State and Metropolitan-Area Base Amyotrophic Lateral Sclerosis (ALS) Surveillance

Part B

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B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Data from the states and metropolitan areas will be compared with the National ALS Registry. Descriptive statistics will be used to describe the differences, if any, between the state/metropolitan area data and the National ALS Registry. This information will be used to identify if there is underreporting in the National ALS Registry for specific groups based on demographics, and to develop strategies to improve the completeness of the National ALS Registry. Although sensitivity and specificity cannot be calculated because the surveillance activities will only report cases of ALS, positive predictive value (PPV) will be calculated. ATSDR will use this information to direct resources for the National ALS Registry. This information will be used to focus promotion and outreach to groups found to be missing or under reported in the National ALS Registry. Individual state/metropolitan area data may be analyzed by the respective health departments.

State and metropolitan-area health departments are expected to write a report about the surveillance activity within their specific jurisdiction. This report will include information on:

- Number of people identified with ALS
- Number of providers participating
- Distribution of the ALS classification
- Age distribution of case
- Sex distribution of the cases
- Racial distribution of the cases

The ALS registry coordinator may employ the following methodology:

- Data transformation
- Case classification
- Baseline estimation

1. Respondent Universe and Sampling Methods

This activity is surveillance; respondents are not sampled. Furthermore, no sample selection is involved in this activity. The surveillance activity will identify medical providers likely to treat ALS patients and ask them to participate in the activity. The objective of this project is to develop state-based and metropolitan area-based surveillance activities for ALS. The primary goal of the state-based and metropolitan area-based surveillance activities is to use these data to evaluate the completeness of the National ALS Registry.

ATSDR has a multi-pronged approach for recruiting medical provides to participate in the project. First, ATSDR will identify neurologists, especially those who are ALS specialists, in the participating states. Lists of neurologists will be obtained from sources such as state licensing board, state neurological society, state medical society, and the American Academy of Neurology. Available lists will be combined and deduplicated. Internet resources will be used

to update mailing information, telephone number, and subspecialty. Neurologists who do not treat ALS patients, pediatric neurologists, neurosurgeons, and neuroradiologists will be removed. ATSDR will send an introductory letter and then contact these individuals by phone to determine if they diagnose or treat patients with ALS and make appointments to visit the offices of those who do treat or diagnose ALS patients. Second, ATSDR will identify advocacy groups such as, the ALS Association (ALSA) and the Muscular Dystrophy Association, ALS Division, to identify providers and endorse the project. Neurologists identified during this process will be added to the list. Third, ATSDR will identify professional groups within the states such as the state neurological association and the state medical association. These groups will be contacted to seek endorsement for the project, and to identify conferences or publications they might have in which ATSDR can participate. (Attachment 8, letters and scripts)

The OMB approved racial categories have not been used because the data is being abstracted from medical records. Our experience with Center for Medicare and Medicaid Services data indicate that the best we can do is White, Black/African American, Asian, Other, and Unknown.

2. Procedures for the Collection of Information

Individuals with an ALS diagnosis as of January 1, 2009 – December 31, 2011 will be included in the surveillance activity. Reporting is expected to begin in March 2011 and continue through March 2012. Initially reporting will be a mixture of prevalent and incident cases, however as time progresses only incident cases will be reported. A contract has been awarded for the development and implementation of the state and metropolitan area-based surveillance. The contractor will hire and place staff in the health departments.

The contract and state staff will be responsible for identifying the neurologists in the geographic areas as described in Section 1. An initial letter will be mailed to providers to introduce the project and a second letter will be sent to neurologists who are difficult to reach. Per the letter, the surveillance specialist will contact the neurologist's office to determine if he./she diagnoses or treats ALS patients. There is not a script for these calls but a serious of points to be covered. When the surveillance specialist begins to visit doctors' offices, additional materials can be left with the neurologist including fact sheet, reporting procedures, and El Escorial Criteria instructions. Samples of these materials are in Attachment 8 – Outreach materials. These materials, except for the El Escorial Criteria instructions, will be customized for each area.

The contract surveillance staff assigned to the state and metropolitan area health departments will train medical personnel how to complete the ALS Case Reporting Form (Attachment 3) and assist with abstracting records as requested. To assist with the completing reporting forms, a token of appreciation will be available to medical care providers calculated on a per case basis. Physicians will receive $100 for each case reported to offset reporting costs. An additional $$50 will be available as necessary to offset costs related to medical records abstraction necessary to complete the Medical Record Verification Form (Attachment 4). Each medical provider reporting source should keep a line listing of individuals diagnosed with or thought to have ALS along with information on whether or not the case was reported and if not, the reason. Contract surveillance staff will be in frequent contact with physician's offices and will be available to assist with this activity.

3. Methods to Maximize Response Rates and Deal with Non-response

ATSDR has a multi-pronged approach for recruiting medical provides to participate in the project. First, ATSDR will identify neurologists, especially those who are ALS specialists, in the participating states. Lists of neurologists will be obtained from sources such as state licensing board, state neurological society, state medical society, and the American Academy of Neurology. Available lists will be combined and deduplicated. Internet resources will be used to update mailing information, telephone number, and subspecialty. Neurologists who do not treat ALS patients, pediatric neurologists, neurosurgeons, and neuroradiologists will be removed. ATSDR will send an introductory letter and then contact these individuals by phone to determine if they diagnose or treat patients with ALS and make appointments to visit their offices. Second, ATSDR will identify advocacy groups such as, the ALS Association (ALSA) and the Muscular Dystrophy Association, ALS Division, to identify providers and endorse the project. Neurologists identified during this process will be added to the list. Third, ATSDR will identify professional groups within the states such as the state neurological association and the state medical association. These groups will be contacted to seek endorsement for the project, and to identify conferences or publications they might have in which ATSDR can participate. (Attachment 8, letters and scripts)

4. Tests of Procedures or Methods to be Undertaken

Five physicians or their office staff not working in ALS specialty clinics completed the Medical Verification Form and did not have any problems with the form. Each was able to complete the entire form in less than 20 minutes using only the first and last visit record. No further procedures or methods are needed at this time.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Individuals consulted on statistical aspects:

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List of Attachments

Attachment 1 Authorizing Legislation: Public Law No: 110-373, amendment to the Public Health Service Act to provide for the establishment of an Amyotrophic Lateral Sclerosis Registry

Attachment 2 Federal Register Notice

Attachment 3 ALS Case Reporting Form

Attachment 4 ALS Medical Record Verification From

Attachment 5 IRB Approved Protocol

Attachment 6 IRB Approval

Attachment 7 IRB Amendment Approval

Attachment 8 Outreach and Recruitment Materials for Neurologists