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# To Bolster Expert Advice In Vaccination Policy Beyond COVID-19, Improve Coordination And Trust

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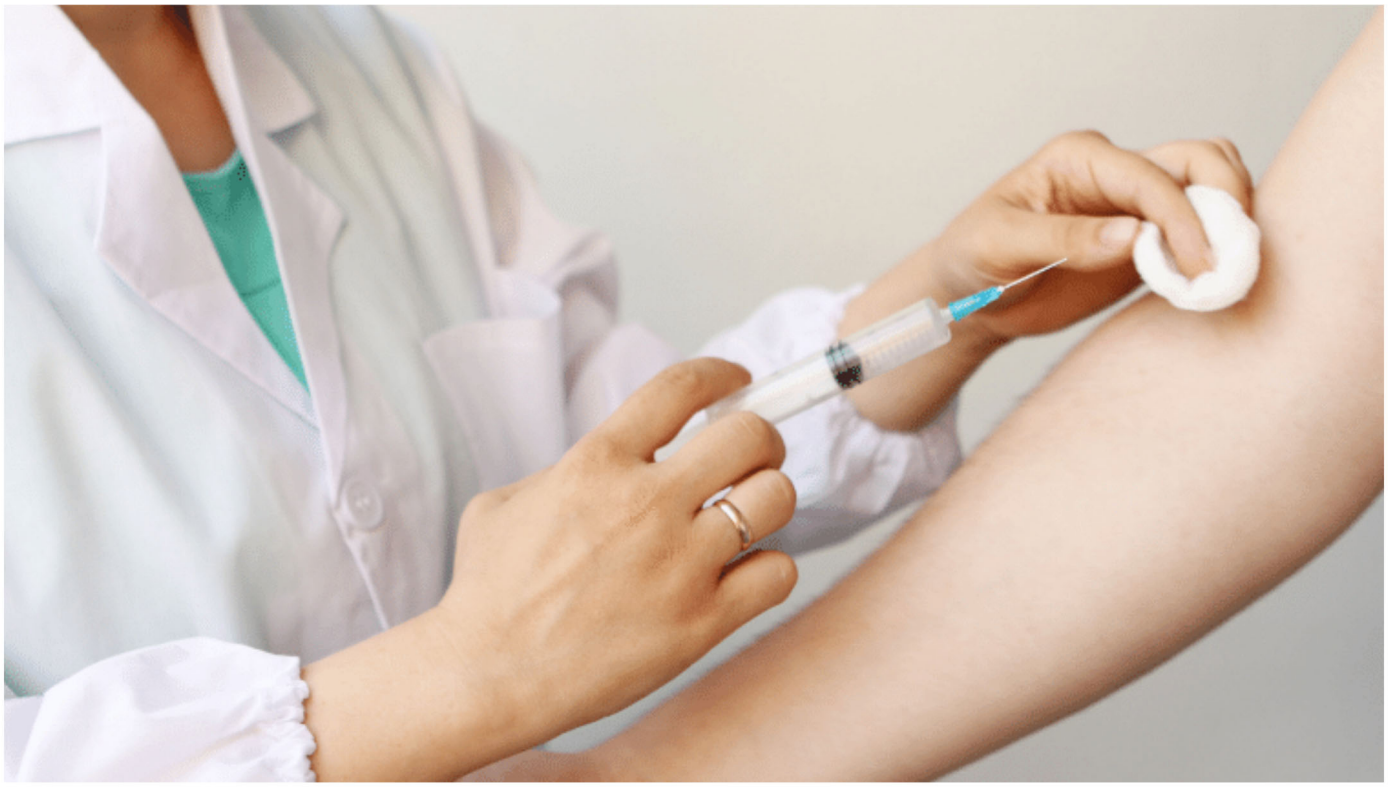

An integral part of public health policy-making activities has been engagement with expert advisers and transparent discourse <https://uscode.house.gov/statviewer.htm?volume=111&page=2689> with the federal agencies responsible for key policy decisions. In regards to vaccines and vaccination efforts, this work has long included deliberation of multiple streams of scientific evidence by expert advisory

bodies meeting in public—a transparency that is thought to enhance public trust <https://www.nejm.org/doi/full/10.1056/NEJMp2026393> in the eventual decisions reached—and close engagement with the federal agencies that ultimately craft the policies and regulations.

