Ontology Summit 2013 Symposium NIST, Gaithersburg, Maryland, USA May 3, 2013 Ontology Evaluation Across the Ontology Lifecycle

Quality assurance of biomedical ontologies (and derived artifacts) in the era of Meaningful Use



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OUTLINE

- Meaningful Use
- Standard vocabularies in Meaningful Use
- Value sets for clinical quality measures
- Quality assurance of biomedical terminologies
- Quality assurance of value sets



MEANINGFUL USE



"Meaningful Use"

- Health Information Technology for Economic and Clinical Health (HITECH) Act
 - Eligible health care professionals and hospitals can qualify for Medicare and Medicaid incentive payments when they adopt certified EHR technology and use it to achieve specified objectives
- Two sets of regulations



- Incentive Program for Electronic Health Records Medicare and Medicaid Services (CMS)
- Standards and Certification Criteria for Electronic Health Records
 Office of the National Coordinator (ONC)



Meaningful Use stages

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	Stage 1 2011-2012 Data capture and sharing	Stage 2 2014 Advance clinical processes	Stage 3 2016 Improved outcomes	
Stage 1: Meaningful use criteria focus on:		Stage 2: Meaningful use criteria focus on:	Stage 3: Meaningful use criteria focus on:	
Electronically capturing health information in a standardized format		More rigorous health information exchange (HIE)	Improving quality, safety, and efficiency, leading to improved health outcomes	
Using that information to track key clinical conditions		Increased requirements for e-prescribing and incorporating lab results	Decision support for national high-priority conditions	
Communicating that information for care coordination processes		Electronic transmission of patient care summaries across multiple settings	Patient access to self-management tools	
Ini cli pu	tiating the reporting of nical quality measures and ıblic health information	More patient-controlled data	Access to comprehensive patient data through patient- centered HIE	
Us pa th	sing information to engage atients and their families in eir care		Improving population health	



Fact Sheets

Details for: CMS MEDICARE AND MEDICAID EHR INCENTIVE PROGRAMS: STAGE 2 FINAL RULE

Return to List

For Immediate Release:

Contact:

Thursday, August 23, 2012 CMS Office of Public Affairs 202-690-6145

CMS MEDICARE AND MEDICAID EHR INCENTIVE PROGRAMS: STAGE 2 FINAL RULE

On August 23, 2012, the Centers for Medicare & Medicaid Services (CMS) announced a final rule to govern Stage 2 of the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs. The rule specifies the Stage 2 criteria that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet in order to continue to participate in the EHR Incentive Programs.

Rule Provisions

Through the Stage 2 requirements of the Medicare and Medicaid EHR Incentive Programs, CMS seeks to expand the meaningful use of certified EHR technology. Certified EHR technology used in a meaningful way is one piece of a broader health information technology infrastructure needed to reform the health care system and improve health care quality, efficiency, and patient safety. Highlights of the rule's provisions follow.

Stage 2 Timing



In the Stage 1 meaningful use regulations, CMS established an original timeline that would have required Medicare providers who first demonstrated meaningful use in 2011 to meet the Stage 2 criteria in 2013. The Stage 2 rule gives providers more time to meet Stage 2 criteria. A provider that attested to Stage 1 of meaningful use in 2011 would attest to Stage 2 in 2014, instead of in 2013. Therefore, providers are not required to meet Stage 2 meaningful use before 2014. The table below illustrates the progression of meaningful use stages from the first year a Medicare provider begins participation in the program.

Clinical Quality Measures (CQMs)

Measure Sets and Reporting

The rule finalized that:

- · EPs must report on 9 out of 64 total clinical quality measures (CQMs)
- · Eligible hospitals and CAHs must report on 16 out of 29 total CQMs

In addition, all providers must select CQMs from at least 3 of the 6 key health care policy domains from the Department of Health and Human Services' National Quality Strategy:

- · Patient and Family Engagement
- Patient Safety
- Care Coordination
- · Population and Public Health
- Efficient Use of Healthcare Resources
- Clinical Processes/Effectiveness





ONC Fact Sheet: 2014 Edition Standards & Certification Criteria (S&CC) Final Rule

Summary

The 2014 Edition S&CC final rule completes the Office of the National Coordinator for Health IT's (ONC) second full rulemaking cycle to adopt standards, implementation specifications, and certification criteria for EHR technology. This final rule complements the newly released Centers for Medicare & Medicaid Services (CMS) final rule which establishes Stage 2 of the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, updates Stage 1, and includes other program modifications.

