Response to ONC 2016 Standards Advisory: A PRO Perspective
Public comments submitted on April 24, 2016

Introduction

The Office of the National Coordinator for Health Information Technology (ONC) has opened a public comment period[1] for the 2016 Interoperability Standards Advisory document[2] in preparation for developing the 2017 advisory.

We appreciate the opportunity to provide our feedback, which we hope compliments earlier responses[3]. These comments represent the individual views of the authors. 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.

Patient-Reported Outcomes (PROs) in the Standards Advisory

The Standards Advisory is important for a national Learning Health System (LHS)
The ONC Standards Advisory is very important to the development of a national learning health system. Because these standards are targeted to clinical system implementation, they also have a critical impact on all downstream uses of these data, including population health improvement and research to benefit patients[4]. Standards are a key driver of data collection practices, structuring, semantic compliance, and syntactic interoperability.

A core standard does not exist for PROs in healthcare
A category does not exist for PROs in the 2016 Interoperability Standards Advisory. This reflect the current reality: health systems who desire to collect PROs do not have a clear mechanism for best practices in use of validated instruments that are well-suited for comparison across multiple institutions and regions.

This lack of standard can be manifested in PROs being collected in similar but not consistent ways, leading to issues in ensuring appropriateness of comparability, and barriers to more large-scale adoption.

PROMIS is already a key resource and investment
PROMIS (the Patient Reported Outcomes Measurement Information System)[5] is a repository of measures is so valuable that it warrants a cross-over into healthcare standards terminology.

PROMIS measures (like nearly all health surveys) are copyrighted. This technically makes them not in the "Public Domain" similar to a measure that requires a license or that has a patent. However, copyright is less restrictive and is to protect the intellectual integrity of the measure so that others cannot come along and revise the questions and call it "PROMIS". It should be made clear that copyright is not an obstacle to free use of PROMIS measures, because the will of the copyright holder in the PROMIS copyright notices grant free use of the measures.

PROMIS is one of the few freely available modern instruments that we can use without a licensing fee and contracting process.

If there is a downside to PROMIS it is that the FDA has not accepted it as means of demonstrating efficacy for drug trials because the items are generic and not disease specific. That said, the PROMIS researchers are working hard to get the FDA to approve PROMIS measures for efficacy studies. One advantage of PROMIS is that it is based on item-response theory rather than the 1st generation "Domain Sampling Model." With Item Response theory, each item is scaled in a way that it is able to contribute to the understanding of an individual's true location on the continuum of a construct with varied precision across the full construct. In addition to using the standard short forms or computer adaptive instruments, researchers are free to pick and choose items in particular symptom or problem areas without having to use the whole

[1] https://www.healthit.gov/standards-advisory/2016, accessed 2016-02-21.
[2] https://www.healthit.gov/sites/default/files/2016-interoperability-standards-advisory-final-508.pdf, retrieved 2016-02-21.
[3] Several members of this group contributed to comments on the draft Interoperability Roadmap v1.0 and 2015 draft Standards Advisory; please see https://github.com/CDMFORUM/CDM-GUIDANCE/wiki/CDM-related-Public-Reponses
[4] This includes, but is not limited to, Comparative Effectiveness Research (CER) and pragmatic clinical trials.
[5] http://www.nihpromis.org/

measure and can pick items that provide the most information (order respondents well across the population). Non-item-response theory measures do not have this capability.

What about LOINC and SNOMED?
LOINC and SNOMED are important mechanisms for consistent representation of such data where they are collected; however, they do not take the place of a strong PRO standard to facilitate systematic collection of measures and ensuring consistency, generalizability, and best practices across multiple settings. These areas include the validated items, response, options, and quantitative characteristics about item properties (i.e., item difficulty, item information, scoring). There are also a myriad of contextual metadata that go into the environment of measurement (e.g., time of day measure was given, who was the examiner, was it completed on paper or by computer, what item proceeded the item being answered now).

Experiences from the PCORnet Common Data Model (CDM)

We incorporated PROs into development of the PCORnet CDM v2.0 in winter 2014/spring 2015. A key activity in this scope was the assessment and recommendations for a core set of PCORnet "Common Measures" for PRO data collection.

Jason Doctor chaired the data modeling committee for the PRO Task Force led by Amy Abernathy and worked with David Cella to recommend adoption of items by data partners and a simple set of tables and LOINC codes to represent item metadata. We were very constrained with time and PCORnet data model limitations, but were successful in recommending a handful of items for adoption and produced a simple addition to the PCORnet data model.

Although the development of the PRO Common Measures allowed us to delineate a set of measures that would be consistently defined for the PCORnet "network of networks," the experience also led us to recognize a set of important issues.

Key barriers
1. Given lack of consistency in source data collection, harmonization of common measures has led to concerns in the quality of such data.
2. Burden of project-specific prospective data collection where institutional adoption has not taken place.
3. Lack of guidance for health systems who would like to deploy validated, generalizable measures.
4. Inefficiency in current implementation and deployment.

Related areas
We expect that these barriers and issues may also apply to emerging areas of patient-generated data, both device-mediated and direct response.

Related areas include patient privacy and engagement, but without the rigor of a standard, these areas remain without a clear mode of application.

Conclusions

The lack of a core PRO ontology is a barrier for best practices in PRO data collection and generalizability across health systems. The ONC Standards Advisory has the potential to promote recognition of this important issue.

Our experiences lead us to believe that many health systems would like to more systematically collect PROs in clinical practice, but encounter a key barrier: the lack of formal, recognized, and acknowledged standard in this area. Although these experiences are often anecdotal and do not represent a systematic survey, we believe that our membership allows expert opinion to inform this area.

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