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Better Humans and evolutionary nudge

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Abstract

Gene therapy especially newly developed CRISPR gene editing spawns complex conversations, ethically, emotionally, politically, and economically, within and among countries. As new technology makes its way through the experimental development, assessment, refinement and application, it is not too soon to begin the policy and ethical dialogues about how and when and for what purpose it is used. Certainly experiments should continue to assess whether CRISPR is the long sought for means to effective gene therapy. It will probably be used in somatic cell gene therapy trials sooner than later. Policy and ethical discussions ought to precede its use at the germline stage.

Introduction

The recent discovery and application of clustered irregularly interspaced short palindromic repeats (CRISPR) Cas9 editing of DNA has generated great optimism for its potential to correct harmful genetic traits. Eliminating all "genetic diseases" stretches the imagination and posits an objective that may be feasible in theory while doubtful in application. New applications, tests, and successes with CRISPR/Cas9 saturate the scientific literature. So prevalent are such reports that the faculty in the Biomedical Sciences Master of Science program at Hood College offered a special topic graduate course on "Gene Editing" in summer 2017. The course had three units: (i) the science of editing, how the guide RNA matches the target DNA to specify where to cut and repair the genetic

sequence, (ii) how the guide RNA and target DNA sequences are evaluated using bioinformatics to insure the most correct fit and the least off-target possible "mistakes" which would create new mutations even while editing a chosen site, (iii) ethical evaluation of the technology. Students were asked to write an address they would give to a policy forum about using CRISPR/Cas9 for gene therapy.

Discovery and Response

Genome editing technology using CRISPR-associated nuclease Cas9 opens the possibility of therapeutic genome editing in diseased cells and tissues (Hsu, 2014). Applying the technology to human embryos, Liang et al. (2015) reported using CRISPR/Cas9 to edit human beta-globin gene in 86 donated human embryos obtained from in vitro fertilization (IVF) clinics. The scientists were careful to report that of the 86 embryos used, 71 survived the manipulation and 54 had corrected DNA sequence in the beta-globin gene. Unintentional mutations were also documented revealing the possibility that the guide RNA would bind to sites other than the target globin sequence and create unintended mutations. Safety and efficacy are the guidelines used to justify moving new "therapeutic" discoveries into clinical practice. Finding ways to hit only the target sequence and eliminating off target hits is the current focus of research using CRISPR for gene editing. Delivery of the CRISPR/Cas9 to the intended cells is equally important if the editing technique is to be used in patients to reduce symptoms of a genetic disease.

UNESCO, the Council of Europe and the European Union has stated that modification of the germline is unethical and an abuse of human rights. The National Institute of Health (NIH) director, Francis Collins, released a statement saying no national research money would be used to edit human embryos within weeks of a report by Zhang (2015). Similar protests have been made about establishment of human stem cell therapeutics but private enterprises have found ways to continue applications. Denial of European or US federal support drives technology into the private sphere. It is not a given but a recognized risk that privatization of technology may result in inequitable access.

If the potential for gene editing is shown to be reliable and therapeutic, what is to prevent using the technology? Three considerations are important in reaching an answer: the history of eugenics as it affected gene therapy policy, genetic literacy among the population, and just allocation. Eugenic laws in the 1920s in the US and other countries aimed at improving the human species through selective breeding. Once legalized, it took decades to reverse the perception that involuntary sterilization was for the "greater good" when in truth it is a breach of human rights. Eugenics is a dark chapter in human history and before germline gene editing becomes the new eugenics, care ought to be taken to ensure applications are understood regarding risks and benefits and that personal autonomy is protected and respected (Sparrow, 2011). Moving away from negative eugenics toward a positive application aimed at correction of genes with disease and disability phenotypes, gene therapy became the hope of scientists late 20th century. One of the lessons of the gene therapy experiments is that results using cell culture in vitro generates more positive data than when used in vivo in living organisms, especially in human clinical applications. The amount of DNA that can be inserted into a virus vector is limited as well as the ability to direct the DNA to the right genomic location to either replace the mutated sequence or to add a functional gene (Misra, 2013).

To date somatic gene therapy protocols have been limited to somatic (non-reproductive) cells, specifically in experimental treatment of cystic fibrosis, hemophilia B, Fanconi's anemia, hypercholesterolemia, adenosine deaminase (ADA) deficiency and three types of cancer (Misra, 2013). Each of the clinical trials aimed at reliving symptoms of a genetic deficiency by supplying a functioning gene or its product. Delivery has been problematic as well as consequences of adding a third gene to restore function. In cases where the foreign DNA can integrate into the genome, the site has not been limited to the target gene causing unanticipated damage and/or pathology (Check, 2002). Enthusiasm for ADA gene therapy turned to disappointment when the patients subsequently developed leukemia (Misra, 2013). The lesson learned is that the results of gene therapy applications are not always immediately obvious.

