NCVHS
Patient Medical Record Information
Terminology Analysis Reports

Prepared for
the National Committee on Vital and Health Statistics
Subcommittee on Standards and Security*

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Scope and Criteria
For Selection of PMRI Terminologies

A Report to the
National Committee on Vital and Health Statistics
Subcommittee on Standards and Security*

Version 3

December 23, 2002

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Contents

1. Introduction

This document describes the approach of the National Committee on Vital and Health Statistics (NCVHS) to scoping and selecting standard controlled terminologies for patient medical record information (PMRI). The identification of such an approach is the first step in the NCVHS's task of making recommendations to the Department of Health and Human Services on the creation/promotion of national terminology standards for PMRI. Recommendations regarding terminology standards are part of a larger undertaking by the NCVHS to study the issues related to the adoption of uniform data standards for PMRI and the electronic exchange of such information, as mandated by the HIPAA legislation of 1996. The NCVHS has already reported to the Secretary of HHS its recommendations regarding messaging standards.

The concepts in this report follow from the testimony before the NCVHS Subcommittee on Standards and Security on August 28, 2002, from pursuant review of the testimony and discussions at a subcommittee meeting on October 23, 2002, and from comments on two previous drafts of this document (dated November 15, 2002 and December 10, 2002). The concepts presented here provide the background and context for the gathering of further information from various stakeholders, including terminology developers, terminology users, information technology vendors, and industry experts. The subcommittee's recommendations on the selection and organization of standard terminologies will follow from the forthcoming discussion and information gathering.

The first part of the document emphasizes the importance of identifying specific requirements of and goals for terminology standards. This is followed by a general description of the proposed approach for standardizing controlled clinical terminologies. The last part of the document discusses the core element of this approach in more detail, and identifies relevant features and issues related to this element.

2. Identifying the Requirements for Standard PMRI Terminologies

The recommendations of the NCVHS regarding uniform data standards for PMRI, including terminology standards, must be made in the context of clearly identified goals for such standards. The recommendations represent nothing less than the *design of a national data standards system* for PMRI, and all successful designs follow from an understanding of the functional and operational requirements of the resulting system. In the case of terminology standards for PMRI, one may ask "what should specifically be enabled by the creation and adoption of such standards that is not possible today?" Although certain general goals have been identified in previous documents, such as *interoperability*, *data comparability*, *improved data quality*, etc., it is important to identify specific objectives in order to compare and evaluate proposed recommendations against clear design goals. The intent of this document is to provide example requirements and to suggest a framework for identifying an "official" set of requirements through further discussions and information gathering at the NCVHS.

2.1. Intermediate-Level Requirements

A more specific articulation of the goals for controlled terminology standards is important. Statements of such goals might include:

- Widespread availability of clinically specific terminologies to enable the development of electronic medical record systems that capture structured and coded clinical data in the course of patient care, and to reduce the costs of developing such systems.

- Widespread adoption of standards that enable two clinical information systems developed independently of each other to exchange clinically specific data that is structured and coded with no human intervention.
- Widespread adoption of standards that allow similar data to be aggregated from many independently developed information systems into a single, uniformly structured and coded data repository with no human intervention
- Standards that allow "computerized" decision support rules and clinical guidelines to be encoded just once and subsequently shared among healthcare facilities that are using different, independently developed information systems (without site-specific human translation)
- A terminology standards architecture that allows specific institutions or vendors to augment the set of standard concepts to accommodate local or urgent needs without "breaking" the standard, losing all interoperability benefits of the standard in their environment, or precluding the adoption of future, updated versions of the standard. For example, an architecture that allows the addition of locally specific terms (and the merging of these terms with subsequent versions of the standard terminology), as well as the addition of locally specific or task-specific classification hierarchies (again, allowing the merging of these structures with subsequent versions of the standard terminology).

It's worth noting that these requirements do not all suggest the same terminology-standards solution, nor are all of the requirements necessarily met by the creation/promotion of terminology standards alone (i.e. terminology standards are necessary but not sufficient elements). For example, enabling the development of electronic medical record systems that capture clinically specific data doesn't necessarily require *standard* terminologies to be widely available (just some set of clinically specific terminologies), whereas seamless exchange of structured and coded data among information systems does specifically require standards. Also, the widespread use of EMRs is not guaranteed by the availability of clinically specific terminologies alone (since difficult human-factors issues related to the capture of structured and coded clinical data may remain), nor does the sharing of decision support rules rely on terminology standards alone (a standard information model may also be required).

Nevertheless, it is important for the NCVHS to articulate requirements for a terminology-standards architecture at this level of detail and to prioritize the requirements with respect to importance and feasibility. It may also be useful to seek input from other branches of government or sectors of the healthcare industry to ascertain the appropriate requirements and expectations for a clinical terminology standard. This will enable the committee to truly understand the goals that motivate its terminology recommendations, as well as to lay out a phased approach to achieving all of the requirements over time.

2.2. Use Cases

Use cases are specific examples of the goals expressed by the intermediate-level requirements. As such, use cases are tools to better understand the intermediate-level requirements and to validate specific terminology recommendations against the requirements. Use cases also help to motivate the adoption of NCVHS recommendations by communicating their benefits in the most concrete terms. Examples of use cases related to some of the requirements listed above include:

- A patient is seen in the emergency department of a hospital. The documentation of this encounter is captured electronically and later transmitted to the office of the patient's primary care physician. There, the data is imported and integrated into the electronic medical record of the patient. Specifically, the diagnosis of kidney stones is added to the

patient's problem list, a prescription for a pain killer is added to the patient's medication list, and the results of several lab tests and a spiral CT scan are added to the patient's past medical history. The decision-support and reporting components of the EMR recognize these new data items and process them correctly. All this occurs automatically provided that both systems are compliant with the national PMRI standards.

- A public health biosurveillance program is implemented to detect a population's exposure to certain infectious organisms and chemical toxins. Each night, de-identified encounter data is uploaded from the information systems of most ambulatory care facilities in a large metropolitan area, and the data are aggregated and analyzed within a biosurveillance data repository. These data include presenting complaints, vital signs, reported symptoms, physician exam findings, and the results of diagnostic tests performed during the encounter. Because a single national standard exists for the structure and coding of clinical data, most vendors' systems export (as well as import) data in the appropriate format because there exists market demand to support this capability. The uploaded data are hence readily aggregated and analyzed using tools based on the national standard.

Obviously, many other use cases exist for the intermediate-level requirements listed above as well as for other requirements as yet unstated. As part of the upcoming information-gathering phase of the project, it may be useful to solicit specific use cases from the various stakeholders who are asked to comment (especially the users of terminologies and the vendors of information systems). This will not only identify specific requirements that may have been previously overlooked, but it will force the commenters to think through their stated requirements and thereby offer more useful and valid information.

3. The Proposed Approach to Organizing Terminology Standards

The approach entails promoting the creation and adoption of a "core" group of terminologies that, together, are sufficiently comprehensive, mutually consistent, and readily available so as to deliver most of the envisioned functionality of a national standard clinical terminology (i.e. with respect to the identified requirements). The approach also describes the relationship of the core group to certain related terminologies. The related terminologies include (1) terminologies that are neither suited nor intended for representing clinically-specific data, but that are standards for administrative, financial, or regulatory functions, and (2) prominent legacy terminologies that are intended for representing clinically-specific data, but, for one or more reasons, will not be included in the core terminology group.

3.1. Core Terminology Group

The central element of the proposed approach is a core group of terminologies with several important features.

- Together, the core terminologies should be sufficiently comprehensive to represent most of the clinically relevant information documented in the course of multi-disciplinary patient care. This information includes the observations of direct care givers (such as physicians and nurses), the assessments of specialists reviewing secondary data (such as radiologists and pathologists), and the output of testing machinery (such as lab analyzers and spirometers). The content of the core terminologies should also include relevant

abstractions of primary data (i.e. hierarchies) required for common data-analysis functions.

- The core terminologies should be sound with respect to recognized technical criteria, such as concept orientation, concept permanence, and non-ambiguity. Together, they should comprise a mutually consistent and cohesive whole that is created and maintained within a closely coordinated process. For example, the concepts in the core terminologies should map to each other in all appropriate cases and should reference each other in any formal definitions. Also, the creation of each new concept or term should be done in the context of the entire core terminology group, to prevent overlaps, gaps, and inconsistencies.
- The core terminologies should be developed and maintained via an open and efficient process that is responsive to the needs of myriad stakeholders in the healthcare system. At the same time, final editorial decisions should be made by professional experts who can maintain the desired technical properties of the terminologies while expanding the terminologies' domain coverage and maintaining the terminologies' respective scopes.
- The core terminologies should be widely available to participants in the national healthcare system in a manner that is economically and legally feasible for all of them. Also, the stated mission, organizational structure, and funding mechanism(s) of the body or bodies responsible for the core terminologies must be such as to instill confidence that the terminologies will continue to be widely available indefinitely. An essential feature of a true standard is widespread adoption, and this should not be impeded by excessive costs, intellectual property restrictions, or perceived risks.

3.2. Relationship of the Core Group to Important Related Terminologies

Certain terminologies outside of the core group bear consideration during the creation and maintenance of the core terminologies. These terminologies serve different purposes than the core terminologies, but are sufficiently prominent today and sufficiently related to the core (semantically) that the issue of mapping to these terminologies is of practical importance. At least two groups of such terminologies are important. Note: No terminologies in these related groups will be selected as parts of the PMRI terminology standards recommendations. Rather, the recommendations will only highlight the need to map the core terminologies to these related terminologies in order to facilitate adoption of the proposed standard.

3.2.1. Standard Administrative, Financial, and Regulatory Terminologies

This set includes existing terminologies used for administrative, financial, or regulatory functions. These terminologies are currently in use and serve important practical purposes (most notably, HIPAA-mandated transaction coding). They differ from the core terminologies in that they typically are not intended nor designed for the primary documentation of clinical care. The codes in these terminologies represent abstractions and combinations of clinical concepts that were defined to support non-clinical[1] documentation needs, such as billing or regulatory reporting. Examples of terminologies in this category are:

- ICD-9-CM
- CPT-4

[1] "Clinical" documentation processes are those related to the primary documentation of clinical care, as well as clinical decision support and clinical data analysis.

- HCPCS
- CDT-2
- NDC

Although these terminologies are not well suited for representing patient medical record information, *per se*, a large number of important legacy applications using these terminologies exist and it will be important to support mapping to these terminologies from the core terminology for the latter to gain acceptance. Identification of certain terminologies in this set as part of the PMRI terminology standards recommendations will compel (or, at least, encourage) the creators and maintainers of the core terminologies to factor in the need for such mappings as the core terminologies are developed and modified.

3.2.2. Prominent Legacy Clinical Terminologies

These terminologies are existing clinical terminologies that are prominent and/or widely used, but are not needed or are not appropriate for the core terminology group. Reasons for exclusion from the core terminology group may include:

- Inconsistency with the identified technical criteria for the core terminologies
- Inconsistency with other requirements for the core terminologies, such as professional maintenance, low cost, favorable intellectual property provisions, or prospects of long-term availability
- Substantial overlap with one or more terminologies that are already included in the core terminology group

The terminologies in this set, however, are important in that they share certain characteristics:

- Content consistent with a "clinically specific" terminology
- Sufficiently widespread use in existing clinical software systems that compatibility with and/or mappings to the core terminology group is important (as a practical matter) in promoting acceptance of and use of the core terminology standard.
- Adherence to a minimum set of technical criteria so that mapping to the core terminologies is feasible and sensible

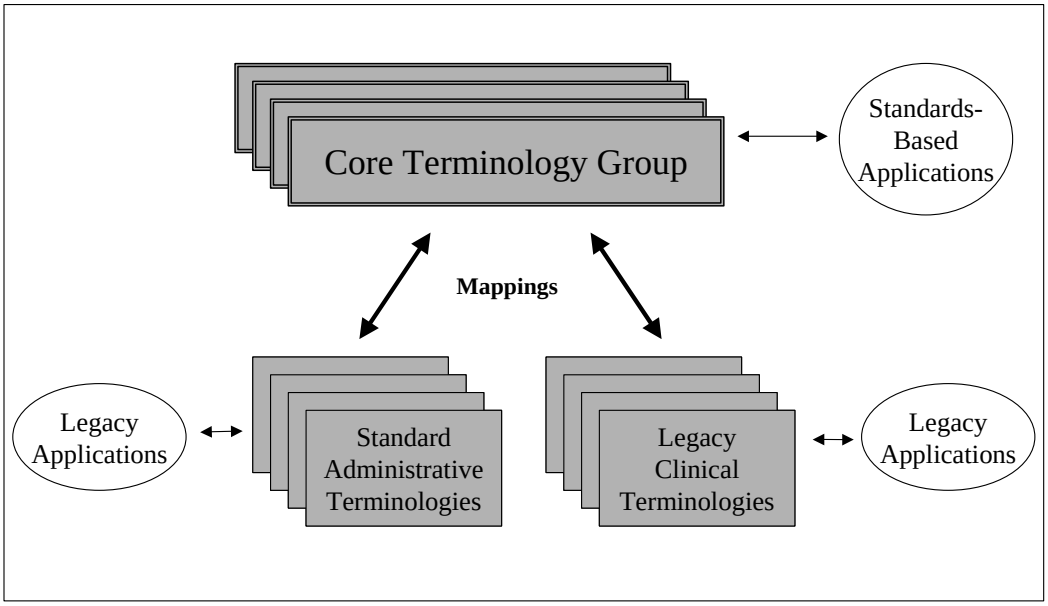
The rationale for specifying such a group of terminologies is to assist in and promote the adoption of the core terminology group. In the absence of a government mandate, voluntary adoption of the core terminology standard will depend on its compatibility with existing clinical systems and processes, as well as on support for a migration path from currently used terminologies to standard terminologies, where appropriate. Therefore, it is desirable to support the creation and maintenance of mappings between these legacy terminologies and the core terminologies, so that data represented using legacy terminologies may be converted to and/or interoperate with data represented using the core terminologies. This model allows clinical applications using certain legacy terminologies to generate and/or use standards-compliant data, which will facilitate data exchange and data comparability in the short run. Note: This model does not necessarily imply that mappings to any legacy terminologies will be part of the core terminology, itself; only that the *ability* to map to legacy terminologies will be considered as the core terminology is developed and maintained.

The prototypical examples of such legacy terminologies are drug-coding systems used by commercial vendors of drug databases and drug decision-support systems. Other terminologies may include certain "interface" terminologies designed to facilitate structured data entry, or terminologies

specific to nursing and other professional functions that are not otherwise already included in the core terminology group.

3.3. The Terminology Standards Architecture

The Core and related terminologies will fit into a standard terminology architecture for clinical data that supports interoperability and data aggregation (via the Core Terminology Group), as well as a certain measure of compatibility with legacy applications and non-clinical terminologies (via mappings to the related terminologies). The following graphic illustrates these roles and relationships.



4. The Standard Core Terminologies for PMRI

The core terminology group is the essential element that will provide most of the benefits with respect to interoperability and comparability of PMRI. Therefore, additional features and issues of the core terminology group are addressed in this section.

4.1. Rationale for a Tightly Integrated Core Terminology Group

At the NCVHS hearings on August 28th, a number of alternatives were suggested for organizing terminology standards for PMRI. Several of these are discussed below.

- Organizing existing terminologies by clinical function and selecting the best or most appropriate terminology(ies) in each functional area. For example, terminologies would be selected for diagnoses, procedures, lab tests, medications, etc. This approach is pragmatic and efficient in that it entails selecting from existing, functionally-specific terminologies. It is also consistent with the needs of messaging standards, which typically communicate data in discrete, well-defined functional areas. However, in the absence of a tightly integrated process for creating and maintaining this standard terminology set, this approach may not meet the important requirement of supporting reliable *analysis* of patient medical data across functional areas. The deficiency arises

because semantic overlaps, gaps, and inconsistencies will exist among the independently maintained terminologies (as they do today) and inter-relating concepts from different terminologies will be difficult. For example, this approach would make it difficult to answer queries such as "retrieve the results of assays that detect the level of any drug that a patient is currently taking" because different and unrelated terminologies are used to represent lab tests and medications.

- Select the best terminologies from those already widely used by the government and private sector. This approach provides the best "backward compatibility" with legacy applications, and requires the least change and investment on the part of terminology users, terminology developers, and information system vendors. However, it also does little to address the inadequacies of currently used terminologies with respect to the interoperability and data comparability goals for patient medical record information. This is because terminologies currently in wide use (i.e. de facto standards such as ICD-9-CM, CPT-4, and NDC) do not represent clinical data at the appropriate level of abstraction to be useful for many EMR, decision support, biosurveillance, or clinical research purposes.
- Tightly integrate standard clinical terminologies with standard clinical information models (which are used, in turn, to define standard medical record structures and messaging structures). Although this ultimate integration may achieve the greatest functionality and may be an important part of the long-term solution (see Section 4.5), it may not be a practical objective in the near term. No comprehensive and clinically-specific information models exist today, and such integration would require the coordination and cooperation of numerous standards bodies and the modification of many systems and processes currently in place. An intermediate and interim solution involving the coordination of fewer entities (for example, terminology and message developers) may be more pragmatic, while still achieving important benefits.

It is felt at this time that a comprehensive and tightly integrated group of core terminologies that is also loosely coordinated with certain administrative/billing and legacy clinical terminologies will best achieve the objectives of terminology standardization. The proposal is for NCVHS to make recommendations based on this general architecture.

4.2. Domain Coverage of the Core Terminologies

It is premature to select the terminologies that will be the elements of the standard core terminology group. This determination will require further consideration of the requirements/use cases for terminology standardization, as well as the domain coverage, technical criteria, integration requirements, and administrative infrastructure of the envisioned core terminologies. As a first step towards identifying candidates for the core terminology group, however, it is useful to specify the desired domain coverage of the standard. The core terminology group must support the documentation of clinical care with respect to at least the following areas:

- Clinical disorders (diagnoses)
- Subjective symptoms
- Observed findings
- Procedures performed by clinicians (preventive, diagnostic, and therapeutic)
- Laboratory tests and test results, including specimen types, testing methods, micro-organisms, etc.

- Radiology tests and test results/findings
- Anatomical structures
- Medications
- Chemical substances other than medications (e.g. toxins, contrast agents, etc.)
- Medical devices and supplies relevant to the documentation of clinical care (pacemakers, heart valve prostheses, indwelling catheters, ventilators, etc.)
- Social and care-management concepts (marital status, occupation, health care facility type, etc.)
- Standardized assessment tools (pain scales, Glasgow coma scale, APGARs, etc.)

This list is not exhaustive, but a complete description of the relevant domain coverage for terminology standardization will be included in the final report to the secretary.

It is likely that the required domain coverage and the desired support for mappings to legacy terminologies will not be provided by any single existing terminology. In making its recommendations, the subcommittee must consider the technical and organizational aspects of combining and coordinating terminologies in order to create the desired core terminology group.

4.3. Requirements for the Core Terminology Group

The requirements for inclusion in the core terminology group include both technical criteria and organizational/process criteria.

4.3.3. Desired Technical Criteria for the Core Terminologies

Certain recognized "desiderata" of controlled medical terminologies should be applied to the selection of terminologies for the core group[1]. These technical criteria express properties that enable or enhance accurate analysis of data encoded using the terminology. In applying these criteria, it is important to distinguish *essential* properties (without which the core terminology group will fail to meet its goals and requirements) from *desired* but not essential features (which may simply facilitate maintenance, promote adoption, etc). In other words, it's important to distinguish the "must haves" from the "nice to haves".

4.3.3.1. Essential Features

Concept orientation : Elements of the terminology are coded concepts, with possibly multiple synonymous text representations, and hierarchical or definitional relationships to other coded concepts.

Concept permanence : The meaning of each coded concept in a terminology remains forever unchanged. If the meaning of a concept needs to be changed or refined, a new coded concept is introduced. No retired codes are deleted or re-used.

Non-ambiguity : Each coded concept in the terminology has a unique meaning.

Explicit version identifiers : Each version of the terminology is designated with a unique identifier, such that parties exchanging data can readily determine if they are using the same set of terms.

[1] Cimino JJ. Desiderata for controlled medical vocabularies in the twenty-first century. Methods Inf Med. 1998 Nov;37(4-5):394-403.

4.3.3.2. Desirable Features

Comprehensive Domain Coverage : The terminology includes most of the concepts and terms needed for primary clinical documentation in the defined domain area.

Meaningless identifiers : The unique codes used to identify concepts in the terminology are unrelated to the meaning of the concepts or to their locations in the concept hierarchy.

Multi-hierarchies : A coded concept may be the child of more than one other coded concept in the terminology's hierarchy

Non-redundancy : Each unique meaning is represented by just one coded concept in the terminology. Each concept may have multiple synonymous terms, but the relationship of the terms to the concept must be explicitly represented.

Formal concept definitions : The terminology includes logical definitions of coded concepts, allowing redundancy to be automatically detected and appropriate hierarchical relationships to be automatically inferred.

Infrastructure/tools for collaborative terminology development : The terminology is maintained using tools that (1) allow many people to work on a terminology at the same time and (2) support the assignment, scheduling, collection, and integration of their work.

Change sets : Each new version of the terminology includes a complete accounting of the added, retired, and modified concepts and terms (i.e. a "delta" file).

Mappings to other terminologies : The content of the terminology includes mappings to other relevant terminologies, and these mappings have been validated.

Support for local customization : Tools and processes exist that allow users of the terminology to make local additions and customizations, and to later merge these changes with the subsequent version of the terminology.

In addition to these technical criteria, a model for mapping and/or integrating the core terminologies to create the envisioned cohesive and mutually consistent whole should also be considered. This model may have implications for the required technical features of the constituent terminologies.

