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Salt And Public Health: Contested Science And The Challenge Of Evidence-Based Decision Making

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ABSTRACT For more than four decades, starting in the late 1960s, a sometimes furious battle has raged among scientists over the extent to which elevated salt consumption has adverse implications for population health and contributes to deaths from stroke and cardiovascular disease. Various studies and trials have produced conflicting results. Despite this scientific controversy over the quality of the evidence implicating dietary salt in disease, public health leaders at local, national, and international levels have pressed the case for salt reduction at the population level. This article explores the development of this controversy. It concludes that the concealment of scientific uncertainty in this case has been a mistake that has served neither the ends of science nor good policy. The article poses questions that arise from this debate and frames the challenges of formulating evidence-based public health practice and policy, particularly when the evidence is contested.

For more than four decades, the question of whether high salt consumption has a marked impact on the prevalence of cardiovascular disease has been the subject of scientific controversy. One recent and widely cited analysis, based on modeling, suggested that reducing salt intake in the United States might save between 44,000 and 92,000 lives annually. Such an impact would place efforts to limit salt consumption on par with the benefits of reductions in tobacco use.[1] However, to those who question the empirical basis of such modeling exercises, these conclusions are utterly unwarranted.

The salt controversy has played out in generalist and specialist medical journals as well as in the news media. At times, the disagreement has been cautious—even decorous—in tone;[2] at the present time, it has risen to a fever pitch.

In 2011 two authors involved in the conduct of systematic reviews on salt declared, "It is surprising that many countries have uncritically adopted sodium reduction, which probably is the largest delusion in the history of preventive medicine."[3] Concurrently, a group of scientists long associated with studies on the harmful consequences of salt consumption wrote, "Denial and procrastination about dietary salt reduction will be costly in terms of avoidable illness and costs; it will also be ethically irresponsible."[4]

In June 2012 the *New York Times* ran an article by Gary Taubes, a prominent science writer, reporting that recent evidence "actually suggests that restricting how much salt we eat can increase our likelihood of dying prematurely."[5] In response a group of scientists committed to sodium reduction called the article "extraordinarily deceptive" and warned that it might give ammunition to those who wish to derail public health efforts on salt, resulting in "more hypertension, heart disease, deaths, misery, and medical costs down the road."[6]

In September 2012 the journal *Pediatrics* published a study by the Centers for Disease Control and Prevention decrying children's high salt intake.[7] The editor of the *American Journal of Hypertension*, a longtime skeptic on the risks of salt, responded that he knew of "no information" that

suggested cutting back on sodium would do most kids any good.[8]

In sharp contrast to this intensifying argument over what the available evidence actually says, public health recommendations at global, national, and local levels have been nearly unanimous in asserting that the evidence is incontrovertible that salt consumption should be reduced. Remarkably, this policy consensus emerged in the early years of the salt controversy and has been virtually untouched by the ongoing scientific dispute. In 2008, for example, the New York City Department of Health coordinated the launch of the National Salt Reduction Initiative, a public-private partnership of more than eighty-five state and local health authorities and national health organizations that has set voluntary targets to lower salt levels in packaged and restaurant food.[9]

It is not our intention in this article to provide a conclusion on the merits of the evidence on salt and public health. Rather, we seek to underscore a set of questions of great significance for policy makers—questions that too often remain obscure.

What does the enduring scientific controversy over salt represent? Does it simply reflect an ideological rigidity on the part of those who cannot or will not acknowledge what the weight of the evidence makes clear? Or does it suggest something of greater significance, involving questions about what does and should count as evidence, and about the circumstances under which scientists and policy makers may determine that the state of the evidence is good enough and the time for closure has arrived? How are we to understand the gulf between the certainty that has framed recommendations on salt and the persistence of scientific debate?

