Streamlining the Lab Connection

The ELINCS-HL7 Specification

TEPR Conference

May 21, 2007

Speaker

- Walter Sujansky
  - Sujansky & Associates, LLC
  - Contracted by California Healthcare Foundation
  - Technical lead for development of ELINCS

The Problem: No EHR is an Island

"The practice was told that the EHR would interface with a national lab; that turned out to be untrue, says Dr. Gutman, because the lab does not have uniform systems throughout the country, or even on Long Island. The lab interface has been operational for a year, but the practice still hasn't hooked up its internal lab; they've had to hire an outside programmer to write that interface. The practice also had difficulty interfacing to its scheduling system, necessitating manual entry.

“As a result of all this, says Gutman, the EHR has created extra work for the staff, rather than savings. So, in his view, the group isn't seeing any return on the $150,000 it paid for the system initially or on the extra costs for additional licenses, computers, and interfaces."

["Why EHRs Falter". Medical Economics, April 7, 2006]

Lab Connectivity Matters

Desired EHR Capabilities Ranked by Physicians*

Rank	Feature
1	Displays a summary of patient's clinical condition (problem list, med list, etc.)
2	Allows documentation of progress notes
3	Displays patient's demographic and insurance information
4	Captures billing codes and transmits them to billing system
5	Allows access to EMR system from home or another office
6	**Imports and displays lab results**
7	Imports and displays radiology reports
8	Displays clinical notes from consulting or referring physicians
9	Displays history of immunizations, screening tests, and other preventive procedures
10	*Alerts to interactions and contraindications in prescriptions*
11	*Documents and prints prescriptions*
12	Can incorporate information originating with patient (intake questionnaires)
13	Documents and prints orders for lab tests
14	Provides secure e-mail communication with patients and colleagues
15	Provides administrative reports on clinical practice
…	
19	*Sends prescriptions electronically to the pharmacy*
…	
21	*Electronically transmits orders for lab tests*
…	
23	*Displays disease management guidelines and other references*

* Survey of 376 MDs in small (< 11) practices – California HealthCare Foundation, 2004 [unpublished]

