Conformance Testing of Healthcare Data Exchange Standards for EHR Certification

HIMS'15 - The 2015 International Conference on Healthcare Informatics and Medical Systems

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NIST
National Institute of Standards and Technology

Why you should care?

US healthcare safety/quality is low and cost is high

➢ Premature deaths associated with preventable harm to patients in hospital estimated at more than 400,000 per year[1]

➢ Medical errors are the third leading cause of death behind heart disease and cancer[2]

➢ Healthcare is expensive → over 1/6 of US GDP[3]

Reasons (Some)

➢ Wrong information, lack of information

➢ Timeliness of information, misinterpretation of information

One Solution (Part of)

➢ Access to and use of electronic health records (EHR-S) that are seamlessly integrated into patient care workflow and provide right data at the right place at the right time

Method

➢ EHR-S that are certified as conformant to testable interoperability standards

NIST Role

➢ Aid in healthcare interoperability standards development

➢ Develop EHR-S conformance and interoperability test tools for certification

[1] http://journals.lww.com/journalpatientsafety/fulltext/2013/09000/a_new,_evidence_based_estimate_of_patient_harms.2.aspx
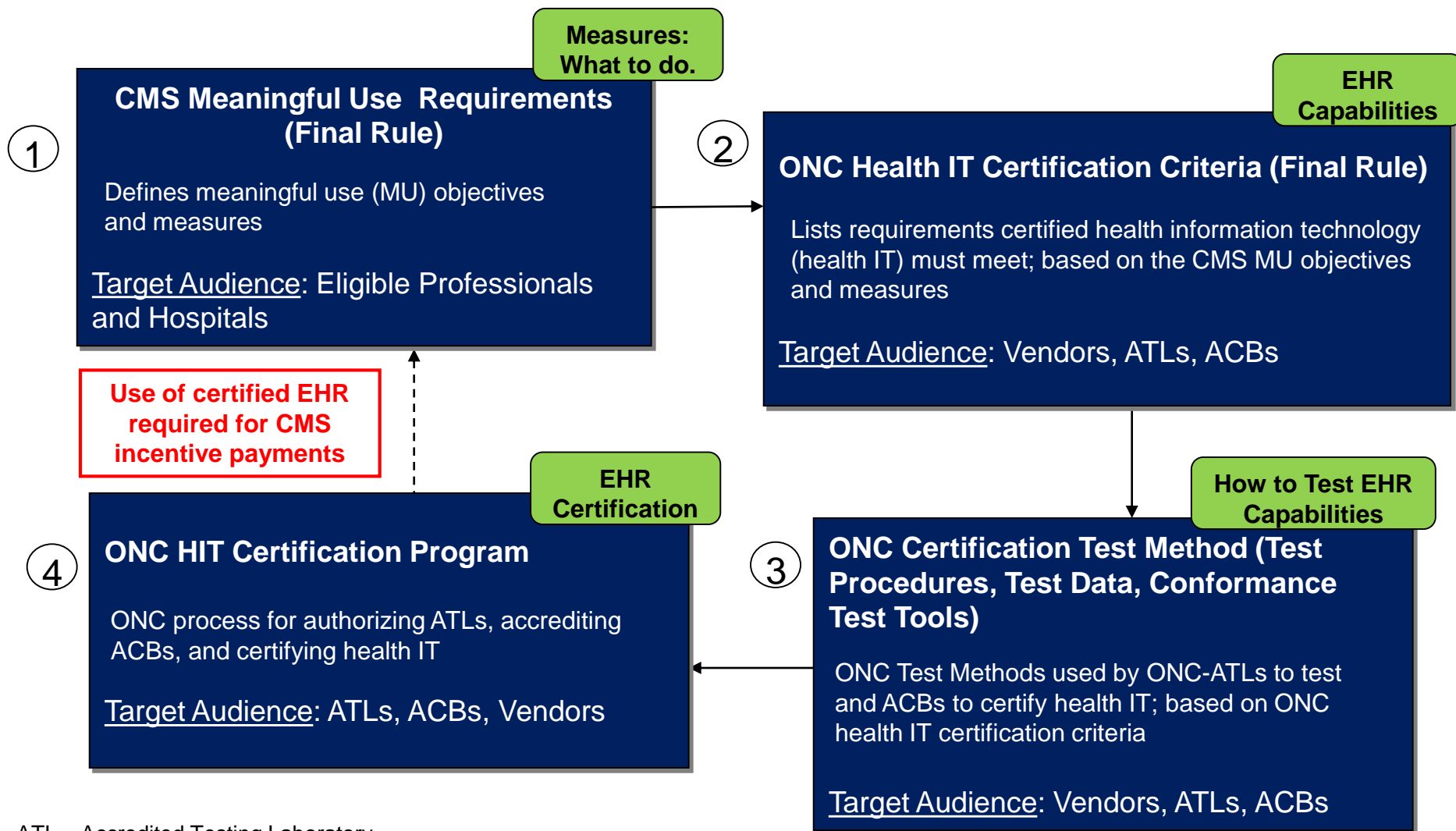
[2] http://www.forbes.com/sites/leahbinder/2013/09/23/stunning-news-on-preventable-deaths-in-hospitals/

[3] http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS?order=wbapi_data_value_2013+wbapi_data_value+wbapi_data_value-last&sort=desc

Outline

- ➢ EHR Adoption (National Incentive Program)
  - ➢ CMS Meaningful Use
  - ➢ HHS Office of the National Coordinator (ONC) EHR Certification
  - ➢ NIST Role in EHR Standard Development and Conformance Testing
- ➢ HL7 V2 Standard Overview
  - ➢ Messaging Standard for Exchanging Administrative and Clinical Data
  - ➢ Constraining the Standard for Specific Use Cases (Profiling)
- ➢ Perspectives of Testing
  - ➢ Localization
  - ➢ Conformance (Capability vs. Site) and Interoperability
- ➢ Conformance Testing
  - ➢ Testing Sending Systems
   - ➢ Context-free and Context-based
  - ➢ Testing Receiver Systems

CMS MU Program and ONC HIT Program

Measures: What to do.

① CMS Meaningful Use Requirements (Final Rule)

Defines meaningful use (MU) objectives and measures

Target Audience: Eligible Professionals and Hospitals

EHR Capabilities

② ONC Health IT Certification Criteria (Final Rule)

Lists requirements certified health information technology (health IT) must meet; based on the CMS MU objectives and measures

Target Audience: Vendors, ATLs, ACBs

Use of certified EHR required for CMS incentive payments

EHR Certification

④ ONC HIT Certification Program

ONC process for authorizing ATLs, accrediting ACBs, and certifying health IT

Target Audience: ATLs, ACBs, Vendors

How to Test EHR Capabilities

③ ONC Certification Test Method (Test Procedures, Test Data, Conformance Test Tools)

ONC Test Methods used by ONC-ATLs to test and ACBs to certify health IT; based on ONC health IT certification criteria

Target Audience: Vendors, ATLs, ACBs

ATL – Accredited Testing Laboratory
ACB – Authorized Certification Body

Percentage of office-based physicians with EHRs: United States, 2001–2013
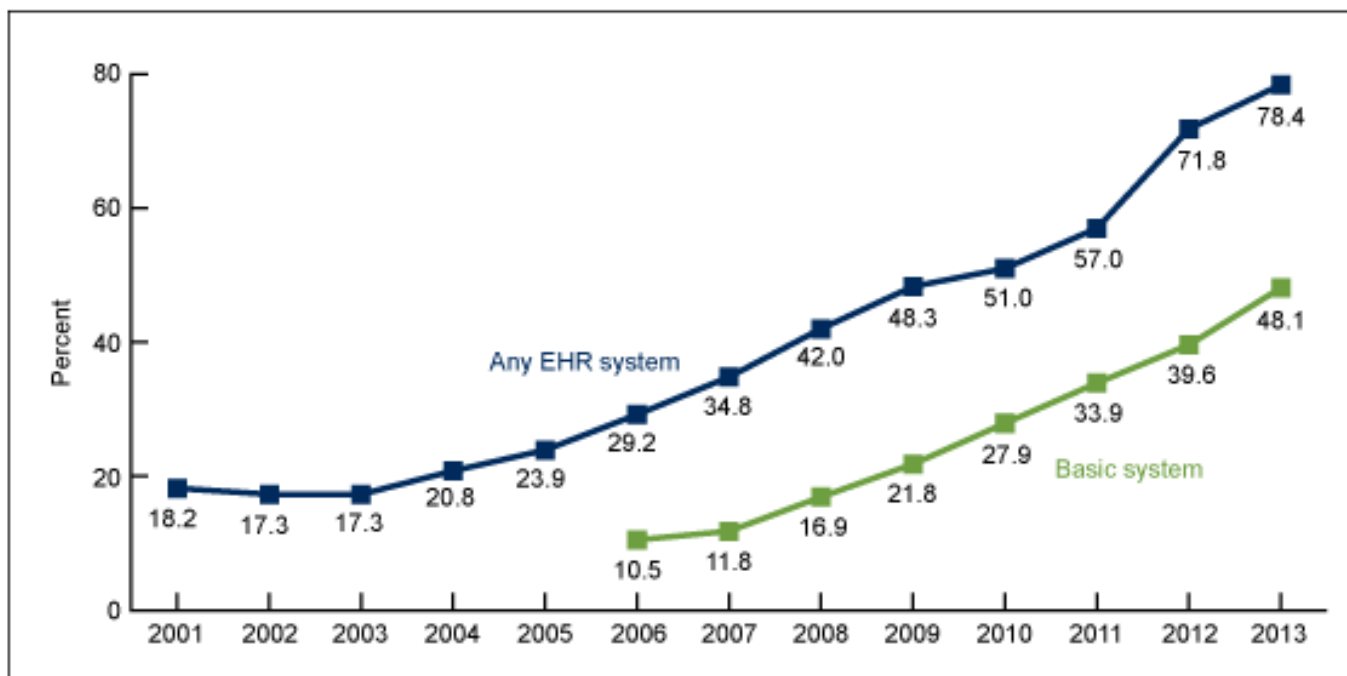

