An HL7 v2 Platform for Standards Development and Testing

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Agenda

- ❑ Overview of NIST
- ❑ NIST Activities in HIT
- ❑ What are we trying to solve?
  - ❑ Foundation for Interoperability
  - ❑ An End-to-End Strategy
- ❑ NIST HL7 v2 Platform Overview
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  - ❑ Testing Infrastructure & Framework
- ❑ NIST HL7 v2 Tooling Portfolio

National Institute for Standards and Technology (NIST)

❑ Part of the Department of Commerce

❑ Founded in 1901 as National Bureau of Standards

❑ The mission of NIST is to promote **U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology** in ways that enhance economic security and improve our quality of life.

❑ Laboratories and Centers

  ❑ Communications Technology Laboratory
  ❑ Engineering Laboratory
  ❑ **Information Technology Laboratory**
  ❑ Material Measurement Laboratory
  ❑ Physical Measurement Laboratory
  ❑ Center for Nanoscale Science and Technology
  ❑ Center for Neutron Research

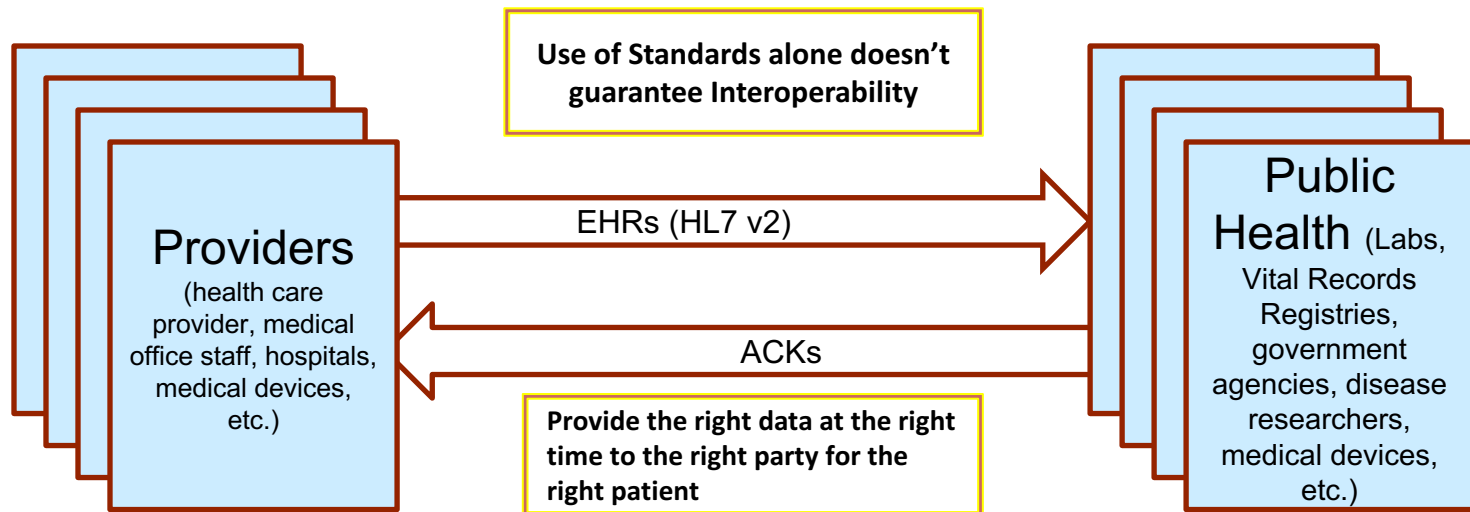❑ Campuses in Gaithersburg, MD and Boulder, CO, ~3000 employees

NIST Activities in HIT

❑ Under HITECH ACT, developing a **health IT standards testing infrastructure** to support current and future testing needs within the healthcare domain

  ❑ Developed the conformance test method (test procedures, test data, and test tools) to measure HIT compliance with the ONC 2011, 2014, and 2015 Edition certification criteria that named interoperability standards

  ❑ Developed conformance test tools to assure that the standards are implemented correctly and consistently (HL7, IHE, ONC, CDC, AIRA, …)

  ❑ Supports Standard Development Organizations (SDOs) via guidance; and assessment and certification programs via tools, but does not perform certification

What is the problem we are trying to solve?

Correct data exchange is critical for ensuring reliable healthcare systems. Standards based systems are the foundation for achieving this goal. **However, standards alone are not enough to ensure this promise; conformance and interoperability testing are essential.**

Use of Standards alone doesn't guarantee Interoperability

Providers (health care provider, medical office staff, hospitals, medical devices, etc.)