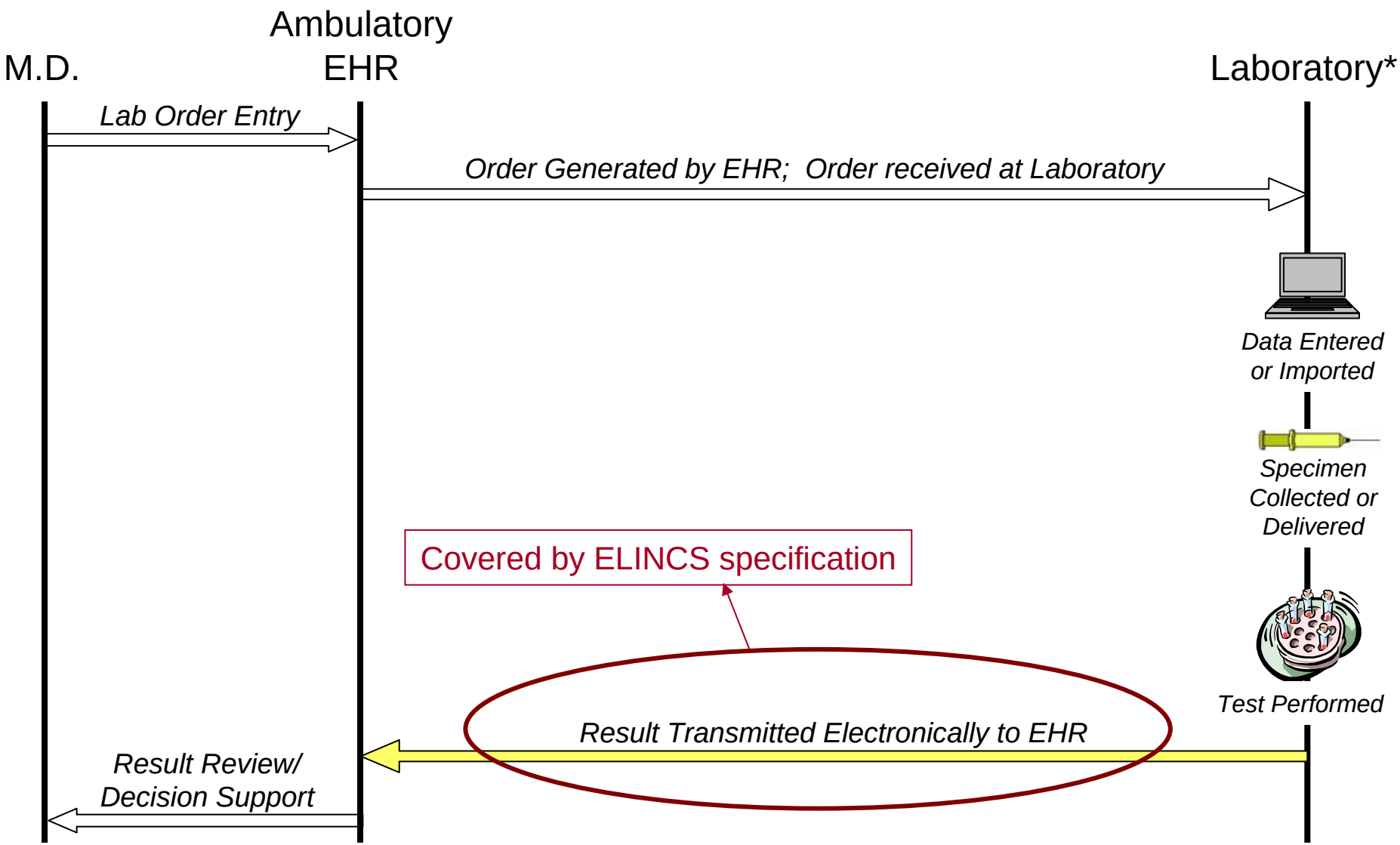
Structured Lab Connectivity Matters

- Free-text or scanned lab results are inadequate…
- For Efficiency
  - Convenience of graphical result review
  - Manual entry of lab results => costly, error-prone
- For Quality/Safety
  - Guideline-based decision support
  - Drug-lab interaction checking
- For Revenue Enhancement
  - Pay-for-performance reporting

ELINCS Project Overview

- A national project sponsored by the California HealthCare Foundation (www.chcf.org)
- Motivation
  - Streamline the implementation of structured electronic data interfaces between labs and ambulatory EHRs
  - Expand the electronic delivery of laboratory results to clinicians in the office setting
  - Promote the adoption of EHRs among ambulatory-care providers
  - Improve the quality of chronic disease care
- Initiated in February, 2005

ELINCS Use Case: Outpatient Lab Testing



* Hospital, Reference, or Clinic

ELINCS Project Goals

- An *implementation guide* for the electronic reporting of lab results
  - Detailed specification of the format and coding of lab-result messages
  - Detailed interaction rules for laboratory information systems and EHRs
  - Based on requirements of varied stakeholders
    - EHR vendors, commercial labs, L.I.S. vendors, clinician users, government bodies, standards organizations
  - Balance of ideal requirements and practical capabilities => enable near-term adoption
  - *Support for objective conformance testing*

ELINCS Technical Working Group Representation

Commercial Laboratories

Ameripath
LabCorp
Quest Diagnostics

EHR Vendors

AllScripts
Emdeon (WebMD)
e-MDs
NextGen

Hospital L.I.S. Vendors

GE Medical Technologies
Misys

Government

CDC
CMS
V.A.

