Response to ONC Interoperability Roadmap by Curtis, Brown, et al
Comments Submitted on April 3, 2015

Introduction

On January 30, 2015 the Office of the National Coordinator (ONC) issued the draft version of the Interoperability Roadmap, *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Draft Version 1.0*[1]. This document is in response to the call for public comments[2], and we appreciate the opportunity to provide our feedback.

These comments represent the individual views of the authors, each of whom collaborate on the Data Standards, Security, and Network Infrastructure (DSSNI) Task Force of PCORnet, the National Patient-Centered Clinical Research Network. These comments do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), the PCORI Board of Governors, or other organizations and governmental entities collaborating in the development of PCORnet.

Background

Distributed research networks repurposing clinical and administrative data, such as the PCORnet National Patient-Centered Clinical Research Network (PCORnet)[3], the FDA's Sentinel Initiative[4], and the NIH Collaboratory Distributed Research Network[5], are an important area of national infrastructure development to benefit healthcare and research[6]. There are several key elements of this infrastructure pertinent to our assessment for the Interoperability Roadmap:

- In a distributed research network, the source data held by individual data partners never leave their institutional firewalls[7]. This distributed systems architecture is distinct from the IT platforms that typically support clinical care delivery, but both approaches benefit from infrastructure development to support interoperability.
- Performing analysis of data on distributed data stores is a specialized activity that has different systems requirements than typical clinical care software; however, these distributed analytic methods may be particularly pertinent as the Interoperability Roadmap vision fosters scalability to a national Learning Health System.
- Interoperability has important benefit to research initiatives repurposing data generated in the delivery of healthcare. However, the clinical drivers must be recognized and appreciated for appropriate repurposing of these data for research.

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[1] http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf

[2] http://www.healthit.gov/policy-researchers-implementers/interoperability-roadmap-public-comments

[3] http://www.pcornet.org/

[4] http://www.fda.gov/Safety/FDAsSentinelInitiative/ucm2007250.htm

[5] https://www.nihcollaboratory.org/

[6] Curtis LH, Brown J, Platt R. Four health data networks illustrate the potential for a shared national multipurpose big-data network. Health Aff (Millwood). 2014 Jul;33(7):1178-86. http://www.ncbi.nlm.nih.gov/pubmed/25006144

[7] Brown JS, Holmes JH, Shah K, Hall K, Lazarus R, Platt R. Distributed health data networks: a practical and preferred approach to multi-institutional evaluations of comparative effectiveness, safety, and quality of care. Med Care. 2010 Jun;48(6 Suppl):S45-51. http://www.ncbi.nlm.nih.gov/pubmed/20473204

Assessment

1. Intersections of Documentation

It was initially unclear where the detailed specifications would be found, given that many parts of this document lacked implementation-level details. The organization became clearer with a close reading of the document, especially the complimentary role of the Interoperability Standards Advisory document[8], but a clear description of the various interrelated ONC artifacts and document stores will aid the reader. An infographic similar to page 9 could be helpful for this purpose.

2. Common Clinical Data Set

The proposed Common Clinical Data Set is completely compatible with the PCORnet Common Data Model[9]. We appreciate the simplicity of the presentation, which is intuitive to both clinicians and technical experts.

However, the Common Clinical Data Set currently combines both high-level domains and individual fields:

- In the PCORnet Common Data Model, we define domains as "high-level concepts of data organization based upon existing data sources, workflows, and processes"[10]. Domains in the Common Clinical Data Set include: Problems, Vital Signs, and Medication Allergies
- Fields are granular data elements within domains. Fields in the Common Clinical Data Set include: Sex, Race, and Ethnicity, which would typically belong to a Demographics domain.

This combination of both domains and fields may be confusing for communications and common understanding of the Common Clinical Data Set features. Fields may be more likely to change over time[11]. In contrast, domains that are well-positioned in existing healthcare workflows and data-generating activities can be expected to have more stability. Consider listing high-level domains in the roadmap, which are then fully specified in implementation-level guidances and documentation, and integrated into the context of Meaningful Use specifications.

