Science has made the public healthier

The 2025 Frank A. Calderone Prize in Public Health Lecture

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by

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My title for this Calderone Prize lecture reflects the tremendous, evidence-driven gains in life expectancy globally. They date to the start of the 20th century in the United States and other now high-income countries and and more recently to gains in low- and middle-income countries (LMICs).[1] Some of the rise resulted from basic public health measures and the improved housing, sanitation, and food quality that came with growing income. The gains were also driven by new therapeutics, e.g., for tuberculosis (the largest cause of death in the United States at the start of the 20th century) and for diabetes, effective vaccines, e.g., for smallpox, measles, and polio and other childhood infections, enhanced diagnostics, and stronger disease control strategies. In LMICs, life expectancy rose with reduction of malnutrition, introduction of oral rehydration therapy for diarrheal diseases, and vaccination to control childhood respiratory infections.

This Calderone Prize presentation addresses how scientific evidence advances public health. Simplified, evidence-based policy making involves characterizing what is known about the evidence supporting the measure under consideration and what is not known, generally referred to as uncertainty. Beyond where the balancing point lies between strength of evidence and uncertainty, many "real-world" considerations figure in: the often powerful forces of advocacy, politics, costs, justice, and others. The landmark 1964 Report of the Surgeon General's Advisory Committee offers a powerful example of how evidence can make a difference.[2] The report concluded that cigarette smoking caused lung cancer in men (studies were lacking on women at the time) and reduced life expectancy. The report findings reach these causal conclusions but stopped short of offering policy recommendations. Instead, it set the stage for tobacco control policy by offering a strong

imperative for action: "Cigarette smoking is a health hazard of sufficient importance in the United States to warrant appropriate remedial action." More than 60 years later, the report remains a model for assembling research results for reaching conclusions on causation.[3]

Drawing on the tobacco control example and others, particularly those in which I have been engaged, Figure 1 provides a general framework that spans from the elaboration of evidence to action. The framework begins with the design of research to address a question, generated by researcher(s) who understand where the evidence stands on a question and how new evidence on the question will advance the state of knowledge. Biomedical research is inherently applied in nature and researchers and funders may be able to look ahead to the impact of the new evidence coming from a study.

Once available, generally through the peer-reviewed literature, the findings of a study are incorporated into some process that identifies relevant evidence for decision-making, brings it together (evidence synthesis), and combines all lines of evidence in an integrative process that characterizes the "weight-of-evidence," typically for causation, and uncertainty. Today, this step often involves systematic review, a process for identifying and evaluating all relevant evidence on a topic in a transparent fashion.[4] Actions taken might involve promulgation of a regulation, a guideline for clinical care or prevention, a recommendation to the public, or a decision in litigation, as examples.

I offer one extended example: the US National Ambient Air Quality Standards (NAAQS) set by the Environmental Protection Agency under the Clean Air Act.[5] Sections 108 and 109 specify how the NAAQS are to be set and revised. Section 109 directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS for pollutants identified under section 108. Section 109(b)(1) defines a primary standard as one *"the attainment and maintenance of which in the judgment of the Administrator,* ***based on such criteria*** *and* ***allowing an adequate margin of safety****, is requisite to* ***protect the public health****."* Here, "criteria" are intended to "accurately reflect the **latest scientific knowledge** useful in indicating the kind and extent of identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in ambient air…"

The current process for fulfilling the requirements of Sections 108 and 109 has been in place since 2006 (figure 2).[6] It begins with a workshop to identify key questions and ends with a (possible) revision by the Administrator of the NAAQS under consideration, e.g., airborne particulate matter or ozone. The Integrated Science Assessment incorporates a systematic review and integration process to determine the strength of evidence for adverse outcomes and the levels of associated risks. The Risk/Exposure Assessment uses the findings of the Integrated Science Assessment to model the comparative public health consequences of potential changes to the NAAQS.