EHRs (HL7 v2) →

ACKs

Public Health (Labs, Vital Records Registries, government agencies, disease researchers, medical devices, etc.)

Provide the right data at the right time to the right party for the right patient

Challenges:

- Standards are not well-defined
- Difficult to decipher requirements
- Many mistakes
- Many requirements left to interpretation

- Gaps in requirements
- Lack of reference and pilot implementations
- Lack of testing

Foundation for Interoperability

❑ Well-defined Standards

❑ Testing

❑ Implementation

❑ Standards Development Lifecycle
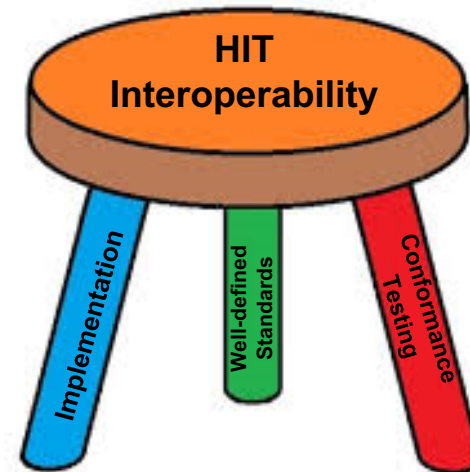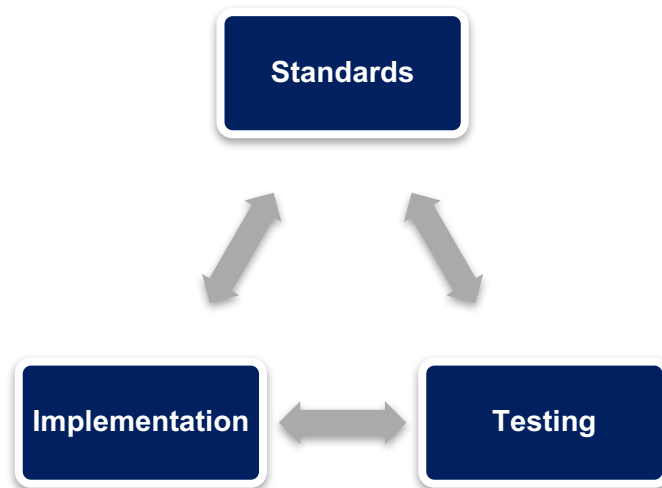
Success depends on:

- ❑ Well-defined Standards – precise and complete requirement specification
- ❑ Testing standards and trial implementations
  - ❑ Conformance Test tools
  - ❑ Initial test implementations
    - ❑ Reference
    - ❑ Pilot
- ❑ Standards Development Lifecycle
  - ❑ Feedback to authors, tool developers, and implementers
- ❑ Interoperability Testing

Failure happens when:

❑ One or more components are omitted or are not sufficient
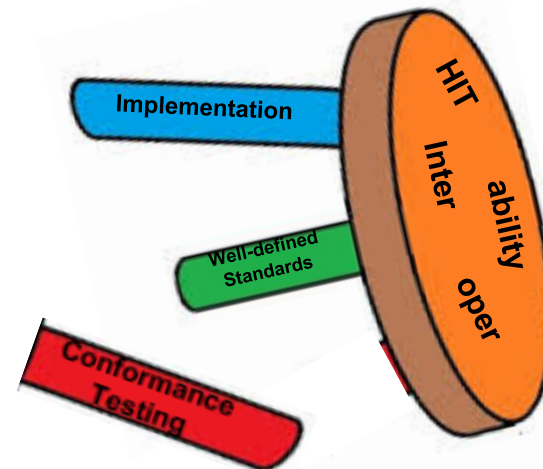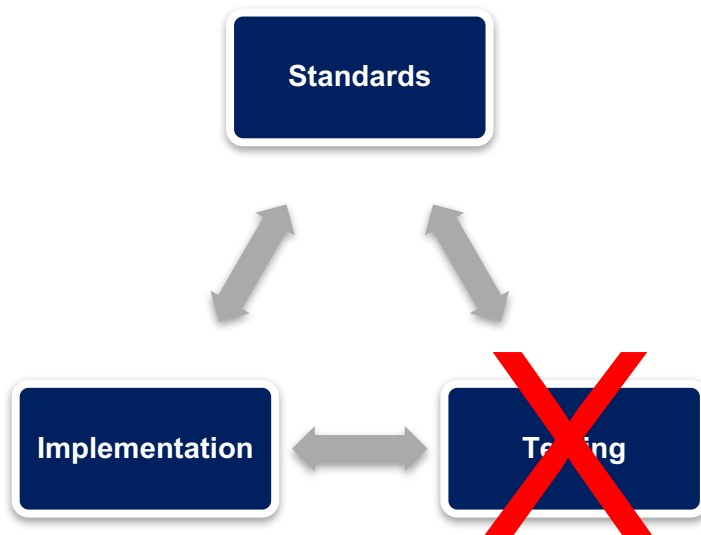
An End-to-End Strategy