Other considerations:

- "Notes/narrative" references a mode of data collection and representation that can be associated with many data-generating activities. We recommend disambiguating this broad category; for example, if the intent is to capture progress reports and discharge summaries, more specificity would be helpful. This is particularly important if methods of Natural Language Processing (NLP) are to be cohesively integrated.
- "Patient name" is not as granular as the name-related elements in the linkage discussion (page 93), which decomposes this concept into: First/Given Name, Current Last/Family Name, Previous Last/Family Name, Middle/Second Given Name (includes middle initial).

A Common Clinical Data Set

- Patient name
- Sex
- Date of birth
- Race
- Ethnicity
- Preferred language
- Smoking status
- Problems
- Medications
- Medication allergies
- Laboratory test(s)
- Laboratory value(s)/result(s)
- Vital signs
- Care plan field(s), including goals and instructions
- Procedures
- Care team members
- Immunizations
- Unique device identifier(s) for a patient's implantable device(s)
- Notes/narrative

Figure from Interoperability Roadmap, pages 12 and 80.

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[8] http://www.healthit.gov/standards-advisory

[9] http://www.pcornet.org/resource-center/pcornet-common-data-model/; see also Brown JS, Rusincovitch SA, Kho AN, Marsolo K, Curtis LH. Development of a National Distributed Research Network Data Infrastructure: Design of the PCORnet Common Data Model. AMIA 2014 Joint Summits on Translational Science, March 23-27, 2015, San Francisco, California.

[10] Rusincovitch SA, Kho AN, Puro JE, Meeker D, Rivera P, Sorensen AA, Brown JS, Curtis LH. Pragmatic Data Domain Selection for a National Distributed Research Network: The PCORnet Common Data Model Strategy. AMIA 2014 Joint Summits on Translational Science, March 23-27, 2015, San Francisco, California.

[11] For example, if the Census chooses to examine its distinction between race and ethnicity, these individual fields may change over time, but their membership in the demographic domain will be predictable; see http://www.pewresearch.org/fact-tank/2014/03/14/u-s-census-looking-at-big-changes-in-how-it-asks-about-race-and-ethnicity/

- “Sex” is different from the linkage discussion (page 93), which lists “Gender”; this distinction is very important, and it is not clear how the Common Clinical Data Set is positioned, including the special considerations of gender identity and biological sex.
- We recommend disambiguating “Medications,” which is a very broad category that includes multiple, disparate data-generating activities that should not be confused. We suggest that four medication-related domains should be assessed:
    1. Prescribing: Provider orders for medication prescriptions, which may include Computerized Provider Order Entry (CPOE) workflows
    2. Medication Administration: Medications filled and administered directly within a healthcare setting, generally within an inpatient hospital context; may include the eMAR (electronic Medication Administration Record) and/or barcode scanning
    3. Medication Reconciliation, also known as the active medication list: The review of active medications with a patient, normally led by a nurse or provider
    4. Dispensing: Specifically outpatient pharmacy dispensing, such as prescriptions filled through a neighborhood pharmacy with a claim paid by an insurer; not commonly captured within healthcare systems, and not to be confused with medications that are filled by inpatient pharmacy units and administered within a healthcare setting
- The two items related to laboratory data are somewhat unspecific, and in the “Laboratory value(s)/result(s)” item, it is not clear why there is a distinction between values and results. We suggest that two laboratory-related domains should be assessed:
    1. Laboratory Test Orders: Provider orders for laboratory testing, which may include Computerized Provider Order Entry (CPOE) workflows
    2. Laboratory Test Results: The actual quantitative and qualitative measurements returned from blood and other body specimens

3. Patient-Generated Health Data

Although the Interoperability Roadmap emphasizes patient-centeredness as being integral, we were disappointed to find that Patient-Reported Outcomes (PROs) were not included in the Common Clinical Data Set[12]. This lack of patient-generated perceptions and outcomes is a missed opportunity. Although some domains may be patient-initiated (such as vital sign data generated by personal devices), the direct voice of the patient is not represented in the current clinical domains.

