Health IT Standards Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

Consumer Technology Workgroup

Patient Generated Health Data Recommendations

Leslie Kelly Hall, Chair
Russ Leftwich, Co-Chair

February 18, 2014

Consumer Technology Workgroup (WG) Members

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WG Members

- **Leslie Kelly Hall, Healthwise**
- **Russ Leftwich, TN Office of eHealth**
- Brian Ahier, Advanced HIE Resources
- Christine Bechtel, National Partnership for Women & Families
- Brian Carter, Cerner
- AJ Chen, HHS NPA Region IX Health Equity Council
- John Derr, Golden Living, LLC
- Arthur Henderson, Affinity Networks, Inc.
- Susan Hull, Wellspring Consulting
- Elizabeth Johnson, Tenet Healthcare Corporation
- Mohit Kaushal, Aberdare Ventures
- Holly Miller, MedAllies, Inc.
- John Ritter, HL7 EHR Work Group
- Anshuman Sharma, Ubiqi Health
- Fred Trotter, Not Only Dev

Ex Officio Members

- Kim Nazi, Veterans Health Administration
- Susan Woods, Veterans Health Administration

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

- **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.

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

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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

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	Messaging	Structured/ Questionnaire	Unstructured /Narrative	Device	Care Plans	Collaborative Care
Assumed Standards	**COMMON MU DATA SET Standards and vocabulary, device/technology agnostic**					
	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

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 O2891, 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

