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Evaluating the completeness of the national ALS registry, United States

WENDY E. KAYE¹, LAURIE WAGNER¹, RUOMING WU², and PAUL MEHTA²

¹McKing Consulting Corporation, Atlanta, GA, USA

²Agency for Toxic Substances and Disease Registry, Atlanta, GA, USA

Abstract

Our objective was to evaluate the completeness of the United States National ALS Registry (Registry). We compared persons with ALS who were passively identified by the Registry with those actively identified in the State and Metropolitan Area ALS Surveillance project. Cases in the two projects were matched using a combination of identifiers, including, partial social security number, name, date of birth, and sex. The distributions of cases from the two projects that matched/did not match were compared and Chi-square tests conducted to determine statistical significance. There were 5883 ALS cases identified by the surveillance project. Of these, 1116 died before the Registry started, leaving 4767 cases. We matched 2720 cases from the surveillance project to those in the Registry. The cases identified by the surveillance project that did not match cases in the Registry were more likely to be non-white, Hispanic, less than 65 years of age, and from western states. The methods used by the Registry to identify ALS cases, i.e. national administrative data and self-registration, worked well but missed cases. These findings suggest that developing strategies to identify and promote the Registry to those who were more likely to be missing, e.g. non-white and Hispanic, could be beneficial to improving the completeness of the Registry.

Keywords

Amyotrophic lateral sclerosis (ALS); National ALS Registry; ALS surveillance; Registry data

Introduction

Amyotrophic lateral sclerosis (ALS) is a rare progressive neurodegenerative disease that is diagnosed through a combination of signs and symptoms. A recent review of longstanding

Declaration of interest

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Correspondence: Wendy Kaye, PhD, McKing Consulting Corporation, 2900 Chamblee Tucker Road, Building 10, Suite 100, Atlanta, GA 30341, USA. Tel. 770-220-0608. wek1@cdc.gov.

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European registries estimates incidence at 2.6 per 100,000 person years and prevalence rates of 7–9 per 100,000 persons (1). Some studies suggest that ALS rates are higher among non-Hispanic Caucasians (whites) in western countries compared with those of African, Asian, and Hispanic descent (minorities) (2–4). There are limited data regarding the population-based epidemiology of ALS in the United States (US) with most studies having been conducted in limited geographic areas (5–7). Recent data from the National ALS Registry estimated prevalence of ALS in the United States at 5.0 per 100,000 population in 2013 (8).

In October 2010, the Agency for Toxic Substances and Disease Registry (ATSDR) launched the National Amyotrophic Lateral Sclerosis (ALS) Registry (Registry) to implement Public Law No: 110-373 which signed into law a bill to amend the Public Health Service Act to provide for the establishment of an Amyotrophic Lateral Sclerosis Registry. Because of the challenges experienced by ATSDR and other researchers trying to obtain information directly from medical care providers, the National ALS Registry uses nontraditional methods to identify persons with ALS including using administrative data from the Centers for Medicaid and Medicare Services (CMS), the Veterans Health Administration (VHA), and the Veterans Benefits Administration (VBA), and a self-registration component (9,10). In order to evaluate the completeness of the National ALS Registry, ATSDR conducted a separate ALS surveillance project using active case-finding methods in three states (Florida, New Jersey, and Texas) and eight metropolitan areas (Atlanta, Baltimore, Chicago, Detroit, Las Vegas, Los Angeles, Philadelphia, and San Francisco) (11) and calculated the concordance between the two sources. A bill to amend the Public Health Service Act to provide for the establishment of an Amyotrophic Lateral Sclerosis Registry, S. 1382: ALS Registry Act, was signed into law on October 10, 2008 by President George W. Bush and became Public Law No: 110-373. The purpose of the Registry as described in the bill, is to (1) better describe the incidence and prevalence of ALS in the United States; (2) examine appropriate factors, such as environmental and occupational, that might be associated with the disease; (3) better outline key demographic factors (such as age, race or ethnicity, gender, and family history of individuals who are diagnosed with the disease) associated with the disease; and (4) better examine the connection between ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS (12). The Registry collects personal health information that may provide a basis for further scientific studies of potential risks for developing ALS.

ATSDR developed and tested case-finding methodology for the National ALS Registry that identified ALS cases using administrative data from CMS, VHA, and VBA. The Registry pilot study developed an algorithm using variables from the administrative data that identified true cases of ALS. The best algorithm had a sensitivity of 87% and a specificity of 85%. The pilot study sites identified <1–22% of the cases in only the clinical databases and therefore missed by administrative data alone. The study results showed that administrative data could be used to create an ALS surveillance system although it would be necessary to identify other sources of data or methods to capture those ALS cases not covered by the administrative databases (13). A self-registration component was initiated because of previous experience trying to obtain information directly from medical care providers. In October 2010, ATSDR launched a web-portal where persons with ALS could enroll in the National ALS Registry. To enter the National ALS Registry through its web portal, patients

must answer a series of validation (screening) questions. These validation questions were obtained from the Veterans Administration's ALS Registry (which is no longer enrolling persons with ALS) and were found to be effective; 93.4% of those who passed the screening questions were determined by a neurologist to have ALS/motor neuron disease (14). This two-pronged approach tries to identify all cases of ALS within the United States (8–10).

