# VACCINE DELIVERY RESEARCH DIGEST

UNIVERSITY OF WASHINGTON STRATEGIC ANALYSIS, RESEARCH & TRAINING (START) CENTER

REPORT TO THE GATES FOUNDATION

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## **List of Articles**

1 Variations in Routine Childhood Vaccination Gaps: A Decomposition Analysis Across 80 Lowand Middle-Income Countries.

{Abstract & START Commentary} {Full Article}

- This study disaggregates measures of immunization coverage across several countries to highlight pathways for targeted interventions.
- 2 Widening Geographical Inequities in DTP Vaccination Coverage and Zero-Dose Prevalence Across Nigeria: An Ecological Trend Analysis (2018-2024).

{Abstract & START Commentary} {Full Article}

- This study explores trends in vaccine access and utilization across different regions in Nigeria.
- 3 The future impact of zero-dose children in inaccessible conflict-affected areas of Somalia: aligned with the immunization agenda 2030.

{Abstract & START Commentary} {Full Article}

- This review examines the burden, drivers, and health-system consequences of zero-dose in conflict-affected regions of Somalia.
- 4 The global poliovirus eradication initiatives in Kano state, Nigeria: a case report on the African regional commission pre-certification visit and lessons learnt.

{Abstract & START Commentary} {Full Article}

- Kano state worked toward polio-free status through integrated surveillance, community engagement, and strong verification systems.
- 5 Effectiveness of the RTS,S/AS01E malaria vaccine in a real-world setting over 1 year of followup after the three-dose primary schedule: an interim analysis of a phase 4 study in Ghana, Kenya, and Malawi.

{Abstract & START Commentary} {Full Article}

- Interim findings from the EPI-MAL-003 study show reduced incidence of malaria-related endpoints among vaccinated individuals.
- 6 MPOX outbreak in Africa: the urgent need for local manufacturing of the vaccine and decolonized health systems.

{Abstract & START Commentary} {Full Article}

- The review links delayed MPOX vaccine access in Africa to structural constraints and highlights African-led regulation and local manufacturing.
- 7 Financial risk protection from vaccines in 52 Gavi-eligible low- and middle-income countries: A modeling study.

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- Different vaccines can have differential effects on financial risk protection based on wealth status.
- 8 Gender Barriers to Immunization: A Synthesis of UNICEF's Analyses to Advance Equity and Coverage.

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- Gender-related barriers to vaccination exist at every level of the SEM.
- 9 Cost-effectiveness and budget impact of malaria, measles, and meningitis vaccines in Africa: a scoping review.

{Abstract & START Commentary} {Full Article}

- Vaccine cost-effectiveness is influenced by delivery strategy, target age groups, and disease burden.
- 10 A landscape analysis of the vaccine ecosystem in Africa: research and development funding, clinical trials, regulation, and manufacturing readiness.

{Abstract & START Commentary} {Full Article}

 Africa's vaccine capacity is growing but remains uneven, highlighting the need for more equitable investment.

Additional Articles of Interest

**Appendix** 

## **Details of Articles**

Variations in Routine Childhood Vaccination Gaps: A Decomposition Analysis Across 80 Low- and Middle-Income Countries.

Phillips D, Thomas J, Ikilezi G.

Vaccines (Basel). 2025 Nov 26;13(11).

PubMed ID: 41295510

#### **ABSTRACT**

Background: Despite remarkable progress in expanding access to childhood vaccines in the last two decades, global coverage with the third dose of the diphtheria-tetanus-pertussis-containing vaccine (DTP3) has recently plateaued, with many countries yet to meet the targets of the Immunization Agenda 2030 (IA2030). As countries cluster around the 80% coverage mark, further gains require targeted interventions for unreached populations. This analysis disaggregates children missing DTP3 into three groups-zero dose (ZD), missed DTP (MD), and drop-out (DO)-which, with DTP3, form four mutually exclusive groups, and examines which of these groups contributes most to coverage changes across countries. Methods: A total of 295 Demographic and Health Surveys from 1986 to 2023 were analyzed across 80 countries, comprising over 2.4 million children. Children were classified into mutually exclusive groups: DTP3, ZD, MD, and DO. We described trends over time and conducted decomposition analyses using a naïve approach and a structural model with isometric log-ratio transformations and causal mediation pathways. Results: Among the 2.4 million children across 80 countries, 63.8% had received DTP3, while 16.2% were DO, 8.8% were MD, and 11.2% were ZD. Countries showed important variations: some mainly reduced ZD, others reduced MD or DO, many achieved balanced progress, and a few experienced setbacks. The naïve model showed that coverage changes reflected different combinations of shifts across ZD, MD, and DO depending on context. The structural model indicated that DO had the strongest direct association with DTP3 coverage, followed by MD and ZD. Conclusions: This analysis highlights the differential contribution of intermediate groups to coverage variations over time. Understanding the association between coverage gains and shifts in ZD, MD, or DO can complement existing strategies to inform targeted planning and accelerate progress towards IA2030 equity goals.

