The Role of Standards in Preventing & Mitigating Health IT Patient Safety Risks

Health IT Community Technical Workshop

Standards for Interoperability: Life and Death Implications in Health IT

September 7, 2016

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Final

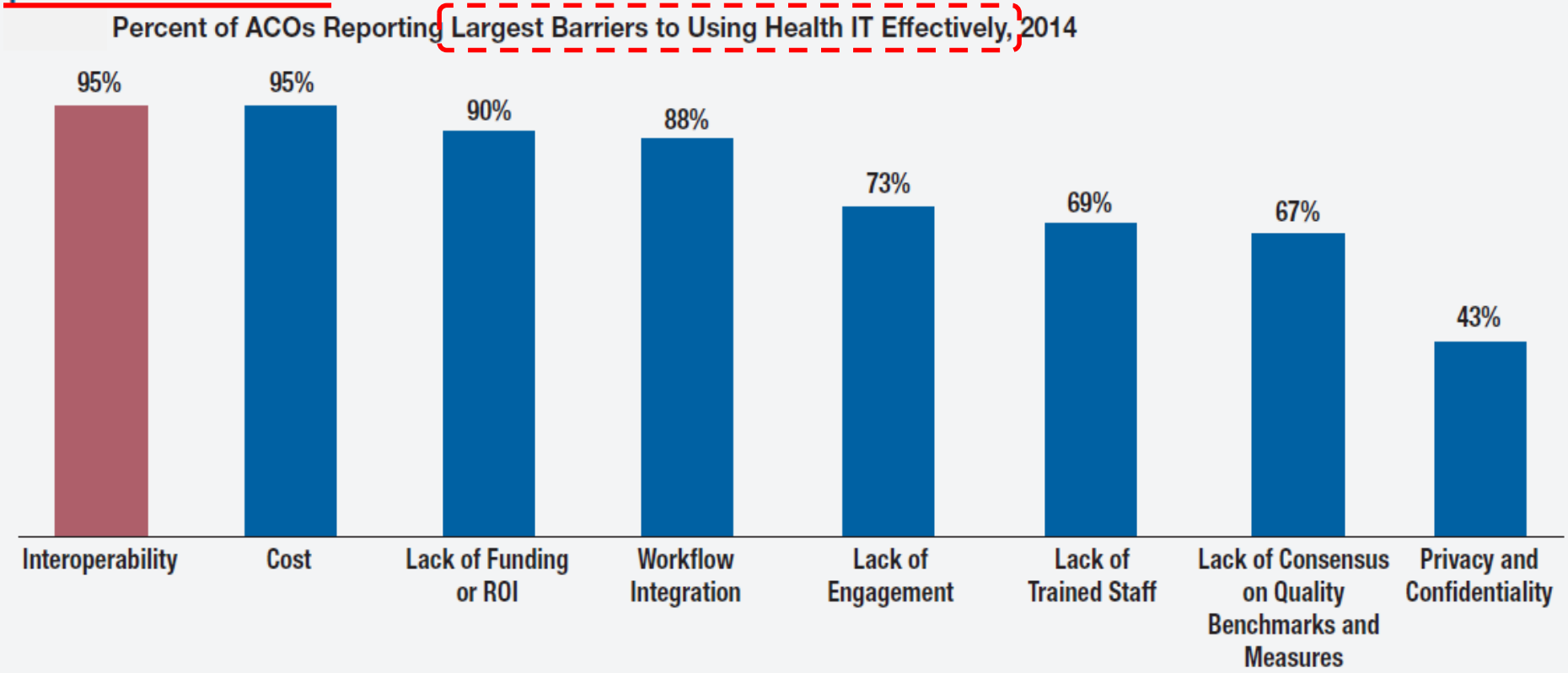
Purpose

Make the case for the link between use of Health IT interoperability standards and patient safety

- Provide definition of interoperability, relationship to standards
- Describe four levels of Health IT (HIT) interoperability
- Provide examples of the impact each level of HIT interoperability / use of standards could have on patient safety
- Describe the role NIST plays in development and use of HIT interoperability standards
- Introduce examples of HIT interoperability standards used by NIST
- Introduce examples of available documents that provide guidance about HIT interoperability and use of standards

Perception of Interoperability for Healthcare

Interoperability is almost universally seen as a major obstacle to effectively using and meeting the potential of health IT.



Source: Premier, Inc. and eHealth Initiative survey of accountable care organizations fielded July – August 2014. 62 organizations responded to the survey.

Interoperability Definitions

Interoperability

- Ability of different information technology systems and software applications to **communicate, exchange data, and use the information** that has been exchanged.

  HIMSS *Dictionary of Healthcare Information Technology Terms, Acronyms and Organizations*, 2nd Edition, 2010, Appendix B, p190, original source: Wikipedia.
  http://www.himss.org/library/interoperability-standards/what-is-interoperability

HIT Interoperability

- Ability of a system to exchange **electronic health information** with and use electronic health information from other systems **without special effort on the part of the user**

  Definition derived from the Institute of Electrical and Electronics Engineers (IEEE)
  http://www.ieee.org/education careers/education/standards/standards glossary.html

- Ability of **health information systems** to work together **within and across organizational boundaries** in order to advance the effective delivery of healthcare for individuals and communities.

  HIMSS Dictionary of Healthcare Information Technology Terms, Acronyms and Organizations, 3rd Edition, 2013, p. 75.
  http://www.himss.org/library/interoperability-standards/what-is-interoperability

Made possible (not guaranteed) by the implementation of standards

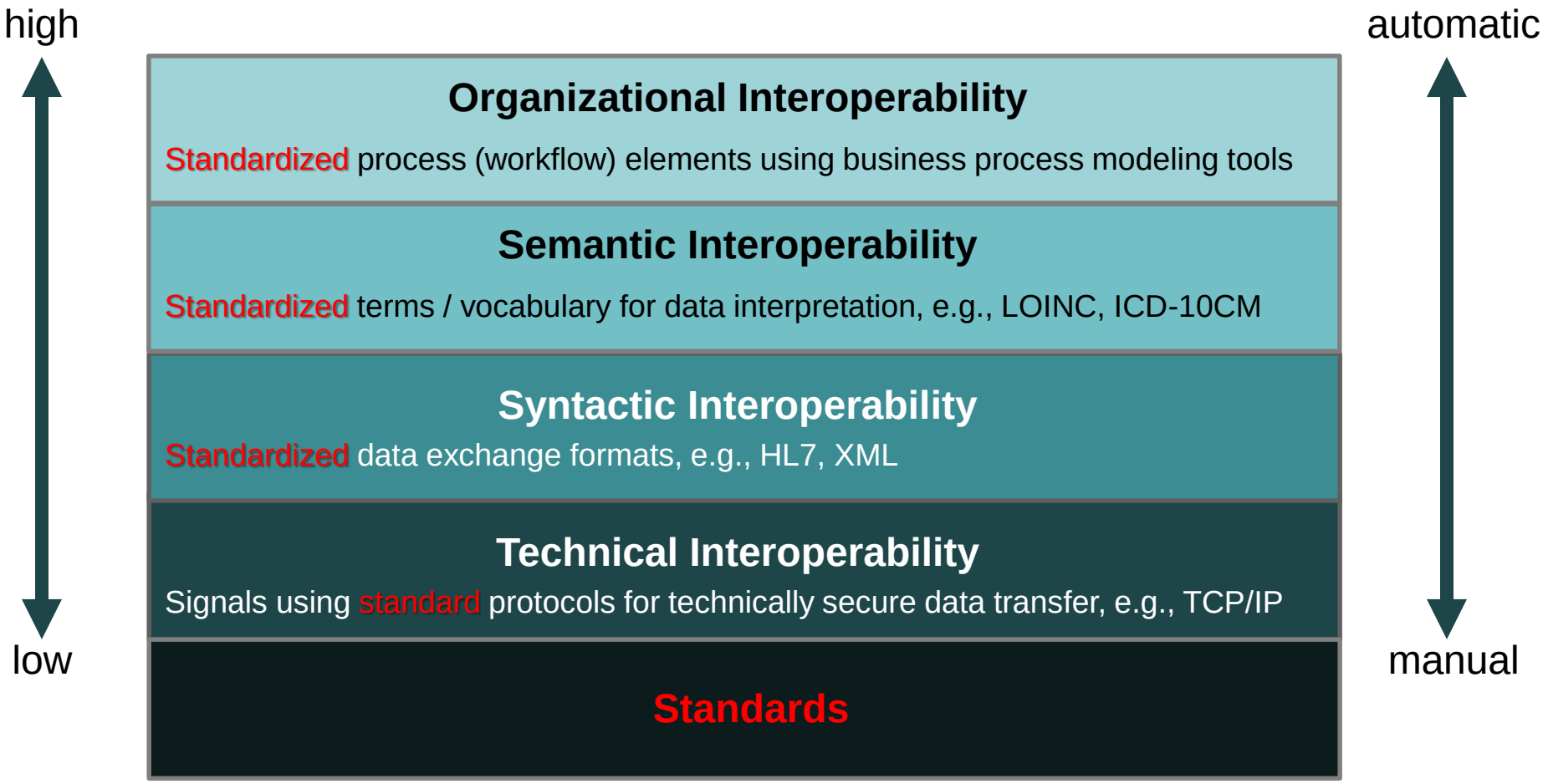
Challenges with HIT Interoperability Standards