Traditionally in the United States, surveillance systems have relied on physicians and other health care providers to report notifiable health information to state or local health departments and when appropriate this information is reported to federal health authorities. In the United States, the designation of a "reportable" health condition is conferred by the Council of State and Territorial Epidemiologists (CSTE) and this designation is usually reserved for infectious diseases. Because ALS is not an infectious disease, it is not considered a "reportable/notifiable" disease. In this assessment, we evaluated the completeness of the Registry by comparing ALS cases identified in the selected state and metropolitan areas which used traditional case ascertainment methods to those ALS cases identified by the Registry which used non-traditional surveillance case ascertainment methods.

Materials and methods

We compared the cases of ALS identified by the two different case ascertainment methods, the National ALS Registry and the state and metropolitan surveillance project. In brief, the National ALS Registry uses a two-pronged approach, i.e. administrative databases and self-registration. The state and metropolitan area surveillance projects used active case ascertainment, i.e. physician reporting, medical records abstraction, and death certificates. In the state and metropolitan area surveillance project, areas were selected to over-represent racial and ethnic minorities so that the number of cases in these groups would be sufficient to estimate prevalence by race and ethnicity. A detailed description of this methodology can be found in the paper by Wagner et al. (11).

The state and metropolitan surveillance project collected prevalent cases of ALS for January 1, 2009 through December 31, 2011 while the National ALS Registry began to identify cases on October 19, 2010. Therefore, we submitted the cases identified by the state and metropolitan surveillance project to the National Death Index to obtain date of death when available. All cases identified in the state and metropolitan area surveillance project who died before the start of the Registry, October 19, 2010, were removed from further analysis. This adjustment made the time-period for both projects' case ascertainments the same, October 19, 2010 through December 31, 2011.

Because of state privacy and human subjects protection regulations, ALS cases identified in the state and metropolitan projects could not be added to the National ALS Registry and could only be used for comparison purposes. Cases in the two projects were matched using a combination of information identifying including partial SSN, name, date of birth, and sex. The distribution of cases from the state and metropolitan surveillance system that matched or did not match the National ALS Registry were compared. Chi-square tests were conducted to determine whether there was a statistically significant difference in the

characteristics of cases identified in the state and metropolitan area surveillance project being/or not being identified by the Registry. An alpha level of p = 0.05 was used to determine statistical significance.

Multivariable regression analyses were used to examine whether cases matched between the two data sources differed, as well as to examine interaction between case characteristics. When examining interactions, we included the main effect variables along with the corresponding interaction terms. The interaction terms examined included: age group and Medicare, race and state, age group and El Escorial criteria, and race and El Escorial criteria. Stepwise model selection method was applied with an inclusion criterion of p 0.10. All data analysis was performed using SAS[©] (15).

Results

The state and metropolitan surveillance project identified 5883 cases of ALS. Of these, 1116 died before the National ALS Registry started, leaving us 4767 cases. Of the 4767 cases identified by the state and metropolitan surveillance project and alive during the eligibility period (October 19, 2010 through December 31, 2011), 2720 (57%) matched a case identified by the National ALS Registry. The cases identified by the state and metropolitan area surveillance project that did not match cases in the Registry were more likely to be non-white, Hispanic, less than 65 years of age, and from western states (Table 1). In addition to demographic differences between those identified by the state and metropolitan surveillance project who matched and those who did not match cases identified by the Registry, there were significant differences in the stage of ALS at the time of the report and the types of insurance used, i.e. those who were diagnosed with possible or unclassified ALS and those who did not use Medicare were less likely to be identified by the National ALS Registry (Table 2).

The best model for the multiple logistic regression analysis showed an ALS case identified in the state and metropolitan surveillance projects was less likely to be in the National ALS Registry if nonwhite, Hispanic, living in the western part of the US, and not having Medicare for insurance (Table 3). According to the stepwise methods, no interactions were significant (data not shown).

