A PRIVACY AND CONFIDENTIALITY PRIMER

Mary S. McCabe
May 4, 2004

Privacy

- The right of individuals to limit acces by others to some aspect of their person.

- Operates in two ways-
  1. What is known
  2. Who may know it

Privacy

- Relates to-
  - Self-respect
  - Self-determination

- Not an absolute right
  - Must be balanced with competing values.

Loss of Privacy Abandonment

- Being given up
  - Positive desire
  - Voluntary conduct
  - Expected result

- Taken away
  - Lose self-determination
  - Usurps control over how, to whom and on what occasion

Respect for Individual Autonomy

"It is generally accepted in the United States... that ethics for dealing with public records, including health care records, should have as its core respect for the individual. The person is entitled to a degree of autonomy and is expected to extend that shield to others.

George Duncan

Privacy and Autonomy

- Related but not the same.

- An offense to privacy is an offense to autonomy, but not all offenses to autonomy are offenses to privacy.

Arguments in Support of Informational Privacy

- Consequentialist-based arguments
  - Strict obligation
  - Non-absolute rules
  - Goals and consequences

- Rights-based autonomy and privacy arguments
  - Value of privacy gives weight to rules of confidentiality to protect it.

- Fidelity-based arguments
  - Fidelity to implicit and explicit promises.

Definitions

- Informational Privacy

  The ability of an individual to deny others access to information regarding that individual.

- Confidentiality

  A form of informational privacy characterized by a special relationship, such as the physician-patient relationship.

The Need for Health Information

Any health care system (including clinical research) is functionally supported by and requires data that is readily accessible.

Essential Functions of the Health Care System

- Treatment and prevention services
- Quality assurance reviews
- Financial reimbursement
- Monitoring of fraud and abuse
- Conduct of research
- Public health services

Rationale for Collection and Use of Health Data

- Allow consumers to make informed choices about providers and plans.
- Provide more effective clinical care
- Assess the quality and cost effectiveness of services
- Monitor fraud and abuse
- Track and evaluate access to health services
- Track patterns of morbidity and mortality among the underserved
- Conduct research on the etiology, prevention and treatment of disease.

Informational Privacy Factors to Balance

- The type of health records and information it contains.
- The potential for harm from unauthorized disclosure.
- The injury from disclosure to the relationship in which the record was generated.
- The adequacy of safeguards to prevent non-consensual disclosure.
- The degree of need for access.

Unites States vs Westinghouse

The Tension

- Individual Rights
  - Autonomous decision-making
  - Protection of private sphere from government

- Individual Responsibilities
  - Obligation to cooperate
  - Societal needs
    - Proper function of government
    - Civic duties in society
    - Educational institutions
    - Health care
    - Research

The Balance

Protecting health information privacy

while

Allowing communal uses of the data for societal good.

Informational Privacy Protection
Federal

- Constitutional protection
- Statutes and regulations
  - Privacy Act of 1974
  - Freedom of Information Act
  - Americans with Disabilities Act
  - Medicare Condition of Participation
  - Common Rule
  - FDA Regulations

Informational Privacy Protection
State

- Wide variation
- Incomplete protection and penalties
- Restricted to government-held data
- Super - statutes for specific diseases or certain kinds of data

Privacy Protection in Research

- Common Rule 45 CFR 46

  Adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

- FDA regulations 21 CFR 50, 56

  A statement describing the extent, if any to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the FDA may inspect the records.

Focus on Informational Privacy
The Driving Force

- Revolution in information technology
  - Acquisition, use disclosure and storage of electronic data.
- Ongoing health care reform
  - Organization, financing and delivery of integrated systems.
- Revolution in biomedical research
  - Human genome project
- Uneven state laws
- Perception of widespread, unauthorized disclosure of personal health information

Privacy Rights
Concerns of Americans

- 80% - Concerned about threats to privacy.

- 80% - Consumers have lost all control over how personal information is used.

Support for Privacy Rule
Proposed Benefits

- Quality and reliability of personal medical information
  - Fair information practices may lead to better quality data.
  - Privacy assurances enhance trusting relationship between patients and physicians.
  - National standards encourage data sharing.

Privacy Rule
History

Health Insurance Portability and Accountability Act	1996
1st Privacy Rule Issued	December 28, 2000
NPRM Published	March, 2002
2nd Privacy Rule Issued	August, 2002
Main Compliance Date	April 14, 2003

The Rule

- Establishes a federal "floor" of medical privacy protections.

- Will replace (preempt) only those state laws that are contrary to the Rule or offer individuals less protection.

- Offers individuals greater control over their own health information.

- Imposes limits on the ways in which health care providers and other regulated entities may use or disclose health information for a variety of purposes.

- Treats similar research activities differently depending on the status of the individual or entity that creates or receives the research data.

Privacy Rule
How is Research Covered?

- Research is not a covered function in itself.
- Covered functions-
  - Treatment
  - Payment
  - Health care operations
- Researchers not covered entities by virtue of their research, even if their activities involve identifiable health information.
- Research covered if-
  - Involves provision of health care by a covered entity
  - Medical record or biological samples maintained by a covered entity and labeled with health information

Privacy Rule
Scope

- Who is covered-
  - Limited to "covered entities"
    - Health care providers who transmit health information in electronically in connection with a HIPAA transaction.
    - Health plans
    - Health care clearinghouses
  - Business Associate relationships
    - An agent, contractor, others hired to do the work of or for covered entities that requires use/disclosure of PHI.

Privacy Rule
Scope

- What is covered-
  - Protected health information
  - Individually identifiable health information
  - Transmitted or maintained in any form or medium by the covered entity or their business associate
- What is not covered-
  - Human biological tissue
  - De-identified information

Privacy Rule
Research

- Use or disclosure of "protected health information" for research purposes requires:
  - Written **authorization** from the individual
  - **Waiver** approved by the Privacy Board/IRB
  - **Without authorization**
    - Reviews preparatory to research
    - Research on decedents' information
    - Limited data set with a data use agreement
  - Pursuant to transition provisions

Privacy Rule
National Challenges

- Lack of specificity of regulations
- Limited guidance to IRBs
- Inconsistent interpretation by IRBs
- Current focus on conforming to regulations rather than protection of private information
- Multi-centered studies hampered
- Protections tied to the concept of a "covered entity"
- Evolving definition of identifiable
- Ongoing need for identifiable information

Privacy Rule
Institutional Challenges

- Lack of specificity of the regulations
- Need for education of investigators
- Need for education of IRB members
- Development of understandable information for research participants
- Current focus on compliance, not on appropriate protections of research participants through the protection of their identifiable information
- Development of data-sharing approaches

Privacy Rule and the
Common Rule

- Coded data are considered de-identified rather than identifiable.
- Applies to all research regardless of funding source.
- Applies only to data held by a covered entity.
- Authorization plus consent needed for the use and disclosure of identifiable data.
- No permission for future unspecified research.

Competing Values
or
Co-existing Values

- Need for privacy
- Need for information
- Develop a balance
  - Protect privacy through security measures
  - Provide carefully described data access

I am a living candle.
I am consumed that you may learn.
New things will be seen in
Light of my suffering.

a post-encephalitic
patient of Oliver Sacks