“The South Carolina Health Outcome Project on Epilepsy”: Project End Interim Report

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SC HOPE Interim Project End Report

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(Principal Investigator)

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(Project Manager)
Annotated Overview (SC HOPE Proposal)

Overview

Epilepsy is a neurological condition characterized by recurrent seizures and is a major public health problem affecting over 2.7 million Americans at an estimated annual cost of $15.5 billion. About 10% of Americans will have a seizure sometime during their lifetime, and about 3% will have had epilepsy by age 80. Our recent data indicates an estimated 35,000 to 47,000 South Carolina residents have epilepsy.

The cause of epilepsy is unknown in approximately 70% of individuals diagnosed with epilepsy. In most instances, persons with epilepsy take medications that help to reduce the number of seizures they have. Many times these drugs cause adverse side effects and prove to be very costly. Individuals with epilepsy also face many problems such as stigma, job discrimination, increased risk for depressive symptoms and anxiety, medication side effects, difficulty in obtaining insurance coverage, and driving restrictions. The effects of these issues on the health outcomes of patients have been largely unexplored.

The SC HOPE study addresses many of these unexplored issues and will contribute to better understanding of the factors influencing health outcomes in people with epilepsy. The findings of the study will ultimately help to build evidence that will improve the lives of people with epilepsy by informing public policy and subsequently addressing the most pressing needs of those experiencing the condition.

The goal of SC HOPE is to improve the lives of persons with epilepsy by providing the evidence on the role of socioeconomic and healthcare determinants as mutable factors of immediate importance in the outcomes of epilepsy.
Project Objectives
1) Compare the condition of epilepsy, as indicated by seizure type and frequency, among persons with epilepsy as a function of socioeconomic status (SES) and healthcare system determinants,

2) Compare the quality of life outcomes among persons with epilepsy as a function of SES and healthcare system determinants,

3) Compare the secondary conditions and adverse effects of epilepsy and its treatment among persons with epilepsy as a function of SES and healthcare system determinants,

4) Compare the medical care cost among persons with epilepsy as a function of SES and healthcare system determinants, and

5) Assess whether the effect of SES and healthcare system is mediated through attitudes, beliefs, coping skills, and perceived stigma.

These objectives were developed in accordance with a conceptual framework crafted by the SC HOPE research team that provided structure and guidance in the development and execution of the project (APPENDIX 1).

Of particular importance in the development of the SC HOPE study was the determination of inclusion criteria. To participate in the study, an individual must have
• had a seizure within the past five years (or received treatment for epilepsy including medications, VNS, ketogenic diet, or surgery),
• be 11 years and older, and
• reside in South Carolina (note: the original geographic scope of the SC HOPE study was limited to the following 16 counties before expansion to the entire state: Allendale, Bamberg, Barnwell, Beaufort, Berkeley, Calhoun, Charleston, Clarendon, Colleton, Dorchester, Georgetown, Hampton, Jasper, Orangeburg, Richland, and Williamsburg.)

Persons meeting the eligibility criteria are sent information on the study, including informed consent forms which they sign and return should they wish to participate. All identification of patients with epilepsy diagnoses and subsequent mailings are conducted by organizations having authorization to view patient information and contact potential participants. Researchers have access to identifiable information only if the individual consents to participate in the study and returns his/her contact information. Persons choosing not to participate will receive no further contact and are not identifiable by researchers. Once a participant is enrolled in the study, the participant is asked (in writing) for his/her primary epilepsy care provider in order to verify the epilepsy diagnosis. The participant is also asked to take part in a 50-60 minute phone interview every six-months for at 3 subsequent interviews. The interviews examine various aspects of the patient’s life with epilepsy over time including access to healthcare, perception of epilepsy severity and treatment, service needs, mental and emotional wellness, social function and social support, stigma, self-efficacy, perceived limitations, employment, and transportation issues. Data collected will be analyzed, and the results published in a
manner that ensures confidentiality to participants. Participation in the SC HOPE study is voluntary and those taking part may withdraw at any time.

**Key Personnel and Partners**

**Personnel**

Principal Investigator - Anbesaw Selassie, DrPH  
Co-Investigators - David Griesemer, MD  
Elisabeth Pickelsimer, DA  
Gigi Smith, CPNP  
Robert Turner, MD  
Janelle Wagner, PhD  
Braxton Wannamaker, MD

Project Manager - Chris Koutsogeorgas, MEd

Interviewers - Robin Butler, BS, Lead Interviewer  
Sharon Stokes, Interviewer

Epidemiologist - Pamela Ferguson, PhD

PhD Candidate - Lee Lineberry, BS

CDC Technical Officer - David Thurman, MD

**Funding Organizations**

Centers for Disease Control and Prevention (CDC)  
American Association of Medical Colleges (AAMC)

**Partners for Data Utilization**

South Carolina Office of Research and Statistics (ORS)  
South Carolina Department of Health and Human Services (DHHS)  
State Health Plan (SHP)  
Medical University of South Carolina (MUSC)  
Braxton Wannamaker, MD

**Other Partners**

Epilepsy Foundation of South Carolina (EFSC)

**Project Management Plan and Oversight**

The management plan is designed to enhance efficiency and accountability. It provides administrative oversight for the program's research activities. Its major objectives are leadership and oversight, communication/training, quality assurance, and strategic planning. Responsibility for project management oversight rests with Mr. Koutsogeorgas. A team of three investigators have assumed the core administrative responsibilities. Dr.
Selassie is in charge of the overall project activities. Dr. Ferguson is responsible for the day-to-day statistical operations of the program and technical oversight. Dr. Pickelsimer is responsible for IRB compliance, development of the survey tool, and administrative activities. Dr. Selassie monitors all program activities and sets general policies relying on the support of a series of formal committees: The Steering Committee and an Investigators’ Committee. These committees provide supplemental instructions and suggestions to advance the research objectives and also evaluate project milestones and the quality of the science conducted by the project.

**Steering Committee**

The Steering Committee includes all investigators and key representatives from the community. Its meetings are organized and led by Mr. Koutsogeorgas and held quarterly in Charleston. The Steering Committee oversees the management component of the project and evaluates the progress. It reviews periodic reports prepared by the management team (Drs. Selassie, Ferguson, and Pickelsimer) on issues pertaining to cohort accrual, response rates, attrition rate, and data collection measures. The Steering Committee also reviews quarterly interim results and progress of the sub-projects. Potential problems and action plans to resolve problems detected in the project are identified. The minutes from the Steering Committee meetings are discussed at the subsequent meetings to ensure that the committee’s input and feedback is effectively implemented.

**Investigators’ Committee**

The Investigators’ Committee is comprised of the research team of the project. It includes Drs. Selassie, Wannamaker, Pickelsimer, Wagner, Ferguson, Griesemer, Ms. Smith, and Mr. Koutsogeorgas. The CDC Technical Adviser joins as needed. Project interviewers and consultants also participate on an “as needed” basis. This group meets weekly to review research topics slated for publications and data updates. The Investigators’ Committee evaluates the research progress of the project through interim analyses and generates suggestions and strategies to address challenges that may arise. The general format of the meeting includes presentations by the PI on research progress, data update by Dr. Ferguson and Mr. Koutsogeorgas, and progress on publication plans. The Investigators’ Committee also formulates publication topics, identifies and responds to special research opportunities and challenges, and refines the research hypotheses.
Status of Project Timeline

Timeline Key

**RED**  
- Date completed in the next fiscal year

**GREEN**  
- Date started in the previous fiscal year

- Minor revisions ongoing after completion

- Subsequent approvals needed as part of prescribed data acquisition process

- Continues to next fiscal year
SC HOPE Timeline - Year 1 (’04 - ’05)

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JUL: July; AUG: August; SEP: September; OCT: October; NOV: November; DEC: December; JAN: January; FEB: February; MAR: March; APR: April; MAY: May; JUN: June

Major milestones:
- Oct '04: 1st Interviewer Training Conducted
- May '05: Adult Survey Developed
- Dec '06: State Health Plan Data Approval
- Aug '06: 1st Subjects Enrolled/Interviewed
- Jan '07: Data Manage System Demo Tested
SC HOPE Timeline - Year 3 (’06 – ’07)

- Adult Survey Developed
- Adolescent Survey Developed
- MUSC Recruitment Expansion
- Adult Follow-Up Survey Developed
- Adolescent Follow-Up Survey Developed
- Data Management System Developed
- 1st Subjects Enrolled/Interviewed
- 1st Follow-Up Calls Made (MUSC)
- 2nd Follow-Up Calls Made (MUSC)
- Attendance at MUSC Clinics
- Medicaid Follow-Up Approval (DHHS)
- Medicaid Follow-Up Letters Sent
- Medicaid Follow-Up Calls Made
- Dr. Wannamaker Recruitment
- Dr. W. Follow-Up Calls Made
- IRB Amendment #4 Approved
- IRB Amendment #5 Approved
- IRB Continuation Request Approved
- 2nd Interview Training Conducted
- Follow-Up Surveys Programmed
- Data Checks

JUL  AUG  SEP  OCT  NOV  DEC  JAN  FEB  MAR  APR  MAY  JUN

Oct '04  May '05  Jun '06  Oct '05  Nov '05  Sep '05  May '06
Recruitment

To meet the objectives of the SC HOPE research objectives, members of the research team have developed recruitment strategies which will facilitate successful completion of the study. Originally, the recruitment strategies developed by the research team involved the identification of patients with epilepsy from five sources: 1) Hospital Discharge, 2) Emergency Department, 3) Medicaid, 4) State Health Plan, and 5) Community Outreach. This initial recruitment effort focused on a sample from the first four of these strategies and was limited to the original 16 counties outlined in the introduction. Due to low response rates to these early recruitment strategies, two additional strategies were developed utilizing billing data from the MUSC (to identify patients diagnosed with epilepsy) and patients from Dr. Braxton Wannamaker’s neurology/epileptology practice. Although these latter strategies violated identification of patients from a defined sample frame, thereby limiting inference to a population base, we decided to make post-hoc adjustment to the distributions in the desired sample frame and went ahead with these new recruitment strategies. Further, it was determined to expand the Medicaid recruitment strategy to include all Medicaid beneficiaries with an epilepsy diagnosis in the 16-county study area. While these expanded recruitment strategies bolstered enrollment, participation in the study was still far below expectations. Subsequently, the MUSC recruitment effort was expanded to include all epilepsy patients outside the original 16 county study area that received care at MUSC and had a diagnosis of epilepsy. Follow-up measures such as second mailouts and phone calls were also implemented to assist in the enhancement of enrollment. Thus, a total of seven recruitment strategies have been implemented; each having its own challenges and level of success. These strategies are outlined below.

