Alternative Views of the HIPAA Elephant

Research, Government, Patient, Lawyer

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Disclaimer

The following remarks represent opinions of the speaker and do not reflect the positions of any organization listed in the presentation or to which the speaker is affiliated

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It was six men of Indostan
To learning much inclined,
Who went to see the Elephant
(Though all of them were blind),
That each by observation
Might satisfy his mind

John Godfrey Saxe (1816-1887)

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Four positions and perspectives: each of which I occupy at certain times – in decreasing order of frequency

Research -- CCEB at University of Pennsylvania

Government – Member, National Committee on Vital and Health Statistics

Patient – Fortunately not often, but potentially always

Lawyer – "You can take Russell out of the law but not the law out of Russell"

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Topic of this talk:

What are some of the features of the four perspective?

What issues should each perspective consider?

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Research -- examples of new burdens

ACE – Testimony to NCVHS November 20, 2003

“Epidemiologists report mixed experiences, apparently due to highly variable interpretation of HIPAA requirements by Institutional Review Boards (IRBs) and hospitals.”

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AAMC – Testimony to NCVHS, November 20, 2003

"Turning basic science advancements into clinical application and, ultimately,heatlh outcomes is threatened by dangerous overburdening the research endeavor. … Reseachers and Covered Entities proceed at their peril through bewilderingly complex pathways that appear to double back on themselves in terms of duplicative processes."

Particularly affected:

- **Population-based research**
- **Registry research**
- **Outcomes and public health research**
- **Genetic longitudinal**

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Access to medical records – personal experience

Regardless of "consent" or authorization approved by an IRB, the hospital claims:

The patient's signature is "too old"

The researcher must use the hospital special form

The researcher must pass through the hospital's IRB

(Nothing in HIPAA requires a new signature, a special form, or a local IRB approval to obtain access to a medical record for an authorizing patient)

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Issues for researchers

(1) How much of a perceived negative impact of HIPAA arises from the Privacy Rules as written (and interpreted rationally and fairly) and how much represents the reactions of regulated entities to the Rules?

(2) Are complaints about the Privacy Rules more appropriately directed at the Common Rule and how the Common Rule is and has been implemented by IRBs?

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(3) If patients, or those who would be patients, object to the use of their medical information (for research) without their consent, how can researchers meet the needs of these patients for privacy?

(4) Is tracking research disclosures by patient a “burden” or should many more aspects of patient care and information be tracked via automated data systems?

(5) Are long and confusing forms a new phenomenon resulting from HIPAA?

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Government

National Committee on Vital and Health Statistics

"As part of its responsibilities under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the National Committee on Vital and Health Statistics (NCVHS) monitors the implementation of the Administrative Simplification provisions of HIPAA, including the Standards for Privacy of Individually Identifiable Health Information (Privacy Rule)."

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Position of Office of Civil Rights as of HIPAA effective date

"We do not believe that the Privacy Rule will hinder medical research. Indeed, patients and health plan members should be more willing to authorize disclosures of their information for research and to participate in research when they know their information is protected. … The Privacy Rule both permits important research and, at the same time, encourages patients to participate in research by providing much needed assurances about the privacy of their health information." HHS, OCR, FAQ #302, 03/03/2003 http://www.hhs.gov/ocr/hipaa/

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NCVHS Recommendations on Research (March 2004)

(to Secy HHS) based on hearings on Nov 19,20.

"The witnesses at the hearing provided frank testimony describing the" *potential* "detrimental impact of the Privacy Rule's research provisions on research activities."

[The term potential appeared in a draft dtd Feb 11, 2004; Why and how was it removed from the final version?]

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NCVHS Recommendations (March 2004)

(1) Review preparatory to research

"…the Privacy Rule permits a researcher who is a workforce member of the covered entity to contact potential research subjects for the purpose of seeking an authorization as part of the covered entity's health care operations. Even though such contact is construed as coming within health care operations, the interpretation permits recruitment of potential research subjects (an element of research) without IRB approval, and thereby violates the Protection of Human Subjects Rule."

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(2) Authorization for future research

Unless the Privacy Rule interpretation is changed, it will be exceedingly difficult to compile research repositories, including repositories containing collections of biological specimens linked to medical records, which are essential to many forms of research. While it is clear from the January 2004 document, *Research Repositories, Databases, and the HIPAA Privacy Rule*, that a waiver of authorization could be obtained from an IRB or privacy board for disclosure from the repository, this additional step further complicates the process.

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(3) Reluctance of institutions to participate

"The witnesses also identified some areas in need of additional outreach and education initiatives to counteract the reluctance or refusal of smaller institutions to participate in research because of misunderstanding the Privacy Rule and the standards for the de-identification of individually identifiable information."

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(4) Accounting for disclosures

"Compounding the burden is the fact that many mandatory reports are submitted on paper because automated systems for filing the reports have not been developed. At the same time, the number of requests by consumers for an accounting of disclosures to date has been extremely small. The Committee will continue to examine the impact of the requirement to account for disclosures, and to consider whether to recommend changes."

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Current position of OCR (NCVHS meeting 09/01/2004)

OCR continues to listen to interested research representatives

OCR works with NIH (as liaison to the research community), as well as with Office of Human Subjects Protection.

