Consolidated Health Informatics

Standards Adoption Recommendations

Laboratory Result Content
&
Units

Index

Summary

Domain: Laboratory Result Contents

Standards Adoption Recommendation:

Systematized Nomenclature of Medicine Clinical Terms® (SNOMED CT®)

SCOPE

This standard will be used to exchange results of laboratory tests between facilities. These results are contained within a laboratory report that includes additional items such as patient and order demographics, laboratory test name (expressed as a LOINC® code as approved by CHI and adopted as a federal standard), specimen type and other items as may be required by business needs or messaging structures.

RECOMMENDATION

Systematized Nomenclature of Medicine Clinical Terms® (SNOMED CT®).

OWNERSHIP

SNOMED CT® is a copyrighted work of the College of American Pathologists (CAP).

The CAP and the National Library of Medicine (NLM) entered into an agreement to provide the SNOMED CT® core content via the NLM's Unified Medical Language System® (UMLS®) at no charge to those who execute a license agreement. This agreement is for healthcare applications and uses within the US and any application of use of SNOMED CT® by any US government facility or office, whether permanent or temporary, wherever located.

APPROVALS AND ACCREDITATIONS

The CAP is an ANSI Standards Development Organization. The SNOMED CT® Healthcare Terminology Structure is ANSI approved.

ACQUISITION AND COST

SNOMED CT®. will be available from the NLM UMLS® at no charge to anyone in the US who agrees to the license terms. This no-charge feature has been supported by HHS (NLM, NIH/OD, CDC, ASPE, AHRQ, CMS, FDA, HIS, SAMSHA, HRSA), DoD and VA.

Health care entities can also choose to purchase SNOMED CT® as a stand-alone terminology directly from SNOMED® International at (http://www.snomed.org)

REVISION HISTORY

DATE	VERSION	COMMENT
2/12/2003	Public Document	Final Recommendation
2/24/2006	1.1	AHRQ reference added

Summary

Domain: Units

Standards Adoption Recommendation:
Health Level Seven ® (HL7®) Version 2.X +

SCOPE
This standard will be used to define common units of measure, such as Celsius or mg/ml, that are intended to be combined with a numeric value to accurately express a result.

RECOMMENDATION
HL7® codes for Units, Versions 2.X +, derived from the ISO 2955-83 standard (withdrawn by ISO in 2001) and ANSI X3.50.

OWNERSHIP
Health Level Seven® (HL®7) holds the copyright, www.hl7.org

APPROVALS AND ACCREDITATIONS
HL7® is an ANSI-accredited Standards Developing Organization. This standard has been approved by full organizational ballot voting.

ACQUISITION AND COST
Standards are available from HL7®. HL7® asserts and retains copyright in all works contributed by members and non-members relating to all versions of the Health Level Seven® standards and related materials, unless other arrangements are specifically agreed upon in writing. No use restrictions are applied.

HL7® sells hard and computer readable forms of the various standard versions, cost from $50 - $500 depending on specific standard and member status.

Part I – Team & Domain Scope Identification

Target Vocabulary Domains

Common name used to describe the clinical/medical domains or messaging standard requiremenst that has been examined.

Laboratory Result Content
Units

(Note: The primary focus of these recommendations concern laboratory results from human samples. It is recognized by this group that non-human samples provide laboratory results that are important and recommendations are made in that area as well.)

Describe the specific purpose/primary use of this standard in the federal health care sector (100 words or less)

This standard will be used to exchange **results** of laboratory tests between federal facilities. These results are contained within a laboratory report that includes additional items such as: patient and order demographics, laboratory test names (expressed as a LOINC® code as approved by CHI Governance Council and adapted as a federal standard), specimen type and other items as may be required by business needs or messaging structures. For the purpose of this report the following was used to define a laboratory result:

- A laboratory result has four basic parts: the result itself; result units if applicable; normal ranges or indicator flags; and any comments associated with the result.
- The result itself has many forms:
    - Numerical results, including titers, representing quantities found and **do not need a terminology**.
    - Ordinal results such as 1+ that infer relative quantities but are not standardized. These also do not need a terminology but it was felt that in order to achieve the goal of CHI, interchange understanding between agencies, a proposal should be made to introduce standardize reporting of these results.
    - Results a cut-off value, including >< numerical results where the cut-off value is generally not known and requires interpretative information in the form of normal ranges or indicator flag.
    - Alphanumeric results that now generally take the form of free-text but could be expressed as coded values. These include results from anatomical pathology, microbiology, hematology, molecular pathology and immunohematology.
- The group felt that we should emphasize in the report the need to transmit normal ranges and any indicator flags in an appropriate place in messages for all applicable laboratory results, but the form was test dependant and outside the scope of the workgroup. Applicable laboratory results were considered to be those non-descriptive in nature.