4.3.4. Desired Organizational and Process Criteria for the Core Terminologies

In order to achieve widespread adoption as a standard for representing and exchanging PMRI, the core terminology must be owned, maintained, and distributed in a fashion that produces the highest quality, allows the widest use, and instills the greatest confidence of ongoing availability. To this end, the appropriate organization, governance structure, processes, and funding of the terminology developers responsible for the core terminologies must be established. Specific issues include:

- Intellectual property and licensing terms for the core terminologies (perhaps as a group) that allow the widest use while preventing proliferation of local, non-standard "dialects."
- Governance structure of the core terminology developers (perhaps as a group) that guarantees responsible stewardship of the standard and responsiveness to all stakeholders within the defined scope
- Funding mechanism for the core terminology developers and their development activities (perhaps as a group) that guarantees professional support, timely updates, and long-term viability

- Appropriate policies and processes for maintenance of the core terminology that preserve quality while maximizing the rate of enhancement. These policies may entail ANSI-accredited balloting procedures, less formal consensus-based processes, or other methods.

An important decision will be the degree of organizational coordination that is deemed necessary and achievable among the developers of the core terminologies, and the new or existing body (if any) that will oversee this coordination. The subcommittee should be prepared to make recommendations with respect to each of these factors in the report submitted to the Secretary of HHS.

4.4. The Role of the Unified Medical Language System

The National Library of Medicine's Unified Medical Language System (UMLS) is an important resource for inter-relating terminologies. As such, it can play a vital role in integrating the terminologies selected for the core group into a cohesive whole, by supporting mappings and cross-references among the constituent terminologies. The UMLS content can also provide support for the mapping of the core terminology group to the related terminologies, and may ultimately be the repository of these mappings. Lastly, the UMLS is an important and widely used vehicle for the distribution of public-domain and other terminologies to the terminology-user community. The expansive content and regular update cycles that have been provided by the UMLS for well over a decade have made it a well-known and trusted source of terminology content. Whichever terminologies are selected for the core and other groups will almost certainly be included in and distributed via the UMLS (perhaps among other distribution mechanisms).

Although the UMLS is a rich repository of mappings among synonymous terms from many terminologies, the specification of precise semantic relationships among concepts from different terminologies (as will be required for integration of the terminologies in the core group) may require significant enhancements to the UMLS content and, perhaps, certain changes to the UMLS terminology model. The evolution of the UMLS in this regard is consistent with the goals of the NLM and well within its capabilities.

4.5. Relationship to Message Standards and Information Models

Certain interoperability and data comparability objectives for PMRI may not be achievable through terminology standardization alone. A standard representation of the full meaning of patient medical data requires integrating terminology models with models of context and other structural relationships, as well as negation and time. Together, these elements constitute a complete "information model." If context, structure, negation, and time are not also part of the standardized representation, then uniform data standards for PMRI and the electronic exchange of such information will remain incomplete.

For example, the coded representation of "Myocardial Infarction" has different clinical significance when it appears in the context of "Current Diagnosis", "Past Medical History", or "Family History." In the absence of context information, the full meaning of "Myocardial Infarction" within a standard representation may remain ambiguous, leading to incorrect reporting or decision-support behavior. Even if context information is incorporated into the terminology model itself, lack of integration with message standards may result in redundant representations of the same information. For example, a message communicating the same information could include the coded concept "Family History of Myocardial Infarction" in the field "Subjective Finding", or it could include the coded concept "Myocardial Infarction" in the field "Family History." Lack of coordination between messaging and terminology standards allows such redundant representations, which render data exchange more difficult and error prone.

Additionally, mapping from the core terminology to administrative, financial, and regulatory terminologies requires (in many cases) the consideration of multiple coded concepts in multiple contexts of the patient record. For example, mapping from clinically specific data to billing codes such as “511.0 : Pleurisy without mention of effusion or current tuberculosis” cannot be achieved without a knowledge of where the coded concepts for findings and diagnoses are represented in a structured medical record. If PMRI standards do not include a comprehensive information model *and* terminology model, mapping between the core terminology and layer 3 terminologies will require a knowledge of the specific (non-standard) medical record structures at each institution. This will increase the cost of such mappings and limit, to some extent, the benefits of standardizing PMRI data.

Although integration of terminology standards and information model standards is the ideal, no clinically specific information models yet exist. Hence, a recommendation to integrate terminology and information model standards would be premature and beyond the scope of the current standardization effort. However, a valuable and feasible interim approach would be to strive for coordination with widely used message standards (such as HL7), to minimize the kinds of ambiguities and redundancies exemplified above in information exchanges using both message standards and the core terminology standard.

Summary and Analysis of Responses to the NCVHS PMRI Terminology Questionnaire

A Report to the National Committee on Vital and Health Statistics Subcommittee on Standards and Security*

Version 5

Oct. 30, 2003

* This report was prepared by Walter Sujansky, MD. For comments and suggestions, please contact the author at wsujansky@sujansky.com.

Contents

1. Introduction

This report summarizes and analyzes the responses to a questionnaire sent to 46 developers of controlled medical terminologies in January 2003 by the Standards and Security Subcommittee (SSS) of the National Committee on Vital and Health Statistics (NCVHS). The questionnaire was an information-gathering tool to assist in the formulation of recommendations by the NCVHS to the Department of Health and Human Services. The recommendations will address the creation/promotion of national terminology standards for Patient Medical Record Information (PMRI), part of a larger undertaking by the NCVHS to study the issues related to the adoption of uniform data standards for PMRI and the electronic exchange of such information, as mandated by the HIPAA legislation of 1996. The goals of the questionnaire were to help evaluate the features of existing medical terminologies with respect to a set of normative criteria for the selection of PMRI terminologies. The relevant criteria were specified in an earlier report published by the SSS[1] ("Scope and Criteria Report").

2. Objectives

The analysis of the questionnaire responses reported here is intended to guide decision making regarding, specifically, the composition of a "Core Terminology Group" for a national standard medical terminology. The Core Terminology Group is intended to comprise a "core" set of PMRI terminologies that, together, are sufficiently comprehensive, technically sound, mutually consistent, and readily available so as to deliver most of the envisioned functionality of a national standard medical terminology. Characterization of the Core Terminology Group and criteria for inclusion of a terminology in this group were described at length in the Scope and Criteria Report.

A secondary objective of this document is to provide information to guide the identification of important terminologies related to the Core Terminology Group. These related terminologies include standard administrative, financial, and regulatory terminologies, as well as important legacy clinical terminologies. No terminologies in these related groups will be selected as part of the PMRI terminology standards recommendations. The recommendations may, however, highlight the need to map the core terminologies to certain of these related terminologies in order to facilitate adoption and use of the proposed standard.

In its final recommendations, the SSS will select one or more terminologies as specific elements of a standard Core Terminology Group. This report provides a quantitative and qualitative analysis of information provided by the terminology developers themselves to help guide these selections. The following section describes the questionnaire used and provides general information about the responses received. Section 4 quantitatively scores the questionnaire responses with respect to a set of technical, organizational, and process criteria for inclusion in the Core Terminology Group. Section 5 discusses data related to usage and market acceptance of terminologies that was obtained through the questionnaire responses, and comments on the implications of this data. Section 6 summarizes the findings from the questionnaire responses.

[1] Scope and Criteria For Selection of PMRI Terminologies: A Report to the National Committee on Vital and Health Statistics Subcommittee on Standards and Security. Version 3. December 23, 2003. Report prepared by Walter Sujansky, MD on behalf of the Subcommittee on Standards and Security of the NCVHS.

3. The Questionnaire and the Responses: General Description

This section describes the questionnaire itself, the terminology developers who received and responded to the questionnaire, and the general quality of the data they provided.

3.1. Questionnaire Design and Contents

The SSS prepared the 13-page NCVHS PMRI terminology questionnaire consisting of over 100 questions. The questions were designed to reflect the NCVHS criteria for selecting PMRI Standards which were set forth in the NCVHS report on PMRI Standards dated August 8, 2000. However, in order to make the original NCVHS criteria for selecting PMRI standards appropriate for terminology standards, some modification to the criteria was necessary. The principal guidance for these modifications was derived from the terminology characteristics set forth in the ASTM Standard Specification for Controlled Health Vocabularies, 2000. The questions were divided among several categories:

1. Administrative and contact information
2. General information regarding purpose and use
3. Content, structure, and features
4. Maintenance and updates
5. Delivery and implementation
6. Licensing and intellectual property
7. Organizational aspects of terminology developers

The questions called for either multiple-choice or free-text responses. Sixty of the questions were *unconditional questions*, i.e., they called for a response regardless of the answer to other questions. The remaining questions were optional, i.e., the need for a response was dependent on other responses. For example, the question "Does your terminology include hierarchical relationships between concepts or terms" was an unconditional question, whereas "If yes, please indicate which kinds of hierarchical relationships are represented" was a conditional question. To review a complete copy of the questionnaire, as well as the request-for-information that was sent by the SSS with the questionnaire, please see Appendix IV.

3.2. Questionnaire Distribution and Response Rates

The SSS sent the questionnaire to the developers of 46 healthcare terminologies on January 6, 2003. For a complete list of the terminology developers who were sent a questionnaire, please see Appendix I. 42 completed questionnaires were received, a response rate of 91%. 41 questionnaires were included in this analysis[1]. Subsequent to the preparation of an initial draft of this report, all of the terminology developers were invited to submit feedback on the evaluation of their terminologies, and this feedback was reviewed and incorporated, as appropriate, into the final report presented here.

The completed questionnaires were divided into 10 general categories to facilitate analysis and comparison. The Terminologies that were analyzed in this report are listed alphabetically in Table 1, along with their assigned categories and terminology developers. The terminologies are listed by category in Appendix II. Note that the categorization is for organizational purposes only and is not intended to make any statement about the terminologies' suitability for PMRI standards selection. The "General" category was used for those terminologies whose contents span

[1] The UMLS was not analyzed for the PMRI terminology standard, as it comprises an inter-related set of terminologies, rather than a single terminology source.

numerous domain areas of the patient medical record. The following table shows the distribution by organization type of the terminology developers whose responses were analyzed:

Organization Type	Questionnaires
Prof. Society/Trade Group	17
U.S. Government	8
Private - For-profit	6
Private - Non-profit	5
Academic	5

Terminology (Abbr)	Terminology (Full Name)	Category	Terminology Developer/Owner	Organization Type
ABC codes	ABC codes, Version 2003	Alternative	Alternative Link [The Foundation for Integrative Healthcare (FIHC) maintains the contents]	Private - For-profit
CDT-4	Code on Dental Procedures and Nomenclature	Dental	American Dental Association (ADA)	Prof. Society/Trade Group
CHDE	Core Health Data Elements	StatAbst&Admin	National Committee on Vital and Health Statistics (NCVHS) /National Center for Health Statistics/CDC	U.S. Government
CPT-4	Current Procedural Terminology, Fourth Edition	StatAbst&Admin	American Medical Association (AMA)	Prof. Society/Trade Group
DEEDS	Data Elements for Emergency Department Systems	Other	National Center for Injury Prevention and Control (NCIPC) [in CDC]	U.S. Government
DICOM	DICOM Controlled Terminology Definitions	Messaging	DICOM	Prof. Society/Trade Group
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders	StatAbst&Admin	American Psychiatric Association (APA)	Prof. Society/Trade Group
HHCC	Home Health Care Classification	Nursing	Sabacare Inc.	Private - Non-profit
HL7 v.2 Codes	Health Level Seven Version 2 Codes	Messaging	Health Level Seven, Inc.	Prof. Society/Trade Group
HL7 v.3 Codes	Health Level Seven Version 3 Codes	Messaging	Health Level Seven, Inc.	Prof. Society/Trade Group
ICD-10-CM	International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Clinical Modifiation	StatAbst&Admin	National Center for Health Statistics	U.S. Government
ICD-10-PCS	ICD-10-PCS	StatAbst&Admin	Centers for Medicare and Medical Services (CMS)	U.S. Government
ICF	International Classification of Functioning, Disability and Health	Other	World Health Organization	Private - Non-profit
ICNP	International Classification for Nursing Practice	Nursing	International Council of Nurses (ICN)	Prof. Society/Trade Group
ICPC	The International Classification of Primary Care	Other	World Organization of Family Doctors (WONCA)	Prof. Society/Trade Group
IEEE 1073.1.1.1	IEEE Health informatics Point-of-care medical device communication Nomenclature	Messaging	Institute of Electrical and Electronic Engineers (IEEE)	Prof. Society/Trade Group
ISBT 128	International Society of Blood Transfusion	Lab	International Council for Commonality in Blood Banking Automation, Inc (ICCBBA)	Prof. Society/Trade Group
ISO Tooth Designations	International Standards Organization (ISO) TC 106 Designation System for Teeth and Areas of the Oral Cavity	Dental	American Dental Association (ADA)	Prof. Society/Trade Group
LOINC	The Logical Observation Identifier Names and Codes	Lab	Regenstrief Institute, Inc.	Academic
MEDCIN	MEDCIN	General	Medicomp Systems, Inc.	Private - For-profit
MedDRA	Medical Dictionary for Regulatory Activities	General	Northrop Grumman Mission Systems (MedDRA Maintenance and Support Services Organization)	Private - For-profit
Medi-span	Medi-Span Drug Terminology	Drug	Medi-Span, division of Wolters Kluwer Health, Inc.	Private - For-profit
Multum	Multum Lexicon	Drug	Cerner Multum, Inc.	Private - For-profit
NANDA	NANDA/Nursing Diagnosis Definitions and Classification	Nursing	NANDA International, formerly the North American Nursing Diagnosis Association	Prof. Society/Trade Group
NCI Thesaurus	NCI Thesaurus	General	National Cancer Institute	U.S. Government
NCPDP	NCPDP Message Codes	Messaging	National Council for Prescription Drug Programs (NCPDP)	Prof. Society/Trade Group
NDC + others	FDA Data Standards Manual	Drug	U.S. Food and Drug Administration	U.S. Government
NDDF Plus	NDDF Plus	Drug	First DataBank, Inc	Private - For-profit
NDF-RT	National Drug File Reference Terminology	Drug	U.S. Department of Veterans Affairs, with National Library of Medicine	U.S. Government
NIC	Nursing Interventions Classification	Nursing	College of Nursing, the University of Iowa	Academic
NMMDS	Nursing Management Minimum Data Set	Nursing	NMMDS Research Team, College of Nursing, The University of Iowa	Academic
NOC	Nursing Outcomes Classification	Nursing	Iowa Outcomes Project at The University of Iowa, College of Nursing, Center for Nursing Classification and Clinical Effectiveness	Academic
Omaha System	Omaha System	Nursing	Martin Associates	Private - Non-profit
PCDS-VU	The Patient Care Data Set—Vanderbilt University	Nursing	Vanderbilt University Medical Center	Academic
PNDS	Perioperative Nursing Data Set	Nursing	AORN: the Association of periOperative Registered Nurses	Prof. Society/Trade Group
PTCS	Provider Taxonomy Code Set	Other	National Uniform Claim Committee (NUCC)	Prof. Society/Trade Group
RxNorm	RxNorm	Drug	National Library of Medicine	U.S. Government
SNODENT	Systematized Nomenclature of Dentistry	Dental	American Dental Association (ADA)	Prof. Society/Trade Group
SNOMED CT	SNOMED Clinical Terms	General	SNOMED International, a division of the College of American Pathologists	Private - Non-profit
UMDNS	Universal Medical Device Nomenclature System	Devices	ECRI (formerly the Emergency Care Research Institute)	Private - Non-profit
Universal/National Tooth Designation System	Universal/National Tooth Designation System	Dental	American Dental Association (ADA)	Prof. Society/Trade Group

Note: "StatAbst&Admin" = Statistical Abstraction and Administrative

Table 1. Terminologies Represented by Completed Questionnaires

3.3. Data Quality in Questionnaire Responses

The thoroughness and accuracy with which the questionnaires were completed was generally good, but varied across the 41 respondents. On average, respondents answered 83% of the unconditional (i.e., non-optional) questions. Only 1 respondent answered all of the unconditional questions, while 2 respondents answered fewer than 50% of the unconditional questions. The statistical breakdown of the thoroughness with which the questionnaires were completed is as follows:

Statistics Across 41 Respondents	
Avg % of unconditional questions answered	83%
Median % of unconditional questions answered	84%
Min % of unconditional questions answered	32%
Max % of unconditional questions answered	100%

Even when the unconditional questions were answered thoroughly, responses to important follow-up ("conditional") questions were sometimes omitted. This happened most frequently with respect to questions about licensing issues. For example, the question "Are there standard licensing terms for your terminology" was often answered "No," but the follow-up question "If there are no standard licensing terms, please describe the licensing process" was left unanswered. The missing information was obtained through follow-up conversations and correspondence with the terminology developers.

When questions were answered, they were usually answered accurately. However, cases did occur in which it was clear that a question was answered incorrectly (perhaps due to misinterpretation) or vaguely. This occurred notably in responses to the following questions:

1. "Do you distinguish between "concepts" and "terms" in your terminology?" Numerous respondents answered this incorrectly, based on subsequent examples and explanations of the structure of their terminology. For example, several respondents interpreted "concepts" to mean categories of terms, and "terms" to represent the individual coded entities themselves. These issues were resolved in follow-up conversations and correspondence with the terminology developers.
2. "How is the meaning of each coded concept represented?" Several respondents answered this multiple-choice question with "Formal logic-based definitions." However, it was clear from subsequent examples that purely text definitions were, in fact, used to define concepts in their terminology.
3. "Please describe how the proposed [content] changes are prioritized." This question was often answered vaguely, with responses including
    - "An algorithmic process is used to assist internal editorial staff"
    - "All subscriber change requests are given priority"
    - "By the technical advisory groups"

In general, however, the quality of the data collected via the surveys was adequate and suitable for making judgments with respect to the discriminating features defined in the Scope and Criteria Document. The notable exception to this, as demonstrated in the data analysis below, is information regarding specific licensing terms. For several terminologies, insufficient

information was collected in the questionnaires to make useful judgments, probably because the relevant questions were not sufficiently specific. Additional information was, therefore, collected through follow-up questions posed directly to the terminology developers.

4. Quantitative Analysis Against Selection Criteria

To assist in the selection of terminologies for the Core Terminology Group, the features of each terminology were evaluated with respect to the various selection criteria specified in the Scope and Criteria Report. This was done in a quantitative way by *scoring* each terminology with respect to each criterion. Three sets of criteria were evaluated in this way.

1. Essential Technical Criteria
2. Desired Technical Criteria
3. Desired Organizational and Process Criteria

For each individual criterion, a scoring metric was specified to quantify the degree to which a terminology meets that criterion. The set of questions in the questionnaire that are relevant to that scoring metric was then identified, and the responses to these questions were analyzed to generate a numerical score for each criterion.

For example, the scoring metric for the criterion "Meaningless Identifiers" was specified as follows:

Criterion	0	1	2
Meaningless Identifiers	Identifiers represent the concept/term position in the hierarchy or the concept/term meaning	Some identifiers carry meaning, although other (alternative) identifiers may be meaningless	All identifiers are meaningless

The set of questions relevant to this scoring metric was identified as:

Criterion	Question ID	Question Text
Meaningless Identifiers	II_E	How is the meaning of each coded concept represented?
	II_F	Please provide examples of 3 concepts in your terminology and the way that their meanings are represented.
	II_J2	If you have hierarchical relationships, how are they represented?
	II_J2a	Please provide several examples of this representation for one or two hierarchical relationships.
	III_C	How do you determine the code to assign to each new concept or term?

The responses to these questions were subjectively evaluated in order to derive a score of 0, 1, or 2 for each terminology.

In the sections that follow, the scoring metric is presented, along with the computed scores for each terminology. The sets of questions used to generate the score for each criterion are listed in Appendix III.

4.1. Essential Technical Criteria

The Scope and Criteria Report identified four *essential* features of terminologies in the Core Terminology Group. These features are so important with respect to the objectives of PMRI terminology standards that a candidate terminology must possess all of them for consideration to be included in the Core Terminology Group. All 41 terminologies were scored against these criteria in a binary fashion, i.e., a score of "1" or "0" was assigned. If one could not determine from the survey responses whether a terminology met one of the criteria, a "?" was assigned, pending further analysis, if necessary. Note that terminologies that received a "0" for any of the essential technical criteria were not scored on other criteria nor included in further analysis.

The essential criteria and scoring metrics are shown in Table 2 (see Section 9.1 for the specific questions that were used to evaluate these criteria). The scoring results are shown in Table 3.

Criterion	1	0
Concept Orientation	Elements of the terminology are coded concepts, with possibly multiple synonymous text representations, and hierarchical or definitional relationships to other coded concepts. No redundant, ambiguous, or vague concepts exist.	The terminology is not concept oriented.
Concept Permanence	The meaning of each coded concept in a terminology remains forever unchanged. If the meaning of a concept needs to be changed or refined, a new coded concept is introduced. No retired codes are deleted or re-used.	The meanings of coded concepts may change OR retired codes are deleted OR retired codes are re-used
Non-Ambiguity	Each coded concept in the terminology has a clear, unique meaning	Certain coded concepts in the terminology have a vague meaning or more than one meaning
Explicit Version IDs	Each version of the terminology is designated with a unique identifier, such that parties exchanging data can readily determine if they are using the same set of terms.	The terminology has no version identifiers, or the terminology content may change without a change to the version identifier.

Table 2. Scoring Metrics for Essential Technical Criteria

Comment: Concept Orientation. Concept orientation is the most subjective criterion and was the most difficult to assess based on the survey responses. Terminologies were deemed to meet this criterion if they distinguish concepts and terms, explicitly and accurately denote synonymy among terms, and provide hierarchical and other concept relationships. Terminologies were deemed to fail this criterion if they (1) include redundant, synonymous terms that are not formally associated with a single concept, (2) include vague terms (including terms defined using "other…" or "not elsewhere classified"), or (3) describe only record structures rather than sets of context-independent medical concepts.