NOTES: EHR is electronic health record. "Any EHR system" is a medical or health record system that is either all or partially electronic (excluding systems solely for billing). Data for 2001–2007 are from in-person National Ambulatory Medical Care Survey (NAMCS) interviews. Data for 2008–2010 are from combined files (in-person NAMCS and mail survey). Estimates for 2011–2013 data are based on the mail survey only. Estimates for a basic system prior to 2006 could not be computed because some items were not collected in the survey. Data include nonfederal, office-based physicians and exclude radiologists, anesthesiologists, and pathologists.
SOURCE: CDC/NCHS, National Ambulatory Medical Care Survey and National Ambulatory Medical Care Survey, Electronic Health Records Survey.

http://dashboard.healthit.gov/index.php

Non-federal acute care hospitals EHR Adoption: 2008-2014

http://dashboard.healthit.gov/index.php
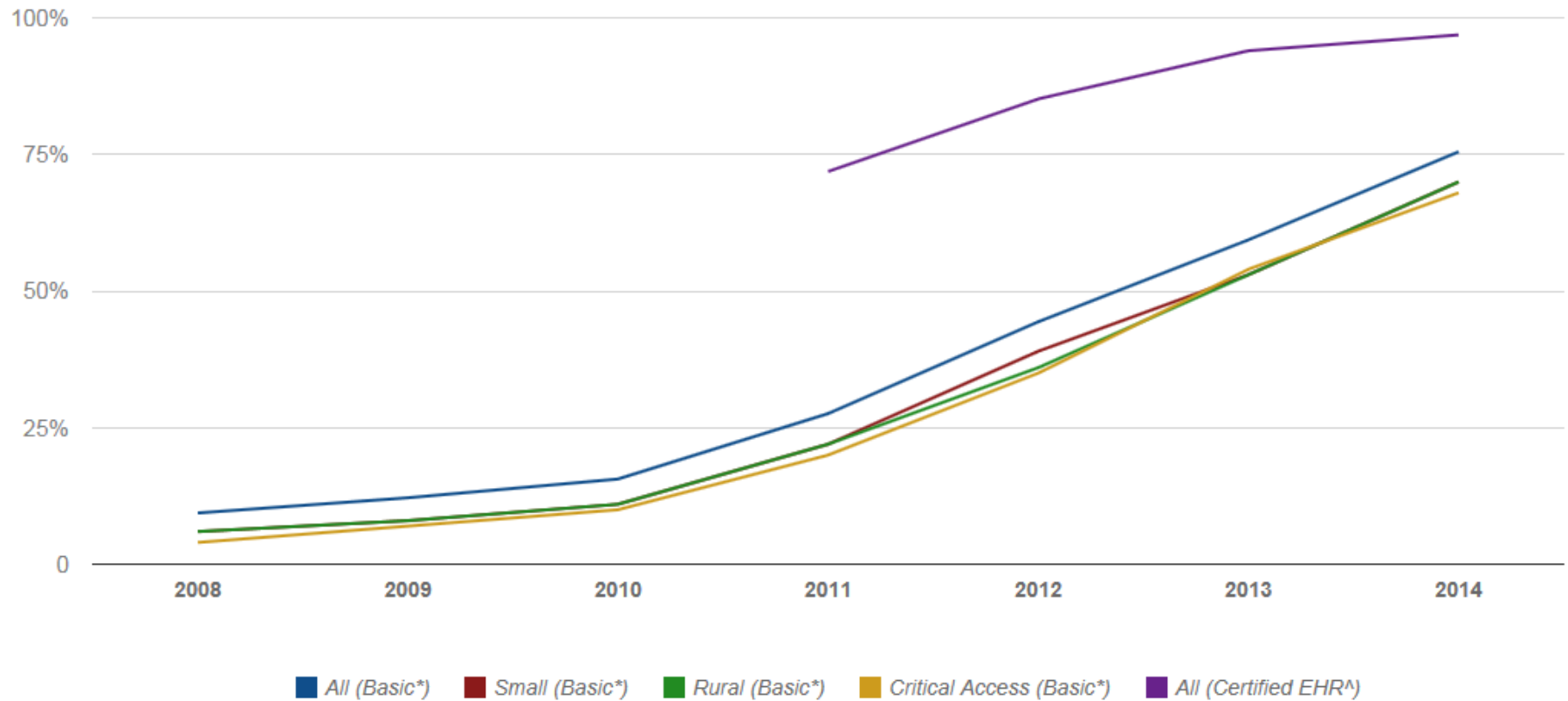
NIST Role: Meaningful Use/Certification Process
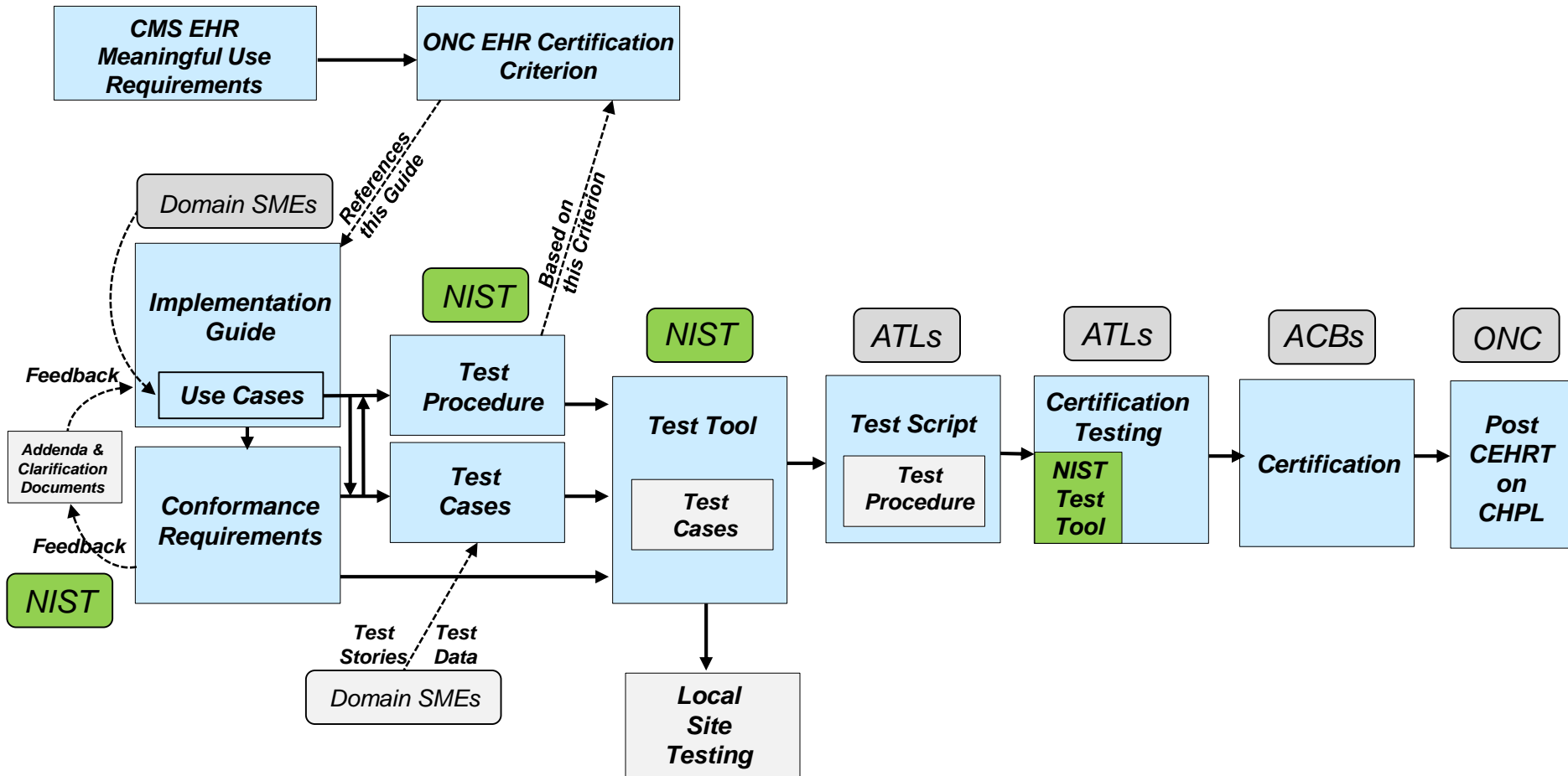
NIST – National Institute of Standards and Technology
ACB – Authorized Certification Body
SME – Subject Matter Expert
CHPL – Certified Health IT Product List

ATL – Accredited Testing Laboratory
ONC – Office of the National Coordinator for Health Information Technology
CEHRT – Certified Electronic Health Record Technology

