Consumer Technology WG: Patient Generated Health Data (PGHD) Task Force

Leslie Kelly Hall, chair
Russ Leftwich, co-chair

January 23, 2014

Agenda

- Briefing on the use of the C-CDA Release 2.0 standard

- DIRECT

- Continua Alliance

- Questionnaires

Office of the National Coordinator for Health Information Technology

PGHD Task Force Members

- Leslie Kelly Hall, Healthwise
- Chuck Parker, Continua Alliance
- David Kibbe, DirectTrust.org
- Dixie Baker, Martin, Blanck and Associates
- Lisa Nelson, Consultant
- Russ Leftwich, State of TN Office of eHealth
- Susan Woods, Veterans Health Administration

Consumer Technology WG (CTWG) Charge & Scope

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to the National Coordinator for Health IT

- **Charge:** Provide recommendations on standards and interoperability issues and opportunities related to strengthening the ability of consumers, patients, and lay caregivers to manage health and health care for themselves or others.

- **Scope:**
  - Examples of issues to be addressed include portability of patient data, patient access to and generation of their health data, and incorporating patient preferences for a variety of issues, such as care plans.
  - Important touch points with other workgroups:
    - HITPC Consumer Empowerment Workgroup
    - Meaningful Use Workgroup

CTWG Discussion Questions

- What standards are needed to support the flow and use of PGHD by providers, including acceptance of PGHD?

- Specific submission use cases
  - PHR to EHR or other document based submission
  - Direct to patient portal (structured questionnaire or other)
  - Secure messaging
  - Other?

- Vocabulary/content standards

Background

- Provide feedback on two PGHD related Meaningful Use stage 3 and identify issues that would prohibit widespread use of PGHD
- PGHD
    - Menu: Eligible Professionals and Eligible Hospitals accept provider-requested electronically submitted patient-generated health information through structured or semi-structured questionnaires (e.g., screening questionnaires, medication adherence surveys, intake forms, risk assessment, functional status) or secure messaging.
    - Although not a part of the certification criteria, if an organization's EHR accepts patient-generated information using interfaces to remote devices such data count as patient-generated health information.
    - Threshold: Low

- Amendments
    - **Certification Criteria:** Provide patients with an easy way to request an amendment to their record online (e.g., offer corrections, additions, or updates to the record)

Recommendations of standards use

- Emphasis is on interoperability between systems
- Tethered PHRs may continue to operate with proprietary approaches for internal use.
- Interoperability encourages non tethered, consumer applications and products, devices
- Consistent with EHR to EHR communication expanding to patient generated data
- Patient preferred systems can be used
  - "I don't want a bunch of PHRs and portals to go to, I want to send the same information in the same way to all of them".

Continuum of PGHD

Meaningful Use 3 Standards Ready to Support:

Messaging	Structured/ Questionnaire	Unstructured/ Narrative/Hybrid	Device	Plan(s) of Care	Collaborative Care Planning
Secure non-tethered w/wo attachments	**History(s)** **Medication** **Personal profile** **Pre-visit** **Decision aids** **Smoking status** **Screenings** **Problems** **Symptoms** **Consents** **Participants*** **HRA/HCAPS** **Experience of Care** **POLST/AD** **Nutrition** **Allergies** **Amendments** **Barriers to Care** **Preferences** **Self outcomes**	Consumer centric (word, excel, other) **Hybrid (Structured template with unstructured narrative)**	**Provider directed** **Bio-metric telemetry Repositories mobile** Consumer directed consumer products mobile	Episodic or chronic condition (siloes) Versioning Reconciliation Harmonization	Holistic and integrative (horizontal) Multiple care plans Governance Curating

Assume technology/device agnostic

Meaningful Use 3: Ready

	Messaging	Structured/ Questionnaire	Unstructured /Narrative	Device	Care Plans	Collaborative Care
Assumed	COMMON MU DATA SET Standards and vocabulary, device/technology agnostic					
Standards	DIRECT HL7 Care Team Roster SAML HDATA OATH2 Restful BB+PULL	HL7- CCDA HL7 Care Team Roster FHIR		HL7- CCDA DIRECT FDA Continua HL7 Care Team Roster (IEEE Bluetooth NFC ZIGBEE USB HL7 Restful OATH2 SAML CCDA HDATA more)	HL7 – CCDA Care Plan HL7 Care Team Roster	
Vocabularies	SNOMED CT LOINC RX-Norm					

About Consolidated CDA (C-CDA R2) Templates

- A set of harmonized templates covering efforts dating back to 2007 across 4 different SDOs
- Each **template** is a set of instructions about how to use the HL7 Clinical Document Architecture Standard (CDA R2) for a particular use
- Templates from C-CDA are combined to form different types of documents
- Includes two header templates
  - Providers
  - Patients/Consumers

Header Approach

- All benefits apply to all authors
- No separate but equal approach for patients
- Encourages innovation in collaborative records
- EHR capable for any CCDA is capable for all

Document Header
for Providers or Patients/Consumers

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Author
IDs: NPI, Direct, VUHID
Role (can be the patient or relative or legal rep.)
Address, Telecom

RecordTarget (the Patient)
IDs: Direct, VUHID, MRN
Address, Telecom
Demographics

Guardians
Specific Roles

Custodian
(steward of the document)
Address, Telecom

Document Header

Patient	Janie Appleseed
Date of birth	August 28, 1962
Sex	Female
Race	White
Ethnicity	Not Hispanic or Latino
Contact info	Primary Home: 1234 Orchard Street Westerly, RI O2891, US Tel: (816)276-6909
Patient IDs	998991 2.16.840.1.113883.19.5.99999.2 111-00-2330 2.16.840.1.113883.4.1 12345-99999 2.16.840.1.113883.19.5.9999.1393
Document Id	TT988 2.16.840.1.113883.19.5.99999.1
Document Created	January 13, 2014, 17:00:00 -0400
Healthcare service	Advance Directives from January 13, 2014, 16:30:00 -
Performer	0f9dc26 1.2.3.4.5.6.7.8
Author	Janie Appleseed
Contact info	Primary Home: 1234 Orchard Street Westerly, RI 02891, US Tel: (401)123-1234
Author	MyDirectives.com v2.0
Contact info	17304 Preston Road Dallas, TX 75252, US Tel: (972) 733-6814
Document maintained by	Rhode Island Quality Institute
Contact info	50 Holden Street Providence, RI 02908, US Tel: (401) 858-4815

Component Of /
Encompassing Encounter
Encounter Participants

Documentation Of/
Service Event
Performers

In Fulfillment Of/
Order

Participant
IDs: NPI, Direct, VUHID
Role (care team members)
Address, Telecom

Authorization /
Consent

Care Team Roster

	2014 Certification Criteria	Future Certification Criteria
Content	• Primary care provider of record or referring provider, receiving provider, other known care team members	• Health professionals, family and community members who provide care to patient or are involved in care planning
Encoding	• Text List	• HL7 CDA Entries
Health professional attributes	• No specified attributes	• Contact information including physical and electronic address, taxonomy, role, unique identifier (NPI)
Family caregiver attributes	• Not mentioned	• Included with contact information including electronic address, e.g. Direct address, familial relationship, legal relationship
Use case	• Transitions of Care	• Longitudinal care coordination and care plan

Patient Generated Data Use Cases: Patient Response

Share Patient Information

- Patient provided data improves how medical histories can be kept up to date

Share Advance Directives

- Access to patient's wishes improves care planning and leads to better health outcomes

Form and Questionnaire

- Standard Forms are defined
- Standard CDA document record the patient's answers

Device Data from Patient

- Data reporting uses industry standards
- Data provenance is encoded

Standards supporting the Use Cases

	Patient Generated Medication List Informs PCP of current medications being taken.	Patient Generated Advance Directives Provide Physicians with information for care plans
Content	C-CDA R2 Templates Narrative text and may include structured data, depending on template used; Minimum: Unstructured body provides view of static information or link to current view	C-CDA R2 Templates Narrative text and may include structured data, depending on template used; Minimum: Unstructured body provides view of static information or link to current view
Encoding	US Realm + PGD Header Medications Section	US Realm + PGD Header Advance Directives Section
Vocabulary	Constrained by C-CDA R2 templates	Constrained by C-CDA R2 templates
Push	IHE ITI XDS Provide and Register, XDR, XDM Direct, or IHE ITI RFD	IHE ITI XDS Provide and Register, XDR, XDM Direct, or IHE ITI RFD
Pull	IHE ITI XDS Retrieve Doc Set (ITI-43) or Blue Button Plus	IHE ITI XDS Retrieve Doc Set (ITI-43) or Blue Button Plus
View	IHE PCC Content Consumer options for view, import and import discrete data	IHE PCC Content Consumer options for view, import and import discrete data
Proof Point	NoMoreClipboard.com	MyDirectives.com

Patients provide current Medication List information

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Current Medications [Edit]

- **albuterol sulfate inhalation** 90mcg/actuation (Take one puff.)
- **zolpidem oral** 5mg (Take a bedtime for sleeplessness)

Previously taken medications:
- **eletriptan HBr** 20mg (Take at onset of headache) (02/04/2009 - 01/01/2014)

Current Illnesses [Edit] [Conditions Review]
- None entered

Past Illnesses [Edit]
- None entered

Surgeries/Procedu...
- No Procedure H...

Pregnancy History
No pregnancies

Immunizations [Edi...
- None.