- Standards can be non-existent for certain domains
- Existing standards can be poorly defined
- Poorly-defined standards can be poorly implemented
- Well-defined standards can be poorly implemented
- Well-defined standards can be ignored

Standards don't always mean interoperability

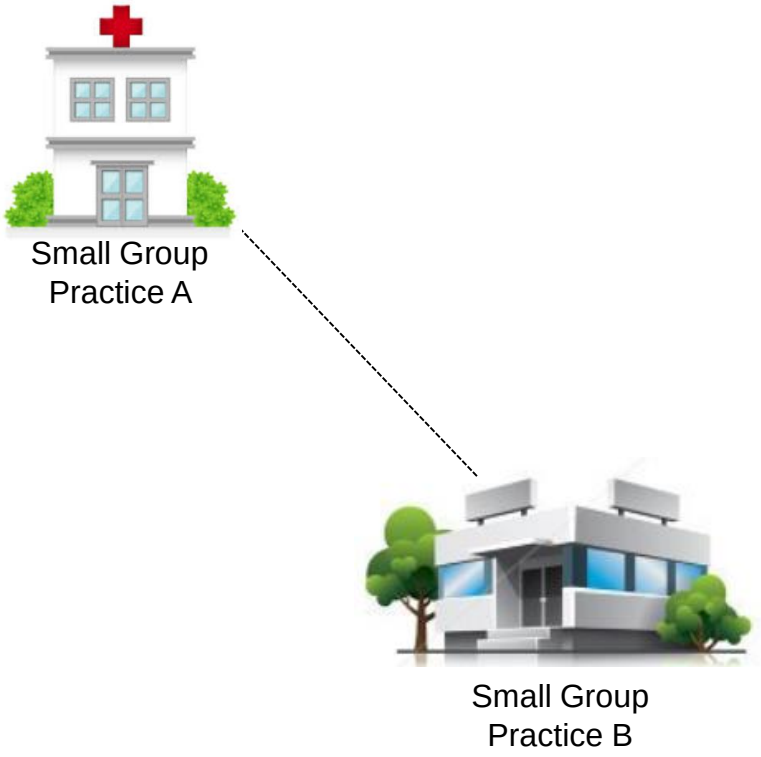
"We are now in the Electronic Health Record business. We found a teenage hacker in _____ who can build us an EHR system on the cheap. Start the marketing campaign."

Four Levels of HIT Interoperability



Based on diagram in a soon-to-be published book on HIT conformance testing co-authored by Rob Snelick of NIST Information Technology Laboratory (ITL)

HIT Interoperability and Patient Safety – Scenario 1

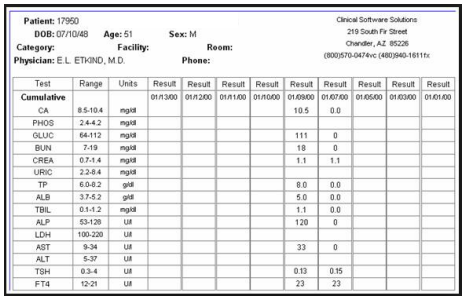


- An interface has been installed between the HIT systems used by two small group practices
- Interface consists of signals using standard protocols for technically secure data transfer
- Practices send / receive encrypted emails with attachments using a feature of the HIT systems
- These systems are interoperable only at a primitive level that requires significant manual processing

Technical (Foundational) Interoperability

Interoperability Gaps and Patient Safety – Scenario 1

- Group Practice A electronically transmits encrypted email with pdf attachment containing patient's lab **test results** to Group Practice B
- Nurse at Group Practice B opens email message
  - Downloads, prints, makes copies of attachment
  - Reads and interprets data in attachment
  - Gives copies to physician and other care team members
  - Manually enters data on attachment into patient's record in office HIT system (e.g., EHR*)
- Errors made during manual transcription of test results into HIT system cause delay in initiation of patient's treatment, resulting in hospitalization



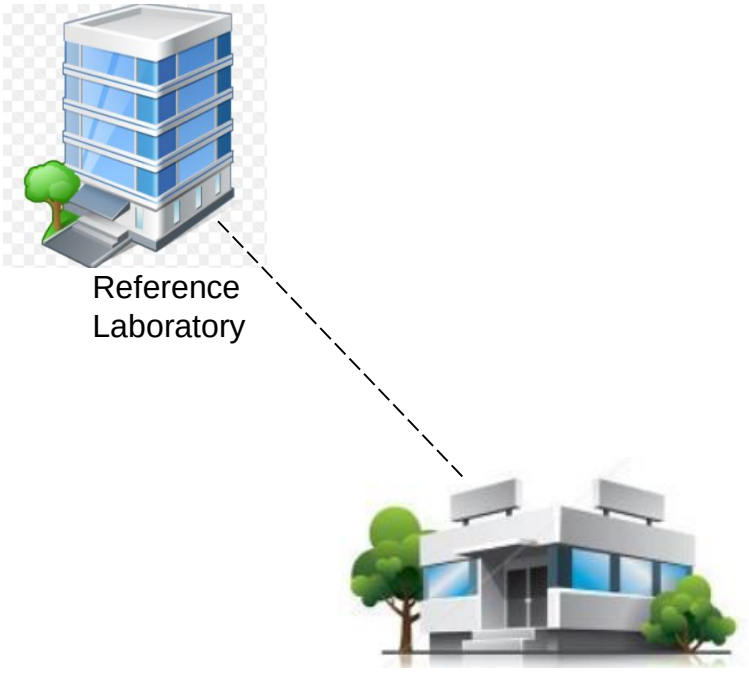
Patient: 17950
DOB: 07/10/48 Age: 51 Sex: M
Category: Facility: Room:
Physician: E.L. ETKIND, M.D. Phone:

Clinical Software Solutions
219 South Fir Street
Chandler, AZ 85226
(800)570-0474vc (480)940-1611fx

Test	Range	Units	Result	Result	Result	Result	Result	Result	Result	Result	Result
Cumulative			01/13/00	01/12/00	01/11/00	01/10/00	01/09/00	01/07/00	01/05/00	01/03/00	01/01/00
CA	8.5-10.4	mg/dl					10.5	0.0			
PHOS	2.4-4.2	mg/dl									
GLUC	64-112	mg/dl					111	0			
BUN	7-19	mg/dl					18	0			
CREA	0.7-1.4	mg/dl					1.1	1.1			
URIC	2.2-8.4	mg/dl									
TP	6.0-8.2	g/dl					8.0	0.0			
ALB	3.7-5.2	g/dl					5.0	0.0			
TBIL	0.1-1.2	mg/dl					1.1	0.0			
ALP	53-128	U/l					120	0			
LDH	100-220	U/l									
AST	9-34	U/l					33	0			
ALT	5-37	U/l									
TSH	0.3-4	U/l					0.13	0.15			
FT4	12-21	U/l					23	23			