Hospital Discharge/Emergency Dept

Recruitment of persons with epilepsy initially involved the use of hospital discharge (HD) and emergency department (ED) data as the sampling frame. The South Carolina Office of Research and Statistics (ORS) is the repository of these data by legal authority. The availability of a centralized data system was deemed highly desirable to select the sample from the targeted 16-county study area as stated in the proposal. Before this could occur, however, authorization from the South Carolina Data Oversight Council (DOC) was required. The DOC is the regulatory body appointed by the Governor of South Carolina to review study applications that seek to use HD and ED for research purposes. The charge of the DOC is primarily to ensure data integrity and confidentiality.

Although the DOC has reviewed numerous applications for data use, our request was the first to identify and contact patients using ORS personnel on behalf of SC HOPE researchers. Because this was the first study that identified the legal custodians of the data (i.e., ORS) to be involved in subject selection, there was a major concern by the DOC regarding HIPAA regulation that limits such activities only to ‘covered entities’ and ORS has no covered entity status. This prompted the DOC to require ORS permission from each hospital and ED that submits data to it. Only through this authorization would ORS be able to identify and contact patients on behalf of SCHOPE. Over the course of 5 months (from January 2005
to June 2005), the DOC developed a series of letters of support and authorizations that were required to be in place before HD and ED recruitment could begin. These include the following steps. Examples included:

1. Letters from the South Carolina Hospital Association (SCHA) and South Carolina Medical Association (SCMA) expressing support and encouraging their respective members to facilitate the study,
2. Approval letter from the CEOs of the hospitals and EDs identified as sources of patients,
3. Notifications to the individual hospitals and EDs specifying the patients that were treated at their respective facilities who are eligible for the study,
4. Confirmation of participation from the various Hospital Patient Data Managers regarding their willingness to support the recruitment effort, and
5. Permission allowing ORS to use letterheads of the respective hospitals’/EDs’ for the introductory letters to be sent to the patients (all mailouts sent by ORS).

The research team felt the acquisition of these tiers of approvals would very likely result in protracted delays to accomplish recruitment of patients from ED and HD in an effective and timely manner as noted in the timeline presented on page 12. As expected, the multiple layers of approval put forth by the DOC resulted in outright refusal or non-response even after reminder phone calls and letters sent by ORS. This resulted in very few individuals ultimately receiving enrollment materials from this recruitment strategy (n=585). As of February 11, 2007 only 16 individuals have been enrolled into the SC HOPE study through the HD and ED recruitment strategy due, in large part, to the unwieldy process put in place by the DOC approval.
Medicaid

Although a few Medicaid patients could be captured through the HD/ED strategy, it was felt that the best strategy to capture epilepsy patients whose primary insurance was through Medicaid was to select these patients from the Medicaid database. The original sample drawn from this data was limited to the 16 county study region and was restricted to those Medicaid beneficiaries who received a diagnosis (ICD-9) of epilepsy within the predetermined parameters put forth in the sampling frame. In order to utilize the Medicaid data at ORS to recruit participants for the SC HOPE study, authorization was required from the South Carolina Department of Health and Human Services (DHHS).

An initial application to utilize this data was completed and sent to ORS in May 2005. ORS, in turn, was responsible for coordinating approval between the research team at MUSC and the authorizing body (DHHS). Due to a series of unfortunate events including the misplacement of the application and illness of the ORS liaison, a second application was submitted in September 2005. The three month delay set in motion subsequent events, including change of key personnel involved in the original DOC approval, which affected timely recruitment of patients.

Despite the delay, DHHS had given preliminary approval by mid-December 2005 to contact epilepsy patients for the SC HOPE study. To a great extent, this approval was made possible by the director of data utilization at DHHS. At the end of December this director retired and was replaced with an individual from within the agency. Though preliminarily approved, the new director deemed it necessary to submit the application one last time in January 2006 through the chain of command at DHHS including other legal advisors and the medical director of the agency. The application remained unchanged from the time tentative approval was granted, but the new reviewers became increasingly concerned about potential HIPAA violations and ensuing liability of the agency. For example, the reviewers were particularly distressed about the possibility of recruitment materials being sent to an incorrect address and then opened by the unintended recipient (thus revealing a patient’s epilepsy diagnosis). Although this is a violation of federal law and the likelihood of this scenario occurring is low, the doubts and anxiety generated from this and similar situations resulted in DHHS reversing its previous approval for data usage. Subsequent calls were conducted over the following months between MUSC and DHHS to allay concerns over HIPAA issues and to negotiate a mutually agreeable solution to the issues on the table.

After much deliberation, DHHS granted approval in May 2006 to contact its Medicaid beneficiaries. However, the authorization to do so was tempered by the stipulation that all mailings to identified individuals could only include a one page letter that invited recipients to call a toll free number to learn more about the study. This letter was to have no mention of the word epilepsy or “SC HOPE” (in case the letter fell into unintended hands). Because of the vague nature of this letter, contacted individuals had no idea why they were sent a letter. As one could
Imagine, the response rate to this approach was very low. Of the 1,247 letters that were sent, there were only 28 responses seeking more information about the study. Of the 28 requesting information, 8 enrolled in the study. However, 2 of these were duplicates from other recruitment strategies. Thus, a total of 6 individuals were enrolled with the last enrollee joining the study in early October 2006.

Complications regarding this recruitment strategy were compounded when it was observed that all 28 respondents who requested more information about the study had last names beginning with the letters A-L. Because this could not be attributed to coincidence, this oddity was brought to the attention of ORS which was assigned the responsibility of all mailouts to identified Medicaid beneficiaries. Though no cogent explanation was found for this omission, the issue was promptly addressed. Because contact with Medicaid beneficiaries (diagnosed with epilepsy) with last names M-Z had been delayed, ORS was requested to immediately mail to all individuals M-Z in the original 16 county study area. Due to the low response rate, ORS was also instructed to mail to all other Medicaid beneficiaries with epilepsy in the 16 county study area who were not included in the original sample.

To bolster Medicaid recruitment, members of the SC HOPE research team approached DHHS to request permission to conduct follow-up phone calls to those who received the recruitment letters. Because SC HOPE researchers are prohibited from directly contacting potential participants due to patient confidentiality issues, ORS was requested to conduct the follow-up phone calls on behalf of the SC HOPE study. DHHS granted permission to implement this initiative in October 2006. As a result of the expansion of the Medicaid recruitment strategy and especially because of the follow-up phone calls to Medicaid patients, the SC HOPE study has experienced an increase in the number of Medicaid enrollees. As of February 11, 2007, 52 individuals have been enrolled through the Medicaid recruitment strategy with approximately 150 epilepsy patients with Medicaid insurance expressing interest in having enrollment packages mailed to them. Thus, there are 98 Medicaid patients with epilepsy that have expressed interest and whose decision on participation is pending.

**State Health Plan Insurance**

In addition to HD/ED and Medicaid data, ORS is also the repository of patient data for Blue Cross & Blue Shield State Health Plan (SHP) subscribers and their beneficiaries. The State Health Plan is the largest health insurance plan in South Carolina and covers state employees, school system employees, and other employees in the public sector.

As part of the SC HOPE recruitment plan, a sample frame was devised by the research team for the purpose of selecting individuals diagnosed with epilepsy that were enrollees of the State Health Plan. This recruitment plan was also found to be ideal to capture patients with epilepsy who receive their treatment in physician offices. After sampling, those selected would receive enrollment
materials for the SC HOPE study and return completed informed consents to the project manager if they wished to participate in the study.

From the beginning of the study, ORS notified the research team that approval for SHP data usage would follow that of Medicaid. Therefore, any delays in obtaining Medicaid data usage approval would also delay approval of SHP data usage. This link between the two recruitment strategies magnified the ramifications of the hindrances experienced in obtaining Medicaid approval. Because of this, initial mailouts from ORS did not go out to persons with epilepsy identified from SHP until May 2006.

Unfortunately, the response rate to the SHP mailouts was low, much like the aforementioned recruitment strategies—33 out of 1002 individuals contacted through the SHP recruitment process were enrolled to date. As in the Medicaid strategy, the research team petitioned SHP administrators to include all beneficiaries diagnosed with epilepsy in the 16 county study area (in addition to those sampled). Furthermore, authorization was requested to expand recruitment statewide to all subscribers and beneficiaries with epilepsy. In spite of the authorization provided for the initial mailout to the sample drawn from the 16 counties, SHP denied the requests. Though uncorroborated, it was learned at a later date that the requests were not granted due to the displeasure of one SHP beneficiary over having received recruitment materials for the SC HOPE project. His/her complaints made their way to the administrative levels of the organization to negatively influence the decision.

