More and Better Data for Research:
U.S. Health Data Content Standards

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AcademyHealth
Annual Research Meeting
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Presidential Executive Order
April 27,2004

With goal of ubiquitous electronic health records and a national health information infrastructure in 10 years:

New National Health Information Technology Coordinator in HHS with responsibility for strategic plan to:

"(i) Advance the development, adoption, and implementation of *health care information technology standards* nationally through collaboration among public and private interests, and *consistent with current efforts to set* health information technology *standards for use by the Federal Government;*

(ii) …."

www.whitehouse.gov/news/releases/2004/04/20040427-4.html

ONCHIT

www.hhs.gov/healthit

HIT Strategic Framework Goals
JULY 2004

- **Inform Clinicians**
  - Incentivize and reduce risk of EHR adoption

- **Interconnect Clinicians**
  - Foster regional collaborations, develop NHIN, coordinate Federal systems

- **Personalize Care**
  - Encourage PHRs, enhance informed consumer choice, promote use of telehealth systems

- **Improve Population Heath**
  - Unify surveillance systems, streamline quality and health status monitoring, accelerate research and dissemination of evidence

Report on Nationwide Health Information Exchange

- HHS issued "Request for Information" (RFI) in November 2004
  - Sought recommendations on the best way to achieve widespread interoperability of health information through a nationwide health information network (NHIN)

- Received over 500 responses totaling nearly 5,000 pages of information

- Report summarizing the responses to the RFI published in June 2005

  www.hhs.gov/healthit/rfisummaryreport.pdf

- Results used to prepare "Request for Proposal" (RFP)

HHS Requests for Proposals
June 2005

- Nationwide Health Information Network (NHIN) prototype architectures, operational models – up to 6 awards (ONC)

- State-based assessments/plans re: security & privacy laws/business practices – up to 40 awards (ONC & AHRQ)

- EHR compliance & certification process (ONC)

- Standards harmonization process (ONC)

HHS Secretary Leavitt's 500-Day Plan to Transform Health Care Systems

- Expressing a clear vision of health information technology that conveys the benefits to patients, providers and payers

- Convening national collaboration re: developing setting, and certifying HIT standards and outcomes for interoperability, privacy and data exchange

- Realizing the near-term benefits of health information technology in: adverse drug-incident reporting, e-prescribing, lab and claims-sharing data, clinic registrations, insurance forms

- Creating an integrated network of population data, genetic information, and medical records to accelerate discovery

- Improving the clinical research network

- Providing early warning of threats through improved domestic and international surveillance

Congress Drafting Health IT Bills

	McHugh - Gonzalez (H.R. 747)	Murphy - Kennedy (H.R. 2234)	Kennedy (S. 16)	Jeffords (S. 544)	Dodd (S. 1223)	Stabenow - Snowe (S. 1227)	Frist - Clinton (S. 1262)
Health IT Legislation Crosswalk							
Official Title	National Health Information Incentive Act of 2005	21st Century Health Information Act of 2005	Affordable Health Care Act	Patient Safety and Quality Improvement Act of 2005	Information Technology for Health Care Quality Act	The Health Information Technology Act of 2005	Health Technology to Enhance Quality Act of 2005
HIMSS Endorsed	TBD	Yes	TBD	Yes	TBD	Yes	Yes
Co-sponsors	40	19	18	9	1	2	2
Status	Referred to Energy & Commerce and Ways & Means	Referred to Energy & Commerce and Ways & Means	Referred to Finance Committee	Referred to Health, Education, Labor and Pensions (HELP)	Referred to Health, Education, Labor and Pensions (HELP)	Referred to Finance Committee	Not Referred Yet
Codifies ONCHIT	Yes	No	Yes	No	Yes	No	Yes
							Yes - mandatory federal program; voluntary for private sector
Promotes Standards Adoption	Yes	Yes	Yes	Yes	Yes	Yes	
Proposes Advisory Body	No	No	No	No	No	No	Yes

www.himss.org/Content/files/LegislationCrosswalk-109thcongress.pdf

NLM's Role in Health Data Interoperability Standards

Electronic Health Data Standards
(including Standard Vocabularies)

- Key element of the health information technology infrastructure for:
    - Effective decision support
    - Safe, evidence-based, and coordinated health care
    - Cost-effective care, assisted by robust market-place and increased/informed choice
    - More efficient clinical, public health, and health services research
    - Timely public health and bioterrorism surveillance

Types of Health Data

- Administrative health data
  - e.g., health insurance claims

- Clinical data
  - e.g., lab test results, problems, diagnoses, history and physical

- Public health data
  - e.g., disease prevalence, immunization rates, environmental monitoring

All potentially relevant to health services research

Data Content Standards include:

- Data elements, e.g., gender, presenting complaint
- Descriptions of entities, e.g., birth certificate
- Messages, e.g., medication order
- Allowable values for data elements, which can be entire *vocabularies*
- Mappings between different vocabularies
- Survey questions and any coded responses
- Guideline, protocol, and algorithm formats
- Information models that define the context for standards

Standard Clinical Data

- Enhanced ability to provide access to knowledge where clinical decisions are being made (e.g. guidelines, decision logic, etc.)