*Electronic Health Record

HIT Interoperability and Patient Safety – Scenario 2

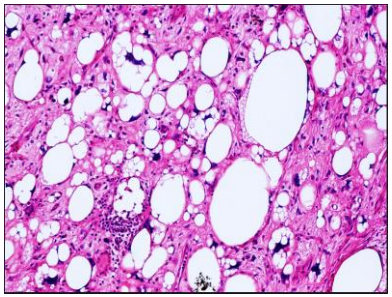


- An interface has been installed between the HIT systems used by reference laboratory and small group practice
- Applicable syntactic interoperability standard is used to develop the interface
- These systems are not interoperable because of misinterpretation of interoperability standard by developers of lab system

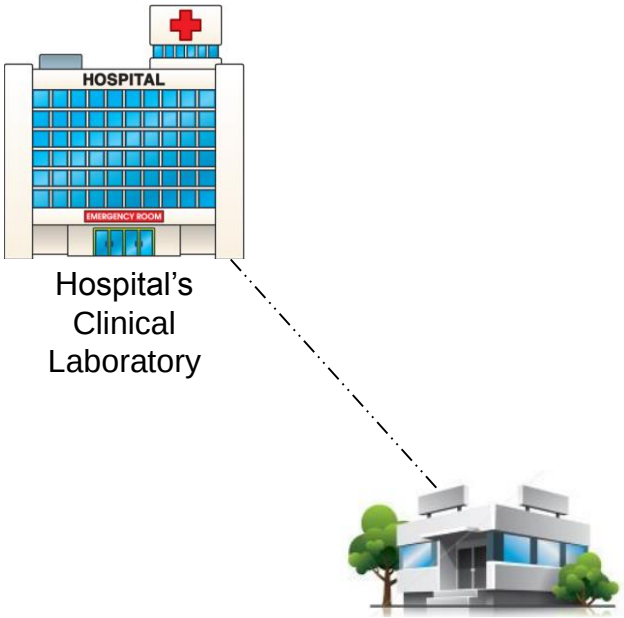
Syntactic Interoperability – Faulty Technical Interoperability

Interoperability Gaps and Patient Safety – Scenario 2

- Anatomical pathology reference laboratory electronically transmits patient's **test results** to physician's HIT system
- Electronic messages created by lab information system (LIS) use **interoperability standard** that was **loosely interpreted** by lab system's developers, and physician's HIT system is unable to process transmitted test results completely
- No s**tandardized behavioral requirements** defined to provide guidance to developers as to how receiving HIT system must handle this situation
- Physician unaware that test results were transmitted by LIS
- Treatment of patient's illness delayed causing her to die of what was initially a curable condition



HIT Interoperability and Patient Safety – Scenario 3



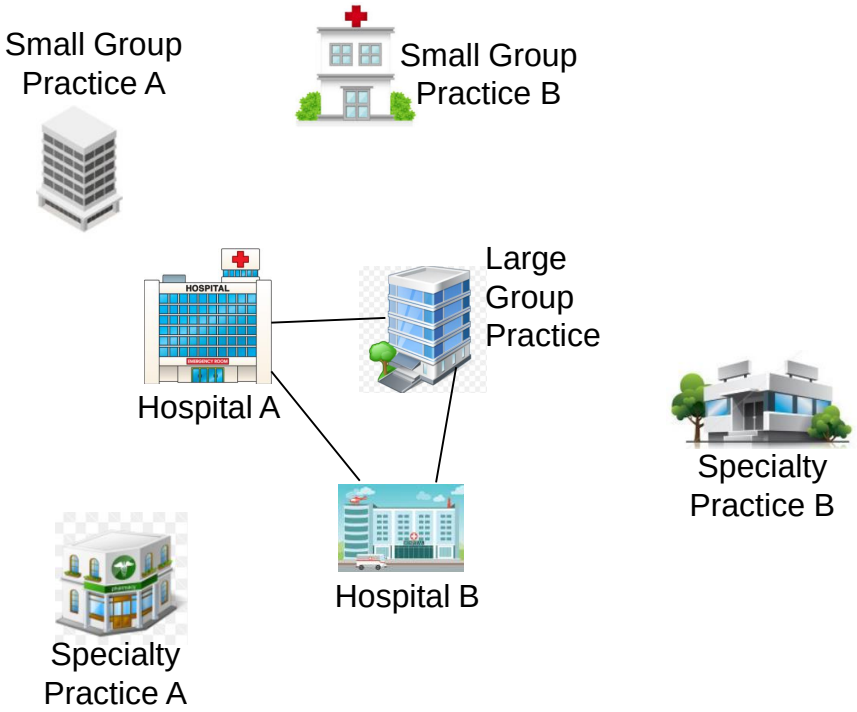
- An interface has been installed between the HIT systems used by a hospital's clinical laboratory and a pediatrician's office
- An applicable interoperability standard is used to develop the interface
- These systems are not interoperable because the vocabulary (semantic) requirements were poorly-defined in the interoperability standard

Semantic Interoperability – Faulty
Syntactic Interoperability
Technical Interoperability

Interoperability Gaps and Patient Safety – Scenario 3

- A clinical laboratory's information system creates electronic messages with a child's **test results** and transmits them to her pediatrician's HIT system
- Because this electronic data exchange uses an interoperability specification with **poorly-defined vocabulary requirements**, the pediatrician's system does not process the transmitted test results correctly
- Diagnosing of the child's illness is delayed causing her to require a painful surgery and prolonged hospitalization

HIT Interoperability and Patient Safety – Scenario 4



- Two hospitals are interoperable with each other and a large group medical practice
- Small group practices and specialties are not interoperable with the hospitals, the large group practice, or each other

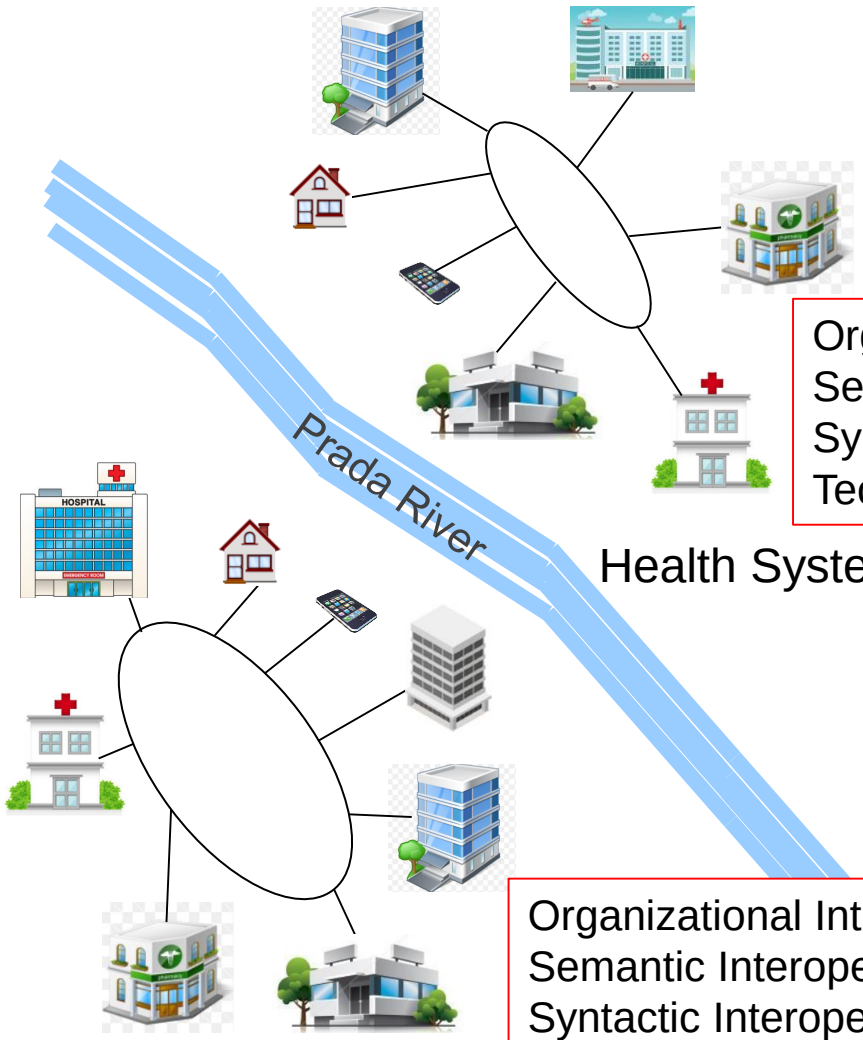
Organizational Interoperability
Semantic Interoperability
Syntactic Interoperability
Technical Interoperability

