

Board of Scientific Counselors
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The Value Set Authority Center

Validating and delivering value sets for Meaningful Use Stage 2

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

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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.



Overview

- ▶ **Background**
 - ▶ Clinical quality measures
 - ▶ Value sets
- ▶ Value set curation
- ▶ Value set delivery





Background

Anatomy of a clinical quality measure

eMeasure Title	Thrombolytic Therapy
Measure Steward	Joint Commission
Measure Developer	Joint Commission
Endorsed By	National Quality Forum

Clinical Recommendation Statement

The administration of thrombolytic agents to carefully screened, eligible patients with acute ischemic stroke has been shown to be beneficial in several clinical trials. Intravenous recombinant tissue plasminogen activator (IV r-TPA or t-PA) should be used for the treatment of acute ischemic stroke when given within 3 hours of stroke symptom onset.



Anatomy of a clinical quality measure

Initial Patient Population	Patients admitted to the hospital for inpatient acute care with a Principal Diagnosis Code for ischemic or hemorrhagic stroke with hospital stays \leq 120 days during the measurement period for patients age 18 and older at the time of hospital admission.
Denominator	Acute ischemic stroke patients whose time of arrival is within 2 hours (less than or equal to 120 minutes) of time last known well.
Denominator Exclusions	Patients enrolled in clinical trials, or Patients admitted for Elective Carotid Intervention, or Patients with a documented Reason For Not Initiating IV Thrombolytic
Numerator	Acute ischemic stroke patients for whom IV thrombolytic therapy was initiated at this hospital within 3 hours (less than or equal to 180 minutes) of time last known well.



Anatomy of a clinical quality measure

Population criteria

- **Initial Patient Population =**
 - AND: "Patient Characteristic Birthdate: birth date" \geq 18 year(s) starts before start of "Encounter, Performed: Inpatient Encounter"
 - AND: "Encounter, Performed: Inpatient Encounter (length of stay \leq 120 day(s))"
 - AND: "Encounter, Performed: Inpatient Encounter (discharge datetime)" during "Measurement Period"
 - AND:
 - OR: "Diagnosis, Active: Ischemic Stroke (ordinality: 'Principal Diagnosis')"
 - OR: "Diagnosis, Active: Hemorrhagic Stroke (ordinality: 'Principal Diagnosis')"
 - starts during "Encounter, Performed: Inpatient Encounter"
- **Denominator =**
 - AND: "Initial Patient Population"
 - AND: "Diagnosis, Active: Ischemic Stroke (ordinality: 'Principal Diagnosis')" starts during "Encounter, Performed: Inpatient Encounter"
 - AND: "Encounter, Performed: Inpatient Encounter (admission datetime)" \leq 1 hour(s) starts after end of "Encounter, Performed: Emergency Department Visit"
 - AND:
 - OR: "Symptom, Active: Neurologic Symptoms of Stroke (start datetime)"
 - OR: "Symptom, Active: Baseline State (stop datetime)"
 - \leq 120 minute(s) starts before start of "Encounter, Performed: Emergency Department Visit (facility location arrival datetime)"
- **Denominator Exclusions =**
 - AND:
 - OR: "Encounter, Performed: Inpatient Encounter (reason: 'Carotid Intervention')"
 - OR: "Patient Characteristic Clinical Trial Participant: Clinical Trial Participant" during "Encounter, Performed: Inpatient Encounter"
 - OR: "Risk Category Assessment: National Institute of Health Stroke Scale (result = 0)" \leq 180 minute(s) starts after start of "Symptom, Active: Neurologic Symptoms of Stroke (start datetime)"
 - OR: "Medication, Administered: Thrombolytic (t-PA) Therapy" \leq 2 day(s) starts before start of "Encounter, Performed: Inpatient Encounter"
 - OR: "Risk Category Assessment: National Institute of Health Stroke Scale (result = 0)" \leq 180 minute(s) starts after start of "Symptom, Active: Baseline State (stop datetime)"
 - OR:
 - OR: "Medication, Order not done: Medical Reason" for "Thrombolytic (t-PA) Therapy RxNorm Value Set"
 - OR: "Medication, Order not done: Patient Refusal" for "Thrombolytic (t-PA) Therapy RxNorm Value Set"
 - OR: "Medication, Administered not done: Medical Reason" for "Thrombolytic (t-PA) Therapy RxNorm Value Set"
 - OR: "Medication, Administered not done: Patient Refusal" for "Thrombolytic (t-PA) Therapy RxNorm Value Set"
 - \leq 180 minute(s) starts after start of "Symptom, Active: Baseline State (stop datetime)"
 - OR:
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 - \leq 180 minute(s) starts after start of "Symptom, Active: Neurologic Symptoms of Stroke (start datetime)"
- **Numerator =**
 - AND:
 - OR: "Medication, Administered: Thrombolytic (t-PA) Therapy" \leq 180 minute(s) starts after start of "Symptom, Active: Baseline State (stop datetime)"
 - OR: "Medication, Administered: Thrombolytic (t-PA) Therapy" \leq 180 minute(s) starts after start of "Symptom, Active: Neurologic Symptoms of Stroke (start datetime)"
- **Denominator Exceptions =**
 - None



Anatomy of a clinical quality measure

Data criteria (QDM Data Elements)

