EDITORIAL COMMENTARY

The IOM Report Fails To Detect Evidence to Support Dietary Sodium Guidelines

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The recent Institute of Medicine (IOM) report "Sodium intake in populations: Assessment of Evidence" has provided critical information concerning the dietary sodium guidelines currently recommended by agencies of the US government.2 The American Journal of Hypertension has assembled a set of commentaries providing the range of official and independent views addressing how the IOM report will (or should) influence dietary sodium policy and practice.³⁻⁷ Our purpose is to provide a concise and comprehensive assessment of how things stand in the immediate aftermath of the IOM report. Our hope is that these manuscripts will further inform what promises to be a lively public and scientific debate about the implications of the IOM report.

The balanced review and analysis has the credibility to make this report a paradigm shifting publication. The hypothesis from which sodium guidelines emerged - i.e., that because reduced sodium intake lowered blood pressure, it would inevitably prevent cardiovascular morbidity and mortality - has failed to find support in the IOM report. The Committee found that the modest blood pressure effect is not a certain surrogate for health outcomes associated with sodium intake. Instead, the

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Committee's case rested upon evidence of actual health consequences associated with reducing sodium intake from the current average of 3,400 mgs/day, to <2,300 or, for half the population, to <1,500 mgs/day. The following are 6 substantial conclusions reached by the IOM Committee.

First, while recognizing both the value of blood pressure as a surrogate for cardiovascular outcomes, as well as its association with sodium intake, the Committee concluded, in regard to human health, that effects on actual morbidity and mortality were the measure by which harm or benefit could be

Second, in a sharp break from many previous reviews and meta-analyses, the Committee recognized heterogeneity of results among observational and experimental studies, on the basis of ambient or starting sodium intake. This understanding avoids the inappropriate extrapolation of effects seen at very high levels (>5,000 mgs) of sodium to all lower intake levels.

Third, based upon the large body of mostly observational data reported over the past 8 years, it found that a possibility of harm existed at the lower (<2,300 mgs) end, and more confidently, at the higher (unspecified other than as "excessive") end as well. This implies that a "safe" range for sodium exists.

Fourth, the committee specifically declined to identify any "target" for sodium intake, or a safe range of intakes consistent with optimal human health.

Fifth, the committee found insufficient evidence of either harm or benefit from sodium consumption below 2,300 mgs, and cautioned against intakes <1,500 mgs/day.

Sixth, and finally, the report specifically failed to find evidence to support current guidelines promoted by both the US Centers for Disease Control and Prevention (CDC) and the New York City Department of Health.

Given the prominent role played by the CDC and the New York City Department of Health in promoting current guidelines, the directors of both have been invited to respond to the IOM report.^{3,4} While all submissions have been subject to peer review, wide latitude has been afforded authors. Investigators who have contributed important data on both sides of the current controversy have also been invited to submit their views.^{5,6} In addition, a report describing sodium intake in much of the world over the past half century provides critical background for examining the sodium issue.7 And, finally, a distinguished scholar of nutrition and nutrition policy has described how nutrient guidelines have and can be reached, and describes a method, based upon pathophysiology, and consistent with clinical outcomes, for defining a safe range for sodium intake.8

Response from the CDC and NYDH

Both the CDC and the NYDOH, in invited Commentaries, indicate that the IOM report will not deter them from vigorously pursuing efforts to reduce the sodium intake of all Americans.^{3,4} Without specifically endorsing current guideline goals, they give no indication that reconsideration is required. Both emphasize the blood pressure effect of reducing sodium, and contend that this surrogate endpoint will surely translate into dramatic reductions in cardiovascular morbidity and mortality. The inability of the IOM to find evidence to confirm this hypothesis is not contested. The CDC report parses the IOM language and contends that the IOM report is actually consistent with the goal of 2,300 mgs for all, even though the IOM report specifically declined to identify

a healthy intake target or range. IOM Chairperson, Brian Strom was quoted in a press release that "These new studies support previous findings that reducing sodium from very high levels to moderate levels improves health. But they also suggest that lowering sodium intake too much may actually increase a person's risk of some health problems." 9

