**ELR 2.5.1**
**Applying the Lessons Learned From ELR 2.3.X**

NCPHI – Division of Informatics Shared Services



National Center for Public Health Informatics
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**Disclaimer**

- The findings and conclusions in this presentation are those of the author(s) and do not necessarily represent the views of the Centers for Disease Control and Prevention/the Agency for Toxic Substances and Disease Registry

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**Agenda**

- ELR History – Timeline of various ELR versions
- Important lessons learned from ELR implementations
- The ELR 2.5.1 project
- ELR 2.5.1 development process
- High points of the 2.5.1 ELR Implementation Guide
- Future of ELR Implementation Guide
- Q&A

ELR
In a Galaxy
WARS

## First There was 2.3.z ELR

- There were a number of implementers who wanted to do ELR
- There were lots of ways of doing ELR
- Then there was 2.3.z ELR
- Which quickly turned into 2.3.1 ELR
- And then there were many versions of ELR

## ELR History – Timeline of various ELR versions

- 2.3.z ELR - 1997
- 2.3.1 ELR - 2003
- 2.3.1 ELR for Microbiology – 2003
- 2.4.z ELR for Bioterrorism - 2003
- 2.3.1 ELR Update - 2005
- 2.5 ELR Draft - 2004/2006
- 2.5.1 ELR Draft - 2008

## Important Lessons Learned From ELR Implementations

- Reduce or eliminate optionality to make implementation simpler
- Retain backwards compatibility where possible
- Avoid dramatic changes which will cause labs and vendors to ignore the IG

## The ELR 2.5.1 Project – Some Background

- The document is drawn from the HL7/HITSP 2.5.1 Interoperable Lab Result to EHR Implementation Guide
- Aligned with and extends the existing 2.3.1 ELR Implementation Guides
- Cross-fertilization with the PHLIP and LIMSi projects
- Working with the PHIN Vocabulary Community of Practice and ELR Community of Practice

## The ELR Implementation Guide Team

- Project Leaders:
  - Steve Steindel (CDC)
  - Austin Kreisler
  - Rita Altamore
- Participants
  - CSTE members
  - CDC
  - APHL PHLIP team
  - LIMSi team
  - Commercial lab partners
  - LIMS vendors

# Why Move To HL7 2.5.1 For ELR?

**Actually, The Answer Is Anything But Simple**

There have been a lot of changes to the HL7 standard between 2.3.1 and 2.5.1

- New messages have been added
- New segments have been added
- Segments have been added to old messages
- Old messages have been retired
- New fields have been added to old segments
- New data types have been added
- Old data types have been retired
- Clarifications have been added all over the place

**Where Did All These Changes Come From?**

# YOU
## The Implementer

## Why Should I Care About All These Changes?

- Although HL7 is an international standard, the U.S. provides the majority of members and drives the majority of changes requested for 2.x
- Many organizations here in the U.S. want to move to the new HL7 2.x versions so they can use the new features they have pushed into the standard
- Many organizations do not want to change because change is costly and time consuming

## The Role Of HITSP

- HITSP is a public/private collaborative to induce change in U.S. healthcare messaging
- HITSP's job is to select standards to be used to promote interoperability in U.S. healthcare
- HITSP also identifies where standards are missing

