

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL LIBRARY OF MEDICINE
SUMMARY OF THE MEETING OF THE
WORKING GROUP ON HEALTH DATA STANDARDS
OF THE BOARD OF REGENTS
January 26-27, 2009**

The Working Group on Health Data Standards of the National Library of Medicine's Board of Regents met on January 26 and 27, 2009 in the NLM Board Room, Building 38, National Library of Medicine (NLM), National Institutes of Health (NIH), Bethesda, Maryland.

MEMBERS OF THE WORKING GROUP PRESENT:

William W. STEAD, M.D. (Chair), Professor of Biomedical Informatics, Vanderbilt University

Carol FRIEDMAN*, Ph.D. Professor, Department of Biomedical Informatics, Columbia University

Gail GRAHAM*, Director, Health Data and Informatics, Veterans Health Administration

C. Martin HARRIS, M.D., Chief Information Officer, Information Technology Division, Cleveland Clinic Foundation (attended by telephone)

Stanley M HUFF, *M.D., Chief Medical Informatics Officer, Intermountain Health Care, Information Systems

Martin LAVENTURE, Ph.D., M.P.H., Center for Health Informatics, Minnesota Department of Health

Joyce A. MITCHELL, Ph.D., Professor, Biomedical Informatics, University of Utah

(* Indicates also current member of the NLM Board of Regents)

FEDERAL EMPLOYEES PRESENT:

Dr. Donald A. B. Lindberg, Director, NLM
Betsy L. Humphreys, Deputy Director, NLM
Vivian Auld
Olivier Bodenreider
Milton Corn
Kin Wah Fung
John Kilbourne
Rachel Kleinsorge
Lisa Lang
Clement McDonald
Stuart Nelson
Suresh Srinivasan
Jan Willis

Barbara Rapp
Sally Howe
Christine Ireland
Sheldon Kotzin
Steven Emrich (contractor)
Victoria Wilder (contractor)

I. CHARGE TO THE WORKING GROUP

In September 2008, the NLM Board of Regents approved the establishment of an ad hoc Working Group on Health Data Standards. The group was formed to review NLM's current activities related to health data standards for electronic health records, identify opportunities to advance the development and deployment of robust standards, and provide advice and recommendations that respond to the following questions:

- 1) Are NLM's current standards activities useful? Worth the resources devoted to them? Adequately funded?
- 2) Which opportunities to advance standards development and deployment play to NLM's strengths and capabilities? What resources would NLM need to pursue these opportunities?

The Working Group is expected to have one face-to-face meeting at NLM, with additional teleconferences and email contact as appropriate. The Chair of the Working Group will present an oral report to the Board in February 2009 and submit a written report in April 2009.

II. BACKGROUND

To amplify the Charge to the Working Group, Dr. Donald Lindberg and Betsy Humphreys, both at the meeting and in extensive background materials sent to the Working Group in advance of the meeting, defined the evolving role of NLM in health data standards.

NLM has a long history of supporting and conducting research, infrastructure development, and policy studies to promote the design and deployment of robust electronic health records with effective integrated decision support. Since the mid-1980s, the production and dissemination of the Unified Medical Language System (UMLS) resources has been a key part of the Library's strategy to promote the creation of more effective biomedical information systems and services, including electronic health records. Within this context, NLM has played a leading role in US government efforts to select and designate key health data standards for US-wide use; to support the ongoing maintenance and free dissemination of important clinical terminology standards; and to promote and enable efforts to make health data standards more useful and usable within the US.

As the NIH budget doubled (from FY1998 to FY2003), NLM substantially increased its investment in health data standards; from FY 2003 through FY2006, this was augmented by financial support from other federal agencies for these activities. In FY 2008, NLM spent more than \$14 million, virtually all from funds directly appropriated to NLM, on health data standards activities. The Library currently supports ongoing development and US-wide access to core

clinical terminology standards (SNOMED CT, LOINC, RxNorm) and directs efforts to align these terminologies with each other and with billing codes. The NLM is also an active player in expanding and developing standards to enable robust reporting of genetic/genomic tests and newborn screening. The Library also plays an important role in the training of informatics researchers and health information technology leaders who represent both the current and future community of researchers and practitioners in this field.

