Alliance FOR AGING RESEARCH
Catalyzing Innovation for Healthy Aging

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Centers for Disease Control and Prevention
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Arkansas Secretary of Health
Director, Arkansas Department of Health
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and Respiratory Diseases
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
Atlanta, GA

Re: Docket No. CDC-2021-0034 for Request for Comments for "Advisory Committee on Immunization Practices (ACIP) June 23-24, 2021"

Dear Dr. Romero and Dr. Cohn,

Thank you for the opportunity to submit a public comment to the Advisory Committee on Immunization (ACIP) June 23-25, 2021, meeting. Our organization, the Alliance for Aging Research (the "Alliance"), is the leading non-profit organization dedicated to accelerating the pace of scientific discoveries and their application to improve the experience of aging and health. The Alliance believes that advances in research help people live longer, happier, more productive lives, and reduce health care costs over the long term.

ACIP's accelerated timeline for voting on COVID-19 vaccine and prioritization group recommendations led to a precipitous drop in cases and deaths among older adults. Until COVID-19 becomes endemic, ACIP should continue its accelerated review process for new vaccines approved by the Food and Drug Administration (FDA). The lessons learned from the COVID-19 pandemic should be applied to other infectious disease areas, including pneumonia and influenza, to improve health outcomes for older adults and other high-risk groups.

The June 2021 ACIP meeting agenda includes presentations and discussion about PCV15 and PCV20 pneumococcal vaccines, and the Alliance urges the Centers for Disease Control and Prevention (CDC) and the Committee to consider the following broad policy issues and recommendations.

Recommendation One: ACIP Should Prioritize Recruitment of Members with Geriatric Expertise

As with COVID-19, older adults are more likely to contract pneumonia, have severe pneumonia-related complications, and die from pneumonia than other age cohorts. These risks are due to the natural decline of immune systems with age and the prevalence of one or more chronic conditions in older adults. From 1999-2019 in the United States, 743,881 people died from pneumonia, and adults aged 65 and older accounted for 83.3 percent of those deaths.[1]

[1] About Underlying Cause of Death, 1999-2019 via CDC Wonder, National Vital Statistics System: https://wonder.cdc.gov/controller/saved/D76/D99F514.

The FDA approved two pneumococcal vaccines for use in adults—PPSV23 in 1983 (for use in those aged 18 or older) and PCV13 in 2011 (for use in adults aged 50 years or older). Studies show that one dose of PPSV23 protects 50 to 85 percent of healthy adults against invasive pneumococcal disease.[2] For PCV13, the *NEJM* reported that adults aged 65 and older received 75 percent protection from invasive pneumococcal disease and 45 percent protection from pneumococcal pneumonia.[3] Yet, ACIP has recommended limiting access to these vaccines for those aged 65 and older, departing from FDA age indications. In June 2019, ACIP voted to further restrict use by removing its standing recommendation from 2014 that all adults over the age of 65 receive the PCV13 vaccine. This decision was based on the indirect impact PCV13 use in children had in overall reduced rates of pneumococcal disease, except among those with certain conditions, and after they speak with their clinicians to make the decision.

The Alliance is concerned that ACIP is not providing effective infectious disease prevention guidance for older Americans due to the lack of geriatric expertise on the Committee. ACIP consists of fifteen medical and public health experts, who are also voting members. Fourteen of these members have expertise in vaccinology, immunology, internal medicine, nursing, family medicine, virology, public health, infectious diseases, and/or preventive medicine. The fifteenth member is a consumer representative who provides perspectives on the social and community aspects of vaccination. Noticeably, half of the Committee specializes in pediatrics (seven members), and none are geriatricians. There have been similar issues with the development and FDA approval of enhanced flu vaccines and the inability of ACIP to better specify geriatric-specific recommendations due to lack of expertise. Additionally, the 2020 ACIP meetings on COVID-19 included several time-consuming debates on basic long-term care/nursing home structure issues that could have been easily resolved with adequate geriatric expertise on the Committee.