The 2014 Edition S&CC final rule reflects ONC's commitment to reduce regulatory burden; promote patient safety and patient engagement; enhance EHR technology's interoperability, electronic health information exchange capacity, public health reporting, and security; enable clinical quality measure data capture, calculation, and electronic submission to CMS or States; and introduce greater transparency and efficiency to the certification process.





NLM'S LONG RANGE PLAN 2006-16

Goal 3. Integrated Biomedical, Clinical, and Public Health Information Systems that Promote Scientific Discovery and Speed the Translation of Research into Practice

Continue/enhance standards work in response to U.S. government priorities and feedback from "real" use in electronic health records

- e.g., Unified Medical Language System (UMLS), key clinical terminologies (SNOMED CT, LOINC, RxNorm)



STANDARD VOCABULARIES

(Biomedical terminologies and ontologies)



London Bills of Mortality







Many biomedical terminologies

- Diagnoses / Diseases / Conditions
 - International classification of diseases (ICD)
 - SNOMED CT
- Procedures
 - Current Procedural terminology (CPT)
 - ICD10-PCS
 - SNOMED CT
- Drugs
 - RxNorm
- Laboratory tests
 - LOINC



Standard vocabularies for Meaningful Use

- Diagnoses / Diseases / Conditions
 - International classification of diseases (ICD)
 - SNOMED CT
- Procedures
 - Current Procedural terminology (CPT)
 - ICD10-PCS
 - SNOMED CT
- Drugs
 - RxNorm
- Laboratory tests
 - ► LOINC



SNOMED Clinical Terms



SNOMED CT Characteristics (1)

- Current version: January 31, 2013 (2 annual releases)
- Type: Reference terminology / ontology
- Domain: Clinical medicine
- Developer: IHTSDO
- Funding: IHTSDO
- Availability
 - Publicly available: Yes* (in member countries)
 - Repositories: UMLS
- URL: <u>http://www.ihtsdo.org/</u>



SNOMED CT Characteristics (2)

Number of

- Concepts: ~300,000 active concepts (Jan. 31, 2013)
- Terms: ~1.1M active "descriptions"
- Major organizing principles:
 - Utility for clinical medicine (e.g., assertional + definitional knowledge)
 - Model of meaning (incomplete)
 - Rich set of associative relationships
 - Small proportion of defined concepts (many primitives)

◆ Formalism: Description logics (EL++)



SNOMED CT Top level

Hierarchy	Subtype hie	erarchy
Ė > 138	875005 5	6NOMED CT Concept
E 🖸 🖸 36	62981000	qualifier value
e <mark>c</mark> 10	6237007	linkage concept
E 🖸 37	/0115009	special concept
E C 48	3176007	social context
⊡ ⊡ 41	9891008	record artifact
e c 36	3787002	observable entity
e <mark>c</mark> 30)8916002	environment or geographical location
e <mark>c</mark> 12	23038009	specimen
ē <mark>c</mark> 25	54291000	staging and scales
ē c 12	23037004	body structure
ē <mark>c</mark> 27	2379006	event
ē c 78	3621006	physical force
ē <mark>c</mark> 40)4684003	clinical finding
ē c 28	80787004	physical object
Ē <mark>⊂</mark> 41	0607006	organism
ē <mark>c</mark> 71	388002	procedure
ē <mark>c</mark> 37	73873005	pharmaceutical / biologic product
ē c 24	13796009	situation with explicit context
😐 🖸 10)5590001	substance



