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Citation	Waghlikar, K. B., R. Jain, E. Oliveira, J. Mandel, J. Klann, R. Colas, P. Patil, et al. 2017. "Evolving Research Data Sharing Networks to Clinical App Sharing Networks." AMIA Summits on Translational Science Proceedings 2017 (1): 302-307.
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Evolving Research Data Sharing Networks to Clinical App Sharing Networks

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Abstract

Research networks for data sharing are growing into a large platform for pragmatic clinical trials to generate quality evidence for shared medical decision-making. Institutions partnering in the networks have made large investments in developing the infrastructure for sharing data. We investigate whether institutions partnering on Patient-Centered Outcomes Research Institute's (PCORI) network can share clinical apps. At two different sites, we imported patient data in PCORI's clinical data model (CDM) format into i2b2 repositories, and adapted the SMART-on-FHIR cell to perform CDM-to-FHIR translation, serving demographics, laboratory results and diagnoses. We performed manual validations and tested the platform using four apps from the SMART app gallery. Our study demonstrates an approach to extend the research infrastructure to allow the partnering institutions to run shared clinical apps, and highlights the involved challenges. Our results, tooling and publically accessible data service can potentially transform research networks into clinical app sharing networks and pave the way towards a learning health system.

Introduction

Patient-Centered Outcomes Research Institute's (PCORI) research networks are evolving into a large platform for pragmatic clinical trials to generate quality evidence for shared medical decision-making. Institutions partnering in the networks, store data using a common data model (CDM), and they have made large investments in the data infrastructure to facilitate comparative effectiveness research. We investigated whether the network partners can share clinical apps, which can potentially transform the delivery of healthcare. Specifically, we have developed and evaluated a platform that supports execution of SMART-on-FHIR apps, on data that is stored using PCORnet's common data model (CDM).

Background

PCORnet

In 2010 the Congress authorized creation of the Patient-Centered Outcomes Research Institute (PCORI) as an independent nonprofit, nongovernmental organization, with the mandate of improving the quality of evidence for deciding on healthcare options and for making such information available to patients and providers. [1] PCORI identifies critical research questions, and funds clinical effectiveness research (CER) for improving outcomes in high-burden and high-impact conditions.

PCORI has funded the development of a national Patient-Centered Clinical Research Network (called PCORnet), which the goal of fostering observational and experimental CER. PCORnet serves as a source of clinical data gathered across diverse healthcare settings.[2] Data are collected in standardized and interoperable formats, and shared across the network uses secure protocols. Patient confidentiality is protected, by removing patient identifiers from the data. PCORnet is made up of 33 partner networks—13 Clinical Data Research Networks (CDRNs), based in healthcare systems, and 20 Patient-Powered Research Networks (PPRNs) that are managed by patient groups.

PCORnet is initially focused on specific conditions, but is eventually expected serve broader array of topics. Each PCORnet partner network maps data to the same consistent format (e.g., with the same variable name, attributes, and other metadata). This format is called the Common Data Model (CDM). Use of the CDM format is critical for efficient data exchange across organizations in the network, given the diversity of organizations in PCORnet. The

PCORnet CDM is based on the Mini-Sentinel CDM [3] and is informed by HMO Research Network,[4] the Vaccine Safety Datalink, various AHRQ Distributed Research Network projects, and the ONC Standards & Interoperability Framework Query Health Initiative.[5] The data elements in PCORnet CDM are coded using standard terminologies and coding systems to facilitate interoperability.

The initial version of the CDM focused on a set of data items that are frequently available. Subsequent versions added data elements, which are analytically important for patient-centered outcomes research and feasible to standardize across sites. The CDM is oriented towards observational research and clinical trials. Several PCORnet sites use i2b2 software for their repository (Figure 1).

Substitutable Medical Apps, Reusable Technologies (SMART)

A major obstacle for EHR use is the lack of user-friendly interfaces— providers are limited by the functionality offered by their institutional EHR, as it is not economically viable to develop standalone interfaces that can be installed on different EHRs. [6, 7] The vision of SMART project is to address this obstacle, by allowing care providers to move beyond the interface of their institutions EHR system, and choose the applications (app) of their liking. [8-10] Major EHR vendors are increasingly adopting SMART FHIR profiles, to create SMART apps that can run on any EHR or data-repository supporting the FHIR standard. SMART apps transform EHR user interfaces into a smartphone-like platform [11].

Smart-phone platforms lower the barrier to app development by providing a uniform API for a set of core services such as camera, contact list, and geo-location. These platforms can functionally separate the core system from the apps so that a consumer can download, for example, a camera app, and then reject it, and replace it with another one. The SMART project supports an app-store called the SMART-app gallery, which is intended to catalogue and demonstrate the apps, and serve as a market place for apps. The goal is to drive down healthcare technology costs and spur innovation, by fostering market competition for evolution of applications that better support the care provider needs.