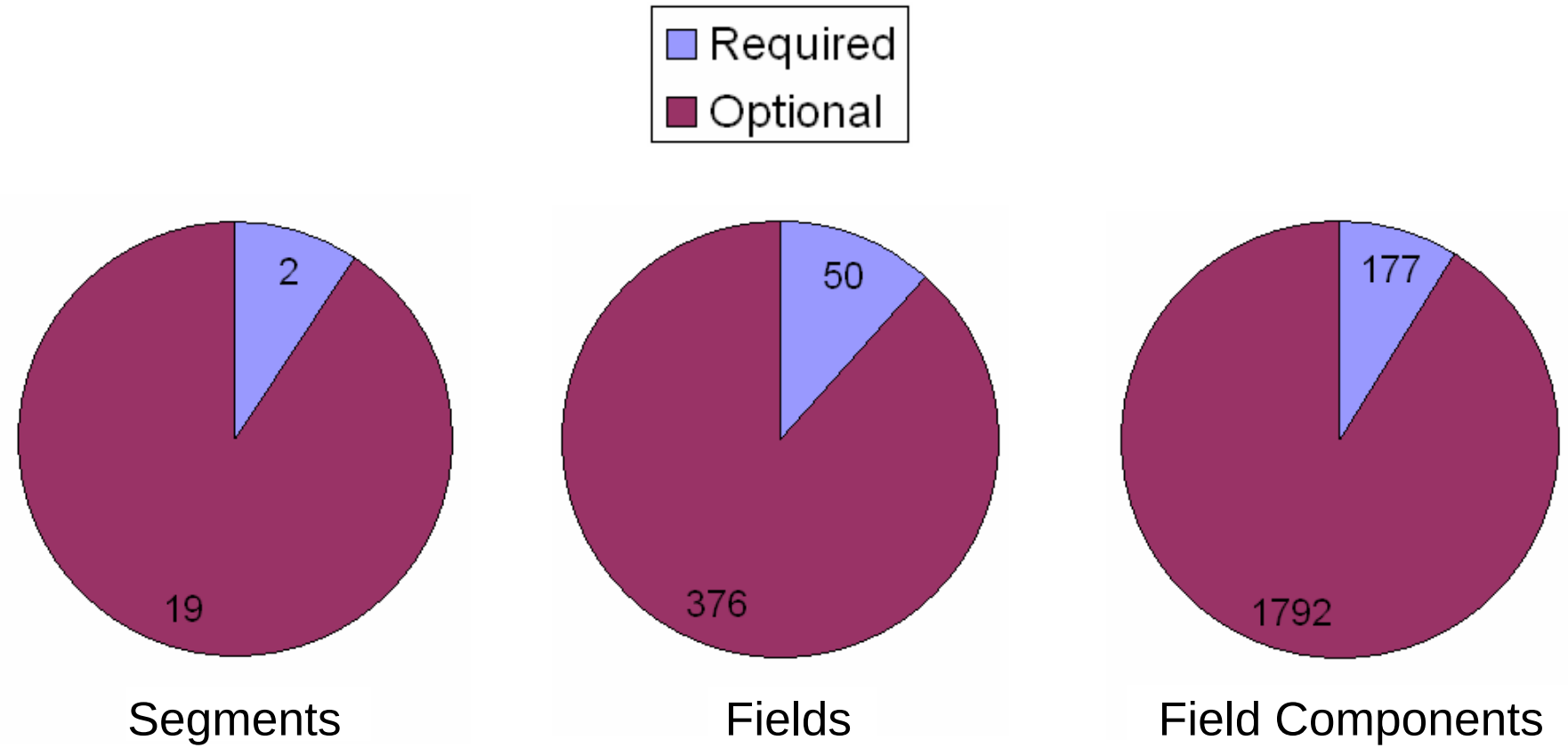
Other Organizations

American College of Physicians
eHealth Initiative
Indiana Health Information Exchange

What about HL7? Necessary But Not Sufficient

- HL7 = A useful *general framework* for messaging results of many kinds and for many use cases
  - Lab, radiology, imaging, physical exam
  - Inpatient, outpatient
  - Highly structured, text based
  - Patient care, clinical research, veterinary medicine, etc.
- Result = Significant optionality and variation
  - “When you’ve seen one HL7 lab interface, you’ve seen one HL7 lab interface…”
  - Great foundation, but much negotiation/customization still required to implement a working interface

