**GENOMIC SCREENING: THE SOCIAL AND LEGAL IMPLICATIONS OF SCIENTIFIC INTERVENTIONS IN REPRODUCTIVE HEALTH**

**ABSTRACT**

Although a global phenomenon, a demographic shift towards the spread of non-communicable genetic disorders/diseases is becoming a huge burden on India’s health sector. The problem is further exacerbated by the fact that the subcontinent is home to a diverse, heterogenous population which has multiple cultural conceptions about marriage and child bearing which are deeply entrenched within the family institutions. The load of genetic illnesses varies from community to community based on their reproductive practices and various other factors specific to them for example, the prevalence of consanguineous marriages within some communities has been noted to have contributed towards an increase in the spread of genetic disorders. Moreover, the sheer magnitude of the country’s population ensures that even a rarest of the rare disease has a chance of spreading amongst a sizeable number.

In such a scenario, the technological advancements in the medical field pertaining to pre-natal genetic counselling, testing and diagnosis have a fundamentally important role to play in curbing the spread of such diseases. However, utilizing such resources to their full potential would also include dealing with an independent set of challenges. This article shall examine the social, legal and ethical implications of genetic testing and the policy contours which shall be given special consideration for its implementation.

Key words: Genetic screening, Invasive medical procedures, Amniocentesis, Disability-based abortions, Reproductive autonomy, Confidentiality, Privacy, Medical liability.

**INTRODUCTION**

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The technology of genetic screening is designed to identify in a given population, all of those who are at a higher risk of having or developing a particular disorder or having certain ‘mutant genes’[[1]](#footnote-1) which could cause genetic disorders in their future offspring. Today, genetic screenings are performed for various purposes like reproductive healthcare[[2]](#footnote-2), research purposes[[3]](#footnote-3) as well as for predicting the incidence of genetic disorders[[4]](#footnote-4). In fact, rapid advancement in these technologies has enriched our understanding of gene expressions and their impact on human lives and diseases. More than 1800 ‘gene diseases’[[5]](#footnote-5) have been identified and more than 2000 genetic tests[[6]](#footnote-6) are available with many bio-technology based products being released in the market. Additionally, there are many emerging legal considerations which go beyond medical academic interests[[7]](#footnote-7) into the domain of future litigations and legislative polices which could pave the way for newer principles and thresholds.

Part I of this article would begin with the acknowledgement that the level of discourse and awareness pertaining to the aforementioned issues particularly in Asian countries has been largely unsatisfactory. Secondly, it would also explain the necessity of navigating through as well as carving out newer legal principles of medico-legal jurisprudence regarding the subject. It has been understood that the technologies and screening tests required for identifying and curbing the spread of such disorders require the applicability of various invasive medical procedures which broach into the purview of uncomfortable subjects like confidentiality, privacy, parental autonomy and its conflicting cultural notions, right to life and various other ethical and legal considerations which the written piece shall expound on.

Part II shall focus on the nature of the ethical and legal duties of medical practitioners and the possibility of assessing and fixing compensatory liability on medical practitioners who are by virtue of their position assumed to have a considerable degree of expertise in risk assessment of genetic dispositions but fail in the discharge of such duties. The courts do recognise the presence of vindictive and baseless suits against medical practitioners, however, instances of withholding vital information, whether purposefully or neglectfully, denies the prospective parents the opportunity of exercising an informed choice. These claims have to be analysed on their own merits on a case by case basis and the judicial principles and legislative policies shall have to step in and create the required precedents for the development of this jurisprudence. Arguments and case laws from other jurisdictions may be supplemented to fill in any judicial or legislative lacunae.

Part III will firstly demonstrate how several jurisdictions cite financial constraints as one of the principle reasons for less than desirable levels of health implementation. It shall also demonstrate how international cooperation through state capacity building as well as the revision of internationally understood socio-economic principles could play a vital role in the practicable realization of the health ideals of genetic testing. It is pertinent to note that health services are socio-economic goods/positive obligations which are legally distinct from the nature of civil and political rights also known as negative covenants. International legal instruments like UNHRC and their general comments recognize how socio-economic goods like education and health are distinct from negative covenants wherein the positive obligations remain subject to financial resources as well as state capacity and may not be as realizable as much as it is ideally desired keeping in mind that there are many developing economies with a significant resource crunch.

Lastly, Part IV would give recommendations for improvement in the quality of medical care and diagnostic facilities as well as strategies for a sustained increase in general awareness and improving the accuracy of identifying congenital disorders.

1. **GENE EXPRESSION - THE TECHNOLOGY OF GENETIC SCREENING AND MEDICAL LITERATURE**

With its overwhelming population and a high birth rate, India is distinctly given the status of the second most populous country in the world[[8]](#footnote-8). The population is a curious amalgamation of genetically divergent and heterogenous population groups[[9]](#footnote-9) who had engaged in ceaseless migration during the ancient times. Currently it houses around ‘4000 anthropologically distinct’[[10]](#footnote-10) groups mixed with 22 languages and innumerable dialects and cultural signifiers. This makes the process of categorizing and mapping out any information pertaining to genetic disorders a very complicated and tedious task with largely incomplete and inaccurate results.

It has been well established that the role played by our genetic makeup as well as the condition of major environmental factors have a fundamental role to play as on-setting factors which influence the transfer of non-communicable genetic deformities and disorders to the next generation (especially in cases of monogenic diseases)[[11]](#footnote-11).Consequently, strategies for the prevention, management and treatment[[12]](#footnote-12) of these diseases are gaining recognition on account of their accurate detection with respect to congenital condition of a to-be born offspring. Based on the knowledge doled out and the undertaking of risk-assessment, prospective parents may choose to terminate any pregnancy which shall have predictively worrisome indicators. However, as it is in other developing economies, there is a worrying gap[[13]](#footnote-13) between the availability of screening tests and diagnostic tools which are the recommended scientific solutions for these problems and the actual utilization these services.

