Consumer Technology Workgroup

Patient Generated Health Data Recommendations

Leslie Kelly Hall, Chair
Russ Leftwich, Co-Chair

February 18, 2014
Consumer Technology Workgroup (WG) Members

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
• **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

### Meaningful Use 3 Standards Ready to Support:

<table>
<thead>
<tr>
<th>Messaging</th>
<th>Structured/Questionnaire</th>
<th>Unstructured/Narrative/Hybrid</th>
<th>Device</th>
<th>Plan(s) of Care</th>
<th>Collaborative Care Planning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secure non-tethered w/wo attachments</td>
<td>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</td>
<td>Consumer centric (word, excel, other) Hybrid (Structured template with unstructured narrative)</td>
<td>Provider directed Bio-metric telemetry Repositories mobile</td>
<td>Episodic or chronic condition (siloes)</td>
<td>Holistic and integrative (horizontal)</td>
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<td>Versioning</td>
<td>Multiple care plans</td>
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<td>Reconciliation</td>
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<td>Harmonization</td>
<td>Curating</td>
</tr>
</tbody>
</table>

Assume technology/device agnostic
## Meaningful Use 3: Ready

<table>
<thead>
<tr>
<th>Assumed Standards</th>
<th>Messaging</th>
<th>Structured/Questionnaire</th>
<th>Unstructured/Narrative</th>
<th>Device</th>
<th>Care Plans</th>
<th>Collaborative Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>COMMON MU DATA SET Standards and vocabulary, device/technology agnostic</td>
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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

#### RecordTarget (the Patient)
- **IDs**: NPI, Direct, VUHID
- **Address, Telecom**

#### Demographics
- **Name**: Jane Appleseed
- **Date of birth**: August 26, 1962
- **Gender**: Female
- **Race**: White
- **Ethnicity**: Not Hispanic or Latino
- **Contact info**:
  - **Primary Home**: 1234 Orchard Street, Westerly, RI 02891, US
  - **Tel**: (816)76-9909
- **Patient IDs**:
  - 999991: 2.16.840.1.113853.16.5.99999.2
  - 111-00-2320: 2.16.840.1.113833.4.1
  - 12345-99999: 2.16.840.1.113853.19.5.99999.1393

#### Component Of / Encompassing Encounter

#### Encounter Participants
- **Performers**
  - **Document Id**: T7988 2.16.840.1.113853.19.5.99999.1
  - **Document Created**: January 13, 2014, 17:00:00 - 0400
  - **Healthcare service**: Advance Directives from January 13, 2014, 16:30:00
  - **Performer IDs**: 09ac26 1.2.3.4.5.6.7.8
  - **Author**: Jane Appleseed
  - **Contact info**:
    - **Primary Home**: 1234 Orchard Street, Westerly, RI 02891, US
    - **Tel**: (401)123-1234
  - **Document maintained by**: Rhode Island Quality Institute
  - **Contact info**:
    - 50 Holden Street, Providence, RI 02908, US
    - Tel: (401) 868-4619

### Custodian
- **(steward of the document)**
- **Address, Telecom**

### Guardians
- **Specific Roles**

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

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2/18/2014
## Care Team Roster

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

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

Current Medications [Edit]
- albuterol sulfate inhalation 90mcg/actuation (Take one puff)
- zolpidem oral 5mg (Take a bedtime for sleeplessness)

Previously taken medications:
- eledriptan 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/Procedures
- No Procedure History

Pregnancy History
- No pregnancies

Immunizations [Edit]
- None

Allergies [Edit]
- No allergies entered

Family Medical History
- No family history

Social History [Edit]

MEDICATIONS
- prescribed by: Henry Seven [NPI 9999999] 06/20/2004 22:44:11
- Label: Information
  - Type: Rx
  - Brand Name: eledriptan 20 MG Oral Tablet [Relpax] (RxN 4044443)
  - Generic Name: eledriptan 20 MG Oral Tablet (RxN 4044443)
  - Form: Oral Tablet (SCT 421026006)
  - Drug Vehicle: by mouth (SCT 26643006)
  - Medication Route: completed
  - Start Date: 02/14/2009
  - End Date: 01/01/2014
  - Instructions: Take at onset of migraine; take second tablet if head
  - Where to Administer: By mouth (SCT 26643006)
  - Administrative unit: tablet (SCT 38505001)
  - Repeat Number: 2
  - Precondition: Headache (SCT 25064002)
  - Dose Quantity: 20 mg

Populate your PHR with cc:Me
cc:Me makes it easy to get medical informa

Download your NoMoreClipboard file
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
Advance Directives

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.
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)
• 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

<table>
<thead>
<tr>
<th>Using C-CDA R2 Templates</th>
<th>Exchange of Patient Generated Device Data – Active link</th>
<th>Exchange of Patient Generated Device Data - email</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Content</strong></td>
<td>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</td>
<td>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</td>
</tr>
<tr>
<td><strong>Encoding</strong></td>
<td>US Realm + PGD Header Personal Health Medical Record</td>
<td>US Realm + PGD Header Personal Health Medical Record</td>
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<tr>
<td><strong>Vocabulary</strong></td>
<td>Constrained by C-CDA R2 templates</td>
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<td><strong>Push</strong></td>
<td>IHE ITI XDS.b Provide and Register, XDR, PHMR Interface</td>
<td>IHE ITI XDM</td>
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<td><strong>Pull</strong></td>
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<tr>
<td><strong>View</strong></td>
<td>IHE PCD-01 XDR PHMR</td>
<td>IHE PCD-01 XDM</td>
</tr>
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<td><strong>Proof Point</strong></td>
<td>NIST Continua Conformity Test Continua Certification</td>
<td>Email exchange of data HIMSS Interop showcases Continua Certification</td>
</tr>
</tbody>
</table>
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**

- WiFi, 2G to 4G/LTE

**Interfaces**
- Personal Area Network (PAN) Interface
- Wide Area Network (WAN) Interface
- Health Record Network (HRN) Interface

**Standards**
- ISO
- IEEE
- Bluetooth
- USB
- ZigBee
- H7
- W3C
- IHE

**Health IT Standards Committee**
A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT
• 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.
<table>
<thead>
<tr>
<th></th>
<th>Exchange of PROM using QFD IG</th>
<th>Exchange of Patient Response to PROM using QR IG</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Content</strong></td>
<td>PROM questions such as multiple choice, numeric, free-text, analog slider, discrete slider, pre-conditions and the related copyright represented as structured entries.</td>
<td>Patient response to PROM questions such as multiple choice, numeric, free-text, analog slider, discrete slider and the related copyright represented as structured entries.</td>
</tr>
<tr>
<td><strong>Encoding</strong></td>
<td>US Realm + PGD Header Questionnaire Form Definition Section and templates (for question and pre-conditions)  Copyright Section and template</td>
<td>US Realm + PGD Header Questionnaire Response Section and templates Copyright Section and template</td>
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<tr>
<td><strong>Vocabulary</strong></td>
<td>Constrained by C-CDA R2 templates</td>
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<td><strong>Push</strong></td>
<td>RESTfull HTTP via Continua’s hData and OAuth 2.0 profiles</td>
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<tr>
<td><strong>Pull</strong></td>
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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)
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

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
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.
• 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**

- **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

**Stage 3 Functionality Goals**

- 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