The Intersection Between Research and Care Delivery: Leveraging Health IT to Advance Precision Medicine

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ONC Annual Meeting
November 29, 2018
Agenda

- ONC Chief Scientist Division (CSD) Overview
- Patient-Centered Outcomes Research (PCOR) Overview
- ONC and the Precision Medicine Initiative (PMI)
ONC Chief Scientist Division Overview

• Develop and evaluate ONC’s scientific efforts and activities, and recommend scientific policy to the National Coordinator

• Direct a wide variety of innovative health IT programs and projects to advance an interoperable health care system that also supports biomedical and health services research

• Promoting activities that spur innovation, support patient-centered outcomes research, and advance precision medicine, through the sharing of electronic health data (clinical, genomic, and personal) between patients, providers, and researchers
At the Intersection Between Research and Care Delivery

• To realize the benefits of a 21\textsuperscript{st} Century health system, more needs to be done to support the sharing of electronic health data

• Current health IT infrastructure is distinct for clinical care and for research, although the two may intersect in organizations that conduct both research and deliver care
### ONC Patient-Centered Outcomes Research (PCOR) Portfolio

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<td>Patient-Generated Health Data (PGHD)</td>
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<td>Patient Matching, Aggregating, and Linking (PMAL)</td>
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<td>Coordinated Registry Network (CRN) for Women’s Health Technologies</td>
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<td>Patient-Reported Outcomes through Health IT (PRO)</td>
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### ONC Precision Medicine Initiative (PMI) Projects

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ONC Patient-Centered Outcomes Research (PCOR) Portfolio

• **LAUNCHED**: 2013

• **MISSION**: To develop the policy, standards, and services necessary to expand the data infrastructure for patient-centered outcomes research
ONC Patient-Centered Outcomes Research (PCOR) Portfolio

• CURRENT PROJECTS LAUNCHED IN 2017:

» Coordinated Registry Network (CRN) for Women’s Health Technologies
  – To establish a standards-based CRN and develop the tools to facilitate collection of data in three clinical registries focused on women’s health

» Common Data Model Harmonization (CDM)
  – To harmonize the common data models (CDMs) in Sentinel, PCORnet, OHDSI, and i2b2 to further advance the utility and interoperability of the data within these networks for use in PCOR

» Patient-Reported Outcomes through Health IT (PRO)
  – To standardize the integration of structured PRO data into EHRs and other health IT solutions supporting the interoperable exchange of this information
The Precision Medicine Initiative (PMI)

- **LAUNCHED**: 2015
- **MISSION**: To enable a new era of medicine through research, technology, and policies that empower patients, researchers, and providers to work together toward development of individualized care
ONC and the Precision Medicine Initiative

- Accelerate innovative collaboration around pilots and testing of standards that support health IT interoperability for research
- Adopt policies and standards to support privacy and security of cohort participant data
- Advance standards that support a participant-driven approach to patient data contribution

https://healthit.gov/topic/precision-medicine
The All of Us Research Program

• **LAUNCHED**: 2018

• **MISSION**: To accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care for all of us
  
  » One million or more volunteers, reflecting the broad diversity of the U.S.

  » Opportunities for volunteers to contribute their health data and biospecimens on an ongoing basis

  » Data will inform a variety of research studies

https://allofus.nih.gov/
What is Sync for Science (S4S)?

With a click of a button, you’ll be able to voluntarily share your health data to help scientists perform groundbreaking research.

Patients Sharing EHR Data
Sync for Science (S4S)

- **LAUNCHED:** 2016
- **MISSION:** Promote patient-mediated access to data; establish structures that facilitate data sharing to the PMI cohort
- National collaboration among EHR developers, NIH, ONC, and Harvard Medical School’s Department of Biomedical Informatics

[http://syncfor.science/](http://syncfor.science/)
Hospital Center Recruitment

Recruitment at point of care
Patient trust
Well-defined data, specimens

Network creation expensive/slow
Limited cohort diversity
Poor coverage for rare conditions
Person-Centered Recruitment

- Reach communities of patients
- Recruit non-patients
- Clear route to participation (PROs)
- Faxing records expensive/slow
- Painful EHR sharing workflows
- Diversity of data formats
S4S as a Component of the *All of Us* Direct Volunteers (DV) Program

~700,000
HPO Recruits

EHR Data via
Custom Data Extraction

~300,000
Direct Volunteers

EHR Data via
Sync for Science + Other Services

Direct Volunteer focus…
but not exclusive
Traditional Out-of-Network Barriers
Traditional Out-of-Network Barriers
NIH and ONC Launch the Sync for Science (S4S) Pilot: Enabling Individual Health Data Access and Donation