WEB: <u>10.3390/vaccines13111136</u>

IMPACT FACTOR: 3.4 CITED HALF-LIFE: 2.8

START COMMENTARY

In many countries, immunization coverage has plateaued around 80%. This study disaggregated DTP coverage into intermediate outcomes including observed DTP3 coverage, zero dose, missed DTP, and dropout to characterize where progress has occurred and where gaps remain across the immunization cascade and to identify patterns of country-level priorities. Across the decades of data analyzed, different countries achieved higher DTP3 coverage through different mechanisms, largely due to variation in baseline coverage gaps. Several countries saw large reductions in zero dose that led to higher coverage, while others improved mainly through decreased dropout or more balanced reductions in zero dose, missed DTP, and dropout. Interestingly, in some countries, progress in one group occurred alongside setbacks in others. For example, although DTP3 coverage in Ethiopia grew from 2000-2020, the country's zero dose category increased, but reductions in missed DTP and dropout were large enough to offset this. A strength of this study is that it examined 80 countries to identify sources of coverage gaps in a variety of LMIC settings. While global estimates often highlight zero dose children as the largest group missing vaccinations, this multi-country analysis reveals substantial variation between countries, with no single predominant category. A limitation of this study is that DHS data may contain recall, nonresponse, and survival biases that could skew estimates of DTP3 coverage. By distinguishing coverage statuses that require different types of outreach and follow-up, this analysis can help countries better identify which barriers are most limiting their progress. High prevalence of MD may require different approaches than high zero dose or dropout; for example, the authors suggest closing the dropout gap with incentives and reminder systems, while missed DTP populations may be better served by strategies that link them to campaigns or supplementary immunization activities. Overall, these findings can help country-level stakeholders frame discussions about where to intervene along the immunization pathway to improve coverage.

# 2. <u>Widening Geographical Inequities in DTP Vaccination Coverage and Zero-Dose</u> Prevalence Across Nigeria: An Ecological Trend Analysis (2018-2024).

Umar H, Onah S, Popoola O, Jibril H, Oyewole F.

Vaccines (Basel). 2025 Nov 26;13(11).

PubMed ID: 41295508

#### **ABSTRACT**

Background/Objectives: Nigeria continues to face major challenges in achieving equitable immunisation coverage, with marked subnational disparities. This study aimed to assess trends in vaccine access and utilisation across Nigeria's six geopolitical zones between 2018 and 2024, focusing on inequities in DTP coverage, dropout rates, and zero-dose prevalence. Methods: We conducted a comparative ecological analysis using secondary data from the Nigeria Demographic and Health Surveys (2018, 2024) and the 2021 Multiple Indicator Cluster Survey/National Immunisation Coverage Survey. Geometric mean coverage for penta 1 (DTP1) and penta 3 (DTP3), DTP1-DTP3 dropout rates, and zero-dose prevalence were calculated for each of the six geopolitical zones and analysed using WHO's Health Equity Assessment Toolkit Plus. Absolute (difference, D) and relative (ratio, R) summary measures of inequality were also assessed. Results: Findings revealed statistically significant differences in indicators across the various regions during the period of study. While the South-East maintained >90% DTP1 coverage, the North-West declined from 37.3% (2018) to 33.4% (2024). In the same period, the absolute inequality (D) in DTP1 coverage increased from 55.3 to 58.4 percentage points. Zero-dose inequities worsened sharply: prevalence in the North-West rose from 25.7% (2021) to 47.4% (2024) compared to ~4% in the South-East, with a relative inequality (R) of 11.29 in 2024. In contrast, service utilisation improved, as dropout rates in the North-West fell from 38.7% (2018) to 14.3% (2024), reducing absolute inequality to 11.0 pp. Conclusions: Despite progress in reducing dropout, access to vaccination services remains highly inequitable, particularly in northern Nigeria. Declines since 2021 suggest systemic fragility compounded by COVID-19-related disruptions. Strengthening sustainable routine immunisation systems and investing in demand generation, especially through social and behaviour change communication, are essential to achieving equity.