The US Healthcare Market
HITSP Is Just The Tip Of the Iceberg

HITSP

US Healthcare
Market

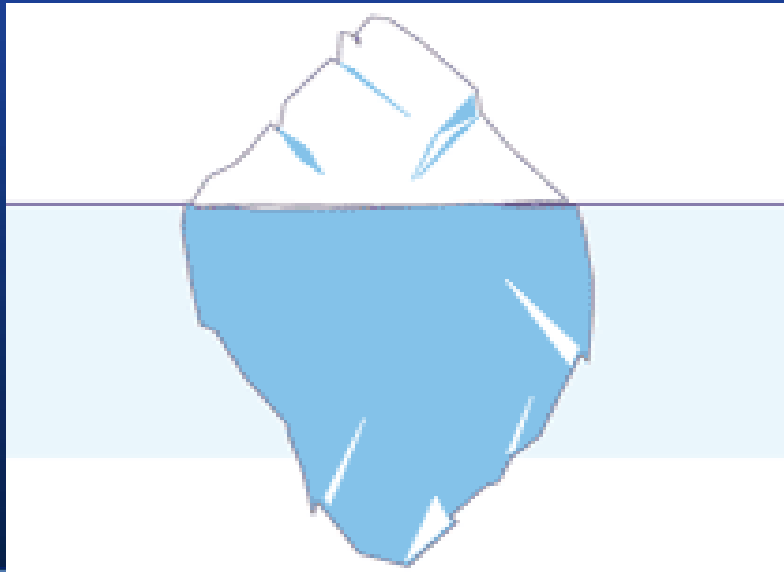NCPHI – Division of Informatics Shared Services    CDC
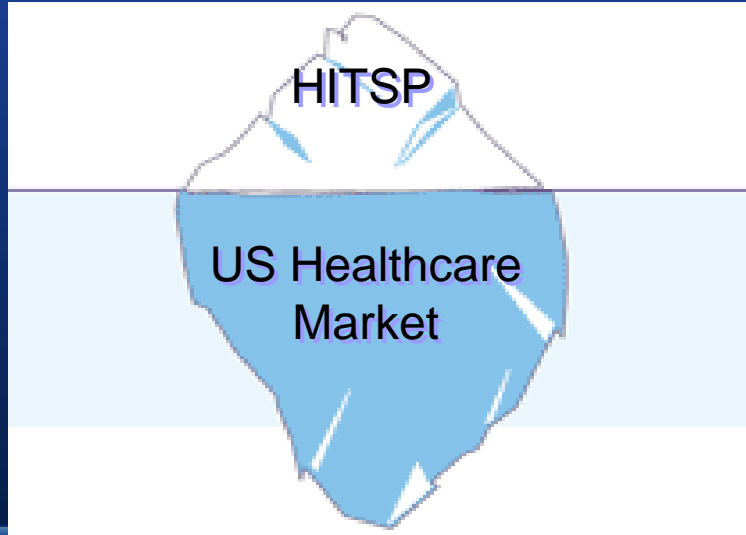
## HITSP And The Changing US Healthcare Market

- The growing emphasis on HITSP and organizations desiring interoperability is evidence that we are approaching or have already passed the "tipping point"
- This is happening because market forces are pushing everyone towards the newer HL7 versions

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## Icebergs Do Tip Over

## Tipping Point

- Like an iceberg tipping over seeking equilibrium, the pressure for the US healthcare industry to change will overcome the resistance to change
- You can prepare for changes now, or you can ignore the coming changes and be overwhelmed by the changes that are going to occur
- Late adopters will be left behind as changes accelerate

## ELR 2.5.1 Development Process

- ELR IG developed as an HL7 Message Profile
- Initial guide developed starting from the HITSP/HL7 Lab to EHR IG based on HL7 2.5.1
- Applied best guess as to what elements needed to be supported from the HITSP/HL7 Lab to EHR IG based on what was supported by the 2.3.1 ELR IG
- Additional elements needed for ELR added from 2.3.1 ELR (such as NK1 Segment)
- Pre-adopted material from 2.6 where deemed necessary
- We could of moved this guide up to 2.6 but didn't to stay consistent with HITSP and the CSTE mandate to move to 2.5

## ELR 2.5.1 Development Process

- Reviewed 2.5.1 draft ELR with a small group of public health related people at HL7
- Review 2.5.1 draft ELR IG with a joint CSTE+CDC+APHL (mainly the National ELR group)
- This involved 20+ conference calls over the course of 6 months, with the pace of the review picking up in July to meeting twice weekly with 2 hour conference calls
- This is the primary mechanism by which lessons learned through implementations are incorporated into the IG
- Final draft version is now available