❑ Specification of Requirements

❑ Development of Specifications

❑ Development of Test Cases

❑ Testing Infrastructure

❑ Platform to build and manage tools

❑ NIST builds the platform—let domain experts create and maintain guides, test cases, and tool instances via productivity tools

NIST HL7 v2 Platform Overview
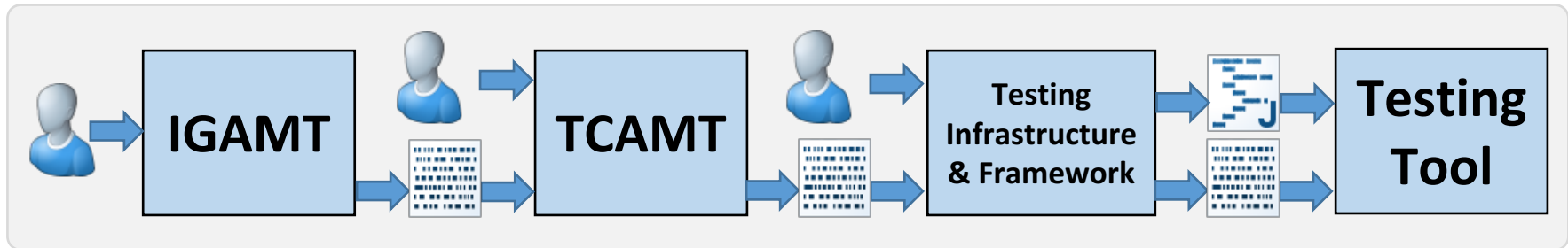
- ❑ IGAMT – Implementation Guide Authoring and Management Tool

- ❑ TCAMT – Test Case Authoring and Management Tool

- ❑ Testing Infrastructure and Framework

- ❑ Testing Tool

Implementation Guide Authoring and Management Tool (IGAMT)

❑ **Tool to create standards (i.e. HL7 v2 implementation guides)**

❑ Narrative + Message Definition

❑ **Built-in template**

❑ Supports current conformance constructs

❑ **Enforces conformance rules**

❑ **Promotes consistency in requirements**

❑ XML export is gateway to other services

❑ **Single source of truth**

❑ **Constraints for basic testing (context-free)**

Test Case Authoring and Management Tool TCAMT

❑ Tool Test Plans and Test Cases

❑ **Import XML profiles in IGAMT format**

❑ XML profiles provides underlying model

❑ Expands testing capabilities

❑ Example/test messages

❑ XML export is gateway to other services
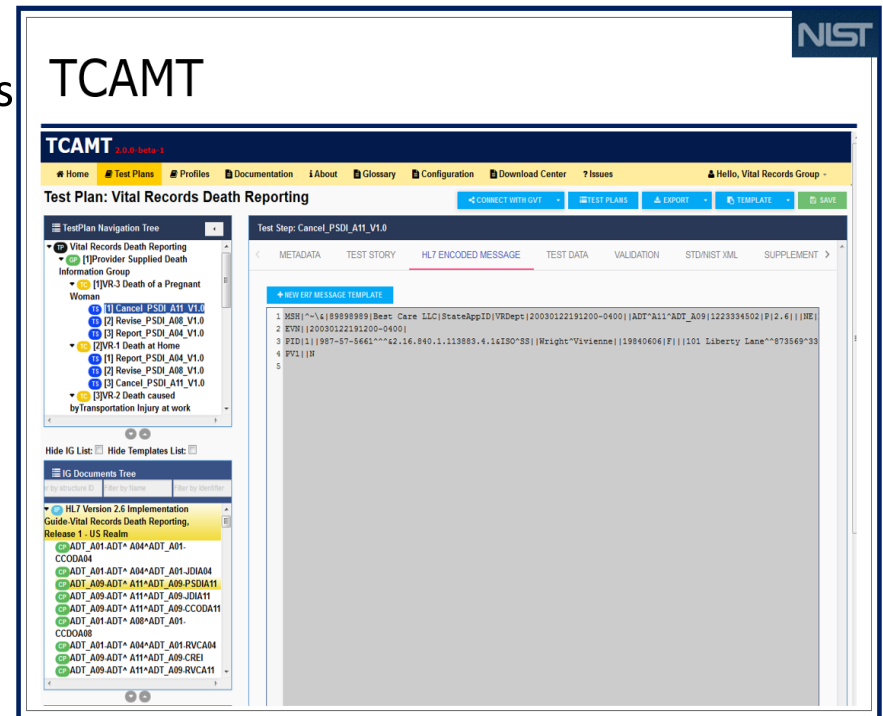
Context-free Validation