**Community-based Recruitment**

Though the recruitment efforts for the SC HOPE study mainly focused on the utilization of existing data sets to contact potential participants, many community-based recruitment strategies were employed to enhance enrollment.

One of the largest endeavors involved the inclusion of inserts in approximately 98,000 local water bills in January 2006. These inserts gave a brief overview of epilepsy, featured the SC HOPE study, and provided a means by which readers could obtain further information on how to participate. While this effort reached a substantial number of individuals, the yield in participants from the undertaking was very disappointing.

Other initiatives involved direct contact with potential participants. Several presentations were conducted in the community to raise awareness of the study including talks at the annual SC Epilepsy Conference, MUSC’s summer seminar series on epilepsy, CDC Skill Building Institute, Pediatric Neuroscience Update, a local minor league baseball game, and at an event featuring Tony Coelho, Chairman of the Board of Directors of the Epilepsy Foundation of America. Information on how to participate in the SC HOPE study was made available to all interested participants.

Various forms of media were also utilized in publicizing the SC HOPE project with the objective to enroll more participants. An article exploring the SC HOPE project was included in August 2006 issue of “The Catalyst”, the weekly
newspaper of the Medical University of South Carolina. “The Catalyst” also runs a continuous, weekly advertisement of the SC HOPE project for those interested in learning more about the study. A separate article was included in the quarterly newsletter of the Epilepsy Foundation of South Carolina (EFSC) which was distributed to the entire membership of the organization. In addition to these efforts, press releases describing the study were forwarded to 29 newspapers in the Lowcountry area of South Carolina. Information about the SC HOPE study was also posted on Epilepsy Foundation of South Carolina’s website (www.epilepsysc.org) and the official SC HOPE website (www.musc.edu/schope). Lastly, the SC HOPE project manager was invited to appear on the local Public Broadcasting System (PBS) radio station to talk about the study. During the radio interview, an opportunity was given to share with the audience ways to participate in the SC HOPE study.

The efforts put forth in the community approach certainly raised awareness about the SC HOPE study, but this did not translate into enhanced enrollment figures. Only 6 individuals joined the study through all of the community efforts. This experience proved a targeted approach to recruiting individuals with specific medical conditions is significantly more successful than other general methods.

**MUSC**

As noted, the responses to the initial recruitment strategies for the SC HOPE project were disappointing. Anticipating a low volume of enrollees, the SC HOPE research team devised a recruitment plan utilizing billing data from MUSC. Patients with a primary or secondary diagnosis of epilepsy who sought medical care at the Medical University of South Carolina were sent recruitment materials. Before this could take place, the research team took steps to gain the support of the MUSC neurologists who provided care to the MUSC epilepsy patients. This was of immense importance since SC HOPE researchers could not initiate contact with patients due to patient confidentiality issues. Therefore, the neurologist would not only need to agree to participate in the study but also have to agree to allocate work time for their staff to dedicate to mailouts. Dr. Selassie and Mr. Koutsogeorgas met with the neurologists and presented the recruitment plan for their considerations. All agreed to participate and signed forms that confirmed their participation in the SC HOPE study. Furthermore, all but one neurologist agreed to allow time for their staff to assist in the study mailouts.

The MUSC recruitment process began in the spring of 2006 utilizing a sample frame for those identified as having epilepsy in the MUSC billing data who reside in the 16 county study area. We amended this strategy at a later date (early summer 2006) to include all identified patients with epilepsy in the 16-county study area. In August 2006, the recruitment strategy was expanded to include all patients with epilepsy from South Carolina that had sought medical care at the MUSC.

A total of 1,943 packets were mailed through the MUSC recruitment strategy. Although it was the most successful recruitment approach in terms of volume, the strategy yielded only a 3% response rate. Measures were initiated to ensure data from the MUSC recruitment strategy was maximized. Two series of follow-up
calls were enacted that would eventually double the response rate to 6%. The first involved the efforts of two individuals from the neurology clinics who were hired on a part-time basis in the summer of 2006. These individuals completed follow-up phone calls only with those patients who were identified through the initial sample of MUSC billing data. The second series of follow-up calls was conducted by another employee of the neurology department at MUSC in the late fall of 2006. This employee followed up by phone all 1,943 patients who were mailed enrollment materials. 365 of those who were contacted indicated an interest to participate in the study and requested a second set of enrollment materials to be forwarded to them. As of February 11, 2007, 128 individuals were enrolled through the MUSC recruitment strategy. Approximately 235 persons who expressed interest for enrollment have yet to be enrolled.

A supplemental effort undertaken in the last 3 months involves the presence of the SC HOPE project manager in the epilepsy clinics at MUSC. On average this involves attendance at one adult clinic and two pediatric clinics per week. Neurologists identify potential study participants and ask the patient if they would be interested in learning more about the study. The project manager is then invited into the examination room to share the recruitment materials and answer any questions. Patients may fill the paperwork out at that time or may take the materials home and mail them in upon completion. The patients are informed in all instances they are under no obligation to take part in the study. Thus far, 7 individuals have been enrolled in the study through the MUSC epilepsy clinics. This approach has much promise. However, it would experience greater success if an employee were in place that could devote more time to the clinics.

_Epileptology Practice (Braxton Wannamaker, MD)_

Even with the relative success of the MUSC recruitment process, the SC HOPE project still was short of its minimum recruitment goal of 400 participants. Because the original sampling scheme was no longer a consideration, Dr. Braxton Wannamaker was approached to inquire about the possibility of forwarding recruitment materials to his patients evaluated in 2004. Dr. Wannamaker is a co-investigator for the SC HOPE study and is also a highly respected epileptologist with practice spanning more than 30 years. Dr. Wannamaker agreed to this request and was provided packets to mail to his 2004 patients. Of the 299 that were sent in November 2006, 61 have already been enrolled. This has certainly been the most successful recruitment effort (by percentage of enrollees). Currently, Dr. Wannamaker and his assistant are conducting follow-up calls to non-respondents to ensure they have received the recruitment materials and have an opportunity to participate in the study if they wish to do so. There is a high prospect to enroll at least 100 (33%) of the patients from his practice.

**Enrollment Results by Recruitment Strategy**

SC HOPE Recruitment as of 01/31/2007

<table>
<thead>
<tr>
<th>AGE</th>
<th>RECRUITMENT METHOD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Community</td>
</tr>
<tr>
<td>Adult</td>
<td>6</td>
</tr>
<tr>
<td>Youth</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
</tr>
</tbody>
</table>
Administrative Issues (IRB)

As part of the requirements put forth by MUSC in its research endeavors, the SC HOPE study was presented to the university’s Institutional Review Board (IRB) for review of its methodology and consideration for approval. Due to several factors, including the continual adaptation of the recruitment process, the IRB approval process proved to be cumbersome. The SC HOPE project was never denied approval by the IRB. However, the presentation of the SC HOPE project to the IRB created a protracted review process because of the IRB’s unfamiliarity with the unique methodologies put forth in the study.

The initial submission requested for expedited IRB approval in September 2005. This initial IRB packet included approval requests for the four recruitment strategies outlined in the previous section:

1. HD/ED
2. Medicaid
3. State Health Plan
4. Community Efforts

Since the IRB did not have previous experience with research proposing such a large number of recruitment strategies, the IRB chairperson (with responsibility to give expedited approval) became overwhelmed by the total number of documents associated with the various strategies. These documents included introductory letters, informed consents, Epilepsy Verification Forms, letters to private physicians, initial adult survey, and IRB specific forms. Though the process was drawn out as a result of the introduction of these many documents, approval for the initial request to conduct the SC HOPE study was granted in late November, 2005.

In spite of the initial approval, the IRB raised certain issues that required resolution. One of these issues was whether the SC HOPE study fell under more stringent HIPAA guidelines as it related to the amount of risk to the participants. It was ultimately decided by the IRB Chair that these HIPAA requirements would be waived for the SC HOPE project since the study was deemed to be no more than minimal risk to the participants. However, the IRB Chair was concerned about the HD/ED recruitment strategy which involved hospitals providing patient names to be contacted (via ORS). Therefore, Protected Health Information (PHI) for these patients had to be resolved before final approval could be granted. In an effort to abate the chair’s concerns, a member of the SC HOPE research team met with her to illustrate that PHI was not the MUSC IRB’s responsibility in this instance. If PHI happened to be violated, each hospital or agency that allowed their patients to be contacted would be in violation, not MUSC. It should be noted in preceding Traumatic Brain Injury and Spinal Cord Injury studies conducted by the same investigators, legislative authority was in place to access patient data. This negated the need to demonstrate separately to the IRB that PHI violations would not be the responsibility of MUSC. However, the SC HOPE study does not have the legislative authority to access patient data as the previous TBI studies did. Therefore, the IRB requested the MUSC Compliance Officer to justify why PHI would not be violated. The Officer submitted a four-page report to the IRB explaining that the study did not violate...
PHI. The process from initial submission to receiving IRB approval took approximately three months.