- Though not part of the terminology recommendation, we note the need to modify the laboratory result message to include the name of the methodology used to produce the result or pointer to unique resource identifier (URI) used to find the unique protocol used. Knowing the method is essential for report interpretation. Also the actual method lends significance to non-human test results when the test was performed using standard methods such as those accepted by AOAC International or non-clinical specimens such as those used for forensic testing.
- The group felt that comments were an essential part of a laboratory result. Standardization of the form of these comments was required before we could achieve interchange understanding. A terminology should be selected that has the ability to code comments. Associated with comments were abbreviations and the group felt a common set should be developed and placed within the terminology.
- The group felt that abbreviations form a nomenclature in laboratory medicine and should be considered part of this domain.
- For non-human samples the identification of specimen type is viewed as part of this domain.

Sub-domains *Identify/dissect the domain into sub-domains, if any. For each, indicate if standards recommendations are or are not included in the scope of this recommendation.*

Domain/Sub-domain	In-Scope (Y/N)
Numerical results including titers	*N*
Normal result and other flag indicators	*N*
Out of range results	*N*
Ordinal results	Y
Anatomical Pathology report codes	Y
Living Organism codes	Y
Hematology result codes	Y
Immunohematology (Blood Bank) result codes	Y
Units	Y
Other descriptive laboratory test result codes	Y
Standard Comments	Y
Abbreviations	Y
Non-human Specimen Type	Y

Information Exchange Requirements (IERs) *Using the table at appendix A, list the IERs involved when using this vocabulary.*

Care Management Information
Case Management Information
Population Member Health Data

Team Members: *Team members' names and agency names with phone numbers.*

Name	Agency/Department
Steven J Steindel, PhD (team lead)	**CDC/HHS**
Jules Berman MD	NIH/NCI/HHS
Ron Schifman MD	VA
Maj. Martin Tenney	US Army/DoD/Laboratory
Capt. Leann Bauer	DoD/Laboratory
Emilio Esteban DVM,MBA,PhD	USDA

Work Period: *Dates work began/ended.*

Start	End
2/3/03	3/31/03

Part II – Standards Adoption Recommendation

Recommendation *Identify the solution recommended.*

SNOMED CT® codes, when available as true Category 0 codes in National Library of Medicine's (NLM) Unified Medical Language System (UMLS®) Metathesaurus®, were found to adequately cover the domain of laboratory result content coding. Where codes do not exist, an adequate mechanism exists to add new codes in a timely fashion. Codes for living organism are augmented in Category 0 of the UMLS® by the National Center for Biotechnology Information (NCBI) Taxonomy codes (Note: Information on the UMLS® is found at www.nlm.nih.gov/research/UMLS and on the NCBI taxonomy at www.ncbi.nlm.nih.gov/Taxonomy/.)

The specific locations in the SNOMED CT® hierarchy that form the basis of our recommendation are:

Quantifier Value:Unit
Qualifier Value: Modifier:Linkage Term and/or Qualifier
Organism: Living Organism
Body Structure: Morphologically Altered Structure:Morphologically Abnormal Structure
Disease: Disease by Body Site:Disorder of Body System:Disorder of Hematopoietic System
Findings: Clinical History and Observation Findings:General Finding of Observation of Patient:Genetic:Molecular and/or Cellular Finding:Genetic Finding:Phenotype:Blood Group Phenotype
Findings: Finding by Method:Test Finding:Laboratory Test Finding.
Substance: Dietary Substance

It is our recommendation for laboratory result content coding that we use Category 0 UMLS ®codes in this terminology domain where they exist. This will effectively encompass all of SNOMED CT® for this domain. For microorganism, the UMLS® Concept Unique Identifier (CUI) will refer to the SNOMED® code or the equivalent NCBI code. We recommend the sending of both SNOMED® and UMLS® codes when available, but the sending of a SNOMED® code alone is essentially equivalent to sending a UMLS® CUI because of the UMLS® mapping. As this represents an expanded use of the CUI, we have contacted NLM and they support this use. We anticipate that this approach will be sufficient for anatomical pathology, microbiology, hematology, immunohematology, and units. We did not explore, but anticipate that the approach will also be adequate for other general laboratory results. Gaps found in the area of comments and ordinal results are discussed below.

