Healthcare Innovation Seminar

Clinical Data Interoperability 101

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About J P Systems, Inc.

We are a Woman Owned Small Business, WOSB, founded in 1983. We perform clinical interoperability and terminology services and specialize in HL7 data standards and clinical data quality improvement.

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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

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Learning Objectives

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- What is Data Interoperability (IOP)
- The US Ecosystem for IOP
- How to employ Interoperability to improve patient safety
- Current state of device Interoperability
- How Data Standards contribute to Interoperability
- Why Data Standards are not automatically interoperable

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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

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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

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Why is Interoperability so Important Today?

Data must cross multiple system boundaries – Patients are treated by multiple clinicians, organizations, and increasingly devices, which must intelligently share data.

- **Interoperability leads to:**
  - **Better care coordination**
  - **Improved patient safety**
  - **Improved population health reporting**
  - **Costs savings**
- **A complete and accurate longitudinal patient record is needed for an electronic health record's (EHR) Clinical Decision Support or Patient Safety systems to work properly.**

Government regulations are increasingly demanding behaviors that require interoperability to comply.

- **New payment models – especially Value Based Care (VBC)**
- **More complex and numerous Quality Measures**
- **A push against "data blocking"**
- **US Core Data for Interoperability (USCDI) begun to set standards for various classes of data.**

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

HL7 FHIR	SMART	CDS Hooks	Argonaut	SQA
CCDA	CDA	CCR	KNARTs	CIMI
SNOMED	LOINC	RxNorm	NDC	SOLOR
CQL	BPMN	CMMN	DMN	UML
X.12	NCPDP	Continua	DICOM	IHE
XACML	SLS	RBAC	DURSA	TEFCA

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Source: Dr. Stan Huff, Intermountain HealthCare

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How Can Interoperability Improve Patient Safety?

The more data flows into your EHR → The more complete your patient records will be → 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.

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“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 terminologies

