Boston: Donald Bae, Andrea Bauer, Fernanda Canizares, Ashley Tartarilla, Carley Vuillermin

Saint Louis: Charles Goldfarb, Lindley Wall Sarah Loving (Shriners), Summer Roberts

Seattle: Suzanne, Steinman, Viviana Bompadre, Nicole Strauss

Nationwide: Julie Samora, Jim Popp, Molly Duncan, Natasha Yanes

Gillette: Deb Bohn, Ann Van Heest, Jamie Price

Sacramento Shriners: Michelle James, Claire Manske, Kory Bettencourt, Nayla Hojman

Salt Lake City Primary: Doug Hutchinson, Jared Potter

CHOP: Apurva Shah, Ben Chang, Faris Fazel

Shriners Salt Lake City: Janice Davis

Mystery: nsy001

1. Update on CoULD progress

Enrollment has increased by 711 children since Jan 2019, 613 of which are participating in Arm A. Basic statistics such as median age of enrollment, mean age of participants, percentage of children classified with malformations of entire limb and hand plate, deformations, dysplasias and syndromes has remained strongly stable as enrollment has increased. The most common diagnosis recorded is now thumb deficiency, representing 8.5% of the participants. About 80% of the 1114 surgeries recorded are participants’ first surgeries. Second surgeries increased over the year from 13.7% to 15.7%.

Follow-up rates are declining, even for the younger participants. The PODCI completion rate for 3 year olds declined from 71% in 2019 to 35% in 2020. The window remains open for 38% of this age group and sites are encouraged to attempt to reach as many families as possible.

The lead centers continue to work towards automating the collection of follow-up data. As the database continues to grow, the number of children requiring questionnaires increases exponentially. For example, the number of 3 year olds requiring PODCIs has increased from 279 (in 2019) to 775.

Regarding the analysis of follow-up data rates, the current plan is to analyze data collected in windows that encompass the target ages. For example, the 3yr FU window will include questionnaires data collected between 2yr-3y11m.

1. Committee Updates
   1. Classification Update shared by Lindley Wall
      1. Dr. Wall gave an overview of the purpose of the committee and a reminder of how to refer cases when a PI is not absolutely clear about the diagnosis. In such situations, the PI indicates on the study form that they are uncertain or they do not think the diagnosis fits the classification system. The coordinator will mark the corresponding box in REDCap and save the form as “unverified.” The form will then be reviewed at the next committee meeting. Committee reviews take place 1-2 times/year in conjunction with a study group meeting. There are currently 5-7 cases awaiting review.
      2. Lessons learned from the CoULD database contributed to the recent revision of the OMT. Members of the CoULD Research and Classification committees collaborated with Kirby Oberg and others to propose a revision, recently published. Dr. Wall briefly reviewed the new OMT and some of the changes were highlighted. Dr. Wall directed the study group the published paper for more in depth details and discussion of the revision.
   2. Data Cleaning Update shared by Don Bae
      1. The Data Cleaning committee recently met with representation from nearly every site. As the incoming chair, Dr. Bae is working with Dr. Steinman to reinvigorate the data cleaning effort. Dr. Shah is welcomed as a new member. Dr. Bae reviewed the charges, emphasizing the importance of a plan that will produce data of high quality and integrity. Once an assignment is established, the plan will be for each site to cleanse 10% of their site’s data per quarter. The committee is renewing their effort to meet quarterly—PHSG & ASSH in person, and summer & winter via Zoom.
         1. ACTION ITEM: % to be determined.
   3. Marketing Update Shared by Chuck Goldfarb
      1. Dr. Goldfarb gave a brief tour of the kidshandregistry.com website, highlighting the new research page added for families. As soon as the final sites (Shriners, CHOP, Primary Children’s) have IRB approval for the website modification, the new page will be published for the public. Dr. Goldfarb also reviewed password-protected section of the website that houses information about submitting study proposals, submission forms and a list of studies completed, on-going and under review.
   4. International Update shared by Michelle James
      1. The International committee has had interactions with Dr. Marianne Arner, representing the Scandinavian group. The group expressed interest in collecting data that mirrors the CoULD registry for future comparison. In the last exchange, Dr. James provided a response to the Scandinavian’s concerns regarding CoULD data collection.
      2. Due to the continuing difficult situation in Nicaragua, the site is no longer under consideration as a location for collaboration. Dr. James remains optimistic the CoULD registry may expand internationally. She sees Shriners’ interest and effort to reach out internationally as a potential opportunity for us, especially in the Philippians (local support, ortho surgeons, huge volume of interesting pathology), Puerto Rico (Scott Kozin is in charge), or Brazil (many plastic and orthopedic surgeons). The International committee will monitor what infrastructure and resources develop over the next few years and keep us updated.
   5. Onboarding Update shared by Don Bae
      1. CHOP joined the group as few months ago. The study group really appreciates all of the effort, enthusiasm and resources added to the project.
      2. Salt Lake City Shriners has submitted an IRB application and will be onboarding this summer. Dr. Hutchinson will be the PI of this site.
      3. There is a running queue of interested sites. Due to the limitations of lack of funding, there are no plans to add more sites at this time.
   6. Research Update shared by Chuck Goldfarb
      1. Share Excel Spreadsheet with project, PI, and lead center
2. Genomics Opportunity (5 minutes)

Dr. Goldfarb is submitting a grant to Shriners to fund the genetic assessment of a subset of children in the database. Children with selected diagnoses from St. Louis Children’s Hospital, St. Louis Shriners and Shriners in Northern California-Sacramento will be included if the study is funded. Dr. Goldfarb is hopeful that if this grant is successful it will pave the way for future CoULD grants to perform genetic studies, a long-time goal of the study group.

1. Authorship guidelines. (15 minutes)

In this discussion lead by Dr. Goldfarb, revised authorship guidelines were discussed. Many in the group expressed that they value inclusivity and that contributions of as many people’s work as possible should be acknowledged.

Dr. Bauer shared that rules around authorship are variable between journals. CoULD Study Group should be listed on each paper that utilizes the database. Authors may designate members of the CoULD Study Group depending on the paper. There are valid reasons to push back again a journal to request more authors when the situation is justified.

There seemed to be general consensus that a good time to initiate authorship discussions might be after the second round of FINER when the numbers of participants have been assessed. The suggestion of the submitter circulating their approved proposal to all PIs via email to assess participation and authorship interest was also well received.

ACTION ITEM: Goldfarb to share updated instructions on authorship

Documents shared/reviewed

1. CoULD data update (numbers, etc) ppt
2. Data Cleaning Committee update ppt
3. New OMT
4. Updated Research List
5. Original authorship guidelines and new authorship guideline proposal