Allergies [Edit]
- No allergies ent...

Family Medical His...
- No family histor...

Social History [Edi...

Download your NoMoreClipboard H...

Click a link below to generate a file in
- Plain Text/ASCII Format ("Blue Button")
- PDF Format
- PHR Extract (Personal Health Record)
- CCD (Continuity of Care Document)
- CCR (Continuity of Care Record)

cc:Me

Populate your PHR with cc:Me

cc:Me makes it easy to get medical informa...

MEDICATIONS

Section Author: 586125927.10688286 2.16.840.9.9.9.9.9.9

Prescribed by: Henry Seven [NPI 99999999] 06/28/2004 22:44:11

Label	Information
Type	Rx
Brand Name	eletriptan 20 MG Oral Tablet [Relpax] (RxN 404443)
Generic Name	eletriptan 20 MG Oral Tablet (RxN 404443)
Form	Oral Tablet (SCT 421026006)
Drug Vehicle	
Medication Route	by mouth (SCT 26643006)
Status	completed
Start Date	02/14/2009
End Date	01/01/2014
Instructions	Take at onset of migraine; take second tablet if heada
Where to Administer	By mouth (SCT 26643006)
Administrative unit	tablet (SCT 385055001)
Repeat Number	2
Precondition	Headache (SCT 25064002)
Dose Quantity	20 mg
Rate Quantity	

```xml
<entry typeCode="DRIV">
    <substanceAdministration classCode="SBADM" moodCode="INT">
        <!-- ** Medication activity ** -->
        <templateId root="2.16.840.1.113883.10.20.22.4.16"/>
        <id root="cdbd33f0-6cde-11db-9fe1-0800200c9a66"/>
        <text>
            <reference value="#Med_2"/></text>
        <statusCode code="completed"/>
        <effectiveTime xsi:type="IVL_TS">
            <low value="20090214"/>
            <high value="20140101"/>
        </effectiveTime>
</entry>
```

Advance Directives
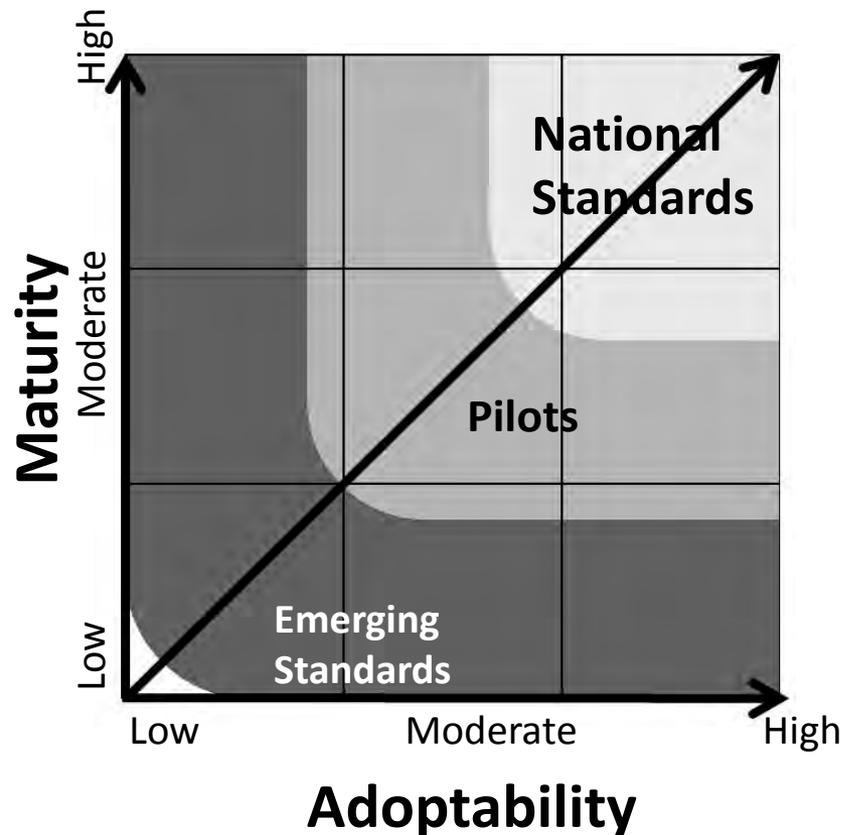
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My Advance Directives

Patient	Janie Appleseed
Date of birth	August 28, 1962
Sex	Female
Race	White
Ethnicity	Not Hispanic or Latino
Contact info	Primary Home: 1234 Orchard Street Westerly, RI O2891, US Tel: (816)276-6909
Patient IDs	998991 2.16.840.1.113883.19.5.99999.2 111-00-2330 2.16.840.1.113883.4.1 12345-99999 2.16.840.1.113883.19.5.9999.1393
Document Id	TT988 2.16.840.1.113883.19.5.99999.1
Document Created	January 13, 2014, 17:00:00 -0400
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Author	Janie Appleseed
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Author	MyDirectives.com v2.0
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Document maintained by	Rhode Island Quality Institute
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ADVANCE DIRECTIVES

Directive Type	Effective as of:	Expires on:	Patient's Directive	Document of Record
Resuscitation	January 13, 2014	n/a	If I am terminally ill, I prefer they stop all life-sustaining treatments and let me die as gently as possible. I realize that I would not receive life-sustaining treatments including but not limited to breathing machines, blood transfusions, dialysis, heart machines, and IV drugs to keep my heart working. Also, I realize that cardiopulmonary resuscitation (CPR) would not be attempted, and I would be allowed to die naturally. If I Have a Severe, Irreversible Brain Injury or Illness and Cannot Communicate or Perform Basic Self-Help: I prefer that they stop all life-sustaining treatments and let me die as gently as possible. I realize that I would not receive life-sustaining treatments including but not limited to breathing machines, blood transfusions, dialysis, heart machines, and IV drugs to keep my heart working. Also, I realize that cardiopulmonary resuscitation (CPR) would not be attempted, and I would be allowed to die naturally.	• Verify against most current directives • Link to patient's managed uADD

- Provider accesses the Advance Directive information from the HIE or AD repository. The document includes a link to the most current version of the patient-managed Advance Directive document. Link enables clinician to verify that directives on file (pulled from HIE/or repository) are current.

MyDirectives

LEARN MORE   REAL STORIES   GET STARTED   LOG IN

Review: uADD | HIPAA Authorization Form | Summary for Physicians | Signing Certificate

Complete your own Directive or help a loved one today.
It's free. It's priceless.
GET STARTED >

Watch the video

MyDirectives

Universal Advance Digital Directive (uADD)™

Janie Appleseed

It is very important for you to discuss your medical treatment goals and wishes with your healthcare agent, your family, and your medical care providers. Keep in mind that advance medical directives are simply expressions of your medical treatment goals and preferences. There is no guarantee that your medical care providers will follow all of your wishes, but one thing is certain: **If your advance medical directives cannot be quickly located and retrieved in a time of need, then medical care providers, your family and friends will not be able to take your wishes into consideration when they make critical decisions regarding your treatment.**

Part 1   **Appointment of a Primary Healthcare Agent and Alternate Healthcare Agents**

IF THIS PART OF THE uADD™ IS LEFT BLANK, I AM DELIBERATELY DECLINING TO DESIGNATE A HEALTHCARE AGENT AND REQUESTING THAT THE DOCTORS ON DUTY MAKE DECISIONS BASED ON MY GUIDELINES.

I am appointing the person or persons below as my healthcare agent and, if applicable, as my alternate healthcare agent(s), and I am granting to each of them the legal authority to make medical treatment decisions

I DECIDE .ORG

See what others are saying, and share your thoughts!

Evaluation and Classification of Technical Specifications
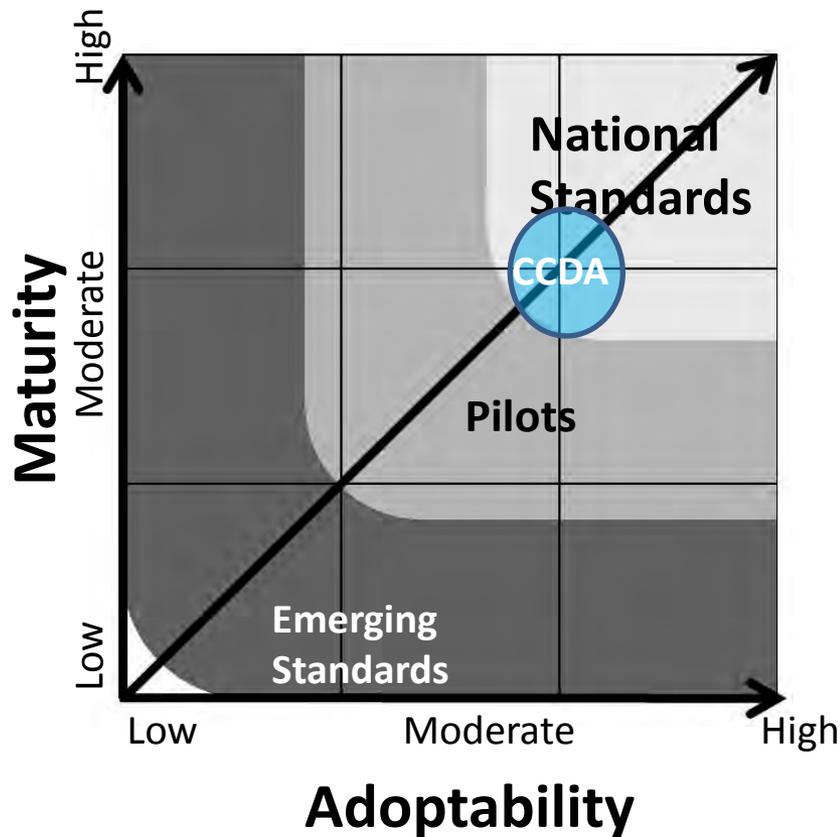
Maturity Criteria:

