ASTP Assistant Secretary for Technology Policy

Quality In, Quality Out: Challenges and Opportunities for Improving Data Quality

December 5, 2024

Agenda

- Moderator and panelist introductions

- Discussion

- Audience questions

Moderator and Panelists

Ryan Howells

- Moderator
- Principal, Leavitt Partners

Niall Brennan

- Chief Data and Analytics Officer, Horizon Blue Cross Blue Shield of New Jersey

Keith Campbell

- Program Director, Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD), Food and Drug Administration

Didi Davis

- VP, Informatics, Conformance & Interoperability, The Sequoia Project

Charlie Harp

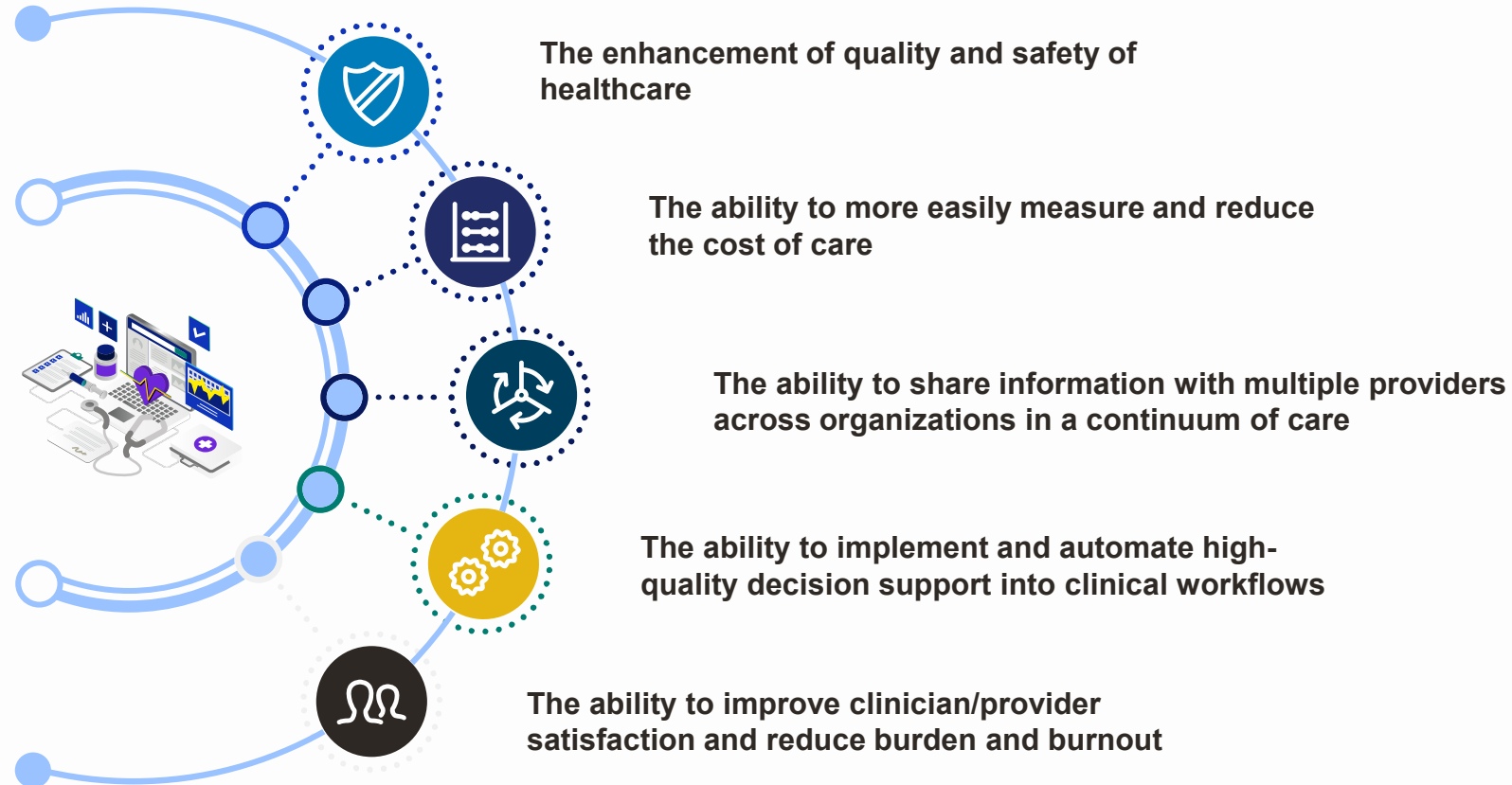- Founder and CEO, Clinical Architecture

Ilana Yurkiewicz

- Oncologist & Internist, Stanford Health Care
- Clinical Assistant Professor, Stanford University School of Medicine
- Journalist

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Slides from Moderator Ryan Howells

The Promise of Health IT

In a connected world, Health Information Technology (IT) has become a critically important form of organizing, managing, analyzing, and exchanging patient health information. Health IT entered the scene and obtained widespread adoption in the early-1990s promising:

The enhancement of quality and safety of healthcare

The ability to more easily measure and reduce the cost of care

The ability to share information with multiple providers across organizations in a continuum of care

The ability to implement and automate high-quality decision support into clinical workflows

The ability to improve clinician/provider satisfaction and reduce burden and burnout

On the surface, exciting new technology has continued to advance in the healthcare ecosystem, but cases of patient harm, redundant testing, and over-expenditure persists. This then begs the question: **is Health IT truly fulfilling its promises?**

The Promise Unfulfilled

Health IT is intended to ease provider workload and ultimately improve patient care and population health; however, the current state presents inconsistencies that can result in negative effects at both the patient and enterprise levels.

