Is informed consent possible in the rapidly evolving world of DNA sampling?

John Lyttle

In Brief

ETHICAL CONCERNS ABOUT THE HUMAN GENOME DIVERSITY PROJECT were discussed in Montreal last year during the 1st International Conference on DNA Sampling and Banking. This, the first article in a 2-part series on the conference, examines issues related to informed consent.

En bref

DES PRÉOCCUPATIONS ÉTHIQUES SOULEVÉES PAR le projet sur la diversité du génome humain ont fait l'objet de discussions à Montréal l'année dernière au cours de la première Conférence internationale sur l'échantillonnage et les banques d'ADN. Dans ce premier article d'une série de deux sur la conférence, on examine les enjeux liés au consentement éclairé.

Geneticists have projected that by the year 2005, the Human Genome Project (HGP) will have achieved its goal of identifying all 70 000 or so human genes and mapping them in a massive DNA database. Some scientists have predicted that the sequencing will be achieved even sooner — perhaps by 2003 — but even if the HGP goal is reached a year late it will still be only 6 decades since DNA was identified as the principal molecule responsible for carrying genetic information.

The rapid advances in genetic research have been extraordinary, but the ethical, legal and social policies that govern this research have not kept up with the science. What, for instance, does the concept of "informed consent" mean when even DNA researchers cannot know what information research done years from now might yield about samples being taken today? Concern about how policy is lagging behind science prompted ethicists, lawyers and geneticists to meet in Montreal last year for the 1st International Conference on DNA Sampling and Banking.

"The purpose wasn't to come out with any consensus or policy statement," explained Bartha Knoppers, chair of the conference's organizing committee and a professor at the University of Montreal's law faculty. "The purpose was to bring together for the first time [gene] bankers, samplers and people concerned with the ethical, legal and social issues.

"We're going beyond the usual discussions on issues that come up for every ethical and legal debate [about things] such as consent. What is the law? Are there any policies? We're going beyond that to new issues that are unique to human genetics.

"These are experts who normally work in separate fields, not just separate countries, and [who] are now united around an issue which I think merits attention from the first little extra piece of blood or tissue to the very end."

Informed consent

Researchers agree that participants who are willing to donate their DNA should do so only after being adequately informed about how the blood or tissue will be used in the laboratory. But truly informed consent in this rapidly evolving field is difficult, since even researchers may not know what tests will eventually be

Features

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possible at the time the consent form is being drawn up. What information should those who collect DNA pass on to patients to ensure they are adequately informed? How should a consent form be worded?

The information that ethicists consider vital may greatly exceed both what participants usually receive and what they expect, said Robert Weir, director of the Program in Biomedical Ethics and Medical Humanities at the University of Iowa's College of Medicine.

According to a study on DNA banking and informed consent[1,2] that was published in 1995 by Weir and Jay Horton, none of the consent forms obtained from 155 genetic researchers in the US answered what Weir considered "reasonable questions people might ask." These include:

- Will information about my DNA sample get into the wrong hands?
- How long will the sample be kept?
- Will third parties have access to my DNA in the future?
- Can I have my sample withdrawn at any time?

Weir and Horton concluded that current consent forms do not "contain enough to give participants information that we feel is important." It would only take a few pages to answer the questions a reasonable participant would ask, they reasoned, but between 60% and 80% of the lay people they queried said 3 pages of consent-related information would be too much.

Bent Norgaard-Pedersen, a professor of biochemical screening at the University of Copenhagen, said there is consensus among Danish ethicists and politicians that samples taken for nationwide screening for phenylketonuria should be stored "to benefit not only the newborn infant but also the parents, society and future generations."

He suggested that there is a danger of overinforming sample donors by giving them more facts than they can absorb, but this proved to be a controversial point. "Believe me, the problem in the United States is that we need to say a lot more," argued Ellen Wright Clayton, associate professor at Vanderbilt University's schools of medicine and law. Review and consent practices are woefully inadequate, she said, and "the fact that [it] has been the process for the past 25 years does not mean that it has been acceptable."

Bernard Dickens, a bioethicist and professor of law at the University of Toronto, said Canada's legal approach to consent relies on "judge-made" law. In its 1980 decision in the case of *Reibl* v. *Hughes*, the Supreme Court of Canada decided that the physician had not sufficiently informed his patient before surgery because he did not warn him of all serious risks. The patient, who suffered a stroke during surgery, might have elected not to have the surgery at that time had he been sufficiently informed, the court ruled. The principle emerging from the ruling was that patients "must be given information that is material to a reasonable and prudent person in the individual's circumstances."

One thing the prudent participant must consider is privacy. It is not uncommon for law and ethics to intersect, Dickens said, but sometimes they also conflict. Knoppers said the difficulty is to draw the line between the duty to maintain confidentiality and the geneticists' obligation to pass information on to at-risk families.

In most cases the completion of a consent form should not be rushed so that potential participants don't feel pressured to understand a large amount of background science and hastily sign on a dotted line, an official from the National Institutes of Health (NIH) said. Elizabeth Thomson said hasty completion of consent forms happens too often in American hospitals.

Thompson, a registered nurse, said patients are sometimes asked for consent when they are in highly stressful situations, such as delivering a baby. Instead of informed consent, "uninformed nondissent" is achieved. "Most of them don't get it," she said. "They don't even remember it."

On the other hand, excessive bureaucracy could cause research to "grind to a halt," warned McGill geneticist Clarke Fraser. Expanding on this sentiment, Dr. Patricia Baird, professor of medical genetics at the University of British Columbia, suggested that "protection of privacy is not above the health of the population." The right to control information about oneself should be protected by regulation, she added, but the possible benefits of DNA sampling are amazing.

"Using a computerized record linkage approach, very large follow-up studies are now possible in epidemiology, and such data files could provide an increasingly powerful test bed for a range of hypotheses about the genetic factors that affect people's health," Baird reported in a conference abstract.

But genuinely informed consent must precede that research, insisted Lori Andrews, a professor at Chicago-Kent College of Law and last year's chair of the Working Group on the Ethical, Legal and Social Implications of the Human Genome Project. When considering consent and call-back policies, concerns about patients' right to know and the discrimination risks that might follow must be considered.

"We need to put aside the issue of whether those of us in the room would want to know [about genetic findings] and consider the [actual] people involved," Andrews said, referring to potential psychologic, financial and sociologic pitfalls.

Access to health insurance can also be a major consideration, she noted. In the US, patients can be punished with higher costs or may become uninsurable if knowledge about a genetic disorder becomes widely known.

References

1. Weir RF, Horton JR. DNA banking and informed consent — part I. *IRB Hum Subject Research* 1995;17(4):1-4.
2. Weir RF, Horton JR. DNA banking and informed consent — part II. *IRB Hum Subject Research* 1995;17(5-6):1-8.

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