- Maturity of Specification
- Maturity of Underlying Technology Components
- Market Adoption

Adoptability Criteria:

- Ease of Implementation and Deployment
- Ease of Operations
- Intellectual Property

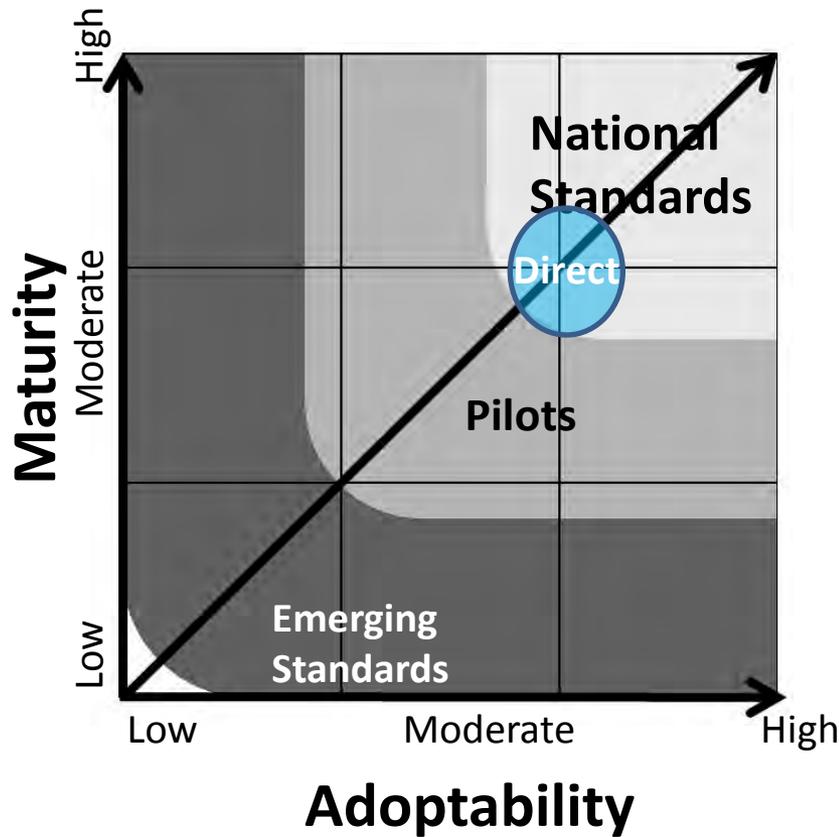**Mature for provider world new to patients= moderate**

- Questionnaires
- Care Team Roster
- Device use
- *Build on current efforts*

NwHIN Applicability: PGHD

- Person based design
  - Directories
  - Privacy
  - LOA
  - Acquisition
  - Security
  - Trust framework

  Most issues apply to all participants, work ongoing in DIRECTTRUST

How does Continua work?
ITU Version H8.10

- Continua constrains existing standards by creating a set of implementation guidelines

- Further Constrains underlying standards by requiring specific implementations when optionality is available

- Includes Device data, security, and Health records connectivity
  – Personal Area Network(PAN)/Local Area Network (LAN)/Touch Area Network (TAN) describes devices and transports for device information
  – Application Hosting Device describes the hub that collects information from one or more devices and transforms data into Packets
  – Wide Area Network (WAN) describes how a packet is transferred using HL7 and Security wrapper over IP networks along with Patient ID information
  – Health Records Network (HRN) interface describes how information is transformed into CCDA 2 Personal Health Medical Record Data for structured input into EHR, PHR, HIE etc.

- Certification takes place that a device or other interface is compliant and meets interoperability requirements (7 international test houses today)

Model

- Continua allows certification at device, AHD (Hub), WAN, or HRN level.
- This allows an existing infrastructure to become compliant over time
  - Typically, first HRN interface, then WAN or HUBs, then devices
  - Does not force implementation across entire set immediately so can be scalable
- On version 5 of Implementation Guidelines
  - Driven by Use Case process
  - Driven by open submission process
  - All Guides are published to the Public
  - ITU standard now (H8.10) December 19, 2013
    http://www.itu.int/net/pressoffice/press_releases/2013/75.aspx#.UtXF3IaA3wG
- Continua only utilizes Existing Standards – no new IP nor acts as a Standards Development Organization
  - Profiling only like IHE

Use Cases

Using C-CDA R2 Templates	Exchange of Patient Generated Device Data – Active link	Exchange of Patient Generated Device Data - email
Content	Personal Health Device observations Structured in accordance with HL7 IG for CDA r2 – Personal Healthcare Monitoring Report; Minimum: Structured data format for individual device measurement	Personal Health Device observations Structured in accordance with HL7 IG for CDA r2 – Personal Healthcare Monitoring Report; Minimum: Structured data format for individual device measurement
Encoding	US Realm + PGD Header Personal Health Medical Record	US Realm + PGD Header Personal health Medical Record
Vocabulary	Constrained by C-CDA R2 templates	Constrained by C-CDA R2 templates
Push	IHE ITI XDS.b Provide and Register, XDR, PHMR Interface	IHE ITI XDM
Pull		
View	IHE PCD-01 XDR PHMR	IHE PCD-01 XDM
Proof Point	NIST Continua Conformity Test Continua Certification	Email exchange of data HIMSS Interop showcases Continua Certification

Underlying IEEE Specifications Completed

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1. IEEE Std 11073-20601™ Optimized exchange protocol + Amendment
2. IEEE Std 11073-10404™ Dev specialization – Pulse oximeter
- IEEE Std 11073-10406™ Dev specialization – Basic ECG
- IEEE Std 11073-10407™ Dev specialization – Blood pressure monitor
- IEEE Std 11073-10408™ Dev specialization – Thermometer
- IEEE Std 11073-10415™ Dev specialization – Weighing scale
- IEEE Std 11073-10417™ Dev specialization – Glucose meter + Revision
- IEEE Std 11073-10418™ Dev specialization – INR (blood coagulation)
- IEEE Std 11073-10420™ Dev specialization – Body composition analyzer
- IEEE Std 11073-10421™ Dev specialization – Peak flow
- IEEE Std 11073-10441™ Dev specialization – Cardiovascular
- IEEE Std 11073-10442™ Dev specialization – Strength
- IEEE Std 11073-10471™ Dev specialization – Activity hub
- IEEE Std 11073-10472™ Dev specialization – Medication monitor

Continua Model of Connectivity

Personal Device
- Thermometer
- Pulse Oximeter
- Pulse / Blood Pressure
- Weight Scale
- Glucose Meter
- Cardio / Strength
- Independent Living Activity
- Peak Flow
- Medication Adherence
- Physical Activity
- Electrocardiogram
- Insulin Pump

Aggregation Manager

Optional Telehealth Service Center

Health Records/ Networks

ISO
IEEE
Bluetooth
USB
ZigBee

IHE
HL7
W3C
HL7
IHE

WiFi, 2G to 4G/LTE

Personal Area Network (PAN) Interface

Wide Area Network (WAN) Interface

Health Record Network (HRN) Interface

PHR
EHR
NHIN
HIE
BB+

Patient Reported Outcome Measure Uses

- PROMs are used to get patients input about how they feel or function in relation to a health condition and its therapy.

- PROMs provide a means of gaining an insight into the way patients perceive their health and the impact that treatments or adjustments to lifestyle have on their quality of life.

- PROMs can provide the means to gather Patient Directives.

- Investment in PCORI emphasizes the need to advance PROM standards.

Standards supporting the Use Cases

	Exchange of PROM using QFD IG	Exchange of Patient Response to PROM using QR IG
Content	PROM questions such as multiple choice, numeric, free-text, analog slider, discrete slider, pre-conditions and the related copyright represented as structured entries.	Patient response to PROM questions such as multiple choice, numeric, free-text, analog slider, discrete slider and the related copyright represented as structured entries.
Encoding	US Realm + PGD Header Questionnaire Form Definition Section and templates (for question and pre-conditions) Copyright Section and template	US Realm + PGD Header Questionnaire Response Section and templates Copyright Section and template
Vocabulary	Constrained by C-CDA R2 templates	Constrained by C-CDA R2 templates
Push	RESTfull HTTP via Continua's hData and OAuth 2.0 profiles	RESTfull HTTP via Continua's hData and OAuth 2.0 profiles
Pull	RESTfull HTTP via Continua's hData and OAuth 2.0 profiles	RESTfull HTTP via Continua's hData and OAuth 2.0 profiles

Structured/Semi-structured Questionnaires

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HL7 IG for CDA® Release 2.0: Form Definition and Questionnaire Response Document, Release 1

- Defines templates for questions such as multiple choice, numeric, free-text, analog slider and discrete slider in a questionnaire (aka PROM-Patient Reported Outcome Measure)

- Also defines templates for pre-conditions to ask a question (e.g. ask this question if answer to previous question is "Yes")

- Template for a copyright info related to a patient reported outcome/measure (PROM)

```
section>
  <templateId root="2.16.840.1.113883.10.20.32.2.1"/>
  <id extension="aa127024.aa127024-dpfeelings" root="2.16.840.1.113883.3.342.1"/>
  <title>What matters most to you?</title>
  <text>Your personal feelings are just as important as the medical facts. Think about what matters most
      to you in this decision, and show how you feel about the following statements.</text>
- <entry typeCode="DRIV">
    - <organizer moodCode="EVN" classCode="CLUSTER">
        <!-- Answers Organizer template -->
```

HL7 IG for CDA® Release 2.0: Form Definition and Questionnaire Response Document, Release 1

- For the patient generated responses, make use of C-CDA header + PGD header templates

- For the clinician generated responses, make use of C-CDA header template.