- "Diagnosis, Active: Hemorrhagic Stroke" using "Hemorrhagic Stroke Grouping Value Set (2.16.840.1.113883.3.117.1.7.1.212)"
- "Diagnosis, Active: Ischemic Stroke" using "Ischemic Stroke Grouping Value Set (2.16.840.1.113883.3.117.1.7.1.247)"
- "Encounter, Performed: Emergency Department Visit" using "Emergency Department Visit Grouping Value Set (2.16.840.1.113883.3.117.1.7.1.293)"
- "Encounter, Performed: Inpatient Encounter" using "Inpatient Encounter SNOMED-CT Value Set (2.16.840.1.113883.3.117.1.7.1.23)"
- "Medication, Administered: Thrombolytic (t-PA) Therapy" using "Thrombolytic (t-PA) Therapy RxNorm Value Set (2.16.840.1.113883.3.117.1.7.1.226)"
- "Medication, Administered not done: Medical Reason" using "Medical Reason SNOMED-CT Value Set (2.16.840.1.113883.3.117.1.7.1.473)"
- "Medication, Administered not done: Patient Refusal" using "Patient Refusal SNOMED-CT Value Set (2.16.840.1.113883.3.117.1.7.1.93)"
- "Medication, Order: Thrombolytic (t-PA) Therapy" using "Thrombolytic (t-PA) Therapy RxNorm Value Set (2.16.840.1.113883.3.117.1.7.1.226)"
- "Medication, Order not done: Medical Reason" using "Medical Reason SNOMED-CT Value Set (2.16.840.1.113883.3.117.1.7.1.473)"
- "Medication, Order not done: Patient Refusal" using "Patient Refusal SNOMED-CT Value Set (2.16.840.1.113883.3.117.1.7.1.93)"
- "Patient Characteristic Birthdate: birth date" using "birth date LOINC Value Set (2.16.840.1.113883.3.560.100.4)"
- "Patient Characteristic Clinical Trial Participant: Clinical Trial Participant" using "Clinical Trial Participant SNOMED-CT Value Set (2.16.840.1.113883.3.526.2.643)"
- "Risk Category Assessment: National Institute of Health Stroke Scale" using "National Institute of Health Stroke Scale LOINC Value Set (2.16.840.1.113883.3.117.1.7.1.269)"
- "Symptom, Active: Baseline State" using "Baseline State SNOMED-CT Value Set (2.16.840.1.113883.3.117.1.7.1.417)"
- "Symptom, Active: Neurologic Symptoms of Stroke" using "Neurologic Symptoms of Stroke SNOMED-CT Value Set (2.16.840.1.113883.3.117.1.7.1.399)"
- Attribute: "Ordinality: Principal Diagnosis" using "Principal Diagnosis SNOMED-CT Value Set (2.16.840.1.113883.3.117.2.7.1.14)"
- Attribute: "Reason: Carotid Intervention" using "Carotid Intervention Grouping Value Set (2.16.840.1.113883.3.117.1.7.1.204)"



Associated value sets

2.16.840.1.113883.3.117.1.7.1.247 **Ischemic Stroke** Condition/Diagnosis/Problem

Ischemic Stroke Grouping VS	2.16.840.1.113883.3.117.1.7.1.250	Ischemic Stroke ICD-9 value set
	2.16.840.1.113883.3.117.1.7.1.251	Ischemic Stroke ICD-10 value set
	2.16.840.1.113883.3.117.1.7.1.252	Ischemic Stroke SNOMED-CT value set

2.16.840.1.113883.3.117.1.7.1.250 Ischemic Stroke ICD-9 value set

433.01	Occlusion and stenosis of precerebral arteries, basilar artery, with cerebral infarction
433.10	Occlusion and stenosis of precerebral arteries, carotid artery, without mention of cerebral infarction
433.11	Occlusion and stenosis of precerebral arteries, carotid artery, with cerebral infarction
433.21	Occlusion and stenosis of precerebral arteries, vertebral artery, with cerebral infarction
433.31	Occlusion and stenosis of precerebral arteries, multiple and bilateral arteries, with cerebral infarction
433.81	Occlusion and stenosis of other specified precerebral artery with cerebral infarction
433.91	Occlusion and stenosis of unspecified precerebral artery with cerebral infarction
434.00	Cerebral thrombosis, without mention of cerebral infarction
434.01	Cerebral thrombosis, with cerebral infarction
434.11	Cerebral embolism, with cerebral infarction
434.91	Cerebral artery occlusion, unspecified, with cerebral infarction
436	Acute, but ill-defined, cerebrovascular disease



