

Principles for Profiling Healthcare Data Communication Standards

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Software Engineering Research and Practice*

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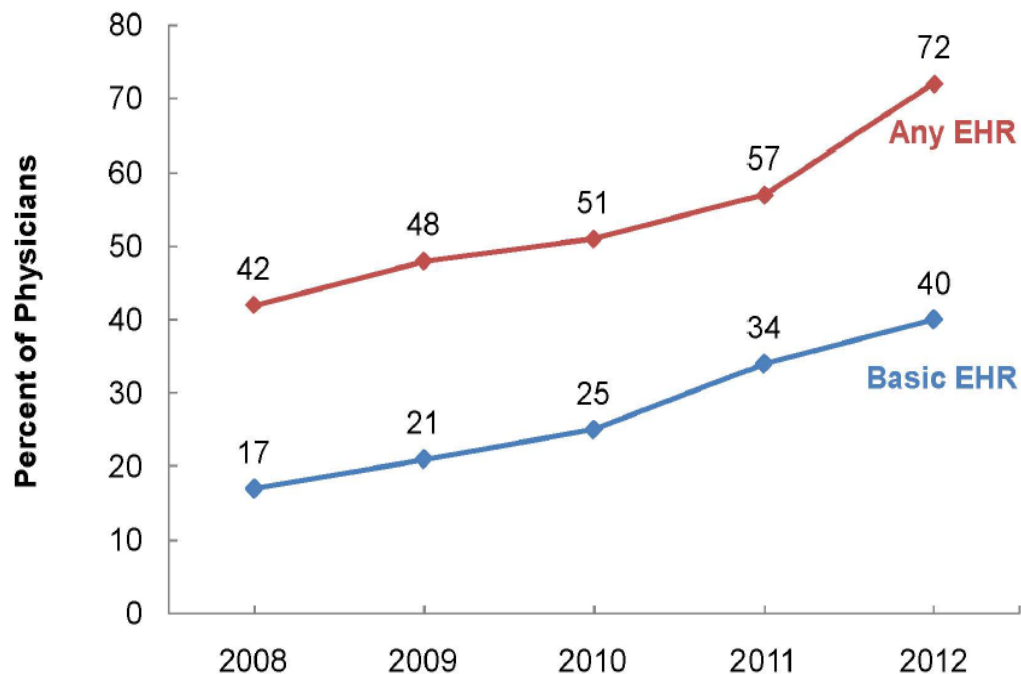
Why is this Important?

- Use of electronic health records (EHRs) has been shown to enable quality improvement in healthcare as well as to help reduce the cost of that care
- Health Information Technology for Economic and Clinical Health (HITECH) Act, a component of the American Recovery and Reinvestment Act (ARRA) of 2009, provides funding for incentive payments to physicians and hospitals that adopt health information technology (HIT).
- Initially focusing on adoption of EHRs, approximately \$17 billion in the Center of Medicare and Medicaid Services (CMS) incentive payments are available through CMS's HITECH-based EHR Meaningful Use (MU) Program, to be paid to providers that attest to or demonstrate "meaningful use" of "certified" EHR technology (CEHRT).
- Office of the National Coordinator (ONC) established a certification program and published EHR certification criteria.
- Multiple stages of Meaningful Use (MU-1 → 2011, MU-2 → 2014, MU-3 → ????)

NIST Role?

- National Institute of Standards and Technology (NIST) developed test procedures and conformance test tools based on the ONC's EHR certification criteria.
- Standards for interoperability (exchange of clinical and administrative data) are not well specified.
- Related standards not harmonized—there by hindering interoperability.
- Use of message profile and message profile components will improve specification and organization of the standard.
- Techniques described in this paper are being applied to the set of HL7 V2 Laboratory Specifications
- Techniques and associated tools anticipated to be used for stage 3 MU Certification
- There is an immediate impact of this work

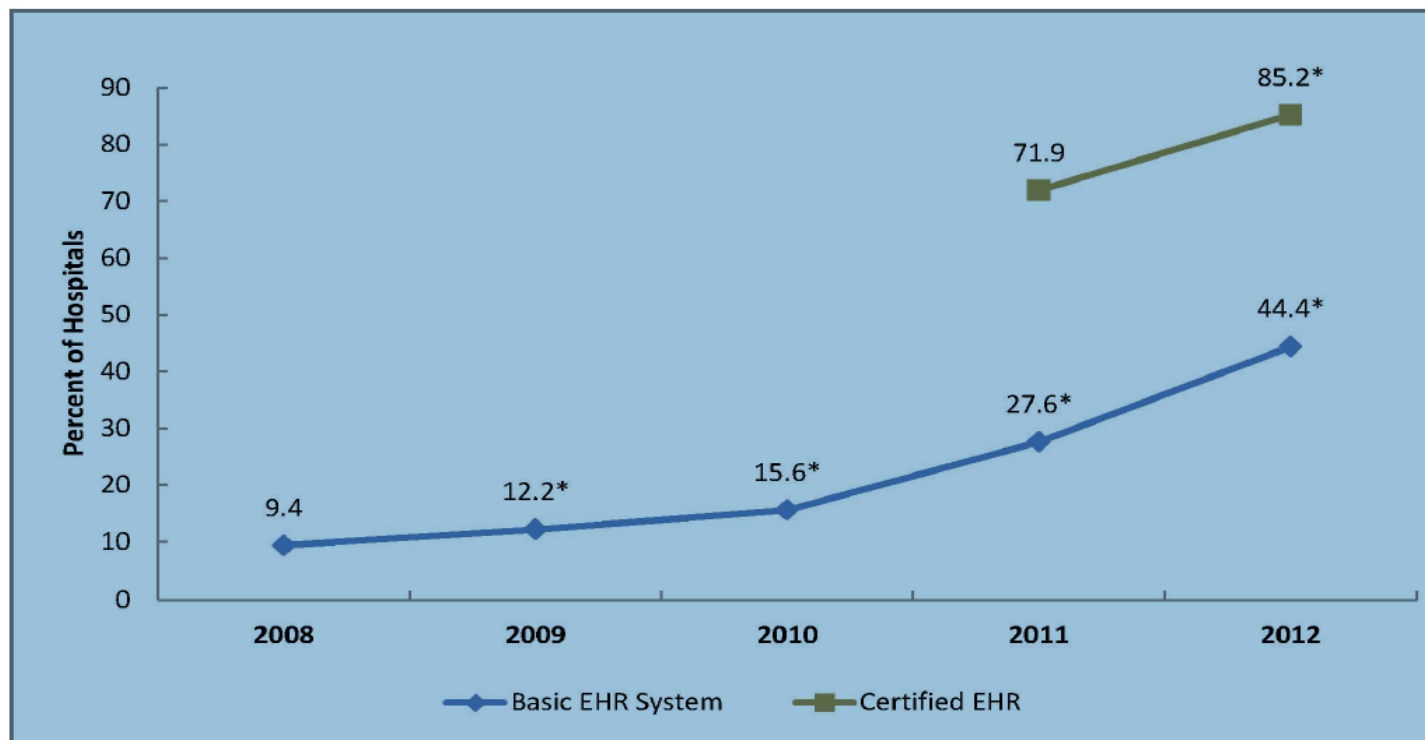
Percentage of office-based physicians with EHRs: United States, 2008–2012



NOTES: "Any EHR system" is a medical or health record system that is all or partially electronic (excluding billing systems). A basic EHR includes: patient history and demographics, patient problem lists, physician clinical notes, comprehensive list of patients' medications and allergies, computerized orders for prescriptions, and view laboratory and imaging results electronically.

