August 22, 2002

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Dr. Lumpkin,

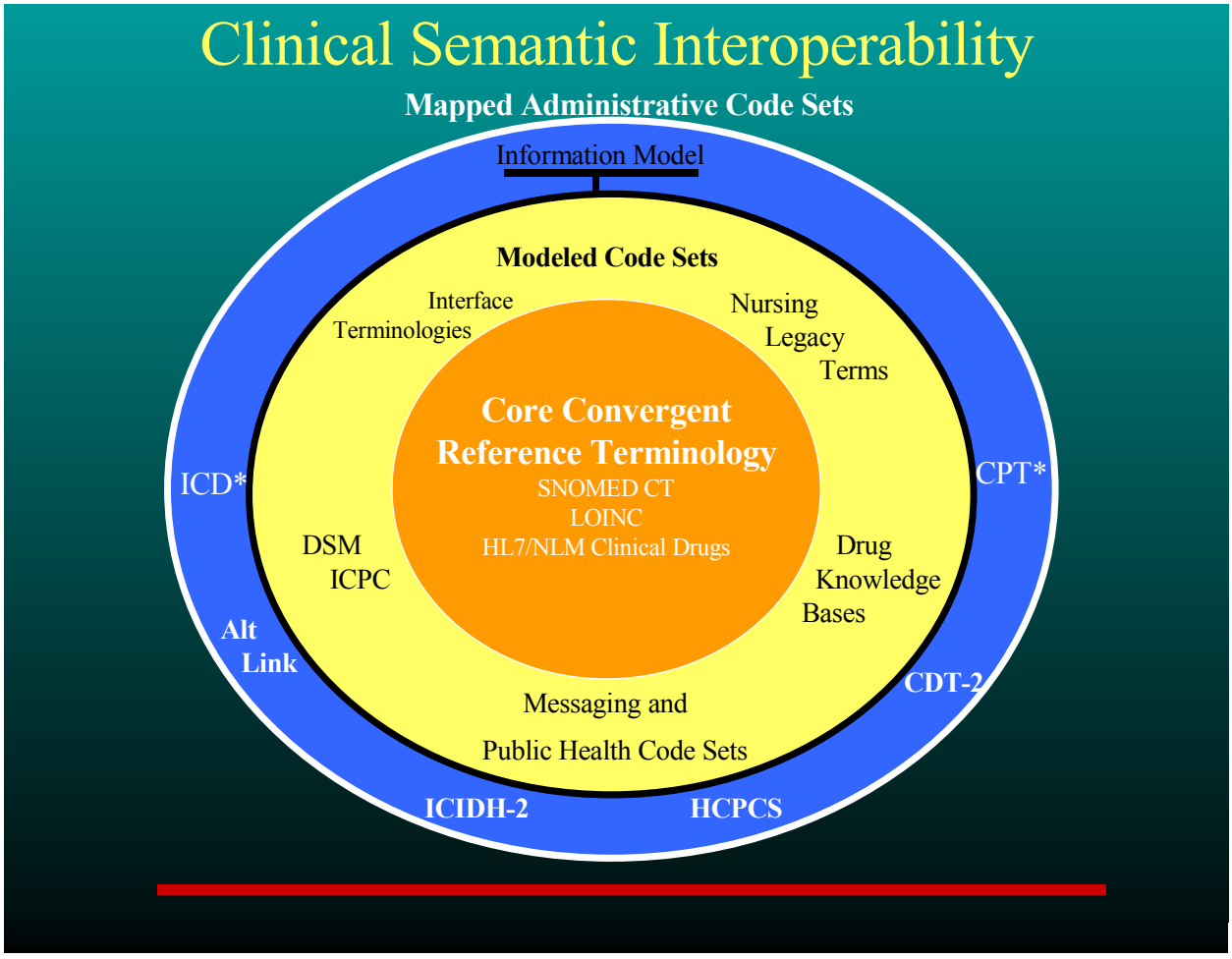
The report on the computer-based patient record by the Institute of Medicine[1](IOM) one decade ago described a national agenda for the development of accessible and standardized clinical records. These record systems would improve outcomes of the patient care process by providing decision support to the clinician while developing standardized data for research, education and healthcare administration. The need for standardized clinical vocabulary was emphasized as a central requirement for that vision.