Associated value sets

2.16.840.1.113883.3.117.1.7.1.252 Ischemic Stroke SNOMED-CT value set

64586002	Carotid artery stenosis (disorder)
71444005	Cerebral arterial thrombosis (disorder)
111297002	Nonparalytic stroke (disorder)
116288000	Paralytic stroke (disorder)
195185009	Cerebral infarct due to thrombosis of precerebral arteries (disorder)
195186005	Cerebral infarction due to embolism of precerebral arteries (disorder)
195189003	Cerebral infarction due to thrombosis of cerebral arteries (disorder)
195190007	Cerebral infarction due to embolism of cerebral arteries (disorder)
195212005	Brainstem stroke syndrome (disorder)
195213000	Cerebellar stroke syndrome (disorder)
195216008	Left sided cerebral hemisphere cerebrovascular accident (disorder)
195217004	Right sided cerebral hemisphere cerebrovascular accident (disorder)
195230003	Cerebral infarction due to cerebral venous thrombosis, non-pyogenic (disorder)
230690007	Cerebrovascular accident (disorder)
230691006	Cerebrovascular accident due to cerebral artery occlusion (disorder)
230692004	Infarction - precerebral (disorder)
230693009	Anterior cerebral circulation infarction (disorder)
230694003	Total anterior cerebral circulation infarction (disorder)
230695002	Partial anterior cerebral circulation infarction (disorder)
230696001	Posterior cerebral circulation infarction (disorder)
230698000	Lacunar infarction (disorder)
230699008	Pure motor lacunar infarction (disorder)
230700009	Pure sensory lacunar infarction (disorder)
233964008	Internal carotid artery stenosis (disorder)
288723005	Acute ill-defined cerebrovascular disease (disorder)
300920004	Carotid atherosclerosis (disorder)



MU2 clinical quality measures and associated value sets

- ▶ **94 clinical quality measures**
 - ▶ Developed by some 20 measure developers
- ▶ **3095 value sets**
 - ▶ 1558 unique
- ▶ **201,126 codes**
 - ▶ 84,228 unique

