

Data Operations Advisory Group Meeting March 02, 2010 6:00 PM EDT – 7:00 PM EDT Meeting Summary

I. **Introductions/Overview** – Roll call was taken. Please see the attached list of participants.

- E. Briggs-King explained the shifts in activities for the NCCTS Data and Evaluation Program. She noted that the Cross Site Evaluator (ICF MACRO) will be the entity responsible for collection for the NICON system, the successor to the current InForm™-based Core Data Set (CDS) following the closure of that system at the end of September 2010. FY09 cohort centers that have not had previous CDS experience, should work with ICF MACRO to prepare for the new NICON system. FY07, FY08, previously funded FY09, and affiliate centers may continue to enter data into the CDS operated by the NCCTS in the InForm™ system, until 30 September 2010.
- B. Sukumar stated that the new version of the CDS, via the NICON system, will be released soon. The data collection components for Phase 1 are being finalized, and will be provided to SAMHSA for review on 09 March 2010. The NICON system will include all of the measures available in the current CDS. Phase 2 will be the launch of the clinical and aggregate reporting features, and should be complete in May 2010.
- The FY08 cohort of centers will receive training on the NICON system. In addition, ICF MACRO will provide assistance and resources (e.g., templates, etc.) to centers for the development of IRB applications/amendments and materials, as appropriate, in order to gain approval for the data collection in the NICON system. The goal is for all centers planning/required to enter data into the NICON system to have received approval/exemption from their IRB prior to October 2010, so that they may begin data collection at that time or sooner.

II. **Publication Guidelines**

- The Publication Guidelines were approved by SAMHSA in September 2009. The NCCTS Data Operations Advisory Group has been instrumental in the drafting, revising, and receiving approval of the document. Other stakeholders have contributed to the approved document along the way.
- This document will guide collaboration between the centers as it relates to the use of data for publications, manuscripts, and posters.
- The process for submitting a proposal and the review of that proposal is described in the Publication Guidelines. Included as appendices to the Guidelines are the Publications Review Form and the Publication Flow Chart. The Publications Review Form is the form used to submit a proposal. This form, however, is now electronic and available on the NCCTS intranet site. The Publication Flow Chart describes the basic process by which each proposal is reviewed by the Publications Review Committee (PRC) after submission.
- Upon approval of a proposal, the collaborators will be provided a de-identified Aggregate (NCTSN-wide) Datasets for use in their analyses. Technical assistance with the Aggregate Datasets will be available from the NCCTS and the Data Operations Advisory Group, if necessary. In addition, other centers within the NCTSN with experience and resources for conducting analyses can be consulted or included in the collaboration for a proposal.
- The Publication Guidelines are intended to provide an infrastructure for the NCTSN to generate quality manuscripts that promote awareness and expand the field. The three main objectives of the Publication Guidelines are: 1) Facilitate Collaboration; 2) Reduce Redundancy; 3) Track the proposed publications.

Questions & Answers:

Q: Is there any concern that the PHI included in the Core Data Set will violate HIPAA?

A: Each center was required to submit a description of their data collection strategy, including the CDS to their IRB of record for review and either approval or exemption (not human subjects research). Depending on the ruling of the IRB for each center, a consent form describing the nature of the data collected and its use(s) should have been used as directed by the IRB of record prior to collecting data from clients. In addition, the data received and aggregated at the NCCTS is a coded dataset, such that only the site from which the data originates has a key to reconnect the client data entered into the CDS with the original client and their clinical

record. Finally, as part of standard practice, the data will be de-identified; scrambled; and any remaining limited PHI variables will be removed.

NOTE: In addition to these measures, each center or collaborator listed on the approved proposals must have IRB approval from their IRB of record in order to receive the Aggregate Datasets and conduct the analyses necessary to generate their proposed publication, manuscript, poster, etc. A data use agreement will also be executed with the lead investigator before they will receive the Aggregate Datasets.

Q: Can we apply a variable that denotes geographic region of the client or site? Or, can we designate a variable that identifies whether the center or client are from a rural or urban area?

A: There are several situations that make either of these scenarios difficult to implement without: a) indirectly implying the center at which a client was assessed; or b) inconsistently defining urban and rural based upon a standard reference. We did explore both of these requests, but it is not possible to pursue either of these options.

Q: What happens if two, very similar proposals are submitted at nearly the same time?

A: The contributors of the proposals will be encouraged to work together, or to narrow their proposals such that they become distinctly different enough to merit separate reviews and approvals by the PRC.

Q: Even after the Aggregate Datasets become available, will the centers currently receiving monthly transfers of their own center-specific data still receive these datasets?

