January 29, 2004

The Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Dear Secretary Thompson:

The National Committee on Vital and Health Statistics (NCVHS) commends you for your commitment toward government wide adoption of clinical data standards that you first announced on March 21, 2003. NCVHS recognizes and appreciates that there is new momentum to adopt clinical data standards that is driven by you and the Consolidated Health Informatics Initiative (CHI). Consequently, NCVHS is working closely with CHI to study, select and recommend domain specific patient medical record information (PMRI) terminology standards. We have mutually developed a process that allows NCVHS to discuss in open, interactive sessions CHI recommendations as part of the CHI Council's acceptance process.

The NCVHS has the following comments on the attached set of CHI domain area recommendations. The NCVHS:

- concurs with the CHI recommendations for the Anatomy & Physiology domain as modified. We also concur with the need to revisit the Physiology domain in 12-18 months, beginning with a reevaluation of the domain definition.
- concurs with the CHI recommendations for the Billing domain as modified.
- concurs with the CHI recommendation not to adopt a terminology for the Medical Devices and Supplies domain at this time. Additionally, we recommend HHS further investigate device type as a component of device identification.
- concurs with the CHI recommendation for the Nursing domain as modified.
- concurs with the recommendation to defer the History & Physical domain until the next phase of CHI.
- concurs with the recommendation not to adopt a terminology for the Disability domain at this time. We agree with the need for a future research agenda and concur with the basic list presented. We also recommend investigating how the "question and answer style" format can facilitate representation of information in this domain. We further recommend that future activities consider the unique needs and perspectives of the different disability groups and other domain stakeholders.
- concurs with the recommendation for the Genes & Proteins domain for the human genome, the one area fully covered. We note that the domain scope included Inherited Genetic Variation, Infectious Disease, and Protein and Gene Nomenclature, but the report does not note explicitly the status of terminologies available for those areas, and closure is needed.

- concurs with the recommendation for the Diagnosis and Problem List domain. We further recommend the addition of the International Classification for Primary Care (ICPC) to the list of terminologies for early mapping efforts.
- concurs with the recommendation for the Non-laboratory Interventions & Procedures domain as presented.
- concurs with the recommendation for the Clinical Encounters domain as modified to include the explicit notation of the CHI-noted gaps and listing the personal health record as out-of-scope. NCVHS understands that the CHI definition of an encounter refers broadly to all types of practitioners interacting with patients; however, some explicit clarification may be in order. We note the CHI workgroup scope does not include many encounters observed in healthcare as might be enumerated in an electronic health record. NCVHS notes that a similar concept of an encounter exists within the HIPAA process, and harmonization should occur between the two.
- concurs with the recommendation for the Text-based Report domain as presented. The Committee will be further studying both the HL7 Clinical Document Architecture and the Continuity of Care Record as part of on-going work. We further note that the need for e-signature is an important component that has been investigated by the Committee in the past and will be explored further as part of our investigation into standards for ePrescribing over the next year.
- concurs with the recommendation of the Population Health Domain as presented.
- concurs with the recommendations of the Chemical Domain as presented. We note and support the explicit need for resources at the Environmental Protection Agency to accomplish the additional work required.

During our deliberations on the scope of the CHI work, we have observed that the personal health record has not been explicitly discussed, and we encourage future investigation by CHI.

We understand that the next stage is formal government adoption, which the NCVHS supports. We are excited about the value of this continuing process.

Sincerely,

/s/

John R. Lumpkin, M.D., M.P.H.
Chairman, National Committee on Vital and Health Statistics

Cc: HHS Data Council Co-Chairs
Enclosures

Consolidated Health Informatics Initiative
Final Recommendation Information Sheet1

Domain Title and Team Lead:

Anatomy/Physiology: Steven J. Steindel, PhD (CDC)

Scope:

Anatomy

Used to describe anatomical locations for the following purposes:

- ***Clinical***
  - ***Site of a procedure such as:***
    - Source of culture specimen
    - Surgical site
    - Location of blood pressure, temperature, other measurement
    - Etc.
  - ***Location of an observation such as:***
    - Site of fracture
    - Site of injury
    - Etc.
- Surgical:
  - ***Precise anatomical structure involved in procedure***
- Pathology:
  - ***Detailed gross description of item observed***
  - ***Cellular description of item observed***
- Research:
  - Uses many clinical terms
  - ***Subcellular components***

and having the following requirements:

- ***Is-a hierarchy***
- ***Part-of hierarchy***
- ***Laterality***
- ***Synonyms***
- Virtual locators (Concepts added to the terminology that may not physically exist but are added for representational purposes. An example might be liver as a physical object that is the concept used when referring to the entire liver and liver structure when describing the relationships of the various parts of the liver such as left lobe. SNOMED CT uses concepts similar to those just described.)
- ***Modifiers of basic terms such as "necrotic"***
- Compatibility with animal models

1 Information Sheet designed specifically to facilitate communication between CHI and NCVHS Subcommittee on Standards and Security resulting from May 20, 2003 testimony. CHI may seek assistance to help further define scope, alternatives to be considered and/or issues to be included in evaluation process.

Physiology

Used to describe or infer human physiology at least at the organ system, cellular, and biochemical levels. Physiology terminology includes tests that are used to infer the physiological state at any of the levels noted. Terminology that infers cellular physiology by direct inspection of cells is also included. The terminology must include concepts for both normal and abnormal physiology.

Domain/Sub-domain	In-Scope (Y/N)
Anatomical location of a procedure	Y
Anatomical location of an injury	Y
Anatomical description of specimen	Y
Subcelluar anatomy	Y
Physiology of patient	N
Measured or inferred physiology of organ or organ system	Y
Measured or inferred physiology of cell	Y
Morphology	Y

Alternatives Identified

1. MESH (Medical Subject Headings)
2. National Cancer Institute (NCI) Anatomical Terminology
3. SNOMED CT
4. Clinical LOINC
5. Foundational Model of Anatomy (University of Washington)
6. HL 7 (Site Table)
7. Veteran's Administration NDF-RT Physiology Effects Hierarchy

Final Recommendations:

Anatomy:

1. **SNOMED CT (Systematized Nomenclature of Medicine Clinical Terms)**

   The specific locations in the SNOMED CT hierarchy that form the basis of our recommendation are:
   Body structure:acquired body structure
   Body structure:acquired body structure:post-surgical anatomy
   Body structure:anatomical concepts:combined site
   Body structure:anatomical concepts:physical anatomical entity:anatomical spatial entity
   Body structure:anatomical concepts:physical anatomical entity:anatomical structure
   Body structure:anatomical concepts:physical surface topography
   Body structure:morphologically altered structure

For modifer terms not pre-coordinated above:
Qualifier Value:Additonal Values
Qualifier Value:Modifer and/or Qualifier

2. **HL7 Site table**

   The Workgroup determined that the HL7 Site table would provide for a more simple anatomy terminology for use in the general practice of healthcare. While a subset of SNOMED-CT would serve this purpose, the HL7 Site table is recommended to fill this role.

3. **NCI Thesaurus**

   To support its research programs and international based clinical trials, the National Cancer Institute is revising the anatomy component of its widely use Thesaurus (http://www.nci.nih.gov/cancerinfo/terminologyresources). This work extends present anatomy terminologies into sub-cellular structures that are required for research and is primarily recommended for that purpose. Additionally, the remaining terminology appears well ordered and complete. The two terminologies can relate through mapping.

*****Mapping is an essential requirement of the anatomy domain. It is the workgroup's recommendation that these mappings be developed, maintained, validated and distributed through the UMLS.

Physiology: No Recommendation

Cellular physiology is a basic medical concept that is not widely used at the clinical level and has diverse requirements at the research level. It is not surprising that a terminology was not found to meet this need. We note the potential need for terminology at this level to serve as a reference terminology that would link other terminologies that use physiology concepts. We recommend that the NLM investigate funding such a development, perhaps using the VA NDF-RT medication physiologic effect axis as a basis.

Clinical physiology, which we defined as the identification of tests and their results to infer the underlying cellular physiology, is an area that requires good terminology. We observed that both candidates, SNOMED-CT and Clinical LOINC approached this area differently. We also felt that the approaches did not fully meet the needs of the area from a content or organization viewpoint.

Content Coverage:

The range of coverage for SNOMED-CT and corresponding UMLS Category 0 terms appears adequate for use now, containing approximately 3-5,000 concepts (synonyms can expand the number by a factor of 10), for expressing general descriptive clinical and anatomical concepts. No large gaps in coverage in this area were noted. It is noted;

however, that the coverage is weak in the sub-cellular structures required for research, hence the augmentation with the NCI Thesaurus.
The NCI Thesaurus covers vocabulary for clinical care, translational and basic research, and public information and administrative activities. The NCI Thesaurus provides definitions, synonyms, and other information on more than 7000 cancers and related diseases, 5500 single agents and combination therapies, and a wide range of other cancer-related topics. The HL7 site table, even in expanded form, is envisioned to contain approximately 100-200 terms.

Acquisition:

An in-principal agreement has been reached that provides, in the US, SNOMED CT as one of the Category 0 codesets, essentially allowing free distribution and use in the US.

Standards and associated terminology 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.