It may well be that the imprecision with which the IOM defined a harmful level of sodium intake (i.e., "excessive") has led to misunderstanding in some quarters. However, the evidence cited by the IOM to reach its conclusions reveals that benefit is found in studies that compare levels above 5,000-6,000 mg/ day with levels of 3,000 -4,000 mg/ day. The Committee recognized that sodium intakes, like all other essential nutrients, when above and below some middle range, may cause harm. However, neither the CDC nor the New York Department of Health responses present any evidence, either considered by IOM, or to be found elsewhere in the large body of observational, or fewer randomized trials, that reducing sodium intakes of about 3,400 mgs/ day, to <2,300 mg/day produces benefit. In short, this IOM report is a sharp departure from previous IOM reviews of sodium intake, and clearly in conflict with current CDC recommendations.

Invited Commentaries

Professors Lawrence Appel and Paul Whelton, are respected authorities who have published widely in support of efforts to reduce sodium intake from current levels. They take the view that the IOM report has been misinterpreted, and that subsequent statements have clarified and corrected the language and intent of the full Committee's report.5 Specifically, reference is made to a post report paper, by 3 members of the committee, which implies that reduction of sodium intake from 3,400 to 2,300 mg/ day was endorsed by the Committee. ¹⁰ In fact, the IOM report stated that "excess" sodium intake is harmful, but did not identify any target level, nor any healthy range of sodium intake. Professors Appel and Whelton emphasize the difficulty in measuring sodium intake, as well as interpreting clinical studies. Nevertheless, although endorsing the need for more research, and not

presenting any evidence of favorable effect on health, they conclude that "[f] lawed evidence should not derail sound policy."

IOM Committee Chairman Strom saw it differently: "It's not a question of studies showing benefit being better than those showing harm; there are no studies showing benefit."9

Professors David McCarron and Andrew Mente et al., contributed separate commentaries. McCarron explains that, instead of current intakes being excessive, and a non-physiological aberration, they actually reflect physiological normality.⁷ He indicates that this level of intake is a biological set point and unlikely to be altered by environmental interventions. Based upon data from more than 45 studies, over more than 50 years, with contributions from more than 70 countries, he has found them to be remarkably consistent across time and place. Mean sodium intake is 3,400 mg/day, and <10% of the world's population is outside the range of 2,500 to 5,000 mg/day.

Mente et al., present a comprehensive case that supports the IOM findings, reviews data on health outcomes, and concludes by answering the question, "should Americans reduce their consumption of Na from current average intake levels?" by saying "We don't know, and definitely not yet."6

Associated State-of-the-Art

Professor Robert Heaney has reviewed strategies for determining nutritional guidelines employed by the National Academy of Sciences.⁸ He suggests that a "J" shaped relationship of nutrients to health outcomes is characteristic of all dietary elements. Recognizing the difficulty of identifying "healthy" targets and ranges, Heaney notes that the mid-range of sodium intakes is consistent with the "normal" range of plasma renin activity (PRA), and intakes above this range suppress, while intakes below stimulate PRA - a process that sustains adequate tissue perfusion. Notably, this physiological pattern is consistent with a healthy range consistent with current and long standing population intakes. Moreover, morbidity and mortality has been observed to be higher at intakes above and below this range.12

Summary

The IOM Report has changed the paradigm through which the issue of sodium intake can be addressed. The default position is no longer "lower is always better," but rather whether there is evidence that reductions below current intake levels will improve health.

The salient facts regarding dietary sodium and health not in question are:

- 1) More than 90% of Americans consume sodium in a narrow range surrounding 3,400 mgs/day and have done so for the 50 years that records are available.
- 2) The IOM review failed to identify a study showing a health benefit associated with sodium intakes <2,300 mgs/day, and concluded that there is insufficient evidence to determine whether sodium intakes of less than 2,300 mgs are harmful or beneficial.

Nevertheless, the CDC and the New York Department of Health appear to remain committed to efforts to have all Americans consume <2,300 mg/day, and for nearly 50%, <1,500 mg/day.

Science is a powerful, evolving force that will ultimately produce evidence to define the "healthy" range for sodium intake. Until that evidence becomes available, calls to reduce long established sodium intakes by one-third to one-half must be viewed with great skepticism.

Meanwhile, most Americans may be wise to maintain their sodium consumption pattern that, in any event, appears impervious to change.

DISCLOSURE

The authors declared no conflict of interest.

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