The concept orientation of several terminologies could not be determined with confidence based on the survey responses alone. When a terminology met all of the other essential criteria and only its concept orientation was "indeterminate," the concept orientation was further analyzed to assign a definitive score. This required inspecting the complete terminology or samples of the terminology. However, if a terminology received a score of "0" on one of the other essential technical criteria, its concept orientation was not further analyzed. Because the selected terminologies must possess *all* of the essential criteria, the concept orientation was not relevant to the selection process in these cases.

Comment: Concept Permanence. Concept permanence required that the meanings of codes never change and that obsolete or retired codes are retained within the terminology (appropriately designated). Many terminology developers maintain a list of retired codes on file at their offices or include with each version only those codes that have been retired in the latest update. However, this is not sufficient for concept permanence for purposes of PMRI terminology standards. In order to support longitudinal data analysis, a terminology must retain *within its corpus* all codes that have been retired across any version. Only in this way can users of the terminology evaluate patient data longitudinally, such that retired codes from any version can be properly handled by the analysis software (e.g., "proper" handling may entail applying a mapping from a retired code to an existing code or mapping both retired and existing codes to some newly created abstraction or ignoring certain retired codes entirely because they're not relevant to the analysis). In order to make these decisions, however, all of the codes ever retired must be available for consideration in each version of the terminology -- terminology user cannot know which codes may appear in the longitudinal data.

Comment: Non-Ambiguity. The Non-Ambiguity of terminology contents cannot generally be assessed without inspection of the contents themselves, so this criterion was scored as "1" for most terminologies (i.e., most terminologies were given "the benefit of the doubt," pending further analysis, if necessary). Five terminologies were assigned a "0" because they are known to include ambiguous terms.

Based on the scoring results, only 10 of the 41 terminologies were candidates for further consideration. These terminologies were analyzed with respect to desired technical criteria and desired organizational and process criteria. Table 3 shows which terminologies did and did not meet the essential technical criteria.

	Category	Terminology	Concept Orientation	Concept Permanence	Non-Ambiguity	Explicit Version Ids
Meet Essential Technical Criteria	General	Medcin	1	1	1	1
	General	SNOMED CT	1	1	1	1
	General	NCI Thesaurus	1	1	1	1
	Lab	LOINC	1	1	1	1
	Drug	Multum Lexicon	1	1	1	1
	Drug	NDDF Plus	1	1	1	1
	Drug	NDF-RT	1	1	1	1
	Drug	RxNorm	1	1	1	1
	Dental	SNODENT	1	1	1	1
	Messaging	HL7 v.3 Codes	1	1	1	1
Do Not Meet Essential Technical Criteria	General	MedDRA	0	1	1	1
	Lab	ISBT 128	0	1	1	1
	Dental	ISO TOOTH DESIGNATION CODES	1	0	1	1
	Devices	UMDNS	1	0*	1	1
	Drug	Medi-Span	1	0*	1	1
	Drug	NDC+ Others	?	0	?	1
	Nursing	HHCC	0	1	1	1
	Nursing	ICNP	1	0	1	1
	Nursing	NMMDS	0	1	1	1
	Nursing	NANDA	?	0	1	1
	Nursing	NIC	0	0*	1	1
	Nursing	NOC	?	0*	1	1
	Nursing	Omaha System	?	0*	1	1
	Nursing	PCDS-VU	0	1	1	1
	Nursing	PNDS	?	0	1	1
	Alternative	ABC codes	?	0*	1	1
	Dental	Code on Dental Procedures and Nomenclature	?	0	1	0
	Dental	Universal/National Tooth Designation System	?	0	1	0
	Messaging	DICOM	0	1	1	1
	Messaging	HL7 v.2 Codes	0	1	1	1
	Messaging	ISO-11073	1	0*	1	1
	Messaging	NCPDP Message Codes	0	1	1	1
	StatAbst&Admin	Core Health Data Elements	0	?	1	?
	StatAbst&Admin	CPT	0	0	0	1
	StatAbst&Admin	DSM-IV-TR	1	0	0	1
	StatAbst&Admin	ICD-10-CM	0	1	0	?
	StatAbst&Admin	ICD-10-PCS	0	?	0	1
	Other	DEEDS	0	?	1	1
	Other	ICPC	0	?	1	1
	Other	ICF	0	1	0	1
	Other	PTCS	?	0	1	1

Note: SNOMED CT includes contents from HHCC, NANDA, NOC, NIC, Omaha System, and PNDS.
?: Could not be ascertained from questionnaire responses.
*: Retired codes are deleted from the terminology, but are available by request from the terminology developer.

Table 3. Results of Scoring Terminologies Against Essential Technical Criteria

Discussion:

The 32 terminologies classified as "*Do Not Meet Essential Technical Criteria*" did not meet one or more of the criteria. The absence of concept permanence was the most common reason that a terminology failed to meet the essential criteria (15 terminologies), followed by lack of concept orientation (14 terminologies). Two terminologies exhibited neither concept permanence nor concept orientation. No terminologies failed to meet the essential criteria solely due to concept ambiguity or a lack of explicit version identifiers.

If there existed any doubt or uncertainty in the scoring of an essential criterion for a terminology, the terminology received a score of "?" for that criterion. If a terminology failed to meet the essential technical criteria solely due to *uncertainty* with respect to one or more criteria, further information was solicited from the terminology developers for those criteria (this was the case, for example, with the ISO Tooth Designation Codes and the ISBT 128 terminology; definitive classification with respect to meeting or not meeting the essential criteria was possible once further information was received). If uncertainty existed with respect to one or more criteria for a terminology, but the terminology had already scored "0" with respect to another essential criterion, no further information was solicited for the uncertain criteria (there was no value in seeking further information in these cases). This was the case, for example, with NANDA, the ABC codes, and ICD-10-PCS.

Ten terminologies met the essential technical criteria. Notably, the domain coverage of these terminologies (based on the questionnaire responses) includes concepts from most of the areas identified as important to the documentation of clinical care (see Section 4.2 of the Scope and Criteria Report). These concept areas include diagnoses, symptoms, findings, procedures, medications, laboratory tests, radiology exams, and medical devices. Note that SNOMED CT, which meets the essential technical criteria, includes the contents of several of the nursing terminologies that did not meet the essential criteria. Specifically, SNOMED CT includes the diagnostic concepts from NANDA, NOC, HHCC, Omaha, and PNDS, as well as the nursing-intervention concepts from HHCC, Omaha System, PNDS, and NIC. Although the UMDNS did not meet the essential technical criteria, SNOMED includes 5,000 device concepts, and Medcin includes 1,500 device concepts, so that content coverage for medical devices may be provided by one or both of these terminologies. Additionally, significant dental content appears in the SNODENT terminology (see Table 5), as well as in SNOMED CT (per information provided by the terminology developer). The favorable (albeit tentative) conclusion is that no terminologies from the "Do Not Meet Essential Technical Criteria" categories are required to provide adequate domain coverage for the Core Terminology Group. As discussed in the next section, however, a definitive assessment of domain coverage requires further analysis.

4.2. Desired Technical Criteria

The Scope and Criteria Report also identified several "desired" (although not essential) features of terminologies in the Core Terminology Group. Seven of these features are amenable to scoring based on the questionnaire responses. The scoring metrics for these features are listed in Table 4 (see Section 9.2 for the specific questions that were used to evaluate these criteria). Table 5 shows the results of scoring the terminologies against these criteria.

Another desired technical feature is "Comprehensive Domain Coverage." In Table 5, the questionnaire data relevant to this criterion are summarized by displaying only the raw data, with no assignment of numeric scores. The reasons for this special treatment are discussed below.

Criterion	0	1	2
Meaningless Identifiers	All identifiers represent the concept/term position in the hierarchy or the concept/term meaning	Some identifiers carry meaning, although other (alternative) identifiers may be meaningless	All identifiers are meaningless
Multi-Hierarchies	No multiple classification of concepts/terms is possible OR the terminology does not have any hierarchical structure	Multiple classification is possible, but the primary classification and other (secondary) classifications are represented in different ways	Multiple classification is directly supported by the terminology structure
Non-Redundancy	Redundancy among concepts may exist and is not explicitly represented in any way	Redundancy among concepts may exist, but is explicitly represented in some way (e.g. a cross-mapping table)	No redundancy may exist among concepts (although redundancy may exist among terms, in which case it is explicitly represented)
Formal Concept Definitions	Concepts are defined by text descriptions and hierarchy position only	Concepts are defined via structured roles/attributes, but not represented in description logic	Concepts are defined via formal roles/attributes represented in description logic
Infrastructure/Tools for Collaborative Terminology Development	No tools or processes exist to manage collaborative development	Processes exist to manage collaborative development, but they are not enforced/supported by software tools	Software tools support and enforce a collaborative terminology-development process
Change Sets	No change sets are provided with updates; only a complete updated version is provided.	A partial change set is provided, e.g. only listing those concepts/terms that have been retired OR listing changes in a non-electronic form	A complete change set is provided electronically as part of each update
Mappings to Other Terminologies	No mappings exist to any other relevant terminologies	Mappings exist to other relevant terminologies, but they have not been validated	Validated mappings exist to other relevant terminologies

Table 4. Scoring Metrics for Desired Technical Criteria

Category	Terminology	Comprehensive Domain Coverage* # of Concepts	# of Terms	Meaningless Identifiers	Multi-Hierarchies	Non-Redundancy	Formal Concept Definitions	Infrastructure/Tools for Collaborative Terminology Development	Change Sets	Mappings to Other Terminologies	Total Score [max = 14]
General	Medcin	216,000	N/A	2	0	2	0	2	2	2	**10**
General	SNOMED CT	345,000	914,000	2	2	2	2	2	2	2	**14**
General	NCI Thesaurus	27,000	84,000	2	2	2	2	2	2	2	**14**
Lab	LOINC	33,000 (25,000 labs)	?	2	2	2	1	1	2	1	**11**
Drug	Multum Lexicon	121,000	N/A	2	2	2	1	2	2	0	**11**
Drug	NDDF Plus	500,000	N/A	2	2	2	1	1	2	1	**11**
Drug	NDF-RT	100,000	N/A	2	2	2	2	2	2	1	**13**
Drug	RxNorm	41,000	138,000	2	0	2	1	2	2	2	**11**
Dental	SNODENT	3,900	6,500	2	2	2	2	0	2	2	**12**
Messaging	HL7 v.3 Codes	6,500	6,000	2	2	2	0	0	0	0	**6**

* "Comprehensive Domain Coverage" displays the raw data provided in the questionnaire responses, since consistent scoring of domain coverage is not possible based on the questionnaire responses alone. The total score for each terminology excludes the data in these columns.

Table 5. Results of Scoring Terminologies Against Desired Technical Criteria

Discussion:

The criterion of "Comprehensive Domain Coverage" cannot be scored based on the questionnaire responses alone, which provide data only on the number of concepts and terms in each terminology across various domain areas (e.g., diseases, findings, medications, etc.). The adequacy of domain coverage depends also on the *intended* domain to be covered (i.e., intended by the terminology developers and intended by those defining the Core Terminology Group). For example, the LOINC terminology contains concepts for laboratory tests, as well as concepts for other types of clinical observations. Assessing the comprehensiveness of LOINC's domain coverage may depend on whether LOINC's role in the Core Terminology Group encompasses laboratory tests alone or laboratory tests plus other clinical observations.

Assessing the comprehensiveness of domain coverage also depends on the level of abstraction needed in a domain versus the level of abstraction represented in a terminology. Quantitative analysis and quantitative comparison of the questionnaire responses alone cannot address this factor. For example, the NDDF terminology contains over 500,000 concepts, but these include NDC codes, which are very detailed and may not be useful for PMRI terminology standards. Conversely, the RxNorm terminology contains only 41,000 concepts, but these are designed to represent medications at a clinically appropriate level of abstraction. RxNorm's domain coverage may, therefore, be just as comprehensive as NDDF's. To appropriately assess the adequacy of domain coverage of any terminology, a more detailed analysis of the terminology's role in the Core Terminology Group and the specific composition of the terminology's contents will be required. This step will be undertaken in a subsequent round of analysis.

By category, the terminologies with the highest scores for the desired technical criteria are:

Category	Terminology [Score]
General	SNOMED CT [14] NCI Thesaurus [14]
Lab	LOINC [11]
Drug	NDF-RT [13]
Nursing	N/A
Dental	SNODENT [12]
Devices	N/A
Messaging	HL7 v.3 Codes [6]
StatAbst&Admin	N/A
Other	N/A

The scoring results in Table 5 are notable in that 9 of the 10 terminologies that definitively met the *essential* technical criteria also scored highly (>= 10) when evaluated against the *desired* technical criteria. The exception to this observation is the HL7 v3 codes (6). There appears to be a general consistency in the quality of terminologies with respect to all of the technical criteria.

4.3. Desired Organizational and Process Criteria

In addition to the essential and desired technical features, the Scope and Criteria Report also identified a set of desired organizational and process criteria related to terminology developers and the terminology-development process. These criteria are:

- Intellectual property and licensing terms for the core terminologies that allow the widest use while preventing proliferation of local, non-standard "dialects."
- Governance structure of the core terminology developers that guarantees responsible stewardship of the standard and responsiveness to all stakeholders within the defined scope
- Funding mechanism for the core terminology developers and their development activities that guarantees professional support, timely updates, and long-term viability
- Appropriate policies and processes for maintenance of the core terminology that preserve quality while maximizing the rate of enhancement. These policies may entail ANSI-accredited balloting procedures, less formal consensus-based processes, or other methods.

Not all of these criteria can be evaluated quantitatively based on the questionnaire responses, but a subset of them is amenable (at least partially) to such analysis. This subset may be roughly divided into "Licensing Costs and Restrictions" and "Responsiveness to Constituents."

4.3.5. Licensing Costs and Restrictions

The questionnaire explicitly addressed three aspects of licensing costs and restrictions. The scoring metrics for these are listed in Table 6 (see Section 9.3 for the specific questions that were used to evaluate these criteria).

Criterion	0	1	2
Low Licensing Costs	Per-user or per-site licensing cost	Significant fixed licensing cost	Free or nominal fixed licensing cost
Few Intellectual Property Restrictions	Cannot make derivative works of terminology or resell/redistribute terminology without additional fees	Can either make derivative works of terminology OR resell/redistribute terminology without additional fees	Can make derivative works of terminology AND resell/redistribute terminology without additional fees
No Requirements for 3rd-Party Platform/Tools	Platform/tool requirements exist and entail additional costs	Platform/tool requirements exist, but not to use terminology itself (e.g. only for browser tools), or requirement entails no additional costs (i.e., platform/tool is free of charge)	No platform/tool requirements OR no response to question

Table 6. Scoring Metrics for Licensing Costs and Restrictions.

The scoring results for licensing costs and restrictions are listed in Table 7. It was difficult to assess the specific licensing costs for several terminologies based on the questionnaire responses alone, primarily because the relevant questions were left unanswered or answered vaguely (see Section 3.3). Follow-up information was requested from several of the terminology developers, which was usually sufficient to resolve these uncertainties. Only in the case of SNODENT did sufficient uncertainty remain regarding licensing costs that a score could not be assigned[1]. If additional information becomes available Additional licensing information will be incorporated into the scoring and the terminology evaluation as it becomes available.

Category	Terminology	Low Licensing Costs	Few Intellectual Property Restrictions	No Requirements for 3rd-Party Platform/Tools	Licensing/ Intellectual Property Score [max = 6]
General	Medcin	0	1	2	**3**
General	SNOMED CT	2	1	2	**5**
General	NCI Thesaurus	2	2	2	**6**
Lab	LOINC	2	2	2	**6**
Drug	Multum Lexicon	1	1	1	**3**
Drug	NDDF Plus	0	1	2	**3**
Drug	NDF-RT	2	0	2	**4**
Drug	RxNorm	2	2	2	**6**
Dental	SNODENT	?	0	2	**?**
Messaging	HL7 v.3 Codes	2	2	2	**6**

Table 7. Results of Scoring the Licensing Costs and Restrictions of Terminologies

[1] The terminology developers stated: "There is no licensing fee for clinicians to use SNODENT. For organizations that use SNODENT for processing, analytical or reporting purposes, or to generate income, there will be a modest, cost-based licensing fee, with the exact pricing to be determined." This did not provide enough specific information to assign a definitive score for the "Low Licensing Costs" criterion.

4.3.6. Responsiveness to Constituents

The questionnaire also addressed three criteria related to each terminology developer's responsiveness to constituents: Update frequency, sources of update requests, and availability of training. These criteria represent important elements of responsiveness that can be evaluated quantitatively. The scoring metrics for these criteria are listed in Table 8 (see Section 9.3 for the specific questions that were used to evaluate these criteria). The scoring results for these criteria are listed in Table 9.

Criterion	0	1	2
Update Frequency	Updated less than once per year OR "as needed"	(not used)	Updated at least once per year
Varied Sources for Update Requests **(- Internal staff - Outside consultants/advisors - users, user groups, or prof. societies)**	1 source type	2 source types	All 3 source types
Availability of Training	No training OR no response to question	Modest training	Extensive training

Table 8. Scoring Metrics for Responsiveness to Constituents.

Category	Terminology	Update Frequency	Varied Sources of Update Requests	Availability of Training	Responsiveness Score [max = 6]
General	Medcin	2	2	1	**5**
General	SNOMED CT	2	2	2	**6**
General	NCI Thesaurus	2	2	1	**5**
Lab	LOINC	2	2	2	**6**
Drug	Multum Lexicon	2	2	0	**4**
Drug	NDDF Plus	2	2	2	**6**
Drug	NDF-RT	2	2	1	**5**
Drug	RxNorm	2	2	0	**4**
Dental	SNODENT	0	2	0	**2**
Messaging	HL7 v.3 Codes	2	2	1	**5**

Table 9. Scoring Results for Responsiveness to Constituents

Discussion:

LOINC and RxNorm have the most favorable licensing and intellectual property (IP) provisions. SNOMED CT and the NCI Thesaurus also have favorable licensing provisions (neither entail a licensing fee), although the domain coverage of SNOMED CT appears to be significantly superior to the NCI Thesaurus (see Table 5). Note that favorable licensing terms are available for SNOMED CT only for use in the United States. The other terminology in the "general" category, Medcin, has less favorable licensing costs and IP restrictions (scoring "3") and may not be a good candidate for national PMRI terminology standards on that basis. Specifically, licensing of the Medcin terminology entails a per-site fee (albeit a modest one) and licensees may not redistribute the terminology without paying additional fees.

If SNODENT is deemed an important component of PMRI terminology standards, the specific licensing fees for SNODENT will need to be considered at the time they are determined. Given that SNOMED CT also contains significant dental content (most of it derived from an earlier version of SNODENT[1]), the NCVHS will need to carefully consider the required role of SNODENT in a national standard terminology.

Note that very few terminologies require costly 3rd-party tools for their use, so this criterion did not contribute significantly to distinguishing candidate terminologies.

Most of the terminologies that met the essential technical criteria also scored well in terms of responsiveness to their constituents. With the exception of SNODENT, all of these terminologies are updated at least annually and all of them solicit update requests from a wide variety of sources. The greatest disparities among these terminologies are with respect to the level of training provided. This criterion may be a less important aspect of responsiveness in the long run, however, because training may be and likely would be available from third parties for any terminologies identified as part of a national standard.

Qualitative Scoring

A number of other important organizational and process criteria exist that are not amenable to straightforward scoring. These criteria should also be considered in terminology-selection decisions, although they do not appear in Tables 7 and 9.

For example, a very important feature of a standard terminology is a funding mechanism that guarantees professional support, timely updates, and long-term viability. Although a questionnaire item did address the source of funding for each terminology, the responses ranged from the federal budget to government grants to individual license fees. There is no way to simply compare these responses to derive a numerical assessment of the relative or absolute merit of one funding mechanism versus another. When a "short list" is developed of otherwise viable terminologies, an assessment of the developers' ongoing financial viability will need to be made.

Another complex factor is the governance structure of a terminology developer and the effect of that structure on the quality and the timeliness of terminology updates. Because a trade-off may exist between the quality and speed with which a terminology is updated, for example, one cannot score the relative merits of consensus-based versus centralized editorial practices. Again, a detailed assessment of the complete editorial practices of the terminology developers should be undertaken once a short list of otherwise viable terminologies is determined.

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[1] Per email communication from College of American Pathologists (CAP), June 12, 2003. This communication included the following information: "In 1999… the CAP was licensed to incorporate into SNOMED® the entire nomenclature of dentistry [from SNODENT] and to assign SNOMED codes to the terms. Today… SNOMED CT contains approximately 4,000 concepts and 10,000 terms that are necessary to document, manage and evaluate the care of dental patients.

Lastly, the degree to which the market has accepted a candidate terminology is among the guiding principles for selecting PMRI standards. The questionnaire solicited information related to market acceptance, but the assessment of the responses was not amenable to quantitative scoring because the types and sizes of organizations currently using various terminologies is highly variable and may not be directly comparable. The collected information regarding the number and types of licensees is important, but should, again, be evaluated qualitatively once a short list of candidate terminologies for the Core Terminology Group has been specified. Additionally, consideration of market acceptance is also relevant to the identification of important legacy terminologies that should be mapped to the Core Terminology Group. This issue is addressed in Section 5.

4.4. Aggregated Scoring

To summarize the quantitative analysis of the questionnaire responses, an aggregate score was derived for each terminology, based on the sum of the scores for "Desired Technical Criteria" and "Desired Organizational and Process Criteria." The scores for "Essential Technical Criteria" are not included in this aggregate score, because the viable terminologies must meet all four of the essential technical criteria in any case (i.e., these metrics do not contribute to distinguishing viable terminologies)

If any metric for a terminology could not be calculated (i.e., was assigned the value "?"), the aggregated score for that terminology is also assigned "?." This occurred for the SNODENT terminology only. A final score will be computed for this terminology if more information becomes available. Table 10 shows the aggregate scores.

