Healthcare Innovation Webinar
Clinical Data Interoperability 101

ABOUT J P SYSTEMS, INC.

Founded in 1983, we perform clinical interoperability and terminology services.

We specialize in HL7 data standards and clinical data quality improvement.

BETTER DATA
BETTER PATIENT CARE
BETTER OUTCOMES

Our Healthcare IT Services

- Data Quality Improvement and Analysis
- Interoperability Planning
- Clinical Document Improvement for CDAs
- Standardized Clinical Terminologies
- Clinical Terminology Mapping
- Exchange Partner Onboarding
- HL7 Standards Development
- HL7 FHIR® Queries
- Data Architecture
- Health IT Program Management
- Data Modeling
- Requirements and Business Analysis

3/31/2022

Learning Objectives

A. Define Data Interoperability (IOP)
B. Describe the US Ecosystem for IOP
C. Describe how to employ Interoperability to improve Patient Safety
D. Current state of device Interoperability
E. Describe how Data Standards contribute to Interoperability
F. Explain why Data Standards are not automatically interoperable

What is Clinical Data Interoperability?

"Interoperability is the ability of different information systems, devices or applications to connect, in a coordinated manner, within and across organizational boundaries to access, exchange and cooperatively use data amongst stakeholders, with the goal of optimizing the health of individuals and populations."

Source: HIMSS

Levels of Interoperability

Process interoperability - Standardizes the behavior based on the content

Semantic interoperability - Standardizes the meaning of the content

Syntactic interoperability - Standardizes the structure of the content

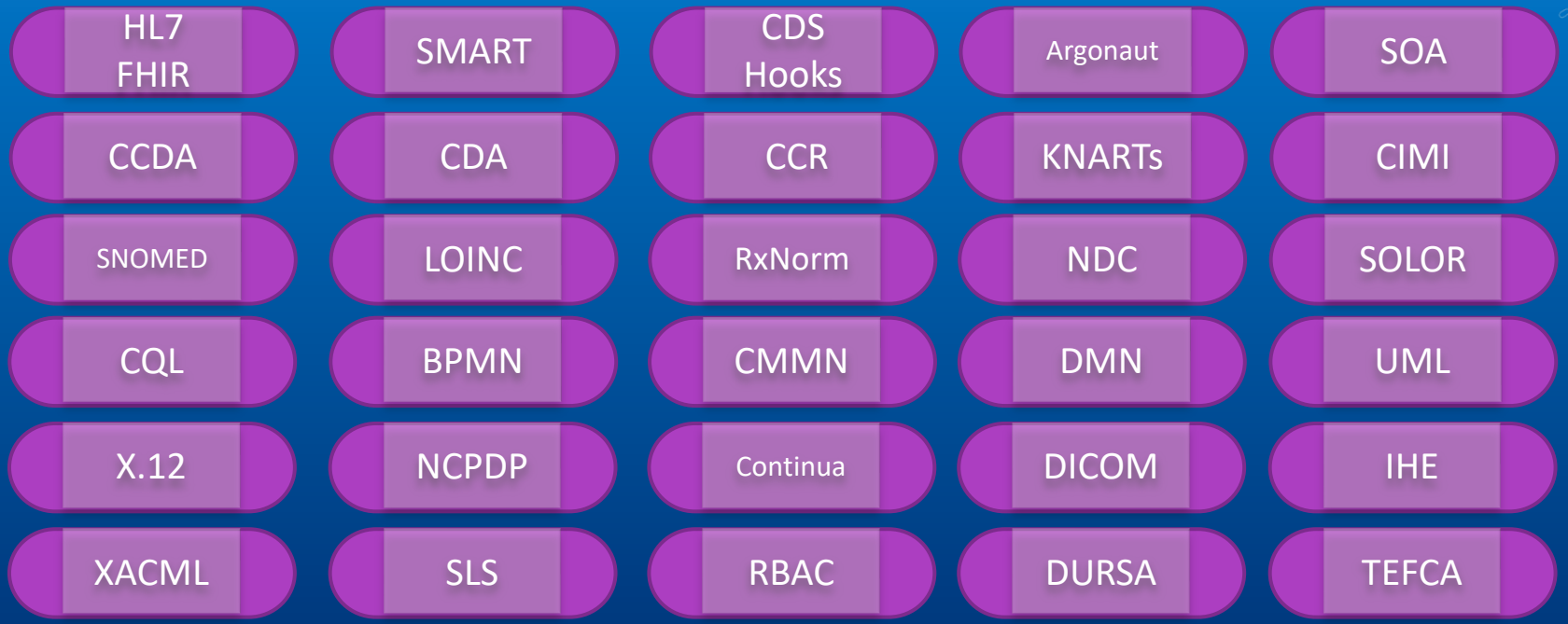
Standardizes the transport layer (communications, discoverability)

Type	Example
Machine “reason”-able	Automated Clinical Decision Support, Workflows
Machine interpretable	Coded FHIR instance
Machine organizable	Indexed CDA document
Machine transportable	Email / Fax
Non-electronic	Paper Notes

Why is Interoperability so Important Today?

