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Ethics and Genetic Privacy

Jennifer C. Robinson

Abstract

With the mapping of the Human Genome and increasing interest in genetic testing and therapies, the potential for ethical problems has increased. Nursing and medicine have the ethical responsibility to "do no harm" and to protect the privacy of clients. However, our clients may also be family members and descendants of those we care for. The purpose of this article is to discuss issues related to genetic privacy using a deontological approach and to outline methods to protect clients and research participants.

Keywords:

Genetics; Ethics; Deontology; Privacy; Human Genome

Ethics and Genetic Privacy

Introduction

The field of genetics has made rapid advances in the past ten years. It has been enthusiastically embraced and supported by researchers, the public, and the world governments as a means to understand, prevent, or treat human disease in the future. While the possibilities for ameliorating human suffering are exciting and the benefit of scientific advances are great, so are the potential risks involved. A formerly secret or unknown code for human development is now becoming accessible. The question of how accessible it should be and who will have access, remains. Without an understanding and respect for the issues involved, the scientific genetic advances have the potential to harm people through lack of truly informed consent or breaches in privacy. For this article, issues involving the Human Genome Project and research involving genes will be discussed.

Although genetics has been in the popular news and medical literature in greater amounts in the past fifteen years, it is not a new scientific topic. O. Avery, C. MacLeod, and M. McCarty identified deoxyribonucleic acid (DNA) in 1944. In 1953 F. Crick and J. Watson first described the three-dimensional structure of DNA. M. Nirenberg and H. G. Khorana broke the genetic code in 1966 when they found that triplet base pairs of messenger ribonucleic acid (mRNA) specified each of the twenty amino acids. Recombinant DNA molecules, or the combination of genetic materials from different sources through gene splicing, were first produced in 1972 (Lane, 1994).

During the rapid increase of genetic knowledge, the development of potential ethical problems was recognized. By 1975, scientists from around the world adopted guidelines for recombinant DNA experiments. In 1989, the Department of Energy (DOE) and the National Institute of Health (NIH) formed an Ethical, Legal, and Social Issues (ELSI) working group to study the implications of genome research. The working group became a branch of the National Center for Human Genome Research (NCHGR) in 1990 (ELSI, 2000; National Human Genome Research Institute [NHGRI], n.d.). Three to five percent of the NHGRI=s and the DOE=s budgets are dedicated to support ELSI (ELSI, 2000; NHGRI, 2000). The ELSI program provides the largest amount of federal funding for bioethics research with a budget of over $10 million a year (NHGRI, 2000).

Ethical Concerns Involved with Genetic Research

Potential ethical concerns are for privacy, confidentiality, and informed consent. Areas of concern in privacy and confidentiality are breaches that may lead to discrimination and stigmatization of racial groups or individuals in employment or health insurance, or whether to inform family members of genetic markers for disease, especially if the original participant donor (proband) refuses to release the information. Respect for persons issues include: (a) the use of DNA stored samples without consent, (b)

autonomy issues such as who owns the data after it is collected and stored and if participants and families have the right to choose whether to know about genetic risks or not, and (c) the use of genetic information by other researchers especially in for-profit ventures.

Deontological Principles Applied To Genetic Research

Using a deontological ethical approach and common ethical principles, some of the areas of potential harm will be discussed. Deontology, derived from I. Kant's metaphysics of morals, holds that an act is right or moral based on following certain principles (Solomon, 1989). It focuses on duties and obligations (Davis, Aroskar, Liaschenko, & Drought, 1997). In Fundamental Principles of the Metaphysics of Morals (Kant, 1797/1898, T. K. Abbott, Trans., as cited in Solomon, 1989), Kant writes "to be beneficent when we can is a duty....the moral worth of the character is brought out which is incomparably the highest of all, namely, that he is beneficent, not from inclination, but from duty....So act as to treat humanity, whether in thine own person or in that of any other, in every case as an end, withal, never as a means only" (Solomon, 1989, pp. 580-581, 588). Beneficence and non-maleficence, duty to the rights of others, and respect for persons are ethical principles that must be upheld to prevent unanticipated harm from genetic advances.