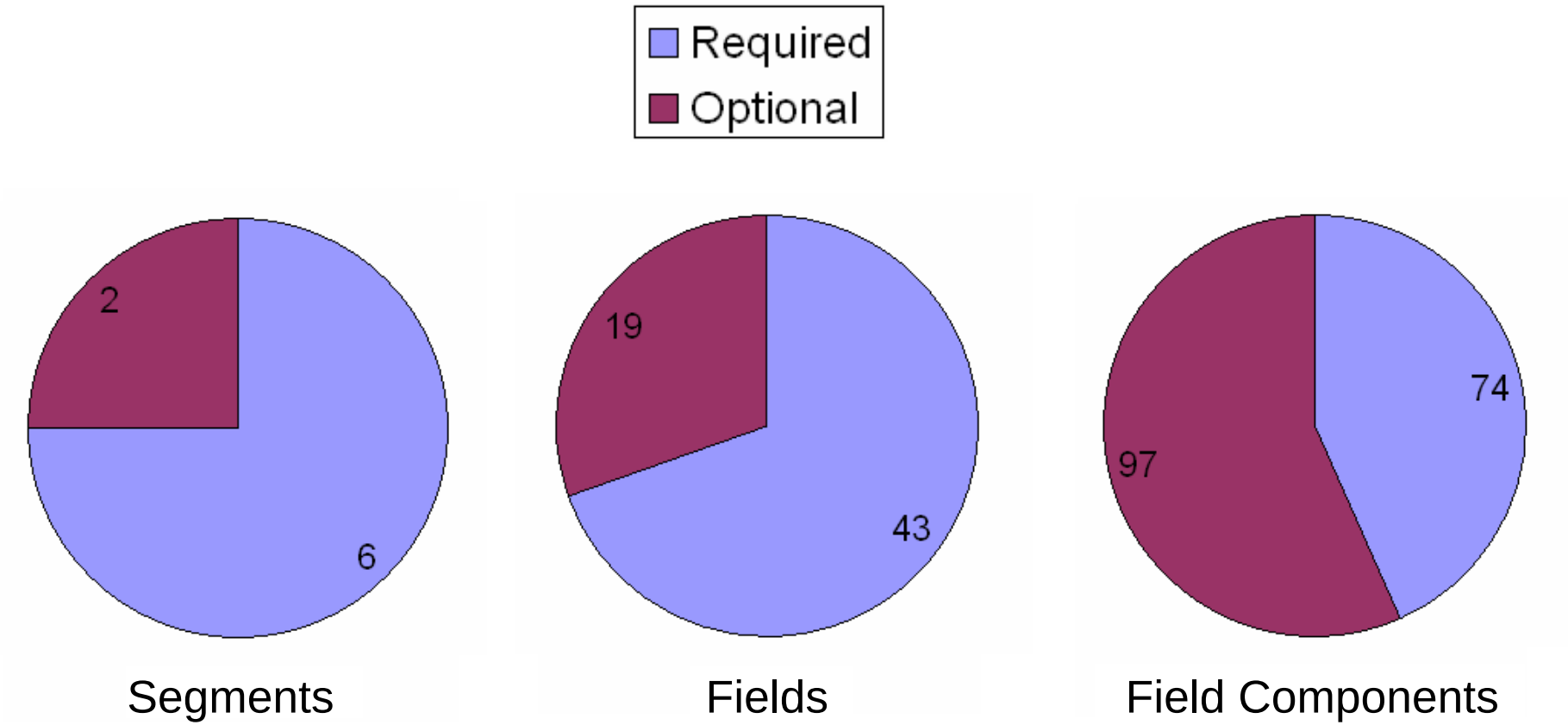
Optionality in HL7 Result-Reporting Message*