1. Data must cross multiple system boundaries: Patients are treated by multiple clinicians, organizations, and increasingly devices, which must intelligently share data.
    1. Interoperability leads to better care coordination, improved patient safety, improved population health reporting, and costs savings.
    2. A complete and accurate longitudinal patient record is needed for an EHR's Clinical Decision Support or Patient Safety systems to work properly.
2. Government regulations are increasingly demanding behaviors that require interoperability to comply.
    1. New payment models, especially Value Based Care (VBC)
    2. More complex and numerous Quality Measures
    3. A push against "data blocking"
    4. US Core Data for Interoperability (USCDI) begun to set standards for various classes of data.

INTEROPERABILITY ISN'T SO HARD, WE JUST NEED TO USE…



Source: Dr. Stan Huff, Intermountain HealthCare

How Can Interoperability Improve Patient Safety?

The more data flows into your EHR, the more complete your patient records will be and the more data Clinical Decision Support systems will have to mine.

Interoperability and Clinical Data Quality together are keys to the patient safety safeguards in your EHR system.

“TRUE INTEROPERABILITY” REQUIRES:

- Data shared using standard structures (“messages”, “payloads”)…
  - Ideally based on logical models so concepts common to multiple messages are represented the same way
- …using standard terminology
  - Ideally, a full ontology, so computers can reason over the data
- … and accessed via standard services or APIs
  - Eliminating the need and cost to have different versions for different EHRs
- … and in an idealized future, authenticating the same way
  - Use the same mechanisms (OAuth, etc.) to communicate access privileges

The US Ecosystem of Interoperability

- US HHS ONC
- US NIST, NIH
- US VA
- US DOD
- US CMS

- eHealth Exchange Network Sequoia
- CommonWell Carequality

HL7, OMG,
LOINC, X12, NCPDP
SNOMED,
Open Group

HIMSS, AHIMA,
AMIA, HSPC, …

Interoperability between HIEs - What is TEFCA?

TEFCA strives to **establish a single "on-ramp" for a US Health Information Exchange (HIE)** will enable providers, stakeholders to join any US Health Information Network (HIN) and then to automatically connect in nationwide health information exchange.

TEFCA establishes "Qualified Health Information Networks" (QHINs) to facilitate a standardized methodology for HIE inter-connectivity, along with a new administrative organization, the Recognized Coordinating Entity (RCE).

ONC AND CMS RULING 3/9/2020

The two rules, issued by ONC and CMS, implement interoperability and patient access provisions of the 21st Century Cures Act, supporting President Trump's MyHealthEData initiative.

Core Concept: Patient control of their electronic health information which will drive a growing patient-facing healthcare IT economy, and allow apps to provide patient-specific price and product transparency.

ONC AND CMS RULINGS 3/9/2020

Requires insurance plans to share health data with their patients in a format suitable for their phones or other device of their choice, holding payers to a higher standard while protecting patient privacy.

Requires electronic health records to provide the clinical data necessary to promote new business models of care using the U.S. Core Data for Interoperability (USCDI) The USCDI is a standardized set of health data classes and data elements that are essential for nationwide, interoperable health information exchange.

https://www.hhs.gov/about/news/2020/03/09/hhs-finalizes-historic-rules-to-provide-patients-more-control-of-their-health-data.html

ONC AND CMS RULINGS 3/9/2020

CMS Interoperability and Patient Access final rule requires health plans in Medicare Advantage, Medicaid, CHIP, and through the federal Exchanges to share claims data electronically with patients.

The CMS final rule establishes a new Condition of Participation (CoP) for all Medicare and Medicaid participating hospitals, requiring them to send electronic notifications to another healthcare facility or community provider or practitioner when a patient is admitted, discharged, or transferred.

ONC AND CMS RULINGS 3/9/2020

For more information on the ONC final rule, please visit: https://healthit.gov/curesrule.

For more information on the CMS final rule, please visit: https://www.cms.gov/newsroom/fact-sheets/interoperability-and-patient-access-fact-sheet.

To view the CMS final rule, please visit: https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index.