Principals of Respect and Beneficence

Respect for persons is one of the foundational beliefs of medicine and nursing. This belief undergirds the landmark documents used to protect human subjects in research. The Belmont Report calls it one of the three basic ethical principles involved in research, with beneficence and justice the other two (Sugarman, Mastroianni, & Kahn, 1998). Autonomy and privacy are two of the issues that are relevant under respect for persons. Autonomy is gained through giving the participant the knowledge necessary to make a decision. However, problems with autonomous decisions and maintaining privacy and confidentiality can occur because genetic material is not just about an individual, but about the genetics of related families (HUGO Ethics Committee, 1998; Sommerville & English, 1999; Wachbroit, 1993). In that case, the issue becomes who is the subject or a patient. The Genetic Privacy Act defines private genetic information as information that can identify a person by DNA or other genetic markers in samples obtained from an analysis of the individual=s DNA or from the analysis of the DNA of a relative, recognizing that genetics isn't just individual data (Annas, Glantz, & Roche, 1995). Wachbroit (1993) discusses decision making and confidentiality when the wish for privacy and confidentiality on the part of the proband and refusal to notify relatives of inheritable disease causes an ethical dilemma. Wachbroit suggests that since the information is not just about the individual, the duty is to the family. In situations of inheritable diseases, he believes the duty to prevent harm by giving blood relatives who are potential parents the information needed to make reproductive choices outweighs the individual=s right to privacy. In that case, he argues from a beneficence and non-malficence view similar to the approach used in public health in preventing the spread of

communicable disease to protect a community even if individual confidentiality has to be broken. The ethical dilemma occurs because of conflicting rights between the individual and the family and future generations. Wachbroit believes the health care provider has an ethical obligation to inform the family. However, the Genetic Privacy Act does not provide an exception to privacy and confidentiality but believes that the individual proband retains the responsibility to notify family members of genetic conditions (Annas et al., 1995).

Principle of Autonomy

Another issue in viewing people as autonomous is the ability of the person to maintain control and ownership of DNA material donated. Researchers frequently argue that obtaining consent for each future use of stored DNA samples would be difficult and would likely result in less research due to the increased cost and burden on the researcher (Troy, 1997). However, landmark documents such as the Helsinki Conference, Belmont Report and the Common Rule specify that informed consent must be obtained to protect human subjects (Sugarman et al., 1998). The real question is whether a consent form that gives researchers specific donor wishes for future use are adequate. Present guidelines issued by the Human Genome Organization (HUGO Ethics Committee, 1998; Stephenson, 1998) and the Genetics Privacy Act (Annas et al., 1995) recommend a consent that does give the participant the opportunity to specify how they want the sample used. The Genetic Privacy Act assumes the person donating the sample retains property rights to the sample (Annas et al., 1995; Troy, 1997). Reilly, Boshar, & Holtzman (Reilly et al., 1997) also outlined what they believed to be key elements in informing and obtaining consent for genetic studies. Earlier research consents frequently did not allow the donor to retain control over the sample. For samples obtained prior to the guidelines that allowed the participant to control what would be done with the sample, the HUGO Ethics Committee recommends that the sample can be used for research if the sample has been anonymized prior to use (HUGO Ethics Committee, 1998).

