

Interoperable Information:

Enhancing NLM's Contribution to the Nation's Health IT Agenda

**Final Report to the NLM Board of Regents
from its
Working Group on Health Data Standards**

William W. Stead, M.D., chair

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Executive Summary

Working Group Charge and Scope

In September 2008, the NLM Board of Regents approved the establishment of an ad hoc Working Group on Health Data Standard: to review NLM's current activities related to standards for electronic health records, to identify opportunities to advance the development and deployment of robust standards, and to provide advice and recommendations that responded 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?

Current Activities

In FY 2008, NLM spent \$14 million and allocated 49 FTE (13.6 NLM, 35.4 contract) to health data standards activities. Most of the budget supported free access and maintenance of terminology standards and ongoing maintenance and dissemination of the Unified Medical Language System (UMLS), a responsible use of available resources.

NLM's current health data standards activities are focused on: (1) value-added dissemination of standards via the UMLS and DailyMed; (2) support for development, maintenance, and free access to key terminology and content standards (LOINC, RxNorm, SNOMED CT, RefSeqGene); (3) standards policy development and coordination, particularly related to terminologies and code sets; (4) outreach and assistance for users of UMLS and terminology standards; (5) research and education.

The majority of NLM's current activities provide essential infrastructure for promoting standards-based electronic health records and for enabling effective decision support in complex clinical contexts. Any significant reduction in NLM's support for the UMLS resources or for maintenance of and access to key clinical terminology and reference sequence standards would be highly detrimental to national health IT priorities. NLM's existing plans for incremental steps to improve content development, dissemination, documentation, and user training and support activities are sound. More attention should be paid to defining specific objectives, identifying how to evaluate impact in real health care systems, and engaging appropriate partners in the evaluations.

Several important NLM activities have been significantly underfunded. These include standard policy development and coordination (despite some notable successes), tools and services that facilitate adoption and effective use of standards, outreach to those who could benefit from existing resources, research, and standards workforce development.

The American Revitalization and Recovery Act of 2009 (ARRA) funding may provide a short-term fix for research and the informatics workforce.

5. Recommended Priorities

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. As an agency that traverses the spectrum from basic biological data to consumer health information, NLM should:

5.1 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.

5.2 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.

5.3 Promote clinical and translational research use of standards adopted for routine health care.

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

6. Immediate Actions

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

6.1 Establish a formal NLM Office for Health Information Interoperability

6.2 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.

6.3 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.

6.4 Provide additional tools and services that help vendors and user sites to incorporate standards where they will have a positive impact.

6.5 Initiate a “UMLS Phase2” Research and Development effort to revisit the original UMLS goal (helping computer systems “understand” biomedical meaning) in the current electronic health record environment

7. Resource Requirements

NLM will need at least an additional \$10 million per year above the FY 2008 budget level for health data standards activities to carry out these recommendations with the speed required to make a positive difference on the US health IT agenda. This additional funding is essential if the Library is to move beyond support for standards maintenance and dissemination to more active engagement with the many stakeholders who must work together to realize the goal of interoperable electronic health data that can support safe, high quality health care, effective public health measures, and more rapid translation of research results into practice.

1. Introduction

The National Library of Medicine (NLM) has a long history of supporting and conducting research, infrastructure development, and policy studies to promote the design and use of electronic health record systems that can enable effective and efficient health care through secure data access and advanced decision support and generate useful clinical and health services research data as a by-product of care. Broad deployment of robust standards-based electronic health records will provide enhanced opportunities for NLM to fulfill its statutory mission to improve access to biomedical information for research, education, health care, and the public health.

NLM has supported informatics research and training since the early 1970s. A high percentage of today's informatics researchers and health information technology (IT) leaders are current or former NLM grantees, research contractors, and/or graduates of NLM-funded informatics research training centers, including many involved in developing and implementing health data standards and demonstrating their value in health information exchanges. For the past two decades, the production 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 robust electronic health records.

NLM launched and provided significant funding for a number of influential policy studies and reports by the National Academies that relate to electronic health records, including *Telemedicine: A Guide to Assessing Telecommunications in Health Care* (1996), *For the Record: Protecting Electronic Health Information* (1997), *Networking Health: Prescriptions for the Internet* (2000), and, most recently, *Computational Technology for Effective Health Care: Immediate Steps and Strategic Directions* (2009).

Within this context, NLM and its National Information Center on Health Services Research and Health Care Technology (established by Congress in 1993) have made significant contributions to Federal efforts to promote health data standards. Standardization of key elements of health data is critical to the efficient exchange, accurate interpretation, and aggregation of health data for patient care, prevention, and research – and can be an important enabler for effective decision support in electronic health record systems. NLM has been heavily involved in Federal initiatives to select and designate key health data standards for US-wide use; to support 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 U.S.

As the NIH budget doubled between 1998 and 2003, NLM substantially increased its investment in health data standards, adding to the list of important NLM infrastructure programs that may suffer when budget levels do not cover inflation. The Library currently supports ongoing development and US-wide access to core clinical terminology

standards (SNOMED CT, LOINC, RxNorm); directs efforts to align these terminologies with each other and with billing codes; and is an active player in expanding and developing standards to enable robust reporting of genetic/genomic tests and newborn screening.

