

**U.S. EPIDEMIOLOGICAL RESEARCH
SINCE IMPLEMENTATION OF HIPAA:
ISSUES AND IMPLICATIONS**

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Outline of Presentation

- I. Early experience and problems**
- II. Cross-cutting issues: impact on participation rates; financial and legal issues**
- III. Ongoing assessment of impact of HIPAA**
- IV. Possible remediation measures**

Initial Reactions to HIPAA

- **Early days – only 6 months has passed**
- **Reports are mixed**
 - **ongoing studies may be less influenced**
 - **industry may be less impacted**
 - **new studies encountering some difficulties**
- **Different and variable interpretation by IRBs and hospitals**

Problem: Database Access Restricted

- Prior to HIPAA: could identify
 - controls from Centers for Medicare and Medicaid Services (CMS, formerly HCFA) databases
 - subjects from hospital records
- Since implementation of HIPAA: access denied
 - to CMS databases for control selection
 - to hospital records without a waiver (IRBs variable in granting waivers)

Problem: Variable Access to Medical Records of Individual Subjects

- Prior to HIPAA: universal simple release form generally accepted, but epidemiological studies impacted by
 - signed release effective for shorter intervals
 - increasing costs to obtain records
- Since implementation of HIPAA: variable access to records, notable complexity of release forms, and increased requirements for subjects to
 - designate specific record components for release
 - absolve hospitals from liabilities, responsibilities, damages and claims arising from release of record information
 - recognize hospital's right to deny or revoke a release

Problem: Increasing Length and Complexity of Consent Forms

- Prior to HIPAA: consent forms
 - generally simpler and more standardized
 - fewer legal requirements
- Since implementation of HIPAA: forms include more institution-specific and/or expanded wording
 - increased requirements for witness, notarization, proof of kinship/power of attorney
 - copy of protocol; dates of treatment, expiration of authorization

Problem: Expanded Disclosure of Confidential Data to More Entities

- **Prior to HIPAA: access to confidential data restricted to investigators directly involved in research project**
- **Since implementation of HIPAA: expansion of entities (IRBs, funding agencies, adjunct investigators) to which confidential data from subjects can be disclosed**

Decline in Participation

- Factors that may cause decline in participation:
 - unwillingness of IRB to grant waiver ⇒ investigator can't identify eligible subjects
 - lack of access to medical records ⇒ investigator can't confirm diagnosis, ascertain 'exposure'
 - length and complexity of consent form ⇒ subject may not understand or object to one component
 - expanded disclosure of confidential information ⇒ subject may refuse participation

Financial and Legal Impact

- **Financial**: increased costs from additional time for
 - designing forms and training staff in HIPAA requirements
 - preparing IRB packages
 - answering subject queries, obtaining agreement of hospitals to provide records
- **Legal**: some hospitals have expressed concern about
 - risk of federal audit \Rightarrow may preclude hospital IRB from granting waiver

Ongoing Assessment of Impact

- Continue to Evaluate Experiences of Individual Investigators: goal is to identify patterns
- Conduct Survey: goal is to prepare and administer standardized data collection survey instrument when patterns have become apparent
- Communication with Members of Epidemiological Organizations: goal is to keep epidemiologists apprised of impact of HIPAA on research

Possible Remediation Measures - I

Problem

- Database access
- Complexity of consent forms
- Too many parties given access to confidential information

Potential Solution

- Re-examine granting access
- Provide simplified template for universal record release
- Limit parties given access (no need for IRB or funding agencies to have access)

Possible Remediation Measures - II

Problem

- **Differential interpretation of HIPAA requirements**
- **Falling participation rates**
- **Institutional unwillingness to grant waivers**

Potential Solution

- **Clearer communication of HIPAA requirements**
- **Education by DHHS of IRBs, hospitals, etc.**
- **DHHS should proactively reassure institutions**