Geriatric expertise would also aid ACIP in addressing vaccine disparity issues for older adult communities of color. In 2018, non-Hispanic white people were much more likely (72.5 percent) than both non-Hispanic Black people (59.5 percent) and Hispanic people (54.1 percent) to have ever received a pneumococcal vaccine.[4]

Experts from the geriatric field could provide meaningful input when decisions that affect older adults are being made in the future. Such experts could offer additional recommendations to ACIP/CDC to better focus on geriatric-specific options for optimal vaccine protection, including a possible ACIP Older Adult Immunization Schedule workgroup chaired by a licensed geriatrician.

Recommendation Two: CDC/ACIP Should Leverage the Pharmacy Partnership for Long-Term Care (LTC) Program for All Older Adult Vaccines

The COVID-19 pandemic delayed routine healthcare for many Americans—the combination of an overwhelmed healthcare system and patient fears of contracting COVID-19 resulted in reduced pneumococcal vaccination rates. A June 2021 analysis from Avalere found that adults in the markets studied (commercial healthcare, managed Medicaid, Medicare Advantage, and Medicare FFS) missed an estimated 17.2 million doses of recommended vaccines from January to November 2020 compared to vaccination levels over the same period in 2019.[5] As the country reopens and people return to their pre-pandemic lifestyles, the healthcare system needs to prioritize older adult adherence to recommended immunization schedules.

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[2] Pneumococcal disease prevention among adults: Strategies for the use of pneumococcal vaccines, Vaccine. 2015 Nov 27;33 Suppl 4:D60-5: https://www.sciencedirect.com/science/article/pii/S0264410X15007872?via%3Dihub.

[3] Polysaccharide conjugate vaccine against pneumococcal pneumonia in adults, N Engl J Med. 2015 Mar 19;372(12):1114-25: https://pubmed.ncbi.nlm.nih.gov/25785969/.

[4] National Health Interview Survey, National Center for Health Statistics: https://public.tableau.com/app/profile/nhis6957/viz/FIGURE5_3/Dashboard5_3.

[5] Updated Analysis Finds Sustained Drop in Routine Vaccines Through 2020, Avalere: https://avalere.com/insights/updated-analysis-finds-sustained-drop-in-routine-vaccines-through-2020.

The ACIP and CDC should explore expanding and utilizing the Pharmacy Partnership for Long-Term Care (LTC) Program[6] for all long-term care communities and at the local level for older adults and people with disabilities living at home and in community-based settings. The program could be reasonably modified to work with a broader group of long-term care pharmacists, community pharmacists, state health departments, and immunization programs.

Recommendation Three: HHS/CDC Should Remove Economic Considerations and Analyses from the ACIP Charter

ACIP's purpose is to control the spread of diseases in the United States by providing expert recommendations on the use of vaccines. It is troubling that ACIP uses economic considerations when determining its recommendations on the public use of vaccines. ACIP's charter allows for "economic analyses" to be used as a basis to revise or withdraw its recommendations. Additionally, the 2018 ACIP adoption of the "Evidence to Recommendations Framework" and the 2019 adoption of updated guidance allowed for further consideration of health economics studies in its recommendations.

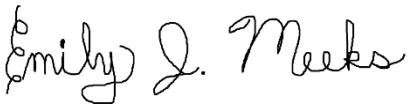
Federal law prohibits the use of quality-adjusted life-year (QALY) and similar cost-effectiveness assessments for coverage and reimbursement decision-making in both the Medicare and Medicaid programs. The QALY is a discriminatory metric that assigns a financial value to the patients for whom a given treatment is intended. If the respective group is sicker, older, and/or disabled, the QALY calculates treatments for them as less valuable. When applied to healthcare decision-making, the results can mean that some patients—people with disabilities, veterans, and older adults— are deemed "too expensive" to receive care.

Economic analyses should not be included as part of ACIP's consideration of vaccine recommendations, nor should ACIP be tasked with deciding whether a vaccine under its consideration is cost-effective. Effectiveness should be measured by improvements to a patient's condition and quality of life rather than personal characteristics or health status.

The U.S. Department of Health and Human Services and the CDC should eliminate economic considerations and analyses from its charter and discontinue the presentation of such analyses at ACIP meetings.

Thank you again for the opportunity to provide written comments for ACIP's June 2021 meeting. If you have any questions regarding our comments, please contact us at speschin@agingresearch.org or emeeks@agingresearch.org.

Sincerely,



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[6] Understanding the Pharmacy Partnership for Long-Term Care Program, Center for Disease Control: https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships.html.