Subsequently, the data demonstrating the readiness with which these preventive services are actually availed by the general population leaves much to be desired. For example, Down Syndrome in India is one of the most common intellectual disabilities which can be passed down through genetic mutations and is considered by the medical community as the ‘commonest genetic cause of mental retardation’[[14]](#footnote-14) in many countries including India. Furthermore, it is also one of the most easily ‘preventable’ and ‘detectable’[[15]](#footnote-15) disease provided the concerned patients are given satisfactory counselling and easy accessibility to the requisite medical technologies.

However, the testing statistics for the disease paint a very grim picture. It is much more likely that an average patient availing the said services shall be a lay-user with little to no grasp over the nuances of a thorough pre-natal screening and its significance for the future offspring[[16]](#footnote-16). It is also unfortunate that not all medical practitioners would be ideally inclined to or be competent enough to impart the requisite genetic information which shall translate into the manifestation of informed choices on part of the parents. The onus for making parents understand the risk involved in birthing lies with the agencies involved in these testing facilities. Therefore, the screening tests for Down Syndrome are mostly run by private facilities where the issue of accessibility is a fundamental problem[[17]](#footnote-17). Moreover, there is no discernible action plan or concrete health program envisioned by the state in order to tackle glaring inadequacies with respect to the issue of accessibility and awareness[[18]](#footnote-18).

In the western jurisprudence, there have been debates about the termination of pregnancies owing to high risk mutations in the future offspring. There are discussions about how invasive the medical procedures could get in order to determine whether the fetus belongs to a high risk category or not and how autonomous decision-making is to be envisioned[[19]](#footnote-19). Contrary to this, developing economies like India are still battling the preliminary hurdles in the form of lack of information and even worse, misinformation. Around 23,000 to 29,000 children are still born with this congenital affliction every year[[20]](#footnote-20). The existence of outdated counselling procedures, information asymmetry and little to no open dialogue ensure the sustenance of these horrid state of affairs. Whatever little data which could be derived from the studies relating to Down Syndrome points to the frequency of Down Syndrome cases and other such cytogenetic abnormalities. Medical literature has identified ‘population awareness, risk distribution and performance of the screening tests especially at regional levels’[[21]](#footnote-21) as the principle points of focus for formulating an actionable plan.

Genetic tests and diagnostic screenings are crucial for determining genetic pre-disposition of couples towards congenital diseases and maps out as accurately as possible, the probabilities and risks involved in giving birth to their offspring. The objective of familiarizing the prospective parents with the likelihood of transferring unfortunate genetic mutations allows them to be aware of the possible consequences for the offspring in going ahead with the pregnancy.

Therefore, the introduction of accurate methods for genetic screening has provided us with an exceptional opportunity for exercising a greater deal of reproductive decision-making and parental autonomy. It is precisely for this reason that a greater need for an open dialogue and awareness gets arisen. Unless there are open and transparent mechanisms installed to discuss these issues, one won’t be able to navigate other important issues like the various policy contours for effective parental autonomy and the resultant cultural fissures[[22]](#footnote-22) in values of child birthing which may or may not be at loggerheads with these invasive technologies. The fundamental importance of making these choices becomes incumbent on the building of steady structures for improving information symmetry. It is also imperative in the seeking of genetic counselling; a culture of voluntariness should be instilled on part of the general population. Besides, in order to ensure completely independent decision making in reproductive autonomy, the counselling narrative and directives shall be ‘value-neutral’[[23]](#footnote-23) as well as directory.

Gene expressions and their mutations form the fundamental basis for the transfer of hereditary traits to our offspring. Upon fertilization, a human embryo gets encoded with the genetic makeup of all the autosomal chromosomes from both the parents. The process of embryological development is a complex process of gene expression whereby multiple areas get activated or repressed during cell division. During such a process, it is probable to have mutations in cell division. Mutations occur when gene expressions get altered or fail to function at all which is harmful at best and lethal at worst. In its graver manifestations it leads to serious chromosomal abnormalities[[24]](#footnote-24).

Once it has been detected that either one or both the parents are carriers of defective gene sequencing, it would open the doors for genetic counselling. There has been considerable scientific progress and sophistication in the domain of genetic detection with various processes like ‘fetoscopy, radiography, and ultrasound and most notably amniocentesis’[[25]](#footnote-25) cropping up with great potential for increased accuracy and quality of prediction.

For instance, Amniocentesis is one such pre-natal diagnostic technique which is considered to be one of the most ‘invasive’[[26]](#footnote-26) one. The procedure involves the ‘tapping of a small amount of amniotic fluid from the gestational sac’. The procurement of fetal cells from the fluid enables the medical practitioners to diagnose any possible chromosomal problems antenatally, thus allowing parents to make an informed decision. There are several conflicting studies which bring up the effectiveness as well as the risks involved in these diagnostic procedures[[27]](#footnote-27).

For example, the procedure is usually performed around the fifteenth week of pregnancy. The results are posited to come out by around the twentieth week of the pregnancy. Abortions are generally avoided post the twentieth week of pregnancy and therefore it becomes really cumbersome to reconfirm the diagnosis[[28]](#footnote-28). Although in India, recent amendments have raised the limit from the twentieth week to the twenty fourth week, it is not the case in all jurisdictions across the world.