Principal of Non-maleficence

Potentially, any tissue or blood sample could be used for genetic studies if it had been stored properly (Goodman, 1996). These tissues are valuable resources that can be maintained, accessed, and used without the knowledge of the donor (Nelkin & Andrews, 1998). In a recent lawsuit filed against a researcher and a southern children=s hospital in the United States, families of Ashkenazi Jewish children who had died of a degenerative brain disease opposed a patent of the gene that causes the disease on the grounds that the researcher is profiting from the discovery and limiting access for the gene by charging for testing. Dr. J. Tsipis, a professor of biology at Brandeis University states that this incident is the ultimate nightmare of how a gene patent can be used against the very families who made possible the discovery of the gene@ (Associated Press, 2000, p. A-19). It is not clear if the participants or the families gave consent for research to develop a patented gene or if IRB approval was given for the

development of the patent. It is clear that many people do feel victimized when tissues are used in ways that were not originally consented for. In 1951, H. Lacks died of ovarian cancer. Her tissue was taken and used to develop a commercial cell line for research without consent. Even forty-three years later, her husband stated that he felt like both he and his wife were being exploited by researchers who were making a profit at their expense (Nelkin & Andrews, 1998). Legally it is not clear if it is necessary to disclose to the participants plans to develop genetic products for commercial gain. In a 1990 legal case brought by Moore versus Regents of the University of California, the court ruled that the individual did not retain property interest in tissue that was used to develop a commercial product (Moore vs. Regents of the University of California 793 P. 2d 479) (Reilly et al., 1997). Reilly and colleagues (1997) argue that ethically such disclosure is necessary under the principles of respect for persons and for the principles of informed consent.

Informed Consent and Threat of Discrimination

These cases open the door for a discussion of discrimination and stigmatization. Genetic data leads to the possibility of discrimination in employment or insurance coverage because of genetic markers for a disease and the possibility of further discrimination and stigmatization of a particular ethnic group based on genetic predisposition to a disease. Many people do not want their genetic information used to link a gene to a particular behavioral disorder, to identify a disease that occurs in a certain ethnic group, or in studies to link certain genes with IQ or stigmatizing social problems such as crime (Nelkin & Andrews, 1998). Genetic information has been used in the past to justify governments such as the United States, China, and Nazi Germany in their actions against people considered genetically inferior (Troy, 1997; Wikler, 1999). Mistrust of research endeavors is understandable from certain ethnic groups who have been discriminated against or whose rights have not been protected in previous research.

Numerous recommendations and legislation have been proposed in an effort to protect people from harm related to the use and misuse of genetic material. Most of the documents to protect human subjects have focused on protection from physical harm. However, genetic information carries a risk for psychological harm, harm from discrimination and stigmatization, or economic and other social harm (Clayton, 1995; NCHGR-DOE, 1996; Reilly, 1997; Reilly, Boshar, & Holtzman, 1997). Guidelines for genetic data release were announced by DOE and NIH in 1992, and recommendations from ELSI on genetic and insurance information release were issued in 1993. The Genetic Privacy Act was passed in 1994 as the first United States legislation to regulate genome information. However, only DNA is controlled and other materials such as RNA from which genetic material can be removed are not regulated (Troy, 1997). The DOE and NCHGR issued guidelines to protect subjects in large scale sequencing studies in 1996. The United Nations Educational, Scientific, and Cultural Organization (UNESCO)

adopted the Universal Declaration on the Human Genome and Human Rights in 1997 (United Nations, 1998).

Genetic discrimination in employment or insurance availability and coverage has been one of the major concerns in the Human Genome Project. The Equal Employment Opportunity Commission (EEOC) extended the Americans with Disabilities Act (ADA) employment protection to cover genetics information in 1995. The Health Insurance Portability and Accountability Act (HIPAA) was passed in 1996 prohibiting the use of genetic information in employer-based and commercially issued group health insurance eligibility decisions (U. S. Department of Energy [USDOE] Human Genome Program, 2002). A predisposing gene for a disease is covered under the protection unless the person has already developed the disease prior to seeking health insurance (Reilly, 1997). In 2000, President W. Clinton issued an executive order prohibiting federal departments or agencies from using genetic information in hiring or promoting employees. Currently, there are no federal laws specifically related to genetic discrimination in individual insurance coverage or discrimination in the workplace (USDOE Human Genome Program, 2002). Many states have passed laws to attempt to regulate access to genetic data and protect people (NIH, 1999). HUGO Ethics Committee and UNESCO recommend that no disclosure should be made to third parties to prevent discrimination (HUGO

