Telephone checklist

Checklist of points to be covered in each initial call to neurologists and neurology practices:

All practices:

- ☐ Identify self, where calling from and project
- ☐ Identify name and title of person who answered the phone
- ☐ Identify name(s) of neurologist(s) within practice
- ☐ Determine if the neurologist(s)/practice treats ALS patients?

If practice does not see ALS patients:

- ☐ To whom are ALS patients referred?
- ☐ Who else in the area sees ALS patients?
- ☐ Thank speaker for their time

If practice does see ALS patients:

- ☐ How many ALS patients since January 2009
- ☐ Your practice will be contacted again to ask neurologists to report cases
- ☐ Name and info of person to contact within practice the next time
- ☐ Confirm contact information
- ☐ Who else in the area sees ALS patients?
- ☐ Thank speaker for their time

If speaker doesn't know if the neurologist(s)/practice treats ALS patients:

- ☐ Determine if there is someone else that can answer the question
- ☐ Thank speaker for their time

Frequently Asked Questions
State-Based Amyotrophic Lateral Sclerosis (ALS) Surveillance

Project Background

WHAT IS SURVEILLANCE?
Public health surveillance is defined as "the ongoing, systematic collection, analysis, and interpretation of health data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know".[1]

WHY IS SURVEILLANCE IMPORTANT?
Surveillance is important to monitor changes in incidence and prevalence of a condition. Surveillance data can be used in planning for health care needs, detecting changes in health practices, and assessing the burden of disease. To date, national disease surveillance systems have been related primarily to infectious diseases with the exceptions of cancer and birth defects. In 1992, directors of the World Health Organization (WHO) non-communicable disease collaborating centers and key officials in centers for non-communicable diseases advocated for the increased surveillance of non-communicable diseases. This recommendation was based on the lack of incidence data for non-communicable diseases.

WHY SHOULD WE CONDUCT ALS SURVEILLANCE?
Uncertainty about the incidence and prevalence of ALS, as well as the role of the environment in the etiology of ALS, supports the need for a surveillance system for this disease. This information will allow the public health community to have better estimates of incidence and prevalence, detect changes in disease prevalence, describe who develops the disease, investigate the health care needs of the population, detect changes in health care practice, and assess the burden of the disease.

WHY DO WE NEED STATE-BASED ALS SURVEILLANCE PROJECTS?
To evaluate the completeness of the National ALS Registry and to obtain reliable information on the incidence and prevalence of ALS in a defined geographic area, the Agency for Toxic Substances and Disease Registry (ATSDR) awarded McKing Consulting Corporation a contract to oversee the development and implementation of three state-based ALS Surveillance Projects. The surveillance data collected from this Project will be compared with the data in the National ALS Registry to evaluate its completeness. The states will use these data to learn more about ALS in their areas.

WHY ARE STATE HEALTH DEPARTMENTS INTERESTED IN ALS SURVEILLANCE?
State health departments play an important role in monitoring and evaluating disease conditions among their residents through various population-based public health surveillance systems. This Project is an important step in improving the understanding of non-reportable conditions, such as ALS.

WHY WERE FLORIDA, NEW JERSEY, AND TEXAS CHOSEN TO CONDUCT STATE-BASED ALS SURVEILLANCE?
McKing solicited proposals from nine states who indicated interest in this Project in November 2009. A total of six proposals were received. McKing selected Florida, New Jersey, and Texas based on their population demographics, experience conducting similar projects and proposed costs for the project.

WHOM DO I CONTACT FOR MORE INFORMATION ABOUT THE [STATE ACRONYM] ALS SURVEILLANCE PROJECT?
[INSERT ALS SURVEILLANCE SPECIALIST CONTACT INFORMATION]

National ALS Registry

WHAT IS THE NATIONAL ALS REGISTRY?
The National ALS Registry, established through an amendment to the Public Health Service Act and signed into law in October 2008,is a program to collect, manage, and analyze data about people with ALS. It includes data from existing national databases and information provided by patients who choose to participate. Researchers can use Registry data

[1] Thacker SB, Berkelman RL. Public health surveillance in the United States. *Epidemiology Rev* 1988;10:164-90.

to look for disease pattern changes over time and try to identify whether there are common risk factors among ALS patients.