Context-based Validation

Testing Infrastructure & Framework

- ❑ Provides core services
  - ❑ E.g., Validation Engine
- ❑ Building Blocks
- ❑ XML profiles provides underlying model
- ❑ NIST-built constraint mechanism
- ❑ Expands testing capabilities
- ❑ Builds test/example messages
- ❑ XML export is gateway to other services
- ❑ Single source of truth

NIST Testing Platform

Testing Resources

Single source of truth

IGAMT

Standard Constraints

Word
PDF
HTML

TCAMT

Standard Constraints and Test Case Constraints

Test Plan

Testing Infrastructure & Framework

General Validation Tool (GVT)

NIST Testing Tools (Web Apps)

✓ Web Services
✓ Validation Jar
✓ Source Code

Standard Constraints and Data Quality Constraints

= XML

Used to integrate in 3ʳᵈ party environments

NIST HL7 v2 Tool Portfolio

❑ https://hl7v2tools.nist.gov

Standard	Owner	Testing Program	Links
Immunization R1.4*	CDC	✓ ONC 2014 Ed. Certification	http://hl7v2-iz-testing.nist.gov
Immunization R1.5*	CDC	✓ ONC 2015 Ed. Certification ✓ AIRA IIS Assessment ✓ HIMSS/CDC EHR Certification	http://hl7v2-iz-r1.5-testing.nist.gov http://iztool-cdc.hit.icsl.net:8080/iztool
Syndromic Surveillance R1.1*	CDC/ISDS	✓ ONC 2014 Ed. Certification	http://hl7v2-ss-testing.nist.gov
Syndromic Surveillance R2.0*	CDC/ISDS	✓ ONC 2015 Ed. Certification	http://hl7v2-ss-r2-testing.nist.gov
ELR (Reportable Labs) R1.0*	HL7	✓ ONC 2014/2015 Ed. Certification	http://hl7v2-elr-testing.nist.gov
LOI R1 DSTU R2	HL7/ONC	✓ ONC Pilot Testing	http://hl7v2-loi-r1-testing.nist.gov
LRI R1 DSTU R2	HL7/ONC	✓ ONC Pilot Testing	http://hl7v2-lab-r2-testing.nist.gov
eDOS R2 DSTU R2	HL7/ONC	✓ ONC Pilot Testing	http://hl7v2-edos-r1-testing.nist.gov
Vital Records DR R1	CDC/HL7/IHE	✓ CDC ✓ IHE Connect-a-thon	http://hl7v2-vr-r2-testing.nist.gov
Height and Weight	CDC/IHE	✓ CDC ✓ IHE Connect-a-thon	http://hl7v2-cf-validator.nist.gov
Patient Care Devices (PCD)	IHE	✓ IHE Pre-connect-a-thon ✓ IHE Connect-a-thon	http://ihe-pcd-precon.nist.gov http://ihe-pcd-con.nist.gov
PIX and PDQ	IHE	✓ IHE Pre-connect-a-thon ✓ IHE Connect-a-thon	http://pixpdqtests.nist.gov http://hl7.connectathon-pixpdq.nist.gov/

*State Registries use for on-boarding   ✓ **Unknown number of local installations**