} Limited deployment

Interoperability Gaps and Patient Safety – Scenario 4

- A 75-year-old male is under the care of several physicians for different chronic conditions
- He is seen today by a nephrologist for a suspected kidney problem
- Nephrologist's HIT system is not set up to exchange data with HIT system used by the rheumatologist who saw this patient yesterday, and patient forgets to tell nephrologist about new **medications prescribed** by rheumatologist
- Nephrologist prescribes a medication that is counteracted by a medication prescribed by rheumatologist, which causes patient to suffer kidney failure and ultimately to require dialysis

HIT Interoperability and Patient Safety – Scenario 5



Two Health Systems are intra-operable but are not inter-operable with each other

Organizational Interoperability
Semantic Interoperability
Syntactic Interoperability
Technical Interoperability

Health System A

No deployment across organizational boundaries

Organizational Interoperability
Semantic Interoperability
Syntactic Interoperability
Technical Interoperability

Health System B

Interoperability Gaps and Patient Safety – Scenario 5

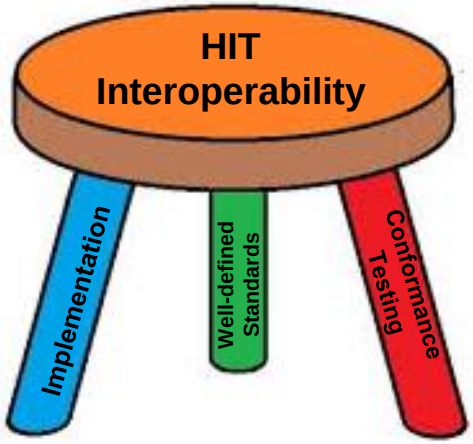
- An unconscious 25-year-old male is brought to Health System A's Trauma Center after the car he was driving was struck by a tractor trailer
- His health records are stored in HIT used by Health System B that is not set up to exchange data with Health System A's HIT
- Patient's records are inaccessible to the Trauma Center's physicians and nurses caring for him
- Physician orders a medication to be given intravenously, causing patient to suffer a cardiac arrest and die
- Information about patient's **allergy** to this medication had been documented in the Health System B's HIT

Foundation for HIT Interoperability

Successful implementations that support interoperability need

- Well-defined standards - precise and complete requirement specification
  - Conformance constructs - some standards have sophisticated conformance constructs to support a good specification, others do not
  - SDOs* need to do a better job at specifying requirements
- Tested standards and trial implementations
  - Conformance test tools
  - Initial test implementations
    - Reference
    - Pilot
- Feedback to authors, tool developers, implementers
- Interoperability testing

NIST contributes in these areas



Three-legged Stool

*Standards Development Organizations

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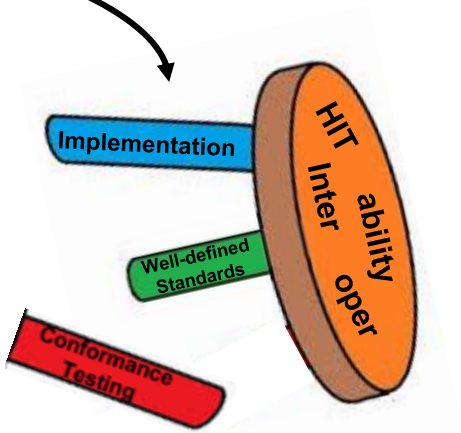
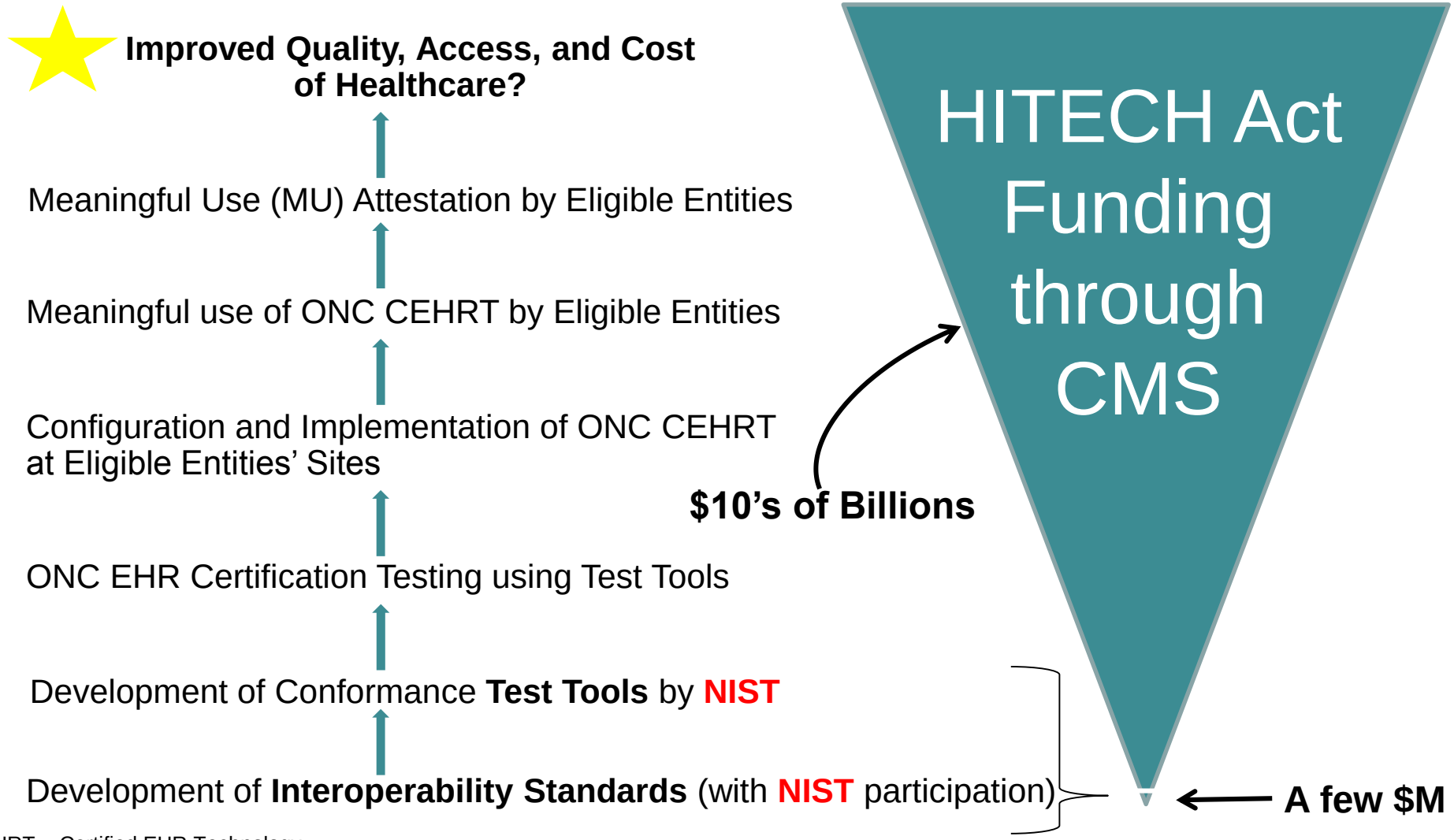