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

Component Of / **Encompassing Encounter**
Encounter Participants

Documentation Of/ **Service Event**
Performers

In Fulfillment Of/ **Order**

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

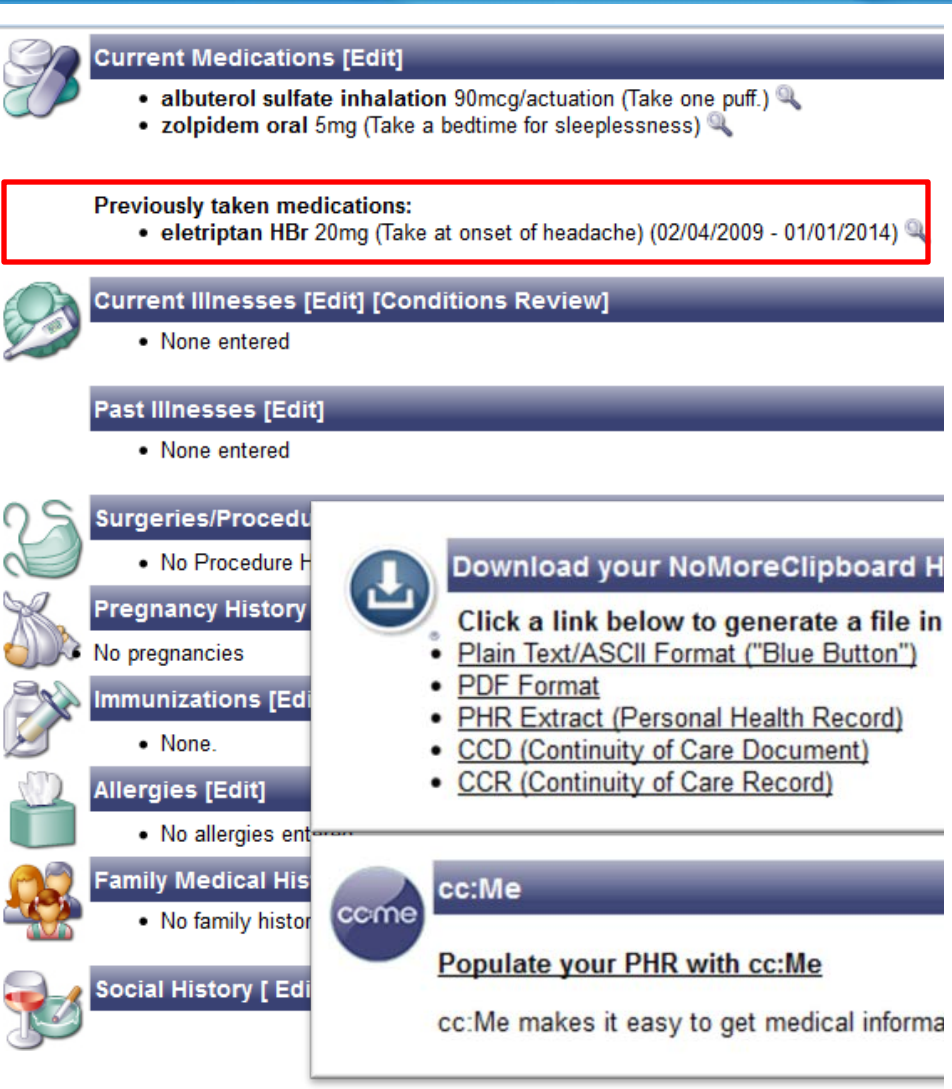
Device Data from Patient

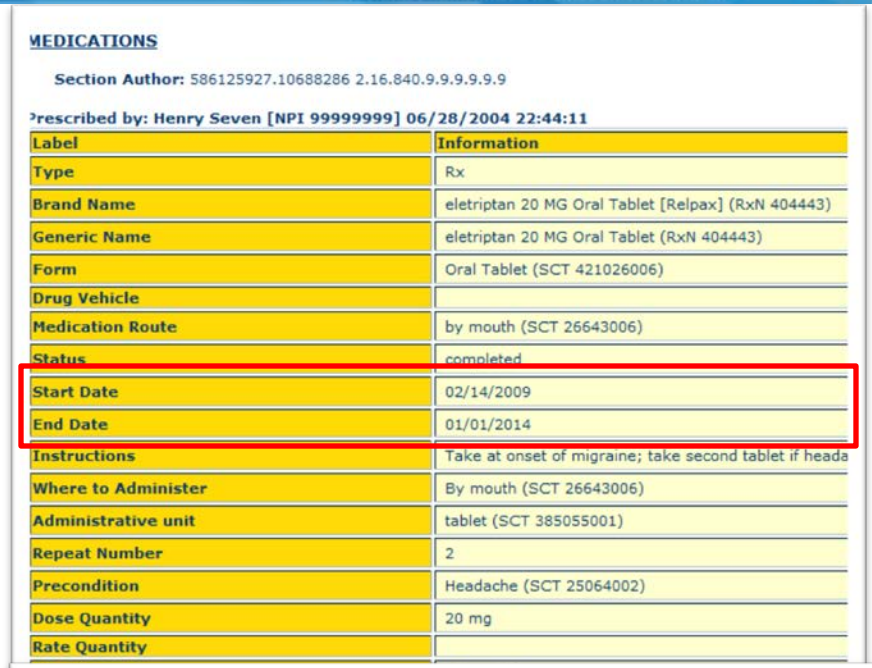
- Data reporting uses industry standards
- Data provenance is encoded

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






```
<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>
```

Advance Directives

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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Document maintained by	Rhode Island Quality Institute
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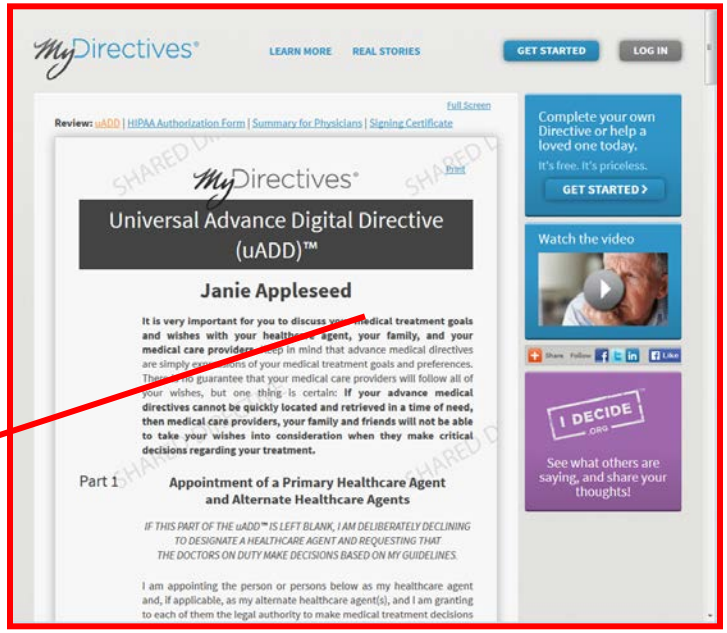
ADVANCE DIRECTIVES

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.