Primary Challenges

Patient Care

1 — **Enhanced Safety & Efficacy**

Challenge: Disparate systems and organizations across the healthcare ecosystem lead to variation in how data are handled.

Impact: When critical health information is not accessible to a patient's clinicians, **there is a risk that providers will not have sufficient information to make informed decisions, compromising patient safety**.

Enterprise Analytics Capabilities

2 — **Limited Population Health Analysis**

Challenge: Denormalized data formats reduce the quality of data processing and the ability to conduct safe and reliable analytics.

Impact: When incongruent data is collated, it **requires extensive resources to synthesize basic trends and insights that should be readily available to inform population health decision making.**

Though Health IT has enabled healthcare organizations to provide better patient care and public health decision-making, there is still a long way to go in achieving high quality data that can be used safely and reliably by individuals across the healthcare ecosystem.

A Call for Data Quality and Metrics

As of December 2024, several major federal entities have made public commitments to improve health care data quality and patient safety.

The White House

President Biden's Council of Advisors on Science and Technology (PCAST) made several actionable recommendations to **address system and pervasive challenges regarding patient safety.**

Assistant Secretary for Technology Policy (ASTP)

"Patient data quality must be improved at its **point of collection** as well as when it is **exchanged between organizations."**

- ONC/ASTP in collaboration with the Data Normalization Workgroup

Centers for Disease Control and Prevention (CDC)

"Transparent, reliable data is the foundation for truth and catalyst for action, and the key to strengthening health in the US."

- Mandy Cohen, Director of CDC

US Department of Veterans Affairs (VA)

All Epic and Cerner hospitals can connect to VA systems to identify veterans and connect them to earned benefits… **Interoperability is changing Veteran lives**…"
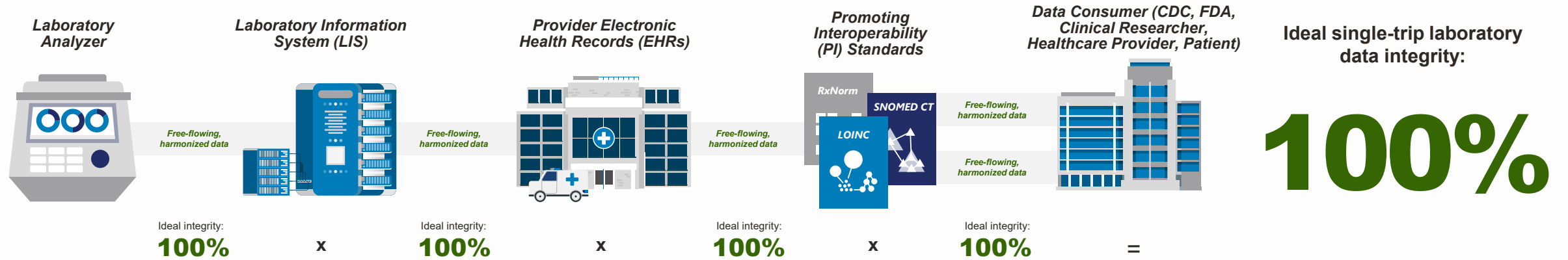
- Shereef Elnahal, Under Secretary for Health

To succeed at these goals, interagency collaboration between Federal Health agencies is required. There is still a long way to go in achieving high quality data that can be used safely and reliably by individuals across the healthcare ecosystem.
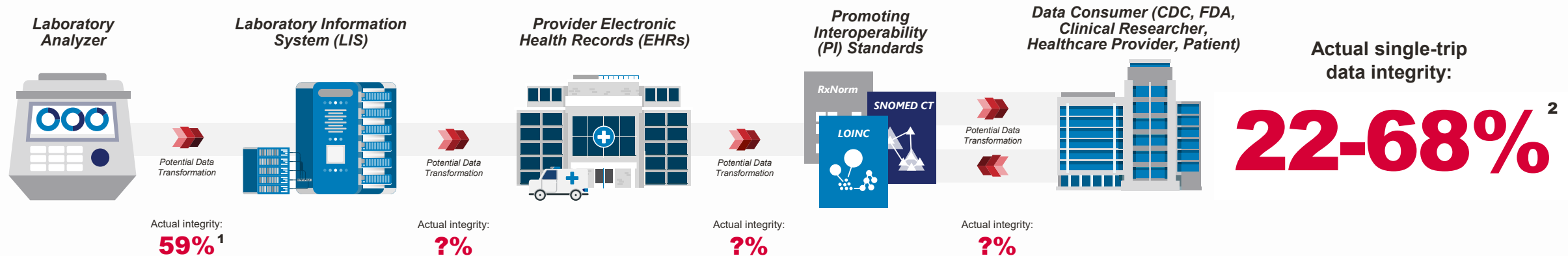
The Current State of Healthcare Data Quality