WEB: <u>10.3390/vaccines13111135</u>

IMPACT FACTOR: 4.3 CITED HALF-LIFE: 2.8

#### START COMMENTARY

Nigeria bears a disproportionate share of the world's unvaccinated infants and faces stark regional disparities in immunization access and utilization, driven by economic, cultural, and behavioral

factors. This ecological trend analysis used national survey data and WHO equity metrics to track DTP1 & DTP3 coverage, dropout, and zero-dose inequities across Nigeria's six geopolitical zones from 2018–2024. A persistent and widening north–south divide was observed for most indicators. For DTP 1 coverage, regional gaps narrowed between 2018-2021 but widened again by 2024 with the best-performing region having almost three times the coverage of the worst performing one. A similar trend was observed for DTP3, but overall inequity in 2024 remained slightly better than in 2018. Zero-dose children showed the most severe and rapidly growing inequities, with the highest-burden region having over 11 times the zero-dose prevalence of the best-performing region by 2024. In contrast, DTP series dropout was the only indicator with steady, nationwide improvement. Strengths of this study include the use of multiple nationally representative surveys and standardized equity measures. Limitations include the ecological design and focus on geography alone which limit causal inference. The authors recommend strengthening advocacy, communication, and social mobilization through tailored messaging that addresses regionally specific barriers, community engagement through partnership with local leaders, and further integration of routine immunization programs with other primary health systems, especially in northern Nigeria.

3 The future impact of zero-dose children in inaccessible conflict-affected areas of Somalia: aligned with the immunization agenda 2030.

Hussein S, Osman M, Hassan M, Hassan Y, Hussein A, Mohamed A, et al.

Trop Med Health. 2025 Nov 13;53(1):162.

PubMed ID: 41225680

#### **ABSTRACT**

**BACKGROUND:** The Immunization Agenda 2030 (IA2030), led by WHO and partners, targets the global challenge of zero-dose children, who face higher risks of vaccine-preventable diseases. Globally, 18 million children remain zero-dose, with over half in conflict or humanitarian settings. In Somalia, about 60% of children are zero-dose, and during the 2022-2024 drought, over 70,000 deaths occurred, with nearly 40% among children under five. This review explores the burden, determinants, and geographic distribution of zero-dose children in Somalia's conflict-affected regions.

**METHODS:** This narrative review followed SANRA guidance. We searched PubMed, Scopus, Web of Science, Google Scholar, and key institutional sites (WHO, UNICEF, ReliefWeb, MoH Somalia, NGOs) for English-language literature (1990-July 31, 2025). From 197 records were identified, 82 new studies were included, resulting in a total of 279 studies after de-duplication and two-reviewer screening. Evidence was synthesized thematically and aligned to Immunization Agenda 2030 (IA2030) priorities.

**RESULTS:** Zero-dose hotspots are concentrated in rural, nomadic, and conflict-affected zones, with Lower Juba reaching a peak of 62%. Key challenges include insecurity, limited access, disrupted supply chains, workforce shortages, and demand-side barriers like mistrust and misinformation. Humanitarian efforts are frequently hindered by checkpoints, blockades, and security concerns. From 2000 to 2024, Somalia's routine immunization program showed significant progress, with MCV-1 coverage rising from 50 to 71%, and MCV-2 from 5 to 55%, as per the WHO/UNICEF WUENIC data for the African region.

**CONCLUSION:** Zero-dose children in inaccessible Somali districts are a pressing equity and health-security challenge. Sustaining recent national gains while fulfilling Immunization Agenda 2030 (IA2030)'s "leave no one behind" requires tailored outreach to remote communities, strengthened surveillance and e-registries for defaulter tracing, resilient cold-chain and WASH linkages, empowered community health workers (especially women), negotiated humanitarian access, and a progressive domestic co-financing roadmap alongside partner support.

WEB: 10.1186/s41182-025-00833-2

IMPACT FACTOR: 3.5 CITED HALF-LIFE: 4.3

#### START COMMENTARY

Conflict, displacement, and under-funding in Somalia have weakened routine immunization programs and undermined broader health system capacity, leaving approximately three out of five children in the country classified as zero-dose. This narrative review synthesizes evidence on the prevalence, predictors, and consequences of zero-dose status in conflict-affected regions of Somalia, particularly in districts that are physically inaccessible due to insecurity and humanitarian access constraints. Somalia has some of the highest zero-dose rates globally while also facing outbreaks of infectious disease worsened by climate shocks, conflict, and reduced humanitarian aid. Additionally, conflict and displacement have left millions with limited access to clean water, sanitation, and health care increasing vulnerability to preventable disease. One aspect of this review highlights how cholera outbreaks cluster in zero-dose hotspots characterized by weak immunization coverage and poor water, sanitation, and hygiene (WASH) infrastructure. Outbreaks from vaccine preventable disease and water-borne disease strain already fragile surveillance and emergency response systems, diverting resources away from routine services and reinforcing a feedback loop that further undermines vaccination delivery. A key recommendation is the integration of WASH and primary health care services with immunization programs, recognizing that in highly displaced, resource-constrained settings, meeting basic needs simultaneously is essential for sustained impact. This study provides actionable, policy-relevant insights for addressing zero-dose communities in Somalia, though its conclusions are limited by heterogeneous data quality in insecure areas and reliance on incomplete surveillance and household survey data.

4. The global poliovirus eradication initiatives in Kano state, Nigeria: a case report on the African regional commission pre-certification visit and lessons learnt.