Salt, Health, And Disease: Debate Without End

Investigations of the impact of salt on health date to the early decades of the twentieth century. However, the contemporary controversy over the health consequences of elevated salt consumption began with the work of Lewis Dahl in the 1950s and 1960s. His unambiguous conclusions reflected what would become a striking feature of ensuing discussions: an intimate link between science and advocacy. "The evidence that salt induces permanent and fatal hypertension is direct, quantitative and unequivocal in the rat," he wrote. "Because the extensive evidence is circumstantial in man, it is therefore dismissed almost casually by some. If equal evidence had related salt to a similarly fatal but far less common disease, cancer, it would have evoked intense campaigns against it long ago."[10(p242)]

Dahl was particularly alarmed at the salt content of baby food, and he was invited to testify before Sen. George McGovern's (D-SD) Select Committee on Nutrition and Human Needs in 1969. He told the committee that his research had led him to believe that "chronic ingestion of excess salt can play a causal role in human hypertension" and that the time was right for caution on sodium "rather than plowing ahead blindly as we have been doing for a quarter of a century."[11(p3985–6)] This view was shared by Jean Mayer, a nutritionist who had just been tapped by President Richard Nixon to host a White House Conference on Food, Nutrition, and Health in December 1969.[12] The salt content of infant food was a key focus of the conference, but in an indication of the disagreements that were to follow, opinions differed on the evidence. One panel found "no scientific basis" for removing salt, while others concluded salt reduction was desirable.[13]

The next year, in 1970, a National Academy of Sciences committee convened to evaluate the safety of salt levels in infant food and likewise found the evidence against salt inconclusive. The committee found "no evidence" that prevailing salt levels had any effect, good or bad, on the infant. It found "no valid scientific evidence" to suggest that salt in baby food contributed to the development of hypertension later in life—or any evidence that it did not—and "no good basis" for recommending any particular sodium ceiling. Nonetheless, the committee recommended that baby food contain no more than 0.25 percent added salt because such a standard seemed to satisfy infants' nutritional needs.[14]

As questions about the safety of sodium surfaced in the press, baby food producers began to see a market opportunity in offering "no salt added" products.[15] Senator McGovern continued to focus on nutrition in a series of hearings titled "Diet Related to Killer Diseases." In 1977 his committee staff issued a report titled *Dietary Goals for the United States*, with the nation's first salt goal—three grams per day—at a time when average consumption was thought to be three to four times that amount.[16]

The McGovern report and the market-driven assault on sodium by baby food producers struck some scientists as capricious.[17] They questioned the nature of the evidence relied upon by proponents of sodium reduction and the design of the studies that had produced the data.[18–21] Nevertheless, the claim that excess salt consumption resulted in elevated blood pressure and that elevated blood pressure resulted in increased rates of cardiovascular disease and mortality rap-

idly became the prevailing wisdom.

The pace at which US federal agencies came to embrace the importance of salt reduction in the 1970s and early 1980s was later remarked on in a report from the surgeon general. The report noted that this pace stood in stark contrast to how long it had taken for recommendations to emerge on the importance of reducing blood cholesterol levels.[22] This difference was all the more remarkable because the report itself acknowledged that nutritional policy development on salt had proceeded even in the absence of published research studies that tested the hypothesis that a low-salt diet might prevent age-related increases in blood pressure. Given the prevalence of chronic disease and its presumed connection with the American diet, there was a sense among some federal nutrition policy makers that they "had to go after something" and that, compared with other suspected food hazards such as saturated fat, salt represented "the easier target."[17]

By the end of the 1970s, those who challenged the hypothesis that salt was harmful felt compelled to identify themselves as "skeptics," insisting only on the need for more evidence on the two central questions: Would low-sodium diets prevent the development of hypertension and age-related increases in blood pressure? Would population-level decreases in salt-induced blood pressure have an impact on mortality? Where the "advocates" argued with some urgency for remedial public health interventions, the skeptics warned against premature action. "We seem…to have got into a situation where the most slender piece of evidence in favor [of the link between dietary salt and hypertension] is welcomed as further proof of the link, while failure to find such evidence is explained away by one means or another.… It is not right to go to the public and launch an anti-salt campaign unless we have evidence."[2(p463S)]