March 21, 2016, 11:46 am / Jon White, M.D. / Acting National Coordinator for Health IT, Office of the National Coordinator for Health IT,
Josephine Briggs, M.D. / Interim Director, Precision Medicine Initiative Cohort Program, and
Josh Mandel, M.D. / Research Scientist, Harvard Medical School Department of Biomedical Informatics
• NIH + Harvard Medical School + EHR Vendors

• Leveraged HIPAA and Meaningful Use Stage 3 + 2015 EHR Certification
  » Patient has right to access her/his EHR data (HIPAA)
  » Patient application access *so patients can share their data via apps* (MU3)
  » Common Clinical Data Set *covering a core set of summary elements* (MU3)

• Built on **open standards** for healthcare data + security

• Emphasizes **automated testing** of EHR vendor systems
S4S EHR Vendors – Implemented Patient Portal for S4S Pilot

- Epic
- eClinicalWorks
- Cerner
- Allscripts
With a few clicks, research participants can share their EHR data.
Research App – Share Your EHR Data

1. Electronic Health Record Data
   Share my electronic health record (EHR) data: [On, Off]
   At the moment, you do not share your electronic health record (EHR) data from your health care provider.
   + add a new health care provider

2. Add Health Care Provider
   Please enter the code from the brochure you received at your health care provider.
   Enter signup code: [input field] Submit Code

3. Confirm Health Care Provider
   You have chosen to share your electronic health records (EHR) from Berkshire Health Systems.
   Next, you will be directed to the (patient portal) provided by Berkshire Health Systems.
   You can use your Berkshire Health Systems account information to log in.
   Do you wish to proceed?
   Yes [button] No [button]

Don't have a provider code?
Contact your health care provider to see if they are supported. We only support Sync for Science at the moment. You should be able to get provider code if your health provider supports Sync for Science.
Learn more about how to get the code (eligibility)
S4S at the EHR Patient Portal

Personal Health Information Sharing

Patient Portal Login

Approve Sharing EHR Data
Research App – Return Paths

“I decided ... for now!”

Electronic Health Record Data Sharing Successful
Thank you.
You have successfully shared your health data from Berkshire Health Systems to the All of Us Research Program.
We will periodically access your health data from Berkshire Health Systems.
You can stop sharing data with the All of Us Research Program at any time by visiting your profile.

Return To Profile

Electronic Health Record Data Sharing Not Completed
We were unable to access your health records.
If you need help, call 1 (844) 842 2855 or email help@joinallofus.org.

Try Again Return to Profile
Research App – Cancel Sharing

Electronic Health Record Data

Share my electronic health record (EHR) data

- On
- Off

Shared Sync for Science Medical Data

We’ve connected to your electronic health records. You’re sharing your data from:

- Fairfax Family Practice (SMART)
- + add a new health care provider

“I want to stop sharing from my EHR”

Are you sure?

You will stop sharing your data from [insert hospital], but data you shared before will still be available to researchers.

[Cancel] [Remove]
Sync for Science Demonstration

This demo shows how S4S helps patients share clinical data with researchers. The public-facing components are:

**demo portal**
A mock EHR "portal" where a patient can sign in and make the decision to share data with an app

**demo app**
a mock research application where the patient can share EHR data

These components are available as part of an open-source reference implementation at: [https://github.com-sync-for-science-reference-stack-docker](https://github.com-sync-for-science-reference-stack-docker).
S4S Standards – **SMART on FHIR** (OAuth 2.0 + FHIR)

**OAuth 2.0**
- Security authorization standard
- Modern web technology
- Helps users delegate permissions to apps, e.g., to share data

**FHIR (Fast Healthcare Interoperability Resources)**
- Clinical data standard
- Modern web technology
- Breaks data into "Resources" like patient, condition, immunization
Initial S4S Data Scope – Common Clinical Data Set (CCDS)

- Patient demographics (name, birthdate, race, ethnicity, ...)
- Allergies and intolerances
- Immunizations
- Lab results
- Medications (administrations, dispensations, orders, statements)
- Patient documents (*)
- Problems
- Procedures
- Smoking status
- Vital signs
S4S Test Suite – Verifying EHR Compliance with S4S
Big Picture – Long-Term Strengths of S4S

- **Quick** Setting up access is fast and easy for participants
- **Cheap** Incremental cost for sharing EHR data closer to $0.01 than $100
- **Ubiquitous** Widely available to participants across the country
- **Transparent** Participants understand what is happening & which data are shared
- **Deterministic** Providers/researchers do not need to guess or match patients::participants
- **Structured data** Common structures and vocabularies for core clinical, imaging, payor, lab data
- **Free-text data** Access to free-text notes and other unstructured clinical components
Growing the S4S Platform – Not Just Research