The general unavailability of reconfirmation is further problematized by the fact that many tests including amniocentesis are prone to diagnose ‘false positive’ or a ‘false negative’[[29]](#footnote-29) which may have a bearing on the reproductive decision-making by the parents. There have been confirmed cases of abortion of ‘false positive’ in recorded medical literature and the happening of such an event is a statistical probability, albeit very low. Furthermore, not every nation may have properly trained practitioners or good quality paraphernalia so as to replicate successful diagnosis in every possible case. Many studies have displayed how a significant number of such errors can and do occur from time to time which could potentially vitiate timely decision making for the parents.

On the other hand, false negatives have the potential to attract glaring litigation suits and penalties for medical negligence/malpractice. A false positive which may get aborted may not appear as tragic as a false negative born with glaring genetic defects. Medical staff may not give assurances of a hundred percent accuracy, however, it is difficult to gauge whether the issue involves an avoidable neglect or technical errors which are beyond one’s control which would be under the scrutiny of the judiciary. Either way, one needs to identify and fill the lacunae which shall rear its head with all the consequences of increased testing and discourse around the issues of genetic screening and disorders. One shall carefully calibrate the threshold question for assessing liabilities and affixing blame if any in cases involving a certain degree of neglect or involvement of technical errors.

SOCIAL, LEGAL AND ETHICAL CONSIDERATIONS

Genetic disorders were once viewed as an ‘act of god’[[30]](#footnote-30)- an unpreventable tragedy rooted in fate. However, later stages of development in scientific temperament led us to an understanding that parents could be identified as carriers of harmful gene mutations which could radically impact the health and lifestyle of their children. These developments included an increasing acceptance of an idea that the destiny of our progeny could now be scientifically calibrated and undesirable outcomes can be vitiated using these rapid advancements.

Parental autonomy in countries like India is not an unqualified right. While the regulation of parental autonomy has negative connotations in western circles, the Indian context demands a blanket ban on the usage of sex-selection technologies because of its ‘epidemic of femicide and an entrenched tradition of discrimination against women’[[31]](#footnote-31). The proclivity towards the ‘male child’[[32]](#footnote-32) has led to a dangerously unscrupulous deployment of these technologies and therefore a complete ban on its access is a justifiable step towards the right direction.

On the other hand, complete suppression of reproductive autonomy is not the answer either. For women in any society, a healthy agency in reproductive autonomy is an indicator of progressive and healthier attitudes towards childbearing and sustenance of familial institutions. Apart from the necessary regulation of sex selection technologies, another roadblock which arises while availing the benefits of these technologies is the traditionally entrenched conception of child bearing within the Indian communities. It is difficult to predict the beliefs underlying the practices of pregnancy and childbirth as they are neither simple nor unanimous. For example, in many Asian countries having children is seen as a ‘socio-religious’[[33]](#footnote-33) obligation which has to be followed through with obedience and religiosity. Studies show that even now, in various ways, the Indian landscape is dominated by the pressing need for people to fulfill their social roles within the familial institutions. Any departure from such a tradition could invite scrutiny and even censure[[34]](#footnote-34).

It is also true however, that increasing number of women in urban as well as rural settings are becoming amenable to availing pre-natal screening. While the extent of this ‘proliferation’[[35]](#footnote-35) cannot be gauged very easily, research has shown that there are plenty of other factors which influence a woman’s decision making in child birthing and its linkage with genetic diseases. Depending on the culture and tradition of the place as well as the adequacy of information in their possession, there could be different attitudes towards pregnancies and child rearing. Research also suggests that there are strong possibilities of ‘coercion, stigmatization and marginalization’[[36]](#footnote-36) in certain circumstances which could become straining for women. Any apprehension towards availing these technologies could be tackled by satisfying another fundamental belief which would be intrinsic in all traditional couples which is the desire to produce healthy and ‘normal’[[37]](#footnote-37) children. A significant number of parents agree to undergo genetic screening as giving birth to a healthy child is also seen as extremely important cultural signification in India.

Therefore, the principle of informed choice and parental autonomy are principle factors along with the existence of a scientific appreciation of the relationship between genes and diseases. It is also tied to several other indicators which ensure that ‘self-determination’[[38]](#footnote-38) in reproductive decision-making varies as per the educational attainment and financial independence of the woman in family structures. This leads to a lot of decisions to not be individually exercised especially in Asian communities where family as a unit take these decisions which in turn function patriarchally, even though it leads to a desirable outcome i.e. reduction in the birth rate of disease-ridden children. There are very little public debates among feminists and social activists regarding these issues. While these technologies should be wholeheartedly accepted as a medical relief, feminist literature must question the ‘gendered responsibilities for producing acceptable children’[[39]](#footnote-39), which are implicit in such decisions.

While informed choices were included into the discourse by the ‘second wave of feminism’, concepts like self-determination, right to privacy and confidentiality and right to life are also linked to the ethical and legal principles in medical decision-making and ethics. The legalities involved beg the question: What are the standards involved in dealing with the information collected through genetic screening? And how much third-party intrusion is to be warranted in the availability of such information? (insurers, employers, educational institutions, spouses, researchers, other social agencies)?

Furthermore, following the procedure of Amniocentesis, the threshold for determining the point where termination of pregnancy shall be considered wrongful termination of ‘life’[[40]](#footnote-40) must be given a lot of introspection. Article 21[[41]](#footnote-41) of the Indian Constitution promises the right to life to every person, citizen and alien. On the other hand, it is also a judicially acknowledged signification of personal liberty and acts as a vital check on the state’s intrusion into an individual’s life and his or her choices. Moreover, various progressive precedents have also ensured that right to healthcare shall include the right to live with ‘human dignity’[[42]](#footnote-42), free from the ‘dangers of disease’[[43]](#footnote-43) and to lead an aspirational life. It is also reasonable to argue that knowingly bringing a child into this world who may have debilitating mental and physical deformities runs against the fundamental objective of seeking the services of geneticists in the first place. It could also result in an undesirable abrogation of an individual’s right to privacy and body autonomy in case there is little agency deployed in the making of the choice.

