Consumer Technology Workgroup

Patient Generated Health Data Recommendations

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Consumer Technology Workgroup (WG) Members

WG Chairs

- Leslie Kelly Hall, Healthwise
- Russ Leftwich, TN Office of eHealth

WG Members

- Brian Ahier, Gorge Health Connect, Inc.
- Christine Bechtel, National Partnership for Women & Families
- Brian Carter, Cerner
- AJ Chen, HHS NPA Region IX Health Equity Council
- John Derr, Golden Living, LLC
- Tonya Dorsey, BCBS/South Carolina
- Arthur Henderson, Affinity Networks, Inc.
- Susan Hull, Wellspring Consulting
- Elizabeth Johnson, Tenet Healthcare Corporation
- Mohit Kaushal, West Health
- Tom Jones, Tolven Health
- Holly Miller, MedAllies, Inc.
- Marcia Nizzari, PatientsLikeMe
- Yair Rajwan, Visual Science Informatics, LLC
- John Ritter, HL7 EHR Work Group
- Anshuman Sharma, Ubiqi Health
- Fred Trotter, Not Only Dev
- Wes Rishel, Gartner
- David Harlow, The Harlow Group LLC

Ex Officio Members

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

Background

- Asked to provide feedback on two Meaningful Use Stage 3 recommendations for Patient Generated Health Data (PGHD) and to identify applicable existing standards and gaps.

Stage 2 Final Rule	Stage 3 Recommendations
New (204B)	**EP/EH MENU Objective:** Patients have the ability to electronically submit patient-generated health (PGH) information. **EP/EH MENU Measure:** Provide the ability to electronically submit PGH information through structured or semi-structured questionnaires (e.g., screening questionnaires, intake forms, risk assessment, functional status) for more than **10 percent of all unique patients seen by the EP** during the EHR reporting period. Standards work needed: Certification criteria for devices, continued work with HITSC.
New (204D)	Provide patients with an easy way to request an amendment to their record online (e.g., offer corrections, additions, or updates to the record) (Certification Only)

Key Takeaways from 7/18 PGHD Listening Session

- Patient Generated Health Data Definition
  - "PGHD are health-related data—including health history, symptoms, biometric data, treatment history, lifestyle choices, environmental factors and other information—created, recorded, gathered, or inferred by or from patients or their designees (i.e., care partners or those who assist them) to help address a health concern.
  - PGHD are distinct from data generated in clinical settings and through encounters with providers in two important ways.
    - First, patients, not providers, are primarily responsible for capturing or recording these data.
    - Second, patients direct the sharing or distributing of these data to health care providers and other stakeholders. In these ways, PGHD complement provider-directed capture and flow of health-related data across the health care system."

Source: Patient-Generated Health Data White Paper. Prepared for ONC by RTI, International, April 2012.

Key Takeaways

- PGHD is not new; it's already valued and incorporated into the record today (e.g. patient reported outcomes, tx history, etc.)
- There are several mechanisms for incorporating PGHD: Primary electronic methods include:
  - secure messaging, surveys (structured and semi-structured), biometric/device data in cloud, etc.
- There are four things providers need to be able to do with PGHD: receive, review, respond and record.

Key Takeaways

- Implementation requires developing workflows and clear policies/procedures for clinicians and patients that help set mutual expectations around PGHD.
  - Including communicating policies and expectations to patients and families

- “When PGHD is implemented appropriately, concerns are addressed and PGHD use becomes routine.”

Key Takeaways

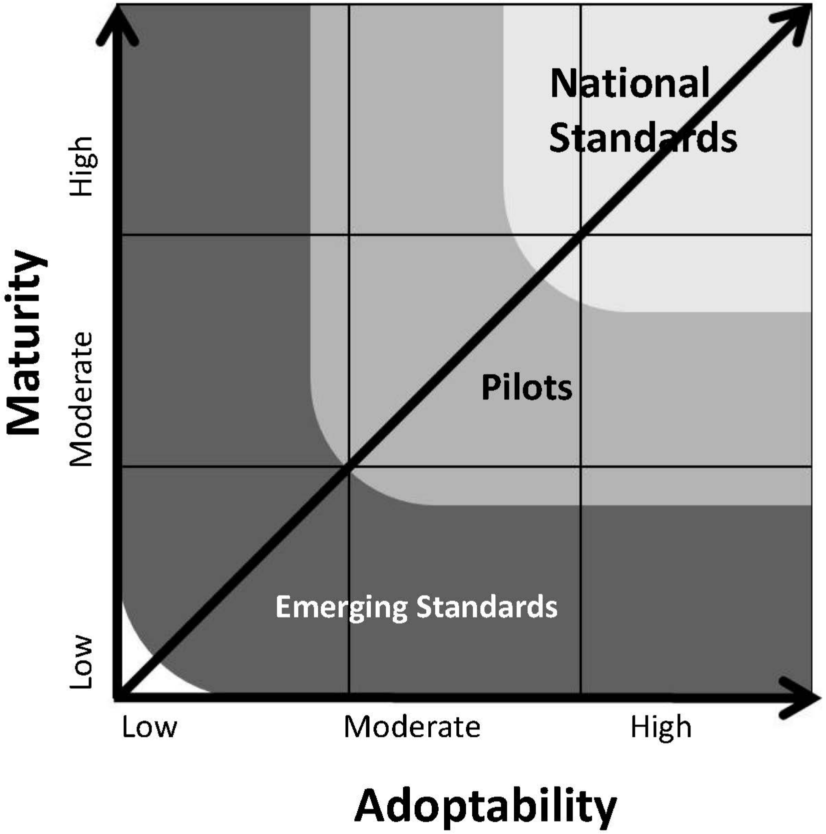
- Concerns about liability are reduced or eliminated when there is a mutually agreed upon set of information to be shared and clear policies/procedures for handling it.
- HIPAA: Sets a floor, not a ceiling. Establishes rights around corrections.
- Providers and patients are aligned around wanting information to be high quality and accurate.
  - We just need to make it easier and make sure we're ready.