OCR is formulating guidance based on the AAMC recommendations

OCR wants to ensure that unintended barriers do not occur

But – there is no HHS initiative to evaluate the burden of HIPAA on research

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Issues for Government to Consider

(1) Bias – Convenience sampling

“You have 20 IRBs you have to go through and 10 of them say "no," because this is the way we interpret the privacy rule and 10 of them say "yes," because this is the way we interpret the privacy rule. That is a detrimental impact on research because you have a biased sample. By the way that is a severe problem in research.” (Comments of R Localio. NCVHS Meeting March 4-5, 2004)

http://www.ncvhs.hhs.gov/040304mn.htm

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(2) Shifting and incidence of the burden of compliance

Covered entities want to shift the burden of compliance and risk of noncompliance onto research, but:

(a) covered entity cannot shift risk to researcher

(b) researchers are sometime not funded to absorb this burden

Federal initiative towards electronic medical record, but where is the initiative toward common electronic accounting for research participation?

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(3) Evidence-based vs faith-based beliefs

Someone must collect objective data on

(1) The impact of HIPAA as implemented

(2) The degree of variability of practices

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Patient

Most of us are researchers

Few of us work for (or represent) the government

Some of us are lawyers (some more repentant than others)

All of us are patients

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What do the patient polls say?

What do some patients say?

The Polls:

"After hearing a description about how medical records are used by medical researchers to study the causes of disease, 41% of those surveyed said that they would find it at least somewhat acceptable if their records were used for such research. If a federal law made it illegal for any medical researcher to disclose the identity or any identifiable details of a person whose health records had been used, 28% of those who were initially opposed to having their records used would change their position, increasing the acceptance of this practice to over half of those surveyed (58%)."

1994 Equifax/Harris Consumer Privacy Survey, Summary

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One patient (emphasis in original):

"I bought and paid for the medical care I have received.

I AM THE OWNER OF THE INFORMATION OF MY RECORDS, NOT YOU, NOT THE BUSH, NOT THOMPSON AND NOT POINDEXTER. I have already been a victim of your filthy so called researchers and data collecting companies, all of those that you are working with on giving our lives away to, all of those that have you in their back pockets. This is nothing less than psychological rape. YOU ARE A DOCTOR, PROTECT YOUR PATIENTS, DON'T BETRAY THEM FOR ONE MORE DOLLAR IN YOUR POCKET." S.S. 02/24/2003

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One editorial:

"If someone can threaten to post patient medical records on the Internet, what does it matter if doctors talk in whispers? … Policymakers cannot ignore the perception of patients that their medical privacy is threatened. … Patients can be granted greater control over their medical records. Why wouldn't they – whose records are they, anyway?"

Medical Privacy Rules. An Intolerable Breach. Editorial. The Philadephila Inquirer. Sunday. Dec 7, 2003, p. C6.

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Issues for “patients” to consider

(1) De-identified Data

Patients (consumers) have little or no objection to use and transfer of data if patient identifiers are redacted (removed or obliterated) (Hatch 2002)

So, when a patient objects, what exactly is the objection?

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(2) What do patients consider to be “research”?

What if hospitals use patient medical record data for

- Quality assurance?
- Utilization review?
- Patient safety?
- Peer review?
- Satisfaction surveys?

These activities are not “research” under HIPPA.

But do patients also object to these uses of their identified data for these purposes?

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(3) What if patients were excluded from research that might benefit them in terms of better quality of care, free care, or lower cost care because:

They were unaware of the research protocol, or

Someone else decided for them that they do want to participate in research, or

Someone was too busy to inform them about the research?

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(4)There is no such thing as a free lunch

Does a sick patient want to benefit from past use of medical information by researchers?

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LAWYER

There is one HIPAA, but 10,000 lawyers interpreting it

Some “legal” interpretations

(1) If there is any risk to the institution, then do not do the research

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(2) Recruiting telephone calls from a researcher and not from the treating physician might upset the patient and incite litigation

(3) Disclosure of the list of research protocols that might have included a patient under a waiver of authorization might easily fall into the hands of the plaintiffs bar

(4) When a covered entity gives a “limited dataset” to a researcher, there is a disclosure of patient identifiers that requires an accounting

(5) The correct answer to a HIPAA question can depend on which government attorney you ask

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Issues for the lawyer to consider:

(1) HIPAA is permissive (when may institutions release information), but is there a common law duty to inform patients about alternative treatments , including alternatives that arise only in the context of research protocols?

(2) How does the liability of a covered entity for a researcher's improper disclosure of identifiable patient data compare to the liability of risks of errors in medication, diagnosis, and surgery?

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Issues for researcher, government, patient and lawyer:

(1) Patient ownership:

The patients owns her records. But who owns the patient?

Hospital?
Treating physician?
Insurer (managed care organization, Medicaid, Medicare)?

(2) How much of the difference of opinion on HIPAA arises out of difference of opinion on ownership?

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CONCLUSIONS

(1) We still do not know what works for patients, covered entities, and researchers – we are all still blind and data are few

(2) Some entities (people) think they are “experts”

Overconfidence is most pronounced for hard questions--those that are answered correctly by relatively few people

(Lichtenstein and Fischhoff (1977)

(3) We are going to hear more about this before we hear less

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