Policy Debates

Individuals and groups who take a test, evaluate, move forward deliberately in advancing new technology, are often labeled "bioconservatives". In contrast, advocates for swift application of new technology to benefit suffering patients are called "bioliberals" (Giubilini, 2015). Bioconservatives tend to bring the gene therapy lack of success into debates about gene editing whereas bioliberals tend to move from a failed system to a new opportunity with renewed enthusiasm, such as the promise of gene editing with CRISPR. Representing two ends of a continuum, the policy debates have resurrected an earlier debate about somatic vs germline gene therapy. It should be clear to all that empirical data is needed to establish risks and benefits of embryo manipulation (without

implantation for the purpose of giving birth to a child), in animal and plant model systems should inform the debate.

It matters how the question is framed and which philosophical foundation is used for the debate. One foundation is the concept of human nature, imperfect but functional. There are groups with specific disabilities that are sensitive to being regarded as inferior, "in need of fixing." Of course there is a significant difference between a genetic loss of hearing in contrast to a genetic loss of muscle strength that steadily progresses. Hearing loss can be compensated for by learning to use sign language and live a life of dignity, whereas in diseases such as Parkinson's the person is reduced to total dependency and lacks the pleasures of communication, mobility, independence, etc. It is not that a person with Parkinson is robbed of dignity as a human being, but that the progressive nature of the disease deprives him or her of capacities that contribute to human dignity, justifying the bioliberals' appeal for aggressive progress towards treatment. Claiming an intent to correct genes that rob individuals of the basic functional abilities we associate with being human aligns with the duty to help relieve suffering.

Beyond 'therapy' at the aggressive end of the spectrum, gene editing enthusiasts dream of applications well beyond therapeutic potential, such as the ability to master engineer evolution in favor of better humans (Powell and Buchanan, 2011). Taking the framework of species survival in an evolving ecosystem that is challenging or even threatening, DNA editing become more than a therapy – it becomes a survival strategy. Harris and Savulescu suggests that we are morally obligated to use genetic technology to produce the best children possible for the survival of the human species (Harris, 2007; Savulescu, 2005). Bioliberals clearly intend to help both relieve suffering from a specific genetic trait and push evolution forward in ways that prevent death from environmental hazards. Modification of a harmful gene to reduce or relieve suffering from a genetic disease benefits the one patient and is therapeutic, however, none of the somatic gene therapy protocols have been successful enough to be standard of care for the thousands of genetic diseases affecting human beings. Therefore, regarding the intervention as a therapeutic tool is good only so far as it has been effective and for the relatively few who have access. There is no evidence that the genes that could confer species improvement are known or what specific changes would lead to better humans.

Bioconservatives tend to frame the question in terms of concern for just allocation. As new discoveries become therapeutic options and the risk-benefit potential inherent in such technologies is quantified, the new technique replaces older or less effective treatments. This is a long process taking decades of clinical trials and regulatory approval. Careful and sequential development, testing, evaluation, and objective analysis of data slows progress but in the minds of bioconservatives is the means to avoiding harm as much as possible. To counter excitement of a new scientific breakthrough, the conservative is patient enough to see that the uncertainties, and moral concerns are addressed first. Considerations about future impact on the human gene pool may be overstated in the sense that relatively few individuals may elect to use it. It is a leap without supporting data to project improving human beings by gene editing. If approved for enhancement at the germline level unless many participate the human gene pool will not be enhanced, but a minority of individuals may become gene-rich.

Assisted Reproduction

More than five million babies have been born through assisted reproduction since the birth of Louise Brown. In some countries, pre-implantation genetic diagnosis (PGD) is fast becoming part of the IVF process whereby embryos are selected on the basis of their genetics. Within hours of fertilization, the embryo reaches 8 – 16 cells. DNA can be extracted from one of the cells and sequenced revealing entire genetic blueprint. Against a panel of markers for specific genetic diseases it is possible to select embryos that do not have genetic diseases. Families with known risks may request screening Tay-Sachs, Cystic Fibrosis, Sickle Cell, Huntington's Disease, Cooley's anemia etc. In using PGD-IVF a negative selection is taking place: sorting out embryos with risk of a genetic disease and implanting those that do not have risk for the traits being tested. As the list of reliable genetic tests increases and as the cost of sequencing the whole genome of the embryo decreases, the full genetic "score" of the embryo will be within reach. While PGD-IVF was not designed for positive selection, there has been success in selecting siblings with a tissue match suitable to supply cord blood to treat a sibling with leukemia (Kahn and Mastroianni, 2004). The Nash family went through several cycles of IVF and PGD before finding the embryo match for their daughter. It is a success story but has not been replicated often, either because a matching embryo was not found or because of the expense of the procedure.