Three-legged Stool Minus One Leg

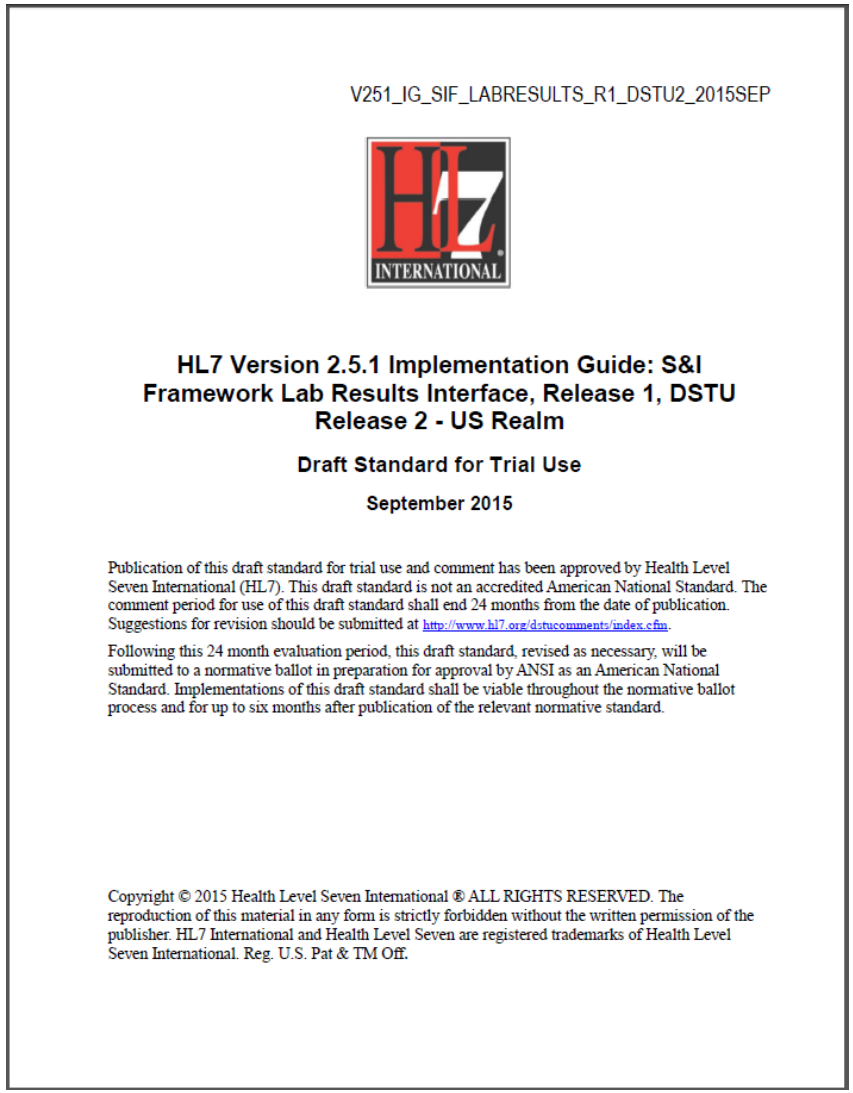
*Standards Development Organizations

Funding for Interoperability Standards and Test Tools



CEHRT = Certified EHR Technology

Standards Document – Implementation Guide



V251_IG_SIF_LABRESULTS_R1_DSTU2_2015SEP

HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1, DSTU Release 2 - US Realm

Draft Standard for Trial Use

September 2015

Publication of this draft standard for trial use and comment has been approved by Health Level Seven International (HL7). This draft standard is not an accredited American National Standard. The comment period for use of this draft standard shall end 24 months from the date of publication. Suggestions for revision should be submitted at http://www.hl7.org/dstucomments/index.cfm.

Following this 24 month evaluation period, this draft standard, revised as necessary, will be submitted to a normative ballot in preparation for approval by ANSI as an American National Standard. Implementations of this draft standard shall be viable throughout the normative ballot process and for up to six months after publication of the relevant normative standard.

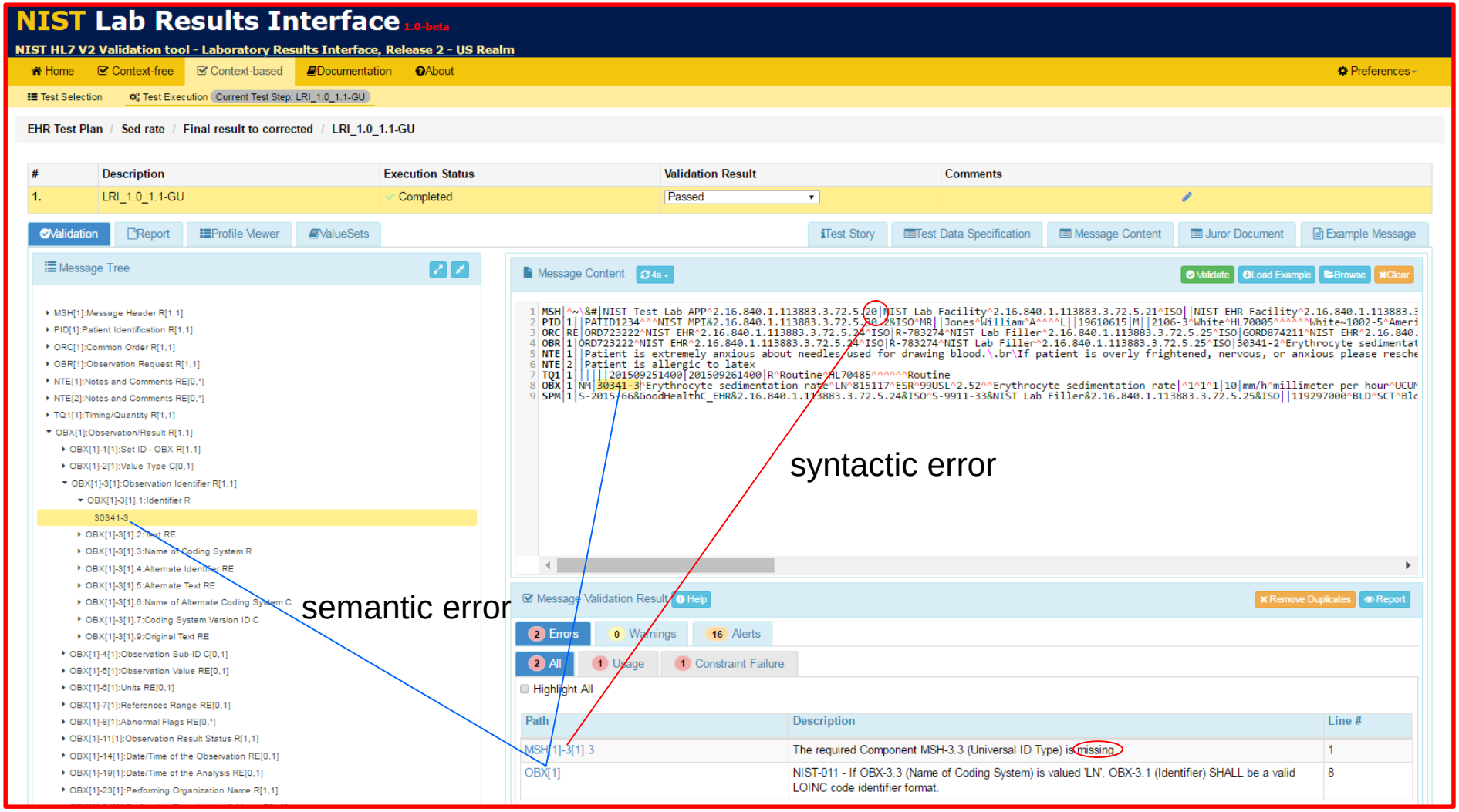
- Laboratory Results Interface (LRI) specification for standardized exchange of clinical lab test results
- Product of ONC-sponsored Standards & Interoperability (S&I) Framework* to enable development of harmonized interoperability specifications
- Balloted by Health Level 7 (HL7)
- Uses LOINC and SNOMED as standard vocabularies
- Uses HL7 Value Sets as standard codes
- NIST leads HL7 Conformance & Guidance for Implementation/Testing Work Group

