

## **Metropolitan Area-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”.<sup>1</sup>

#### **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 and about 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 METROPOLITAN AREA-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 four to six metropolitan area-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 metropolitan areas will use these data to learn more about ALS in their areas.

### **WHY ARE LOCAL HEALTH DEPARTMENT INTERESTED IN ALS SURVEILLANCE?**

Local 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 ATLANTA, DETROIT, CHICAGO, LOS ANGELES, PHILADELPHIA, AND SAN FRANCISCO CHOSEN TO CONDUCT METROPOLITAN AREA ALS SURVEILLANCE?**

ATSDR asked McKing to focus metropolitan area-based ALS surveillance in areas with large minority populations. McKing selected Atlanta, Chicago, Detroit, Los Angeles, Philadelphia, and San Francisco based on their population demographics .

### **WHOM DO I CONTACT FOR MORE INFORMATION ABOUT THE LOS ANGELES AND SAN FRANCISCO BAY AREA ALS SURVEILLANCE PROJECT?**

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ALS Surveillance Specialist

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### **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 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 METROPOLITAN AREA-BASED ALS SURVEILLANCE PROJECTS DIFFERENT FROM THE NATIONAL ALS REGISTRY?**

The metropolitan area-based ALS Surveillance Projects will gather case reports of ALS diagnosed or treated by a neurologist during the period January 1, 2009 through December 31, 2011. Patients will not be able to self-register into the metropolitan area-based surveillance projects; only healthcare providers will be able to submit case reports on confirmed ALS patients. Only patients who reside 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. The California Committee for the Protection of Human Subjects 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 or a contractor of a federal government agency to conduct public health surveillance. HIPAA also permits providers to release this information without HIPAA authorization for research purposes when a waiver of HIPAA authorization has been granted by an IRB or privacy board. The CDC/ATSDR IRB has granted a waiver of HIPAA authorization for this project.

**WHY IS PATIENT INFORMED CONSENT NOT REQUIRED FOR THIS PROJECT?**

The CDC/ATSDR IRB 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 California Committee for the Protection of Human Subjects 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 California Department of Public Health, ATSDR, McKing Consulting Corporation, and any other organizations involved with this Project will never contact patients.

**WHAT WILL BE DONE WITH THE DATA ONCE I SEND THEM TO YOU?**

Project 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?**

ALS Surveillance Project data will be collected and maintained in a confidential and secure manner. Project staff has been trained in data collection and data storage. Data will be stored 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 the Los Angeles area who may see Los Angeles county residents with ALS and all neurologists practicing in the San Francisco Bay Area who may see Alameda, Contra Costa, San Francisco, Solano, and San Mateo counties 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 (510) 412-1660. Neurologists and/or their staff will be asked to keep a list of cases to avoid sending duplicate records. A sample of cases will be selected for case verification. The neurologists and/or their staff will fill out and fax a longer form for a small number of 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 ALS Surveillance 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 California Department of Public Health via a secured fax line at (510) 412-1660. The ALS Surveillance 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 Spring 2012. Patients diagnosed or treated from January 1, 2009 through December 31, 2011 who reside in Los Angeles, Alameda, Contra Costa, San Francisco, Solano and San Mateo counties 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 will be available to neurologists and/or their staff. Please contact ALS Surveillance Specialist, Susan Paulukonis at (510) 620-3667 or [susan.paulukonis@cdph.ca.gov](mailto:susan.paulukonis@cdph.ca.gov) for more details.

**WHAT IF WE WANT TO PARTICIPATE BUT DON'T HAVE THE TIME TO COMPLETE THE CASE REPORTING FORMS?**

The California Department of Public Health Project staff will be able to offer compensation for time and effort related to filling out project forms in the form of cash cards. 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 Susan Paulukonis at (510) 620-3667 or [susan.paulukonis@cdph.ca.gov](mailto:susan.paulukonis@cdph.ca.gov) 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 Los Angeles and San Francisco Bay Area cases to compare to the National Registry, and you will be at the forefront of efforts to improve care and services for these patients.

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