Readiness Evaluation and Classification Criteria for Technical Specifications

Acknowledge: Mature standards are new to patient/provider workflow

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

Adoptability Criteria:
- Ease of Implementation and Deployment
- Ease of Operations
- Intellectual Property



This methodology will be used in assessing readiness for specific standards

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**					

Standards Recommendations

- ONC should consider the Direct transport standard for secure messaging and data from devices
- ONC should consider the HL7 Care Team Roster standard
- ONC should consider the HL7-CCDA for structured and unstructured questionnaires
- ONC should consider the Continua standard for data from devices
- We encourage standards that support mobile access to patient data and PGHD given the proliferation of mobile devices. However, we do not recommend mandating a specific standard at this time given that might stifle innovation.

Recommendations for Development of Consumer Standards

- ONC should consider an S&I Initiative to create needed collaborative care document structure to address versioning, expanded provenance, reconciliation, data governance and curation.

- ONC should consider creating a process to align consumer product and provider standards

- ONC should consider using BlueButton+ API approach to accommodate PGHD

- Trust Framework expanded for consumer/patient adoption in emerging technologies (BB+)

- ONC should ask the HITSC to prioritize consumer vocabularies to support wider consumer, patient and family engagement

Supplemental information:
PGHD Policy Recommendations ACCEPTED-

- The Policy Committee accepted the recommendations on the following slides at the December 4, 2013 HITPC meeting.

- A transmittal letter to the National Coordinator is expected to be delivered the week of 12/17/2013.

Supplemental information:
ACCEPTED: PGHD Policy Recommendations

We are ready for the Patient Generated Health Data criteria in Stage 3 of Meaningful Use, with some modifications:

1. The Meaningful Use WG should expand the objective to also give providers additional options for incorporating PGHD through secure messaging and provider-selected devices*, in addition to structured and semi-structured questionnaires.

2. The Meaningful Use Stage 3 certification requirement that addresses amendments/corrections also represents a form of PGHD, and as such we note that our recommendations for how to handle PGHD also apply to this criterion.

3. EHR technology should have the functionality to allow providers to receive, review, respond (acknowledge), and record PGHD, including amendments and corrections.

4. For provider organizations that choose the menu item for PGHD in Stage 3, they should establish policies and procedures for handling PGHD in advance of or during implementation of Stage 3, including, but not limited to, the content to be received; the mechanisms by which it can be submitted/received; and how it will be received, reviewed, acknowledged, and recorded (including but not limited to provenance).

*Awaiting final feedback from HITSC to confirm feasibility of provider-selected devices

Supplemental information:
ACCEPTED: PGHD Policy Recommendations

5. Providers should collaborate with patients in implementation – including crafting of policies and procedures to ensure PGHD collection and use works for both parties, as well as selecting the PGHD type as well.

6. PGHD should be sourced as patient-generated in the record. In addition, sourcing of data as PGHD should follow the data if they are later shared for other purposes, including Treatment, Payment and Operations.

7. ONC should work through its own channels and with federal partners (CMS and others) to equip providers with clear guidance on how to implement the PGHD menu requirement and the amendments criterion.
   - This guidance should include tips on what PGHD is, why it's useful, the need to establish clear policies and workflows, the providers' obligations under HIPAA with respect to corrections/amendments, and how to design and communicate these policies and procedures with patients and families in their preferred language and at the appropriate literacy level -- including information about their rights under HIPAA regarding amendments and corrections.

   - This information should be disseminated through existing mechanisms such as the ONC and CMS web sites, RECs, and National Learning Consortium.

   - Guidance should build off the work currently being done by the Patient Generated Health Data Technical Expert Panel on defining processes and procedures for PGHD.

Supplemental information:
ACCEPTED: PGHD Policy Recommendations

8. New policies for PGHD are not needed for Meaningful Use Stage 3; HIPAA should govern that data as it does other data in the record. But for the future, ONC and the Office for Civil Rights should undertake work to address data sharing by consumer devices and apps that providers may also use in clinical care.

9. Work is also needed in the medium term to examine policy, workflow and liability issues around unsolicited PGHD.

10. The work to provide patients with interoperable Direct email addresses should continue in order to open up more options for efficient and effective collection of PGHD in the future.

11. Additional work is needed in the short to medium term to explore shared care plans. For example, issues remain around version control, reconciliation, harmonization, etc.