To be useful, healthcare data must move through numerous systems maintaining the data's original meaning. However, ever-increasing system complexity and reliance on low-quality data has ultimately decreased the quality of care across the healthcare ecosystem.
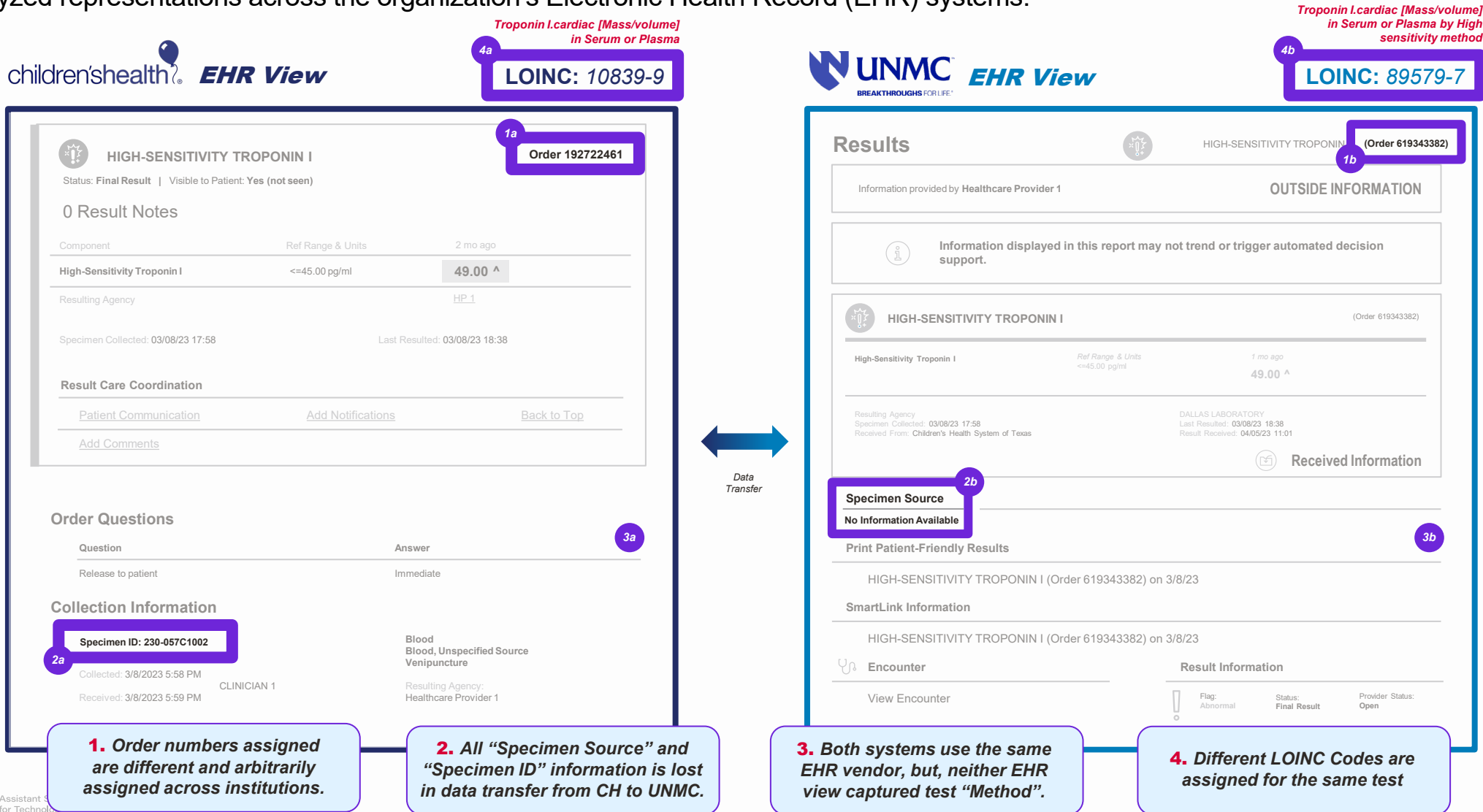
Expectations:

Laboratory Analyzer

Laboratory Information System (LIS)

Provider Electronic Health Records (EHRs)

Promoting Interoperability (PI) Standards

RxNorm

SNOMED CT

LOINC

Data Consumer (CDC, FDA, Clinical Researcher, Healthcare Provider, Patient)

Free-flowing, harmonized data

Ideal single-trip laboratory data integrity:

Ideal integrity: 100%	x	Ideal integrity: 100%	x	Ideal integrity: 100%	x	Ideal integrity: 100%	=

100%

Reality:

Laboratory Analyzer

Laboratory Information System (LIS)

Provider Electronic Health Records (EHRs)

Promoting Interoperability (PI) Standards

RxNorm

SNOMED CT

LOINC

Potential Data Transformation

Data Consumer (CDC, FDA, Clinical Researcher, Healthcare Provider, Patient)

Potential Data Transformation

Actual single-trip data integrity:

Actual integrity: 59%[1]	Actual integrity: ?%	Actual integrity: ?%	Actual integrity: ?%

22-68%[2]

References: [1]Encoding laboratory testing data: case studies of the national implementation of HHS requirements and related standards in five laboratories. [2]Quantitating and assessing interoperability between electronic health records

Data Quality Can Impact Clinical Decisions

To better understand how laboratory information flows across systems, the FDA SHIELD team conducted a study with two premiere laboratories and analyzed representations across the organization's Electronic Health Record (EHR) systems.

children'shealth *EHR View*

Troponin I.cardiac [Mass/volume] in Serum or Plasma

4a LOINC: *10839-9*

1a Order 192722461

HIGH-SENSITIVITY TROPONIN I
Status: **Final Result** | Visible to Patient: **Yes (not seen)**

