Data Rather Than Opinion Dictates That a Definitive Clinical Trial Must Determine if the US Government’s Sodium Guideline Is Safe and Effective

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The 2010 US Dietary Guidelines recommend that all Americans over age 50 and all individuals with, or at risk of, a variety of common health conditions restrict their sodium intake to <1,500 mg/day (65 mEq/day). Healthy persons under 50 were advised to limit sodium to 2,300 mg/day (100 mEq/day). The discussion surrounding these guidelines claimed dramatic benefits in terms of reduced morbidity and mortality as well as billions in healthcare cost savings annually.

The evolution of these guidelines has relied on the opinions and interpretation of the published science by a limited number of government-funded scientists working in tangent with various agencies and/or review entities supported by federal funds. These guidelines have not been based on appropriate science, i.e., morbidity and mortality data derived from properly designed, prospectively executed, long-term studies in a large representative population. The paper by Taylor et al. in this issue documents the unquestionable need for such a trial. Based on the seven trials that met the criteria of their Cochrane review, the authors could not identify any significant cardiovascular disease benefit of sodium reduction. Further, they were unable to document the claimed benefit from earlier meta-analyses or trials that advocates of sodium restriction frequently cite. Finally, they noted that in the one randomized control trial involving high-risk patients (congestive heart failure (CHF)), modest sodium restriction actually significantly increased morbidity and mortality.

Two recent developments based on multiple reports have profound implications for the current US sodium policy and add greater urgency to Taylor et al.’s call for a definitive trial of sodium reduction in the general population. Three prospective studies—one in healthy middle-aged Europeans, one in persons with type 1 diabetes, and one in type 2 diabetes—have identified a significant increase in mortality and, in the case of diabetes, disease progression associated with lower sodium intakes. These reports involve over 7,000 persons from seven ethnically unique populations followed for 8–10 years.

The second recent development is the characterization by us and others of a “normal range” of sodium intake based on government-funded surveys in healthy subjects that measured 24-h urinary sodium excretion (UNaV), span 5 decades, and include >30 countries and >50,000 subjects. The reproducible mean of this normal range of UNaV is ~155 mEq/day (3,500 mg/day) with a range of 100–210 mEq/day (2,300–4,800 mg/day). A narrow, reproducible, and stable range of human sodium intake is consistent with decades of basic science research that provides a physiologic basis for its neuroregulation.

Of even greater concern is that the lower sodium intake associated with an increased risk of death identified in the three recent publications and that of Taylor et al. is within the lower end of this apparent normal range. Increased mortality was associated with sodium intake levels 20–30% greater than what the US Dietary Guidelines call the “safe upper limit” for healthy individuals under age 50 and more than twice that recommended for those over 50 and/or those with specific disease states such as CHF and diabetes, populations whose risk of death has now been linked to the very level of sodium intake current US nutrition policy advocates.

If sodium restriction were a pharmaceutical intervention, its feasibility and safety would now be challenged by some of the same federal agencies and their leaders who have promoted it. Their dismissive public comments surrounding these recent developments and those of the “experts” they have funded are not only irresponsible but, until proven otherwise, are likely harmful to millions of Americans. Proof to the contrary can only come from the very clinical trial called for by Taylor et al. which government and its spokespersons have long opposed.

It is a clinical trial whose time has come and the straw man excuse that the food industry is the culprit preventing it can no longer withstand the winds of science.

Disclosure: Dr McCarron currently serves on a Medical Advisory Board for ConAgra Foods. He holds no economic interest in any food or pharmaceutical company.