SOURCE: ONC analysis of the National Center for Health Statistics' 2008-2012 National Electronic Health Records Surveys.

Percent of non-federal acute care hospitals with adoption of at least a basic EHR system and possession of a certified EHR: 2008-2012

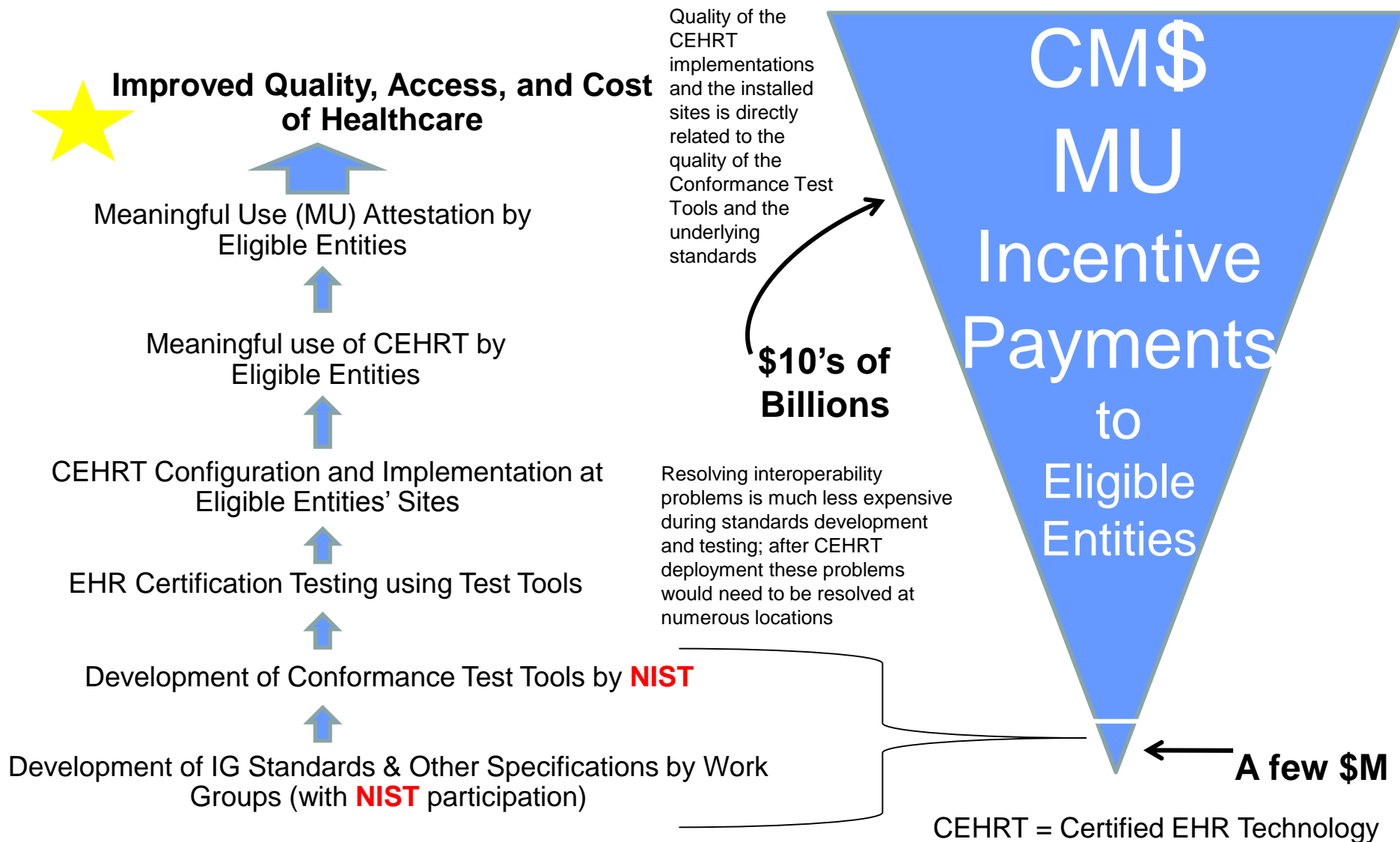


NOTES: Basic EHR adoption requires the EHR system to have at least a basic set of EHR functions, including clinician notes. A certified EHR is EHR technology that has been certified as meeting federal requirements for some or all of the hospital objectives of Meaningful Use. Possession means that the hospital has a legal agreement with the EHR vendor, but is not equivalent to adoption.

*Significantly different from previous year ($p < 0.05$).

SOURCE: ONC/American Hospital Association (AHA), AHA Annual Survey Information Technology Supplement

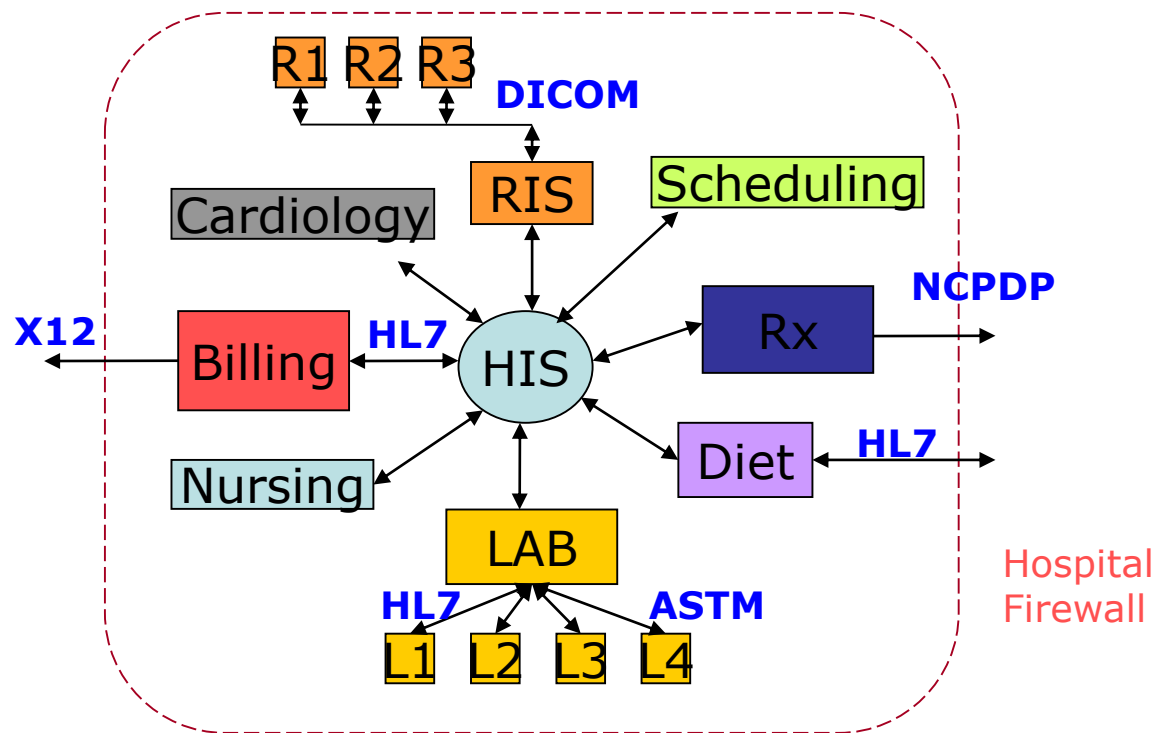
Standards and Test Tools are foundation for MU success