As mentioned earlier, the IRB process for the SC HOPE study proved to be unwieldy at times and required repeated visits to the IRB for submission of amendments to the original request. Below is a summary of the amendments tendered to the IRB:

1. Amendment #1 – January 2006
   - Revisions to the initial adult survey and recruitment documents were approved.

2. Amendment #2 – March 1, 2006
   - The initial adolescent survey received approval.

3. Amendment #3 – March 28, 2006
   - Direct recruitment of MUSC patients was not in the original sampling plan although some of these patients would have been randomized into the overall Hospital/ED cohort. As a result of the lower than anticipated number of enrolled participants from the original recruitment strategies, the MUSC recruitment strategy was developed and required IRB approval. The MUSC recruitment strategy was deemed not to be in violation of PHI or HIPAA because members of the SC HOPE research team are MUSC faculty and provide healthcare to MUSC patients (thus having legal access to patient information). Despite this, securing approval of this strategy required one key issue to be resolved. This issue, raised by the IRB Chair, stipulated that approval would not be granted for this strategy unless each specific MUSC physician who provided care to a potential study participant furnished written documentation of his/her involvement in the SC HOPE project. Subsequently, a printout of patients was generated and forwarded to applicable physicians. Each physician in agreement was then required to sign the introductory letter that was to be mailed to patients under the MUSC recruitment strategy.

   - A revised MUSC recruitment letter was submitted and approved

5. Amendment #5 – August, 2006
   - A revised Medicaid recruitment letter was submitted and approved

In September 2006, a continuation request for the SC HOPE study was presented to the MUSC IRB as required. The request was consequently approved for a period of one year.

Ensuring patient confidentiality and adhering to regulatory guidelines is of paramount importance to the SC HOPE study. Although this is demonstrated through the collaborative efforts with the MUSC IRB, the study wished to ensure further protection to its participants by obtaining a Confidentiality Certificate from the NIH. This certificate would, among other things, protect study participants from having their data and voluntary survey responses subject to subpoena. The request for the Confidentiality Certificate was put forth at the end of December 2005 to NIH/NIAAA. By mid-January 2006, the Confidentiality Certificate was received, allowing for the implementation of recruitment efforts.
Data Collection and Management Activities

The task of data collection and management is imperative to the success of the SC HOPE project. Careful planning and much effort have gone into this aspect to assure data is relevant to the objectives of the study and is collected in a manner that reflects high standards of quality and ethics. To better understand the data collection and management methods of the study and the effort expended in developing the methods, the following description is presented specifically addressing survey development, interviewing, data management, and data quality.

Survey Development

Development of the survey instrument for the SC HOPE study began in October 2004 under the leadership of Drs. Janelle Wagner and Elisabeth Pickelsimer utilizing the adult and adolescent operational models (APPENDIX 2 and APPENDIX 3). Initial efforts focused on literature review, consultation with content experts and the CDC advisors, and supplementary research for the development of two similar, but separate surveys: adult and adolescent. This effort was both time and resource intensive. The creation of the surveys was an iterative process, resulting in the formation of multiple drafts that were amended to implement findings from research, peer review, pilot-testing, etc. Original efforts in developing the survey focused on the adult version. Most of the survey consists of scales of validated questions derived from previously developed instruments with normative data. The following are validated scales that were included in the survey:

- Seizures (ILAE Classification), Seizure Severity Questionnaire (Cramer et al, 2002)
- Behavioral Risk Factor Surveillance System (BRFSS)
- QOLIE-89 (SF-36 included), QOLIE-48 (Devinsky, Cramer, et al)
- Epilepsy Self Efficacy Scale (DiIorio et al); Seizure Self-Efficacy Scale for Children (Caplin et al)
- Stigma Scale (DiIorio et al)
- Centers for Epidemiology Scale-Depression (CES-D; Radloff et al): adult and youth forms

These scales explore issues that persons with epilepsy face such as access to healthcare, perception of epilepsy severity and treatment, service needs, mental and emotional wellness, social function and social support, stigma, self-efficacy, perceived limitations, employment, and transportation issues. The survey further addresses a number of other topics related to the study objectives including the following:

- Personal Epilepsy/Seizures Information
- Quality of Life
- Own Views on Participant’s Health
- Own Views on Participant’s Epilepsy
- Physical Function
- Attention/Concentration/Memory/Language Function
- Drug and Alcohol Use
• Other topics to include age, race, gender, marital status, living situation, social and income status, insurance status, education level

With assistance from the Epilepsy Foundation of South Carolina (EFSC), a pre-test of a draft version of the adult survey was administered in written form to a group of 9 individuals in Greenville, SC on January 27, 2005. The participants represented a small sample of the targeted population (adults with epilepsy). The pre-test results assisted in making the survey more user friendly with specific improvements in readability and format.

Upon completion of the pre-test, the adult survey went through several revisions before pilot-testing it on 25 persons with epilepsy during a phone interview. Data obtained from the pilot test were analyzed in March 2005 (APPENDIX 4). After several subsequent revisions, the lessons learned from the pilot-test were incorporated into a finalized adult survey tool in August 2005. Minor changes based on quality reviews have been made since the final adult survey was generated (as recent as December 2006). However, the survey, in large part, has remained the same since interviews were initiated. Subsequent to the finalization of this survey, the follow-up adult survey (to be administered six months after the initial survey) was developed. Work began on the follow-up survey in October 2005 with the final version completed in December 2005. As with the initial adult survey, revisions continued with the latest in December 2006.

The development of the adolescent survey for the SC HOPE study was based on the constructs of the adult survey. Work started on the adolescent survey in late May 2005 and was completed in late November 2005. Similar activities were utilized in the creation of the adolescent survey as in the adult survey. Of special note was pre-testing of the survey which was carried out in collaboration with the epilepsy program at Wake Forest University through the facilitation and support of Ms. Pat Gibson, MSW in late August 2005. The adolescent survey differed from the adult survey in some ways, focusing on topics pertinent to the teenage population (e.g., epilepsy and school, social isolation, epilepsy and academics, etc.). For the most part, the survey developers attempted to be as consistent as possible between the adult and adolescent versions. Yet, certain questions specific to the administration of the adolescent survey had to be addressed. Of particular concern was the need for both the parent/guardian and the adolescent to participate in the survey and to determine a way in which this could be done effectively and seamlessly. Unfortunately, no simple solution existed to remedy this issue. Therefore, study interviewers often have to make several calls to an adolescent participant and their guardian in order to complete an interview. This obviously makes obtaining a full interview from the adolescent participants more labor intensive than the adults. Still, Drs. Wagner and Pickelsimer were successful in developing the adolescent survey and began working on the adolescent follow-up survey in November 2005. The adolescent follow-up survey was completed in March 2006 and has been revised to some extent over the following months based on quality measures. This follow-up survey is to be administered six months after the initial survey is completed.

One challenge that deserves mention and was regularly encountered during the development of all surveys was overall length. The surveys take, on average,
about an hour to complete. Of special concern was the potential for respondent fatigue. With the assistance of technical advisors at the CDC, the project’s staff has met on several occasions to shorten the survey, while still retaining its integrity. The suggestions generated from these meetings were incorporated into various forms of the survey.

**Interviewing**

The surveys mentioned in the previous section are administered by trained interviewers. Robin Butler and Sharon Stokes, based in Columbia, SC, serve as project interviewers for the study. They possess substantial experience with research interviews and have successfully conducted 194 interviews as of February 11, 2007. In addition to conducting interviews, they are responsible for scheduling interviews, tracking individuals whose address and/or phone numbers have changed, reporting areas for improvement in the interview process, keeping investigators apprised of participants’ comments and/or complaints concerning the questionnaire, submitting interview status reports, and identifying problems with the SC HOPE data management system (into which the interviewers input participant responses). Initial training of interviewers on February 10, 2006 included education concerning epilepsy, phone etiquette, an introduction to the SC HOPE surveys, and techniques to maintain validity and reliability of questionnaire administration. Follow-up training on January 11, 2007 focused on reviewing interviewer operations, data management system utilization, data review, and interviewer quality measures. Below is a summary of the interviews conducted as of January 31, 2007.

<table>
<thead>
<tr>
<th>AGE (Yrs)</th>
<th>Total Interviews</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult (18 &amp; Older)</td>
<td>156</td>
</tr>
<tr>
<td>Youth (11-17)</td>
<td>38</td>
</tr>
<tr>
<td>Total</td>
<td>194</td>
</tr>
</tbody>
</table>

**Data Management System**

Discussion began in September 2005 with the Data Coordination Unit (DCU) at MUSC to develop a comprehensive data management system to facilitate the day-to-day operations of the project. Some tasks that the data management system were intended to address were participant enrollment, enrollment notification to interviewers, scheduling of interviews, interview reminders, study status reports, project management, and participant reimbursement. Of primary importance, however, was the programming of the data entry platform for the initial adult and adolescent surveys. In order to successfully complete this task, the research team conducted logic checks of the data so that appropriate skip patterns could be implemented into the adult and adolescent surveys (as well as their follow-up versions). These skip patterns would reduce data entry error by restricting entries to certain parameters within a given logical framework.

After receiving input from the research team, DCU developed a demonstration version of the data management system in January 2006, which was tested for approximately three months. Testing was completed by May 2006 with initial utilization of the system beginning with the first enrollment and interviews of the
project in mid-May 2006. Throughout the development, testing, and utilization phases of the data management system, all precautions were taken to ensure the security of patient data and to comply with patient confidentiality guidelines.

Though testing was conducted in the initial months of 2006, “live” interviews revealed the need for improvement in certain areas of the data management system. Also, data analysis and quality measures have prompted some recoding of both the adult and adolescent versions of the survey on the data management system. Recently, the DCU staff programmed the follow-up versions of the surveys and incorporated other requests to facilitate the management of the project. The DCU staff has been responsive in implementing the research team and interviewers’ requests for updates to the data management system and has proven to be valuable resources in maximizing the capabilities of the system.

