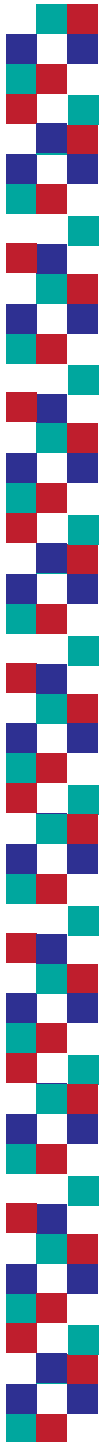


PRO Core Update

Kevin Weinfurt, PhD
Duke Clinical Research Institute
August 19th 2014

The Collaboratory



Purpose of the PRO Core

- The PRO Core was established to help researchers to identify opportunities for collection and assessment of patient reported outcomes (PRO) within Collaboratory projects.
- To give guidance to researchers on PRO data collection, with regards to the 4 major issues in PRO data collection:
 - Addressing IT infrastructure software/hardware issues
 - Choosing appropriate instruments for PRO data collection
 - Defining how to integrate their research and collection in the care process in a meaningful appropriate way.
 - Preparing for real-time reporting/analytic feed, as well as statistical analysis of PRO data



Review of Year 1

1. Documented PRO data collection capabilities of UH2

- Used proposals and later communications to create a Use Case portfolio for all current UH-2 projects
 - Included: PROs measures being used, process of data collection and likely issues

2. Landscape summary of successful PRO implementation

- Months reviewing recent literature and conducting formal and informal interviews regarding the use and implementation of PROs for clinical care.

3. On-site Investigations

- “On the ground” review of how PRO data collection activities are being implemented in various settings.
- Focused on healthcare systems/institutions that have successfully established processes for routine collection of PRO data.

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Review of Year 1

4. PRO/PROMIS Workshop

- Expressed need for Core to be a leader in identifying knowledge gaps PROs could fill.
- Began planning 1 day meeting workshop (~30 participants)
- The intention of the workshop was to address state of PRO use in clinic settings, with focus on PROMIS measures.
 - Includes:
 - Show impact of PRO data/implementation on clinical outcomes.
 - Address areas where PROMIS/ current PRO instruments work well/do not work at all/ effect can not be ascertained and explain why.
 - Highlight best methods for using PROs in clinical care/research.
 - Demonstrate superior data/analytics use of PROs/PROMIS.

Review of Year 1

5. Generalizable knowledge about PROs and useful resource links distributed via the HCS Collaboratory Living Textbook



The Collaboratory



Progress in Year 2

1. Two papers in progress^{*}

- **Article on titled “*Practical Guide to Initiating and Implementing Patient Reported Outcomes Measures*” written for eGEMs special issue**
 - Product of the past year of literature review, formal and informal interviews, and on-site visits.
 - Article documents real-world solutions for ePRO implementation from strategies for early end-user involvement to understanding and assessing data for completeness and consistency.
 - Submission planned for August 27th. Reviewed by the C3PC Committee. Final revisions in progress
- **White paper titled “*Strategies for Overcoming Barriers to the Implementation of Patient Reported Outcomes Measures*”**
 - Product of the past year of literature review, formal and informal interviews, and on-site visits.
 - Article examines barriers to PRO use in the routine clinical setting from the clinician, administrator, and patient perspective (e.g. clogging workflow) and provides real-world solutions.



Progress in Year 2

2. PROMIS Workshop

- **Goal:** to identify current gaps in knowledge regarding the use of PROMIS and other PRO tools to provide PRO data relevant for clinical care as well as for comparative effectiveness research.
- Meeting planned for early January.
- Agenda proposed and several presenters identified
- Scouting location

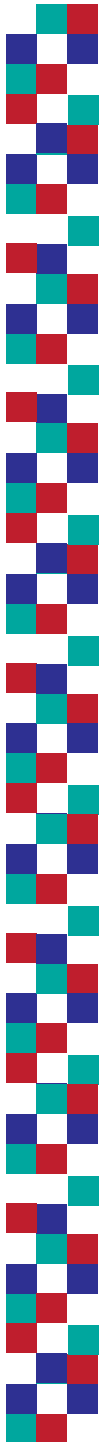
3. Continued contributions to HCS Collaboratory Living Textbook

- Added new material on NIH Toolbox, NeuroQOL, and PROMIS.
 - E.g. PROMIS APIs and videos
- Plans to add blog posts about barriers and facilitators to PRO implementation



Other Ongoing Activities

- **UH2 Projects**
 - Review PRO Data Collection Capabilities in Current UH2 Projects
 - Develop PRO Plans in collaboration with UH2 Projects
- **UH3 Projects**
 - Work together with UH3 projects to finalize plans for implementing PRO data collection in the studies
 - Development and initiation of plans for monitoring missing PRO data
 - Develop an overview of PRO-related issues recommendations
- ***Core hosts monthly calls and monitors Issue Tracker biweekly***



Engagement with UH2 PIs and Expectations

- **Continues to offer expert advice and technical assistance**
 - Including: support with PRO implementation, measure selection and/or development, etc.
 - Help developing PRO plans and shoring up PRO data collection capabilities
- **PRO Core expectations from UH2/UH3 groups**
 - Foster open lines of communication between Core and project leaders
 - Participation of project representative on monthly calls
 - Contribute to data gathering and publications when appropriate (e.g. real-world experiences)