Outline

- Problem Statement
 - Healthcare Data Communication Interfaces
- HL7 V2 Standard Overview
 - Framework
 - Issues
- Message Profiles
- Message Profile Hierarchy
- Message Profile Components
- Message Profile Design
- Case Studies
- Information Mapping
- Message Profile Tooling and Publishing
- Improved specification of the standards for MU Certification

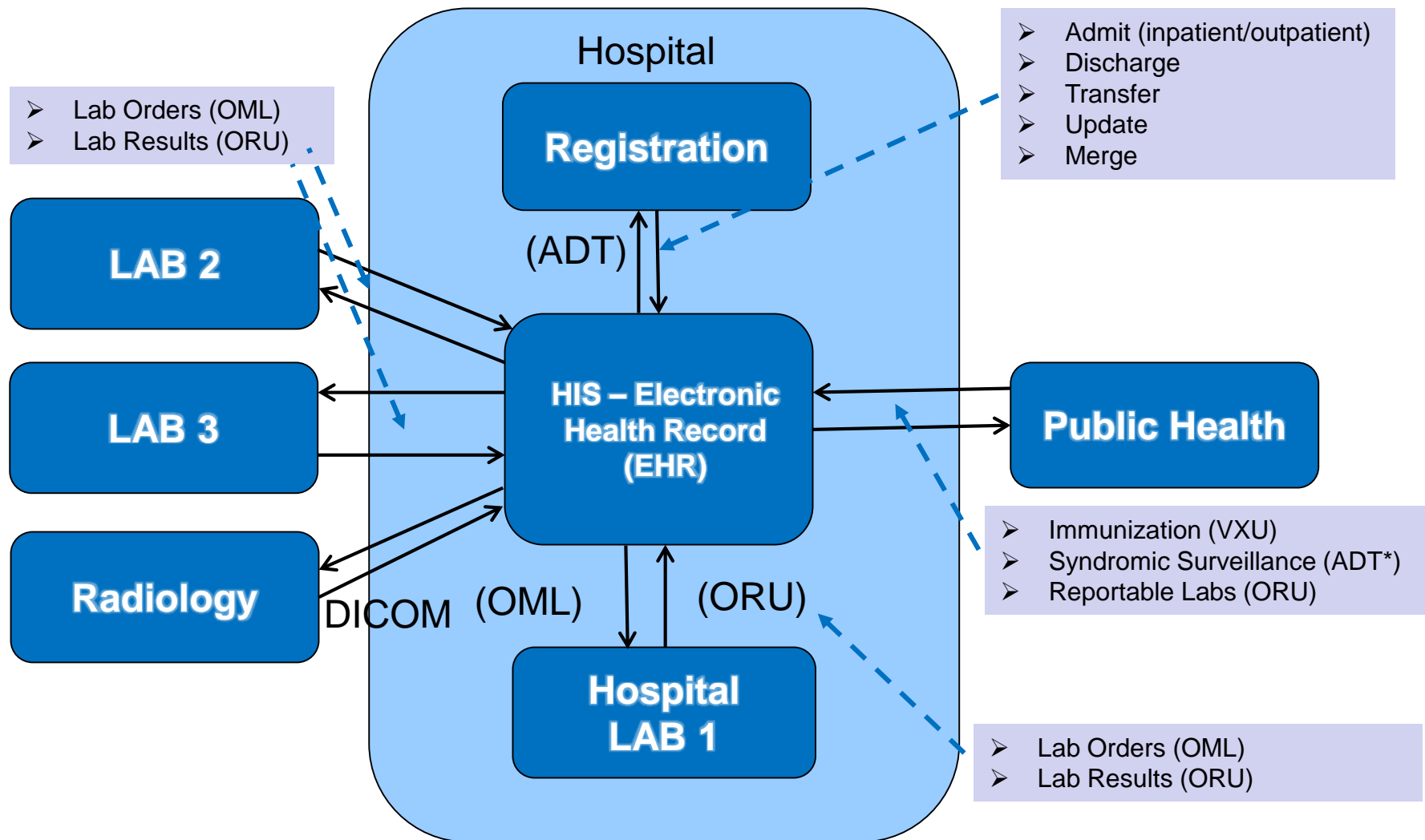
HL7 and Healthcare Integration



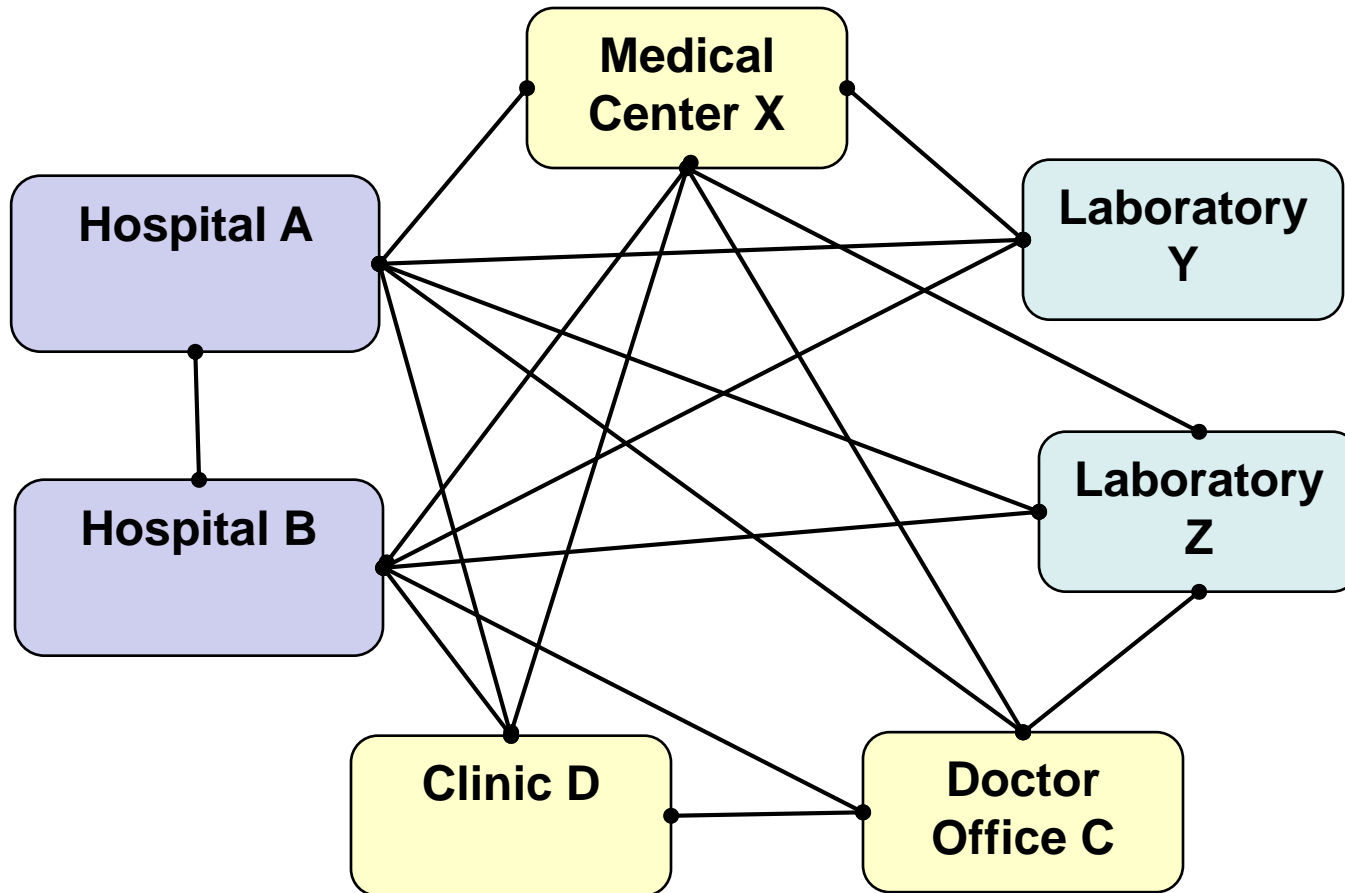
- HL7 (Health Level Seven) Messaging Standard (Application level)
- Standards for the exchange, management, and integration of data for clinical care
 - Messages model real world events
 - e.g., Messages for registering a patient or requesting a lab order
- HL7 provides a flexible framework to build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