Through the decade of the 1980's, the US healthcare system had been limited in terminology support to billing and epidemiologic systems. In more recent years, clinically focused terminologies have emerged with large bodies of content, offering the vendor community advantages for implementation of limited computer-based patient record (CPR) systems. A few efforts have focused upon integration and development of reference terminology standards which could lead to a convergent shared terminology. Growing from the huge investments in intellectual capital which have characterized these activities, we are poised to support the vendor community in achieving the next aspects of the IOM goal. However, development costs for the largest of these systems exceeds $75 million.[2,3] Coordination of the intellectual effort to assemble the content has taken decades. Efficiency and prudence would therefore dictate that a strategy for an alliance of these bodies of work is most likely to achieve the IOM concept which we have been pursuing for the last 11 years.

Within an abundance of standards, how should we formulate our strategy for terminology development? I suggest that we organize and categorize our vision of vocabulary support for the CPR, not as a host of competing elements, but rather as interconnected and mutually dependent layers of support for CPR function (Figure one). Moving from the central clinical focus to the governmental, I suggest that the committee consider a tri-partite model with priorities for deliverables as follows:

1) Layer 1: Core convergent reference terminology will deliver accurate patient records, improvement of clinical outcomes and decision support,
2) Layer 2: Modeled departmental, professional and legacy terminology will provide for clinical system integration and departmental function, and
3) Layer 3: Mapped administrative and financial classifications and codes will offer administrative and governmental reporting.

Figure 1
Conceptual Model for Clinical
Semantic Interoperability



Within such a strategy, these layered terminologies could mature and grow, serving the universe of CPR needs including clinical, departmental (or professional) and administrative realms. Public policy should support the budget and strategy for rapid convergence of the reference terminology core. This will serve as a central knowledge structure for development and enhancement of the CPR and transportable decision support. It will serve as a common language which the vendor community will use to share utility. Without such a central resource, in a fragmented national strategy, decision support and knowledge bases must be redeveloped by each vendor.

Since the fundamental deliverable of the convergent reference terminology is support for knowledge-based systems, editorial policies for this layer should depend heavily upon analytical study of the needs for guideline implementation. Evaluation strategies should employ testing in real clinical systems which support clinical guidelines. Content should pragmatically be defined to be inclusive of the needs of US healthcare disciplines with patient care as the primary focus. Content maintenance and evolution should be coordinated and supported by responsible standards development organizations(SDOs) but gradually assumed by professional societies representing the clinical experts who publish the guidelines and care standards.

Layer two terminologies are best identified as clinical systems that are important to the overall function of the CPR system, but are not comprehensive in content or independent in purpose. Within a shared information model maintained by a standards development organization, the second layer of terminology integrates these coding systems by creating and publishing definitions of the reference semantic classes. The organizations supporting the core reference terminology, in turn, assure that reference atomic concepts and relationships support layer two implementation within clinical systems. Interface terminologies, which are term sets designed to encourage effective use of vendor systems, are reconciled and modeled within the reference core. Departmental management systems and knowledge sources such as drug data banks that provide important CPR functions are modeled to the reference terminology. This modeling will support effective clinical interfaces and add value to the decision support that the drug system vendors provide in their product. Coding subsets that are required for messaging, departmental function, or proper indexing of the data within the CPR will be negotiated for content and modeled within the framework of the reference core terminology.

The third layer of terminology support for the CPR is the collection of those codes that are required for administrative, financial, billing, epidemiological, or governmental reporting. The primary purpose of these code sets is not clinical, and so they should not fundamentally control CPR vocabulary functionality. Nonetheless, for delivery of condensed or reorganized clinical information as required by the US healthcare system, mapping of clinical data to these codes is an important deliverable for the CPR system. Editorial control is always exercised by the public administrative body and so regularly scheduled and timely mapping maintenance is required for compliance.