**High points of the 2.5.1 ELR Implementation Guide**

- Introduction
- Messaging Infrastructure
- Message Profile
- Messages
- Segment and Field Descriptions
- Code Systems and Value Sets
- Example Laboratory Result Messages
- Appendix A. HL7 Reporting of Culture and Susceptibilities
- Appendix B. Clinical Laboratory Improvements Amendment Considerations US Realm Only

**Introduction - Purpose**

- Specification for laboratory results reporting to local, state, territorial and federal public health agencies
- Addresses messaging content and dynamics related to the transmission of Laboratory Reportable Result Messages/ELR
- Each state and territory has its own requirements for laboratories to report certain findings to health officials

## Introduction - Purpose

- Message described in this guide is not specific to any pathogen or reportable condition and is applicable for most biological and chemistry laboratory-reportable findings
- Intended to meet the needs and requirements of implementation guidance in Public Health entities, replacing the previous documentation regarding Electronic Laboratory Reporting (ELR)
- Does not replace the need for documentation of the constraints for specific implementations
- This guide does not replace having access to the 2.5.1 standard itself

## Introduction - Scope

- This specification covers the exchange of laboratory results from the testing source to appropriate local, state, territorial and federal public health agencies

- Focuses on key points of broad interoperability

    - **Use of strong identifiers for key information objects**

    - **Use of vocabulary standards**

- Does not cover environmental lab reporting or result reporting to cancer registries
- It does cover reporting of laboratory results for individual human and animal testing.

## Messaging Infrastructure

- Messaging Framework
  - Includes message delimiters, null values, lengths, and snapshot processing
- Use of Escape Sequences
  - Discusses the required use of escape sequence processing
- Data Types
  - Provides a detailed description of the data types used in the specification

## Message Profile

- Use Case Model
  - Describes the use case, actors, assumptions and business rules associated with the use case
- Dynamic Interaction Model
  - Documented using a UML activity diagram
- Dynamic Definition
  - Documents the details needed for an HL7 profile including the profile id, HL7 version, acknowledgment details, type of profile, message types used, and allowed encodings
- Interactions
  - Documents the supported interactions, including trigger events, message types, receiver actions, important data values, and usage requirements

## Messages

- The Messages chapter defines the structure for the two messages detailed in the specification:
  - ORU^R01^ORU_R01 (Unsolicited Observation Message)
  - ACK^R01^ACK
- The chapter describes the HL7 message structures of the two messages as well as the constraints applied to the message structures.

## Messages (continued)

| Segment in Standard | Name | Usage | Cardinality | Section | Description |
|---|---|---|---|---|---|
| TABLE 4-2 – ORU^R01^ORU_R01 ABSTRACT MESSAGE SYNTAX |
| MSH | Message Header | R | [1..1] | 5.1 | The message header (MSH) segment contains information describing how to parse and process the message. This includes identification of message delimiters, sender, receiver, message type, timestamp, etc. |
| [{SFT}] | Software Segment | R | [1..*] | | Each HL7 aware application that touches the message on the way to the destination application must add a SFT segment for its application. For instance, PHIN MS is not HL7 aware and would not be expected to add an SFT. On the other hand, an integration engine is HL7 aware and would be expected to add an SFT. The first repeat (i.e., the originator) is required. Any other application that transforms the message must add an SFT segment for that application. Other applications that route or act as a conduit may add an SFT but are not required to do so. |
| { | *PATIENT_RESULT Begin* | R | [1..1] | | The patient result group has been constrained to support only one patient result. |
| [ | *PATIENT Begin* | R | [1..1] | | For public health reporting, the patient group is required. |
| PID | Patient Identification | R | [1..1] | 1.1.1 | The patient identification (PID) segment is used to provide basic demographics regarding the subject of the testing. The subject may be a person or animal. |
| [PD1] | Additional Demographics | X | [0..0] | | Not supported |
| [{NTE}] | Notes and Comments for PID | RE | [0..*] | | This notes and comments (NTE) segment should contain notes or comments pertaining to the patient identified in the PID segment. It should not contain order or result related comments. |

