



Region 4 Priority 2 Workgroup
Telemeeting Notes - Friday, November 21, 2008

Participating: Carolyn Anderson - Co-Lead, Susan Berry Co-Lead, Kristi Bentler, Darin Erickson, Anne Jurek, MN; Barb DeLuka, IL; Susie Romie, IN; Jan Askren, KY; Ayesha Ahmad, Jerry Feldman, MI; Nancy, Leslie, Shawn McCandless, Kim Regis, OH; Bill Rhead, WI; Jill Skrabel, NE; Sara Copeland, IA; Jill Shuger, HRSA; Sally Hiner, Region 4 Genetics Collaborative Coordinator.

I. IBEM-IS Participation Updates:

Sue updated on total enrollment to date: 47 subjects enrolled, 43 were MCADD

State/Lead	Center	Status
IL/Burton	Children's Memorial Hospital	No Report
	University of IL	No Report
	Rush University Medical Center	No Report
IN/Hainline	Riley Hospital for Children	Consented 14, none enrolled yet
KY/Gowans	University of KY	No Report
	University of Louisville (Askren)	Application development in process
MI/Feldman	Wayne State	Consenting, none entered to date
	University of MI	Trained
MN/Berry	University of MN	Enrolling all disorders for which data elements are in process - so have consented more than have entered; Done enrollment data for several, starting to add interval surveys
	Mayo	No Report
OH/ Leslie	Cincinnati Children's Hospital	Enrolling, none entered-to-date
	Case Western Reserve	IRB in process
	Nationwide Children's, Columbus	7 Consented, entering data on six of the 7; amended IRB to include phone consent and phone script to be able to contact and enter "in-actives"
	Akron	No Report
	Dayton	No Report
WI/Rhead	Waisman Center	No Report
	Medical Center of WI	IRB Approval, staff change,
NE/Skrabel	Nebraska	Developing IRB Application
IA/Copeland	University of Iowa	Developing IRB Application

Resources for IRB

- Kim Regis will forward her phone consent and script to Sally to post to the Region 4 Website.
- Anyone desiring IRB assistance should contact Sally (shiner@mphi.org)

Resources for Data Entry

- MN has discovered that using the paper visit planner to collect the data and then add it to the Registry later is quickest. We will continue to post the visit planners in pdf form on the Region 4 website so they can be accessed from the Region 4 Website

II. IBEM-IS Update - Building the Information System

A. No disorders have been added this month.

B. Disorder Pending:

a. Disorders which we have ready to add include:

- C5 Hydroxy
- Biotinidase
- C3

They will be added in the above order

b. Next to be finalized into final form for submitting to DocSite

- SCADD
- Carnitine update
- IBD

c. Disorders needing further input

- Glutaric Acidemia Type 1 – we are waiting on input on the neuro elements

d. Disorders needing finalizing by the group

- Tyrosynemia
- Galactosemia

This will be on the December Agenda

III. IBEM-IS Implementation

A. Issues and concerns

- 1 Question about MTC Oil – this question on the survey will be reworded to make sure it reflects our intent – want to differentiate when MTC oil is prescribed separately from the metabolic formula.
- 2 As questions/concerns arise or ambiguity is noted, please forward to Sally. (shiner@mphi.org)
- 3 Consents – permission for re-contact. A large number of individuals have not given consent to be re-contacted. It seems the forms may be from one institution. It may be that individuals really did want the “no” box checked, it may mean that the neither the yes or no box was checked. People are reminded to ask the question. Lack of response cannot be taken as consent, so by default must be assumed to be a “no” response. Being able to re-contact is essential for future cohort studies.

B. SOPs for Implementation

- 1 Reminder – IRB Renewals must be submitted to MPHI.
- 2 Data and information required for IRB Renewals – please submit requests for information to Sally. Information of interest to the broader group, such as number enrolled in entire project, will be posted on the Region 4 website so that in the future you will be able to access it without requesting.
- 3 Update on number/case entry for each participating site
 1. This is a reminder that we will be asking each site to report this data at a minimum of every six months.

C. Clinical State Lead Activities

1. Updates on involving other sites within state
 - i. No activity was reported
 - ii. Reminder – this is part of the Clinical State Lead Role and activity will need to be reported when invoicing for the honoraria.

IV. Region 4 Carryforward Request

Jill announced this has been approved and we should be receiving our Notice of Grant Award any day. Of interest to this workgroup, the following activities are funded:

- Support for the IRB process, including completing required forms. As the IBEM-IS expands (EHDI, additional IBEM D/O; and CAH/DSDs) more and more clinicians will be working through the IRB process, perhaps for the first time. MPHI will provide staff support to facilitate the process for all partners.
- Family Functioning and Chronic Disease Project - focus groups of families in 3-7 Region 4 states to gather qualitative data to be used to develop a survey tool
- Expanding our evaluation activities to measure change in practice resulting from Regional activities

Other activities to be supported with carryforward include:

- Case enrollment in the EHDI Registry
- Addition of CAH & DSD to the IBEM-IS
- State meetings on site with the Region 4 Staff Team
- Expanding 3 year follow-up of CH study to additional states
- Expansions of the modified second tier CAH screening protocol
- Adapt MEMSCIS for Sickle Cell, expand beyond IL
- Develop and conduct a survey of families of children with heritable disorders to assess families knowledge of and perceived need for genetic services
- Market and disseminate Region 4 products and best practice guidelines
- MS/MS training of one additional rep from each Region 4 NBS Lab at Mayo Clinic

V. Family Functioning and Chronic Disease Project

Darin will begin to develop an action plan.

VI. Expanding to include other Regions

Sally had a telemeeting with representatives from the Heartland Region and a series of follow up phone calls. The Heartland RC has requested use of carryforward to support clinician participation in the IBEM-IS. Out of the conversations with interested persons from this region, Sally developed and provided a document of FAQs. We have received contact information for 7 individuals in this region who will be participating. Several Heartland sites have already initiated the IRB application process.

VII. December meeting 12/19 –

Sally will poll the workgroup for RSVPs as requested by Sue.

VIII. Comments

A. NBS Symposium - Sue presented on the IBEM-IS at the APHL NBS Symposium in early November. The audience was primarily public health, not as many clinicians. There was a bit of interest in long term follow up, especially as it pertains to public health outcomes since these kids are identified through NBS. It

was a good opportunity for our work to be showcased. Especially since the workgroup has been struggling to foster the partnership between clinicians and public health – we both have the same goal of improved outcomes.

B. Meeting of National data group – The national data Group which ACMG has received funding to support held their first meeting in late October. The group will be working to facilitate national evaluations that will support long term follow up data. We are positioned well to participate because we already have a data collection mechanism

C. Jill Shuger reported that the Secretary's Advisory Committee on Heritable Disorders will be hosting a session on long-term follow-up during a regularly scheduled session this winter. CA, UT and the New England Region will be presenting. UT and NEW England have public health labs collecting the information from clinicians. They are CDC grantees whose goal is to expand the already in place birth – 3 registries to see if they can expand into long term follow up.

D. Jill Shuger noted that regions who are not yet participating in the IBEM-IS may consider writing the activity into their reapplication.

Notes by Hiner