SNOMED CT Example

	Definition: Fully defined by
Hierarchy Subtype hierarchy	bis a
 27010001 partial excision of large intestine operation on appendix 80146002 appendectomy 82730006 incidental appendectomy 49438003 appendectomy with drainage 174036004 emergency appendectomy 174045003 interval appendectomy 6025007 laparoscopic appendectomy 235313004 non-emergency appendectomy 235314005 inversion appendectomy 1299000 excision of appendiceal stump 	partial excision of large intestine operation on appendix Group method emethod fmethod fmethod<
appendectomy - Definition Concept Status: Current Descriptions - appendectomy (procedure) - appendectomy - sexcision of appendix - appendicectomy	Codes Codes Criginal SnomedId : P1-57450 Read Code (Ctv3Id) : X20Wz



RxNorm

RxNorm Characteristics (1)

 Current version: April 1, 2012 (monthly releases) Type: Controlled terminology Domain: Drug names Developer: NLM Funding: NLM ♦ Availability • Publicly available: Yes* • Repositories: UMLS

URL: <u>http://www.nlm.nih.gov/research/umls/rxnorm/</u>



RxNorm Characteristics (2)

Number of

- Concepts: 213,500 drug entities (April 2013)
- Terms: ~1.3 term per concept
- Major organizing principles:
 - Generic vs. brand
 - Combinations of Ingredient / Form / Dose
 - No hierarchical structure
 - Links to all major US drug information sources
 - No clinical information
- Formalism: UMLS RRF format



RxNorm Normalized form





Rx Norm Generic vs. Brand

♦ Generic	♦ Brand		
 Ingredient ←	Brand name (BN)		
 Clinical drug form < (SCDF) 	Branded drug form (SBDF)		
 Clinical drug component (SCDC) 	Branded drug component (SBDC)		
 Clinical drug (SCD) 	Branded drug (SBD)		
tradename_	_of		

NLM

RxNorm Relations among drug entities



Logical Observation Identifiers, Names and Codes (LOINC)



LOINC Characteristics (1)

◆ Current version: 2.42 (Dec. 2012) Type: Controlled terminology* Domain: Laboratory and clinical observations Developer: Regenstrief Institute Funding: NLM ♦ Availability • Publicly available: Yes • Repositories: UMLS URL: www.regenstrief.org/loinc/loinc.htm



LOINC Characteristics (2)

Number of

- Concepts: ~70k active codes (2.42) (2 annual releases)
- Terms: n/a*

Major organizing principles:

• No hierarchical structure among the main codes

• 6 axes

- Component (analyte [+ challenge] [+ adjustments])
- Property
- Timing
- System
- Scale
- [Method]

Formalism: "DL-like"



LOINC Example

Sodium:SCnc:-Pt:Ser/Plas:Qn
 [the molar concentration of sodium is measured in the plasma (or serum), with quantitative result]

Axis	Value
Component	Sodium
Property	SCnc – Substance Concen-tration (per volume)
Timing	Pt – Point in time (Random)
System	Ser/Plas – Serum or Plasma
Scale	Qn – Quantitative
Method	



QUALITY ASSURANCE OF STANDARD VOCABULARIES



Analytical framework for QA research

Special issue of JBI on "Auditing terminologies"
Zhu et al. JBI 2009 review article
Analytical framework

What is analyzed
Which source of knowledge
Which method

Zhu, X., J.W. Fan, D.M. Baorto, C. Weng, and J.J. Cimino, A review of auditing methods applied to the content of controlled biomedical terminologies. J Biomed Inform, 2009. 42(3): p. 413-25.



What is analyzed

Term/concept

- Coverage (missing terms/concepts)
- Wrong synonymy relation
- Redundant concepts
- Relation
 - Missing relations
 - Inaccurate relations
- Categorization
 - Wrong categorization



Which source of knowledge

◆ Intrinsic – the terminology itself

- Terms/Concepts
- Relations
- Categorization
- Extrinsic external resources
 - Corpus
 - Text corpus identify terms in text
 - Annotation corpus identify relations from co-occurring terms
 - Mapping



- Properties of the term
- Structural
 - Properties of the organizational structure (relations)
- ♦ Semantic
 - Semantic properties of the concept (semantic type)
- Statistical
 - Associations among entities





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 Compliance with ontological principles

- Operational definitions
- Comparative
 - Comparisons between ontologies (mapping)
- Transformative
 - Representation formalism
- ◆ Use in an application