The NCI Thesaurus is covered by an open content license. The license allows free distribution and modification of the NCI Thesaurus content. Modification of NCI Thesaurus, including development of extensions, may be made using either Protégé available from Stanford University (http://protege.stanford.edu/) or DTS/TDE terminology development/distribution environment available from Apelon, Inc (www.apelon.com). Developers of extensions are encouraged to share their extensions.

Conditions:

Temporal Condition: The current HL7 site table is incomplete and requires addition of more general anatomy terms before it will be completely ready for use. HL7 has a mechanism to facilitate the addition of these terms through their Vocabulary Technical Committee. It is further recommended that the present and added terms to the site table be closely coordinated with the corresponding SNOMED-CT terms.

The NCI Thesaurus anatomy terminology is, at the time of this report, not released and is a work in progress. A development version was shared with the Workgroup for review. It is anticipated that the anatomy terminology will be included in the NCI Thesaurus by March, 2004. Hence this recommendation is conditional upon completion of the work. Review should be made in six to 12 months.

Consolidated Health Informatics Initiative
Final Recommendation Information Sheet2

Domain Title and Team Lead

Billing/Financial: Cynthia Wark, CMS

Scope

The Billing/Financial standards are used to implement electronic exchange of health related information needed to perform billing/administrative functions in the Federal health care enterprise. It is assumed that the HIPAA transaction and code sets will serve as the basis for these standards.

Domain/Sub-domain	In-Scope (Y/N)
Claim Submission for reimbursement	Y
Health Care Claim Payment/Advice	Y
Eligibility Determination	Y
Prior Authorization and Referral	Y
Enrollment/Disenrollment	Y
Coordination of Benefits	Y
Claims Status Inquiry	Y
Appeals	Y
Certificate of Medical Necessity	Y
Claims Attachments	N
Report of Injury	N
Non-Claim Payment Electronic Funds Transfer	N
Purchasing, i.e. Medical Supplies purchases	N
Provider Identifiers	N
Unique Patient Identifiers	N
Employer Identifiers (Compliance date July '04)	Y
Health Plan Identifier	N
Advance Beneficiary Notification	N
Electronic Signatures (being addressed by Text-Based Reports Workgroup)	N

Alternatives Identified

The alternatives identified have been those code sets adopted under HIPAA:

1. HCPCS and CPT 4, Healthcare Common Procedure Coding System and Current Procedural Terminology for physician services and other health services
2. HCPCS for all other substances, equipment, supplies and other medical supplies
3. ICD-9-CM, Vols 1&2 for diagnosis codes
4. ICD-9-CM, Vol 3 for inpatient hospital procedures

2 Information Sheet designed specifically to facilitate communication between CHI and NCVHS Subcommittee on Standards and Security resulting from May 20, 2003 testimony. CHI may seek assistance to help further define scope, alternatives to be considered and/or issues to be included in evaluation process.

5. NDC, National Drug Codes for retail pharmacy claims
6. CDT, Common Dental Terminology for dental services
7. DRG, Diagnostic Related Groups
8. Code sets internal to the approved X12 and NCPDP transaction implementation guides
9. ABC codes

Additional codes sets identified*:*

10. ICD-10-CM
11. ICD-10-PCS

Recommendation

The HIPAA approved identifiers, transactions and codes set, both those currently approved as well as future updates, are recommended for adoption.

HIPAA Medical Code Sets	HIPAA non-Medical Code Sets
• ICD-9-CM: Volumes 1 & 2 for diagnosis codes • ICD-9-CM: Volume 3 for inpatient hospital procedures • NDC: National Drug Codes for retail pharmacy claims • HCPCS and CPT-4 for physician services and other health services • HCPCS for all other substances, equipment, supplies, and other medical supplies • CDT for dental services • ABC Codes for registered users during the pilot period • Diagnostic Related Groups (DRGs)	ASC X12N 837 ASC X12N 820 ASC X12N 834 ASC X12N 835 ASC X12N 270/271 ASC X12N 278 ASC X12N 276/277 NCPDP Telecommunication Standards

- Health plans (insurers) and health care providers who transmit any of the designated HIPAA transactions electronically within the Federal Government (Medicare, Veteran's Administration, Department of Defense's Military Health System and TRICARE Program, Indian Health Service, etc.) or external to it, are considered HIPAA covered entities and were required to be compliant with HIPAA transactions and code sets as of October 16, 2003. Therefore, the HIPAA transactions and code sets are assumed to be the minimum standards for the CHI billing/administrative domain.

- In addition to the HIPAA transaction and code set standards, the workgroup has identified ICD-10-CM as a standard to be considered. The workgroup is aware that the NCVHS SSS has ICD-10-CM under study, therefore will follow this work as it evolves.

- Claims attachments are considered out of scope due to the scheduled publication of the Attachment NPRM by HHS in 2004. Work is underway between HL7 Attachments Special Interest Group and CHI staff to map and align CHI clinical standards with the proposed HL7 claims attachment standard. Therefore, until this work has evolved further, the workgroup considers this out of scope and suggests the area be revisited in 12 months.

- The X12 837 transaction could be used for certificates of medical necessity, however it is not a HIPAA approved transaction/code set. There are no federal agencies using an electronic standard for data or structure related to certificates of medical necessity, therefore no standard for this function is being recommended.

Consolidated Health Informatics Initiative
Final Recommendation Information Sheet[1]

Domain Title & Team Lead:

Medical Devices and Supplies: Brock Hefflin, FDA

Scope:

This domain is defined as a terminology used to inventory or exchange information on medical devices and medical supplies within and between agencies, and between agencies and the public. The workgroup excluded "staff" resources from the domain's scope, as its members were unfamiliar with terminologies that covered the subject and believed it was relatively unrelated to medical devices and supplies.

The group believes that the terminology should be highly comprehensive and sufficiently specific, to the generic device/supply group level, to accommodate regulatory and inventory activities. The terminology should provide definitions for device/supply terms. The terminology should be organized in a simple hierarchy to enhance structure and facilitate navigation.

Alternatives Identified:

1. SNOMED-CT
2. UNSPC (United Nations System for Product Classification)
3. ICD-9
4. HCPCS (Healthcare Common Procedure Coding System)
5. GMDN (Global Medical Device Nomenclature)
6. UMDNS (Universal Medical Device Nomenclature System)
7. FDA Medical Device Classification

Final Recommendation:

No one terminology is recommended, rather the recommendation is to wait for the Global Medical Device Nomenclature (GMDN) and the Universal Medical Device Nomenclature System (UMDNS) to merge and to adopt the resulting terminology.

[1] Information Sheet designed specifically to facilitate communication between CHI and NCVHS Subcommittee on Standards and Security resulting from May 20, 2003 testimony. CHI may seek assistance to help further define scope, alternatives to be considered and/or issues to be included in evaluation process.

Content Coverage:

The GMDN and the UMDNS are very similar in scope, i.e., each provides names, definitions, and unique codes for essentially all medical devices and supplies at the generic device group

level (device attributes, however, are being considered for the GMDN which will increase its level of specificity significantly). Both terminologies are being used internationally, the GMDN primarily by regulatory agencies and the UMDNS primarily by healthcare institutions.

Acquisition:

The GMDN is owned by the European Standards Body (CEN) and is a CEN/ISO standard. It was recently developed largely through the harmonization of six established medical device terminologies including a previous version of the UMDNS and the terminology used by the Center for Devices and Radiological Health, U.S. Food and Drug Administration (FDA). The GMDN is managed and its content maintained by an International Maintenance Agency with significant FDA representation.

The UMDNS is owned by ECRI, a U.S.-based non-profit health services research agency. The terminology has been used internationally for a few decades, especially by healthcare institutions. The UMDNS is managed and its content maintained by ECRI.

The UMDNS is supported by an established business plan and is incorporated into the U.S. Library of Medicine's Unified Medical Language System (UMLS). The business plan for the GMDN is still in formation, however the terminology is an international standard and is strongly supported by the FDA for global medical device data communication and to eventually replace the FDA medical device terminology. Efforts are being made to merge the GMDN and UMDNS into one terminology, hopefully within the next three years. The GMDN Maintenance Agency has recently invited ECRI to participate in the GMDN effort. In addition, the FDA and ECRI are collaborating on a CRADA (Cooperative Research and Development Agreement) to map/link the UMDNS to the GMDN in the first step towards merging the terminologies. The terminology resulting from a merge of the GMDN and UMDNS will enable the U.S. federal system components to utilize one set of medical device/supply names, definitions, and codes, and to use these same product identifiers to communicate with foreign establishments.

Conditions:

This recommendation is contingent upon the success of the GMDN business plan and/or other resources (e.g., from medical device regulators or industry) to adequately support the terminology.

Consolidated Health Informatics Initiative
Final Recommendation Information Sheet3

Domain Title & Team Lead:

Nursing: Alicia Bradford, CMS

Scope:

This domain is defined as a terminology that is used to identify, classify, and name the delivery of nursing care. Sub-domains are derived from the Nursing Process and American Nurses Association (ANA) approved Nursing Minimum Data Set (NMDS), emphasizing nursing assessment, diagnosis, interventions, and outcomes of nursing care.

Domain/Sub-domain	In-Scope (Y/N)
Assessment / Observations	Y
Plan / Goals	Y
Diagnosis	Y
Interventions	Y
Evaluation / Outcome	Y
Intensity of Nursing Care	N*
Patient Demographics	N*

*Intensity of nursing care, part of the NMDS, is out of scope as no rating or vocabulary standard exists or is widely implemented. Patient demographic data is out of scope and being covered by the demographics workgroup.