HL7 and Healthcare Integration
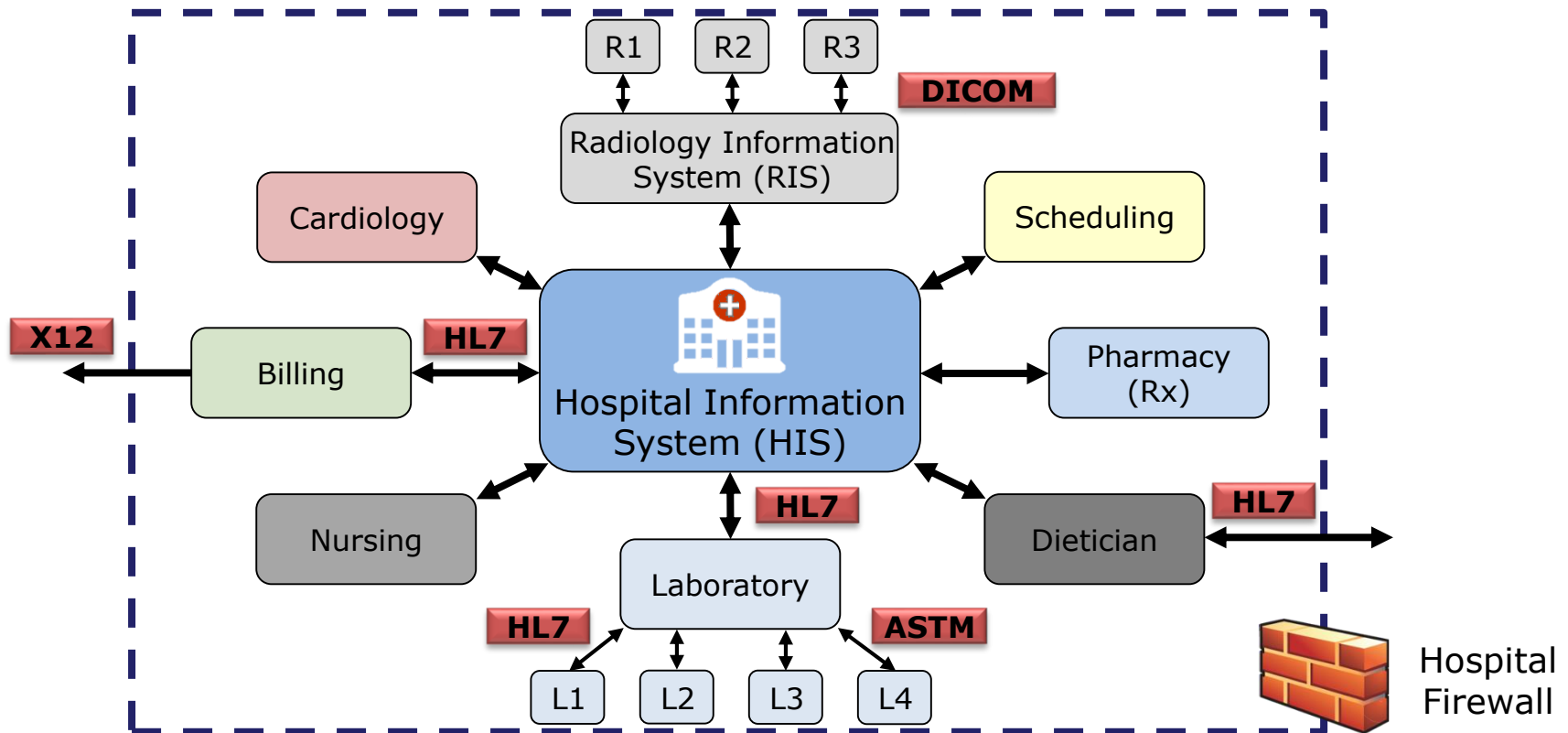
- HL7 (Health Level Seven) Messaging Standard (Application level)
- Standards for the exchange, management, and integration of data for clinical care
  - Messages model real world events
  - e.g., Messages for registering a patient or requesting a lab order
- HL7 provides a flexible framework to build messages
- Widely used; 90% of hospitals

Adapted from HL7 Desktop Reference Guide—NeoTool 2002
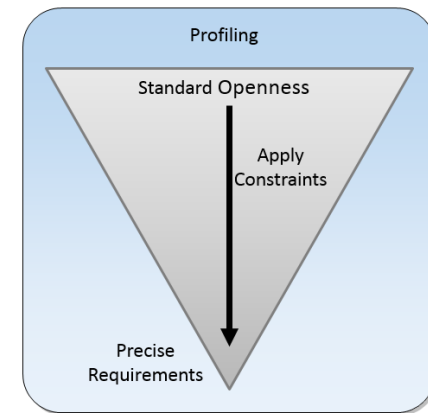
Example Healthcare Integration

Hospital Information System (HIS)

- Lab Orders (OML)
- Lab Results (ORU)

Registration

- Admit (inpatient/outpatient)
- Discharge
- Transfer
- Update
- Merge

Laboratory 2

Laboratory 1

Radiology Information System (RIS)

Electronic Health Record (EHR)

ADT

VXU
ADT*
ORU

- Immunization (VXU)
- Syndromic Surveillance (ADT*)
- Reportable Labs (ORU)

Public Health

DICOM

OML   ORU

- Lab Orders (OML)
- Lab Results (ORU)

Hospital Lab 1

HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

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HL7 V2 Message Framework

- HL7 V2 Standard - Hierarchy of Message Elements
  - Groups, Segments, Fields, Components, and Sub-Components
  - Groups and Segments can contain additional elements
  - Fields and Components can contain additional elements or are primitive elements
  - Sub-components are primitive elements (i.e., can data values)
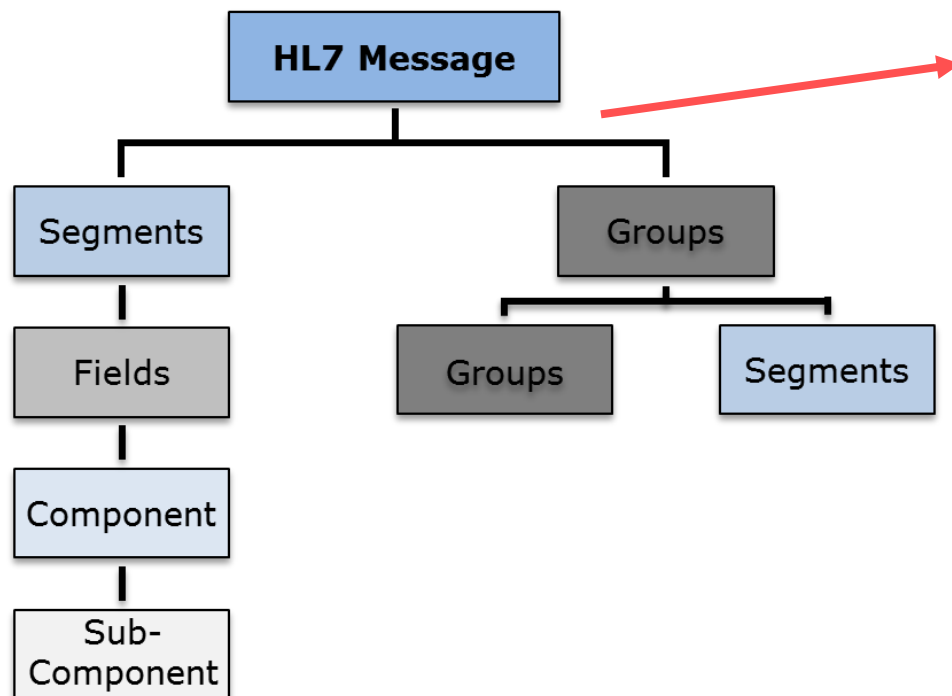
- Many Message Events (100s)
- Model Real World Events, such as
- Admit/Discharge/Transfer (ADT)
  - ADT A04 (Register Patient)
  - ADT A08 (Update Patient Data)
  - Etc.
- Lab Orders (OML)
  - OML O21 (Order)
- Lab Results (ORU)
  - ORU R01 (Result)
- Immunization
- Etc.

HL7 V2 Is a Framework (Broad Scope by Design)

- Overwhelmingly large with many optional features
- Little agreement on how to define an interface
- Applications didn't know what to expect
- Profiling is necessary

Profiling

Standard Openness

Apply Constraints

Precise Requirements

HL7 Message

Segments

Groups

Fields

Groups

Segments

Component

Sub-Component
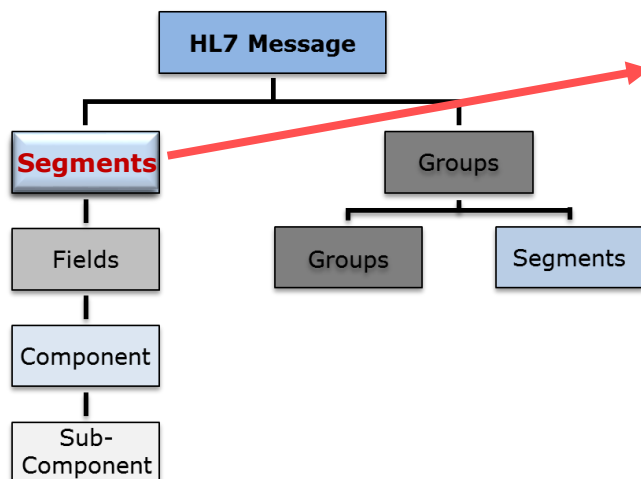
Example: PID Segment

SEQ	LEN	DT	OPT	RP#	TBL#	ITEM	ELEMENT NAME
. . .							
5	250	XPN	R	Y		00108	Patient Name
6	250	XPN	O	Y		00109	Mother's Maiden Name
7	26	TS	O			00110	Date / Time of Birth
8	1	IS	O		0001	00111	Administrative Sex
9	250	XPN	B	Y		00112	Patient Alias
10	250	CE	O	Y	0005	00113	Race
11	**250**	**XAD**	**O**	**Y**		**00114**	**Patient Address**
12	4	IS	B		0289	00115	County Code
13	250	XTN	O	Y		00116	Phone Number – Home
. . .							
37	80	ST	O			01541	Strain
38	250	CE	O	2	0429	01542	Production Class Code