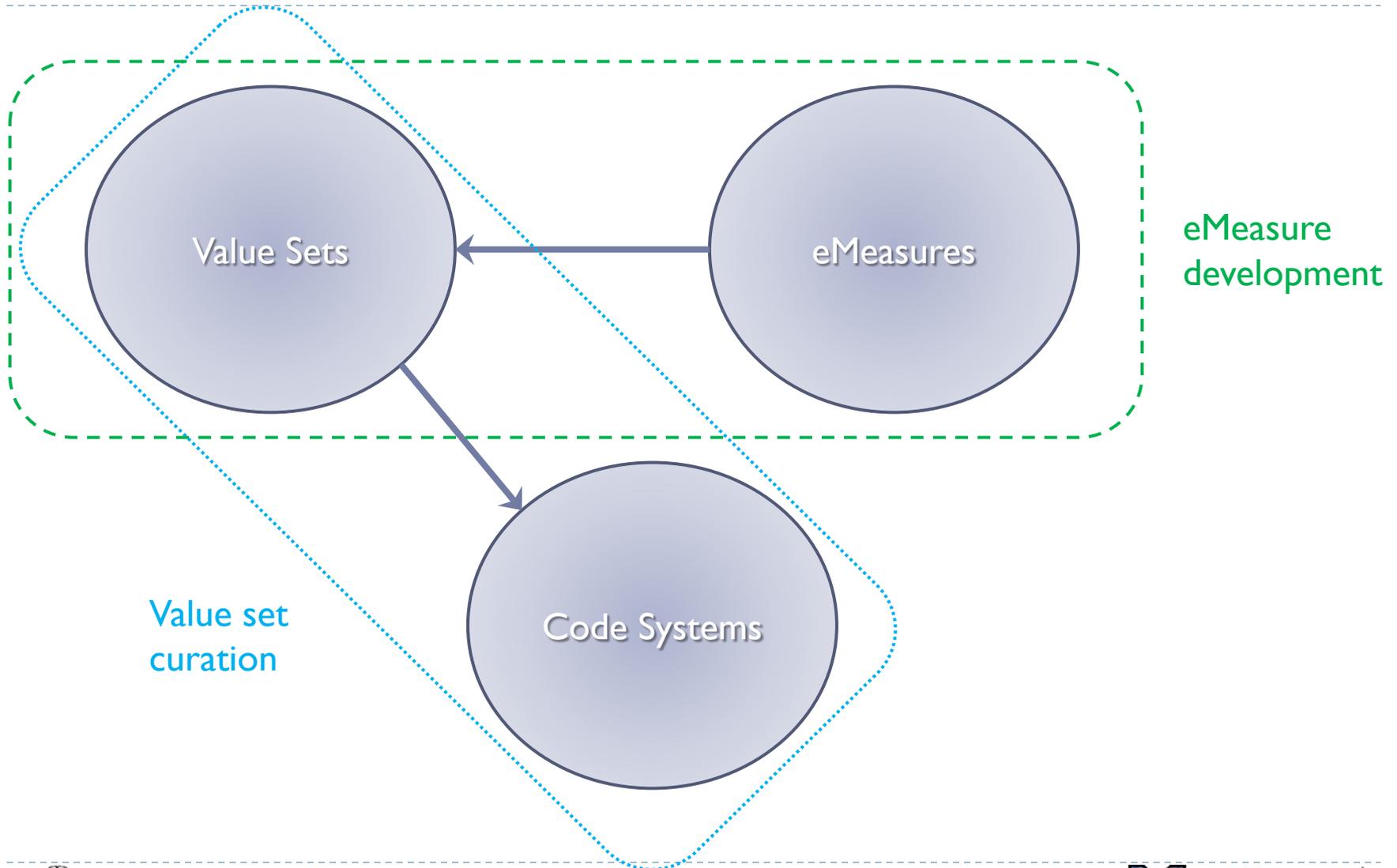


Reference code systems

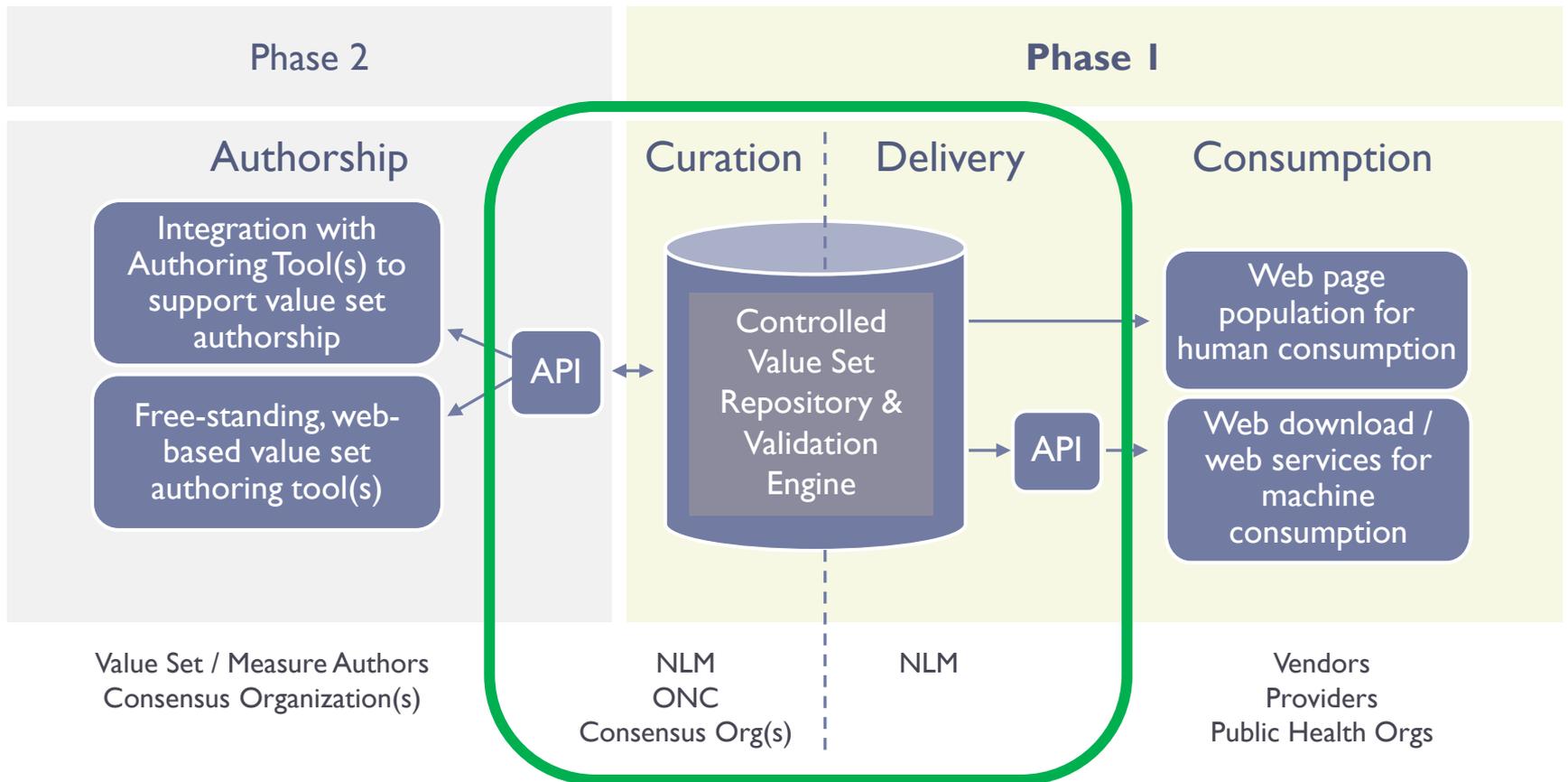
- ▶ **3 main code systems**
 - ▶ RxNorm [Aug. 2012]
 - ▶ SNOMED CT [July 31, 2012]
 - ▶ US extension of SNOMED CT
 - ▶ LOINC [2.40]
- ▶ **Transitional code systems**
 - ▶ CPT, CDT
 - ▶ ICD9-CM
 - ▶ ICD10-CM, ICD10-PCS
 - ▶ CVX (vaccines)
 - ▶ HCPCS
- ▶ **Other code systems**
 - ▶ CDC Race and ethnicity
 - ▶ HL7
 - ▶ ONC Administrative Sex (created by NLM)
 - ▶ ...
- ▶ **Additional codes**
 - ▶ Look-back codes (“legacy”)
 - ▶ Look-ahead codes (not yet in a published code system)



Between eMeasures and Code Systems



Between developers and consumers of VSs



Courtesy of J. Reider (ONC)



Preliminary analysis of the retooled measures endorsed by NQF (Jan. 2012)

To be presented at AMIA 2012

Issues in Creating and Maintaining Value Sets for Clinical Quality Measures

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Abstract

Objective: To develop methods for assessing the validity, consistency and currency of value sets for clinical quality measures, in order to support the developers of quality measures in which such value sets are used. **Methods:** We assessed the well-formedness of the codes (in a given code system), the existence and currency of the codes in the corresponding code system, using the UMLS and RxNorm terminology services. We also investigated the overlap among value sets using the Jaccard similarity measure. **Results:** We extracted 163,788 codes (76,062 unique codes) from 1463 unique value sets in the 113 quality measures published by the National Quality Forum (NQF) in December 2011. Overall, 5% of the codes are invalid (4% of the unique codes). We also found 67 duplicate value sets and 10 pairs of value sets exhibiting a high degree of similarity (Jaccard > .9). **Conclusion:** Invalid codes affect a large proportion of the value sets (19%). 79% of the quality Measures have at least one value set exhibiting errors. However, 50% of the quality measures exhibit errors in less than 10 % of their value sets. The existence of duplicate and highly-similar value sets suggests the need for an authoritative repository of value sets and related tooling in order to support the development of quality measures.