## How The Government Solicits Expert Advice

The federal government receives expert advice through several federal advisory committees <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3001822/pdf/phr1260004.pdf> . For example, the Vaccines and Related Biological Products Advisory Committee (VRBPAC) advises the Food and Drug Administration (FDA) on the safety and efficacy of investigational new vaccines, the Advisory Committee on Immunization Practices (ACIP) provides guidance to the Centers for Disease Control and Prevention (CDC) on the optimal use of authorized or approved vaccines, and the National Vaccine Advisory Committee (NVAC) counsels the Office of the Assistant Secretary for Health at the Department of Health and Human Services on national vaccination activities and strategies to ensure adequate supply of vaccines and the optimal use of vaccines (as seen in exhibit 1).

## Exhibit 1: Principal US federal advisory committees related to vaccines and vaccination programs and their activities regarding COVID-19 vaccines, 2020–22

| Committee Name | Primary Government Agency and Official Committee Advises | Committee Purpose and Scope of Activities | Number of Meetings Where COVID-19 Vaccines and Vaccination Were Discussed | Primary Topics Examined and Activities Undertaken Regarding COVID-19 Vaccines and Vaccination |
|---|---|---|---|---|
| Advisory Committee on Immunization Practices (ACIP) | Director, Centers for Disease Control and Prevention | Provides advice on the use of vaccines and related agents for the effective control of vaccine-preventable diseases in the civilian population of the United States; and establishes and periodically reviews and, as appropriate, revises the list of vaccines for administration to children and adolescents eligible to receive vaccines through the Vaccines for Children Program, along with schedules regarding the appropriate dose and dosing interval, and contraindications to administration of the pediatric vaccines. Under the Affordable Care Act, ACIP-recommended vaccines are required to be covered by most private health insurance plans without cost-sharing. | 25 since February 2020 | Recommendations for vaccine use following Food and Drug Administration (FDA) authorizations or approvals, including booster doses; evaluation of post-authorization or post-approval vaccine safety and effectiveness; assessment of vaccine adverse events and risk-benefit considerations; Prioritization of vaccine doses, equity, and disparities; |
| National Vaccine Advisory Committee (NVAC) | Assistant Secretary for Health, Department of Health & Human Services | Supports National Vaccine Program, the nation's immunization program, in optimizing prevention of disease through immunization and prevention against adverse vaccine reactions; studies and recommends ways to encourage the availability of an adequate supply of safe and effective vaccines in the U.S.; recommends research priorities to enhance the safety and efficacy of vaccines | 9 since February 2020 | Discussions and recommendations regarding vaccine hesitancy, confidence, and acceptance; incentives to promote vaccine uptake; equity; safety evidence and messaging; vaccine development and clinical trial design considerations |
| Vaccines and Related Biologic Products Advisory Committee (VRBPAC) | Commissioner of Food and Drugs, Food and Drug Administration | Provides advice related to ensuring safe and effective vaccines and biological products for human use; reviews and evaluates data on safety, effectiveness, and appropriate use of vaccines and related biological products for which the FDA has regulatory responsibility | 9 since October 2020 | Recommendations regarding Emergency Use Authorization or Biologics License Application submissions or amendments for different vaccines in different age groups, including booster doses; evaluation of safety, efficacy, and effectiveness information from clinical trials and post-authorization or -approval use; vaccine trial design considerations |

*Sources: US General Services Administration, Federal Advisory Committee Act (FACA) Database and advisory committee websites. Note: These advisory committees typically meet three times a year.*

Since the onset of the pandemic, vaccine decisions have unfolded in near real time, been widely publicized, disseminated through news outlets and social media, and been subjected to misinformation that has contributed to confusion and hesitancy. Urgent questions as to which vaccines should be authorized for use and for whom, which groups should receive the limited number of initial doses, and many others, all required swift resolution. However, the historically well-regarded processes involving expert committee guidance have been enormously challenged, highlighting vulnerabilities in the mechanisms that support evidence-based policy making during a crisis and potentially contributing to diminished confidence in public health agencies and their recommendations during, and likely after, the crisis.

Historically, external expert advice has strengthened the quality and transparency of the public health decision-making process. And in the best of worlds, during a crisis such as the COVID-19 pandemic, this approach has the potential to not only support the work of health officials but also enhance public understanding and trust in the decisions. These roles are especially important when scientific evidence is limited, ambiguous, or rapidly evolving <https://pubmed.ncbi.nlm.nih.gov/34239479/> .