Nwaze E, Ieren I, Okafor C.

Front Public Health. 2025 Nov 13;13:1690423.

PubMed ID: 41221229

#### **ABSTRACT**

**BACKGROUND:** Polio eradication in Kano State, Nigeria, represents a major milestone in the Global Polio Eradication Initiative (GPEI). Formerly the epicentre of wild poliovirus (WPV) in Africa, Kano experienced multiple outbreaks between 2003 and 2008, threatening national and regional stability. Persistent transmission, vaccine resistance, and surveillance gaps kept Kano in global focus. By 2020, following intensive interventions, Kano was certified polio-free by the African Regional Certification Commission (ARCC).

**METHODS:** This narrative report draws from ARCC field verification visits, peer-reviewed literature, unpublished reports from the National Primary Health Care Development Agency (NPHCDA), and records from WHO, UNICEF, and partners. Data (2008-2020) included surveillance indicators, immunisation coverage, cold chain assessments, supplementary immunisation activities (SIAs), and stakeholder interviews. Emphasis was on Acute Flaccid Paralysis (AFP) surveillance, technological innovations such as AVADAR and GIS mapping, and the role of traditional and religious leaders in overcoming resistance.

**RESULTS:** Kano achieved AFP surveillance sensitivity above the WHO benchmark (2/100,000 children under 15), expanded environmental surveillance, and improved routine immunisation with coverage exceeding 80% in most Local Government Areas by 2019. ARCC verification noted strong documentation, political commitment, advocacy, and correction of case investigation and outbreak records.

**CONCLUSION:** Kano's transformation from a WPV hotspot to polio-free status resulted from integrated strategies combining technology, advocacy, surveillance, and independent verification. These lessons offer a model for sustaining polio-free gains, addressing circulating vaccine-derived polioviruses, and strengthening wider health systems.

WEB: 10.3389/fpubh.2025.1690423

IMPACT FACTOR: 3.4 CITED HALF-LIFE: 2.7

#### START COMMENTARY

This case report identifies determinants that enabled Kano State to transition from a high-risk wild poliovirus (WPV) setting to a certified polio-free context and examines lessons for sustaining poliofree status. The primary outcome was successful pre-certification by the African Regional Certification Commission (ARCC), assessed through sustained interruption of WPV transmission, Acute Flaccid Paralysis (AFP) and environmental surveillance, and verification of program documentation. The authors draw on program records from the ARCC and National Primary Health Care Development Agency (NPHCDA), WHO surveillance data, and peer-reviewed literature, supplemented by site visits to two health facilities across two local government areas (LGAs). Increasing trends in routine immunization were linked to improved microplanning, strengthened coldchain infrastructure, and integration with maternal, newborn, and child health (MNCH) services to improve caregiver convenience. Pockets of underperformance prompted more frequent supplemental immunization activities (SIAs), increased use of transit vaccination interventions, and targeted engagement of influencers in areas with persistent vaccine refusal. Social mobilization efforts engaging the involvement of traditional rulers, Muslim clerics, and women's groups were central to shifting community norms and improving vaccine acceptance. Integrated health camps offering combined interventions such as vitamin A supplementation, deworming, and malaria nets added value beyond polio immunization alone. A strength of the report is its detailed operational insight into how verification processes functioned as accountability mechanisms that addressed surveillance and documentation gaps. Limitations include reliance on administrative and grey literature data, lack of primary data collection, and limited generalizability beyond Kano state. The coordinated use of surveillance tools and leveraging community leadership structures offers valuable lessons for cVDPV prevention and broader primary health-care strengthening in similar high-risk settinas.

5. Effectiveness of the RTS,S/AS01E malaria vaccine in a real-world setting over 1 year of follow-up after the three-dose primary schedule: an interim analysis of a phase 4 study in Ghana, Kenya, and Malawi.

Ndeketa L, Haine V, Debois M, Asante K, Agyapong P, Kaali S, et al.

Lancet Glob Health. 2025 Nov 09.

PubMed ID: 41207319

#### **ABSTRACT**

**BACKGROUND:** RTS,S/AS01E was first introduced within the Malaria Vaccine Implementation Programme in selected areas in Ghana, Kenya, and Malawi. A series of post-introduction observational studies were initiated in these areas to assess RTS,S/AS01E safety and effectiveness in real-world settings. Here, we report the results of the interim analysis of the EPI-MAL-003 study secondary objectives related to vaccine effectiveness.