0 Result Notes

Component	Ref Range & Units	2 mo ago
High-Sensitivity Troponin I	<=45.00 pg/ml	49.00 ^
Resulting Agency		HP 1

Specimen Collected: 03/08/23 17:58   Last Resulted: 03/08/23 18:38

Result Care Coordination

Patient Communication   Add Notifications   Back to Top
Add Comments

Order Questions

Question	Answer
Release to patient	Immediate

3a

Collection Information

Specimen ID: 230-057C1002
2a
Collected: 3/8/2023 5:58 PM
CLINICIAN 1
Received: 3/8/2023 5:59 PM

Blood
Blood, Unspecified Source
Venipuncture
Resulting Agency:
Healthcare Provider 1

Data Transfer

UNMC *EHR View*
BREAKTHROUGHS FOR LIFE®

Troponin I.cardiac [Mass/volume] in Serum or Plasma by High sensitivity method

4b LOINC: *89579-7*

Results   HIGH-SENSITIVITY TROPONIN I **(Order 619343382)** **1b**

Information provided by **Healthcare Provider 1**   OUTSIDE INFORMATION

ℹ Information displayed in this report may not trend or trigger automated decision support.

HIGH-SENSITIVITY TROPONIN I   (Order 619343382)

High-Sensitivity Troponin I	Ref Range & Units	1 mo ago
	<=45.00 pg/ml	49.00 ^

Resulting Agency   DALLAS LABORATORY
Specimen Collected: **03/08/23 17:58**   Last Resulted: **03/08/23 18:38**
Received From: **Children's Health System of Texas**   Result Received: **04/05/23 11:01**

Received Information

Specimen Source **2b**
No Information Available

Print Patient-Friendly Results   **3b**

HIGH-SENSITIVITY TROPONIN I (Order 619343382) on 3/8/23

SmartLink Information

HIGH-SENSITIVITY TROPONIN I (Order 619343382) on 3/8/23

Encounter   **Result Information**

View Encounter   Flag: Abnormal   Status: **Final Result**   Provider Status: **Open**

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1. *Order numbers assigned are different and arbitrarily assigned across institutions.*

2. *All "Specimen Source" and "Specimen ID" information is lost in data transfer from CH to UNMC.*

3. *Both systems use the same EHR vendor, but, neither EHR view captured test "Method".*

4. *Different LOINC Codes are assigned for the same test*

ASTP Assistant S... for Technolog...

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Reference: Analysis of laboratory data transmission between two healthcare institutions using a widely used point-to-point health information exchange platform: a case report

Data Quality Has Patient Safety Implications

Stories of patient harm have continued to reveal medical devices might not be as safe and effective as they should be. Failure to collect and properly transmit granular test details can lead to...

Mis-Diagnosis and Unnecessary Testing ...

*A 2014 case study showed that a woman was mis-diagnosed with a liver condition and **prescribed unnecessary medication due to multiple conflicting test results from numerous laboratories** all using different instruments, test kits, and reference ranges, but this granular data was not included in the exchange with the patient care team.[1]*

1. *Fluctuating Serum Aspartate Aminotransferase Activity in a Complicated Pregnancy*

... Failure to Receive Proper Therapy

*An analysis of serum albumin laboratory test data found that **21-59% of patients are at risk for treatment error** when granular test characteristics (e.g., reference range, test kit, test method, etc.) are not appropriately recorded and transmitted between systems, causing serious impacts to clinical decision making and may result in serious patient harm.[2]*

2. *The bias between different albumin assays may affect clinical decision-making - Kidney International (kidney-international.org)*
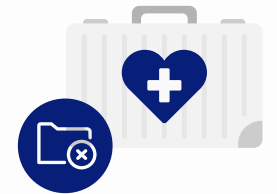
... Mis-Prescription of High-Risk Medication

*Up to **270,000 patients were affected by errors** in a software-as-a-medical-device (SAMD), cardiovascular disease risk digital calculator, due to the incorrect data translation, which led to patients who required a statin prescription not receiving one and other patients unnecessarily receiving statin treatment, causing for both patient groups to be faced with potentially harmful consequences.[3]*

3. *Analysis of clinical decision support system malfunctions: a case series and survey - PubMed (nih.gov)*

A Patient Information Quality Improvement (PIQI) Framework

The Primary Objective

Provide a common approach to measuring and improving the quality of **patient information** in a **message** in flight, **regardless of message format**.

The Design Principles
- Establish a **simplified patient data model** to support **standard processing**
- Establish a **healthcare data quality taxonomy** to better understand qualitative issues
- Define a **modular, portable, sharable** approach to assessing facets of patient information
- Support **user definable evaluation profiles** to support standard and individual use cases

Principle 1 : Simplified Data Model
USCDI Data Classes and Elements

Patient Demographics/Information

Data used to categorize individuals for identification, records matching, and other purposes.

First Name
Last Name
Middle Name (including middle initial)
Name Suffix
Previous Name
Date of Birth
Date of Death
Race
Ethnicity
Tribal Affiliation
Sex
Sexual Orientation
Gender Identity
Preferred Language
Current Address
Previous Address
Phone Number
Phone Number Type
Email Address
Related Person's Name
Related Person's Relationship
Occupation
Occupation Industry

Vital Signs

Physiologic measurements of a patient that indicate the status of the body's life sustaining functions.

