

Cerebral Palsy Research Network Meeting Minutes

Monday, February 22 and Tuesday, February 23, 2016

via Teleconference

Attending Monday: Amy Bailes, Kristie Bjornson, Pritha Dalal, Marcia Greenberg, Paul Gross, Ed Hurvitz, Jeff Leonard, Christopher Lunsford, Garey Noritz, Jerry Oakes, Bill Oppenheim, Ben Shore, Michele Shusterman

Attending Tuesday: Nancy Clegg, Paul Gross, Aga Lewelt, Freeman Miller, Dennis Matthews, Allison Oki, Ken Rogers, Brandon Roque, Debbie Thorpe, Amy Viehoever

Action Items:

All: If you have not completed your acceptance letter, please do so and send by email with a PDF to paul@cpresearch.net by March 1. Please name your alternate PI in that letter or email before then.

Nancy: Email intro of Lawson Copley to Paul.

Paul: Connect Nationwide Epic effort with Epic Corporate.
Send link on [Pediatric Research Alliance](#) about reliance IRBs.
Determine if we can start the Business Associates Agreement process in parallel.
[Send out or post New York Times article on sharing patient data.](#)
Send technical plan from DCC for sites when ready.
Distribute Patient Reported Outcomes survey data.

Agenda/Notes:

Call Playback: Playback Number: (605) 562-0029 Access Code: 881-975-274# Reference #15 (Monday) #16 (Tuesday)

Monday Playback Download MP3: <https://www.dropbox.com/s/uyclmzqb4kn736s/CPRN-Investigator-Kickoff-20160222.mp3?dl=0>

Tuesday Playback Download MP3 <https://www.dropbox.com/s/ydhnr50f9i9n2jz/cprn-investigator-kickoff2-20160223.mp3?dl=0>

Roll Call (10 min) — If you want to know more about your peers in CPRN, you can read about them on the [Investigator Committee page](#) on the CPRN site.

Status and Direction (25 min) — overview of where we are and where we are going (milestones/key deliverables)

- Quick summary of background – See <http://www.cpresearch.net> for information.
- Status of Registry ([Common Data Model](#), REDCap Forms, Epic Forms, Patient Reported Outcomes)

Everyone who has not participated in the creation/review of the Common Data Model (CDM) should. These have been shared with the AACPD/M/NINDS CDE effort.

The REDCap forms are 80%+ done and will be shared as an additional mechanism to review the data elements as they will be deployed. QUESTION: Which will we use? ANSWER: REDCap forms have been developed both as a test bench as well as to provide sites not ready for EMR based forms to participate in the registry by allocating their own clinical research assistant. Epic / Cerner sites are not required to use the REDCap forms but may want to share them with their IT staff to get a sense of the scope of the effort in the EMR.

Nationwide review of CDM relative to their existing forms is progressing but taking longer than anticipated. Garey Noritz conveyed that once complete the process to create the new forms should not take long. The Nationwide CMIO has estimated that it would take approximately two months to develop the new forms. Ben Shore of Boston Children's Hospital indicated that the approval process for creating Cerner forms is moving forward. Kristie Bjornson stated that Dr. McGuire of Seattle Children's had been in touch with Boston Children's to discuss collaboration.

Ken Rogers of Al duPont gave an update on their forms effort. They have decided not to do it locally and have given the CPRN Common Data Model to the Pediatric Orthopedic Steering Committee led by Lawson Copley of Texas Scottish Rite. This group is working with Epic to build a version of the CPRN registry into Epic Foundation. The goal is for this work to be complete in October. QUESTION: What percentage of the CPRN data model is being implemented? ANSWER: Nancy Clegg, who sits on the committee, said that 100% of it is being implemented. Paul asked Nancy to introduce him to Lawson Copley. QUESTION: If getting my orthopedic surgeon on board with the CPRN forms is a challenge, would this effort help convince him/her? ANSWER: Maybe. Please don't hesitate to ask for help with introductions to other orthopedic leaders who are committed to this change in practice.

Patient Reported Outcomes (PRO) represent a significant number of elements in the CDM. PRO collection is quite varied at participating sites (Paul distributed results from a site survey). Nationwide has agreed to build multiple collection methods for these (MyChart patient portal in Epic and provider interview based). REDCap versions of primary outcome measures, CP-Child and GOAL, are already built in REDCap courtesy of Unni Narayanan and SickKids.