To view the ONC final rule, please visit: https://healthit.gov/curesrule.

DATA NEEDS TO MOVE.
DATA MUST BE TRUSTWORTHY AND COMPLETE!

The Trusted Exchange Framework is built on a foundation of standards and data quality assumptions.

Qualified Health Information Networks (QHINs) will have to meet certain qualifications under ONC's TEFCA.

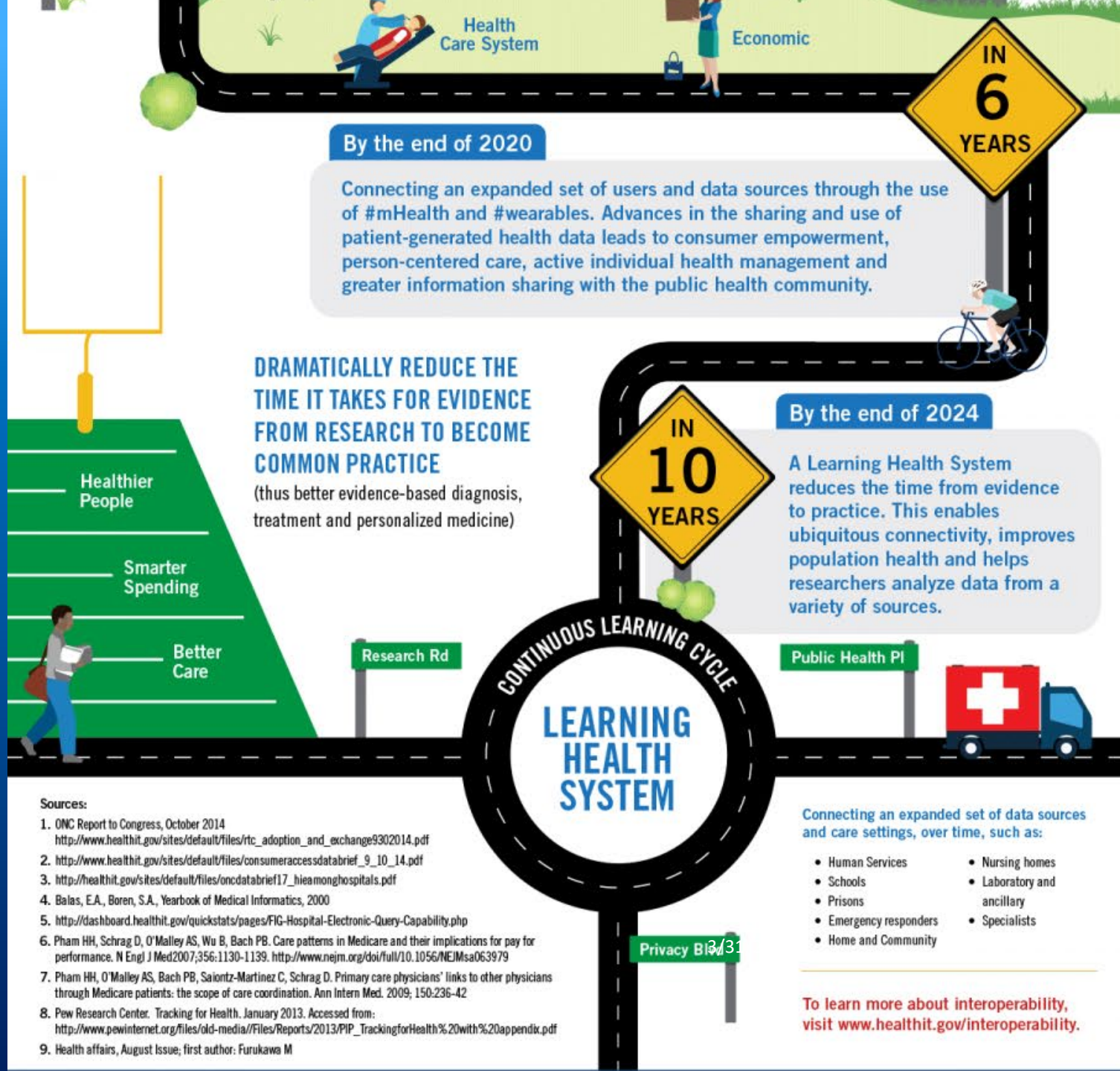
Interoperability creates a more complete patient record, which can lead to better care coordination, improved patient safety, improved population health reporting, and better costs savings by avoiding test duplication.