## Segment and Field Descriptions

- The Segment and Field Descriptions chapter provides segment attribute tables for all the segments supported in the document
  - MSH, SFT, MSA, ERR, PID, NK1, PV1, PV2, ORC, OBR, OBX, SPM and NTE segments
- The segment tables provide information about the constraints applied to the fields within the segments
- Constraints include
  - Usage (R, RE, O, C, CE or X)
  - Cardinality [0..n]
  - Value Sets
  - Description/Comments

## Segment and Field Descriptions (continued)

| TABLE 5-11 – OBSERVATION/RESULT SEGMENT (OBX) | | | | | | | |
|---|---|---|---|---|---|---|---|
| Seq | Len | DT | Usage | Cardinality | Value Set | HL7 Element Name | Description/Comments |
| 1 | 4 | SI | R | [1..1] | | Set ID – OBX | **For the first repeat of the OBX segment, the sequence number shall be one (1), for the second repeat, the sequence number shall be two (2), etc.** |
| 2 | 3 | ID | CE | [0..1] | | Value Type | **This field identifies the data type used for OBX-5. Conditional statement: If OBX-5 is populated, OBX-2 is required. See Section 5.8.1, HL7 Table 0125 for the data types that will be supported for this field and OBX-5. Note that the field length has been extended to 3 characters to allow the 3-character data type codes from HL7 Table 0125.** |
| 3 | 705 | CWE | R | [1..1] | LOINC | Observation Identifier | Unique identifier for the type of observation. This field provides a code for the type of observation. OBX-3 in conjunction with OBX-4 Observation Sub-ID should uniquely identify this OBX from all other OBXs associated with this OBR. LOINC is used as the coding system … |

**Observation Identifiers, Observation Values, Interpretations and Comments**

- Provides guidance use of observation identifiers (OBX-3) in conjunction with observation value (OBX-5), interpretations (OBX-8) and comments
- Links the LOINC ® scale property with the data type to be used with OBX-5 value

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# Types of Observations

| Testing situation Discussion | OBX.2 Observation Type | OBX.3 Observation Identifier: LOINC part = scale | OBX.5 Observation value | OBX.6 Units | OBX.8 Abnormal Flags | OBX.7 Reference Range | NTE Segment |
|---|---|---|---|---|---|---|---|
| Numeric result along with interpretation | NM | QN | number | UCUM Units required | May be populated with codes from HL7 table 0078 | May be populated | May be populated with comments, not clinical findings. |
| Numerical intervals, ratios, inequalities | SN | QN | structured numeric | UCUM Units required | May be populated with codes from HL7 table 0078 | May be populated | May be populated with comments, not clinical findings. |
| Time like quantitative result with interpretation | TS, TM, DT, | QN | timestamp, time or date | [empty] | May be populated with codes from HL7 table 0078 | May be populated | May be populated with comments, not clinical findings. |
| Conveys ordinal value and interpretation | CWE | ORD | Ordinal as a code. SNOMED CT shall be used when code exists, otherwise it's a local code. Sending ordinals as codes is the preferred ELR approach. | [empty] | May be populated with codes from HL7 table 0078 | May be populated | May be populated with comments, not clinical findings. |
| Conveys ordinal value and interpretation | SN | ORD | Ordinal as structured numeric | [empty] | May be populated with codes from HL7 table 0078 | Required | May be populated with comments, not clinical findings. |
| Conveys observation and interpretation | CWE | NOM | Coded observation. SNOMED CT shall be used when code exists, otherwise it's a local code. | [empty] | May be populated with codes from HL7 table 0078 | May be populated | May be populated with comments, not clinical findings. |

**Code Systems and Value Sets**

- Includes a brief discussion of code system vs. value set
- Describes vocabulary constraints applied to the following external code systems:
  - LOINC
  - SNOMED CT
  - UCUM
  - UB-04
  - HL7 Table 0396
  - PHLIP Coding systems and value sets