It has been previously explained how certain medical procedures like Amniocentesis[[44]](#footnote-44) are still marked by limitations like lack of information, unverifiable accuracy and poor understanding of risk assessment. On top of that if the procedural conclusion of the screening is going beyond the stipulated time period which allows for abortion, then the approval for abortion becomes even more cumbersome. For example, in a decision made by the Indian Supreme Court in 2017, the abortion petition of a 26-week old fetus was rejected on the grounds that it posed no significant dangers to the life of the mother or the life of the to-be born offspring[[45]](#footnote-45). The Supreme Court had sided with the notion that abortion in such cases shall only be allowed if either the mother or the fetus had no chance of survival. The Supreme Court paternalistically maintained that a child afflicted with Down Syndrome is just as ‘affectionate’[[46]](#footnote-46) and ‘lovable’[[47]](#footnote-47) as any other child and would be thoroughly capable of leading a normal life.

Although the legislature has relaxed the abortion threshold from 20 to 24 weeks in the light of ‘humanitarian, social and eugenic’[[48]](#footnote-48) grounds, it is still a great cause for concern that the Supreme Court is refusing to see that it is operating under a stubborn but rebuttable belief that for all its intents and purposes, life is and always will be a blessing. Life isn’t always a blessing. It is precisely because life isn’t always a blessing that a couple would want to go through with the process of genetic screening and counselling. What is really at stake is a reasonable desire to give birth to a healthy child who could aspire for a life as good as any other life, without the burden of malformities hindering his or her growth and aspirations. The precedent should also have taken into consideration that not every parent would have the financial capacity to support the upbringing of genetically defective child. Raising a child with these disabilities would warrant extra care and medical attention which would not be possible for every couple functioning under limited resources and capacity.

In the analysis of these decisions, precedents from foreign jurisprudence may shed some light in understanding the nature of the arguments involved in these considerations. For example, the Supreme Court in the United States has always struggled to define the outer limits of the abortion precedent set out in Roe v. Wade[[49]](#footnote-49). The principle carved out in the decision was that the scrutiny of abortion based laws is dependent on the stage of the pregnancy and in order to outlaw abortion practices it has to be made sure that it is done so in the pursuance of compelling governmental and medical interests. The compelling interests are legitimate when they are pursued in order to fight sex-selective and race-selective abortions. The US has had an uncomfortable history with eugenics which has fueled the white supremacist notions[[50]](#footnote-50).

However, in the area of disability based abortions, the notions become further divided. The issue becomes deeply divided even amongst the liberal community. Although, body autonomy is cherished amongst all considerations, there exist glaring concerns on disability-based abortion which are tied to anti-discriminatory laws[[51]](#footnote-51). The concern is that discrimination against disabled community cannot be eliminated by eliminating the ‘discriminated community’ itself. Simply put, the rejection of a potentially disabled or congenitally defective offspring further devalues their worth in today’s society. Therefore, it becomes a consequentialist argument.

However, this position displays more of an ideological divide than a reasoned argument against the practice of disability-selective abortion. Firstly, this negates the fundamental contention that bodily autonomy and reproductive agency is sacrosanct and is prioritized amongst all considerations. Either bodily autonomy is sacrosanct, or it isn’t, there cannot be opposite predications. Secondly, racism and sexism are socially conditioned evils which could be tackled at a societal level through increased sensitization and education about gender and race relations. Being born in particular gender or a race is not an inherent disability. However, physical and mental malformities have actual harmful, tangible and continuous effects on the child’s lifestyle and will interfere in the standard of living of the person afflicted by them as well as the caretakers who are responsible for them regardless of the fact that they are discriminated against or not.

The trump card remains that any criteria which is unrelated to a woman’s aspirations and priorities is a regressive interference into her bodily autonomy. Therefore, these intellectual inquiries are profoundly useful for developing jurisprudence on these matters particularly for India where right to life has had a progressively expansionist reading by several precedents and should be given due weightage in these conversations.

Lastly, in the medico-legal sphere, access to sensitive information about one’s body and the control and authorization of its access is also a crucial theme to emanate out of them. Confidentiality in the medico-legal sphere is maintained using a set of social, legal and moral principles which restrict its access and are often expressed in written terms and conditions. The medical procedures today are as much effective as they are invasive. Modern reports suggest that confidentiality is breached either through faulty mechanisms in place or through deliberate breaches in order to protect other values[[52]](#footnote-52).

Institutions which are responsible for storing personal DNA information and profiling[[53]](#footnote-53) also differ on account of determining the threshold where a breach of confidentiality could be threatened. It has become a norm to conduct additional tests on samples, share it with other institutions without the consent of the person to whom it belongs. These possibilities raise a lot of pertinent questions and demand the installation of appropriate safeguards regarding the need for obtaining the consent of the patient involved particularly with respect to additional and subsequent uses. It shall be the duty of any institutional structure to put in place, a mechanism for advanced reviews of genetic testing as well as an overarching authority responsible for ensuring scientific merit, accuracy as well as the protection of privacy[[54]](#footnote-54) and confidentiality.