Systolic Blood Pressure
Diastolic Blood Pressure
Heart Rate
Respiratory Rate
Body Temperature
Body Height
Body Weight
Pulse Oximetry
Inhaled Oxygen Concentration
BMI Percentile (2 - 20 years)
Weight-for-length Percentile (Birth - 24 Months)
Head Occipital-frontal Circumference Percentile (Birth - 36 Month

Laboratory

Analysis of clinical specimens to obtain information about the health of a patient.

Tests
Values/Results
Specimen Type
Result Status

Clinical Tests

Allergies and Intolerances

Harmful or undesired physiological responses associated with exposure to a substance.

Substance (Medication)
Substance (Drug Class)
Reaction

Medications

Pharmacologic agents used in the diagnosis, cure, mitigation, treatment, or prevention of disease.

Medications
Dose
Dose Units of Measure
Indication
Fill Status

Procedures

Activity performed for or on a patient as part of the provision of care.

Procedures
SDOH Interventions
Reason for Referral

Problems

Condition, diagnosis, or reason for seeking medical attention.

Problems
SDOH Problems/Health Concerns
Date of Diagnosis
Date of Resolution

PIQI Patient Information Model

Element	Attr1	Attr2	Element	Attr1	Attr2	Element	Attr1	Attr2	Element	Attr1	Attr2

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Principle 2 : Healthcare Data Quality Taxonomy
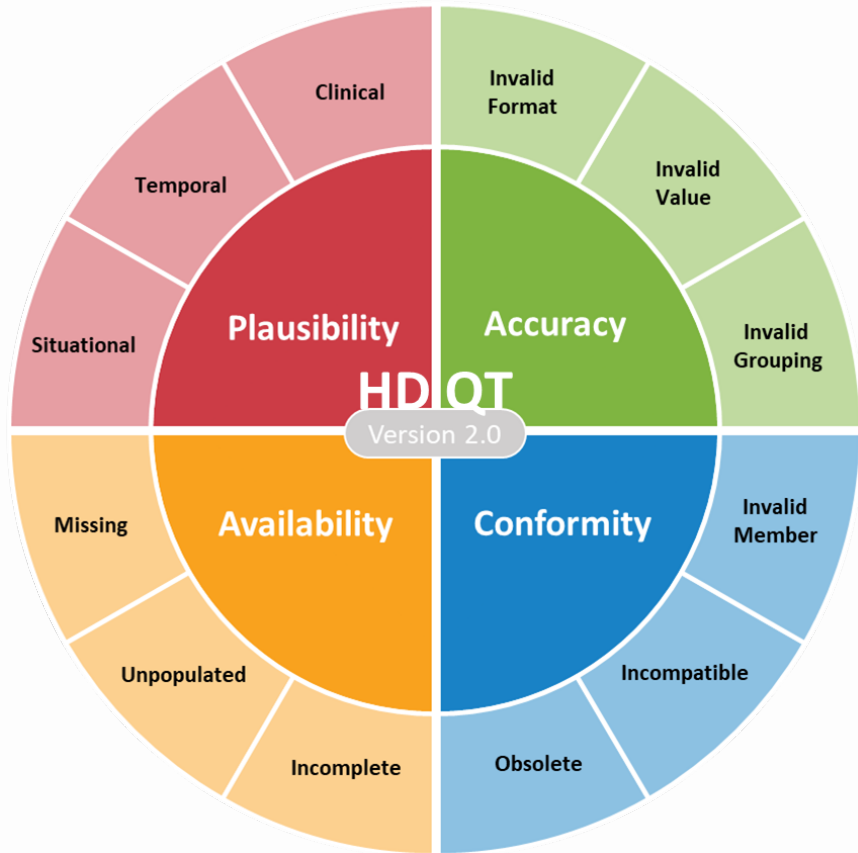
CATEGORY	DIMENSION	Attribute	Element	Patient
Availability	**Missing**		☑	
	Unpopulated	☑		
	Incomplete	☑	☑	
Accuracy	**invalid Format**	☑		
	Invalid Value	☑		
	Invalid Grouping	☑	☑	
Conformity	**Invalid Member**	☑		
	Incompatible	☑	☑	
	Obsolete	☑		
Plausibility	**Clinically Implausible**		☑	
	Temporally Implausible	☑	☑	☑
	Situationally Implausible	☑	☑	☑
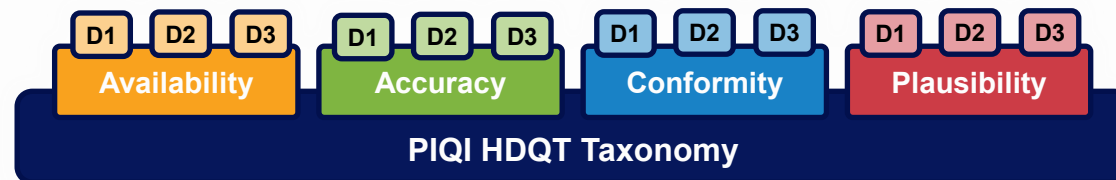
Principle 3 : Simple Assessment Modules

- Accepts a specific input type from the model
- May have prerequisite SAMs
- Simple parameters can be added

- Bound to a dimension in the HDQT
- Returns a simple pass or fail

| SAM	ENTITY TYPE	PREREQUISITE SAM	DIMENSION	PARAMS
Attribute is Populated	Simple Attribute	-	UNPOPULATED	-
Attribute is Valid Date	Simple Attribute	-	INVALID FORMAT	-
Concept is Complete	Codable Concept	Attribute is Populated	INCOMPLETE	-
Concept is Valid	Codable Concept	Concept is Complete	INVALID MEMBER	-
Concept is Active	Codable Concept	Concept is Valid	OBSOLETE	-
Concept is Compatible	Codable Concept	Concept is Valid	INCOMPATIBLE	System list
Lab Result is Plausible	Lab Element	Lab Result is Complete	CLINICALLY IMP	-

