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Progress Toward Achieving National HIV/AIDS Strategy Goals for Quality of Life Among Persons Aged ≥50 Years with Diagnosed HIV — Medical Monitoring Project, United States, 2017–2023

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Abstract

Ensuring good quality of life (QoL) among persons with diagnosed HIV (PWH) is a priority of the National HIV/AIDS Strategy (NHAS), which established 2025 goals for improving QoL. Goals are monitored through five indicators: self-rated health, unmet needs for mental health services, unemployment, hunger or food insecurity, and unstable housing or homelessness. Among the growing population of PWH aged ≥50 years, progress toward these goals has not been assessed. Data collected during the 2017–2022 cycles of the Medical Monitoring Project, an annual complex sample survey of U.S. adults with diagnosed HIV, assessed progress toward NHAS 2025 QoL goals among PWH aged ≥50 years, overall and by age group. The recent estimated annual percentage change from baseline (2017 or 2018) to 2022 was calculated for each indicator. Among PWH aged ≥50 years, the 2025 goal of 95% PWH with good or better self-rated health is 46.2% higher than the 2022 estimate. The 2025 goals of a 50% reduction in the other indicators range from 26.3% to 56.3% lower than the 2022 estimates. Decreasing hunger or food insecurity by 50% among PWH aged ≥65 was the only goal met by 2022. If recent trends continue, other NHAS QoL 2025 goals are unlikely to be met. Multisectoral strategies to improve access to housing, employment, food, and mental health will be needed to meet NHAS 2025 goals for QoL among older PWH.

Introduction

As advances in HIV treatment have resulted in improved health and longevity (*1*), a large and growing proportion of U.S. persons with diagnosed HIV (PWH) are now aged ≥50 years (*2*). PWH are disproportionately affected by adverse social determinants of health, which affect their HIV-related health (*3*,*4*). To ensure good quality of life (QoL) among PWH, in 2022 the National HIV/AIDS Strategy (NHAS) set 2025 goals for improving five QoL indicators (*5*). These include 1) good or better self-rated health,* 2) unmet need for mental health services,† 3) unemployment,§ 4) hunger or

* Good or better self-rated health was defined as reporting one's general health at the time of interview to be good, very good, or excellent as opposed to poor or fair.

† Unmet need for mental health services among those with any need was defined as reporting needing but not receiving services from a mental health professional during the previous 12 months among all persons reporting receiving, or needing but not receiving, services from a mental health professional.

§ Unemployment was defined as reporting being out of work at the time of interview, as opposed to being employed for wages, a homemaker, a student, retired, or unable to work.

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food insecurity,[¶] and 5) unstable housing or homelessness.[**] Indicator goals are designed to increase good or better self-rated health to 95% and decrease all other indicators by 50% from their respective baselines by 2025. Baseline values and 2025 goals are presented in Figures 1 and 2 and in the Table. As persons age, their needs might change because of increasing age-related comorbidities and becoming eligible for Medicare. Thus, age-stratified estimates of QoL, and factors affecting QoL, among older age groups can help guide intervention strategies. QoL indicators are monitored using data from the Medical Monitoring Project (MMP) (*6*), a CDC-funded HIV surveillance system. This analysis examined recent trends in QoL indicators among PWH aged ≥50 years (overall and stratified by age 50–64 and ≥65 years), assessed whether recent trends are sufficient to meet NHAS 2025 QoL goals, and examined selected theoretically related factors potentially affecting the indicators (hereafter referred to as factors) to help guide intervention efforts to improve QoL among older PWH.

[¶] Hunger or food insecurity was defined as reporting being hungry and not eating because of lack of money for food during the previous 12 months.

[**] Unstable housing or homelessness was defined as reporting moving in with others because of financial issues, moving more than two times, being evicted, or living on the street, in a shelter, in a single-room–occupancy hotel, or in a car during the previous 12 months.

Methods

Data Collection

MMP uses a two-stage sample design: 1) 16 states and Puerto Rico were sampled from among all U.S. states, the District of Columbia, and Puerto Rico and 2) simple random samples of adult PWH were selected annually within participating jurisdictions from the National HIV Surveillance System (NHSS) (*6*). Interview and medical record abstraction data were collected in annual cycles during June 2017–May 2023. Annual response rates were 100% at the state and territory level and ranged from 40% to 46% at the PWH level. MMP was reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy.[††]

Statistical Methods

Data were weighted for unequal selection probabilities, adjusted for nonresponse, and poststratified to NHSS population totals. Among 13,475 PWH aged ≥50 years who participated in the 2017–2022 MMP cycles, weighted prevalence estimates and 95% CIs were calculated for each QoL indicator and theoretically related factors, overall and stratified by age (50–64 versus ≥65 years). For each indicator and theoretically related factor, Poisson regression models were used to calculate the recent estimated annual percentage change (EAPC) from

[††] 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

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baseline (2017 or 2018 cycle, depending on the indicator) to the 2022 cycle. EAPC measures the average percentage change per year over the period for which it is calculated. The percentage difference between the 2025 NHAS goal and the 2022 estimate, expressed as a percentage of the 2022 estimate, was also calculated (i.e., [2025 goal – 2022 estimate] / 2022 estimate).

Results

Good or Better Self-Rated Health

The 2025 NHAS goal for PWH aged ≥50 years to self-report good or better health is 95%. During 2018, 65.6% (95% CI = 63.5%–67.6%) of these adults reported good or better health and 65.0% (95% CI = 62.7%–67.2%) reported this in 2022. (Figure 1) (Supplementary Table 1, https://stacks.cdc.gov/view/cdc/160729). The 2025 goal is 46.2% higher than the 2022 estimate. Change in factors influencing self-rated health was minimal (Table) (Supplementary Table 2, https://stacks.cdc.gov/view/cdc/160728). Age-stratified trends were similar across the goal and factors that might influence it.

Unmet Need for Mental Health Services

The 2025 NHAS goal for PWH aged ≥50 years with unmet need for mental health services among those with a need is 9.4%. The observed need in this population was 18.8% (95% CI = 15.4%–22.1%) in 2017 and 21.5% (95% CI = 16.5%–26.5%) in 2022 (Figure 1) (Supplementary Table 1, https://stacks.cdc.gov/view/cdc/160729). The 2025 goal is 56.3% lower than the 2022 estimate. Overall and stratified by age, minimal change in symptoms of major or other depression and symptoms of generalized anxiety disorder among those with a mental health need during 2017–2022 was observed (Table).

Unemployment

The 2025 NHAS goal for unemployed PWH aged ≥50 years is 5.9%. Unemployment declined from 11.7% (95% CI = 9.7%–13.6%) in 2017 to 8.0% (95% CI = 6.6%–9.5%) in 2022 (Figure 2) (Supplementary Table 1, https://stacks.cdc.gov/view/cdc/160729). The 2025 goal is 26.3% lower than the 2022 estimate. Over time, unemployment was lower among those aged ≥65 years than those aged 50–64 years. Minimal change overall or by age group among factors contributing to unemployment was observed (Table) (Supplementary Table 2, https://stacks.cdc.gov/view/cdc/160728).

Hunger or Food Insecurity

The 2025 NHAS goal for PWH aged ≥50 years experiencing hunger or food insecurity is 9.0%. Among this population, hunger or food insecurity was 17.9% (95% CI = 15.4%–20.4) in 2017 and 14.1% (95% CI = 12.5%–15.8%) in 2022; those aged ≥65 years experienced the largest reduction in hunger or food insecurity, and this was the only group that met the NHAS 2025 goal by 2022 (Figure 2), (Supplementary Table 1, https://stacks.cdc.gov/view/cdc/160729). The 2025 goal is 36.2% lower than the 2022 estimate for PWH aged ≥50 years. Change in unmet need for food assistance or food stamps was minimal, as was unmet need for food or meal delivery overall and by age group (Table), (Supplementary Table 2, https://stacks.cdc.gov/view/cdc/160728).

Unstable Housing or Homelessness

The 2025 NHAS goal for PWH aged ≥50 years experiencing unstable housing or homelessness is 7.4%. Unstable housing or homelessness was 14.7% (95% CI = 13.0%–16.4%) in 2018 and 12.5% (95% CI = 10.8%–14.2%) in 2022 (Figure 2) (Supplementary Table 1, https://stacks.cdc.gov/view/cdc/160729). The 2025 goal is 40.8% lower than the 2022 estimate. Over time, except during the 2022 cycle, unstable housing or homelessness was lower among those aged ≥65 years than those aged 50–64 years. Overall and stratified by age, there was little change in unmet need for shelter or housing services during 2017–2022 (Table).

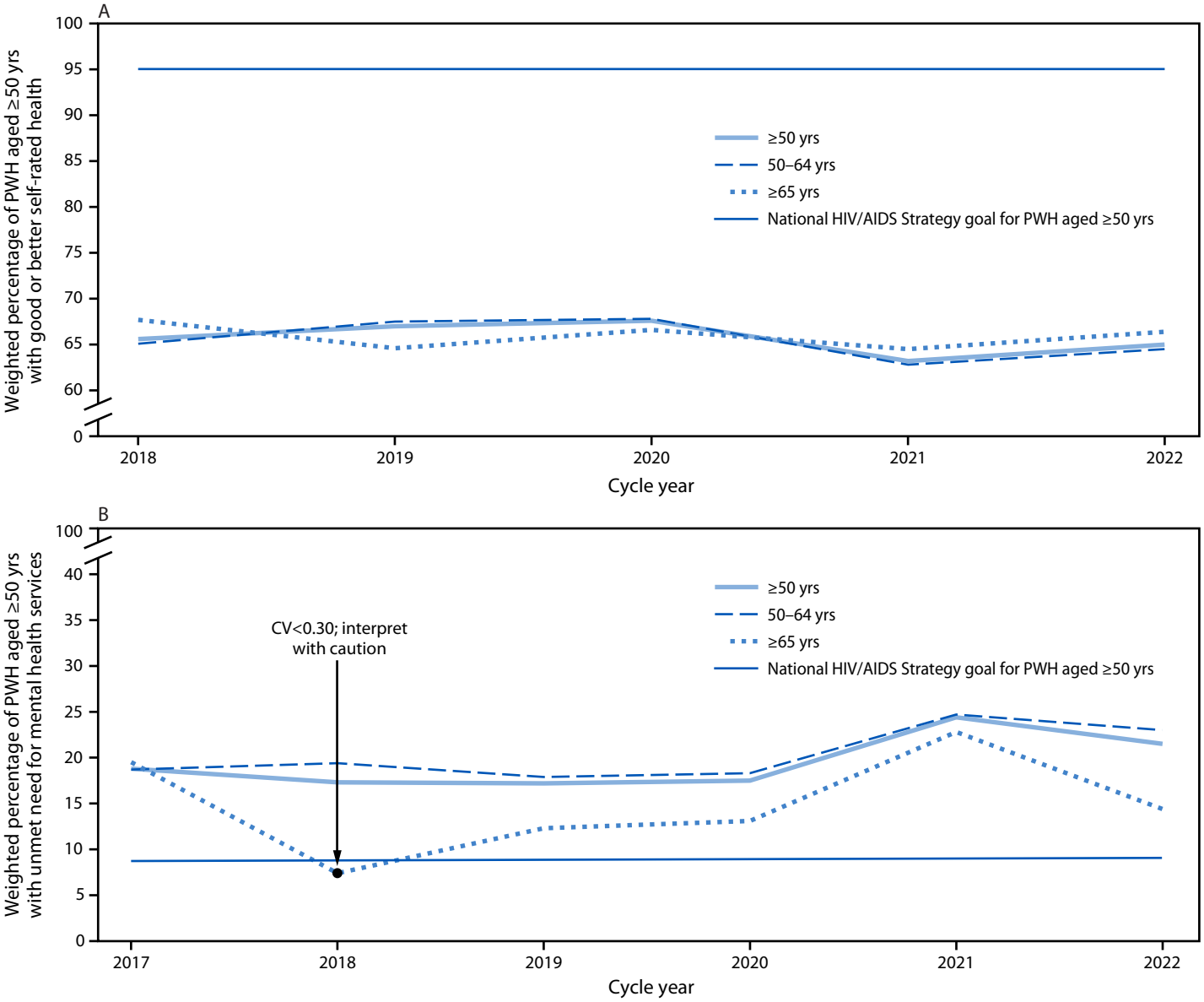
Discussion

Overall, the five QoL indicators among PWH aged ≥50 years changed little during 2017–2022. QoL estimates among PWH aged ≥65 years were more favorable for unemployment, hunger or food insecurity, and unstable housing or homelessness than among those aged 50–64 years. By 2022, the 2025 goal for decreasing hunger or food insecurity was exceeded among PWH aged ≥65 years. However, for all other indicators and age groups, the magnitude of improvement required to meet 2025 goals suggests these QoL goals will not be met if recent trends continue. The NHAS QoL indicators were adopted in late 2022, leaving <2 years to implement changes to reach 2025 goals (*5*). A federal implementation plan for achieving QoL goals is still being developed (*5*).

