VERMONT

State of Vermont
Department of Health
Commissioner's Office
108 Cherry Street • PO Box 70
Burlington, Vermont 05402
HealthVermont.gov

[phone] 802-863-7280

Agency of Human Services

February 20, 2019

Elijah Stommel
Geisel School of Medicine at Dartmouth
Department of Neurology
Dartmouth-Hitchcock Medical Center
Lebanon, NH 03756

Dr. Rup Tandan
1 South Prospect Street
Arnold, Level 2
Burlington, VT 05401

Dear Drs. Stommel and Tandan:

We appreciate the opportunity to review your proposal for a mandatory surveillance registry for ALS in the State of Vermont. My apologies for not providing this information in as a timely a manner as I had hoped.

This is obviously a challenging and as yet inconclusive area of investigation which raises abundant issues surrounding the role of disease registries in general and if they represent a productive solution to the problem at hand.

Our Environmental Health Division has rigorously reviewed the proposal and literature review that was provided and conclude that much of the existent literature is comprised of ecological studies that have significant epidemiologic flaws or are environmental or cluster analyses. Little primary research is cited, many recent citations are review articles, and many studies lack any contributions by epidemiologists. Moreover, uncertainty remains regarding how common BMAA production is among cyanobacterial species. Causal or contributory linkage of chronic exposure to cyanobacterial BMAA with development of ALS remains far from established.

We have been asked to consider establishing a mandatory surveillance registry for ALS in Vermont. We do not take this request lightly by any means, and understand it represents your good faith effort at trying to further elucidate the gaps in scientific evidence and causality described above. There are however several concerns that in aggregate discourage VDH from supporting such a registry:

VERMONT

The prevalence of ALS in the US is 2/100,000; even if it were to double in Vermont, this would be in marked contrast to a condition like cancer, for which we have a registry, and is far more prevalent. Additionally, the burden of disease is less than that of a number of conditions where public health monitoring of occurrence rates could potentially lead to greater population-wide interventions but for which there is no registry. Moreover, there are postulated genetic-environmental factors at play in the pathogenesis of multiple disease conditions, the majority of which do not have disease registries.

The type of data collected in a registry is typically very basic demographics, and not necessarily data that allows for comprehensive hypothesis testing (past residence, exposures, risk factors, etc.).

The costs (financial, logistical, regulatory) are significant. A rule for reportable disease would need to be created and the clinician community would need substantial education. IT expenses would be large, in a very budget constrained environment. Human resources would be required for maintenance, management of cases and website, cleaning and verification of data and diagnoses. Small states typically are underfunded by the Federal government because, although fixed costs are high and similar to larger states, funding allocations are aligned with the number of cases diagnosed, which underrepresents the actual costs of the registry.

Additionally, there are reporting challenges for clinicians even in diseases like Hepatitis A and Lyme where rapid real time reporting is of the essence that are magnified in conditions where there is no laboratory testing, hence the lab cannot become the de facto reporter. There can also be a significant lag time in reporting which hinders the research process.

We are fortunate that since 2009, the federal Agency for Toxic Substances and Disease Registry (ATSDR) implemented the National ALS Registry to collect and analyze data regarding persons with ALS in the US. The express reasons for creating this registry align directly with your own: establish incidence and prevalence, examine risk factors, and characterize the demographics of those living with ALS. Case identification occurs via the use of existing national administrative databases and use of a secure web portal for patient registration.

Ultimately, in light of the significant cost and abundant other considerations presented above regarding establishment of a state registry, along with the existence of this federal registry, drawing upon patient experiences across the nation, we find it challenging to support the development of a mandatory Vermont surveillance registry for ALS.

Sincerely,

Mark A. Levine, MD
Commissioner