Note: Category 0 UMLS® Codes have no license restrictions on their use beyond the minimal restrictions provided by the National Library of Medicine on UMLS®. They can be used and distributed without further license fees.

The investigation by this workgroup has also revealed existing coverage for the Unit domain described below. These recommendations are sufficient for defining that domain as well.

Ownership Structure *Describe who "owns" the standard, how it is managed and controlled.*

UMLS ® is maintained by the National Library of Medicine and is available at no charge to those who execute a license agreement. They have an extensive internal and contracted group that maintains content. (see www.nlm.nih.gov/research/UMLS®/ for more information.)

Recently, the NLM has negotiated and anticipates enactment of an agreement with the College of American Pathologists (CAP) for the distribution of SNOMED CT® that effectively makes it a perpetual Category 0 codeset for use in the United States. The CAP owns SNOMED® and maintains both the content and structure of the terminology. (see www.snomed.org for more information.)

Terminology found in both the UMLS® and SNOMED® extends beyond the domain of laboratory results. It is only the domain of laboratory results that this recommendation applies. The specific domains are enumerated in the item labeled "Number of Terms" below.

Summary Basis for Recommendation *Summarize the team's basis for making the recommendation (300 words or less).*

The specific hierarchies associated with laboratory test result coding from SNOMED CT® form the basis of the CHI interchange specification. Equivalent UMLS® Category 0 codes may also be used.

Conditional Recommendation *If this is a conditional recommendation, describe conditions upon which the recommendation is predicated.*

No conditions apply to the above recommendation but gaps are noted with respect to standardization of comments and abbreviations that may for part of a laboratory result. Also, the CHI messaging recommendation for laboratory results needs to include the specific method used.

Approvals & Accreditations

Indicate the status of various accreditations and approvals:

Accreditation not applicable to laboratory result terminologies.

Approvals & Accreditations	Yes/Approved	Applied	Not Approved
Full SDO Ballot	Y		
ANSI	Y		

Options Considered:

Medical Subject Headings (MESH) [see www.nlm.nih.gov/mesh/meshhome.html]
NCBI Taxonomy
SNOMED CT®
Logical Observation Identifiers Names and Codes (LOINC®)
Other UMLS® Category 0 Terminologies
HL Version 2 and 3 Unit Coding

Current Deployment

Summarize the degree of market penetration today; i.e., where is this solution installed today?

****The responses below apply to SNOMED CT® as it forms the core of our recommendation.**

What number of or percentage of relevant vendors have adopted the standard?

The Workgroup had a good discussion regarding the following table. We note that the table represents results regarding vendor intent. We could not find reliable information on the actual use of SNOMED CT® or earlier versions of SNOMED®. Hence, inferences regarding actual current use should not be made.

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Enterprise-wide Computerized Patient Record Systems*:*

Vendor	% Market	Use SNOMED
Siemens	17	Yes
McKesson	16	Yes
Meditech	13	Yes
Cerner	10	Yes
IDX	6	Yes
Eclipsys	5	Yes
Epic	3	Yes
Per-Se	2	No
HC Mgmt	6	No

Achieve	4	No
Other	14	No

64% of the Computerized Patient Record Vendors are currently developing systems using SNOMED®

Laboratory Computerized Systems*:*

Vender	% Market	Use SNOMED
Meditech	26	Yes
Misys	20	Yes
Cerner	19	Yes
McKesson	11	Yes
Siemens	4	Yes
Soft	4	Yes
Dynamic	1	Yes
CPSI	2	No
Outsource	1	No
Keane	1	No
Other	11	No

85% of the LIS Vendors are currently developing systems using SNOMED®

What number or percentage of healthcare institutions have adopted the standard*?*

Unknown. Number not available through CAP.

What number or percentage of federal agencies have adopted the standard?

A subset of the current version of SNOMED®, SNOMED® II created in 1972, is used extensively in the VA for coding of anatomical pathology reports. This coding, however, is limited to only the Final Diagnosis portion of the Anatomical Pathology report. Successful use of coding for Anatomical Pathology reports will require extension to other report sections and standardization of those sections.

SNOMED CT® is the recommendation for use in reporting organism names for programs at CDC including routine surveillance, bioterrorism event investigation and hospital safety (noscomial infections and adverse drug reactions to identify any organism involve).

DoD currently uses SNOMED® II in a fashion similar to the VA for coding of anatomical pathology information.

Is the standard used in other countries?

SNOMED CT® as a whole is the national standard in the UK. SNOMED® II is widely implemented for anatomical pathology coding in many countries.

Are there other relevant indicators of market acceptance?