Discussion

There have been a number of smaller efforts to establish surveillance systems for neurodegenerative diseases in the US such as ALS, Parkinson's disease, and Alzheimer's disease/dementia (7,16–19), the National ALS Registry however, is the first attempt in the US to create a national surveillance system for any neurodegenerative disease. These smaller efforts used a variety of case ascertainment methods including physician reporting, medical claims data, prescription data for disease specific medications, advocacy group reporting, and self-reporting making them difficult to compare. ALS registries in Europe have been operating for about two decades and provide insights in how to operate a successful registry along with limitations (1,20). However, because of the health care delivery system along with the ethnic/racial diversity and population size of the US (more than 300 million

compared with the approximately 26 million in the six population registries used to estimate ALS incidence in Europe) (21), it is not possible to create a national registry in the US using the same methodology as used in Europe. What is clear is that it is important to obtain information from multiple sources such as medical claims data, prescription data, physician reporting, when feasible, and self-identification in order to have the most complete ascertainment possible.

Therefore, because of the fractured health care system in the United States, the National ALS Registry has used a unique two-pronged approach to identify persons with ALS, i.e. cases identified via an algorithm in federal administrative datasets and self-registration (8,10,13). Although the Registry identified 13,282 for a revised prevalence of 4.3 in 2011 (8), it was anticipated that individuals with ALS could be missing. The comparison of a cohort of ALS cases actively collected from neurologists in a geographically and racially/ ethnically diverse population allowed for the identification of subgroups of the population that are more likely to be missing from the Registry. This comparison showed that a person with ALS was more likely to be missing from the Registry if they were non-white, Hispanic, living in the western part of the United States, and were not using Medicare for insurance. This could be because those who are non-white or Hispanic are less likely to be seen in ALS specialty clinics and therefore less likely to learn about the Registry. It could also be because they have less access to computers which are needed for self-registration. Racial difference could also explain the difference seen by region of the country as the West Census Region is 47% minority according to the 2010 census (22). Although those with ALS are eligible for Medicare once receiving Social Security Disability Insurance (SSDI) (23), this group may be less likely to be eligible for SSDI because of the jobs held, length of employment, or knowledge about this benefit. In addition, those with a less definitive diagnosis of ALS based on the El Escorial criteria reported in the state and metropolitan surveillance project were also more likely to be missing. This could be because those being told that they "possibly have ALS" are less likely to seek benefits for ALS or self-register even though studies have shown that those given a diagnosis of suspected or possible ALS El Escorial category do have ALS (24). An El Escorial criteria category is not available in the Registry because it is not available in administrative claims data and not something that is selfreported in the registration portal.

Age was not significant in the logistic regression analysis; however, those identified in the state and metropolitan surveillance project who were not in the Registry were more likely to be less than 65 years of age. Like race, this could be related to those less than 65 years of age only being eligible for Medicare after receiving SSDI. This could delay identifying them in administrative data and making their identification more reliant on self-enrollment in the Registry.

Although the incidence rate of ALS among nonwhites is lower than that for whites (2,3), this should not impact who is identified by the Registry, e.g. the percentage of people identified by race and ethnicity should be the same. The National ALS Registry has partnered with national and regional ALS patient advocacy groups such as the ALS Association (ALSA), Muscular Dystrophy Association (MDA), and the Les Turner ALS Foundation to educate and increase awareness. These groups directly work with ALS patients and their caregivers

providing assistance and coordinating care. In general, the patient population served by these groups tends to be white with a mixture of chapter and clinic locations where a larger percentage of minority groups are represented, such as Los Angeles, San Francisco, Atlanta, Chicago, and Miami. ATSDR will work with these groups to target outreach to minority populations. However, more targeted outreach will likely be needed because minority populations tend to be under-represented in support groups (25,26).

In 2017, in order to reach more Hispanics with ALS, ATSDR will launch a site in Spanish where individuals can learn more about ALS, register, and take risk factor surveys. Once launched, a Spanish public service announcement will be disseminated via social media such as Facebook and Twitter and through our partner groups to educate individuals about ALS and facets of the Registry. In addition, ATSDR is exploring opportunities to work with national Spanish groups such as the National Hispanic Medical Association, National Council of La Raza, and others.

To better reach African Americans with ALS, the Registry plans to reach out to organizations such as the National Medical Association, large churches located in metropolitan areas serving the African American community, as well as the National Association for the Advancement of Colored People. This targeted approach should allow the Registry to reach underserved and under-represented populations.

The Registry is also exploring ways to work with neurologists not practicing at major academic facilities or ALS specialty clinics to make them aware of the Registry so that they can inform their patients. However, this is particularly challenging because this group of neurologists changes frequently due to relocations, retirements, and new graduates entering the specialty. In addition, this group of neurologists may only occasionally see an ALS patient (11). It will be important to develop messaging specific for this group that can be used on a regular basis so that the neurologists remembers the Registry and can provide materials to an ALS patient when one is seen.

