

Priority 2 Workgroup Telemeeting Notes
Friday, June 18, 2010 @ 2 PM ET/1PM CT

I. Welcome & Roll Call (Berry, Members)

Participating: Barb DeLuka, IL; Kathy Wood, IN; Jerry Feldman, MI; Carolyn Anderson, Kristi Bentler, Sue Berry, MN; Sandy van Calcar, WI; Casey Mullins, OK; Jill Shugar, HRSA; Sally Hiner, Maria Ostrander, Region 4.

II. IBEM-IS Update

1. DocSite revisions/surveys available (Bentler)

Two M3HBA interval surveys have been revised and are now available. Most changes have been made, but there are still some clarifications from the national level that need to be incorporated. These changes will not affect the way in which data is input. A new list of surveys will be made available soon.

The Dialysis survey is now available.

Currently the Neuropsych and Dialysis surveys do not appear as managed conditions. Berry is working with DocSite to see how this can be improved. For now, clinics can print out an excel spread sheet to use as a paper guide when entering data.

Pregnancy data activity will be completed at the next visit.

Berry invited the group to contact her if they have questions related to site access, data entry, etc. She also added that R4 staff are available to assist them as well.

Hiner injected that the quick reference user guide has been updated to mirror what is on DocSite and that it is available on the R4 website.

2. Pregnancy Survey – Review of data elements (Handout 1) (Bentler/Members)

An older version of the pregnancy survey was attached to this month's agenda. As a result, this item has been tabled until the next meeting. Bentler will provide the survey with revisions recommended during the April workgroup meeting. This will be on July agenda.

3. IBEM-IS Reports

- **Intake/Interval Survey data (Handout 2) (Berry)**

Berry provided a summary of cases as represented in the graph provided to workgroup members. The data is steadily increasing as there is a regular accumulation of cases. Berry invited members to let her know if they would like to have this information in a different format, or to see other diseases referenced in/added to the report.

- **Consent/Decline/Withdraw Report (Handout 3) (Hiner/Ostrander)**

Hiner reported that some clinics are not reporting quarterly and reminded them that even if there are no changes, they need to inform Maria Ostrander by the given deadline.

- **Training participation (Berry/Ostrander)**

The most recent IBEM-IS training took place on Monday, 6/14/10. Participation was good, with 9 attendees. Berry encouraged participants to join in and see what's involved if they are considering IRB approval. For clinics that already are part of the collaborative, it provides a good review. Berry also informed the group that they were in the process of preparing a webinar version of this training as an on-line reference tool.

III. National Update (Berry/Hiner)

1. NBSTRN (Berry)

Berry informed the group that they are continuing to work on defining both general and disease-specific data elements. They are reviewing and refining data sets that already exist. Berry shared with the group that she remains very confident the data collected in the collaborative will be very closely representative of what will be in the national dataset. Long-term follow-up for disease-specific activities remains ongoing and progress has been good. Berry has been working closely w/ Janet Thomas from the Mountain States Region to complete additional data sets, allowing for a smoother segue into ones where we do not currently have planned, data-collection forms.

2. Secretary's Advisory Committee (SAC) Long-term Follow-Up Subcommittee (Berry)

The SAC is working to develop overarching questions for data collection, and that long-term follow up data should address. Berry continues to work with stakeholders to ensure that the data sets we have capture data elements that will allow us to answer these overarching questions. She does not anticipate that this will be a problem or that the collaborative will have to gather a lot of data

elements. The project is moving quite nicely. A white paper that helps clarify what the goals are for long-term follow up will likely follow. Jill Shugar noted that the National Committee on Quality Assurance is charged with drafting this document. The committee is looking to develop some quality measures to accompany the overarching questions. Data elements will have to be able to answer to those quality measure questions. They are working with the Translational Information Network to review the language attached to those data elements. R4 work will be strongly reflected in the processes.

3. R01 (Berry)

Berry provided the group with an update on the status of the RO1 grant opportunity. The RO1 is not explicit, which makes it difficult to know what will be favored by the reviewers. MPHI, on behalf of Region 4 and the University of Minnesota will be submitting a proposal. Also, the FAOD group we have submitted collaborative proposals for funding with before feels their application could be complemented by work we are doing in R4. R4 will be written into the FAOD Consortium proposals. These represent both different goals and different opportunities, but Berry conveyed to the group that pursuit of the funding both as an expansion of Region 4 and as a partner with FAOD did not have to be competitive. She sees this as an opportunity to extend the project and secure additional funding for R4 activities.

Berry framed a hypothesis that would test the general question of how "...long-term follow-up data permits comprehensive planning for care of individuals with inborn errors of metabolism diagnosed by newborn blood spot screening". Workgroup members are asked to review and comment on the hypothesis. (Handout 4).

Berry informed the group that the general budgetary plan for the Region 4 proposal includes support for a project coordinator, some PI time, and actual data collection activity. We are exploring cooperating with the NBSTRN and the NCC for project support with respect to IT needs, logistics, etc.

Berry solicited suggestions/thoughts from the group on Handout 4, and for their assistance in writing the proposal. If generally accepting, Berry will contact individuals for support documents, budgets, letters, etc. The letter of intent is due July 3, 2010. The application is due August 3, 2010.

Berry added that the grant would be home-based at MPHI. She added that this provided an added benefit to the group, in that MPHI has a comparatively modest indirect cost-rate that would allow more money to be funneled directly to centers.

4. NCC PD/PM Presentation (Hiner)

Hiner participated in the NCC Technical Assistance Meeting in Chicago, IL in early June 2010. Hiner spoke to the group on the IRB processes associated with implementing a multi-site study or registry. Topics covered were that of lessons learned, standard operating procedures, how we work together as a collaborative, and our infrastructure. Hiner reported that meeting attendees were very impressed with the work of this group and the resources we have to offer.

5. NYMAC Region (Hiner)

We will be expanding to include NYMAC in our collaborative very soon as a partner. They are putting out an RFP, inviting clinics to respond and participate. They have decided to provide support to clinics each time they enter survey information on a patient.

Berry added that incorporating additional partnerships w/ other collaboratives/ clinics is an exciting opportunity that will help make sure IRB is congruent with what is being reported.

Berry also encouraged call participants to participate in future IBEM-IS data entry training sessions, as they are helpful to see how data is being grown.

6. Other (Berry)

No additional topics for discussion.

IV. Other Business Announcements (Members)

Berry informed the group that updates on the progress of the RO1 opportunity would be forthcoming.

V. Adjourn (Anderson/Berry)

Mtg. adjourned at 2:36 PM. Next meeting scheduled for Friday, July 16, 2010 @ 1 PM CT/2PM EST.

Notes by Ostrander