1. **LIABILITY OF MEDICAL PRACTITIONERS**

Lately, the level of patient awareness has markedly heightened within the medical sphere. There is a discernible rise in the litigations pertaining to misdiagnosis, failure to diagnose, breach of confidentiality as well as instances of questionable consent[[55]](#footnote-55). The medical proclivity towards patient centric initiatives in India has also come in the wake of decreased state spending towards the health sector as well as the rapid privatization of medical services which has created corridors for more regulation either through traditional (civil or criminal) litigation or through the Consumer Protection Act[[56]](#footnote-56). The Supreme Court of India has taken gigantic leaps in its interpretation[[57]](#footnote-57) of Article 21 of the Constitution which now recognizes the right to health as an indubitable fundamental right.

For assessing the liability of medical practitioners, the litigative practice in India has been marked by two opposing concerns. On one hand, there is a general agreement that patient centric initiatives within the medical sector are a dire necessity. On the other hand, it has to be acknowledged that the practice of expanding the patient rights model should not be conflated with giving credence to the rising levels of vindictive prosecutions and baseless accusations against various medical establishments[[58]](#footnote-58). Therefore, in the light of such adversarial interests, the jurisprudence is in the need of a delicate balance. The national legislation of Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act 1994[[59]](#footnote-59) has been enacted to not only tackle the deeply entrenched problem of sex-determination in India, but also to identify genetic disorders and medical procedures to be brought under the purview of the act’s regulatory influence. The act also deals with the establishment of centers linked to genetic counselling, genetic laboratories and clinics.

According to the Act, any person having adequate space and being or employing a gynaecologist who would be having a certain degree of experience[[60]](#footnote-60) can set up a genetic clinic for the purposes under the Act. The list of offences under the act have been delineated, with the punishment of any violation going up to 5 years of imprisonment and Rs. 50,000 in fine[[61]](#footnote-61). However, data reveals that most offences invoked under the act are either pertaining to failure in the registration of the clinic, or sex determination. As of itself, the Act has generated very little dialogue on the nature of liability assessment in instances of misdiagnosis or a blatant failure to diagnose any medical disorder. For adjudication on these matters, Indian courts would naturally rely on common law principles of medical negligence[[62]](#footnote-62) and steer towards the identification of reasonable standards to objectively determine medical negligence/malpractice and any redressal incidental to it.

Health infrastructure and services in India are administered as a public service under the Ministry of Health and Family Welfare as well as a private service by various private corporations and many other individual practices[[63]](#footnote-63). Although we have seen an unparalleled private expansion in this sector, the system also consists of secondary and tertiary health institutions which operate as primary health sectors and cater to wide ranging urban as well as rural populations. However, there also exists a deep seated limitation of discrepant access whereby premier cities are much more likely to have stable and dependable conditions for genetic screening and counselling which exacerbates the already existing limitations in the equality of access. The advancement in these sophisticated technologies has undoubtedly revolutionized health diagnostics but at the same time, in order to achieve its effective utilization, it is imperative that the system be operated by competent geneticists who are capable of interpreting these technologies and communicate the risk indicators in a timely and professional manner.

The common law principles regarding medical malpractice/negligence dictate that medical liability arises when the standard of care employed by a health professional falls below the reasonable degree standard as determined through a case by case basis[[64]](#footnote-64). Even in cases where there is no direct client-doctor relationship the courts reserve the authority to impose duty on the medical professionals. The standard of care which has been established for the medical professional is to ‘bring his or her task to a reasonable degree of care and knowledge’[[65]](#footnote-65). The principle however, does not concern itself with the aftermath of the treatment as long as the treatment meted out has fulfilled the reasonable standard criteria. This means that the medical professional in question does not have to per se ‘ensure’[[66]](#footnote-66) that every patient who comes to him or her should have a desirable outcome.

Furthermore, a charge of professional negligence does not hold water merely because of the possibility that ‘greater competence’[[67]](#footnote-67) could have been exercised by the professional so long as the duty exercised is in line with the standard of practice as accepted by a reasonable body of medical professionals. Therefore, the legal implications of the catena of decisions laid out by the Indian courts, point to the conclusion that in the event of a misdiagnosis or a failure to diagnose any genetic disorder, a liability may be fixated only if it is sufficiently established that either the doctor has withheld crucial information, or he/she has displayed blatant incompetency during the diagnostic procedure which lead to a grave misdiagnosis.

Furthermore, it must be established that there was a causal connection between the information/misinformation granted and the reproductive decision taken by the parents i.e. if not for the misinformation, the reproductive decisions taken by the parents would have been glaringly different. Although, in principle it is easy to establish the relevance of common law principles which can be used to shape the jurisprudence required for matters of such nature, however, the usage of these principles may lead to unavoidable anomalies which have to be looked at more seriously.

Firstly, it is admitted that causal connection has to be established and that it is one of the fundamental elements required for proving negligence, however, the standards to be set up for the appreciation of evidence and the balancing of probabilities are difficult to gauge. For example, how do you separate the wheat from the chaff when it comes to differentiating between a grave human error and an unavoidable technical error? Tests like Amniocentesis, although efficient, do not promise complete reliability[[68]](#footnote-68). Technical errors in swab collections and minute unavoidable circumstances can cause ripples of consequences in test results- not all of which may be within the medical professional’s agency. It has to be asserted that in such cases of acute medical technicalities, the court developing its own wisdom has the potential to lead to absurd results. Therefore, it is reasonable to suggest that the standards for appreciation of evidence would have to be solidified through steady reliance on expert opinions from the medical body and its literature.