**METHODS:** EPI-MAL-003 was a phase 4, disease surveillance study with prospective cohort event monitoring. The study was performed in routine medical practice settings at 12 sites (four per country) in Ghana, Kenya, and Malawi. Children younger than 18 months were enrolled in exposed clusters (sites where RTS,S/AS01E was introduced) and unexposed clusters; data were collected via active surveillance. In an interim analysis, we estimated the effect of vaccination on the incidence of malaria, all-cause hospitalisations, and malaria-related hospitalisations, the prevalence of anaemia among hospitalised children, and mortality over 1 year of follow-up after primary vaccination with three RTS,S/AS01E doses. These endpoints were analysed in the effectiveness analysis set. The primary endpoints are reported elsewhere, together with secondary safety endpoints. This study is registered with ClinicalTrials.gov, NCT03855995, and is completed.

**FINDINGS:** The first child was enrolled on March 21, 2019, and the cutoff date for the current analysis was Nov 2, 2023. 45 000 children were enrolled (22 426 [49·8%] were female and 22 574 [50·25%] were male). 39 463 children were included in the analyses. When comparing vaccinated children from exposed clusters with unvaccinated children from unexposed clusters, country-adjusted incidence rate ratios were 0·70 (95% CI 0·67-0·73; p<0·001) for any malaria, 0·42 (0·30-0·60; p<0·001) for severe malaria, 0·64 (0·56-0·72; p<0·001) for malaria-related hospitalisations, 0·79 (0·74-0·84; p<0·001) for all-cause hospitalisations, and 0·83 (0·64-1·09; p=0·18) for all-cause mortality. The adjusted odds ratio for the prevalence of anaemia among children who were hospitalised (vaccinated children from exposed clusters vs unvaccinated children from unexposed clusters) was 0·81 (95% CI 0·73-0·90; p<0·001). Similar trends were observed in a before-after comparison with unvaccinated children enrolled in the EPI-MAL-002 study conducted before the RTS,S/AS01E introduction.

**INTERPRETATION:** Over 1 year of follow-up after the third vaccine dose, vaccination with RTS,S/AS01E in real-world settings showed significant reductions in malaria burden. These findings reinforce the continued use of RTS,S/AS01E vaccination in children as an effective public health measure to reduce malaria-related illness and mortality in endemic regions, and highlight its relevance for future malaria control strategies.

FUNDING: GSK.

WEB: 10.1016/S2214-109X(25)00415-2

IMPACT FACTOR: 18.0 CITED HALF-LIFE: 4.8

#### START COMMENTARY

The EPI-MAL-003 study is a large prospective phase 4 observational cohort evaluating the safety, effectiveness, and public health impact of the RTS,S/AS01E malaria vaccine in Ghana, Kenya, and Malawi. This interim analysis examines vaccine effectiveness over one year after completion of the three-dose primary series. Effectiveness outcomes include: malaria incidence, all-cause and malaria-related hospitalizations, anemia prevalence among hospitalized children, and mortality. For all endpoints, vaccinated children experienced lower incidence rates compared to unvaccinated children. Country-adjusted estimates indicated approximately a 30% reduction in malaria incidence and a 58% reduction in severe malaria during the year following the third dose. These findings aligned closely with results from prior clinical trials. Interestingly, authors noted that the observed reduction in all-cause mortality among vaccinated children may reflect broader health benefits beyond direct protection from malaria, potentially through reduced vulnerability to other infections or malaria complications. Interpretations of this study are limited by its observational design, and potential residual confounding between vaccinated and unvaccinated individuals related to healthseeking behaviors and prevention habits, and heterogeneity in malaria transmission across sites. Implications of this study support the continued use and scale-up of RTS,S/AS01E as an effective measure to reduce malaria in endemic regions.

6. MPOX outbreak in Africa: the urgent need for local manufacturing of the vaccine and decolonized health systems.

Cynthia A, Nchanji G.

BMC Public Health. 2025 Nov 08;25(1):3838.

PubMed ID: 4120415841366359

#### **ABSTRACT**

**BACKGROUND:** The resurgence of MPOX (formerly known as Monkeypox) across African countries has highlighted longstanding deficiencies in epidemic preparedness, vaccine access, and healthcare infrastructure on the continent. Despite bearing a significant disease burden, African nations continue to face delays in vaccine acquisition and distribution, reflecting more profound structural and historical inequities.

**METHODS:** This systematic review synthesizes literature published between 2016 and 2024, including peer-reviewed articles, policy documents, and institutional reports. The review aims to explore the dynamics of MPOX outbreaks in Africa, patterns of vaccine inequity, and the systemic limitations that hinder local response capacity. A narrative synthesis approach was employed to analyze data relating to vaccine access, production capacity, regulatory environments, and structural determinants of health.

**RESULTS:** The findings reveal Africa's continued dependency on external vaccine sources, shaped by colonial legacies and weak local pharmaceutical systems. During the 2022 global MPOX outbreak, high-income countries swiftly secured vaccine supplies, while African nations experienced significant delays despite high transmission rates. Although efforts to establish local manufacturing are emerging, they are constrained by limited infrastructure, fragmented regulatory systems, shortages of skilled workers, and restrictive intellectual property regimes. Furthermore, the review identifies a need for harmonized regulatory frameworks and sustainable investment in regional manufacturing capabilities.