**Final Chapters**

- Example ELR Messages

- Appendix A - HL7 Reporting of Culture and Susceptibilities

- Appendix B - Clinical Laboratory Improvements Amendment Considerations

## How To Use The ELR IG

- The ELR IG is an HL7 constrainable message profile
- That means the ELR IG still has optional elements
- Implementers will need to determine what additional constraints are necessary for their implementations
- Goal for implementers would be to produce an implementation message profile (a profile with nothing left optional)

## Future of ELR Implementation Guide

- What should the final approval process look like?
  - HL7 Balloting?
  - National ELR group decision (Wed night)
  - None?

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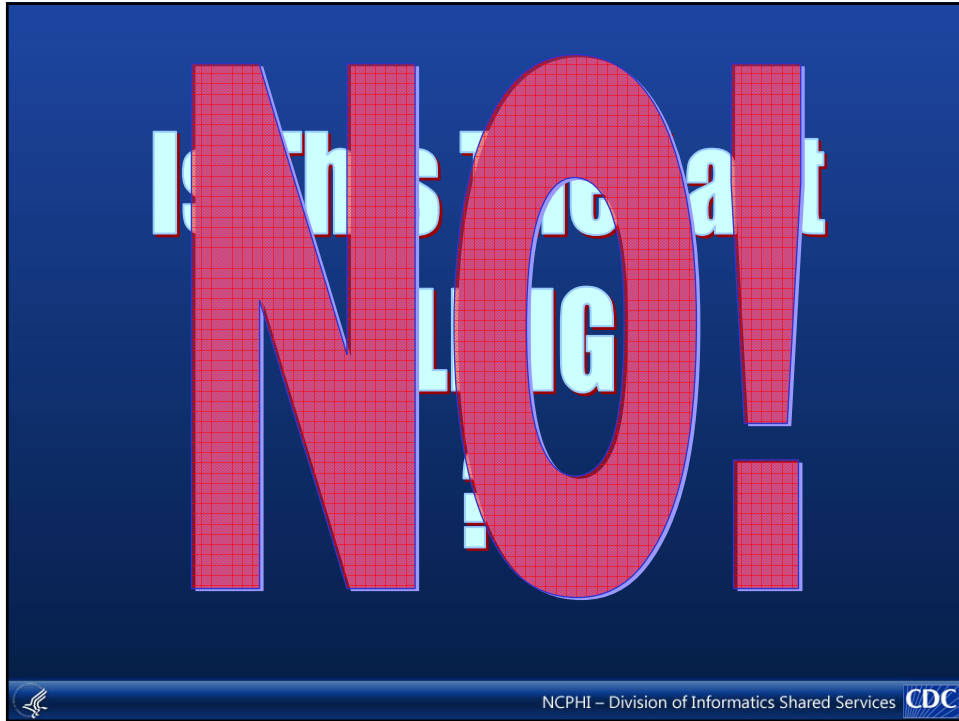
## The history of ELR teaches us that:

- Revisions to the 2.5.1 IG are inevitable
  - Correct errors
  - Accommodate new requirements
- New ELR IGs will be required to address newer HL7 versions (Version 3, CDA, 2.7, 2.8 ???)

## Change Control Process

- If the ELR IG goes through HL7, then HL7 will manage that process
- If it doesn't go that route, then we need to create a change control process
  - CSTE-CDC ELR Change Control Board?
  - CDC Internal Change Control Process?
  - Other?

## Maintenance and Distribution of the ELR IG

- Who should be responsible for maintaining the ELR IG?
- How will it be distributed?
- These questions may be answered by the change control process we decide to follow

**Thank You**

- This was definitely a group effort
- We want to thank all the people who made an effort to join the conference calls and provide feedback on the guide
- Our special thanks goes to Riki Merrick who without any prompting took on the task of taking notes for most of the conference calls.

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**Questions & Answers**

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