A: Yes. Centers that request to do so, or have already been receiving monthly datasets containing their own center-specific data will continue to receive that data until the InForm™-based CDS closes at the end of September 2010. After that, they will receive one final transfer of all of the data collected in the InForm™-based CDS. If a center does not currently receive a monthly issue of the data it enters, the center may either request that this begin, or submit a request to receive the one time final transfer after the close of the InForm™ CDS system. The Aggregate Datasets will only be available upon approval of a proposal by PRC or upon an approved request from the NCCTS Data and Evaluation Program Director for ad-hoc analyses (Ernestine Briggs-King at brigg014@mc.duke.edu).

The form that must be completed and submitted to request this final dataset, or to receive monthly transfers of the center specific data is available via the following link to the NCCTS Data and Evaluation Program NCTSN intranet. Please submit this form no later than 31 July 2010 in order to guarantee receipt of your center's data.

<http://intranet.nctsn.org/sites/data/Data%20Transfer%20Forms%20and%20Resources%20Library/Center%20Data%20Request%20Form.doc>

REMINDER: Each center is responsible for communicating the activities of its program to its IRB of record, including the use of the datasets received monthly. Depending on the proposed projects, the activities of a center may require an amendment or formal submission of a new protocol to their IRB of record for review and approval/exemption prior to the performance of these activities.

Q: Will there be any tracking of individual centers' analyses and plans for publications, to guarantee that there is no overlap with the publications subject to the Publication Guidelines, and adequate IRB approval for those proposals?

A: The NCCTS Data Operations Advisory Group will consider this question and implement a solution. It is important to note, however, that all analyses involving the receipt of the Aggregate Datasets by a center or collaborator will be subject to a review by the PRC, and will therefore be tracked via the system in place on the NCCTS Intranet. As part of the terms and conditions delineated in the Publication Guidelines, all materials submitted for publication and/or published should be provided to SAMHSA. In addition, the NCCTS would like to request that copies of all accepted publications, manuscripts, posters, etc., be provided to the NCCTS Data and Evaluation Program Director (Ernestine Briggs-King at brigg014@mc.duke.edu).

NOTE: It is a requirement of the NCTSN grant funding from SAMHSA that any and all publications or manuscripts supported by grant funds must be provided to the SAMHSA GPO.

Q: Will it be possible to combine the current InForm™-based CDS datasets with the NICON system?

A: The details of how the two systems or data from the two systems will be integrated have not been finalized. Please provide questions and feedback to your SAMHSA GPO regarding the interests your center has for continuous data flow and integration.

Q: Will the same clinical assessment measures be available in the NICON system, as have been available in the InForm™-based CDS?

A: The current design plan of the NICON system includes all of the same clinical assessment measures as are found in the InForm™-based CDS.

Q: Can a center receive all of the data that was contributed to the InForm™-based CDS?

A: Yes. After the closure of the InForm™-based CDS at the end of September 2010, for those centers that request a final center-specific dataset, one will be delivered to them. The form that must be completed and submitted to request this final dataset, or to receive monthly transfers of the center specific data is located on the following page of the NCTSN intranet.

<http://intranet.nctsn.org/sites/data/Data%20Transfer%20Forms%20and%20Resources%20Library/Center%20Data%20Request%20Form.doc>

REMINDER: Each center is responsible for communicating the activities of its program to its IRB of record, including the use of the datasets received monthly. Depending on the proposed projects, the activities of a center may require an amendment or formal submission of a new protocol to their IRB of record for review and approval/exemption prior to the performance of these activities.

Q: If a center wants to compare the center-specific data to the overall NCTSN data, does this also fall under the jurisdiction of the Publication Guidelines?

A: No. Benchmark comparisons are available via the current InForm™-based CDS. For additional requests, please contact the NCCTS Data and Evaluation Program Director (Ernestine Briggs-King at brigg014@mc.duke.edu). In addition, for smaller centers that do not have the statistical capacity to conduct analysis of their center-specific data may still submit requests for analyses to the NCCTS Data and Evaluation Program via the Director.

Q: Are conceptual papers, white papers, training papers, and other discussions and analyses that will result in products or product development materials subject to the Publication Guidelines in addition to the Product Development Guidelines?

A: Information of this nature will be subject to one of the guideline documents or the other, but never both.

Q: Is there a process for influencing how data will be collected in the NICON system? Several NCTSN Collaborative Groups have been discussing changes and/or expansion of the InForm™-based CDS to more adequately collect data for their respective domains (e.g., military families, young children, substance abuse, traumatic grief, new assessments, etc.) for some time. These Collaborative Groups want to carry that information forward.