- Templates for capturing patient response to questions in a PROM

Form Definition DSTU establishes how to create standard form-based questionnaires

7. Are you experiencing side-effects from medications?

None	O
Very mild	O
Mild	O
Moderate	O
Severe	O
Very severe	O

A multiple choice question from CHF Questionnaire

XML representation according to the template for Multiple Choice Question in the QFD IG.

```
<observation classCode="OBS" moodCode="DEF">
  <!--templateID for the Multiple Choice Question Pattern-->
  <templateId root="2.16.840.1.113883.10.20.32.4.8"/>
  <id extension="ob9" root="2.16.840.1.113883.3.1817.1.6"/>
  <code code="q9" codeSystem="Continua-OID">
    <originalText>Are you experiencing side-effects from medications? </originalText>
  </code>
  <value xsi:type="CE" code="GUID1" codeSystem="Continua-ANS-OID" displayName="None"/>
  <value xsi:type="CE" code="GUID2" codeSystem="Continua-ANS-OID" displayName="Very mild"/>
  <value xsi:type="CE" code="GUID3" codeSystem="Continua-ANS-OID" displayName="mild"/>
  <value xsi:type="CE" code="DSUID4" codeSystem="Continua-ANS-OID" displayName="Moderate"/>
  <value xsi:type="CE" code="GUID5" codeSystem="Continua-ANS-OID" displayName="Severe"/>
  <value xsi:type="CE" code="GUID6" codeSystem="Continua-ANS-OID" displayName="Very severe"/>
</observation>
```

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Supporting Documentation

How does the PGD Header Template work?
templateId 2.16.840.1.113883.10.20.29.1

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- PGD Header Template is a C-CDA v2.0 template
- Further constrains the US Realm Header Template (templateId 2.16.840.1.113883.10.20.22.1.1.2)
- Includes additional semantics for a patient generated document
  - US Realm Header Template establishes the vocabulary for clinician types
    - NUCC Taxonomy (ie 207RC0000X Cardiologist, 221700000X Art Therapist) (a large, very broad and very specific value set)
  - PGD Header Template adds vocabulary for people in the care team who are not clinicians
    - The patient themselves (ONESELF)
    - Personal relationships to the patient (ie MTH, FTH, DAU, FAMMEMB, FRND) (90 codes, very general to fairly specific)
    - Legal relationships (POWATT, HPOWATT, GUADLTM, GUARD, RESPRSN) (8 codes)
    - Vocabulary Binding allows encoding of concepts not represented in the value set (CWE)
- Supports documenting the full roster of Care Team members
  - Care Team members are encoded in the CDA document as participants
- Includes persistent authorship and reference to persistent documents
  - Data provenance is preserved, for patients/consumers as well as providers

A document comprised of standard sections is a standard document

Document Types (partial list)

- Continuity of Care Doc (CCD)
- Discharge Summary
- Referral Note
- Consultation Note
- Progress Note
- Unstructured Document
- Care Plan
- Transition of Care
- Clinical Summary
- Ambulatory Summary
- Inpatient Summary
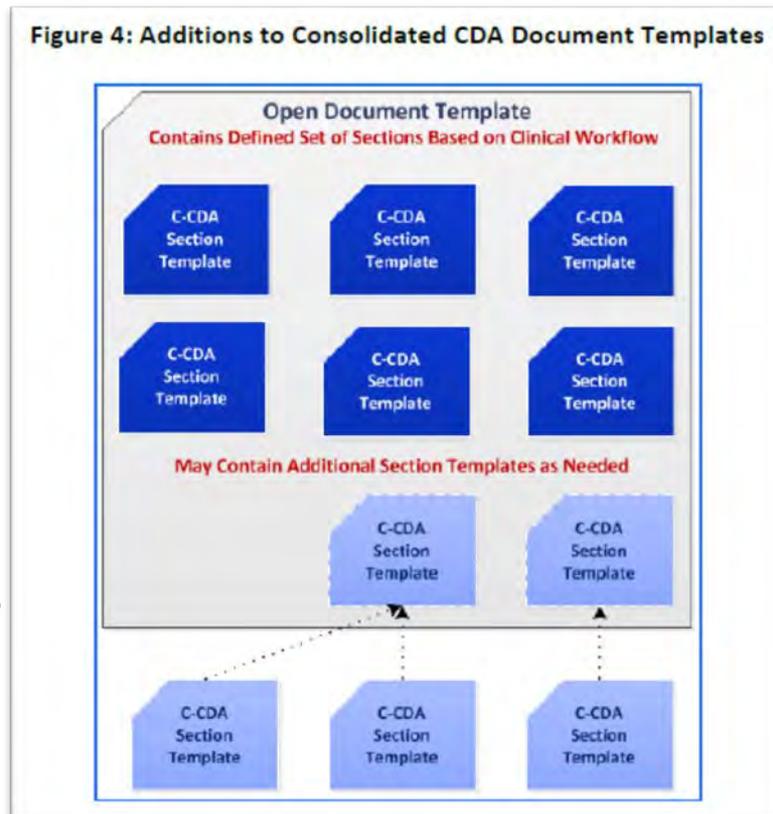- Data Portability Export

Blue: 9 document templates in C-CDA
Red: 9 document types explained in Meaningful Use Companion Guide, with no explicit document templates
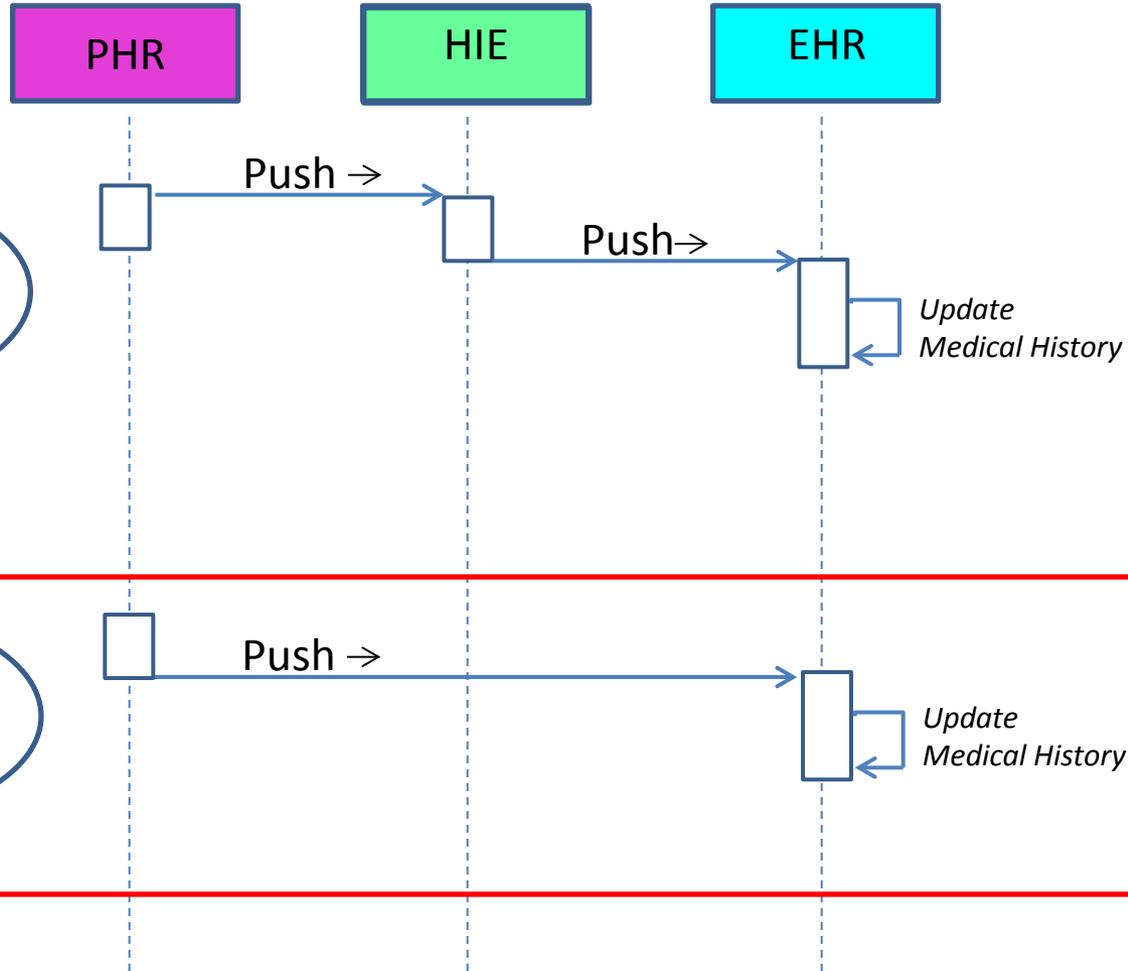
C-CDA R2 Section Templates*