*S&I Framework: forum where healthcare stakeholders focus on solving real-world interoperability challenges

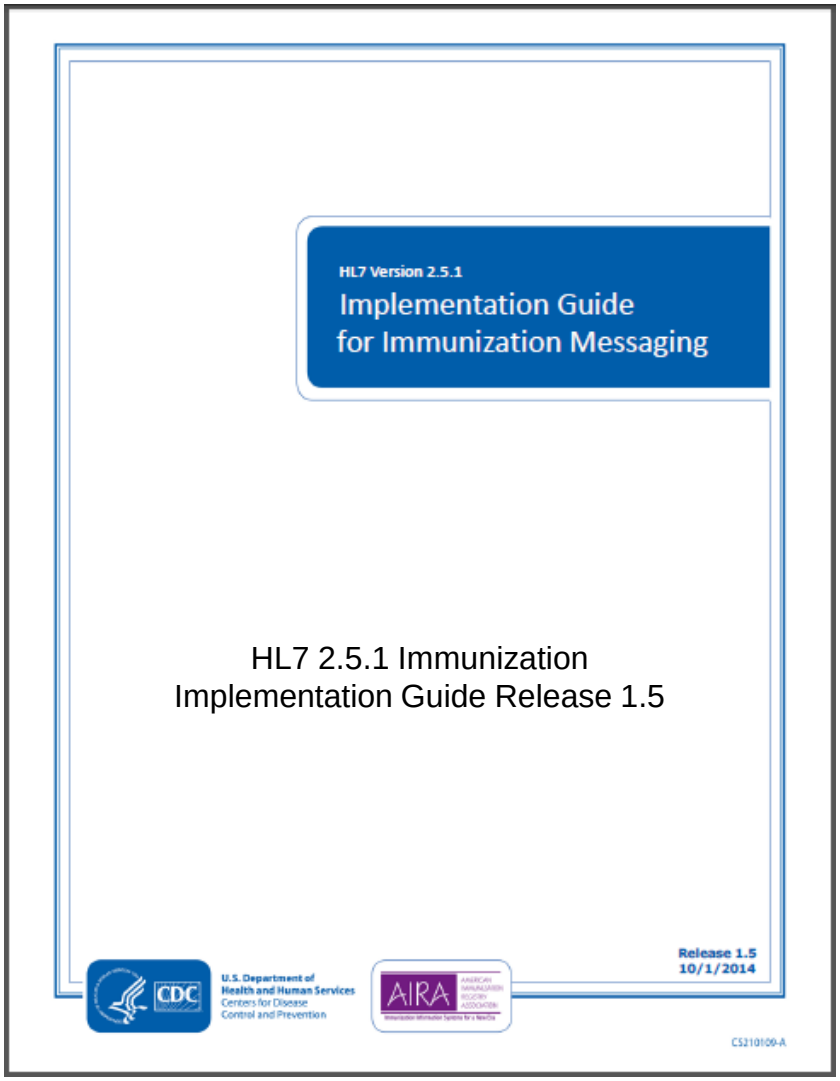
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=279

NIST Conformance Test Tool

Developed while LRI specification was being written



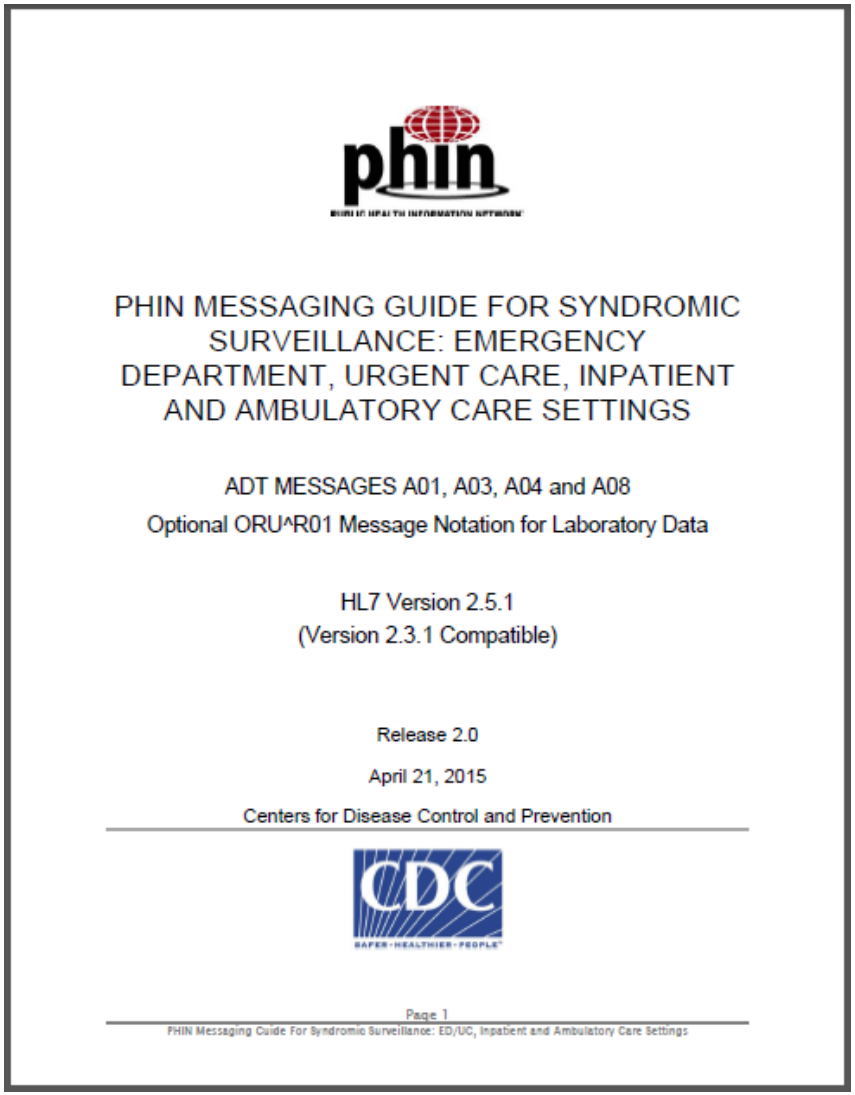
Standards Document – Implementation Guide



- Immunization Messaging Implementation Guide for standardized exchange of vaccine administration and forecasting data
- HL7 messaging *reference standard*
- Principle authors
  - The Centers for Disease Control and Prevention (CDC)
  - American Immunization Registry Association (AIRA)
- Reviewers
  - National Institute of Standards and Technology (NIST)

http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf

Standards Document – Messaging Guide



PHIN MESSAGING GUIDE FOR SYNDROMIC SURVEILLANCE: EMERGENCY DEPARTMENT, URGENT CARE, INPATIENT AND AMBULATORY CARE SETTINGS

ADT MESSAGES A01, A03, A04 and A08

Optional ORU^R01 Message Notation for Laboratory Data

HL7 Version 2.5.1
(Version 2.3.1 Compatible)