NLM's health data standards efforts have received strong policy support from the Department of Health and Human Services (HHS), the Department of Veterans Affairs (VA), and the Department of Defense. Especially from FY 2003-2006, the Library also received some financial support from other agencies for these activities. 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 US government and private organizations to advance health data standardization.

The NLM Long Range Plan for 2006-2016 recommends that the Library continue and enhance its standards efforts "in response to specific US 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 barriers to access to standards and significant new federal initiatives to select and promote adoption of US-wide standards, deployment of robust standards-based electronic health records is not yet widespread in this country. Given what has been accomplished, the challenges that remain, and the then-imminent change in Federal Administrations, in September 2008 the NLM Board of Regents determined that it was a propitious time for a review of NLM's health data standards activities.

2. Working Group Charge and Process

At its September 2008 meeting, the Board approved the establishment of an ad hoc Working Group to conduct the review. Board Members Carol Friedman, Gail Graham, and C. Martin Harris agreed to serve on the Working Group. William Stead, M.D., a former Chair of the NLM Board, was asked to chair it. Stanley Huff, a current Member of the Lister Hill Center's Board of Scientific Counselors, Martin LaVenture, and Joyce Mitchell also served on the group. A list of the Working Group Members and their affiliations appears in Appendix 1 to this report.

The charge to the ad hoc Working Group on Health Data Standards was to review NLM's current standards activities, to identify opportunities to advance the development and

deployment of robust standards, and to provide advice and recommendations that responded to the following questions:

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

To assist the Working Group in its deliberations, the NLM staff prepared a detailed summary of NLM's current standards related activities and the resources devoted to them and answered a series of questions posed by the Working Group chair about NLM's standards-related products, their use, and immediate plans for enhancements.

With this as background, the Working Group held one face to face meeting at NLM on January 26-27, 2009. NLM staff members directly involved with standards related activities attended the meeting to respond to questions from the Working Group and contribute to the discussions. An outline of the Working Group's principal findings and recommendations was circulated shortly after the meeting for comment. It served as the basis for a preliminary report to the Board by the Working Group chair on February 11, 2009. As requested by the Board, the Working Group's final report is being submitted in April 2009 for review and action at the May 2009 Board meeting.

3. Scope of Activities Reviewed

NLM plays an active role in the development, dissemination, and use of a wide range of information and data standards, including standards for published literature, advanced imaging, clinical trials and other clinical research studies, basic scientific data, and the content of electronic health records. Although the distinctions among these kinds of standards are blurring, the Working Group focused its review on NLM standards activities that are directly related to the content of electronic health records and health care and public health transactions.

4. Findings – Current NLM Portfolio

4.1. Budget and Personnel

NLM began direct support for the development, maintenance, and dissemination of standard clinical terminologies as a new activity during the doubling of the NIH budget (FY 1998-2003). In FY 2008, NLM spent \$14 million and allocated 49 FTE (13.6 NLM, 35.4 contract) to health data standards activities. (Figure 1). These numbers include resources for ongoing development, dissemination, and user support for the UMLS resources, which NLM has issued at least annually since 1990.

In FY 2008, most of NLM's health data standards budget was devoted to basic support that makes terminology standards freely available and allows ongoing maintenance and

electronic dissemination of the UMLS resources. This is a responsible use of the level of resources that has been available to NLM over the past several years. Nonetheless, as

