

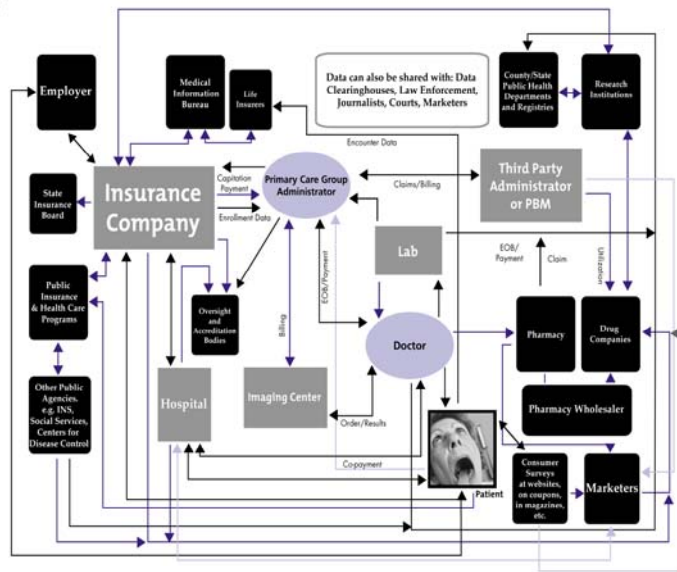
Genetic Privacy

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Do You Know Where Your Medical Information Goes?

Sample Data Flow

Based on a presentation developed by the California HealthCare Foundation



Please note that the explanations are meant to be illustrative. They are not comprehensive.

Genetic Privacy - A Special Status?

- Why do we have a separate presenter for genetic privacy?
- Is genetic information different from other protected health Information (PHI)?
- This is the controversy of
Genetic Exceptionalism
- With many partisans on both sides of the issue
- Even if genetic *information* is not exceptional, one might ask...
- Is the emotional experience of *privacy* different around genetics?

Genetic Privacy - Genetic Exceptionalism

- Pamela Sankar concludes:
- The debate on uniqueness of genetic information has been useful exercise in forcing an examination of variety and formal features of medical information.
- Genetic information has no unique subset of features consistently distinguish it from other health information
- Except for persistent belief that it is different !

• P Sankar, Annu. Re. Med.2003, 54:393-407

Genetic Privacy:A Video Based Case Presentation

- Testing for BRCA1 and BRCA2 in a Multiply Effectuated African American Family
- Spending a few minutes focusing on the thoughts, feelings, and decisions of a family going through genetic testing might clarify these issues
- (More memorable than the slides I've cut out to make time)
- Video segment is from ELSI project *Genetic Dilemmas in Primary Care*.
- See <http://www.geneticdilemmas.org>

Genetic Privacy:A Video Based Case Presentation

- Things to watch for
- Multiple definitions of genetic information
 - Information from genetic testing *vs.*
 - Information from testing with genetic implications *vs.*
 - Information from personal medical history *vs.*
 - Information from family medical history

Genetic Privacy:A Video Based Case Presentation

- Things to Watch for (continued)
- Multiple Conflicting *Meanings* of Genetic Information
 - Deterministic
 - Probabilistic
 - Dominate over other health inputs
 - Immutable
 - Non-individualistic (conflict with privacy?)
 - Future oriented – loss prevention, rather than illness management or health state improvement

Genetic Privacy:A Video Based Case Presentation

- Things to Watch for (continued)
- Multiple Definitions of Privacy
 - Protection from discrimination based on Genetic Information
 - Protection from misuse of Genetic Information
 - Protection from disclosure of Genetic Information
 - The desire (right?) not to share information with strangers
 - The desire (right?) not to share information with family
 - The desire (right?) for a personal domain or space
 - The desire (right?) not to know - one's future, one's past
 - *Essential Privacy*, non-instrumental, non-consequentialist definitions

**Genetic Privacy: A Video Based
Case Presentation**

(Video segment is approx. 7 min.)