Profile Hierarchy

Considerable Optionality and Openness

Some Optionality and Openness

No Optionality and Openness

Standard

Constrainable Profile

Implementable Profile

Adding Constraints
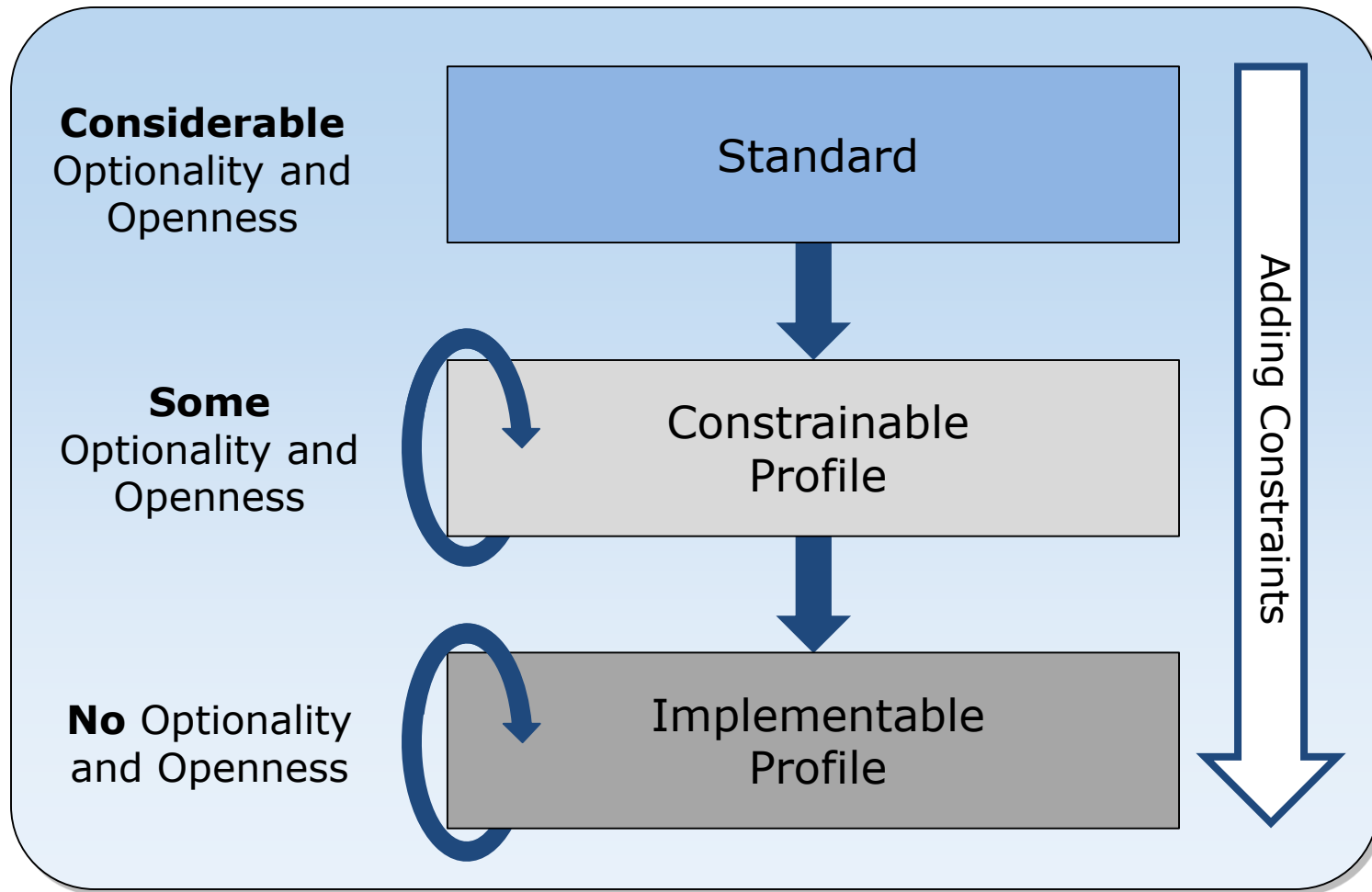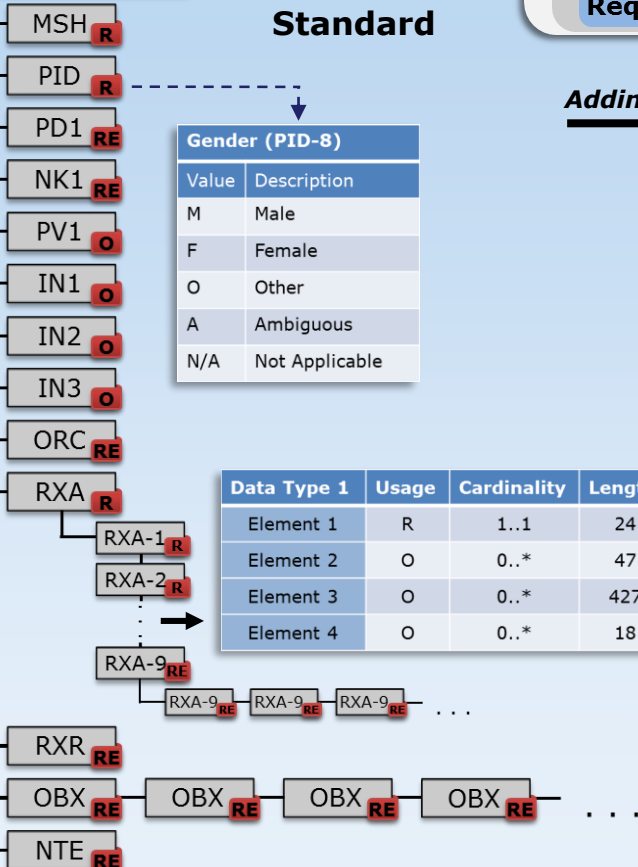
Profiling: Applying Constraints
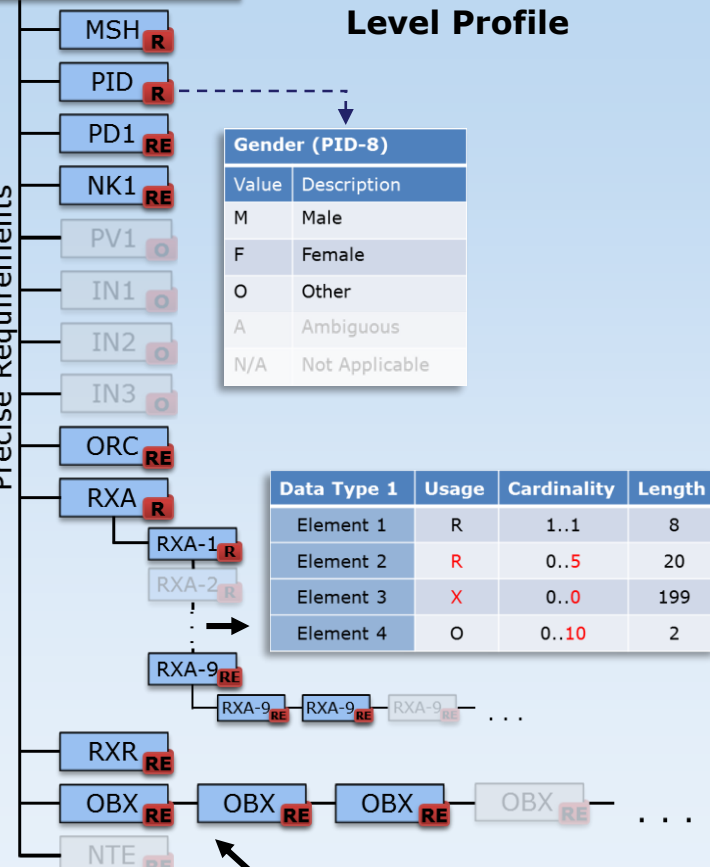
Explicit Constraint: OBX-11 (Status) SHALL be valued 'F'.

