HEALTH IT STANDARDS AND TESTING

Test Method Development for IFR Certification Criteria and Standards

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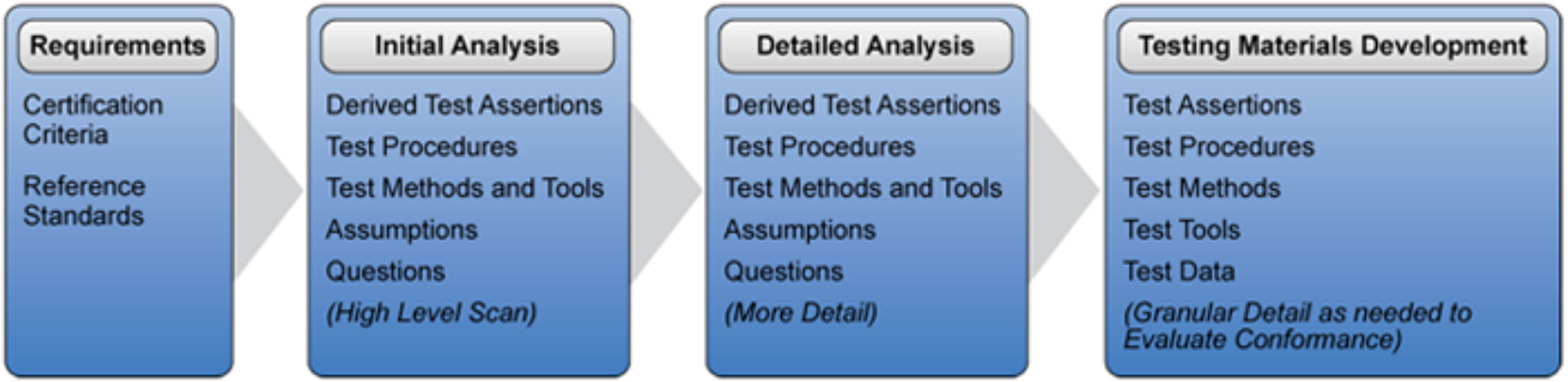
NIST Role in Meaningful Use

- In support of the Health IT Certification Program, NIST is developing the Test Method (test procedures, test data, and test tools) to ensure conformance with the IFR technical criteria and standards.

- NIST roles called out in ARRA:
  - Consult on voluntary health IT certification programs
  - Ensure health IT standards are complete and robust
  - Establish a health IT standards testing infrastructure that supports industry consensus standards development and provides robust conformance and interoperability testing capabilities
  - In consultation with NSF and other federal agencies, establish an R&D grants program for multidisciplinary Centers for Health Care Enterprise Integration Research
  - Consult on health IT implementation assistance

Methodology used in development of test methods

- Conducted an analysis of the HHS/ONC Interim Final Rule (IFR) published in the Federal Register on January 13, 2010 including:
  - the functional and interoperable requirements
  - the referenced standards
  - the derived test requirements based on the functional and interoperable requirements and referenced standards
  - the test methods and test procedures which could be used to validate conformance with the derived test requirements
  - the assumptions which may influence the selection of a specific test method or the scope of testing



Test Method Rollout Schedule

Developed an incremental wave rollout of the test methods based on the normative certification criteria from the IFR published in the Federal Register on January 13, 2010.