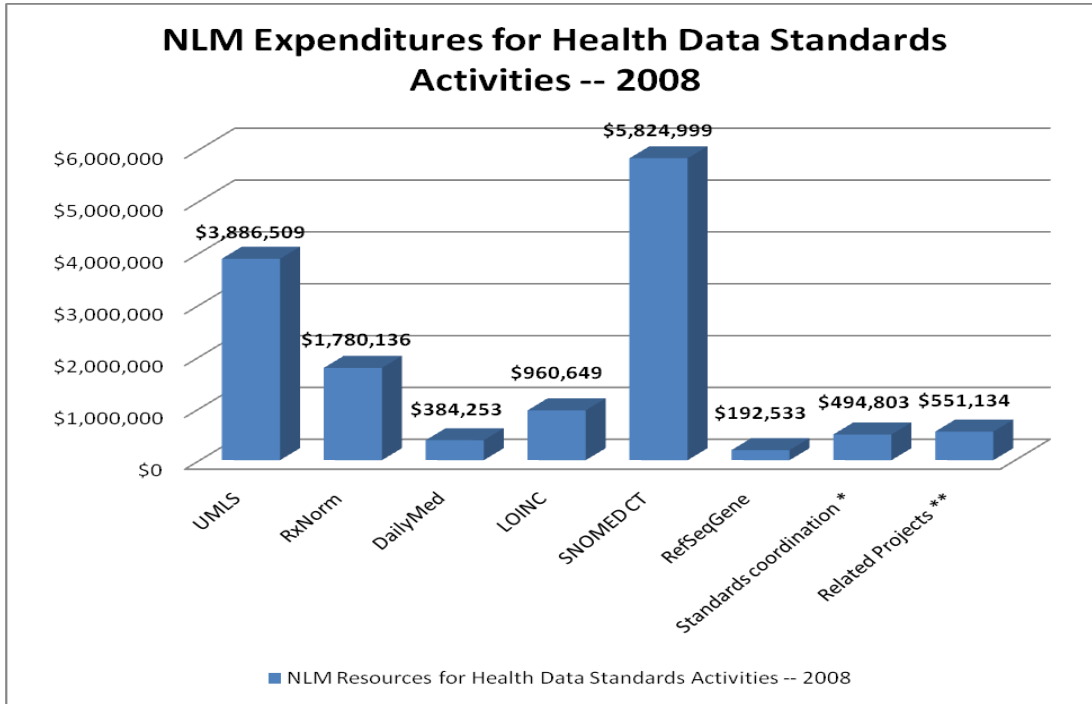


Figure 1

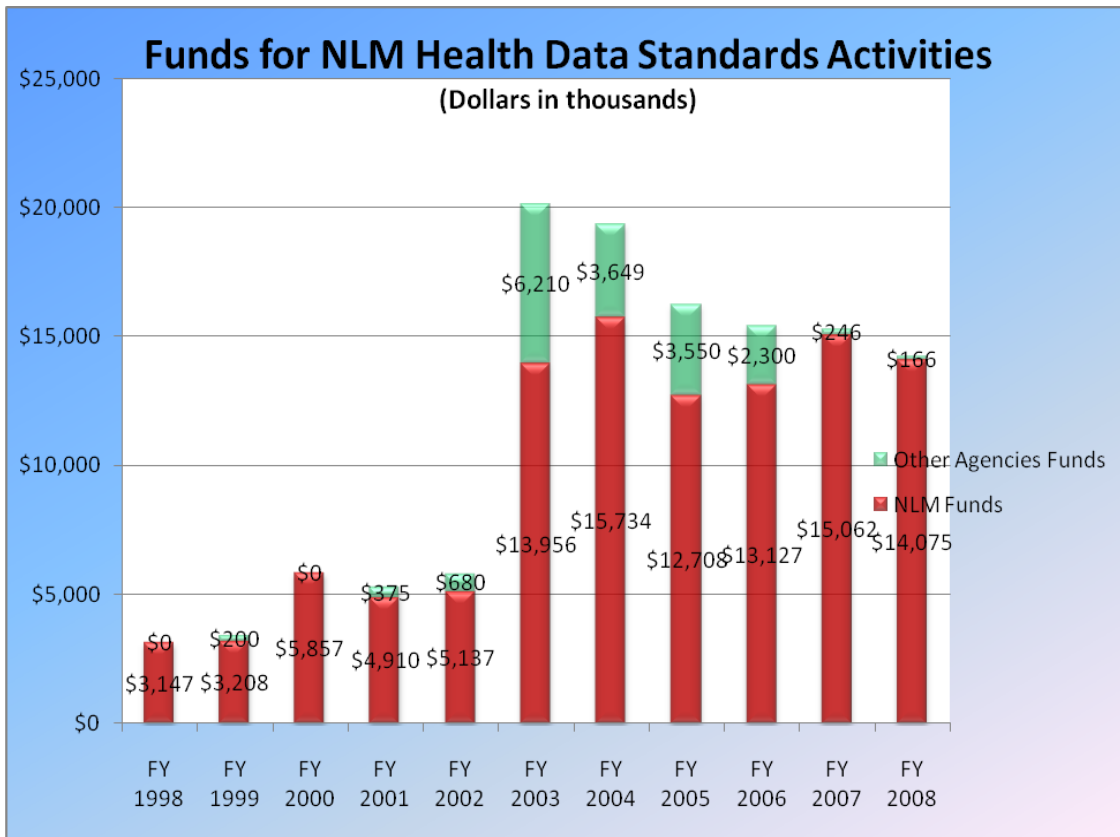


Figure 2

discussed in the next section of this report, many important activities have suffered from significant underfunding, which has had the effect of reducing the benefit realized from the funds that are being expended. This has been particularly unfortunate at a time when rapid national deployment of interoperable electronic health records is a high US priority.

NLM received substantial funding from other Federal agencies to support its health data standards activities from FY 2003-FY 2006. (Figure 2). More recently such funding has been minimal. For many policy makers, “standards” are not a compelling topic. Even among those who strongly promote the use of health data standards, there is often little understanding of the need for perpetual support for their ongoing development, maintenance, and dissemination.

NLM’s regular FY 2009 appropriation, a 2.5% increase over FY 2008, does not provide scope for increasing investments in the UMLS and health data standards activities. The Library’s share of stimulus funds received by NIH from the American Revitalization and Recovery Act of 2009 (ARRA) provide an opportunity for a short-term increase in funding for key research and development activities. Funds available under ARRA’s Health Information Technology for Economic and Clinical Health (HITECH) provisions may provide an opportunity for increased focus by NLM on activities that can help drive adoption over the next few years. The law reflects Congressional commitment to interoperable exchange of health care data and widespread use of electronic health records in the US by 2014, and provides incentives for “meaningful use” of standards-based, certified technology beginning as early as 2011. In its emphasis on near-term adoption, the ARRA funding will not meet the need for higher NLM base funding for ongoing standards maintenance and development that is informed by a tight feedback loop with electronic health record developers and users.