Quality Measures
In order to ensure data quality, SC HOPE researchers have implemented several measures that provide mechanisms for continuous analysis and improvement of the project. This effort, led by Dr. Pamela Ferguson in collaboration with other SC HOPE researchers, utilizes systematic and statistical methodologies to maintain the credibility and integrity of the data collected. Timely correction of errors and controls are built into the data collection program whenever possible. Regular checks of the data take place as it is collected. Thus far, data checks have been carried out in July, September, and December of 2006. The data checks as well as other quality initiatives have proven to be integral to the continued enhancement of the SC HOPE study. The project’s quality measures focus on the following:

1. Consistency of Coding
   Responses that are to be used throughout the interview will remain the same throughout the data entry. For example, ‘don’t know’ will always be entered as ‘777’, ‘refused’ will always be entered as ‘888’, and ‘not applicable’ will always be entered as ‘999’ to keep entry as simple as possible for the interviewers.

2. Entry Boundaries
   When possible, entry boundaries were built into the data entry program to prohibit skipping mandatory entries or entry of illogical data. For example, mandatory variables such as receipt of signed consent must be entered or the interviewer will not be able to continue data entry. Variables with logical boundaries, such as a variable with five possible responses categorized as 1 through 5, will allow only 1, 2, 3, 4, 5, 777, 888, or 999 to be entered.

3. Skip Patterns
   Skip patterns were built into the data entry program to streamline the interview as well as to ensure appropriate actions as a result of specific responses. If a response makes the next question not applicable, the program automatically skips to the next applicable question. For instance, if asked whether a participant’s eyes move during a seizure, and they respond that they stare straight ahead, the next question concerning direction of eye movement is skipped.
4. Responsiveness
Prior to the questionnaire being implemented, pilot-tests were performed, and frequencies run on all of the variables to check for responsiveness. In addition, comments and questions concerning the variables from the participants were collected by the interviewer and examined by the researchers to look for potential problems with the interview variables. Non-response was considered to be responses such as ‘don’t know’ and ‘refused’. Variables to which a high percent of the sample do not respond could not be considered to accurately represent the population. Also, non-response could indicate questions that are confusing, embarrassing, or offensive to the participant, which could affect future participation in the interview. Thus, those variables should either be modified to correct the problem or eliminated from the interview. Checks on the responsiveness to variables will be done throughout the interview period. However, they are being done more often in the initial period so that the questionnaire can be altered early on, if necessary. At present, frequencies are being run every two to three months.

5. Missing Data
Missing data may represent an issue with interview delivery or data entry. The responsibility for these problems may either rest with the interviewer or the entry program. “Missingness” will be checked regularly whenever frequencies are completed for responsiveness and the interviewers contacted concerning potential problems.

6. Logic Checks
Responses to certain variables may contradict responses to other variables measuring the same underlying construct. For instance, if an individual responds that they are ‘limited a lot’ in walking several hundred yards, it is illogical if they respond ‘not limited at all’ in walking more than a mile. Such responses could indicate either a problem on the part of the participant in understanding the questions, or on the part of the interviewer in either delivering the questions or in recording the responses. Illogical entries by an interviewer or illogical responses by a participant might indicate the need for further training, or a proxy respondent, respectively. Regular checks on logic will be done on a predetermined number of pairs of variables, and the interviewers contacted as needed to determine possible causes for illogical entries.

7. Inter-rater Reliability
In order to evaluate whether interviewers are uniform in how they interpret participant responses and accurate in their data entry, a sub-sample of interviews is conducted with a second interviewer listening. Participants are not aware there is a second interviewer present during a specific interview, but they are informed during consent that this may take place for quality assurance. Two interviewers coordinate their schedules to be present for a scheduled interview. One interviewer conducts the interview entering the responses as usual using the interactive database. The other interviewer listens to the responses given by the participant and enters responses separately into the database. This is conducted for a total of 20 different interviews, with the interviewers both getting a chance to conduct the interview online and to listen in. The results of each of the two interviews are compared using kappa statistics to evaluate inter-rater reliability,
while taking into account the prevalence of responses within the categories and
the presence of cells with zeros or ones (either of which conditions can distort the
values of kappa).

8. Intra-rater Reliability (Test-Retest Reliability)
It is also important to determine if interviewers are consistent in their delivery of
the interview, their data entry, and whether the participants give reliable responses
to the questions. In order to help evaluate this, a sub-sample of re-interviews is
conducted. Once a scheduled interview is conducted, participants are given the
option to participate in the same interview one week later. This is continued until
a total of 20 participants agree to undertake and complete a second interview.
These participants are compensated for their time in each of the interviews. The
same interviewer conducts the second interview approximately 1 week later on a
“dummy” database. Assuming the participant responds consistently the same as
the interview conducted a week earlier, agreement between the two interviews
reflects the manner in which the rater (interviewer) conducts the interviews.
However, it can also be interpreted as test-retest reliability indicating the extent to
which the respondent provides consistently the same response as the first
interview assuming that the interviewer (rater) codes the responses consistently
the same. In both instances, the variables used must not be strongly time
dependent (ie, affected by one week’s time) and respondents should not be chosen
who happen to have had a life-impacting event during that week’s time (ie, major
surgical procedure, job change, etc.). Results are compared using kappa statistics
to estimate reliability, while taking into account the prevalence of responses
within the categories and the presence of cells with zeros or ones (either of which
conditions can distort the values of kappa).

9. Internal Consistency
Aggregate measure of how responses are internally consistent among a set of
items that measure a single one-dimensional latent construct is conducted using
the Cronbach’s alpha coefficient. This measure provides the evidence that the
responses that are intended to measure the same underlying construct when asked
in various format, are producing the similar response. High alpha (near 1)
suggests the responses are internally inconsistent.

10. Interviewer to Researcher Feedback
It is vital to the quality of the data for there to be good communication between
those collecting the data and those analyzing and interpreting the data.
Interviewers are instructed to keep notes during and after interviews on items that
provoke new questions, concerns, or other comments from either the interviewers
or participants, and send them regularly to the research team. Researchers then
review these and send responses back promptly. Interviewers are also urged to
share any ideas they have concerning the interviews or interviewing process with
the researchers at MUSC.

11. Researcher to Interviewer Feedback
Along with responses to interviewer-initiated items, the researchers at MUSC
provide feedback to the interviewers on breaks in the skip patterns, high levels of
non-responsiveness, missing data, and illogical entries. Response frequencies on
the variables will be run by interviewer to determine whether an interviewer has
unusually different responses compared to the other interviewer(s). This information is then shared with the interviewers to determine whether there are irregularities in the interview, the data entry program, the interviewing process, or the participant responses. Any changes to the interview are reviewed with the interviewers prior to initiating. Finally, periodic workshops are utilized not only for additional training, but to share information back and forth between the interviewers and the researchers at MUSC.

Conclusion and Suggestions

This report summarizes the efforts made by the employees and researchers of SC HOPE to fulfill the stipulation of the award. The report also provides particular emphasis to explain the lag in accomplishing the objectives according to the proposed timeline. Although SC HOPE activities were proposed to be completed in three years—with funding provided in two years—there were numerous challenges regarding the start date of the project and how the funding should be disbursed as a result of the “off-cycle” funding of SC HOPE. As noted in the award letter from AAMC, the starting date of the project was slated for October 1, 2004. However, it was retro-dated to July 19, 2004 to make the funding cycle compatible with the AAMC award schedule. Although there was no financial problem with this arrangement, it shortened the time allocated for the project’s operation by 71 days. Yet, the biggest and most challenging problem was the gap between what we expected to be the time needed to accomplish the various activities and the actual time it took to complete them. Notable examples include the approval to get access to the data through the DOC approval process. It took not only an extended time—October through June 2005—but also the protocol was mired with multiple tiers of approval. The receipt of the DOC approval, notwithstanding the aforementioned 5-step preconditions needed before individuals are contacted, was a relief for the research team. Our hopes were dashed when it became apparent that the responses from some of the hospitals were either outright disapproval or total disregard even when they were contacted by phone. (Of note, there are still a few hospitals that did not respond to the letter sent from ORS.) Perhaps the most vivid example that typifies this protracted delay is the time that had elapsed from the funding date (July 19, 2004) to obtaining approval from DOC (June 17, 2005) to enrollment of the first person with epilepsy (July 16, 2006). This is 2 years to the date of the beginning of the funding.

Further challenges included human subject issues and the convoluted process of accessing identifiable patient data created by HIPAA regulation even when such access is sought through legally authorized third party. Although there is adequate documentation about the unintended implications of HIPAA on subject recruitment, the challenges encountered by SC HOPE is worthy of mention. As indicated earlier, the conditions included in the IRB and DOC approvals indicate that the research team could only identify and communicate with a participant after informed consent is granted. This in effect implies “passive” recruitment strategy that puts the onus of initiating interest to participate in the study on the person to be recruited rather than the researchers. The Medicaid mailouts were not even allowed to mention the word “epilepsy” or the title of the project for fear of the mail being opened by another person. No opportunity existed to call and remind the individuals who received the invitation letters regarding the prospect of participating in the study and/or clarify any issues that may not be clear. This is perhaps the major barrier between the research team and the participants, which
eliminated rapport to advance the purposes of the study. While numerous epidemiological studies indicate the low response rate to passive recruitment strategies, the most serious disadvantage of the legacy of HIPAA is perhaps the lack of bonding and partnership with study participants when such studies are carried out outside of the scope of clinical practice. As expected, the passive recruitment strategy resulted in very low response rate even when a second mail was sent. Another major operational disadvantage of the passive recruitment strategy was the lack of involvement in the critical phases of the research activities. These include frame selection, sampling, and mailing since personal identifiers such as names and addresses were not allowed to be known by the research team until consent was granted. As a result, ORS carried out all sampling activities based on the sampling scheme the research team developed.

