

MINUTES
Observational Study Monitoring Board
Hispanic Community Health Study - Study of Latinos
Meeting, 11/08/2013

PARTICIPANTS:

OSMB Members Present: Odilia Bermudez, Judy Dubno, George Howard, Anne Newman, Roberto Treviño

OSMB Members Absent: Hannia Campos

Investigators: Susan Cheng, Martha Daviglius, Robert Kaplan, Neil Schneiderman, Sylvia Smoller, Scott Solomon, Gregory Talavera. By phone: Linda Gallo, Cathie Laurie, Yasmin Mossavar-Rahmani, Kari North, Carlos Rodriguez, Bruce Weir

Data Coordinating Center Investigators and Staff: Jianwen Cai, Wayne Rosamond, Marston Youngblood, Jeff Oberhaus, Gerardo Heiss, Krista Perreira (for SOL Youth)

NHLBI Staff: Jean Olson, Executive Secretary; Larissa Avilés-Santa (by phone); Tara Knox, George Papanicolaou, Lorraine Silsbee

NIDDK Staff: Peter Savage

INTRODUCTION

The HCHS-SOL OSMB is responsible for oversight of both the Hispanic Community Health Study-Study of Latinos (HCHS-SOL) and the SOL Youth study. The HCHS-SOL is a multi-center longitudinal cohort study of Hispanics/Latinos in the US initiated in October 2006 by NHLBI with co-support from six other NIH Institutes. The study objectives are to identify the prevalence of protective and harmful factors for diseases, disorders, and conditions in Hispanic/Latino populations; and to determine the role of acculturation and other mediators in their prevalence and development. SOL Youth is an HCHS-SOL ancillary study funded by an NHLBI grant that is recruiting 1600 adolescents with a parent in SOL to investigate the role of acculturation and other factors in prevalence and development of CVD and diabetes in this age group.

The morning closed session of this regularly scheduled meeting of the HCHS-SOL OSMB was called to order at 8:34 a.m. by OSMB Chair Dr. Howard. Executive Secretary Dr. Olson confirmed that no OSMB members had conflict of interest issues not previously reported and addressed via the annual NHLBI COI reporting process. Ms. Silsbee, representing Project Officer Dr. Avilés-Santa, gave a brief overview of major current activities in SOL. The main study activities at present include cohort retention, preparing and submitting manuscripts for publication, and planning for the upcoming cohort Visit 2.

HCHS-SOL

Responses to 2012 Recommendations

The investigators summarized their responses to the OSMB's 2012 recommendations, previously presented to the Board in writing in June 2013, which the OSMB accepted. No genetic findings have yet been generated in SOL that warrant reporting of genetic results to participants, but this may change after the OLa sequencing project is completed. At that time, the steering committee plans to seek expert consultation to give advice on reporting genetic results to participants. A tracking system is in place for phone vs. in-home annual follow-up

(AFU) completions, with 98% of AFU interviews completed by phone. SOL's protocol for identifying potential clinical endpoints enables capture of health care encounters in newer care delivery settings such as same-day surgical centers and hospital observation stays, and has a mapping system in place for the upcoming change to ICD-10 diagnosis coding. Several strategies for cohort and community relations have been implemented, with evaluation of their impact used to modify and refine these strategies where needed. The Steering Committee recently revised its policy to allow conduct of interventional ancillary studies in SOL, but will require that participants complete Visit 2 in order to be eligible for such studies. Cohort retention has been a high priority for the study and is going well.

Adverse Events

Not applicable; Visit 1 ended in 2011.

Study Progress

The main study activities at present include cohort retention, endpoints investigation, preparing and submitting manuscripts for publication, and planning for the upcoming cohort Visit 2. AFU interviews are proceeding on schedule, with response rates generally well above 80%. Contact rates vary across field centers and are notably lower at one of the sites. This site has some unique challenges but has employed new strategies to retain participants and to find and re-engage those lost to follow-up.

Roughly 14% of self-reported clinical events are for study endpoints of interest. Approximately 10,000 records have been retrieved thus far for clinical endpoints investigations. Overall, just over 4% of records sought are irretrievable, but this rate is much higher (9.3%) for Mexicans. Possible reasons for this potential source of bias and strategies to address it were discussed. For safety reasons, the San Diego Field Center does not allow staff to enter Mexico to retrieve records.

To date, the study has four papers published; however, only one main study paper plus two ancillary study papers have been published in the last year. The Steering Committee acknowledges this rate is lower than expected and has implemented several policy and procedural changes to improve these numbers. Additional suggestions to increase productivity were offered from Board members. A Data Book presenting Visit 1 prevalence data (published by NIH) and a brochure targeted specifically to study participants (published by the National Alliance for Hispanic Health) were produced this year and will be released for distribution in 2014 after the study's primary papers are published.

The related Omics in Latinos (OLa) project has completed GWAS genotyping of all consenting SOL participants. Quality control checks are currently underway, and procedures are being implemented to deconvolute relatedness, population structure, and admixture in the cohort. The chip set developed by this project to differentiate among Hispanic groups will be made available by the genotyping contractor to the research community for other uses. Gene sequencing is planned next.

