

Inborn Errors of Metabolism (IBEM-IS) Clinical Leads Workgroup Meeting
Monday, November 19, 2007
Minneapolis, MN

Participating: Susan Berry, MN (co-lead); Carolyn Anderson, MN (co-lead); Rachel Katz (representing Barbara Burton), IL; Bryan Hainline, IN; Ayesha Ahmad, Jerry Feldman, MI; Kristi Bentler, Anne Jurek, Darin Erickson (family member), MN; Nancy Leslie, OH; Bill Rhead, WI; Sally Hiner (Project Coordinator), Cynthia Cameron (Project Director), Region 4 Genetics Staff. Guest presenters: Jehad Adwan; Lee Pyles (MEMSCIS).

I. Welcome, Intro and Housekeeping: (*Meeting resource – handouts 1 & 2*)

Sue Berry welcomed participants. Round table introductions followed. Kristi Bentler reviewed the contents of the meeting packets. Sally Hiner circulated a workgroup member list for people to review and edit contact information. A travel reimbursement form is included in packets, please remember to attach receipts.

II. Inborn Errors of Metabolism Information System (IBEM-IS): (*Meeting Resource – IBEM-IS accessed via internet*)

Progress update and discussion: Following are highlights from the update and discussion, lead by Sue Berry:

- Reason for Request to Stop Entering Data - When Anne Jurek reviewed the data elements, she discovered some items that did not make sense as written or that were ambiguous. As a result, trained sites were asked to not enter data while changes were made to the IBEM-IS parent site. Following today's meeting; trained sites will be able to resume entering data immediately. With more sites and more people using the information system, we learned that the questions needed to be worded more specifically to elicit the desired information.
- Change log – the registry has a standard EMR (Electronic Medical Record) change log built in that tracks all changes to data entered.
- Race - mixed, bi-racial; issues: lots of options, but may not be totally accurate. At this time, enter the best description, although it may not be perfect. If it continues to be an issue, the workgroup can address later on. Entering information in the “ethnicity” field in addition to “race” is usually adequate.
- Sharing information across sites: It is possible to share information when a child is followed up in more than one place. Built into the system, the entering individual can grant access to another designated individual. Outside of this type of sharing designation, sites cannot see other sites' data. Only Anne Jurek and Susan Berry, who both had administrator privileges in the information system (IS) can see the data from other sites.
- Information System Surveys - Enrollment survey is separate from interval survey. This is because the interval survey is the one that specialists will want to print and reference for each follow-up clinic visit, not the entire history.
- Using “set all dates” option – if a new value is not entered, the system ignores the new date. The user has to enter a date and value for the system to save the new value. For the Enrollment Survey, the date assigned should be the date of enrollment in IBEM-IS; for the Interval Update Survey, the date assigned should be the actual date of the follow-up visit.
- Allele – can alleles be provided in a drop down menu on the Enrollment Survey? - No, there are a handful of common alleles, but there are too many to list. Concern prompting the suggestion is the possibility of transposing or other entry errors. The IS can be monitored to assess for this concern and the workgroup could consider addressing in the future.
- Days of age from birth to initiation of intervention for IBEM – when initiation of intervention is more than a year, instructions will be added to guide the person entering to multiply age in years X 365.
- Days of age at time of initial metabolic face-to-face consultation – if initial face-to-face consult occurs after 1 year of age, instructions will be added to guide the person entering to multiply age in years x 365.
- Once a child is enrolled, you can delete the Enrollment Survey from the Patient Information page under the Surveys section. The survey data is not being deleted, just the immediate access to this aspect of

data entry. This will de-clutter the entry option list. The complete enrollment survey data entered is still saved. If new data that belongs in this survey needs to be entered, the Enrollment Survey can be “added” again.

