

Advisory Committee on Genetic Privacy and Research

Meeting Minutes — May 5, 2004

Attendees

Gwen Dayton (Co-Chairperson), Robb Moses, Jon Zonana, Rita Aikins, Ron Marcum, Bob Koler, Ted Falk, Kara Manning, Michael Garland, Paul Newton, Andrea Meyer, Greg Fowler, Kiley Ariail, Kerry Silvey, Patricia Backlar, Laura Zukowski

Matthew Wolk, Geoffrey Dauven, and Vincent Wurm (Portland State University students)

Introduction

- Welcome and Introductions — Everyone introduced himself or herself.
- Review of Draft Minutes from Last Meeting (April 7, 2004)
Draft minutes from April 7, 2004, had been circulated in the e-mail prior to this meeting. No one present had any requests for corrections or additions.
Outcome: Bob Koler moved that the draft minutes of April 7, 2004, be approved. Rita Aikins seconded the motion. Minutes from April 7 were approved.

Overarching Question — Oregon's Genetic Privacy Law: Is It Still the Right Thing?

Use and Disclosure of Genetic Information within the Clinical Setting

Today's discussion was about Oregon's genetic privacy law and how it is functioning within the clinical setting, that is, in physicians' offices and hospitals where patients receive medical care. Clinicians and hospital and health system administrators have identified problems with the state law's definition of genetic information, which protects both the results of a genetic test and all subsequent care resulting from it and requires authorization from a patient for doctor-to-doctor disclosure and for routine treatment, payment, and health care operations. Feedback from clinicians and administrators indicates that genetic information is embedded throughout a patient's medical records, which makes compliance with the law difficult for routine treatment and operations in the clinical setting. It is not always known whether or not a genetic test was used to diagnose a genetic condition, and the list of genetic tests is ever expanding.

The committee considered whether HIPAA (in conjunction with other state statutes that govern informed consent and protection of health information) would provide sufficient coverage for genetic information in a clinical setting without the genetic privacy law. Entities not covered under HIPAA, their uses and disclosures of genetic information,

along with potential problems to changing Oregon's law, were the focus of this discussion.

HIPAA covers health care providers, insurance plans, and clearinghouses. No authorization is required for (minimally necessary) disclosures for routine treatment, payment, and health care operations. HIPAA does not apply to numerous entities, such as employers, schools, independent researchers, law enforcement, life insurance underwriters, non-covered physicians (who don't transmit information electronically), publicly employed emergency medical technicians, and adoption agencies.

Multiple people in the room expressed the opinions that Oregon's definition of genetic information might be too broad and create what seems to be an arbitrary distinction between a clinical diagnosis and a genetic test diagnosis. Some people also believe that the original intent of the privacy law was to address presymptomatic genetic testing and not routine clinical care. Others were more cautious about changing the definition, because it is woven throughout the law and impacts more than just one provision.

Other considerations include ORS 677.097 (Procedure to obtain informed consent of patient), which covers only the obtaining of medical information and does not address future usage of retained samples.

Alternative changes to the genetic privacy law that would not involve changing the definition of genetic information are:

- exempting HIPAA-covered entities entirely from the genetic privacy law;
- specifically allowing private right of action for violations by HIPAA-covered entities;
- creating a carve out for HIPAA-covered entities for treatment, payment, and health care operations only.

There was disagreement among members as to whether HIPAA covers the obtaining of genetic information or just the use and disclosure of this information (and all other medical information). Different entities have interpreted this legal point differently.

Outcome 1: The committee will discuss the definition of genetic information in the state statute.

Outcome 2: The committee will have future discussion about whether private right of action for violations of genetic privacy within the clinical setting should be preserved in the state law. HIPAA does not allow for private right of action for these situations.

Outcome 3: Gwen Dayton will draft a synopsis of today's discussion. She will include the framework of defining the "problem" and proposing a "fix" or possibly "fixes."

Other Business: Student Forum

Greg Fowler introduced three students from Portland State University who are putting together a public forum about genetic privacy as part of their senior capstone program. The forum, "Genetic Privacy: The Science, Legal and Ethical Implications," will be on Monday, May 24, from 3:30 to 5:00 p.m., in Smith Memorial Center. It is intended for

the general public and will be structured around a case brief. The purpose of the event is to help inform the public about genetic privacy issues and to invite public input on policy issues. Everyone in the community is invited.

Outcome: *The committee invited the students to return to present information about the forum or to submit a written summary of the event for distribution.*

Adjourn

2004 Meeting Schedule

June 2	October 6
July 7	November 3
August 4	December 1
September 1	

First Wednesday of each month
1:00 to 3:00 p.m.
Oregon Medical Association
5210 SW Corbett Avenue in Portland