It's important to note that the aggregated scores are of the coarsest comparative value only and should not be used to "rank" terminologies. A simple linear summation does not take into account the relative importance of various criteria in selecting a national terminology standard. Although weights could have been assigned to the criteria to incorporate these considerations, it's likely that the weighting would have been different for different domain areas. For example, formal concept definitions may be more important for diseases, findings, and other general concepts than they are for drugs or devices. Given these variations in the weighting of criteria across domain areas and the relative small number of terminologies under consideration (i.e., those meeting the essential technical criteria), weighting was not applied in computing aggregate scores. It is possible (and will be necessary) to compare terminologies directly against each other by considering their scores for individual criteria.

Category	Terminology	Total Score (with licensing/IP) [max = 26]
General	Medcin	**18**
General	SNOMED CT	**25**
General	NCI Thesaurus	**25**
Lab	LOINC	**23**
Drug	Multum Lexicon	**18**
Drug	NDDF Plus	**20**
Drug	NDF-RT	**22**
Drug	RxNorm	**21**
Dental	SNODENT	**?**
Messaging	HL7 v.3 Codes	**17**

Table 10. Aggregate Scores for Each Terminology

5. Usage and Market Acceptance with Respect To Important Related Terminologies

The questionnaire also solicited usage and market acceptance data. This data is useful, among other things, to help identify important related terminologies that should be considered in the NCVHS terminology-standards recommendations, although they may not be appropriate for the core terminology group. Table 11 summarizes the data received on usage and market acceptance from all terminology developers.

	Category	Terminology	Earliest Use	Number of Licensing/Subscribing Organizations	Number of Licensing/Subscribing Software Developers	Number of End Users
Meet Essential Technical Criteria	General	Medcin	1987	11	10	21,500
	General	SNOMED CT	2001[7]	317	51	-
	General	NCI Thesaurus	1999	Unknown[3]	0	Unknown
	Lab	LOINC	1995	> 100	"10% to 35% of current instrument vendors"	Unknown
	Drug	Multum Lexicon	1997	Unknown	88	Unknown
	Drug	NDDF Plus	1984	Confidential	Confidential	Confidential
	Drug	NDF-RT	Pending 2003	N/A	N/A	N/A
	Drug	RxNorm	Pending 2003	N/A	N/A	N/A
	Dental	SNODENT	Pending 2003	N/A	N/A	N/A
	Messaging	HL7 v.3 Codes	Pending	N/A	N/A	N/A
Do Not Meet Essential Technical Criteria	General	MedDRA	1997	843	50	Unknown
	Lab	ISBT 128	1994	748	Unknown	-
	Devices	UMDNS	1979	1700	7	"several thousand"
	Drug	Medi-Span	1987	2012	236	298,000
	Drug	NDC+ Others	1970	Unknown	Unknown	Unknown
	Nursing	HHCC	1991	Unknown	30	Unknown
	Nursing	ICNP	2000	~100	1	"hundreds"
	Nursing	NMMDS	1997	-	-	Unknown
	Nursing	NANDA	1975	32	3	> 200,000[4]
	Nursing	NIC	1994	Unknown	10	Est. 100,000+
	Nursing	NOC	1996	24	10	Est. 100,000+
	Nursing	Omaha System	1978	220	10	Est. 4000
	Nursing	PCDS-VU	N/A [1]	1	0	2000
	Nursing	PNDS	1995	Est. "hundreds"	13	Unknown
	Alternative	ABC codes	1998	13	6	Est. 1000+
	Dental	Code on Dental Procedures and Nomenclature	1969	"several hundred"	~20	Unknown[5]
	Dental	ISO TOOTH DESIGNATION CODES	1994	"several hundred"	~20	Unknown[5]
	Dental	Universal/National Tooth Designation System	1968	"several hundred"	~20	Unknown[5]
	Messaging	DICOM	1999	-	-	-
	Messaging	HL7 v.2 Codes	1987	90% of large hospitals	Unknown	Unknown
	Messaging	ISO-11073	2002	Unknown	Unknown	Unknown
	Messaging	NCPDP Message Codes	1996 (SCRIPT)	Unknown	90% pharmacy software vendors	Unknown
	StatAbst&Admin	Core Health Data Elements	-	Unknown	-	-
	StatAbst&Admin	CPT	1966	100% healthcare institutions	350	Unknown
	StatAbst&Admin	DSM-IV-TR	2000[2]	Unknown	Unknown	Unknown[6]
	StatAbst&Admin	ICD-10-CM	Pending	N/A	N/A	N/A
	StatAbst&Admin	ICD-10-PCS	Pending	N/A	N/A	N/A
	Other	DEEDS	1997	Unknown	Unknown	Unknown
	Other	ICF	-	Unknown	0	Unknown
	Other	ICPC	1987	Unknown	Unknown	Unknown
	Other	PTCS	-	Unknown	Unknown	Unknown

[1] Not used outside of Vanderbilt University
[2] Earlier DSM versions used since 1954
[3] Numerous NCI intramural programs and extramural collaborators
[4] Estimated use in approximately 3,000 academic and community hospitals
[5] Used in ANSI X12 dental claims transactions
[6] "All organizations, institutions, and vendors that deal with mental disorder diagnoses use the DSM…impossible to give a count."
[7] Use of earlier forms of SNOMED (SNOMED, SNOMED II, SNOMED RT, etc.) dates back to 1974.
"-": Question not answered

Table 11. Usage/Market Acceptance Data from Terminology Questionnaires

Discussion: Several of the terminologies under consideration for the national standard have not yet been completed and officially released. These include, notably, NDF-RT and RxNorm (the non-proprietary drug terminologies that are being developed by the federal government). Although these terminologies score well with respect to the essential and desired technical criteria (see Tables 3 and 5), their use in practice remains to be demonstrated. Due to this fact, extra consideration should be given to whether the content and structure of these terminologies will support the practical uses that are envisioned for the national terminology standard.

A second general observation is that the precise usage and market acceptance of many of the terminologies is unknown (at least, by the terminology developers). In many cases, this is because the terminologies are available free-of-charge, often over the internet. There is no way for the terminology developers to assess which organizations and individuals who have acquired a copy of their terminology are actually using the terminology in practice. There are several terminologies that are known to be widely used, such as LOINC and Multum, that fall into this category. Other terminologies that are not free of charge, such as DSM-IV, were also unable to provide specific information regarding usage, although usage is known to be widespread. In cases where terminology developers were unable to provide usage data, the NCVHS will need to assess the market acceptance of the terminologies in other ways (e.g., anecdotally or using "proxy" indicators from the questionnaire, such as the number of government agencies or professional organizations that have officially approved the terminology for their internal use). These considerations may be important in assessing which terminologies *outside of the core terminology group* bear special consideration in terms of mappings or coordinated development with the core terminologies.

Based on the data provided, however, one can draw several tentative conclusions regarding important legacy terminologies:

1. The Medi-span GPI/DDID codes and the FirstDatabank NDDF-plus terminologies are in very widespread use today, often in clinical information systems (although FirstDatabank has asked the NCVHS to keep their specific usage data confidential, usage of FirstDatabank's NDDF-plus is on a scale comparable to the Medi-span GPI/DDID codes). The Multum Lexicon may also be in widespread use. When used in clinical systems, these terminologies often provide the proprietary coding of drug concepts that are needed for drug decision-support functions in computerized physician order entry systems. Given the importance of these functions, the co-existence and compatibility of these legacy terminologies with the drug-coding sections of the standard core terminologies will have to be carefully considered.
2. Several other terminologies that didn't meet the essential technical criteria are in widespread use, including MedDRA, ISBT-128, UMDNS, NANDA, NIC, NOC, the HL7 v2 codes, the NCPDP message codes, CPT, DSM-IV, and the dental terminologies used in X12 claims transactions. When the use of these terminologies relates directly to the documentation of clinical care in patient medical records, issues of co-existence or migration between these terminologies and the standard core terminologies should be considered in the NCVHS's final recommendations.

6. Conclusions

A large and diverse sample of medical terminologies was represented in the completed terminology questionnaires. Forty-one responses to the NCVHS PMRI Terminology Questionnaire were analyzed for this report. The terminologies range from general terminologies that include hundreds of thousands of concepts across numerous clinical domains to highly focused terminologies that include as few as 75 concepts. The evaluated terminologies were designed to support different and various functions, including the general-purpose capture and analysis of clinical data, the exchange of clinical messages among information systems, the encoding of interventions in nursing units and emergency departments, and the consistent bar-coding of blood products.

The quality of the data collected via the questionnaire instrument was generally quite good. Most respondents answered 80% – 90% of the "unconditional" questions, and the responses were usually clear and accurate. The completeness and accuracy of the data were sufficient to score the terminologies against many of the important selection criteria. In certain cases, important criteria could not be evaluated based on the content responses alone. In the majority of such cases, follow-up information was successfully obtained from the terminology developers sufficient to make the required assessments.

The majority of the terminologies (31 of 41, or 76%) did not meet all of the technical criteria that the sub-committee specified as essential for inclusion in the core terminology group. These terminologies were not evaluated with respect to subsequent technical and organizational criteria. Most of these terminologies lacked concept permanence (i.e., they removed concepts or changed the meanings of concepts over time) or they were not concept oriented in nature.

Although more than 3/4ths of the terminologies lacked essential technical features, the remaining candidate terminologies may adequately represent the clinical domains required for a complete PMRI terminology standard. This possibility exists because significant overlap exists in coverage between the terminologies that met the technical criteria and those that did not, and because several terminologies that did not meet the technical criteria have been incorporated into the qualifying terminologies (notably, several nursing terminologies and SNODENT have been incorporated into SNOMED CT). Whether important gaps in domain coverage exist across the qualifying terminologies must be investigated, however, through further evaluation of specific content.

Favorably, nine of the ten terminologies that met all of the *essential* technical criteria also scored well with respect to the *desired* technical criteria that were amenable to quantitative scoring. This group of "technically sound" terminologies comprises Medcin, SNOMED CT, NCI Thesaurus, LOINC, Multum Lexicon, NDDF Plus, NDF-RT, RxNorm, and SNODENT. These terminologies will be carefully considered for the core terminology group of the PMRI standard recommendations. The application of further selection criteria will certainly be necessary, as there is considerable overlap among certain members of this group. Particularly, Medcin, SNOMED CT, and the NCI Thesaurus overlap significantly with respect to general clinical concepts, whereas the Multum Lexicon, NDDF Plus, NDF-RT, and RxNorm overlap significantly with respect to medications.

Although data regarding the usage and market acceptance of terminologies was incomplete, several inferences could be made. Specifically, certain of the commercial drug terminologies are in very widespread use. Additionally, there are several terminologies that are not good candidates for the national PMRI terminology standard but which are widely used within existing administrative and clinical processes. Accommodating the users of these terminologies through mappings and/or migration tools may be an important consideration in the adoption of a new PMRI terminology standard.

7. Appendix I: Terminology Developers Who Received Questionnaire

Terminology (Abbr)	Terminology (Full Name)	Terminology Developer/Owner	Response
ABC codes	ABC codes, Version 2003	Alternative Link [The Foundation for Integrative Healthcare (FIHC) maintains the contents]	Received
ASTM Terminologies	ASTM Terminologies	American Society for Testing and Materials	Not Received
CDT-4	Code on Dental Procedures and Nomenclature	American Dental Association (ADA)	Received
CHDE	Core Health Data Elements	National Committee on Vital and Health Statistics (NCVHS) /National Center for Health Statistics/CDC	Received
CPT-4	Current Procedural Terminology, Fourth Edition	American Medical Association (AMA)	Received
DCS/CDT	Current Dental Terminology	American Dental Association (ADA)	Not Received
DEEDS	Data Elements for Emergency Department Systems	National Center for Injury Prevention and Control (NCIPC) [in CDC]	Received
DICOM	DICOM Controlled Terminology Definitions	DICOM	Received
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders	American Psychiatric Association (APA)	Received
HCPCS	HCFA Common Procedure Coding System	Centers for Medicare and Medical Services (CMS)	Not Received
HHCC	Home Health Care Classification	Sabacare Inc.	Received
HL7 v.2 Codes	Health Level Seven Version 2 Codes	Health Level Seven, Inc.	Received
HL7 v.3 Codes	Health Level Seven Version 3 Codes	Health Level Seven, Inc.	Received
ICD-10-CM	International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Clinical Modification	National Center for Health Statistics	Received
ICD-10-PCS	ICD-10-PCS	Centers for Medicare and Medical Services (CMS)	Received
ICF	International Classification of Functioning, Disability and Health	World Health Organization	Received
ICNP	International Classification for Nursing Practice	International Council of Nurses (ICN)	Received
ICPC	The International Classification of Primary Care	World Organization of Family Doctors (WONCA)	Received
IEEE 1073.1.1.1	IEEE Health informatics Point-of-care medical device communication Nomenclature	Institute of Electrical and Electronic Engineers (IEEE)	Received
ISBT 128	International Society of Blood Transfusion	International Council for Commonality in Blood Banking Automation, Inc (ICCBBA)	Received
ISO Tooth Designations	International Standards Organization (ISO) TC 106 Designation System for Teeth and Areas of the Oral Cavity	American Dental Association (ADA)	Received
LOINC	The Logical Observation Identifier Names and Codes	Regenstrief Institute, Inc.	Received
MEDCIN	MEDCIN	Medicomp Systems, Inc.	Received
Medi-span	Medi-Span Drug Terminology	Medi-Span, division of Wolters Kluwer Health, Inc.	Received
MedDRA	Medical Dictionary for Regulatory Activities	Northrop Grumman Mission Systems (MedDRA Maintenance and Support Services Organization)	Received
Multum Lexicon	Multum Lexicon	Cerner Multum, Inc.	Received
NANDA	NANDA/Nursing Diagnosis Definitions and Classification	NANDA International, formerly the North American Nursing Diagnosis Association	Received
NCI Thesaurus	NCI Thesaurus	National Cancer Institute	Received
NCPDP	NCPDP Message Codes	National Council for Prescription Drug Programs (NCPDP)	Received
NDC + others	FDA Data Standards Manual	U.S. Food and Drug Administration	Received
NDDF Plus	NDDF Plus	First DataBank, Inc	Received
NDF-RT	National Drug File Reference Terminology	U.S. Department of Veterans Affairs, with National Library of Medicine	Received
NIC	Nursing Interventions Classification	College of Nursing, the University of Iowa	Received
NMMDS	Nursing Management Minimum Data Set	NMMDS Research Team, College of Nursing, The University of Iowa	Received
NOC	Nursing Outcomes Classification	Iowa Outcomes Project at The University of Iowa, College of Nursing, Center for Nursing Classification and Clinical Effectiveness	Received
Omaha System	Omaha System	Martin Associates	Received
PCDS-VU	The Patient Care Data Set—Vanderbilt University	Vanderbilt University Medical Center	Received
PNDS	Perioperative Nursing Data Set	AORN: the Association of periOperative Registered Nurses	Received
PTCS	Provider Taxonomy Code Set	National Uniform Claim Committee (NUCC)	Received
RxNorm	RxNorm	National Library of Medicine	Received
SHML	Structured Health Markup Language	Health Language Center	Not Received
SNODENT	Systematized Nomenclature of Dentistry	American Dental Association (ADA)	Received
SNOMED CT	SNOMED Clinical Terms	SNOMED International, a division of the College of American Pathologists	Received
UMDNS	Universal Medical Device Nomenclature System	ECRI (formerly the Emergency Care Research Institute)	Received
UMLS	Unified Medical Language System	National Library of Medicine	Received - N/A
Universal/National Tooth Designation System	Universal/National Tooth Designation System	American Dental Association (ADA)	Received

Note: The questionnaire response for the Unified Medical Language System was not included in the analysis (by mutual agreement with the National Library of Medicine), because the UMLS does not represent a single terminology. Note that RxNorm was analyzed separately.

8. Appendix II: Terminology Developers (By Category) Who Responded to Questionnaire

Category	Terminology (Abbr)	Terminology (Full Name)	Terminology Developer/Owner	Organization Type
General	MEDCIN	MEDCIN	Medicomp Systems, Inc.	Private - For-profit
General	MedDRA	Medical Dictionary for Regulatory Activities	Northrop Grumman Mission Systems (MedDRA Maintenance and Support Services Organization)	Private - For-profit
General	NCI Thesaurus	NCI Thesaurus	National Cancer Institute	U.S. Government
General	SNOMED CT	SNOMED Clinical Terms	SNOMED International, a division of the College of American Pathologists	Private - Non-profit
Lab	ISBT 128	International Society of Blood Transfusion	International Council for Commonality in Blood Banking Automation, Inc (ICCBBA)	Prof. Society/Trade Group
Lab	LOINC	The Logical Observation Identifier Names and Codes	Regenstrief Institute, Inc.	Academic
Drug	Medi-span	Medi-span Drug Terminology	Medi-Span, division of Wolters Kluwer Health, Inc.	Private - For-profit
Drug	Multum	Multum Lexicon	Cerner Multum, Inc.	Private - For-profit
Drug	NDC + others	FDA Data Standards Manual	U.S. Food and Drug Administration	U.S. Government
Drug	NDDF Plus	NDDF Plus	First DataBank, Inc	Private - For-profit
Drug	NDF-RT	National Drug File Reference Terminology	U.S. Department of Veterans Affairs, with National Library of Medicine	U.S. Government
Drug	RxNorm	RxNorm	National Library of Medicine	U.S. Government
Nursing	HHCC	Home Health Care Classification	Sabacare Inc.	Private - Non-profit
Nursing	ICNP	International Classification for Nursing Practice	International Council of Nurses (ICN)	Prof. Society/Trade Group
Nursing	NANDA	NANDA/Nursing Diagnosis Definitions and Classification	NANDA International, formerly the North American Nursing Diagnosis Association	Prof. Society/Trade Group
Nursing	NIC	Nursing Interventions Classification	College of Nursing, the University of Iowa	Academic
Nursing	NMMDS	Nursing Management Minimum Data Set	NMMDS Research Team, College of Nursing, The University of Iowa	Academic
Nursing	NOC	Nursing Outcomes Classification	Iowa Outcomes Project at The University of Iowa, College of Nursing, Center for Nursing Classification and Clinical Effectiveness	Academic
Nursing	Omaha System	Omaha System	Martin Associates	Private - Non-profit
Nursing	PCDS-VU	The Patient Care Data Set—Vanderbilt University	Vanderbilt University Medical Center	Academic
Nursing	PNDS	Perioperative Nursing Data Set	AORN: the Association of periOperative Registered Nurses	Prof. Society/Trade Group
Alternative	ABC codes	ABC codes, Version 2003	Alternative Link [The Foundation for Integrative Healthcare (FIHC) maintains the contents]	Private - For-profit
Dental	CDT-4	Code on Dental Procedures and Nomenclature	American Dental Association (ADA)	Prof. Society/Trade Group
Dental	ISO Tooth Designations	International Standards Organization (ISO) TC 106 Designation System for Teeth and Areas of the Oral Cavity	American Dental Association (ADA)	Prof. Society/Trade Group
Dental	SNODENT	Systematized Nomenclature of Dentistry	American Dental Association (ADA)	Prof. Society/Trade Group
Dental	Universal/National Tooth Designation System	Universal/National Tooth Designation System	American Dental Association (ADA)	Prof. Society/Trade Group
Devices	UMDNS	Universal Medical Device Nomenclature System	ECRI (formerly the Emergency Care Research Institute)	Private - Non-profit
Messaging	DICOM	DICOM Controlled Terminology Definitions	DICOM	Prof. Society/Trade Group
Messaging	HL7 v.2 Codes	Health Level Seven Version 2 Codes	Health Level Seven, Inc.	Prof. Society/Trade Group
Messaging	HL7 v.3 Codes	Health Level Seven Version 3 Codes	Health Level Seven, Inc.	Prof. Society/Trade Group
Messaging	IEEE 1073.1.1.1	IEEE Health informatics Point-of-care medical device communication Nomenclature	Institute of Electrical and Electronic Engineers (IEEE)	Prof. Society/Trade Group
Messaging	NCPDP	NCPDP Message Codes	National Council for Prescription Drug Programs (NCPDP)	Prof. Society/Trade Group
StatAbst&Admin	CHDE	Core Health Data Elements	National Committee on Vital and Health Statistics (NCVHS) /National Center for Health Statistics/CDC	U.S. Government
StatAbst&Admin	CPT-4	Current Procedural Terminology, Fourth Edition	American Medical Association (AMA)	Prof. Society/Trade Group
StatAbst&Admin	DSM-IV	Diagnostic and Statistical Manual of Mental Disorders	American Psychiatric Association (APA)	Prof. Society/Trade Group
StatAbst&Admin	ICD-10-CM	International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Clinical Modifiation	National Center for Health Statistics	U.S. Government
StatAbst&Admin	ICD-10-PCS	ICD-10-PCS	Centers for Medicare and Medical Services (CMS)	U.S. Government
Other	DEEDS	Data Elements for Emergency Department Systems	National Center for Injury Prevention and Control (NCIPC) [in CDC]	U.S. Government
Other	ICF	International Classification of Functioning, Disability and Health	World Health Organization	Private - Non-profit
Other	ICPC	The International Classification of Primary Care	World Organization of Family Doctors (WONCA)	Prof. Society/Trade Group
Other	PTCS	Provider Taxonomy Code Set	National Uniform Claim Committee (NUCC)	Prof. Society/Trade Group

9. Appendix III: Specific Questions Used in Scoring Metrics

Each scored criterion is associated with one or more questions whose responses were used to assign the appropriate numerical score for that criterion. For the complete text of the questionnaire, please see Appendix IV.