"Each concept, except for the root, must have (at least) one parent concept"



 Compliance with ontological principles • Operational definitions ♦ Comparative • Comparisons between ontologies (mapping) ♦ Transformative • Representation formalism ◆ Use in an application









- Compliance with ontological principles
 - Operational definitions
- Comparative
 - Comparisons between ontologies (mapping)
- Transformative
 - Representation formalism
- ◆ Use in an application







Identifying errors in SNOMED CT

Rector AL, Brandt S, Schneider T, *Getting the foot* out of the pelvis: modeling problems affecting use of SNOMED CT hierarchies in practical applications. J Am Med Inform Assoc, 2011. 18(4): p. 432-440.

Alan Rector's motivation

- Knowledge source for clinical applications (industrial collaboration)
 - Retrieval of clinical records for a given diagnosis
 - Decision support
 - Eligibility for clinical trials
- Development of ICD 11 (WHO Health Information Modelling TAG)
 - Ontological component for ICD 11
 - ICD hierarchies derived from SNOMED CT

Investigation methods

- Technology-assisted review by domain experts
 - With focus on the CORE problem list (clinical relevance)
- Methods
 - Leveraging description logics (stated version converted to OWL, module extraction, OWL classifiers, scripting against OWL API)
 - Lexically suggest-logically refine (association between words from labels and roles)
 - Navigation (up and down the hierarchies for missing/extraneous ancestors/descendants)

Findings – Qualitative (1)

- Errors of omission
 - Primitive concepts
 - Ischemic heart disease: due to ischemia, but not defined
 - Missing axioms
 - Morphology
 - acute endocarditis (disorder): <u>not</u> *clinical course* = acute; *morphology*: acute inflammation
 - Other
 - Myocardial infarction: <u>not</u> *due to* ischemia

Findings – Qualitative (2)

- Errors of commission
 - Wrong
 - Diabetes mellitus *isa* Disease of the exocrine pancreas (true of type I, not type II)
 - Subdural hemorrhage: finding site Subdural space structure (intracranial is implied by usage, but not formally represented)
 - Wrong (but <u>only indirectly</u>)
 - Hypertension *isa* disorder of soft issue
 - Hypertension: finding site Systemic arterial structure (→ soft tissue) (not clinically thought of as a disorder of soft tissues)
 - Neoplasm of cranial nerve: *isa* Neoplasm of cranial nerve: *isa* Neuropathy (neuropathy denotes <u>functional</u> disorder of nerve)
 - Anatomy (branches inherit from root)
 - Structure of right popliteal artery isa [...] isa Structure of pelvic region ("getting the knee out of the pelvis")

Consequences

Incorrect inferences

- By omission
 - Search on Ischemic heart disease fails to retrieve Myocardial infarction
- By commission
 - Search on Disorder of pancreas retrieves all cases of diabetes mellitus, including type II
- Missing equivalences from post-coordination
 - acute endocarditis (disorder):
 - Pre-coord: *morphology*: acute inflammation
 - Post-coord: *clinical course* = acute; *morphology*: inflammation

Identifying errors in RxNorm

Bodenreider, O. and L.B. Peters, *A graph-based* approach to auditing *RxNorm. Journal of Biomedical Informatics, 2009.* **42(3): p. 558–570.**

Motivation

Large terminology
Relies heavily on human editors
High quality

Systematic evaluation
Exploiting the graph structure





Methods

- Normalize multi-ingredient drugs
- Define "meaningful" paths between 2 nodes
- Instantiate all meaningful paths
- Compare alternate paths
 - Alternate (meaningful) paths are expected to be functionally equivalent





Results

348 inconsistencies identified (April 2008)
Reported to the RxNorm team
215 (62%) fixed (January 2009)



- missing link
 Sochlor → Sodium chloride
- Brand name without a direct relation with an ingredient





VALUE SETS IN CLINICAL QUALITY MEASURES



CLINICAL QUALITY MEASURES (CQMs)

Tools that help measure and track the quality of healthcare services provided by eligible professionals, eligible hospitals and critical access hospitals within our health care system