Alternatives Identified

1. SNOMED CT
2. ABC Codes
3. NANDA (The North American Nursing Diagnosis Association)
4. NIC (Nursing Interventions Classification)
5. NOC (Nursing Outcomes Classification)
6. Omaha System
7. HHCC (Home Health Care Classification)
8. PCDS (Patient Care Data Set)
9. PNDS (Perioperative Nursing Data Set)
10. ICNP (International Classification for Nursing Practice)
11. Clinical LOINC (Logical Observation Identifiers Names & Codes)

Final Recommendation:

3 Information Sheet designed specifically to facilitate communication between CHI and NCVHS Subcommittee on Standards and Security resulting from May 20, 2003 testimony. CHI may seek assistance to help further define scope, alternatives to be considered and/or issues to be included in evaluation process.

SNOMED CT (Systematized Nomenclature of Medicine Clinical Terms)

Content Coverage:

SNOMED CT contains: over 1,000 nursing intervention concepts modeled from the Georgetown Home Health Care Classification, the Omaha System and the Nursing Interventions Classification (NIC); Intervention Concepts from the Perioperative Nursing Data Set (PNDS); Nursing diagnosis and problem concepts from NANDA, PNDS, HHCC, and Omaha. NOC will be integrated into the January 2004 release. The outcomes and new interventions from HHCC and Omaha Systems will be included in July 2004. Discussions continue with ICN and PCDS.

For nursing assessments and documentation of care, nurses often choose medical terms. Many of these would fall within multiple SNOMED CT concept nodes, such as: **Disease** (i.e. petechaie, blood transfusion reaction); **Physical object** (Hickman catheter); **Specimen** (catheter tip specimen); **Body structure** (subclavian vein); **Qualifier Value** (Blood Products, HLA matched platelets); **Organism** (Pt on isolation for MRSA of the nares); **Context-Dependent Categories** (sick child at home); **Staging and scales** (Likert scale for pain rating); & **Substance** (sweat). Essentially, nursing documentation could easily involve all of the 19 SNOMED CT concept hierarchies. Obviously, the workgroup could not examine the entirety of SNOMED CT therefore; the workgroup is recommending SNOMED CT as it contains nursing concepts from the previously mentioned source nursing terminologies. The specific concepts in the SNOMED CT hierarchy that form the basis of our recommendation are primarily found in the Findings & Procedures hierarchies, as they represent the majority of nursing diagnoses, interventions and outcomes.

For example:

A Nursing Diagnosis (NANDA) of "**Acute Pain**"
Finding
Clinical history and observations finding
Pain / sensation finding
Pain finding
Finding of pattern of pain
Acute Pain

A Nursing Intervention (NIC) of "**Pain Management**"
Procedure
Procedure by Intent
Therapeutic Procedure
Medical Therapies
Pain Management

A Nursing Outcome (NOC) of "**Pain Control**"
Observables
Procedure by Intent
Therapeutic Procedure
Medical Therapies
Pain Management

Pain Control behavior

Observables

Clinical history/examination observable

Personal health management behavior

Pain control behavior

Acquisition:

An in-principal agreement has been reached that provides, in the US, SNOMED CT as one of the Category 0 codesets, essentially allowing free distribution and use in the US.

Conditions:

No conditions noted.

The workgroup would like to see mappings between the source nursing terminologies and SNOMED CT, and for these mappings to be maintained, validated, and distributed through the UMLS. The workgroup recognizes the importance of the collaboration of the source nursing terminology owners and the SNOMED CTG for Nursing in the appropriate inclusion and representation of nursing terms within SNOMED CT.

Appendix A

ANA-Recognized Terminologies	**Assessment**	**Diagnosis**	**Interventions**	**Outcomes**	**Updates / Cost**	**Mapped or Concepts Integrated in SNOMED CT?**	**In the UMLS?**	**NOTES**
	Scope Intent							
SNOMED CT	X	X	X	X	Free thru UMLS in 01/04		Category 0 as of 01/04	Convergent Terminology Group for Nursing—collaborates with ANA and terminology owners
ABC Codes			X			**No**	Category 3	Primarily administrative / billing codes
NANDA		X			"License fee based on usage"	**Integrated** & mapping tables available	Category 3	Fully integrated in SNOMED CT
NIC			X		$5.00 per end user/yr	**Integrated** & mapping tables available	Category 3	
NOC				X	$5.00 per end user/yr	Plan to complete **integration** for 1/2004 release	Category 3	
OMAHA System		X	X	X	**Public Domain**	**Integrated**	Category 1	
HHCC		X	X	X	Annually / Copyrighted but in **Public Domain** —free with permission	**Integrated** (Diagnoses & Interventions ; Outcomes pending)	Category 1	Integrated into SNOMED CT

ANA-Recognized Terminologies	**Scope Intent**				**Updates / Cost**	**Mapped or Concepts Integrated in SNOMED CT?**	**In the UMLS?**	**NOTES**
	Assessment	**Diagnosis**	**Interventions**	**Outcomes**				
PCDS		X	X	X	Only at Vanderbilt University	Discussions Continue	Category 3	ONLY in use at Vanderbilt University; Plan to have it coded according to clinical LOINC and mapped into SNOMED
PNDS		X	X	X		**Integrated** & mapping tables available	N	
ICNP	X	X	X	X	Demonstration /testing versions	Discussions continue	N	Version I not due for release TIL 2005
Clinical LOINC	X		X	X		Workgroup convened by NLM	Y	Unidentified overlap with SNOMED-CT; Not comprehensive of nursing terms. Has convened a nursing subcommittee—early stages.

Consolidated Health Informatics Initiative
Final Recommendation Information Sheet

Domain Title and Team Lead

History and Physical: Linda Nugent and Viet Nguyen, VA Co-Leads

Scope

This domain is defined as the terminology that is used to identify, classify, and name the components incorporated into a patient's medical history and the physical exam process performed by a practitioner.

Domain/Sub-domain	In-Scope (Y/N)
Document Components and Data Domains	
Demographics	*N**
History of Present Illness	Y
Review of Systems	Y
Past Medical/Surgical History	Y
Family History	Y
Social History	Y
Medications	*N**
Immunization	*N**
Non-Medication Allergies	Y
Vital Signs	Y
Physical Exam Observations	Y
Physical Exam Findings	Y
Laboratory Findings	*N**
Interventions and Procedures	*N**
Diagnoses and Problems	*N**

**Coverage by other CHI domains.*

Final Recommendation

Recommendation to defer this domain to the next phase of CHI as:

- There is considerable variability, in the format and content of a History & Physical. It is presently not standardized and is typically dependant upon the clinical judgment of the practitioner.
- This recommendation to defer the work on standardizing the History & Physical format will give us time to align our efforts with the efforts of other Standards Development Organizations. For instance, the HL7 Electronic Health Record [EHR] SIG recently voted to defer work on developing standard formats for History and Physicals in their current efforts. [See: "Public Response to HL7 Ballot 1 Electronic Health Record", August 29, 2003].

- Additionally, by moving the effort to a later date, the H&P group would be better able to align its recommendations for the components of an H&P with the accepted/recommended terminologies for each component, that have been approved by the CHI Council

Conditions: NA

Consolidated Health Informatics Initiative
Final Recommendation Information Sheet 4

Domain Title and Team Lead

Disability: Jennie Harvell and Samuel Shipley, ASPE Co-chairs

Scope

Disability terms are used in the federal health care sector for payment, policy development, surveys, public quality reports, external quality monitoring, internal quality monitoring, and eligibility determinations.

Alternatives Identified

1. SNOMED CT (Systematized Nomenclature of Medicine Clinical Terms)
2. ICF (International Classification of Functioning, Disability and Health)
3. UMLS (Unified Medical Language System) Metathesaurus.

Recommendation

At this time, the workgroup does not endorse either SNOMED CT or ICF as the standard for disability content needed by the Federal Government. The workgroup recommends support for research that will facilitate the development of (i) needed disability and functional content into core terminologies, and (ii) algorithms that can be used to equate the alternative scaling concepts used across federal classification systems.

Rationale and Study Findings:

The disability workgroup conducted a content coverage analysis using a sample of disability concepts and phrases provided by workgroup members. The analysis involved determining the degree of content coverage provided by SNOMED CT, ICF, and other sources available in UMLS Metathesaurus. Specifically, the workgroup used the MetaMap Transfer (MMTx) Program, developed by the National Library of Medicine, a highly configurable program that maps biomedical text to concepts in the UMLS Metathesaurus. MetaMap works by parsing text into simple noun phrases, identifying variants (acronyms, abbreviations, synonyms, etc.), listing candidate strings within the UMLS Metathesaurus that contain at least one of the variants, and finally identifying the most likely concept match within the UMLS Metathesaurus.

