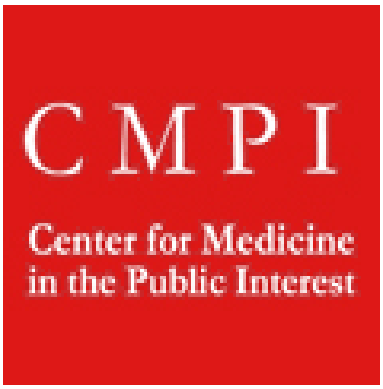
WHITE PAPER: EXPANDING ACCESS TO PNEUMONIA VACCINES—A VITAL PUBLIC HEALTH MEASURE



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White Paper: Expanding Access to Pneumonia Vaccines—A Vital Public Health Measure

Introduction

The CDC's Advisory Committee on Immunization Practices (ACIP) serves a critical role in formulating recommendations that guide national immunization strategies. These recommendations directly affect individual healthcare decisions, shape public health outcomes, and influence the financial and logistical planning of healthcare providers and vaccine manufacturers.

Vaccines, particularly pneumonia vaccines, are essential tools in the prevention of life-threatening illnesses. They reduce healthcare costs, prevent long-term complications, and save lives by protecting individuals from diseases like pneumococcal pneumonia. While the current routine ACIP recommendation for the adult pneumonia vaccination begins at age 65, in addition to those age 19 – 64 who are deemed "at-risk", there is mounting evidence to support lowering the routine age-based recommendation to 50. This proactive public health policy would provide earlier protection, especially for at-risk groups, and would reduce preventable deaths and healthcare costs.

This paper advocates for ACIP to lower the age-based routine recommendation for pneumococcal vaccines to 50 while supporting the use of all available vaccines—to ensure comprehensive protection and maintain supply chain resilience. Furthermore, it underscores the importance of fostering innovation in the vaccine market by avoiding sole-source contracts or preferring one vaccine over another based on cost-effectiveness analyses.

The Role of ACIP in Public Health

ACIP's decisions are based on a thorough review of epidemiological data, clinical trial results, and healthcare resource utilization. The recommendations made by ACIP help:

- **Prevent infectious diseases** by providing timely vaccine guidance.
- **Guide healthcare providers** in determining when and how to administer vaccines to optimize patient care.
- **Reduce healthcare costs** associated with treating vaccine-preventable diseases.

By extending their vaccine recommendations to earlier ages, ACIP has the opportunity to safeguard millions of Americans from illnesses like pneumonia, which remains one of the leading causes of preventable hospitalizations and deaths.

Resurgence of Interest in Pneumococcal Vaccines

Antibiotic resistance in S. pneumoniae became a growing concern, and interest in vaccines was reignited. In 1977, the pneumococcal polysaccharide vaccine (PPSV) was developed by Merck and approved by the FDA.

The first-generation PPSV, known as Pneumovax, contained antigens from 14 different serotypes of the bacterium. The vaccine was designed to stimulate an immune response to the polysaccharide outer coating of the bacterium, which varied between different serotypes. However, it was found that the polysaccharide vaccine did not elicit strong immune responses in infants and young children due to their immature immune systems.

Introduction of Pneumococcal Conjugate Vaccines

In 2000 the first pneumococcal conjugate vaccine (PCV), PCV7 (Prevnar), was introduced by Wyeth (now Pfizer). This vaccine targeted seven of the most common pneumococcal serotypes causing severe disease in children. Unlike polysaccharide vaccines, conjugate vaccines were created by attaching a protein carrier to the polysaccharide antigens, which elicited a stronger immune response, especially in young children.

PCV7 was a major breakthrough, as it not only reduced the incidence of invasive pneumococcal disease (IPD) in vaccinated children but also led to herd immunity, significantly decreasing the disease burden in unvaccinated populations, such as the elderly. The success of PCV7 helped pave the way for further developments in conjugate vaccines.

PCV13 (Prevnar 13), an expanded version of the original PCV7, was approved in 2010. PCV13 covered 13 serotypes of S. pneumoniae and became the standard pneumococcal vaccine for infants, young children, and adults at higher risk. This vaccine provided broader protection against pneumococcal disease, reducing the incidence of both invasive disease and non-invasive diseases, such as otitis media and pneumonia.

Following the success of PCV13 in children, the ACIP extended its recommendation to include adults aged 65 and older. Studies have shown that PCV13 can protect older adults

from pneumococcal pneumonia and invasive pneumococcal disease, leading to a significant reduction in hospitalization and mortality rates.

Recent Advances and Future Developments

The FDA approved PCV20 (Prevnar 20), an expansion of the conjugate vaccine platform that targets 20 serotypes of S. pneumoniae. This new vaccine covers the most prevalent serotypes found in both invasive and non-invasive diseases and is expected to further reduce the burden of pneumococcal disease in both children and adults.

This past summer the Food and Drug Administration approved 21-valent pneumococcal conjugate vaccine for adults aged ≥18 years. PCV21 does not contain certain serotypes that are included in other licensed pneumococcal vaccines but adds eight new serotypes.[1]

These strains closed the gap in coverage, especially as more resistant strains of S. pneumoniae emerge globally.

Why Lowering the Age-Based Recommendation for Pneumonia Vaccines Makes Sense

Extending pneumonia vaccine coverage to adults aged 50 and older would have a significant positive impact on public health for several reasons:

1. Earlier Protection for At-Risk Populations

By age 50, many adults begin to experience a natural decline in immune function, making them more susceptible to infections like pneumonia. Additionally, adults in this age group are more likely to develop chronic conditions such as diabetes, chronic obstructive and pulmonary disease (COPD).