Value set curation

Motivation Value set curation

▶ Value set curation

▶ Ensure referential integrity

- ▶ All codes in a VS are valid codes in the corresponding code system
 - ❑ 2474318017 (urine screen for chlamydia) – code for the term (wrong)
 - ❑ 412761009 (urine screen for chlamydia) – code for the concept (OK)
- ▶ Update VSs when the code systems are updated (no “stale” codes)
 - ❑ 346892 (Amoxicillin 25 MG/ML Oral Suspension) – obsolete code
 - ❑ 313797 (Amoxicillin 25 MG/ML Oral Suspension) – active code

▶ Avoid duplication

- ▶ Find value sets having similar members
 - ❑ In the same code system
 - ❑ Across code systems (using UMLS concept mappings)
 - ❑ Between intensional and extensional definitions



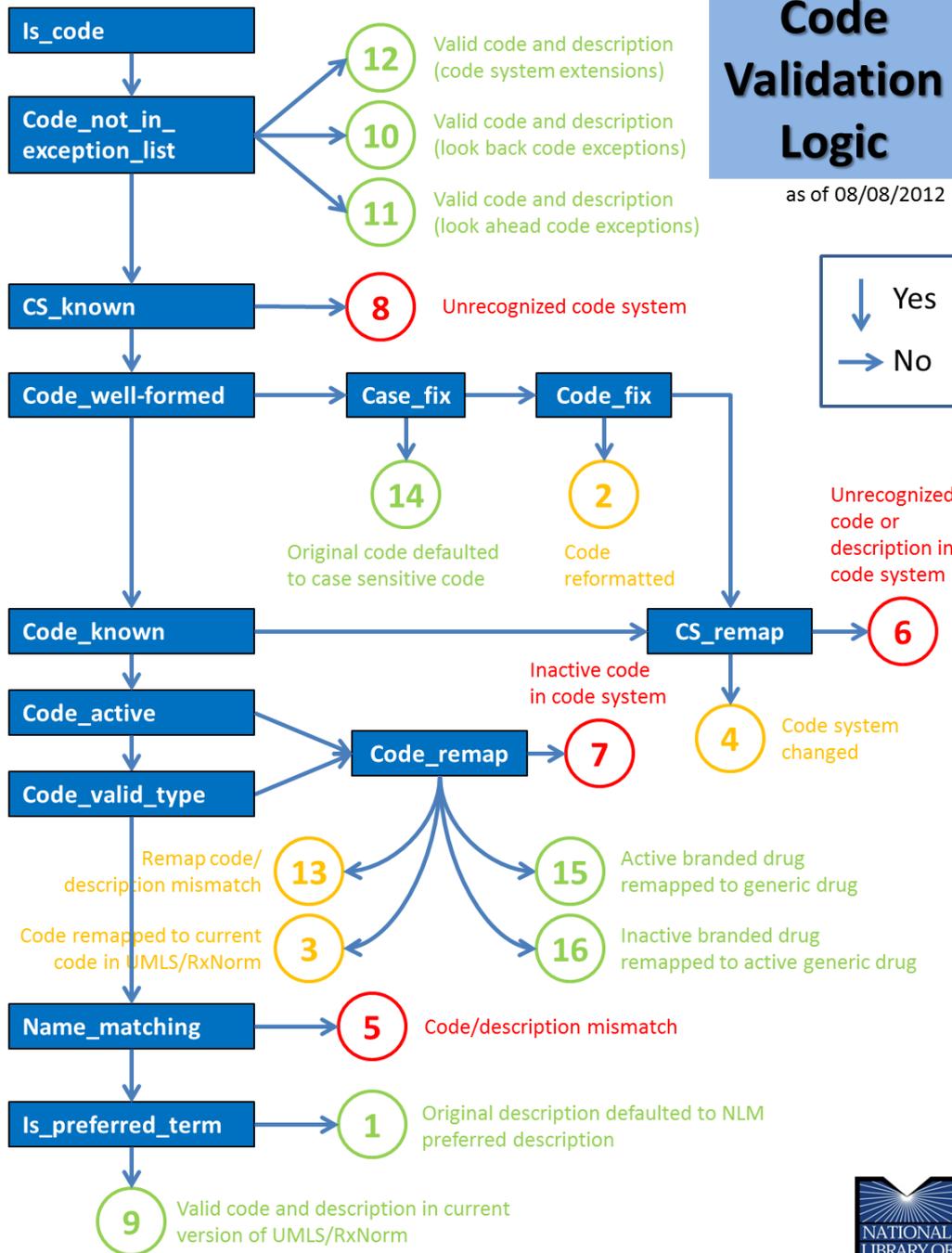
Iterative validation strategy

- ▶ Value sets exported from the measure development environment
 - ▶ 94 separate Excel spreadsheets
- ▶ Analysis pipeline
 - ▶ Triangulation between code system–code–description
 - ▶ Validation against terminology servers (UMLS, RxNorm API, specific terminology server for codes not in UMLS)
 - ▶ Results stored in a database (RDF triple store)
 - ▶ Queries for generating reports
- ▶ Report sent to developers
- ▶ 9 rounds