- US Realm Header
- Allergies
- Medications
- Advance Directives
- Chief Complaint
- Reason for Visit
- Procedures
- Vital Signs
- Social History
- Family History
- Encounter Diagnosis

* C-CDA defines 71 standard section templates with standard entry templates for some types of information
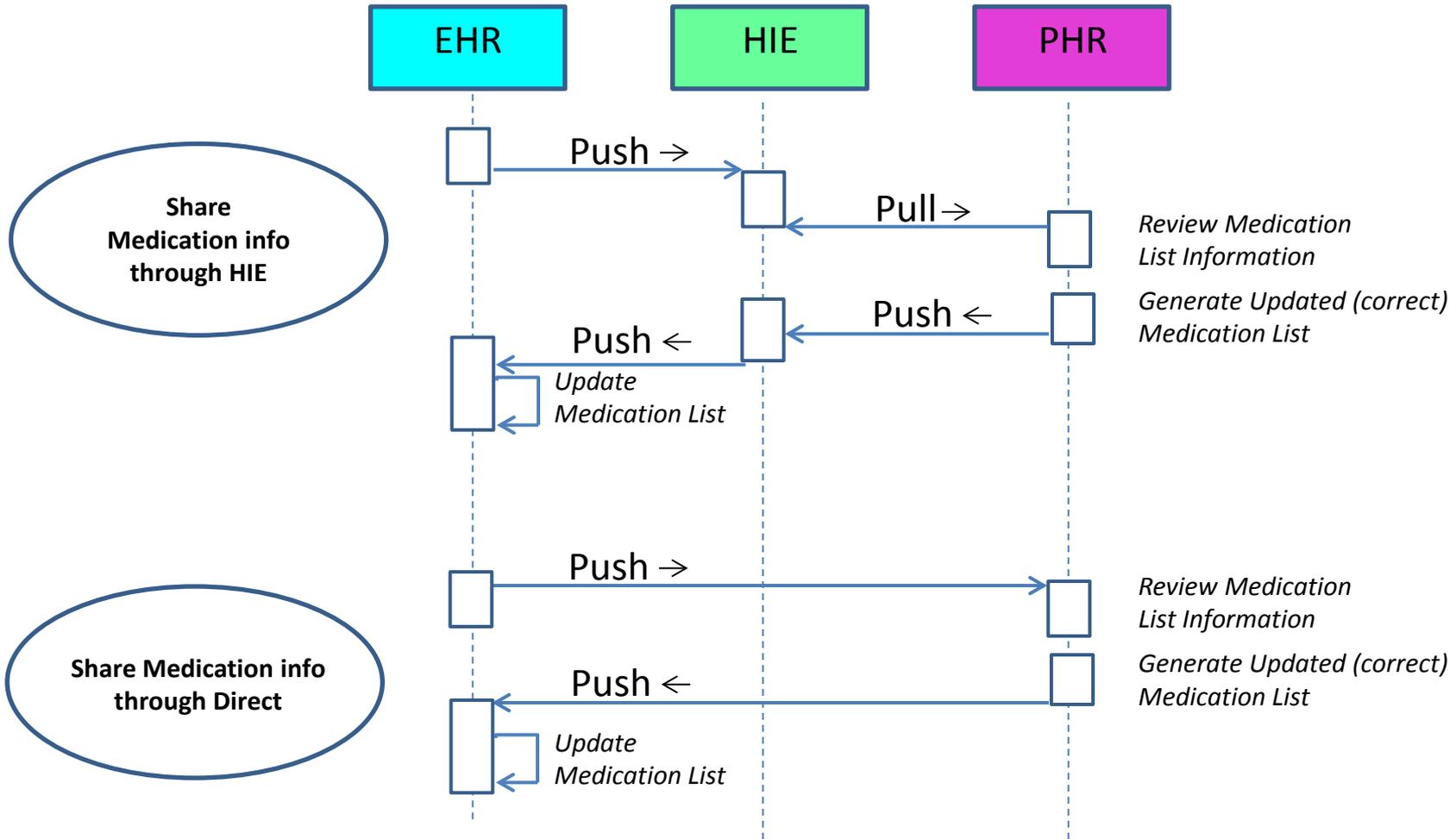
Figure from HL7 DSTU
MU Companion Guide for C-CDA

Figure 4: Additions to Consolidated CDA Document Templates

Open Document Template
Contains Defined Set of Sections Based on Clinical Workflow

C-CDA Section Template

May Contain Additional Section Templates as Needed

Provide Medical History

Exchange Medication List Information with Patients

The CDA, Clinical Document Architecture
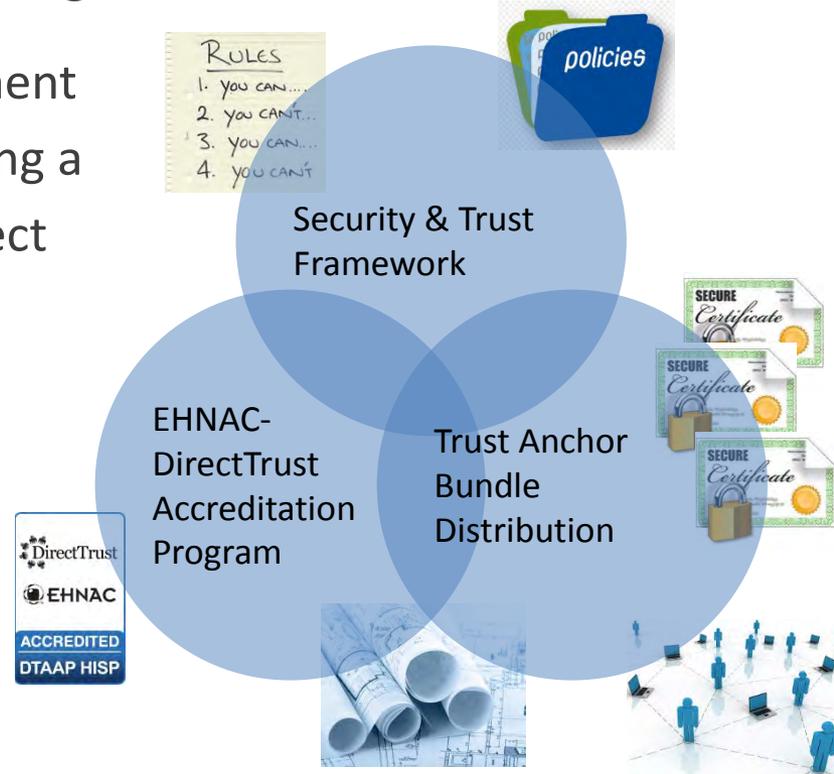# 8 years of evolution

CDA and Implementation Guides	HL7 CDA Clinical Document Architecture "Base Standard"	Continuity of Care Document (CCD)	Consolidated CDA R1 IG for CDA R2 IHE Health Story Consolidation, DSTU R1.1	Consolidated CDA R2
Date Published	R1: 2000 R2: 2005	2006-2010	2012	2014
SDO Publisher		HL7 ASTM CCR + HL7 CDA = CCD	Multiple separate – HITSP, HL7, IHE Health Story	HL7
Vocabulary		Constrained by CCD templates	Constrained by C-CDA R1.1 templates plus MU Companion Guide	Constrained by C-CDA R2 templates
Templates to support the following document types		CCD	CCD, H&P, Discharge Summary, Op Note Procedure Note, Diagnostic Imaging, Progress Note, Consult Note, Unstructured document	Prior templates plus… Referral Note, Transfer Summary, Care Plan, Patient Generated Data Header
Certification criteria vocabulary constraints			Smoking status, race, ethnicity, language, medications, problem list, diagnoses, laboratory, immunizations, procedures	

Mission and Goals: DirectTrust

- A voluntary, self-governing, non-profit trade alliance

- Dedicated to the growth of Direct exchange at national scale

- Operates under a Cooperative Agreement with ONC to support its work of creating a national network of interoperable Direct exchange services providers.

- Establishes policies, interoperability requirements, and business practice requirements

Security & Trust Framework

EHNAC-DirectTrust Accreditation Program

Trust Anchor Bundle Distribution

DirectTrust Members

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Fully Accredited and Audited

- CareAccord
- Cerner Corporation
- DigiCert
- Infomedtrix
- ICA
- Inpriva
- MaxMD
- Surescripts
- MedAllies
- DataMotion

DirectTrust
EHNAC
ACCREDITED
DTAAP HISP

Candidate Status

- Applied Research Works, Inc.
- Athenahealth
- Covisint
- EMR Direct
- GlobalSign, Inc.
- HIXNy
- Health Companion
- Health Connection CNY
- Health Info EXchange of NY
- iMedicor
- IOD Inc.
- Medicity
- NYeC
- RelayHealth
- Rochester RHIO
- Secure Exchange Solutions
- Simplicity Health Systems
- Truven Health Analytics
- Updox
- Utah Health Information Network
- Vitalz, Inc.
- West Virginia HIN

HISPs will serve patients and consumers

- Emphasis in the marketplace for Direct services has been on providers as Direct addressees

- Many of the HISPs and Certificate Authorities in DirectTrust's membership are preparing to accept patients and consumers as Direct addressees.