In response to the very low enrollment, the research team proposed to conduct follow-up calls through authorized personnel. In October 2006, permission was granted to carry out follow-up calls to persons who had received the invitation letters to participate in the study. Agreement was made to hire PRN employees within ORS and MUSC who have “covered entity” status to make the follow-up calls. With the implementation of this active recruitment strategy, an additional 376 persons among the MUSC cohort and 146 among the Medicaid insured patients expressed interest to participate or to re-assess their decisions for enrollment into the study. This in effect increased the potential number of persons with epilepsy that are highly likely to be enrolled and participate in the study above the targeted sample size of 500. By February 11, 2007, there were 296 persons enrolled in the study, making the cohort 59.2% of the targeted ideal sample size or 74.0% of the minimum sample size needed to test the hypotheses with 82% power (Please see Figure 1 below).
The rigorous methodological emphasis put in the development of the survey tools has also been time and resource intensive. There was extensive consultation and input from various field experts and CDC Technical advisors requiring more time than what we anticipated. The development of the tools involved extensive review of the instruments that have been used among persons with epilepsy. The draft tools went through two sets of testing—pre-test and pilot test—in various locations and populations. The process of developing the adult and adolescent versions of the tool took 6 months and the testing needed an extra month. The follow-up survey tool was recently finalized. The development of the tools was followed by development of the Data Management System. This system is the state-of-the-art computer platform with various interfaces. It is a remarkable system whose multi-faceted usefulness had been demonstrated on various studies, including a multi-center trial on neurological emergencies. The development of this system required 6 additional months, mostly to refine the problems noted during testing and the changing needs of the interview process.

Finally, it is important to mention the length of interview and the time it takes to administer as one of the factors contributing to the slow progress we are making. The time needed to complete the interview averages around 75 minutes. Many of the epilepsy patients are on medications that slow the reaction time to respond to questions. Older AEDs—which cloud cognitive functions related to receiving and processing of information—are widely used in our cohort, necessitating questions to be repeated twice or thrice. In some cases, participants are exhausted needing interruption and completing the interview at another time. Consequently, each interviewer can complete 2 interviews per day and the interview administration rate is at 60% of the enrollment rate. This implies a waiting period of 3-4 weeks to conduct the interview after enrollment in the study. Another delaying factor in our progress is the epilepsy verification form, an important component of our survey that is completed by the physician. The response rate is very low and physician offices have to be called repeatedly to complete the form. We have devised alternative plans to ease the time demand from physicians to the office attendant (nurse practitioner, physician assistant, etc.) to complete the form for the physician to sign. While improvement is noted, nonresponse is still a challenge.

In summary, we would like to make the following suggestions for consideration:

1. The SC HOPE activities are critical to understand the impact of socioeconomic and health care system determinants that are suspected to have profound effect on the outcomes of epilepsy. SC HOPE is designed to unravel these relationships and we suggest preserving the study design and the frequency and intensity of the data collection methods until the targeted interviews are completed.

2. We firmly believe the delays noted in the timeline are the result of conditions and problems that have plagued similar researches in the US due to multiple tiers of approvals and the barriers created between the researchers and potential participants. While SC HOPE is not unique in this regard, the two-year time allocated for operation is inadequate to complete 500 interviews with 750 person-years of follow-up data. We suggest 2 more years of funding to complete the study.

3. The resources developed and the data being collected are tremendous assets that could be used in other similar studies. Due to the slow progress of the study and time demand on the researchers, we suggest a wait time of two years before putting that data in public domain.
APPENDIX 1

SC HOPE Conceptual Model

Conceptual Model

Socioeconomic Determinants
- ↓ Income
- ↓ Level of education
- ↓ Occupation
- Poor neighborhood

Healthcare System Determinants
- ↓ Resources (insurance)
- ↓ Quality providers
- ↓ Quality facilities
- ↓ Specialty care
- Problems of access

Mediators (Internal and External)
- ↓ Attitude to care
- ↓ Coping skills
- Wrong beliefs
- Distrust of providers
- Stigma

Allostatic Load (Physical & Mental stress)

Poor Epilepsy Outcomes

Seizure Condition
- Higher Severity of seizure
- More frequent attacks
- Epilepsy sudden death

HR-QOL
- General Health
- ↓ Mental Health
- Low Functional independence

ER-QOL
- Unable to work
- Unable to drive
- Unable to attend school
- ↑ Family burden

2 Conditions
- ↑ Systemic diseases
- ↑ Mental disorders
- ↑ Abuse of Substances
- ↑ Drug-related side effects

Medical cost
- ↑ Rate of hospital admissions
- More Medical procedures
- More Physician visits
# APPENDIX 2

## Operational Model for SC HOPE (Adult Version—18 years and older) and Sources for Questions Used

### Characteristics & Personal Factors

- **Age**
- **Gender**
- **Race**
- **Marital Status**
- **County**
- **Zip code**
- **Income (personal & household)**
- **Education**
  - Level
  - Goals
  - Special assistance
  - Discrimination
- **Employment**
  - Limitations
  - Hours
  - Discrimination
- **Occupation**
- **Living situation**
- **Other health conditions**
- **Age at sz onset**
- **Seizures**
  - Cause(s)
  - Family History
  - Type
  - Severity
  - Frequency
  - Interfere with QOL

### Health Care

- **Health Insurance**
  - Availability
  - Type
- **Cost of Coverage**
  - OOP cost of MD visit
  - OOP cost of Rx meds
  - Other OOP medical costs
  - Amount of outstanding medical bills
  - Able to pay medical bills
  - Gets all Rx's filled
- **Diagnosis and Treatments**
  - EEG, MRI, PET etc.
  - Meds, VNS, surgery, diet
  - Bone density scan
- **Access and Utilization of Epilepsy Specialty Care**
- **Availability of Personal Physician**
  - How long a wait for an appt.
  - Does MD speak first language
  - Can you understand MD
- **Access and Utilization to Other Specialty Care Providers**
  - Dietician, PT, OT, psych
- **Availability and Access to Services**
  - Case management
  - Respite care
  - Information
  - Vocational help

### Psychological Mediators

- **Coping Skills**
  - Self efficacy
  - Medication management
- **Emotional well being**
- **Social**
  - Family and social support
  - Social isolation
  - Social integration
- **Stigma**
  - Who knows about epilepsy
  - Related to school/work
  - Social acceptance

### Medical and Psychological Outcomes

- **HRQL-General**
  - Global health
  - Physical function
  - Role Limitations
  - Memory/Concentration
- **HRQL-Epilepsy Specific**
  - Employment
  - Seizure worry
  - Driving/transportation
  - Social limitations
  - Overall impact of epilepsy
  - Adverse side effects of AEDs/ESD Rx
  - Hormonal influence
    - Affect physical health
    - Affect mental health
- **Secondary Mental Health Conditions**
  - Depressive symptoms
  - Substance use
  - ADHD/ADD & other cognitive issues
- **Medical Care Cost**
  - MD visit
  - Procedures
  - Referrals
  - Hospitalization
- **Change in seizure severity, frequency**

---

+ denotes questions that were created by the SC HOPE team

Risk Factors → Risk Modifiers → Outcomes
Reference List

(3) Begley C. Health Outcomes Study Questionnaire. 2005.
### Characteristics & Personal Factors

- **Age**
- **Gender**
- **Race**
- **Marital Status**
- **County**
- **Zip code**
- **Income (household)**
- **Education**
  - Grade
  - Goals
  - Special assistance
  - Discrimination
- **Employment**
  - Limitations
  - Discrimination
- **Living situation**
- **Other health conditions**
- **Age at sz onset**
- **Seizures**
  - Cause(s)
  - Family History
  - Type
  - Severity
  - Frequency
  - Interfere with QOL

### Health Care

- **Health Insurance**
  - Availability
  - Type
- **Cost of Coverage**
  - OOP cost of MD visit
  - OOP cost of Rx meds
  - Other OOP medical costs
  - Amt. of outstanding medical bills
  - Able to pay medical bills
  - Gets all Rxs filled
- **Diagnosis and Treatments**
  - EEG, MRI, PET, etc.
  - Meds, VNS, surgery, diet
  - Bone density scan
- **Access and Utilization of Epilepsy Specialty Care**
  - Availability of Personal Physician
  - How long a wait for an appt.
  - Does MD speak first language/Can you understand MD
  - Do you like your MD
  - Frequency of physician visits/year
  - Frequency of ED visits (ESD)
  - Frequency of Inpt. visits (ESD)
- **Access and Utilization to Other Specialty Care Providers (dietician, PT, OT, psych)**
- **Availability and Access to Services**
  - Case management
  - Respite care
  - Information
  - Vocational help

### Psychological Mediators

- **Coping Skills**
  - Self efficacy
  - Medication management
- **Attitudes Toward Epilepsy**
- **Seizure Worry**
- **Social**
  - Family and social support
  - Social isolation
- **Stigma**
  - Who knows about epilepsy
  - Related to school/work
  - Social acceptance

### Health-Related Quality of Life

- **HRQL-General**
  - Global health
  - Physical function
  - Role Limitations
  - Memory/Concentration
  - School Behavior
- **HRQL-Epilepsy Specific**
  - Driving/transportation
  - Social limitations
  - Sports/Physical Activities
  - Adverse side effects of AEDs/ESD Rx
- **Secondary Mental Health Conditions**
  - Depressive symptoms
  - Substance use
  - ADHD/ADD & other cognitive issues
- **Medical Care Cost**
  - ↑ MD visit
  - ↑ Procedures
  - ↑ Referrals
  - ↑ Hospitalization

### Overall Outcome

- **Death**
- Change in seizure severity, frequency
South Carolina
Health Outcomes on
People with Epilepsy
Pilot Study Report

November 2005
METHODS

Quantitative Analysis

Descriptive Statistics
Statistical analyses were conducted for the pilot study on both the Adult Part I and Adult Part II surveys. Only descriptive statistics are reported because of the small sample size. Frequencies were calculated for categorical variables and percentages reported. Since the sample size was small (N=25), medians were reported for continuous variables. The exception is the reporting of length of time to administer the survey, where means were reported.