The federal government spent almost two years negotiation a license so that the terminology could be more widely implemented without fiscal barriers.

Part III – Adoption & Deployment Information

Provide all information gathered in the course of making the recommendation that may assist with adoption of the standard in the federal health care sector. This information will support the work of an implementation team.

Existing Need & Use Environment

Measure the need for this standard and the extent of existing exchange among federal users. Provide information regarding federal departments and agencies use or non-use of this health information in paper or electronic form, summarize their primary reason for using the information, and indicate if they exchange the information internally or externally with other federal or non-federal entities.

Column A: Agency or Department Identity (name)
Column B: Use data in this domain today? (Y or N)
Column C: Is use of data a core mission requirement? (Y or N)
Column D: Exchange with others in federal sector now? (Y or N)
Column E: Currently exchange paper or electronic (P, E, B (both), N/Ap)
Column F: Name of paper/electronic vocabulary, if any (name)
Column G: Basis/purposes for data use (research, patient care, benefits)

Department/Agency	B	C	D	E	F	G
Department of Veterans Affairs	Y	Y	Y	B		Patient
Department of Defense	Y	Y	Y	B		Patient
HHS Office of the Secretary						
Administration for Children and Families (ACF)						
Administration on Aging (AOA)						
Agency for Healthcare Research and Quality (AHRQ)						
Agency for Toxic Substances and Disease Registry (ATSDR)						
Centers for Disease Control and Prevention (CDC)	Y	Y		B		Public Health
Centers for Medicare and Medicaid						

Services (CMS)						
Food and Drug Administration (FDA)						
Health Resources and Services Administration (HRSA)						
Indian Health Service (IHS)						
National Institutes of Health (NIH)	Y			P		Research
Substance Abuse and Mental Health Services Administration (SAMHSA)						
Social Security Administration						
Department of Agriculture						
State Department						
US Agency for International Development						
Justice Department						
Treasury Department						
Department of Education						
General Services Administration						
Environmental Protection Agency						
Department of Housing & Urban Development						
Department of Transportation						
Homeland Security						

Number of Terms

Quantify the number of vocabulary terms, range of terms or other order of magnitude.

Units:
UMLS® CUIs were found for most common laboratory units. They exist in the section

"Quantitative Concepts" of which approximately 3190 exist, most not laboratory related. Most of the UMLS® codes derive from the Read code system that was subsumed by SNOMED® and hence exist, even more extensively, in SNOMED CT®. Note – these are not Category 0 codes until the US license for SNOMED CT® goes into effect. The SNOMED® codes are found under **Quantifier Value:Unit**.

Additional unit descriptions, but not codes are found in various standards used by HL7® derived from ISO 2955-83 (withdrawn by ISO in 2001) and ANSI X3.50. Inclusion in the HL7® documentation without restriction indicates free use for interchange messaging. HL7® defines a number of common relative units used in medicine such as mg/dL and the ISO/ANSI standards define ways to create others from core units. These combined and core units include mixed case forms where appropriate. While a complete analysis of the HL table was not conducted against all possible units, investigation of the laboratory domain and a quick review of other areas of medicine indicates it is sufficient to recommend.

Living Organism codes:
CDC distributes for use the SNOMED® hierarchy **Organism:Living Organism**, containing approximately 17,000 concepts. A cross-mapping of those of public health interest to concepts found in MESH reveals adequate coverage for reporting but not case-investigation purposes of about 2500 organism. No count is readily available for the NCBI taxonomy, but the UMLS® lists approximately 107,570 concepts. No check was made to see if all of the SNOMED® organism codes correspond to NCBI codes but it is assumed they do. If that is the case, it is safe to assume that MESH forms an adequate subset for reporting purposes, SNOMED® for clinical use and NCBI for research purposes. Organisms in each should map to the same UMLS® CUI, making interchange of codesets easy.

Anatomical Pathology report codes:
Anatomical pathology concepts were found in previous versions of SNOMED®. The last version of SNOMED® International (V 3.5) had approximately 5,900 morphology terms. In the present version of SNOMED CT® these are found primarily in the following hierarchy: **Body Structure:Morphologically Altered Structure:Morphologically Abnormal Structure**. It is difficult to compare the completeness of the SNOMED® Terms with other terminologies due to classification differences. For example, Hodgkin lymphoma and Morbilliform rash are both found in this hierarchy of SNOMED CT®. In UMLS®, Morbilliform rash is classified as a finding and appears in six other terminologies. Hodgkin lymphoma is classified as a neoplastic process and appears in 25 other terminologies.