**CONCLUSION:** Addressing MPOX and future health threats in Africa demands a shift toward decolonized health systems that emphasize South-South collaboration, indigenous knowledge, and local ownership. Strategic interventions, such as regulatory harmonization, equitable technology transfer, and capacity-building, are essential to reduce external dependency. Coordinated short-term actions and long-term investments are crucial for fostering resilient, self-sustaining health systems that can respond effectively to emerging infectious diseases.

WEB: 10.1186/s12889-025-25120-x

IMPACT FACTOR: 3.6 CITED HALF-LIFE: 5.4

#### START COMMENTARY

This scoping review investigates recent MPOX outbreaks in Africa and advocates for decolonizing health systems and establishing local vaccine manufacturing to address historical and systemic public health challenges. The authors illustrate how differential colonial legacies have produced fragmented regulatory dependencies across African countries which shapes how medicines have been procured and authorized. During the 2022 and 2024 MPOX outbreaks, these dependencies contributed to delayed vaccine access despite high disease burden and reinforced Africa's reliance on external suppliers. However, these legacies are now being actively reshaped through localized African regulatory leadership. Regional initiatives such as the African Vaccine Regulatory Forum (AVAREF) and the African Medicines Agency (AMA) are establishing unified, African-led regulatory pathways that align with international standards while maintaining local control. AVAREF greatly accelerated vaccine trial approvals during the West African Ebola outbreak and demonstrated the capacity of regionally tailored mechanisms to expedite access to essential vaccines without compromising safety. Despite these advances, fragmented approval processes persist and contributed to delays in MPOX vaccine deployment, underscoring the need to operationalize regulatory reliance and emergency response pathways across the continent. A strength of this review is its synthesis of policy discussions linking regulation, manufacturing, and outbreak response in Africa. However, the study provided limited insights into specific, country-level capacities. The authors recommend pairing investments in local manufacturing with regional research and clinical trial capacity and strengthening reliance pathways between national and regional regulators such as AMA and AVAREF.

7 Financial risk protection from vaccines in 52 Gavi-eligible low- and middle-income countries: A modeling study.

Jiao B, Sato R, Mak J, Patenaude B, de Villiers M, Deshpande A, et al.

PLoS Med. 2025 Nov 04;22(11):e1004764.

PubMed ID: 41187138

#### **ABSTRACT**

**BACKGROUND:** Poverty alleviation is a major global development goal. Vaccines have the potential to provide financial risk protection (FRP) by preventing illnesses and associated healthcare costs. We estimate the lifetime FRP benefits generated by major vaccines among individuals vaccinated between 2000 and 2030 in low- and middle-income countries (LMICs).

METHODS AND FINDINGS: We developed a microsimulation model to quantify the number of cases of catastrophic health expenditure (CHE) averted by a range of vaccines in 52 Gavi-eligible countries, stratified by wealth quintile. Vaccines protecting against five pathogens were considered, i.e., hepatitis B (routine and birth dose vaccine), Haemophilus influenzae type B, rotavirus, measles (routine and supplementary campaign vaccine), and Streptococcus pneumoniae. Model inputs were obtained from secondary data sources, including infection reduction rates under various immunization coverage scenarios, out-of-pocket health expenditures, transportation costs, wage losses, and healthcare utilization associated with disease treatment and consumption expenditures. CHE cases were defined as exceeding 10% of annual consumption, with sensitivity analyses conducted using thresholds of 25% and 40%, as well as impoverishing health expenditures were estimated. All vaccines, singly and collectively, showed a large impact on FRP and could avert ~200 million CHE cases across 52 Gavi-eligible countries from 2000 to 2030. Importantly, about half of all CHE cases were prevented among the poorest quintiles. When evaluated at a 10% threshold for CHE, the first dose of measles vaccine stood out in averting around 1,400 CHE cases per 10,000 vaccinated individuals in the poorest quintile, that is a total of 44 million CHE cases averted. A key limitation is the assumption of uniform disease risks in the absence of vaccination across quintiles, which may underestimate benefits for poorer groups.

**CONCLUSIONS:** Vaccines can provide substantial FRP benefits, particularly among the most disadvantaged populations. Sustained investments to ensure vulnerable populations receive vaccinations in LMICs can therefore not only improve health outcomes but also contribute to poverty reduction.