**From Private Concerns
to
Public Policy**

Public Concern Regarding Genetic Privacy

- Last five years has seen dramatic increase in use of genetic testing, with estimates hovering at 250, 000 per year. Still, this is less than annual STD testing. People may be hesitant to take genetic test because of privacy concerns.
 - P Sankar, Annu. Re. Med.2003, 54:393-407
- Among a group that turned down recommendation for genetic counseling services in Univ. of Virginia, the most cited reason for declining genetic counseling service was concern about health insurability.
 - Geer KP, et al, J Genet Couns 2001 Feb;10(1):25-40
- At NIH cancer genetics program for first degree relatives of cancer patients, 39% identified the potential effect on their health insurance as the most important reason to not undergo testing.
 - DW Hadley, et al, Arch Intern Med 2003 Mar 10;163(5):573-82

Public Concern Regarding Genetic Privacy

- *Time* magazine survey in July 2000. 75% would not want insurers to know what disease predispositions they have.
 - D. Thomson, *Time*, 3 July, 2000 p.23
- Genetic professionals surveyed in a Yale study indicated that 68% would not bill genetic testing to health insurance and 26% would go so far as to use an alias for genetic testing.
 - ET Matloff, et al J Clin Oncol 2000 Jun;18(12):2484-92
- In a 1997 survey reported by Us Dept of Labor, 63% of those surveyed would not take genetic test if health insurance or employers could obtain results, 85% believed that employers should be prohibited from obtaining information on employees genetic tests.
 - US Dept of Labor Report, *Genetic Information and the Workplace*, 1998

State and Federal Response to Genetic Privacy Concerns

- HIPPA does not single out genetic information - **No genetic exceptionalism here.**
- The only information singled out for special treatment are psychotherapy notes.
- The HIPPA privacy regulations protect privacy of genetic information to the same extent as it protects any other protected health information (PHI).
- In issuing its final regulations for the implementation of HIPPA, however, HHS did specifically confirm that..
- **“The definition of protected health information includes genetic information that otherwise meets the the statutory definition.”**
 - 65 Fed. Reg.82621 (Dec 28, 2002)
- However 2/3 of states have passed laws to protect privacy of genetic test results. Also Executive Order (2000) by Pres. Clinton bars the federal government from discriminatory use of genetic information.
 - P Sankar, Annu. Re. Med.2003, 54:393-407

Genetic Privacy Concerns and Potential Genetic Discrimination

- Are public concerns about genetic privacy justified?
- Depends who you ask. The debate is worth a moments discussion
- General agreement, even by staunch supporters of more protective federal legislation, that there has not been widespread reporting of genetic discrimination.
 - KH Rothenberg et al, Science. 2002 Jul 12;297(5579):196-7.
- In a widely quoted study Hall and Rich came to the following conclusions:
- Patients' and clinicians' fear of genetic discrimination greatly exceeds reality, at least for health insurance.
- It is uncertain how much this fear actually deters genetic testing.

Genetic Privacy Concerns and Potential Genetic Discrimination

- Hall and Rich (continued)
- The greatest deterrence is to those who do not want to submit the costs of testing for reimbursement and who cannot afford to pay for testing.
- Little deterrence for tests that are more easily affordable or when the need for the information is much greater.
- Fear of discrimination plays virtually no role in pediatric or prenatal situations, but is significant for adult-onset genetic conditions.
- Existing laws have not greatly reduced the fear of discrimination. This may be due, in part, to clinicians' lack of confidence that these laws can prevent discrimination until there are test cases of actual enforcement.
- Ironically, there may be so little actual discrimination that it may not be possible to initiate good test cases.
 - Hall MA, Genet Med 2000 Jul-Aug;2(4):214-21

Genetic Privacy Concerns and Potential Genetic Discrimination

- William Nowlan
- Health Insurers have little incentive to underwrite based on theoretical future risk because policies are in effect only a few years
- **Life Insurers** should have access to genetic information otherwise we face markets with asymmetric information and adverse selection
- The 2001 Nobel prize was given for work demonstrating the serious market distortions that arise from consequences of asymmetric information
- Thus, it is the people with genetic information who will potentially be unfair to others in the market for life insurance. This is essentially insider trading in the life insurance market.
- Hence no legislation should make this information unavailable for life insurance underwriting
 - W Nowlan Science. 2002 Jul 12;297(5579):195-6.