Conclusions

Although the comparison of a cohort of ALS cases actively collected from neurologists in a geographically and racially/ethnically diverse population compared with those identified by the National ALS Registry identified subgroups of the population that are more likely to be missing from the Registry, the Registry has been able to increase the number of cases detected since the first report (6) covering October 19, 2010 through December 31, 2011. In addition, the Registry can use this valuable information to target under-represented groups and has developed a plan for outreach to these populations. The National ALS Registry is committed to increasing racial and ethnic minority enrollment on a local and national scale in order to have more complete epidemiological data on ALS in the United States.

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Table 1

Comparison of demographic characteristics for matched and unmatched cases.

Unmatched	hed		Matched	P		Chi-square
Age At DX	Number	%	Age at DX	Number	%	43.93, p< 0.00001
<65	1321	64.5%	<65	1500	55.1%	
65	705	34.4%	65	1195	43.9%	
Unknown	21	1.0%	Unknown	25	0.9%	
Total	2047		Total	2720		
Race			Race			34.01, p < 0.00001
White	1409	68.8%	White	2071	76.1%	
Black	213	10.4%	Black	237	8.7%	
Asian	98	4.8%	Asian	84	3.1%	
Other	6	0.4%	Other	10	0.4%	
Unknown	318	15.5%	Unknown	318	11.7%	
Total	2047		Total	2720		
Sex			Sex			1.78, p = 0.18
Male	1148	56.1%	Male	1578	58.0%	
Female	668	43.9%	Female	1142	42.0%	
Total	2047		Total	2720		
Hispanic			Hispanic			37.60, p < 0.00001
Yes	300	14.7%	Yes	270	9.9%	
No	1454	71.0%	No	2136	78.5%	
Unknown	293	14.3%	Unknown	314	11.5%	
Total	2047		Total	2720		
$Area^*$			$Area^*$			84.05, <i>p</i> < 0.00001
TX, FL, AT	797	48.7%	TX, FL, AT	1606	59.0%	
LA, SF, LV	544	26.6%	LA, SF, LV	440	16.2%	
NJ, BA, PH, DT, CI	506	24.7%	NJ, BA, PH, DT, CI	674	24.8%	
Total	2047		Total	2720		

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Table 2

Comparison of ALS diagnosis criteria and insurance for matched and unmatched cases.

Unmatched			Matched			Chi-square
El Escorial criteria						65.79, <i>p</i> <0.00001
Definite	961	46.9%	Definite	1460	53.7%	
Probable	430	21.0%	Probable	603	22.2%	
Probable + Lab	165	8.1%	Probable + Lab	254	9.3%	
Possible	358	17.5%	Possible	290	10.7%	
Unclassified	133	6.5%	Unclassified	113	4.2%	
Total	2047		Total	2720		
Combined El Escorial criteria						47.63, <i>p</i> <0.00001
Definite + Probable	1556	76.0%	Definite + Probable	2317	85.2%	
Possible + Unclassified	491	24.0%	Possible + Unclassified	403	14.8%	
Total	2047		Total	2720		
Medicare						359.82, <i>p</i> <0.00001
Yes	788	38.5%	Yes	1799	66.1%	
No	1236	60.4%	No	902	33.2%	
Unknown	23	1.1%	Unknown	19	0.7%	
Total	2047		Total	2720		
Veterans Administration (VA)						3.54, p = 0.17
Yes	116	5.7%	Yes	175	6.4%	
No	1908	93.2%	No	2526	92.9%	
Unknown	23	1.1%	Unknown	19	0.7%	
Total	2047		Total	2720		
Private Insurance						3.14, p = 0.21
Yes	868	43.9%	Yes	1232	45.3%	
No	1126	55.0%	No	1469	54.0%	
Unknown	23	1.1%	Unknown	19	0.7%	
Total	2047		Total	2720		

Table 3

Regression on significant univariate variables, age group and the two interactions.

			95% Confi	95% Confidence Limits		
Effect	DF	Parameter Estimates	Lower	Upper	Wald Chi-Square <i>p</i> Value	<i>p</i> Value
Intercept		0.0353	-0.0776	0.1482		
Medicare	7				323.92	<0.0001
Yes		1.1173	0.9954	1.2391		
Unknown		0.2940	-0.3292	0.9172		
State Combined	7				65.13	< 0.0001
LA, SF, LV		-0.6398	-0.7982	-0.4813		
NJ, BA, PH, DT, CI		-0.2967	-0.4448	-0.1486		
Ethnicity	2				12.40	<0.0020
Hispanic		-0.3590	-0.5614	-0.1566		
Unknown		-0.1509	-0.3498	0.0481		
Race	4				12.10	0.0167
African American		-0.2339	-0.4422	-0.0256		
Asian		-0.2692	-0.5884	0.0501		
Other		-0.4302	-1.3832	0.5228		
Unknown		-0.2486	-0.4511	-0.0462		

Goodness of Fit p-value = 0.082.