Consolidated Health Informatics

Standards Adoption Recommendation

Medications
Subdomain: Clinical Drugs

Index

Summary

Domain: Medications

Sub-Domain: Clinical Drug

Standards Adoption Recommendation:
Semantic Clinical Drug (SCD) of RxNorm

SCOPE
The purpose of this standard is to enable the federal health care sector to share information regarding medication active ingredients.

A "clinical drug" is a name for a pharmaceutical preparation consisting of its component(s), defined as active ingredients and their strength, together with the dose form of the drug as given to the patient. It expresses the equivalence of pharmaceutical preparations at a generic level, in the form in which medications are prescribed for the patient.

RECOMMENDATION
The CHI Medications subgroup has identified the Semantic Clinical Drug (SCD) of RxNorm, a portion of the UMLS® as the CHI standard for clinical drug nomenclature. .

OWNERSHIP
The National Library of Medicine has primary responsibility for the RxNorm terminology. As steward, NLM works in close collaboration with other governmental agencies (e.g. the AHRQ, VA, DOD and the FDA, with the private sector (e.g. First Databank, Micromedex, Multum, Medispan) and other Nations (e.g. Britain, and Australia).

APPROVALS AND ACCREDITATIONS
RxNorm is a public domain system developed by the NLM in conjunction with the VA and the FDA, and in consultation with HL7®.

ACQUISITION AND COST
RxNorm is distributed via UMLS® without restriction.

REVISION HISTORY

DATE	VERSION	COMMENT
2/13/2004	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.

Clinical Drug, a subdomain of Medications

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

A "clinical drug" is a name for a pharmaceutical preparation consisting of its component(s), defined as active ingredients and their strength, together with the dose form of the drug as given to the patient. For example, an amoxicillin 250 milligram oral tablet is a clinical drug. It expresses the equivalence of pharmaceutical preparations at a generic level, in the form in which medications are prescribed for the patient.

The purpose of this standard is to enable the federal health care sector to share information regarding medication active ingredients.

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.*

Medication active ingredients is itself a sub-domain of the Medications Domain. Please see the overarching domain analysis for more information.

Domain/Sub-domain	In-Scope (Y/N)
This template is included as part of the medications domain	

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

Customer Health Care Information
Care Management Information
Customer Risk Factors
Referral Information
Body of Health Services Knowledge
Tailored Education Materials
Beneficiary Tracking Information
Patient Satisfaction Information
Case Management Information

Cost Accounting Information
Population Member Health Data
Population Risk Reduction Plan
Provider Metrics
Improvement Strategy
Resource Availability
Beneficiary Inquiry Information
Clinical Guidelines
Customer Approved Care Plan

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

Name	Agency/Department
Steven Brown (Team lead)	VA
Randy Levin	FDA
Kathy Hollinger	FDA
Bill Hess	FDA
Stuart Nelson	NLM
Nancy Orvis	DoD
William Trick	CDC
Dan Budnitz	CDC
Carlene McIntyre	InHs

Work Period *Dates work began/ended.*

Start	End
Feburary 2003	June 2003

Part II – Standards Adoption Recommendation

Recommendation *Identify the solution recommended.*

The CHI Medications subgroup recommends the following standard for clinical drugs:

The CHI Medications subgroup has identified the Semantic Clinical Drug (SCD) of RxNorm, a portion of the UMLS® as the most promising candidate for a CHI standard for clinical drug nomenclature. Because RxNorm is still under development, it is recommended on a provisional basis.***(Update April 04: Provision lifted as RxNorm is now available via the UMLS®)***

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

The National Library of Medicine has primary responsibility for the RxNorm terminology. As steward, NLM works in close collaboration with other governmental agencies (e.g. the VA, and the FDA, with the private sector (e.g. First Databank, Micromedex, Multum, Medispan) and other Nations (e.g. Britain, and Australia).

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

RxNorm is a public domain system developed by the NLM in conjunction with the VA and the FDA, and supported by the AHRQ and in consultation with HL7®. The current lack of interoperability among the terminologies used in the proprietary pharmaceutical knowledge bases was the primary motivation for RxNorm's development. A user wishing to use one pharmaceutical knowledge base system for pricing and inventory control, for example, and a different system for interaction checking finds it difficult to merge the two systems into a larger environment. This issue was discussed at HL7® meetings for several years, with representatives from each of the pharmaceutical knowledge base providers as active participants. It became apparent that interoperability at the clinical drug level might be an achievable goal, if a standard clinical drug nomenclature were developed and the terminologies in the various proprietary systems were mapped to it. The NLM initiated the development of the public domain RxNorm vocabulary to achieve this goal – and simultaneously to eliminate the problem of undetected synonymy among proprietary clinical drug names within the UMLS® Metathesaurus®. The RxNorm has a robust information model that also supports ordering of medications. The VA, the FDA, the NCI, and the DOD are building use of RxNorm into their system development plans. The NLM continues to add new clinical drugs and links to additional drug terminologies and to refine the model in response to feedback. The last released version had 19,048 clinical drugs, a sufficient quantity to support initial use, and links to terminology in the VA National Drug File, and other terminologies from commercial vendors. However,