Indeed, even as the notion that sodium consumption boosts blood pressure attained the status of something that "everyone knew," epidemiological studies sometimes failed to lend the theory clear support. The Framingham study, which has followed cohorts of Americans from Framingham, Massachusetts, since 1948 to study cardiovascular disease, found no correlation between sodium and blood pressure.[23] A study of more than 8,000 men of Japanese ancestry published in 1985 found no relationship between sodium intake and stroke.[24] A brief report from the Scottish Heart Health Study, which looked at 7,000 men, concluded that "the true association between sodium and blood pressure is extremely weak."[25(p330)]

The landmark Intersalt study of more than 10,000 men and women at fifty-two centers around the world aimed to bring clarity at last to the epidemiology of salt. Instead, the study produced a cloud of claims and counterclaims. The findings appeared in the *British Medical Journal* in 1988 and reported that populations that ate less salt experienced a smaller rise in blood pressure with age than did populations that ate more.[26] Coverage in the *Chicago Tribune* appeared under the headline: "To All Adults: Cut Your Salt Intake."[27]

But the founding editor of the *Journal of Hypertension*, John Swales, viewed the results very differently. Writing in the same issue of the *British Medical Journal*, Swales argued that the effect of salt on blood pressure appeared to be so small that it "would hardly seem likely to take nutritionists to the barricades (except perhaps the ones already there)" and warned that the safety of a reduction in salt intake should not be assumed.[28(p307)]

Other skeptics began to insist that Intersalt had not proved salt was harmful but the opposite.[29] One health policy analyst pronounced the study "as clean an outright refutation as can be found in science."[30(p198)] A 1990 wire story that ran under the headline, "For 90 Percent of Americans, Salt Doesn't Matter Much" quoted the Food and Drug Administration's director of nutrition, who said, "There is no conclusive evidence that salt consumption causes hypertension. It's only a hypothesis." In the same article, the chair of the American Heart Association's Nutrition Committee acknowledged, "You make these recommendations and the science changes and you have to be able to back away from them.… You've got to do that in such a way that you don't destroy your credibility."[31]

In the end, the vagaries of Intersalt made it possible for both advocates and skeptics to find support in its data. As one scientist remarked of the challenge of interpreting the study, "It's like reading the Bible.… Whatever bias you enter with, you leave with."[31]

Toward Evidence-Based Policy

At the very moment that this controversy was unfolding, a movement to reduce bias in science and make the provision of health care more "evidence based" was taking shape.[32] In health research and the social sciences during the 1980s, the typical approach to constructing a review article was narrative and relied on idiosyncratic judgments about which studies to include and which to leave out, resulting in reviews that were "subjective, scientifically unsound, and inefficient."[33(p485)]

Awareness of the biases built into such over-

view articles led to a search for systematic methods of weighing evidence. The Scottish physician Archibald (Archie) Cochrane insisted that only randomized controlled trials could be trusted and hence compiled into analytical syntheses of the research.[34] The power of the randomized clinical trial was its ability to reduce bias; by randomly assigning participants to either the treatment or the placebo arm of a study, on average the groups would differ only with respect to the experimental intervention.

In 1993 a nonprofit called the Cochrane Collaboration was established in the United Kingdom in the physician's honor to conduct rigorous, systematic reviews of the evidence on narrow but critically important empirical questions.[35] Cochrane reviews typically included a "meta-analysis"—a technique that uses statistics to combine the results of different studies to obtain an overall quantitative estimate of the effect of a particular intervention (for example, salt restriction) on a defined outcome (for example, blood pressure). The Cochrane Collaboration would play a leading role in the "evidence-based" movement and reflected a belief that the most exacting efforts to conduct systematic reviews of research could anchor both clinical practice and public health decisions in hard evidence. Implicitly, these institutions sought to increase the extent to which such decisions could be freed from preconceptions, misplaced faith in badly conducted investigations, and narrow professional or corporate interests.