- Ideally, a full ontology, so computers can reason over the data

- Eliminating the need & cost to have different versions for different EHRs

- Use the same mechanisms (OAuth, etc.) to communicate access privileges

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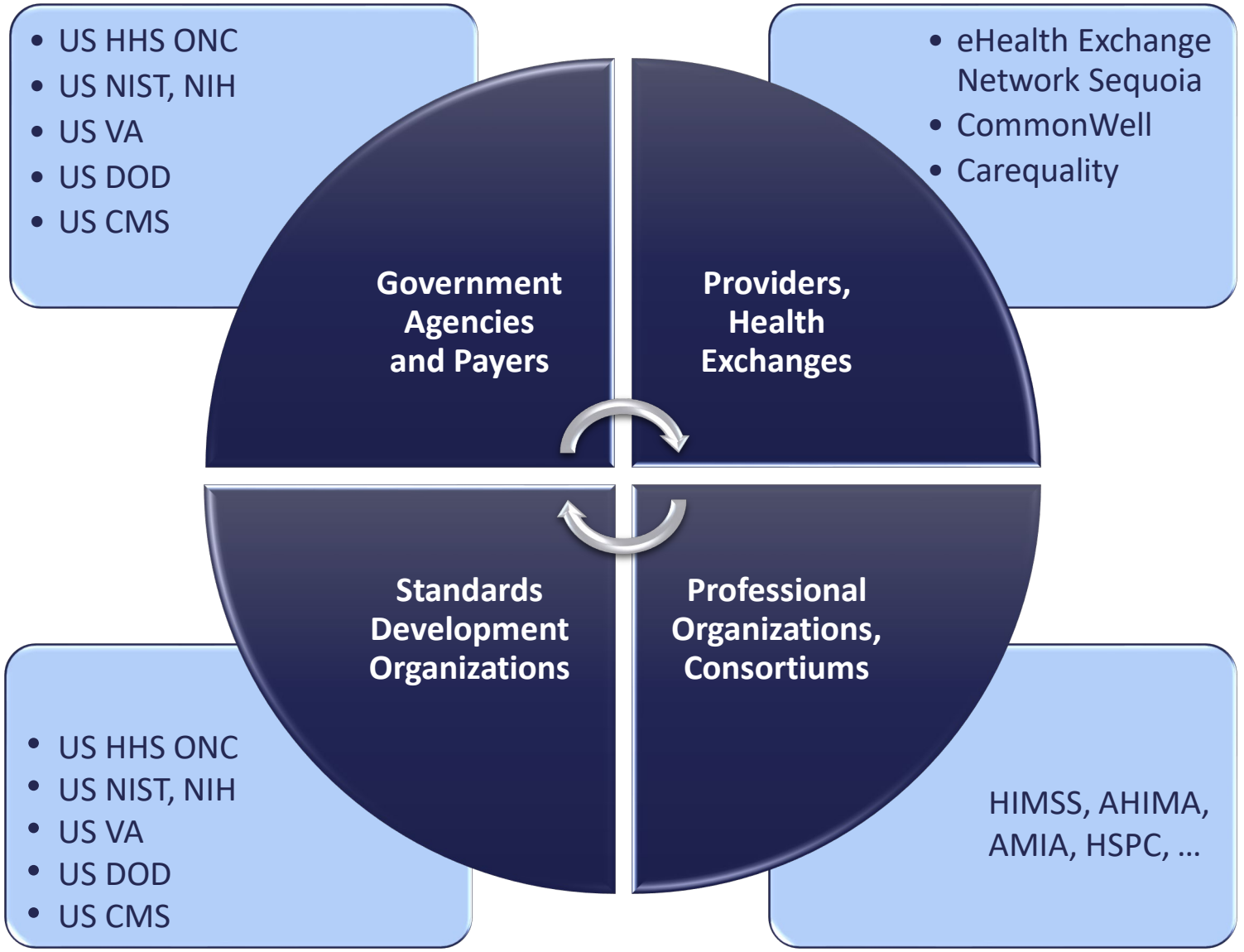
The U.S. Ecosystem of Interoperability



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Interoperability Between HIEs – What is TEFCA?

TEFCA strives to establish a single “on-ramp” for US Health Information Exchange (HIE) which enables 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).

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ONC and CMS Final Ruling

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 Final Rule

CMS Final Rule

CMS Interoperability & Patient Access Fact Sheet

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ONC and CMS Final Ruling

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 EHRs 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 HIE.

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

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ONC and CMS Final Ruling

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.

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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 more cost savings by avoiding test duplication.

