



Region 4 Priority 2 Workgroup
Telemeeting Notes - Friday, February 20, 2009

Participating: Susan Berry Co-Lead, Carolyn Anderson, Co-Lead; Kristi Bentler, Anne Jurek, MN; Barb DeLuka, IL; Stephanie Gurnon, IN; Jan Askren, KY; Allison Bannick, MI; Nancy, Leslie, OH; Sandy vanCalcar, WI; Jill Skrabel, NE; Sally Hiner, Region 4 Genetics Collaborative Coordinator.

I. IBEM-IS Participation Updates:

- Anyone desiring IRB assistance should contact Sally (shiner@mphi.org)

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	No Report
KY/Gowans	University of KY	No Report
	University of Louisville (Askren)	Getting closer to complete application.
MI/Feldman	Wayne State	No report
	University of MI	No report
MN/Berry	University of MN	No change
	Mayo	No Report
OH/ Leslie	Cincinnati Children's Hospital	No change
	Case Western Reserve	IRB in process
	Nationwide Children's, Columbus	No Report
	Akron	No Report
	Dayton	No Report
WI/Rhead	Waisman Center - WI center #2	Awaiting IRB approval (Sandy vanCalcar)
	Medical Center of WI - WI center #1	No Report
NE/Skrabel	Nebraska	Working on application
IA/Copeland	University of Iowa	No report

II. IBEM-IS Update - Building the Information System

- A. Monthly Report: Sue provided a monthly report for the workgroup on IBEM-IS implementation progress. She revised the report to include the unique center identifier of the registry ID (last four numbers).

IRBs request an enrollment report for the reapplication. Generally, they require both the total number enrolled and the individual clinic enrollment numbers. For IRB purposes, consented = enrolled. Currently, we do not have a means to gather this information. We will be asking for it on a quarterly or bi-annual basis.

- B. Disorders Pending: DocSite is finalizing building of several surveys. No surveys were added this month. Sally will send out an email as surveys go live.
 - a. Disorders needing finalizing by the group
 - i. Glutaric Acidemia Type 1 – Kristi forwarded to DocSite for addition to the IBEM-IS following the Tuesday, January 20, 2009 deadline for additional comments.
 - ii. Galactosemia-
 - 1. enrollment survey during January meeting. Kristi requested clarification on a two items. Kristi will make changes agreed upon and will forward to DocSite for adding to the IBEM-IS.
 - 2. Interval survey. Nancy Leslie led the discussion on Handout 1. Kristi will make the changes agreed upon and forward to DocSite for inclusion.
 - iii. Tyrosinemia – Tabled until all of the interval surveys are completed for disorders for which enrollment surveys are already done.
 - iv. Biotinidase will be on agenda for March meeting. MN will take the lead on drafting elements.

III. IBEM-IS Implementation

A. Issues and concerns

- 1 Consents – Consents - permission for re-contact. A reminder that 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 be default must be assumed to be a “no” response. Being able to re-contact is essential for future cohort studies.

IV. Family Functioning and Chronic Disease Project

The state site visits are being used as an opportunity to conduct discussion groups with parents in each of the 7 Region 4 states to gain qualitative data on the impact of chronic disease on family functioning. Information will be provided to Darin to jump start identifying a research question or questions for further study. The Office for Human Research Protections (OHRP) has made ruling concerning focus groups. If the intent is to use data gathered to formulate questions for other data collection (e.g. survey development) then the activity is considered research. A regional application will be developed and submitted to MPHI IRB.

V. Engaging Department of Health Partners

Carolyn Anderson discussed the value of access to the data from a public health perspective. As the project has been evolving we have lost some of our public health representatives from active participation. We have two opportunities to re-engage these partners, or identify new partners. The first opportunity is that

there is data in the system DHS partners can be granted access to. The other is the round of state site visits scheduled where the IBEM-IS will be showcased.

Data for public health use is not considered research access. However, it is advantageous to identify the state DHS as having access. Keep this in mind to include in IRB re-applications and application revisions. Permissions can be set for public health that allow the person to see state data (not individual clinic data).

VI. Clinical State Lead Activities: The state site visits provide an opportunity to identify and solicit involvement of other genetic centers in your state. Please identify other specialists to be invited. P2 Workgroup members will be asked to lead the presentation on the P2 workgroup activities and the IBEM-IS. This is a good opportunity to extend the invitation to partner.

Sue offered to share slide shows she has used for presentations for workgroup members to modify for their presentation to their state partners during the site visits.

VII. Mountain States "care plans" meeting

Sue Berry has been invited by Mike Watusn (NCC & ACMG) to participate in this meeting scheduled for February 22 to develop minimal expectations for care. Representatives from most of the regions will be participating. Sue will ask for permission to share products that come out of the meeting.

VIII. MEMSCIS – tabled until March meeting due to lack of time.

IX. National Data Workgroup – Sue reported that it seems the intention is to have the IBEM-IS be the core data set for national data collection. More information will be provided as it becomes available.

X. Additional agenda items:

Through use of the IBEM-IS, Stephanie Gurnon has raised some questions. Reaching consensus on the responses to her questions will improve the quality of the data collected:

1. For item "Number of days of age from birth to age at initiative of intervention" – what is meant by *initiative of intervention*?

Consensus: It is not necessarily first face-to-face contact. It refers to the first contact (not necessarily first visit) to inform or share information to improve quality of care for the child.

2. Data on parents when the baby is adopted – is data entered data on the bio mom or the adopted mom?

Consensus – not reached. Leads will look at the screen shots and surveys to determine develop a recommendation for group consideration.

3. At what point is someone considered bi-racial (example, $\frac{3}{4}$ African America, $\frac{1}{2}$ Caucasian)

Consensus: DocSite already allows for this scenario. Options include "primarily... (race)"

The group will eventually need to decide how to make this Q & A information accessible and available.

XI. Announcements:

- A. Presentations – please report presentations you do about IBEM-Is. Let us know how we can help you prepare for presentations
- B. Next Meeting – March 20th 1 pm, CT / 2 pm ET
- C. Please enter/update your member information in the member registry www.region4genetics.org
- D. Rescheduling May meeting – if you have not already replied to the Doodle email, please do so. Decision re: reschedule data pending.

Notes by Hiner