Example HL7 Message: Immunization History and Forecast

```
MSH|^~\&|MyIIS|StatePH|MYEHR|DCS|20141031145233-0500||RSP^K11^RSP_K11|443533469|P|2.5.1|||NE|NE|||||Z42^CDCPHINVS|DCS^^^^DCS^XX^^^6439432|StatePH
MSA|AA|793543||||
QAK|37374859|OK|Z44^request evaluated Immunization history^CDCPHINVS|||
QPD|Z44^Request Evaluated History and Forecast^CDCPHINVS |37374859|123456^^^MYEHR^MR|Stanley^Clement^S^^^^L|Smith|19500214|M|10 East Main
St^^Titletown^WI^^^L|^PRN^PH^^1^690^1231234
PID|1||123456^^^MYEHR^MR~34500907^^^^MyIIS^SR||Stanley^Clement^S^^^^L||19500214|M|||10 East Main St^^Titletown^WI^^^L
ORC|RE||197023^DCS|||||||^Clerk^Myron|||||||DCS^Dabig Clinical System^StateIIS
RXA|0|1|20090415|20090415|31^Hep B Peds NOS^CVX|999|||01^historical record^NIP001|||||||||||CP|A|
OBX|1|CE|30956-7^vaccine type^LN|1|45^Hep B NOS^CVX ||||||F||||||||||||||
OBX|2|CE|59779-9^Immunization Schedule used^LN|1|VXC16^ACIP^CDCPHINVS||||||F|||20141031
OBX|3|ID|59781-5^dose validity^LN|1|Y||||||F|||20141031
ORC|RE||1970213^DCS|||||||^Clerk^Myron|||||||DCS^Dabig Clinical System^StateIIS
RXA|0|1|20090515|20090515|31^Hep B Peds NOS^CVX|999|||01^historical record^NIP001|||||||||||CP|A
OBX|4|CE|30956-7^vaccine type^LN|2|45^Hep B NOS^CVX ||||||F||||||||||||||
OBX|5|CE|59779-9^Immunization Schedule used^LN|2|VXC16^ACIP^CDCPHINVS||||||F|||20141031
OBX|6|ID|59781-5^dose validity^LN|2|Y||||||F|||20141031
ORC|RE||1197023^DCS|||||||^Clerk^Myron|||||||DCS^Dabig Clinical System^StateIIS
RXA|0|1|20091215|20091215|31^Hep B Peds NOS^CVX|999|||01^historical record^NIP001|||||||||||CP|A
OBX|7|CE|30956-7^vaccine type^LN|3|45^Hep B NOS^CVX ||||||F||||||||||||||
OBX|8|CE|59779-9^Immunization Schedule used^LN|3|VXC16^ACIP^CDCPHINVS||||||F|||20141031
OBX|9|ID|59781-5^dose validity^LN|3|Y||||||F|||20141031
.......
ORC|RE||197789023^DCS|||||||^Clerk^Myron|||||||DCS^Dabig Clinical System^StateIIS|||||||||||||
RXA|0|1|20101015|20101015|141^influenza seasonal^CVX |999|||01^historical record^NIP001|||||||||||CP|A|||||
OBX|34|CE|30956-7^vaccine type^LN|12|88^influenza NOS^CVX ||||||F||||||||||||||
OBX|35|CE|59779-9^Immunization Schedule used^LN|12|VXC16^ACIP^CDCPHINVS||||||F|||20141031|||||||||||
OBX|36|ID|59781-5^dose validity^LN|12|Y||||||F|||20141031
ORC|RE||193337027^DCS|||||||^Clerk^Myron||^Pediatric^MARY^^^^^^L^^^^^^^^^^^MD|||||||||||||||||
RXA|0|1|20110901|20110901|140^seasonal flu^CVX|0.5|mL^^UCUM||00^new immunization record^NIP001|^Sticker^Nurse|^^^DCS_DC||||33k2a||PMC^sanofi^MVX|||CP|A|||||
RXR|C28161^IM^NCIT|||||
OBX|37|CE|30956-7^vaccine type^LN|13|88^influenza NOS^CVX ||||||F||||||||||||||
OBX|38|CE|59779-9^Immunization Schedule used^LN|13|VXC16^ACIP^CDCPHINVS||||||F|||20141031|||||||||||
OBX|39|ID|59781-5^dose validity^LN|13|Y||||||F|||20141031
ORC|RE||19537023^DCS|||||||^Clerk^Myron|||||||DCS^Dabig Clinical System^StateIIS|||||||||||||
RXA|0|1|20141031|20141031|998^no vaccine admin^CVX|999||||||||||||||NA|||||
OBX|40|CE|30956-7^vaccine type^LN|14|152^pcv NOS^CVX ||||||F||||||||||||||
OBX|41|CE|59779-9^Immunization Schedule used^LN|14|VXC16^ACIP^CDCPHINVS||||||F||||||||||||||
OBX|42|DT|30980-7^Date vaccination due^LN|14|20150214||||||F||||||||||||||
OBX|43|DT|30981-5^Earliest Date to give^LN|14|20150214||||||F||||||||||||||
OBX|44|CE|30956-7^vaccine type^LN|15|88^influenza NOS^CVX ||||||F||||||||||||||
OBX|45|CE|59779-9^Immunization Schedule used^LN|15|VXC16^ACIP^CDCPHINVS||||||F||||||||||||||
OBX|46|DT|30980-7^Date vaccination due^LN|15|20150914||||||F||||||||||||||
OBX|47|DT|30981-5^Earliest Date to give^LN|15|20150914||||||F||||||||||||||
```

Standard	**HL7 V2.5.1 VXU V04 Message Definition**
↓	↓
Constrainable Profile	**CDC HL7 V2.5.1 VXU V04 Profile**
↓	↓
Constrainable or Implementable Profile	**Texas HL7 V2.5.1 VXU V04 Profile** / **Wisconsin HL7 V2.5.1 VXU V04 Profile**
↓	↓
Implementable Profile	**Texas HL7 V2.5.1 VXU V04 Profile (As Implemented)** / **Wisconsin HL7 V2.5.1 VXU V04 Profile (As Implemented)**
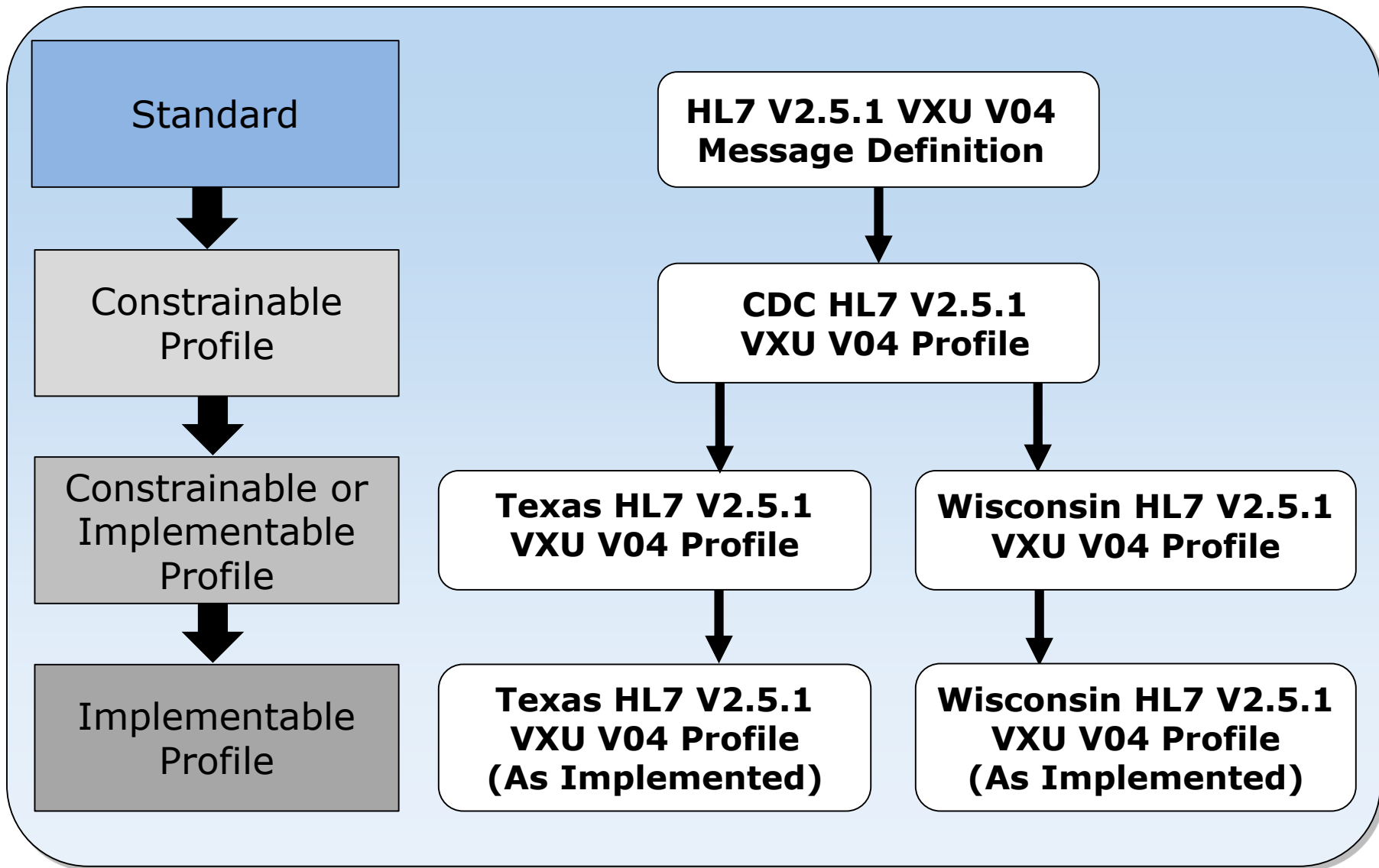
Focus of ONC Certification testing is on EHR Product Capabilities

Phase 1: Capabilities Testing *(Conformance Testing)*

Vendor Product → Testing Tool → Results *Pass/Fail*

Test Cases
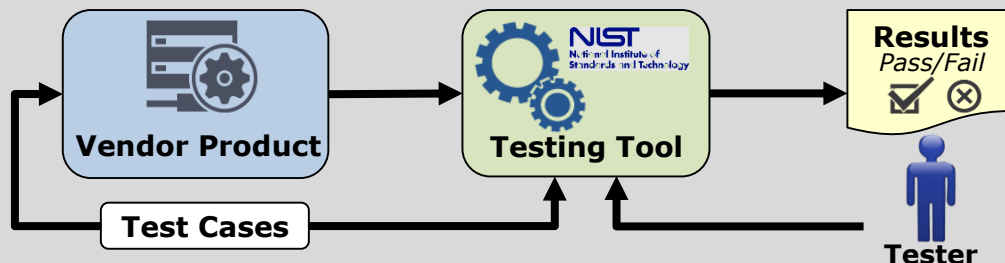
Tester

Certification Criteria:

- National Requirements (*National Profile*)
- Vendor Product (*Test Environment*)

Phase 2: Capabilities Testing *(Conformance Testing)*

Installed Vendor Product → Testing Tool → Results *Pass/Fail*

Test Cases

Tester
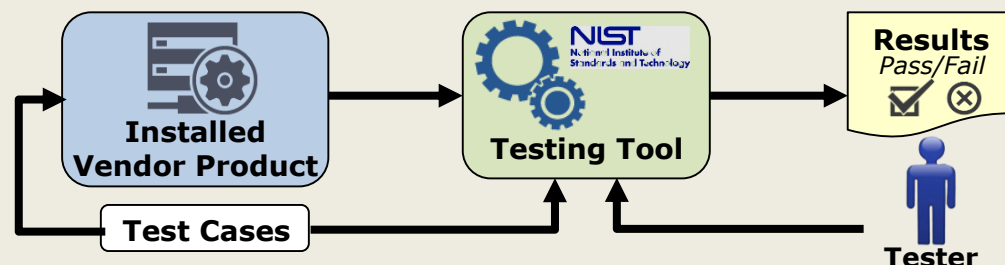
Certification Criteria:

- Add Local Requirements (*Implementation Profile*)
- Vendor Product (Configured and *Installed*)

Phase 3: Site Specific Testing *(Interoperability Testing)*

Site A
Purchases CEHRT 'ABC'

Vendor CEHRT Product

← Working Interface →
Harmonize local requirements

Site B
Purchases CEHRT 'XYZ'

Vendor CEHRT Product

CEHRT = **C**ertified **EHR** **T**echnology

Site A Specific:
- Revised Test Cases
- Local Requirements
- Local Regulations
- Configuration
- Local Testing
- Results

Site B Specific:
- Revised Test Cases
- Local Requirements
- Local Regulations
- Configuration
- Local Testing
- Results

Conformance

Interoperability

HEALTH IT STANDARDS TESTING INFRASTRUCTURE

NIST

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The NIST EHR-S Certification HL7 V2 Test Tools

2015 Edition Criterion (Proposed Rule)	NIST Test Tool
Transmission to immunization registries (Send + Q/R)	Immunization Messaging
Transmission of reportable laboratory tests and results	Electronic Laboratory Reporting (ELR)
Transmission to public health—syndromic surveillance	Syndromic Surveillance
1) Transmission of laboratory test reports 2) Incorporate laboratory tests and values/results	LRI-Laboratory Results Interface (LRI)
Computerized provider order entry–lab (Orders)	Electronic Directory of Services-(eDOS)
Computerized provider order entry–lab (Compendium)	Laboratory Order Interface (LOI)
2014 Edition Criterion	**NIST Test Tool**
Transmission to immunization registries (Send Only)	Immunization Messaging
Transmission of reportable laboratory tests and results	Electronic Laboratory Reporting (ELR)
Transmission to public health—syndromic surveillance	Syndromic Surveillance
1) Transmission of laboratory test reports 2) Incorporate laboratory tests and values/results	LRI-Laboratory Results Interface (LRI)
2011 Edition Criterion	**NIST Test Tool**
Submission to Immunization Registries (Send Only)	Immunization Messaging
Reportable Lab Results	Electronic Laboratory Reporting (ELR)

Syndromic Surveillance
HL7 V2 Validation Tool - Meaningful Use 2014 Edition Certification Testing

Home | Context-free Validation | Context-based Validation | Profile Viewer | Vocabulary | Documentation | Settings | About

Welcome to the NIST Syndromic Surveillance Validation Suite

The NIST Syndromic Surveillance Validation Suite is intended for certifying 2014 Edition Meaningful Use EHR technology. The validation suite provides functionality to test EHR senders. The Syndromic Surveillance test tool covers the *§170.314(f)(3) Transmission to public health agencies - Syndromic Surveillance* Test Procedure. Use the *Context-based Validation* Tab for Meaningful Use certification testing.

A Google Group (HL7v2 Syndromic Testing) has been established for discussion/questions of the Implementation Guide, testing tool and testing issues. No membership is required. A google account is required for posting.

- Site: https://groups.google.com/d/forum/hl7v2-syndromic-testing
- Email: hl7v2-syndromic-testing@googlegroups.com

The following browsers are supported: Internet Explorer versions 8 and 9, Firefox, and Chrome. Recommended browsers are Internet Explorer 9, Firefox and Chrome.

Key Capabilities

Context-free Testing	**(No Test Cases - Test any Syndromic Surveillance message created by EHR**) • Context is unknown to validation tool • Provides a simple and convenient method for testing message structure and most vocabulary
Context-based Testing	**(Test Cases - Test Syndromic Surveillance message associated with a specific test scenario)** • Context is known to validation tool • All conformance requirements of the SS Implementation Guide can be assessed • Used for certifying 2014 Edition Meaningful Use EHR technology
Profile Viewer	Provides a browsable version of the conformance profile which encapsulates the requirements. Can be used to assist in the interpretation of errors.
Vocabulary Browser	Provides a browsable view of the vocabulary requirements. Can be used to assist in the interpretation of value set errors.
Documentation	Provides access to documents which will assist in using the tool (including test procedure, test cases, profile descriptions, vocabulary descriptions and validation tool download).

On-line Requirements: Message Elements

1 Click on Profile Viewer tab.

2 Data elements may be filtered by Usage.

Select R, RE, C (Only) to view only required, required but may be empty and conditional elements.

Select R, RE, C, O, X (All) to view all data elements, including optional and not supported elements.

3 Click on a tab to filter data elements by segment. The Full tab displays data elements of all segments.

4 Locate data element using element name from the location link.

5 Usage will indicate whether data element is required. The value RE indicates it is but may be empty.

6 Minimum and maximum valid lengths of data element are listed.

7 Make a note of the table ID.

Home   Context-free Validation   Context-based Validation   **Profile Viewer**   Vocabulary   Documentation

Profile   Data Type

G Group **S** Segment **F** Field **C** Component **S** Subcomponent

● R,RE,C (Only)   ○ R,RE,C,O,X (All)

| FULL | MSH | PID | **PD1** | NK1 | ORC | RXA | RXR | OBX | NTE |

Location	Usage	Cardinality	Data Type	Length	Table	Predicate	Conformance Statement
▼ ● PD1.11 : Publicity Code	RE	[0,1]	CE_IZ	[1,483]	0215		
◉ PD1.11.1 : Identifier	R	[1,1]	ST	[1,50]			
◉ PD1.11.2 : Text	RE	[1,1]	ST	[1,999]			
◉ PD1.11.3 : Name of Coding System	R	[1,1]	ID	[1,20]	0396		
◉ PD1.11.4 : Alternate Identifier	RE	[1,1]	ST	[1,50]			
◉ PD1.11.5 : Alternate Text	RE	[1,1]	ST	[1,999]			
◉ PD1.11.6 : Name of Alternate Coding System	C(R/X)	[1,1]	ID	[1,20]	0396	If CE.4 (Alternate Identifier) is valued.	
● PD1.12 : Protection Indicator	RE	[0,1]	ID	[1,1]	0136		
● PD1.13 : Protection Indicator Effective Date	C(RE/X)	[0,1]	DT	[1,8]		If PD1-12 Indicator) is valu	
● PD1.16 : Immunization Registry Status	RE	[0,1]	IS	[1,1]	0441		

Profile Viewer page

This page allows tester to view data element information including usage, cardinality, data type, length, table, condition predicate and conformance statements.

On-line Requirements: Vocabulary

8 Click on Vocabulary tab.

9 Locate and select table ID.

10 Valid values are listed.

11 Use the search box to search for value code, value set, table name, table ID or description.

12 Click on Context-based Validation tab to return to message.

Vocabulary page

This page provides the ability to browse the vocabulary requirements. Search capabilities are provided and include searching on value, table name, table ID and description.

Context-free Testing: HL7 Content
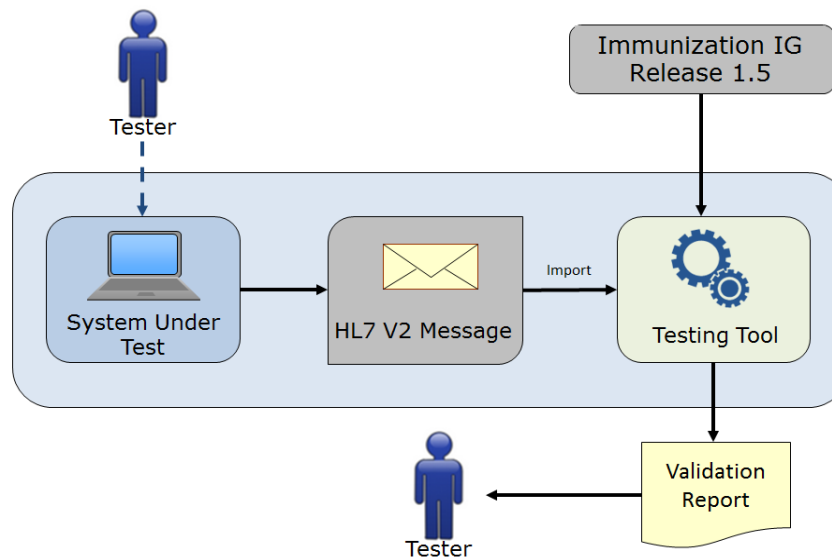
- ➤ No Test Cases provided
- ➤ Context (Test Scenario, etc.) is unknown to validation tool
- ➤ May be used to test any message created by an EHR
- ➤ Provides a simple and convenient method for testing message structure and   most *vocabulary*
- ➤ Typically is not used for certifying EHR technologies for the ONC certification criteria, but may be used for certification testing in specific instances (the Tester must perform visual inspection to validate content of message)

Validate test message and review message validation errors

**HEALTH IT
STANDARDS TESTING INFRASTRUCTURE**

6) Generate Message Validation Report

1 Click on Report Details icon to display Message Validation Report.

2 Message Validation Report may be downloaded as a PDF, XML, Word doc, HTML file.

3 Message Validation Report may be printed.

Context-based Testing (Sending Application)

Test Case

Test Story

Sets the clinical backdrop

Test Data

Typical data available in the real world

Tester

Enters Test Data

EHR

HL7 V2 Message

Content Requirements

Implementation Guide

Requirements

Test Tool

Validation

Validation Report

Tester

Test Story

Description

Following treatment, the patient's vital signs gradually return to normal. At 2 PM, the patient's laboratory and radiology tests results are provided to the attending physician. The tests indicate that the infant has influenza and pneumonia. The patient's mother is provided with treatment information and prescriptions for her infant son. The working diagnosis (ICD-9 CM 487.1) is resolved/inactivated, and at 5 PM the patient is discharged home with a final primary diagnosis of pneumonia, and secondary diagnosis of influenza. Big City Children's Urgent Care routinely sends electronic syndromic surveillance data to the Big City Health Department (BCHD) in accordance with a city regulation. At 6:00 PM on February 20, 2010, the facility's electronic health record module for syndromic surveillance data assembles and transmits a Discharge ADT message about this patient encounter to BCHD.