A: The data collected as part of surveys, discussion and technical assistance sessions with each of these groups was shared with ICF MACRO. The minutes and resources available as a result of the Data Operations Advisory Group are available to the entire network, including SAMHSA and ICF MACRO via the NCTSN Intranet. The Evaluation Steering Committee (led by ICF Macro) to be formed around the implementation of the NICON system and other data collection and evaluation activities will ultimately evaluate, prioritize, and authorize the implementation of changes to the NICON system.

NOTE: A task force is revitalizing the “measures/assessments” database. Interested members should contact Ernestine Briggs-King at brigg014@mc.duke.edu or Melissa Brymer at MBrymer@mednet.ucla.edu.

III. Publications Review Committee

- The PRC, including the association and make-up of its membership, is described in detail in the Publications Guidelines. The NCCTS Data and Evaluation Program, however, invited anyone interested to self-nominate, or to nominate others for membership to the PRC. Please submit your nominations to the NCCTS Data and Evaluation Program Director (Ernestine Briggs-King at brigg014@mc.duke.edu). The

PRC will be made up of stakeholders from various partners and levels of the NCTSN, and will also include members with diverse interests and areas of expertise.

- Using the electronic workflow established on the NCTSN Intranet, the PRC will receive proposals for review. The PRC Chairperson will assign the review for proposals by matching the domain or focus of the proposed publication with the expertise of one or more PRC members. If a domain or topic for publication should be submitted for which the current PRC membership does not have the expertise, ex-officio members may be consulted by the PRC in order to make a determination about the proposal submitted.

IV. Aggregate Datasets

- An executed Data Use Agreement (DUA) is required by DUKE and the DUHS IRB from each institution involved in a group of collaborators in order to receive the Aggregate Datasets. A template DUA will be available on the NCTSN Intranet. In addition, the IRB(s) of record involved in each collaboration may require additional documentation or submissions of an amendment or new application to receive and perform the planned analyses with the Aggregate Datasets.
- The complete set of Aggregate Datasets includes six individual datasets. These are: Baseline, Trauma, Follow-up/End of Treatment, Brief Intervention Services, Breakthrough Series Learning Collaborative, and Baseline+End of Treatment. The first five datasets are simply subsets of the overall data based on visit type. The sixth dataset, Baseline+End of Treatment, is a derivative of the Baseline and Follow-up/End of Treatment datasets, in which the data for each client includes only the baseline and end-of-treatment visits. In addition, some variables have been reformatted in order to make analyses of this dataset more facile.
- The datasets will be available in different formats: SAS and SPSS.
- Date of Birth will be replaced with Age during the de-identification process.
- Please be specific about the objectives of your proposed analyses and the variables in which you are interested on the Publications Review Form (submitted electronically via the NCTSN Intranet). This will allow the NCCTS Data and Evaluation Program to consult with the collaborators about the datasets, variables, and strategies that might be best for the planned analyses.
- REMINDER: The benchmarking reports available in the InForm™-based CDS allow the user to run reports showing outcome trends on the client and site level against the NCTSN level.
- The NCCTS Data and Evaluation Program will make available a data dictionary for all of the Aggregate Datasets, and will host webinars for the launch of the datasets to orient interested collaborators.

V. Planned Analysis

- From the NCTSN Aggregate Datasets, there are a few initial, foundational papers planned, including demographics, methodology, descriptive (exposure data), policy and issues paper, treatment paper, and an outcomes paper. In addition, there are a series of planned analyses for ACES.
- Subsequent analyses, subject to the Publication Guidelines, will build upon these initial analyses and publications, further unpacking the valuable information available from the InForm™-based CDS.
- One example of the volume of data, especially in terms of sample size, is the lowest frequency traumatic event, which is kidnapping with n=219.
- About 5K+ cases in the Aggregate Datasets for which there is data at least for baseline and end-of-treatment visits.
- Approximately 80% of the cases in the Aggregate Datasets have multiple traumas (two or more), with a mean number of three traumas
- The Data Operations Advisory Group may have brainstorming sessions during future meetings to develop categories of domains for analysis. The Group may also use the discussion board on the NCTSN Intranet, Data and Evaluation Program to develop ideas for analysis.
- The Data Operations Advisory Group may survey its members and members of the NCTSN to determine who has interests in what topics and domains, as a means of encouraging collaboration.

Note: Additional discussions of other priority areas, particularly as they relate to the SAMHSA Strategic Initiatives will be discussed during a subsequent meeting.

Thank you to our inspiring and amazing leader!! Ernestine is the best!!!!

<http://intranet.nctsn.org/sites/data/default.aspx>

For additional information, or if you have any questions, please email us at nctsn@dcri.duke.edu.