

Title “Ethical issue related to gene therapy”

## **Introduction**

Gene therapy is a genetic technique in which genes are used as a means to treat or even prevent a disease. A gene does not have an ability to function as an insert directly. So a vector is designed and used as a carrier for the gene delivery. Very often viruses are used as such vectors along with disabling their infective abilities. Gene therapy technique is used for introducing genetic material into the target cells for expression of the properties which are not present in the cells of the host in order to make up for the function of abnormal genes. If some gene mutation leads to the expression of an abnormal protein as a result of an abnormal or missing gene, gene therapy may be used as a technique for introducing a functional copy of the same gene in order to help restore the functionality of the host cell's protein. This will be an upcoming field and gene therapy in the future may assist doctors for the treatment of a genetic disorder. As gene therapy tries to modify the host's system, it simultaneously touches many raises ethical issues. Various ethical issues that may be involved regarding gene therapy may be from the discussed below points.

First and foremost ethical issue regarding this technique is the categorization of genes as either ‘bad/good’ gene therapy and who will be the decision maker with respect to deciding the traits of some individual being normal/abnormal. The Higher cost of such therapy makes it an ethical concern as this will not be affordable for the common man. Gene therapy also raises the concern whether such techniques can question the social acceptance of the people with different genetic makeup and whether we can let the gene therapy technique alter the human traits and individual characteristics height, IQ, memory etc. In this report we aim to discuss the various ethical issues associated with the gene therapy technique.

Various genetic diseases where gene therapy can be beneficial are Huntington's disease, cystic fibrosis, etc. There are some other diseases' wherein genes may be crucial factors involved like diabetes and various cancers. Such diseases have been targeted at the genetic level by using gene therapy. The somatic cell genes may be altered in order to modify the genetic makeup, but if such changes are made in the germ line cells the changes are inherited to the progeny as well. Review by Ayala (2015) discussed various biological, social and also ethical factors associated with the gene therapy technique along with the gene cloning technique. The article questioned the feasibility of such complex gene therapy techniques. The study also discussed the example of

severe combined deficiency syndrome (SCID). SCID was the first case of successful genetic intervention using gene therapy which was first done on a four year old child in 1990 which was soon replicated successfully in other countries as well. But the gene therapy treatment was stopped temporarily due to some patients showing leukemia-like condition, which was attributed to gene therapy. Since early 2000, several successful clinical trials in SCID have been carried out (Cavazzana-Calvo et al. 2004; Fischer et al. 2010).

Public discussion over the use of gene therapy technique began early in 1970s and it started soon after the use of discovery of recombinant DNA technology even long before the technique was initiated over the protocols were optimized. The bioethical issues regarding such alteration of 'God's work' raised eye brows. The reason was simple and understandable as here the genes were trying to solve the problems and it means correcting what was made by God as a part of the God's plan for that individual. Many scientists discussed the use of such gene therapy techniques for eliminating the viral diseases and some people that the potential advent of eugenics following gene therapy may be a completely unethical concept to encourage.

Another aspect that needs to be discussed in this regard is the portrayal of such techniques and their results. The Article by Ostergren et al (2015) discussed such an issue and reported that the media and other modes of communication with the common public may be considered responsible for causing such optimism regarding genetic research. Review by Freire et al. (2014) discussed bio-ethical concepts of gene therapy. They questioned the bioethical issues pertaining to the methodology employed for gene therapy. Such clinical interventions based on gene therapy techniques have been using the viral vectors for transporting the gene of interest and less is known about the potential harm such vectors may cause. Despite the scientific and also the advancements in technology, there are many issues yet unaddressed regarding the possible side effects of the gene therapy techniques.