Adapted from HL7 Desktop Reference Guide—NeoTool 2002

Example Healthcare Integration



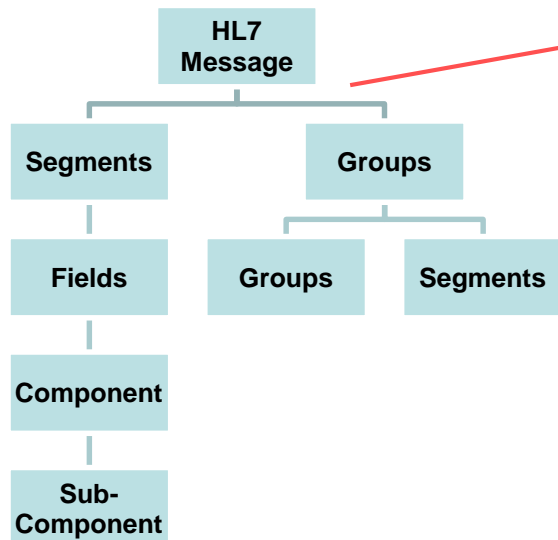
Disparate System (Many Point-to-Point Interfaces)



- Typically each interface is different between organizations
- Different vendor (with different solutions)
- Each new connection requires customization (costly, time consuming, error prone)

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
- 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)
- Etc.

Anatomy of an HL7 Message

PID Segment

ADT^A04^ADT_A01

```
MSH
EVN
PID
[ PD1 ]
[ { ROL } ]
[ { NK1 } ]
  PV1
  PV2
  .
  .
  .
[ { GT1 } ]
[ {
  IN1
  [ IN2 ]
  [ { IN3 } ]
  [ { ROL } ]
} ]
[ ACC ]
[ UB1 ]
[ UB2 ]
[ PDA ]
```

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1	4	SI	O			00104	Set ID - PID
2	20	CX	B			00105	Patient ID
3	250	CX	R	Y		00106	Patient Identifier List
4	20	CX	B	Y		00107	Alternate Patient ID - PID
5	250	XP	R	Y		00108	Patient Name
6	250	XP	O	Y		00109	Mother's Maiden Name
7	26	TS	O			00110	Date/Time of Birth
8	1	IS	O		0001	00111	Administrative Sex
...							
37	80	ST	O			01541	Strain
38	250	CE	O	2	0429	01542	Production Class Code

Components: <family name (FN)> ^ <given name (ST)> ^
 <second and further given names or initials thereof (ST)> ^ <suffix (e.g., JR or III) (ST)> ^
 <prefix (e.g., DR) (ST)> ^ <degree (e.g., MD) (IS)> ^ <name type code (ID)> ^
 <name representation code (ID)> ^ <name context (CE)> ^
 <name validity range (DR)> ^ <name assembly order (ID)>

Subcomponents of family name: <surname (ST)> ^ <own surname prefix (ST)> ^
 <own surname (ST)> ^ <surname prefix from partner/spouse (ST)> ^ <surname from partner/spouse (ST)>

Subcomponents of name context: <identifier (ST)> & <text (ST)> &
 <name of coding system (IS)> & <alternate identifier (ST)> & <alternate text (ST)> &
 <name of alternate coding system (IS)>

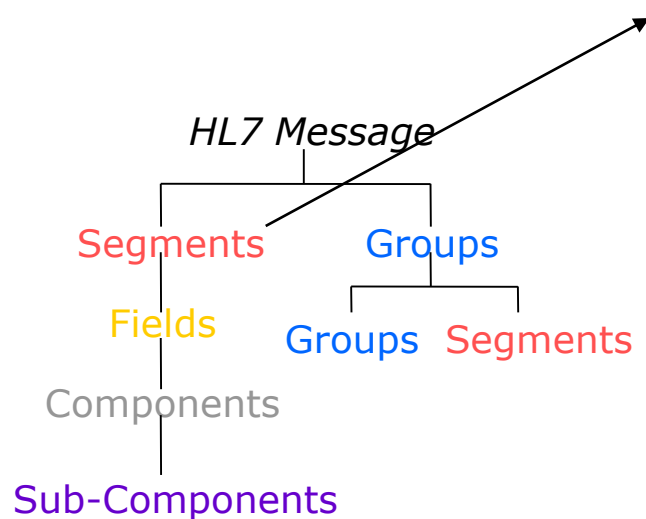
Subcomponents of name validity range: <date range start date/time (TS)> &
 <date range end date/time (TS)>

HL7 0001 - Admin Sex	
A	Ambiguous
F	Female
M	Male
U	Unknown

The Problem: HL7 V2 Too Flexible

- The Base Standard is a Framework
- Overwhelmingly large with many optional features
- Little agreement on how to define an interface
- Applications didn't know what to expect
- No two interfaces were alike