Code Validation Logic

as of 08/08/2012



Tests used for validation

- **Is_code**
 - Code is not empty
- **Code_not_in_exception_list**
 - Check exception lists (look back, look ahead, other convenience)
- **CS_known**
 - Code system in UMLS, RxNorm or ancillary code system
- **Code_well-formed**
 - Code conforms with code profiles and no error found in validating digits
- **Case_fix**
 - Code differs by case only (and description matches)
- **Code_fix**
 - Minor error in code only (and description matches)
- **Code_known**
 - Code found in UMLS, RxNorm or ancillary code system
- **CS_remap**
 - Match found for the code and the description, but in a different code system
- **Code_active**
 - Code listed as active in the code system
- **Code_active_type**
 - Active branded drug in RxNorm (remap to generic)
- **Code_remap**
 - Obsolete code can be remapped to an active code (RxNorm) and original description matches
 - Obsolete code can be remapped to an active code (RxNorm) and original description does not match
- **Name_matching**
 - Original description matches the code in the code system (match any synonym; minor variations accepted)
- **Is_preferred_term**
 - Original description matches the preferred term in the UMLS, RxNorm or ancillary code system
 - Automatically defaulted to preferred NLM description otherwise



Outcome of the analysis

- ▶ **Green – “Good to go”**
 - ▶ Concordance of the code system, code and description
 - ▶ Minor variation (case) allowed in the code
 - Codes harmonized to the preferred variant in UMLS
 - ▶ Minor variation (close match) allowed in the description
 - Descriptions harmonized to the preferred terms in UMLS
 - ▶ Look ahead / look back codes
- ▶ **Orange – Fix provided with high confidence, Simple review needed**
 - ▶ Code reformatted or remapped
 - ▶ Code system changed (ICD10 → ICD10-CM/ICD10-PCS)
- ▶ **Grey – Remapped to a code already present and green, Ignore**
 - ▶ Same subcategories as Orange
- ▶ **Red – Human intervention required**
 - ▶ Unrecognized code or description in code system
 - ▶ Code/description mismatch
 - ▶ Inactive code in code system



Examples of errors

- ▶ Code/description mismatch
 - ▶ **99411** Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)
 - ▶ **96411** Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)
- ▶ Remapped code/description mismatch
 - ▶ **197846** Isoxsuprine 10 MG Oral Tablet
 - ▶ **1298834** Isoxsuprine Hydrochloride 10 MG Oral Tablet



Validation of codes

unique	RO (7/10)
GREEN	94.89%
ORANGE	1.20%
GREY	0.00%
RED	3.91%
	100.00%
all	RO (7/10)
GREEN	94.42%
ORANGE	0.98%
GREY	0.00%
RED	4.59%
	100.00%

Issues in Creating and Maintaining Value Sets for Clinical Quality Measures

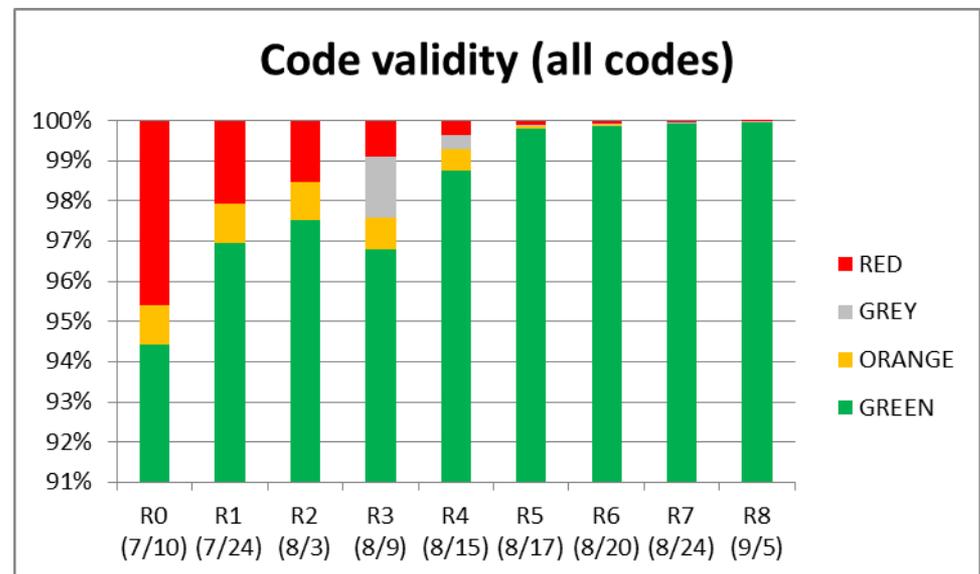
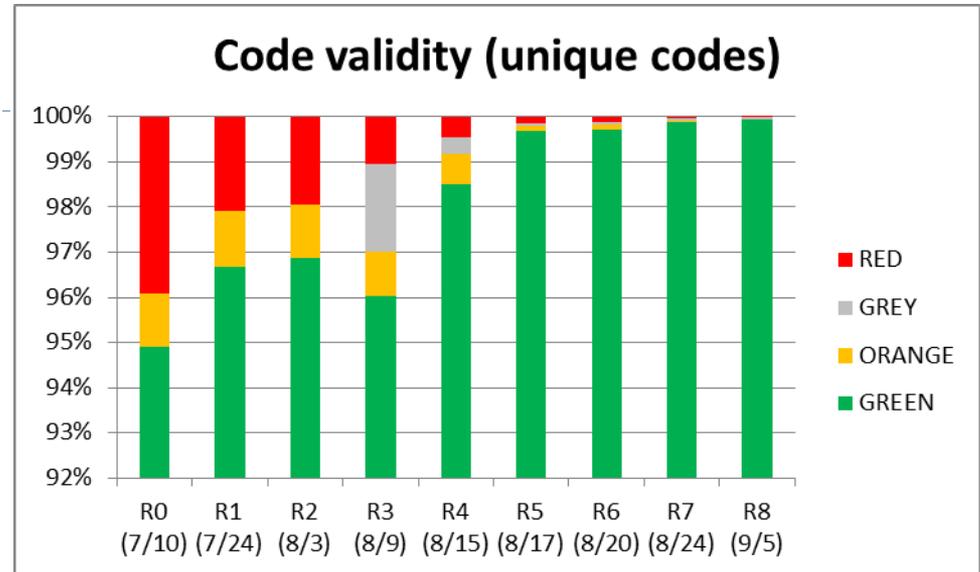
December 2011. Overall, 5% of the codes are invalid (4% of the unique codes). We also found 67 duplicate value