Measures of Association
Measures of association were implemented to measure the extent to which certain items on the surveys captured the same construct. All questions were ordinal in nature and weighted kappa statistics were reported. A value of > 0.5 was used to determine good agreement.

Measures of Concordance
The Gamma test measures the extent to which respondents answer the same way on two survey questions. The closer the Gamma statistic is to 1, the better concordance between the two items. Gamma of 0 indicates independence of the items.

Measures of Internal Consistency
Cronbach’s alpha examines the internal consistency of items in the survey tool. A cutoff of 0.70 represents an acceptable coefficient. The standardized alpha is reported.

RESULTS

Interview Time

Two interviewers administered the survey tool to 25 persons with Epilepsy. One initial concern with the survey tool is the length of time to complete. Table 1 includes the times of each section as well as the total time it took to complete.

<table>
<thead>
<tr>
<th>Section</th>
<th>Time mean (sd)</th>
<th>(Min, Max)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Part I</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health Care</td>
<td>5.7 (1.6)</td>
<td>(3.0, 9.0)</td>
</tr>
<tr>
<td>Med/Tx</td>
<td>6.1 (1.7)</td>
<td>(4.0, 10.5)</td>
</tr>
<tr>
<td>Access to Health Care</td>
<td>7.3 (2.2)</td>
<td>(2.0, 12.0)</td>
</tr>
<tr>
<td>Comorbid Conditions</td>
<td>2.4 (0.7)</td>
<td>(1.0, 4.0)</td>
</tr>
<tr>
<td>Service Needs</td>
<td>3.9 (1.9)</td>
<td>(1.0, 9.0)</td>
</tr>
<tr>
<td>General HRQOL</td>
<td>15.5 (3.2)</td>
<td>(10.3, 19.5)</td>
</tr>
<tr>
<td>Epilepsy QOL</td>
<td>3.9 (0.9)</td>
<td>(2.0, 5.5)</td>
</tr>
<tr>
<td>Employment</td>
<td>5.5 (1.6)</td>
<td>(3.0, 8.0)</td>
</tr>
<tr>
<td>Transportation</td>
<td>0.8 (0.4)</td>
<td>(0.3, 1.5)</td>
</tr>
</tbody>
</table>

Table 1. Time analysis per section of the survey tool (N=25)
Self Efficacy 3.4 (0.8) (2.0, 5.0)
Stigma 3.1 (0.8) (2.0, 5.0)
Income 2.2 (0.5) (1.3, 3.0)
Illicit Drug Use 1.6 (1.1) (0.5, 4.8)
Depressive Symptoms 2.8 (0.6) (2.0, 4.0)
Total (-Part I) 63.8 (12.6) (36.0, 83.0)
Total (+Part I) 85.5 (14.0) (53.0, 112.0)

The interviewers recorded the administration time by section of the survey. Part I required the most time on average. However, this portion of the interview will be offered at another time so as not to make the interview as long. The General HRQOL section, in Part II, required the most time to complete (average 15.5 minutes). When Part I is completed during a separate call, the average time for the Part II is 64 minutes. When Parts I and II completed during the same call, the average time to completion is 86 minutes. The primary complaint during the Pilot-Testing was that the survey was too long.

Qualitative Data

Qualitative data was gathered through the documentation of specific and general comments from the respondents. Specific feedback from the respondents focused on areas ranging from grammatical corrections to suggestions for the rephrasing of questions. Most feedback on individual questions focused on respondent frustration over the inconsistency of response patterns that led to confusion and to an increase in questionnaire administration time. Many comments were additionally put forth regarding the perceived repetitiveness of questions and the necessity of such questions during the interview. These comments are particularly germane to portions of the questionnaire that were based on SF-36. Of particular note are questions PFC-01 through PFC-10.

General feedback from the respondents highlighted the need to reduce the administration time of the interview (see Table 1). Some of those putting forth such comments cited fatigue during the survey and needed to take a break or complete the remainder of the survey at a separate time. Despite this, it should be noted that the overall impressions of the survey from the respondents was positive with most willing to endure the questionnaire’s areas for improvement in order to contribute to the body of knowledge regarding epilepsy.

Table 2. Examples of respondent qualitative feedback

<table>
<thead>
<tr>
<th>Topic</th>
<th>Respondent Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Response Patterns</td>
<td>“The changes in the answer sets were frustrating”.</td>
</tr>
<tr>
<td></td>
<td>“I got confused going back and forth with the answers.”</td>
</tr>
<tr>
<td></td>
<td>“I was thrown off by the changes in the answers. They weren’t consistent.”</td>
</tr>
<tr>
<td>Repetitiveness</td>
<td>“Why ask this question again when you asked the same thing a different way before?”</td>
</tr>
<tr>
<td></td>
<td>“You are asking the same question.”</td>
</tr>
<tr>
<td></td>
<td>“Why are you asking this question when you asked essentially the same thing (in ESS-04) before?”</td>
</tr>
<tr>
<td></td>
<td>“This survey repeated a lot.”</td>
</tr>
<tr>
<td></td>
<td>“These questions are stupid. Why do I have to answer the follow-up questions? (comment at PFC-08)”</td>
</tr>
<tr>
<td>Administration Time</td>
<td>“This survey is too long.”</td>
</tr>
</tbody>
</table>
“When are we going to be finished?”

Fatigue

“It would be better if there was a way to take out some of the questions. It was tiring.”

“Can we take a break for a minute?”

Quantitative Data

Table 3. Demographical Characteristics of Participants in the Pilot-Testing.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Source of Question</th>
<th>% (N=25)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGE</td>
<td>PAI-04</td>
<td>39</td>
</tr>
<tr>
<td>Median</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-29</td>
<td></td>
<td>24.0</td>
</tr>
<tr>
<td>30-44</td>
<td></td>
<td>28.0</td>
</tr>
<tr>
<td>45-64</td>
<td></td>
<td>44.0</td>
</tr>
<tr>
<td>65+</td>
<td></td>
<td>4.0</td>
</tr>
<tr>
<td>RACE</td>
<td>PAI-06</td>
<td>96.0</td>
</tr>
<tr>
<td>White</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian/Pacific Isl.</td>
<td></td>
<td>4.0</td>
</tr>
<tr>
<td>GENDER</td>
<td>PAI-05</td>
<td>16.0</td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td>84.0</td>
</tr>
<tr>
<td>MARITAL STATUS</td>
<td>MAS-01</td>
<td>36.0</td>
</tr>
<tr>
<td>Married</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unmarried Couple</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>Separated</td>
<td></td>
<td>8.0</td>
</tr>
<tr>
<td>Divorced</td>
<td></td>
<td>20.0</td>
</tr>
<tr>
<td>Widowed</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>Never Married</td>
<td></td>
<td>36.0</td>
</tr>
<tr>
<td>INSURANCE</td>
<td>INS-01</td>
<td>88.0</td>
</tr>
<tr>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td>12.0</td>
</tr>
<tr>
<td>INSURANCE TYPE</td>
<td>INS-02</td>
<td>52.0</td>
</tr>
<tr>
<td>Private (emp)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private (not emp)</td>
<td></td>
<td>4.0</td>
</tr>
<tr>
<td>Medicare</td>
<td></td>
<td>16.0</td>
</tr>
<tr>
<td>Medicaid</td>
<td></td>
<td>8.0</td>
</tr>
<tr>
<td>Military</td>
<td></td>
<td>8.0</td>
</tr>
<tr>
<td>State Indigent</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td>12.0</td>
</tr>
<tr>
<td>EDUCATION</td>
<td>EDU-01</td>
<td>20.0</td>
</tr>
<tr>
<td>Never attended</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>1-8</td>
<td></td>
<td>8.0</td>
</tr>
<tr>
<td>9-11</td>
<td></td>
<td>4.0</td>
</tr>
<tr>
<td>12 or GED</td>
<td></td>
<td>8.0</td>
</tr>
<tr>
<td>College 1-3</td>
<td></td>
<td>40.0</td>
</tr>
<tr>
<td>College Grad</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This population was overwhelmingly female (84%), younger (52% less than 45 years), and White (96%). The socioeconomic status (SES) is fairly high in this group as identified by education, 80% have some college or more; living situation, 100% live in a private residence; and insurance status, 88% are insured. Thirty-six percent of respondents reported more than one type of seizure, with 1 person reporting 4 types. Complex Partial was the most reported type of seizure (see Table 3). On average, respondents had their first seizure at 13 years of age.
Table 4. Problem questions in Part I

<table>
<thead>
<tr>
<th>Question</th>
<th>% Answering “Do not know”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you become stiff and fall? (ESS-21)</td>
<td>12.0</td>
</tr>
<tr>
<td>Do you become limp and fall over? (ESS-22)</td>
<td>20.0</td>
</tr>
<tr>
<td>Do you blackout or lose consciousness? (ESS-23)</td>
<td>12.0</td>
</tr>
<tr>
<td>Does your face change color? (ESS-24)</td>
<td>16.0</td>
</tr>
<tr>
<td>Does you face turn pale, red, blue, or another color? (ESS-24a)</td>
<td>12.0</td>
</tr>
<tr>
<td>Does your face tremble, shake, or twitch? (ESS-32)</td>
<td>16.0</td>
</tr>
<tr>
<td>Does your face pull or does your head turn to one side? (ESS-33)</td>
<td>20.0</td>
</tr>
<tr>
<td>To which side does your face pull or does your head turn? (ESS-33a)</td>
<td>16.0</td>
</tr>
<tr>
<td>Do your eyes move or do they look straight ahead? (ESS-34)</td>
<td>36.0</td>
</tr>
<tr>
<td>Do your hands pick at or fumble with clothes or objects? (ESS-35)</td>
<td>12.0</td>
</tr>
<tr>
<td>Do you stare? (ESS-36)</td>
<td>16.0</td>
</tr>
<tr>
<td>Do your eyelids flutter or blink? (ESS-37)</td>
<td>20.0</td>
</tr>
<tr>
<td>Is it your arms of legs that stiffen or have spasm? (ESS-38a)</td>
<td>12.0</td>
</tr>
</tbody>
</table>

Part I form is used to verify each type of seizure. Gigi Smith, CPNP and Braxton Wannamaker, MD will review the responses to Part I and determine the specific seizure type of that participant. It is important that participants answer the questions to the best of their knowledge in order for the seizure type to be correctly identified. Table 4 represents the questions that 12% or more of participants responded that they did not know the answer. Question ESS-38a includes one person who refused to answer and two people who did not know the answer.