Example: PID Segment



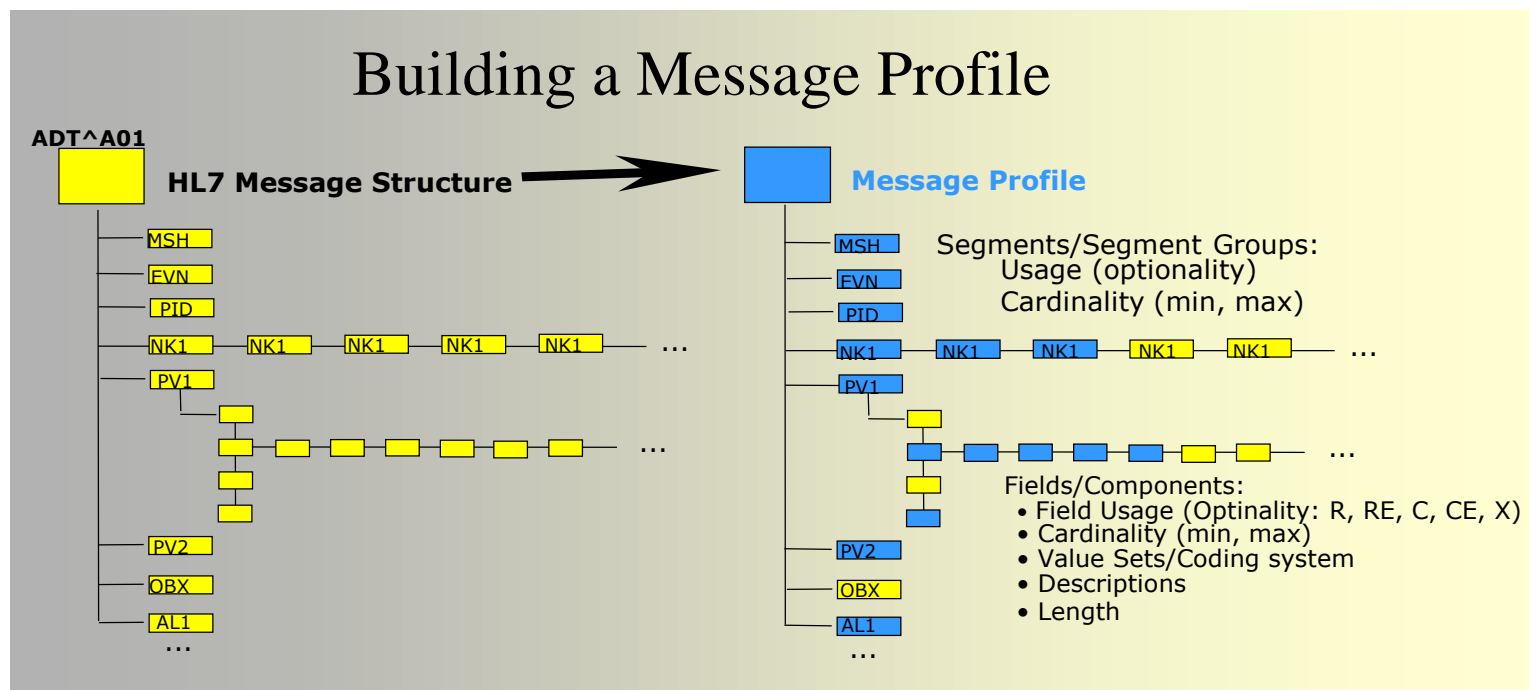
SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
...							
5	250	XPN	R	Y		00108	Patient Name
6	250	XPN	O	Y		00109	Mother's Maiden Name
7	26	TS	O			00110	Date/Time of Birth
8	1	IS	O		0001	00111	Administrative Sex
9	250	XPN	B	Y		00112	Patient Alias
10	250	CE	O	Y	0005	00113	Race
11	250	XAD	O	Y		00114	Patient 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

Problem with HL7 Base Standard

- Overwhelmingly large with many optional features
 - Framework for negotiations
 - Little agreement on how to define an interface
 - Applications didn't know what to expect
 - “No two interfaces are alike”; “standard-of-standards”
- Described as “total chaos” during implementation
- Local Extensions (e.g., Z-segments) complicate matters further
- Interoperability Issues – not plug-and-play
 - Two systems could be HL7 compliant but not interoperable
 - e.g., sending system could support 10 repetitions of a segment while the receiving systems may only support 5.

The Message Profile Approach

- Refinement of the HL7 Standard (applies implementation constraints)
- Agreement between Trading Partners
- Profiled at each level in the message structure (.i.e., segment, field, etc.)
- Each element attribute is constrained (e.g., usage)
- Specification can be directly implemented



Message Element Constraints

- **Usage**
 - Indicates how the element (e.g. a field) can be used
 - Required (R), Not Supported (X), Conditional (C), Required or Empty (RE), etc.
- **Cardinality**
 - Indicates how many time the element can appear
 - [0..0], [0..1], [1..1], [0..3], [3..5], [0..*]
- **Value Sets (Tables)**
 - Indicates a set of valid values for a given primitive element
 - e.g., LOINC – Lab Order and Results (Standardized Vocabulary)
- **Length**
 - Indicates the minimum or maximum length of a primitive element or a compound element
- **Regular Expressions**
 - Restricts the data content of a particular primitive element

Example Profiling: Field Level

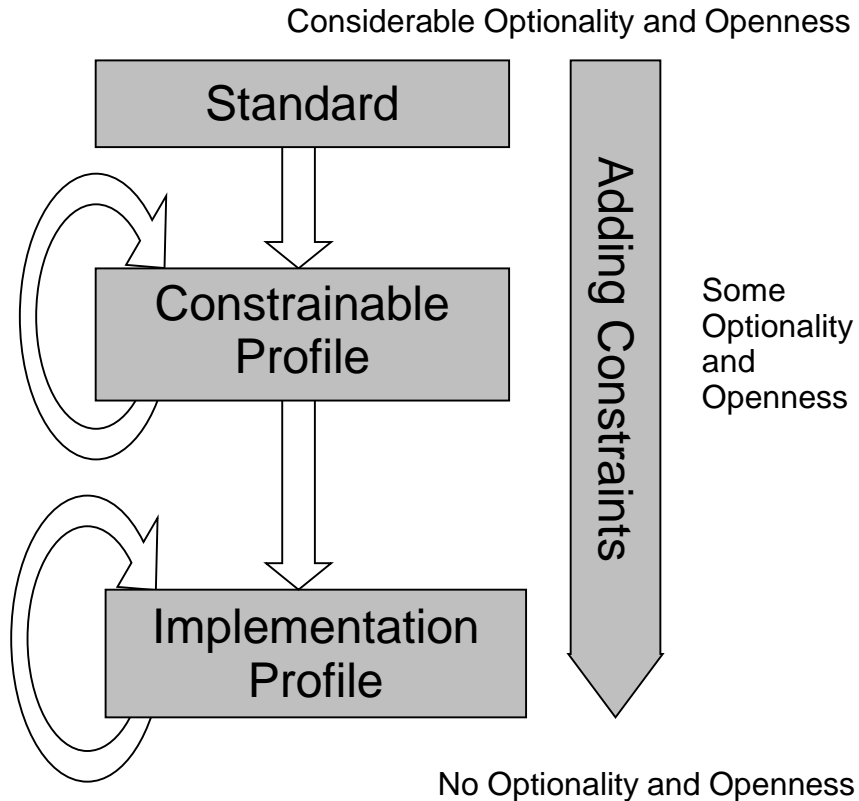
SEQ	LEN	Min Len	Max Len	DT	OPT	OPT	RP/#	RP# Min	RP# Max	TBL#	ITEM#	ELEMENT NAME
1	4	1	4	SI	O	R					00104	Set ID - PID
2	20			CX	B	X					00105	Patient ID
3	250	1	150	CX	R	R	Y	1	3		00106	Patient Identifier List
4	20			CX	B	X	Y				00107	Alternate Patient ID - PID
5	250	10	200	XPN	R	R	Y	1	3		00108	Patient Name
6	250			XPN	O	X	Y				00109	Mother's Maiden Name
7	26 → 4		8	TS	O → R						00110	Date/Time of Birth
8	1	1	1	IS	O	R				→ 0001	00111	Administrative Sex
9	250			XPN	B	X	Y				00112	Patient Alias
10	250 → 3		20	CE	O → RE		Y → 0		8	0005	00113	Race
11	250	1	300	XAD	O	R	Y	1	3		00114	Patient Address
12	4			IS	B	X				0289	00115	County Code
13	250	10	30	XTN	O	RE	Y	1	3		00116	Phone Number - Home
14	250	10	30	XTN	O	RE	Y	1	3		00117	Phone
...												
37	80			ST	O	X					01541	Strain
38	250			CE	O	X	2			0429	01542	Product

Each table reference contains the allowed values

Benefits of Conformance Profiles

- Eliminates the potential ambiguities that the standard allows as implementation alternatives
- Promotes interoperability
- Provides a better way to manage system integration
- Standardized XML representation
 - Profile Registries
 - Reuse
 - Comparison
 - Enables interoperability among tools
 - Automated message validation
 - Automated message generation
 - Can expose vendors' value added product features
- Provides a clear method to document localizations