During the COVID-19 pandemic, policy makers and the public relied on these committees heavily. For example, since the outset of the pandemic, the CDC's ACIP, a group that traditionally convenes in-person three times a year on dates scheduled months in advance, has had 25 meetings devoted in whole or in part to COVID-19 vaccination. Many of these meetings were publicly announced only days before they were held. These online, formal public meetings are supported by dozens of work group and supporting group meetings to synthesize, discuss, and prepare for the full group deliberations.

## Decision Making Under Crisis Conditions

Expert committees offer the ability to make sense of volumes of information, published rapidly and more recently, often made available initially via non-peer-reviewed preprint servers. These expert groups also bring a collective knowledge that is important when dealing with many unanswered questions and unknown outcomes. In some respects, these challenges are not atypical to all decision making during a crisis, when incomplete information, significant uncertainty, and the need to act under pressing time constraints are common. But during a crisis, there are many inputs for policy makers to consider, digest, and act on, with advice from expert advisers being just one stream.

Unfortunately, the pandemic showed us that during a crisis, the views of expert committees can also be diminished or discounted. For example, in August 2021, the White House preempted the open, public discussions and recommendations from VRBPAC and ACIP when announcing a plan to offer COVID-19 vaccine booster shots to the public:

"Pending final Food and Drug Administration (FDA) evaluation and recommendations from the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP). Under this plan, a booster would be administered, eight months after an individual's second dose, beginning the week of September 20 <https://www.whitehouse.gov/briefing-room/statements-releases/2021/08/18/fact-sheet-president-biden-to-announce-new-actions-to-protect-americans-from-covid-19-and-help-state-and-local-leaders-fight-the-virus/> ."

This atypical announcement, publicly anticipating a specific outcome prior to the deliberations and recommendations of expert panels, and subsequent determinations by the health agencies they advise, was a marked deviation from the well-established, evidence-based decision-making process.

Following VRBPAC deliberations and FDA authorization of booster doses for a narrower group of citizens than the August 2021 White House announcement anticipated, the CDC recommended a booster dose for adults older than the age of 65, adults between the ages of 18 and 64 with underlying medical conditions, and adults at elevated risk for exposure because of where they live or work. This latter group was included despite an unfavorable vote from the ACIP, a policy action that, while within the purview of the CDC director, is exceedingly rare in the committee's nearly 60-year history.

The VRBPAC discussions on boosters were notable for the deliberation and recommendation that certain populations be boosted with additional doses since this is a conversation far more typical of the charge and activities of the ACIP. Like so much of the work regarding COVID-19 vaccines and the broader pandemic response, the conversations around boosters by both groups drew upon a wide range of considerations and corresponding types of expertise, often beyond the typical scope of each individual committee. In this regard, the pandemic showed us that during a crisis, traditional models—such as the typical separate approach for each advisory body—could be replaced by alternative models—such as bringing the groups together to deliberate collaboratively. This approach could have enhanced the quality of advice produced and its public reception. It also could have facilitated the participation of

additional experts and expertise—such as from the social sciences, communication, and ethics, to name a few. These areas of expertise were deeply relevant to the situation but were not represented on these types of expert committees.

Such an approach would not be unprecedented. In 2009, the NVAC and ACIP held joint meetings when charged with establishing priority groups for limited supplies of the H1N1 influenza vaccine. Currently, the lagging performance of COVID-19 booster vaccination efforts—with more than 80 million Americans eligible for a booster dose yet to receive one—may in part reflect the lingering consequences of the manner in which the evidence and importance for booster doses was presented, debated, and communicated by political appointees, health officials, and their expert advisers in recent months.

## Transparency Builds Trust

Ultimately, the value of expert advice and the process by which it is obtained comes not only from the knowledgeable and independent guidance provided by committee members, but by the rigorous, transparent, and open deliberative process through which it is provided, in routine times and crises alike. The substantial challenges of COVID-19 vaccine policy making highlight the importance of preserving the many assets of traditional expert advisory mechanisms while also suggesting a need for adaptation to reflect the unique pace, difficulties, and questions associated with public health decision making in a crisis. This type of examination informed by the experiences of the COVID-19 pandemic would strengthen the remaining work ahead regarding COVID-19 vaccination as well as preparedness for future health emergencies.



## Article Metrics