



May 24, 2011

HIT Standards Committee Vocabulary Task Force
Jamie Ferguson, Chair
Betsey Humphreys, Co-Chair
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201
Email: jamie.ferguson@kp.org; humphreb@mail.nlm.nih.gov

National Committee on Vital and Health Statistics
Justine M. Carr, M.D., Chair
Chief Medical Officer
Steward Health Care
500 Boylston Street, # 569
Boston, MA 02116
Phone: 617-419-4703
Email: justine.carr@caritaschristi.org

RE: Interoperable Medication Allergy Vocabulary Recommendations

Dear Distinguished Colleagues:

The National Council for Prescription Drug Programs (NCPDP) is committed to furthering the electronic exchange of information between healthcare stakeholders. NCPDP Telecommunication Standard is the standard used for eligibility, claims processing, reporting, and other functions in the pharmacy services industry. The NCPDP SCRIPT Standard and the Formulary and Benefit Standard are the standards in use in electronic prescribing. In November of 2010, NCPDP Work Group 10 Professional Pharmacy Services established the Allergy Value Set Task Group to review the vocabulary issues surrounding the capture, documentation and reporting of medication allergies with the goal to provide a core value set upon which to build and validate cross-references.

Background

The terminology currently supporting electronic healthcare record documentation of active patient medication allergy and drug sensitivities is dominated by the use of proprietary code sets. Although many applications have adopted the use of smaller terminology subsets to optimize the effectiveness of end-user selection of patient allergies, other applications commonly use broader orderable dictionary based collections of branded and generically named clinical drug concepts.

While the use of proprietary allergy and drug sensitivity value sets deliver documentation efficiencies to the Electronic Health Record (EHR), interoperable exchange barriers are introduced when allergy and drug sensitivity information is shared between disparate systems. As a result, codified allergy and drug sensitivity information is commonly exchanged as free-text or converted to interoperable code sets in which the original meaning of the documented allergy is lost.

The Health Information Technology Standards Panel (HITSP) provided preliminary terminology recommendations for allergy and drug sensitivity concepts.¹ The Veterans Health Administration National Drug File Reference Terminology (NDF-RT) Mechanism of Action, Physiologic Effect and Structural Class was named by NCVHS to be part of the collection of terminologies designated as Federal Medication Terminology (FMT). HITSP subsequently specified the use of this NDF-RT subset in expressing “medication class” values within the context of the “Allergy/Adverse Event Product.” Similarly, HITSP named RxNorm for medication brand name and medication clinical drug names; and named FDA Unique Ingredient Identifiers (UNII) for food and substance allergies.² More recently, the Office of the National Coordinator for Health Information Technology (ONC) named FDA UNII amongst “Candidate standards(s) to support meaningful use stage 2” in the context of a medication allergy list.³

Despite the recommendations of NCVHS and HITSP, named vocabularies have yet to be endorsed by ONC. The presence of overlapping content between all three sources is confusing to prospective implementers. For example, “amoxicillin,” a very common allergen, spans four different codes within the named vocabularies.

Term	Code	Terminology	RxNorm RXCUI
Amoxicillin	804826J2HU	FDA UNII	723
Amoxicillin	723	RXNORM	723
Amoxicillin	N0000005840	NDF-RT [Chemical/Ingredient]	723
AMOXICILLIN	N0000145985	NDF-RT [Preparations]	723

Lack of consensus regarding best practices for the use of FMT in the interoperable expression of patient medication allergies and drug sensitivities has caused problems for smooth adoption. The NCPDP Allergy Value Set Task Group was formed to provide pragmatic recommendations toward the current use of FMT in the context of interoperable medications. Task Group participation is comprised of representatives spanning provider, EHR vendor, medication knowledge base vendor, medical informatics consultant firms, Federal entities and professional society organizations. Seven health care provider organizations provided lists of the most frequently used allergy class concepts documented within patient allergy histories⁴. Upon review of available FMT sources and given the group’s intimate knowledge of medication allergy concepts typically documented within patient histories, the Task Group was able to reach agreement on a set of consensus based recommendations.

NCPDP is offering the following recommendations as an initial step to enable the interoperable exchange of patient medication based allergy and drug sensitivity information.

¹ HITSP C80 Clinical Document and Message Terminology Component v 2.0, Section 2.2.3.3.9 “Medication Drug Class” and Section 2.2.3.1.1 “Problem”

² HITSP C83 CDA Content Modules v 2.0, 2.2.2.6.3 “Product Coded Vocabulary Constraints”

³ 45 CFR Part 170 Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Table 2A – Adopted Content Exchange and Vocabulary Standards

⁴ Indiana University Health, Mayo Clinic, Partners HealthCare, St. Luke Episcopal Health System, Stanford, Tufts, UMass Memorial Health Care

Recommendations

An idealized interoperable allergy value set would span the same terminology code base and would include concepts selected to support the context of documenting patient allergies and drug sensitivities. Applicable allergy class concepts, ingredients, brands and clinical drugs would be published within a single source vocabulary. Within the same source vocabulary, relationships between allergy class concepts and member ingredients would be stated, as would the relationship between clinical drugs and compositional ingredients.