- Generation of research data as a by-product of health care

- Efficient exchange of data between health care and public health

NLM Long Range Plan

- Work with other agencies and organizations to support establishment, maintenance, testing and use of health data standards.

  - Active partners: *Office of the Secretary - HHS, AHRQ, CDC, CMS, FDA, other NIH components, VA, DoD, NCVHS, standards development organizations, vocabulary producers, professional associations*

- Use the UMLS Knowledge Sources and programs to facilitate maintenance and distribution of vocabulary standards.

Federal Standards Selection Mechanisms

- **HIPAA** (1996)- *Health Insurance Portability and Accountability Act of 1996 requires administrative standards*

- **NCVHS** - *National Committee on Vital and Health Statistics, a long-standing (50+ years) advisory committee to HHS expanded by HIPAA, recommends standards*

- **CHI** (2001) – *Consolidated Health Informatics project, a cross-agency eGov initiative designates U.S. gov't-wide clinical data standards; now part of the Federal Health Architecture*

- **Medicare Modernization Act** (2003) *- requires e-Prescribing standards; establishes Commission on Systemic Interoperability*

Recommended Steps to Achieving U.S. Health Data Standards (1990-2003)

- ☑ Establish a mechanism for designating U.S. Standards - HIPAA, NCVHS, CHI, MMA

- ☑ Pick best available as starting point - NCVHS, CHI

- ☑ Support development, maintenance, and low/no cost distribution – *ongoing NLM commitment*

- Coordinate development of selected standards to achieve non-overlapping, interlocking set

- Broaden participation in standards development

- Promote use and improvement

Standards Have Been Selected

- U.S. *National* Administrative Standards
  - HIPAA transactions and code sets
    www.cms.hhs.gov/hipaa/hipaa2/default.asp

- U.S. *Government-wide* Target Clinical Standards
  - CHI message and vocabulary standards
    www.whitehouse.gov/omb/egov/c-3-6-chi.html

- U.S. *National* Public Health Reporting Standards
  - PHIN (Public Health Information Network)
    www.cdc.gov/phin/index.html

NLM-led Support for Development and Maintenance

- **1999** – LOINC (lab tests/instrument observations) - contract support

- **2002** – RxNorm (clinical drugs) - direct development

- **2003** – SNOMED CT contract & license for U.S-wide use *(as distributed by NLM in UMLS)*

NLM No-Cost Distribution

UMLS® Metathesaurus®
a *Vocabulary* Database

- Preserves the meanings, hierarchical connections, and other relationships between terms present in its source vocabularies

- Adds certain basic definitional information about each of its concepts

- Establishes new relationships between concepts and terms from different source vocabularies

- Distributes many vocabularies in a common, explicit format

2005AB UMLS Metathesaurus (June 2005)

- 1,196,265 concepts
- 4,752,383 unique "strings"

   (Eye, Eyes, eye = 3)

- 5,578,532 source vocabulary terms
- 114 source vocabularies
- 17 different languages

Other UMLS Resources

- Semantic Network
- SPECIALIST lexicon
- Natural language processing programs
  - In combination with the Metathesaurus, powerful tools for interpretation/indexing of electronic full text

Letter from HHS Secretary to NCVHS
Sept. 2004

- "As you requested …, NLM to serve as the central coordinating body within HHS for PMRI [Patient Medical Record Information] terminologies. … several … mapping recommendations currently are being implemented by the NLM."

Coordination means:

- Uniform distribution of designated standard vocabularies through the UMLS Metathesaurus

- Reducing peripheral overlap and establishing explicit relationships between standard clinical vocabularies (e.g., SNOMED, LOINC, RxNorm)

- Aligning standard clinical vocabularies with standard record and message formats

- Mapping between standard clinical vocabularies and administrative code sets and/or other important vocabularies

NLM- HL7 Contract Arrangement
Sept. 2004

- Align HL7 message standard with standard vocabularies (*NLM-initiated)*
  - Specify which subsets of standard vocabularies are valid for particular message segments
  - Replace HL7-maintained lists of coded values with subsets of standard vocabularies, where feasible

- Create implementation guide(s) for transmitting an entire Electronic Health Record between systems *(on behalf of HHS)*

Mapping Projects planned/underway

- CHI standards – HIPAA code sets
  - SNOMED CT - ICD-9-CM, ICD-10-CM
  - SNOMED CT – CPT
  - LOINC – CPT

- SNOMED CT - "other" vocabularies
  - Medical Dictionary for Regulatory Affairs (MedDRA)
  - International Classification of Primary Care (ICPC)
  - Medcin