The Workgroup approached a content coverage analysis of SNOMED CT, ICF, and the UMLS Metathesaurus by sampling disability terms/concepts used across participating federal agencies. Sampled terms included those used in Medicare and Medicaid programs, Social Security Administration, Veterans' Health Administration, and surveys conducted by the National Center for Health Statistics (NCHS). In sampling terms, the Workgroup identified disability

---

4 Information Sheet designed specifically to facilitate communication between CHI and NCVHS Subcommittee on Standards and Security resulting from May 20, 2003 testimony. CHI may seek assistance to help further define scope, alternatives to be considered and/or issues to be included in evaluation process.

terms/phrases/content that were applicable to physical and mental disability, children and adults, and are used by the Federal Government to meet a variety of purposes (e.g., payment, quality, eligibility, research, statistics, and policy development). Specifically, disability terms and concepts were sampled from the:

1. Nursing Home Minimum Data Set (MDS);
2. Home Health Outcome and Assessment Information Set (OASIS); and
3. Functional Independence Measure (FIM) for Rehabilitation;
4. Residual Functional Capacity Form (RFC); and
5. National Health Interview Survey and National Health and Nutrition Examination Survey.

NLM performed the analysis using the MetaMap Transfer Program.
No Validation was performed on results.
Match rates were reported as complete, partial, or none.

FINDINGS

At best, the Workgroup found that SNOMED CT and ICF provided a partial match of Scaling concepts because at a minimum, and in all cases, both SNOMED CT and ICF would require the development of algorithms to translate the scaling embedded in the terminology/classification scheme to support the scaling needs of SSA (i.e., the metric needed by) SSA. Neither ICF nor SNOMED CT includes the scaling concepts needed by SSA. The Workgroup concluded that this would be the same result for SNOMED CT and ICF coverage of the scaling embedded in the FIM, OASIS, and MDS.

Some times the scaling content was either unavailable or only partially available.

The table below summarizes the results of the CHI Disability Workgroup content coverage analysis.

Content Coverage Table

			SNOMED CT			ICF	
		Complete	Partial	None	Complete	Partial	None
FIM (n=100)	Quality	58	40	2	30	64	6
	Total	58	40	2	30	64	6
FIM -(IRF-PAI)							
	Payment						
	Total						
OASIS (n=39)	Payment	7	1	1	1	6	2
	Quality	8	13	9	6	9	15
	Total	15	14	10	7	15	17
MDS (n=31)	Payment	10	16	0	3	17	6
	Quality	8	3	0	3	5	3

	Indicators						
	Quality Measures	8	3	0	3	5	3
	Care Planning	8	3	0	3	5	3
	Total	14	17	0	4	21	6
RFC (n=81)	Eligibility Adults	41	8	2	39	11	1
	Eligibility Children	17	13	0	25	5	0
	Total	58	21	2	64	16	1
NCHS (n=70)	Survey	32	34	4	12	40	18
	Total	32	34	4	12	40	18
Grand Total (n=321)		177	126	18	117	156	48

(*) Columns don't add up because items are used for multiple purposes.

As a classification system, the ICF often bundles multiple concepts. However, in many cases, the Federal Government needs disability data for only a part of the bundled concepts. Thus, a classification system will not always permit the extraction of data needed by the Federal Government.

The ICF is intended to be complementary to the International Statistical Classification of Diseases and Related Health Problems (ICD).

The Workgroup was concerned about whether the multi-axial hierarchies that are the foundation of SNOMED CT presently support or could be modified in the future to support disability terms and constructs needed by the Federal Government (and by health care providers). This issue was raised in part because of the origins of SNOMED CT (i.e., a model originally intended to represent diseases and procedures and its continued emphasis on medical content) and also because we found SNOMED CT providing more complete coverage of medically-related terms compared to the ICF (e.g., the provision of Nursing, Rehabilitative, Restorative Care such as in the areas of active and passive range of motion, and training and skills practice in amputation/prosthesis care).

Further, even to the extent that all relevant disability and functioning terms were included in SNOMED CT (or some other terminology) endorsed for future federal use, additional work would be needed to map to the classification systems used by federal agencies (including, but not limited to, classifications (derived from patient assessment tools) that are used to generate Medicare and Medicaid payments, and the ICF). The Workgroup notes the terminology itself would also not be sufficient by itself to provide a conceptual framework for understanding functioning and disability (i.e., a strength of the ICF).

The Workgroup is aware of recent research completed by the Mayo Clinic that found, in a review of the domains of pressure ulcer, incontinence, and pain, most of the information

collected using the MDS for these domains is not captured by either SNOMED CT or ICF. Specifically, SNOMED CT was found to provide a complete match for 46% of the MDS terms. The ICF was found to provide a complete match rate of terms in the MDS 2 percent of the time.

The Disability Workgroup recommends the following:

1. At this time, we do not endorse either SNOMED CT or ICF for future use in the federal health care IT enterprise.
2. We recommend future research that:
    a. examines whether the underlying hierarchies of SNOMED CT will support the incorporation of disability terms, concepts, and phrases needed by the Federal Government, and if not, whether the underlying hierarchies could be modified to support the incorporation of needed disability terms, concepts, and phrases;
    b. conducts a more complete content coverage analysis of SNOMED CT, ICF, and other sources within the UMLS Metathesaurus for disability terms needed by the Federal Government for inclusion in a core terminology;
    c. develops terminology content that will support the scaling concepts embedded in federal classification systems and assessment instruments;
    d. once needed scaling concepts are included in a core terminology, develop algorithms that can be used to equate alternative scaling concepts across federal classification systems;
    e. if the research under item (a) above finds that SNOMED CT will support the incorporation of needed disability terms, concepts, and phrases; supports research that will incorporate the needed disability content identified under items (b) and (c); and
    f. if the research under item (a) above finds that SNOMED CT will not support the incorporation of needed disability terms, concepts, and phrases, develops a disability terminology that meets the criteria of reference terminology (as specified above) using the disability content identified under items (b) and (c).

Consolidated Health Informatics Initiative
Final Recommendation Information Sheet5

Domain Title and Team Lead:

Genes and Proteins: James Sorace, CMS

Scope:

To allow the federal health care sector to exchange information regarding the role of genes in biomedical research and healthcare, using a single unambiguous genetic nomenclature. This information would be used to support the federal health care sector in a wide variety of emerging sectors such as pharmacogenomics, genomic medicine, genomic applications of clinical trials, early detection of malignancies, as well as a wide variety of uses in infectious disease such as epidemiology and disease surveillance.

Domain/Sub-domain	**In-Scope (Y/N)**
Inherited Genetic Variation (e.g. Genetic disease, Pharmacogenomics, Disease susceptibility traits)	Y
Acquired Genetic Changes (e.g. Cancer)	Y
Infectious Disease: Genes/Proteins involved in pathogenesis, drug resistance, or identification	Y
Protein Nomenclature	Y
Gene Nomenclature	Y

Alternatives Identified:

1. SNOMED-CT
2. Gene Ontology (GO) Nomenclature
3. Human Gene Nomenclature (HUGN)

Final Recommendation:

Human Gene Nomenclature (HUGN) sponsored by the Human Genome Organization (HUGO).

Content Coverage:

HUGN is a recognized standard for human gene nomenclature that has a systematic process for establishing genetic nomenclature. It contains names for approximately one half of the expected number of protein coding human genes using established criteria (see http://www.gene.ucl.ac.uk/nomenclature/guidelines.html). HUGO has also approached issues

5 Information Sheet designed specifically to facilitate communication between CHI and NCVHS Subcommittee on Standards and Security resulting from May 20, 2003 testimony. CHI may seek assistance to help further define scope, alternatives to be considered and/or issues to be included in evaluation process.

regarding non-structural genes. The federal government already extensively utilizes HUGN. For example, LocusLink an NCBI resource supports the HUGN as well as Online Mendelian Inheritance in Man (also supported by NIH funding). Thus it is the *de facto* standard for human genomic nomenclature. HUGO works closely with a wide variety of scientific organizations including publishers to assure that its nomenclature is consistently updated.

Acquisition:

The HUGN is free via FTP for nonprofit uses. Commercial use requires a license.
HUGO is a non-profit body and is jointly funded by the UK Medical Research Council (40%) and the US National Institutes of Health, contract N01-LM-9-3533 (60%).

Conditions:

No conditions noted.

As this is an emerging science, the workgroup has identified additional areas of focus:

1) Translational research would be greatly accelerated if implementation of the HUGN standard were coupled with close coordination with other CHI vocabularies. The NCI is working actively in trying to bridge the gaps between basic and clinical science in these fields, but similar efforts by other entities appears uncoordinated.
2) The field of infectious disease represents a very significant gap in current planning. More active coordination between government agencies is necessary not only for translational research, but also for disease surveillance and bio-defense. CDC input on these issues is of great importance, as is coordinating efforts with NIAID as well as other institutes.
3) Genomic medicine will require the adoption of structured vocabularies by content providers. Data standards should be developed with the active participation of the content providers/clinicians, with implementation mandated when possible by the NIH/NLM.

Consolidated Health Informatics Initiative
Final Recommendation Information Sheet6

Domain Title and Team Lead:

Diagnosis & Problem List: Karla Porter and Beth Acker, VA Co-chairs

Scope:

A series of brief statements that catalog a patient's medical, nursing, dental, social, preventative and psychiatric events and issues that are relevant to that patient's health care (e.g. signs, symptoms, and defined conditions).

Domain/Sub-domain	In-Scope (Y/N)
Clinical Diagnosis/Problems	Y
Subjective Symptoms/Observed Findings	Y
Nursing Diagnoses	*N**
Modifiers and Descriptors	**N****
Synonyms	Y
Dental	N
Alternative Medicine	*N*

* Nursing Diagnoses will be addressed by the nursing domain workgroup.