WHAT IS THE GOAL OF THE NATIONAL ALS REGISTRY?
The primary goal of the National ALS Registry is to obtain reliable and timely information on the incidence and prevalence of ALS and to better describe the demographic characteristics (age, race, sex, and geographic location) of those with ALS. The registry will collect personal health information that may provide a basis for further scientific studies of potential risks for developing ALS.

HOW ARE THE STATE-BASED ALS SURVEILLANCE PROJECTS DIFFERENT FROM THE NATIONAL ALS REGISTRY?
The state-based ALS Surveillance Projects will gather case reports of ALS diagnosed or treated by a neurologist for the period January 1, 2009 through December 31, 2011. Patients will not be able to self-register into the state-based surveillance projects; only healthcare providers will be able to submit case reports on confirmed ALS patients. Only cases in the selected areas will be eligible to be reported.

WHOM DO I CONTACT FOR MORE INFORMATION ABOUT THE NATIONAL ALS REGISTRY?
To learn about the National ALS Registry, please visit the ATSDR website at http://www.cdc.gov/ALS

Patient Consent, HIPAA Authorization, and Data Security

DID AN INSTITUTIONAL REVIEW BOARD (IRB) REVIEW AND APPROVE THIS PROJECT?
The Centers for Disease Control and Prevention (CDC)/ATSDR IRB approved this project in June 2010. Subsequently, the Texas Department of State Health Services IRB approved the project for Texas. The Florida Department of Health and New Jersey Department of Health and Senior Services IRBs determined this project to not be human subjects research.

DOES THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) APPLY TO THIS PROJECT?
HIPAA explicitly permits providers to release this information without a HIPAA authorization to the state health department to conduct public health surveillance.

WHY IS PATIENT INFORMED CONSENT NOT REQUIRED FOR THIS PROJECT?
The CDC/ATSDR and the Texas Department of State Health Services IRBs granted the research a waiver from obtaining informed consent because data are only being abstracted from medical records and no patients will be contacted. The Florida Department of Health and the New Jersey Department of Health and Senior Services determined this Project to be public health surveillance and not research; therefore patient consent is not needed.

WILL ALS PATIENTS BE CONTACTED BY ANY ORGANIZATION INVOLVED IN THIS PROJECT?
No. The [STATE ACRONYM], ATSDR, McKing Consulting Corporation, or any other organizations involved with this Project will never contact patients.

WHAT WILL BE DONE WITH THE DATA ONCE I SEND THEM TO YOU?
State staff will enter the data into a secure database. Once all the data have been collected, the information will be transmitted to ATSDR for comparison with the National ALS Registry.

WILL THE SURVEILLANCE DATA COLLECTED BE PUBLICLY AVAILABLE?
No. The data collected for this Project will be confidential and will not be made available to the public.

HOW WILL DATA BE PROTECTED?
The [STATE ACRONYM] is accustomed to maintaining confidential data collected for surveillance of a variety of disease and conditions such as cancer, HIV, TB, occupational health exposures, and elevated blood lead levels. ALS Surveillance Project data will be collected and maintained in the same confidential and secure manner as other surveillance data. Project staff has been trained to conduct data collection and data storage. Data will be stored at the [STATE ACRONYM] in a secured data storage system. Secure methods, approved by state and federal security experts, will be used to transmit data to ATSDR.

Data Collection and Compensation

ARE OTHER NEUROLOGISTS IN THE AREA PARTICIPATING IN THIS PROJECT?
Yes. The ALS Surveillance Specialist is contacting all neurologists practicing in [RELEVANT STATES] who may see [STATE] residents with ALS. The Project has been well-received and many neurologists have already expressed their support, interest, and involvement in the Project.