All forms and instruments for Visit 2, scheduled to begin in October 2014, have been developed and are undergoing local IRB reviews. The exam duration will be between approximately 2-4 hours, depending on participants' eligibility for cardiac echo and certain questionnaires to be administered to specific subgroups. Safety exclusions were described. Results reporting and alert notifications will be handled as was done in Visit 1. The Visit 2 echocardiograms will create the largest community-based echocardiographic data set to date. Both standard and novel measures of cardiac structure and function will be obtained. Details of the scanning and reading

protocol, sonographer training, and quality control/quality assurance strategies were presented. Procedures to identify and report echocardiogram clinical alerts were discussed at length. Board members commented that timely identification of critical abnormalities seems to depend on the sonographer, with central readings taking weeks to complete; whether and when local readings will be done was unclear. Many ancillary studies are being proposed to enrich Visit 2.

Four scientific presentations focused on the status and recent findings from selected active SOL ancillary studies. One of these, Echo SOL, is planning a renewal to repeat echocardiograms in the roughly 1800 Echo SOL participants, since these will be excluded from the Visit 2 echocardiography component. The protocols are comparable so the data may be combined and analyzed as a single data set.

Recommendations

The OSMB enthusiastically endorsed continuation of the study, highlighting these particular strengths and accomplishments: excellent medical records retrieval rate, decision to consider participants eligible for recruitment into an intervention study only after they complete Visit 2, flexibility and success of approaches to maximize cohort retention, and recognition of the low publication rate and measures taken to address it. No issues of serious or immediate concern were identified.

The following recommendations were made:

- 1) Summarize the approach to coordinate echocardiography alert identification and notifications between the Field Centers and the Echo Reading Center, and justify why this approach meets the standard of care – due by **January 15, 2014**.
- 2) Provide an updated report in six months on papers published and the scientific impact of those publications -- due by **May 15, 2014**. Consider the following strategies to help improve the publication rate:
 - a. When submitting manuscripts to journals, include statements in cover emails or letters explaining why the findings have unique scientific impact
 - b. Conduct webinars and tutorials to assist investigators with data analysis and interpretation and manuscript preparation
 - c. Propose a journal supplement with multiple papers reporting study findings
- 3) Investigate the reasons for and consider the potential impact of the lower medical records retrieval rate for Mexican participants as compared with other subgroups. It was noted that many of unretrievable records for Mexicans may not be primary interest endpoints. The investigators are encouraged to investigate this possibility, and should consider the implication if there be a sizable number of suspected primary endpoint records that cannot be retrieved.
- 4) Clarify the relationship and plans for coordination between the Visit 2 echo component and the Echo SOL ancillary study. Make appropriate plans to ensure that the data already collected and to be collected can and will be harmonized.
- 5) Clarify eligibility criteria for the Visit 2 oral glucose tolerance test, including the maximum finger stick glucose cut-off level and whether self-report of diabetes must be accompanied by use of glucose-lowering medications.
- 6) Now that the Affordable Care Act (ACA) has been implemented, revisit last year's recommendation that the study consider opportunities for research to assess the impact of this legislation on its cohort.
- 7) Review the assumptions made in the SOLNAS ancillary study about estimates of food items and nutrient values of mixed dishes, particularly for Dominicans and Puerto Ricans, as those, in addition to obesity and other factors, may help to explain some of the differences observed across study groups.

- 8) Consider data mining of the wealth of information to be collected from readings of the Visit 2 echocardiograms.
- 9) Include in future annual OSMB reports
 - a. Information on how morbid event and death rates in SOL compare to expected rates
 - b. Publications report
 - c. More summary information rather than detailed tables, as was presented in the slide presentations during the meeting
 - d. Ancillary studies summary table (distributed as a hard copy at the meeting)

SOL YOUTH

Responses to 2012 Recommendations

No recommendations were given by the OSMB at the 2012 meeting.

Adverse Events

No adverse events occurred in the last year.

Study Progress

Participant recruitment is proceeding ahead of schedule and data collection is almost complete. The actual participation rate of approximately 70% is as expected. Some sites are below their recruitment goals but other sites are over-recruiting in order to achieve the overall target. This is acceptable, since making comparisons across groups with different backgrounds is not among the study's primary hypotheses. Two papers have been published so far and others are in progress. One SOL Youth ancillary study is active and three more are proposed.

Recommendations

The OSMB endorsed continuation of the study. No issues of serious or immediate concern were identified. The following recommendations were made:

- 1) Provide written reports on the study's status and progress made since this verbal report in advance of future OSMB meetings, including but not limited to details on completeness and retention and a publications report.
- 2) Explore differences in characteristics between consenters and refusers.

NEXT MEETING

The meeting adjourned at 2:30 p.m. The next meeting is scheduled for November 7, 2014.

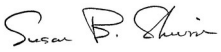
SIGNATURES

Respectfully submitted,

_____/s 11/22/2013_____
 George Howard, DrPH
 Chair, HCHS-SOL OSMB

_____/s 11/22/2013_____
 Jean Olson, MD, MPH
 Executive Secretary, HCHS-SOL OSMB

___X___ APPROVAL ___ ___ DISAPPROVAL



 Deputy Director, NHLBI

November 26, 2013

 Date