**Note about Modifiers: Many modifiers or "attributes" of a diagnosis or problem often accompany the concept itself. These attributes are as a rule not well defined or standardized. Furthermore, the attributes represent the diagnosis at just one of many possible arbitrary slices in time (i.e., "final" is truly in the eyes of the beholder). The term "Modifiers and Descriptors" above refers to a grouping of these terms rather than attempting to list each specific one. The scope of this report does not cover any of these attributes.

Alternatives Identified

4. SNOMED-CT
5. ICD-9-CM
6. ICD-10-CM
7. DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, 4th ed.)
8. MEDCIN
9. ICPC
10. MedDRA

Final Recommendation:

6 Information Sheet designed specifically to facilitate communication between CHI and NCVHS Subcommittee on Standards and Security resulting from May 20, 2003 testimony. CHI may seek assistance to help further define scope, alternatives to be considered and/or issues to be included in evaluation process.

The workgroup recommends the adoption of Systematized Nomenclature Medicine-Clinical Terms (SNOMED CT), a comprehensive health care reference terminology that includes concepts for diagnoses, findings and disorders.

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

- Diseases
- Findings

Content Coverage:

No terminology is complete, but SNOMED CT is sufficiently complete in the areas of diagnoses and problem lists, especially in comparison to other available terminologies. However, it is essential that accurate mappings exist between SNOMED-CT and other administrative code sets and terminologies including ICD-9/10-CM, DSM (Mental Health) and MedDRA (Adverse Event Reporting). Consistent with NCVHS recent recommendations, mapping needs are being referred to the National Library of Medicine.

Acquisition:

An agreement has been signed between the U.S. Government and the College of American Pathologists (CAP) to distribute SNOMED CT in all future releases of the Unified Medical Language System (UMLS) Metathesaurus. UMLS license terms allow use for all patient record uses and messaging. In the US, SNOMED CT will be one of the Category 0 codesets. This permits free distribution and use in the US.

Conditions:

No conditions apply to the above recommendation. The workgroup would like to see mappings of the diagnosis/problem list terminologies in the UMLS to SNOMED-CT to be maintained, validated, and distributed through the UMLS. The workgroup recognizes the importance of the collaboration of the source diagnosis/problem list terminology owners and the SNOMED CT for diagnosis/problem list with the appropriate inclusion and representation of diagnostic terms within SNOMED-CT.

For example, mapping considerations must be given for administrative (ICD-9/10), financial and HIPAA requirements, as well as collaboration with DSM IV for Mental Health and MedDRA for adverse event reporting.

Diagnoses and Problems

Criteria	SNOMED CT	MEDCIN (reference terminology)	ICD-10-CM
Concept Orientation	1	1	0
Concept Permanence	1	1	1
Non-Ambiguity	1	1	0
Explicit Version Ids	1	1	?
Content Coverage	The July 2003 SNOMED-CT contains 73,171 concepts in the Disease hierarchy and 40,106 concepts in the findings hierarchy.	MEDCIN contains the entire content of International Classification of Diseases version 9, Clinical Modification (ICD-9-CM) codes.	140,000 including modifiers
Settings (inpatient, outpatient, etc.)	All Settings	All Settings	All Settings
Scope	Includes content for multiple disciplines involved in health care	MEDCIN's content applies to physician documentation and appears to contain little content for nurses and allied health care providers, therapists, social workers, dieticians, etc.	Physician based coding system
Ownership	College of American Pathologists, Multidisciplinary Editorial Board	Proprietary, Internal Editorial Board, Physicians Only	NCHS
Availability Cost	No additional cost (beyond funds expended by Govt) to US users. Available through UMLS	Small cost for reference terminology, interface application costly	Available free from NCHS
Use	Limited current usage	Limited Deployment DoD uses interface application	Used for mortality reporting since 1999
Mapping	Mapped to ICD-9-CM and ICD-10: Needs work if to be used for billing	MEDCIN does not include mappings to ICD-10, SNOMED, or ABC codes.	
Considerations	Needs interface to enhance use in clinical setting.		Improved structure from ICD-9-CM Developed for administrative purposes

Consolidated Health Informatics Initiative
Final Recommendation Information Sheet7

Domain Title(s) & Team Lead:

Non-laboratory Interventions & Procedures: Dr. Jorge Ferrer, CMS

Scope:

The standard will be used to describe specific non-laboratory interventions and procedures performed/delivered. Interventions represent the purposeful activities performed in the provision of health care; organized by site, method, intent, focus, device and other characteristics. Procedures are concepts that represent the purposeful activities performed in the provision of health care.

Domain/Sub-domain	In-Scope (Y/N)
Procedure by site (on body system, on body part, on organ)	Y
Procedure by method	Y
Procedure by intent (therapeutic, preventive, palliative, diagnostic, monitoring, surveillance, screening)	Y
Procedure by focus	Y
Regime / Therapy	Y
Procedure by device	Y
Dental	N
Alternative Medicine	N
Laboratory Procedures (addressed in Part B report)	N
Administrative / Management procedure	N

Alternatives Identified:

1. SNOMED CT
2. MEDCIN
3. ICD-10-PCS
4. CPT-IV
5. HCPCS

Final Recommendation:
The non-laboratory interventions and procedures workgroup recommends the adoption of Systematized Nomenclature of Medicine-Clinical Terms (SNOMED CT).

7 Information Sheet designed specifically to facilitate communication between CHI and NCVHS Subcommittee on Standards and Security resulting from May 20, 2003 testimony. CHI may seek assistance to help further define scope, alternatives to be considered and/or issues to be included in evaluation process.

Terminology found in SNOMED CT extends beyond the domain of interventions and procedures. Therefore, the entirety of SNOMED CT is not being recommended, only the content that pertains to interventions and procedures, found within specific hierarchies in the **procedure axis** of SNOMED CT, **excluding** the hierarchies of:

1. Procedures by method: Evaluation procedure: subtype hierarchy: **Laboratory test**
    - Covered by the Laboratory Domain
2. Administrative procedures
    - Covered by HIPAA and the Billing Domain
3. Laboratory Procedures
    - Covered by the Laboratory Domain

Content Coverage:

Of the 344,549 concepts and 913,696 terms in SNOMED-CT-- the January 2003 release of SNOMED CT procedure hierarchy consists of 50,139 concepts and 178,814 descriptions.

Acquisition:

Beginning January 2004, SNOMED-CT will be available without additional fees through the UMLS to US registered users.

Conditions:

This is not a conditional recommendation. The standard is ready for use with identified gaps:

- The timeliness by which emerging procedures are incorporated in the updating of SNOMED CT needs to be improved.
- The workgroup recognizes the importance of mappings to be validated and maintained between SNOMED CT, CPT, HCPCS, ICD-9-CM Volume 3, and ICD-10-PCS via the UMLS.

Criteria	SNOMED CT	MEDCIN (terminology component)	CPT	ICD-10-PCS
Concept Orientation	1	1	0	0
Concept Permanence	1	1	0	?
Non-Ambiguity	1	1	0	0
Explicit Version Ids	1	1	1	1
Content Coverage	The January 2003 release of SNOMED CT	MEDCIN contains the entire content of Current Procedural	4,000	197,000

Criteria	SNOMED CT	MEDCIN (terminology component)	CPT	ICD-10-PCS
	procedure hierarchy consists of 50,139 concepts and 178,814 descriptions.	Terminology-IV (CPT) and CPT modifiers. Less than 20% of HCPCS are included.		
Settings (inpatient, outpatient, etc.)	All Settings	All Settings	Outpatient claims and physician inpatient bills	Developed for use in inpatient setting
Scope	Includes content for multiple disciplines involved in health care	MEDCIN's content applies to physician documentation and appears to contain little content for nurses and allied health care providers, therapists, social workers, dieticians, etc.	Physician based coding system	Hospital based coding system
Ownership	College of American Pathologists, Multi-disciplinary Editorial Board	Proprietary, Internal Editorial Board, Physicians Only	Proprietary, AMA Review Board CMS assigns codes for Level II HCPC	CMS
Availability Cost	No additional cost (beyond funds expended by Govt) to US users. Available through UMLS in January 2004	Small cost for reference terminology, interface application costly	Available from AMA with charges to users (VA pays approx. $12,000/yr)	Available free from CMS
Use	Limited current usage	Limited Deployment DoD uses interface application	Widely deployed for billing (required	Not being used but has been tested

Criteria	SNOMED CT	MEDCIN (terminology component)	CPT	ICD-10-PCS
			for HIPAA)	
Mapping	Mapped to ICD-9-CM and ICD-10: Needs work if map to be used for billing. Older map to CPT-4 available in UMLS. NLM negotiating with AMA to update.	MEDCIN does not include mappings to ICD-10, HCPCS level I or II codes, SNOMED procedures, the various dental procedure terminologies, or ABC codes.	Maps being developed by AMA to SNOMED (Unknown if procedures will be included) Prototype scheduled to be available November 2003	More comprehensive system than ICD-9-CM Volume III for billing purpose
Considerations	Missing some newer therapies. Needs interface to enhance use in clinical setting. UK developing hierarchies.	Lack of formal terminology structures other than the is-a relationships in its poly-hierarchies means that aggregation of like procedure terms will probably be unreliable or difficult.	Billing purposes only	Billing purposes

Consolidated Health Informatics Initiative
Final Recommendation Information Sheet8

Domain Title(s) and Team Lead

Clinical Encounters: Gregg Seppala, VHA

Scope

Clinical encounter is defined by ASTM as "(1) an instance of direct provider/practitioner to patient interaction, regardless of the setting, between a patient and a practitioner vested with primary responsibility for diagnosing, evaluating or treating the patient's condition, or both, or providing social worker services. (2) A contact between a patient and a practitioner who has primary responsibility for assessing and treating the patient at a given contact, exercising independent judgment." Encounter serves as a focal point linking clinical, administrative and financial information. Encounters occur in many different settings -- ambulatory care, inpatient care, emergency care, home health care, field and virtual (telemedicine).