Well-developed and validated instruments for measuring the patient experience are vitally important, especially given the expertise needed to create appropriate measures that support patients with variable levels of reading ability, health literacy, and numeracy. The Patient Reported Outcomes Measurement Information System (PROMIS) libraries[13] are a key resource for these measures, and the Interoperability Roadmap can help to foster an acknowledgement of their importance and role in a Learning Health System.

We recommend that the Interoperability Roadmap consider the role of patient-centered data instrument development. Perhaps organizations fostering such activity would be analogous to the role of Standards-Development Organizations (SDOs), and appropriate for more prominent placement.

4. Role of Administrative Data

Page 10 of the Interoperability Roadmap states, “The intersection of clinical and administrative electronic health information is a critical consideration, but is out of scope for the Roadmap at this particular time.”

However, this distinction does not reflect the underlying data-generating activities. For example, data associated with the Procedures domain (listed in the Common Clinical Data Set) will be heavily driven by reimbursement-related workflows, and some EHR systems may not contain a clear distinction between the clinical data and administrative data. Our experience is that encounter-level diagnosis codes assigned by medical coders are also frequently used by clinical research, despite being generated by administrative data-generating activities.

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[12] We might assume that patient-reported pain scores (the “fifth vital”) would be included in the Vital Signs domain, although this is not explicit.

[13] http://www.nihpromis.org/

5. Biospecimens and Biobanking

The Interoperability Roadmap provides an opportunity to support development related to interoperability supporting biospecimens and biobanking activities. Although this infrastructure is still maturing, projects such as the Precision Medicine Initiative[14] demonstrate the potential applications and importance of developing this capacity. Although lab results are emphasized in the Common Clinical Data Set, the larger infrastructure related to Laboratory Information Management System (LIMS) functionality is not addressed, as well as potential extensibility to biospecimens and biobanks.

6. Mortality Data

Patient mortality is one of the most important endpoints in both research and clinical analytics, but unless the patient dies in the hospital or en route, clinical data systems generally do not capture mortality. Moreover, routine access to morality data sources, such as state-level vital statistics data sources or national-level stores like the National Death Index (NDI), may be limited. In the theme of interoperability between sources, we encourage an assessment of how these mortality data can be made more readily available to support Learning Health Systems.

7. Linkage and Evolving Models of Consent

Pages 92-95 of the Interoperability Roadmap contain a detailed discussion of issues related to individual patient-level linkage. We are glad to see emphasis of this concept and its key role in patient-centered health interoperability, which is also often a factor for research-related activities. It would be helpful to provide a more detailed assessment of implications related to patient and business privacy and security in the exchange of individually identifiable data elements.

Many patients receive care from multiple healthcare systems. To function optimally, a learning health system should be aware of all information that is available on a patient, not just the data from a single health system. As a result, the Interoperability Roadmap should consider models of consent where a patient could agree to share all of their information for a given project, as opposed to the current model, which would require a separate consent decision with each healthcare system with which they have a record.

It will also be helpful to consider the situations where encounter-level linkage will be an important consideration for quality of care. Although this consideration may be more pertinent in situations where EHR and claims data sources are integrated, it is worth noting that such linkage may also be performed without using direct identifiers.[15]

8. Data Transport

The Interoperability Roadmap emphasizes the development of consistent, secure transport techniques. However, attention to the state of "data at rest" is also essential. Intra-institutional use of data stores for clinical care, population health management, and research, should be recognized as an inherently valuable and productive activity that is an integral component of interoperability and benefit to the Learning Health System. "Data at rest" in data stores securely held behind institutional firewalls is also a focus of the federated querying methods used by many distributed research networks.

Interoperability instilled by data transport is an important mechanism, but cannot be considered to be a complete solution. More emphasis on robust source data solutions would have exponentially great efficiency and benefit to interoperability at all levels.