Optionality ≅ 90%

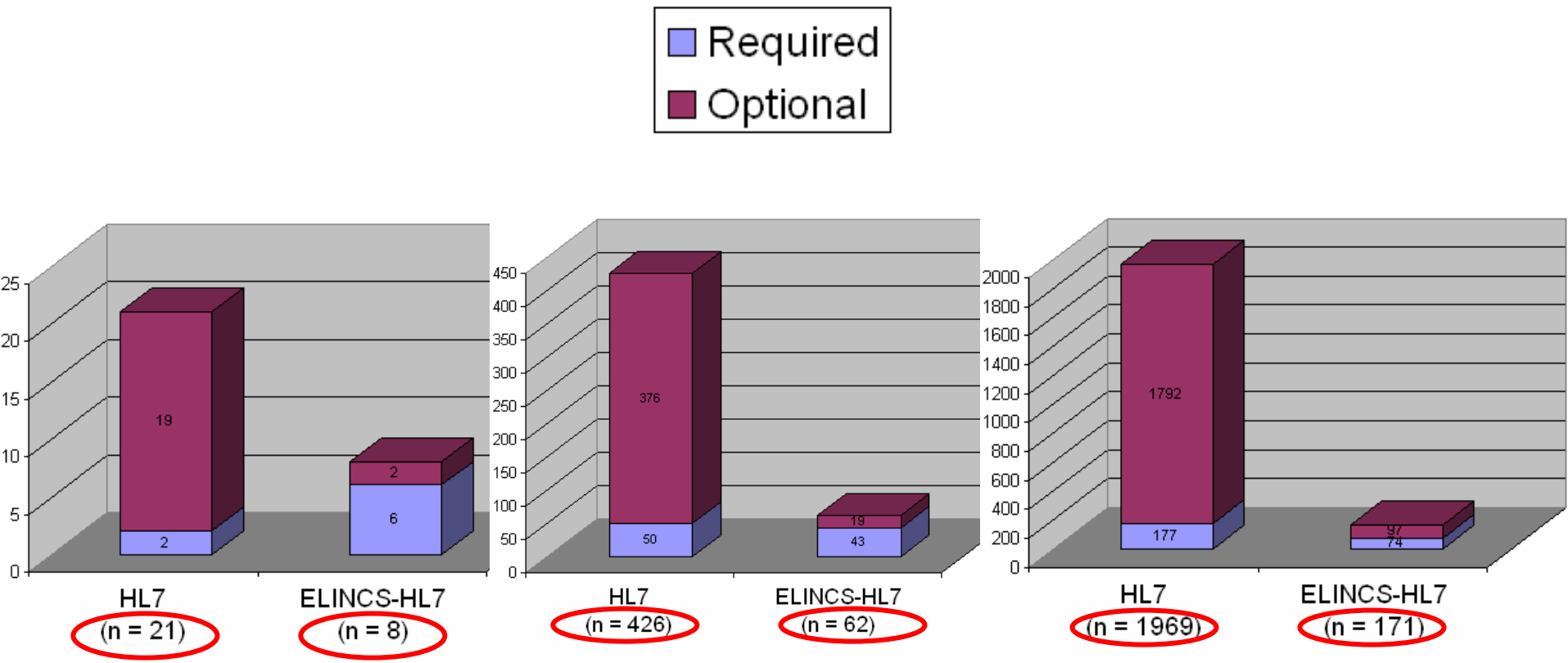
* v2.5.1 ORU Message

Optionality in ELINCS-HL7 Result-Reporting Message



Optionality ≅ 38%

Complexity of ELINCS-HL7 Result-Reporting Message



Segments Fields Field Components

Total Possible Objects (HL7) = 4,132 [with 90% opt.]

Total Possible Objects (ELINCS-HL7) = 439 [with 38% opt.]

Standard Coding for Tests in ELINCS-HL7

- LOINC codes required for top 95% of tests (by frequency)
  - ~ 170 tests; Based on data from 3 large CA provider groups
- Tests specified in ELINCS-HL7 specification
- Examples:

Test Category	Test	Test Description	LOINC Code(s)	Sample Values
Common blood cell count and differential WBC count analytes				
	RBC	Red Blood Cells (Erythrocytes), patient blood	790-6, 789-8, 26453-1	4.41 M/uL
	WBC	White Blood Cells (Leukocytes), patient blood	6690-2, 26464-8, 804-5	7.3 K/uL
	PLATELETS	Platelets, patient blood quantitative	778-1, 777-3, 26515-7	400 K/uL
	HEMOGLOBIN	Blood count, hemoglobin	30350-3, 718-7	12.2 g/dL
	BANDS	Neutrophil bands, patient blood, quantitative	26507-4. 30229-9, 763-3	1.14 K/uL
	BANDS %	Neutrophil bands as percent of total leukocytes	26508-2, 35332-6, 764-1	7%
	...			

The Vision: ELINCS in the Practice

A four-physician practice in a suburban community recently purchased an EHR system. During installation of the system, the vendor called the local hospital lab and the local reference lab and confirmed that they offer electronic result reporting using the ELINCS messaging specification. Following two days of configuration and testing by the vendor, the four physicians began seeing test results from both labs appear in their EHR.

Several months later, the lead physician received an alert from the EHR that a patient she had recently placed on Lisinopril had had no serum creatinine monitoring performed at either lab since the prescription, a variance from best practices and pay-for-performance criteria. She forwarded the alert to her staff to arrange a follow-up appointment for the patient.

The Vision: ELINCS in the Lab

Lakeville hospital provides outpatient lab testing in a community also served by a larger hospital lab and a reference lab. Lately, physicians in the community have been purchasing various EHR systems and requesting that Lakeville report lab results to them electronically.