9.1. Questions for Scoring Metrics Related to Essential Technical Criteria

Criterion	Question ID	Question Text	Comment
Concept Orientation	II_A	Do you distinguish between "concepts" and "terms" in your terminology?	An important facet of concept orientation, but not strictly essential
	II_E	How is the meaning of each coded concept represented?	Structured roles/attributes more characteristic of concept orientation
	II_F	Please provide examples of 3 concepts in your terminology and the way that their meanings are represented.	
	II_I	Do you allow multiple concepts and/or terms to have the same (synonymous) meanings?	To assess redundancy
	II_I1	If yes, how do you denote the synonymy?	To assess redundancy
	II_J1	Does your terminology include hierarchical relationships between terms?	Contributory, but not essential
Concept Permanence	II_G	Does your terminology allow the descriptions of concepts or the definitions of concepts to be changed from version to version?	
	II_H	If you allow changes, are there rules or guidelines regarding the extent to which a concepts description or definition may be changed:	If not, cannot assume concept permanence. Further information required.
	II_H1	If you answered "Yes", please describe these rules or guidelines:	If changes to meaning allowed, rules out concept permanence
	III_D	Do you remove concepts and terms from the terminology when they are obsolete or no longer needed?	Affirmative response rules out concept permanence
Non-Ambiguity	N/A	N/A	Cannot be assessed from survey questions; requires inspection.
Explicit Version IDs	III_B	How are versions of your terminology identified?	
	III_B1	Please give an example of your version identifiers.	

9.2. Questions for Scoring Metrics Related to Desired Technical Criteria

Criterion	Question ID	Question Text	Comment
Meaningless Identifiers	II_E	How is the meaning of each coded concept represented?	
	II_F	Please provide examples of 3 concepts in your terminology and the way that their meanings are represented.	Example Ids used to assess how "meaningless" they appear to be
	II_J2	If you have hierarchical relationships, how are they represented?	To assess whether the hierarchy is encoded into the identifiers
	II_J2a	Please provide several examples of this representation for one or two hierarchical relationships.	
	III_C	How do you determine the code to assign to each new concept or term?	
Multi-Hierarchies	II_J1	Does your terminology include hierarchical relationships between terms?	
	II_J3	If you have hierarchical relationships, does your terminology support the multiple classification of a single coded concept, i.e., can a single concept have more than one parent in the hierarchy?	
Non-Redundancy	II_I	Do you allow multiple concepts and/or terms to have the same (synonymous) meanings?	
	II_I1	If yes, how do you denote the synonymy?	
	II_I2	Please give three examples from your terminology of synonymous concepts or terms, if applicable	
Formal Concept Definitions	II_E	How is the meaning of each coded concept represented?	Multiple choice response, but often incorrect
	II_F	Please provide examples of 3 concepts in your terminology and the way that their meanings are represented.	Used to verify accuracy of response to II_E

Criterion	Question ID	Question Text	Comment
Infrastructure/Tools for Collaborative Terminology Development	III_H	What, if any, specific software tools are used by contributors and/or editors to maintain the terminology?	
	III_H1	Do the tools explicitly support the concurrent editing of the terminology by multiple people?	
	III_H2	If yes, please indicate how (e.g. by managing work assignments, detecting inconsistencies and conflicts, etc.)	
Change Sets	III_E	How do you provide updates?	
	III_E1	If changes with respect to the previous version are provided, please describe how these changes are represented. (You may give examples, if relevant.)	
Mappings to other terminologies	II_K	Does the terminology content include mappings to any other terminologies?	
	II_K1	If yes, please identify the other terminologies	
	II_K3	Were the mappings validated as complete and correct?	
	II_K3a	If "Yes", please describe how the validation was done.	

9.3. Questions for Scoring Metrics Related to Desired Organizational and Process Criteria

Criterion	Question ID	Question Text	Comment
Low Licensing Costs	V_A	Are there standard licensing terms for your terminology?	
	V_A1	If yes, please describe these terms, including the specific license fees (you may reference an attached document)	
	V_A2	If there are no standard licensing terms, please describe the licensing process, and what factors are used to determine the licensing fees and other terms for your terminology. Additionally, please provide one or more examples of the licensing terms that you have offered	
Few Intellectual Property Restrictions	V_B1	May licensees make derivative works of the terminology without further compensation to you?	
	V_B2	May licensees resell the terminology with further compensation to you?	Typo in the question, but I believe it was correctly interpreted by most respondents.
	V_B4	If applicable, please provide any standard provisions related to intellectual property that are included in your contract language.	This was used to verify or gather information related to questions V_B1 and V_B2 only.
No Requirements for 3rd-Party Platform/Tools	IV_D1	Does the use of your terminology require any of the following specific third-party tools or products?	
	V_C	If there are specific software tools that are required to use the terminology, and you provide these tools, what are the specific license fees or costs for these tools?	

Criterion	Question ID	Question Text	Comment
Update Frequency	III_A	How frequently are new versions of the terminology published?	
	III_A1	What is the schedule for these updates:	Used for scoring only if the response to III_A was “as-needed”.
Varied Sources for Update Requests	III_F1	How are additions/deletions/changes proposed (select all that apply)?	
Availability of Training	IV_C	Is instructor-based training available for the use of your terminology?	
	IV_C1-5	If training is available, please use the following table to describe the nature, setting, and source of the training	Subjective assessment as to whether training is “modest” or “extensive”

10. Appendix IV: Terminology Questionnaire and Request for Information

A request-for-information in the form of an email message containing a terminology questionnaire was sent to 45 developers of controlled medical terminologies in January 2003 by the Standards and Security Subcommittee (SSS) of the NCVHS. This section contains the text of the request-for-information and the full contents of the questionnaire that was distributed. The list of recipients is shown in Appendix I.

10.1. Request for Information

Subject: RE: NCVHS PMRI Terminology Questionnaire
Date: Mon, 6 Jan 2003 17:07:30 -0500
From: "Jeff Blair" <jeffblair@medrecinst.com>
To: "Virginia Saba" <vsaba@worldnet.att.net>, "Amy Coenen" <Amy.Coenen@marquette.edu>, "Andrea Feight" <feighta@cder.fda.gov>, "Bill Hess" <hess@cder.fda.gov>, "Bob Owens" <OWENS@ADA.ORG>, "Carol Bickford" <Cbickfor@ana.org>, "Chris Chute" <chute@mayo.edu>, "Cindy Hake" <Chake@cms.hhs.gov>, "Clem McDonald" <CLEM@regen.rg.iupui.edu>, "Connie Delaney" <connie-delaney@uiowa.edu>, "Daniel Pollock" <DAP1@cdc.gov>, "Darryl Regier" <dregier@psych.org>, "Dave Lareau" <dave@medicomp.com>, "David Rothwell" <rothwell@execpc.com>, "Dawn Bergen" <bergen.dawn@mayo.edu>, "Debra Konicek" <dkonice@cap.org>, "Diane Huber" <diane-huber@uiowa.edu>, "Dianne Aschmann" <daschma@cap.org>, "Donna Pickett" <dfp4@cdc.gov>, "Ed Steane" <esteane@iccbba.com>, "Elizabeth Richardson" <erichardson@ecri.org>, "FIHC" <mail@fihc.org>, "George Robinson" <george.robinson@firstdatabank.com>, "Gloria Bulechek" <gloria-bulechek@uiowa.edu>, "H. Lambert" <h.lambert@amc.uva.nl>, "Howard Clark" <how_clark@nema.org>, "Jay Scully" <jscully@psych.org>, "Jean Narcisi" <Jean_Narcisi@ama-assn.org>, "Jim Mundell" <jim.mundell@trw.com>, "Joanne Dochternman-McCloskey" <joanne-dochterman@uiowa.edu>, "Judy Ozbolt" <judy.ozbolt@vanderbilt.edu>, "Karen Martin" <Martinks@msn.com>, "Kay Avant" <kavant@grandecom.net>, "Kent Spackman" <spackman@ohsu.edu>, "Lynne Gilbertson" <lgilbertson@ncpdp.org>, "Marc Overhage" <moverhage@regenstrief.org>, "Marion Johnson" <marion-johnson@uiowa.edu>, "Marjorie Greenberg" <msg1@cdc.gov>, "Melinna Giannini" <melinna.giannini@alternativelink.com>, "Michael Beebe" <michael_beebe@ama-assn.org>, "Patricia Brooks" <pbrooks@cms.hhs.gov>, "Paul Placek" <PJP2@cdc.gov>, "Peter Goltra" <pgoltra@medicomp.com>, "Peter Hasiakos" <hasiakosp@ada.org>, "Peter Waegemann" <peter@tepr.com>, "Randy Levin" <levinr@cder.fda.gov>, "S. Beyea" <sbeyea@metrocast.net>, "Sandy Sporemba" <sporemba@regenstrief.org>, "Stan Huff" <coshuff@ihc.com>, "Steve Brown" <Steven.Brown@med.va.gov>, "Sue Bakken" <Suzanne.bakken@dmi.columbia.edu>, "Synthia Molina" <synthia.molina@alternativelink.com>, "Terri Meredith" <terrim@multum.com>, "Todd Cooper" <t.cooper@ieee.org>
CC: <sujansky@pacbell.net>, "Jeff Blair" <jeffblair@medrecinst.com>

To: Terminology Developers

Subject: Patient Medical Record Information (PMRI) Terminology Questionnaire

The Sub-Committee on Standards and Security of the National Committee on Vital and Health Statistics (NCVHS) invites you to reply to the attached questionnaire. The information that you provide in this questionnaire will be used by the NCVHS to evaluate and recommend PMRI terminologies for adoption by HHS in accordance with the Health Insurance Portability and Accountability Act (HIPAA).

The Administrative Simplification Provisions of HIPAA call for the NCVHS to"study the issues related to the adoption of uniform data standards for
patient medical record information and the electronic exchange of such information". The NCVHS presented a report with a framework for PMRI recommendations to the Secretary of Health and Human Services in August 2000. Feel free to review this report (about 60 pages) at www.ncvhs.hhs.gov. This report provided the framework and criteria for the selection of specific HIPAA PMRI standards.

The selection of specific PMRI Standards is being done in phases. The First phase focused on PMRI Message Format Standards and the NCVHS recommendations on these standards were sent to the Secretary of HHS on February 27, 2002. The Second phase is focusing on PMRI terminology standards and is the subject addressed by this questionnaire.

Please complete this questionnaire for each terminology (i.e., vocabulary, nomenclature, or code set) that you would like to have considered as a HIPAA PMRI terminology and return your questionnaire electronically to jeffblair@mindspring.com and a copy to Walter Sujansky at sujansky@pacbell.net by February 14th, 2003. The questionnaire is comprehensive, so be sure to schedule enough time to complete it. If you have any questions please let me know.

Sincerely,

Jeff Blair

Vice-Chair, Sub-Committee on Standards and Security

NCVHS

Attachment: PMRI Terminology Questionnaire.doc
Type: WINWORD File

10.2. Terminology Questionnaire

NCVHS PMRI Terminology Questionnaire

Instructions

1. Please fill in this questionnaire if you wish to have your terminology considered as a HIPAA Patient Medical Record Information (PMRI) terminology standard.
2. If you have more than one terminology that you wish to have considered, fill in separate questionnaires for each terminology.
3. Please respond to this questionnaire electronically. You may use any version of Microsoft Word or rich text format.
4. When you respond to this questionnaire, retain all of the section numbers, question numbers and the text of each question with your responses. Do not delete any of the numbers or text for each question. If you choose to not answer a particular question then enter a response of "no comment", "not available" or "not applicable".
5. You may decide to have different individuals complete different sections of the questionnaire for your terminology. If you do, be sure to consolidate all of the sections into one complete questionnaire before you submit it.
6. Please send your completed questionnaires to Jeff Blair at jeffblair@mindspring.com and a copy to Walter Sujansky at sujansky@pacbell.net by February 14th, 2003.

The questions reflect the characteristics and attributes of an ideal PMRI terminology. The NCVHS understands that most PMRI terminologies do not possess all of these characteristics and attributes, and in many cases, they still provide value with their present constructs. So please provide the most complete and accurate information that you can and do not be concerned if you are unable to give affirmative responses to all of the questions.

NCVHS PMRI Terminology Questionnaire

Name of the terminology. (Include the version of the terminology, if appropriate.)

Name of the organization that develops/maintains the terminology:

Contact Information:

Primary Contact: Title:
Email address: Phone number:

Secondary contact: Title:
Email address: Phone number:

I. **GENERAL INFORMATION**

A. Briefly state the purpose (primary uses) of this terminology. (For example, codes for nursing interventions, laboratory orders, laboratory results, dental procedures, etc.)

B. How long has your terminology been used in practice by an organization or institution that is independent of the developing organization (i.e., within applications and processes that provide clinical functionality of some kind)?

C. Please indicate the date of the earliest practical use of your terminology by an organization or institution that is independent of the developing organization.

D. Please indicate the specific information system, process, etc., in which it was first used.

E. Please characterize how widely your terminology is used:

1. How many healthcare organizations, institutions, or vendors are currently using your terminology (or using software applications or other processes that incorporate your terminology)? If you wish, please attach a listing of your current licensees/customers (optional).

2. Please indicate how this number was calculated:

___ count of organizational/institutional licenses (total)
___ count of implemented vendor systems that use your terminology
___ count of organizations or institutions that have at least one license for your terminology
___ Other (please describe)_____

3. How many commercial healthcare software developers have incorporated your terminology into their system? (If appropriate, please identify these vendors.)

4. What government agencies or professional organizations, if any, have officially approved your terminology as a standard for the electronic reporting, storing, or communication of patient medical data with respect to their organizations? Please describe the nature of the use of your terminology by these organizations.

Agency/Organization	**Approved**	**Description**
AHRQ		
ANSI		
CDC		
Consolidated Health Initiative (CHI)		
CMS		
DoD		
FDA		
HHS		
NIH/NCI		
Professional Nursing Associations		
Quality Practice Groups		
Tumor Registries		
VHA		

5. How many end-users of your terminology (or end-users of the applications/processes that incorporate your terminology), are there?

6. How was the number of end-users derived:

___ based on number of end-user licenses
___ based on the number of clinicians working for licensing entity(ies)
___ estimated
___ Other (Please describe)_____

7. If you have some other quantitative way of indicating the market acceptance of your terminology, please provide this information.

F. Is your terminology commonly used within or recognized by any of the following PMRI message format standards?

HL7 v2.2 and higher

___ Formally recognized as a standard code set within the messaging standard
___ Recommended as a possible code set for use within the messaging standard
___ Other status, Please describe:
___ Not Recognized

DICOM

___ Formally recognized as a standard code set within the messaging standard
___ Recommended as a possible code set for use within the messaging standard
___ Other status, Please describe:
___ Not Recognized

IEEE 1073

___ Formally recognized as a standard code set within the messaging standard
___ Recommended as a possible code set for use within the messaging standard
___ Other status, Please describe:
___ Not Recognized

NCPDP SCRIPT

___ Formally recognized as a standard code set within the messaging standard
___ Recommended as a possible code set for use within the messaging standard
___ Other status, Please describe:
___ Not Recognized

II. TERMINOLOGY CONTENT, STRUCTURE, & FEATURES

A. Do you distinguish between "concepts" and "terms" in your terminology?
___ Yes ___ No

Comment and clarification: Concepts are unique medical meanings and terms are the textual representations of those meanings. For example, a terminology that distinguishes concepts and terms might contain a *concept* with the identifier "5748839" that is described by the *terms* "Coronary Artery Disease" and "CAD", and that is classified as a child of the *concept* with the identifier "7748399" (itself described by the *terms* "Cardiovascular Disease" and "CVD").

B. How many total concepts are in your terminology?
Number: _____

C. How many total terms are in your terminology?
___ Not Applicable, do not distinguish between Concepts and Terms
Number: _____

D. Please use the chart below to categorize your terminology by the areas of clinical medicine that it covers, and provide the approximate number of concepts/terms in each category. (If your terminology distinguishes concepts and terms, please specify the number of each).

Domain Area	Example Concepts/Terms	Approx. Number Concepts	Approx. Number Terms*
Clinical disorders (diagnoses)	Rheumatoid Arthritis Coronary Artery Disease Spiral Fracture of the Humerus Paranoid Schizophrenia		
Subjective symptoms	Fatigue Lower Back Pain Radiating to Foot Vertigo Numbness		
Observed findings	S3 Gallop Tenderness in Right Lower Quadrant Maculopapular Rash Papilledema		
Procedures performed by clinicians (preventive, diagnostic, and therapeutic)	Sigmoidoscopy Urinary Catheterization Hip Arthroplasty FEV-1 Test		
Laboratory tests and test results, including specimen types, testing methods, and micro-organisms	Serum Potassium Level CSF Culture Hepatitis B Surface Antigen RIA		
Radiology tests and test results/findings	Abdominal CT Scan Chest X-Ray Mammogram Thyroid Scan		
Anatomical structures	Fibula Cerebellum Facial Nerve Vertebral Artery		
Medications	Glucophage lisinopril Benadryl		
Chemical substances other than medications	Vaccines Toxins Contrast Agents		
Medical devices and supplies relevant to the documentation of clinical care	Pacemaker Heart Valve Prosthesis Greenfield Filter Indwelling Catheter Ventilator		
Social and care-management concepts	Marital Status Values Occupations Healthcare Facility Types		

Standardized assessment tools	Glasgow Coma Scale Components APGAR Score Components Hamilton Depression Inventory Questions		

* Only provide number of terms if you distinguish between a concept and a term.

E. How is the meaning of each coded concept represented?
___ free-text descriptions
___ formal logic-based definitions (e.g. description logic)
___ another means? Describe: _____

F. Please provide examples of 3 concepts in your terminology and the way that their meanings are represented. If possible, please include relatively complex as well as simple concepts.

Concept Identifier	**Representation of Meaning**

G. Does your terminology allow the descriptions of concepts or the definitions of concepts to be changed from version to version?
___ Yes ___ No

H. If you allow changes, are there rules or guidelines regarding the extent to which a concepts description or definition may be changed:
___ Yes ___ No

If you answered "Yes", please describe these rules or guidelines:

If you answered "Yes", please provide an example of a description or definition that was changed:

I. Do you allow multiple concepts and/or terms to have the same (synonymous) meanings?
___ Yes ___ No

If yes, how do you denote the synonymy?
___ synonymy not denoted
___ within mapping tables
___ as a property of the main concept/term
___ Other, Describe: _____

Please give three examples from your terminology of synonymous concepts or terms, if applicable:

Concept/Term	**Synonymous Concept/Term**

J. Description of hierarchical relationships.

1. Does your terminology include hierarchical relationships between terms?
   ___ Yes ___ No

   If yes, please indicate which kinds of hierarchical relationships are represented:
   ___ is-a
   ___ part-of
   ___ Other, describe: _____

   Please provide several examples of hierarchical relationships in your terminology, if applicable (at least one for each kind of relationship that appears).

Concept/Term A	**Relationship**	**Concept/Term B**

2. If you have hierarchical relationships, how are they represented?
   ___ in structure of the codes themselves (E.g. “245.1” is child of “245”)
   ___ in tables containing “parent-child” pairs
   ___ Other, please describe: _____

   Please provide several examples of this representation for one or two hierarchical relationships.

3. If you have hierarchical relationships, does your terminology support the multiple classification of a single coded concept, i.e., can a single concept have more than one parent in the hierarchy?
   ___ Yes ___ No

   If yes, how is this represented?

   Please provide an example.

4. Are higher level categories in the hierarchy represented differently than lower level codes?
   ___ Yes ___ No

   If yes, how are they different?
   ___ not represented as coded concepts
   ___ represented using different kinds of codes
   ___ not formally defined
   ___ Other, please describe: _____

5. Does your terminology include other (non-hierarchical) relationships among concepts that are explicitly represented, such as “caused-by” or “treated-by”?
   ___ Yes ___ No

   If yes, please describe each kind of non-hierarchical relationship, with examples, if relevant.

K. Does the terminology content include mappings to any other terminologies?
   ___ Yes ___ No

1. If yes, please identify the other terminologies:

2. Describe the method by which the mappings were generated:

3. Were the mappings validated as complete and correct?
   ___ Yes ___ No

   If “Yes”, please describe how the validation was done.

4. How are the mappings represented:

   ___ By properties within each concept
   ___ In mapping tables
   ___ Other, describe _____

III MAINTENANCE & UPDATES

A. How frequently are new versions of the terminology published?

   ___ On as-needed basis
   ___ Annually
   ___ Semi-annually
   ___ Monthly
   ___ Other, describe: _____

1. What is the schedule for these updates:
   ___ Jan. 1 of each year
   ___ Fixed date each year (please specify date:_____)
   ___ First day of each quarter
   ___ ad hoc schedule
   ___ Other, describe:_____

B. How are versions of your terminology identified?
   ___ Numeric version identifier (e.g. “Version 4.6”)

___ Release date
___ Applicable date range
___ Other, describe: _____

Please give an example of your version identifiers. _____

C. How do you determine the code to assign to each new concept or term?

___ Sequential Number
___ By position of the concept/term in the hierarchy
___ Other, describe: _____

D. Do you remove concepts and terms from the terminology when they are obsolete or no longer needed?

___ Yes ___ No

If you do not remove concepts and terms, do you designate obsolete ones?

___ Yes ___ No

If yes, how do you designate obsolete codes?
___ Concept property
___ Code number change
___ Separate list
___ Other, describe: _____

If you do remove concepts and terms, do you take the opportunity to re-use their codes for new concepts and terms?

___ Yes ___ No

Please provide an example in which you have done this:

E. How do you provide updates?
___ a complete updated version
___ a set of changes with respect to the previous version ("delta")
___ both
___ Other, describe: _____

If changes with respect to the previous version are provided, please describe how these changes are represented. (You may give examples, if relevant.)

F. Please describe the policies, processes, and tools used to update your terminology. Specifically:

1. How are additions/deletions/changes proposed (select all that apply)?
___ Requests from individual users
___ Requests from user groups
___ Requests from professional societies
___ Suggestions from internal editorial staff
___ Suggestions from external consultants/advisors
___ Other, describe: _____

2. Please describe how the proposed changes are prioritized:

3. Please describe how editorial decisions are made regarding the way changes will be represented within the existing terminology (e.g. the text descriptions of new concepts, the location(s) of new concepts in the hierarchy, etc.)?

4. If you allow end-users and/or licensees to propose additions/deletions/changes to the terminology, what is the mechanism by which their input is solicited?