The US Interoperability Roadmap: speedbumps to Interoperability

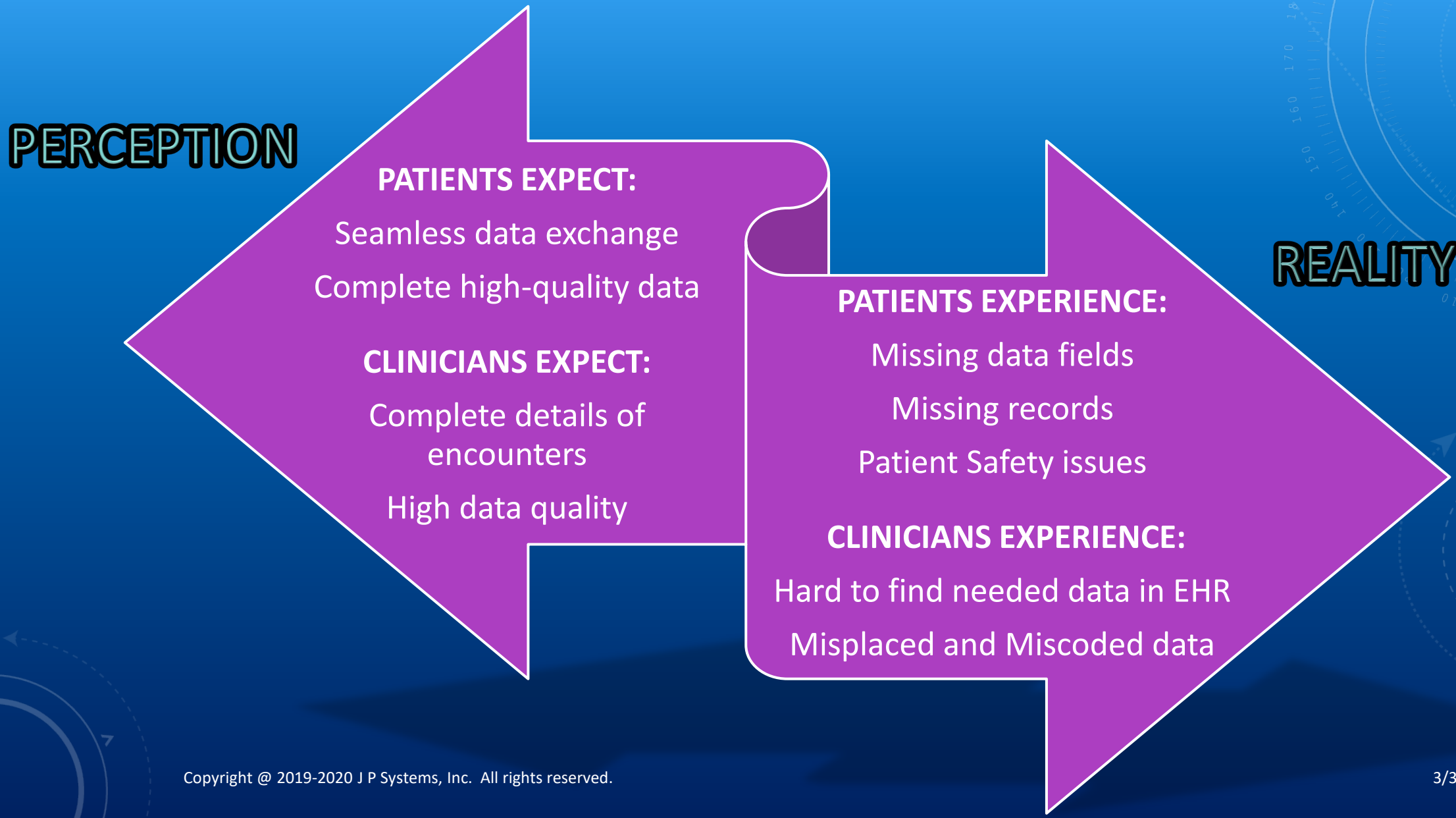
See the US Nationwide Interoperability Roadmap here: ONC roadmap

Speedbumps:

- Lack of standardized data
- Lack of trust in the data
- Confusion about privacy laws



Interoperability Nationally: Perception vs. Reality



90% of hospitals use six or more devices that could be integrated into EHRs, but currently only 1/3 of them integrate those devices with EHRs.

Devices that could be integrated with EHRs include defibrillators, electrocardiographs, vital sign monitors, ventilators, and infusion pumps.

Of the devices that can be found in a hospital setting, fewer than 3 devices are integrated with EHRs on average.