4.2. Summary of Current Activities

NLM’s health data standards activities can be categorized as follows:

4.2.1 Value-added dissemination of standards

Among its other attributes, the **UMLS Metathesaurus** is a value-added dissemination mechanism for key terminology, classification, and coding standards. It distributes them to more than 4,700 UMLS licensees in a common fully-specified format with consistent semantic categorization; establishes synonymous relationships among them; and facilitates their use in conjunction with UMLS lexical tools. The UMLS Metathesaurus and other UMLS resources provide key infrastructure for informatics research and systems development; for many current information services for researchers, health professionals, and the public; for health care and public health information systems; for terminology standards maintenance; and for validation of compliance with terminology standards. The UMLS resources have been highly influential and empowering for research and systems development involving information retrieval, natural language

processing and data-mining. They are heavily used in building clinical data repositories and in establishing central terminology services for health data and clinical research systems.

NLM's **DailyMed** website provides value-added dissemination of Structured Product Labels (SPLs) for medication products released by the Food and Drug Administration (FDA). (The content of the labels is created by the product manufacturers according to FDA specifications.) DailyMed provides both interactive and batch electronic dissemination of the labels and links them to standard clinical drug nomenclature and to related information in PubMed, ClinicalTrials.gov, MedlinePlus.gov, and other resources. DailyMed also allows manufacturers to validate the format of their SPLs prior to submission to the FDA. Usage of the DailyMed website and RSS feeds is very high.

4.2.2. Standards development, maintenance, free access

NLM supports the development, ongoing maintenance, and free US-wide and international access to three clinical terminologies/code sets that are designated US national standards: **LOINC**, **RxNorm**, and **SNOMED CT**. NLM also produces **RefSeqGene**, a reference standard for identifying the location of clinically significant genetic variation.

Since 1999, NLM has partially supported the maintenance, expansion, and free worldwide dissemination of **LOINC** (Logical Observation Identifiers, Names, Codes) under a contract with the Regenstrief Institute. NLM staff also assist in LOINC development. LOINC provides multi-part structured names and standard identifiers for observable entities, including laboratory tests, measurements, patient questionnaires, and clinical document types. LOINC has been a key component of federal efforts to develop standardized representations of genetic tests, newborn screening tests, and patient assessment instruments for recipients of long term care.

Since 2002, NLM's Medical Subject Headings Section has developed, maintained, and disseminated **RxNorm**, which provides standards names and identifiers for "clinical drugs" (active ingredient + strength + dose form) and links them to alternate names used in many different drug information sources (e.g., SPLs, FirstDataBank, etc.) and to drug product codes (i.e., National Drug Codes (NDCs)). RxNorm fills a need identified by the HL7 standards development organization - that is, for a standard that represents what a clinician prescribes rather than the specific product that is used to fill the prescription and provides a more efficient hook for decision support rules. It complements other drug terminology development efforts by the FDA, VA, and NCI.

In 2003, NLM completed negotiations with the College of American Pathologists (CAP) for a perpetual license for free US-wide access to **SNOMED CT** (Systematized Nomenclature of Medicine – Clinical Terms), which many Federal agencies helped to purchase and assumed responsibility for paying a multi-million dollar annual maintenance fee on behalf of the country. NLM began disseminating the vocabulary within the UMLS Metathesaurus in 2004. In 2007, ownership of SNOMED CT was

transferred to the International Health Terminology Standards Development Organisation (IHTSDO), formed by nine countries to provide international governance and promote international adoption of the terminology. NLM is the US Member of IHTSDO, with responsibility for licensing and distribution of SNOMED CT within the US. The change in ownership provided the US. with more favorable license terms, a reduction in the annual increase in its fee, and an effective mechanism for promoting standards coordination and free access to key standards in low-income countries.

In 2006, NLM's National Center for Biotechnology Information (NCBI) began producing **RefSeqGene**, a subset of the Reference Sequence (RefSeq) project, structured to provide genomic sequence of well-characterized genes as a reference standard for communicating information about the position of gene-related variation that is of clinical interest. Sequences of the RefSeqGene project provide stable, gene-specific genomic sequence including upstream and downstream flanking regions and can be used as reference values for genetic test results. RefSeqGene is therefore an important early step in providing appropriate infrastructure for personalized medicine that will require significant expansion over time. RefSeqGene is a recognized source of values for relevant HL7 messages. HL7 is a designated US standard.

NLM's ongoing support for maintenance and free access to LOINC, RxNorm, SNOMED CT, and RefSeqGene enabled (and now sustains) their status as US standards and also contributes to their international availability and use.

4.2.3 Standards Policy Development and Coordination

NLM has been a significant player in Federal standards policy development and coordination for more than 15 years, now working closely with the Office of the National Coordinator for Health Information Technology (ONC). In addition to taking a leading role in the development of the code set provisions of the HIPAA Transactions regulation, NLM was instrumental in developing and implementing a policy of federal support for ongoing maintenance and enhancement of key clinical terminologies to enable free use; in proposing and negotiating the US-wide license for SNOMED CT with the CAP; and in ensuring that the transfer of ownership of SNOMED CT to the IHTSDO did not reduce US rights or increase its annual maintenance fees. NLM helped to establish the IHTSDO principle of collaboration with other standards developers and was a strong proponent of its policy to provide SNOMED CT licenses free of charge in low-income countries.