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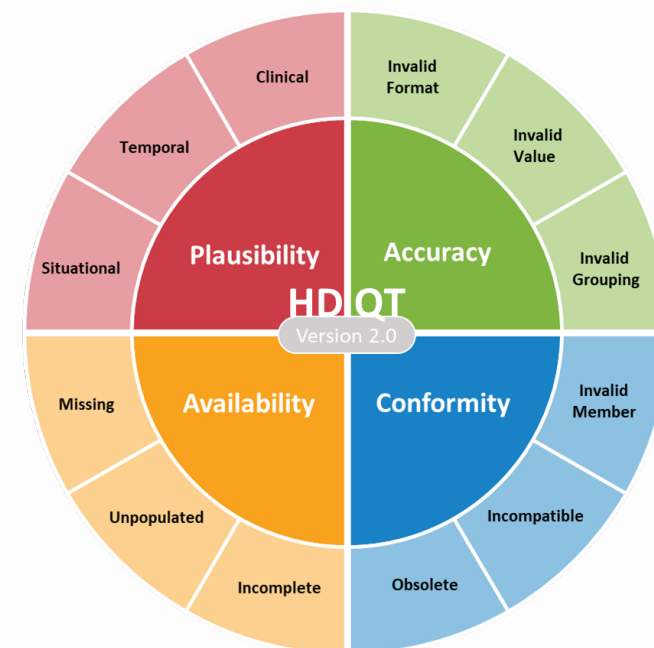
Principle 4 : Evaluation Profiles

- Establishes an assessment criteria
- Aligns the SAMs to the PIQI Model
- Determines the Scoring Approach

EVALUATION PROFILE	SEQ	ENTITY	SAM	PARAMS	EFFECT	CONDITIONAL	WEIGHT	CRITICAL
USCDI v3+	1	LAB.TEST	Concept is Conformant	LOINC	SCORING	NO	1	YES
	2	LAB.ORDER	Concept is Conformant	LOINC	SCORING	NO	1	NO
	3	LAB.RESULT_VALUE	Value matches Type	-	SCORING	NO	1	NO
	4	LAB.RESULT_VALUE	Concept is Conformant	SCT	SCORING	YES	1	NO
	5	LAB.RESULT_UNIT	Attribute is in list	UCUM	SCORING	YES	1	NO
	6	LAB.SPEC_TYPE	Concept is Conformant	LOINC	SCORING	NO	1	NO
	7	LAB.RESULT_STATUS	Attribute is Populated	-	SCORING	NO	1	NO
	8	LAB.TEST	Concept is Semantic Match		INFORMATIONAL	NO	0	NO