WHAT DOES THE NEUROLOGIST HAVE TO DO?
A neurologist or a member of his or her staff will fill out a brief case reporting form, containing 14 items, for each ALS patient diagnosed or treated between January 1, 2009 and December 31, 2011. Forms should be faxed via a secured fax line to the ALS Surveillance Specialist at [fax number]. Neurologists and/or their staff will be asked to keep a list of cases to avoid sending duplicate records to [STATE ACRONYM]. A sample of cases will be selected for case verification. The neurologist and/or their staff will fill out and fax a longer form for the cases selected in this verification process.

HOW MUCH TIME WILL IT TAKE TO REPORT A CASE?
Each case reporting form is designed to take no longer than five minutes to complete. The case verification form, to be completed for a small percentage of overall cases, may take upwards of twenty minutes to complete.

HOW DO I FILL OUT AND SUBMIT THE CASE REPORTING FORM?
The state ALS Specialist will train each participating neurologist and/or their staff in completion of both the case reporting form and the case verification form. The completed, handwritten forms should be faxed to the [STATE ACRONYM] via a secured fax line at [fax number]. The state ALS Specialist will be available by phone or email to troubleshoot as needed.

WHAT TYPE OF DATA ARE YOU COLLECTING?
The case reporting form includes 14 items in the following three areas: identification of the patient, demographic information, and diagnosis information.

WHAT IS THE DATA COLLECTION PERIOD?
Data collection is expected to begin in early 2011. Patients diagnosed or treated from January 1, 2009 through December 31, 2011 who reside in [STATE] should be reported.

ARE YOU COLLECTING INCIDENT OR PREVALENT CASES?
We are collecting both incident (newly diagnosed) and prevalent (existing) cases.

IS THERE ANY COMPENSATION FOR MY STAFF TIME?
Yes. We are prepared to offer compensation to help offset expenses for time and effort related to filling out case reporting forms and case verification forms. Cash cards and continuing education credits may be available to neurologists and/or their staff. Please contact ALS Surveillance Specialist [NAME] at [desk phone, cell phone or email address] for more details.

WHAT IF WE WANT TO PARTICIPATE BUT DON'T HAVE THE TIME TO COMPLETE THE CASE REPORTING FORMS?
The [STATE ACRONYM] Project staff may be able to offer compensation for time and effort related to filling out project forms in the form of cash cards or continuing education credits. If the neurologist and/or their staff are still unable to fill out the forms, the ALS Surveillance Specialist will be able to come to the office to abstract the records. In this instance, the neurologist and/or their staff forego the option to receive cash cards. Please contact [NAME] at [desk phone, cell phone or email address] if you would like to participate, but are finding it difficult to find the time and resources to do so. The ALS Surveillance Specialist will make every effort to assist you in reporting cases.

Other questions

HOW WILL MY PARTICIPATION BENEFIT MY PATIENT?
There may not be a direct benefit to your patients; however, with these data, public health agencies will be able to prepare accurate estimates of people affected by ALS to better assess the health care needs of the population, detect changes in health care practices, and assess the burden of the disease.

HOW WILL MY PARTICIPATION BENEFIT ME?
There is no direct benefit to you; however, as a provider of care for those with ALS, you will receive the personal satisfaction of helping to create the most complete list of [STATE] cases to compare to the National Registry and you will be at the forefront of efforts to improve care and services for these patients.

REPORTING PROCEDURES
ALS SURVEILLANCE PROJECT

TRAINING

- [HEALTH DEPARTMENT/ORGANIZATION] will provide training to physician's office staff who will be responsible for completing ALS Case Reporting Forms and ALS Case Verification Forms

- Training options include a one CEU credit course certified by [CERTIFYING ORGANIZATION] [for Texas and Florida}

OR

- One CEU credit, certified by [CERTIFYING ORGANIZATION] may be available upon completion of the training. [for NJ and metro areas where the certifying group will accept CEU from Florida]

ALS CASE REPORTING FORM

- Trained neurologists and/or office staff will complete a brief ALS Case Reporting Form for all ALS patients who have been diagnosed or treated between January 1, 2009 and December 31, 2011

- Neurologists and/or office staff will submit completed forms for [STATE/METRO] residents to [HEALTH DEPARTMENT/ORGANIZATION] via secure fax at [FAX NUMBER]

OR

- Neurologists/and/or office staff will submit completed forms for [STATE/METRO] residents to [HEALTH DEPARTMENT/ORGANIZATION] via FedEx in the provided pre-addressed FedEx envelope. Completed forms should be sealed inside a plain envelope marked "Confidential" before they are inserted inside the FedEx envelope.