Major ethical concerns may arise regarding the germ-line gene therapy and such discussions were initiated right from the start of the Human Genome Project (HGP). If we compare the germ line gene therapy with the somatic gene therapy there seems to be a valid difference as there are technical differences. Germ-line gene therapy is clearly more complex as compared to the somatic gene therapy. The respective interactive pathways between the genes and their corresponding repressors/activators are quite complex and this also depends on the precise location of the genes on a particular chromosome. The genetic makeup at the precise

location affects various processes and even a slight mistake on the part of the genetic engineering team for altering the function of gene may cause catastrophic results for that individual. Such gene therapy technology may mistakenly introduce some unwanted genetic changes in the chromosome. The human genome has a specific makeup thus the unintentional elimination/modification of some gene associated with vital properties or crucial proteins may prove to be a serious condition. The therapeutic aspects of gene therapy can be extremely beneficial. All though all medical experiments related to gene affect the evolutionary factors, yet the effect of gene therapy in accelerating the genetic evolution may be considered unprecedented and such interventions affect the genetic makeup in a shorter time period as compared to other evolutionary pathways. An important point to be considered here is that other medical interventions can only disturb the individual's systemic make-up, while in case of germ-line gene therapy these modifications affect not only the individual but also the future generations of that individual thus raising the risk to many folds. Some deleterious or lethal effects of such events may not be reflected in the first generation of but these may be subsequently manifested in further generations. Gene therapy experiments have been causing serious dent in the economies of many developed and developing nations since the experiments started in 1970s (Chan & Harris, 2006). The mammoth amount of money which went in to these experiments may prove to be completely wasted if the resulting procedures and protocols are not put to use and improving the quality of human health. Simultaneously these gene therapy procedures are really expensive and unreachable for the common man which raises the questions of bioethics again. Euphenics which deals with the effort to normalize the genetic condition of a human being is also a very talked about area in the present world. The concept of trying to improve the genetic makeup of an individual by trying to alter the genes of a person raises serious concern. The behavioral genetics and psychiatric genetics may be a potential area of discussion as the possible gene therapy modules may intend to alter the intelligence and other behavioral traits of the person which is raises definite serious issues.

## **Conclusion**

As discussed above it may be concluded that there is an urgent need to understand the concepts of bioethics with both the social and ethical angle regarding the use of such genetic engineering techniques simultaneously keeping in mind the benefits such techniques may provide if used optimally and for the common public. We also need to prioritize and assess the risk-benefit scenario based on the results of clinical data made available to us. The simultaneously adverse event reporting is also integral to the trials and experiments of such gene therapy procedures.

## **Recommendation**

Altering the genes is considered as a human intervention in the work of God and this mindset may prevent us from going on with the gene therapy procedures which otherwise may prove to be very beneficial for the treatment of genetic disorders. The use of such advancement in molecular biology and years of research can only prove to be fruitful if we will use these advanced techniques for the betterment of society and human life. Health and welfare of man have to be given priority, but keeping in mind the corresponding ethical issues. The research fraternity also needs to weigh the objectivity of the results coming out of such experiments as it may be ethically implicated. We need to focus on the use of gene therapy for the improvement of the human health, but not at the cost of ethics and the possible harms these therapeutic modules may cause must not outweigh the benefits.

## References

1. Ayala FJ. Cloning humans? (2015). Biological, ethical, and social considerations. *Proc Natl Acad Sci U S A*. 112(29):8879-86.
2. Cavazzana-Calvo M, Thrasher A, Mavilio F. The future of gene therapy. *Nature*. 2004;427(6977):779–781.
3. Chan S & Harris J (2006). The ethics of gene therapy. *Curr Opin Mol Ther*. 8(5):377-383.
4. Fischer A, Hacein-Bey-Abina S, Cavazzana-Calvo M. 20 years of gene therapy for SCID. *Nat Immunol*. 2010;11(6):457–460
5. Freire JE, Medeiros SC, Lopes Neto AV, Monteiro Júnior JE, Sousa AJ, Rocha AJ, Menezes LM. (2014). Bioethical conflicts of gene therapy: a brief critical review. *Rev Assoc Med Bras*. 60(6):520-4.
6. Ostergren JE, Dingel MJ, McCormick JB & Koenig BA. (2015). Unwarranted optimism in media portrayals of genetic research on addiction overshadows critical ethical and social concerns. *J Health Commun*. 20(5):555-565.