The SMART project specifies a protocol for apps to authenticate with and run against existing Health Information Technology (HIT) systems. The project publishes a Javascript library that uses JSON format for payload representation. The JSON templates are defined in the Fast Health Interoperability Resources (FHIR) standard. [12] FHIR is an emerging standard for exchanging healthcare information electronically. It is based on emerging industry approaches, and builds on the lessons from previous healthcare standards. Several projects are underway through standards organizations to facilitate adoption of FHIR including the Argonaut Project, [13] Data Access Framework (DAF) and Clinical Information Modeling Initiative (CIMI). [14]

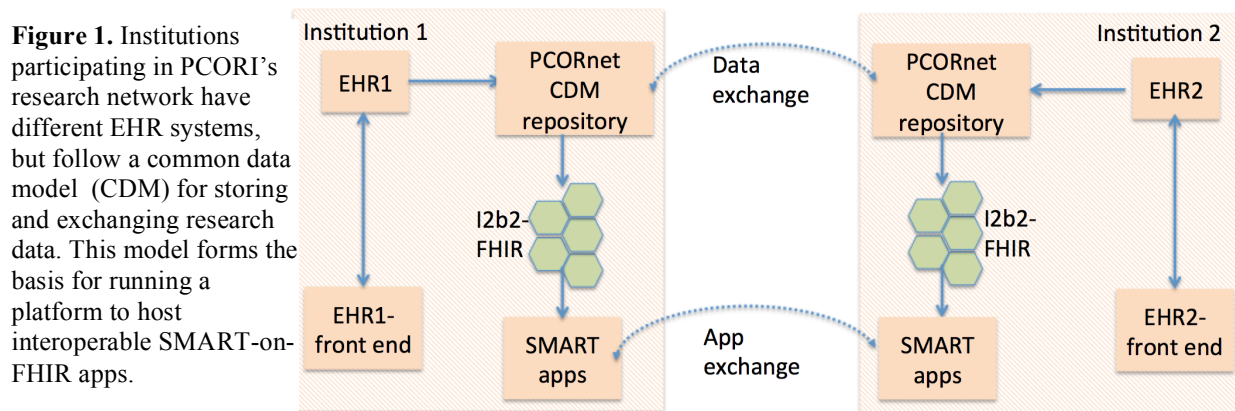
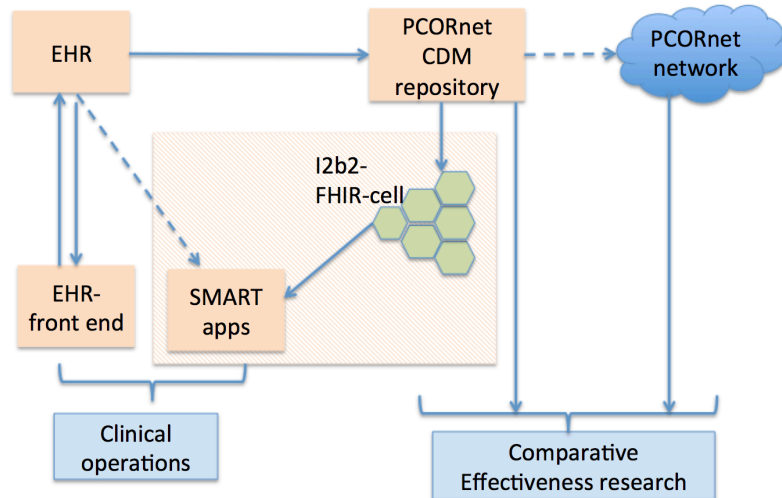


Figure 1. Institutions participating in PCORI’s research network have different EHR systems, but follow a common data model (CDM) for storing and exchanging research data. This model forms the basis for running a platform to host interoperable SMART-on-FHIR apps.

Informatics for Integrating Biology and the Bedside (i2b2)

I2b2 is an open source clinical data analytics platform originally sponsored by the National Institutes of Health. [15-17]. It is used at over 120 sites nationally for querying patient data to address clinical questions. I2b2 has been adapted to build multi-institutional networks, and is a central component in the infrastructure for many institutions that have Patient-Centered Outcomes Research Institute (PCORI) awards. [18, 19]

Figure 2. Our proposed approach facilitates the use of high quality research data to drive innovative applications to directly support clinical operations



We investigated whether data in the PCORnet CDM format, can be readily utilized to serve SMART-on-FHIR apps. (Figures 1 and 2). The goal of this study is to reduce barriers for sharing clinical applications across the PCORI's research network. Our work can significantly reduce the efforts at the networks to develop a platform for running SMART apps, which will facilitate sharing of the apps across the network.

