EFFECT OF HIPAA PRIVACY RULE ON RESEARCH STUDIES: EXPERIENCE AND CHALLENGES

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Topics

I. Summarize early experiences and problems

II. Describe effects of variable interpretation and implementation of HIPAA requirements

III. Need for ongoing assessment, opportunity to modify regulations, ideas for remediation, and benefits in joining other organizations

Initial Reaction to New HIPAA Regulations

- Only 17 months since compliance date (4/14/03) for most entities covered by HIPAA Privacy Rule

- IRBs, institutions, providers, and researchers confused

- Reports are mixed
  - over-reaction by some IRBs and institutions
  - since 2000: ↑ human subjects' requirements, ↑ IRB burden, and notable costs for HIPAA compliance
  - requirement for consent to include data in registries is impacting completeness of registration
  - industry studies may be less impacted

Problems: Release of Patient Information

- **Pre-HIPAA: complete medical records released to researchers with 'simple universal' written consent**

- **Post-HIPAA: more difficulty in obtaining medical records, and components of records often deleted**
  - **providers reluctant to release patient information**
  - **providers obliterate more information than required**
  - **universal simple release forms replaced by complex releases effective for shorter intervals**

Problems: Consent Forms

- **Pre-HIPAA: consent forms simpler, more standardized, & fewer legal requirements**

- **Post-HIPAA: consent forms longer, more institution-specific wording, & increased requirements for**
  - **witness**
  - **notarization**
  - **proof of kinship or power of attorney**
  - **copy of protocol**

Problems: Disclosure of Confidential Data

- **Pre-HIPAA: access to confidential data restricted to investigators directly involved in research project**

- **Post-HIPAA: expansion of entities to which confidential data from subjects can be disclosed**
  - **IRBs**
  - **funding agencies**
  - **adjunct investigators**

Problems: Database Access Restricted

- **Pre-HIPAA: investigator could**
  - **identify research subjects from hospital records**
  - **select controls for epidemiological studies from Centers for Medicare and Medicaid Services (CMS, formerly Health Care Financing Administration)**

- **Post-HIPAA: access to medical records for selecting study subjects generally not possible without waiver, and access to CMS databases for control selection no longer available**

Variable Interpretation of HIPAA by Different Medical Institutions

- **Prior to HIPAA: easier to implement standardized methods as designated in research protocols of multi-center studies**

- **Post-HIPAA: variability of IRBs in requirements or in granting waivers can cause problems in implementing standardized methods of multi-center studies due to differences among centers in**
  - **investigators' access to medical records**
  - **subjects' overall participation rates or participation in specific components of study**

Financial and Legal Impact of HIPAA on Research Studies

- **Financial:** increased costs of research studies due to additional time required for
  - preparing IRB packages
  - designing HIPAA-compliant medical abstract forms
  - training staff in HIPAA requirements
  - answering subject queries, obtaining agreement of hospitals to provide records

- **Legal:** some institutions express concern about
  - risk of federal audit ⇒ may preclude IRB granting waiver

Need for Ongoing Assessment of Impact

- **Evaluate Experiences of Individual Investigators:**
  to identify sufficient data and range of experiences to design survey instrument

- **Conduct Periodic Surveys of HIPAA Effects:**
  to ascertain extent, type, and pattern of problems

- **Join Other Organizations:**
  to inform investigators and professional organizations of survey results (*e.g.*, impact of HIPAA on research)

Opportunity to Modify Privacy Rule Annually

- **Must Document Objectively Any Adverse Effects:**
  requires systematic data collection & documentation of repeated problems; anecdotes are insufficient

- **Advantages of Joining with Other Organizations:**
  results from standardized, large-scale surveys would clarify extent, type, and pattern of problems; benefit of enhanced communications and joint reporting to DHHS

- **Subcommittee on Privacy and Confidentiality of the National Committee on Vital and Health Statistics Hears Testimony Regularly to Advise DHHS**

Possible Remediation Measures - I

Problem	Potential Solution
• Complexity of consent forms	• AAMC & ACE press DHHS to provide simplified template for universal record release
• Too many parties given access to confidential information	• AAMC & ACE press DHHS to limit access (IRB, funding agencies, 'business associates,' etc. should not have access)

Possible Remediation Measures - II

Problem	Potential Solution
• Differential interpretation of HIPAA requirements	• DHHS, AAMC, ACE, & journals educate IRBs on HIPAA requirements
• Falling participation rates are major cause for concern	• DHHS, AAMC, ACE, others educate IRBs to reduce unnecessary barriers
• Institutional unwillingness to grant waivers	• DHHS proactively reassure institutions & encourage granting waivers