This process has led to progressive tightening of the NAAQS for airborne particles, resulting in cleaner air, and facilitated the conduct of research to address critical uncertainties. One notable example followed the promulgation of the 1997 NAAQS for $PM_{2.5}$ (small particles less than 2.5 microns in aerodynamic diameter).[7,8] This new NAAQS was controversial, and its evidence foundation was questioned. In response, the Congress requested that the National Academies of Sciences appoint a committee to set a research agenda on airborne particulate matter for the Environmental Protection Agency, assigning priorities and funding.[9,10] From 1998 through 2004, the committee, which I chaired, did so, assuring that the most critical uncertainties were the focus for funding and research.

In the instance of airborne particles, as with many other public health threats, there are numerous studies and the literature needs to be carefully assembled, evaluated, and collated. Another challenge in the Agency's framework is the scope of the literature; in 1997, there was only a small number of pivotal studies.[11] Now, there are thousands of studies relevant to the $PM_{2.5}$ NAAQS and the task of assembling the Integrated Science Assessment is monumental. Meta-analysis (quantitatively summarizing findings from multiple studies) is used to estimate the risks of exposure.

Nonetheless, expert judgment has a key role in the NAAQS process. A committee, the Clean Air Scientific Advisory Committee (CASAC), provides scientific review and guidance to the agency up to the point when the agency begins its decision-making (Figure 2). The make-up of the core membership is specified in the Clean Air Act to cover needed scientific and air quality control expertise. Expert judgment is implicit to the general framework of Figure 1 and actualized by CASAC in the NAAQS revision process. In the face of uncertainty, as with the 1997 $PM_{2.5}$ NAAQS, opinions among members of an expert panel may differ and consensus, i.e., convergence of opinions, may not occur and is not requisite for CASAC. Table 1 nicely illustrates the differing opinions of members of the CASAC panel advising on the $PM_{2.5}$ and PM_{10} NAAQS.[8] It was assembled by the CASAC chair, who asked each committee member to provide their opinions on the potential levels for a new $PM_{2.5}$ NAAQS and also on revision of the PM_{10} NAAQS, already in place.

The framework (Figure 1) also provides a vehicle for categorizing efforts to undermine evidence-based policy actions in public health. Each step may be touched by those seeking to delay or stop action. More than two decades ago, my Johns Hopkins colleague, Dr. Tom Burke, and I wrote a paper entitled: "Turning Science into Junk: The Tobacco Industry and Passive Smoking," which listed out the industries strategies: funding targeted research intended to create doubt; hiring consultants (with unrevealed funding in some instances) to raise methodological concerns about studies; convening expert panels and conducting literature reviews; harassing researchers; and even creating scientific societies

with journals.[12] The industry's misleading efforts around secondhand smoke contributed to the guilty verdict in the successful litigation brought against the tobacco industry under the Racketeering Influenced and Corrupt Organizations (RICO) Act. The 1,700 page opinion by Judge Gladys Kessler in the case provides a comprehensive summary of the industry's actions on secondhand smoke.[13] She powerfully opined that: The tobacco industry has "marketed and sold their lethal product with zeal, with deception, with a single-minded focus on their financial success and without regard for the human tragedy or social costs that success exacted."

Another strategy is to change elements of the framework, as took place during the first Trump Administration with the CASAC. Its chair was dismissive of the process in-place for selecting and evaluating evidence, claiming that only studies involving "manipulative causation" should be considered. The reference was to studies considering circumstances of exposure had been changed in an informative way in regard to causation, thereby dismissing most observational studies, which were the foundation for revision of the NAAQS. A National Academies' committee was later convened on the topic; its consensus opinion reaffirmed the original approach in place for causality determinations.[14]

Sometimes political considerations hold sway. During the first Obama presidential administration, consideration was given to lowering the NAAQS for ozone.[15] The process had been initiated during the Bush administration but stalled. The Environmental Protection Agency carried out an accelerated update of the Integrated Science Assessment that would have led to possible lowering of the NAAQS. Politics intervened and reduction of the ozone NAAQS became labeled as "job killing." As chair of the CASAC at the time, review of any proposed reduction would have been reviewed by the committee under my direction. On September 2, 2011, the White House announced that it would delay potential revision of the ozone NAAQS, concerned by political fall-out during an election year.