Evidence-based interventions exist to improve adherence to antiretroviral therapy, and thus viral suppression[§§]; however, few are tailored to older PWH, who might have specific challenges (e.g., numerous prescribed medications and social isolation).[¶¶] PWH have poorer physical and mental health than does the overall U.S. population (*7*). Structuring HIV care delivery for older PWH to encompass comprehensive management of chronic diseases and disabilities, including

[§§] https://www.cdc.gov/hiv/effective-interventions/treat/index.html
[¶¶] https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/aging-guide-new-elements.pdf (Accessed May 2024).

FIGURE 1. Trends in the weighted percentage of adults aged ≥50 years with diagnosed HIV with good or better self-rated health* (A) and unmet need for mental health services among those with any need for services† (B), compared with National HIV/AIDS Strategy 2025 goals,§ overall and stratified by age group — Medical Monitoring Project, United States, 2017–2022¶



Abbreviations: CV = coefficient of variation; PWH = persons with diagnosed HIV.

* PWH aged ≥50 years who reported their general health at the time of interview to be good, very good, or excellent as opposed to poor or fair.

† PWH aged ≥50 years who reported needing but not receiving services from a mental health professional during the previous 12 months among all PWH aged ≥50 years reporting receiving, or needing but not receiving, services from a mental health professional.

§ National HIV/AIDS Strategy 2025 goals for PWH aged ≥50 years are available online. https://files.hiv.gov/s3fs-public/2022-09/NHAS_Federal_Implementation_Plan.pdf

¶ Annual data collection cycles began June 1 of the cycle year and ran through May 30 of the following year. Collection of data on good or better self-rated health began in the 2018 cycle.

programs that support living with health challenges,*** might improve self-rated health and decrease unmet need for mental health services (*8*). Increasing routine mental health screening and integrating HIV and mental health care could decrease unmet need for these services among PWH (*9*).

Improving QoL and addressing social determinants of health requires a multisectoral approach that moves beyond clinical care. Addressing unemployment can include delivery

*** The Chronic Disease Self-Management Program (https://selfmanagementresource.com/programs/small-group/chronic-disease-self-management-small-group/), Positive Self-Management Program (https://selfmanagementresource.com/programs/small-group/hiv-positive-self-management-small-group/), or the Living Well with a Disability program (https://www.cdc.gov/mmwr/volumes/65/su/su6501a10.htm).

TABLE. Estimated annual percentage change in factors related to National HIV/AIDS Strategy quality of life indicators* among persons aged ≥50 years with diagnosed HIV, overall and stratified by age — Medical Monitoring Project, United States, 2017–2022†

Characteristic§	Age group, yrs	2017 cycle No.	2017 cycle Weighted % (95% CI)	2022 cycle No.	2022 cycle Weighted % (95% CI)	EAPC 2017 to 2022 cycles
Factors related to good or better self-rated health¶						
Sustained viral suppression	≥50	1,593	68.9 (65.4 to 72.3)	1,614	67.3 (63.4 to 71.3)	−0.5 (−0.6 to −0.5)
	50–64	1,320	67.9 (64.5 to 71.3)	1,159	66.4 (62.0 to 70.9)	−0.8 (−0.9 to −0.7)
	≥65	273	74.2 (67.7 to 80.8)	455	69.8 (64.4 to 75.2)	−0.5 (−0.6 to −0.3)
Antiretroviral dose adherence, previous 30 days	≥50	1,396	66.5 (64.1 to 68.8)	1,515	71.8 (69.3 to 74.4)	1.9 (1.8 to 2.0)
	50–64	1,139	64.4 (61.7 to 67.2)	1,053	68.9 (66.0 to 71.7)	1.7 (1.6 to 1.8)
	≥65	257	77.4 (72.6 to 82.3)	462	79.7 (75.9 to 83.5)	1.2 (1.1 to 1.4)
Self-reported disability	≥50	1,155	52.8 (49.7 to 55.8)	1,037	48.0 (45.7 to 50.3)	−2.1 (−2.2 to −2.1)
	50–64	952	51.4 (48.3 to 54.4)	743	47.9 (45.3 to 50.4)	−1.9 (−2.0 to −1.8)
	≥65	203	60.4 (54.0 to 66.8)	294	48.4 (44.1 to 52.7)	−3.8 (−4.0 to −3.6)
Emergency department visit	≥50	849	38.7 (36.2 to 41.2)	802	36.5 (34.7 to 38.4)	−2.0 (−2.1 to −1.9)
	50–64	727	39.6 (36.9 to 42.2)	597	36.7 (34.5 to 38.9)	−2.2 (−2.4 to −2.1)
	≥65	122	33.8 (28.6 to 38.9)	205	36.0 (32.4 to 39.6)	−1.1 (−1.3 to −0.9)
Hospitalization	≥50	460	21.4 (19.5 to 23.2)	400	18.2 (16.3 to 20.1)	−3.7 (−3.9 to −3.6)
	50–64	378	20.8 (18.6 to 22.9)	284	16.8 (14.7 to 18.9)	−4.8 (−4.9 to −4.6)
	≥65	82	24.7 (19.8 to 29.5)	116	22.3 (17.5 to 27.1)	−1.9 (−2.2 to −1.6)
Factors related to unmet needs for mental health services**						
Symptoms of major or other depression among those with any mental health service need	≥50	263	33.9 (29.1 to 38.7)	211	27.0 (22.4 to 31.6)	−4.2 (−4.3 to −4.0)
	50–64	237	34.4 (29.3 to 39.5)	177	27.8 (23.1 to 32.4)	−4.0 (−4.3 to −3.8)
	≥65	26	29.9 (19.5 to 40.3)	34	23.3 (15.0 to 31.7)	−3.8 (−4.3 to −3.2)
Symptoms of generalized anxiety disorder among those with any mental health service need	≥50	218	27.0 (23.2 to 30.8)	200	25.3 (20.7 to 30.0)	−0.9 (−1.1 to −0.7)
	50–64	198	27.6 (23.7 to 31.5)	170	26.7 (22.0 to 31.4)	−0.2 (−0.5 to −0.0)
	≥65	20	22.3 (13.6 to 31.0)	30	19.1 (11.2 to 27.0)	−2.6 (−3.3 to −2.0)
Factors related to unemployment††						
Some college education or higher educational attainment	≥50	1,230	55.6 (51.3 to 59.9)	1,300	60.3 (57.7 to 63.0)	2.0 (1.9 to 2.1)
	50–64	1,016	54.5 (50.5 to 58.4)	921	59.4 (56.7 to 62.1)	2.2 (2.1 to 2.3)
	≥65	214	62.1 (54.0 to 70.1)	379	63.0 (57.7 to 68.2)	0.2 (0.0 to 0.4)
Household income at or below poverty threshold	≥50	879	41.6 (36.3 to 46.8)	707	35.2 (31.0 to 39.4)	−3.8 (−3.9 to −3.7)
	50–64	758	42.4 (37.0 to 47.8)	538	36.8 (32.4 to 41.1)	−3.8 (−3.9 to −3.6)
	≥65	121	37.1 (30.3 to 43.9)	169	31.0 (25.5 to 36.5)	−2.4 (−2.6 to −2.1)
Factors related to hunger or food insecurity§§						
Unmet need for food assistance or food stamps	≥50	243	11.8 (9.9 to 13.8)	211	10.4 (8.5 to 12.3)	−2.8 (−3.0 to −2.6)
	50–64	214	12.7 (10.7 to 14.8)	180	12.3 (10.0 to 14.7)	−1.1 (−1.3 to −0.9)
	≥65	29	6.9 (3.9 to 9.9)	31	5.0 (3.1 to 6.9)	−6.9 (−7.5 to −6.4)
Unmet need for food or meal delivery	≥50	161	7.6 (6.3 to 8.8)	160	8.3 (6.2 to 10.4)	−0.4 (−0.6 to −0.2)
	50–64	138	7.9 (6.5 to 9.3)	131	9.2 (6.7 to 11.7)	0.5 (0.2 to 0.8)
	≥65	23	5.7 (3.0 to 8.3)	29	5.9 (3.3 to 8.5)	−0.6 (−1.2 to 0.1)
Factors related to housing instability or homelessness¶¶						
Unmet need for shelter or housing services	≥50	194	9.6 (8.0 to 11.2)	210	10.4 (8.4 to 12.3)	1.6 (1.4 to 1.8)
	50–64	178	10.3 (8.6 to 12.0)	178	11.7 (9.7 to 13.7)	2.6 (2.4 to 2.9)
	≥65	16	6.0 (2.8 to 9.1)	32	6.7 (3.8 to 9.5)	4.6 (3.9 to 5.3)

Abbreviation: EAPC = estimated annual percentage change.

* Includes good or better self-rated health, unmet need for mental health services, unemployment, hunger or food security, and housing stability or homelessness.

† Factors were collected in annual data collection cycles that began June 1 of the cycle year and ran through May 30 of the following year.

§ All measures self-reported and measured over the previous 12 months except where otherwise noted.

¶ Includes 1) sustained viral suppression, defined as all viral load measurements documented undetectable or <200 copies/mL as measured by medical record review; 2) antiretroviral dose adherence, defined as having taken all prescribed antiretroviral doses during the previous 30 days among persons taking antiretroviral therapy; 3) self-reported disability, defined as serious difficulties with hearing, seeing, cognition, mobility, self-care, or independent living; 4) emergency department visit, defined as any visit to an emergency department; and 5) hospitalization, defined as any inpatient hospitalization.

