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ETHICAL ASPECTS IN THE PRACTICE OF GENE THERAPY

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Medicine is a growing field of knowledge with outstanding changes in modern genetics devoted to the process of altering the DNA in an organism called genetic engineering or genetic modification. Genetic engineering is used by scientists to enhance or modify the characteristics of an individual organism. Genetically engineered bacteria are currently used to produce human insulin, human growth hormone, a protein used in blood clotting, and other pharmaceuticals.

The researchers adopted the new gene-customizing technology called Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR), a technique much like a

word-processor finding and snip out segments of DNA named as “gene editing” tool. CRISPR system allows researchers to quickly change the DNA of nearly any organism: viruses, bacteria, animals, including humans and makes editing genomes cheap and easy [1]. Current areas of genetic modified innovations are widely implemented in both drug discovery and in the treatment of pathologies with defective genes that are responsible for diseases development. Advanced technologies in a form of gene therapies enable scientists to correct errors in DNA and treat incurable illnesses in new ways by repairing the dysfunctional DNA or by replacing it by means the insertion of healthy genes into an affected cells and tissues. According to the American Society of Gene and Cell Therapy “Gene therapy is defined as a set of strategies that modify the expression of an individual’s genes or that correct abnormal genes. Each strategy involves the administration of a specific DNA (or RNA).”

Somatic gene therapy involves modifying a patient’s DNA by treat a disease caused by genetic mutation. For example, use CRISPR technique to correct the genetic mutation that cause producing defective blood cells, than infused ‘corrected” cells into the patient, where they produce healthy hemoglobin and thus compensate the pathophysiological disorders and improve the outcome of the disease. Germline editing affects all cells in an organism including eggs and sperm.

Over the past decades gene therapy has contributed to the treatment of human pathologies, such as cardiovascular diseases, cystic fibrosis, Gauscher’s disease, Huntington’s disease, lysosomal storage diseases, muscular dystrophy, sickle cell disorder, hemophilia, eye disease and blindness, cancer, diabetes, AIDS and others. [2].

While gene therapy brings significant benefits to patients, it also poses with some incredible hefty ethical problems and has been surrounded by a wide variety of moral and social dilemmas. The ethics of gene therapy are multifaceted. Bioethicists and researchers suggest that genome editing is new and unpredictable technology, Germline editing alters the genome of a human embryo at its earliest stages at the same time are there insufficient knowledge relevant to the gene regulation and mechanisms of embryonic development. However it is revealed that changes resulted on germline manipulations may pass to future generation and impact on the offspring. In such case it is difficult to predict the possible outcomes and the consequences of germline therapy can be fatal.

In order to achieve a sufficient result of gene therapy it is necessarily to deliver functional gene directly into a cell of patient to replace missing or defective gene. Rather, it usually has to be inserted using a carrier, called a vector. The most common gene therapy vectors are viruses because they can recognize certain cells and carry genetic material into the cells' genes [3]. Viruses have evolved specialized molecular mechanisms to efficiently transport their genomes inside the cells therefore they infect introduce the therapeutic gene into the patients target cells. However in clinical application of gene DNA techniques that allow manipulation with virus vectors for delivery of exogenous material to target cell in human have been received severe adverse events, even patient death. Side effect of gene therapy is unwanted immune system reaction. The newly introduced viruses act as intruders and immune system attack them. This may cause inflammation and, in severe cases, organ failure.

Because viruses can affect more than one type of cells, it's possible that the altered viruses may infect additional cells, not just the wrong targeted cells containing mutated genes. If this happens, healthy cells may be damaged, causing other illness or diseases, including cancer. Moreover that once introduced into the body, the viruses may recover their original ability to cause disease. If the new genes get inserted in the wrong spot in patient's DNA, there is a chance that the insertion might lead to tumor formation. This has occurred occasionally in some clinical trials.

In order to protect humanity from the potential danger that may occur from the implementation of emerging technologies such as genetic engineering and prevent the complications the scientists should have the responsibility for the deep ethical advancement. Significant issues of individual freedom, legitimacy, rights of human genome and prevention of discrimination are reflected in publications, guidelines of leading international organizations and authorities of different countries [4, 5]. Ethical arguments in the areas in genetics research have been created and introduced in forms of the safe and effective models. Patient-centered solutions have been transformed into the informed consent. With every decision that participants undergoing gene therapy must be extensively educated on the potential risks and benefits associated with treatment to provide them with enough information on which to decide to participate or not without coercion [6]. A study by the National Human Genome Research Institute proposed the need and importance of informed consent in CRISPR somatic genome editing after surveying patients with sickle cell disease. [7].

To control the use of an intervention at altering the human genome with therapeutic purposes the legal regulation should be highlighted more strongly with public ethical perspectives of scientific technologies in gene therapy.

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