- Will require:
  - Robust testing/validation
  - Alignment of update schedules

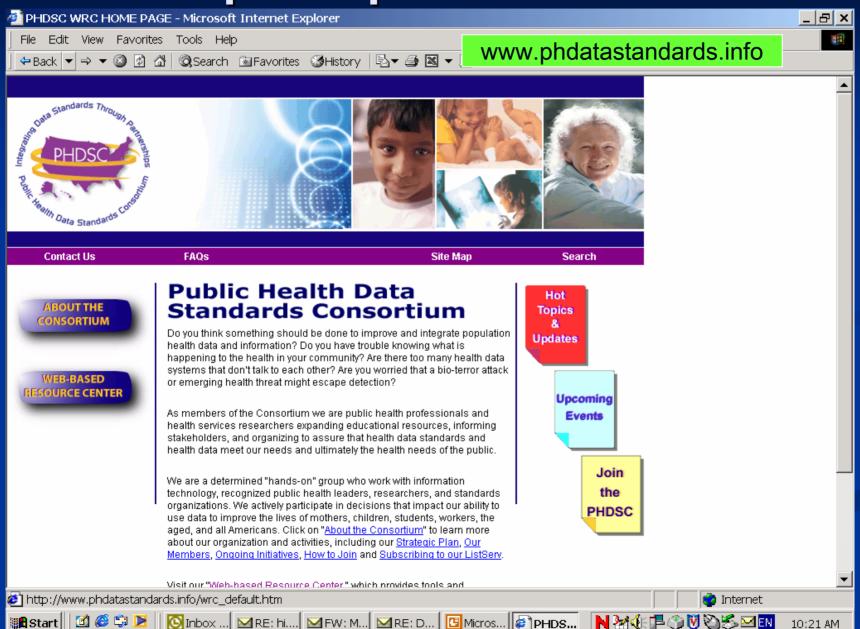- Draft mappings available in the UMLS Metathesaurus for testing by end of 2005

Key NLM Assumptions about Mappings

- Participants must include:
  - Producers of vocabularies on both ends; prospective users and recipients of the output, e.g., health care providers, payers, as testers and validators

- Mapping may/will prompt changes/corrections to content and adjustment to update schedules

- Mappings must be updated every time either end is updated

- Mappings will be distributed in the UMLS (not exclusively); use will be governed by terms applicable to both ends

- Mapping is still an R & D problem - it will take iteration to build highly functional maps

Accelerate Adoption and Use

- Promote testing use of standards by Federal partners, grantees, and contractors
  - *CDC's Public Health Information Network (PHIN) (www.cdc.gov/phin)*
  - *NIH emphasis on use in clinical research networks*

- Encourage manufacturers to include standard identifiers (e.g., LOINC) in device output/test kit packaging

- Collaborate with other HHS agencies to support demonstration/testing

Broaden participation: Public Health

Broaden participation: Clinical Research

Strategy for Adoption and Implementation of Standards

www.nlm.nih.gov/csi/csi_home.html

Commission on Systemic Interoperability Members - appointed late 2004

- **Scott Wallace**, JD, Chair, National Alliance Health IT

- **Simon Cohn**, M.D, Kaiser

- **Don Detmer**, M.D., Pres & CEO, AMIA

- **Vicki Gregg**, CEO, BlueCross BlueShield TN

- **Gary Mecklenberg**, Pres. & CEO, Northwestern Memorial Healthcare

- **C. Martin Harris**, MD, CIO, Cleveland Clinic

- **Herbert Pardes**, M.D., Pres. & CEO, NY-Presbyterian Hosp

- **Thomas S. Priselac**, Pres. & CEO, Cedars-Sinai

- **Ivan Seidenberg**, Chm. & CEO, Verizon of NY

- **Frederick Slunecka**, CEO, Avera McKennan Hosp

- **Bill Stead**, M.D. Assoc. Vice Chancellor for Health Affairs, Vanderbilt

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HIPAA Privacy Rule
Information for Researchers

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privacyruleandresearch.nih.gov

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Authorizations

Clinical Research

HIPAA Privacy Rule Booklet for Research

Institutional Review Boards

Privacy Boards

Research Repositories, Databases

Slide Presentations

Overview

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule is the first comprehensive Federal protection for the privacy of personal health information. Research organizations and researchers may or may not be covered by the HIPAA Privacy Rule. This website provides information on the Privacy Rule for the research community.

HIPAA Resources

- The Privacy Rule - Final Modification (PDF/TXT)

- Office for Civil Rights HIPAA Information (Medical Privacy Home Page)

- Office for Civil Rights HIPAA Guidance (PDF/RTF)

- Office for Civil Rights Summary of the HIPAA Privacy Rule (PDF/RTF)

- Center for Medicare & Medicaid Services HIPAA Information (Covered Entity Decision Tool)

Highlights

- NEW HRSA Issues a Privacy Rule Resource Guide for HIV Services Providers

- Clinical Research and the HIPAA Privacy Rule

- The Privacy Rule and Public Health

- Research Repositories, Databases

- NIH/AHRQ May 2004 conference on the HIPAA Privacy Rule and Research

Internet

Take Home Messages

- Health data standards have "arrived"; electronic health records are arriving

- Both will affect health care, public health functions, and the data available for HSR

- It's not too early (*or too late*) to get involved:
  - to contribute to standards development, testing, and refinement
  - to study the impact of standards on health care, public health, and clinical research

- If you work with electronic data, the UMLS resources might be helpful