Secondly, many judgements have time and again cemented the position that beyond the statutory time limit, abortions cannot be allowed unless there is a potential harm to the life of the mother or the to-be born offspring[[69]](#footnote-69). Now there have been reported cases wherein the physician’s failure to inform about the risks involved, has led to an inordinate delay in decision-making. In such cases it would be absolutely unfair to block not only a bid for abortion but at the same time to deny the possibility of availing compensation for the additional costs which would have to be incurred for raising a genetically defective offspring. The question thus arises: Can we measure ‘the value of an impaired life versus no life at all?’[[70]](#footnote-70) A precedent set by the courts in the United States had considered the possibility of affixing liability on a physician for an absolute failure to inform a prospective couple of the genetic risk indicators in the pregnancy. The court had determined that compensation had to be owed to the couple[[71]](#footnote-71).

The court’s decisional philosophy was buttressed on the belief that it would lead to an unjustifiable situation if a couple is denied the requisite information which shall enable them to terminate an unwanted pregnancy and on top of that to deny the right to seek compensation for such negligence displayed by the physician. This policy which forces the congenitally harmed embryo to be carried to its full gestation and even denies the right to recover from the tortfeasor, the costs of treating as well as caring for the infant has to be considered absurd.

Therefore, contrary to the running common principles, the consequences/aftermath of a diagnosis has to be given greater significance and put into more scrutiny by the judiciary so that there is a possibility for a proper appreciation of facts. Moreover, the technical wisdom[[72]](#footnote-72) regarding the profession should not be within the domain of the judiciary and heavy reliance has to be placed on expert committee reports and medical professional body for establishing precedents which would shape the appropriate and accepted standards for determining future liabilities and compensations. Moreover, in cases where it’s not clear whether there were technical errors or human negligence, state should step in and depending on the couple’s financial capacity, award compensation through setting up of state funds.

In addition to the aforementioned contentions, the growing sphere of litigation specific to inheritable disorders makes it a huge possibility that parents themselves may be made subject to tortuous liabilities for having knowingly given birth to children with genetic diseases despite being privy to information which would have reasonably led them to believe that their offspring may be afflicted by congenital malformations. Genetic technology has ‘revolutionised’[[73]](#footnote-73) the way we conceive reproductive technology and therefore such a radical alteration should make space for renewed legal relations and liabilities. Indian jurisprudence has witnessed compensation claims[[74]](#footnote-74) for being born with certain afflictions, however it shall also ready itself for possible precedents whereby certain reproductive decisions or even genetic implantations which knowingly reduce a child’s capability to function in the world could be categorised as legally cognisable tortuous injuries[[75]](#footnote-75).

The Constitution has adequate safeguards, interpretations and readings which put right to health both as a fundamental right within Article 21 as well as to be treated as a ‘positive obligation’[[76]](#footnote-76) on part of the state to take extra-ordinary efforts to cause no harm to any individual medically afflicted by unavoidable difficulties. It is therefore, reasonable to suggest that a compensational jurisprudence model shall be infused in the future rulings and decisions. Any parent seeking the pre-natal screening of an offspring should have the right to know every possible risk indicator which shall impair the chances of giving birth to a healthy offspring. Compensation shall be owed because the desire to give birth to a genetically healthy offspring is the driving motivator behind the seeking of genetic counselling and screening services in the first place. Any erroneous procedure which shall impinge on the objective of these screenings shall be treated gravely.

1. **INTERNATIONAL PRINCIPLES AND SOCIO-ECONOMIC OBLIGATIONS**

The international principles related to health and welfare rights describe how imperative the ‘highest attainable standard of health’[[77]](#footnote-77) is for every nation. It implies that it is an ever-present obligation on the states to secure appropriate and conducive conditions for the implementation of the right to health without any discrimination. A human rights-based conceptualization of right to health, welfare and housing etc., allows the state to traverse the notional divide between the socio-economic obligations and civil and political rights envisioned in international human rights treaties[[78]](#footnote-78). A negative right is about inaction on part of the agent, whereas positive obligations oblige the state to performatively realize the objective of welfare. Therefore, positive duties are harder to realize and require more complex and planned efforts by virtue of the fact that every country has its own set of finite resources and its own unique sense of resource management. This differential sense of resource management allows us to develop a better understanding of the implications of ‘highest attainable standard of health’[[79]](#footnote-79) which is recognized as binding by various international instruments like the International Covenant on Economic, Social and Cultural Rights (ICESCR).

The core element of this requirement is the need for ‘progressive realization’[[80]](#footnote-80). The principle of progressive realization entails an acknowledgement that states do not necessarily have an obligation towards a socio-economic right until a certain level of economic development has been achieved. The ICESCR General Comment No. 14 for the right to health points out how the notion of ‘highest attainable standard of health’[[81]](#footnote-81) takes into consideration the state’s available resources as well as overall socio-economic landscape. The comment further goes on to state that in particular, good health cannot be ensured by a State nor can States provide protection against every possible cause of human ills.

Although, progressive realization is not to be confused with permitting the states to be lax with their obligations, however, in its practical effect, it has the potential to allow states to deny healthcare in certain circumstances and at an international level to make it entirely discretionary[[82]](#footnote-82).As of now, the area of genomic testing and sequencing is a niche subject. Furthermore, not every state may have the same resources or capacity to realize the core essentials of health standards. Therefore, in order to ensure the adequate paraphernalia of genetic equipment at a large scale every state would have to commit to a deliberate and structural actionable plan for its implementation. This is why the infusion of positive obligations in the notion of fundamental rights (negative covenants) becomes an essential starting point for every state.