   ___ Informal request mechanism via email, letters, phone conversations, etc.
   ___ Formal request mechanism through user groups
   ___ Formal request mechanism through e-mail
   ___ Formal request mechanism through web-site
   ___ Other, describe: _____

5. Are editorial decisions based on group consensus?
   ___ Yes ___ No

   If yes, what is the process by which consensus is reached?
   ___ Informal internal consensus building meetings (i.e. among editors)
   ___ Informal external consensus building meetings (i.e. among users/licensees)
   ___ Formal voting or balloting process among all constituents (e.g. the ANSI-accredited balloting process)
   ___ Other, describe: _____

G. Human Resource Allocation

1. How many total FTEs are involved in the update process for your terminology (i.e., the editorial process as well as the specific terminology-development process)?

2. Please describe the approximate number of FTEs involved and their level of involvement in the following roles:

Role	Number of Employee FTEs Involved	Number of Member/Volunteer FTEs Involved	Total Number Involved
Terminology Editing			
Terminology Design			
Terminology Development			
Testing/Quality Control			
Support/Education			
Training			

3. Is there any specific training provided for the people involved in the terminology-development process?
___ Yes ___ No

If yes, please describe:

H. What, if any, specific software tools are used by contributors and/or editors to maintain the terminology?

Do the tools explicitly support the concurrent editing of the terminology by multiple people?
___ Yes ___ No

If yes, please indicate how (e.g. by managing work assignments, detecting inconsistencies and conflicts, etc.):

IV DELIVERY & IMPLEMENTATION

A. What media do you use to distribute your terminology (select all that apply):
___ CD-ROM
___ Floppy Disk
___ Web Download
___ Printed Materials
___ Other, please describe: _____

What file format do you use to distribute your terminology (select all that apply):
___ Delimited ASCII Records
___ Fixed Width ASCII Records
___ ASN.1 ASCII Files
___ Microsoft Excel Files
___ Microsoft Access Files
___ Other, please describe: _____

B. Describe the nature and the extent of the documentation provided:
___ descriptions of file formats
___ implementation guides
___ terminology browser applications
___ sample software
___ Other, please describe: _____

C. Is instructor-based training available for the use of your terminology?
___ Yes ___ No

If training is available, please use the following table to describe the nature, setting, and source of the training:

Training Provided (Y/N)?	**Training Setting**	**Provided By***
	At your site	
	At user's site	
	At professional society	

	meeting	
	At user group meetings	
	Other:	

* Options may include your staff, volunteers, paid consultants, etc.

D. Specific Tool or Product Requirements

1. Does the use of your terminology require any of the following specific third-party tools or products:
___ a terminology server
(specify:_____)
___ specific software application(s)
_____
___ specific database management
system(s)_____
___ specific operating system(s)
_____
___ specific hardware platform(s)
_____
___ Other, please describe:
_____
___ No specific third-party tools or products are required

2. If use of your terminology is dependent on any specific tools or products, please describe the dependencies below (E.g. "Terminology browser requires MS-Windows 98 operating system"):

Third Party Tools or Products	**Dependency**

E. Which of the following conformance-testing resources, if any, are available for licensees of your terminology:

Resource	**Provider (yourself, 3rd party, etc.)**
Conformance-testing tools	
Conformance-testing test suites	
Conformance-testing services	

V LICENSING & INTELLECTUAL PROPERTY

Licensing information is important to the terminology-evaluation process, so please address these questions thoroughly.

A. Are there standard licensing terms for your terminology?
___ Yes ___ No

If yes, please describe these terms, including the specific license fees (you may reference an attached document):

If there are no standard licensing terms, please describe the licensing process, and what factors are used to determine the licensing fees and other terms for your terminology. Additionally, please provide one or more examples of the licensing terms that you have offered, i.e., the terms of a specific licensing arrangement that you actually have in place (for an organization of a certain size and type, with a certain number of users, applying the terminology for a certain purpose). Please omit any identifying information about the customers/organizations.

B. The intellectual-property restrictions related to the licensing of your terminology

1. May licensees make derivative works of the terminology without further compensation to you?
___ Yes ___ No

2. May licensees resell the terminology with further compensation to you?
___ Yes ___ No

3. Must licensees cite the source of the terminology in their materials and application screens?
___ Yes ___ No

4. If applicable, please provide any standard provisions related to intellectual property that are included in your contract language.

C. If there are specific software tools that are required to use the terminology, and you provide these tools, what are the specific license fees or costs for these tools?

VI ORGANIZATIONAL ASPECTS

A. Is your organization for-profit?
___ Yes ___ No

B. Is your organization part of a larger organization (e.g., a subsidiary or business unit)?
___ Yes ___ No

If so, please specify the parent organization: _____

C. What is/are the primary funding source(s) for your organization's content-development work?
   ___ Income from license fees for the terminology
   ___ Federal grants
   ___ Other grants_____
   ___ Other, please describe: _____

D. Is your organization formally accredited?
   ___ No accreditation
   ___ Accredited by ANSI
   ___ Accredited by another standards body_____

E. Does your organization participate in any cross-terminology standards organization bodies (such as ANSI-HISB or HL7)? If so, please describe the nature of your participation.

Organization	**Nature of Participation**
ANSI-HISB	
HL7	
ASC X12N	

Thank you very much for taking the time to complete this questionnaire. Your input is very important and highly valued.

Summary and Analysis of User Testimony for PMRI Terminology Standards

A Report to the National Committee on Vital and Health Statistics Subcommittee on Standards and Security*

Version 3

Sept. 1, 2003

* This report was prepared by Walter Sujansky, MD. For comments and suggestions, please contact the author at wsujansky@sujansky.com.

Contents

1. Introduction

This report summarizes testimony given to the National Committee on Vital and Health Statistics (NCVHS) by invited users of 12 clinically relevant terminologies. At the time of the testimony, the NCVHS was considering these 12 terminologies as candidates for the core set of patient medical record information (PMRI) terminologies[1]. The 12 terminologies are a subset of over 40 existing clinical terminologies whose features were previously assessed by the NCVHS to identify suitable candidate PMRI terminology standards[2]. The previous assessment was based on information provided by the developers of the terminologies. In this phase, *users* of the terminologies were asked to provide written and oral testimony to the Standards and Security Subcommittee (SSS) of the NCVHS on the strengths, weaknesses, and general utility of the terminologies in practice. Written testimony was solicited in the form of a questionnaire circulated to the respondents. Oral testimony was taken in person at the May 21 – 22, 2003 meeting of the SSS. Eighteen users of the selected terminologies provided written and/or oral testimony to the sub-committee. Two additional testifiers provided general information not specifically related to the 12 terminologies. Their testimony is addressed separately in Section 5.

2. The Respondents

The goal of the user testimony was to ascertain the ways the candidate terminologies are used in practice and the terminologies' strengths and weaknesses. Eighteen users from various types of organizations provided testimony on the candidate terminologies. The names of the users, their affiliations, and the specific terminologies that they addressed appear in Table 1. Note that no testifiers specifically addressed the RxNorm drug terminology or the ISO 11073 device-communication terminology.

The types of organizations represented by the users who testified appear in the table below:

Organization Type	# Testifiers
Commercial Information System Vendor	5
Academic/Research Institution	5
Government Entity	3
Integrated Delivery Network	2
Terminology Middleware Vendor	2
Private Practitioner	1

[1] Note that 3 of these 12 terminologies were subsequently removed from consideration (ISO Tooth Designations, ISO 11073, and UMDNS). Another terminology was added to the set of terminologies under consideration subsequent to the terminology-user hearings (Multum Lexicon), therefore no testimony was heard from Multum Lexicon users during these hearings.

[2] Summary and Analysis of Responses to the NCVHS PMRI Terminology Questionnaire: A Report to the National Committee on Vital and Health Statistics Subcommittee on Standards and Security. Version 5. October 30, 2003. Report prepared by Walter Sujansky, MD on behalf of the Subcommittee on Standards and Security of the NCVHS

Testifier(s)	Organization	Type of Testimony		Terminology(ies) Addressed											
		Written	Oral	Medcin	NCI Thesaurus	SNOMED CT	NDDF Plus	NDF-RT	RxNorm	LOINC	ISO Tooth Designations	SNODENT	ISO 11073	UMDNS	HL7 v3
Diane Oliver, M.D. Ph.D.	Stanford University	X	X					X							
Keith Larsen, R.Ph.	Intermountain Health Care	X	X				X			X					
Albert H. Guay, D.M.D	Private Practitioner	X	X								X	X			
Brian Levy MD	Health Language, Inc.	X	X			X									
Ian Z. Chuang, MD, MS	Cerner Corporation	X	X			X				X					
John Faughnan, MD, MS	McKesson Information Solutions	X	X			X	X			X					
Lee Min Lau, M.D.	3M, Inc.		X							X					
Daniel J. Zinder, M.D.	Department of Defense	X	X	X											
Dr. Judy Warren	University of Kansas		X			X									
Verlyn Peterson, M.D.	University of Colorado		X	X											
John F. Madden, M.D. Ph.D.	Duke University Medical Center	X	X			X									X
Sam Brandt, MD	Siemens Medical Solutions	X	X			X									
Eric Mays, Ph.D.	Apelon, Inc.	X	X		X	X		X		X					
Leslie Wood	Department of Defense	X	X											X	
Sam Butler, M.D.	Epic Systems, Inc.	X	X	X		X				X					
Beverly Meadows	NCI, NIH	X	X		X										
Bob Dolin, M.D.	Kaiser-Permanente	X	X			X	X			X					
Mark Pittelkow, M.D.	Mayo Foundation	X	X			X									
Totals				3	2	10	3	2	0	7	1	1	0	1	1

Table 1. Testifiers and the Terminologies They Addressed

3. Responses to the Written Questionnaire

This section describes the responses to a written questionnaire that was used to collect information prior to the oral testimony. The questionnaire consisted of a *general section* and a *terminology-specific* section. The general section solicited information about the appropriate role for the government in creating terminology standards, as well as a few other issues. The terminology-specific section solicited information about how an individual terminology is used, what its perceived strengths and weaknesses are, and which of its features enable or impede accurate data analysis. The complete text of the questionnaire appears in Appendix I.

3.1. Role of the Federal Government

One of the important general questions asked in the questionnaire regarded the appropriate role of the federal government in advancing clinical terminology standards. The multiple-choice question provided options ranging from "do nothing" to "develop a master clinical terminology from scratch," and the respondents were asked to rank their preferences. A summary of the responses is provided in Table 2.

Discussion: The respondents indicated that neither extreme of "do nothing" nor "create a master clinical terminology from scratch" was appealing. Rather, the user community appears to prefer that the government select a core set of existing terminologies to serve as a national standard, and help the developers of these terminologies to extend and improve their content to fully meet users' needs. These preferences are consistent with the general approach favored by the NCVHS as articulated in a previous document[1].

The specific methods in which the federal government can help terminology developers to extend and improve content remains to be determined, but these methods may include directly funding terminology development, funding research to better understand gaps in existing terminologies, establishing forums (electronic and otherwise) to collect and distribute information regarding content gaps, and coordinating terminology-maintenance activities to prevent redundant, overlapping addition of new content to terminologies.

[1] Scope and Criteria For Selection of PMRI Terminologies: A Report to the National Committee on Vital and Health Statistics Subcommittee on Standards and Security. Version 3. December 23, 2003. Report prepared by Walter Sujansky, MD on behalf of the Subcommittee on Standards and Security of the NCVHS.

Testifier(s)	Organization	Recognize and/or adopt one or more clinically-specific terminologies that can serve as the core set of national PMRI terminology standards	Analyze clinical functions and identify the gaps in existing terminologies for fulfilling these functions	Develop PMRI terminology standards to fill these gaps	Support existing terminology developers to fill the gaps	Do nothing in terminology development and let the private sector fill the gaps as it will	Develop a single master terminology from scratch
Diane Oliver, M.D. Ph.D.	Stanford University	1	4	3	2		
Keith Larsen, R.Ph.	Intermountain Health Care	1	2				
Albert H. Guay, D.M.D	Private Practitioner	1			2		
Brian Levy MD	Health Language, Inc.	1	2		3		
Ian Z. Chuang, MD, MS	Cerner Corporation	1	3		2		
John Faughnan, MD, MS	McKesson Information Solutions	1	2		3		
Lee Min Lau, M.D.	3M, Inc.						
Daniel J. Zinder, M.D.	Department of Defense				1		
Dr. Judy Warren	University of Kansas						
Verlyn Peterson, M.D.	University of Colorado						
John F. Madden, M.D. Ph.D.	Duke University Medical Center	1	2		3		
Sam Brandt, MD	Siemens Medical Solutions	1	2	4	3		
Eric Mays, Ph.D.	Apelon, Inc.	3	1		2		
Leslie Wood	Department of Defense	1					
Sam Butler, M.D.	Epic Systems, Inc.	1	2		3		
Beverly Meadows	NCI, NIH		1				
Bob Dolin, M.D.	Kaiser-Permanente	1	3		2		
Mark Pittelkow, M.D.	Mayo Foundation	1	2	3	5		4
SUMMARY	Average Ranking	1.15	2.17	3.33	2.58	N/A	4.00
	Ranked as 1	12	2	0	1	0	0
	Ranked as 2	0	7	0	5	0	0
	Ranked as 3	1	2	2	5	0	0
	Ranked as 4	0	1	1	0	0	1
	Ranked as 5	0	0	0	1	0	0
	Ranked as 6	0	0	0	0	0	0

Table 2. Respondent Preferences Regarding Role of Federal Government in Terminology Standards

3.2. Terminology Uses in Practice

The questionnaire asked respondents to indicate the applications and clinical functions in which they applied the various terminologies that they use. A set of 9 "basic" functions was provided as a set of choices, and the respondents were invited to add other functions to this list. Table 3 shows how the 12 terminologies are being applied collectively at the institutions represented by the testifiers. Each cell contains the number of testifiers who indicated they apply a given terminology for the given application/clinical function. The total number of testifiers who provided information about a specific terminology is indicated below the terminology's name in square brackets. For example, 6 of the 9 testifiers who commented on SNOMED CT use SNOMED CT to populate physician notes. Given the small number of testifiers for each terminology, it would be inappropriate to draw any general conclusions about the use of various terminologies across the healthcare information landscape. However, this table provides useful background information to assess other data provided by the testifiers as a group (such as perceived strengths and weaknesses of various terminologies).

	Terminology											
Applications/Clinical Processes	Medcin [2]	NCI Thesaurus [2]	SNOMED CT [9]	NDDF Plus [4]	NDF-RT [1]	RxNorm [0]	LOINC [6]	ISO Tooth Designations [1]	SNODENT [1]	ISO 11073 [0]	UMDNS [1]	HL7 v3 [1]
Laboratory Orders			4				3		1			
Laboratory Results Reporting		1	4	1			5		1			1
Drug orders		1	1	3								
Physician notes	2		6				1					
Nursing notes	2		5				2					
Operative Notes			6						1			
History/Physical	2	1	6						1			
ED Charting	1		4									
Patient Referrals			3					1	1			
Clinical Observations							1					
Patient-care Orders			2									
Radiology Orders			1									
Allergy Documentation			1	3								
Medication Charting				3								
Formularies				1								
Immunization History			1									
Decision Support			4	1								
Problem List		1	3									
Report Generation			2									
Adverse Event Reporting		1										
Surgical Pathology Reporting			1									1
Administrative and Statistical									1			
Education and Research									1			
Terminology Middleware			1		1							
E&M Calculation	1											
ICD/CPT Lookup	1		1									
Claims Adjudication				1								
Equipment Management											1	
Documentatin of DME and Consumables			1									
Indexing Pharmacogenetics Abstracts in Medline					1							
Indexing Experimental Datasets					1							
Indexing Images			1									

Table 3. Uses of Terminologies

3.3. General Terminologies

Medcin, the NCI Thesaurus, and SNOMED CT were previously identified as "general" terminologies under consideration for the NCVHS terminology-standards recommendations. They are general in the sense that their contents span numerous domain areas of the patient medical record. This section summarizes the written comments of the testifiers on the strengths and weaknesses of these terminologies, as well as their features that enable or impede data analysis. The strengths and weaknesses of each terminology were assessed with respect to a specific set of 10 terminology attributes. Table 4 presents the data for Medcin and the NCI Thesaurus; Table 5 presents the data for SNOMED CT.

Terminology Attribute	Medcin		NCI Thesaurus	
	Testifier #1	Testifier #2	Testifier #1	Testifier #2
Overall usefulness as a PMRI (clinical) terminology	3	1		1
Adequacy of Domain coverage	3	2 thru 5*	1	1
Clarity of Concept/term meanings	4	1	1	2
Usefulness of semantic hierarchy and/or terminology organization	4	1	1	2
Degree of non-redundancy (i.e. absence of multiple concepts with the same meaning)	4	1	1	1
Version control	3	1	1	1
Timeliness of updates	2	1	1	2
Availability and quality of user education	3	N/A**	1	3
Responsiveness to adding new concepts, answering questions, providing support, etc.	4	4	1	1
Reasonableness and equity of licensure costs	2	1	1	1

Scale: 1 = Excellent, 3 = Adequate, 5 = Poor
*Varies by specialty
**User education provided through EMR vendor

Table 4. Scoring of Medcin and NCI Thesaurus with Respect to Terminology Attributes

Terminology Attribute	SNOMED CT								
	Testifier #1	Testifier #2	Testifier #3	Testifier #4	Testifier #5	Testifier #6	Testifier #7	Testifier #8	Testifier #9
Overall usefulness as a PMRI (clinical) terminology	1	1	3	2	1	1	1	2	2
Adequacy of Domain coverage	1	1	3	3	1	1	2	2	2
Clarity of Concept/term meanings	2	1	2	2	1	1	1	2	3
Usefulness of semantic hierarchy and/or terminology organization	1	1	1	1	1	1	1	2	3
Degree of non-redundancy (i.e. absence of multiple concepts with the same meaning)	1	1	1		1	2	1	1	3
Version control	1	1	1		1	2	1	2	2
Timeliness of updates	1	1	3		1	1	1	2	
Availability and quality of user education	1	1	4	3	1	1	1	2	3
Responsiveness to adding new concepts, answering questions, providing support, etc.	1		3		1	1	1	3	4
Reasonableness and equity of licensure costs		3	5		1	3		3	3

Scale: 1 = Excellent, 3 = Adequate, 5 = Poor

Table 5. Scoring of SNOMED-CT with Respect to Terminology Attributes

In addition to scoring against general terminology attributes, the respondents also indicated the features of a terminology that enabled or hindered effective data analysis, as well as specific gaps or deficiencies in the terminology in general. For the general terminologies, a summary of these responses is provided in Table 6 (Note: this table aggregates the responses across all testifiers, rather than specifying the response of each one).

Terminology Attribute	Medcin	NCI Thesaurus	SNOMED CT
Data Analysis - Enabling Features	*Each concept is clinically relevant *Very little redundancy or ambiguity *Supports structured data entry task efficiently and conveniently	*Standardization of terms and valid values allows aggregation and consistent analysis of data	*Excellent breadth and detail in coverage *Non-redundancy *Extensive multi-hierarchies and other formal (semantic) relationships among concepts *Synonyms *Availability of mappings to administrative code sets [Note: not part of NLM license] *Availability of vendor tools
Data Analysis - Impeding Features	*Gaps in content coverage require free-text entry, which undermines analysis; insufficient specificity in certain areas *Lack of multiple hierarchy		*Difficult to determine equivalence of pre-coordinated and post-coordinated concepts in certain cases, due to "unconstrained post-coordination"
Gaps	*Content coverage is variable, depending on the specialty *Process for submitting new term requests is ad hoc *Content addition process is too centrally controlled, which slows it down *Process for QA'ing new terms could be improved *Adequate medication content	*More emphasis on needs of end-users involved in clinical research (I.e., support for data entry)	*Navigation hierarchies for data entry *More synonyms (including foreign-language synonyms) needed to reduce localization work *Adequate medication content *More orderables, including nursing orderables *Standard syntax for expressing post-coordination ("combinatorial grammar" or "semantic normal form") *Lack of tight integration with HL7 RIM

Table 6. Assessment of General Terminologies for Data Analysis Functions

Discussion: There was considerable variability regarding the strengths and weaknesses of Medcin between the two testifiers who provided written comments. This may reflect the different uses of the terminology by each testifier – testifier #1 is involved with the use of Medcin for a variety of data capture as well as data-analysis functions, whereas testifier #2 is primarily involved in the use of Medcin as a front-end, clinical documentation tool. However, there was agreement that the content coverage of Medcin was only adequate and that the responsiveness of the terminology developer to user requests/questions was below adequate. These opinions were echoed in describing the impeding features and gaps of Medcin with respect to data analysis.

The NCI Thesaurus was considered excellent or very good by both testifiers across most categories. The only complaint of the terminology was that it did not support data entry as well as it could.

SNOMED CT was also considered excellent or very good across most categories, with the exception of equitable licensing costs (note that the testimony was provided prior to the completion and announcement of the NLM license for SNOMED CT, which will presumably change the perceived “reasonableness” of licensing costs). With respect to data analysis, most users felt SNOMED CT possesses many excellent features to support this function, although the lack of a grammar for creating compositional expressions was deemed a deficiency. SNOMED CT was also judged to be lacking content for orderables and medications, as well as navigation structures suitable for data entry.

3.4. Drug Terminologies

Written testimony on the drug terminologies also addressed the strengths and weaknesses with respect to the pre-defined criteria (Table 7), as well as the features of the terminologies that support or impede data analysis (Table 8). Note that no testimony (written or oral) was received on the RxNorm terminology.