These conditions increase the risk of severe pneumococcal infections, including pneumonia, which can lead to hospitalization or death. By extending vaccine coverage to this age group, we can significantly reduce the incidence of pneumococcal disease in a population that is more vulnerable but not yet covered under current guidelines.

[1] Kobayashi M, Leidner AJ, Gierke R, et al. Use of 21-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:793–798. DOI: http://dx.doi.org/10.15585/mmwr.mm7336a3

2. Prevention of Severe Health Outcomes

Pneumonia can lead to severe complications, especially in older adults, such as: bacteremia (bloodstream infections),meningitis (inflammation of the protective membranes around the brain and spinal cord) and long-term lung damage.

By vaccinating adults aged 50 and older, many of these serious outcomes can be prevented, reducing the burden on individuals and healthcare systems alike. This is especially important in a population that is growing as life expectancy increases.

3. Reduction in Hospitalizations and Healthcare Costs

Extending routine pneumonia vaccine coverage to those aged 50 and up could reduce hospitalization rates and healthcare costs related to treating pneumococcal infections. Pneumonia is a leading cause of hospitalization for adults, particularly those with underlying health conditions. The costs of treating pneumococcal pneumonia, especially when intensive care is required, are significantly higher than the cost of preventive vaccination.

4. Protection During Disease Outbreaks

As seen during the COVID-19 pandemic, individuals with pneumococcal disease are at increased risk of complications from respiratory infections. Extending vaccine coverage to those aged 50 and up would provide additional protection during disease outbreaks or pandemics, reducing the risk of severe co-infections, hospitalizations, and deaths.

This proactive measure could also help during other outbreaks of respiratory diseases, where preventing bacterial pneumonia is essential to reducing mortality rates and ensuring healthcare resources remain available.

Challenges of Choosing One Pneumococcal Vaccine Over Another

Limiting procurement to a single vaccine producer can significantly increase the risk of shortages:

The impact of limited or single source vaccine production was “ brought to national attention by severe vaccine shortages in 2001 and 2002, which affected 8 of the 11 routine childhood vaccines. Such shortages have the potential to result in serious outbreaks of disease and can erode public health programs and infrastructure that have taken years to

build. But the greatest threat is that the discovery and development of future vaccines, many of which are now well within reach, will be delayed or abandoned."[2]

During this period, the United States experienced nationwide shortages of five childhood vaccines that protect against eight of the eleven childhood diseases prevented through routine immunization The shortages affected most of the manufacturers of childhood vaccines, with three of the four experiencing supply problems during the period

"Supply problems were especially severe for vaccines that are in continuous demand, such as those for tetanus and influenza. In March 2000, there were two major producers of tetanus vaccine in the United States— Aventis Pasteur and Wyeth-Ayerst—and no shortages. By early January 2001, Wyeth had ceased production of the vaccine, leaving Aventis as the only supplier.6 Aventis could not scale production up rapidly enough to meet demand and was forced to ration supply.

Several of these shortages were severe enough that the Advisory Committee on Immunization Practices (ACIP) recommended suspension of booster doses for tetanus–diphtheria (Td), DTaP, and pneumococcal conjugate. Shortages were most severe for Td and pneumococcal conjugate, for which there was a 40 percent shortfall in doses shipped."[3]

A similar scenario could unfold if ACIP were to favor one pneumonia vaccine over the other. Recommending one vaccine over another could reduce competition, discourage innovation, and increase the risk of supply shortages during public health emergencies or disease outbreaks.

Reducing the Risk of Supply Shortages and Supporting Innovation

Supporting multiple vaccines ensures redundancy in the system, reducing the risk of shortages. If a sole-source manufacturer faces production challenges or supply chain disruptions, vulnerable populations could be left unprotected during critical periods. A broader recommendation encourages manufacturers to invest in research, explore new delivery methods (such as combination vaccines), and improve vaccine efficacy, ultimately strengthening pandemic readiness and public health infrastructure.

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[2] Vaccine Supply [Internet]. Nih.gov. National Academies Press (US); 2024 [cited 2024 Oct 8]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK221811/#ddd00084

[3] Vaccine Supply [Internet]. Nih.gov. National Academies Press (US); 2024 [cited 2024 Oct 8]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK221811/#ddd00084

Clear, Inclusive Recommendations Build Trust

A broader, clearer recommendation from ACIP not only improves public health outcomes but also builds goodwill among healthcare providers, patients, and the public. Clear, evidence-based recommendations instill confidence in the healthcare system and reduce vaccine hesitancy, a critical issue in today's climate.

Simplifying the decision-making process for healthcare providers by supporting both vaccines ensures that they can offer the best possible care to their patients. Patients will also feel more confident knowing that their health needs are being addressed comprehensively.

Conclusion

By lowering the routine age-based recommendation for pneumococcal vaccination to 50 years and supporting the use of both PCV and PPSV vaccines, the CDC's Advisory Committee on Immunization Practices has a unique opportunity to improve public health outcomes, prevent severe illnesses, and reduce healthcare costs.

Avoiding a binary decision about vaccines will encourage a competitive vaccine market, drive innovation and ensure a resilient vaccine supply chain. These proactive steps will not only safeguard millions of Americans but also strengthen trust in public health institutions, paving the way for a healthier, more prepared population.