

Policy Forum - HIPAA and Beyond

ACE Policy Committee Response

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Once upon a time...

- No IRBs
- No informed consent
- No professional ethics code

1974 Privacy Act (45CFR46) ‘The Common Rule’

- Governs the conduct of *federally* funded human subjects research.
- System of institutional assurances to protect human subjects.
- Requires Institutional Review Boards (IRBs).
- Requires informed consent from participants.

1974 Privacy Act

- Gordis, Gold, Seltzer - 1977 in AJE
 - “a major threat to epidemiologic...research”
- Little evidence of violation of privacy by epidemiologic research.
- Documentation of epidemiologic studies that have benefited medical care and the public health.

Increased concerns for privacy in the 1990s

- Computers
- Electronic transmission of data
- Began in Europe in early 1990s
- ACE became involved through efforts of its Policy Committee

ACE Policy Statement on Health Data Control, Access, and Confidentiality

- Open debate and discussion within Policy Committee, Board, and membership.
- Background of problem.
- Nine principles.
- Sought balance between individual right to privacy and societal benefits of epidemiologic research.
- <http://www.acepidemiology.org/policystmts/DataAccess.htm>

ACE Impact on Policy

- Focus on issues important to the practice of epidemiology rather than on health and medical practices and procedures.
- Usefulness of open discussion and attention to policy within the profession.
- Value of joining with other organizations to increase impact (e.g. SER, AAMC).

HIPAA -April 14, 2003

- Originally conceived as broad legislation that required administrative simplification provisions for ‘portability’ of health information and insurance in the electronic age.
- Part of initiative was to pass privacy legislation. Responsibility fell to DHHS if Congress failed to do it in 3 years.

HIPAA - The Privacy Rule - New?

- Adds to Common Rule
- Applies to all research
- Requires specific authorization in addition to informed consent
- Authorization limited to specific use
- Defines specific identifiers as ‘personal health information’ (PHI)

References for details...

- Annas GJ. HIPAA regulations - a new era of medical record privacy? NEJM 2003;348:1486-90.
- NIH. HIPAA Privacy Rule.
<http://privacyruleandresearch.nih.gov>
- Hiatt RA. HIPAA of 1996: The end of epidemiology, or a new social contract? Epidemiology 2003;14 (in press, November)

Exceptions

1. PHI is 'de-identified'
2. PHI is disclosed as 'limited' dataset
3. IRB or Privacy Board waives authorization
4. Uses solely to prepare a protocol
5. Information of deceased individuals
6. 'Grandfathered' in pre- 4/13/03
7. Disclosure required by law or for public health activities

What is happening post 4/13/03?

- We don't know much.
- New HIPAA industry
- Increased time with IRBs
- Access to potential participants more difficult (?blocked) - selection bias
- Fear of penalties making 'covered entities' cautious and conservative in interpreting HIPAA

Problems include...

- HIPAA does not preempt state law but provides a ‘floor’ of regulation
- Thus, no national standards
- Authoritative guidance from DHHS and Office of Civil Rights needed
- Burden on IRBs and likely over-reactions

What can we do?

- Read and understand new privacy regulations
- Work with local IRBs and ‘covered entities’ to establish reasonable procedures early
- Work towards new legislation
- Support and respond to AAMC survey
- Keep value of epidemiologic research in the public eye

AAMC HIPAA Impact Survey

- Provides systematic attempt to capture real world examples of impediments to *bona fide* research
- Individuals and institutions can respond electronically
- <http://www.aamc.org>
- ‘Costs’ of compliance
- Will be made available to DHHS as they develop formal guidelines for compliance with HIPAA
- May be useful in annual review of HIPAA and in formulating new legislation

American College of Epidemiology

- Policy Committee - Chair - Brian Strom
- Subcommittee on HIPAA - Chair - Hiatt
- Support of AAMC via Steering Committee
- Call for documented incidents of impediments to or blocked research to either Subcommittee or AAMC.
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What can we do?

- Our professional code of ethics includes:
 - Protection of privacy of participants
 - Provision of benefit from research
 - Maintenance of the public trust
- Pay attention to the relevance and applications of epidemiologic research
- Translate its value to the public

Questions?

- <http://privacyruleandresearch.nih.gov>
- <http://acepidemiology.org/policystmts>
- <http://www.aamc.org>