NLM is the "central coordinating body for clinical terminology standards within the Department of Health and Human Services" (designated by HHS Secretary Tommy Thompson in 2004) and an ONC-designated Member of the Board of the Healthcare Information Technology Standards Panel. In 2008, HHS Secretary Michael Leavitt asked NLM to take the lead in promoting international adoption of US standards for genetic tests and newborn screening. NLM helped to develop and implement policy in these areas through participation in the American Health Information Community (AHIC) Working Group on Personalized Health Care.

Over the past few years, NLM's standards coordination efforts have been focused on reducing duplication in terminology standards development, attempting to align messaging and terminology standards, and developing useful mappings between clinical terminologies and statistical classifications and administrative code sets. The Library was instrumental in negotiations that led to the recently announced trial of cooperative laboratory terminology development between SNOMED CT, LOINC, and NPU, which is likely to lead to international adoption of US. standards for genetic tests. (http://www.nlm.nih.gov/news/loinc_npu_snomed_trial.html) NLM is involved in efforts to produce mappings between LOINC and CPT and between SNOMED CT and ICD-9-CM, ICD-10, and MeSH. It helped to launch the AMA's project to produce a SNOMED CT to CPT mapping.

4.2.4 Outreach, Training, and Customer Service/Assistance for Users of UMLS Resources and Terminology Standards

NLM has been slowly, but steadily expanding outreach, training, and customer service for UMLS and clinical terminology users over the past 5 years. The Library uses listservs, RSS feeds, Webcasts and in-person tutorials, "office hours," FAQs, a UMLS Community site to which users can contribute scripts and tools, and user group sessions at professional meetings to good effect and has been expanding the range and types of Web documentation and resources. In the case of RxNorm and LOINC, NLM staff members have provided specialized technical advice to the Centers for Medicare and Medicaid Services, the Agency for Healthcare Research and Quality, and to others engaged in federally sponsored e-prescribing pilots and health information exchanges.

4.2.5 Research and Education

NLM has been funding research related to health data standards for more than 30 years, but its real emphasis on research in this area began in 1986 with the Unified Medical Language System (UMLS) project. As a result of the UMLS project, standards-related research became one of the primary foci of NLM's Lister Hill Center. The UMLS project also supported standards-related R & D in a number of university-based informatics research groups, most of which were also NLM-funded informatics training centers and some of which were Integrated Advanced Information Management Systems (IAIMS) grantees. Many NLM informatics fellows participated in UMLS research and a number of them continued to work on standards-related research subsequently. Throughout the 1990s, NLM issued several special research grant and contract solicitations that emphasized data and imaging standards as well as use of high performance computing and communications and electronic health records. Via these mechanisms, NLM partially supported the initial development of LOINC and enabled establishment of the Indianapolis Patient Care Network, the first sizeable demonstration of the benefits of standards-based health information exchange.

NLM continues to conduct considerable intramural research and development related to UMLS resources, terminology standards, standard methods of knowledge representation, natural language processing, and tools that facilitate the use of standards in electronic

health records, including MyMedicationList <http://mml.nlm.nih.gov/> and the NLM Personal Health record research project. NLM also continues to provide grants for standards-related research projects.

4.3 Assessment of Current Portfolio

The majority of NLM's current activities provide essential infrastructure for promoting standards-based electronic health records and for enabling effective decision support in complex clinical contexts. Any noticeable reduction in NLM's support for the UMLS resources or for maintenance of and access to key clinical terminology and reference sequence standards would be highly detrimental to current US efforts to develop and deploy interoperable electronic health records.

Some minor trimming may be possible without significant negative effect, e.g., a possible reduction in the number of vocabularies that are routinely updated in the UMLS. Given the technical, synchronization and inter-organizational problems involved, the value of developing and maintaining purpose-specific pair-wise mappings between clinical terminology standards and classifications/administrative code sets should be re-assessed. The scaleable automated parts of mapping (using general semantic tagging and lexical techniques to suggest synonymy or mappings between related concepts, leveraging the semantic relationships present in the vocabularies being mapped) are already highly developed and in use in building the UMLS Metathesaurus, in automated indexing programs, etc. Purpose-specific, manually curated mapping between non-synonymous entries in different, independently evolving vocabulary systems is not a scaleable process. It is questionable whether such mappings will help to drive the adoption of clinical terminologies in electronic health records, as has been claimed. Research and development could lead to other, more efficient ways to derive higher level statistical or billing classifications from detailed information in clinical records. NLM should consider reallocating the time and resources devoted to pair-wise mapping efforts to something of more obvious direct benefit.

Given current appropriations levels, NLM's plans for incremental steps to improve content development, dissemination, documentation, and some user training and support activities appear to be sound. Regardless of whether NLM receives additional resources, the Library should pay more attention to defining specific objectives, identifying how to realize and evaluate their potential and actual impact in real health care systems, and then engaging appropriate partners (providers and vendors) in the evaluations.

Although NLM has been allocating available resources in a responsible and appropriate fashion, a number of important activities have suffered from significant underfunding at a time when additional emphasis could have significant positive effects.

- *Standards policy development and coordination* – Despite some important accomplishments, NLM has insufficient staff to take advantage of many current opportunities to promote standardization of key data elements at their source, e.g., in medical devices; to further reduce duplication of effort and

improve interfaces among standards; and to identify specific opportunities for demonstrating the value of standards in improving quality of care.