- Health Department will review case forms and acknowledge receipt within XX hours

RE-ABSTRACTION

- 10% of all reported cases will be re-abstracted by trained [ALS Surveillance Project/Health Department] staff for data accuracy
- If one of your cases is selected for re-abstraction, [ALS Surveillance Project staff/Health Department] personnel will contact your office staff to make an appointment for re-abstraction

CASE VERIFICATION

- Trained neurologists and/or office staff will complete a Medical Record Verification Form on selected cases
    - This form will document more detailed information on signs and symptoms including a copy of the EMG report (if available)
    - If the EMG report is available, provider office staff will mark it with a ID number provided by [HEALTH DEPARTMENT/ORGANIZATION] and remove patient name and identifying information from the document

- [ALS Surveillance Project/Health Department] personnel will contact provider office staff to identify cases requiring completion of the Medical Record Verification Form

- Neurologists and/or their office staff will submit completed form to [HEALTH

DEPARTMENT/ORGANIZATION] via fax at [FAX NUMBER]

COMPENSATION

- For ALS Case Reporting Forms completed by Physician Offices, a $XX Visa Gift Card will be mailed to you following acknowledgement of receipt by Health Department
- For Case Verification Forms completed by Physician Offices, a $XX Visa Gift Card will be mailed to you following acknowledgement of receipt by Health Department
- Compensation for completed cases will be provided on a monthly basis to a specified name and address.

FOR ADDITIONAL INFORMATION OR QUESTIONS, CONTACT:
NAME
ALS Surveillance Specialist
[HEALTH DEPARTMENT]
[PHONE NUMBER]
[EMAIL]

FRONT OF CARD

El Escorial Criteria

Approved by the World Federation of Neurology Research Group on Neuromuscular Diseases, the El Escorial Criteria are the diagnostic criteria for ALS commonly used to determine inclusion in clinical trials and research studies.

Definite ALS	Presence of Upper Motor Neuron (UMN) and Lower Motor Neuron (LMN) signs in the bulbar region and at two of the other spinal regions
Probable ALS	UMN and LMN signs in at least two regions with UMN signs rostral to LMN signs
Probable ALS Lab Supported	UMN and LMN signs in one region with evidence by electromyography (EMG) of LMN involvement in another region
Possible ALS	UMN and LMN signs in one region or UMN signs in two or three regions, such as monomelic ALS, progressive bulbar palsy, and primary lateral sclerosis

BACK OF CARD

For questions about using the El Escorial Criteria to classify your ALS patients, please contact the following Consulting Neurologist on the State- and Metropolitan-Area Based ALS Surveillance Projects:

Eric Sorenson, MD
Department of Neurology
Mayo Clinic – Rochester, MN

Phone: (507) 538-1037
Email: Sorenson.Eric@mayo.edu

Additional information on the El Escorial Criteria can be found in the following articles:

1. Brooks, BR. El Escorial World Federation of Neurology criteria for diagnosis of amyotrophic lateral sclerosis. Subcommittee on Motor Neuron Disease/Amyotrophic Lateral Sclerosis of the World Federation of Neurology Research Group on Neuromuscular Diseases and the El Escorial “Clinical limits of amyotrophic lateral sclerosis” workshop contributors. J Neurol Sci. 1994 Jul. 124 Suppl 96-107.
2. Ross MA, Miller RG, Berchert L, Parry G, Barohn RJ, Armon C, Bryan WW, Petajan J, Stromatt S, Goodpasture J, McGuire D, and the rhCNTF ALS Study Group. Toward earlier diagnosis of amyotrophic lateral sclerosis: Revised criteria. Neurology, 1998 Mar:50(3) 768-72.