Important Concept: Scoring
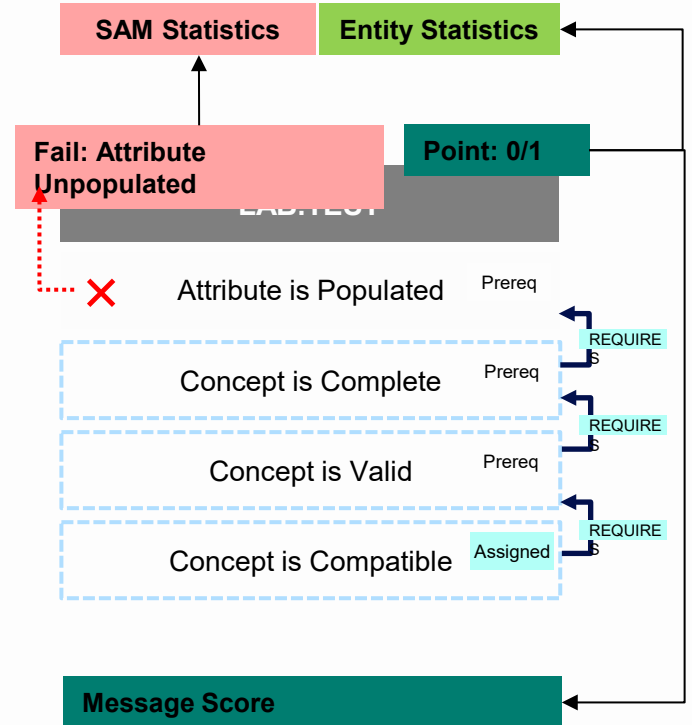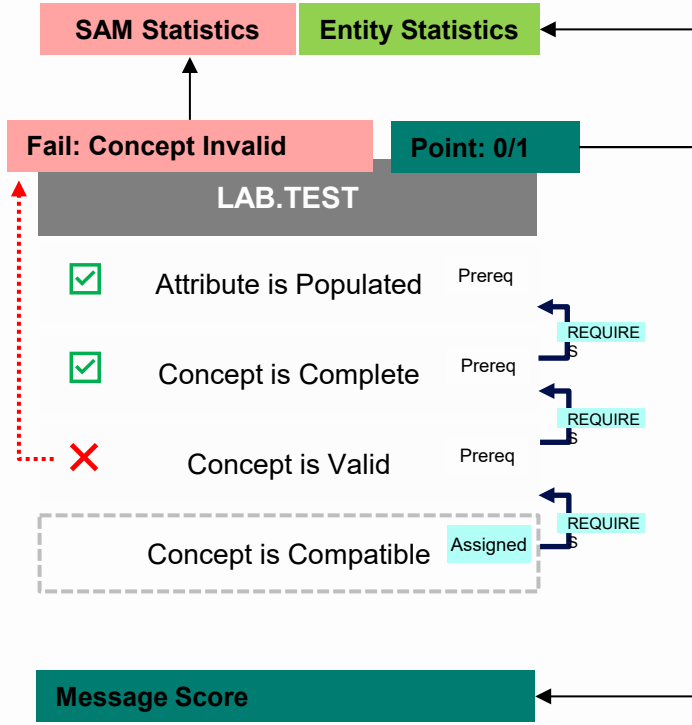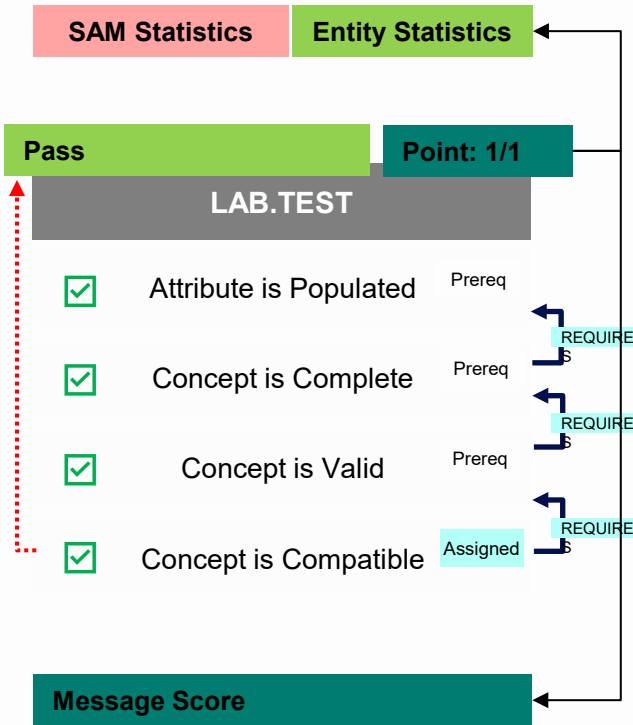
The Assessment Process
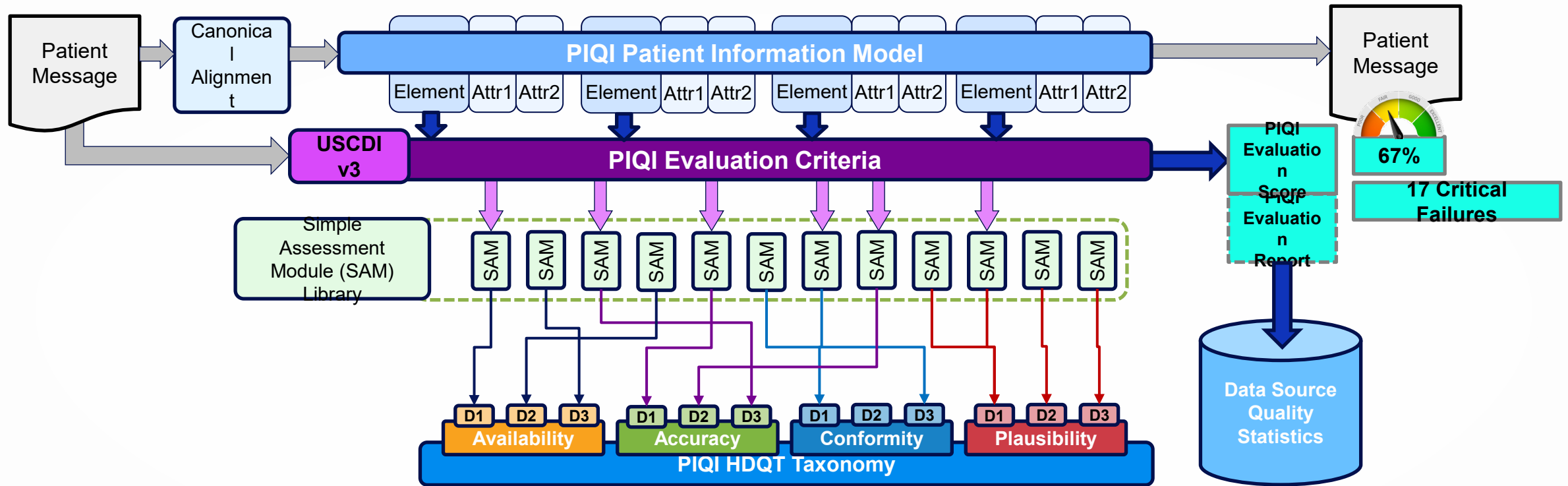
Quality Scorecard Statistics – Across Data Sources

PIQXL Gateway

Channel: Demo Channel

Dashboard | Data Sources | Details | Activity

Source Review

Period: 30 Days

Provider	Source	Onboarding	Messages	Assessment Pass Average	Assessment Pass Weighted	Assessments Pass
Iota	Iota 3	false	183,066	68%	68%	68%
Lambda	Lambda 5	false	199,650	67%	68%	67%
Omega	Omega 2	false	620,501	33%	33%	33%
Pi	Pi 3	false	615,623	33%	33%	33%