- System Time Out - System “times out” after 15 minutes. The time clock at the top of the page is not necessarily precise (counts down at 30-60 second intervals while data is being entered in survey). There is no warning, no time keeper, person entering data has to do own monitoring. DocSite will be approached about options to alleviate this issue – (building in some type of warning that the system will time out, auto-save prior to timing out, prompt/message to save work (.e.g click here to save) pop-up at intervals. However, this is a HIPAA issue. Currently, no workaround exists. We can build prompts into each Enrollment and interval Update survey to remind data entry person to save at points along the survey.
- How long does initial enrollment take? – An initial enrollment can be completed in approximately 45 minutes if done directly on line. If entering data from a pre-printed survey, entry is faster. . Follow-up/interval survey takes about 10 minutes to complete.
- Emergency and non-emergent hospital stays – It was suggested to do an audit of physician records, as available, cross referencing with IBEM-IS subjective data from caregiver, to check validity of data entered re: ER and Hospital admissions. University of Minnesota offered to pilot this with their enrolled patients and report back to group at the next face-to-face meeting.
- Can Enrollment Survey be edited - Add a prompt to edit enrollment survey tests, if applicable (as new data becomes available – enter using date of receipt of new information).
- Medication – Medications specific to each IBEM are build into each Interval Update Survey. Also, there is an option to enter other medications in a more detailed way through DocSite. (You do NOT need to do the more detailed entry for the purposes of the IBEM Information System. However, more detailed medication information may be useful for your clinic work flow.)
- Visit Planner – when the complete visit planner is printed, it is a 9 page PDF document containing every element in enrollment and interval surveys. For interval update visit planner only, delete the Enrollment Survey (under the Survey section) as well as MCAD Enrollment under Managed Conditions section; make sure Interval Survey is assigned as BOTH a Managed Condition and a Survey; then print the visit planner (details are provided in the IBEM-IS Quick Reference folder available in hard copy and on the Region 4 website). Suggestion - Print off prior to visit with family, use to guide visit, document notes, and enter new visit survey from the hardcopy.
- Test-demo site – all users have access to the test-demo site.
- Customizing data elements by center/site - Individual sites can add individual elements in the future; but adding to an individual site DOES NOT change the parent site or other partner sites. If it is determined by the workgroup that addition of an identified element would be beneficial to the greater IBEM-IS, it will need to be added to the parent site using the procedures outlined for communication with DocSite.
- How to print visit planner – detailed instructions were provided in the IBEM-IS Quick Reference folder handout (November 19 meeting handout #3).
- Data Elements in IBEM IS are for the following disorders/families of disorders –
 - 1st MCAD
 - 2nd MSUD
 - 3rd LCFAODs (LCHAD/TFP as template LCFAOD disorder)
 - 4th 3-MCC (as template organic academia)
 - Then we will proceed with remainder of data elements in the order the group reviewed them (i.e. remainder of LCFAODs, other OAs, non-MS/MS condition (biotinidase))
- Blank surveys – Sue added blank enrollment and interval surveys to the demo-site to allow all access to blank hard copy surveys. Suggestion – complete notes during visit on the hard copy, enter into IBEM-IS later. Please keep hard copies that you have filled out for future reference, e.g. questions raised during data analysis, random audits for quality assurance of data entered.
- Deceased patients – Yes, deceased patients can be added. This data is important to have.
- Neuropsych survey does not print in patient planner (this is due to the unwieldy length and to avoid transcription errors; please enter data directly from neuropsych report). Please make sure Connors is included in the neuropsych battery listed. Neuropsych survey is still being updated with additional tests.

- Reducing Report Duplication - Can sites generate their own reports from this data to possibly replace other reports they are required to generate for/in their own system? (i.e., new patients, existing patients, number of visits for this time period, number of visits with dietician, etc). Anne Jurek will learn how to generate reports and draft a brief how-to which will be posted on the web site.
- Is IBEM-IS user-friendly in multiple platforms? DocSite does not work in any Mac-based browser. This is a point for update with DocSite.
- Data Quality: It will be helpful if all source documents are saved in hard copy in a folder, including visit planners with handwritten notes used during a visit and to update the patient surveys, etc. These may be helpful in the future if Anne identifies data anomalies. Kristi will add this directive to the IBEM-IS Quick Reference.

IBEM-IS Quick Reference: (*meeting resource – Handout 3*)

Kristi Bentler developed a quick reference for entering data into the IBEM-IS. Members are asked to provide feedback as they use the reference. Sally Hiner will clear with DocSite prior to posting on the Region 4 Website. Electronic copies are available from Sally.