Terminology Attribute	NDF-RT		NDDF Plus		
	Testifier #1	Testifier #2	Testifier #1	Testifier #2	Testifier #3
Overall usefulness as a PMRI (clinical) terminology		1	1	3	1
Adequacy of Domain coverage	2	1	1	2	1
Clarity of Concept/term meanings	1	1	2	2	1
Usefulness of semantic hierarchy and/or terminology organization	1	1	1	2	
Degree of non-redundancy (i.e. absence of multiple concepts with the same meaning)	1	1	2	3	1
Version control			2	1	1
Timeliness of updates			1	1	1
Availability and quality of user education			2	3	1
Responsiveness to adding new concepts, answering questions, providing support, etc.			1	3	1
Reasonableness and equity of licensure costs			3	3	

Scale: 1 = Excellent, 3 = Adequate, 5 = Poor

Table 7. Scoring of Drug Terminologies with Respect to Terminology Attributes

Terminology Attribute	NDF-RT	NDDF Plus
Data Analysis - Enabling Features	*Explicit (formal semantic) representation of generic drugs *Normalization of strengths and units	*Ingredient associations to medications *Multi-hierarchy for therapeutic classes *Multiple levels of abstraction (named drug, routed drug, dispensable drug, etc.) *Absence of redundancy *Rich set of concepts and relationships among concepts *Relationship between generic and trade drug
Data Analysis - Impeding Features		*Non-numeric unit codes *Composite (non-discrete) concentration units
Gaps		*Orderables - terminology not oriented around ordering *Set of NDC codes is incomplete *Allergens, indications, allergic reactions, and micro-organisms should be mapped to SNOMED

Table 8. Assessment of Drug Terminologies for Data Analysis Functions

Discussion: Although NDF-RT was assessed as excellent or very good with respect to many of the terminology attributes, not all of the attributes could be judged since NDF-RT has just recently been introduced. For NDF-RT, therefore, the attributes related to updates, version control, and user education were not addressed at all. The comments on NDDF Plus indicated some variability of opinion, although the terminology was judged at least "adequate" by all testifiers for all criteria. With respect to data analysis more comments were made on NDDF Plus than NDF-RT, also probably due to the longer standing use of NDDF Plus. Nevertheless, both terminologies were judged effective for clinical data-analysis functions, with relatively few gaps in general.

3.5. LOINC

LOINC was similarly addressed in the written testimony of 5 of the testifiers. Scoring regarding the strengths and weaknesses of LOINC appear in Table 9 and an assessment of LOINC's features related to data analysis and its general gaps appear in Table 10.

Terminology Attribute	LOINC				
	Testifier #1	Testifier #2	Testifier #3	Testifier #4	Testifier #5
Overall usefulness as a PMRI (clinical) terminology	4		1	1	1
Adequacy of Domain coverage	3	3	3	2	1
Clarity of Concept/term meanings	2	3	1	1	2
Usefulness of semantic hierarchy and/or terminology organization	5	4	4	2	3
Degree of non-redundancy (i.e. absence of multiple concepts with the same meaning)	1	2	1	3	2
Version control	4		2		2
Timeliness of updates			2	3	1
Availability and quality of user education	4	3	1	2	1
Responsiveness to adding new concepts, answering questions, providing support, etc.	5		1	1	1
Reasonableness and equity of licensure costs	1	1	1	1	1

Scale: 1 = Excellent, 3 = Adequate, 5 = Poor

Table 9. Scoring of LOINC with Respect to Terminology Attributes

Terminology Attribute	LOINC
Data Analysis - Enabling Features	*Unique, non-redundant concepts
Data Analysis - Impeding Features	*Hierarchies and domain associations ("classes") are limited.
Gaps	*Orderables/Panels *Synonyms *Explicit (formal) semantic model & hierarchies for test components

Table 10. Assessment of LOINC for Data Analysis Functions

Discussion: Although LOINC was judged adequate or better with respect to most terminology attributes, users did express specific concerns with respect to LOINC's absence of hierarchical structure and synonyms. These are significant concerns, as these features are important enablers for querying, abstracting, and analyzing laboratory result data. The absence of orderables/panels is a practical concern that limits the usefulness of LOINC in order-entry applications, but it is less relevant to the data-interoperability and data-analysis functions of standard terminologies, the primary subjects of the NCVHS's standardization activity.

3.6. Additional Terminologies

Testifiers commented on four additional terminologies in the written testimony. These comprised SNODENT, the ISO Tooth Designation System, and the UMDNS. The strengths and weaknesses of these terminologies are summarized in Table 11 and the enabling and impeding features with respect to data analysis are summarized in Table 12. Note that no written or oral testimony was received on the ISO 11073 standard for communication of device data. Additionally, although testimony was received on HL7, the content was specific to the HL7 Clinical Data Architecture and Reference Information Model rather than the HL7 terminology, per se. Hence, the testimony on HL7 was not directly relevant to the NCVHS terminology recommendations activity and is, therefore, not summarized in this format.

Terminology Attribute	SNODENT Testifier #1	ISO Tooth Designation Testifier #1	UMDNS Testifier #1
Overall usefulness as a PMRI (clinical) terminology	1	1	2
Adequacy of Domain coverage	1	1	2
Clarity of Concept/term meanings	1	1	2
Usefulness of semantic hierarchy and/or terminology organization	1	1	2
Degree of non-redundancy (i.e. absence of multiple concepts with the same meaning)	1	1	2
Version control	2	2	2
Timeliness of updates	2	2	2
Availability and quality of user education	3	3	2
Responsiveness to adding new concepts, answering questions, providing support, etc.	2	2	2
Reasonableness and equity of licensure costs	1	1	3

Scale: 1 = Excellent, 3 = Adequate, 5 = Poor

Table 11. Scoring of Additional Terminologies with Respect to Terminology Attributes

Terminology Attribute	SNODENT	ISO Tooth Designation	UMDNS
Data Analysis - Enabling Features	"SNODENT provides unambiguous reporting of dental diagnoses, descriptions, conditions and other characteristics in patient records, electronic commerce, clinical and educational research." - Dr. Albert Guay	"The ISO Designation System for Tooth and Areas of the Oral Cavity supports unambiguous reporting of the oral cavity geography and dentition in three-dimensional space. This system is readily mapped to the Universal/National Tooth Designation system that is in common use within the United States." - Dr. Albert Guay	*Use of standard 5-digit code rather than text descriptions of devices
Data Analysis - Impeding Features			
Gaps		"Until such time that a change to the human genome influences the number of teeth in normal dentition, the ISO system and the Universal/National system are sufficiently robust." - Dr. Albert Guay	*Fact that no universal standard has been adopted for coding medical devices [this would facilitate device recalls, for example]

Table 12. Assessment of Additional Terminologies for Data Analysis Functions

Discussion: Each terminology was addressed by only one testifier, so one cannot judge the generality of the observations. From the written testimony that was submitted, the terminologies were deemed at least adequate with respect to all of the terminology attributes. Additionally, the testifiers found these terminologies quite adequate for data analysis functions.

4. Summary of Oral and Written Testimony on Terminologies

In addition to the written testimony submitted via the questionnaires, 18 testifiers gave oral testimony before the NCVHS subcommittee on May 21 and 22, 2003. In their oral testimony, testifiers summarized their written comments, emphasized specific areas of importance, and added new information. Additionally, three testifiers submitted no written testimony (see Table 1), so their oral comments before the subcommittee comprised the entirety of their testimony to the NCVHS.

Several important themes emerged from the written and oral testimony given to the SSS that are worth summarizing. However, the summaries below do not necessarily constitute the conclusions of the NCVHS regarding any terminology or any issue related to a terminology's suitability for a national standard. The summaries simply encapsulates the testimony received.

4.1. SNOMED CT

SNOMED CT is an excellent basis for a standard clinical terminology. It has very good domain coverage and rich multi-hierarchies. SNOMED is based on a sound terminology model, and demonstrates good update and maintenance practices (with the possible exception of the term-submission process). SNOMED is used in a variety of applications and clinical functions, including various forms of clinical charting, as well as the ordering of laboratory, drug, and other patient-care services. The use of SNOMED is typically driven by the business need for decision support and outcomes analysis.

Despite its sound features and widespread applicability, SNOMED CT is not currently sufficient as a comprehensive clinical terminology. Specifically, it lacks sufficient content in the areas of medications and laboratory tests. Also, SNOMED's hierarchy and other navigation structures are not well suited for user data entry. This is a significant concern, because effective mechanisms and methods for structured data entry are important elements of clinical applications. Organizations must typically create their own data-entry hierarchies or use existing data-entry terminologies; in either case, some mapping is required between the data-entry structures and the SNOMED content.

Although SNOMED CT is highly regarded by many of the users who testified, it is not widely deployed in commercial systems. This is owing to its historically high licensing costs. The testifiers representing commercial vendors indicated that their customers simply won't pay the additional licensing costs required to use SNOMED. These vendors expressed a hope and expectation that the NLM's efforts to license SNOMED on behalf of the domestic marketplace will be successful (this has now occurred).

4.2. Medcin

Medcin is an effective terminology for clinician data entry, with intuitive and useful navigation paths. There is very little redundancy or ambiguity in the terminology, and the concepts within it are clinically relevant. However, Medcin's content coverage is variable, with some specialty areas lacking adequate content. Also, Medcin's lack of multi-hierarchies impedes its usefulness and effectiveness in reporting and decision-support functions, because each concept can be abstracted along one hierarchical path only. Also, the process by which requests for new terms are submitted and the process by which new terms are added and validated could be improved.

4.3. Drug Terminologies

The oral testimony indicated that "routed generic" is an appropriate level of abstraction for most decision-support functions, but not for order entry. The order-entry function requires more specific and expansive information, including discretely represented trade names, dosage forms, strengths, etc.

Timely updates are very important for drug content, which changes rapidly. The ideal frequency of such updates should be weekly to monthly.

Although the users of FirstDatabank's NDDF Plus terminology are generally very satisfied with it as a general-purpose terminology for reporting and decision support, certain testifiers expressed that its content was not adequate for order-entry functions. Also, several testifiers expressed the desire for a low-cost *standard* terminology to enable interoperability among systems using disparate commercial drug applications.

4.4. LOINC

LOINC is a terminology that is recognized as valuable *and* widely deployed in commercial and other systems. Among the five testifiers who use LOINC, all agreed that the terminology had adequate domain coverage, clarity of concepts, non-redundancy, and very reasonable licensing costs. The deficiencies of LOINC stem primarily from its lack of concept hierarchies, which prevent the abstraction and aggregation of similar lab tests, an important feature for data-analysis. Although testifiers also remarked that LOINC would benefit from more lab panels, this deficiency primarily affects order-entry applications.

4.5. Terminology Mapping

Numerous testifiers stated that mapping concepts from different terminologies to each other is very difficult and costly, although necessary for many practical functions such as reporting, decision support, and the integration of clinical and administrative functions. The effort and complexity of mapping increases quickly ("logarithmically") with the number of terminologies involved. Additionally, a single mapping between terminologies may not suffice, as mappings are sometimes specific to particular contexts or uses. Several testifiers suggested that the issue of mapping will become very important in the NCVHS's terminology standards recommendations, given the NCVHS's intent to recommended a core *set* of terminologies for the national standard. To better manage the integration and mapping of the core terminologies, the testifiers recommended that terminologies be selected that have minimal overlap in content and maximum consistency in their representational models. Additionally, the testifiers underscored the need for interoperability among the core terminologies, as well as cooperation and coordination in the maintenance of these terminologies.

4.6. Support for Business Processes

Several testifiers emphasized that the clinical terminologies selected for the PMRI standard must co-exist with and support important non-clinical (business) processes within healthcare enterprises. These processes include billing for services, supporting existing regulatory requirements, and enabling efficient workflow practices. The substantial impediment of these processes by a terminology standard will quickly outweigh any benefits conferred by the standard with respect to clinical reporting, interoperability, and decision support. The healthcare community will not embrace a standard that creates such impediments, so the effect (if any) of a proposed terminology standard on existing business processes is very important.

5. Additional Testimony Not Related to Specific Terminologies

In addition to the 18 testifiers who specifically addressed one or more of the candidate terminologies, two individuals testified on general topics related to the NCVHS terminology-recommendation activity: James Cimino, M.D., professor of Medical Informatics at Columbia University Medical Center, and Ed Larsen, an independent consultant. Dr. Cimino testified representing the "Connecting For Health" initiative, a public-private collaborative whose goals include the promotion of data standards for interoperability in the health care system. Mr. Larsen testified on behalf of the Health Information and Management Systems Society (HIMSS), a professional association and trade organization for healthcare information technology and management.

5.1. Summary of Testimony from James Cimino

Dr. Cimino presented the results of a terminology conference sponsored by the Connecting for Health initiative[1]. The conference addressed the role of terminology standards in realizing an interoperable health care system. Dr. Cimino presented several "draft consensus statements" that emerged from the meeting regarding the structure and ongoing support for such terminology standards.

- The terminology (or core set of terminologies) should be *open and inclusive*, i.e., the ongoing control of content and structure should be subject to an open, inclusive process that is accessible to all stakeholders.
- The terminology should be uniform in structure.
- The terminology should be sufficiently general and comprehensive ("cross-domain") to support use by *all stakeholders* who apply controlled terminologies for clinical applications.
- The relevant terminologies should be integrated into a single reference terminology set. Users require an integrated single reference terminology.
- There should be a clear delineation of the respective domains that are covered by each terminology in the core terminology set. If multiple terminologies include content relevant to a particular domain (overlap), the terminologies should be merged, not mapped. Redundancies should be eliminated.
- There should be a "terminology integration function" that encompasses the following responsibilities: oversight, process management, and repository maintenance. Different bodies could carry out each of these roles or they could be combined within a single organization. The oversight body should have public/private representation, be independent, have stable funding, and have the authority/mandate to overcome barriers.
- There should be a single repository for the standard set of terminologies.
- There should also be an integrated information model, to provide the context for the use of terms and enable interoperability.

The recommendations of Dr. Cimino and the Data Working group are cogent and consistent with many of the objectives of the NCVHS for its terminology standards recommendations. The details regarding roles and responsibilities, terminology integration, delineation of non-overlapping content domains, and a repository for the standard terminology remain to be specified, but the general concepts proposed are useful and important.

[1] See www.connectingforhealth.org.

5.2. Summary of Testimony from Ed Larsen

Mr. Larsen expressed concern whether the forthcoming recommendations of the NCVHS for PMRI terminology standards would move the healthcare industry closer to a "universal electronic health record" (E.H.R.), assuming that this was the purpose of the recommendations. In fact, he felt that the recommendation of terminology standards at this time would *impede* the creation of a universal E.H.R., because the development of E.H.R. technology within industry is still very nascent and in flux. Hence, the "freezing" of terminology in the form of a standard would stifle innovation. Mr. Larsen's reasoning was that the specification of terminologies and other E.H.R. components (such as record structures and document structures) are tightly interwoven. By creating a terminology standard at this time, choices regarding the design of other E.H.R. components would, as a result, become unduly constrained.

Mr. Larsen also expressed concern that the rationale and business case for medical terminology standards had not been adequately outlined by the NCVHS, so that the context of the terminology-selection process was not clear. As a result, the selection criteria used in the terminology-analysis process were too focused on "technology issues" (such as concept orientation, non-redundancy, etc.), and too little focused on the practical issues of need and use. He suggested that, at a minimum, adequate consideration should be given to other non-technical selection criteria, such as market acceptance, compatibility with administrative functions, intellectual property concerns, and cost.

6. Conclusions and Next Steps

The testimony given to the NCVHS by users of the candidate terminologies provided input from a variety of perspectives on the strengths, weaknesses, and general quality of the terminologies. Although the input was heterogeneous, several themes did emerge. These themes may suggest certain directions with respect to the terminology-selection process of the NCVHS:

- SNOMED CT remains a good choice as a terminology for the set of core PMRI terminologies. However, it must either be augmented with additional medication content and laboratory-test content or it must be complemented by other terminologies that have adequate coverage in these areas.
- The structures and navigation paths within SNOMED CT do not support the clinician data-entry function well. Although data-entry is not within the primary scope of the NCVHS terminology-standard recommendations, data entry is a very important function with respect to real-world clinical information systems, since no coded data can be aggregated, exchanged, or analyzed in its absence. The expectation is that terminology structures that do support data entry will continue to be created and used by individual organizations in the near to mid term, and these structures will be mapped to SNOMED CT and the other core PMRI terminologies. The alternative (inclusion of a user-interface terminology, such as Medcin, in the standards recommendation) is not appropriate because (1) the content of Medcin does not adequately encompass all specialties, and (2) individual organizations may wish to design user-interface structures different than those in Medcin and they should be free to do so since this will not undermine the utility of the PMRI terminology standard for exchanging and aggregating data (as long as suitable mappings are also created). At the same time, other organizations remain free to use Medcin if Medcin meets their needs.
- LOINC is a very effective terminology for the standard representation of laboratory test results and (to a lesser extent) for the ordering of lab tests. To the extent that ordering is a "user-interface" function, it is possible and feasible that organizations will continue to create their own test panels and other orderable items, similar to the way that they will create user-interface structures for the general content represented by SNOMED CT. LOINC must be augmented, however, to address its deficiencies with respect to the hierarchical organization of individual LOINC concepts. This augmentation could take the form of adding higher-level concepts to LOINC itself or classifying LOINC concepts comprehensively using the concepts within another core terminology (such as SNOMED CT). Although individual organizations also could create their own hierarchical structures on top of the LOINC code set, such hierarchical abstractions are fundamental to data-analysis functions (much more so than user-interface structures are), so adoption of the LOINC terminology as a national standard for the aggregation and interoperability of laboratory data would benefit from the availability of such structures within the terminology standard itself.
- The user testimony did not yield enough information regarding the utility, in practice, of NDF-RT and RxNorm. Given that these license-free terminologies are just now emerging, one cannot recommend them yet for the core set of PMRI Terminologies over widely used and well-accepted terminologies such as NDDF Plus (despite the barriers to universal adoption posed by the significant licensing costs of the latter). Additional analysis that compares the content and structure of NDF-RT/RxNorm against the specific requirements for the drug content in the core set of PMRI Terminologies is required.

- Similarly, not enough information has been collected to choose between SNODENT and the dental content within SNOMED CT for the dental components of the terminology standard. Although one user testified that SNODENT was of high quality and effective for data analysis, additional research that compares the dental content within SNODENT and SNOMED is required, as well as additional information regarding the respective licensing provisions for these terminologies. In the interest of minimizing the number of distinct terminologies in the core terminology set, it may be preferable to use the dental content within SNOMED if it is comparable in all material respects to that in SNODENT.
- Insufficient information was gathered regarding the use of UMDNS in clinical applications. The one testifier who addressed the UMDNS is using the terminology for administrative "equipment management" purposes. The need and/or utility of this terminology for clinical purposes remains to be determined and requires further investigation. It is possible that the device and equipment content within SNOMED CT may already provide enough or almost enough coverage in this area (it may be noteworthy that one testifier listed "documentation of durable medical equipment" among the uses of SNOMED CT at his institution).

7. Appendix I: Questionnaire Completed by Terminology Users

(see next page)

Questions for Testimony - PMRI Terminology Users

DIRECTIONS:

- Please complete **BOTH** 'Terminology Specific' (3 questions) AND 'General' (6 questions) portions of the questionnaire for **EACH** terminology you intend to respond (see selection box below)
- Return the completed questionnaire(s) in one separate e-file per terminology to: Suzie Burke-Bebee **zxj6@cdc.gov** **by 5/12/03** (Monday)

I. Questions for Testimony - PMRI Terminology Users 'Terminology Specific'

Name of the clinical terminology that you use:

_____

(Select the above from the following list of clinically specific PMRI terminologies)

SNOMED CT	**MedCin**
RX-Norm	**NCI Thesaurus**
LOINC	**NDDF Plus**
NDF-RT	**UMDNS - Universal Medical Device Nomenclature System**
SNODENT	**HL7 v3 Codes**
ISO Tooth Designation Codes	**ISO 11073**

1. **Check those applications or clinical processes that you use this terminology for**:

Laboratory Orders	❑	Nursing notes	❑	Drug orders	❑
Laboratory Results Reporting	❑	Physician notes	❑	Operative Notes	❑
Patient referrals	❑	History/Physical	❑	ED Charting	❑
Other (name)	❑	Other (name)	❑	Other (name)	❑
Other (name)	❑	Other (name)	❑	Other (name)	❑

2. **Please indicate the strengths and weaknesses of this terminology**.

	Excellent		**Adequate**		**Poor**
Overall usefulness as a PMRI (clinical) terminology	1	2	3	4	5
Adequacy of Domain coverage	1	2	3	4	5
Clarity of Concept/term meanings	1	2	3	4	5
Usefulness of semantic hierarchy and/or terminology organization	1	2	3	4	5
Degree of non-redundancy (i.e. absence of multiple concepts with the same meaning)	1	2	3	4	5
Version control	1	2	3	4	5
Timeliness of updates	1	2	3	4	5
Availability and quality of user education	1	2	3	4	5
Responsiveness to adding new concepts, answering questions, providing support, etc.	1	2	3	4	5
Reasonableness and equity of licensure costs	1	2	3	4	5

List other strengths or weaknesses <u>briefly</u> and indicating score:

	Excellent		**Adequate**		**Poor**
	1	2	3	4	5
	1	2	3	4	5
	1	2	3	4	5
	1	2	3	4	5

3. **Do you map your terminology to another terminology to make applications successful**?

Yes	❑	No	❑

Identify the terminologies that you map to, and describe the mapping method, product or service that you use:

II. Questions for Testimony - PMRI Terminology Users 'General'

1. **What gap(s) in the PMRI terminology(s) can you identify that you would like to see filled? What benefits would it bring? Please list with <u>brief</u> description**:

Gaps	Description

Benefits	Description

2. Do you routinely use or provide subsets of this clinical terminology?

Yes	❑	No	❑

3. What are the <u>features</u> of this terminology you use that make it easier or more difficult to later analyze the data you've collected (for example, extensive concept hierarchies with multiple inheritance paths are very important, whereas redundant representations of the same clinical concepts make analysis very difficult and unreliable)?