Salt restriction first underwent meta-analysis in 1986.[36] The initial review found that lowering salt might reduce blood pressure, especially in people with hypertension, but that the effect was small. The authors concluded that a low-salt diet unfortunately appeared to be "of limited use" for those most eligible for nondrug treatment—young patients with mild hypertension. Over the next fifteen years, at least four more meta-analyses were completed, and all reached similar conclusions: A large sodium reduction might cut blood pressure in the general population by a very small amount.[37]

Despite the consistent findings, interpretations of how salt reduction might affect population health differed wildly. In the face of this enduring controversy, Michael Alderman, then president of the American Society of Hypertension, argued that only long-term trials with hard endpoints—stroke and heart attack—could hope to end the debate. For Alderman, a singular focus on salt reduction might, in fact, increase the risks of all-cause morbidity and mortality.[38]

By contrast, for those convinced that the evidence implicating salt was sufficient, the time had long since passed for further study. They asserted that corporate greed was driving the controversy, abetted by scientists who had accepted money as consultants for the food industry and were demanding a level of scientific exactitude that was neither reasonable nor feasible. British newspaper reporters revealed that the salt and food industries had covertly paid for studies that played down the risks of excess salt to "reduce the pressure on sodium for the time being" and had quietly convinced a government task force to omit salt reduction from a healthy eating initiative.[39(p15)]

Skepticism, under such circumstances, appeared to serve only the corporate bottom line. Fiona Godlee, an editor of the *British Medical Journal*, wrote, "The food industry has lobbied fiercely against the threat to its profits." Godlee remarked that the industry had "everything to gain from keeping controversy alive."[40(p1239)]

It was against this backdrop that, in 1998, the internationally respected journal *Science* published Taubes's controversial "The (Political) Science of Salt," which would win the National Association of Science Writers' Science in Society Journalism Award. A detailed analysis based on some eighty interviews, the article challenged the very foundations of the idea that there was incontrovertible evidence linking salt to morbidity and mortality. Taubes observed that "the controversy over the benefits, if any, of salt reduction now constitutes one of the longest running, most vitriolic and surreal disputes in all of medicine."[41(p898)]

For public officials who had committed institutional resources in an effort to shift perceptions of salt, persistent reports challenging the evidentiary basis for populationwide recommendations were troubling. Claude Lenfant, director of the National Heart, Lung, and Blood Institute, lamented that the battle of the experts provided the grounds for a "salt reduction doesn't matter" attitude.[42]

Then, in 2001, the results of the thirty-day Dietary Approaches to Stop Hypertension trial suggested that cutting salt substantially lowered blood pressure for people without hypertension who were eating a typical American diet. The authors asserted in the *New England Journal of Medicine* that the study "should settle the controversy" over whether salt reduction made sense for people without high blood pressure.[43]

Echoing this claim six years later were the authors of the 2007 Trials of Hypertension Prevention Collaborative Research Group follow-up, which appeared to answer skeptics' call for a study of hard endpoints. Acknowledging the extent to which prior studies had failed to document the clinical impact of salt reduction, the study concluded that "sodium reduction, previ-

ously shown to lower blood pressure and prevent hypertension, also seems to prevent cardiovascular disease. ...The observed reduction in cardiovascular risk...was substantial and provides strong support for population-wide reduction in dietary sodium intake."[44(p7)] The results sufficiently impressed the *British Medical Journal* editor Godlee that she declared that the study might be "the final bugle call in the battle of the evidence."[45(p0.1)] An accompanying editorial asserted that it was long past time for exhortations; legislation to force industry to limit salt in processed food was "necessary and justified."[46]

In 2010 the Institute of Medicine took up the call for policy change in its report *Strategies to Reduce Sodium Intake in the United States*. Starting with the premise that elevated salt consumption was harmful, the report went on to ask: What is to be done? "For 40 years we have known about the relationship between sodium and the development of hypertension and other life threatening diseases but we have had virtually no success in cutting back the salt in our diets," the report stated.[47] The report was welcomed by the incoming president of the American Society of Hypertension, who warned that the "outcomes mafia" might challenge the justification for a regulatory approach.[48] In the same month, Thomas Frieden, the director of the Centers for Disease Control and Prevention, and his colleague Peter Briss asserted that 100,000 deaths a year could be attributed to excess sodium.[49]

In 2011 the policy momentum continued to build. The Food and Drug Administration issued a call for data and recommendations that would help it shape regulatory policy on salt in food.[50] However, skeptics who believed the science was anything but certain continued to challenge those initiatives.

