

5. Industry-specific, self-regulating organizations and the office of privacy officer as primary authority for enforcement of provisions of the act should be established.

V. Evaluation of the National Privacy Framework

As of now, in India there is no national privacy framework in general or as it relates to genomic research except the guidelines of ICMR. While some guidance can be drawn from the judgments of the courts, that is not sufficient as these cases have not addressed any issue of privacy in biobanks. In the absence of a national framework, evaluating the guidelines for privacy, security, and governance is needed. As pointed out, the guidelines need to be revisited and revised. A better option would be to enact a new law on biobanks and replace the guidelines with that Act. But such an exercise will have to address issues on data transfer, handling of genomic data through bioinformatics, and the implications for privacy and the interfaces/linkages between different acts and regulations in protecting and promoting privacy. The current approach of invoking Article 21 or fundamental rights in violation of privacy cases is not sufficient to address the complex issues as fundamental rights per se in India are enforceable against the government but not always against private parties. Hence, it is necessary to enact a new law on biobanks and replace current guidelines with that Act and harmonize relevant guidelines of other Acts and ethical guidelines issued by different bodies. This will ensure that biobanks are governed under distinct principles on privacy.

VI. Conclusion

This article has emphasized two main points. First, there is no national framework in India to address privacy issues, and for biobanks, the ICMR guidelines are the operative guidelines. The guidelines issued in 2006 can be revised, but a better option would be to enact a new separate law on biobanks. Given the proliferation of different types of biobanks in India, in both the public and private sectors, regulatory oversight is all the more important. How to facilitate that is an important question.

Second, harmonization with global laws/regulatory frameworks is desirable, but it cannot be done in one go. India will have to evolve a credible regime on privacy issues in biobanks first, and after testing that, harmonization can be pursued. The global laws/regulatory frameworks cannot be simply imposed or taken as the sole norms in regulating biobanks. Instead, the right approach would be to address the legal principles on privacy in the context of biobanks and arrive at regulations that are relevant and appropriate for India based on globally accepted norms of privacy and...
compatible with the provisions of the Constitution of India.

Capacity building in biobank governance is a must and international collaboration can go a long way. This is the right time to develop a comprehensive framework for biobank governance in India and to address privacy concerns in biobanks.

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