- We can expect HISPs who are accredited in 2014 to offer Direct exchange accounts and addresses to non-provider customers, including patients, payer representatives, federal and state agency employees.

Utilizes Direct for IDs

- Use of Direct Address as a proxy for ID

- Market for HISP Services

- 10 fully accredited HISPS

- 39 in the pipeline

- Many beginning to focus on providing Direct addresses to consumers/patients, not just providers

Level of Assurance: Identity proofing

- **LOA1:** Healthvault, Nomoreclipboards e.g.
- **LOA2**: Provider assured
- **LOA3:** Notarized letter sent to a HISP

Direct: Consumer Friendly Integration

- Possible for any person with proper id and/or notarized letter to obtain associated LOA

- Easy, familiar e-mail process

- Certificate protected and able to interact with other accredited HISPs

- Use/acceptance based upon LOA and other policies

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Simple, secure transport

Supports provider to patient, patient to provider communication with attachments like CCDA
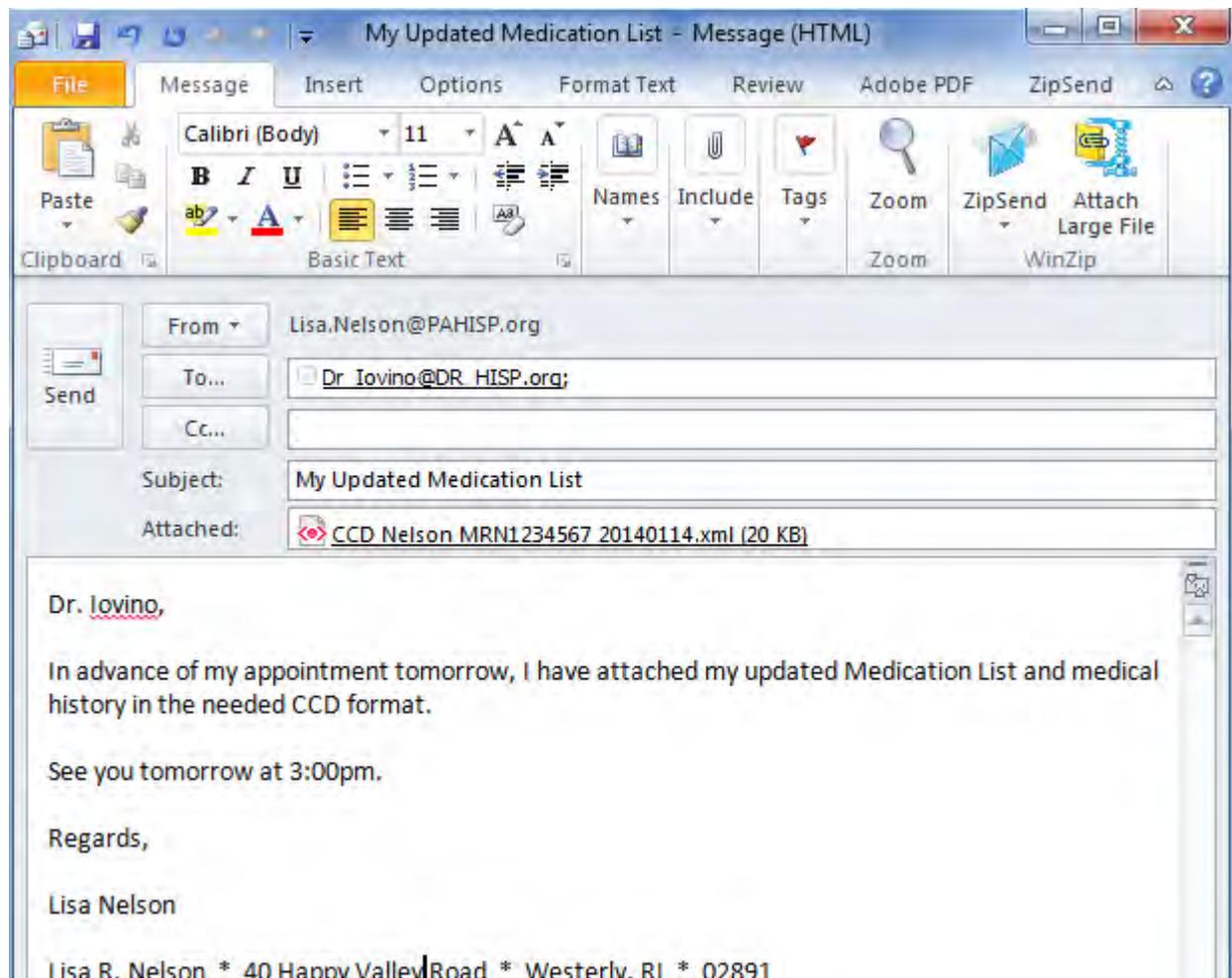
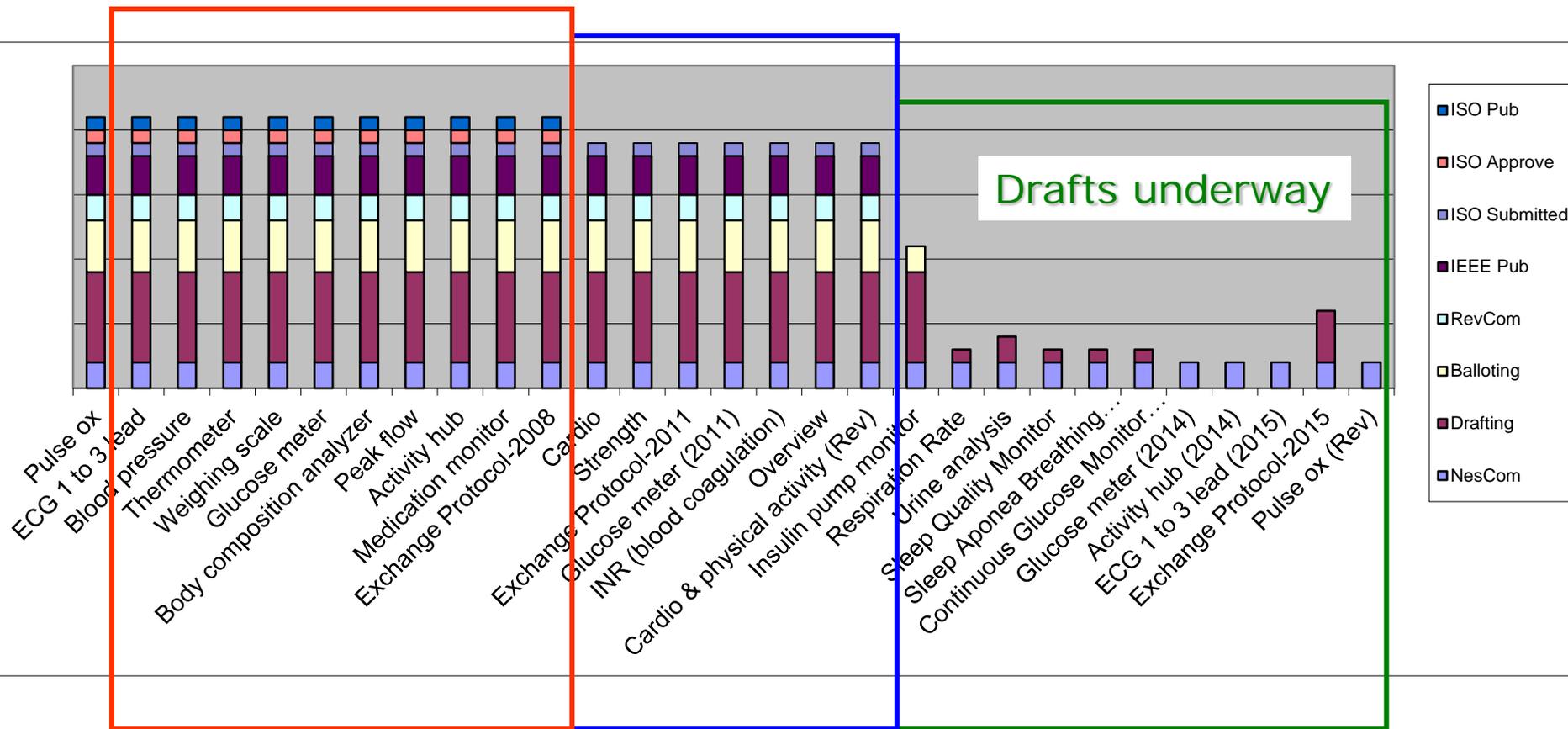# Continua's Health Records Network Interface with CDA Document Roles