Within the allergy value set, substance allergens that span environmental, foods and medication inactive ingredients (i.e., excipients) would be included, with classification attributes assigned to enable application designation of allergen “type” (e.g., medication, food, environmental agent, inactive ingredient).

The idealized interoperable allergy value set would be continuously updated, compiled and published in the public domain with companion cross-references to conceptually equivalent terms distributed by alternative vocabulary sources.

Of available FMT sources, the National Library of Medicine’s (NLM) RxNorm source vocabulary concepts and cross-referenced vocabulary terms best meet the characteristics of the idealized allergy value set. That said, current editorial policy restricts the composition of RxNorm source vocabulary concepts to those that span therapeutically active medication ingredients. Despite this limitation, RxNorm provides a robust data source for expression of the vast majority of medication concepts likely to be documented in the context of a patient allergy.

The Task Group provides the following specific recommendations toward the adoption of medication-based allergy and drug sensitivity vocabularies within clinical information exchanges:

- When practical, the interoperable concept type selected to express a patient allergy or drug sensitivity should be analogous to the concept type native to the source system. For example, if a clinical drug concept type is used in the source system, a clinical drug concept should be used to express the interoperable allergy or drug sensitivity. This principle enables the specificity of the concept to be maintained within interoperable exchange applications.
- The term (i.e., original text) native to the allergy or drug sensitivity selected by the health care provider within the source system should always accompany the interoperable code within interoperable exchanges so that the proper context of the patient allergy or drug sensitivity may be expressed to the recipient.
- Virtually any RxNorm terminology type with compositional associations to a therapeutically active ingredient can be used to express a patient medication allergy. For example, a patient allergy could be expressed as “amoxicillin,” “AMOXIL,” “amoxicillin oral capsules,” “amoxicillin 250 mg oral capsules,” or “Penicillins.”
- The RxNorm Unique Identifier (RXCU) is the preferred interoperable code for use in the expression of the allergy or drug sensitivity. Use of RXCU enables the recipient of an interoperable allergy or drug sensitivity the ability to go to a single RxNorm data repository to meet translation or cross-reference needs. In contrast, use of the NDF-RT code or FDA UNII code adds complexity to supportive translation service applications.
- Use of FDA UNII concepts should be limited to those integrated within RxNorm with assignment of a RXCU value. We would prefer that UNII concepts likely to be associated to patient environmental, food, or inactive ingredient allergens be compiled within a subset and integrated within RxNorm as a dependency for use.

- Allergen and drug sensitivity concepts not found within RxNorm and NDF-RT sources should be expressed in interoperable exchanges using free-text. Along with free text, systems may include an interoperable code reference to SNOMED Clinical Terms (SNOMED-CT), FDA UNII or a proprietary code set as appropriate.
- In the context of providing implementers guidance toward the integration of a targeted set of common medication allergy classes, the Task Group has provided a starter set in *Appendix A*. Implementers may augment the starter set with class concepts available in RxNorm assigned the source vocabulary of “NDFRT” and attribute name values “NDFRT_KIND” that span attribute values of “INGREDIENT_KIND,” “MECHANISM_OF_ACTION_KIND,” or “PHYSIOLOGIC_EFFECT_KIND.” This approach provides a subset of medication allergy classes that are consistent with previous NCVHS and HITSP recommendations. Note that in some cases, the NDF-RT based description may not be recognizable to the average clinician in the context of allergy (e.g., “sulfanilamides,” “Triiodobenzoic Acids”). In these situations, the NDF-RT class spans collections of ingredients that typically are grouped under a more recognizable proprietary allergy class name (e.g., “sulfonamide antibiotic,” “iodinated contrast media”).
- In the context of reporting the “reaction” which is commonly documented in concert with the reported allergy or drug sensitivity, the Task Group endorses the “Problem” constraint provided by HITSP within the C80 – Clinical Document and Message Terminology Component, Version 2.0. In the C80, SNOMED-CT terms, “descending from the Clinical Findings (404684003) or Situation with Explicit Context (243796009) hierarchies” define the Problem Value Set. Anecdotally, we observe that a relatively small number of reaction terms are commonly used. Similar to the starter set offered for allergy class, we believe a relatively small number of SNOMED-CT concepts could be named as a subset to encourage adoption amongst implementing entities. The Task Group may be able to provide a starter subset of reaction terms at a future date, if it would be valued by the Vocabulary Task Force.

To satisfy longer term idealized allergy value set functional requirements, the Task Group has the following recommendations:

- Establish a sustainable governance process to guide the ongoing interagency maintenance and publication of Federal Medication Terminology vocabularies and context-sensitive subsets to ensure that functional medication and allergy interoperability use cases are satisfied.
- The Veterans Health Administration author and publish a subset of NDF-RT class concepts to satisfy the context of medication allergy and drug sensitivity class-based interoperable exchange.
- NDF-RT allergy class subset members be integrated within RxNorm and assigned an appropriate RxNorm source vocabulary terminology type to enable the programmatic selection by implementing systems.
- The Food and Drug Administration author and publish subsets of UNII values likely to be relevant in the documentation of food, inactive ingredient and environmental allergens; such UNII values would be integrated within RxNorm and given subset attributes to enable the programmatic selection by implementing systems.

