

Gene Therapy - The Ethical Debate

Akbar M Mohammad, MD, FAAP*

The literature addressing ethics of gene therapy is voluminous. One can access more than half-a-million references over the Internet. The concerns expressed by scientists and the public are justified because research in this field is making rapid strides and many centers have already embarked on implementation¹. At the heart of this concern is the need for guidelines and monitoring. Who should provide these guidelines? Should they be national or international? What are the hazards of this kind of therapy? Is it rational to use every technology that becomes available? Where do society, scientists or governments draw the line? These and many more questions are raised about gene therapy^{2,3}.

Gene therapy has already proven to be a useful tool with the first successful federally approved experiment done in September 1990 at the National Institute of Health (NIH), USA, where Ashanti De Silva, a 4 year old with severe combined immunodeficiency (SCID) due to adenosine deaminase (ADA) deficiency was able to leave her strict isolation set up and attend school following several courses of this therapy. She is an 11 year old youngster now who enjoys her normal life^{4,5}. Since this initial encouraging result numerous centers around the world have undertaken clinical trials of gene therapy in a large number of diseases (Table 1). These clinical trials in a number of countries are raising the questions whether different ethical standards can be justified in different countries. One key issue is how divergent are the perceptions and bioethical reasoning of peoples around the world.

An International Bioethics Survey with 150 questions including 35 open ones was developed to look at how people think about diseases, life, nature and selected issues of science, bio-technology, genetic screening and gene therapy. The survey was conducted in 1993 among the public in Australia, India, Israel, Japan, New Zealand, Russia and Thailand. The same survey was conducted among University students in Australia, Hong Kong, India, Japan, New Zealand, The Philippines, Russia, Singapore and Thailand⁶. Similarly questions were included in an international high school education bioethics survey among high school teachers in Australia, Japan and New Zealand⁷. Further comparisons to studies from USA⁸ and Europe are made⁹.

* Chief Editor
Bahrain Medical Bulletin &
Associate Professor of Paediatrics
College of Medicine & Medical Sciences
Arabian Gulf University
State of Bahrain

Table 1. Diseases being treated in clinical trials of gene therapy¹⁴

Cancer

Melanoma, renal cell cancer, ovarian cancer, cancer of: brain, head and neck, lung, liver, breast, colon, and prostate; neuroblastoma, leukaemia, lymphoma, multiple myeloma.

SCID

Cystic fibrosis
Gaucher's disease
Familial hypercholesterolemia
Haemophilia
Perrine nucleoside phosphorylase deficiency
Alpha-1, antitripsin deficiency
Fanconis anaemia
Hunter's syndrome
Chronic granulomatous disease
Rheumatoid arthritis
Peripheral vascular disease
AIDS

Muscular dystrophy
Hypertension
Sickle cell anaemia
Huntingtons disease
Tay Sach disease
Parkinson disease

About three quarters of all samples supported personal use of gene therapy, with greater support for children's therapeutic use. The diversity of views was generally similar within each country. The major reasons given were to save life and to improve the quality of life. About 5-7 % rejected gene therapy considering it to be playing God or unnatural. Support for specific applications was significantly less for "improving physical characters", "improving intelligence" or "making people more ethical" than curing disease(s) like cancer or diabetes, but there was little difference between inheritable or non-inheritable gene therapy⁶⁻⁸.

It has become standard to classify gene therapy into somatic cell gene therapy with or without enhancement and germ-line gene therapy with or without enhancement^{2,10}. In USA, according to NIH and Food and Drug Administration (FDA) guidelines, only somatic cell gene therapy is approved¹¹. This is also true of all European¹², Australian, Japanese and Canadian guidelines and reports¹³.

There have been concerns that scenarios of germ-line enhancement may ignite public opposition to somatic cell gene therapy, and therefore a distinction has been maintained³.

In every society there are people who are willing to use new genetic techniques and there are those who reject the concept. In the USA (1992) when individuals from the public were asked "how much have you heard or read about gene therapy", 60 % said "almost nothing", 26 % said "relatively little", 10 % a "fair amount" and 3 % "a lot"⁸. In Bahrain during the Ramadhan Seminar held by Bahrain Medical Bulletin about gene therapy, February 1997, a pilot questionnaire was distributed to the audience which comprised of 66 medical and para-medical personnel. In response to the question that addressed the issue of familiarity with gene therapy, 93 % indicated that they have heard about the subject prior to the seminar. Of those who responded to the second question about acceptance of gene therapy, as a last resort, 82 % indicated their willingness to use it for themselves or their beloved ones and only 18 % rejected its use on religious grounds, because of lack of adequate information or fear of future sequelae.

UNESCO International Bioethics Committee is drafting general guidelines and an international declaration on the human genome and human genetics. It is hoped that this draft will be approved by the United Nations General Assembly in 1998 during the 50th anniversary of the Declaration of Human Rights¹⁶. The position adopted in 1994 report on gene therapy is summarised as:

1. encouragement of somatic cell gene therapy for any disease, not only genetic disease,
2. not making somatic gene enhancement or germ-line gene therapy illegal,
3. outlawing germ-line enhancement.

CONCLUSION

In conclusion it is appropriate to emphasise that in every society there are people who show enthusiasm for therapeutic use of gene therapy besides those who reject the concept. This division in opinion will prevail and may widen unless international guidelines for monitoring are implemented at national levels. Moreover, there seems to be dire need for public education on the subject because several surveys indicate that informed populations tend to accept this new technology in a progressive pattern over the years.

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