Release 2.0

April 21, 2015

Centers for Disease Control and Prevention

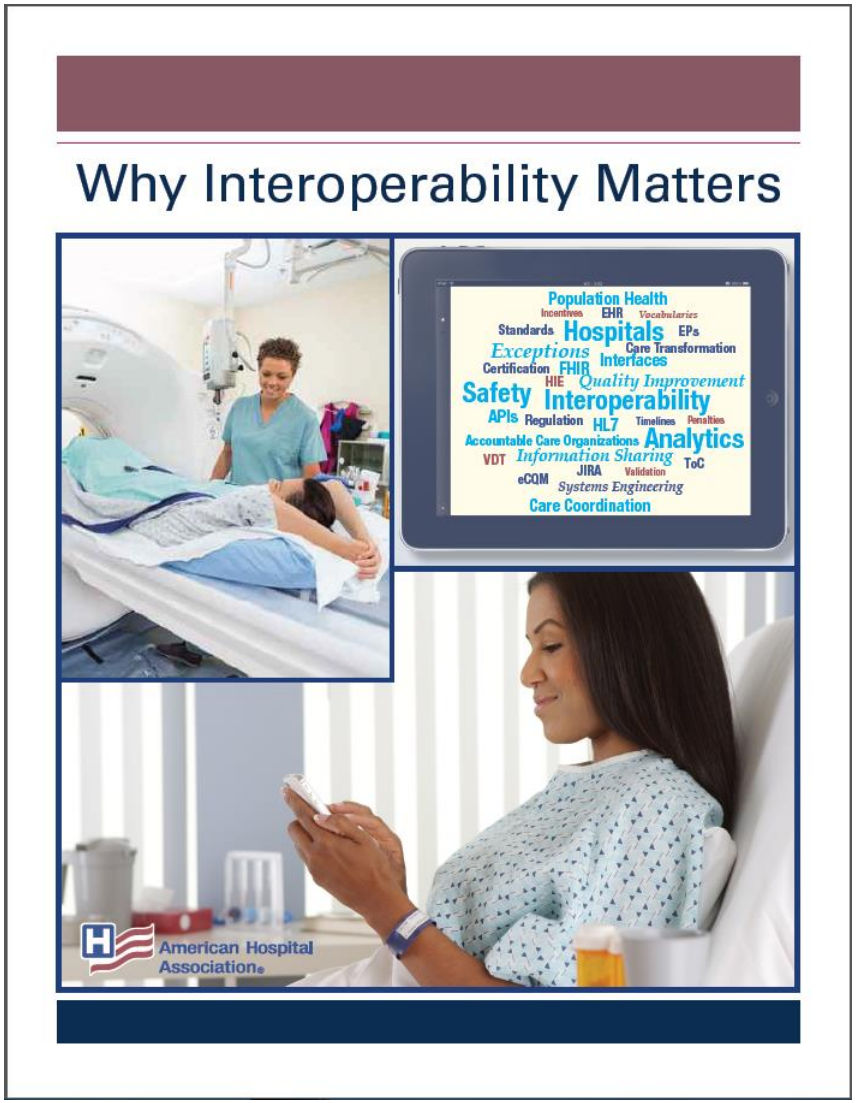
Page 1
PHIN Messaging Guide For Syndromic Surveillance: ED/UC, Inpatient and Ambulatory Care Settings

- Syndromic Surveillance Public Health Information Network Guide for standardized messaging of clinical data used for illness surveillance information about the health of a community
- HL7 messaging and content *reference standard*
- Principle authors
  - The Centers for Disease Control and Prevention (CDC)
  - Office of Surveillance, Epidemiology and Laboratory Services (OSELS)
  - Public Health Informatics and Technology Program Office (PHITPO)
- Reviewers
  - Joint Public Health Informatics Taskforce (JPHIT)
  - Public Health Data Standards Consortium (PHDSC)
  - Health Level 7 (HL7)
  - American Health Information Management Association (AHIMA)

http://www.cdc.gov/nssp/documents/guides/syndrsurvmessagguide2_messagingguide_phn.pdf

CDC site with links to Syndromic Messaging Guides http://www.cdc.gov/nssp/mmg/index.html

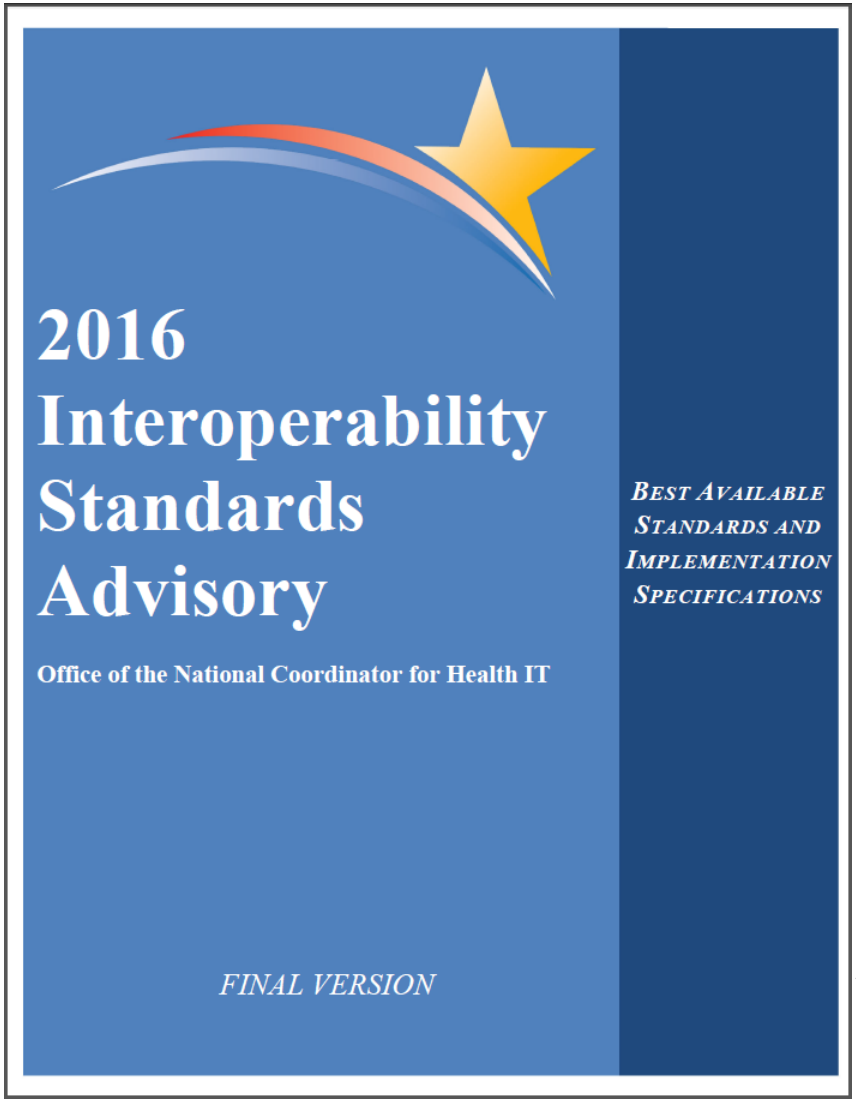
Interoperability Informative Document



- American Hospital Association pamphlet (2015)
- Information explaining
  - Patient safety issues related to current inability for electronic systems to be interoperable (speak the same language and efficiently/correctly transmit information)
  - Current status of HIT interoperability standards
  - Actions clinical stakeholders can take to address the issues

http://www.aha.org/content/15/interoperabilitymatters.pdf

Interoperability Standards Document



- The ONC* Interoperability Standards Advisory (ISA)
- A list of and assessment for “best available” interoperability standards for specific clinical health IT needs
  - Vocabulary/Code Systems
  - Implementation Guides
  - Interoperability Services
- Draft 2017 version to be published for Public Comment in October 2016