Profile Hierarchy

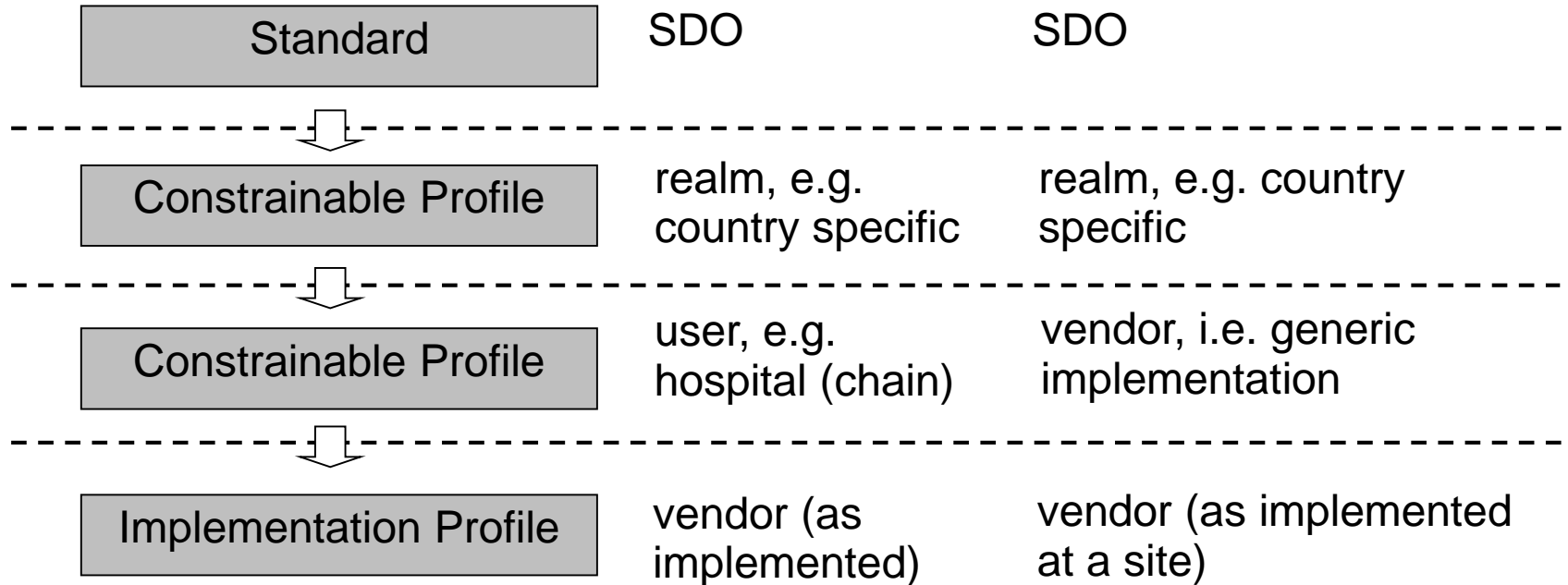


- EHR MU Certification specifications are examples of constrainable profiles.
- They are “national” level profiles providing core capabilities.
- Are likely to be further constrained/refine to meet local requirements.
- For example, state immunization requirements.

Use of Profile Hierarchy

Example 1:

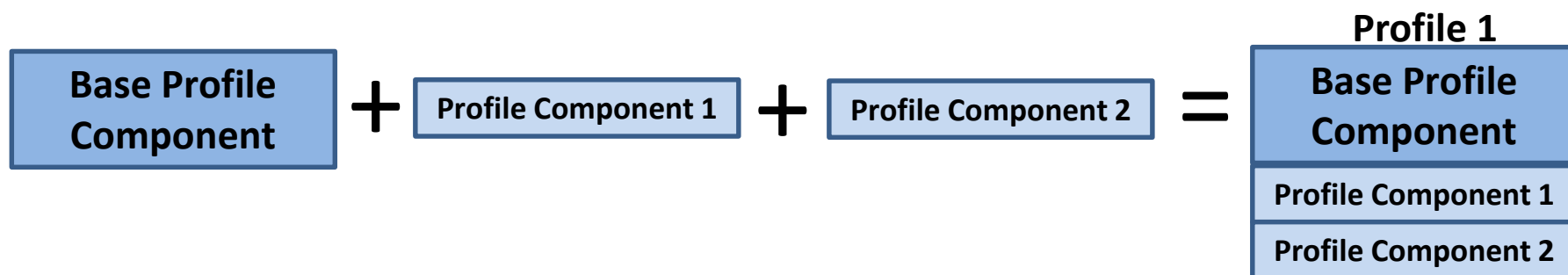
Example 2:



Profile Components

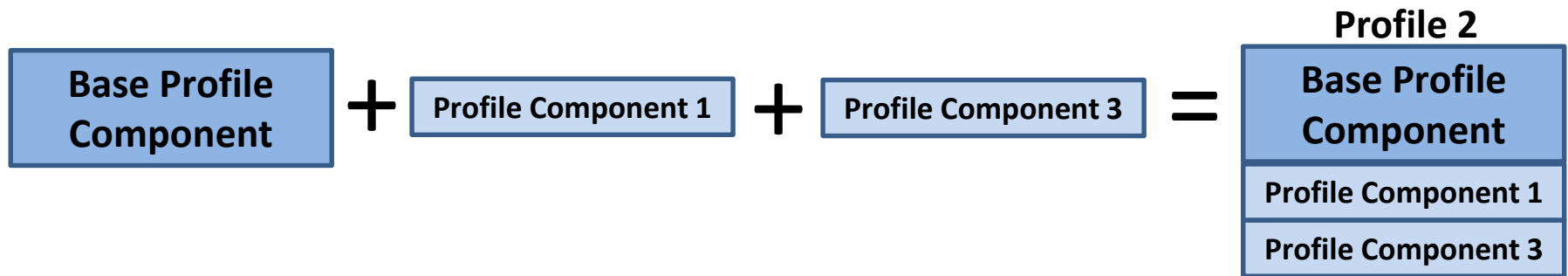
- Defines a part or a certain aspect of a message profile and is used to differentiate requirements from another message profile or profile component.
- Can be applied to any construct or section of a message profile.
- A profile component in a family of message profiles can be used to identify different levels of requirements for the same use case or to identify the differences in requirements for different, but closely related, use cases.

