Industrial Pharmacy Residency Program

The Faculty of Pharmacy of the University of Toronto, along with the companies participating in the Industrial Pharmacy Residency Program (AltiMed, Apotex Inc., AstraZeneca, Baxter Corporation, Eli Lilly Canada Inc., ESI Canada, Genpharm Inc., GlaxoSmithKline, Hoffmann-La Roche Ltd., and Nycomed Amersham Canada Ltd.) are pleased to announce that the following Industrial Pharmacy Residents have completed the program:

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Ethics and Pharmacogenomic Research

I read Mary Ensom's editorial[1] discussing the implications of pharmacogenomics research with interest. I agree that the results of such research will provide tools to help personalize drug therapy and that pharmacists will need to be able to apply this knowledge in their care of patients. In this context, it may be helpful for pharmacists to be aware of the hotly debated issues that surround genetic research and its application. Knowledge of these controversies and of ongoing educational efforts and policy development will help pharmacists to understand the process of genetic research and to improve their ability to discuss the research and its outcomes with colleagues and patients.

As a member of a research ethics board, I was very excited when projects that included a genetic research component began to cross my desk for review. The possibilities seemed fantastic, and it was tempting to rush forward with approval without first examining the implications for research subjects. A research ethics board, however, is entrusted with the responsibility to ensure that the welfare and rights of research subjects are in no way compromised and that these subjects make their decisions to participate in the research in a fully informed manner. To protect the welfare of research subjects, researchers are asked by the research ethics board to describe potential harm to the subjects. The problem with genetic research is that potential harm is poorly understood.

Most harm could arise from the possibility of linking, in the research records, biological material to the person from whom it was taken and thereby revealing clinically relevant information about the individual and his or her family. The risks associated with such linkage and revelation of information include loss of confidentiality of the information and possible psychological and socioeconomic impacts on the research subject and his or her family. Receiving information about susceptibility to a genetic disease may cause anxiety, identify a need for additional tests, and necessitate access to genetic counselling. Knowledge of this information could limit the availability of medical services or insurance for the subjects and could lead to discrimination, stigmatization, or even ostracism. Blood relationships and information that affects family planning could be revealed, and family conflict created.

The research ethics board requires researchers to conduct an informed consent process so that subjects fully understand the research, the implications of their decision to participate, and their rights within the project. In early projects reviewed by our research ethics board, these aspects of informed consent were difficult to understand, as the consent for the use of biological materials was either included as a small section of a consent form for a clinical trial or was added as a separate consent form, without an accompanying research protocol specifically for the genetic material. The goal of the research, how long the samples might be kept and what they would be used for, whether or not they could be linked to the individual from whom they came—all of these aspects were unclear.

Several groups have now developed guidelines for obtaining consent related to use of biological materials.

Table 1. Web Sites Presenting Information about Ethical Issues Related to Genetic Research

Web Site	URL*
Human Genome Project	http://www.ornl.gov/TechResources/Human_Genome/home.html
National Council of Ethics in Human Research	http://www.ncehr-cnerh.org/english/mstr_frm.html
Section 8, Human Genetic Research, in Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (published by Medical Research Council, Natural Sciences and Engineering Research Council, and Social Sciences and Humanities Research Council)	http://www.nserc.ca/programs/ethics/english/sec08.htm#A
Statement of Principles: Human Genome Research, Version 2000 (published by Réseau de médecine génétique appliquée)	http://www.rmga.qc.ca

*URLs up to date as of August 2001.

Experts agree that this consent process must be separate from the consent for a clinical trial, that it must be explicit about the uses to which the material will be put, and that it should clearly outline the subject's options for participation. Some of these options include refusal to participate, choice of one or more projects for which the genetic material could be used, and whether further contact with the research subject is permitted. Typical consent procedures should also apply (for example, the subject should have the right to participate with no pressure and should be able to withdraw at any time without affecting other care). The consent form should state that subjects can request that the sample be destroyed and should specify when the sample's identifiers will be removed, so that the subject can request destruction of the samples before that date, if so desired. Finally, if there is a risk to a specific group (for example, cultural or geographic), that should also be described. If the personal identifier is removed but an ethnic link remains, data can be generalized to a specific group, with both positive and negative results. Research subjects need to be aware of this possibility.

The application of the results of genetic research is also rife with controversy. The first questions are, who owns the results of this research and who has the right to profit? These issues could be clarified if consent forms clearly stated the commercial sponsors and the potential for commercialization of products or drugs developed as a result of the research and if they also stated clearly that individual research subjects would not be paid. There is controversy over whether biological material should be patented. Is it right to limit ownership of potential diagnostic approaches or cures for diseases? Yet without patents, how could researchers be paid? It is difficult to find a balance that makes everyone happy. Now that DNA maps are readily available, might insurers ask applicants to provide their DNA maps and decline to insure those who refuse to comply or limit insurance on the basis of the map? Some argue that DNA results could also affect a person's ability to obtain a job or a bank loan or could even affect salary scales. The need for antidiscrimination policies has thus been identified.

There are also ethical concerns related to the use of samples that cannot be linked to their donors. With identifiers removed, there is no way to contact donors if, for instance, the treatment for a genetic disease is designed. The donors may not have given explicit consent for the particular gene to be tested, but does the obligation to treat supercede the constraints of the research project?

This letter cannot describe in detail all the issues inherent to this field of research, so I have included some Web sites that present some of the information papers, conference results, and policies being developed to assist researchers and research ethics boards dealing with these challenges (Table 1). Genetic research is a rapidly advancing field, one that may provide answers about the causes of and treatments for various diseases and one that we need to examine carefully so that we can anticipate its impact on the human subjects who agree to donate biological material in the hopes of helping others.

Reference

1. Ensom MHH. 2001: a pharmacogenomics odyssey. *Can J Hosp Pharm* 2001;54:6-9.

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