Anatomy forms an important part of the anatomical pathology report but the workgroup offers no recommendation as to a terminology. We note that another Workgroup, History and Physical, is charged to look into this domain. We note that one of the difficulties in an anatomy terminology is that the concepts and hierarchy are use dependant. For instance a dermatologist assigns a topology of "skin" to a demrofibroma of the foot. The podiatrist would assign a topology of "foot" or something more detailed, such as "planter

foot" for the same lesion. A pathologist may assign a topology of "soft tissue" to the same lesion. The Workgroup requests that others looking into anatomy take these comments into consideration.

Hematology result codes:
Codes for hematological disorders appear focused in SNOMED CT® under the **Disease:Disease by Body Site:Disorder of Body System:Disorder of Hematopoietic System** hierarchy, as well as other areas. UMLS® places the hematological diseasaes in a similar hierarchy. A count of these codes is not available. Codes for various hematological cells are found primarily in the Body Structure hierarchy, Cell Structure, Blood Cell. Again, a count is not possible. UMLS® places the hematological cells in a similar hierarchy.

Immunohematology (Blood Bank) result codes:
Blood groups appear to be classified in SNOMED CT® under **Findings:Clinical History and Observation Findings:Clinical History and Observation Findings:General Finding of Observation of Patient:Genetic:Molecular and/or Cellular Finding:Genetic Finding:Phenotype:Blood Group Phenotype**. In UMLS®, these appear to also be findings, but are noted as laboratory results. A count is not possible.

Other descriptive laboratory test result codes:
SNOMED CT® includes many general laboratory result codes, including some appropriate to the above specific sections, under **Findings:Finding by Method:Test Finding:Laboratory Test Finding**. UMLS® Groups similar terms under Laboratory Test Results. A count is not possible.

Standard Comments:
SNOMED CT® includes many general laboratory result comments also under **Findings:Finding by Method:Test Finding:Laboratory Test Finding**. UMLS® Groups similar terms under Laboratory Test Results. In addition, other general comment codes are found in **Qualifier Value:Modifier:Linkage Term and/or Qualifier**. A count is not possible.

Abbreviations:
In general, neither SNOMED® nor UMLS® contain abbreviations. UMLS® contains an Abbreviation Table that is a list of acronyms used within the system but does not represent common clinically used abbreviations. The US Army has a standard set of abbreviations used for their internal purposes and the Workgroup recommends this be reviewed and considered as a basis for a National Standard Abbreviation set to be maintained by a designated organization, not necessarily the DoD.

Non-human codes:
Under **Organism:Living Organism**, SNOMED® has concepts for many plants and animals. Basic food products are listed under **Substance:Dietary Substance** but have no commercial codes.

How often are terms updated?
SNOMED® is updated twice yearly. UMLS® is updated quarterly**.**

Range of Coverage

Within the recommended vocabulary, what portions of the standard are complete and can be implemented now? (300 words or less)

The range of coverage for SNOMED CT® and corresponding UMLS® Category 0 terms appears adequate for use now for expressing general descriptive clinical and anatomical laboratory results. No large gaps in coverage in this area were noted.

Coverage for comments appears incomplete (see Gaps).

No source for standard abbreviations was found.

SNOMED® II, but not SNOMED CT®, has been implemented widely, but not universally, for anatomical pathology reporting. Use in other areas can only be considered as prototype.

Non-human codes exist. While the original terminology was developed with veterinary input the maintenance of those codes is weak. Food codes are basically from the UK Reed Code set added to form CT and are British in flavor.

Acquisition: *How are the data sets/codes acquired and use licensed?*

UMLS® is available at no charge to anyone who agrees to the license terms. UMLS® license terms allow use for all patient record uses and messaging. An in-principal agreement has been reached that provides, in the US, SNOMED® as one of the Category 0 codesets essentially allowing free distribution and use in the US.

Cost

What is the direct cost to obtain permission to use the data sets/codes? (licensure, acquisition, other external data sets required, training and education, updates and maintenance, etc.)

There is no acquisition cost, assuming the federal license is in effect. We have no knowledge of the cost of implementing SNOMED® as a source terminology from UMLS® but it is our understanding that it can be extracted easily and then implemented as the current stand-alone version is. Successful implementation of the current version of SNOMED® requires knowledge of the file and data structure that can be obtained from extensive provided documentation or training courses, offered for a fee, on-site or at the CAP offices on a regular basis. Similarly, full use of the hierarchies and relationships in SNOMED® also require extensive training, education and in many cases extensive software changes. The United Kingdom has been working with CAP for 3+ years on implementation, Kaiser Permenate in US has for 5+ years, and various other prototype sites exists. To our knowledge, none have successfully used all features of SNOMED CT®. Hence, no estimates on cost in this area can be offered.