NIST Productivity Tool – IGAMT

IGAMT – Implementation Guide Authoring and Management Tool			
Standard	**Developer**	**Use**	**HL7 Version**
Immunization HL7 R1	CDC	✓ May 2017 HL7 Ballot	HL7 v2.8.2
Immunization R1.5	NIST	✓ NIST Internal for ONC 2015 Ed. Certification	HL7 v2.5.1
Syndromic Surveillance R2.?	CDC/ISDS	✓ In Progress	HL7 v2.5.1
Syndromic Surveillance R2.0	NIST	✓ NIST Internal for ONC 2015 Ed. Certification	HL7 v2.5.1
Vital Records Death Reporting	NIST	✓ NIST Internal for 2017 Connectathon Testing	HL7 v2.6
Vital Records Birth Reporting	CDC	✓ May 2017 HL7 Ballot	HL7 V2.6
LOI R1 DSTU R2	NIST	✓ NIST Internal-In Progress	HL7 v2.5.1
LRI R1 DSTU R2	NIST	✓ NIST Internal-In Progress	HL7 v2.5.1
eDOS R2 DSTU R2	NIST	✓ NIST Internal-In Progress	HL7 v2.5.1
Patient Care Devices (PCD)	NIST	✓ NIST Internal-In Progress for IHE	HL7 v2.6
Electronic Case Reporting	CDC	✓ In Progress	HL7 v2.5.1
Local Use	Vendors/States	✓ Unknown	Unknown

✓ **= 30+ registrations**

IGAMT-generated implementation guides balloted by HL7

NIST Productivity Tool – TCAMT

TCAMT – Test Case Authoring and Management Tool		
Standard	**Developer**	**Use**
Immunization R1.5	CDC/CNI/HIMSS	✓ HIMSS Certification
Immunization R1.5	CDC/NIST	✓ ONC 2015 Ed. Certification
Immunization R1.5	AIRA	✓ AIRA IIS Assessment Program
Syndromic Surveillance R2.0	ISDS/NIST	✓ ONC 2015 Ed. Certification
Vital Records Death Reporting	CDC/NIST	✓ IHE Pre-connect-a-thon/Connect-a-thon, CDC
Vital Records Birth Reporting	CDC/NIST	✓ IHE Pre-connect-a-thon/Connect-a-thon, CDC – In Planning
LOI R1 DSTU R2	NIST	✓ NIST Internal-In Progress
LRI R1 DSTU R2	NIST	✓ NIST Internal-In Progress
eDOS R2 DSTU R2	NIST	✓ NIST Internal-In Progress
Patient Care Devices (PCD)	NIST	✓ NIST Internal-In Progress for IHE
ePrescribing	NIST/NCPDP	✓ Tool in development (Adapted)

❑ **TCAMT allows domain experts to develop test scenarios and test cases, with example messages—set in the foundation of the XML Profile created in IGAMT.**

❑ **Scenarios can be created to test capabilities, workflow, functional requirements, and robustness via "negative" testing.**

NIST Testing Tools & Resources – HL7 v2 Portal

Menu

- All Tools
- Technical Support
- Interoperability Testbed

Tools By Standard
- HL7 v2
- HL7 v3
- CDA/CCDA
- ISO/IEEE 11073
- XD* (Profiles)
- NCPDP

Tools By Functional Domain
- Document Sharing
- Medical Devices
- ePrescribing
- Lab
- Pubilc Health
- Patient Identification

Tools By Operational Domain
- Meaningful Use
- IHE
- NwHIN (Healtheway)

HL7v2 Immunization Test Suite (2015 Edition)	HL7v2 Syndromic Surveillance Test Suite (2015 Edition)	Electronic Lab Reporting (2014 and 2015 Edition)	Immunization (2014 Edition)	Syndromic Surveillance (2014 Edition)	Laboratory Results Interface (2014 Edition)
IHE PCD Pre-Connectathon	IHE PCD Connectathon	IHE PIX and PDQ Pre-Connectathon	IHE PIX and PDQ Connectathon	HL7v2 Context-free (Vital Records Death and Height and Weight)	HL7 Web Services
HL7v2 Lab Compendium (eDOS)	HL7v2 Lab Results Interface (LRI) Release 2 (2015)	Test Case Authoring and Management Tool (TCAMT)	Implementation Guide Authoring Tool (IGAMT)	NIST Vital Records (2016)	

Tools to Build Tools

http://hl7v2tools.nist.gov/portal/#/tools

In Summary

❑ NIST research provides an end-to-end methodology and platform for developing standards, test plans, and testing tools in the HL7 v2 technology space.

❑ The platform addresses the three foundational components of HIT Interoperability:

  ❑ a tool to create implementation guides and conformance profiles and promote well defined standard
  ❑ a tool to author and manage test cases
  ❑ a testing infrastructure and test framework to build testing tools.

❑ Our goal is to operationalize the platform

  ❑ Could be part of HL7 v2 ballot process

Thank You

Questions

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