Getting Centers Started: (*meeting resource – Handouts 4, 5, & 6*)

Sally Hiner reviewed proposed standard operating procedures for bringing centers on board with IBEM-IS, as follows:

- 1) Obtain IRB approval – resources for completing IRB applications for participation in IBEM-IS are available on the Region 4 website. Members discussed additional resources that would facilitate the process. Some workgroup members have been looking for a narrative protocol description. Nancy Leslie has developed a protocol and will forward to Sally to develop a template for use by other sites. Copies of the data elements for individual disorders would be helpful for most IRB submissions. Kristi will provide this to Sally in excel spreadsheet format to post on the website.
- 2) Forward written documentation of IRB review to Sally. MPHI IRB and University of Minnesota IRB both require documentation of partner site IRB reviews for their roles in facilitating project coordination (MPHI) and project leadership, monitoring and data analysis (University of Minnesota).
- 3) Designate Users/Providers

Kristi Bentler reviewed a proposed communication process between workgroup members, DocSite and IBEM-IS users. It will be important to capture IBEM-IS issues and facilitate those issues being addressed in a timely manner. Issues identified by one site/user may be issues other sites have been struggling with. Issues will be reviewed for appropriateness of posting as FAQs to the Region 4 website. Designating one primary contact from the IBEM-IS project to DocSite will allow for more effective and efficient follow-up.

Actions taken:

The group reviewed and accepted as presented the following documents

- Participating in the Region 4 Inborn Errors of Metabolism – Information System (meeting resource handout 4)
- IBEM-IS User/Provider Designation Form (meeting resource handout 5)
- Communication with DocSite (meeting resource handout 6)

Case Enrollment, Reporting and Invoicing (*meeting resources – handouts 7 & 8*)

Sally reviewed the proposed process and draft forms to document enrollment reporting and invoicing. Case enrollment needs to be reported to Anne Jurek for data monitoring purposes. This will become increasingly more important as we expand into research activities using IBEM-IS data. The project budget allows for sites to request a per-case-entered stipend to offset the cost of participation in the project. Case enrollment invoices need to be completed and provided to MPHI to access the stipend. Draft forms for these two activities were reviewed.

Actions taken: Members reviewed the draft forms, discussed the process and accepted as presented the following documents:

- Case enrollment reporting form (meeting resource handout 7)
- Case enrollment invoice form (meeting resource handout 8)

Next steps regarding IBEM-IS:

- Follow up with DocSite on IBEM-IS issues identified (Sally, Kristi)
- Develop issues into FAQs for posting to the website, as appropriate (Sally)
- Develop a list of the order in which the disorders will be added to the IBEM-IS. This will allow sites to consent individuals who have those disorders as they are seen at the center, so that data can be entered when the disorder is added to the IBEM-IS. (MSUD will be added by 12/01; next to be added is LCFAOD, around 12/14/2007) (Kristi)
- IRB protocol - Nancy Leslie drafted a protocol, she will forward to Sally to develop a template for use by other sites. (Nancy, Sally)
- Individual disorder templates – Kristi will provide so they can be posted to the website as PDFs. (Kristi, Sally)
- Follow-up with DocSite on posting IBEM-IS materials that contain information about DocSite on the Region 4 Website. (Sally)
- Post process and operating procedure documents to the website. (Sally)
- All sites who have obtained IRB approval need to provide written documentation to Sally. Sally will forward copies to University of Minnesota. (Bill Rhead, Rachel Katz, Sue Berry, Nancy Leslie; Sally Hiner)
- Develop instructions for how to print the visit planner (Kristi)

III. State Clinical Lead Role: (meeting resources Handouts 9 & 10)

Sue and Cindy described the history of the state clinical lead. Original plan was to have one clinical lead per state. There is a small stipend to support the state clinical lead. Sue suggested the group entertain the idea of sharing the state clinical lead role and stipend. Cindy indicated that should be discussed with the individual states' Region 4 State Lead. She will contact the state leads where there is concern about who the state lead(s) should be. If it is decided to share the lead role, issues will need to be addressed including process for deciding who participates in face-to-face meetings (budget is for one state clinical lead per state); and the roles and responsibilities, including who is ultimately accountable for the work to involve all metabolic centers in the state in the IBEM-IS project. Sally referenced Handouts 9 and 10 which describe the role of the state clinical lead and list the metabolic centers in each state. It was suggested that quarterly reporting on activities in the state related to all the metabolic centers be added to the role of the clinical state lead.