NLM's health data standards efforts have received policy support and recognition from the Department of Health and Human Services (HHS), the Department of Veterans Affairs (VA), and the Department of Defense. NLM was designated by the Secretary as the HHS central coordinating body for clinical terminology standards in 2004 and in late 2008 was asked to take the HHS lead in promoting international adoption of recently expanded US standards for genetic testing and newborn screening. NLM works closely with the Office of the National Coordinator for Health IT and many other U.S. government and private organizations to advance health data standardization. NLM is also the US Member of the International Health Terminology Standards Development Organisation (IHTSDO), the international, not-for-profit organization that purchased the IP rights to SNOMED CT in 2007 in order to provide international governance and promote international adoption of the terminology.

The NLM Long Range Plan for 2006-2016 recommends that the Library continue and enhance its standards efforts "in response to specific U.S. government priorities and feedback from those attempting to implement standards in current electronic health records and personal health records, regional health information exchanges, clinical research systems, and public health applications." The Plan also calls for continued NLM support for research, development, and policy studies that will help to define and develop the "next generation of electronic health records" and advanced decision support capabilities to assist the public, clinicians, and the public health workforce, and for continuing support for informatics research education.

Despite some noticeable progress over the past decade, including removal of some barriers and new Federal initiatives, deployment of robust standards-based electronic health records is not yet widespread in the US. With the recent enactment of the American Recovery and Reinvestment Act of 2009 (PL 111-5), Congress formally articulated its commitment to interoperable exchange of health care data and widespread use of electronic health records in the US by 2014. The Act provides support for substantial investments in health information technology infrastructure, including sizeable incentives for "meaningful use" of standards-based, certified technology, beginning as early as 2011.

III. OVERVIEW OF MEETING

The meeting began with a brief introduction and statement of the charge to the Working Group by Donald Lindberg, MD, Director of NLM, and review of the agenda and structure of the meeting by William Stead, M.D., Working Group Chair. NLM staff participating in the meeting spoke informally, giving their perspectives on their current activities, and their views of the challenges and opportunities facing NLM. Members of the Working Group asked questions and engaged in active discussion with staff, expanding the topics to include areas of NLM activity or responsibilities that could be modified or eliminated. NLM staff and Working Group members brain-stormed to identify a list of opportunities to advance standards development, adoption, and

use, with particular attention to activities that would draw upon and reinforce NLM's mission and strengths. Each attendee was then asked to flag the 3 items on the list they felt were most important. The Chair then divided the attendees into three smaller groups; two of which were asked to more fully develop the top two priorities on the list (a definition of the organization and functions of an office within NLM to better coordinate its activities both internally and externally with regard to the development, maintenance and dissemination of standards, and identification of tools, services and approaches to promote implementation of standards, starting with a use case based on medication resources). The third group was asked to review and summarize the remainder of the list, consolidating items where appropriate. The outcomes of these three smaller groups formed the basis for the group's findings and recommendations.

The Working Group was informed in its deliberations by the observations of the Chair, Dr. Stead, particularly with regard to his discussion of the findings and recommendations from the recently-released National Research Council report, "Computational Technology For Effective Health Care: Immediate Steps and Strategic Directions." Dr. Stead chaired the NRC committee that produced the report; the project was partially funded by the NLM with the goal of engaging the computer science research community in identifying how computer science-based methodologies and approaches might be applied more effectively to health care. The report was also included in the background materials for the Working Group.

Stead noted that the report calls for a fundamental rebalancing of the efforts in health care IT – both research and development -- to place a greater emphasis on providing cognitive support for health care providers, patients and caregivers. He suggested that the Working Group's review of NLM's role in health data standards be considered in this larger context.

