DEVELOPING THE HIPAA-AWARE FINDING AID

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CONTEXT FOR PROJECT

Archives subject to the Privacy Rule (2001) promulgated under the Health Insurance Portability and Accountability Act HIPAA (1996) must comply with the requirements of the Privacy Rule. Absent an explicit set of requirements for archives in the Privacy Rule, entities subject to HIPAA have made different interpretations of how particular provisions of the Privacy Rule apply to archives within their entities. As a consequence, there has been much confusion among archivists and researchers over the different interpretations that have been made. Of greatest concern is how the holdings of archives regulated by the Privacy Rule may be accessed and used in reference and research.

PURPOSE

The purpose of the project is to define options for archival reference and research that are HIPAA compliant and that foster intellectual inquiry.

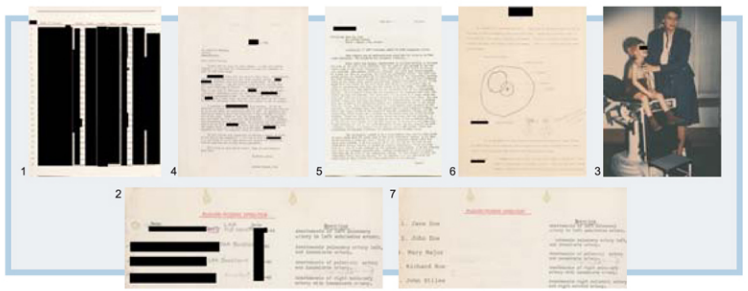
JOINT RESEARCH OBJECTIVES

Development of HIPAA- compliant guidelines for archival reference and research that will foster intellectual inquiry

Development of an Encoded Archival Description (EAD) finding aid model that is HIPAA compliant Privacy Regulations and a viable tool for archival reference and research

GOAL

The ultimate goal is to develop a set of uniform HIPAA-compliant guidelines for access and use of archival holdings and a standard for a HIPAA-aware finding aid that will enhance reference and research at archives regulated under the HIPAA Privacy Rule.



OPTIONS FOR HIPAA-COMPLIANT ARCHIVAL REFERENCE AND RESEARCH

This section focuses on the challenges faced by archives regulated by the HIPAA Privacy Rule and presents options for meeting these challenges. Special attention is devoted to how certain provisions of the HIPAA Privacy Rule impact reference and research at these archives. Recommendations are made for HIPAA-compliant modes of access and use that will foster intellectual inquiry.

HOW HIPAA IMPACTS ARCHIVES IN THE HEALTH FIELDS

Types of Entities Regulated by the HIPAA Privacy Rule

HIPAA Privacy Regulations apply to "covered entities" which include "health care providers", "health care clearinghouses" and "health plans" as defined in the Privacy Rule

Entities of the U.S. government are exempt from HIPAA (http://www.hhs.gov/ocr/hipaa/finalreg.html).

Covered entities may have covered and non-covered functions

The HIPAA Privacy Rule allows covered entities to have "hybrid" status by designating only those parts of their organization that are performing covered functions to be subject to the HIPAA Privacy Rule. This means that the parts that are not so designated are not subject to the HIPAA Privacy Rule. However, a covered entity must include in its designation all those parts of the organization that support the covered functions.

This last point is particularly important in hybrid covered entities that include archives. Each hybrid covered entity must make a determination as to whether all, part or none of its archives is part of its covered function(s).

To the extent the archives serves as a repository of individually identifiable health information that was created, received or maintained by the covered function, e.g., the hospital or clinical practice, the archives likely would be designated as part of the covered function. On the other hand, to the extent the archives does not serve as a repository for the covered function, e.g., the archives holds only the records of the non-covered function, the archives likely would not be part of the covered function. And, of course, the archives might serve as both, e.g., a repository for the hospital (covered function) and a

HIPAA Privacy Rule applies to archives designated as part of the covered function of the covered entity

Covered entity
Covered function
Covered archives

Major challenges to archives designated as part of covered functions

The Privacy Rule regulates access to and use of individually identifiable health information in any format and medium

- Individually identifiable health information is ubiquitous and may be found in every type of document held by archives
- Health law prior to the HIPAA Privacy Rule regulated access to and use specific record types at the document level.
- Archives have traditionally regulated access to and use of holdings by document type at the series and file levels while the Privacy Rule goes beyond these levels to individual documents and individually identifiable health information imbedded therein

The Privacy Rule applies to individually identifiable health information of living individuals and decedents in perpetuity with no provision for the length of time an individual has been

Health law prior to the HIPAA Privacy Rule provided protection to the health records of living individuals and did not extend to decedents

Scope of "individually identifiable health information"

DEFINITION: the Privacy Rule defines individually identifiable health information as health information that is created or received by a covered entity and relates to the physical or mental health or condition of an individual, the provision of health care to an individual or the payment for health care for the individual. The information must identify the individual or be able to be used to identify the individual.