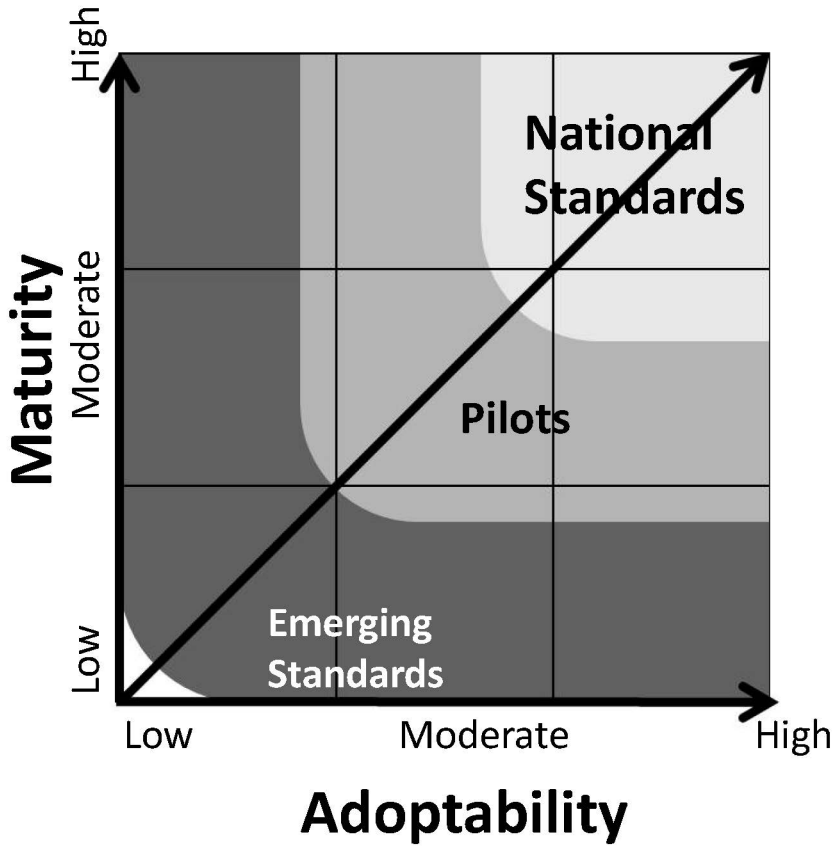
Evaluation and Classification of Technical Specifications

Maturity Criteria:

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

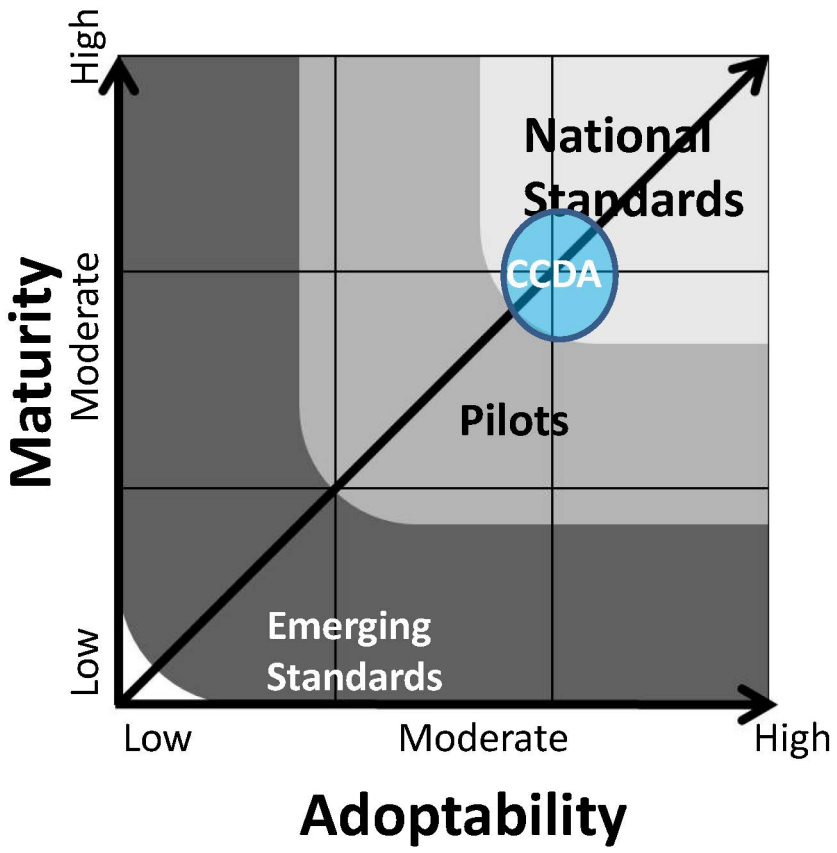
Adoptability Criteria:

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



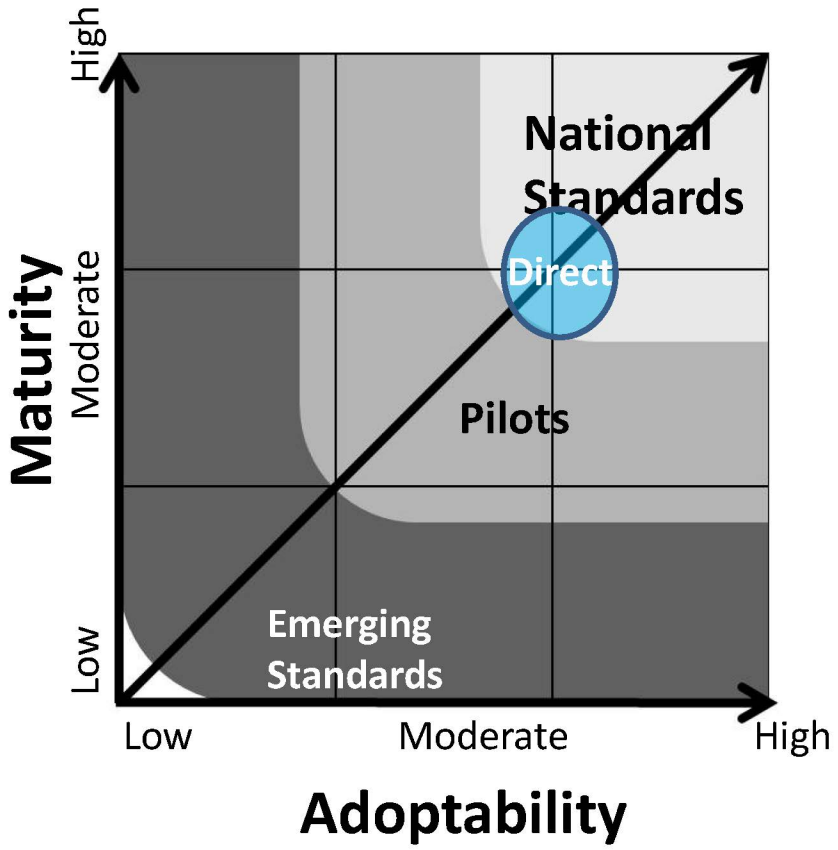
Mature for provider world new to patients= moderate

NwHIN Applicability: PGHD



- 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#.UtXF3laA3wG
- Continua only utilizes Existing Standards – no new IP nor acts as a Standards Development Organization
  - Profiling only like IHE

Use Cases

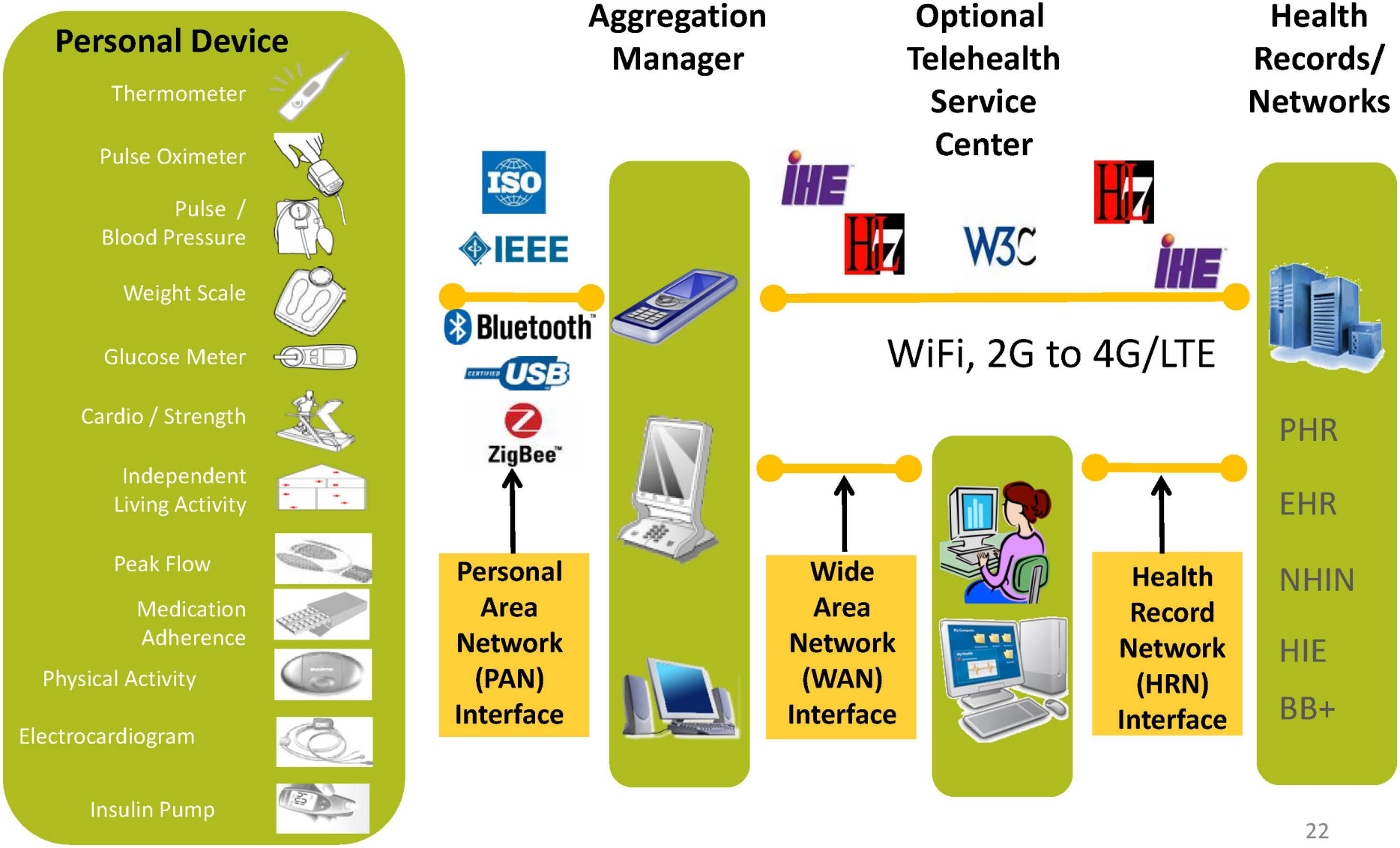
Using C-CDA R2 Templates	Exchange of Patient Generated Device Data – Active link	Exchange of Patient Generated Device Data - email
Content	Personal Health Device observations Structured in accordance with HL7 IG for CDA r2 – Personal Healthcare Monitoring Report; Minimum: Structured data format for individual 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

