Strengthening the Role of – and Respect for – Patient-Generated Data

A discussion on the towering opportunities and unexpected challenges this historic moment presents for patient organizations

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A series of seemingly disparate events led us to this moment.

ARRA EHR Incentive Program

JASON Report on Healthcare

21st Century Cures Act

2009

2012

2014

2015

2016

2019

HL7 FHIR Concept Published

Argonaut Project Launched

“Cures” Rules Proposed (finalized 2020)
Patient data access is now dramatically improving in the US

21st Century Cures Act

The rule provides patients and their providers secure access to health information. It is also expected to increase innovation and competition by creating an ecosystem where new applications that provide patients with more choices in their healthcare can flourish.

HL7 FHIR Standard

Fast Healthcare Interoperability Resources is an interoperability standard created by the standards development organization Health Level 7 (HL7). FHIR is designed to enable health data to be quickly and efficiently exchanged between health systems, patients, payers, and apps.

USCDI

The United States Core Data for Interoperability is a standardized set of clinical concepts and data elements for enabling nationwide, interoperable health information exchange.
Pushing patient-mediated access from “If” to “When”

Adapted from: USCID / ONC Resources  https://www.healthit.gov Isa/united-states-core-data-interoperability-uscdi

December 13
21st Century Cures Act Signed Into Law

March 9
Cures Act Final Rules Released

December 15
Developers Must Submit Real World Testing Plans

April 1
Conditions of Certification Attestations Begin

April 5
Cures Act Final Rule is Active & Information Blocking is Banned

October 16
All EHI must be made available (not just USCDI – incl. nonstandard data)

March 15
Initial Real World Testing Results Published

December 31
New HL7 FHIR API Update Compatibility Must Be Active

December 31
EHI Export Capability Must Be Active

2016 2020 2021 2022 2023

2016 2020 2021 2022 2023
Creating unprecedented opportunities to access EHR data

The ability to digitally follow a patient on their care journey is fast becoming a reality in the US

**Diagnosis / Early Risk**
- Engaging patients early in their experience with disease
- Offering guidance, support, community, and access
- Encouraging data sharing and research participation

**On-Going Care**
Leverage linked and integrated data to manage patient workflow, ensure continuity of care, and provide greater insight into care

**Future HCP / Facility**
- Maintain follow-up with enrolled patients
- Request patient-mediated access to EHR data from alternative real-world care settings

**Specialist**
- Leverage patient-mediated EHR access to monitor for potential specialty treatments
- Obtain specialty data (if available in EHR) and apply NLP to utilize unstructured reports and notes

PLUS the Claims data generated by these encounters

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Driving a new generation of patient-centric designs

(Illustrative)
That need equally modern real-world data capabilities

Patient / Person / Provider Applications
- Support for Direct-to-Patient / Consumer / Clinician
- Bring your own device (BYOD)
- Mobile-friendly Web + iOS / Android apps
- Heavily focused on daily / weekly connections
- Dynamic recruiting channel

Patient Experience
- Tiered marketing-level permissions support
- Self-service enrollment and consenting support
- Dynamic patient engagement
- Rewards Management and Gamification
- Deep partnerships with advocacy organizations

Patient Rewards
- Digital Wallet
- Daily opportunity to earn points
- Points → Dollars / Gift Cards / Discounts
- Support for Hyperwallet, Tremendous, etc.
- Historical Ledger

EMR / EHR Data Provisioning
- Patient-mediated EHR data sharing
- No site permissions needed
- Patient can provision with a few clicks
- Site-mediated EHR integration

Claims Data Provisioning
- Patient-mediated claims / admin data sharing

Device Integration
- Support for patient-mediated sharing of summary and time-series data from wearables and devices

Longitudinal Engagement
- PROs, Pulse, and Experience surveys
- Support for complex protocols, events, notifications, and return of information
- Support for biospecimen collection
Able to leverage the full spectrum of patient data access methods

- **Patient-Mediated Release** – Leverages mandated access rights and named-patient FHIR APIs to facilitate specific record sharing across the care journey.

- **Modern Integration** – Leverages nascent Federal interoperability methods and HL7 FHIR standard to consistently access data across care settings.

- **Legacy Integration** – Leverages “behind-the-firewall” and/or bespoke interfaces to enable one-off data access at each site.

- **Select Data Upload and/or Chart Abstraction** – Leverages data generated by IT exports or manual transcription to populate specific CRFs.
U.S. Core Data for Interoperability: The mandatory set for sharing

- Set by Office of the National Coordinator for Health IT (ONC)
- Mandated in the Cures Act “Final Rule” on Interoperability
  - Compliance dates delayed slightly due to COVID-19
  - Widespread adoption was already underway in 2022
  - Widespread adoption required by end of 2023
- Implemented in the HL7 FHIR international data standard
- Leverages industry-consensus clinical concepts
- Draft Version 4 released in Jan 2023 and expands to include Facility information and much further improved granularity
Fireside Chat