18 IDENTIFIERS OF PHI NOT TO BE REVEALED

names; geographic subdivisions smaller than a state; all elements of dates (except year); telephone numbers; facsimile numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers; device identifiers and serial numbers; web universal resource locators (URLs); internet protocol (IP) address numbers; biometric identifiers; full-face photographic images; Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

http://www.hhs.gov/ocr/hipaa/finalreg.html

Compliance with the HIPAA Privacy Rule for protection of PHI requires archives within covered functions to do the following:

Manage all holdings at the level of Protected Health Information

Administer individual access and use of specific documents with PHI according to patron's status of authorization (or other allowable use or disclosure under the HIPAA Privacy Rule)

- Authorization made by subject of PHI or legal representative of subject
- Waiver of authorization by Institutional Review Board or Privacy Board
- Other allowed use or disclosures per HIPAA Privacy Rule
  - Limited Data Set
  - Research on decedents with specific representations
  - Health emergencies
  - Health care operations, teaching, payment

Administer individual access and use of documents with PHI when patron does not have authorization to access and use PHI or does not fit within any other allowed use for disclosure

- Archives must remove 18 identifiers of PHI from documents before they are provided to patron
- Archives must remove 18 identifiers of PHI from copies of documents provided to patron

Administer IRB/Privacy Board Review of Research Requests

RESEARCH OBJECTIVES AND FINDINGS OF HOPKINS TEAM

Focus of research:
Access and use of types of documents with PHI

Removal of PHI in types of documents

Meeting HIPAA Security Rule Requirements for access, use, and transmission of PHI

Publication of health information

Cost/benefit and risk/benefit analyses of HIPAA compliance requirements for access and use of PHI

Findings:
HIPAA Privacy Rule allows options for access and use of PHI

Options for access

Authorization from individual or legal representative for access to his/her PHI

Institutional waiver of authorization to research records containing PHI

Covered entities may use a Privacy Board or an Institutional Review Board (IRB) to grant a waiver of authorization for research of records that contain PHI.

Role of the Privacy Board and IRB in granting institutional waivers of authorization for research

NIH Fact Sheet on Institutional Review Boards and the HIPAA Privacy Rule
http://privacyruleandresearch.nih.gov/irbandprivacyrule.asp
Office for Human Research Protections (OHRP)
Public IRB Guidebook
http://www.hhs.gov/ohrp/irb/irb_guidebook.htm

Absent an authorization or waiver of authorization or some other specific exception allowing use or disclosure

Access may be granted only when 18 identifiers of PHI are removed from documents

Options for disclosing/publishing health information

De-identified health information may be published without authorization

Authorization must be obtained from individual or legal representative to release his/her PHI

Absent authorization to publish
The Privacy Rule is silent on how to proceed if authorization to publish may not be obtained.

The Office of Civil Rights has not issued a ruling on how to proceed if neither the subject of PHI nor the legal representative of that subject may not be located.

Absent a ruling from the Office of Civil Rights the following options may be considered (although there appears to be no express authority for either):

Request for declaratory judgment in federal court to publish PHI

Request a "No Action Letter" from Office of Civil Rights

Removal of 18 identifiers for access and use of documents
Integrity of original document must be maintained

18 identifiers are to be removed from surrogates of original documents

Usefulness of document after removal of 18 identifiers should be considered before removal of identifiers

Removal of 18 identifiers for access and use of documents (continued)
Impact to core intellectual content of documents must be considered before the 18 identifiers of PHI are removed

Removal of 18 identifiers may annul or severely diminish the core intellectual content of a document

Removing PHI from the page of a logbook in which the structure of the logbook format is designed around the 18 identifiers obliterates the intellectual content altogether
Image 1 of redacted logbook page

Removing PHI from page of logbook in which 18 identifiers do not determine content does not severely diminish informational/intellectual content
Image 2 of redacted OR logbook

Removal of PHI in visual documents may impair aesthetic/informational value
Image 3 of redacted photo

Diminishment of core informational/intellectual content varies according to type of document with PHI

Correspondence may lose significant intellectual content if the 18 identifiers are removed.
Image 4 of redacted letter

Core intellectual content of an operative note remains intact because the 18 identifiers are located in areas of the document that fall outside of the core content.
Images 5 and 6 of 2 operative notes