Because of product-certification requirements for EHRs, all of the purchased EHR systems accept results formatted in the ELINCS specification. Lakeville lab implements a single ELINCS interface and begins sending electronic results to 17 local practices.

The Holy Grail: Plug and Play Interoperability

- Work remains…
  - Standardized transport
    - FTP vs. TCP/IP Sockets vs. Web Services vs….
  - Standardized authentication/encryption
    - Secure FTP vs. PGP vs. SSL vs….
  - Message-routing services
  - Standardized formatting of lab test orders

- but with ELINCS-HL7, much closer than before

ELINCS Status

- Version 1.0 completed and published July 2005
- 4 pilot projects in CA completed in 2006
  - Hospital labs and reference labs
  - Large and small physician practices
  - Successful implementations, demonstrated value
- Result = ELINCS v1.1

ELINCS Status (cont'd)

- ELINCS has been implemented by a number of labs and EHR vendors
  - LabCorp*, Quest*, Spectrum*, DelNor*, Ridgecrest, UCSF
  - AllScripts*, Emdeon*, e-MDs*, NextGen, Nightingale*

* Demonstration at TEPR 2007 (Booth 322)

ELINCS Status (cont'd)

- ELINCS is being transitioned to HL7 (2007)
  - Balloting of "ELINCS-HL7" currently underway
  - HL7 will manage future maintenance/extensions
- CCHIT will use ELINCS test messages in lab certification testing (2007)

Implementing ELINCS v1.1: Checklist for EHRs

- ✓ Ability to generate a lab test order
- ✓ Ability to receive lab result data electronically in HL7 messages (v2.4)
- ✓ Ability to Acknowledge receipt of lab messages
  - Releases lab from need to resend message
- ✓ Ability to store and display certain result data
  - Test cancellations
  - Identity of the lab performing the test
  - Several others…
  - Required to assure labs of CLIA conformance (Clinical Laboratory Improvement Amendments)

Implementing ELINCS v1.1: Checklist for Labs

- ✓ Ability to report test results, cancellations, and corrections electronically
- ✓ Ability to report tests using HL7 v2.4 ORU message
- ✓ Ability to populate ELINCS' required segments and fields
- ✓ LOINC coding for 100 most common tests
- ✓ Ability to capture, store, and report the required data elements from test orders
- ✓ Ability to receive and process acknowledgement messages sent by EHRs

Assistance for EHRs and Labs
(and it's free)*

- ELINCS Data Generation and Evaluation (EDGE) tool
  - Generates ELINCS messages to assist EHR testing
  - Validates ELINCS messages to assist lab testing
  - Standalone desktop tool
  - Available at www.ELINCS.org

- Technical consultation via email and phone
  - Contact ELINCS-Support @sujansky.com

* Courtesy of the California HealthCare Foundation

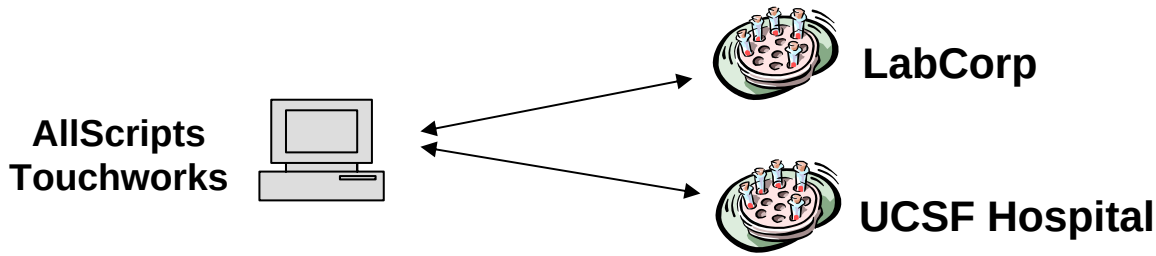
Questions

Walter Sujansky
Sujansky & Associates, LLC
wsujansky@sujansky.com

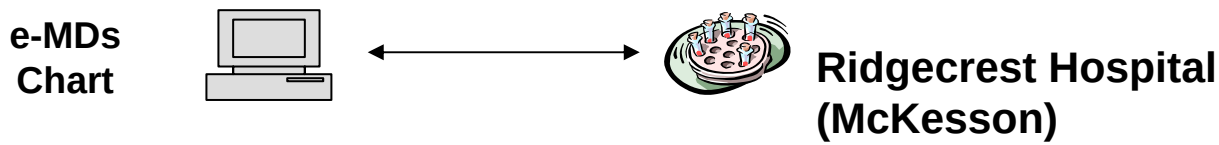
California HealthCare Foundation
www.chcf.org