Since January 20, 2025 with the new administration, we have seen a more or less complete abandonment of evidence-based decision-making. The framework of Figure 1 and its derivates appears to be no longer operative, although what is replacing it is uncertain. For example, with regard to vaccination policy, Secretary of Health and Human Services, Robert Kennedy, has replaced the 17-person Advisory Committee on Immunization Practices (ACIP) with 8 new members, many sympathetic to his anti-vaccination biases.[16,17] He has surfaced discredited speculations about vaccines, including the purported linkage to autism.

Politicization of public health is hardly new and was discussed, for example, in the 1988 Institute of Medicine report, *The Future of Public Health.*[18] Quoting the report: "Tension

between public health and politics can be observed throughout the nation's public health system." And "The idea that politics can be restricted to the legislative arena, while the work of public agencies remains neutral and expert, has been discredited." While the challenge of politicization has long been recognized, its present incarnation was not anticipated in its ferocity, disruption, and fabulistic grounding.

Four months into the new administration, I am worried; my worries include 1) old problems will come back, such as the current measles epidemic; 2) new problems will emerge, as occurred with the COVID-19 pandemic; and 3) preparedness has been diminished. Inevitably, during the years to come, public health will be tested; its resiliency has been diminished. And, I worry that only a catastrophe will remind decision-makers as to the necessity of public health. Let's hope that we don't have such a reminder but unfortunately there is a high likelihood that something will happen.

I close with my gratitude for being selected as the 2025 recipient of the Frank A. Calderone Prize in Public Health. Dr. Calderone had a remarkable career, most notably setting the stage for the World Health Organization. Past winners have advanced health in the United States and globally; I am honored to join them.

Figure 1

Evidence to Action Frameworks
If the world were rational and linear, then:

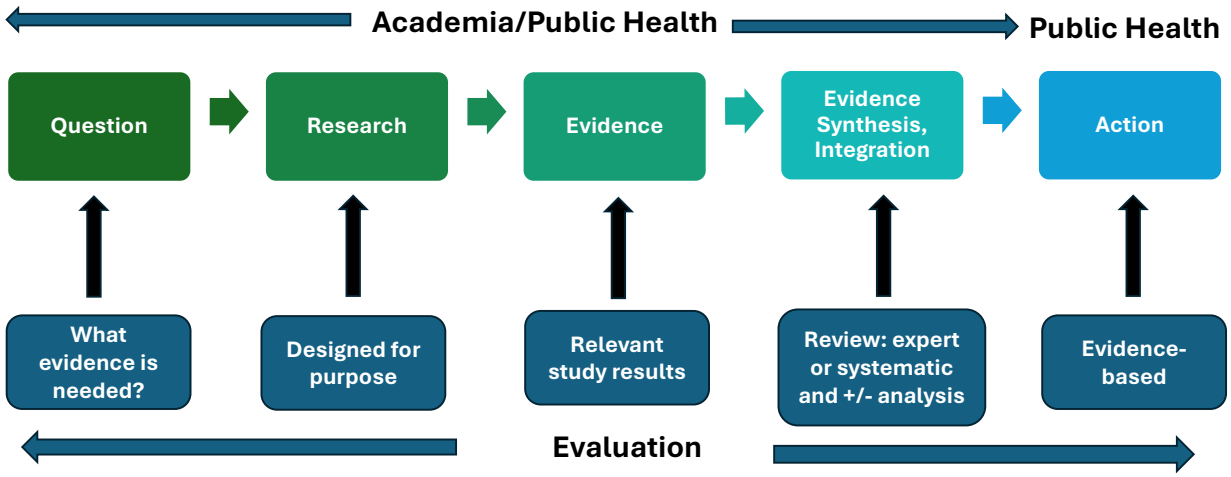

Figure 2

2006 Forward: Using Science to Set NAAQS

A Five-Year Cycle

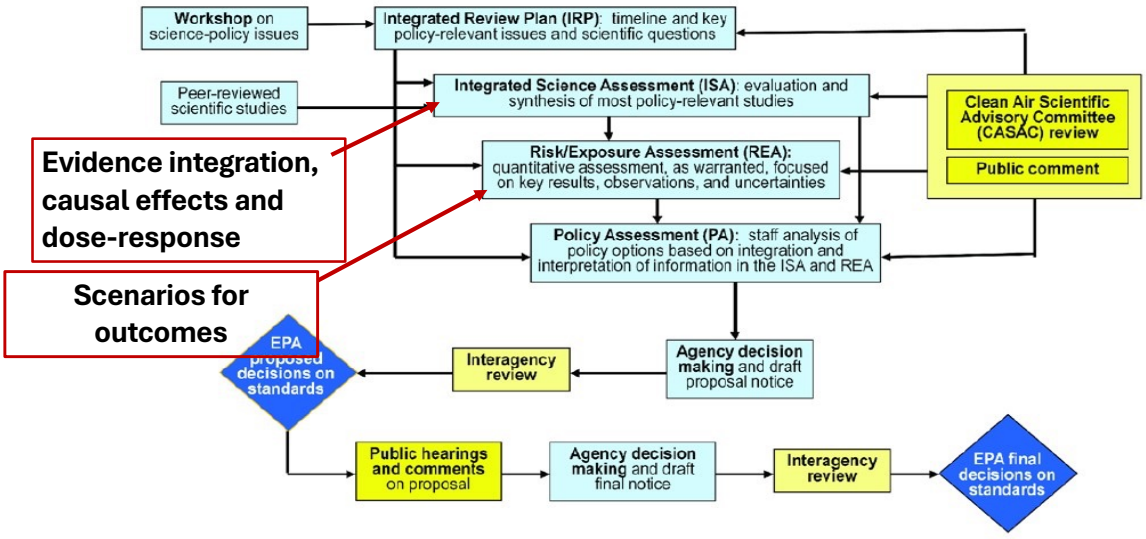

TABLE I
Summary of CASAC Panel Members Recommendations
(all units $\mu g/m^3$)

		$PM_{2.5}$ 24-hr	$PM_{2.5}$ Annual	PM_{10} 24-hr	PM_{10} Annual
Current NAAQS		N/A	N/A	150	50
EPA Staff Recommendation		18 - 65	12.5 - 20	150[13]	40 - 50
Name	**Discipline**				
Ayres	M.D.	yes[2]	yes[2]	150	50
Hopke	Atmos. Sci.	20 - 50[3]	20 - 30	no	40 -50[4]
Jacobson	Plant Biologist	yes[2]	yes[2]	150	50
Koutrakis	Atmos. Sci.	yes[2,5,6]	yes[2,5,6]	no	yes[4]
Larntz	Statistician	no	25-30[7]	no	yes[2]
Legge	Plant Biologist	≥ 75	no	150	40 - 50
Lippmann	Health Expert	20 - 50[3]	15 - 20	no	40 - 50
Mauderly	Toxicologist	50	20	150	50
McClellan	Toxicologist	no[8]	no[8]	150	50
Menzel	Toxicologist	no	no	150	50
Middleton	Atmos. Sci.	yes[2,3,12]	yes[2,5]	150[3,13]	50
Pierson	Atmos. Sci.	yes[2,9]	yes[2,9]	yes[4]	yes[4]
Price	Atmos. Sci./ State Official	yes[3,10]	yes[10]	no[3,4]	yes[4]
Shy	Epidemiologist	20 - 30	15 - 20	no	50
Samet[1]	Epidemiologist	yes[2,11]	no	150	yes[2]
Seigneur	Atmos. Sci.	yes[3,5]	no	150[13]	50
Speizer[1]	Epidemiologist	20 - 50	no	no	40 - 50
Stolwijk	Epidemiologist	75[7]	25-30[7]	150	50
Utell	M.D.	≥65	no	150	50
White	Atmos. Sci.	no	20	150	50
Wolff	Atmos. Sci.	≥75[3,7]	no	150[3]	50

[1] not present at meeting; recommendations based on written comments
[2] declined to select a value or range
[3] recommends a more robust 24-hr. form
[4] perfers a $PM_{10-2.5}$ standard rather than a PM_{10} standard
[5] concerned upper range is too low based on national $PM_{2.5}/PM_{10}$ ratio
[6] leans towards high end of Staff recommended range

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