Code validation

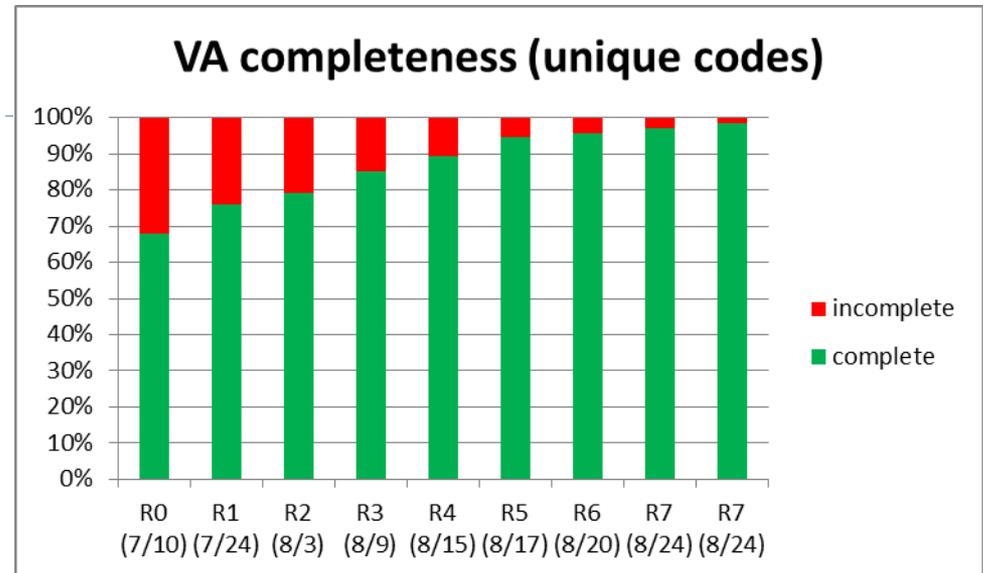
- ▶ Unique
N = 84,228
- ▶ 30 errors remaining
 - ▶ 24 “placeholder” codes

