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# CoULD REGISTRY

**Congenital Upper Limb Differences Registry**

PHSG, Columbus

March, 2018

# Newsletter

*current topics >>>*

## Welcome New Centers

**Sacramento:**

After several months of anxious await, we were pleased to onboard Northern California Shriners Hospital for Children in the CoULD Registry in November 2017. Since the beginning they have impressed us with 72 enrollments in a very short time. We not only praise the volume, but the high quality of their work. We are extremely satisfied with the performance of this newly enrolled site under the direction of Dr. James in collaboration with Dr. Manske, Liz Molnar and Lauren Agatstein.

**University of Utah-Health Care:**

Our latest onboarding is still in process, but we are happy to report that by the end of the month we will complete the incorporation of Dr. Hutchinson and his team into the CoULD registry. We look forward to work with U. of Utah.

## Executive Committee

### A year in review

*Dr. Bae and Dr. Goldfarb, Please write a message for CoULD centers in intro of Newsletter.*

**STATS**

**Enrollment**

From last year we have increased enrollment from 1186 patients to a total of \_\_\_ patients today. Enrollment rate has decreased into what we believe is a stable and more realistic rate (Table 1). Enrollment visit completion rate: \_\_\_% (subjects completed all forms/total enrollments).

**Surgery:** \_\_\_ patients have had one surgery since study inception, \_\_\_ patients have more than 1 surgery. Surgical rate \_\_\_%.

**Follow up:** Considering patients that after a year of enrollment had at least 1 completed follow up. There was \_\_\_% of follow up completion rate.

**GRANT**

Unfortunately for a second year in a row we did not receive the Shriners grant, we were told again that were "very close". Not getting the grant meant that current and prospective centers have to continue normal operations under internal budgets. Initially being self-funded has worked fine for most of us, but for a few centers things are becoming more difficult, specially with coordinator's time and increasing complexity for long term follow ups. Considering sustainability challenges and increasing work load, we decided to modify the long term follow up timeline to reduce the burden for coordinators trying to reach out to patients that do not frequently come back to clinic (—> more on page 2).

**Table 1 (Needs update)**

Enrollment	Arm A	Arm B	Total
BCH			
St. Louis			
Seattle			
Nationwide			
Gillette			
Total			



**Shriners Hospitals  
for Children®  
Northern California**



**UNIVERSITY OF UTAH  
HEALTH CARE**

# CoULD v.2 –UPDATES

## FORMS

**1. Screening:** Diagnostic biopsy doesn't count as an exclusion criteria. Variables Added: Bimanual function in hand dominance, birth order. Family history, orthopedic and medical conditions branched into subcategories. Variables removed: Obesity and reasons for ultrasound referral.

**2. OMT:** Added: ID for MD filling form. Entire limb: clavicle absence and dysplasia; ulnar Madelung; pseudoarthrosis: clavicle, radius, ulna. Hand plate: camptodactyly, clinodactyly and Deformation: amniotic band classifications were broken down by finger. Deleted hand plate classifications that were included in entire limb: symbrachydactyly, ULD.

**3. Surgical form:** Added osteochondroma excision in all regions. Skin graft substitute.

**4. MD Clinical visit:** Added: was there OMT change? Deleted: Return for cast change from complication to general section.

## REDCap

- Screening form separated from OMT.

- OMT: New added classifications in new database will be blank and will need to be updated on a need basis.

- Arm A and arm B share same screening and OMT forms. Before different screening form for non-consents.

- PODCI adolescent parent different from PODCI pediatric parent.

- PROMIS: All domains were updated from v.1 to v.2, and in addition we added autoscoring short forms. We are saving data previously collected in the database in the same v.1 forms, but moving forward PROMIS v.2 will be the version that we will be using. Normative scores (means 50±) are comparable whether they were collected with v.1 or v.2. **(WU needs to confirm)**



## FOLLOW UP TIMELINE

Centers expressed concerns related to the amount of time coordinators were spending contacting patients that didn't return on an annual basis. For that reason it was decided:

- Patients that don't come to clinic annually: FU 3yo-5yo-8yo-11yo-14yo-17yo.

- Patients that come back: collect MD visit every year for 5 years and then e/3 years.

- Continue to collect postoperative questionnaires and MD visit form one year after surgery.

- 2yo PODCI doesn't seem useful (too many N/A), we decide to change the mandatory first PODCI to age 3.

## Current issues>>>



## Subcommittee's Work

**DNA WAREHOUSE** (Dr. Samora): No change. Next step: Determine charges and potential projects.

**ONBOARDING** (Dr. Bae): Assisted with onboarding of Sacramento and Utah. Next step: onboarding CHOP and determine who will be next center.

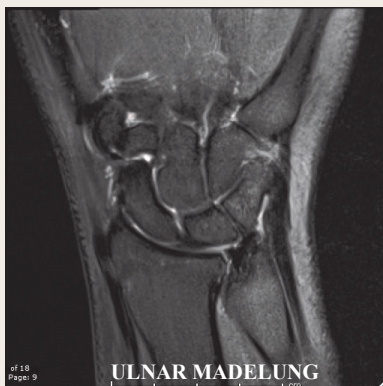
**DATA CLEANING:** (Dr. Steinman) Created data entry guidelines v.1 that are included in the new Manual of Operations (MOP). Next step: Update data cleaning guidelines, data cleaning supervision before a data is downloaded for analysis.

**CONSENSUS CLASSIFICATION:** Met at ASSH 2017 and classified patients that need consensus. Proposed changes to the OMT classification. Next step: implement mechanism for consensus classification on a regular basis.

**RESEARCH:** (Dr. Goldfarb) Created research guidelines that including study proposal, authorship and publication rules. Vetted studies: Adoption study, PROMIS vs. PODCI validation, symbrachydactyly.

**MARKETING & ADVOCACY:** (Dr. Goldfarb) Looking into website creation maybe under PHSG page. Updated brochure. Next step: implement website.

**INTERNATIONAL:** (Dr. James) No change. Next step: Create guidelines for onboarding international teams and connect with potential centers.



## Future...

### Studies:

- Adoption study: Wall (PI), Roberts, Goldfarb.
- PROMIS and PODCI: Wall (PI), Goldfarb, Roberts, Bae, Vuillermin
- Symbrachydactyly (lead Gillette)

### Centers:

**CHOP:** Offer current documents, forms, MOP and link with Legal department for DUA.

**Others have shown interest:** Colorado, Atlanta, Toronto, Australia, Spain. (coordinate with international committee).