CQMs measure many aspects of patient care including: health outcomes, clinical processes, patient safety, efficient use of healthcare resources, care coordination, patient engagements, population and public health, and clinical guidelines

[cms.gov]



93 CLINICAL QUALITY MEASURES in 2014 Meaningful Use criteria





CLINICAL QUALITY MEASURE (example)

Hemoglobin A1c Test for Pediatric Patients



Normal glucose levels in blood Low HbA1c concentration High glucose levels in blood High HbA1c concentration



CLINICAL RECOMMENDATIONS

- 1. American Association of Clinical Endocrinologists (2002): Recommends that a glycosylated hemoglobin be performed during an initial assessment and during follow-up assessments, which should occur at no longer than three-month intervals.
- 2. American Diabetes Association (2006): Recommends obtaining a glycosylated hemoglobin during an initial assessment and then routinely as part of continuing care. In the absence of well-controlled studies that suggest a definite testing protocol, expert opinion recommends glycosylated hemoglobin be obtained at least twice a year in patients who are meeting treatment goals and who have stable glycemic control and more frequently (quarterly assessment) in patients whose therapy was changed or who are not meeting glycemic goals.



CLINICAL QUALITY MEASURE (simplified)

Hemoglobin A1c Test for Pediatric Patients

diabetic patients [age 5-17] tested for HbA1c

diabetic patients [age 5-17]



CLINICAL QUALITY MEASURE (details)

Hemoglobin A1c Test for Pediatric Patients

diabetic patients [age 5-17] tested for HbA1c

diabetic patients [age 5-17]

- Type 1 or Type 2 diabetes

- Excludes gestational diabetes

• Requires date of birth

Tests for HbA1c



CLINICAL QUALITY MEASURE (implementation)

Hemoglobin A1c Test for Pediatric Patients



ANATOMY OF A CLINICAL QUALITY MEASURE

Population criteria

- Initial Patient Population =
 - o AND: "Patient Characteristic Birthdate: birth date" >= 5 year(s) starts before start of "Measurement Period"
 - o AND: "Patient Characteristic Birthdate: birth date" <= 17 year(s) starts before start of "Measurement Period"
 - AND: "Diagnosis, Active: Diabetes" starts before or during (MOST RECENT : "Occurrence A of Encounter, Performed: Diabetes Visit" during "Measurement Period")
 - AND: "Encounter, Performed: Diabetes Visit" >= 12 month(s) starts before start of "Occurrence A of Encounter, Performed: Diabetes Visit"
- Denominator =
 - AND: "Initial Patient Population"
- Denominator Exclusions =
 - o AND NOT: "Occurrence A of Diagnosis, Active: Gestational Diabetes" ends before start of "Measurement Period"
 - o AND: "Occurrence A of Diagnosis, Active: Gestational Diabetes" starts before or during "Measurement Period"
- Numerator =

• AND: "Laboratory Test, Result: HbA1c Laboratory Test (result)" during "Measurement Period"

Denominator Exceptions =

None

Data criteria (QDM Data Elements)

- "Diagnosis, Active: Diabetes" using "Diabetes Grouping Value Set (2.16.840.1.113883.3.464.1003.103.12.1001)"
- "Diagnosis, Active: Gestational Diabetes" using "Gestational Diabetes Grouping Value Set (2.16.840.1.113883.3.464.1003.103.12.1010)"
- "Encounter, Performed: Diabetes Visit" using "Diabetes Visit Grouping Value Set (2.16.840.1.113883.3.464.1003.103.12.1012)"

"Patient Characteristic Birthdate: birth date" using "birth date LOINC Value Set (2.16.840.1.113883.355)





Associated Value Set

Metadata	Name:	OID:			
Contrast est concerne pre- 2	HbA1c Laboratory Test	2.16.840.1.113883.3.464.1003.198.12.1013			
Measure	Type:	Developer:			
	Grouping	National Committee for Quality Assurance			
Grouping	Note:				