Current State of Device Interoperability

DEVICE INTEROPERABILITY: THE STRUGGLE

The struggle: equipment manufacturers have not had to work together and information is proprietary. Currently, data is manually entered into systems, which can delay treatment and result in issues such as infection, sepsis, shock, etc.

To predict these issues, systems that analyze data must have access to vital signs and lab results.

“Part of the reason for limited interoperability is the high cost and complexity of medical device integration, which results from the lack of incentives for medical device and HIT companies to use open interfaces to establish … interoperability.” – West Health

Fortunately, Paul Sherman, CCE, president of St. Louis-based Sherman Engineering says, there are companies that can design mechanisms to capture data from these older systems in a way that can be understood by newer medical devices. Still, as expensive as it is to make legacy systems and newer medical devices interoperable, the option of taking legacy systems offline and replacing them is even more expensive—and potentially disruptive to patient care.

He points out that it's particularly valuable to capture information about alert alarms within a patient's record in the EHR. Why? Because, Sherman says, this level of detail helps clinicians determine the most appropriate treatment plan for the patient.

Moreover, since many older systems haven't been built to enable interoperability, healthcare facilities need to be very specific in their requirements when purchasing new technologies, industry experts say. But before you issue an RFP or RFI, however, you need to first approach the challenge of interoperability with medical devices as a systems issue, says Sarasota, Fla.-based Elliot Sloane, PhD, CCE, an HTM expert; *24×7 Magazine* board member; and president, executive director, and founder of the Foundation for Living, Wellness, and Health.

IF YOU CAN'T TYPE IN THE DATA FAST ENOUGH, GET THE MACHINES TO TALK TO EACH OTHER.

WHY ARE DATA QUALITY & DEVICE INTEROPERABILITY SO IMPORTANT?

Good quality data and system interoperability prevent Miscoded, Misplaced, and Missing data that lead to patient safety risk and economic loss.

- According to a recent DELL EMC report, the amount of health data in hospitals, clinics, and other medical organizations has grown 878% since 2016.
    - In 2018, organizations were managing an average of 9.7 Petabytes of data.
    - Of those organizations with 2+ vendors, 40% have seen data disruption and 30% have seen data loss (an average of 2 TB).
    - Data disruptions can cost more than $500k

Interoperability enables clinicians to implement new ideas that can improve healthcare. – Dr. Julian M. Goldman, MD (Source: PSQH)

Early Sepsis Detection Saves Lives

Current State of Sepsis

- Over 1 million Americans diagnosed with Sepsis every year
- 15-30% mortality rate
- Cause of 50% of in-hospital deaths
- Time is critical in fighting Sepsis, but time is limited by manual data entry
- Interoperable Medical Devices can help

Advances in Medical Device Interoperability

- EarlySense System consists of interoperable medical devices
- Continuously measures and records patient vital signs
- Data entry is automated; Data is analyzed by the Central Display Station
- Alerts nurses and doctors in the case of abnormalities which may lead to an adverse event
- EarlySense System has decreased mortality in one hospital which has implemented it
- Harborview Medical Center in Seattle partnered with EarlySense to reduce mortality due to Sepsis and Opioid-Induced Respiratory Suppression

PHASES OF INTEROPERABILITY PLANNING

1. Identify your data exchange partners and develop a communications plan on how to engage
2. Identify standards and terminologies currently in use on both ends
3. Identify new needed standards and plan how to expand
4. Map your local terms to new international clinical terminologies: e.g. SNOMED CT.

PLANNING FOR INTEROPERABILITY

To send clinical data from point A to point B we:

- Assemble a team of Terminologists, data standards experts, data architects and business architects
- Determine the data fields we want to transmit
- Map those data fields to international standardized reference terminologies (like SNOMED)
- Select a data message standard: HL7 ver 2, CDA or FHIR
- Plan for data security and compliance

PROCESSES WHICH IMPLEMENT INTEROPERABILITY

To send clinical data securely **we write software using standardized data structures and standard terminologies**:
i.e. we implement the standard (e.g. FHIR)

- Assemble a team of Informaticists, HL7 interface specialists, programmers, and an IOP testing team
- Finalize data transport structures
- Follow the Implementation Guide
- Implement the app in Java, etc.
- Test data exchanges initially and on a continuing basis.

HOW DATA STANDARDS CONTRIBUTE TO INTEROPERABILITY

PROBLEM #1: Data is often stored in “Free Text” or in documents
For example, a study of one system revealed 26 different variants of how people expressed the concept of “Oral meds”: Oral, ORAL, Oral, ORALLY, Orally, ORALY, OR, or, PO, P.O., P.O, PO., po, per os, by mouth, etc.