CPRN has selected Patient Crossroads for a patient powered registry. The adult registry questions, primarily PROs, will be built first into the CPRN Patient Powered Registry.

- IRB protocol (plan/timeline/outstanding issues)

The goal is to have a single IRB Protocol that can be used for submission at each site. Nationwide will be the IRB of record for sites that support reliance IRBs (all PEDSNet sites have subscribed to the reliance IRB model). Garey Noritz emphasized the ease of submission in these cases (took five minutes for a Cincinnati study to be submitted at Nationwide.)

We are debating the advantages and disadvantages of requesting waived consent in the IRB as well as the role that QI will play in the registries initial implementation. The leadership team will resolve this and have an IRB protocol later in March. Sites that do not support the reliance IRB model will submit to their own IRB. If waived consent is written into the protocol, sites will have an option for informed consent for their site. Nationwide Children's has this today for their Learn from Every Patient registry and 95% of the clinic patients consent to share their data. QUESTION: Will the system

support using flowsheets with patients that do not consent? ANSWER: Yes. The flowsheet can indicate the consent status for filtering from extraction for the registry. Flowsheets / forms are used regardless of consent.

- Registry pilot

The CPRN registry pilot is the core initiative of this phase of CPRN and for you as charter members. IRB submission will be the next key step. We anticipate Epic forms being ready for integration in the coming months. REDCap forms will be ready imminently for sites that plan to start with collection outside of their EMR. Data extraction and transmission plans have been developed by the DCC. This plan will be available to share with your IT staff shortly.

QUESTION: Will there be separate forms for PM&R and developmental pediatricians? ANSWER: There are single sets of forms based on areas of data collection that will be filled out by appropriate providers. You can the CDM indications for which fields can be filled out multiple times. Any field that can be filled out by multiple providers will either have a transformation (best answer, average, etc.) or multiple answers will be stored.

QUESTION: Who will clean the data? ANSWER: The data, intended to be collected as a sparse matrix, has many fixed field types that will reduce the need for cleaning. The DCC will present an extraction and transformation specification for the sites to use when pulling data from the EMR. Additional mechanisms for transformation and quality assurance will be done at the DCC so data cleaning will happen at multiple stages. Part of the pilot process is to sort out any issues with data cleaning and transformation.

QUESTION: Can we get the Business Associates Agreement going in parallel? ANSWER: Most likely. Many have BAA agreements in place with University of Utah already from PECARN, CPCCRN, and HCRN networks. Paul will explore if this can be done in parallel.

QUESTION: Have others had difficult experiences with getting IT onboard? ANSWER: Al duPont shared their broader experience leveraging tablets for PROs and found it difficult. CPRN is attempting a simpler solution.

QUESTION: Can alternate PIs or others listen in on calls? Yes though the calls are available for audio playback or download (see top of notes).

- Face to face meeting (research and quality agenda setting)

We will plan a face to face meeting for the Investigator Committee over the coming months. The goals for the meeting will be to set the research and quality agenda for CPRN as well as to enhance the collaboration efforts of the network. The meeting will be a 1.5 day format. Paul will poll for best dates in the coming weeks.

- PCORI / NIH applications

We are processing the revisions necessary to the PCORI grant for resubmission. The next cycle begins with a letter of intent on May 4. We will request additional information about your CP practice to sharpen the preliminary data for the application with regard to etiology of CP, indications and interventions. No action required at this stage.

We have also been in dialogue with NINDS and NICHD both of which have expressed interest in this study area. We are working to determine if an application can be developed for the May submission or the September submission dates.

- Additional center wait list

There are 10 additional centers (counting Shriners as "one") that have expressed interest in joining CPRN. They are at various stages of readiness. All of our meeting minutes and deliverables will be made available to them to follow along for our next opportunity to open up participation. All calls are recorded and will be shared along with meeting minutes and deliverables.

Next Deliverables (1 min) – Acceptance letters are due on March 1. The goal of this letter is to make sure there is acknowledged buy-in from both your practice partners and your CMIO. If additional conversations are needed with your CMIO, please contact Paul to arrange. Please also indicate who your alternate PI will be and provide his/her email address. We will also be providing a modified version of the CPRN logo for you to include on your website. The next call will be scheduled later in March. We will also be setting up additional tools such as Basecamp for collaboration within the group.

Q&A / Discussion – Q&A was integrated throughout the call.