Easier to Analyze

More Difficult to Analyze

4. How easy have you found it to design user interfaces that capture coded data from clinical users? What user-interface mechanisms or techniques have you used to enable the capture of coded clinical data (e.g. pick-lists of coded terms, text-based search algorithms, natural language processing, mapping between distinct "interface" and "reference" terminologies, etc.)? Are there any specific features of this terminology that make it more or less amenable to structured data entry?

5. Should the NCVHS recommend that the government (if selecting more than one, rank order by your priority in the last column):

Recognize and/or adopt one or more clinically-specific terminologies that can serve as the core set of national PMRI terminology standards	❑	
Analyze clinical functions and identify the gaps in existing terminologies for fulfilling these functions	❑	
Develop PMRI terminology standards to fill these gaps	❑	
Support existing terminology developers to fill the gaps	❑	
Do nothing in terminology development and let the private sector fill the gaps as it will	❑	
Develop a single master terminology from scratch	❑	

6. Please <u>briefly</u> list suggestions or comments that you have for the NCVHS. Also, rank order your suggestions by priority in the last column.

Questionnaire for:
NCVHS/SSS meeting 5/20-22/03

Summary and Analysis of Testimony on Drug and Device Terminologies for PMRI Terminology Standards

A Report to the
National Committee on Vital and Health Statistics
Subcommittee on Standards and Security*

Version 1

Sept. 1, 2003

* This report was prepared by Walter Sujansky, MD. For comments and suggestions, please contact the author at wsujansky@sujansky.com.

Contents

1. Introduction

This report summarizes testimony given by invited experts on drug terminologies and device terminologies to the Subcommittee on Standards and Security (SSS) of the National Committee on Vital and Health Statistics (NCVHS). The testimony was given during hearings held by the SSS on August 19, 2003. These hearings were part of the NCVHS process to recommend appropriate terminologies for patient medical record information (PMRI) standards, as directed by the Department of Health and Human services under the HIPAA legislation. The purpose and scope of these terminology-standard recommendations are described elsewhere[1]. Prior to these hearings, the SSS had collected considerable data from the developers[2] and users[3] of numerous healthcare terminologies. The sub-committee required additional information in the specific areas of drug terminologies and device terminologies to make definitive recommendations in these areas. Additional testimony was, therefore, solicited on these topics, and the content of that testimony is summarized in this document.

2. Invited Testifiers

The sub-committee invited testifiers to address four specific areas:

- General background information about the use of and requirements for drug-terminologies in clinical systems
- Information about public-sector projects related to drug terminologies
- Information about specific commercial drug terminologies
- Information about specific medical device terminologies

The individuals who testified and their affiliations are summarized in the Table 1. Notable aspects of their testimony are presented in the sections that follow. Please note that a complete transcript of the hearings is available from the NCVHS[4].

[1] Scope and Criteria For Selection of PMRI Terminologies: A Report to the National Committee on Vital and Health Statistics Subcommittee on Standards and Security. Version 3. December 23, 2003. Report prepared by Walter Sujansky, MD on behalf of the Subcommittee on Standards and Security of the NCVHS.

[2] Summary and Analysis of Responses to the NCVHS PMRI Terminology Questionnaire: A Report to the National Committee on Vital and Health Statistics Subcommittee on Standards and Security. Version 5. October 30, 2003. Report prepared by Walter Sujansky, MD on behalf of the Subcommittee on Standards and Security of the NCVHS.

[3] Summary and Analysis of User Testimony for PMRI Terminology Standards: Version 3. September 1, 2003. Report prepared by Walter Sujansky, MD on behalf of the Subcommittee on Standards and Security of the NCVHS.

[4] See http://www.ncvhs.hhs.gov/lastmntr.htm.

Testifier(s)	Affiliation	Terminology Addressed
Barry Blumenfeld, M.D.	Partners Healthcare System, Inc.	N/A (background)
Randy Levin, M.D.	Food and Drug Administration	N/A (background)
Stuart Nelson, M.D.	National Library of Medicine	RxNorm (drug)
Steve Brown, M.D.	Veterans Health Administration	NDF-RT (drug)
George Robinson, R.Ph.	First Databank Inc.	NDDF-Plus (drug)
Tim McNamara, M.D.	Cerner-Multum	Multum Lexicon (drug)
Mark Dubois	Wolters-Kluwer Health, Inc.	Medi-Span (drug)
Kent Spackman, M.D.	SNOMED International	SNOMED (drug subset)
Brockton Hefflin	Food and Drug Administration	Global Medical Device Nomenclature (device)
Vivian Coates	ECRI	Universal Medical Device Nomenclature (device)

Table 1. Testifiers and the Terminologies They Addressed

3. Summary of Testimony

Notable aspects of each testifier's comments are presented in the following sections.

3.1. Testimony on General Background Information

One testifier presented materials on this topic.

3.1.7. Barry Blumenfeld - Partners Healthcare System, Inc.

Dr. Blumenfeld outlined the requirements for a drug-terminology standard. An effective standard terminology must be:

- Maintained by a primary code-assigning authority
- Available for use at little or no cost
- Frequently and promptly updated
- Backwardly compatible with NDC system
- Comprised of abstractions at multiple levels of granularity

He expanded on the levels of granularity for a drug terminology that are needed to support common clinical and administrative functions:

- Active ingredients: important for allergy checking
- Routed generic [generic name + route of administration]: important for drug-drug interaction checking
- Clinical drug [routed generic + strength + dosage form]: important for physician order entry
- Manufactured drug [clinical drug + manufacturer + inactive ingredients]: important for medication administration records at the nursing level

- Packaged Product [Manufactured drug + packaging information]: important for interoperability with pharmacy systems

Dr. Blumenfeld also articulated several challenges to the development and use of a standard drug terminology:

- Support for legacy applications (backward compatibility)
- Appropriate distinction between terminology model and information model (i.e., medical-record model)
- Logistical support: multi-platform delivery, timely updates, adequate technical support

He concluded by emphasizing that there is a pressing need for drug-terminology standards at his institution and generally in the industry.

3.1.8. Discussion

Dr. Blumenfeld's comments indicated that there is, indeed, a strong demand for a centrally managed and low-cost standard drug terminology, but that this terminology must meet certain specific requirements in order to practically meet the needs of the healthcare information technology community. The specific functional requirements that he articulated may provide useful criteria in assessing the suitability and adequacy of any drug terminology(ies) recommended for the PMRI terminology standards.

3.2. Testimony on Public-Sector Projects Related to Drug Terminologies

Three testifiers presented materials on this topic.

3.2.1. Stuart Nelson – National Library of Medicine

Dr. Nelson described the purpose, context, and status of the RxNorm drug-terminology project at the National Library of Medicine. He stated that the purpose of the project was to provide a standard drug terminology to relate the various "source" drug terminologies (commercial and otherwise) in the Unified Medical Language System (UMLS). Given this pivotal role, RxNorm is well suited to provide a degree of standardization and vendor-independence in the exchange of clinical data. The terminology also includes mappings to NDC codes. Dr. Nelson expressed that RxNorm's suitability for order-entry functions, however, is subject to further investigation.

In response to questions about the relationship between RxNorm and NDF-RT (see Section 3.2.2), Dr. Nelson stated that NDF-RT is "built on a core of RxNorm," and that each NDF-RT entry for a clinical drug or a drug component is linked to its counterpart in RxNorm (although not every drug in RxNorm appears in NDF-RT, since not all RxNorm medications are used in the VA Health System).

Dr. Nelson indicated that the development of RxNorm is still underway, although recent studies of the completeness of RxNorm suggest that it is nearing completion. For example, 99% of the 80,000 NDC codes in the FDA database are represented by an RxNorm entry.

Dr. Nelson emphasized that ongoing maintenance of and timely updates to RxNorm will be very important. He pointed out that RxNorm is part of the UMLS and, as such, benefits from the commitment of the National Library of Medicine to maintain that resource, as it has done since 1986. However, he stated that RxNorm would have to be updated and released with a frequency much greater than that of the UMLS, specifically mentioning that changes may need to be incorporated as frequently as weekly.

3.2.2. Steven Brown – Veterans Health Administration

Dr. Brown described the NDF-RT terminology, including its relationship to RxNorm. He echoed Dr. Nelson's assessment that NDF-RT was built on a core of RxNorm and that the two resources were built collaboratively, with NDF-RT adding a more formal representation model and additional types of drug information. Specifically, NDF-RT augments the RxNorm entries with, drug class, mechanism of action, physiologic effect, therapeutic intent, clinical kinetics, and chemical structure.

Although the NDF-RT terminology is not yet complete, it does already include all VA drug products (since the VA NDF file was used to initially populate NDF-RT). The VA plans to include all drug products in NDF-RT eventually, regardless of their inclusion in the VA formulary. The completeness of NDF-RT with respect to this larger universe of drug products, however, is unknown, and the VA plans to contract a study to assess its level of completeness. The VA also plans to make NDF-RT available for widespread use and distribution and is investigating licensing terms that allow cost-free use while preventing appropriation or corruption of the terminology.

Ongoing development and maintenance of NDF-RT is supported under the VA's Enterprise Reference Terminology project, a major initiative tied to the VA's Health Data Repository and computerized patient record system. The project is funded through 2004. The first version of NDF-RT is slated to be released in 2003, and the VA plans to disseminate NDF-RT to the public through the UMLS Metathesaurus.

3.2.3. Randy Levin – Food and Drug Administration

Dr. Levin described a variety of initiatives underway at the FDA to improve the way that drug-product information is collected and disseminated. The core of these initiatives is a proposal to collect drug-labeling information electronically from pharmaceutical manufacturers. Dr. Levin stated that this change would improve the speed and accuracy with which labeling information is made available to the FDA. It would also allow the information to be electronically distributed to other agencies (such as the National Library of Medicine and the VA) to support drug-terminology and drug-information projects at those agencies, such as RxNorm, DailyMed, and NDF-RT. Dr. Levin described the relationship between the labeling information and the derived information that forms the content of RxNorm and NDF-RT. He emphasized, however, that a complete clinical drug terminology requires content that currently falls outside of RxNorm and NDF-RT, such as "Finished Dosage Form" (which includes inactive as well as active ingredients). The FDA is working to develop electronic representations of this content and plans to distribute them via the DailyMed resource.

Dr. Levin also discussed problems with and envisioned improvements to the way that NDC codes (i.e. drug-product and packaging codes) are assigned by manufacturers and reported to the FDA. Problems with this system result in an incomplete and out-of-date accounting of NDC codes at the FDA. Envisioned improvements to the system may entail electronic submission of assigned NDC codes to the FDA, or other methods to improve the accuracy and timeliness of NDC reporting.

Dr. Levin indicated that regulatory changes would be required to effect many of these improvements. The time frame of such regulatory changes is unknown, however.

3.2.4. Discussion

Given that the NCVHS is considering PMRI drug-terminology standard recommendations based on some combination of RxNorm, NDF-RT, and the FDA drug database, the time-to-completion and the respective content contributions of these three resources must be carefully evaluated.

- Although RxNorm now represents 99% of the 80,000 NDC codes drawn from the FDA database, there are indications that the total number of NDC codes might be significantly larger than 80,000. Whether active NDC codes are missing from the FDA database and whether these codes represent new entries at the clinical drug level are open questions.
- Given that RxNorm forms the core of NDF-RT, the NCVHS may wish to evaluate whether the content extensions offered by NDF-RT (such as classes, mechanism of action, physiologic effect, etc.) are needed in a PMRI drug terminology standard, or whether these extensions may constitute *knowledge* rather than *terminology*. Specifically, are the content extensions offered by NDF-RT required for a reference terminology that is intended primarily to support data aggregation and data exchange?
- The FDA is attempting to create an infrastructure to support the creation and maintenance of public-sector drug terminologies, in coordination with other government agencies such as the National Library of Medicine and VA. Given that certain regulatory changes may be required before the entire infrastructure can be put in place, to what degree can practically usable drug-terminology standards be created and maintained prior to such regulatory changes?

3.3. Testimony on Specific Commercial Drug Terminologies

Four testifiers provided information on specific commercial drug terminologies. These testifiers were asked to address specific questions as well as offer general comments on the NCVHS drug-terminology standards recommendations process.

3.3.5. George Robinson – First DataBank, Inc.

Dr. Robinson provided various background information about the First DataBank (FDB) NDDF-Plus drug terminology product, including the structure and content of the terminology, the extent of its market share, and its various uses by FDB customers. In response to specific questions, he also indicated that about 75% of NDDF-Plus customers request content updates at least monthly, and 1/3 of these customers (about 25% of all NDDF-Plus customers) request content updates at least weekly. He also indicated that about 20 FTEs are engaged at First DataBank in tracking and cataloguing changes to the set of NDC codes, indicating that information derived from NDC codes is important to the maintenance of much of the terminology.

Dr. Robinson stated that, if NDDF-Plus were selected as part of the PMRI terminology standards, FDB would continue to charge licensing fees for the terminology to all users unless a third party funded the open distribution of the terminology. He expressed that a standard PMRI drug terminology would be useful for the exchange and aggregation of clinical data, but that a terminology itself (i.e., without a corresponding knowledge base) has limited use in the support of point-of-care decision-support applications. Dr. Robinson encouraged the NCVHS to consider and clearly articulate the types of applications that would be served by the PMRI drug terminology standards, to ensure that the content and organizational factors related to such a standard would support the intended requirements.

3.3.6. Tim McNamara – Cerner-Multum, Inc.

Dr. McNamara endorsed the government's plan to recommend a standard drug terminology as part of its PMRI terminology recommendations, stating that such a standard was good for drug-safety initiatives and good for Multum-Cerner and its clients. He provided general descriptions of two drug-terminology products provided by Multum-Cerner: Multum Lexicon and VantageRx. He explained that the content in Multum Lexicon (a free drug database available for internet download) is a subset of the content in VantageRx (a licensed product that includes more drug-product information and decision-support content). Dr. McNamara made an official offer to make parts of the VantageRx drug database available to the government at no cost to serve as a the "starting point" of a new drug-terminology standard. He indicated that, under this proposal, the government would have unlimited rights to distribute, redistribute, use, and modify the contents.

3.3.7. Mark DuBois – Wolters-Kluwer Health, Inc.

Mr. DuBois provided information about the Medi-Span drug terminology and its user base, as well as the perspective of his company on the PMRI drug-terminology standards activity. He indicated that most Medi-Span customers request weekly or monthly updates to the terminology. He also asserted that commercial drug terminologies such as Medi-Span offer much more content than simply the listing of clinical drug concepts, such as reference information on drug products and drug decision-support knowledge. Mr. DuBois expressed his company's position that the placing into the public domain of a comprehensive drug-terminology resource that included reference information and decision-support knowledge, such as the NDF-RT, would certainly compete with the Medi-Span product offering and jeopardize Medi-Span's business. However, the availability of a more constrained drug-terminology resource, such as RxNorm, was less threatening. Lastly, Mr. DuBois suggested that Medi-Span may be willing to make its database of NDC codes and certain other drug codes freely distributable if a suitable licensing arrangement could be negotiated with the federal government (he cited the agreement between CAP and the National Library of Medicine as a model).

3.3.8. Kent Spackman – SNOMED International

Dr. Spackman described the medication content in SNOMED CT and asserted that this content, itself, could form the basis of the PMRI drug-terminology standard. Specifically, he explained how the SNOMED drug content may be augmented with local "realm extensions" to form geographically specific and clinically specific drug terminologies. He cited how the creation of a U.K. realm extension allows SNOMED CT to serve as the drug terminology for the British National Health Service. Dr. Spackman proposed that a U.S. realm extension could be similarly created by the NLM or FDA as part of the government's drug-terminology initiatives. This extension would be updated frequently (perhaps weekly or semi-monthly), while the SNOMED CT core terminology could remain on its current semi-annual update schedule.

Dr. Spackman emphasized that the NLM license for SNOMED CT already includes the core drug concepts, so that it may make sense to leverage these concepts for the PMRI drug-terminology standards. This leverage could be achieved via the "realm extension" model he described, or by "linking" concepts from a different drug terminology (such as RxNorm) to their appropriate counterparts in SNOMED CT. This tight coupling between SNOMED CT and the PMRI drug-terminology standard would enable many of the semantic relationships already present in SNOMED CT between drugs and clinical conditions (such as relationships between drugs and allergies or drugs and poisonings/overdoses) to be applied by users of the PMRI terminology standards.

3.3.9. Discussion

A variety of observations and proposals were offered by the representatives of commercial drug-terminology vendors. Notable among these are the following:

- Most customers of these commercial drug-terminology products expect and need frequent updates (monthly or even weekly). This requirement for a high update frequency may, however, be specific to the use of NDC codes within these databases (which change very frequently). Hence, it is not clear whether a drug-terminology that only contains drug concepts at a higher level of abstraction (i.e., less granular than NDC codes) will need to be updated as frequently. The maintenance and distribution plan for any public-sector drug terminology standard should, perhaps, research this issue and provide updates of a frequency that is appropriate to its drug content.
- The vendors generally endorsed a drug-terminology standard that supports interoperability among information systems and commercial drug databases, but oppose a standard that includes significant knowledge content in the form of drug-product reference materials or drug decision-support knowledge. The latter is seen as a competitive offering that threatens their business. Given this concern and that fact that the primary stated goals of PMRI terminology standards are data interoperability and data aggregation, the extent to which the recommended drug-terminology standard includes knowledge content should be carefully considered.
- Multum-Cerner offered to contribute substantial parts of its VantageRx drug terminology to the public domain without compensation, to accelerate the development of a national drug-terminology standard. First DataBank and Medi-Span suggested that parts of their terminologies could also be made available in the public domain, but that such arrangements would require licensing by a third party, such as the federal government. The potential benefits of commercial content in the development and maintenance of a public-sector drug terminology standard bears consideration. For example, the availability of a comprehensive database of NDC codes, derived from one or more of the commercial vendors, could improve and accelerate the development and maintenance of a resource such as RxNorm. Until such time that government regulations allow the FDA to receive accurate, complete, and timely NDC data from the pharmaceutical industry, the availability of this data from commercial vendors could contribute significantly to the creation and maintenance of a drug-terminology standard.
- SNOMED International reminded the sub-committee that significant drug content already exists in SNOMED CT and explained how this content may be augmented with up-to-date and locally specific “realm extensions” to form a comprehensive clinical drug terminology. An example of such a use of SNOMED CT exists in the U.K. In the interest of integrating the drug-terminology component of the PMRI terminology standards recommendations with SNOMED CT, it may be worthwhile to further explore variations of this model.

3.4. Testimony on Specific Device Terminologies

Two testifiers provided information on specific controlled terminologies for medical devices.

3.4.10. Brockton Hefflin – Food and Drug Administration

Mr. Hefflin described the history, development, and current status of the General Medical Device Nomenclature (GMDN), an international standard for representing medical device products. The

purpose of the terminology is for regulatory data exchange, including product certification/registration, vigilance reporting, and product recall.

The GMDN, which has been under development since 1997, represents the integration of six pre-existing device nomenclature systems, including the Universal Medical Device Nomenclature System (UMDNS). The GMDN currently contains about 6,400 concepts and 17,000 terms. It was developed and is maintained by a volunteer team of 70 experts from 16 countries, and funding is derived from license fees. The nomenclature has been adopted for use by countries in Europe, Asia/Australia, and South America. The U.S. FDA is apparently also planning to use the GMDN. Lastly, the GMDN is "attempting to develop plans with ECRI to merge."

3.4.11. Vivian Coates – ECRI

Ms. Coates described the structure, content, and uses of the Universal Medical Device Nomenclature System (UMDNS). The purpose and uses of the UMDNS are similar to that of the GMDN. It is used by regulatory agencies for post-market surveillance and vigilance reporting, and by other organizations for inventory control, recall tracking, equipment procurement, and various other device-related functions. It has been part of the NLM's UMLS Metathesaurus since 1991, and it currently has over 1900 licensees in 95 countries.

The UMDNS has about 6,700 concepts and 17,000 terms, organized in a hierarchical structure. Ms. Coates asserted that the UMDNS concepts are more specific, in general, than the medical device concepts in SNOMED CT. Also, the UMDNS is being mapped to terminologies used by the FDA, via relationships with GMDN and the National Library of Medicine.

Ms. Coates confirmed that there have been discussions between UMDNS and GMDN regarding a merger of the terminologies, but expressed concern that the large, international constituency of GMDN would make such a merger challenging.

3.4.12. Discussion

Mr. Hefflin's testimony was the first official description of the GMDN during the NCVHS's investigation into PMRI terminology standards. Specifically, no information about the GMDN terminology was available at the time that candidate terminologies were evaluated with respect to their technical, organizational, and licensing features. Hence, it may be difficult for the subcommittee to consider the GMDN for the terminology standard recommendations in the absence of such an evaluation (paralleling the evaluation conducted for all other terminologies under consideration). Similarly, it may be difficult for the sub-committee to speak to the value of a merger between GMDN and the UMDNS in the absence of more knowledge about the suitability of GMDN for the PMRI terminology standards.

The UMDNS itself, in its current form, does not meet all of the essential technical criteria for inclusion in the core set of PMRI terminology standards (owing to its lack of concept permanence, as previously concluded). Therefore, additional research and consideration may be required to determine the appropriate source of medical device terminology for the PMRI standards. Specifically, the adequacy of content within SNOMED CT (and the possibility of augmenting this content, if necessary) may need to be weighed against lack of concept permanence of UMDNS (and the possibility of remedying that through relatively minor changes on the part of the terminology developer).

4. Summary and Conclusions

Valuable information was gained during the NCVHS SSS hearings on the requirements for a drug-terminology standard, on the features of various commercial and public-sector drug

terminologies, and on the similarities and differences between two prominent device nomenclatures. The sub-committee will consider the testimony received in its deliberations on PMRI terminology standards recommendations, and will determine whether sufficient information is now available to formulate definitive recommendations in the areas of drug and device terminologies, or whether further information and/or research is yet required.