Methods

We imported patient data in CDM format into i2b2 using an i2b2 plugin [17], and adapted the SMART-on-FHIR i2b2 cell (SOFI) to query i2b2 using PCORI ontology that maps to PCORnet CDM. [20] We had earlier developed a SMART-on-FHIR i2b2 cell (SOFI), which translated data stored using from i2b2 ontology into FHIR format [21, 22]. In the current, work we implemented a translation from PCORI's common data model to FHIR format, for a select set of patient data including demographics, laboratory results and diagnoses. The deployment was performed at two locations Partners Healthcare (PHC) in Boston, Massachusetts and the REACHnet Data Center (RDC) in New Orleans, Louisiana.

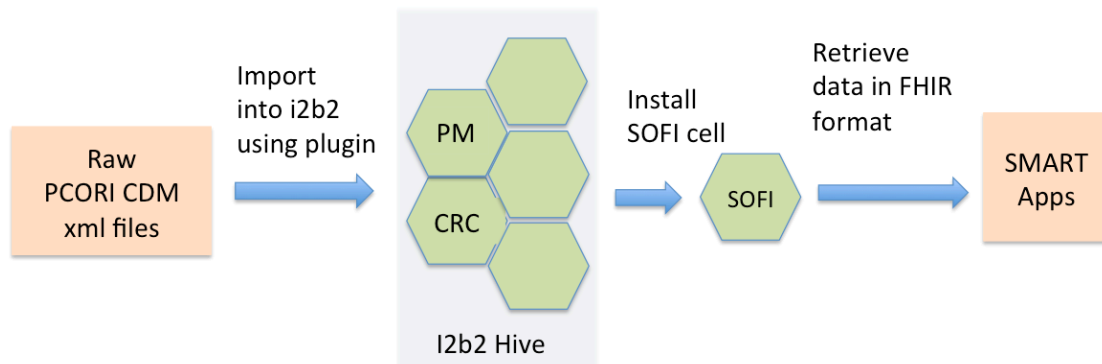


Figure 3. Pipeline for installing and evaluating the SMART on FHIR i2b2 cell (SOFI).

Specifically the PCORnet CDM-FHIR translation was implemented by modifying the SOAP calls from FHIR cell to the CRC cell, to retrieve the i2b2 ‘facts’ assigned to the i2b2-PCORnet ontology that corresponded to the required FHIR resources.

The pipeline to import data from the CDM format, into i2b2 instance and to install SOFI is available at <http://community.i2b2.org/wiki/display/FCC/FHIR+Connection+Cell>. The installation script is tailored to execute on the virtual machine platform at Amazon. This script automatically pulls the SOFI source code from Github and installs the servlet container, database and webservice on a fresh instance.

For evaluating this infrastructure, we assessed the accuracy and completeness of the FHIR output from SOFI, by performing manual inspections, and by running the FHIR validator available with the specification. We performed spot inspection of 30 instances of FHIR resources (Labs, Diagnosis and Demographics) for random patients at both the locations. We verified the dates, codes and code expansions during the spot inspections, by comparing the FHIR output with the i2b2 data. Additionally, at RDC we traced the data-points to the imported CDM. To evaluate compliance of SOFI with the SMART OAuth2.0 specification, [23] we developed and executed a dashboard SMART app on both the installations. We measured the average time required for the platform to respond to request for FHIR resources. [24] Furthermore, we investigated if the platform at RDC can readily support open-source apps ported from the SMART app gallery. We tested using four open-source apps: [Diabetes Monograph](#), [Disease Monograph](#), [Cardiac risk](#) and [Patient demo](#).

Results

The SOFI platform could be installed at both the sites: PHC and RDC. SOFI installation script could be readily run on a CentOS instance at Partners, but needed few modifications for running on Ubuntu instance at RDC’s Openstack node. At PHC we had previously created an i2b2 instance. At RDC’s we created a fresh i2b2 instance by importing CDMs for 300 patients. This data is de-identified, along with date-shifting to protect patient privacy, and is publically available for development of SMART-apps after signing a data use agreement (DUA) at <https://demo.hioh.org/srv-dstu2-0.3/api/>.

The HL7 FHIR validator ran successfully on randomly selected resources at both the sites, and the manual inspections revealed that the FHIR resources were valid and contained accurate data. The developed demonstration SMART app executed successfully at both the sites, demonstrating the validity of the installations. The installation required an average 5 seconds for responding to non-cached calls and 0.5 second for cached calls.

The apps from the SMART-app gallery were tested on the RDC platform by copying the source code from the app gallery to the local server, and a change in the client_id variable in the launch script of the app to include the client_id registered with the FHIR-cell.