A European study of people without cardiovascular disease found no relationship between diet-associated changes in blood pressure and the risk for hypertension or cardiovascular complications. Indeed, it suggested that lower sodium excretion was associated with higher mortality. The authors concluded that their findings "refuted" the bases for recommendations for "generalized and indiscriminate" salt reduction.[51] The publication of this article in the *Journal of the American Medical Association* stimulated a flurry of critical responses. Most strikingly, the *Lancet* editorialized that the *Journal of the American Medical Association* study was "disappointingly weak.... It is likely to confuse public perceptions of the importance of salt as a risk factor for high blood pressure, heart disease and stroke."[52(p1626)]

Representing a more damaging challenge to the sodium consensus were two Cochrane reviews published in 2011. The first found "no strong evidence" that salt reduction reduced all-cause mortality in people without hypertension.[53] This review was sharply challenged by Feng He and Graham MacGregor. In the *Lancet* they wrote, "In our view [this review] reflects poorly on the reputation of the Cochrane Library and the authors. They have seriously misled the press and thereby the public."[54(p381)]

The second 2011 Cochrane report went further. After examining the potential impact of salt reduction on hormones and lipids in people with normal blood pressure, it concluded that the available evidence did not permit a conclusion as to whether low-salt diets improved or worsened health. It was possible, the authors concluded, that further research might be able to detect the beneficial impact of salt reduction, but "after more than 150 RCTs and 13 population studies without an obvious signal in favor of sodium reduction, another position could be to accept that such a signal may not exist."[55(p18)]

Evidence, Skepticism, And The Role Of Certitude In Translational Science

At the beginning of this article, we noted that the salt controversy raises a series of questions about what counts as evidence and how to understand the gulf between the certainty that has framed recommendations on salt and the persistence of scientific debate.

The battle over salt is not unique. Controversies in science, sometimes hard fought, are common. Indeed, the entire field of science and technology studies has sought to analyze carefully the social foundations of scientific disputes for three decades. What is striking in the salt debate, however, is that the combatants cannot be neatly divided between the respected advocates of a mainstream position and a band of marginal dissidents. Respected scientists have found themselves on opposite sides of the divide. References to ideological rigidity or corporate interference do not appear to us an adequate explanation for this encounter.

The bitterness that has marked the forty-year dispute over salt reduction stems largely from the fact that advocates of salt reduction believe that the lives of hundreds of thousands of people hang in the balance. From the beginning, there appeared to be no good reason to believe that more salt was better than less, except insofar as salt was a taste-enhancing condiment. Failure to act under such circumstances seemed no virtue. But to those who insist that the evidence for universal salt reduction is weak, the credibility of the scientific enterprise itself is at stake.

Furthermore, the skeptics have increasingly

concluded that to assume that no deleterious effects would follow from salt reduction at the population level is simply wrong. Although it is plausible from a physiological standpoint that consuming high levels of salt might negatively affect blood pressure and thereby cardiovascular health, medicine and public health are replete with examples of seemingly sound ideas that had devastating unintended consequences. One hundred percent oxygen for newborns can cause blindness. Extensive use of x-rays for screening purposes is associated with greater risk of cancer. The risk of unintended consequences grows dramatically when interventions are translated to a populationwide scale.

The controversies over salt have forced to the foreground critical methodological questions that are too often masked by the universal conviction that clinical practice and public policy must be evidence based. Sometimes indirectly, sometimes explicitly, those engaged in the salt debate have raised questions about the role of randomized controlled trials as the source of definitive evidence and about the relative importance of systematic reviews in general and Cochrane reviews in particular. Advocates of salt reduction have sometimes asserted that the "weight of all the evidence"—including data from observational studies, animal experiments, and clinical experience—should trump the results of analyses that weigh only randomized controlled trials. Insistence on gold-standard evidence would place policy makers in methodological straitjackets and result in policy paralysis. Findings that did not meet the most exacting standards of science might be more than adequate for the purposes of setting policy.