ELINCS Pilot Projects

1. Brown & Toland Medical Group

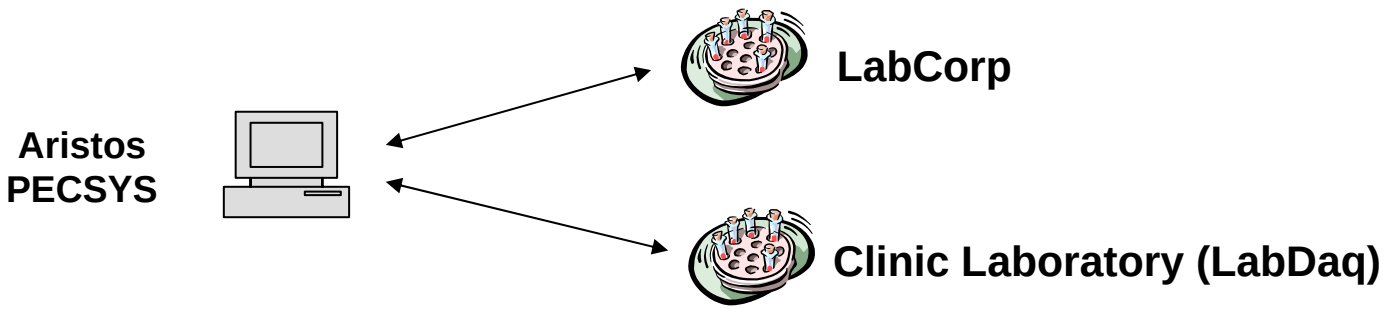


2. Southern Sierra Medical Clinic

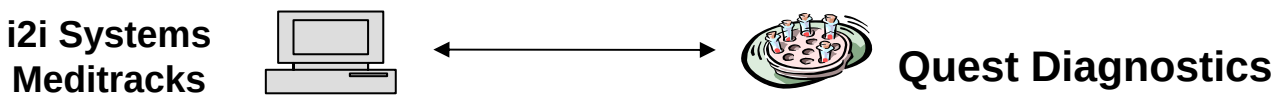


ELINCS Pilot Project Grantees

3. Humboldt Del Note IPA



4. Redwood Community Health Coalition



HL7 Segments: Underspecified

Segments in Result Message ("ORU") *

ORU^R01	**Unsolicited Observation Message**
MSH	Message Header
{	
[	
PID	Patient Identification
[PD1]	Additional Demographics
[{NK1}]	Next of Kin/Associated Parties
[{NTE}]	Notes and Comments
[	
PV1	Patient Visit
[PV2]	Patient Visit - Additional Info
]	
]	
{	
[ORC]	Order common
OBR	Observations Report ID
{[NTE]}	Notes and comments
[CTD]	Contact Data
{	
[OBX]	Observation/Result
{[NTE]}	Notes and comments
}	
[{FT1}]	Financial Transaction
{[CTI]}	Clinical Trial Identification
}	
}	
[DSC]	Continuation Pointer

* Grayed = Optional

ELINCS-HL7 Segments: Highly Specified

Segments in Result Message ("ORU")

Segment ID	Usage	Cardinality	Segment Name
MSH	R	[1..1]	Message Header
{	R	[1..*]	Message Content Block
PID	R	[1..1]	Patient Identification
[PD1]	X	[0..0]	Additional Demographics
[{NK1}]	X	[0..0]	Next of Kin/Associated Parties
[{NTE}]	X	[0..0]	Notes and Comments
[	X	[0..0]	
PV1	X	[0..0]	Patient Visit
[PV2]	X	[0..0]	Patient Visit - Additional Info
]			
{	R	[1..*]	Test Order Block
ORC	X	[0..0]	Order Common
OBR	R	[1..1]	Observations Report ID
{[NTE]}	RE	[0..*]	Notes and comments
[CTD]	X	[0..0]	Contact Data
{	**	**	Test Result Block
OBX	R	[1..1]	Observation/Result
{[NTE]}	RE	[0..*]	Notes and comments
}			
{[FT1]}	X	[0..0]	Financial Transaction
{[CTI]}	X	[0..0]	Clinical Trial Identification
}			
}			
[DSC]	X	[0..0]	Continuation Pointer