CRISPR and Gene Editing

CRISPR/Cas9 enters the horizon of hope because it has the potential to repair a genetic abnormality and prevent the disease not only in the person but also in future descendants if used in embryos

(germline therapy). It has been ethically permissible to wipe out diseases caused by viruses or bacteria using vaccines or antibiotics, respectively. Why should human ingenuity not proceed with a means to convert disease causing genes into normal functioning genes? To limit the research because there is not sufficient evidence of benefit and lack of harm is justifiable. To limit the research because the DNA of an embryo might be changed in ways that promote health and wholeness should be re-evaluated (Boyd, 2016a).

When leaders like National Institute of Health Director, Francis Collins, refer to genome editing as "correcting the typos in the book of life" the average person may think the procedure is entirely safe and expect that something so helpful should certainly be made available. In reproductive freedom, couples would expect to use a technology that "guaranteed" genetically healthy children. The laborious research that is required to move an idea into a therapeutic treatment takes years and great financial and human investment. Technology is by design and intent for the use of people, for their benefit (Boyd, 2016b).

If CRISPR can be made safe and specific, effective and efficient, then like any other biomedical invention, it will proceed from animal models, human cells, embryos, somatic corrections, to someday, perhaps germline therapy through PGD-IVF. The time from theory to practical application and general use is often decades. Is there enough data to encourage us to move deliberately and resolutely down the path of gene editing as a therapeutic tool? Do we have enough bioinformatics information and analytical acuity to ensure the edit happens at the target site and nowhere else? As these questions are answered in the progressive progress of science and technology, the ethical deliberators should revisit why germline therapy has been set aside as unethical. It is difficult to get eager science majors to pause and think carefully about risks and benefits. As they rightly point out, almost every therapeutic intervention has some risks. The most effective way to get students to seriously look at the potential for harm was achieved with an assignment directing students to compare three different search algorithms to look for off target sites for a particular target sequence of DNA. The question to answer was: would the guide RNA find sites other than the intended gene sequence? Each algorithm generated different answers. Students were initially confused by these results until they realized that the search tools are limited in scope such that risk identification is not specific enough to be used in risk-benefit assessment. More data is needed using experimental models before proceeding with human gene editing but this is easier said than done (Boyd, 2016a).

Private enterprise

In vitro fertilization as a reproductive alternative to natural procreation has existed for decades and millions of children have been born with assistance of IVF. In the UK there are national guidelines for the use of IVF that sit within the National Health Service policies of universal health care for all citizens. In the US, where no universal health care has yet been adopted IVF is available within the private sector. Some insurance companies compensate patients for IVF expenses, some do not. This creates a system in which those who have the will, knowledge, and means to use IVF can do so.

The US Census Bureau reports the median household income in 2015 is $55,775 (Bureau, 2015). The American Society of Reproductive Medicine lists the average cost of a single in vitro fertilization cycle at $12,400. The cost of one cycle of IVF is 22% of the average household income per year. It is not reasonable or just to expect that a significant number of citizens will have IVF assistance with reproduction. Further costs would be added for genetic screening of embryos and editing genes with CRISPR or some other gene therapy tool. One estimate for current gene therapy offered by Spark Therapeutics is $500,000 per eye to restore loss of vision caused by a genetic disease (Johnson and Dennis, 2015). While it is possible for costs to decline as the technology becomes more refined, it does not allay fears of injustice based on access.

Social Justice or Injustice

If gene editing is ever approved in the US for germline therapy (which it is not currently) it would most likely be done in the private IVF clinics. If this happens gene editing to correct or improve embryonic genes would be available to a small percentage of the population, unless laws mandated insurance coverage or health care reform in the US moves into a universal single payer system. Current regulations in gene therapy in the US limit clinical trials to somatic cell gene therapy. Bioconservatives generally caution that even if CRRISPR's potential for gene therapy is fantastic, we should tread slowly, cautiously and deliberately.

Bioliberals in contrast argue that we have an obligation to provide all the technology and medical support we have to prevent genetic illness at the beginning of life. Even if successful beyond current empirical evidence, who benefits, at what cost, and with what impact on future generations remain uncertain. If any parent has an obligation to improve the genetic constitution of their child in order to provide a better life, then every parent

should at least have an equal opportunity, otherwise gene editing may emerge as the latest expensive acquisition of the economically privileged. How far from the gate of the uber wealthy are those whose genetic endowment are deemed inferior or worse 'in need of enhancement?"