Ethics Committee, 1998; United Nations, 1998) unless compelled by law. Several authors (Reilly, 1997; Sass, 1998) suggest the use of Certificates of Confidentiality to prevent compelled disclosure. Without legal safeguards, the possibility exists that an individual will be pressured to give permission for access to genetic information to a third party such as an insurance company in order to receive coverage. In addition, if the third party really wants the genetic information, they may require a blood test such as is now required in many cases in order to receive health insurance. Once the blood test is given, genetic tests can be done (Rothstein, 1998).

Many other ethical concerns in genetic research are related to informed consent. Genetic samples can be stored and used in the future for purposes not planned in the original research protocol. Many of the future uses or risks cannot be anticipated now because of the lack of knowledge of how the science will develop (NCHGR-DOE, 1996). In other words, geneticists do not fully understand what can be done with stored genetic samples because the tests and procedures haven=t been developed yet. The potential risks may be great but the benefits to the participant are usually not direct ones but are more altruists in nature (NCHGR-DOE, 1996; Reilly et al., 1997). Because of the ability to store information for long periods from which more research can be done, the potential use for commercial for-profit research, the possibility of breaches in privacy, the impact of genetic data on families, and the possibility of discrimination and stigmatization, participants must be given complete information to be able to make an informed decision about donating genetic tissues.

Measures To Protect People From Harm

Methods recommended to safeguard participants in research are the removal of all identifying links between the person and the sample in most cases, creating anonymous samples, or creating many disconnects between the sample and the individual to maintain confidentiality and privacy. Legal protection of data from third parties such as employers or insurance agencies even when the participant has given consent to release the information is needed (HUGO Ethics Committee, 1998; United Nations, 1998). Completely informing participants of potential future uses of the DNA sample, whether it will be made anonymous or coded, who will have access, the risks and benefits, whether genetic information will be given to the participant, the lack of opportunity to withdraw data after it is made anonymous or becomes information in the public domain, and the potential risks to family or racial groups to which the donor may belong is necessary for informed consent in genetic studies (NCHGR-DOE, 1996). Institutional Review Boards must also review protocols carefully, recognizing the potential economic, social, and psychological risks involved. Under the Common Rule, human subject data includes not only the sample obtained through intervention but also includes data that is identifiable private information (Merz et al., 1999; Sugarman et al., 1998). Thus all genetic research must undergo IRB approval.

Conclusion

With the increased knowledge of the human genome and the expanded interest in the potential for therapies and research that may improve health and reduce disease, comes the potential for harm. Several issues were presented using a deontological ethical view. Among these were respect for persons, autonomy, beneficence, non-maleficence, privacy, confidentiality, and informed consent in which the person is clearly presented the present and possible future implications of genetic testing, therapies, and research. Methods to safeguard people included unlinking genetic material from the identifiers in most cases, and clear consents that specify how the sample will be used, who has access, and benefits and risks, including the potential risk of stigmatization or discrimination.

All researchers have obligations to protect the privacy and confidentiality of participants, to assure that publications identifying a genetic difference in a particular group do not cause emotional distress or lead to a stigma being attached to a group, and to fully inform the public of the potential risks and benefits of donating DNA for sequencing and banking material so that an informed decision can be made. Scientists in the field of genetics have attempted to anticipate potential problems and make recommendations to protect human subjects participating in genetic research because of the unique nature of genetics. The articles adopted by the United Nations (United Nations, 1998) and the supplemental policies issued by the NCHGR-DOE for human subjects research in large-scale DNA sequencing studies (NCHGR-DOE, 1996) offer additional methods that attempt to safeguard human subjects.

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