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



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

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)

```
<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">
```

Structured/Semi-structured Questionnaires

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	○
Very mild	○
Mild	○
Moderate	○
Severe	○
Very severe	○

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="GUID4" 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>
```

Joint Consumer Technology and Clinical Operations Recommendations

John Halamka, Clinical Operations WG, Co-chair
Leslie Kelly Hall, Consumer Technology WG, Chair

- Overarching recommendations
  - Concern regarding certification only items, as systems must be engineered to incorporate standards/processes which may not yet be mature
  - Standards application should be constrained to where they are needed and useful

PGHD Recommendations
Consumer Technology and Clinical Ops WG (II)

- Where there is a need for patient data sharing, the C-CDA is suitable. C-CDA is recommended as a container for certain types of templates that are well understood (e.g. problems, meds, allergies).
  - C-CDA over existing (Direct, Exchange) and other modes of transport are reasonable ways to get data in and out of EHRs, PHRs, and patient facing applications
  - C-CDA should not be required as the architecture that organizations (e.g. ACOs) have to use. The outcome goal is for the entire care team (patient/families/providers) to be able to contribute to an integrated medical record
  - If unable to integrate, systems must have the functionality to receive C-CDA containing specific templates (e.g. to accomplish the same goal of patients participating in problems, med, and allergy reconciliation)
  - Need to allow for innovation and flexibility in this space to not unduly constrain options for individuals to connect with their care teams in the ways they prefer in the future.
    - Suggest using the C-CDA template payloads that are sufficiently mature, but not over-specify how they are to be moved about

PGHD - Devices

- Need to allow for innovation, as the marketplace is still rapidly evolving
  - Continua standards are directionally appropriate, but need to align with FDA guidance and other regulatory or sub-regulatory policy without constraining the marketplace
  - Due to the immaturity of the market, need to allow for the flexible adoption of device data and other remote data source

Engaging patients and families in their care: Patient Generated Health Data

Functionality Needed to Achieve Goals	Stage 3 Functionality Goals
• New • **Menu: Eligible Professionals and Eligible Hospitals** receive provider-requested, electronically submitted patient-generated health information through either: – structured or semi-structured questionnaires (e.g., screening questionnaires, medication adherence surveys, intake forms, risk assessment, functional status) – or secure messaging • Threshold: Low	• Enable patients to access and transmit their information • Provide ability to contribute information in the record, including patient reported outcomes (PRO) • Provide tools to help patients actively participate in their care

Red: Changes
Blue: Newly introduced