Sync for Science
Patients exercising their HIPAA rights to share their health data as they choose
Growing the S4S Presence – Adoption Dynamics

- **2017:** 14 S4S Pilots
- **2018:** More S4S-ready EHRs go live
- **2019:** New vendors implement S4S
- **2015-Certified EHRs with S4S**
- **2020:** Faster Adoption
  - More researchers leverage S4S
  - Slower Adoption
Growing the S4S Platform in Year 2 – More Partners, More Data

- Enhance tech infrastructure
- Streamline authentication
- Develop participant-facing EHR views
- Add free-text clinical notes
- Support Current Pilots
- Add Imaging Data
- Add Insurance Claims Data
- More Studies
- More Vendors
- Expand community
- Promote API regulations

Relationship and Market Building
<table>
<thead>
<tr>
<th>User</th>
<th>One Patient Record</th>
<th>Multiple Patient Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>S4S (SMART Apps)</td>
<td>SMART Apps</td>
</tr>
<tr>
<td>Practitioner</td>
<td>SMART Apps</td>
<td>SMART Apps</td>
</tr>
<tr>
<td>Organization</td>
<td>e.g. Hospital</td>
<td>Backend Services</td>
</tr>
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<td></td>
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<td>&amp; &quot;Bulk Data&quot;</td>
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Sync for Science Application Programming Interface (API) Privacy and Security

- Technical and administrative testing, analysis, and assessment of APIs developed under the S4S Pilot Project
- Outlines Key Privacy and Security Considerations for API implementation

“… as long as healthcare APIs are implemented with appropriate privacy and security safeguards in place, APIs can add value to individual-directed sharing of health information.”

Sync for Genes

- **LAUNCHED**: 2016
- **MISSION**: To standardize the sharing of genomic information between laboratories, providers, patients, and researchers
- **CONCLUDED** Phase 1: Standardizing Genomic Data
  - Updated HL7 FHIR clinical genomic profile and genomic specifications
Sync For Genes Phase 2 Pilot Focus Areas

- **Utah Department of Health: Newborn Screening**
  - Share data with healthcare providers in real-time for optimal clinical care and outcomes for at-risk and vulnerable newborns

- **Weill Cornell Medicine: Cancer Genomic Decision Support**
  - Convert discrete genomic results to FHIR® and pair this data with a physician facing app that provides supplemental knowledge of variant results to pilot clinical decision support scenarios in cancer genomics

- **National Marrow Donor Program (NMDP): Patient/Donor Matching**
  - Convert existing Next Generation Sequencing (NGS)-based human leukocyte antigen HLA genotyping information to FHIR® without losing completeness of the data

- **Lehigh Valley Health Network (LVHN): Pharmacogenomics**
  - Leverage genomic content for diagnosis, care management, and pharmacogenomics to support the advanced cardiology program in their newborn screening program
Testing the HL7® FHIR® Specifications

• HL7 FHIR Connectathon Testing Goals

• Expected outcomes

  » Identify what types of local modifications (customizations) pilot sites made in both the mapping and exchange activities

  » Refine the FHIR® Clinical Genomics resource by identifying gaps in the specification
Identified Challenges and Gaps

- **Genomic Diagnostic Reports**
  - Do not always contain the same information
  - Different use cases have unique data needs
  - Exploring how to handle large raw data files such as variant cell format (VCF)

- **Industry Wide**
  - Data modeling and semantics
  - Data provenance
  - Privacy and security of sensitive data
  - Ethical issues regarding the use of genomic data
  - Storage of the large data files
  - Patient access to their genomic data
  - Cost of integration
Next Steps

• Phase 2 underway
  » Preparing for the HL7 Connectathon in January 2019
  » Project will complete in Spring 2019

• Semantic Modeling Project underway
  » Project will complete in Summer 2019
Advancing Standards for Precision Medicine

• **LAUNCHED:** September 2018

• **MISSION:** To advance standards development and use for sensor and social determinants of health data

• Collaboration with [Open mHealth](https://www.openmhealth.org)
21st Century Cures Act

• Provides resources to expand the Precision Medicine Initiative, find cures and better tailor treatments to the individual patient needs

• ONC is working to implement Cures Act provisions by:
  » Improving the flow and exchange of electronic health information
  » Enhancing the usability, accessibility, and privacy and security of health IT
“When the federal government created the national highway system, it did not tell people where to drive — it built the roads and set the standards for safety. Those investments supported a revolution in transportation, commerce, and personal mobility. **We are now building a national highway system for personalized medicine, with substantial investments in infrastructure and standards.** We look forward to doctors' and patients' navigating these roads to better outcomes and better health.”

-Margaret A. Hamburg, M.D., and Francis S. Collins, M.D., Ph.D.