Value Set Members Expansion 20121025 -

Expanded Code List					
🗅 View 📮 To	ggle 🔅 Clear 😽 Page 🚺 of 1 🔛	1 of 1 🖂 🖬 20 👻 View 1 - 3 of 3			
Code 🕈	Descriptor	Code System	Version		
17855-8	Hemoglobin A1c/Hemoglobin.total in Blood by calcul	lation LOINC	2.40		
17856-6	17856-6 Hemoglobin A1c/Hemoglobin.total in Blood by HPLC		2.40		
4548-4	Hemoglobin A1c/Hemoglobin.total in Blood	LOINC	2.40		



Meaningful Use Criteria - 2014



CURATING VALUE SETS

The NLM Value Set Authority Center



OBJECTIVES OF CURATION

- Ensure referential integrity
 - All codes in a VS are valid codes in the corresponding code system
 - Update VSs when the code systems are updated (no "stale" codes)
- Avoid duplication
 - Find value sets having similar members
- Ensure correctness and completeness
 - Compare intensional and extensional definitions



CODE VALIDATION USING TRIANGULATION





TYPES OF ERROR FOUND IN THE CODES

- Obsolete codes
 - Remap to the current code
- Typo / formatting issue in the code
 - Reformat
- Wrong code system listed
 - Fix code system
- Code/description mismatch
 - Small mismatch: Assign preferred term
 - Large mismatch: Send back to developers



IMPACT ON CLINICAL QUALITY MEASURES

Iterative Analysis

- 13 rounds over 4 months
- Reports provided to measure developers
- Orange codes fixed automatically by NLM
- Red codes fixed by measure developers (and rechecked)

- ~4000 errors
- Affecting 70% of the value sets
- And 100% of the measures
- All fixed by October 2012





Reverse-engineering of the intension





QUALITY METRICS FOR VALUE SETS



Completeness $Compl(VSori) = |VSori \cap VSRE| / |VSRE|.$

Correctness

Correct (VSori) = $|VSori \cap VSRE^*| / |VSori|$, where $VSRE^* \subseteq VSRE \setminus \{singleton nodes\}$.





Value Set Authority Center

NLM U.S. National Library of Medicine

Welcome back, rainerw

Sign Out | Contact Us

Welcome Search Value Sets Help						
Apply Filters Clear Filters Search the NLM Value Set Repository Query: Enter value set id, codes, words Search Narrow search results by selecting Search						Search
from pull-down menus below:	Search Results Value Set Details					
CMS eMeasure (NQF Number) CMS102v1 (0441) +						Export Search Results (Excel)
Quality Data Model Category	Ma 🕫	tched Value Sets Download 🗅 View	ia ka Pagi	e 1 of 2 🏎	▶1 20 ▼	View 1 - 20 of 21
Junear		Name	Туре	Code System	Developer	OID
Value Set Developer		birth date	Extensional	LOINC	NQF	2.16.840.1.113883.3.560.100.4
Select ÷ Meaningful Use Measures		Carotid Intervention	Grouping	ICD10PCS ICD9CM SNOMEDCT	Joint Commissio	2.16.840.1.113883.3.117.1.7.1.204
Select +		Discharge To Another Hospital	Extensional	SNOMEDCT	Joint Commission	2.16.840.1.113883.3.117.1.7.1.87
	Discharged to Health Care Facility for Hospice Care		Extensional	SNOMEDCT	Joint Commissio	2.16.840.1.113883.3.117.1.7.1.207
		Discharged to Home for Hospice Care	Extensional	SNOMEDCT	Joint Commission	2.16.840.1.113883.3.117.1.7.1.209
		Discharged to Rehabilitation Facility	Extensional	SNOMEDCT	Joint Commission	2.16.840.1.113883.3.117.1.7.1.132
Emergency Department Visit		Grouping	SNOMEDCT	Lantana	2.16.840.1.113883.3.117.1.7.1.293	
Ethnicity		Extensional	CDCREC	CDC NCHS	2.16.840.1.114222.4.11.837	
		Hemorrhagic Stroke	Grouping	ICD10CM ICD9CM SNOMEDCT	Joint Commissio	2.16.840.1.113883.3.117.1.7.1.212
Inpatient Encounter Extensional SNOM			SNOMEDCT	Joint Commission	2.16.840.1.113883.3.117.1.7.1.23	

https://vsac.nlm.nih.gov/



Medical Ontology Research

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