From the standpoint of this organization, I suggest that the critical investments and

organizational choices for the committee are made in selecting the collaborative strategy for layer one, and convincing the commercial, academic and professional groups who populate level two to participate in the modeling of a convergent and cohesive terminological system. Layer three term sets are supported as they are required by the needs of society and healthcare administration but are driven primarily by societal pressures. In Table one below, I have reorganized the scope of patient medical record information (PMRI) terminologies within this paradigm, noting minor additions and deletions that I believe are appropriate.

One purpose of this layered model is to allow us to specify necessary attributes for maintenance and function of each segment, as well as to prioritize their importance. As I mentioned in my introductory comments, I believe that choices of the central reference terminology are critical to the delivery of a CPR functioning as specified in the IOM vision. As such, core convergent reference terminologies should have the highest priority attention by the committee. In particular, the organization of collaborative arrangements between the HL7/NLM clinical drug terminology and SNOMED CT, as well as a negotiation of additional work plan for activities of LOINC should receive attention. Current research based upon personal experience would suggest that 90-95% of basic CPR content can be completely encoded using the compositional terminology this collaboration would provide. A secondary consideration in this strategy would be discussion of convergence with the United Kingdom Clinical Product Reference Source (UKCPRS) which will maintain therapeutic terminology for the UK in concert with SNOMED CT.

At the second layer, bringing together of a uniform reference model for nursing concepts within the notion of a shared multi-disciplinary and cohesive record is important for collaborative care delivery. Nursing and medical activities should unify under a common set of definitions in all environments where they share patient care responsibility. I believe this to be necessary so that patient assessments, observations and care plans are unified about the central focus of the patient. Drug knowledge banks in common employment within the US should have a shared clinical drug reference so that systems designed to manage pharmacy inventory and dispensing can freely interoperate with the clinical environments of medication ordering and prescribing. These efforts deserve the highest priority in layer two systems.

In addition to the foregoing considerations, priority should be given to mapping from the core reference terminology to those administrative schemes in layer three which the committee has identified for billing and governmental reporting. This will provide for federal and administrative reporting, an issue important for support of business services within CPR vendor software.

Reflecting upon the foregoing discussion and upon the needs of sustained maintenance and development of a clinically rich environment, I believe that a number of criteria should be considered as modifications to the committee's procedures for selection of terminology. I have recounted my suggestions for a revised set of selection criteria in Table two.

<u>General criteria</u>

Timely delivery would suggest that the editorial cycle of each terminology layer must pace itself with the needs of the CPR vendor community and do so to support a realistic business cycle. Low cost is desirable at every layer of the terminology. However incomplete and patchwork vocabulary systems create burdens due to poor CPR performance. Frequent need for program rewrites due to sloppy or inadequate maintenance of vocabulary creates costs that are passed to users and patients. Furthermore, recent history teaches us that creation of a core reference terminology of the magnitude required for clinical care has involved actual expenditures in excess of $50 million. These costs are real, ignore the accompanying volunteer effort and indirect costs, and lead me to suggest that **core reference terminology developers must have a clear business model which organizes and funds the timely evolution, distribution and perpetual maintenance of the terminology**. The Institute of Medicine mentioned in their document that the distribution of costs and returns on investment for the CPR are not evenly distributed. Clearly, one of the major challenges facing the advance of vocabulary efforts today is arriving at an equitable resolution to the issue of cost sharing.

Clinically-Specific Terminology

Scope and organization

Historically, the search for comprehensive terminology for the CPR has been expensive and prone to duplication. This has occurred because no one SDO could assemble all the requisite knowledge, and due to general confusion as to the best model on which to build the terminology. Within layers one and two of the model that I have proposed, all clinically important terminology support must be provided. It is the primary function of the core layer to provide the semantic models and the necessary atomic concepts, with reasonable exemplars of pre-coordinated terminology. These pre-coordinated concepts are prepared to serve common need and to promote understanding of the underlying model. Layer two developers, in turn, serve one or more user communities by creating specific pre-coordinated vocabularies. These vocabularies take their semantic definitions from the umbrella of a negotiated, over-arching information model created for the CPR vocabulary services. For this paradigm to function, several principles must be promoted:

1) **A reference information model for definition of complex and context-laden concepts will be developed. A standards development organization will be identified to maintain this model.**

2) **Core reference terminology developers must:**

**-cooperate within their negotiated domains to produce complete clinical concept definitions and a semantic network defining all central domains of the clinical patient record**

**-have cooperative agreements with layer two developers for conceptual content and shared editorial development**

I respectfully suggest that the committee consider the task of designating an information model as an implicit imperative within the overall requirements of their task of vocabulary selection.