Current efforts to use gene therapy for monogenic diseases such as Huntington's Disease get first priority because the majority of cases affect adults and the one gene responsible for the disease is known. Data from an in vitro model of Huntington's Disease using CRISPR-Cas9 to silence the mutant gene and allow the normal gene to restore function is promising (Kolli et al., 2017). Therefore, the idea that cells expressing the mutant Huntington protein could be corrected in living patients, reversing the symptoms of the disease is very attractive. Huntington's disease is an autosomal dominant genetic disease that shows no discrimination on the basis of gender or ethnicity. The disease is neurodegenerative typically beginning in mid-life and progressively impairs a person's ability to walk, talk, remember, reason, and finally causes death. There is no cure.

Simultaneously with somatic gene therapy, research should continue on gene editing in human embryos, without implantation to determine specificity and efficiency. The research published to date is promising. Scientists have targeted the beta globin gene (HBB) and found that within a population of embryonic cells generated after "editing" that some cells contained corrected genes. This resulted in a mosaic due to inefficient repair of the targeted sequence. Furthermore genes related to the HBB such as endogenous delta-globin, (HBD) caused an error rate of 25% (Liang, et al., 2015; Tang, 2017; Wang et al., 2016; Cox et al., 2015). These data support both conservative caution and liberal hope for gene editing.

Social concerns

Advances in medicine have increased the average human life expectancy. In 1900, the average life span was approximately 50 years, but in 2011, it exceeds 80 years in many countries (HHS 2012). If the current rate of population growth continues the population is predicted to reach 9.5 billion by 2050. Scientists worry whether natural resources can supply human demand. Population needs and natural carrying capacity of planet earth create the beginnings of a new geologic epoch called the Anthropocene (Powell, 2015). While a small subpopulation of people could become genetically rich through gene editing, it is inconsistent with the intent to help that access may be limited to financial affordability rather than on the basis of need. Genetic injustice challenges us to find pathways to greater equality. Justice corrects injustice.

Ethical Awareness of Technology

Theodore John Rivers recently described the metaphysical significance of human beings and technology (Rivers, 2015). In his analysis he differentiates the process of human maturation and change as a process of will, dependent upon freedom. The appearance of technology changing to meet a purpose may appear to be a process independent of the human agent but will the distinction hold when small computer chips are implanted to trigger a moral response to a repugnant thought? Will there evolve a time when the technology is perceived as having ontological being – a nature of becoming – equivalent to that of the human being?

Human becoming is a way in which humans express their creativity, but it is not true that technology has its own becoming innate to itself. Humans become but technology does not. Technology changes as a consequence of human action. A technique may be improved or replaced or discarded as the need for it changes. Humans are the agents of change.

Technology is a demonstration of our relationship with the world. It reflects our desire, what we will to be. Our desires for what technology does reflects our values and choices, our ideas of the type of world we want or expect. It is quickly becoming the primary means by which we create, manipulate and change the world.

Technology, especially robotics, nanobots, CRISPR-gene editing, gene therapy, enhancement and what we may not yet imagine that hold great hopes for the bioliberal who advocates unimpeded progress using all technology to improve the length and quality of human lives, and maybe the lives of plants and animals too. It is likewise true that technology is becoming a means to the will to power, with an open ended question about whether it will be used for good or ill effect. If or when gene editing is developed and deployed the growing edge of this genetic technology holds the potential to change the world as we currently know it and that may be good or bad.

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The lack of environmental ethics in dealing with particulate matter in Korea

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Abstract

This paper discusses some of the data and the ethical issues associated with problems of particulate matter in Korea. The major sources of household particulate matter are grilling mackerel and pollution from China. Diesel is a further source. Semantic network analysis that focuses on associations between words was used to examine the words used in the media. The issues raised in the media are discussed in light of ethical theory.

Introduction

Problems of particulate matter have recently become a sensational issue in Korea. According to the news search service, Kinds, almost a third of related news articles have been produced in 2016 (as of July 19), since "particulate matter" appeared for the first time in 1993 as an article title(http://www.bigkinds.or.kr).

Particulate matter is known to cause serious illness such as lung cancer, stroke, and heart and respiratory diseases. In spite of its toxic effects, however, it is still confusing to identify what is causing it and what we ought to do for policy decisions. Is China responsible for the harmful dust in Korea? Is grilling mackerel without proper ventilation causing air pollution? Do we have to impose stricter regulations of diesel cars? Media have provided contradictory disputes, and the Korean government has failed to answer these questions.

Therefore, this paper aims to present how Korean government and media have played an ambiguous role in dealing with particulate matter by using a semantic network analysis largely based on news articles. It finally claims that the lack of environmental ethics can be a crucial cause of all these disputes. There are three possible causes for particulate matter:

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