WEB: 10.1371/journal.pmed.1004764

IMPACT FACTOR: 9.9 CITED HALF-LIFE: 9.3

#### START COMMENTARY

This modeling study estimates financial risk protection (FRP) benefits provided by several vaccines in 52 Gavi-supported countries, focusing on the prevention of catastrophic health expenditure (CHE). The modeled populations in each country were stratified into 5 wealth quintiles and results were examined separately by quintile. Results showed that amount of financial protection varied by vaccine. The first dose of measles (MCV1) vaccination generated the largest CHE reduction among households in the poorest quintiles while hepatitis B contributed the greatest number of CHE cases averted overall. Although measles treatments costs are relatively low, the large number of cases averted by measles vaccination still translates into substantial financial protection. In addition to CHE, assessment of impoverishing health expenditure (IHE), which captures whether health spending pushes households below the poverty line, showed that measles vaccines in particular had larger effects under this measure compared to other vaccines. Even though measles treatment costs are often too low to exceed CHE thresholds, they can push already poor households into extreme poverty. Strengths of this study include its evaluation of a large number of countries and its equitycentered lens. Combining both CHE and IHE measures provides a more holistic analysis of FRP for informing policy decisions. The model was limited by not accounting for individuals experiencing multiple diseases, repeated illness episodes, or long-term disease complications that could increase out-of-pocket spending. Findings show that sustained investment in equity informed vaccine delivery is a core strategy for both improved health outcomes and poverty reduction in LMICs. Return to List of Articles

# **8.** Gender Barriers to Immunization: A Synthesis of UNICEF's Analyses to Advance Equity and Coverage.

Mansilla C, Kamlongera A, Dadari I.

Vaccines (Basel). 2025 Oct 28;13(10).

PubMed ID: 41150445

#### **ABSTRACT**

**BACKGROUND/OBJECTIVES:** Despite global efforts to improve childhood immunization rates, gender-related barriers continue to hinder equitable access to vaccines worldwide. This study synthesizes gender barrier analyses conducted in various countries to better understand these challenges. This evidence synthesis aims to (1) identify the main gender-related barriers affecting immunization focusing on zero-dose targets, HPV, and COVID-19 vaccination campaigns; and (2) summarize key recommendations and lessons that have emerged from countries to overcome those gender barriers.

**METHODS:** A documentary analysis was used by reviewing data from gender barrier analyses that were conducted by multiple governments with UNICEF support. The study classified barriers using the socio-ecological model (SEM), encompassing systemic, health service, community, household, and individual-level gender barriers. Descriptive statistics and inductive thematic coding were used to analyze data.

**RESULTS:** This synthesis includes 24 documents representing gender barrier analyses across 29 countries. Findings highlight multiple barriers, including systemic discrimination against women in public and healthcare spaces, limited political will to address gender disparities, and limited (sex)-disaggregated and gender data. At the community and household levels, social norms restrict women's autonomy in seeking immunization services, while household duties (culturally assigned to women) also restrict their access to immunization services. Adolescents face additional challenges, particularly regarding HPV vaccination, due to misconceptions and stigma from families and peers.

**CONCLUSIONS:** Addressing gender-related barriers requires a multi-level approach, integrating gender-responsive policies, and comprehensively addressing gender barriers that are hindering the progress of vaccination efforts. UNICEF's commitment to gender-responsive immunization strategies is critical for achieving the Immunization Agenda 2030 and ensuring equitable vaccine access for all.

WEB: <u>10.3390/vaccines13101059</u>

IMPACT FACTOR: 3.4 CITED HALF-LIFE: 2.8

#### START COMMENTARY

This qualitative study examines how gender-related barriers shape immunization access and delivery across 29 countries using the socio-ecological model (SEM). Barriers were identified at every level of the SEM. Notably, while several system-level barriers were not inherently gender-related, some became gender-related when intersecting with gender dynamics. For example, banning of vaccination outreach services reduces overall access but disproportionately affects women, who already face mobility and access constraints. Reduced clinic hours and long wait times also have greater impact on women due to community-level norms that restrict time and movement. This study draws on analyses across several countries with diverse contexts and includes representation from fragile and conflict-affected settings. Using the SEM allowed for systemic classification of barriers relevant to policy and programming. However, findings are limited by heterogenous country reports without formal quality assessments. This study suggests that gender-responsive immunization requires redesigning service delivery through outreach, clinic hours aligned with caregiver labor, and safer conditions for female health workers.

9. Cost-effectiveness and budget impact of malaria, measles, and meningitis vaccines in Africa: a scoping review.

Anosike C, Ojiakor I, Etiaba E, Uguru N, Ezenduka C, Onwujekwe O.

Vaccine. 2025 Nov 15;67:127853.

PubMed ID: 41110197

#### **ABSTRACT**

**OBJECTIVES:** Despite the availability of malaria, measles, and meningitis vaccines in Africa, limited evidence on their cost-effectiveness and budget impact hinders informed policy decisions and sustainable allocation of scarce healthcare resources. We conducted a scoping review to synthesize available evidence on the cost-effectiveness and budget impact analysis of malaria, measles, and meningitis vaccines in Africa.

