



Priority 2 Workgroup Telemeeting Notes
Friday, January 18, 2008 @ 2 pm ET/1 pm CT

Participating: Carolyn Anderson, Co-lead (MN); Susan Berry, Co-lead (MN); Barb DeLuka, IL; Stephanie Gurnon, Bryan Hainline, Kathy Wood, IN; Jan Asken, Troi Cunningham, Sandy Fawbush, Gordon Gowans, Katherine Platke (?), KY; Ayesha Ahmad, Jerry Feldman, Violanda Grigorescu, Billy Young, MI; Kristi Bentler, Darin Erickson, Kathy Stagni, MN; Nancy Leslie, Shawn McCandless, OH; Bill Rhead, WI.

I. Welcome and Role Call. Susan Berry welcomed new member Kathy Stagni. Kathy shared that she is the mother of a 19 year old who has an OA disorder. We are pleased that Kathy volunteered to work with this group and add her “family member” perspective, expertise and input.

II. Meeting schedule for calendar year.

A. *Regular monthly meetings:* Susan noted that our regularly monthly meetings will continue to be held on the 3rd Friday monthly at 1 pm CT/2 pm ET. We will use the same call-in number and meeting number (1/866/489-0573 at the prompt, enter *4545164*). Sue encouraged people to add these numbers to their outlook to have the readily available.

B. *Regional meeting:* Please save the date for the regional meeting – September 16th & 17th in East Lansing, MI. As written into the IBEM-IS workplan and budget, our bi-annual meeting of Clinical State Leads will be held in conjunction with this meeting.

III. Workgroup membership and Roles.

A. *Clinical State Lead:*

1. Stipends:

a. Reporting requirements: Sally sent a draft reporting form prior to the meeting, for review and input. The form is intended as a vehicle to keep the Priority 2 workgroup advised of Clinical State Lead activities, progress and barriers. It will also be used as the trigger for payment of the honorarium/stipend for the lead; allowing us to document for our funder activities attached to dispersing of funds. Based on discussion, the following changes will be made:

- o Completing the form a minimum of every 6 months is sufficient, but two must be received a year with the final for the year received within 15 days of the end of the fiscal year (June 15).
- o Clinical state leads can complete sooner than 6 months into the calendar year, to leverage the honorarium
- o Change estimating the number of enrolled to number **consented**.

Decision: members are asked to review and provide feedback/recommendations for revising the form to Sally.

Decision: In the interest of leveraging clinical state lead honorariums/stipends without undue delay, clinical state leads may use the form in its current form. Forward completed form to Sally.

2. Year 2 Stipends/Budget issues: MPHI is currently in the process of developing the annual summary and re-application required by HRSA, due in early February. This includes the IBEM-IS project. Sue is working with the University of MN, lead for the IBEM-IS project, to determine the need for any on budget revisions. In the current project budget, the same amount has been designated for each of 6 clinical state leads; regardless of the number of metabolic centers or the current level of participation. Both the number of centers and current level of participation impact the expected activity and effort for the state lead. Given these factors, having the honorarium amount the same across the states may not be the most equitable way to support clinical state lead participation and effort. Sue volunteered to look at

the budget and develop some recommendations. Nancy Leslie asked if she could share her honorarium with others in her state who take on some of the burden of activity to get their centers – or others – involved and participating. Yes – the honorarium is for the clinical state lead and his/her employing entity to use as they see fit in exchange for the Clinical State Lead’s efforts to further the IBEM-IS project in his/her state. Ayesha commented that, having served as the clinical lead in Michigan at the outset of the project, she supports the concept of sharing stipends. Sally reiterated, honorariums are for the clinical state lead, dispensed upon recording activities and efforts to engage the state metabolic centers in the IBEM-IS and Priority 2 workgroup activities. Sue commented that intellectual contributions are equally as important and should be given some consideration.

B. State Follow-up Leads - Role

Sally forwarded the draft description of the role of the state follow up program leads. Carolyn reviewed the document, based on a draft she developed. Carolyn is very interested in feedback from the state follow-up programs. Does this description give the state follow-up programs a clear sense of their contribution to the project? Some of the states do not have representatives designated to the Priority 2 workgroup, or they have not been active. Members were asked to review and provide feedback to Sally. Ayesha proposed the group formalize a process for selecting state follow-up leads, as well as state clinical leads. Sue noted that at the inception of Region 4, our Regional 4 State leads were asked to identify and designate members of the working groups. Some attrition and changes have occurred over time. This is an issue that we can revisit. Sally noted we want to continue to work collaboratively through out Region 4 infrastructure and be care of being too prescriptive when asking assistance of our leaders.