The Indian Supreme Court’s interpretation of right to life in the ‘Ahmedabad Municipal Corporation’[[83]](#footnote-83) case stated that right to life as a fundamental right entailed the assurance that every individual is to be equipped with all the facilities to develop himself/herself as well as to free him/her from any restriction which could inhibit their growth. Therefore, every state shall make it a point to ensure that positive duties should flow from a judicial as well as a legislative affirmation of the continuous obligation towards positive duties of providing genetic testing facilities as well as from the fact that progressive realization is also envisaged as a continuing principle which has no scope for undue ‘retrogression’ by the state.

1. **RECOMMENDATIONS**

All the factors discussed in this article point towards certain identifiable factors which can either improve or exacerbate the existent prevalence of congenital malformations and other rare diseases. The healthcare regime in India has been designed as an integrated network of ‘village health centres, sub-centres, primary health centres, community health centres, district health officers, and medical colleges’. The entire network caters to a wide variety of rural, semi-rural and urban populations. Furthermore, privatized healthcare in India has also witnessed a massive outreach over the last two-three decades.

There are specialized private hospitals and laboratories in various regions which provide state of the art infrastructure and services. However, the rise in India’s health indicators has not been accompanied by consistency. Contrasting results have been produced by various states with many states still performing abysmally. When we look beyond the well-connected and well-furnished urban structures we realize that there exist harrowing divides in the level of accessibility of healthcare services.

Up until now, the genetic laboratories and testing facilities in India have had a principally privatized nature. Although state operated health centers have also been setup, the socio-economic variations and literacy levels are still the deciding factors which influence the level of accessibility that these facilities have. In order to tackle the array of limitations, it must be ensured that genetic counselling and diagnostic techniques for genetic disorders are available at all levels of healthcare whilst constantly interacting with all stakeholders while emphasizing the continuing burden of genetic disorders. The following list of legal and societal changes and recommendations may be adopted for the proper manifestation of this goal:

1. A COMPREHENSIVE NATIONAL HEALTH PROGRAM

From time to time, India’s healthcare system has been beneficially influenced by the introduction of novel health programs which have the potential to tangibly contribute towards better health indicators. In any conceivable way, the importance of a comprehensive and fruitful national health program cannot be negated. The history of health programs in India dates back to 1951[[84]](#footnote-84). The centre has always used its legislative authority to tackle the national health problems by adopting national health programs specifically catering to different objectives. National level programs have the advantage of financial assistance from the centre as well as a broad framework within which there are identifiable and actionable goals with periodic accountability reports and statistics.

Currently, the draft national policy of rare diseases comes close to dealing with rare diseases and its containment. However, the draft policy only covers certain treatable rare diseases and has little to do with genetic disorders, predictive genetic disorders and other preventive measures. What the policy does is that under the government’s flagship program of Ayushman Bharat Pradhan Mantri Yojana[[85]](#footnote-85) it covers the population under the BPL (Below Poverty Line) category by providing a one-cost treatment of up to Fifteen Lakh Rupees. However, as discussed above, there are several inherited diseases which won’t be brought under its purview. Therefore, a comprehensive national health policy specifically targeting genetic diseases is much more likely to tackle the spread of genetic diseases in a holistic manner. Not only will it give a boost to the private laboratories and testing institutions- which are anyway inaccessible to certain rural and semi-rural populations- but it will create a targeted vision for a hitherto scattered testing system network which would be akin to the health centers established at various district and regional areas.

Lastly, instrumental changes in the erstwhile system cannot be brought about without liaising with other programs like the ‘Reproductive and Child Health’[[86]](#footnote-86) and the ‘Adolescent Girl Health’[[87]](#footnote-87) programs. All these programs not only ensure the availability of diagnostic infrastructure but also aim towards the education of families through creative usage of multimedia channels as well as through the professional counsellors in health centers. Similar schemes which draw linkages with other programs could remedy the informational asymmetry amongst the rural poor especially among the women.

1. REVAMPING INDIAN PUBLIC HEALTH STANDARDS- COMMUNITY HEALTH CENTRES (CHCs) AND PRIMARY HEALTH CENTRES (PHCs)

In India, the introduction of National Health Mission (NHM)[[88]](#footnote-88) has led to the creation of vast and far-reaching point of contacts for health interventions cutting across at various grassroot levels (‘rural poor’ and ‘urban poor’ populations). Over the course of many decades these centres (Primary and Community Health Centres) have established a ‘supply chain of medicines, equipment supplies’[[89]](#footnote-89) as well as an increased level of maternal care facilities which has drastically improved the health outcomes for both newborns and mothers alike. Despite the radical impact created by these health units, there are evidentiary reports which claim that these spaces are still plagued by ‘insufficient facility readiness, low provider skill and clinic management capacity’[[90]](#footnote-90). However, as an already conceptualized and manifested chain of health units, these collaborative networks have the potential to act as solid starting points for the deployment of genetic interventions.

The system set in place would have the added advantage of covering most of the grassroots in the country which would help in remedying the problem of accessibility by exploiting and improving the spaces already provided by these health units. The only limitation which we would have is the inadequately equipped and poorly trained staff which operates these institutions. The central government had introduced the recommendatory policy of Indian Public Health Standards (IPHS)[[91]](#footnote-91) Guidelines in order to suggest a referential threshold in order to determine the adequacy of a particular PHC and CHC (availability of hospital beds, syringes, knowledge of the medical staff and efficiency in deliveries). The newly introduced provisions pertaining to genetic equipment, testing and additional training qualifications at district levels and institutions would fundamentally help in furthering the formalization of accepted usage of genetic testing equipment.