Profile Component: Example 1



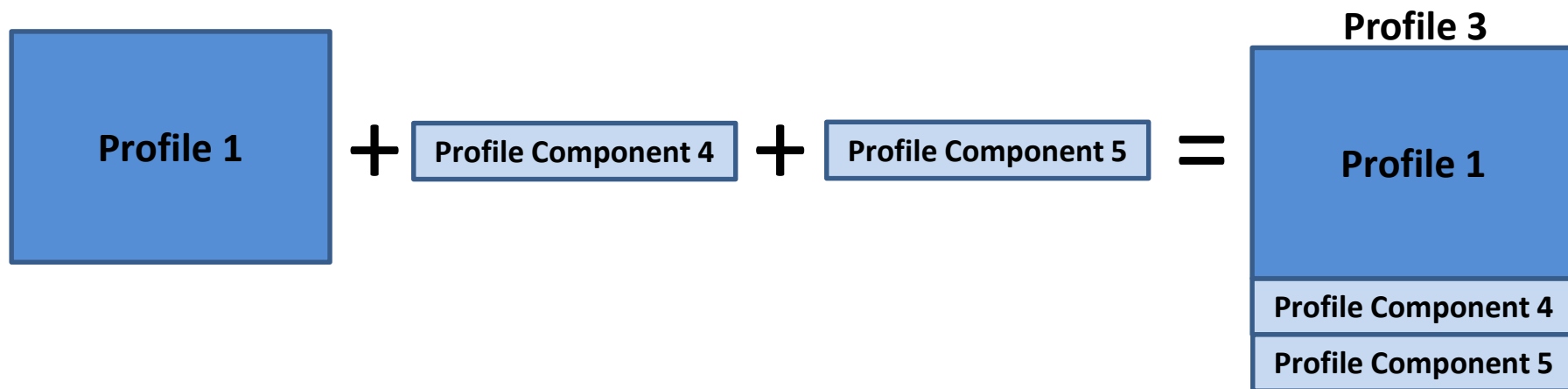
- A base profile component is developed that expresses all of the common requirements for a related set of profiles.
- Profile component 1 and profile component 2 are also created for aspects that are not defined in the base profile component.
- Combined the three profile components are used to describe a complete specification, Profile 1.

Profile Component: Example 2



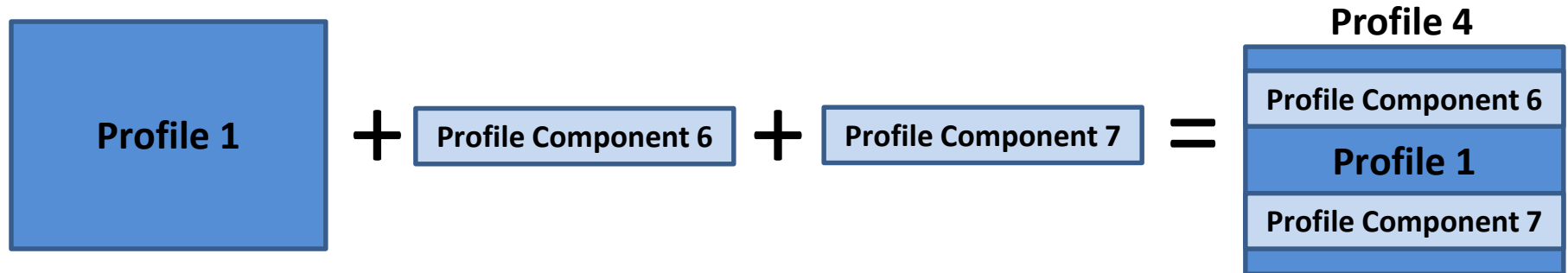
- The base profile component and profile component 1 are reused and combined with profile component 3 to specify Profile 2.

Profile Component: Example 3



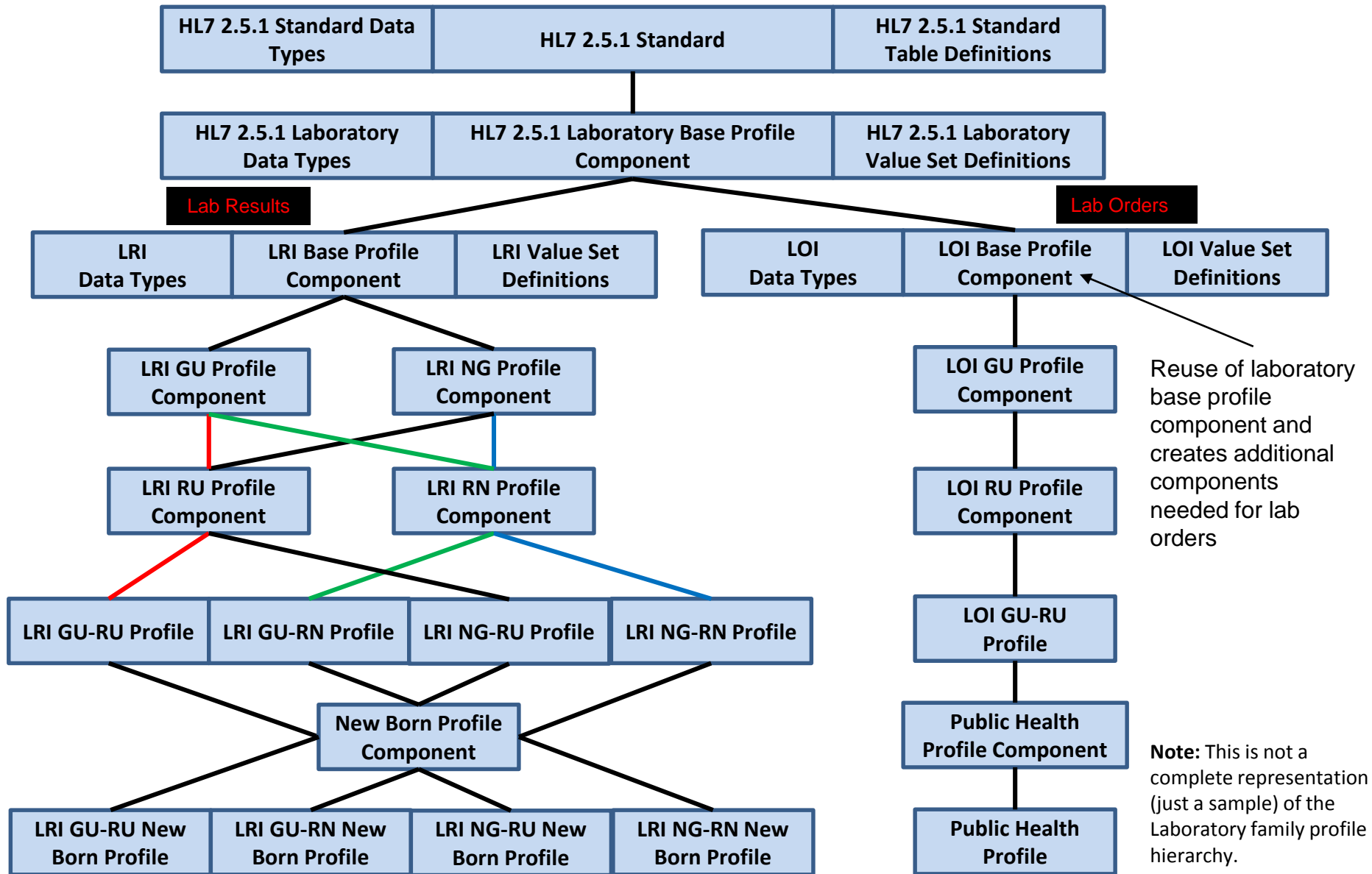
- Profile 1 is combined with profile components 4 and 5 to create Profile 3.