*Office of the National Coordinator for Health Information Technology

https://www.healthit.gov/standards-advisory/2016

Interoperability Standards Advisory Document Details

- Uses six informative characteristics as context for the standard
- Lists an "emerging alternative" to a standard or implementation specification when known

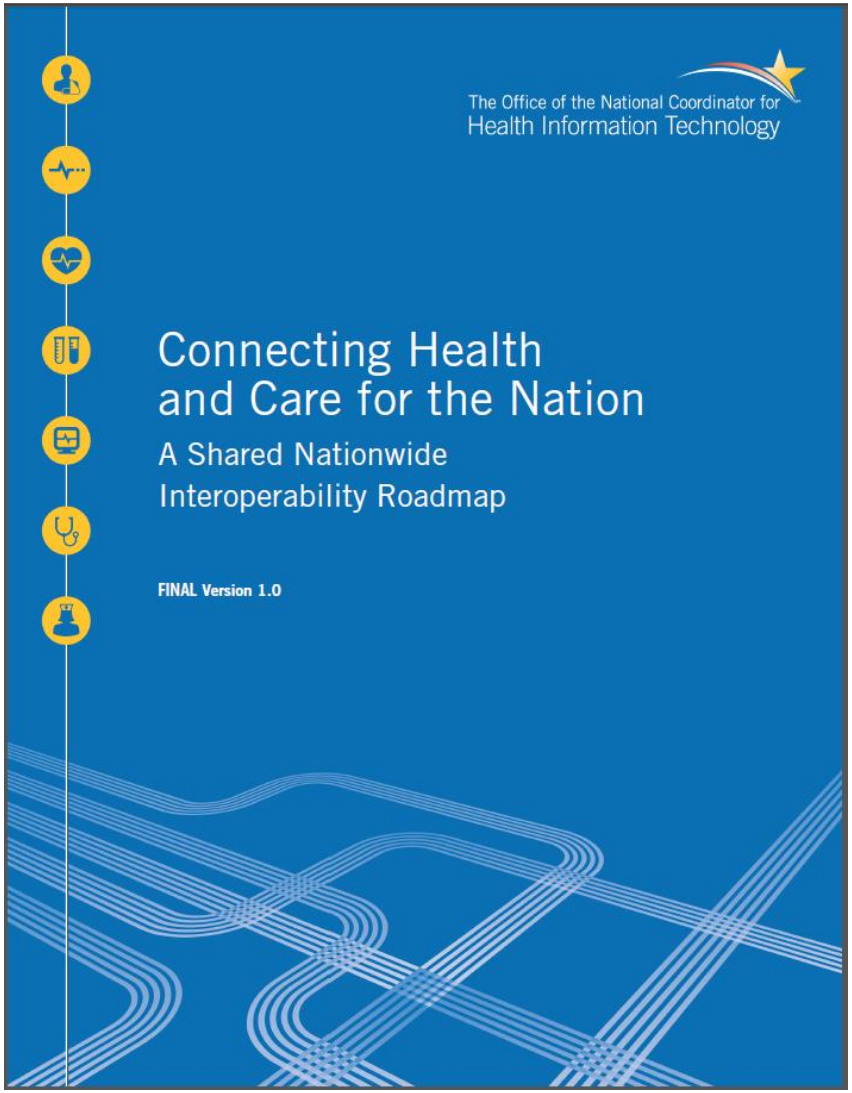
Interoperability need: [Descriptive Text]						
Standard/ Implementation Specification	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	Final	Production	●●●●○	Yes	Free	Yes
Emerging Alternative Standard	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	**Section I: Applicable Value Set(s): Sections II & III: Applicable Security Patterns for Consideration:**
• Descriptive text with "(recommended by the HIT Standards Committee)" included in cases where the HIT Standards Committee recommended the text, and on which public feedback is sought.	• Descriptive text

Adoption Level Legend

- "*Unknown*" Indicates no known status for the current level of adoption in health care.
- ●○○○○ Indicates low adoption.
- ●●○○○ Indicates low-medium adoption.
- ●●●○○ Indicates medium adoption.
- ●●●●○ Indicates medium-high adoption.
- ●●●●● Indicates high or widespread adoption.

Interoperability Roadmap Document

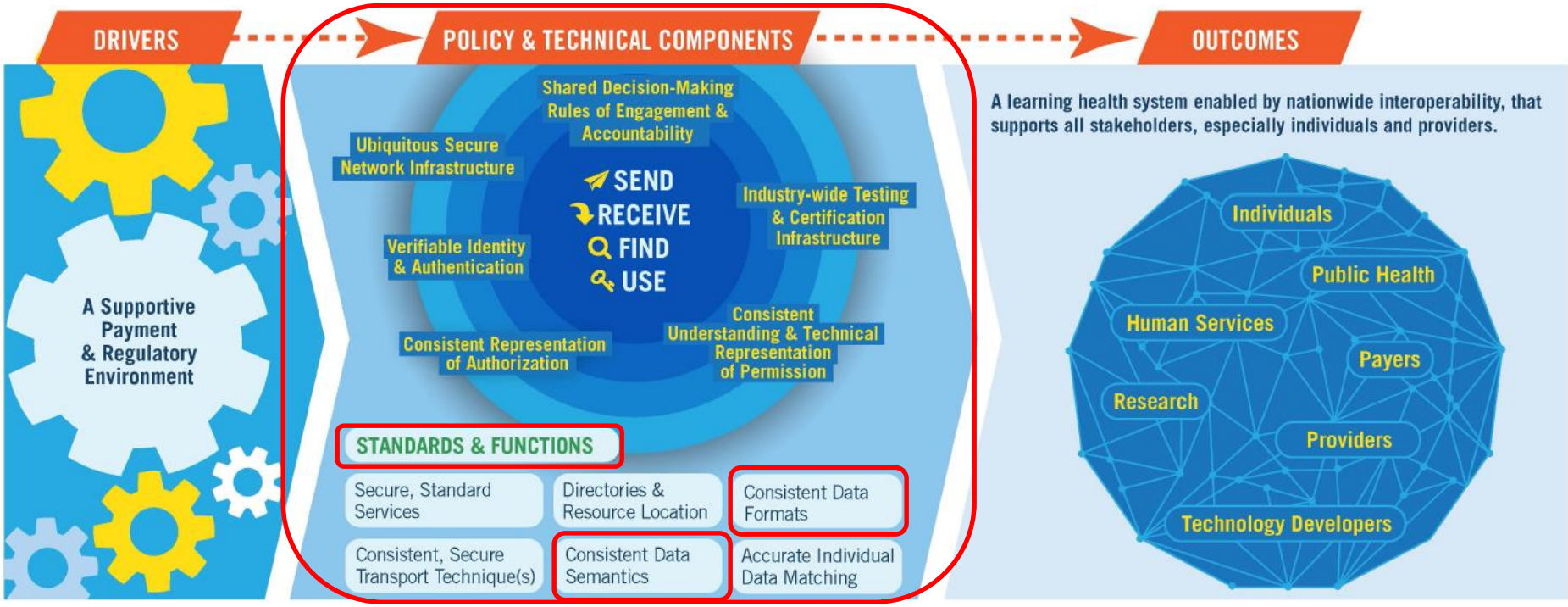


- The ONC* Interoperability Roadmap
- Final Version October 2015
- ONC's vision of HIT interoperability supporting a "learning health system"
  - Health information flows seamlessly and is available to the right people, at the right place, at the right time
  - Better informed decision-making to improve individual health, community health, and population health
- Description of the policy and technical actions needed to realize the vision of a seamless data system

*Office of the National Coordinator for Health Information Technology
https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf

The ONC Interoperability Roadmap

- ***Drivers:*** mechanisms that can propel development of a supportive payment and regulatory environment that relies on and deepens interoperability.
- ***Policy and Technical Components:*** essential items stakeholders will need to implement in similar or compatible ways in order to enable interoperability
- ***Outcomes:*** metrics by which stakeholders will measure progress on implementing the Roadmap



Summary

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Thank You!