- ▶ All
N = 201,126

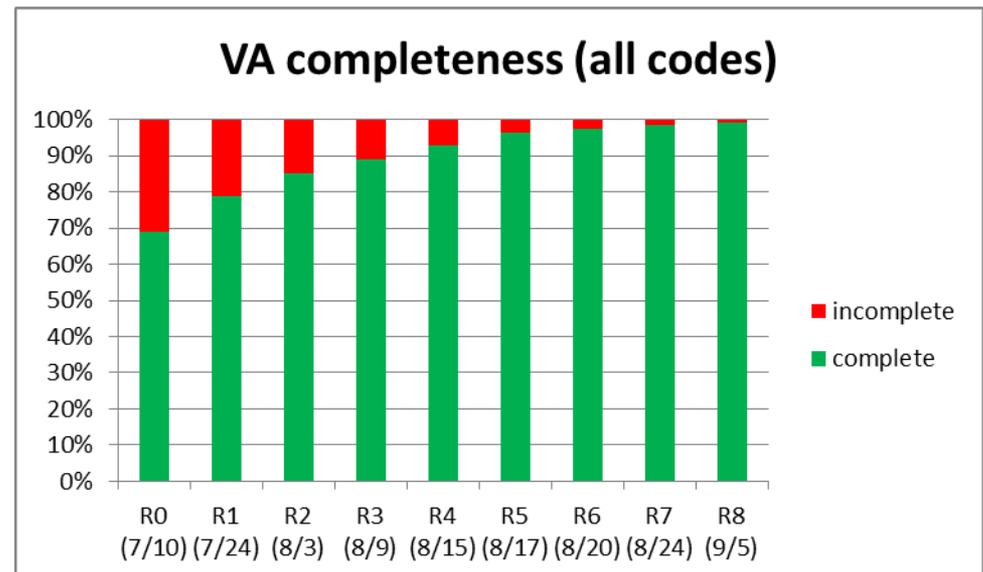


Validation of value sets

- ▶ Unique
N = 1558
- ▶ 26 incomplete VS

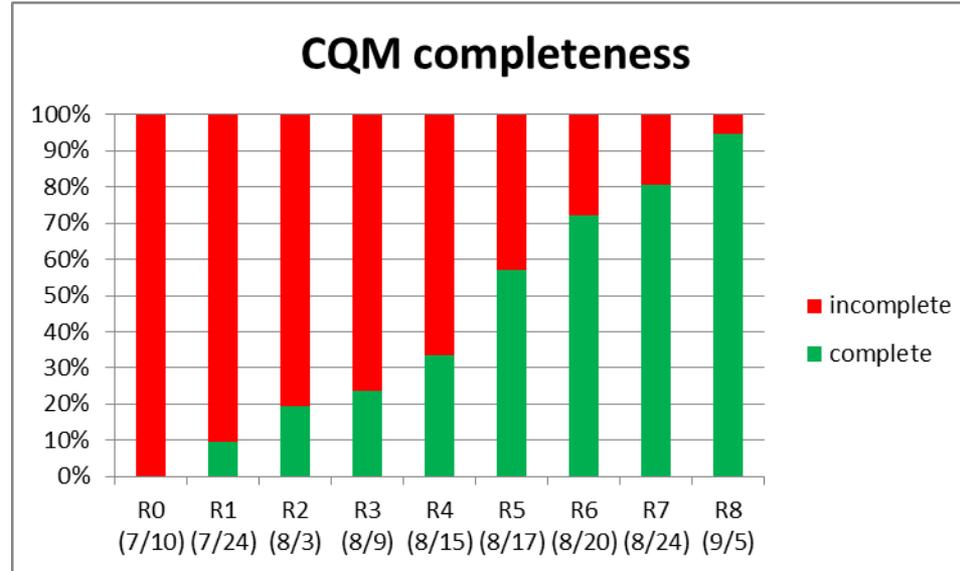


- ▶ All
N = 3095



Impact on clinical quality measures

- ▶ N = 94
- ▶ 5 measures are incomplete



Team Curation

- ▶ **Olivier Bodenreider (PI)**
 - ▶ Contributed to the validation strategy
 - ▶ Interface with ONC, CMS and measure developers
- ▶ **Rainer Winnenbug (post-doc)**
 - ▶ Contributed to the validation strategy
 - ▶ Wrote most of the code for validating against the code systems
 - ▶ Automated the analysis
 - ▶ Developed and maintained the results database (RDF triple store)
 - ▶ Maintained the documentation
- ▶ **Thang Nguyen (contractor)**
 - ▶ Developed the terminology server for non-UMLS code systems
- ▶ **Lee Peters (contractor)**
 - ▶ Extracted LOINC 2.40 and SNOMED CT July 31, 2012
 - ▶ Created the remapping service for RxNorm
 - ▶ Created the remapping service for SNOMED CT



Challenges and lessons learned

▶ Challenges

- ▶ No explicit specs, changing specs
- ▶ Aggressive deadlines
- ▶ Need for developing specific terminology services
 - ▶ Many of the code systems were not in the UMLS
 - ▶ Some services not available through the UMLS (e.g., remapping of obsolete codes)
- ▶ Intellectual property restrictions in some code systems

▶ Lessons learned

- ▶ Much harder than an academic exercise
- ▶ Excellent training opportunity for a post-doc
- ▶ Provided the blueprints for a production system to be implemented by VSAC
- ▶ Measure authoring environment needs to be integrated with terminology services





Value set delivery

Requirements

- ▶ Value set delivery (NLM)
 - ▶ Authoritative
 - ▶ Curated value sets
 - ▶ Latest version
 - Previous versions archived & available for reference
 - ▶ Format
 - ▶ Human-readable format
 - Web site, HTML-based
 - ▶ Machine-readable format
 - Web service, XML-based
- ▶ Synchronized with eMeasures delivery (USHIK)



Value set repository Characteristics

- ▶ One-stop shop for all value sets for MU
- ▶ Authoritative source
 - ▶ Curated value sets
 - ▶ Latest version (& archived previous versions)
- ▶ Publicly available
 - ▶ But does not mean value sets are in the public domain; copyrights and, in some cases licensing restrictions, apply
- ▶ Used by
 - ▶ eMeasure developers (check existing value sets)
 - ▶ Value set developers (get terminology, validate value sets)
 - ▶ eMeasure implementers (get curated value sets)



Value set delivery

- ▶ Search for published value sets
 - ▶ By name, identifier (OID), members (codes)
 - ▶ Additional metadata (author, date, measure(s), message segment(s), etc.)
- ▶ Retrieve value sets and their metadata
 - ▶ Human consumption
 - ▶ Web display
 - ▶ HTML-based
 - ▶ Machine consumption
 - ▶ Download + Access through an API
 - ▶ XML-based
 - ▶ IHE SVS profile, CTS2