Genetic Privacy Concerns and Potential Genetic Discrimination

- Rothenberg and other advocates responds
- We do not yet have widespread use of genetic services, thus we can expect a growing discrimination problem in future
- Individuals may not be filing discrimination complaints because they are not privy to reasons for health insurance denials
- Healthy individuals with genetic predispositions may not file complaints precisely because they are concerned
- Even if public concerns are exaggerated, they are keeping people from seeking potentially beneficial genetic services
 - KH Rothenberg et al, Science. 2002 Jul 12;297(5579):196-7.

Genetic Privacy Concerns and Potential Genetic Discrimination

- Rothenberg and other advocates respond (continued)
- At least one dramatic example:
- The Burlington Northern Sante Fe Railway Company (BNSF) settled a law suit in 2002
- Company had required physical exams and blood work which, without employees knowledge, had genetic test for a marker allegedly predictive of carpal tunnel syndrome
- Under Americans with Disabilities Act, company was required to pay \$ 2.2 Million to employees for secretly doing genetic testing on their blood samples
 - Press Release, May 8, 2002 . The U.S. Equal Employment Opportunity Commission

Genetic Privacy Concerns and Potential Genetic Discrimination

- Rothenberg and other advocates respond (continued)
- The state laws are hopelessly contradictory patchwork for example the definition of genetic information differs:
- Arizona law specifically includes family history as protected genetic information and is so broad as to cover any aspect of medical record with potential genetic content
- Florida and Oklahoma specifically exclude family history
- Florida and Tennessee only include results of tests done specifically for genetic information
- Colorado defines material of genetic test to include only DNA and RNA. It excludes gene products or functions. Connecticut specifically includes these
- Thus, a sweat test for cystic fibrosis is protected genetic information in Connecticut, but not in Colorado
 - P Sankar, Annu. Re. Med.2003, 54:393-407

Genetic Privacy Concerns and Potential Genetic Discrimination

- Given the potential for discrimination and the patchwork of state laws there are advocates for a federal regulations
- The Genetic Nondiscrimination in Health Insurance and Employment Act (H.R. 602) would fill in these gaps
 - Joanne L. Hustead, JD, Senior Counsel, **Health Privacy Project** in Testimony before the U.S. House Committee on the Judiciary September 12, 2002

Genetic Privacy Beyond Instrumentalism

- Most of the discussion around genetic privacy centers around use and disclosure by corporations or institutions for instrumental purposes that are not necessarily in the individuals interest
- Even if we could eliminate these, the privacy issue may not be solved
- Perhaps one's genetic endowment is a "private part" in the sense that we describe other physical and psychological aspects of ourselves
- (May be some primordial connection here to mating displays that define what is public/private and relate to offers of potential genetic endowments)
- Thus, genetic privacy should not be based on the potential for misuse alone, but also on the notion that *privacy needs* are part of our individuality and integrity

Genetic Privacy Beyond Instrumentalism

- Genetic exceptionalism may fail at an instrumental level, because we can't find any instrumental use unique to genetics
- However, at the emotional level, genetic information may be exceptional, or at least at one extreme of the privacy spectrum
- If HIPAA can recognize the uniqueness of psychotherapy notes, perhaps, for similar reasons, we can recognize the unique, intrinsic privacy of our genetic endowment.

Conclusion

- Why do we feel so strongly about the privacy of information regarding our genetic endowment?
- Who knows, its just one of those intrinsic gut feelings .. It must be genetic!