- You can not anticipate all of the ways that information can be recorded in free text.
- You can not reliably execute real time decision logic against free text data
  - Natural Language Processing (NLP) is a promising technology, but isn’t reliable – especially with abbreviations
- CONCLUSION: You need coded or “computable” data

WHAT ARE DATA STANDARDS?

- Data Standards are usually “structural” e.g., messaging, or “terminology”
  - Structural standards define the pieces of data that make up a complete thought
  - Terminologies define how to represent a concept
    - “Myocardial Infarction” (lang = en) = code 123
    - “Heart Attack” (lang = en) = code 123
    - “Herzinfarkt” (lang = de) = code 123
    - “Ataque al corazón” (lang = es) = code 123
    - “Pneumonia” (lang = en) = code 567
- Maintained by Standards Development Organizations (SDOs)

HOW DATA STANDARDS CONTRIBUTE TO INTEROPERABILITY

PROBLEM #2: Even when coded, the same data can be coded differently

- I might use a different coding system than you do – we can't interoperate
  - This problem is exacerbated when data crosses international borders, e.g., US requires RxNorm, Australia requires Australia Medicines Terminology (AMT)
- Some coding systems are very complex; the casual user (e.g., a programmer) can easily choose an inappropriate code
  - e.g., LOINC has > 400 codes for "blood pressure"
- Conclusion: You need agreement on how to represent specific clinical concepts (often called "Detailed Clinical Models")

WHAT DOES HL7 DO?

- HL7 defines rules and regulations for message architecture blueprints (i.e. the meta meta-data). HL7's mission is to provide standards that empower global health data interoperability.
- HL7 has four standards: version 2, version 3, CDA, and FHIR®, none of which are automatically interoperable. All must be made interoperable by the parties exchanging the data.
- How do we format data messages to reliably transmit various kinds of clinical data between providers?

Video on what is HL7?

Healthcare IT Interoperability Communities

WHAT IS HL7'S FHIR® STANDARD?

FHIR® stands for Fast Healthcare Interoperability Resources. It is neither a software package, a database, nor a computer language.

It is an international specification for the exchange of data messages.

It is revolutionizing healthcare in that it is easy to implement on the web with REST and JAVA has very specific data structures (resources) which are used as 'shipping cartons' for predefined types of data.

It is used for sending data about orders and Lab tests, etc. It processes queries and returns data, such as 'Give me all the patients with a diagnosis of diabetes".

HL7 offers a course on FHIR Fundamentals: https://www.hl7.org/training/fhir-fundamentals.cfm

Better Data is realized when our teams of both Healthcare IT experts and clinicians work with your team.

Better Patient Care is achieved when clinical data is complete and accurate.

Better Outcomes result when Clinical Decision Support systems use reliable and standardized data.

sales@jpsys.com

Successful Healthcare IT services require both technical and clinical subject matter experts.

Since 1983, we are your best choice for the complexities of data standards and data quality.

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FIRST GENERATION STANDARDS: EDI MESSAGES (HL7 V2, NCPDP TELCOM, ASC X12)

```
MSH|^~\&|MYEHR|DCS|||20090531145259||VXU^V04^VXU_V04|3533469|P|2.5.1||||AL <CR>
PID|1||432155^^^DCS^MR||Patient^Johnny^New^^^^L||20090414150308|M| |123 Any St^^Somewhere^WI^54000^^L<CR>
ORC|RE||197027^DCS|||||||^Clerk^Myron||^Pediatric^MARY^^^^^^^L^^^^^^^^^^MD<CR>
RXA|0|1|20090531132511|20090531132511|48^HIB PRP-T^CVX|999|||00^new immunization
record^NIP0001|^Sticker^Nurse|^^^DCS_DC||||33k2a||PMC^sanofi^MVX<CR>
RXR|C28161^IM^NCIT^IM^IM^HL70162|<CR>
ORC|RE||197028^DCS|||||||^Clerk^Myron||^Pediatric^MARY^^^^^^^L^^^^^^^^^^MD<CR>
RXA|0|1|20090531132511|20090531132511|110^DTAP-Hep B-IPV^CVX|999|||00^new immunization
record^NIP0001|^Sticker^Nurse|^^^DCS_DC||||xy3939||SKB^GSK^MVX<CR>
RXR|IM^IM^HL70162^C28161^IM^NCIT|<CR>
```

- Traditional messages are very compact and easy to parse. Very efficient.
- But the meaning of the data is dependent on its *position* in the string, and cannot be interpreted without additional documentation
- With out an that documentation, we can guess that the “M” on the second line means “Male”… or…does it mean “Married”?
- Note that the vaccine administered (“DTAP-Hep B-IPV”) is a code (code 110 from the CVX coding system)