Wave 1

§170.302 (b)
Maintain up-to-date problem list

§170.302 (c)
Maintain active medication list

§170.302 (d)
Maintain active medication allergy list

§170.302 (e)
Record and chart vital signs

§170.302 (f)
Smoking status

§170.304 (a)
Computerized provider order entry

Wave 2

§170.302 (h)
Generate patient lists

§170.304 (c)
Record demographics

§170.304 (d)
Generate patient reminder list

§170.304 (g)
Timely access

§170.306 (a)
Computerized provider order entry

§170.306 (b)
Record demographics

§170.306 (e)
Electronic copy of discharge information

Wave 3

§170.302 (a) Drug-drug, drug-allergy, drug formulary checks

§170.302 (l) Medication reconciliation

§170.302 (o) Access control

§170.302 (p) Emergency access

§170.302 (q) Automatic log-off

§170.302 (r) Audit log

§170.302 (s) Integrity

§170.302 (t) Authentication

§170.302 (u) Encryption

§170.302 (v) Accounting of disclosures

§170.304 (e) Clinical decision support

§170.304 (f) Electronic copy of health information

§170.304 (h) Clinical summaries

§170.304 (i) Exchange clinical information and patient summary record

§170.306 (c) Clinical decision support

§170.306 (d) Electronic copy of health information

§170.306 (f) Exchange clinical information and summary record

Wave 4

§170.302 (g)
Incorporate laboratory test results

§170.302 (i)
Report quality measures

§170.302 (j)
Check insurance eligibility

§170.302 (k)
Submit claims

§170.302 (m)
Submission to immunization registries

§170.302 (n)
Public health surveillance

§170.304 (b)
Electronically exchange prescription information

§170.306 (g)
Reportable lab results

Guiding Principles

- Draft test procedures until Final Rule is Published
  - Public comment from various sources such as Vendors, Users, Standards Development Organizations
  - Input from ONC on draft test procedures
- 45 CFR 170.xxx is Normative
  - Informative section of IFR is not normative
  - CMS NPRM requirements not considered; ONC responsibility to align IFR and CMS NPRM
- Conformance-based approach
  - Developing test procedures from the words provided in the IFR with additional guidance from ONC
  - Test data provided for consistency as well as ensure Tester has understanding of expected results of the test

Guiding Principles (continued)

- Do not add requirements
  - Constraining the test procedures to the functional and interoperable requirements as stated in the IFR
  - Describing what needs to be tested and how to perform the testing; not specifying how the Vendor's system should perform a particular function
  - Silent on how an EHR should accomplish some functions; not impose additional requirements
  - Not incorporating related but unspecified capabilities that may be present in EHR systems
- Strategies for minimally specified criteria
  - When functional requirements are open to variable interpretations, test procedure asks the Vendor to identify the EHR functions available to accomplish the requirements
  - Where the IFR specifies a base standard but not an implementation guide, adopted a "minimal but useful" approach for constraining the optionality of the base standard

Each test procedure is organized into different sections with traceability to the criteria within the IFR

- Informative section
  - Includes certification criteria as published in 45 CFR Part 170 Subpart C of the Interim Final Rule (IFR) in the Federal Register on January 13, 2010
  - Describes how the test procedure is organized and conducted
  - Includes standards referenced in the certification criteria
- Normative Test Procedure
  - Describes the required vendor information and test procedures for validating conformance to the criteria and standards
- Example Test Data
  - Provides examples of the test data to be used during the test procedure. The test data sets will be expanded for the final version of the test procedures.
- Conformance Test Tools
  - Provides a description and links to the associated conformance test tools, if applicable, to evaluate conformance to the referenced standards.

Informative Text Example

Exchange Clinical Information & Summary:

The test procedure is organized into two sections:

- Receive and Display. evaluates the capability to receive and display (render) a patient summary record in the EHR when received in HL7 CCD format and when received in ASTM CCR format.
  - The patient summary record includes diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures. Included in the test procedure is an evaluation of the capability of the EHR to display (render) structured data and vocabulary coded values in human-readable form
- Transmit –evaluates the capability to transmit a patient summary record from the EHR in either HL7 CCD or ASTM CCR format as selected by the Vendor.
  - The patient summary record includes diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures. Included in the test procedure is an evaluation of the capability to communicate vocabulary coded values as defined by the referenced standards

The normative test procedure provides information for validating conformance to the criteria and standards

- Each subsection provides additional information on:
  - Required vendor information
  - Required test procedures
  - Inspection test guide
- Traceability is provided in each subsection through a unique numbering sequence

Normative Test Procedures

Derived Test Requirement(s)

DTR170.302.e.2 - 1: Calculate and display body mass index

Required Vendor Information

VE170.302.e.2 - 1.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.302.e.2 - 1.02: Vendor shall identify the EHR function(s) that are available to select the patient, enter the patient's height and weight, and calculate and display BMI.

Required Test Procedure

TE170.302.e.2 - 1.01: Tester shall select height and weight test data from NIST-supplied test data sets

TE170.302.e.2 - 1.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and enter the patient's height and weight

TE170.302.e.2 - 1.03: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the test data has been entered correctly and without omission and that the BMI has been calculated correctly according to the NIST-supplied data set

Inspection Test Guide

IN170.302.e.2 – 1.01: Tester shall verify that the required units of measure are displayed or can be selected at the time the height and weight are entered.

IN170.302.e.2 – 1.02: Tester shall verify that the height and weight test data can be entered correctly and without omission.

IN170.302.e.2 – 1.03: Using the NIST-supplied data sets, the Tester shall verify that the BMI is calculated correctly from the entered height and weight and is displayed without omission and without error. Calculated BMI may deviate +/- 1.0 from the calculated value in the data set.

Resources

- Health IT Standards & Testing
  http://healthcare.nist.gov/

- Draft Test Methods
  http://healthcare.nist.gov/use_testing/under_development.html
  Open comment period; always want useful feedback

- Meaningful Use HL7 Conformance Test Tools
  - CCD: http://xreg2.nist.gov/cda-validation/mu.html
  - V2: http://xreg2.nist.gov:8080/HL7V2MuValidation2011/