

CoULD Newsletter

PHSG Philadelphia

Feb 25th 2017

Progress Report

CoULD PURPOSE

“To describe epidemiology, clinical characteristics, and health status of children with congenital upper limb differences, as well as quantify changes to function and health status with non-operative and surgical care”.

Recruitment:

We have 1186 participants due to the efforts of 5 sites (Table 1). Longitudinal arm has 87.2% and demographic arm 12% of participants. Boston Children’s hospital with 57%, St. Louis 26%, Seattle 13%, Nationwide 3%, Gillette’s 1%.

Table 1. Enrollment counts

Enrollment	Longitudinal arm	Demographic arm	Total
BCH	554	119	673
St. Louis	306	7	313
Seattle	130	23	153
Nationwide	36	3	39
Gillette	8	0	8
	1034	152	1186

Table 2. Form completion by center

Baseline	Baseline		Longitudinal Follow up			Surgery				
	Baseline	Arm A	Arm B	clinical visit-MD form						
screening and OMT	Complete	Incomplete/unverified	Complete	Incomplete/unverified	Total	Complete	Incomplete/unverified	Total	% completion	Total
St Louis	272	34	7	0	313	148	68	216	69%	100
Seattle	95	35	23	0	153	0	2	2	0%	30
Nationwide	24	12	2	1	39	0	0	0	0	-
Gillette	7	2	0	0	9	0	0	0	0	-

* marked as complete

Form completion:

Screening forms marked as incomplete accounted for 20 (2.9%) in BCH, 34 (10.8%) in St. Louis, 35 (22.8%) in Seattle, 13 (33.3%) in Nationwide and 2 (22.2%) in Gillette Children’s Hospital.

Follow up visits are made at annual intervals by many methods, either during clinic visits where researcher places form in patient’s chart, over the phone asking about surgeries in the past or via email.

Surgeries:

Finally, a total of 287 surgical procedures have been documented. BCH had 157, St Louis 100 and Seattle entered 30 surgeries into REDCap.

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During this past year and a half, many patients have met annual deadlines mainly BCH and St. Louis as starting centers. A total of 608 follow up contacts have been made with families.

BCH has obtained 68% and St. Louis 69% response rate respectively.

Now that new centers are joining, maintaining a good system to collect follow ups is mandatory.

Committee structure

SUBCOMMITTEE CHARGES

DNA warehouse: Investigate the feasibility, cost, and practical steps to include genetic warehousing as a part of CoULD. Charges may include establishing list of phenotypes for which: 1) Genetics consultation or evaluation SHOULD be obtained (e.g. RLD and Fanconi's testing) 2) Established syndromes have been described and associations pursued (e.g thumb hypoplasia, Holt-Oram, cardiology evaluation).

Onboarding: Facilitate the onboarding of new CoULD sites. Charges include: a) assisting with IRB approval, b) assisting with Data Use Agreement (DUA) process, c) reaching out to "new" PI's, co-investigators, and research teams to assist with start-up (e.g., REDCap), d) participate in onboarding conference calls to review early pilot enrollments and classifications.

Data Cleaning: Oversee REDCap data to assure data completeness and integrity. Charges include: a) develop and oversee the process by which data from each participating center is entered into REDCap in a timely, accurate, and quality checked fashion, b) communicate with each Center's research support team/research assistant to streamline, troubleshoot, and clean data entered.

Table 3. CoULD subcommittee structure.

DNA Warehouse	Onboarding	Data cleaning	Consensus classification	Research	Marketing/advocacy	International
Samora	Bae	Steinman	Wall	Goldfarb	Goldfarb	James
Bae	Canizares	Mattioli	Van Heest	Samora	Bauer	Canizares
?	Roberts	Canizares	Popp	Bauer	Mattioli	Samora
?	Bohn	Roberts	Steinman	Van Heest	Bohn	Wall
		Moeller	James	Vuillermin	Manske	
				Bae		

Consensus Classification: Review applied classifications for patients at participating sites and lead discussions about revised/alternative/new classifications. Charges include: a) review cases that have been identified as being a challenge to classify and provide appropriate consensus classifications, b) identify conditions/phenotypes for which there are not appropriate OMT classifications and propose alternative classifications (or additions to the OMT).

Research: Oversee and guide scientific research and education related to CoULD. Charges include but are not limited to: a) finalize CoULD research guidelines (study proposal, authorship and publication guidelines -including definition of standards which must be met for investigators to

to have access to CoULD data), b) vet and provide feedback for study proposals, c) provide scientific and/or statistical support for ongoing study protocols, d) oversee CoULD research activities.

Communications/ Marketing/ Advocacy: Conceptualize, guide, execute, and oversee the interaction between CoULD and the public. Charges include: a) provide and distribute content about CoULD activities to professional societies, b) evaluate and recommend responses from CoULD regarding new research, news articles, public policies, etc, c) providing education and information to the public using different media, d) engage industry partners and other healthcare marketplace entities regarding

opportunities for collaboration, improved outcomes, and increased value-based care opportunities, e) help maintain high quality and unified messaging from individual CoULD organizations, f) advocating for the value of hand surgery and general pediatric health, g) consideration of improving accessibility of CoULD by lay public via website, Facebook, twitter, blogs, etc.

International: Investigate international sites for CoULD membership and work with other Committees to facilitate onboarding process. Charges include: a) identification of future potential CoULD sites, b) assist with the onboarding process (along with Onboarding Committee), c) Liaise with investigators/centers outside the United States.

Onboarding process

Next centers to join are Sacramento and St. Lake city. The former has submitted IRB and finalizing DUA. They will be on boarded in the following 2-3 months. The latter has received documentation and will start IRB and DUA process.

After these hospitals are incorporated, next center will be CHOP and Cincinnati if they still interested. For other centers might be useful to fill candidacy questionnaire to gain better understanding of existing resources.