Cindy also noted that the “long term follow-up workgroup” was a group supported by funding from the first HRSA grant to Region 4. The group is not supported by the base funding for this second grant, but is supported by the IBEM-IS project (priority 2 funding). Cindy recommended renaming the broad group, which includes state clinical leads, metabolic specialists and representatives from the state department of health to “Priority 2 Workgroup” to eliminate any confusion using the name of the old workgroup might create.

Actions take: through discussion, agreement was reached on the following actions:

- Add quarterly reporting on state center activities/state clinical lead role and responsibilities to the document Role of State Clinical Lead (meeting resource handout 9)
- Rename to large group to Priority 2 Workgroup
- Cindy will follow-up with the Region 4 State Lead on issues of identifying a state lead or co-leads in Michigan
- Kentucky participants will be contacted directly; as well as having documents from the meeting provided.

Using IBEM-IS Data for Research (meeting resource – Handout 11)

Sue reviewed the proposed rules for research and use of materials (handout 11). Discussion highlights follow:

- There are two types of research projects that would allow us to provide different types of review
 - Data mining
 - Establishing an IS Cohort
- Data mining – requires less stringent review. Data exist and can be made available without identifiers.
 - Form a team of four reviewers – public health, Region 4 Parent Coordinator, clinician, methodologist. Review emphasis – is it a worthwhile research question/idea? Yes, no, need more info.
- Establishing a cohort – this type of research includes intervention or contact with the family.
 - First step in review process is same for data mining (review by 4 person, multi-disciplinary review team)
 - Second step – review by Priority 2 workgroup
- Managing the process
 - Establish quarterly deadlines for receiving proposals. (Exceptions can be made to address timeliness issues such as funding deadlines or policy changes. Researcher must provide a written request explaining the need for the exception)
 - At this time proposals will only be accepted from within IBEM-IS group. Will look at expanding this at next face-to-face meeting (tentatively August 2008)
 - MPHI receives proposals, forms 4 person review team, identifies lead reviewer, disseminates materials
 - Reviewers cannot include the person proposing the research or someone from the proposing institution.
 - Review
 - First review is anonymous – reviewers identity will not be shared by MPHI
 - a tool will be developed to facilitate reviews and provided with research proposal.
 - MPHI will collect, compile review comments, questions and recommendations
 - MPHI will provide questions to researcher
 - MPHI receives responses from researcher, reviews to see if questions have been answered, forward responses to reviewers.
 - MPHI receives final comments, decision from reviewers. Identifies one team member to provide a summary for the Priority 2 workgroup
 - For data mining – decision and summary are shared with Priority 2 workgroup during next telemeeting
 - For Cohort projects – Summary and recommendation are shared with Priority 2 workgroup during next telemeeting. Workgroup members must indicate conflict of interest, if applicable. Decision will be determined by record of motion and vote.
 - Items for future discussion – expanding the first review team
 - As the number of proposals submitted increases
 - As additional regions join the project
 - As other disorders are added to the IBEM-IS

Actions taken by the group:

- identified and defined two types of research proposals
- developed a proposed proposal submission and review process

Next Steps:

The draft Proposed Research Rules (handout 11) will be revised to reflect the meeting discussion.

Research Proposal Submission Guide (*meeting resources - handout 12 & 13*)

Members reviewed the draft submission guide and sample completed form. Highlights:

- Need to reword question 3 to help submitters better describe the proposed research project
- Revise the form to direct submitters to understand the two research categories defined by the group
 - Data mining (relies solely on data from IBEM-IS)
 - Cohort (requires contacting families)

Darin volunteered to forward submission guides for the group to review and consider adapting for our meet our needs.

Next steps: Sue, Kristi, Carolyn, and Darin, and other interested Priority 2 Clinician Leads will review sample submission guidelines and draft proposed guidelines for review by the Priority 2 workgroup.