Comments

This Test Case provides an example of clinical encounter that could take place in either an urgent care or emergency clinical setting. It is therefore applicable to EHR technology used in some ambulatory settings. Dates and times are provided in this test case to illustrate the sequence of clinical and messaging events. Since the exact dates and times are not reproducible when modeling the test case with EHR technology, only date and time format will be validated within tester submitted test data. ICD 9 CM diagnosis codes are acceptable with or without decimals.

TestObjectives

Output an ADT A03 discharge message in HL7 2.5.1 containing the syndromic surveillance data for the patient encounter.

Notes to Testers

This Test Case does not prescribe the method used by the EHR to change a Working diagnosis to a Final diagnosis. The Test Case only validates a specific ADT message type. Although the other units of measure for patient age are acceptable in general (and the Context-free validation accepts any of the valid units of measure for age), the SS_1_1_UC_Visit Test Case specifies that "a" for years be used in this message for the Context-based validation. Certain health departments mandate that the patient age be sent in years only, and the EHR must be able to support sending "0 years".

1) Select Test Case and Review Test Story

1 Open Immunization Validation tool using link: http://hl7v2-iz-testing.nist.gov.

2 Click on Context-based Validation tab.

5 Test Story may be downloaded as a PDF file.

6 Test Case Package may be downloaded as a PDF file.

3 Click on arrows to expand the Test Scenarios and Test Cases. Click on a Test Step.

4 Test Story displays.

| Home | Context-free Validation | Context-based Validation | Profile Viewer | Vocabulary | Documentation |

Test Case   Validation   Report

Test Cases

- ▼ IZ_1_Admin_Child
  - ▼ IZ_1_1_Admin_Child
    - IZ_1_1.1_Max
  - IZ_1_2_Admin_Child
  - IZ_1_3_Admin_Child
- IZ_2_Admin_Adult
- ▶ IZ_3_Historical_Child
- ▶ IZ_4_Consented_Child
- ▶ IZ_5_Refused_Toddler
- ▶ IZ_6_Varicella_History_Child
- ▶ IZ_7_Complete_Record

Title: IZ_1_1.1_Max   ⟲ Download Package(.pdf)   ▶ Select

Test Story   Test Data Specification   Message Content

⟲ Download as PDF

Description

For purposes of reporting immunizations this clinic has been assigned an id of X68 by the Immunization Information System (IIS). A toddler, Madelynn Ainsley Snow, is brought to the clinic on July 4, 2012 by her mother, Morgan Lam, for a well child visit. A clinician staff collects basic identifying information, including name, birth date, sex, address, phone, SSN, race, and ethnicity. A clinician staff review the patient's vaccination history and determines that the patient needs an an Influenza (Fluvin)vaccination. A clinician interviews the mother and determines that the patient qualifies for a Vaccines For Children (VFC) supplied vaccine under the status of VFC eligible - Federally Qualified Health Center Patient (under-insured). The clinic staff gives the mother a Vaccine Information Statement for Inactivated Flu published by the CDC on Jul 2, 2012 to review. After reading the VIS the mother agrees that the child should receive the vaccination. The clinic staff explains that information about this vaccination will be sent to the IIS and ask if the IIS can send a reminder about when the next vaccination is due. The mother indicates that contact should be made by the IIS. The clinic staff then prepares an Influenza vaccination dose, CSL Behring Lot #Z0860BB, from the VFC publicly supplied vaccine stock and administers it to the patient in the left arm. The clinic staff enters the patient demographic information, VFC status, VIS information, contact status, and vaccination administration information into the EHR and transmits it to the IIS, indicating to the IIS that an active patient of the clinic was administered a vaccination.

PreCondition

NO PreCondition.

PostCondition

NO PostCondition.

Test Data

Patient Information

Element Name	Data
Name	Coded Pseudo-Name to ensure anonymity
Gender	Male
Race	Native Hawaiian or Other Pacific Islander
Ethnic Group	Not Hispanic or Latino
Zip Code	02130
County/Parish Code	25025

Visit Information

Element Name	Data
Admit Date and Time	02/20/2010 8:30 AM
Discharge Disposition	Discharged to home or self care (routine discharge)
Diagnosis Type	Final
Diagnosis	Pneumococcal pneumonia [Streptococcus pneumoniae pneumonia]
Diagnosis Type	Final
Diagnosis	Influenza

Observation Results Information

Element Name	Data
Observation Identifier	Chief complaint:Find:Pt:Patient:Nom:Reported
Observation Value	Fever, cough
Units	
Observation Results Status	Final results; Can only be changed with a corrected result.

2) Review Test Data Specification and Message Content

1 Click on Test Data Specification tab.

2 Full tab is selected by default. To view a specific section, click on a tab.

3 Relevant real-world clinical data is displayed.

4 Test Data Specification may be downloaded as a PDF file.

Test Data Specification page

This page specifies the data that are entered (automatically/manually) into the EHR and included in the message that is created and submitted from the EHR to the Immunization validation tool. The tester shall identify an existing patient record in the EHR or shall create a patient record in the EHR using the data in the Data Sheet associated with the Test Case.

Message Content

PID : Patient Identification Segment

Location	Data Element	Data	Categorization
PID.1	Set ID - PID	1	IG Fixed Data
PID.3	Patient Identifier List		
PID.3.1	ID Number	3333	Changeable Data
PID.3.5	Identifier Type Code	MR	Changeable Data
PID.5[1]	Patient Name		
PID.5[1].7	Name Type Code		
PID.5[2]	Patient Name		
PID.5[2].7	Name Type Code	S	Test Case Fixed Data
PID.8	Administrative Sex	M	Test Case Fixed Data

DG1 : Diagnosis Segment

Location	Data Element	Data	Categorization
DG1.1	Set ID - DG1	1	IG Fixed Data
DG1.3	Diagnosis Code - DG1		
DG1.3.1	Identifier	481	Test Case Fixed Data
DG1.3.2	Text	Pneumococcal pneumonia [Streptococcus pneumoniae pneumonia]	Changeable Data
DG1.3.3	Name of Coding System	I9CDX	IG Fixed Data
DG1.6	Diagnosis Type	F	Test Case Fixed Data

DG1 : Diagnosis Segment

Location	Data Element	Data	Categorization
DG1.1	Set ID - DG1	2	IG Fixed Data
DG1.3	Diagnosis Code - DG1		
DG1.3.1	Identifier	487	Test Case Fixed Data
DG1.3.2	Text	Influenza	Changeable Data
DG1.3.3	Name of Coding System	I9CDX	IG Fixed Data
DG1.6	Diagnosis Type	F	Test Case Fixed Data

OBX : Observation/Result Segment

Location	Data Element	Data	Categorization
OBX.1	Set ID	1	IG Fixed Data
OBX.2	Value Type	CWE	Test Case Fixed Data
OBX.3	Observation Identifier		
OBX.3.1	Identifier	SS003	Test Case Fixed Data
OBX.3.3	Name of Coding System	PHINQUESTION	Test Case Fixed Data
OBX.5-CWE	Observation Value		
OBX.5-CWE.1	Identifier	261QU0200X	Test Case Fixed Data
OBX.5-CWE.2	Text	Urgent Care	Changeable Data
OBX.5-CWE.3	Name of Coding System	NUCC	Test Case Fixed Data

5) Validate test message and review validation errors

Testing Immunization Evaluated History and Forecast

- Test the ability of an EHR Requester SUT to query for an Evaluated History and Forecast
- Test receipt and display the Evaluated History and Forecast
- Tester uses Juror Document to assess conformance to Display requirements.