The ASTM definition excludes ancillary service visit, which is defined as "the appearance of an outpatient in a unit of a hospital or outpatient facility to receive service(s), test(s), or procedures." The clinical encounter definition also excludes practitioner actions in the absence of a patient such as practitioner-to-practitioner interaction and practitioner-to-records interaction.

Domain/Sub-domain	In-Scope (Y/N)
Clinical Encounters	Y
Admission Information	Y
Transfer (Patient Movement) Information	Y
Discharge Information	Y
Provider Information	Y
Accident Information	Y
Death and Autopsy Information	Y
Allergy Information	*N*
Demographics	*N*
Diagnosis/Problem Lists	*N*
Financial/Payment	*N*
Insurance Information	*N*
Interventions/Procedures	*N*
Personal Health Record	*N*

8 Information Sheet designed specifically to facilitate communication between CHI and NCVHS Subcommittee on Standards and Security resulting from May 20, 2003 testimony. CHI may seek assistance to help further define scope, alternatives to be considered and/or issues to be included in evaluation process.

Alternatives Identified

Standard	Comments
ASTM E1384-02a Standard Guide for Content and Structure of the Electronic Health Record (EHR)	The work group concluded that E1384 offers the best definition for clinical encounter and adopted that definition to define the scope for our effort. However, E1384 does not contain significant clinical encounter data elements or value sets beyond those in the HL7 v2.x ADT message specification.
ASTM E1633-02a Standard Specification for Coded Values Used in the Electronic Health Record	The work group determined that E1633 offered coded values for only five of the 38 clinical encounter coded data elements. Of the five, one is derived from the UB-92 and another is derived from DEEDS.
CDCP Data Elements for Emergency Department Systems, Release 1.0 (DEEDS)	The work group reviewed DEEDS for data elements and code sets and recommends that several of the HL7 value sets be harmonized with codes in DEEDS.
CMS Form HCFA-1450 (UB-92)	The work group recommends code sets from the UB-92 for several HL7 clinical encounter coded data fields. This is consistent with the HL7 standard which also recommends the UB-92 values for use in the United States.
Health Level 7, version 2.4 and above	The work group determined that the CHI-selected messaging standard -- HL7 v2.4 Application, Transfer and Discharge (ADT) message -- included all of the data elements and most of the value sets for exchanging information about clinical encounters.
SNOMED-CT	The work group matched SNOMED concepts to HL7 data fields but concluded that SNOMED does not provide better coverage overall compared with the suggested values sets in HL7 at this time.
X12N 837 Health Care Claim message	The work group reviewed the Event type (Loop ID 2300) for clinical encounter data elements and value sets but was not able to identify any significant data elements or values sets beyond those in the HL7 v2.x ADT message specification.

Final Recommendation

The workgroup recommends adoption of Health Level Seven (HL7), Version 2.4 and higher, with identified gaps to be addressed in the future.

Content Coverage

The team identified 92 of the 612 data fields in the HL7 v2.4 Application, Transfer and Discharge (ADT) message as falling within the scope of clinical encounter standards recommendation. A gap that needs to be addressed in the future is support for exchanging information about clinical services that do not fall under the definition of encounter such as practitioner to practitioner and practitioner to record interactions.

The team concluded that 37 of the 92 data fields require no further standardization because they hold date and time (16 data fields), yes/no responses (10 data fields), text (6 data fields), address (1 data field), telephone (1 data field), organization name (1 data field) or number (2 data fields) data.

The team concluded that for the 17 data fields that hold identifiers, visit id (2 data fields) does not require standardizing, healthcare facility (1 data field) and practitioner (7 data fields) should use National Provider System identifiers once they are available, but location identifier (7 data fields) cannot be standardized across facilities at this time and must be addressed in the future.

The team concluded that for the remaining 38 data fields that hold coded data, 8 data fields should reference externally-defined value sets, 13 data fields should reference tables published in HL7 v2.4, 7 data fields should reference tables published in HL7 v2.5, 4 data fields should reference value sets published in HL7 v3, but 6 data fields do not have value sets published in any version of HL7 and must be addressed in the future.

Data Element Type	Coverage
Clinical Encounters	29 data elements; 1 needs future work
Admission Information	15 data elements; 2 need future work
Transfer (Patient Movement) Information	9 data elements
Discharge Information	6 data elements; 1 needs future work
Provider Information	15 data elements; 2 need future work
Accident Information	9 data elements
Death and Autopsy Information	9 data elements

Acquisition

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.

Conditions

The workgroup identified issues, noted below, that should be addressed in the future but the standard is usable in its current state so our recommendation is not conditional.

- Explicit support for home health, field and virtual encounters
- Support for clinical services that do not meet definition of clinical encounter

- National Provider System identifiers for practitioners and healthcare organizations
- Standard location identifiers
- Standard hospital service names

Consolidated Health Informatics Initiative
Final Recommendation Information Sheet9

Domain Title and Team Leads:

Text-Based Reports: VA Co-Leads: Linda Nugent and Dr. Viet Nguyen (VA)

Scope:

Identify standards and terminologies used to define the messaging architecture and syntax of clinical text documents. Initially, all clinical documents types were considered as possible sub-domains. Additional sub-domains were further delineated from initial analysis of content of clinical document types, including section headings and data-types. The group reached consensus that inclusion of these sub-domains would result in scope that was much too broad to be completed in the short time frame and resources allocated. Document components and data domains contained in text-documents overlap broadly with areas already covered by other CHI groups.

Domain/Sub-domain	In-Scope (Y/N)
Text-Document structure and syntax	Y
Electronic Signature	Y
Document Section Headings	Y
Clinical Document Types/Titles	Y
Document Components and Data Domains	*N*
Clinical Signs and Symptoms	*N*
Vital Signs	*N*
Physical Exam Observations and Findings	*N*
Laboratory Findings	*N*
Diagnoses and Problems	*N*
Orders	*N*

Alternatives Identified

1. SNOMED CT
2. HL 7CDA (Clinical Document Architecture)
3. Continuity of Care Record
4. ASN.1 (Abstract Syntax Notation One)
5. HTML
6. XML
7. Rich Text Format
8. PDA (Portable Document Architecture)

9 Information Sheet designed specifically to facilitate communication between CHI and NCVHS Subcommittee on Standards and Security resulting from May 20, 2003 testimony. CHI may seek assistance to help further define scope, alternatives to be considered and/or issues to be included in evaluation process.

9. Clinical LOINC (Logical Observation Identifiers Names & Codes)
10. CEN (European Committee for Standardization)
11. ASTM E1384-02 Guide for Content and Structure of the Electronic Health Record

Final Recommendation:

HL7 Clinical Document Architecture (CDA), current (1.0-2000) and subsequent releases. (HL7 released the ballot for CDA Release 2.0 on December 8th, 2003. It is anticipated that this new release will be ANSI-certified before the end of 2004.)

The workgroup considers the GSA/OMB E-Authentication Policy and the NIST FIPS Pub 199 as the defining documents for authentication control. Upon the release of the final E-Authentication Policy and the companion NIST technical guidance, the workgroup recommends that CHI reconvene a workgroup to review the guidelines and recommend adherence to risk assessment evaluation and application of appropriate security technology.

Content Coverage:

The HL7 CDA draws its vocabulary from the HL7 Reference Information Model (RIM). The RIM has internal HL7 vocabulary tables but to the greatest extent possible relies on externally maintained standard vocabularies, such as LOINC, ICD, SNOMED, etc.

Acquisition:

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.

However some of the externally maintained standard vocabularies contained in the HL7 RIM, such as LOINC, ICD, SNOMED CT, etc. require licensing fees. Of note, on July 1, 2003, Secretary Thompson announced that the Department of Health and Human Services (DHHS) entered into a licensing agreement to make a clinical terminology database, SNOMED CT, available without charge to the U.S. health care industry.

Conditions:

No conditions.

Consolidated Health Informatics Initiative
Final Recommendation Sheet Format10

Domain Title and Team Lead:

Population Health: Steven J Steindel, PhD (CDC)

Scope:

To enumerate code sets used to report data to public health and for the purpose of population health statistics that were not specifically defined in other CHI domain reports.

Domain/Sub-domain	In-Scope (Y/N)
Public Health Reporting	Y
Population Health Statistics	Y
Billing Data/Statistics	N
Institution Health Statistics	Y/N*

*The Workgroup recommends that institutions keep local statistics using the same codes as required for reporting, but chooses to defer actual operation to the local level.