By leveraging industry RxNorm-based interoperability work already invested, NCPDP believes the adoption of these recommendations provides the practical means to achieve interoperability in the domain of allergy and drug sensitivities.

NCPDP Medication Allergy and Drug Sensitivity Interoperability Recommendations

Thank you for the opportunity to submit these recommendations. NCPDP remains available to provide further clarification or assistance regarding allergy vocabulary recommendations as needed.

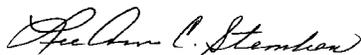
NCPDP is a not-for-profit ANSI-accredited Standards Development Organization consisting of more than 1,600 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the health care industry.

For direct inquiries or questions related to this letter, please contact

Sue Ann Thompson
Standards Advisor, NCPDP
Direct:
HC 88 Box 38
Ripley, WV 25271
(304) 372-5178
sthompson@ncdpd.org

NCPDP WG10 Allergy Value Set Task Group Leader
George Robinson, RPh
Clinical Director, Medi-Span
P: (317) 705-7649
E: george.a.robinson@wolterskluwer.com

Sincerely,



/s/

Lee Ann C. Stember
President
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
~~Scottsdale, AZ 85260~~
(480) 477-1000 x 108
lstember@ncdpd.org

cc: NCPDP Board of Trustees

Attachement A: Interoperable Medication Allergy Class “Starter Set”

RXCUI	Primary Code	Primary Code Type	Primary Code Desc	Comment
7986	N0000011281	NDF-RT Chemical/Ingredient	Penicillins	
10185	N0000008034	NDF-RT Chemical/Ingredient	Sulfanilamides	Narrower definition to Sulfonamide Antibiotics & Furosemide
10215	N0000008048	NDF-RT Chemical/Ingredient	Sulfonamides	Broader "sulfa drug" definition
10813	N0000007599	NDF-RT Chemical/Ingredient	Triiodobenzoic Acids	Spans ioninated contrast media agents
586370	N0000007529	NDF-RT Chemical/Ingredient	Macrolides	
2235	N0000011161	NDF-RT Chemical/Ingredient	Cephalosporins	
991139	N0000175721	NDF-RT Chemical/Ingredient	Nonsteroidal Anti-inflammatory Compounds	
992731	N0000000181	NDF-RT MoA	Angiotensin-Converting Enzyme Inhibitors	
10397	N0000007948	NDF-RT Chemical/Ingredient	Tetracyclines	
5224	N0000006341	NDF-RT Chemical/Ingredient	Heparin	Includes low molecular weight heparins
993150	N0000000121	NDF-RT MoA	Hydroxymethylglutaryl-CoA Reductase Inhibitors	"Statins"
91607	N0000005564	NDF-RT Chemical/Ingredient	Tetanus Toxoid	
993131	N0000000161	NDF-RT MoA	Adrenergic beta-Antagonists	
8146	N0000007544	NDF-RT Chemical/Ingredient	Phenothiazines	
9080	N0000007606	NDF-RT Chemical/Ingredient	Quinolones	
1384	N0000007524	NDF-RT Chemical/Ingredient	Benzodiazepines	
67002	N0000007802	NDF-RT Chemical/Ingredient	Iodine Compounds	
25485	N0000006865	NDF-RT Chemical/Ingredient	Gadolinium DTPA	Spans Gadolinium contrast media agents
9526	N0000007582	NDF-RT Chemical/Ingredient	Salicylic Acids	
985466	N0000000174	NDF-RT MoA	Opioid Agonists	Morphine related
1326	N0000008016	NDF-RT Chemical/Ingredient	Barbiturates	
141801	N0000166469	NDF-RT Chemical/Ingredient	Thiazides	

NCPDP Medication Allergy and Drug Sensitivity Interoperability Recommendations

RXCUI	Primary Code	Primary Code Type	Primary Code Desc	Comment
992696	N0000000151	NDF-RT MoA	Histamine H2 Antagonists	
382320	N0000011402	NDF-RT Chemical/Ingredient	Estradiol Congeners	
678	N0000007853	NDF-RT Chemical/Ingredient	Aminoglycosides	
11357	N0000008118	NDF-RT Chemical/Ingredient	XANTHINES	
5806	N0000170909	NDF-RT Chemical/Ingredient	Influenza Vaccines	
986242	N0000000069	NDF-RT MoA	Calcium Channel Antagonists	
2545	N0000008058	NDF-RT Chemical/Ingredient	Cinchona Alkaloids	Spans quinidine and quinine
4975	N0000005996	NDF-RT Chemical/Ingredient	Gold	
986356	N0000000147	NDF-RT MoA	Proton Pump Inhibitors	
5469	N0000007970	NDF-RT MoA	Hydantoins	
993136	N0000008288	NDF-RT MoA	COX-2 Inhibitors	
3508	N0000007707	NDF-RT Chemical/Ingredient	Diphosphonates	Span biphosponate agents
1027734	N0000000090	NDF-RT MoA	Serotonin 5HT-3 Antagonists	