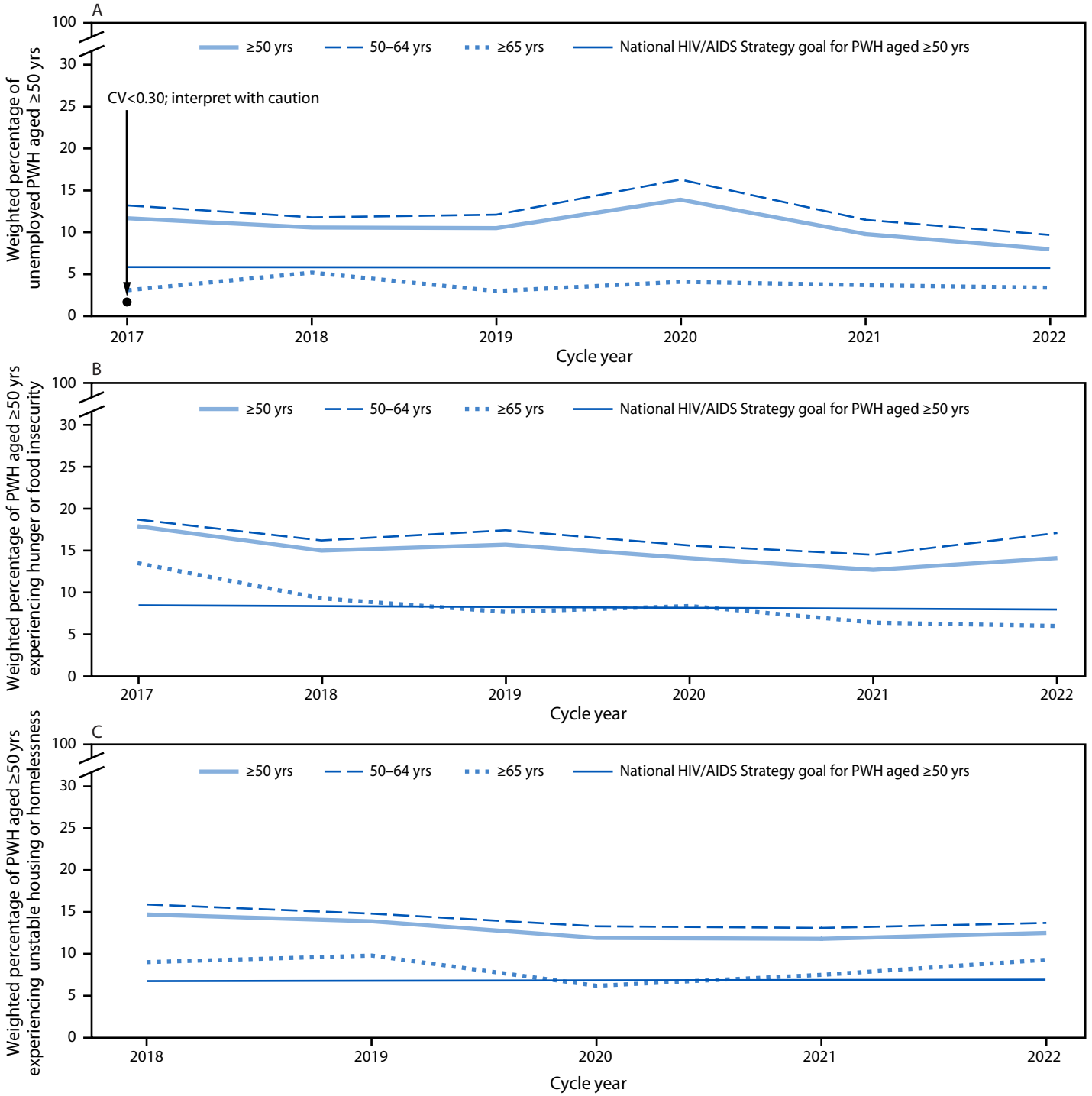
** Includes 1) symptoms of major or other depression, defined as symptoms consistent with a diagnosis of major or other depressive disorder during the previous 2 weeks as measured by the Patient Health Questionnaire-8 among those with any mental health service need and 2) symptoms of generalized anxiety disorder, defined as symptoms consistent with a diagnosis of generalized anxiety disorder during the previous 2 weeks as measured by the Generalized Anxiety Disorder-7 among those with any mental health service need.

†† Includes 1) some college education or higher educational attainment, defined as having attended college or having received a college degree and 2) household income at or below poverty threshold, defined as previous calendar year household income at or below poverty threshold according to U.S. Department of Health and Human Services poverty guidelines.

§§ Includes 1) unmet need for food assistance or food stamps, defined as needing but not receiving food assistance or food stamps and 2) unmet need for food or meal delivery, defined as needing but not receiving food or meal delivery.

¶¶ Includes unmet need for shelter or housing services, defined as needing but not receiving shelter or housing services.

FIGURE 2. Trends in the weighted percentage of adults aged ≥50 years with diagnosed HIV who experienced unemployment* (A), hunger or food insecurity† (B), and unstable housing or homelessness§ (C), compared with National HIV/AIDS Strategy 2025 goals,¶ overall and stratified by age group — Medical Monitoring Project, United States, 2017–2022**



Abbreviations: CV = coefficient of variation; PWH = persons with diagnosed HIV.

* PWH aged ≥50 years who reported being out of work at the time of interview, as opposed to being employed for wages, a homemaker, a student, retired, or unable to work.

† PWH aged ≥50 years who reported being hungry and not eating because of lack of money for food during the previous 12 months.

§ PWH aged ≥50 years who reported moving in with others because of financial issues, moving more than two times, being evicted, or living on the street, in a shelter, in a single-room–occupancy hotel, or in a car during the previous 12 months.

¶ National HIV/AIDS Strategy 2025 goals for PWH aged ≥50 years are available online. https://files.hiv.gov/s3fs-public/2022-09/NHAS_Federal_Implementation_Plan.pdf

** Annual data collection cycles began June 1 of the cycle year and ran through May 30 of the following year. Collection of data on unstable housing or homelessness began in the 2018 cycle.

Summary

What is already known about this topic?

The U.S. National HIV/AIDS Strategy set 2025 goals for improving quality of life among persons with diagnosed HIV (PWH), monitored through five indicators: self-rated health, unmet needs for mental health services, unemployment, hunger or food insecurity, and unstable housing or homelessness. Among the growing population of PWH aged ≥50 years, progress toward these goals has not been assessed.

What is added by this report?

By 2022, no 2025 goal was met for PWH aged ≥50 years. If recent trends continue, goals are unlikely to be met. Although no goal was met for PWH aged ≥50 years overall, the goal for reducing hunger or food insecurity was met for those aged ≥65 years.

What are the implications for public health practice?

Multisectoral strategies to improve access to housing, employment, food, and mental health could improve quality of life among PWH aged ≥50 years.

of skill-building and job-seeking services tailored to older PWH,[†††] who might face barriers to employment because of age-related disability and discrimination, as well as family caregiving responsibilities. COVID-19–related food and housing challenges resulting from increases in unemployment related to the COVID-19 pandemic, and assistance programs instituted to counteract these challenges, might have affected observed trends.[§§§] Reductions in unmet need for food assistance might have contributed to meeting the NHAS goal for hunger or food insecurity among PWH aged ≥65 years. Addressing housing insecurity among older PWH might require additional efforts, such as ensuring that federal housing resources are allocated according to need (*10*).

Limitations

These findings are subject to at least two limitations. First, measurement error might result from recall or social desirability biases, although any biases should not affect assessment of trends if they are constant over time. Second, EAPC is a measure of relative change, so its magnitude is affected by the prevalence of the variable assessed.

Implications for Public Health Practice

CDC will continue to monitor QoL among PWH to identify areas for intervention. This information can be used to direct multisectoral implementation of programmatic efforts and guide future goals for improving health and well-being among older PWH. CDC-funded HIV prevention and care partners provide linkage to behavioral health and subsistence service providers. The Capacity Building Assistance Program[¶¶¶] offers technical assistance for addressing social determinants of health, which are closely linked to the NHAS 2025 QoL goals.

[†††] https://www.dol.gov/agencies/odep/program-areas/hiv-aids

[§§§] For example, although hunger and housing instability might have increased because of pandemic-related job losses and economic impacts, measures like the increase in Supplemental Nutrition Assistance Program benefits, federal eviction moratorium, and authorization for Ryan White HIV/AIDS Program–funded recipients to use Coronavirus Aid, Relief, and Economic Security Act and Emergency Financial Assistance funds to mitigate pandemic-related problems among PWH might have alleviated these increased needs.

[¶¶¶] https://www.cdc.gov/hiv/capacity-building-assistance/index.html

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Progress Toward Poliomyelitis Eradication — Pakistan, January 2023–June 2024

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Abstract

Since its launch in 1988, the Global Polio Eradication Initiative has made substantial progress toward the eradication of wild poliovirus (WPV), including eradicating two of the three serotypes, and reducing the countries with ongoing endemic transmission of WPV type 1 (WPV1) to just Afghanistan and Pakistan. Both countries are considered a single epidemiologic block. Despite the occurrence of only a single confirmed WPV1 case during the first half of 2023, Pakistan experienced widespread circulation of WPV1 over the subsequent 12 months, specifically in the historical reservoirs of the cities of Karachi, Peshawar, and Quetta. As of June 30, 2024, eight WPV1 cases had been reported in Pakistan in 2024, compared with six reported during all of 2023. These cases, along with more than 300 WPV1-positive environmental surveillance (sewage) samples reported during 2023–2024, indicate that Pakistan is not on track to interrupt WPV1 transmission. The country's complex sociopolitical and security environment continues to pose formidable challenges to poliovirus elimination. To interrupt WPV1 transmission, sustained political commitment to polio eradication, including increased accountability at all levels, would be vital for the polio program. Efforts to systematically track and vaccinate children who are continually missed during polio vaccination activities should be enhanced by better addressing operational issues and the underlying reasons for community resistance to vaccination and vaccine hesitancy.

Introduction

Although the Global Polio Eradication Initiative (GPEI) has achieved substantial progress since its establishment in 1988, the goal of polio eradication has remained elusive. Indigenous wild poliovirus type 1 (WPV1) circulation has never been interrupted in Pakistan, and endemic circulation also continues in Afghanistan (*1*,*2*). Both countries constitute a single epidemiologic block because of substantial cross-border population movements along their respective northern and southern borders (*3*). The 2022–2026 GPEI Strategic Plan targeted ending all transmission in 2023 (*4*); however, WPV1 transmission in both countries has continued into 2024. This report describes Pakistan's progress toward eliminating indigenous WPV1 transmission during January 2023–June 2024 (*5*,*6*).

Methods

Data Sources

Poliovirus surveillance data and vaccination information (campaign reports and routine immunization coverage surveys) as of June 2024 were provided by the Pakistan National Emergency Operations Centre and other GPEI partners, including UNICEF and the World Health Organization (WHO). Weekly poliovirus country and regional surveillance reports, including environmental surveillance data, were also reviewed.

Analysis

Genomic sequencing and analyses from the Pakistan National Institute of Health poliovirus laboratory determined the genetic relationship among polioviruses identified in specimens collected from patients with WPV1 infection and from environmental sewage samples. This activity was reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy.*

Results

Immunization Activities

Routine immunization. WHO and UNICEF estimated Pakistan's national coverage with 3 doses of oral poliovirus vaccine† (OPV) and 1 dose of inactivated poliovirus vaccine (IPV) (containing polio vaccine virus types 1, 2, and 3), by age 12 months at 86% for each vaccine during 2023; Pakistan introduced a second IPV dose in 2021, and 2-dose IPV coverage was estimated at 84% (*7*). A 2021 third-party survey sponsored by Gavi, the Vaccine Alliance (https://www.gavi.org), indicated that the proportion of children aged 12–23 months who had received 3 routine immunization OPV doses ranged by province from 45.1% in Balochistan to 94.9% in Punjab. None of the districts in the provinces of Balochistan, Khyber Pakhtunkhwa, and Sindh achieved ≥80% 3-dose routine immunization OPV coverage, compared with 31 (86%) of 36 districts in Punjab province.

* 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

† After the 2016 global synchronized withdrawal of type 2 vaccine viruses, bivalent OPV (bOPV, containing vaccine virus types 1 and 3) has been recommended in all OPV-using countries; however, other OPV formulations, including monovalent OPV (mOPV, containing type 2 vaccine virus) are used in certain situations, including response activities. Estimates of OPV coverage are made using a variety of methods and can include different vaccine formulations.