Alternatives Identified:

Incomplete list and use matrix identified – includes:

ICD-10
ICD-9
ICD-9-CM
MedDRA
CPT-4
LOINC
SNOMED
COSTART
DRG
DSM-IV
HCPCS
Eindhoven Classification-Medical Model
HL7 Terminology
HL7 Vaccine List
ICD-10 E-Codes
ILD Classification
NAACCR
NDC

10 Information Sheet designed specifically to facilitate communication between CHI and NCVHS Subcommittee on Standards and Security resulting from May 20, 2003 testimony. CHI may seek assistance to help further define scope, alternatives to be considered and/or issues to be included in evaluation process.

RxNorm
Units
VAERS

Final Recommendation:

No recommendation / standard ready for adoption.

Population Health Reporting needs to cover a wide range of domains and currently use few standard terminologies while many systems use locally developed code sets. Of those code sets that are in common usage, none currently are domain recommendations of CHI. Several have been mentioned as terminologies to which the recommended domain terminology requires mapping. Some are HIPAA approved code sets. Some are required by regulation or international agreement. Hence, because of this diversity, the workgroup feels a specific CHI recommendation for population health reporting is inappropriate at this time.

Content Coverage:

NA

Acquisition:

NA

Findings:

The Workgroup makes two specific recommendations of CHI to be conducted in a later phase:

1. The terminology systems and uses noted in the appendix are incomplete. Before specific recommendations can be made, a complete understanding of the scope of systems is required. As the nation's health statistics agency, it is recommended that CHI support funding for NCHS to develop this complete list. As part of this task, NCHS should be asked to note areas in which population health reporting requires aggregated data outside of the CHI domains involving clinical data such as occupations, industries and socio-economic data and suggest standard means to address these aggregation issues.
2. Other CHI domain terminologies have specific clinical uses. It is hoped by many that these clinical terminologies can be used for population reporting. It is how they are to be used that is unknown. It is recommended that an appropriate body be asked to develop a report on the use of clinical data for population health reporting and to include in that report recommendations on the incorporation of past, present and future data as they might represent different population health concepts. The report should focus in part on the following:
    - The extent to which mapping between two terminologies can satisfy multiple needs, including population health reporting;

- A description of the forms and complexity of the maps;
- Ability of mapped clinical data to relate to longitudinal data; and
- The problem of using a dual system where part of population health data is derived from computer mapped clinical data to a reporting terminology and part reported as now using human interpretation to the reporting terminology needs enumeration.

It is anticipated that the NCVHS, the Board of Scientific Counselors of the NCHS and The National Library of Medicine would participate in these studies.

Appendix:
Limited Summary of Current Population Health Reporting Systems Using Standard Terminology Maintained by HHS Agencies

Terminology	Population Health Use	First Used	Version	Update Frequency	Fee	Regulatory Requirement	Clinical Relationship
COSTART	Vaccine Adverse Event Reporting System (VAERS)					None	
CPT-4	Minimum Data Elements (National Breast/Cervical Cancer Early Detection - MDE)				Yes	None	Procedure
CPT-4	Vaccine Safety Datalink Project (VSD)				Yes	None	Procedure
CPT-4	Uniform Data System (UDS) for the Consolidated Health Center Program- HRSA Bureau of Primary Health Care				Yes	Section 330(e), 330(h) PHS Act,	Detection and Treatment and availability of health care services
CPT-4	Health Cost and Utilization Project (HCUP)				Yes	None	Procedures
CPT-4	Medical Expenditure Panel Survey (MEPS)				Yes	None	Procedures
CPT-4	IHS – monitoring care		latest	As released	Yes	Yes	Procedures
DRG	Medical Expenditure Panel Survey (MEPS)					None	Diagnoses and inpatient procedures

Terminology	Population Health Use	First Used	Version	Update Frequency	Fee	Regulatory Requirement	Clinical Relationship
DSM IV	Medical Expenditure Panel Survey (MEPS)				?	None	Diagnoses
DSM-4	Metropolitan Atlanta Developmental Disabilities Surveillance Program (MADDSP)				?	None	Procedure
Eindhoven Classification-Medical Model	National Patient Safety Network Itself				?	?	
HCPCS	Health Cost and Utilization Project (HCUP)					None	Procedures
HCPCS	Grantee Researchers using CMS data					None	Procedures
HL7 controlled terminology	National Patient Safety Network Itself					None	
HL7 vaccine list	Vaccine Adverse Event Reporting System (VAERS) - FDA and CDC					None	
ICD-10	122 Cities Mortality Reporting System (122 MRS)					None	Morality
ICD-10	Medical Examiner/Corner Information Sharing Program (MECISP)					None	Morality

Terminology	Population Health Use	First Used	Version	Update Frequency	Fee	Regulatory Requirement	Clinical Relationship
ICD-10	Metropolitan Atlanta Developmental Disabilities Surveillance Program (MADDSP)					None	Morality
ICD-10	National Mortality Follow-back Survey (NMFS)					None	Morality
ICD-10	National Vital Statistics System (NVSS)					None	Morality
ICD-10	National Vital Statistics System - Fetal Death (NVSS)					None	Morality
ICD-10	National Vital Statistics System - Linked Birth/Infant Death (NVSS)					None	Morality
ICD-10	National Vital Statistics System - Mortality (NVSS)					None	Morality
ICD-10	National Vital Statistics System - Natality (NVSS)					None	Morality
ICD-10	Adult Spectrum (HIV) of Disease (ASD)					None	Morality
ICD-10	HIV/AIDS Reporting System (HARS)					None	Morality
ICD-10	Pediatric Spectrum (HIV) of Disease (PSD)					None	Morality

Terminology	Population Health Use	First Used	Version	Update Frequency	Fee	Regulatory Requirement	Clinical Relationship
ICD-10	National Nosocomial Infectious Surveillance System (NNIS)					None	Morality
ICD-10	Central Nervous System Injury Surveillance System (CNSISS)					None	Morality
ICD-10	National Occupational Mortality Surveillance System (NOMS)					None	Morality
ICD-10	National Surveillance System for Pneumoconiosis Mortality (NSSPM)					None	Morality
ICD-10	National Traumatic Occupational Fatalities Surveillance System (NTOF)					None	Morality
ICD-10	Vaccine Safety Datalink Project (VSD)					None	Morality
ICD-10 for Health-related Injury Code and/or modify the E Codes in ICD-9 for iatrogenic injuries	National Patient Safety Network Itself					None	
ICD-9	Title V Information System - HRSA Maternal and Child Health Bureau			Annual		None	Improved health outcomes and needs assessment

Terminology	Population Health Use	First Used	Version	Update Frequency	Fee	Regulatory Requirement	Clinical Relationship
ICD-9 CM	Health Cost and Utilization Project (HCUP)					None	Diagnoses
ICD-9 CM	Medical Expenditure Panel Survey (MEPS)					None	Diagnoses
ICD-9-CM	National Exposure Registry (NER)					None	Diagnosis
ICD-9-CM	Metropolitan Atlanta Developmental Disabilities Surveillance Program (MADDSP)					None	Diagnosis
ICD-9-CM	Longitudinal Follow-up to the National Maternal and Infant Health Study (LFNMIHS)					None	Diagnosis
ICD-9-CM	National Ambulatory Medical Care Survey (NAMCS)					None	Diagnosis
ICD-9-CM	National Home and Hospice Care Survey (NHHCS)					None	Diagnosis
ICD-9-CM	National Hospital Ambulatory Medical Care Survey (NHAMCS)					None	Diagnosis
ICD-9-CM	National Hospital Discharge Survey (NHDS)					None	Diagnosis
ICD-9-CM	National Nursing Home Survey (NNHS)					None	Diagnosis

Terminology	Population Health Use	First Used	Version	Update Frequency	Fee	Regulatory Requirement	Clinical Relationship
ICD-9-CM	National Survey of Ambulatory Surgery (NSAS)					None	Diagnosis
ICD-9-CM	National Mortality Follow-back Survey (NMFS)					None	Diagnosis
ICD-9-CM	Second Longitudinal Study on Aging (LSOA II)					None	Diagnosis
ICD-9-CM	HIV/AIDS Reporting System (HARS)					None	Diagnosis
ICD-9-CM	Hemophilia Surveillance System (HSS)					None	Diagnosis
ICD-9-CM	Streptococcus Pneumoniae and Haemophilus Influenzae					None	Diagnosis
ICD-9-CM	Central Nervous System Injury Surveillance System (CNSISS)					None	Diagnosis
ICD-9-CM	State-Based Emergency Department Injury Surveillance					None	Diagnosis
ICD-9-CM	Fatality Assessment and Control Evaluation (FACE)					None	Diagnosis
ICD-9-CM	National Coal Workers' Autopsy Study (NCWAS)					None	Diagnosis

Terminology	Population Health Use	First Used	Version	Update Frequency	Fee	Regulatory Requirement	Clinical Relationship
ICD-9-CM	Vaccine Safety Datalink Project (VSD)					None	Diagnosis
ICD-9-CM	Uniform Data System (UDS) for the Consolidated Health Center Program- HRSA Bureau of Primary Health Care	1966	2nd	Annual		Section 330(e), 330(h) PHS Act,	Detection and Treatment and availability of health care services
ICD-9-CM	Grantee Researchers using CMS data					None	Diagnosis
ICD-9-CM	IHS – for reporting, monitoring care	Long term	Latest	As released		Yes	Diagnosis
ILD Classification	Coal Workers' X-ray Surveillance Program (CWXSP)					None	
LOINC	Blood Product Deviations (BPD) - FDA					Yes	
LOINC	BPD-Fatalities					Yes	
LOINC	Minimum Data Elements (National Breast/Cervical Cancer Early Detection - MDE)					None	
LOINC	National Healthcare Safety Network (NHSN)					?	
LOINC	National Patient Safety Network Itself					?	