SECOND GENERATION STANDARDS: XML AND DOCUMENT-BASED (HL7 V3, CDA)

- HL7 V3 sought to move to XML and simultaneously reduce the variability possible in EDI messages. It became unwieldy and was effectively abandoned in favor of FHIR
- The HL7 Clinical Document Architecture (CDA) is built on top of V3 and describes how to encode document-oriented data.
  - CDA documents are composed of headers, sections, and section entries.
  - All documents use the same XML schema, which makes it easy to define new document types, but makes it difficult for programmers to understand!
- One important set of CDA document types is the "Consolidated CDA" (C-CDA), so named because it consolidated several existing CDA document types. C-CDA is required for Meaningful Use (MU)
  - C-CDA replaces an older CDA-based specification (HITSP C-32) and a competing ASTM specification (the Continuity of Care Record (CCR)) as the MU-required specification
- CDA is <u>good</u> for verbose summary data, but because it is large and complex, CDA is <u>not good</u> for transactional data

AN EXAMPLE HL7 V3 MESSAGE

```
<component2 typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="2823-1" displayName="Potassium" code System="2.16.840.1.113883.6.1">
      <translation code="K" displayName="Potassium" codeSystem="2.16.840.1.113883.6.100005"/>
    </code>
  <statusCode code="active"/>
  <effectiveTime value="20040119142756+1000"/>
  <confidentialityCode nullFlavor="UNK"/>
  <value value="5.6" xsi:type="PQ" unit="mmol/L"/>
  <interpretationCode code="H"/>
  <subject typeCode="SBJ" nullFlavor="NA" xsi:nil="true"/>
  <performer typeCode="PRF">
    <assignedEntity classCode="ASSIGNED">
      <id extension="Manager" root="2.16.840.1.113883.19.9"/>
      <assignedPerson>
        <name>
          <family>Manager</family>
        </name>
      </assignedPerson>
    </assignedEntity>
  </performer>
  <referenceRange typeCode="REFV">
    <interpretationRange classCode="OBS" moodCode="EVN.CRT">
      <value xsi:type="IVL_PQ">
        <low nullFlavor="NINF"/>
        <high value="3.5" unit="mmol/L"/>
      </value>
      <interpretationCode code="L"/>
    </interpretationRange>
  </referenceRange>
  <referenceRange typeCode="REFV">
    <interpretationRange classCode="OBS" moodCode="EVN.CRT">
      <value xsi:type="IVL_PQ">
        <low value="5.5" unit="mmol/L"/>
        <high nullFlavor="PINF"/>
      </value>
    <interpretationCode code="H"/>
    </interpretationRange>
  </referenceRange>
</observationEvent>
</component2>
```

AN EXAMPLE HL7 FHIR DATA STRUCTURE

```
"resourceType" : "Observation",
 "identifier" : [{ Identifier }], // Business Identifier for observation
 "status" : "<code>", // R!  registered | preliminary | final | amended +
 "category" : [{ CodeableConcept }], // Classification of  type of observation
 "code" : { CodeableConcept }, // R!  Type of observation (code / type)
 "subject" : { Reference(Patient|Group|Device|Location) }, // Who and/or what this is about
 "context" : { Reference(Encounter|EpisodeOfCare) }, // Healthcare event during which this observation is made
 "effectiveDateTime" : "<dateTime>",
 "effectivePeriod" : { Period },
 "issued" : "<instant>", // Date/Time this was made available
 "performer" : [{ Reference(Practitioner|Organization|Patient|RelatedPerson) }], // Who is responsible for the observation
 // value[x]: Actual result. One of these 11:
 "valueQuantity" : { Quantity },
 "valueCodeableConcept" : { CodeableConcept },
 "valueString" : "<string>",
 "valueBoolean" : <boolean>,
 "valueRange" : { Range },
 "valueRatio" : { Ratio },
 "valueSampledData" : { SampledData },
 "valueAttachment" : { Attachment },
 "valueTime" : "<time>",
 "valueDateTime" : "<dateTime>",
 "valuePeriod" : { Period },
 "dataAbsentReason" : { CodeableConcept }, // C? Why the result is missing
 "interpretation" : { CodeableConcept }, // High, low, normal, etc.
 "comment" : "<string>", // Comments about result
 "bodySite" : { CodeableConcept }, // Observed body part
 "method" : { CodeableConcept }, // How it was done
 "specimen" : { Reference(Specimen) }, // Specimen used for this observation
 "device" : { Reference(Device|DeviceMetric) }, // (Measurement) Device
```