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[14] http://www.nih.gov/precisionmedicine/

[15] Hammill BG, Hernandez AF, Peterson ED, Fonarow GC, Schulman KA, Curtis LH. Linking inpatient clinical registry data to Medicare claims data using indirect identifiers. Am Heart J. 2009 Jun;157(6):995-1000. http://www.ncbi.nlm.nih.gov/pubmed/19464409

9. Pressures of Conformity

Interoperability creates an important impetus for improving our national infrastructure, but can also create pressures to comply without addressing underlying root cause issues. Transforming low-fidelity data into high-resolution standards does not improve the data quality, and can actually result in loss of data provenance and the introduction of new errors.

A careful approach to compliance assessment and certification is important for the scope of the Interoperability Roadmap. Recognition of data quality issues and root cause analysis is integral to fostering a culture of quality data and infrastructure development, including the full assessment of all factors including clinical workflows, data entry practices, vendor software platforms, and administrator implementation decisions.

10. Longitudinal Record and Legacy Data

As new standards and systems are implemented in healthcare systems, it is challenging to maintain a longitudinal record, given that legacy data may be collected in ways that do not conform to new standards, or terminologies. These longitudinal data can be especially important for research purposes.

In the letter from the National Coordinator, we were pleased to see an evocative description of this concept as "long' data (wrapping around the individual and telling their health story over time)" (page 4). The Interoperability Roadmap does not appear to address this consideration in great detail, but we suggest that this may be an opportunity to describe appropriate management of legacy data, with methods that do not force transformation of the data in manners incompatible with the original collection. To that end, any transmission mechanisms should include the detail on the "completeness" of a patient's record that is available over an interface, for example, whether the healthcare system contains additional information that is available on a patient.

11. Asking the Questions That Matter

The development of technical infrastructure is an important activity, but we're glad to see emphasis in the Interoperability Roadmap on ultimate benefit to the individual patients. We believe that this approach is very compatible with initiatives like PCORnet[16], which emphasizes "explor[ing] the questions that matter most to patients and their families"[17].

The 56 priority interoperability use cases listed in Appendix H (pages 163-166) is an intriguing mechanism for framing development priorities. We noted that research is not well-represented in this listing although #15 states, "Researchers are able to use de-identified clinical and claims data from multiple sources with robust identity integrity." We recommend expanding the list to include additional high-value research use cases with synergies with distributed research network emphasis.

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[16] Fleurence RL, Curtis LH, Califf RM, Platt R, Selby JV, Brown JS. Launching PCORnet, a national patient-centered clinical research network. J Am Med Inform Assoc. 2014 Jul-Aug;21(4):578-82. http://www.ncbi.nlm.nih.gov/pubmed/24821743

[17] http://www.pcornet.org/why-pcornet-exists/

Summary

The ONC Interoperability Roadmap has the potential to strengthen the capture and management of data generated in the care of patients, which will in turn benefit the analytic use of these data for projects such as PCORnet. We appreciate the thoughtful approach that is evident in this document, and are grateful for the opportunity to review.

Authors

Lesley Curtis, PhD
Professor, Duke University School of Medicine

Jeff Brown, PhD
Associate Professor, Harvard Medical School and the Harvard Pilgrim Health Care Institute

Shelley Rusincovitch
Project Leader in Applied Informatics, Duke Translational Medicine Institute

Richard Platt, MD, MSc
Professor, Harvard Medical School and the Harvard Pilgrim Health Care Institute

Keith Marsolo, PhD
Associate Professor, Cincinnati Children’s Hospital Medical Center and University of Cincinnati College of Medicine

Aaron Sorensen, MA
Director of Informatics, Temple University School of Medicine

Jon Puro, MHA
Senior Research Information Architect, OCHIN, Inc.

Pedro Rivera, MS
Research Programmer Analyst, OCHIN, Inc.

W. Ed Hammond, PhD
Professor, Duke University School of Medicine

Eliel Oliveira, MBA, MS
Associate Director of IS & Analytics, Louisiana Public Health Institute (LPHI)

Rahul Jain, MPH, CPHIMS
Digital Health Analytics Manager, Louisiana Public Health Institute (LPHI)