Table 5. Response patterns to key questions from the survey tool

<table>
<thead>
<tr>
<th>Variable</th>
<th>Source of Question</th>
<th>% Asserting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time after 1st seizure until told have epilepsy</td>
<td>ESD-02</td>
<td></td>
</tr>
<tr>
<td>That day</td>
<td></td>
<td>12.0</td>
</tr>
<tr>
<td>Within a week</td>
<td></td>
<td>16.0</td>
</tr>
<tr>
<td>Within the month</td>
<td></td>
<td>12.0</td>
</tr>
<tr>
<td>1-3 months later</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>At least a year later</td>
<td></td>
<td>8.0</td>
</tr>
<tr>
<td>More than a year later</td>
<td></td>
<td>40.0</td>
</tr>
<tr>
<td>Did not tell me</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>No Response</td>
<td></td>
<td>12.0</td>
</tr>
<tr>
<td>MEDICINE</td>
<td>MED-02</td>
<td>100.0</td>
</tr>
<tr>
<td>Take seizure medicine way doctor tells</td>
<td>TXX-01</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td></td>
<td>88.0</td>
</tr>
<tr>
<td>Vagus Nerve Stimulator</td>
<td></td>
<td>8.0</td>
</tr>
<tr>
<td>Surgery on your brain</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>Ketogenic Diet</td>
<td></td>
<td>4.0</td>
</tr>
<tr>
<td>ACCESS TO HEALTH CARE</td>
<td>ESD-21</td>
<td></td>
</tr>
<tr>
<td>Times have visited doctor for seizure care in past year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>1-3</td>
<td></td>
<td>68.0</td>
</tr>
<tr>
<td>4-6</td>
<td></td>
<td>8.0</td>
</tr>
<tr>
<td>Question</td>
<td>Code</td>
<td>Percentage</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-------</td>
<td>------------</td>
</tr>
<tr>
<td>How much of own money spend on epilepsy most months</td>
<td>ACC-12</td>
<td></td>
</tr>
<tr>
<td>7-12</td>
<td></td>
<td>16.0</td>
</tr>
<tr>
<td>12+</td>
<td></td>
<td>8.0</td>
</tr>
<tr>
<td>Provider is a neurologist or epilepsy specialist</td>
<td>ACC-01a</td>
<td>92.0</td>
</tr>
<tr>
<td>Medical bills related to epilepsy that cannot pay</td>
<td>ACC-13</td>
<td>12.0</td>
</tr>
<tr>
<td>QUALITY OF LIFE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In general health is excellent/very good</td>
<td>GHP-01</td>
<td>48.0</td>
</tr>
<tr>
<td>Limited a little/lot lifting or carrying groceries</td>
<td>PFC-03</td>
<td>28.0</td>
</tr>
<tr>
<td>All/most of time limited in activities because of physical health</td>
<td>RLE-04</td>
<td>36.0</td>
</tr>
<tr>
<td>EMPLOYMENT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Receiving disability income because of epilepsy</td>
<td>EPN-03</td>
<td>24.0</td>
</tr>
<tr>
<td>Limited a lot/little in type of work because of epilepsy</td>
<td>EPN-06</td>
<td>32.0</td>
</tr>
<tr>
<td>Lose income or benefits if were working</td>
<td>EPN-09</td>
<td>32.0</td>
</tr>
<tr>
<td>Epilepsy kept from getting kind of job would like</td>
<td>EPW-08</td>
<td>28.0</td>
</tr>
<tr>
<td>Been treated differently by employer</td>
<td>EPW-11</td>
<td>20.0</td>
</tr>
<tr>
<td>Been treated differently by co-worker</td>
<td>EPW-11</td>
<td>24.0</td>
</tr>
<tr>
<td>SELF-EFFICACY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No/very little confidence to care for day-to-day changes in epilepsy</td>
<td>SEF-03</td>
<td>20.0</td>
</tr>
<tr>
<td>STIGMA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>People who know I have epilepsy treat me differently</td>
<td>STG-01</td>
<td>44.0</td>
</tr>
<tr>
<td>Have problems in intimate relationships because of epilepsy</td>
<td>STG-04</td>
<td>32.0</td>
</tr>
<tr>
<td>Epilepsy attaches a stigma or label</td>
<td>STG-05</td>
<td>56.0</td>
</tr>
<tr>
<td>Feel embarrassed about my epilepsy</td>
<td>STG-07</td>
<td>40.0</td>
</tr>
<tr>
<td>DEPRESSIVE SYMPTOMS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In past week felt could not get going (3-7 days)</td>
<td>DEP-04</td>
<td>40.0</td>
</tr>
<tr>
<td>In past week felt happy (2 days or less)</td>
<td>DEP-07</td>
<td>32.0</td>
</tr>
<tr>
<td>TRANSPORTATION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drivers license ever been suspended because of epilepsy</td>
<td>TRN-04</td>
<td>8.0</td>
</tr>
</tbody>
</table>

There was 1 person who did not respond to any stigma question.
Table 6. Statistical Summary: Convergent-Divergent Validity Measure of Selected Items.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Gamma (ASE)</th>
<th>Cronbach’s Alpha</th>
<th>Weighted Kappa (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In general your health (GHP-01)</td>
<td>0.90 (0.10)</td>
<td>-0.3036</td>
<td>0.45 (0.25, 0.66)</td>
</tr>
<tr>
<td>My health is excellent (GHP-05)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Felt down in the dumps (WEL_02)</td>
<td>0.82 (0.09)</td>
<td>0.9148</td>
<td>0.66 (0.47, 0.85)</td>
</tr>
<tr>
<td>Felt downhearted (WEL_04)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did you feel worn out (ENE_03)</td>
<td>0.88 (0.07)</td>
<td>0.9227</td>
<td>0.72 (0.55, 0.89)</td>
</tr>
<tr>
<td>Did you feel tired (ENE_04)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did you feel full of life (ENE_01)</td>
<td>0.78 (0.12)</td>
<td>0.8522</td>
<td>0.54 (0.33, 0.75)</td>
</tr>
<tr>
<td>Have a lot of energy (ENE_02)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interfere social activities (WDS_01)</td>
<td>0.77 (0.14)</td>
<td>0.8151</td>
<td>0.54 (0.30, 0.78)</td>
</tr>
<tr>
<td>Interfere social activities (WDS_02)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did you feel left out (SIN_01)</td>
<td>0.88 (0.09)</td>
<td>0.9018</td>
<td>0.65 (0.44, 0.87)</td>
</tr>
<tr>
<td>Did you feel isolated (SIN_02)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Questions WDS_01 vs. WDS_02 and GHP-01 and GHP-05 had inverse response patterns. Furthermore, WDS_02 has 6 choices while WDS_01 has 5. WDS_02 was changed in the manner listed in Table 7 in order to be comparable to WDS_01.

All pairs of questions show good concordance, with the lowest Gamma being 0.77. The pair with the lowest Gamma is also the pair that was altered because of different answer sets. Using the Cronbach’s alpha cutoff of 0.70 as the judgment of good internal consistency, all questions but the first pair show good consistency. For those pairs of questions where a weighted Kappa is shown, all but the first pair are above the 0.5 cutoff for good agreement. GHP-01 and GHP-05 had two persons who did not answer in a similar manner on the two questions.

Table 7. Changes in questions for correlation analysis

<table>
<thead>
<tr>
<th>Original Question</th>
<th>Modified for Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>WDS-02: How much of the time during the past 4 weeks have your physical health or emotional problems interfered with your social activities, like visiting friends or relatives? Was it....</td>
<td>WDS-02: How much of the time during the past 4 weeks have your physical health or emotional problems interfered with your social activities, like visiting friends or relatives? Was it....</td>
</tr>
<tr>
<td>1=All of the time</td>
<td>1=None of the time</td>
</tr>
<tr>
<td>2=Most of the time</td>
<td>2=A little of the time</td>
</tr>
<tr>
<td>3=A good bit of the time</td>
<td>3=A good bit/some of the time</td>
</tr>
<tr>
<td>4=Some of the time</td>
<td>4=Most of the time</td>
</tr>
<tr>
<td>5=A little of the time</td>
<td>5=All of the time</td>
</tr>
<tr>
<td>6= None of the time</td>
<td></td>
</tr>
</tbody>
</table>