Consolidated Health Informatics

Standards Adoption Recommendation

Medical Devices and Supplies

Index

Summary

Domain: Medical Devices and Supplies

Standards Adoption Recommendation:
None: Monitor Industry Work

SCOPE
This standard is used primarily to inventory medical devices and supplies and document their utilization by health services establishments and to regulate medical device and supply availability and utilization in the community by public health agencies. The regulation of medical devices and supplies involves premarket approval/classification and post market adverse event surveillance to ensure the safety and effectiveness of the product.

RECOMMENDATION
No one terminology is recommended, rather the recommendation is to encourage the Global Medical Device Nomenclature (GMDN) and the Universal Medical Device Nomenclature System (UMDNS®) to merge and to re-evaluate/adopt the resulting terminology.

OWNERSHIP
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 and AHRQ support.

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.

APPROVALS AND ACCREDITATIONS
-NA-

ACQUISITION AND COST
-NA-

REVISION HISTORY

DATE	VERSION	COMMENT
11/20/2003	Public Document	Final Recommendation
2/24/2006	1.1	AHRQ reference added

Part I – Team & Domain Scope Identification

Target Vocabulary Domain

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

Medical Devices and Medical Supplies

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

This standard is used primarily to inventory medical devices and supplies and document their utilization by health services establishments and to regulate medical device and supply availability and utilization in the community by public health agencies. The regulation of medical devices and supplies involves premarket approval/classification and post market adverse event surveillance to ensure the safety and effectiveness of the product.

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)

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

Body of Health Services Knowledge
Cost Accounting Information
Customer Health Care Information
Encounter (Administrative) Data
Resource Availability
Care Management Information
Case Management Information
Clinical Guidelines
Technical Reference Data
Supply Inventory Information
Product Evaluation Information

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

Name	Agency/Department
Brock Hefflin, MD, MPH (Team Lead)	FDA/CDRH/HHS
Larry Kessler, ScD	FDA/CDRH/HHS
Jonathan Blaker	DoD
Robert M. Baum, BSBA	VA
Gail Janes, PhD, MS	CDC/HHS

Work Period *Dates work began/ended.*

Start	End
July 21, 2003	October 6, 2003

Part II – Standards Adoption Recommendation

Recommendation *Identify the solution recommended.*

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

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

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.

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

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. Both terminologies are being used internationally, the GMDN primarily by regulatory agencies and the UMDNS® primarily by healthcare institutions. 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. The GMDN Maintenance Agency and ECRI are in communication regarding ECRI's participation in the GMDN effort. In addition, the FDA and ECRI are collaborating to map/link the UMDNS® to the GMDN and to coordinate nomenclature practices, which may lead to a merger of the terminologies within the next few years. 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 use these same product identifiers to communicate with foreign establishments.

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

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.

Approvals & Accreditations
Indicate the status of various accreditations and approvals:

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

Options Considered *Inventory solution options considered and summarize the basis for not recommending the alternative(s). SNOMED CT® must be specifically discussed.*

1. SNOMED CT®: referenced domain is relatively new and insufficiently developed (i.e., not comprehensive enough) to accommodate required regulatory and inventory activities; no definitions.
2. UNSPC (United Nations System for Product Classification): referenced domain contains product descriptors that are too coarse (i.e., not specific enough) to accommodate required regulatory activities; no definitions.
3. ICD-9: referenced domain is not sufficiently comprehensive; typically includes only products associated with procedures; no definitions.
4. HCPCS (Healthcare Common Procedure Coding System): terminology lacks a unique code for all products and is not sufficiently specific to accommodate required regulatory activities; no definitions.
5. FDA Medical Device Classification: terminology is sufficiently comprehensive and includes unique codes for products and many definitions; however, its structure is flawed through the sub-optimal classification of many products.

Current Deployment

Summarize the degree of market penetration today; i.e., where is this solution installed today? *What number of or percentage of relevant vendors have adopted the standard?* *What number or percentage of healthcare institutions have adopted the standard?* *What number or percentage of federal agencies have adopted the standard?* *Is the standard used in other countries?*

Are there other relevant indicators of market acceptance?

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						
Department of Defense						
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)						

Department/Agency	B	C	D	E	F	G
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)						
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.

How often are terms updated?

Range of Coverage

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

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

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.)

Systems Requirements

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

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

Is a conformance standard specified? Are conformance tools available?

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

What is the process for adding new capabilities or fixes?

What is the average time between versions?

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

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

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

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

Mapping Requirements

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

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

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 requirements			
HIPAA standards			
HL7 2.x			

Implementation Timeframe

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

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

Gaps

Identify the gaps in data, vocabulary or interoperability.

Obstacles

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

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.

Information Exchange Requirement	Description of IER
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.

Information Exchange Requirement	Description of IER
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.
Technical Reference Data	The Universal Data Repository (UDR), which contains consolidated medical materiel and pharmaceutical information from a variety of federal and government resources as well as commercial/industry sources. This includes information about vendors/suppliers and descriptions of supplies and equipment.
Supply Inventory Information	Information relating to the internal MHS customer who is ordering.

Information Exchange Requirement	Description of IER
Product Evaluation Information	Rating information to be used in evaluating products for potential purchase by the MHS.