Impact of Implementation of the HIPAA Privacy Rule on Research

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Health Insurance Portability and Accountability (HIPAA) Privacy Rule designed to protect disclosure of individually identifiable health information.
Rule requires researchers outside a covered entity to obtain written authorization from each patient or to obtain a waiver to view identifiable health information.
Problem: Adverse Impact on Human Subject’s Research

Since implementation in April, 2003, anecdotal reports in news media suggest Privacy Rule hinders research.
PATIENT RECORDS:
Privacy Rule Creates Bottleneck for U.S. Biomedical Researchers

Outcomes Research

- Limiting ability to do outcome studies based on medical records – smaller hospitals dropping out
Pathology

- Need to re-contact subjects for each study related to stored tissue

FH, contact family members of dead subjects

- Genetic data and family history information – a question
Medical privacy law said to be chilling cancer studies
Scientists fight for fast access to patient files

- California Cancer Registry to recruit subjects into case-control studies shut down
- UC lawyers eventually able to negotiate waiver
PATIENT PRIVACY:
Rule to Protect Records May Doom Long-Term Heart Study

- International registry of brain injury medication delayed
- Refusal of many U.S. hospitals to divulge needed patient data

Intensive Care Med; Feb 2006
25 year old Minnesota Heart Study, based on review of medical records from hospitals in Minneapolis, under attack

Requires identifiers such as SSN to match hospital and death records

Minnesota’s privacy law requires each patient give consent
University of Michigan telephone survey now required to get written consent before call.

Other research shows consent rates plummet (96% → 34%) when surveys switch from phone to mail.
Single Institutional Data: U. Pittsburgh
Pregnancy Cohort Recruitment


Privacy Rule Implemented

2003 Jan-April: Enrollment shut down for 4 months

April 2003-2004: Average Enrollment: 2.5-5.7/week

Single Institutional Data: U. Michigan

Pre-Rule
Verbal Informed consent before phone interview

Post-Rule
Written consent before phone interview

Consent Rate
96.4%
34.0%

Arch Int Med 2005; 165:1125
Single Study Data: SELECT Trial

Post-Rule

Revision of post-rule procedures

Effect

↓ 72.9% subject accrual
↓ 3x staff time/recruitment

Recruitment back up
↑ 30% staff time/recruitment

Cancer 2006; 106:474
Single IRB Data: U. Wisconsin

<table>
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<th>Year</th>
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Annals Surgery 2004; 239:772
IOM – U. Pittsburgh National Survey of Epidemiologists

- 13 societies of epidemiology
- Web-based survey
- Anonymous responses
IOM U. Pittsburgh Survey: Flow Diagram of Participants

2805 Potential respondents/accessed website
429 ineligible

2376 Had IRB submissions since HIPAA enacted
849 ineligible

1527 Eligible
Survey Contents

1) Quantitative responses
   - Types of data collection
   - Pre- and post rule recruitment
   - Experience obtaining waivers
   - Experience obtaining de-identified data

2) Perceptions on 5-point Likert scale
   - Ease and difficulty conducting research under rule
   - Impact of rule on privacy/confidentiality
Survey Contents (continued)

3) Case Studies
   - Would your IRB approve?

4) Open-ended qualitative data collection
Most respondents perceived Privacy Rule’s impact to be strongly negative.

Concerns included variability in local interpretation.
Preliminary Overview of Results

- Added cost and delay were common concerns
News media stories suggest an adverse impact of the Privacy Rule on Research

Single institution reports confirm this
Summary

- IOM – University of Pittsburgh national survey of epidemiologists

- Will accrue data critical to assessing benefits and risks of HIPAA Privacy Rule