AN ACTUAL FHIR INSTANCE


```
{
  "resourceType": "Observation",
  "id": "f001",
  "text": {
    "status": "generated",
    "div": "<div xmlns=\"http://www.w3.org/1999/xhtml\"><p><b>Generated Narrative with
Details</b></p><p><b>id</b>: f001</p><p><b>identifier</b>: 6323 (OFFICIAL)</p><p><b>status</b>:
final</p><p><b>code</b>: Glucose [Moles/volume] in Blood <span>(Details : {LOINC code '15074-8'
= 'Glucose [Moles/volume] in Blood', given as 'Glucose [Moles/volume] in
Blood'})</span></p><p><b>subject</b>: <a>P. van de Heuvel</a></p><p><b>effective</b>:
02/04/2013 9:30:10 AM --&gt; (ongoing)</p><p><b>issued</b>: 03/04/2013 3:30:10
PM</p><p><b>performer</b>: <a>A. Langeveld</a></p><p><b>value</b>: 6.3 mmol/l<span> (Details:
UCUM code mmol/L = 'mmol/L')</span></p><p><b>interpretation</b>: High <span>(Details :
{http://terminology.hl7.org/CodeSystem/v3-ObservationInterpretation code 'H' = 'High', given as
'High'})</span></p><h3>ReferenceRanges</h3><table><tr><td>-
</td><td><b>Low</b></td><td><b>High</b></td></tr><tr><td>*</td><td>3.1 mmol/l<span> (Details:
UCUM code mmol/L = 'mmol/L')</span></td><td>6.2 mmol/l<span> (Details: UCUM code mmol/L =
'mmol/L')</span></td></tr></table></div>"
  },
  "identifier": [
    {
      "use": "official",
      "system": "http://www.bmc.nl/zorgportal/identifiers/observations",
      "value": "6323"
    }
  ],
  "status": "final",
  "code": {
    "coding": [
      {
        "system": "http://loinc.org",
        "code": "15074-8",
        "display": "Glucose [Moles/volume] in Blood"
      }
    ]
  },
  "subject": {
    "reference": "Patient/f001",
    "display": "P. van de Heuvel"
  },
  "effectivePeriod": {
    "start": "2013-04-02T09:30:10+01:00"
  },
  "issued": "2013-04-03T15:30:10+01:00",
  "performer": [
    {
      "reference": "Practitioner/f005",
      "display": "A. Langeveld"
    }
  ],
  "valueQuantity": {
    "value": 6.3,
    "unit": "mmol/l",
    "system": "http://unitsofmeasure.org",
    "code": "mmol/L"
  },
  "interpretation": [
    {
      "coding": [
        {
          "system": "http://terminology.hl7.org/CodeSystem/v3-ObservationInterpretation",
          "code": "H",
          "display": "High"
        }
      ]
    }
  ],
  "referenceRange": [
    {
      "low": {
        "value": 3.1,
        "unit": "mmol/l",
        "system": "http://unitsofmeasure.org",
        "code": "mmol/L"
      },
      "high": {
        "value": 6.2,
        "unit": "mmol/l",
        "system": "http://unitsofmeasure.org",
        "code": "mmol/L"
      }
    }
  ]
}
```


Note the use of a "Code" datatype to declare the "thing being observed", or in this case, the lab test

A NOTE ABOUT CDA VERSUS FHIR

- CDA is “coarse grained” (i.e., large documents) whereas FHIR tends to be more “fine grained” (each FHIR “Resource” represents a stand-alone “chunk” of data, e.g., “Patient”, “Provider”, “Observation”, etc.)
- CDA documents tend to be requested and served up using complex software, whereas FHIR tends to be requested and served up using light-weight mechanisms (e.g., REST, micro-services)
- We expect CDA to remain popular for some time, particularly because several CDA document types are required for MU and other national initiatives. However, we expect most new standards development to focus on FHIR rather than CDA

OK, SO WE HAVE A STANDARD – NOW WHAT?

- Most standards are targeted to deal with the most generic situation – they arrive at a structure that can handle the greatest variety of business situations and needs
- Just because you and I can communicate using a standard doesn't mean we can interoperate.
  - Optional structures (fields, segments)
  - Loose cardinality (e.g., a segment or field can "repeat")
  - No or loose terminology bindings
- Because of this, we often need "Implementation Guides" or further guidance on how to "constrain" the standard

Clinical Data Interoperability 101

Exchanging Usable Clinical Data

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