All the apps successfully completed the OAuth2.0 authentication process and patient selection sequence. Diabetes-Monograph, Disease Monograph and Patient demo displayed well. In the event of data being missing during the app’s execution cycle, table values are marked “null”. The Cardiac-Risk app showed an alert of missing data (C-Reactive Protein, Cholesterol, High-density Lipoprotein). Analysis of the RESTful calls made by the apps revealed that some of the FHIR resources requested by the app were not available in the RDC endpoint. e.g. the disease app cannot display allergies and medication which are not currently available in the sample dataset.

Analysis of the RESTful calls made by the apps to the RDC endpoint revealed that some of the apps used a complex query format, wherein the observation FHIR resource was filtered by specifying a code set. The latter format is not currently supported by SOFI. Summarily, the current implementation of the SOFI platform is limited to a subset of FHIR resources, and does not support filtering of FHIR resources using complex query format.

Discussion

Our approach will facilitate the partnering institutions to leverage their investments in the research data-infrastructure, and will in-turn spur a competition for developing innovative and interoperable clinical apps that can transform the delivery of clinical care. Our results and tooling will be useful for the PCORnet partners to extend their research infrastructure for serving SMART-on-FHIR apps.

The choice of app from the SMART App gallery would be easier, if the app developers provided documentation detailing the list of resources that the app seeks or supports. The resources can be further categorized as mandatory and optional, the former defined as the minimal resource set required for accurate performance of the app, e.g.

factors for risk prediction model.

The primary advantage of the use of CDM based data repository is that it contains data mapped to the preferred coding system, which provides semantic portability. EHR systems, even once they support FHIR interfaces, are not required by the FHIR specification to map all of their terms to standard coding systems. Previous experience with Meaningful Use suggests that the minimal necessary work on mapping is generally performed and a large number of terms are often not mapped.

The disadvantage is that the CDM repository generally does not offer the complete and latest picture, as the data elements are usually restricted to ‘foundational’ or non-specialty-related data elements, and the repositories are not updated real-time. Another advantage of the CDM repositories is that it contains high quality data that is suitable for clinical decision support, as an improvement over EHR data that is often incomplete. [25, 26] CDM datasets can be aggregated across multiple data sources (e.g., EHR, lab, and professional billing systems), rather than the single source of an EHR. Furthermore, CDM datasets are available now in several hospital systems, whereas standardized, functional FHIR interfaces have been slow to appear, despite significant interest by EHR vendors in the standard.

Although the smart apps can be readily executed from a browser on a mobile and desktop device, it desirable to embed the smart apps into the local EHR interface, so that care providers can launch the apps in the context of the patient chart they are reviewing. [27] Such an integration of the apps into local EHR interface is a challenge that the network partners need to address separately.

Given the current limited dataset available in CDM repositories, it is possible to share a big variety of apps among the network partners, which can provide useful functionalities like summarizations and visualization—features that advance the GUI of the EHR can that can would require non-specialty information and the timeliness can be address by adding by performing real-time update.

One obstacle for using research data for supporting clinical operations is that research repositories are generally setup to update from the EHR after a lag of several hours or days. This is because the research use is not significantly hindered by the lack of current data. It is common to perform nightly updates to the data repositories, to avoid overloading the EHR system during clinical working hours. However, utilization of the smart apps based of the CDM research repository, for clinical operations can provide the much needed incentive to invest in real-time updating of research data repositories, which will in turn foster development of more research data-based applications to augment clinical practice.

Innovative clinical apps supported by research repositories will provide the opportunity to increasing incorporate prediction-models derived from analysis of the repositories. Sharing of such apps across the network partners will serve as the cycle for data-derived knowledge generation and dissemination to point-of-care, paving the pathway for the learning health care system.

In summary, the proposed approach 1) allows the utilization of "research-quality clinical data" for apps to support clinical decision support, 2) provides a platform for sharing interoperable clinical apps across institutions, and 3) uses a secure mechanism to protect patient privacy and confidentiality.

Limitations and Future work

We investigated the deployment of the platform at two institutions and tested portability of the app to a single institution. The testing methodology described in this paper needs to be replicated at other PCORnet sites to ensure seamless portability of SMART apps across the sites. We are working on extending SOFI platform for PCORnet CDM to include additional FHIR resources and to support the entire set of the FHIR query format. Furthermore, we are testing the platform by deploying open-source FHIR apps at RDC and PHC in the clinical setting.

Conclusions

Our study demonstrates an approach to extend the research infrastructure to allow the institutions partnering in research networks to run shared clinical apps, and highlights the challenges for deployment of the apps. Our results, tooling and publically accessible data service can be useful for transforming PCORI’s research networks in into clinical app sharing networks and pave the way towards a learning health system.

Acknowledgements: This research is supported by grant under award numbers R00LM011575 from NLM, and R01GM104303 from NIGMS, and CDRN-1306-04864 from the Patient Centered Outcomes Research Institute.

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