Supplementary immunization activities. Since the synchronized withdrawal of trivalent OPV (tOPV; containing Sabin-strain types 1, 2, and 3) by all OPV-using countries in 2016 after the eradication of wild poliovirus (WPV) type 2 (*8*), polio supplementary immunization activities (SIAs)[§] in Pakistan have primarily been conducted using bivalent OPV (bOPV; containing Sabin-strain types 1 and 3). During 2023, three national immunization day (NID) and seven subnational immunization day (SNID) campaigns were conducted using bOPV. NIDs in Pakistan target 45 million children aged <5 years, whereas SNIDs target smaller populations, depending on the areas identified by ongoing risk assessments. Fractional-dose IPV[¶] was administered during vaccination activities conducted in six districts of south Khyber Pakhtunkhwa in June 2023, in Khyber and Peshawar districts of Khyber Pakhtunkhwa in August 2023, and in Chaman and Killa Abdullah districts of Balochistan province in October 2023.

To date in 2024, two NIDs (January and February) and two SNIDs (April and June) as well as an outbreak response campaign in March have been conducted in Pakistan. In the seven districts of south Khyber Pakhtunkhwa, an area facing considerable security challenges, as many as 706,613 eligible children aged <5 years were not vaccinated during the January 2024 NID, because SIAs could not be safely carried out in those areas. In Dera Ismail Khan, the district with the largest number of eligible children (372,726 children aged <5 years), campaigns could not be conducted during three of the four November 2023–April 2024 SIAs. The program continues to be hampered by repeated community boycotts during SIAs for reasons mostly unrelated to vaccination, such as requests for clean water and electricity services that are selectively provided by the government. Safety remains an ongoing concern for frontline polio program workers in several priority areas.

Lot quality assurance sampling (LQAS)[**] surveys, which assess SIA quality, continue to indicate substantial gaps in vaccination campaign quality. Based on a 90% pass threshold and surveyed using finger-marking (the marking of a child's fingernail with indelible ink by vaccinators as a program indicator of having recently received OPV), the proportion of subdistrict union councils reaching the threshold ranged from 82% in Balochistan province to 89% in Punjab province for the June 2024 SNIDs; however, at the district level, pass rates were as low as 25% in Loralai district and 37.5% in Killa Abdullah district, both in Balochistan province. A total of 599,105 children (3.3% of the target population) were missed during the June 2024 SNIDs, including 51,199 refusals.

Poliovirus Surveillance

Acute flaccid paralysis surveillance. A reported nonpolio acute flaccid paralysis (NPAFP)[††] rate of ≥2 cases per 100,000 children aged <15 years is the WHO benchmark for surveillance sufficiently sensitive to detect an occurrent case of poliomyelitis. Pakistan reported a national NPAFP rate of 20.2 cases per 100,000 persons aged <15 years in 2023 (Table); provincial rates ranged from 11.6 to 33.1, exceeding the recommended benchmark. As of June 9, 2024, the annualized 2024 national NPAFP rate is 17.4. Stool specimen adequacy[§§] during 2023 and 2024 exceeded the ≥80% target nationally and in each province, except in Islamabad in 2023 (76.9%). District-level performance indicators continue to indicate gaps in surveillance quality, especially in program priority areas.

Environmental surveillance. A network of 124 environmental surveillance (ES) (the systematic sampling and testing of sewage for the presence of poliovirus) collection sites in Pakistan serves to supplement poliovirus surveillance. Sewage samples collected monthly at these sites are tested for polioviruses and other enteroviruses. During 2023, among 2,563 sewage samples tested, 126 (5%) were positive for WPV1, compared with 37 (3%) of 1,325 in 2022. To date in 2024, among 942 tested sewage samples, 203 (22%) have tested positive for WPV1. As of June 30, 2024, ES samples positive for WPV1 had been identified in Sindh (mostly in Karachi), Balochistan, Islamabad, Khyber Pakhtunkhwa, and Punjab, indicating widespread circulation of the virus in the country. Approximately 60% of all WPV1-positive ES isolates were reported from the traditional polio reservoirs in the cities of Karachi, Peshawar, and Quetta.

Epidemiology of poliovirus cases. Six WPV1 cases were reported in Pakistan in 2023, compared with 20 cases in 2022, one in 2021, and 84 in 2020 (*5*,*9*) (Figure 1) (Figure 2). As of June 30, 2024, eight WPV1 cases had been reported in 2024, compared with a single case reported during the same period in 2023. Among the six WPV1 cases reported in 2023, three

[§] SIAs are mass house-to-house vaccination campaigns targeting children aged <5 years with OPV, regardless of the child's vaccination history.

[¶] Fractional-dose inactivated poliovirus vaccine administration is a dose-sparing vaccination strategy that provides intradermal administration of one fifth the full intramuscular IPV dose.

[**] LQAS uses a small sample size to assess the quality of vaccination activities after SIAs in union councils (referred to as "lots"). LQAS surveys seek evidence of vaccination (finger marking) by randomly selecting 60 children within each lot. If the number of unvaccinated persons in the sample exceeds three, then the union council SIA is classified as having failed at a pass threshold of ≥90%, and additional vaccination activities in those areas are recommended. If the threshold of ≥90% (three or fewer unvaccinated children) is met, the union council SIA is classified as having passed.

[††] AFP cases that are discarded as not having laboratory or other proof of poliovirus as the cause are called nonpolio AFP cases.

[§§] Stool specimens are considered adequate if two specimens are collected ≥24 hours apart within 14 days of paralysis onset and arrive at a WHO-accredited laboratory with reverse cold chain storage maintained and without leakage or desiccation. The standard WHO stool specimen indicator target is adequate stool specimen collection from ≥80% of AFP cases.

were from Bannu district, Khyber Pakhtunkhwa province, two from Karachi East district, Sindh province, and one from Orakzai district, Khyber Pakhtunkhwa province. Among the eight cases reported to date in 2024, six have been reported from Balochistan province and two from Sindh province. Among the 14 WPV1 cases identified during January 2023–June 2024, patients ranged in age from 9 months to 144 months (median = 30 months); seven patients had never received OPV through routine immunization, two had received 1–2 doses, while the remaining five had received 3 routine immunization OPV doses. No circulating vaccine-derived poliovirus type 2 (cVDPV2)[¶¶] cases have been reported in Pakistan since April 23, 2021, when the last of 165 cVDPV2 cases that occurred during July 2019–April 2021 was reported (Table) (Figure 1) (Figure 2).

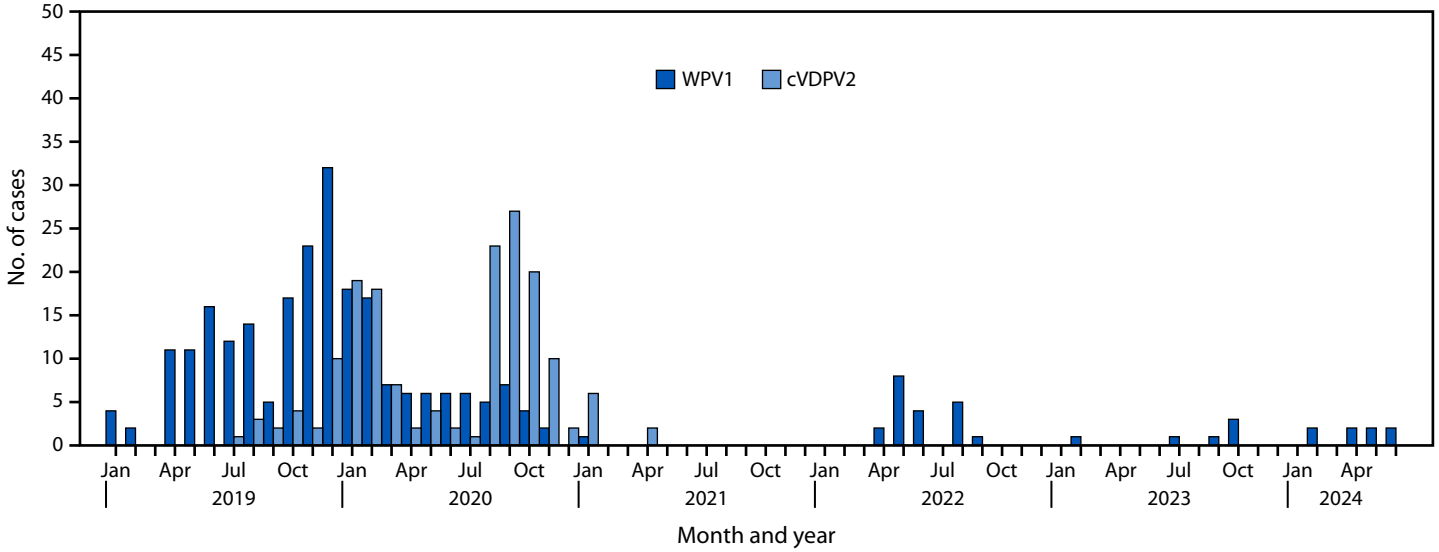
[¶¶] cVDPVs emerge as the result of regaining of neurovirulence of attenuated OPV viruses after prolonged circulation in underimmunized populations; cVDPVs can lead to paralysis.

TABLE. Acute flaccid paralysis surveillance indicators and number of wild poliovirus cases reported, by province and period — Pakistan, January 2023–June 2024

Metric	Reporting period	Region							
		Azad Jammu and Kashmir	Gilgit-Baltistan	Islamabad	Khyber Pakhtunkhwa	Punjab	Balochistan	Sindh	Total
AFP surveillance indicators									
No. of AFP cases	2023	585 (25.9)	172 (21.1)	251 (33.1)	4,934 (24.0)	9,288 (19.8)	759 (11.6)	3,782 (16.5)	**19,771 (20.2)**
(NP AFP rate)*	2024[†]	225 (22.6)	72 (20.0)	90 (26.9)	1,856 (20.4)	3,319 (16.1)	324 (11.1)	1,622 (16.1)	**7,508 (17.4)**
% with adequate	2023	89.2	89	76.9	81.9	84.5	87.1	83.8	**84.1**
stool specimens[§]	2024	93.3	84.7	82.2	87.2	85.3	87.7	88.8	**86.8**
No. of reported poliovirus cases									
WPV1 cases	Jan–Jun 2023	0	0	0	1	0	0	0	**1**
	Jul–Dec 2023	0	0	0	3	0	0	2	**5**
	Jan–Jun 2024	0	0	0	0	0	6	2	**8**
	Total	**0**	**0**	**0**	**4**	**0**	**6**	**4**	**14**
cVDPV2 cases	Jan–Jun 2022	0	0	0	0	0	0	0	**0**
	Jul–Dec 2022	0	0	0	0	0	0	0	**0**
	Jan–Jun 2023	0	0	0	0	0	0	0	**0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

Abbreviations: AFP = acute flaccid paralysis; cVDPV2 = circulating vaccine-derived poliovirus type 2; NP = nonpolio; WHO = World Health Organization; WPV1 = wild poliovirus type 1.
* NP AFP cases per 100,000 persons aged <15 years.
[†] Annualized.
[§] Defined as two stool specimens collected ≥24 hours apart within 14 days of paralysis onset and arriving at a WHO-accredited laboratory with reverse cold chain storage maintained and without leakage or desiccation.

FIGURE 1. Reported cases of wild poliovirus type 1 and circulating vaccine-derived poliovirus type 2, by month — Pakistan, January 2019–June 2024



Abbreviations: cVDPV2 = circulating vaccine-derived poliovirus type 2; WPV1 = wild poliovirus type 1.

Genomic sequence analysis of WPV1 isolates: Analysis of the region coding the VP1 capsid protein of WPVs is used to classify them into genetic clusters (i.e., those that share ≥95% sequence identity). Among the six WPV1 cases and 126 WPV1-positive ES isolates reported in 2023, nine belonged to groups of viruses derived from the YB3C cluster, endemic to Pakistan; the other 123 belonged to groups of viruses derived from the YB3A cluster, cocirculating in eastern Afghanistan. Among the eight WPV1 cases reported to date in 2024, six belonged to the YB3A4A cluster, and two belonged to the YB3A4B cluster. In addition, six orphan viruses (>1.5% VP1 nucleotide divergence, indicating gaps in AFP surveillance) were identified during the preceding 12 months.