Pseudonymizing, the renaming and renumbering of 18 identifiers so as not to reveal identities of individuals, is labor-intensive option of dubious value

Does not enhance core informational/intellectual significance of documents
Image 7 of pseudonymized document

Removal of 18 identifiers of PHI requires highly knowledgeable, intellectually astute reviews of individual documents

Security requirements for access to PHI in digitized documents
Access without Privacy Board/IRB waiver of authorization or individual authorization or other HIPAA allowed use

Open mode of access to documents in which 18 identifiers have been securely removed or pseudonymized

Digitized surrogate of paper document
Born digital document

Access with individual authorization or Privacy Board/IRB waiver of authorization or other HIPAA allowed use

Secure mode of access to documents with 18 identifiers intact
Digitized surrogate of paper document
Born digital document

HIPAA compliant security requirements
Mode of tracking users with authorized access to PHI

Maintain physical security of computers with documents containing PHI

Means of authenticating users
User name
Password

Transmission security
Encryption of PHI

Adapting digital finding aids to meet compliance requirements of the HIPAA Privacy Rule
18 HIPAA identifiers must be removed at every level of description from collection to document level

Collection level description
Series level description
File level description
Document level description
PHI in document

FINAL PHASE OF RESEARCH (AUGUST SEPTEMBER 2006)

Focus:
Defining meta data standards for EAD-compliant finding aid

Descriptive standards for documents in which PHI has been removed.

Assessing security of redacted identifiers

Digital surrogates of original paper documents

Ways to remove PHI so that it may not be restored without authorization

Born digital documents

Ways to remove PHI so that it may not be restored without authorization

Assessing costs/benefits of options for protecting PHI

Removing PHI from documents in which 18 identifiers are imbedded in core content

Highly labor-intensive, costly use of expert staff

May not be financially and intellectually viable on a large scale for types of documents such as correspondence and photographs in which the PHI is an integral part of the content

May be viable for individual on-demand requests for a limited number of documents such as correspondence and photographs

Would primarily serve individual users with special requests

Costs of redaction services could be recovered through charge-back to users

Removing PHI from documents in which 18 identifiers appear in specific areas outside core intellectual content of document

Documents with PHI outside core content such as case files and operative notes may be considered for large-scale automated removal of 18 identifiers

Major start-up funding would be needed to develop and implement project for automated removal of 18 identifiers

Ability to access and use a large body of documents in which 18 identifiers have been removed would be cost-efficient over time for archives to administer and serve a wide audience of users

Source of funding:
NHPRC Electronic Records Research Fellowship Program 2005-2006

THE HIPAA-AWARE EAD FINDING AID

This section focuses on how Clinical Document Architecture (CDA), an evolving standard for electronic health records, may be incorporated with the Encoded Archival Description (EAD) standard to develop a HIPAA-aware finding aid for archives in the health fields.

MARRIAGE OF STANDARDS

Clinical Document Architecture (CDA)
Developed by Health Level Seven (www.hl7.org), the principal international standards organization in health care; Release 2 ANSI-approved, May 2005
Purpose: XML standard enabling secure maintenance, storage, transmission of semi-structured clinical documents within and between healthcare institutions.

Encoded Archival Description
Development began at UC-Berkeley, 1993; standard now maintained by Library of Congress (www.loc.gov/ead)
Purpose: XML standard for machine-readable, sharable text created by libraries, museums, archives and manuscript repositories

FORCES SUPPORTING THE ELECTRONIC HEALTH RECORD (EHR)

EHR is one of many acronyms meaning "computerized medical records". This is the electronic documentation of a patient's encounters with a healthcare system.

Pressures:
Prevalence of chronic disease → information management
Timely access to information
Simultaneous access, multiple users
Multiple settings of need

EHR status
Central theme of National Health Information Infrastructure (http://aspe.hss.gov/sp/nhii)

Only 21% of hospital systems capture 76-100% of patient info electronically
Majority duplicated on paper! (Lorence, Spink & Richards, 2002)

EHR content
Narrative text
(Patient histories, nursing visits, radiology reports, operating room notes, etc.)
Quantitative data
(Numeric: Allergies, immunizations)
(Images: MRI, CT scans)
Data in context of other data

De-identification
To comply with the Privacy Rule, text is considered de-identified if all of the 18 specified data elements have been removed. See Part 1. for list of data elements to be removed

Effect on research
De-identification issues:
Narrative text highly unstructured
Geographic subdivisions complex

The Clinical Document Architecture
www.hl7.org
International Standards Developing Organization (SDO) in healthcare
Academics, healthcare professionals, vendor reps from healthcare IT
HL7 and Institute of Medicine charged with standards development for US EHR

The Clinical Document Architecture
"To support reuse, exchange, and longevity .. In a system-independent manner"
Super-set of XML Document Type Definitions
Constraints define shareability

Example of CDA markup
Family history
Father had fatal MI in his early 50's
No cancer or diabetes.

