

Advisory Committee on Genetic Privacy and Research

Meeting Minutes - Sept 5th, 2007

Attendees:

Andrea Meyer, Kara Manning Drolet, Nan Newell, Steve Nemirow, Bob Nystrom (DHS Staff), Ronald Marcum (alternate member), Stuart Kaplan (alternate member), Ted Falk (alternate member), Gayle Woods, Mary Pat Bland (DHS Staff), John Anderson (DHS Staff), Paul Dorsey (alternate member)

September Agenda overview:

1. Agenda approval
2. Approval of Minutes for August 2007
3. Announcements
4. Update from Privacy Summit – Kara Manning Drolet
5. Genetic Exceptionalism Discussion – walk through two examples of tests. How are they currently protected?
 - a. HepC
 - b. Huntington's
6. *if time allows* Plans for obtaining input on Oregon Genetic Privacy Law – Mary Pat Bland
7. *if time allows* Direct to Consumer Genetic Testing in Oregon – Mary Pat Bland
8. Adjourn

1, 2 - Outcome:

- Agenda was approved. Minutes were approved, with minor corrections. The suggestion was made to distinguish members from visitors in the minutes. Future corrections to minutes can be directed to john.a.anderson@state.or.us.

3. Announcements:

“Challenging Assumptions” – a conference on stem cell research - will be held at the Hilton in Portland October 12-14.

3 - Outcome:

- A handout for the conference was made available.

4. Update from Privacy Summit – Kara Manning Drolet

Carol Pratt discussed HIPAA requirements, and Kara Manning Drolet spoke on requirements of the law and best practices.

We can't rule out somatic changes to which the law applies. For doctors, compliance makes it a challenge every time they need to do a panel.

Note: “somatic” refers to non-heritable characteristics. So there is a distinction here between diagnostic testing and “genetic” testing.

We may not want to rule out somatic changes, which means we may not have made too much progress on the question of the definition of genetic testing. In terms of genetic exceptionalism, we may not see a difference, but the public might. Note that the law doesn't draw the somatic distinction – but it could and should, since the somatic test could be predictive and thus the basis for discrimination.

4 - Outcome:

- We may see a merging of diagnostic and genetic testing, which means the discussion is still on regarding genetic exceptionalism.

5. Genetic Exceptionalism Discussion – walk through two examples of tests. How are they currently protected?

The idea was thrown out to make two hypothetical situations – one clearly not genetic (infection), and one genetic. The comparison documents would be used to show how each would be treated under the law.

The purpose of the discussion would be a possible eventual change in the law as to how genetic information is treated. This is in relation to research, employment discrimination and insurance discrimination. We might also want to compare federal law to Oregon law. It is thought that this exercise will be useful.

Huntington's looks at repeats in dna. It uses a blood test...a nuclear dna test. It might be possible to use other genetics material, such as a cheek swab, that contains enough repeats. Huntington's is not known to correlate to any other characteristics at this time. There is no non-genetic test available, and the condition can be tested for in-utero.

Hepatitis-C test for antibodies of viruses, and the patient is often symptomatic: jaundice, fatigue, and fever. The test is a blood test...the method of transmission could be a needle, sexual, or a blood transfusion. It is more easily transmitted than HIV and is treated with antivirals. Although the test is not genetic, someone could be found to be immuno-suppressed (and therefore more susceptible) through a genetic test.

TF – Why is HIV subject to special treatment, in relation to HepC? Other risks are also not required to be disclosed, since they can sometimes be forgotten due to inexperience, lack of sleep etc.

This may be true, but the privacy act treats HepC and Huntington's the same.

In practice, is the clinician likely to talk about societal impact?

RM – Doctors practice “generically” and answer questions. So employment questions may not come up.

AM – If it's genetic, is there always an extended discussion?

NN –All diseases could have a genetic component. The discussion should be disease-based, not considered test-by-test.

RM – There is the question of whether a primarily genetic disease needs special protection.

AM – It may, because of familial factors.

SN – But congenital syphilis could be treated with exceptionalism.

RM – The HIV situation hampered care, but made a difference socially. Exceptionalism hampered treatment, in this case.

TF – But it created an environment where people could be tested, HIV had social differences that HepC didn't have.

AM – What about the genetic information kept on inmates, like the HepC study and the criminal behavior study?

KMD – The Common Rule has protections for inmates.

TF – Consider a non-genetic test where nothing specific is wrong, what could be called a general diagnostic test. Is there anything similar in genetic testing?

Newborn screening, and tissue typing. Obtaining disclosure doesn't differ.

AM – But is that liver sample ever really anonymous?

RM – HIPAA requires that the sample be deidentified, or you can use statistical methods to make identification unlikely. The analysis to determine identity would be the same as with genetic testing...liver tissue has dna.

Summary

There seems to be exceptionalism in practice, since Huntington's patients receive more information about the social implications of their disease. This exceptionalism may be built into physician's standards of practice. The role it plays in relation to Oregon and federal law remains an open question, and the factors that would require exceptionalism for any particular disease are also not clear.

5 - Outcome:

- The notes should contain a summary of the discussion, with links back to the documents in question.
- Discussion will most likely continue next time.

6,7 if time allows

Not covered at this meeting.

8 Adjourn