Research Proposals: (*meeting resources – handouts 12 & 13*)

The group reviewed the proposals received to date by engaging in discussion based on the process identified during the previous discussion at this meeting). Results of the review for two of the proposals are recorded in Attachment 1. The remaining 3 proposals received will need to be tabled until there is data in the IBEM-IS. A process needs to be developed to identify the following information for proposals:

- Potential funding sources (if not identified)
- Evaluate level of interest by IBEM-IS centers
- Identify lead Priority 2 Workgroup Researcher (this needs to be changed from “clinician” on form)
- Determining authorship. The issue of determining authorship will be taken to the Advisory Group. It can be taken in the form of a recommendation from the Priority 2 Workgroup. The Priority 1 group will also be addressing issues of authorship.

Next steps: identify lead reviewer for each reviewed proposal to present decision to Priority 2 Workgroup during December telemeeting.

Metabolic Emergency Care Plan Data Elements: (*meeting resource – handout 14*)

Prior to this meeting, an email request for emergency plans was made to all sites participating in IBEM-IS. Carolyn developed a spreadsheet of all the options for emergency care (handout 14). Workgroup tasks

- Determine data elements that need to be included in IBEM-IS
- Determine data elements that could be included in an EMR (Emergency Medical Record)

Actions taken:

The group identified elements to include in the registry for MCADD.

The group decided to not address issues related to EMR for the following reasons:

- We are not at the point of implementation of a regional EMR
- Some states are already doing their own web-based EMRs

For future discussion:

- Capturing, for kids with IBEM, protocols for OR, ER and Sick Day.

Midwest Emergency Medical Services for Children Information System (MEMSCIS)

Jehad and Lee provided a PowerPoint overview of MEMSCIS. Information packets with CD-ROMs including information in Spanish and English were available to anyone interested in exploring this project further,

Highlights from the presentation:

- Physicians were initially concerned about the sustained validity of information in the record because both parents and providers have access and can change information. Addressed this in MEMSCIS by adding icons that notate who entered the data – visually identifies originator or data entered.
- Parental concern for privacy – ideally, a parent provides access; however, there is a “break the glass” option for emergency room use.
- PCP time investment to initiate Emergency Information Form (EIC) – for kids with IBEM-IS this would not be an issue as the metabolic clinicians/staff would be the most appropriate professionals to initiate

and already take responsibility for doing so for their patients with IBEM in the form of emergency care plans.

- Emergency provider's lack of awareness, concern for ease of use – if a patient is using the MEMSCIS system, what can be flagged within their hospital system (especially in the EMR) so that the fact the child has an EIF pops up, prompts person registering in the ER to ask for the MEMSCIS access number if the parent doesn't provide. MEMSCIS is accessible anywhere in the world where there is internet access (not tied to one particular health system, state, region or country).
- Initial emergency provider's concern for data accuracy – icons were added to denote who originated data entered and date of entry is included in system.
- Access and language barriers for many parents with greatest needs. Information is available in English and in Spanish (and is in the process of being translated into Hmong). Videos for families are in the process (English, Spanish and Hmong).
- Ownership of the information (parent vs. provider) – ultimately patient/family.
- Legal ramifications/liability (veracity of information).
- Access/privacy.
- Trust and competence of provider.
- Sacredness of medical chart and report.
- Resolutions:
 - Time marked, user authentication (done)
 - Way to ensure a unique identifier beyond name and DOB for every child (ongoing)
 - Electronic scanning alternative to login (needs money)
 - Wider Acceptance/recognition
 - Reimbursement mechanism for data input. Built in to Region 4 base grant funding (\$50 per case enrolled)
 - Self enrollment wizard (in progress) – families can enroll themselves

Systems like MEMSCIS can aid in disaster preparedness – in the event of an emergency, the system can be searched to identify those individuals who have life-dependent medical intervention needs, e.g. oxygen, and plans put in place to address those needs.

MEMSCIS is included in the base-funding for Region 4 Genetics Collaborative in the Care Coordination Workgroup. It was suggested that emergency care plans continue to be collected, and a state-by-state comparison developed for discussion by the Priority 2 workgroup to include:

- Using MEMSCIS as a way to enhance care to patients with metabolic disorders
- Formulate recommendations for consideration by the Region 4 Genetics Collaborative Care Coordination Workgroup.

Notes by Hiner

Reviewed by Berry and Bentler