SNOMED® has been successfully implemented in many sites simply as a source of code values. The cost for this type of implementation is basically the mapping of current results to the appropriate SNOMED® codes and can be compared to that of Laboratory LOINC®, recently approved as a CHI Standard. If result mapping is not possible and conversion to SNOMED® codes requires natural language processing, the cost is much higher and success is limited.

Systems Requirements

Is the standard associated with or limited to a specific hardware or software technology or other protocol?

No

Guidance: ***What public domain and implementation and user guides, implementation tools or other assistance is available and are they approved by the SDO?***

An extensive set of education material is provided as well as training courses for SNOMED CT®. Training an educational material is more limited for UMLS®. Information and current draft documents can be found at www.snomed.org.

The Workgroup notes that the implementation of any coding system for any purpose within an institution is complex and actual guidance is outside the scope of this report and may be outside the scope of the terminology provider.

Is a conformance standard specified? Are conformance tools available?

No. Discussion is under way regarding conformance-testing tools for use in the United Kingdom and subsequent use in the US, but they are at least one to two years away.

Maintenance: ***How do you coordinate inclusion and maintenance with the standards developer/owners?***

What is the process for adding new capabilities or fixes?

SNOMED® has a defined process for requesting additions through standard communication channels (phone, fax, e-mail) and is developing an extensive web entry process that is now in test. A formal editorial board exists to recommend and review more extensive changes. UMLS® relays on the changes in the underlying terminologies to express changes and is governed by their processes.

Both SNOMED® and UMLS® retire but not remove concepts that require changes. Minor changes that do not change meaning, such as spelling corrections, are allowed without retiring the concept.

What is the average time between versions?

SNOMED® – six months. UMLS® – 3 months.

What methods or tools are used to expedite the standards development cycle?

None formally. SNOMED® does respond quickly if emergency codes are need in a new area, such as bioterrorism support codes. The codes, however, are not published until the next release, generally six months or less.

How are local extensions, beyond the scope of the standard, supported if at all?

Both SNOMED® and UMLS® formally support terminology subsets and local extensions. SNOMED® uses subsets to create subspecialty and language variants of the terminology. A local extension policy is still under development. UMLS® supports subsets and local versions of the terminology and provides a tool to form these versions.

Customization: ***Describe known implementations that have been achieved without user customization, if any.***

None known.

If user customization is needed or desirable, how is this achieved? (e.g, optional fields, interface engines, etc.)

Customization is general for these products and involves subsets, extensions and mapping tables. Mappings may involve interface engines or be connected to natural language processing software.

Mapping Requirements

Describe the extent to which user agencies will likely need to perform mapping from internal codes to this standard.

Users have undertaken mappings to both SNOMED® and UMLS® for many years. Depending on the complexity of the user site, the task might be simple or complex but easily handled by topic experts. Both UMLS® and SNOMED® provide many terms for closely related, if not similar, concepts and it would be helpful if federally preferred terms were selected.

The Workgroup feels that the ability to map between terminologies, whether one representing local codes or between external terminologies is critical for this domain. Years of common usage of laboratory result terms has lead to confusion between the concept and the term representing it. For example the term "alkaline phophatase" in common usage can refer both to the test to measure the substance and the substance itself. Mappings must represent or maintain this type of context level distinctions such that the meaning of the concept is maintained through message exchange.

Identify the tools available to user agencies to automate or otherwise simplify mapping from existing codes to this standard.

None are currently available.

Compatibility

Identify the extent of off-the-shelf conformity with other standards and requirements:

Conformity with other Standards	Yes (100%)	No (0%)	Yes with exception
NEDSS/PHIN requirements	**Y**		
HIPAA standards		**N**	
HL7 2.x	**Y**		

Implementation Timeframe

Estimate the number of months required to deploy this standard; identify unique considerations that will impact deployment schedules.

Assuming limited complexity for mapping and limited use of natural language processing

implementation of the laboratory result code portions of SNOMED® and UMLS® is estimated at less than three months in most facilities, size dependant.

If some data sets/code sets are under development, what are the projected dates of completion/deployment?

Not applicable. SNOMED® and UMLS® are mature and available.

Gaps

Identify the gaps in data, vocabulary or interoperability.

Content:
Except for the ever present need to add new concepts as the area expands both SNOMED® and UMLS® appear complete in the coverage of coding for laboratory results.