In describing the four primary functions of IT in healthcare, as identified in the report – automation, connectivity, decision support and data mining -- Stead also suggested that the Working Group consider how NLM's standards and other efforts could contribute to the establishment in the broader health care system of meaningful archives of clinical data that that would amenable to subsequent re-interpretation. Widespread adoption and use of health data standards across all segments of the health care system would be essential to establishing such databases that would enable future advances in biomedical knowledge that would not be bound by today's interpretation of data.

IV. FINDINGS

In deliberating on the questions posed in its Charge, the Working Group reached consensus on several observations concerning NLM's current activities and opportunities:

- The recognition accorded NLM as a significant player in standards policy development and coordination is widespread. NLM's strong support of the UMLS resources, RxNorm and related medication resources, LOINC, SNOMED, and RefSeqGene are seen as enabling the Library to play an important role in systems development, current information services, and research.

- Most of the Library’s current activities in support of health data standards are useful and necessary – but not sufficient – to achieve NLM’s full potential for promoting standards-based EHRs and enabling decision support in clinical contexts.
- Current investments in pair-wise mappings from clinical vocabularies (e.g., SNOMED CT) to classifications/administrative codes (e.g., ICD) are not scalable, and as such should not be considered a long-term strategy for supporting systems that achieve interoperability. The UMLS will continue to be a valuable asset for associating vocabularies in the future since key functionalities -- synonymy, leveraging semantics in different systems – are seen as flexible and scalable. The Work Group felt that, in the long run, NLM should consider supporting research to identify data-mining strategies to use detailed clinical datasets to support public health reporting and billing.
- No current NLM activity was identified as over-funded. Some important activities of the Library were cited as suffering from significant under-funding. These activities include:
 - Standards policy and coordination,
 - Tools and services to facilitate adoption & effective use of standards by vendors, providers,
 - Outreach to those unaware of NLM products,
 - R & D related to development and effective use of standards, and
 - Standards workforce development and support.

V. RECOMMENDED PRIORITIES

The Working Group agreed that NLM already makes critical contributions to the nation’s health IT infrastructure. The ARRA HITECH provisions and the planned use of stimulus funds to promote “meaningful use” of electronic health records provide a propitious environment for NLM to make greater contributions to national goals. Intensified efforts can increase the likelihood that systems deployed over the next few years will be capable of improving safety and quality and of supporting efficient aggregation and exchange of electronic health information for health care, public health, and research. In light of the overall mission of the NLM, the Working Group recommended that NLM should:

- Reorient the NLM standards agenda to focus on interoperable health information that can address key deficiencies in the current generation of electronic health record systems.
- Implement an active feedback loop and enhanced support for users of UMLS and health data standards while U.S. policy is driving rapid deployment of electronic health records.
- Promote clinical and translational research use of standards adopted for routine health care.

- Effect the convergence of genetic and clinical standards needed to support personalized care.

VI. RECOMMENDED IMMEDIATE ACTIONS

To reach its full potential to support the deployment of robust interoperable electronic health records, the Working Group agreed that NLM should take the following actions immediately:

1. Establish a formal NLM Office for Health Information Interoperability
2. Work with appropriate federal partners and manufacturers of drugs, devices, and test kits to achieve standardized identifiers and vocabulary in labels, packaging, and in all data outputs of devices and test kits.
3. Engage with relevant standards developers, government agencies, and users to define and test how information models, clinical data elements, and value sets from standard vocabularies can work together to achieve health improvements in the near term.
4. Provide additional tools and services that help vendors and user sites to incorporate standards where they will have a positive impact.
5. Initiate a “UMLS Phase2” Research and Development effort to revisit the original UMLS goal of helping computer systems “understand” biomedical meaning in a very different environment, with a focus on the integration of patient data and medical knowledge to improve decision support, facilitate quality improvements, and promote effective public health.

VII. RECOMMENDED RESOURCE REQUIREMENTS

The Working Group discussed the resource needs of NLM for its health data standards efforts in general terms, based on the background materials provided prior to meeting. While there was agreement that additional funds would clearly be needed to fund the activities recommended by the group, both initially and on an on-going basis, no specific recommendations (with the exception of those for the Office for Health Information Interoperability) were made at the meeting.