Concept Orientation

Clarity of content, with clear and understandable definitions, should be features of all layers of

the master terminology model, regardless of source. Relationships are essential to the computable definition of concepts that we expect of the inner two layers. Although such features as defining relationships may be desirable even for administrative and financial reporting systems, it is not clear that these can or should be enforced. Within the core layer, however, the nature and definition of the supported relationships clearly becomes a critical element in support of computable clinical inference and decision support. I suggest that the evolution of these relationships should support the pragmatic delivery of knowledge by the CPR. Hence, **reference terminology relationships within the core should be sufficient in definition and scope to support clinical guideline implementation (minimally including subsumption).**

Relationships ~~to other~~ **between cooperating** terminologies

The model I have proposed creates the basis of a cooperative agreement for sharing terminology scope and evolution. Rather than viewing these efforts as competitive, it is important to focus on the nature of the shared work they provide. Within this notion, I would suggest a revision of the vision statement for the model as follows:

1) **Core terminologies provide domain content to support a complete clinical reference terminology**
2) **Layer two terminologies model**, **define and enhance important legacy and departmental classifications and terminologies**
3) Maps to **layer three terminologies support** reimbursement and statistical classifications

Maintenance practices

In the principles above, I have reinforced several issues of terminology maintenance, namely: timely updates, a sound business model and equitable cost distribution. Experience with the controlled evolution of large terminologies has led to several basic principles reinforced by the Committee's criteria. These are: version control, non-reuse of identifiers, audit trail for concept change and scalability of representational forms. Since the clinical content of these vocabulary systems will become more sophisticated and complicated with time, I believe that we must pay further attention to the creation and maintenance of that content. Therefore, I suggest that it is important to consider these additional maintenance issues:

1) **Core reference terminology developers will collaborate to have domain content reviewed and regularly edited by clinical professional societies**
2) **Core reference terminologies will be maintained by an open editorial process, in conjunction with clinical professional societies, preferably within an ANSI accredited standards development organization**

In conclusion, I would add that convergence of effort with international standards work is a desirable, but not necessary end. From this viewpoint I have referenced several terminology efforts, in particular the UKCPRS, ICPC and ICNP that are in active dialogue with American standards developers or are of interest to American professional societies. When synergy can be achieved, as with SNOMED CT, this is a factor which should be a positive factor in consideration of policy.

Respectfully submitted,
James R. Campbell MD

Table 1
Terminology layered support of CPR

| **Terminology Support Layer** | **Sublayer** | **Terminologies for Inclusion** |
|---|---|---|
| I) Convergent Reference Terminology Core | | SNOMED CT<br>LOINC<br>HL7/NLM CLINICAL DRUGS(a) |
| II) Departmental and Legacy Modeled Terminologies | Nursing Terminologies | NANDA<br>NIC<br>NOC<br>OMAHA<br>HHCC<br>PCDS<br>PNDS<br>ICNP(a) |
| | Pharmacy departmental systems and databases | CERNER<br>FDB<br>FDA/VA DRUG RT<br>NDC |
| | Interface Terminologies | MEDCIN |
| | Messaging and Public Health | DICOM<br>NCPDP<br>IEEE<br>HL7<br>X12N<br>DEEDS |
| | Medicine | ICPC(a)<br>DSM<br>ICDO(a) |
| III) Administrative Mapped Code Sets | | ALTERNATIVE LINK<br>CDT-2<br>CPT*<br>HCPCS<br>ICD*<br>ICIDH-2 |

(a) Addition for the committee's consideration
(d) Lacking experience with the terminology, I have no formed opinion on the issue of MedDRA

