ESETT – Community Consultation Summary

7-Aug-15

The OHSU community consultation proposal for the Established Status Epilepticus Treatment Trial (ESETT) targeted community groups and events across the greater Portland Metropolitan area. Our goal was to reach community members who represented the geographic population of future potential patient enrollments, as well as the seizure-related community.

The OHSU – NETT team contacted several groups and received invitations to 7 events. One of the events, a Rotary Club, was unable to accommodate us on their schedule prior to September, and will be included as part of our public disclosure, instead of community consultation. Two additional community events were cancelled due to scheduling conflicts and lack of attendee responses. The community consultation events include Mary’s Woods Health Fair (assisted living facility), OHSU Farmers Market, OHSU Research Week, Portland International Neuroscience Symposium, Epilepsy Foundation Northwest (EFNW) support group, and Epilepsy Foundation Northwest Run/Walk. Additionally, we placed brochures and posters in the OHSU adult epilepsy clinic and informed OHSU pediatric and adult neurologists of the upcoming study. The OHSU epilepsy clinics did not have support groups for us to contact.

The 6 community consultation events totaled approximately 135 participants. Study team members presented information about ESETT, distributed ESETT promotional bracelets, provided brochures, answered questions, and distributed self-administered surveys. We have received 36 completed surveys, to date. The surveys indicated that the majority of the respondents felt that ESETT is an important study to do and would participate in the study and allow their children to participate in the study. At this time, there have not been any requests for “opt-out” bracelets, although 4 respondents indicated that they would tell their doctors that they did not want to participate in ESETT. One of these respondents felt that their current medical condition would confound the results and should therefore be excluded from the study. Two respondents expressed concern about being enrolled in a study without being able to give prior consent.

The 2 events held with the EFNW, provided us with an opportunity to obtain feedback from the seizure-related community. The majority of the people that we spoke with were pleased that more research is being done on providing treatment for individuals with seizures. There were questions about whether or not they would be excluded from the trial, if they were already on seizure medication. The EFNW will be distributing informational flyers about ESETT through their quarterly email newsletter in September.

The OHSU – NETT team has reviewed and submitted the results of the self-administered surveys to the NETT Central Coordinating Center. We request that the IRB review the results of our community consultation events. Attached are the detailed summary of events and the results of the self-administered surveys.

**Survey Data**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  | Me | My child | Another family member or loved one | Someone else | No |
| 1. | Have you or has anyone you know ever experienced a seizure? | 7 | 4 | 9 | 9 | 10 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  | # Strongly Agree | # Agree | #Neutral | # Disagree | # Strongly Disagree |
| 2. | ESETT is an important study to do. | 26 | 8 | 2 | 0 | 0 |
| 3.  | If you developed a seizure that would not stop, you would be okay with being included in ESETT without giving your consent ahead of time. | 23 | 7 | 1 | 2 | 1 |
| 4. | If you are/were a parent, and your child developed a seizure that would not stop, would you be okay with him/her being included in ESETT without giving your consent ahead of time. | 20 | 11 | 0 | 2 | 1 |
| 5. | Do you think that ESETT researchers will seriously consider what community members like you have to say about this study before starting it? | 24 | 0 | 8 | 0 | 2 |
| 6. | Do you feel that you have been given enough information to give your informed opinion about whether you think it is okay for researchers to do the ESETT study? | 32 | 0 | 0 | 0 | 4 |
| 7.  | Would you like to tell doctors that you do not want to participate in ESETT? | 4 | 0 | 1 | 0 | 23 |

**Demographics**

|  |  |  |
| --- | --- | --- |
| Community Categories | Events | Participants |
| Geographic | 4 | 105 |
| Seizure-related | 2 | 30 |
| Total | 6 | 135 |

|  |  |
| --- | --- |
| Age | Participants |
| Average | 50.04 |

|  |  |
| --- | --- |
| Gender | Participants |
| Female | 24 |
| Male | 12 |
| Missing Data | 0 |

|  |  |
| --- | --- |
| Ethnicity | Participants |
| Hispanic/Latino | 0 |
| Non-Hispanic | 35 |
| Missing Data | 1 |

|  |  |
| --- | --- |
| Race | Participants |
| White | 35 |
| Black or African American | 0 |
| Asian | 2 |
| Native Hawaiian or Other Pacific Islander | 0 |
| American Indian or Alaska Native | 1 |
| Other Race | 1 |
| Missing Data | 0 |

|  |  |
| --- | --- |
| Education | Participants |
| Never Attended School or only Kindergarten | 0 |
| Grades 1 through 8 (Elementary) | 0 |
| Grades 9 through 11 (Some high school) | 0 |
| Grade 12 or GED (High school graduate) | 1 |
| College 1 year to 3 years (Some college or technical school)  | 7 |
| College 4 years or more (college graduate) | 28 |
| Missing Data | 0 |