Lastly, it is also to be noted that not all CHCs and PHCs are known to be completely in concordance with the IPHS Guidelines. This is owing to the recommendatory nature[[92]](#footnote-92) of the guidelines as well as little institutional awareness regarding the reference points to be used for judging the standard of care in these health units. Therefore, there is a need for the introduction of additional recommendations for characterizing the IPHS guidelines along stricter lines with periodical accountability checks and possibility of punitive measures in the event of grave deviations from the guidelines. Although, actual implementation could be a different ball game altogether, these fundamental changes could still initiate the re-characterization of accountability in these units.

1. NEW STANDARDS FOR DATA PROTECTION

As discussed in the preceding sections, emerging policy-making on data protection and privacy issues are immensely scrutinized in today’s technological landscape and rapid data transfers. Be it the newly introduced Data Protection Bill[[93]](#footnote-93), or the trade-off between data protection and national security and law and order, it has led to a series of contestations and deliberations on its significance and impact. While genetic data is characterized as personal, it cannot be accurately gauged how much of this data could be considered personal. On a positive note, the scrutinization of these genomes could make the case of evidence based planning and research which helps in gaining newer insights into the medical field and the nature of genomic diseases. However, the issue of privacy is not just a thorny issue in need of a quick fix. It is an accepted fact that in most jurisdictions the ambit of data protection is not wide enough.

How are third party intrusions protected under these procedures? What is the governance structure of the research partner/laboratory/corporate dealing with the genomic data and who profits off the newer medical insights which could be discovered using the data? How far do the existent standards cover the data protection? In order to re-shape and improve the state of genomic treatments, these questions would have to be answered satisfactorily with the establishment of clear standards.

Although DNA Technology Use and Application Bill has been touted as an exception to the overarching framework of Personal Data Protection Bill[[94]](#footnote-94), the proposed legislation is still doubted for its lack of standards for consent, notice, retention as well as security of data[[95]](#footnote-95). However, the act is not concerned with commercial usage or usage for genetic testing by private facilities. Therefore, there is limited doctrinal basis for demanding standards in the domain of genetic privacy. However, any standard would have to be scrutinized on the touchstone of the ‘Puttaswamy Judgement’[[96]](#footnote-96). Indian Supreme Court in its seminal Puttaswamy Judgement had established the test of proportionality i.e. wherever privacy is concerned, any legislative or authoritative encroachment shall have to ‘establish necessity, meaning that a law must be necessary for fulfilling legitimate state purposes and the measure should be proportional to the objective being pursued’. However, the Indian courts are yet to clarify the exact standards in order to maintain the principle philosophy behind the decision. As of now, standards pertaining to genetic testing and DNA retention suffer from being vague and muddled.

1. EXPERT COMMITTEE GROUPS FOR ADJUDICATION

Physicians and other health professionals have often been the target of genetic malpractice lawsuits. As much as it would be a welcome move for the inclusion of more accountability in the entire process of genomic services as well as counselling, physicians also run the risk of bearing the brunt of malicious prosecutions. Today’s medical regime is the regime of personalized medicine. There are various invasive and non-invasive procedures involving genomic determination. All the running factors suggest that medical professionals dealing with the interpretation and maintenance of genomic data are predicted to be at the receiving end of increasing litigation and malpractice allegations. Throughout history it has been seen that newer insights and technologies in the medical field have always created the environment of increased litigation and legal considerations.

Moreover, in the era of personalized medicine and increasing sophistication, there are various disagreements and contestations among the experts over the scope and implementation of genetic testing. For example, in the medical literature there are numerous disagreements about the nature and requirement of drug prescriptions prior to or after the procedure of genetic testing[[97]](#footnote-97). The said example is just one of the many disagreements which occur among the physicians and professionals dealing with these procedures on a regular basis. Such disagreements may provide ample fodder for confused litigation and muddled precedents. Therefore, it is absolutely imperative for the courts to recognize the requirement of sound technical wisdom in the event of determining liability of the medical practitioners and not to substitute too much of its own wisdom in the technicalities of the profession. There shall be formulation of expert committee groups which shall be instrumental in the adjudication of the medical malpractice. Heavy reliance on expert committee groups can determine how the medical strategy being scrutinized is an acceptable practice amongst larger body of medical professionals and could share their insight in the appreciation of evidence put forth in each case.

**CONCLUSION**

As the discussions above suggest, it is possible that the plethora of invasive and non-invasive genetic procedures in the medical community can spur a jurisprudence where all the stakeholders shall be faced with the questions of severity of genetic diseases and the compensability of the harms caused in the event of congenitally defective births. There exists a reasonable desire at the parents’ end to produce healthy offspring who would have the same opportunities as any other and who can aspire to a life filled with ability to realize their own ideals without any undue debilitation or strains. The following desire can very well translate into a legal duty on part of the state as well as the medical professionals associated with this field. It is yet to be seen how this legal duty is to be evolved. However, the formation of judicial precedents, common law principles and legislative measures shall do very little to contribute until the provision of genetic services are satisfactorily improved. Therefore, it is imperative that the entrenchment of legal duties shall be accompanied by a steady supply of genetic services across all levels of healthcare so that these services are significantly more accessible.

Moreover, the objective of the genetic testing may not be adequately understood by the general population. Therefore, it shall be the responsibility of central schemes and other programs for devising special efforts in order to familiarize the citizenry of all the nuances of these screening tests. The potential hazards of false negatives and false positives shall be especially emphasized. Therefore, the challenge ahead lies in not only normalizing the discourse surrounding genetic diseases but also to acknowledge the existence of these medical procedures as a giant step in the direction of increased examination of genetic diseases and establishing the appropriate levels of governmental control and regulation required for its management. While it certainly carries with it several legal and social implications, stable and balanced policy-making and legal implementation can necessarily guide the way.

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