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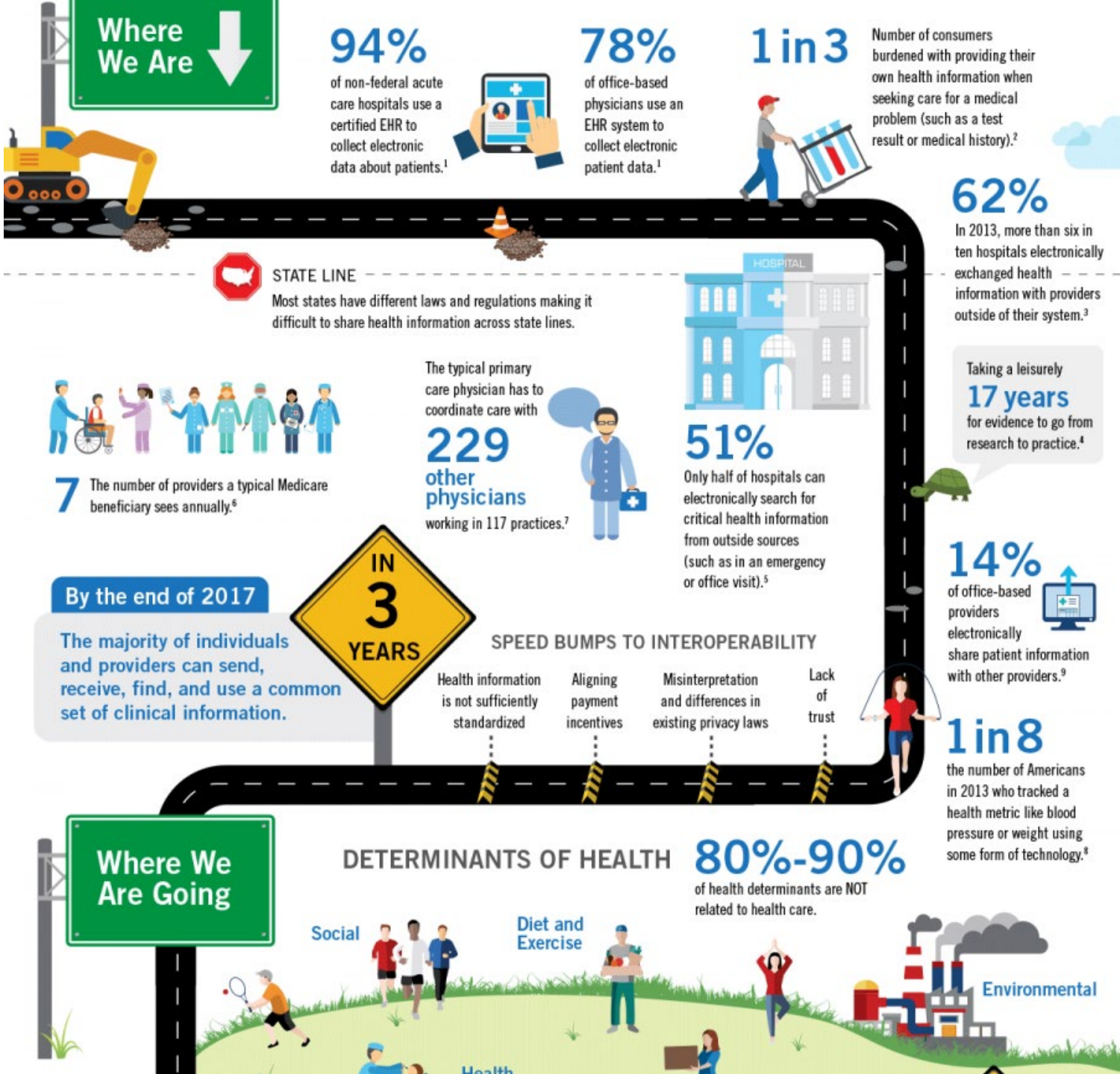
The US Interoperability Roadmap: Speedbumps to Interoperability

Speedbumps:

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

See the US Nationwide Interoperability Roadmap here: ONC roadmap



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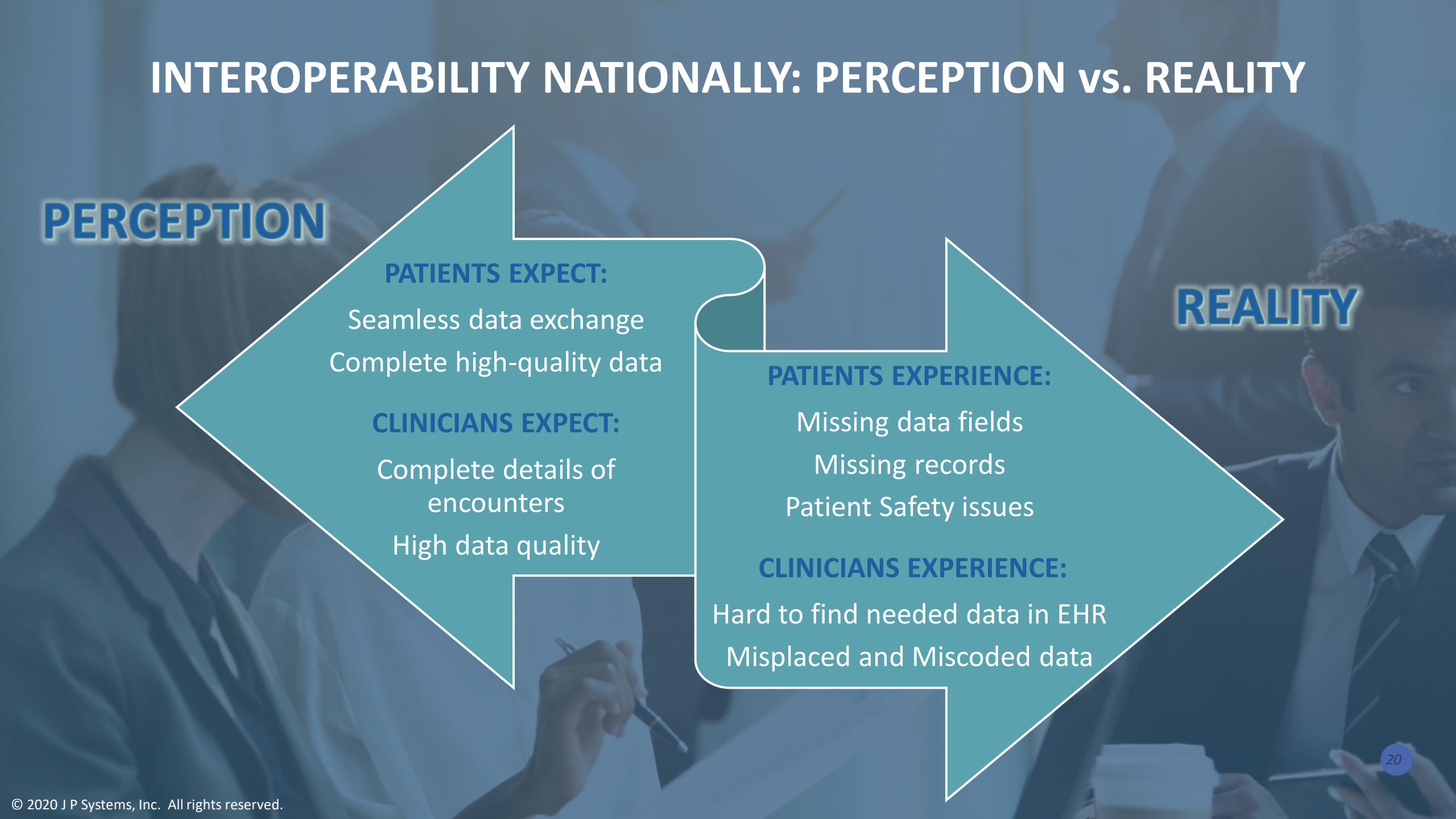
INTEROPERABILITY NATIONALLY: PERCEPTION vs. REALITY



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CURRENT STATE OF DEVICE INTEROPERABILITY

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.

Source: West Health, The Value of Medical Device Interoperability 2013

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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

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

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.

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Why Are Data Quality & Device Interoperability So Important?

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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)

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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

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Phases of Interoperability Planning

Identify your data exchange partners and develop a communications plan on how to engage

Identify standards and terminologies currently in use on both ends

Identify new needed standards and plan how to expand

Map your local terms to new international clinical terminologies: e.g. SNOMED CT.

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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

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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.

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How Data Standards Contribute to Interoperability

PROBLEM: 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 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

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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)

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How Data Standards Contribute to Interoperability?

PROBLEM: 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")

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What Does HL7 Do?

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.

What is HL7?

Healthcare IT Interoperability Communities

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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: Link to FHIR Fundamentals course

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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 good for verbose summary data, but because it is large and complex, CDA is not good for transactional data

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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>
```


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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
```


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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

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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

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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 does not 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

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Clinical Data Interoperability 101
Exchanging Usable Clinical Data

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