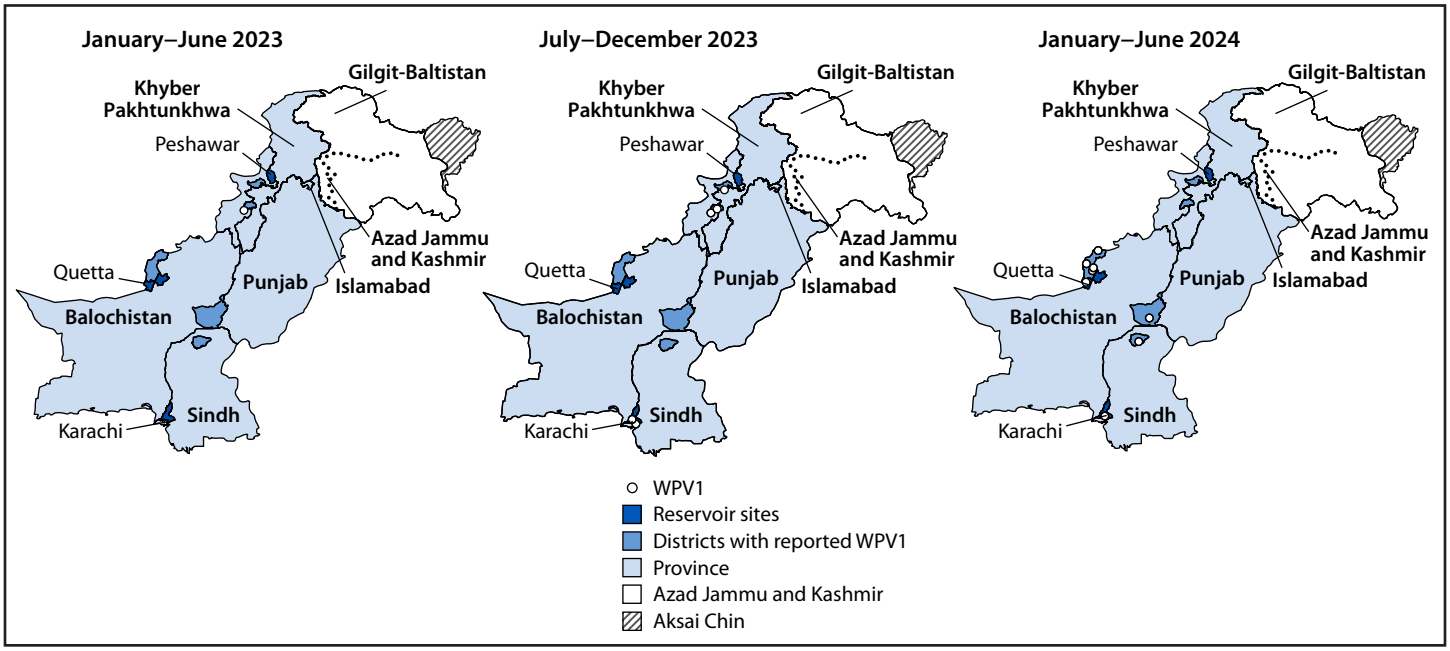
Discussion

Compared with the previous reporting period (January 2022–June 2023), more extensive WPV1 transmission has been evident in Pakistan, beginning in the second half of 2023 through the first half of 2024. The number of reported WPV1 cases rose from a single case in the first half of 2023 to five additional cases during the second half of the year. Eight WPV1 cases had been reported as of June 2024, with cases appearing in historical polio reservoirs in Balochistan and Sindh provinces. This has occurred despite considerable progress in the security-compromised south Khyber Pakhtunkhwa region, which has not reported a WPV1 case in 2024, and the absence of viruses derived from the YB3C genetic cluster of WPV1 from circulation since November 2023. Concomitantly, the proportion of ES samples testing positive for WPV1 has increased from 5% in 2023 to 22% as of June 2024.

The increase in WPV1-positive ES isolates in 2023 and 2024 has been marked by widespread virus transmission in the core polio reservoirs (Karachi, Peshawar, and Quetta blocks) and central Pakistan, even though case counts have remained relatively low. Reasons for this likely include substantial gaps in the quality of surveillance at the district and subdistrict levels, despite AFP surveillance performance indicators remaining high nationally and provincially. The Pakistan polio program continues to work to ameliorate these gaps through regular reviews of its surveillance sites. More attention needs to be placed on ensuring that the proportion of stool specimens collected from persons with AFP meets the 80% benchmark for adequacy to increase the likelihood of isolating WPV1 from AFP cases.

Routine immunization coverage with OPV and IPV has improved in recent years. IPV protects against paralysis; however, because it is an inactivated vaccine that does not replicate in the intestinal tract as does OPV, it does not prevent the spread of poliovirus. This could partly explain the relatively low number of WPV1 cases reported in the context of widespread WPV1 circulation as evidenced by environmental surveillance. However, one half of all WPV1 patients had never received OPV through routine immunization, indicating population immunity gaps. Assessments of SIAs also continue to indicate deficiencies in campaign quality for operational reasons in some areas, necessitating a redoubling of efforts to systematically

FIGURE 2. Location of wild poliovirus type 1 cases, by province and period — Pakistan, January 2023–June 2024



Abbreviation: WPV1 = wild polio virus type 1.

Summary

What is already known about this topic?

Wild poliovirus type 1 (WPV1), the only circulating wild poliovirus serotype, remains endemic in only two countries, Afghanistan and Pakistan, which share borders and are considered a single epidemiologic block.

What is added by this report?

During January 2023–June 2024, 14 WPV1 cases were reported in Pakistan, compared with 21 WPV1 cases during January 2022–June 2023. However, widespread transmission of poliovirus reemerged in the historical polio reservoirs of Karachi, Peshawar, and Quetta, as evidenced by a spike in sewage samples testing positive for WPV1.

What are the implications for public health practice?

Addressing community demands for essential services along with redoubling efforts to track and vaccinate children who are repeatedly missed during polio vaccination activities will help to bring the goal of WPV1 elimination within reach for the Pakistan polio program.

track and vaccinate children who are repeatedly missed during polio SIAs. Although overall community acceptance of vaccination remains high, critical challenges exist in core reservoirs that require enhanced community engagement. Whenever feasible, vaccination activities need to be synchronized with those of neighboring Afghanistan.

Limitations

The findings in this report are subject to at least two limitations. First, caregiver recall might distort reported vaccination histories during AFP case investigations. Second, even when a given child's finger is marked as evidence of vaccination during SIAs, it might not accurately reflect the actual vaccination status of the child, because finger-marking sometimes occurs even when a child has not received the vaccine dose.

Implications for Public Health Practice

Pakistan's frontline workers continue to imperil their safety under challenging conditions to eliminate polio from the country. Although transmission is unlikely to be interrupted by the end of 2024, Pakistan maintains a strong political commitment to achieving the goal in the near future (*10*). Addressing community demands for essential services, such as clean water and electricity, could help improve community participation in vaccination activities. This, along with concerted efforts to track and vaccinate repeatedly missed children, will help to bring the goal of eradication within reach for Pakistan and the GPEI.

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Use of 21-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2024

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Abstract

On June 17, 2024, the Food and Drug Administration approved 21-valent pneumococcal conjugate vaccine (PCV) (PCV21; CAPVAXIVE; Merck Sharp & Dohme, LLC) for adults aged ≥18 years. PCV21 does not contain certain serotypes that are included in other licensed pneumococcal vaccines but adds eight new serotypes. The Advisory Committee on Immunization Practices (ACIP) recommends use of a PCV for all adults aged ≥65 years, as well as adults aged 19–64 years with certain risk conditions for pneumococcal disease if they have not received a PCV or whose vaccination history is unknown. Previously, options included either 20-valent PCV (PCV20; Prevnar20; Wyeth Pharmaceuticals, Inc.) alone or a 15-valent PCV (PCV15; VAXNEUVANCE; Merck Sharp & Dohme, LLC) in series with 23-valent pneumococcal polysaccharide vaccine (PPSV23; Pneumovax23; Merck Sharp & Dohme, LLC). Additional recommendations for use of PCV20 exist for adults who started their pneumococcal vaccination series with 13-valent PCV (PCV13; Prevnar13; Wyeth Pharmaceuticals, Inc.). The ACIP Pneumococcal Vaccines Work Group employed the Evidence to Recommendations framework to guide its deliberations on PCV21 vaccination among U.S. adults. On June 27, 2024, ACIP recommended a single dose of PCV21 as an option for adults aged ≥19 years for whom PCV is currently recommended. Indications for PCV have not changed from previous recommendations. This report summarizes evidence considered for these recommendations and provides clinical guidance for use of PCV21.

Introduction

Streptococcus pneumoniae (pneumococcus) is a common bacterial cause of respiratory tract infections, bacteremia, and meningitis. Invasive pneumococcal disease (IPD), a pneumococcal infection in a normally sterile site (e.g., blood, cerebrospinal fluid, bone, or joint space), can result in severe morbidity or mortality. Adults with certain underlying conditions or risk factors that increase the risk for pneumococcal disease (risk conditions)* and those aged ≥65 years are at increased risk and have experienced IPD case fatality ratios exceeding 10% (*1*).

The Advisory Committee on Immunization Practices (ACIP) recommends receipt of a pneumococcal conjugate vaccine (PCV) by all adults aged ≥65 years as well as those aged 19–64 years with a risk condition who have not received PCV or whose vaccination history is unknown. Options include either 20-valent PCV (PCV20; Prevnar20; Wyeth Pharmaceuticals, Inc.) alone or 15-valent PCV (PCV15; VAXNEUVANCE; Merck Sharp & Dohme, LLC) followed by 23-valent pneumococcal polysaccharide vaccine (PPSV23; Pneumovax23, Merck Sharp & Dohme, LLC). Additional recommendations for use of PCV20 exist for adults who commenced their pneumococcal vaccination series with 13-valent PCV (PCV13; Prevnar13, Wyeth Pharmaceuticals, Inc.) (*2*).

On June 17, 2024, the Food and Drug Administration licensed 21-valent PCV (PCV21; CAPVAXIVE; Merck Sharp & Dohme, LLC) for use in persons aged ≥18 years (*3*). PCV21 does not contain certain serotypes in other licensed vaccines but adds eight new serotypes (Figure). This report summarizes the evidence considered by ACIP regarding the use of PCV21 for adults, highlighting considerations of immunogenicity, safety, and resource use.

Methods

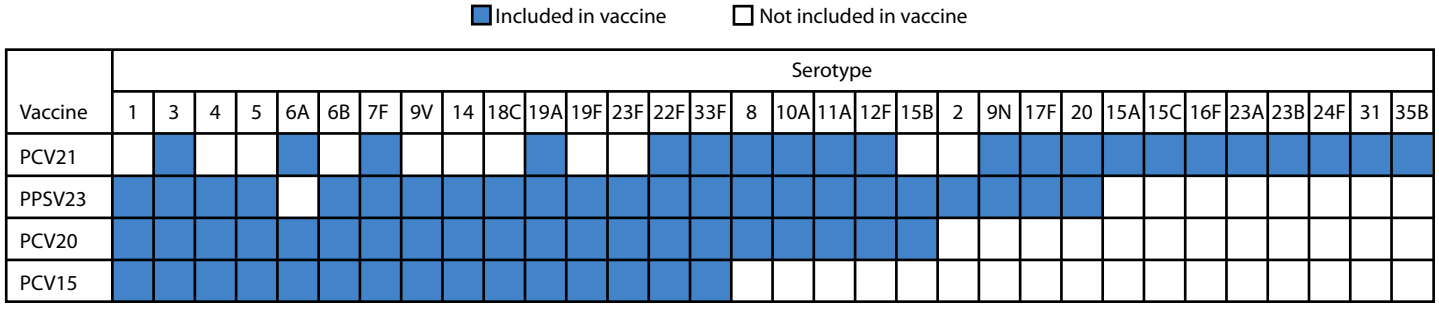
During November 2023–June 2024, the ACIP Pneumococcal Vaccines Work Group evaluated the quality of evidence for PCV21 immunogenicity and safety using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.† Within the Evidence to Recommendations (EtR) framework,§ ACIP considered the importance of the public health problem, benefits and harms, values and preferences of the target populations, resource use, equity, acceptability, and feasibility for PCV21 use among adults aged ≥19 years.