Profile Component: Example 4

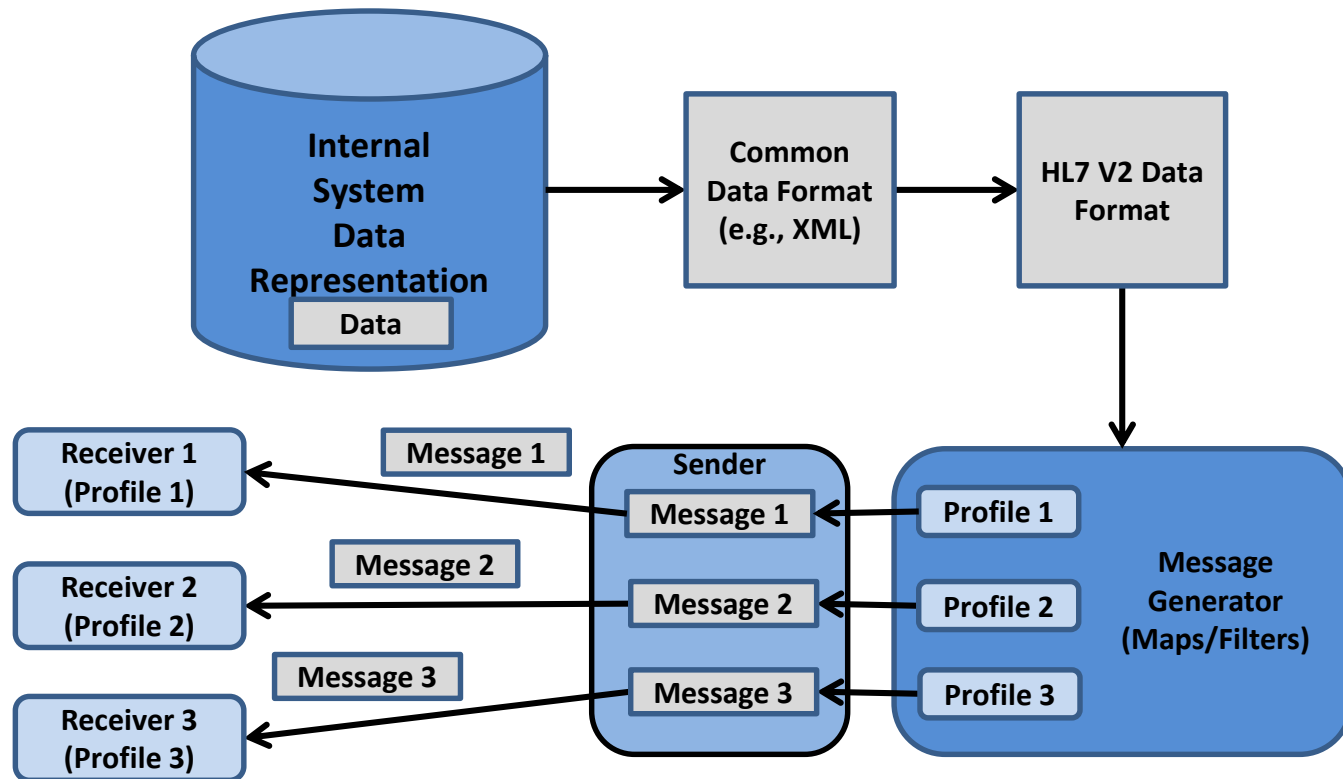


- Profile components can also express requirements that replace requirements established in a base profile component or profile.
- This may often be the case when different levels of profiles are developed or the profile provides utility outside the original set of related profiles.
- This depiction illustrates such a case where a subset of requirements for an existing profile is overridden.
- Here Profile 1 is used. However, certain aspects are redefined according to the rules and documented in profile components 6 and 7 which results in Profile 4.

Laboratory Family of Message Profiles



Possible Information Mapping



Define and Edit Message Profiles

Implementation Guide Editor | Message Profile | Segment Library | Datatype Library | Comparator

▸ Profiles Dashboard

▾ Profile Content

✓ Apply Refresh Export Delete Exit

Meta Information

Name: LRI Description: LRI HL7 Version: 2.5.1 Conformance Version: 2.7.1 Conformance Type: Constrainable

Profile Content

Display Columns ▾

Message	MSH	SFT	PID	PD1	NTE	NK1	PV1	PV2	ORC	OBR	NTE	TQ1	TQ2	CTD	OBX	NTE	FT1	CTI	SPM	OBX	DSC
Name		Usage	Cardinality		Length		DT	Code	Save to Library		Conf Statement		Predicate								
1 : Set ID - OBX	R	1	1	1	4	SI			NA	Segment[OBX]_2 - The value	+ Add										
2 : Value Type	C(R/X)	0	1	1	2	ID	0125		NA	+ Add	If the OBX.5 is valued.										
3 : Observation Identifier	R	1	1	-		CE_LRI	Save		NA	Segment[OBX]_3 - If there are	+ Add										
4 : Observation Sub-ID	C(R/RE)	0	1	1	20	ST			NA	+ Add	If there are multiple OBX segments										
5 : Observation Value	RE	0	1	1	99999	varies			NO	Segment[OBX]_1 - The value Segment[OBX]_4 - If the OBX Segment[OBX]_5 - If OBX-5 is	+ Add										
6 : Units	C(R/RE)	0	1	-		CE_LRI	Save		NA	+ Add	If OBX-2 is valued 'NM' or 'SN'										
7 : References Range	RE	0	1	1	60	ST			NA	+ Add	+ Add										
8 : Abnormal Flags	RE	0	*	1	5	IS	0078		NA	+ Add	+ Add										
9 : Probability	O	0	1	1	5	NM			NA	+ Add	+ Add										

Automatic Generation of Specifications in PDF, Word, etc.

Table 8: OBX

SEC	Field	DT	Usage	Card	Value Set	Conf. Statement	Predicate	Comment
1	Set ID - OBX	SI	R	[1..1]		OBX_2 : The value of OBX-1 SHALL be valued sequentially starting with the value '1' within a given segment group.		Need to handle this
2	Value Type	ID	C(R/X)	[0..1]	0125		If the OBX.5 is valued.	Need to handle this
3	Observation Identifier	CE_LRI	R	[1..1]		OBX_3 : If there are multiple OBX segments associated with the same OBR segment that have the same OBX-3 values for (OBX-3.1 + OBX-3.3) or (OBX-3.4 + OBX-3.6), a combination of (OBX-3.1 + OBX-3.3) or (OBX-3.4 + OBX-3.6) and OBX-4 SHALL create a unique identification under a single OBR.		Need to handle this
4	Observation Sub-ID	ST	C(R/RE)	[0..1]			IF there are multiple OBX segments associated with the same OBR segment that have the same OBX-3 vlaues	Need to handle this

Create Complete Machine Process-able Specification

Implementation Guide Editor Message Profile Segment Library Datatype Library Comparator

File Export Add Message P

IG Editor IG Reports

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B *I*

The *HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface for US Realm, Release 1 (US Realm)* is the result of collaborative efforts between HL7 and the Health and Human Services Standards and Interoperability Framework Laboratory Results Interface Initiative. By consensus the HL7 V2.5.1 *ORU^R01* Message was selected as the basis to define the profile constraints expressed in this guide to meet the requirements of the transmission of laboratory reports. The Standards and Interoperability (S&I) Framework's Laboratory Result Interface Use Case was leveraged and revised, where agreed upon by the working group, to provide the Use Case content, diagrams and foundation for this Implementation Guide.

Examples:

The HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface for US Realm, Release 1 (US Realm) is the result of collaborative efforts between HL7 and the Health and Human Services Standards and Interoperability Framework Laboratory Results Interface Initiative.

Summary

- Healthcare interoperability is critical for successful adoption and use of EHRs
- Quality healthcare data communication standards are central to achieving interoperability
- Message profiling and profile components techniques are one avenue to improving standards specifications
- Automated tools can facilitate and promote use of techniques
- Conformance and interoperability test tools improve standards and implementation during and after development
- Certified EHR systems provide a core set of standardized capabilities that will improve interoperability
- The approach provided in this paper is applicable to the class of data communication standards