

# NCVHS: Privacy and Confidentiality

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# Goals

- Outline important NCVHS initiatives with respect to privacy and confidentiality
  - NHIN and HIEs
  - Personal Health Records
  - Secondary Uses and Data Stewardship Reports
- Consider two current, complex issues of privacy and confidentiality
  - Syndromic surveillance
  - Secondary uses of health data in research

# NCHVS Initiatives: NHIN and HIE

- Privacy and Confidentiality in the NHIN (June 2006 letter)
- Update to Privacy Laws and Regulations Needed to Accommodate NHIN Data Sharing (June 2007 letter)
- Individual Control of Sensitive Health Information Accessible via the NHIN for Purposes of Treatment (February 2008 letter)

# Privacy and Confidentiality in the NHIN

- June 2006 letter: touchstone treatment of these issues, before its time but of its time
- 26 recommendations, including
  - flexibility for providers in how to maintain records
  - patient choice concerning participation in HIE
  - study of individual control of sensitive information
  - role-based access to records
  - Implementation of fair information practices principles

# Privacy and Confidentiality in the NHIN

- Further recommendations
  - Transparency
  - Congruence between state and federal law
    - Federal law needed to establish uniformity
    - State law may vary, consistently with needs for interchange and fundamental privacy protections
    - Harmonization between NHIN and HIPAA
  - Uniform and rigorous enforcement
  - Education and research

# Update to Privacy Laws and Regulations

- June 2007 letter, with one powerful recommendation
- “HHS and the Congress should move expeditiously to establish laws and regulations that will ensure that all entities that create, compile, store, transmit, or use personally identifiable health information are covered by a federal privacy law. This is necessary to assure the public that the NHIN, and all of its components, are deserving of their trust.”

# Protecting Sensitive Information

- February 2008 letter
- Recommendations:
  - NHIN design should permit sequestration of sensitive data types
  - Open and transparent process for identifying categories
  - Break the glass feature, with audit and ongoing privacy protections
  - Continuing study of categories, clinical decision support, segmentation technologies

# Personal Health Records

- Personal Health Records and Personal Health Information Systems (2006 Report Recommendation)
- Protection of the Privacy and Security of Individual Health Information in Personal Health Records (2009 Letter)

# PHR Recommendations

- Benefits of PHRs: record accessibility, record integration, patient self-management tools
- Need for security and privacy protections adequate to protect trust
- Importance for consumers of transparency and choice
- Need for interoperability and transferability of data
- Need for consumer education

# Secondary Uses of Data

- Enhanced Protections for Secondary Uses: A Stewardship Framework (2007 Report); 2008 Stewardship Framework
- Necessary protections
  - Attention to HIPAA requirements
  - Importance of good stewardship practices
  - Different concerns raised by specific categories of uses
    - Research
    - Quality measurement, reporting, improvement
    - Public health
    - Commercialization

# Data Stewardship Principles

- Accountability and chain of trust
- Transparency about uses
- Adherence to fair information practices
- Data quality and integrity
- Security and audit capabilities
- For uses outside of HIPAA protection, required consumer authorization, especially when data are used commercially

# Data Stewardship: specific identified concerns in 2007 Report

- Need for clarification of permissible uses for health care operations
- Need for clarification of business associate responsibilities and chain of trust
- Need for transparency about data uses for public health purposes
- Need for consistency in principles governing the use of data for research
- Need for an overarching set of federal privacy protections
- Importance of enforcement of anti-discrimination laws

# Major Achievements of these Letters

- Extension by Congress of HIPAA protections to business associates
- Further definition of health care operations and limitations on data used for these purposes
- Ongoing study of segmentation technologies for HIE
  - ONC Policy Committee (today!)
  - NCVHS forthcoming letter defining sensitive information categories
- Congressionally mandated study of extension of privacy protections to non-HIPAA covered entities
- Enhanced enforcement by OCR
- Efforts to develop transparent consent processes for consumers
- Announced study of governance by ONC

# Syndromic Surveillance

- Identification of a pattern of occurrences of potential public health significance
- Critical to early identification of potentially pandemic infectious disease and to bioterrorism surveillance
- Capacity may be required for compliance with the World Health Regulations (in force 2007)
- Requires large data sets, possibility of using de-identified data
- Little possibility for consent in advance, as the significance of data are only recognized after the pattern is identified
- Consumer risks: stigmatization, “witch” hunts, discrimination against members of groups identified with disease

# Use of Data in Research

- With patient registries, biobanks, it may be difficult to identify in advance likely research strategies
- De-identified data may be inadequate for research purposes
- HIPAA/Common Rule disconnect and recommendations to address this
- July NPRM proposals
  - Allow compound authorization for cases in which research-related treatment is contingent on use of data but research-related treatment is not contingent on participation in data or tissue bank
  - Seeks comment on whether requirement that authorization state specific purpose is impeding research

# HIPAA/Common Rule Disconnect

- HIPAA does not permit compound authorizations where research-related treatment is conditioned on participation in the research but not on allowing tissue to be banked
- HIPAA authorization requires a specification of “each purpose” of the requested use or disclosure of PHI
- Common Rule permits an IRB to waive consent requirement or alter consent element if it finds and documents that:
  - (1) Research involves no more than minimal risk;
  - (2) Rights and welfare of subjects will not be adversely affected;
  - (3) Research could not be practicably be carried out without waiver or alteration; and
  - (4) When appropriate, the subjects will be provided pertinent information after participation.

# Surveillance and Research: Common Ethical Concerns

- Difficulty of obtaining meaningful informed consent
- Need for public discussion, education, and oversight
- Importance of transparency about data uses to foster trust, avoid surprise
- Need for meaningful anti-discrimination legislation and enforcement
- Special attention to risks of group harms (e.g. Havasupai case)

More work for NCVHS!  
And we look forward to  
doing it . . . .