Health IT Policy Committee

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

Joint PGHD Recommendations

Consumer Empowerment WG and Consumer Technology WG

December 4, 2013

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Background

- Asked to provide feedback on two Meaningful Use Stage 3 recommendations for Patient Generated Health Data (PGHD) and to identify any policy issues we need to address to facilitate more widespread use of PGHD

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 ctd.

- 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 ctd.

- 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 ctd.

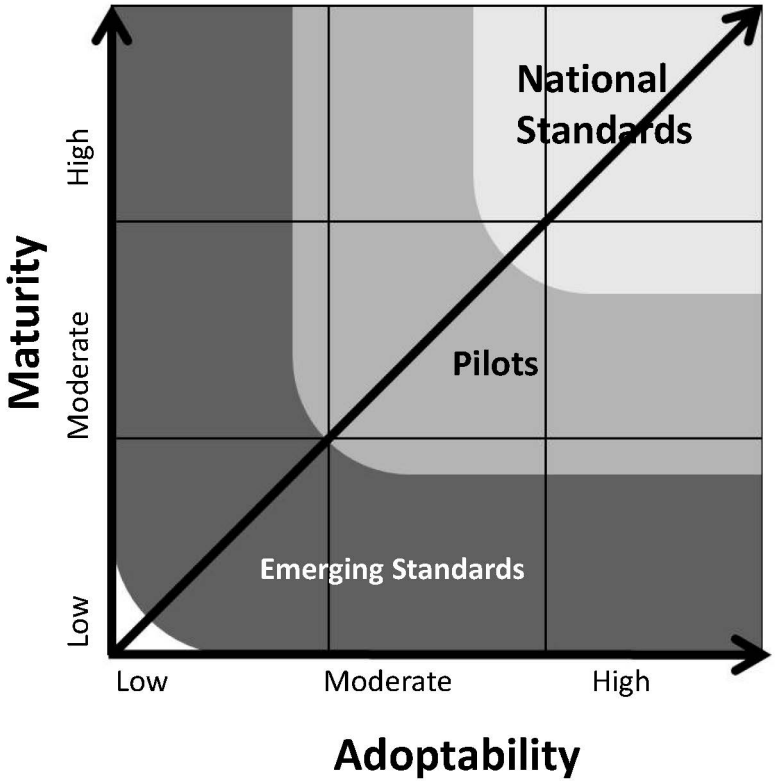
- Concerns about liability are reduced or eliminated when there is a mutually agreed upon set of information to be shared and clear policies/procedures for handling it.
- HIPAA: Sets a floor, not a ceiling. Establishes rights around corrections.
- Providers and patients are aligned around wanting information 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

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	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

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-approved devices*, in addition to structured and semi-structured questionnaires.
2. We also support Meaningful Use Stage 3 certification requirement that addresses amendments/corrections, and note that our recommendations for how to handle PGHD also apply to the amendments criterion, since they too are a form of PGHD.
3. EHR technology should allow providers to receive, review, respond (acknowledge), and record all PGHD, including amendments and corrections. The standards are there for these functions.
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).

PGHD Policy Recommendations

5. Providers should collaborate with patients in implementation and crafting of policies and procedures, to ensure PGHD collection and use works for both parties. This should include selecting PGHD type as well.
6. Sourcing of data as PGHD should also apply if those data are later shared for 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, including what PGHD is, why it's useful, the need to establish clear policies and workflows.
   - This guidance should include tips on 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 to 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.

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 and standards to integrate consumer biometric/device data.
    - For shared care plans – need to consider version control, reconciliation and harmonization, etc.
    - Further work needs to be done on the inclusion of consumer product industry standards for inclusion of device data. For provider-approved devices, standards exist and the group is recommending Continua standards.