

**ATSDR Presentation to ALSRG
International ALS/MND Meeting, Orlando**

Representatives from ATSDR (Kevin Horton, Oleg Muravov and Wendy Kaye) attended the annual ALSRG meeting held at the International ALS/MND meeting in Orlando on December 13th, 2010. Kevin Horton gave a brief presentation in which he outlined the goals of the National Registry and offered responses to the questions that ALSRG had submitted in writing to ATSDR in advance of today's meeting.

Dr. Horton explained that the goals of the National ALS Registry, as defined by the Registry Act are (a) to determine the incidence and prevalence of ALS, (b) to ascertain the demographic characteristics of the ALS population and (c) to identify risk factors for ALS. To this end they are collecting information about ALS patients from two sources: (1) National (CMS and VA) databases and (2) patient self-report using a web portal developed specifically for this purpose. ATSDR estimate that the CMS and VA datasets will capture ~80% of the population of ALS patients and they hope to capture a significant proportion of the remaining cases through the web portal. ATSDR is also funding three statewide projects (Florida, Texas and New Jersey) that will employ more active methods of case finding in order to estimate the degree of under-ascertainment of the National ALS Registry (at least in these three states).

Patients who register through the portal will be invited to complete a series of short surveys/questionnaires in order to learn more about environmental exposures among patients with ALS.

Dr. Horton then addressed the specific questions that had been posed by the ALSRG.

1. Registry Goals

- The ALSRG expressed concern that the goals of the National Registry appear to be in a state of flux.
- Dr. Horton disagreed, and instead he insisted that ATSDR's implementation of the National Registry is consistent with the letter of the ALS Registry Act.

2. Control Group

- The ALSRG has expressed concern that the data collected about environmental risk factors will be of very limited utility given the absence of a control group.

- Dr. Horton explained that the National Registry is set up as a surveillance project and as such, is not charged with collecting information from controls. He expressed the firm belief that it will be up to researchers who request registry data to identify controls in order to perform research (i.e. the burden for collecting control data will firmly rest with researchers). Moreover, he suggested that it might be possible to use the NHANES database to identify control subjects.

Flow of Information to Registrants

- A mechanism could be introduced for registrants to check a box indicating a willingness to receive information about new research opportunities

Access to Registry Data

- Right now, it is not possible for ATSDR to share data with researchers. To change this it would be necessary to amend IRB, OMB, renegotiate with CMS and VA to release data, set up a process for release, etc. This would be difficult and time-consuming.

Oversight

- ALSRG asked whether there was any external oversight of how ATSDR were using resources for construction of the registry
- Dr. Horton didn't really address this issue, but instead focused on their annual meeting at which they solicit broad input from the community

Opportunities for ALSRG to make recommendations to ATSDR

- Dr. Horton clarified that there is formal mechanism for guidance other than annual ATSDR registry meeting
- Dr. Horton did invite the ALSRG to submit their recommendations in writing for future consideration

Discussion

- John Katz - utilization of VA and Medicare datasets seems like we're looking at the wrong population
- Carmel Armon - epidemiological study is set up to produce low class evidence about risk factors
- Kevin Horton - by design, ATSDR has decided not to have a federal advisory committee because they feel it would be too restrictive (because of cap on number of people who could be part of the advisory board); instead they have an annual

meeting inviting direct feedback from patients, physicians, researchers, advocacy groups, etc.