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Spec	Spec Version referenced in Continua CDG	Doc Links
HRN-IF DG v2012	Continua Design Guidelines v2012 Errata (v3.0 - Catalyst)	https://cw.continuaalliance.org/wg/members/document/download/11843
PHMR: HL7 CDA	Implementation Guide for CDA Release 2.0 Personal Healthcare Monitoring Report (PHMR) (International Realm) Draft Standard for Trial Use Release 1 **November 2008 (1st Release)**	http://www.hl7.org/documentcenter/ballots/2008SEP/support/CDAR2_PHMRPTS_R1_DSTU_2008NOV.zip
PHMR: HL7 CCD	HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD) **April 2007**	http://www.hl7.org/Library/General/HL7_CCD_final.zip
DIRECT HRN SENDER: IHE Profiles - XDR	IHE IT Infrastructure Technical Framework Supplement 2006-2007 Cross-Enterprise Document Reliable Interchange (XDR) **August 2009**	http://www.ihe.net/Technical_Framework/index.cfm#IT http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_Supplement_Cross_Enterprise_Document_Reliable_Interchange_XDR_TI_2009-08-10.pdf For IHE XDR and IHE XDM profiles see the "IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles Revision 6.0 – Final Text August 10, 2009" And the IHE IT Infrastructure (ITI) Technical Framework Supplement 2009-2010, Cross-Enterprise Document Reliable Interchange (XDR) Trial Implementation Supplement, Version – Release 4.0 August 10, 2009 Available at: http://www.ihe.net/Technical_Framework/index.cfm#IT, also at http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_6-0_Vol1_FT_2009-08-10-2.pdf
INDIRECT HRN SENDER: IHE Profiles - XDM	Cross-Enterprise Document Media Interchange (XDM). IHE ITI Technical Framework, **Rev. 6.0 (August 10, 2009).** Vol 1 - Section 16 Vol 2b - Section 3.32	http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_6-0_Vol1_FT_2009-08-10-2.pdf
HRN SENDER (ALL): IHE Profiles - ATNA	Audit Trail and Node Authentication (ATNA). IHE ITI Technical Framework, **Rev. 6.0 (August 10, 2009).** Vol 1 - Section 9 Vol 2a - Section 3.1 Vol 2a - Section 3.19 Vol 2a - Section 3.20	http://www.ihe.net/Technical_Framework/index.cfm#IT http://wiki.ihe.net/index.php?title=ATNA
ATNA: IETF - RFC 3881	Security Audit and Access Accountability Message XML Data Definitions for Healthcare Applications. **September 2004**	http://tools.ietf.org/pdf/rfc3881.pdf
HRN SENDER (ALL): IHE ITI TF-2b 3.44 and 3.45 (PIXV3)	IHE ITI Technical Framework Supplement - Patient Identifier Cross-Reference HL7 V3 (PIXV3) (August 10, 2010)	http://www.ihe.net/Technical_Framework/upload/IHE_ITI_Suppl_PIX_PDQ_HL7v3_Rev2-1_TI_2010-08-10.pdf
NON-REPUDIATION HRN SENDER: IHE Profiles - DSG	IHE IT Infrastructure Technical Framework Supplement for Trial Implementation Document Digital Signature (DSG) **August 10, 2009**	http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_Supplement_Digital_Signature-2009-08-10.pdf
CONSENT ENABLED HRN SENDER: HL7 CDA R2 - Consent Directives	HL7 Implementation Guide for Clinical Document Architecture, Release 2: Consent Directives, Release 1. HL7 Draft Standard for Trial Use. January 2011	http://www.hl7.org/documentcenter/public/standards/dstu/CDAR2_IG%20_CONSENTDIR_DSTU_2011JAN.pdf
CONSENT ENABLED (XDS.b) HRN SENDER: IHE ITI TF-2b 3.43	IHE ITI-TF Volume 2b Revision 6.0 (2009-08-10) - Transaction 3.43	http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_6-0_Vol2b_FT_2009-08-10.pdf
CONSENT ENABLED (XDS.b) HRN SENDER: IHE ITI TF-2a 3.18	IHE ITI-TF Volume 2a Revision 6.0 (2009-08-10) - Transaction 3.18	http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_6-0_Vol2a_FT_2009-08-10.pdf
CONSENT ENABLED (XDS.b) HRN SENDER: IHE ITI TF-2b 3.40 (XUA)	IHE ITI-TF Volume 2b Revision 6.0 (2009-08-10) - Transaction 3.40	http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_6-0_Vol2b_FT_2009-08-10.pdf
CONSENT ENABLED (XDS.b) HRN SENDER: IHE ITI TF Supplement XUA++	IHE ITI Technical Framework Supplement - Cross-Enterprise User Assertion - Attribute Extension (August 10, 2010)	http://www.ihe.net/Technical_Framework/upload/IHE_ITI_Suppl_XUA-_Rev1-1_TI_2010-08-10.pdf

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Drafts underway

Legend:
- ISO Pub
- ISO Approve
- ISO Submitted
- IEEE Pub
- RevCom
- Balloting
- Drafting
- NesCom

Categories (x-axis): Pulse ox, ECG 1 to 3 lead, Blood pressure, Thermometer, Weighing scale, Glucose meter, Body composition analyzer, Peak flow, Activity hub, Medication monitor, Exchange Protocol-2008, Cardio, Strength, Exchange Protocol-2011, Glucose meter (2011), INR (blood coagulation), Overview, Cardio & physical activity (Rev), Insulin pump monitor, Respiration Rate, Urine analysis, Sleep Quality Monitor, Sleep Aponea Breathing…, Continuous Glucose Monitor…, Glucose meter (2014), Activity hub (2014), ECG 1 to 3 lead (2015), Exchange Protocol-2015, Pulse ox (Rev)

Approved and published IEEE stds

Approved and published international standards

PAN/LAN/TAN Communication Stack

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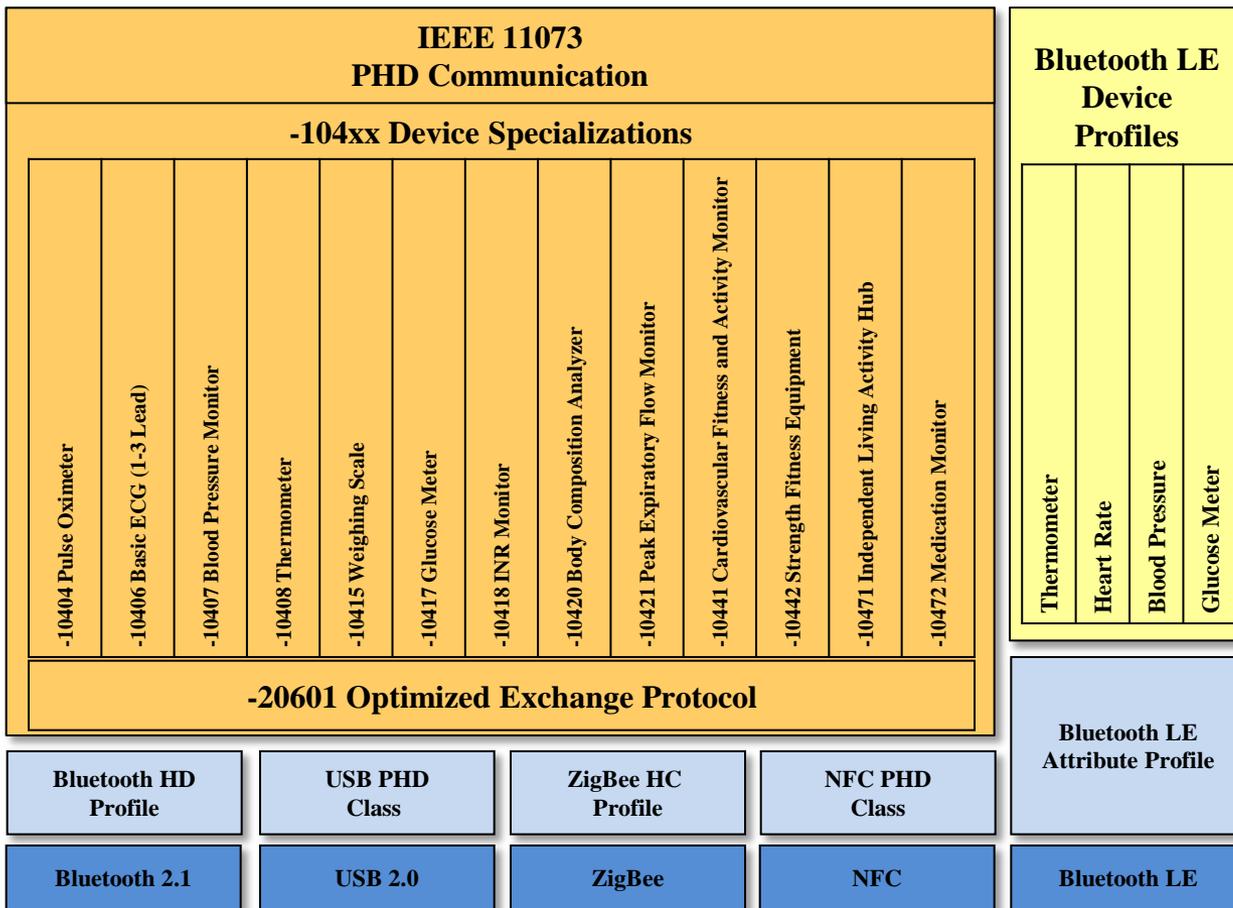to the National Coordinator for Health IT

- Veterans Administration in US has deployed to more than 85,000 individuals who have reached retirement age. It is their intent to roll out to nearly 1 million (all active Veterans)
  - Fixed system for deployment to chronic population
    - Largest deployment in the world
- Many countries now moving to utilize technology at the point of the person.
  - Denmark
  - Abu Dhabi
  - Singapore
  - NHS (UK) 3 million Lives
  - Canada Health Infoway
  - Brussels to Barcelona Diabetes Bike Ride (fully monitored)