- *Tools and services that facilitate adoption and effective use of standards* – NLM has a few excellent projects in this area, including RxTerms, the clinical subset effort, and interfaces to standards such as RxNav (browser and application programming interface), but it is doing relatively little, given the clear need to provide more significant assistance to system developers and implementers.
- *Outreach* – Many who could benefit from NLM’s existing resources are either unaware of them or ill-informed about their characteristics and utility. For example, the genomics community may be reinventing tools that are already available from the Library.
- *Research and Standards Workforce Development* – Previous NLM research support (e.g., UMLS, HPCC, informatics research and training grants) was highly influential in developing today’s state of the art in knowledge representation, in standards development and use, and in electronic health records and health information exchange. NLM’s research and training initiatives also attracted outstanding talent to standards development issues. Relatively flat budgets for the past few years have led to significant cuts in NLM informatics research and training support. ARRA funding provides an opportunity for a short-term infusion of resources for these critical efforts.

5. Recommended Priorities

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 reorient and expand its health data standards efforts in support of national goals. Intensified efforts by the Library can increase the likelihood that the systems deployed over the next few years will be capable of improving safety and quality and of supporting efficient aggregation and exchange of electronic information for health care, safety and quality improvements, benefits determination, public health, and research.

As an agency with significant expertise, databases, and organizational connections that traverse the spectrum from basic biological data to consumer health information, NLM is particularly well-suited to speed the development of interoperable electronic health records. To increase its positive impact, the Library should:

5.1 Reorient NLM’s standards agenda to focus on interoperable health information that can address key deficiencies in the current generation of electronic health record systems.

The recent report of the National Academies’ Computer Science and Telecommunications Board, *Computational Technology for Effective Health Care*:

Immediate Steps and Strategic Direction, highlights significant shortcomings in current electronic health record systems. The report's observations are based on site visits to a number of organizations recognized as being in the forefront of implementing working patient record systems. The systems observed generally inundate clinicians with huge quantities of specific transaction data, without presenting a readily graspable higher level of model of patients, their problems, and current critical decision points. Clinicians using the systems spend inordinate amounts of time on documenting patient encounters, with little or no return in terms of useful decision support. Usually the systems are not flexible or customizable so it is difficult to make enhancements that could assist local groups of clinicians to achieve specific quality or safety objectives. There is a mismatch between computational techniques employed by today's health record systems and the scale of complexity of health information. The report notes that the health care sector makes relatively little use of information technology for connectivity - linking people to each other and systems; decision support - making choices clear; and data mining, discovering relationships among data.

NLM can help to address some of these shortcomings by shifting the goal of its health data standards efforts from standardization to interoperable health information that makes a demonstrable difference in health care quality. Interoperable data are data that can be assembled and interpreted in the light of current knowledge and re-interpreted as knowledge evolves. Standardization of health data is an important part of this larger goal, but should be focused where meaning is explicit and stable over time. NLM should work with others to define objectives for the impact of standards on real health systems, to measure actual use and effectiveness, and to make course corrections to achieve the objectives. Development of standards should be coupled with development of metrics to determine if technology that uses the standards achieves the desired result when combined with people and process in real health systems.

The UMLS resources and RxNorm already provide some key interoperability building blocks that can be used to extract a holistic view of the patient from a sea of detailed data. The standards supported and maintained by NLM can reduce documentation burden if assigned closer to the source of the data, e.g., on drug and test kit packaging, on devices and in their machine readable outputs, etc. NLM should focus on tools and resources that package standards useful in achieving quality improvement objectives.

5.2 Establish an active feedback loop and enhanced support for users of the UMLS and health data standards - while US policy is driving rapid deployment of electronic health records.

US government incentives for rapid implementation of standards-based electronic health records will create a propitious environment for capturing essential user feedback on beneficial improvements to the UMLS and other standards-related products and services – IF the Library positions itself as a credible source of tools and services that can help with standards implementation challenges.

5.3 Promote clinical and translational research use of standards adopted for routine health care.

NLM's position within NIH, its role as the developer of ClinicalTrials.gov, its chairmanship of the Trans-NIH Biomedical Informatics Committee, and its involvement with coordinating the informatics agenda of the Clinical and Translational Science Awards (CTSA) sites provide significant opportunities to prevent unnecessary divergence in the standards used in clinical research and health care. Common data standards will help to facilitate research use of health care data and to speed the translation of research results into clinical practice.

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

As a supporter and developer of standards for representing clinical data and genetic variation, NLM is in a unique position to promote useful convergence of such standards as knowledge of genetic factors affecting drug effectiveness and disease risk increases and the provision of personalized health care becomes more practical and imperative. The Library has been instrumental in linking a standard representation for the location of genetic representation to standards for recording and transmitting genetic test results. In the future, NLM may be able to connect standard representations of genetic variations that affect drug effectiveness to drug information standards.