R: Required Always
RE: Required if data available
X: Not supported

HL7 Fields: Underspecified

Fields in OBX Segment *

SEQ	LEN	DT	OPT	ELEMENT NAME
1	4	SI	O	Set ID - OBX
2	2	ID	C	Value Type
3	250	CE	R	Observation Identifier
4	20	ST	C	Observation Sub-ID
5	65536[1]	*	C	Observation Value
6	250	CE	O	Units
7	60	ST	O	References Range
8	5	IS	O	Abnormal Flags
9	5	NM	O	Probability
10	2	ID	O	Nature of Abnormal Test
11	1	ID	R	Observation Result Status
12	26	TS	O	Date Last Observation Normal Value
13	20	ST	O	User Defined Access Checks
14	26	TS	O	Date/Time of the Observation
15	250	CE	O	Producer's ID
16	250	XCN	O	Responsible Observer
17	250	CE	O	Observation Method
18	22	EI	O	Equipment Instance Identifier
19	26	TS	O	Date/Time of the Analysis

* Grayed = Optional

ELINCS-HL7 Fields: Highly Specified

Example: Fields in OBX Segment

SEQ	ELEMENT NAME	LEN	DATA TYPE	Usage	Cardinality
1	**Set ID - OBX**	**4**	**SI**	**O**	**[0..1]**
2	**Value Type**	**2**	**ID**	**C**	**[0..1]**
3	**Observation Identifier**	**250**	**CE**	**R**	**[1..1]**
4	**Observation Sub-ID**	**20**	**ST**	**O**	**[0..1]**
5	**Observation Value**	**65536**	*****	**C**	**[0..*]**
6	**Units**	**250**	**CE**	**RE**	**[0..1]**
7	**References Range**	**60**	**ST**	**RE**	**[0..1]**
8	**Abnormal Flags**	**5**	**IS**	**RE**	**[0..5]**
9	Probability	5	NM	X	[0..0]
10	Nature of Abnormal Test	2	ID	X	[0..0]
11	**Observation Result Status**	**1**	**ID**	**R**	**[1..1]]**
12	Date Last Observation Normal Value	26	TS	X	[0..0]
13	User Defined Access Checks	20	ST	X	[0..0]
14	Date/Time of the Observation	26	TS	X	[0..0]
15	**Producer's ID**	**250**	**CE**	**R**	**[1..1]**
16	**Responsible Observer**	**250**	**XCN**	**RE**	**[0..*]**
17	Observation Method	250	CE	X	[0..0]
18	Equipment Instance Identifier	22	EI	X	[0..0]
19	**Date/Time of the Analysis**	**26**	**TS**	**RE**	**[0..1]**

R: Required Always
RE: Required if data available
O: Optional
C: Conditional
X: Not supported

HL7 Field Components: Underspecified

Field Components in Observation Identifier Field *

Field Components	OPT
identifier (ST)	O
text (ST)	O
name of coding system (IS)	O
alternate identifier (ST)	O
alternate text (ST)	O
name of alternate coding system (IS)	O

LIP-0988 ^ LDL Cholesterol ?

LDL Cholesterol ?

LIP-0988 ^ LDL Cholesterol ^ 99Local ?

LIP-0988 ^ LDL Cholesterol ^ ^ 2089-1 ^ LDL Chol ?

* Grayed = Optional

ELINCS-HL7 Field Components: Highly Specified

"For the tests listed in Appendix A…the LOINC® code for the reported analyte must appear in the 1st, 2nd, and 3rd components of OBX-3"

Field: OBX-3 Observation Identifier

Component/Sub-Component		Usage
identifier (ST)		RE
text (ST)		RE
name of coding system (IS)		RE
alternate identifier (ST)		R
alternate text (ST)		R
name of alternate coding system (IS)		R

"For *all* tests, the 4th, 5th, and 6th components of OBX-3 must be populated with the laboratory's internal codes for the reported analytes."