Example of CDA markup

```
ClinicalDocument>
<StructuredBody>
  <title>Family history</title>
- <text>
- <list>
  <item>Father had fatal MI in his early 50's.</item>
  <item>No cancer or diabetes.</item>
  </list>
  </text>
</StructuredBody>
</ClinicalDocument>
```

(Health Level Seven, 2004)

Encoded Archival Description (EAD)
Information for Users of the Collection
Access
Collection is open for research.
Publication Rights: Property rights reside with the University of California. Literary rights are retained by the creators of the records and their heirs. For permissions to reproduce or to publish, please contact the Head of Special Collections and Archives.
Preferred Citation: Mildred Davenport Dance Programs and Dance School Materials. MS-P29. Special Collections and Archives, The UC Irvine Libraries, Irvine, California.

Encoded Archival Description

```
<descgrp>
    <head>Important Information for Users of the Collection</head>
    <accessrestrict>
      <head>Access</head>
      <p>Collection is open for research.</p>
    </accessrestrict>
    <userestrict>
    <head>Publication Rights</head>
      <p>Property rights reside with the University of California. Literary rights are retained by the creators of the records and their heirs. For permissions to reproduce or to publish, please contact the Head of Special Collections and Archives.</p>
    </userestrict>
```

Development of a HIPAA-aware Finding Aid
Collaboration between medical archives and medical informatics
First phase: Contemporary
Analysis of content, structure
200 de-identified contemporary clinical documents
Purpose: Determine distribution, frequency of 18 HIPAA-specific data elements
5 popular clinical document types with narrative

Raw data
Testing on Historic Documents
Testing on Historic Documents Prototypes of common document types including history and physical reports, physician letters, and operating room notes were reviewed at the Chesney Medical Archives, JHMI, during March 2006 and analyzed for content and structure. Thus far, comparison of these historic documents with contemporary, electronic clinical descendants reveals extreme consistency across more than 100 years.

Impact
This research will increase our understanding of the contents, the structure, and the safeguards necessary for access to Protected Health Information (PHI)

Twin set of templates
EAD-compliant
HIPAA-aware

Contributions
Better management and preservation of electronic and print-based records
Introduction of CDA to archivists
Better understanding of clinical document content and structure
Improved access and understanding for users
Improved sensitivity for future archiving
Test of the EAD!

Some believe publication of PHI may be allowed as part of the Privacy Board/IRB waiver or as part of the exception for research on decedents. Johns Hopkins Medicine's General Counsel has stated the following regarding this possibility:

"Although the HIPAA Privacy Regulations allow uses and disclosures of Protected Health Information (PHI) 'for research' if a privacy board or IRB grants a waiver of authorization for that purpose, it is not clear that the privacy board/IRB waiver 'for research' allows publication of PHI related to that research. Most covered entities interpret the privacy board/IRB waiver as allowing only those disclosures which are part of the research itself, and that publication of PHI in journals, general magazines, etc., is not part of the privacy board/IRB waiver 'for research'. However, even if one could argue that publication somehow is encompassed within the privacy board/IRB waiver 'for research', most covered entities do not believe they could publish PHI without an authorization of the subject or his/her personal representative. This is so because covered entities may only use or disclose the 'minimum necessary' PHI to accomplish the purpose of the disclosure, i.e., 'for research'. Thus, without clarification on this point from the Office o f Civil Rights ("OCR") - the agency charged with oversight of the HIPAA Privacy Regulations - historians, biographers and other researchers who wish to publish PHI in connection with publishing the results of their research must obtain the authorization of the subject or the subject's legal representative.

There is a special provision in the HIPAA Privacy Rule which permits uses and disclosures for research on decedent's information without a privacy board/IRB waiver or authorization by the decedent's representative. Some have argued that this special provision might be used to allow publication of PHI about decedents learned through that research. Yet the same problem discussed above faces covered entities, i.e., is publication of PHI part of 'research on decedent's information', and even if it is, would publication of PHI meet the 'minimum necessary' test for accomplishing 'research on decedent's information'? Again, without clarification from OCR, most covered entities do not believe they may allow publication without the authorization of the subject's legal representative."