Sir Michael Rawlins, chair of the National Institute for Health and Clinical Excellence in the United Kingdom, which guides the National Health Service, and Anthony Culyer bluntly expressed this view: "Guidance is based on the best available evidence. The evidence may not, however, be very good and is rarely complete."[56(p224)] In this context the privileging of randomized clinical trials was characterized as "oversimplistic" and "pseudoquantitative."[57(p2159)] "Should we refrain from this life-saving measure and let people die of hypertension and its cardiovascular complications while waiting for the 'mother of all trials'?" asked one advocate of salt reduction recently.[58(p831)]

It is abundantly clear, we believe, that policy makers must act in the face of scientific disagreement, even uncertainty. To demand otherwise could well impose substantial and preventable burdens at the population level. But as policy makers press forward with new initiatives that may require confrontations with powerful commercial interests and deeply ingrained patterns of behavior, they are commonly impelled to speak with what the economist Charles Manski has called "incredible certitude," rather than to acknowledge that their policy prescriptions are often made in the face of contested science and degrees of uncertainty.[59]

All of this suggests that the enthusiasm with which the concept of evidence-based practice has been embraced by policy makers has tended to mask an essential, and perhaps irreducible, tension between science and policy. Public health policy makers have to devise policy solutions in the face of the mixed and sometimes uncertain state of the scientific evidence. An action-oriented precautionary posture informs much of the public health outlook. But this is a perspective that can conflict with an equally powerful concern expressed by those committed to the evidence-based practice of never moving beyond what the science can justify. Science must remain open, skeptical, and concerned about unmeasured confounding and selection bias in studies that accompany even the best efforts to articulate the evidence for new interventions.

"In the end, does the harm of exaggerating certainty do more harm than good?" asked one reviewer of this article. "After all, it would be very hard to make any policy from a position of informed, complicated, contextualized ambivalence." After a careful consideration of the debate over salt, we have concluded that the concealment of scientific uncertainty is a mistake that serves neither the ends of science nor good policy. Simplistic pictures of translation from evidence to action distort our ability to understand how policy *is*, in fact, made and how it *should* be made.

At the most fundamental level, we believe that it is essential to recognize the role that judgment and values must play in evidence-informed policy making. As Roger Chou, a central figure in the conduct of systematic reviews for the US Preventive Services Task Force, has stated, "The evidence can tell us the likely benefits and likely harms, burdens and costs, but it does not directly tell us how to weigh all of these factors."[60(p10)] Policy makers must ask: Are the burdens of public health interventions too great, and for whom? Are the expected benefits sufficient given the potential costs? These are not questions that can be answered in the absence of normative judgments. Invoking the mantra of evidence-based policy instead of confronting these questions deprives us of the capacity to think critically about the relationship that ought to prevail between evidence, however contested, and values in the translation of science into policy. ■

NOTES

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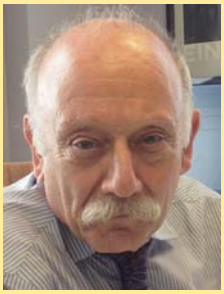

Ronald Bayer is the codirector of the Center for the History and Ethics of Public Health, Columbia University Mailman School of Public Health.

In this month's *Health Affairs*, Ronald Bayer and coauthors examine the long controversy over the relationship between the consumption of salt and cardiovascular disease or stroke. For the authors, the controversy constitutes a case study in how the fields of public health and public policy come to grips with the uncertainty of science—and, in this case, have pressed the case to reduce salt levels despite the uncertainties.

The authors conclude that the concealment of scientific uncertainty in this case has been a mistake and, more broadly, frame the challenges of formulating evidence-based public health practice and policy, particularly when the evidence is contested.

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