HEALTH IT
STANDARDS TESTING INFRASTRUCTURE
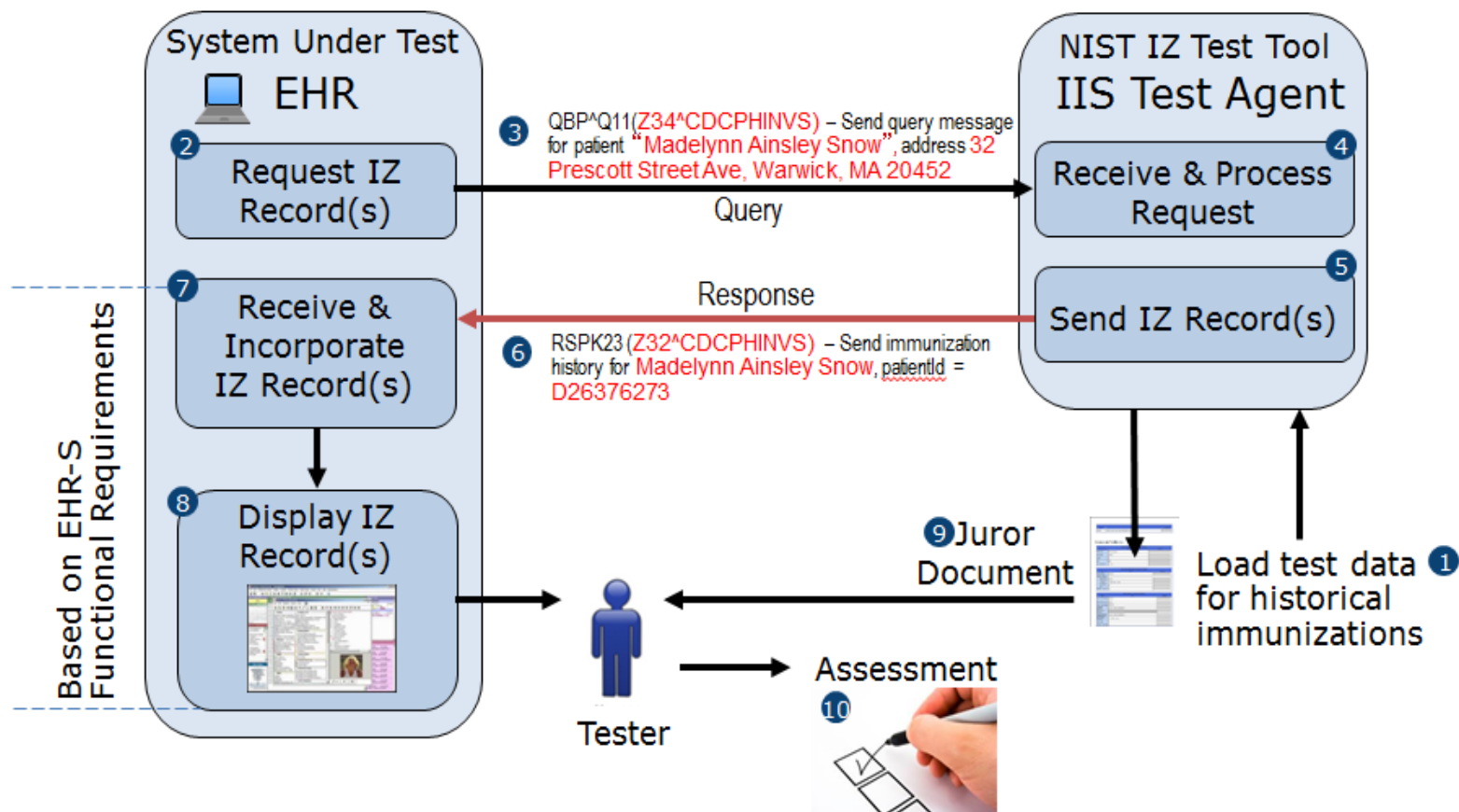
Juror Document: Display Immunization History & Forecast

Evaluated Immunization History and Immunization Forecast (RSP Z42)	
Test Case ID	
Inspection Date/Time	
Inspection Settlement	Pass / Fail
Juror ID	
Juror Name	

Patient Information

Patient Identifier	Patient Name	DOB	Gender	Tester Comment
123456	Clement S Stanley	02/14/1950	Male	

When displayed in the EHR with the Evaluated Immunization History and Immunization Forecast, these patient demographics data may be derived from either the received immunization message or the EHR patient record. When displaying demographics from the patient record, the EHR must be able to demonstrate a linkage between the demographics in the message (primarily the patient ID in PID-3.1) and the patient record used for display to ensure that the message was associated with the appropriate patient.

Evaluated Immunization History

Vaccine Group	Vaccine Administered	Date Administered	Valid Dose	Validity Reason	Completion Status*	Tester Comment
Hep B NOS	Hep B Peds NOS	04/15/2009	YES		Complete	
Hep B NOS	Hep B Peds NOS	05/15/2009	YES		Complete	
Hep B NOS	Hep B Peds NOS	12/15/2009	YES		Complete	
DTAP NOS	DTP	04/15/1960	YES		Complete	
polio NOS	polio NOS	04/15/1960	YES		Complete	
polio NOS	polio NOS	06/15/1960	YES		Complete	
polio NOS	polio NOS	09/10/1960	YES		Complete	
polio NOS	polio NOS	04/15/1961	YES		Complete	
pneumococcal ppv23	pneumococcal ppv23	04/15/2013	YES		Complete	
Td NOS	Td NOS	04/15/2009	YES		Complete	
influenza NOS	influenza NOS	10/15/2009	YES		Complete	
influenza NOS	influenza seasonal	10/15/2010	YES		Complete	
influenza NOS	seasonal flu	09/01/2011	YES		Complete	

* "Completion Status" refers to the status of the dose of vaccine administered on the indicated date and may be interpreted as "Dose Status". A status of "Complete" means that the vaccine dose was "completely administered" as opposed to "partially administered".

Immunization Forecast

Vaccine Group	Due Date	Earliest Date To Give	Latest Date to Give	Series Status	Forecast Reason	Tester Comment
pcv NOS	02/14/2015	09/14/2015	11/11/2015			
influenza NOS	09/14/2015	09/14/2015	11/11/2015			

Select Test Case, Load, and Send Test Message to EHR-S

1 Message displays with configured receiver info in message content.

2 Click on Send button.

Testing Display: Review Juror Document for Test Case

1 Click on Test Case tab.

2 Click on arrows to expand the Test Scenarios and Test Cases under NIST. Click on a Test Case.

3 Click on Juror Document tab.

4 Full version of Juror Document will display.

5 Data elements that should display or be stored in EHR system display based on the selected Test Case.

Juror Document

The Juror Document is the test case-specific checklist the Tester uses to document the presence or absence of the data in the EHR for data elements transmitted to EHR from LIS Test Harness. The data elements are categorized attestation criteria. Some elements are required to be displayed to the clinical user on the EHR screen. Others are attested by viewing database records or configuration files.

Context-based Test Framework Architecture
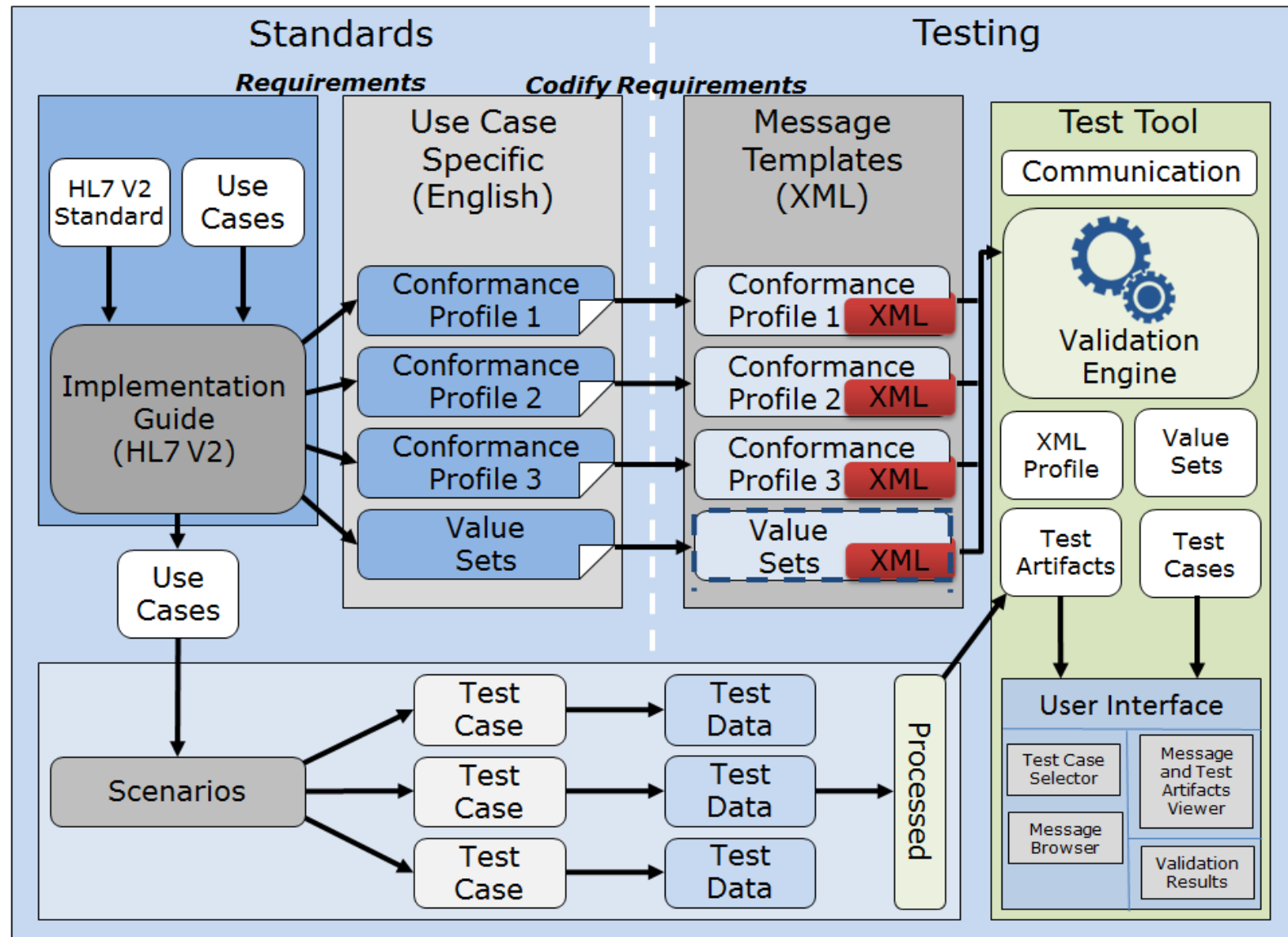
Summary

- ➢ Need quality healthcare data communication standards

- ➢ Standards must be very specific to targeted use cases

- ➢ Conformance and interoperability testing is essential

- ➢ Certified EHR systems provide a core set of standardized capabilities that will improve interoperability

- ➢ Interoperability between systems is critical for successful adoption and use of EHRs