Examples of Solutions implemented:
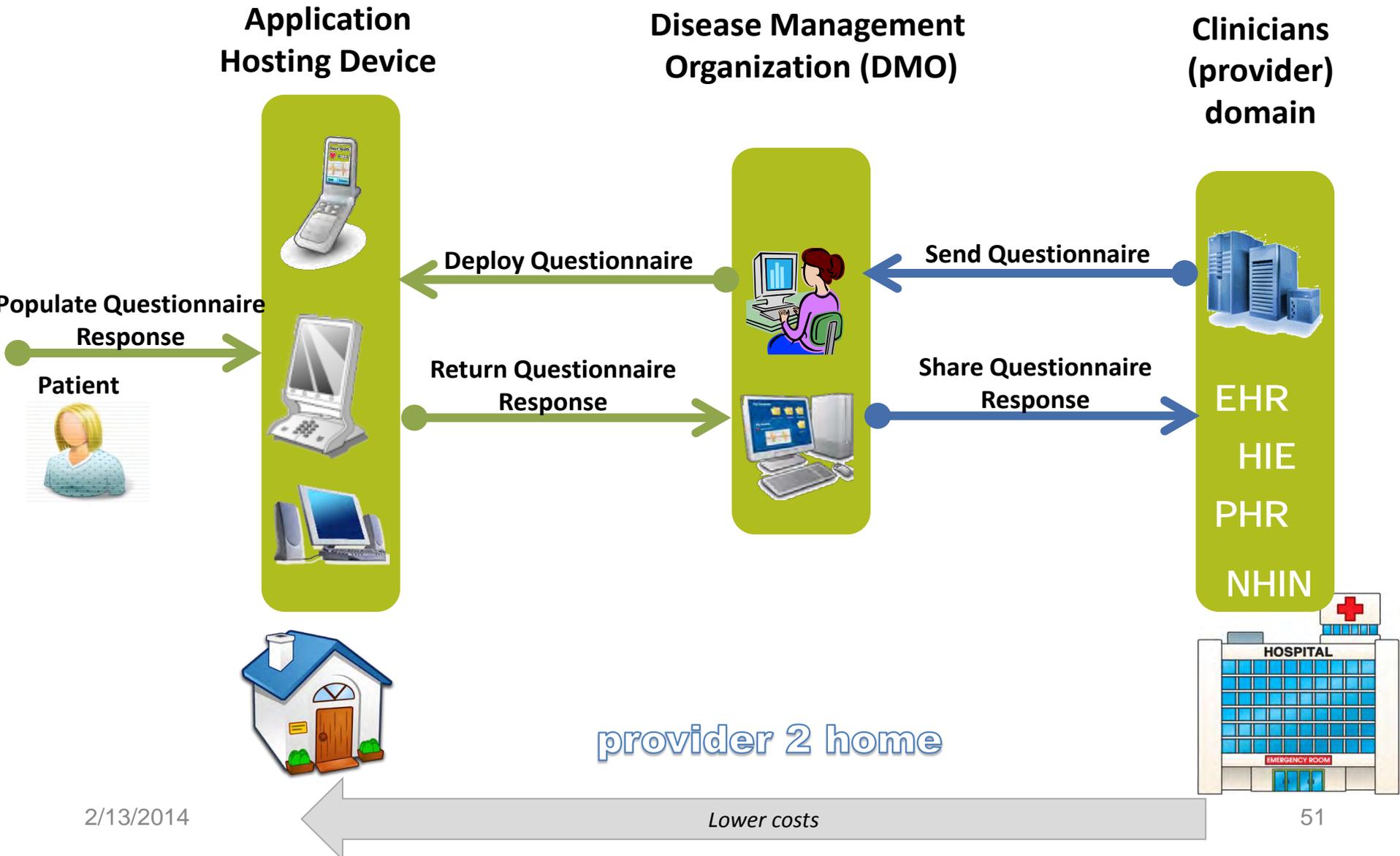
Japan Earthquake/Tsunami:

- Personal Health Records
  - Allows data to be shared quickly as residents are transferred/moved
  - Provides an easy way to acquire data in single location
- Devices
  - Japan has required devices to have standardized interfaces to allow easy implementation
  - Can carry devices from different manufacturers and still acquire data

- *Standardization and Personal Health Record allows transfers of displaced to have records follow them.*

Data Exchange For Patient Questionnaire Data

Application Hosting Device

Disease Management Organization (DMO)

Clinicians (provider) domain

Deploy Questionnaire

Send Questionnaire

Populate Questionnaire Response

Return Questionnaire Response

Share Questionnaire Response

Patient

EHR

HIE

PHR

NHIN

provider 2 home

HOSPITAL
EMERGENCY ROOM

Lower costs

Data Exchange For
Patient Device Generated Data

Application Hosting Device

Disease Management Organization (DMO)

Provider domain

Patient

EHR

HIE

PHR

NHIN

HOSPITAL

EMERGENCY ROOM

Lower costs

Operational and/or Pilots
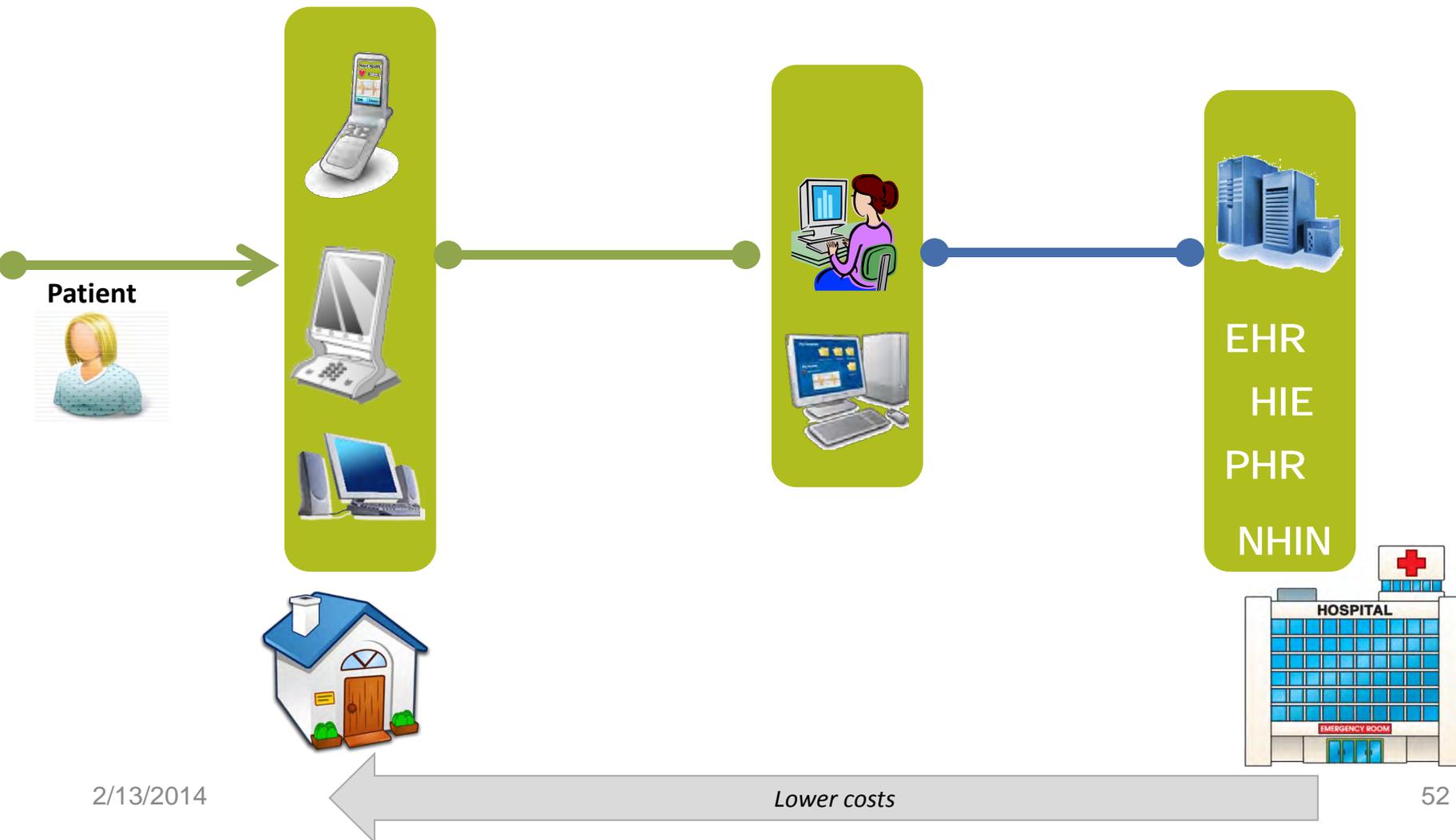
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- Whole System Demonstrator Program
  - 3,200 people with diabetes, chronic obstructive pulmonary disease, or heart failure

  - Telemonitoring w/ biosensors

  - Symptom questions and educational messages via telehealth unit or TV set top box

  - Endpoints: impact on hospitalizations, mortality after one year

- Administrative and operational
- Standards can promote innovation where value is created
- Standards will expire where value is limited
- Existing standards are provider focused and may not be optimal for emerging consumer products
  - Outbound EHR data consumer flexible
  - Inbound PGHD provider focused standards

PGHD Risks :

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- Without standards PGHD will be happenstance and may create more operational burdens and expense
  - Confusion will burden and prohibit patient inclusion
  - Clarity will promote it

- Inclusion of patients in HIT:
  - Transparency
  - Accuracy
  - Efficiency
  - Partnership
  - Community

  "There is no healthcare without the patient"