IV. IBEM-IS.

A. DocSite.

We continue to experience frustration in working with DocSite. DocSite made an enormous, last minute push to have revisions requested over the summer ready for the Clinical State Lead meeting in Minneapolis in November. Much of the eleventh hour push occurred over the weekend just prior to the Monday meeting, leaving Sue without time to determine which changes would actually be in place prior to her DocSite session with the clinicians. Although there was that flurry of response during mid-November, we experienced a lack of activity since. A summary of our current status follows:

- DocSite has been provided with all the information they need to have the MCAD surveys look like they should. Once all of the changes have been made to the MCAD surveys, posting the surveys for the other disorders should go quicker, as so many of the elements carry over.
- The MSUD enrollment survey has been added to the IS by DocSite, Long Chain has not.
- Data dumping – the reports that individual entering sites can generate are ok and provide some valuable, useful feedback. The greater data dump that Anne needs to look at needs to be done in a way that is useful to her. The data can be dumped, but it is difficult and tedious to pull out meaningful data.
- Sally has established a schedule of weekly telemeetings with DocSite to facilitate continuing momentum. It is anticipated that most of these meetings will occur between Sally and our new DocSite contact, Julia Nash. Others will join in the meeting as relevant issues arise. Information and issues will continue to be provided to DocSite in writing prior to these weekly meetings to allow Julia an opportunity to prepare for discussion and response.
- Kristi pulled all of the issues shared with DocSite over the last several months and Sue reviewed the Information System to determine which changes have been put in place and which haven’t. These lists have been shared with Julia. Julia indicated on our weekly call this morning that the simple changes would be made by end of business today (1/18). For those changes that aren’t made by end of business 1/18, a list will be generated with target dates for completion assigned. This list will be made available by end of business Tuesday, 1/22.
- Anne Jurek participated in the 1/18 call with DocSite and raised issues of data dumping and generating reports. Sally asked Anne to provide the issues in writing so they can be provided to

Julia prior to the 1/25 telemeeting. Anne, Kristi and Sue will explore and define the data dumping issues and needs.

B. IRB

Role Call update on IRB progress was conducted. Reports follow:

IL – one center entering data, forwarded IRB Review and Approval and User/Provider designation to Sally.

IN – in progress

KY – in progress. Asked Sally to re-send protocol

MI – in progress. Wayne State is still dealing with issue of IRB fee, getting closer. University of Michigan – preparing the initial application.

MN – University of MN is entering. Has forwarded IRB approval to Sally. Need to complete and forward User/Provider Designation Form. Work to get Mayo on board needs to be initiated.

OH – One center has IRB approval. Approval and User/Provider designation have been forwarded to Sally

WI – one center has IRB approval. Approval and User/Provider designation form have been forwarded to Sally.

C. IRB Questions

Encouragement to submit an IRB application for the entire IS was reiterated. If approval is only obtained for MCAD, IRB's will want a revision submitted each time a disorder is up in the information system. Ask for generic approval with the caveat that additional disorder specific data elements will be provided as developed.

All IRB materials will be on the website when the revised Region 4 website is live. The IBEM-IS pages should be live later this month. Sally will forward the protocol template developed from Nancy Leslie's materials and the consent form in an editable word document to the IBEM-IS clinical state leads e-group.

Sue volunteered the assistance of Kristi and herself to anyone needing help with IRB application, process, issues, questions.

D. Reporting

Kristi reminded everyone that reporting of cases enrolled needs to begin. The directions are on the forms which were distributed at the 11.19 meeting. Kristi asked when case enrollment stipends can be requested. Sally reminded the group that information is included on the case enrollment reimbursement form. We are in the 3rd quarter of the grant year. Reimbursement for the first 6 months should be requested now. Electronic forms will be posted to the website and may be requested from Sally in the meantime.

E. Refresher training

Refresher training will be scheduled for anyone interested. We will need to wait for user names and passwords to be provided for Ohio and Wisconsin. (Designation forms were just received). Goal will be to have one refresher training serving multiple sites, rather than individual site trainings. Sue and Kristi will facilitate the training, rather than DocSite will not be included in this round.

V. National and cross regional collaboration:

A. *National Secretaries Advisory Group :*

1.

This group invited Sue to present on behalf of IBEM-IS – our project and progress. It was very well received, with much enthusiasm demonstrated concerning our progress. This generated informal invitations to present to other audiences. As formal invitations are received, Sue will likely need help from other workgroup members to fill these requests.

2. Expanding to add other regions/states:

There is a tremendous amount of interest in getting involved. NYMAC wants to get on board. We need to address –

- how do we add other regions/states to the group?
- When do we add (especially in light of not having all Region 4 on board yet). There is a tremendous amount of interest. NYMAC want's on board.

3. Secretary's Advisory Group Process for Adding Disorders to the NBS Panel:

Sue updated the group on the process, which follows: HRSA has a form to nominate a disorder for inclusion. A literature review must be conducted and included with the nomination. HRSA reviews forms submitted for completeness of requested information provided. HRSA either sends the nomination on to committee for scientific review; or returns the form to the submitter for additional information. The committee is responsible for formulating a recommendation concerning adding the disorder.

B. Electronic Record meeting

Mike Watson is establishing a group to have continuing discussion on electronic records and their role in genetic care. Sue has asked Anne Jurek to participate on behalf of the Priority 2 group. The first meeting is scheduled for February.

C. Translational Research meeting

No official decision has yet been made on who will be the coordinating center for translational research. This is the activity that Mike Watson contacted Sue about last month and asked for support. Several entities responded to the request for interest, which included providing qualifications. Sue would like the group to go on record saying we will actively participate with whoever is the successful recipient of the contract. The group concurred.

D. ACMG and SIMD

Sue reminded the group that both of these conferences are coming up. Most folks will be attending one or the other, not both. Sue would like to get together, informally, with workgroup members attending SIMD.

V. Items for follow-up of this meeting

- All members, please review and comment on:
 - Reporting Form for Clinical State Leads
 - State Follow-up Program Lead
- Sally will forward protocol and consent to all Clinical State Leads
- Anne and Sue – develop written statement of data dumping issues to be provided to Julia Nash, prior to 1/25 weekly meeting.

Notes by Hiner