6. Immediate Next Steps

NLM should take advantage of current opportunities to expand support for its health information interoperability agenda and to speed the advent of electronic health records that can improve health care, support public health, and facilitate research. To reach its full potential to support the deployment of robust interoperable electronic health records, NLM should take the following actions immediately:

6.1 Establish a formal NLM Office for Health Information Interoperability

NLM should increase its capacity to pursue key opportunities for development, promotion, and coordination of health data and knowledge, in conjunction with other government agencies, national and international standards development organizations, vendors, and implementers of electronic health records. The Library also should provide a visible point of initial contact for outsiders who have no reason to know or care that NLM's wide-ranging standards activities are distributed across different parts of its organization. Both of these requirements can be met by establishing a formal NLM Office for Health Information Interoperability and providing it with a defined mechanism for obtaining regular external input and advice from the many stakeholders affected by NLM's health data standards activities. To be effective, the new Office should have at least three additional staff members (beyond those currently engaged in standards coordination work for NLM) and a budget of at least \$500,000 in new funding to enable NLM to fund special projects to apply, evaluate, and improve standards to support

specific improvements in interoperability that can benefit health care, public health, or research. Use of the term “Interoperability” rather than “Standards” in the name of the Office will put the focus on the goal, instead of the means.

6.2 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.

As stated by the Commission on Systemic Interoperability in its 2005 report, *Ending the Document Game: Connecting and Transforming Your Healthcare Through Information Technology*, there is tremendous cost-benefit to be gained from standardizing health data at its source, rather than applying standardized names and identifiers to data that are generated without them.

NLM’s work with the FDA and VA to develop an integrated set of standards for various levels of medication and medication product data and to enable the production and dissemination of standard Structured Product Labels (SPLs) has provided most of the infrastructure needed so that medication products arrive with standard identifiers that easily connect to electronic medication information needed in clinical decision support. The Library should engage with its Federal partners to identify and complete remaining action items that are required to meet this goal. These include assignment of RxNorm names and identifiers prior to the initial release of SPLs and to more over-the-counter drugs.

NLM should cooperate with the Office of the National Coordinator, FDA, and other relevant agencies to develop a strategy for convening laboratory equipment and test kit manufacturers to develop an action plan that will lead to inclusion of LOINC (and, as applicable, SNOMED CT) identifiers in device outputs or test kit packaging.

NLM should also work with the FDA, and the Office of the National Coordinator to resolve intellectual property and maintenance issues that have stalled selection of a device nomenclature standard for the US and to encourage the use of standard unique identifiers for devices

6.3 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.

The primary goal of Health IT implementations should be to improve patient care and public health. Efforts related to health data standards should be pursued with that larger goal in mind. The standard terminologies that NLM develops and supports are just one of several types of content standards that must fit together to support accurate electronic exchange, interpretation, and aggregation of health data. Terminologies must fit the structure and granularity of the clinical data elements for which they provide valid values. Data elements must be defined for all the entities and transactions required to perform the

essential functions of health care, public health, and clinical research, as defined in a domain information model. NLM should be actively engaged in efforts to define and test how information models, clinical data elements, and value sets from standard terminologies should work together.

NLM should focus its initial efforts in areas where significant work is already underway to define and standardize relevant value sets. These include newborn screening, where the Library is already actively engaged with a range of agencies and other stakeholders, simplified reporting of reportable diseases, where the Centers for Disease Control and Prevention has been actively working with relevant stakeholders, and value sets that are being defined for Interoperability Specifications produced by the Healthcare Information Technology Standards Panel (HITSP). It would also be desirable for NLM to work with NIH and the CTSA sites to identify some compelling clinical and translational research scenarios to pursue.

6.4 Provide additional tools and services that help vendors and users to incorporate standards where they will have a positive impact.

Vendors and health care providers are clearly struggling to determine why, how, and where to begin to implement clinical terminology standards in their health IT systems. To help answer these questions, NLM should define a limited set of high value use scenarios; take any necessary steps to improve the coverage of standard terminologies for these uses; and then develop documentation, training, subsets, tools, etc. around them. Given their importance and the existing level of NLM involvement, two obvious candidates for initial scenarios are “end-to-end” medication knowledge management and standards-enabled functionality in personal health records, including connections to related medication knowledge.

“End-to-end” medication management is an example of what might be achieved in the near term through a coordinated effort. The goal would be to reduce the time and cost of deploying and updating medication decision support content by linking information published by drug developers, FDA, drug knowledge-base vendors, ClinicalTrials.gov, PubMed and other full-text resources. Key steps might include: extending RxNorm’s medication terminology framework of ingredients, dose forms, and strengths to include classes (e.g., as in NDF-RT); linking NDCs and products to RxNorm during the FDA approval process; and employing concept matching algorithms and existing direct and indirect links between RxNorm, NDCs, structure product labels, and commercial drug knowledge bases to automate links from provider site formularies to standard information about ingredients, dose forms, strengths, and classes. Test-bed sites would develop machine-assisted site-specific filters of alert rules (drug-drug, drug-allergy, etc.) by user role (clinician, pharmacist, etc.). Interoperability might be measured by elapsed time from issuance of an urgent drug update to its deployment in operational systems at the sites. Health care improvements could be measured by performance on relevant Leapfrog benchmarks (% of alerts overridden by role, % of adverse events following override, etc.).