* Alcoholism; cerebrospinal fluid leak; chronic heart, liver, or lung disease; chronic renal failure; cigarette smoking; cochlear implant; congenital or acquired asplenia; diabetes mellitus; generalized malignancy; HIV; Hodgkin disease; immunodeficiency; iatrogenic immunosuppression; leukemia, lymphoma, or multiple myeloma; nephrotic syndrome; solid organ transplant; or sickle cell disease or other hemoglobinopathies.

† https://www.cdc.gov/vaccines/acip/recs/grade/PCV21-non-risk-based-adults-19-49.html; https://www.cdc.gov/vaccines/acip/recs/grade/PCV21-non-risk-based-adults-50-64.html; https://www.cdc.gov/vaccines/acip/recs/grade/PCV21-adults-19-and-older.html

§ https://www.cdc.gov/vaccines/acip/recs/grade/PCV21-non-risk-based-adults-19-49-etr.html; https://www.cdc.gov/vaccines/acip/recs/grade/PCV21-non-risk-based-adults-50-64-etr.html; https://www.cdc.gov/vaccines/acip/recs/grade/PCV21-adults-19-and-older-etr.html

FIGURE. Serotypes*,† included in pneumococcal vaccines currently recommended for adults — United States, 2024



Abbreviations: PCV = pneumococcal conjugate vaccine; PCV15 = 15-valent PCV; PCV20 = 20-valent PCV; PCV21 = 21-valent PCV; PPSV23 = 23-valent pneumococcal polysaccharide vaccine.

* PCV21 is approved for the prevention of invasive pneumococcal disease caused by serotype 15B based upon prespecified criteria for the proportion of participants with fourfold or more rise in OPA responses. https://www.fda.gov/media/179426/download?attachment

† PCV21 contains serotype 20A.

Rationale and Evidence

Pneumococcal Disease Incidence in Adults Aged ≥19 Years

Before the COVID-19 pandemic, approximately 100,000 noninvasive pneumococcal pneumonia hospitalizations and 30,000 IPD cases occurred annually among U.S. adults (*4*). During 2018–2022, pneumococcal serotypes contained in PCV21 caused approximately 80% of IPD cases among adults with indications for vaccination, including 20%–30% due to the eight new serotypes contained in PCV21 (Supplementary Figure, https://stacks.cdc.gov/view/cdc/160379). Serotype 4, a serotype contained in other licensed pneumococcal vaccines currently in use (PCV15, PCV20, and PPSV23), is not included in PCV21 (Figure). After introduction of the 7-valent PCV in children, serotype 4 IPD significantly declined, but has recently reemerged as a cause of IPD in certain regions, particularly the western United States, namely Alaska (*5*), the Navajo Nation (*6*), Colorado, New Mexico, and Oregon (CDC Active Bacterial Core surveillance, unpublished data, 2022). Affected persons at risk for serotype 4 IPD are typically adults aged <65 years with a risk condition, with history of substance abuse, or who are experiencing homelessness.

Incidence of pneumococcal disease is disproportionately higher in Black or African American (Black) adults than in non-Black adults, resulting in high U.S. societal costs (*4*,*7*,*8*). The introduction of PCV13 among U.S. children reduced disparities that existed in PCV13-type IPD incidence in adults, likely because of indirect effects from PCV13 vaccination in children; remaining racial disparities are primarily due to disease caused by non-PCV13 serotypes[¶] (*9*).

[¶] Pneumococcal serotypes 22F, 33F, 8, 10A, 11A, 12F, 9N, 17F, 20, 15A, 15C, 16F, 23A, 23B, 24F, 31 and 35B are non-PCV13 serotypes contained in PCV21.

PCV21 Immunogenicity

Findings from one phase II (*10*) and three phase III (*11*–*13*) randomized controlled trials (RCTs) compared the immunogenicity of PCV21 (as measured by opsonophagocytic activity[**] [OPA] geometric mean titers [GMT] and percentage of seroresponders[††]) to that of comparator vaccines (PCV15, PCV20, or PPSV23). One study assessed the safety and immunogenicity of PCV21 with concomitant or sequential administration of the quadrivalent influenza vaccine (QIV) (*13*).

Among immunocompetent, pneumococcal vaccine–naive adults aged ≥50 years, PCV21 met noninferiority criteria for serotypes shared with comparator vaccines (PPSV23 and PCV20) (*10*,*13*). PCV21 elicited statistically significantly higher immune responses for most serotypes unique to PCV21, with the exception of serotype 15C, although the immune response was numerically higher when compared with PCV20 (*13*).

Among immunocompetent adults aged ≥50 years who had previously received a pneumococcal vaccine (PCV13 or PPSV23) ≥1 year before enrollment, PCV21 demonstrated comparable immunogenicity for shared serotypes and was immunogenic for unique serotypes compared with PPSV23 or PCV15; among adults who had previously received PPSV23 followed by or preceded by PCV13, PPSV23 preceded by PCV15, or PCV15 alone, PCV21 was immunogenic for all serotypes (*11*). Among adults aged ≥18 years living with HIV, comparison of recipients of PCV15 followed by PPSV23 8 weeks later with recipients of PCV21 followed by placebo 8 weeks later showed comparable immunogenicity for shared serotypes and was immunogenic for unique serotypes (*12*).

** Opsonophagocytosis refers to engulfment of bacteria that have been coated with immunoglobulin G antibodies by phagocytic cells (e.g., macrophages or neutrophils).

†† Defined as proportion of participants with a fourfold or more rise in serotype-specific OPA responses.

Among immunocompetent adults aged ≥50 years who received PCV21 and QIV concomitantly or sequentially (*14*), coadministration of PCV21 and QIV resulted in numerically lower pneumococcal and influenza antibody titers compared with sequential administration. Coadministration of PCV21 and QIV met noninferiority criteria for immunogenicity[§§] for all except pneumococcal serotype 23B and influenza strain A/H3N2.

PCV21 Safety

Safety data from four PCV21 phase III clinical trials (*11*,*13*–*15*) were pooled for the following participants: pneumococcal vaccine–naive adults aged 18–49 years (*13*,*15*), pneumococcal vaccine–naive adults aged ≥50 years (*13*,*14*), and pneumococcal vaccine–experienced adults aged ≥50 years (*11*,*14*). Safety of PCV21 among 4,020 recipients was compared with that among 2,018 recipients of the comparator vaccine (PCV15, PCV20, or PPSV23). The proportion of participants who experienced at least one solicited adverse event was comparable among PCV21 (63.3%) and comparator vaccine (63.9%) recipients. Injection site pain was the most common solicited injection site event (55.6% among all PCV21 versus 54.5% among control vaccine recipients). Among solicited systemic adverse events, the following were more common among all PCV21 recipients than among comparator vaccine recipients: fatigue (27.1% versus 23.7%), headache (18.4% versus 15.5%), and myalgia (11.3% versus 7.5%). Most solicited adverse events were mild (Grade 1) or moderate (Grade 2). Four (0.1%) potentially life-threatening (Grade 4) solicited adverse events were reported (three in PCV21 group and one in the control group). All were fever (≥104.°F [40°C]), which resolved.[¶¶]

Across one phase II clinical trial (*10*) and five phase III clinical trials (*11*–*15*), serious adverse events[***] were observed in 74 (1.5%) of 4,963 PCV21 recipients and 49 (2.0%) of 2,472 comparator vaccine recipients through 6 months postvaccination.[†††] Two serious adverse events, bronchospasm (*14*) and injection site cellulitis (*11*), were deemed to be vaccine-related in the PCV21 recipients; both resolved.

[§§] Defined as two-sided 95% CI of the pneumococcal serotype-specific OPA GMT ratio (concomitant group/sequential group) to be >0.50 and influenza strain-specific hemagglutination assay GMT ratio (concomitant group/sequential group) to be >0.67.

[¶¶] No occurrences of Guillain-Barré syndrome were observed.

[***] Defined as any untoward medical consequence that results in death, is life-threatening, requires inpatient hospitalization or prolongs existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect, or is another important medical event.

[†††] PCV21 recipient group includes participants who received PCV21 and concomitant influenza vaccine, and participants who received influenza vaccine followed by PCV21.

Economic Analysis

Three economic models (Tulane-CDC, Merck, and Pittsburgh models) (*16*) assessed the cost-effectiveness of using PCV21 in adults who are currently recommended to receive PCV,[§§§] adults aged 50–64 years, and adults aged 19–49 years. For each model, the primary health outcome used to assess cost-effectiveness was the quality-adjusted life-year (QALY).

Across the three models, base case estimates[¶¶¶] of using PCV21 instead of PCV20 for adults who are currently recommended to receive a PCV ranged from being cost-saving[****] to having a cost of $58,000 per QALY gained. In the Tulane-CDC model, replacing PCV20 with PCV21 in adults who currently have a risk-based vaccine indication resulted in fewer QALYs gained when the proportion of serotype 4 disease among all pneumococcal disease cases was ≥35% (*17*). Base case estimates of using PCV21 in adults aged 50–64 years ranged from $3,000 to $270,000 per QALY gained. Economic models that assessed cost-effectiveness of using PCV21 among adults aged 19–49 years were the least economically favorable among the three groups considered (*16*,*17*).

Recommendations for Use of PCV21

ACIP recommended PCV21 as an option for adults aged ≥19 years who are currently recommended to receive a dose of PCV. Indications for PCV have not changed since they were previously published (Table) (*2*).

Selection of PCV in Populations with High Proportions of Serotype 4 Pneumococcal Disease

In certain populations in which ≥30% of pneumococcal disease is due to serotype 4, previously recommended pneumococcal vaccines that include serotype 4 (PCV20 alone or PCV15 and PPSV23 in series) are expected to provide broader serotype coverage against locally circulating strains than does PCV21 (Box).

Coadministration with Other Vaccines

In accordance with ACIP's General Best Practice Guidelines for Immunization, routine administration of a pneumococcal vaccine with other age-appropriate doses of vaccines at the same visit is recommended for adults who have no specific contraindications to vaccination at the time of the health care visit (*18*).

[§§§] Adults aged 19–64 years with risk-based vaccine indication, and all adults aged ≥65 years were considered in the economic models.

[¶¶¶] A base case estimate in cost-effectiveness analysis is the primary scenario used to assess an intervention's costs and health outcomes. It serves as a benchmark for comparison with alternative scenarios and sensitivity analyses to guide health policy decisions.

[****] Lower cost and improved health outcomes compared with the comparator strategy.