RxNorm is still in development and does not have a significant installed user base (***Update April 04: RxNorm no longer a production version***)

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

Because RxNorm is still under development, it is recommended on a provisional basis. ***(Update April 04: Provision lifted as RxNorm is now available via the UMLS®)***

Approvals & Accrediations

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).*

Options
1. The Semantic Clinical Drug (SCD) of RxNorm, as distributed in the Unified Medical Language System 2. Core clinical drug portions of SNOMED CT® 3. NNDF plus produced by First Databank 4. The MediSource Lexicon produced by Multum Informmation Services 5. DRUGDEX produced by Micromedex *6.* Master Drug DataBase produced by Facts and Comparisons

Option Analysis

Option Analysis

NDDF, Multum, MicroMedix, and MediSpan are proprietary products of different pharmaceutical knowledge base providers. All of these products support a range of functions, and they all contain vocabulary and/or codes for multiple levels of drug information – including clinical drugs. These embedded vocabularies/codes vary considerably in completeness, currency, and the robustness of their underlying information models. They were all eliminated from consideration because (1) they are proprietary systems and (2) the current versions of their clinical drug vocabularies are not available except as part of a larger knowledge base product.

RxNorm is a public domain system developed by the NLM in conjunction with the VA and the FDA, and in consultation with HL7®. The current lack of interoperability among the terminologies used in the proprietary pharmaceutical knowledge bases was the primary motivation for RxNorm's development. A user wishing to use one pharmaceutical knowledge base system for pricing and inventory control, for example, and a different system for interaction checking finds it difficult to merge the two systems into a larger environment. This issue was discussed at HL7® meetings for several years, with representatives from each of the pharmaceutical knowledge base providers as active participants. It became apparent that interoperability at the clinical drug level might be an achievable goal, if a standard clinical drug nomenclature were developed and the terminologies in the various proprietary systems were mapped to it. The NLM initiated the development of the public domain RxNorm vocabulary to achieve this goal – and simultaneously to eliminate the problem of undetected synonymy among proprietary clinical drug names within the UMLS® Metathesaurus®. The RxNorm has a robust information model that also supports ordering of medications. The VA, the FDA, the NCI, and the DOD are building use of RxNorm into their system development plans. The NLM continues to add new clinical drugs and links to additional drug terminologies and to refine the model in response to feedback. The last released version had 19,048 clinical drugs, a sufficient quantity to support initial use, and links to terminology in the VA National Drug File.

The recently developed clinical drug vocabulary in SNOMED CT® is based on a model developed by the U.K. National Health Service that is remarkably similar to the model used in RxNorm. The clinical drug information in SNOMED CT® will not be available to U.S. users under the NLM license. Given comparable coverage and use characteristics, RxNorm would be the preferred choice since its free international availability would be beneficial to FDA and other U.S. government agencies with international missions.

Current Deployment

RxNorm is distributed via UMLS® without restriction. A listing of current users is not

kept. At the current time the medications subgroups best guess is that there are a small number of users beginning to explore the use of RxNorm. For example, RxNorm was used in the HIMMS interoperability demo in 2003.

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

RxNorm is distributed via UMLS® without restriction. A listing of current users is not kept

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

RxNorm is distributed via UMLS® without restriction. A listing of current users is not kept

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

RxNorm is distributed via UMLS® without restriction. A listing of current users is not kept

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

RxNorm is distributed via UMLS® without restriction. A listing of current users is not kept

Is the standard used in other countries?

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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.

FDA ESTABLISHED

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)						
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.

The last released version had 19,048 clinical drugs

How often are terms updated?

Quarterly releases

Range of Coverage

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

No vocabulary can be complete. Drug vocabulary, in particular, is constantly changing, with new ingredients, new dosage forms, and new strengths. RxNorm contains all the clinical drugs contained in the other vocabularies, and is establishing an update model. With the understanding as stated, it is ready for implementation in its coverage of prescription drugs. It remains incomplete for multi-ingredient OTC preparations (e.g., multivitamins) and contrast media.

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

Free distribution via NLM

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.)

Free distribution via NLM

Systems Requirements

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

none

Guidance:

Maintenance:

Quarterly updates via NLM - Planning is underway for a more rapid distribution of additions as the FDA approves them.

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.
Little to none, mappings to VANDF, FDB, Micromedex, Medispan, and Multum are freely available from NLM

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

N/A

Compatibility

Identify the extent of off-the-shelf comformity 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?

There is sufficient RxNorm data currently available in the UMLS® to support deployment. It is beyond our capability to predict how rapidly any user could implement it.

A full update model should be available within the next 6 months. The method of covering OTC and contrast materials will be completed within that time frame as well.

Gaps

Identify the gaps in data, vocabulary or interoperability.
As mentioned above, complete data on multi-ingredient OTC drugs and contrast media is lacking.

Obstacles

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

None