Table 2
Suggested changes to PMRI selection criteria

General criteria
- Updated in timely manner
- Relatively inexpensive to acquire and implement
- **Core reference terminology developers have a business model which adequately organizes and funds the timely evolution, distribution and perpetual maintenance of the terminology**
- Flexible to adapt to changing processes and technologies
- Not dependent on a specific vendor or technology
- Accepted by the marketplace

Consistent with the characteristics of a clinically-specific terminology

General characteristics
- Clearly defined purpose and scope
- Comprehensive relative to scope
- Supports atomic and compositional concepts
- **A reference information model for definition of complex and context-laden concepts will be developed.**
- **A standards development organization will be identified to maintain this model.**
- **Core reference terminology developers must:**
  - **-cooperate within their negotiated domains to produce complete clinical concept definitions and a cohesive semantic network defining all central domains of the clinical patient record**
  - **-have cooperative agreements with layer two developers for conceptual content and shared editorial development**

Concept orientation
- Basic units are atomic with one meaning per concept
- Formal and systematic definitions
- Precise and unambiguous
- Relationships should be explicitly defined, internally consistent and non-redundant; **Reference terminology relationships within the core should be sufficient in definition and scope to support clinical guideline implementation (minimally including subsumption**).

Relationships to ~~other~~ **cooperating** terminologies
- ~~Maps to broader clinical reference terminology~~
- **Core terminologies provide domain content to support complete clinical reference terminology**
- **Layer two terminologies model, define and enhance important legacy and departmental classifications and terminologies**
- Maps to **layer three terminologies support** reimbursement and statistical classifications;
- Accommodates users within the population and personal dimensions of the NHII

Maintenance practices
- Updates and modifications must be referable to consistent version identifiers
- Concept identifiers must not be re-used
- Superseded concept identifiers should be marked along with preferred successor
- Representational forms should not create limitations due to structure
- **Core reference terminology developers will collaborate to have domain content reviewed and regularly edited by clinical professional societies**
- **Core reference terminologies are maintained by an open editorial process, in conjunction with relevant professional societies, preferably within an ANSI accredited standards development organization**

Implementation practices
- Includes methods or tools to ease local implementation and updates
- Local implementations include methods or tools to map to external users

Relationships with HIPAA standards
- Works with HIPAA message format standards
- Compatible with HIPAA financial and administrative standards

## Definitions

A Computer-based patient record[1] is an electronic patient record that resides in a system specifically designed to support users by providing accessibility to complete and accurate data, alerts, reminders, clinical decision support, links to medical knowledge and other aids.

Interface terminologies are sets of pre-coordinated concepts, modeled upon one or more reference or controlled vocabularies, organized in such a way as to aid a user community in interacting with, or entering data into, a CPR.

Mapping is the process of creating one way links from a fully coordinated concept within a reference terminology to one or more assigned codes in an administrative code set or classification.

Modeling is the process of developing fully specified semantic definitions of a set of similar information items within the guidelines of a reference terminology

Pre-coordinated concepts have been fully modeled and coded within a reference terminology, in order to expedite the entry of a complete (composed) data item into a CPR.

Semantic class is a set of similar and related concepts within a reference terminology which share a common reference definition and are generally nested within a portion of the reference hierarchy. Concepts of the same semantic class represent a real-world group of information items that have similar function, description and utility.

A Semantic definition is a prescribed set of semantic relationships detailed for a specific semantic class, which creates the computable definition for a concept within the reference terminology

Semantic interoperability assures the sharing of meaning between computer systems by controlling of message structure and coded content so that each system shares a common computable definition of the message. The computable definition is provided by a shared reference terminology.(paraphrased from committee publications)

Subsumption describes the function of a common relationship within semantic networks, namely the "Is a" relationship. This relationship clearly relates all subordinate, or more specific concepts, to their superordinate parent, or more general, concept.

## Bibliography

1) The Computer-based Patient Record: An Essential Technology for Health Care. RS Dick and EB Steen, ed. National Academy Press, 1991.
2) http://www.parliament.the-stationery-office.co.uk/pa/cm199798/cmselect/cmpubacc/657/8032314.htm
3) Personal communication and press releases, College of American Pathologists.