Comments:
No universal agreement exists for the use and contents of comments associated with laboratory results. In many cases, especially if the comment involves the condition of the sample or the inability to collect a sample, the comment has direct implications with regard to the result. In other cases, the comment provides understanding with regard to the interpretation of the result. For example the comment "Some gonorrhea seen" is used by one laboratory as a culture result code, but the meaning is not clear. Similar ambiguous language exists in other laboratory disciplines. A professional organization needs to step forward and undertake the standardization of comments so that we can achieve better understanding when these are received.

Abbreviations:
As with all professions, abbreviations and acronyms are widely used in laboratory medicine and are not standardized. When used in a result they could result in ambiguous understanding. A professional organization needs to step forward and undertake the standardization of comments so that we can achieve better understanding when these are received. One of the work group participants has compiled a list of approximately 12,100 laboratory associated abbreviations, many having multiple meaning and one having 40. Clearly some interchange standard is needed to use these successfully. The US Army has a standard set of abbreviations used for their internal purposes and the Workgroup recommends this be reviewed and considered as a basis for a National Standard Abbreviation set to be maintained by a designated organization, not necessarily the DoD.

Ordinal Results (Method Codes):
While ordinal results such as 1+ or Positive are beyond the scope of this report, the workgroup wanted it noted that some conformance is needed before these can be understood between sites.

One set of tests reports results with respect to a sample containing a fixed amount of the

material tested. If more material is noted in the patient sample it is reported as positive, less is negative and many tests define a borderline zone. Generally these are tests for infectious material as determined by the presence of either the antibody developed in response to the presence of the organism or direct measurement of an antigen found on the organism. Without knowledge of the cutoff value comparison between positive and negative results obtained at different institutions is difficult.

Similarly, values reported on an ordinal scale, such 1+, depend on the amount of material present. Also, within a test, the difference between 1+ and 2+ varies in a non-standard fashion. Again, without knowledge of how these scales are derived interpretation between institutions is difficult.

Ideally, standards should be developed for the tests and universally applied by all test developers, perhaps enforced by the FDA as part of their medical device oversight. Realistically, this will not happen, in part because technology changes and also the sensitivity and specificity of test, which helps determine the cutoff value and ordinal scales, varies with clinical need. Hence, as part of the CHI recommendations we should advise that testing method be sent as part of a laboratory test result so these values can be understood.

It is recommended that the FDA develop a standard and informatically sound means to identify existing approved methods to the device level and publish that information as part of their approval process. This classification system should be also be applied to legacy devices. It is our understanding that the FDA is currently exploring the use of the Global Device Nomenclature for similar purposes. The current list maintained for the Clinical Laboratory Improvement Act (CLIA) should be reviewed as a source for these codes.

Non-Human Content:
Coverage is weak and will need through review and expansion with topic experts. It is recommended that the government partner with the American Veterinary Association to more fully support the animal portion of SNOMED® and find suitable partners for the plant and food portions. Actual food product codes are outside the scope of a terminology and will require agreement between FDA and USDA.

Additional non-human content that was not explored by the workgroup but it is important include environmental samples such as air, soil and water, storage containers, manufacturing sites, etc. While many of these types of sample are not generally involved in health information, it is to the government's benefit for common terminology to exist so that when potential health impacts occur semantic understanding is achieved. It is recommended that and interagency taskforce be formed from DoD, HHS, and EPA at a minimum to make better recommendations in this important area.

Obstacles

What obstacles, if any, have slowed penetration of this standard? (technical, financial, and/or cultural)?

Implementation of SNOMED® has been limited for financial reasons. Without a federal use license, the cost was perceived to be too expensive for widespread use.

CDC has provided public health partners with limited subsets since 1998, but implementation is limited. Further use would involve natural language processing and/or good mapping tables for living organism that are not readily available

Anatomical pathology use of SNOMED® II is more widespread. While natural language processing systems (encoders) are readily available, they are not widely or successfully used. Most SNOMED® coding is done by hand and limited to just portions of the anatomical pathology report, principally the final diagnosis.

Use in other areas of laboratory medicine is very limited.

The Workgroup wishes to note that their review of current Category 0 UMLS® code sets indicate that an adequate coverage of this domain exists through the use of LOINC® and MESH codes for clinical purposes and LOINC®, MESH and NCBI codes for research purposes. Naturally, gaps do exist and these could be addressed if needed.