TABLE. Clinical guidance for implementing pneumococcal vaccine recommendations for adults aged ≥19 years — United States, 2024

Risk or age group	Vaccine received previously	Options for vaccination
Adults aged ≥65 years	None or PCV7 only at any age	A single dose of PCV21, PCV20, or PCV15. If PCV15 is administered, a single dose of PPSV23* should be administered ≥1 year after the PCV15 dose. A minimum interval of 8 weeks can be considered if PCV15 is used in adults with an immunocompromising condition,† cochlear implant, or CSF leak.
	PPSV23 only	A single dose of PCV21, PCV20, or PCV15 ≥1 year after the last PPSV23 dose.
	PCV13 only	A single dose of PCV21, PCV20, or PPSV23≥1 year after the PCV13 dose. When PPSV23 is used for adults with an immunocompromising condition,† cochlear implant, or CSF leak, administer PPSV23 ≥8 weeks after the PCV13 dose.
	PCV13 at any age and PPSV23 at age <65 years	A single dose of PCV21, PCV20, or PPSV23. If PCV21 or PCV20 is used, it should be administered ≥5 years after the last pneumococcal vaccine dose. If PPSV23 is used, it should be administered ≥1 year after the PCV13 dose (or ≥8 weeks since the PCV13 dose for adults with an immunocompromising condition,† cochlear implant, or CSF leak) and ≥5 years after the previous PPSV23 dose.
	PCV13 at any age and PPSV23 at age ≥65 years	Shared clinical decision-making is recommended regarding administration of either a single dose of PCV21 or PCV20 for any adult aged ≥65 years who has completed the recommended vaccination series with both PCV13 and PPSV23 (i.e., PPSV23 administered at age ≥65 years) but PCV21, PCV20 or PCV15 not yet received. If a decision to administer PCV21 or PCV20 is made, a single dose is recommended ≥5 years after the last pneumococcal vaccine dose.
Adults aged 19–64 years with an immunocompromising condition,† a CSF leak, or a cochlear implant	None or PCV7 only at any age	A single dose of PCV21, PCV20, or PCV15. If PCV15 is used, administer a single dose of PPSV23* ≥8 weeks after the PCV15 dose.
	PPSV23 only	A single dose of PCV21, PCV20, or PCV15 ≥1 year after the last PPSV23 dose.
	PCV13 only	A single dose of PCV21, PCV20, or PPSV23. If PCV21 or PCV20 is used, it should be administered ≥1 year after the PCV13 dose. If PPSV23 is used, administer PPSV23 ≥8 weeks after the PCV13 dose. When PPSV23 is used instead of PCV21 or PCV20 for these adults, a single dose of PCV21, PCV20 or PPSV23 dose is recommended ≥5 years after the first PPSV23 dose.
	PCV13 and 1 dose of PPSV23	A single dose of PCV21 or PCV20, or ≥1 dose of PPSV23. If PCV21 or PCV20 is used, it should be administered ≥5 years after the last pneumococcal vaccine dose. When a second PPSV23 dose is used instead of PCV21 or PCV20, it should be administered ≥8 weeks after the PCV13 dose and ≥5 years after the first PPSV23 dose. The pneumococcal vaccination recommendations should be reviewed again when the person reaches age 65 years. If PCV21 or PCV20 is used in place of any dose of PPSV23, the series is complete, and it need not be followed by additional pneumococcal vaccine doses.
	PCV13 and 2 doses of PPSV23	The pneumococcal vaccination recommendations should be reviewed again when the person turns age 65 years. Alternatively, a single dose of either PCV21 or PCV20 should be administered ≥5 years after the last pneumococcal vaccine dose. If PCV21 or PCV20 is used, the series is complete, and it need not be followed by additional pneumococcal vaccine doses.
Adults aged 19–64 years with chronic medical conditions§	None or PCV7 only at any age	A single dose of PCV21, PCV20, or PCV15. If PCV15 is administered, a single dose of PPSV23* should be administered ≥1 year after the PCV15 dose.
	PPSV23 only	A single dose of PCV21, PCV20, or PCV15 ≥1 year after the last PPSV23 dose.
	PCV13 only	A single dose of PCV21, PCV20, or PPSV23 ≥1 year after the PCV13 dose.
	PCV13 and 1 dose of PPSV23	The pneumococcal vaccination recommendations should be reviewed again when the person reaches age 65 years.

Abbreviations: CSF = cerebrospinal fluid; PCV = pneumococcal conjugate vaccine; PCV7 = 7-valent PCV; PCV13 = 13-valent PCV; PCV15 = 15-valent PCV; PCV20 = 20-valent PCV; PCV21 = 21-valent PCV; PPSV23 = 23-valent pneumococcal polysaccharide vaccine.

* For adults who have received PCV15 but have not completed their recommended pneumococcal vaccine series with PPSV23, 1 dose of PCV21 or PCV20 may be used if PPSV23 is not available.

† Chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, HIV infection, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplant, congenital or acquired asplenia, or sickle cell disease or other hemoglobinopathies.

§ Alcoholism; chronic heart disease, including congestive heart failure and cardiomyopathies; chronic liver disease; chronic lung disease, including chronic obstructive pulmonary disease, emphysema, and asthma; cigarette smoking; or diabetes mellitus.

Contraindications and Precautions

Vaccination providers should consult the vaccine package insert for precautions, warnings, and contraindications (*19*). Vaccination with PCV or PPSV23 is contraindicated in persons known to have had a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine. PCVs are also contraindicated in persons known to have had a severe allergic reaction to any diphtheria toxoid–containing vaccine (*2*,*19*).

Reporting of Vaccine Adverse Events

Adverse events occurring after administration of any vaccine should be reported to the Vaccine Adverse Event Reporting

System (VAERS). Instructions for reporting to VAERS are available at https://vaers.hhs.gov/reportevent.html or by calling 800-822-7967.

BOX. Clinical guidance on selection of pneumococcal conjugate vaccine in communities with high proportions of serotype 4 pneumococcal disease — United States, 2024

- PCV21 contains eight pneumococcal serotypes that are not included in previously recommended pneumococcal vaccines (i.e., PCV15, PCV20, and PPSV23). However, PCV21 does not contain certain pneumococcal serotypes that are contained in previously recommended pneumococcal vaccines, one of which is pneumococcal serotype 4.
- In certain adult populations in the western United States, high percentages (i.e., ≥30%) of IPD caused by serotype 4 have occurred. The available IPD serotype data from CDC's Active Bacterial Core surveillance, as well as similar surveillance from Alaska and the Navajo Nation, indicate that these high percentages are particularly prevalent in Alaska, Colorado, the Navajo Nation, New Mexico, and Oregon. Typically, persons living within these geographic areas who develop serotype 4 IPD are adults aged <65 years with specific underlying conditions or risk factors, such as alcoholism, chronic lung disease, cigarette smoking, homelessness, and injection drug use. Importantly, these persons usually have not received a pneumococcal conjugate vaccine containing serotype 4. In such populations, other recommended pneumococcal vaccines (e.g., PCV20 alone or both PCV15 and PPSV23) are expected to provide broader serotype coverage against locally circulating strains compared with PCV21.
- The percentages of serotype 4 IPD cases in other areas of the western United States without IPD surveillance are currently unknown. IPD surveillance from other geographic areas in the United States (e.g., midwestern, eastern, and southern regions) has not detected significant percentages of serotype 4.
- This clinical guidance will be reviewed and updated as pneumococcal disease epidemiology evolves.

Abbreviations: IPD = invasive pneumococcal disease; PCV = pneumococcal conjugate vaccine; PCV7 = 7-valent PCV; PCV13 = 13-valent PCV; PCV15 = 15-valent PCV; PCV20 = 20-valent PCV; PCV21 = 21-valent PCV; PPSV23 = 23-valent pneumococcal polysaccharide vaccine.

Summary

What is already known about this topic?

Adults aged 19–64 years with risk conditions for pneumococcal disease and those aged ≥65 years are recommended to receive either 15- or 20-valent pneumococcal conjugate vaccine (PCV) (PCV15 or PCV20, respectively).

What is added by this report?

On June 27, 2024, the Advisory Committee on Immunization Practices recommended 21-valent PCV (PCV21) as an option for adults aged ≥19 years who are currently recommended to receive PCV15 or PCV20. PCV21 contains eight serotypes not included in other licensed vaccines.

What are the implications for public health practice?

Adding PCV21 as an option in the current PCV recommendation is expected to prevent additional disease caused by pneumococcal serotypes unique to PCV21. Postlicensure monitoring of safety and public health impact of PCV use will guide future recommendations.

Future Research and Monitoring Priorities

CDC and ACIP will assess available data to evaluate whether evidence supports lowering the age for the current adult age-based pneumococcal vaccination recommendation. CDC and ACIP will continue to assess safety and public health impact of PCVs (i.e., PCV15, PCV20, and PCV21) among adults.

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Use of *Haemophilus influenzae* Type b–Containing Vaccines Among American Indian and Alaska Native Infants: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2024

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Abstract

Invasive *Haemophilus influenzae* type b (Hib) disease is a serious bacterial infection that disproportionally affects American Indian and Alaska Native (AI/AN) populations. Hib vaccination with a monovalent Hib conjugate vaccine consisting of Hib capsular polysaccharide (polyribosylribitol phosphate [PRP]) conjugated to outer membrane protein complex of *Neisseria meningitidis* serogroup B, PRP-OMP (PedvaxHIB, Merck and Co., Inc.) has historically been preferred for AI/AN infants, who are at increased risk for invasive Hib disease, because it provides substantial protection after the first dose. On June 26, 2024, CDC's Advisory Committee on Immunization Practices (ACIP) recommended that a hexavalent, combined diphtheria and tetanus toxoids and acellular pertussis (DTaP), inactivated poliovirus (IPV), Hib conjugate, and hepatitis B (HepB) vaccine, DTaP-IPV-Hib-HepB (Vaxelis, MSP Vaccine Company) should be included with monovalent PRP-OMP in the preferential recommendation for AI/AN infants because of the PRP-OMP Hib component. A primary Hib vaccination series consisting of either 1) monovalent PRP-OMP (2-dose series at ages 2 and 4 months) or 2) DTaP-IPV-Hib-HepB (3-dose series at ages 2, 4, and 6 months) is preferred for AI/AN infants. DTaP-IPV-Hib-HepB is only indicated for use in infants at ages 2, 4, and 6 months and should not be used for the booster doses of Hib, DTaP, or IPV vaccines. For the booster dose of Hib vaccine, no vaccine formulation is preferred for AI/AN children; any Hib vaccine (except DTaP-IPV-Hib-HepB) should be used. This report summarizes evidence considered for these recommendations and provides clinical guidance for the use of Hib-containing vaccines among AI/AN infants and children.

Introduction

Before 1985, *Haemophilus influenzae* type b (Hib) was the leading cause of bacterial meningitis and a common cause of other invasive infections among U.S. children aged <5 years (*1*). After the introduction of effective Hib vaccines,* the incidence of invasive Hib disease among U.S. children aged <5 years declined >99% (*1*). Before and since the introduction of Hib vaccines, American Indian and Alaska Native (AI/AN) populations have been disproportionately affected by invasive Hib disease. The five Hib conjugate vaccines currently licensed and available in the United States consist of Hib capsular polysaccharide (polyribosylribitol phosphate [PRP]) conjugated to either outer membrane protein complex of *Neisseria meningitidis* serogroup B (PRP-OMP) or tetanus toxoid (PRP-T).

Hib vaccination with monovalent PRP-OMP (PedvaxHIB, Merck and Co., Inc.) has historically been preferred for AI/AN infants based on the epidemiology of invasive Hib disease among AI/AN populations and the differing immunogenicity of Hib vaccines. Before routine Hib vaccination began, the incidence of Hib meningitis peaked at a younger age (4–6 months) among AI/AN infants than among other U.S. infant populations (6–7 months) (*2*). Monovalent PRP-OMP provides a protective antibody response after the first dose, recommended at age 2 months, whereas PRP-T vaccines do not (*1*). For this reason, Hib vaccination with monovalent PRP-OMP has been preferred for AI/AN infants, to provide earlier protection against invasive Hib disease.