NLM should establish a tight feedback loop with a network of healthcare providers, researchers, and vendors, who may initially focus on these scenarios, so that real world problems encountered in implementing and using standards to improve quality can be identified, analyzed, and addressed. If necessary, NLM should provide funding so that participants in the feedback network have sufficient bandwidth to provide useful input and work with the Library and relevant standards developers to resolve problems.

To further support implementation, NLM should promote and enable collaboration in development of subsets, value sets, national test sets, and clinical decision algorithms, in ways that complement related activities funded by the Agency for Healthcare Research and Quality. The new technical platform recently acquired by the IHTSDO is likely to provide a good vehicle for engaging a set of collaborators in defining useful subsets of SNOMED CT for a range of purposes.

While engaging the health IT community, NLM should also reach out to the genomics community to gain a better understanding of perceived obstacles to their use of the UMLS and related NLM products and to develop a strategy for overcoming these barriers.

6.5 Initiate a “UMLS Phase2” Research and Development effort.

NLM’s Unified Medical Language System (UMLS) project began in 1986 with the award of multiple R & D contracts to multidisciplinary teams at universities with informatics research programs. There was a similar multidisciplinary team at NLM. The overall UMLS goal was – and is – to help computer systems behave as if they “understand” biomedical meaning so that they can retrieve, integrate, and analyze related information from disparate sources, including electronic health records.

The time is right for a Phase2 UMLS R & D effort to revisit the original goal 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 achieve public health efficiency. A new UMLS initiative can take advantage of robust, regularly updated UMLS resources; designated US health data standards; many clinically relevant electronic knowledge sources; electronic health records; health information exchanges; and the World Wide Web – most of which did not exist when the original UMLS project was launched. UMLS Phase2 should again involve competitive contracts to multidisciplinary teams of informatics researchers (both senior and junior investigators) at multiple external sites, as well as a team at NLM. Once again the contracts should involve a combination of joint tasks and site-specific research activities.

A new effort of this kind is likely to have a highly beneficial effect on informatics research, production health information systems, and standards workforce development - similar to the impact of the original UMLS initiative.

7. Resource Requirements

NLM will need at least an additional \$10 million per year above the FY 2008 budget level for health data standards activities to carry out these recommendations with the speed required to make a positive difference on the US health IT agenda.

At least \$3.6 million per year should be allocated to UMLS Phase2 R & D contracts. NLM's portion of the NIH ARRA funds may be an appropriate source of support for initial 2-year contracts.

At least \$6.4 million per year is needed to support the staffing and resources required for: increased efforts to encourage standardization at the source, e.g., in device outputs, test kits, packaging; outreach and active engagement with those implementing standards; development, testing, and iterative refinement of value sets, subsets, and tools that facilitate use of standards and meaningful use of electronic health records; rapid enhancement of standards to fill gaps and solve problems encountered in wide deployment in operational systems; and expanded efforts to reduce duplication and enhance coordination among different types of content standards. These activities do not fit the stated purpose of the ARRA funds received by NIH, but they should be strong candidates for funding from the Office of the National Coordinator for Health IT under the ARRA HITECH provisions.

Additional funding should be built into NLM's base budget beginning in FY 2011 to ensure continuing support for:

- R & D that addresses basic questions about how informatics can improve health and
- Active engagement with – and effective response to feedback from – the many stakeholders who must continue to work together to increase the ability of electronic health records to improve health care safety and quality, public health effectiveness, and the translation of research results into practice.

APPENDIX I

NATIONAL LIBRARY OF MEDICINE BOARD OF REGENTS

WORKING GROUP ON HEALTH DATA STANDARDS

STEAD, William W., M.D. (Chair)
Professor of Biomedical Informatics
Vanderbilt University
2209 Garland Avenue
Nashville, Tennessee 37232-8340
615-936-1424
615-322-8844 (FAX)
bill.stead@vanderbilt.edu

FRIEDMAN, Carol, Ph.D.
Professor
Department of Biomedical Informatics
Columbia University
622 W. 16th Street, VC Building 5
New York, New York 10032
212-305-5399
212-305-3302 (FAX)
friedman.carol@columbia.edu

GRAHAM, Gail
Director, Health Data and Informatics
Veterans Health Administration
810 Vermont Avenue, N.W. (19F)
Washington, DC 20420
202-461-5874
202-273-9387 (FAX)
gail.graham@va.gov

HARRIS, C. Martin, M.D.
Chief Information Officer
Information Technology Division
The Cleveland Clinic Foundation
9500 Euclid Avenue, H-18
Cleveland, Ohio 44195
216-444-4246
216-444-8555 (FAX)
harrisc@ccf.org

HUFF, Stanley M, M.D.
Chief Medical Informatics Officer
Intermountain Health Care
Information Systems
4646 West Lake Park Boulevard
Salt Lake City, Utah 84123
801-442-4885
801-442-6066
stan.huff@ihc.com

LAVENTURE, Martin, Ph.D., M.P.H.
Center for Health Informatics
Minnesota Department of Health
85 E 7th Place
P.O. Box 64882
St. Paul, Minnesota 55164
martin.laventure@health.state.mn.us

MITCHELL, Joyce A., Ph.D.
Professor
Biomedical Informatics
University of Utah
26 South 200 East
5700 HSEB
Salt Lake City, Utah 84112
801-581-4080
joyce.mitchell@hsc.utah.edu