Appendix A

Information Exchange Requirements (IERs)

Information Exchange Requirement	Description of IER
Beneficiary Financial / Demographic Data	Beneficiary financial and demographic data used to support enrollment and eligibility into a Health Insurance Program.
Beneficiary Inquiry Information	Information relating to the inquiries made by beneficiaries as they relate to their interaction with the health organization.
Beneficiary Tracking Information	Information relating to the physical movement or potential movement of patients, beneficiaries, or active duty personnel due to changes in level of care or deployment, etc.
Body of Health Services Knowledge	Federal, state, professional association, or local policies and guidance regarding health services or any other health care information accessible to health care providers through research, journals, medical texts, on-line health care data bases, consultations, and provider expertise. This may include: (1) utilization management standards that monitor health care services and resources used in the delivery of health care to a customer; (2) case management guidelines; (3) clinical protocols based on forensic requirements; (4) clinical pathway guidelines; (5) uniform patient placement criteria, which are used to determine the level of risk for a customer and the level of mental disorders (6) standards set by health care oversight bodies such as the Joint Commission for Accreditation of Health Care Organizations (JCAHO) and Health Plan Employer Data and Information Set (HEDIS); (7) credentialing criteria; (8) privacy act standards; (9) Freedom of Information Act guidelines; and (10) the estimated time needed to perform health care procedures and services.
Care Management Information	Specific clinical information used to record and identify the stratification of Beneficiaries as they are assigned to varying levels of care.
Case Management Information	Specific clinical information used to record and manage the occurrences of high-risk level assignments of patients in the health delivery organization..
Clinical Guidelines	Treatment, screening, and clinical management guidelines used by clinicians in the decision-making processes for providing care and treatment of the beneficiary/patient.

Cost Accounting Information	All clinical and financial data collected for use in the calculation and assignment of costs in the health organization .
Customer Approved Care Plan	The plan of care (or set of intervention options) mutually selected by the provider and the customer (or responsible person).
Customer Demographic Data	Facts about the beneficiary population such as address, phone number, occupation, sex, age, race, mother's maiden name and SSN, father's name, and unit to which Service members are assigned
Customer Health Care Information	All information about customer health data, customer care information, and customer demographic data, and customer insurance information. Selected information is provided to both external and internal customers contingent upon confidentiality restrictions. Information provided includes immunization certifications and reports, birth information, and customer medical and dental readiness status
Customer Risk Factors	Factors in the environment or chemical, psychological, physiological, or genetic elements thought to predispose an individual to the development of a disease or injury. Includes occupational and lifestyle risk factors and risk of acquiring a disease due to travel to certain regions.
Encounter (Administrative) Data	Administrative and Financial data that is collected on patients as they move through the healthcare continuum. This information is largely used for administrative and financial activities such as reporting and billing.
Improvement Strategy	Approach for advancing or changing for the better the business rules or business functions of the health organization. Includes strategies for improving health organization employee performance (including training requirements), utilization management, workplace safety, and customer satisfaction.
Labor Productivity Information	Financial and clinical (acuity, etc.) data used to calculate and measure labor productivity of the workforce supporting the health organization.
health organization Direction	Goals, objectives, strategies, policies, plans, programs, and projects that control and direct health organization business function, including (1) direction derived from DoD policy and guidance and laws and regulations; and (2) health promotion programs.
Patient Satisfaction Information	Survey data gathered from beneficiaries that receive services from providers that the health organization wishes to use to measure satisfaction.

Patient Schedule	Scheduled procedure type, location, and date of service information related to scheduled interactions with the patient.
Population Member Health Data	Facts about the current and historical health conditions of the members of an organization. (Individuals' health data are grouped by the employing organization, with the expectation that the organization's operations pose similar health risks to all the organization's members.)
Population Risk Reduction Plan	Sets of actions proposed to an organization commander for his/her selection to reduce the effect of health risks on the organization's mission effectiveness and member health status. The proposed actions include: (1) resources required to carry out the actions, (2) expected mission impact, and (3) member's health status with and without the actions.
Provider Demographics	Specific demographic information relating to both internal and external providers associated with the health organization including location, credentialing, services, ratings, etc.
Provider Metrics	Key indicators that are used to measure performance of providers (internal and external) associated with the health organization.
Referral Information	Specific clinical and financial information necessary to refer beneficiaries to the appropriate services and level of care.
Resource Availability	The accessibility of all people, equipment, supplies, facilities, and automated systems needed to execute business activities.
Tailored Education Information	Approved TRICARE program education information / materials customized for distribution to existing beneficiaries to provide information on their selected health plan. Can also include risk factors, diseases, individual health care instructions, and driving instructions.