DTaP-IPV-Hib-HepB (Vaxelis, MSP Vaccine Company†) is a hexavalent, combined diphtheria and tetanus toxoids and acellular pertussis (DTaP), inactivated poliovirus (IPV), Hib conjugate, and hepatitis B (HepB) vaccine that contains PRP-OMP as the Hib component. However, DTaP-IPV-Hib-HepB has not previously been included in the preferential recommendation for AI/AN infants, because the dose of PRP-OMP is lower than that in PedvaxHIB, and post–first dose immunogenicity data for DTaP-IPV-Hib-HepB were not previously available (*3*).

Methods

Five Hib conjugate vaccines are currently licensed and available in the United States.§ During December 2023–June 2024, CDC's Advisory Committee on Immunization Practices (ACIP) Meningococcal/Hib Vaccines Work Group (Work Group) held conference calls to review Hib disease epidemiology among AI/AN populations and new data comparing immunogenicity of DTaP-IPV-Hib-HepB and monovalent PRP-OMP. The policy question under consideration was

* Hib polysaccharide vaccines were first introduced in 1985, and conjugate vaccines in 1987.

† MSP Vaccine Company is a U.S.-based partnership between Merck (known as MSD outside the United States and Canada) and Sanofi.

§ PRP-OMP, PRP-T, PRP-T, DTaP-IPV/Hib, and DTaP-IPV-Hib-HepB.

"Should DTaP-IPV-Hib-HepB (Vaxelis) be included with monovalent PRP-OMP (PedvaxHIB) in the preferential recommendation for American Indian and Alaska Native infants based on the Hib component?" In January 2024, CDC's National Center for Immunization and Respiratory Diseases and Office of Tribal Affairs and Strategic Alliances held a listening session to obtain input from tribal communities and Indian Health Service staff members regarding the policy question. To guide deliberations, ACIP used the Evidence to Recommendations (EtR) Framework and considered the importance of Hib disease among AI/AN populations within the following domains: as a public health problem; benefits and harms of DTaP-IPV-Hib-HepB among AI/AN infants; the values of the target population; acceptability; resource use; equity; and feasibility.[¶] ACIP evaluated the available evidence on prespecified outcomes, each with ranked importance, using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach (*4*): invasive Hib disease (important), post–dose 1 immunity (critical), post–primary series immunity (important), and serious adverse events (critical).[**]

Summary of Evidence for Use of DTaP-IPV-Hib-HepB Among American Indian and Alaska Native Infants

The Work Group determined that considerations within each domain of the EtR Framework supported inclusion of DTaP-IPV-Hib-HepB in the preferential recommendation for AI/AN infants. The GRADE assessment of benefits and harms is summarized here.

No data were available to assess the outcome of invasive Hib disease. For the remaining outcomes, the body of evidence comprised data from one phase IV, prospective, open-label randomized controlled clinical trial comparing immunogenicity and safety of DTaP-IPV-Hib-HepB vaccine versus monovalent PRP-OMP vaccine among 333 Navajo Nation and Alaska Native infants (*5*). The clinical trial enrolled healthy infants born at ≥35 weeks' gestational age, aged 42–90 days at the time of first vaccination, and identified as AI/AN by the parent or legally authorized representative. Infants were randomized to a primary series of DTaP-IPV-Hib-HepB (administered at ages 2, 4, and 6 months) or monovalent PRP-OMP (administered at ages 2 and 4 months). Anti-Hib immunoglobulin G (IgG) antibody levels were measured before vaccination and on days 30, 120, and 150 after the first vaccine dose. Constrained longitudinal data analysis was used to evaluate the anti-Hib IgG geometric mean concentration (GMC) ratio (DTaP-IPV-Hib-HepB versus monovalent PRP-OMP) 30 days after dose 1; the investigators' prespecified noninferiority criterion for the lower bound of the 95% CI was >0.67. Safety monitoring for serious adverse events[††] was conducted on days 0, 30, 60, 120, and 150 after the first vaccine dose.

Post–Dose 1 Immunity

The anti-Hib IgG GMC ratio (DTaP-IPV-Hib-HepB versus monovalent PRP-OMP) 30 days after receipt of dose 1 modeled by constrained longitudinal data analysis was 1.03 (95% CI = 0.75–1.41) and met the noninferiority criterion. The proportion of infants with anti-Hib concentration above the putative correlate of short-term protection (≥0.15 μg/mL) 30 days after receipt of dose 1 was similar in the DTaP-IPV-Hib-HepB group (75.7%) and the monovalent PRP-OMP group (71.2%; p = 0.39). The overall level of certainty for this outcome was moderate.

Post–Primary Series Immunity

The proportion of infants with anti-Hib concentration above the putative correlate of long-term protection (≥1.0 μg/mL) 150 days after receipt of dose 1 was higher in the DTaP-IPV-Hib-HepB group (3-dose primary series) (83.6%) than in the monovalent PRP-OMP group (2-dose primary series) (71.8%; p = 0.03). The overall level of certainty for this outcome was moderate.

Serious Adverse Events

The frequency of serious adverse events was similar in the DTaP-IPV-Hib-HepB group (5.4%) and the monovalent PRP-OMP group (7.2%; p = 0.49). The most common serious adverse event was acute respiratory infection (21 of 25; 84%). No serious adverse events were deemed related to study participation. The overall level of certainty for this outcome was moderate.

Recommendations for Use of Hib-Containing Vaccines Among American Indian and Alaska Native Infants and Children

DTaP-IPV-Hib-HepB is included with monovalent PRP-OMP in the preferential recommendation for American Indian and Alaska Native infants. The basis for this recommendation is the Hib component of PRP-OMP.

Hib Vaccine Primary Series

A primary Hib vaccination series consisting of either 1) monovalent PRP-OMP (2-dose series at ages 2 and 4 months) or 2) DTaP-IPV-Hib-HepB (3-dose series at ages 2, 4, and 6 months) is preferred over other Hib vaccine formulations for AI/AN infants. If the first Hib vaccine dose is delayed

[¶] https://www.cdc.gov/vaccines/acip/recs/grade/hib-aian-infants-etr.html
[**] https://www.cdc.gov/vaccines/acip/recs/grade/hib-aian-infants.html

[††] Serious adverse events were defined as hospitalization, death, life-threatening drug experience, or prolongation of hospitalization.

by >1 month, the recommended catch-up schedule should be followed.[§§]

Booster Dose

DTtaP-IPV-Hib-HepB is only indicated for use in infants aged 2, 4, and 6 months and should not be used for the booster doses of Hib, DTaP, or IPV vaccines (Table 1) (*3*). For the booster dose of Hib vaccine, no vaccine formulation is preferred for AI/AN children (*1*); any Hib vaccine except DTaP-IPV-Hib-HepB should be used. In clinics caring for AI/AN children, stocking monovalent PRP-OMP for the Hib booster dose would maintain parent, guardian, and provider flexibility to choose this vaccine for the primary Hib series. Stocking a PRP-T vaccine for the Hib booster dose also is an option (Table 2). A group of 124 AI/AN infants who took part in a phase 3 study of a DTaP-IPV-Hib-HepB primary series with a heterologous Hib booster (PRP-T) demonstrated a robust immune response (*6*).

[§§] https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-catch-up.html?CDC_AAref_Val

If DTaP-IPV-Hib-HepB is inadvertently administered for the booster dose or doses of Hib, DTaP, or IPV vaccines, the dose of the corresponding component does not need to be repeated when the proper spacing of doses is maintained. For additional guidance for use of DTaP-IPV-Hib-HepB in infants, clinicians should refer to previously published recommendations (*3*).

Reporting of Vaccine Adverse Events

Adverse events that occur in a patient after vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS), even if it is uncertain whether the vaccine caused the event. Instructions for reporting to VAERS are available at https://vaers.hhs.gov/reportevent.html or by calling 800–822–7967. Vaccine adverse event reports originating from the Indian Health Service (IHS) I/T/U (IHS Federal/Tribal/Urban) system of care should include the abbreviation "IHS" in item #26 of the VAERS report form to facilitate tracking such events among the IHS service population.

TABLE 1. Child and adolescent immunization schedule for components of Vaxelis vaccine, by age — United States, 2024

	Recommended age for receipt of vaccine dose				
	Primary series			Booster doses	
Vaccine	1st dose	2nd dose	3rd dose	1st booster dose*	2nd booster dose*
HepB[†]	Birth[§]	1–2 mos	6–18 mos[¶]	NA	NA
DTaP	2 mos	4 mos	6 mos	15–18 mos	4–6 yrs
Hib	2 mos	4 mos	6 mos**	12–15 mos	NA
IPV	2 mos	4 mos	6–18 mos	4–6 yrs	NA

Abbreviations: DTaP = diphtheria and tetanus toxoids and acellular pertussis; HepB = hepatitis B; Hib = *Haemophilus influenzae* type b; IPV = inactivated poliovirus; NA = not applicable; Vaxelis = hexavalent DTaP-IPV-Hib-Hep B vaccine.
* Vaxelis is not indicated for the booster doses of DTaP, Hib, or IPV vaccines.
[†] Administration of 4 doses is permitted when a combination vaccine containing HepB is used after the birth dose. Clinicians should refer to previously published recommendations for additional guidance based on maternal hepatitis B infection status, infant birthweight, and vaccine manufacturer. https://pubmed.ncbi.nlm.nih.gov/29939980/
[§] Vaxelis is not indicated.
[¶] For an adequate immune response, the last dose of HepB should be given at age ≥24 weeks.
** Not applicable for monovalent PRP-OMP (PedvaxHIB).

TABLE 2. Characteristics of licensed and available *Haemophilus influenzae* type b–containing vaccines — United States, 2024

		Recommended ages for administration	
Vaccine product	Trade name	Primary series	Booster dose
Monovalent vaccines			
PRP-OMP*	PedvaxHIB	2 and 4 mos	12–15 mos
PRP-T	ActHIB	2, 4, and 6 mos	12–15 mos
PRP-T	Hiberix	2, 4, and 6 mos	12–15 mos
Combination vaccines			
DTaP-IPV/Hib[†]	Pentacel	2, 4, and 6 mos	12–15 mos
DTaP-IPV-Hib-HepB[§]	Vaxelis	2, 4, and 6 mos	Not indicated[¶]

Abbreviations: DTaP = diphtheria and tetanus toxoids and acellular pertussis; HepB = hepatitis B; Hib = *Haemophilus influenzae* type b; IPV = inactivated poliovirus; OMP = outer membrane protein complex of the B11 strain of *Neisseria meningitidis* serogroup B; PRP = polyribosylribitol phosphate; T = tetanus toxoid.
* Contains 7.5 μg PRP and 125 μg OMP.
[†] Hib component is PRP-T.
[§] Hib component is PRP-OMP. Contains 3 μg PRP and 50 μg OMP.
[¶] Not indicated for use as a booster dose. A different Hib-containing vaccine should be used.

Summary

What is already known about this topic?

Haemophilus influenzae type b (Hib) vaccination with a monovalent Hib conjugate vaccine consisting of Hib capsular polysaccharide (polyribosylribitol phosphate [PRP]) conjugated to the outer membrane protein complex of *Neisseria meningitidis* serogroup B (PRP-OMP [PedvaxHIB]) has historically been preferred for American Indian and Alaska Native (AI/AN) infants to provide earlier protection in these populations at increased risk for invasive Hib disease.

What is added by this report?

On June 26, 2024, the Advisory Committee on Immunization Practices recommended that hexavalent Vaxelis (diphtheria and tetanus toxoids and acellular pertussis, inactivated poliovirus, Hib conjugate, and hepatitis B vaccine [DTaP-IPV-Hib-HepB]) should be included with monovalent PRP-OMP in the preferential recommendation for AI/AN infants based on the Hib component.

What are the implications for public health practice?

A primary Hib vaccination series consisting of monovalent PRP-OMP or DTaP-IPV-Hib-HepB is preferred for AI/AN infants.

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