Showing 1 to 22 of 22 Sources

Keyword Search | Clear

Omega 2
Overall Quality

33%

Message Quality Over Time

Quality | Threshold | Critical | Processed | Clean

Entity	SAM	Fail Count	Overall Fail %	Item Fail %
procedure reason	Procedure reason not populated	2,039,625	3.15%	4.73%
medication fill status	Medication fill status not populated	1,883,818	2.91%	4.37%
immunization lot number	Immunization Lot number not populated	1,858,914	2.87%	4.31%
medication indication	Medication indication not populated	1,755,341	2.71%	4.07%
medication dose amount value	Medication dose is invalid	1,042,965	1.61%	2.42%
lab result value unit	Result Unit not in UCUM	1,007,994	1.56%	2.34%
condition resolution date	unpopulated	943,857	1.46%	2.19%
procedure date time	unpopulated	942,561	1.46%	2.19%
lab result status	Result status is invalid value	923,528	1.43%	2.14%
condition onset date	invalid date	862,301	1.33%	2%
immunization effective date	unpopulated	824,102	1.27%	1.91%
medication effective date time	invalid date	796,666	1.23%	1.85%
medication dose amount value	unpopulated	741,128	1.14%	1.72%

Showing 143 items

Quality Scorecard Statistics – Within a Single Data Source
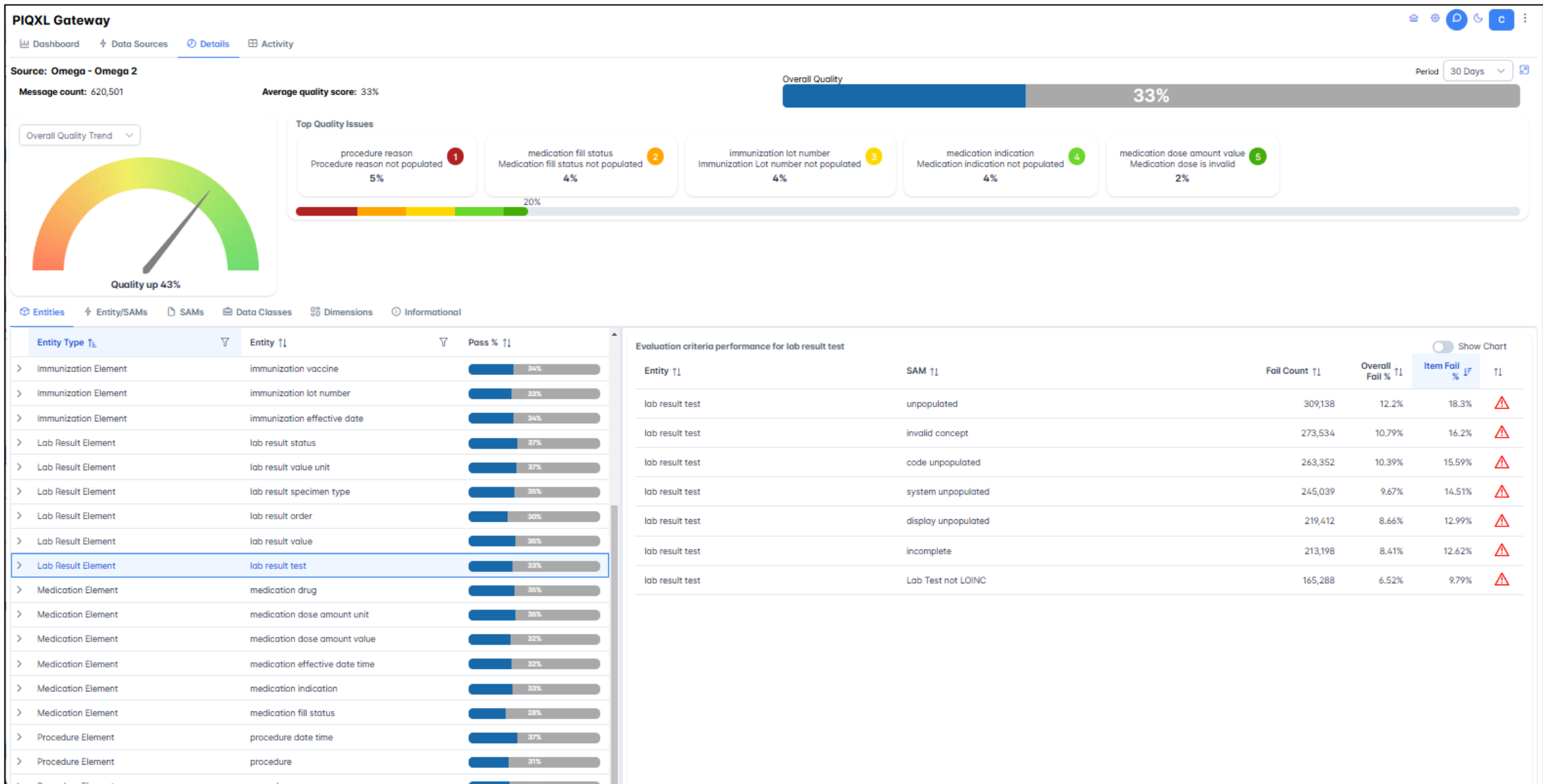
Discussion and audience questions

Reach out

📱 Alison Kemp, alison.kemp@hhs.gov

💬 Feedback Form: https://www.healthit.gov/form/healthit-feedback-form

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