Terminology	Population Health Use	First Used	Version	Update Frequency	Fee	Regulatory Requirement	Clinical Relationship
LOINC	IHS- monitoring care	2002	Latest	As released		None	Test Names
MedDRA	Vaccine Adverse Event Reporting System (VAERS) - FDA and CDC					None	
MedDRA, and SNOMED CT	Adverse Event Reporting System (AERS) - FDA					Yes	
MedDRA, Patient problem list, Device Problem list, Device list (known as standard product nomenclature in UMLS)	Manufacturer and User Facility Experience					Yes	
NAACCR (http://www.naaccr.org/filesystem/pdf/VolumeII10.1FINALPDF5-30-03.pdf)	Cancer Registration including the National Program of Cancer Registries (NPCR) at CDC, the Surveillance Epidemiology and End Results (SEER) at NIH and the American College of Surgeons Commission on Cancer	1995*	10.1**	Annually	0	PA 02060	Typically, a registrar in a hospital abstracts the best available data from the medical record and submits that data to the central cancer registry (CCR). The CCR consolidates the information for the cancer from the multiple hospital sources.

Terminology	Population Health Use	First Used	Version	Update Frequency	Fee	Regulatory Requirement	Clinical Relationship
NDC	Medical Expenditure Panel Survey (MEPS)					None	Drugs
RxNORM	National Patient Safety Network Itself					None	
SNOMED	Minimum Data Elements (National Breast/Cervical Cancer Early Detection - MDE)					None	
SNOMED CT	National Healthcare Safety Network (NHSN)					None	
SNOMED CT	National Patient Safety Network Itself					None	
SNOMED CT	Vaccine Adverse Event Reporting System (VAERS) - FDA and CDC					None	
Units	Childhood Blood-Lead Poisoning Surveillance System (CBLS)					None	
VAERS vaccine list	Vaccine Adverse Event Reporting System (VAERS) - FDA and CDC					None	

Terminology	Population Health Use	First Used	Version	Update Frequency	Fee	Regulatory Requirement	Clinical Relationship
Note: CDC Systems based on 1998 report that has not been updated. Conversion of CDC Surveillance systems to national codes, particularly LOINC and SNOMED is well underway and not reflected in this table							

Consolidated Health Informatics Initiative
Final Recommendation Sheet Format11

Domain Title and Team Lead:

Chemicals: Steven J Steindel, Ph.D (CDC)

Scope:

To provide codes for chemicals of importance to health care outside of medications, which were covered in the CHI Medication standard. The workgroups feels that for health care purposes these chemicals will be those found in the workplace or the environment that might be related to health. Commonly the first, and perhaps only use, of a chemical code would be during a first encounter and perhaps be part of a History and Physical.

Domain/Sub-domain	In-Scope (Y/N)
Non-medicine chemicals	**Y**
Medication ingredients	*N*

Alternatives Identified:

1. **SNOMED CT**: Was not specifically reviewed by the Workgroup. SNOMED CT was reviewed as a means of identifying ingredients as part of the Medication Workgroup and found inadequate. A brief look at the Chemicals area by the Workgroup Chair indicated it was also not adequate for this domain.
2. **CDC NIOSH Registry of Toxic Effects of Chemical Substances (RTECS®):** A database of 152,970 toxic chemicals (January 2001). The database is now privately maintained and available at a modest (starting at approximately $275 for a CD) subscription price. While this database appeared complete and was well targeted for toxicological information of medical importance, the subscription price and availability of a federally maintained system eliminated it from consideration. (See mapping below).
3. **Chemical Abstract Service (CAS) Numbers**: CAS Numbers were investigated as they are the primary identification number assigned in the US. Approximately 22 million chemicals are registered with CAS. Licensing restrictions were viewed as preventing us of CAS Numbers for medical messaging. Note that CAS Numbers may be used freely for regulatory purposes and appear in many chemical databases for that reason.
4. **Environmental Protection Agency (EPA) Substance Registry System (SRS)**: See below for description.

.

11 Information Sheet designed specifically to facilitate communication between CHI and NCVHS Subcommittee on Standards and Security resulting from May 20, 2003 testimony. CHI may seek assistance to help further define scope, alternatives to be considered and/or issues to be included in evaluation process.

Final Recommendation:

Literally thousands of directories of chemicals exist for many purposes. A review of the content and requirements of the EPA SRS indicated that it meet the needs of a CHI Validation study The EPA SRS as chosen because it is reasonably complete, readily available, in current wide-spread use and already has a structure that allows linkage to other data sources. As a federal government resource, there is no cost associated with access or use.

Content Coverage:

Data as of 11/10/03:
Number of substances currently in the SRS: 87707
Number of submitting organizations represented in the SRS: 37
Number of information resources included in the SRS: 965

The SRS contains substance identification information and listings of substances in EPA regulations and Agency programs. Substances are identified by common identifiers such as CAS Number and name (systematic or scientific). Each substance is linked to regulations in which it is referenced and program systems where it has been reported. Searches can also be done by specific regulation or program system.

The Standard in the present new format and in previous formats has been widely used, maintained and available from the EPA for a number of years. The Standard has information for STOrage RETrieval for Water Quality Data (STORET), Air Quality System (AQS), National Emission Inventory (NEI), and EPA Registry Names, substance lists for Green Chemistry Expert System (GCES), Chemical on Reporting Rules (CORR), Emergency Response Notification System (ERNS), Federal Insecticide, Fungicide, and Rodenticide Act Inert Ingredients in Pesticide Products (FIFRA-Inerts), Integrated Taxonomic Information System (ITIS), Safe Drinking Water Information System-Enviro (SDWIS-Enviro), OPP Registration Eligibility Decisions (OPP-REDS), Permit Compliance System-Enviro (PCS-Enviro), and Pesticide Product Information System (PPIS). Previous EPA registries, the Chemical Registry System (CRS) and the Biology Registry System (BioRS) have been retired with full function included in this standard.

Acquisition:

The standard is owned and maintained by Environmental Protection Agency. It is part of the EPA System of Registries (ww.epa.gov/sor). The System of Registries (SoR) provides a gateway and search capability to several registries and repositories residing in the Environmental Protection Agency's (EPA) Office of Environmental Information (OEI). These registries comprise a critical link in EPA's information architecture and are a vital component to the National Environmental Information Exchange Network

(Network). Specifically, the SoR was developed to support the Agency's data standards program and numerous Agency information technology initiatives, including the Agency architecture and data exchange with stakeholders through network nodes.

The registries provide identification information for objects of interest to EPA, Network trading partners, including states and tribal entities, and the public. These objects consist of data elements, XML tags, data standards, substances (chemicals, biological organisms, and physical properties), terms, facilities, regulations, and data sets that the Agency uses in its core business processes.

The Substance Registry System (SRS) is the Environmental Protection Agency's (EPA) central system for information about regulated and monitored substances. The system provides a common basis for identification of chemicals, biological organisms, and other substances listed in EPA regulations and data systems, as well as substances of interest from other sources, such as publications. The SRS supports and conforms to EPA Chemical Identification Data Standard (http://www.epa.gov/edr/fchemid.pdf)and the EPA's Biological Identification Data Standard (http://www.epa.gov/edr/fbiology.pdf).

Included is a download feature that lets you receive information about the contents the registry. There is a download section included at the bottom of each detail page. File formats include text report, Oracle (SQL* Loader), and comma-separated text files (for use in MS Access, MS Excel). Download files are available in a nonstandard, compressed file format that requires decompression software, such as WinZip or PKZip. Download of the complete database does not appear to be available at this time.

The registry data can also be accessed using the Environmental Metadata Gateway (EMG, http://www.epa.gov/emg/), a search engine that enables users to search the metadata registry content using a Universal Resource Locators (URL) with integrated search capabilities. It enables users to search and seamlessly navigate to the detail pages meeting the search criteria. An EMG Search has been developed that enables system developers to build URLs to automatically query various substance data and display the appropriate detail information from EPA's application, the Substance Registry System (SRS).

No license is required.

Conditions:

US Environmental Protection Agency (EPA) Substance Registry System (SRS) (www/epa.gov/srs)

- Establishing interagency communication so that medical needs are addressed in a timely and coordinated fashion. (It is the Workgroup's understanding that this communication has started.)
- Developing a mechanism so that similar tables from other agencies can be matched against the SRS table and missing elements added. (Note: this will require new, unidentified resources.)

- Investigate availability of a subset or view of information from the database in an acceptable format for healthcare use as a no or low-cost distribution item. (EPA is willing to provide this view as a periodically updated, perhaps every six-months, compressed file for Internet download.)
- Requirement for registering an Object Identifier (OID) if it is to be used in HL7 messaging.