**METHODS:** A literature search of PubMed, HINARI, and EBSCO Host databases was conducted to identify studies published in English between 2004 and 2024. The review was conducted and reported according to PRISMA-ScR guidelines. Eligible studies focused on the cost-effectiveness or budget impact of malaria, measles, and meningitis vaccines in African countries. Retrieved articles were subjected to title, abstract, and full text screening to determine if they met the eligibility criteria. Data was extracted from included papers, and incremental cost-effectiveness ratios were extracted or computed, when feasible, in 2024 US dollars.

**RESULTS:** Forty-one (41) of the 885 retrieved articles were included in this review. The costing approach varied, with most studies valuing only direct costs. Transmission, mathematical, and Markov models were the predominant cost-effectiveness modelling methods. The cost per fully vaccinated child for malaria and measles vaccines ranged from US\$4.20 to \$52.35 and US\$1.66 to \$4.31, respectively. The costs per disability-adjusted years (DALYs) averted for malaria, measles, and meningitis vaccines ranged from US\$22.63 to US\$3314.01, US\$1.60 to US\$1239.35, and US\$66.64 to US\$4586.72, respectively. Most studies found that the three vaccines were more cost-effective than no intervention or other public health interventions. The budget impact of introducing the malaria vaccine in 41 African countries is about US\$185 million.

**CONCLUSION:** There is limited evidence on the cost-effectiveness of the malaria, measles, and meningitis vaccines in Africa. The vaccines were largely cost-effective in Africa, although the budget impact of malaria vaccine is substantial.

WEB: 10.1016/j.vaccine.2025.127853

IMPACT FACTOR: 3.5 CITED HALF-LIFE: 8.2

#### START COMMENTARY

This scoping review synthesizes economic evaluations of malaria, measles, and meningitis vaccines and delivery strategies in Africa with a focus on cost-effectiveness using cost per DALY averted and budget impact. Cost-effectiveness of malaria vaccines improved when vaccines were delivered using age-targeted, four-dose schedules in high-burden settings and when combined with insecticide treated nets and other existing control strategies. Campaigns targeting children aged 2-12 years had lower incremental cost-effectiveness ratios (ICERs) compared to those targeting infants because child vaccination strategies were driven by higher effectiveness of the malaria vaccine for this age group. For measles, broader vaccination strategies covering wider age groups were more costeffective than narrow approaches. Delivering measles through both routine immunization or a combination of routine and supplemental immunization provided the best value for maximizing coverage. Meningitis vaccines were likely to be cost-effective if the incidence rate did not exceed the epidemic threshold of meningitis among children living in the African meningitis belt. Findings are limited by substantial heterogeneity in costing methods and limited reporting of budget impact across studies. The study suggests that African policymakers can use this evidence to inform decisions on vaccine delivery and targeting while considering local epidemiology and implementation context.

10. A landscape analysis of the vaccine ecosystem in Africa: research and development funding, clinical trials, regulation, and manufacturing readiness.

Fleck-Vidal C, Le Moal A, Mogeni O, Shaffer D, Canouet V, Ndembi N, et al.

Lancet Glob Health. 2025 Oct 18;13(11):e1983-e1990.

PubMed ID: 41109268

#### **ABSTRACT**

Vaccines are vital for global health, and despite bearing the highest burden of infectious diseases, Africa manufactures less than 1% of its vaccine needs. This Health Policy paper offers an overview of Africa's vaccine ecosystem, examining research and development funding, clinical trials, regulatory maturity, and manufacturing readiness with publicly available data. Funding for research and development (2007-23) was analysed with data from the G-FINDER database, which focuses on diseases disproportionately affecting low-income and middle-income countries. Clinical trial activity (2007-24) was assessed with data from multiple sources. Disease burden context was provided by the Global Burden of Disease Study 2021, and regulatory maturity levels were obtained from WHO's list of National Regulatory Authorities. Findings show that Africa received less than 2% of global vaccine research and development funding, with 95% of that funding channeled through high-income countries. Only 8% of global vaccine clinical trials included sites in Africa. Progress in regulatory and manufacturing capacity is emerging, with eight countries reaching WHO maturity level 3 and several countries planning vaccine production facilities. Our findings highlight the need for better vaccine data in Africa and the opportunity to build on existing strengths to reach enhanced sovereignty and resilient health systems.

WEB: <u>10.1016/S2214-109X(25)00314-6</u>

IMPACT FACTOR: 18.0 CITED HALF-LIFE: 4.8

#### START COMMENTARY

This landscape analysis provides an overview of Africa's end-to-end vaccine value chain by examining vaccine research and development funding, clinical trials, regulatory capacity, and manufacturing readiness. While the region has made progress in manufacturing and regulatory capacity, vaccine development activity is concentrated in a small number of countries, with Senegal and South Africa emerging as having the strongest capacity across the vaccine development pathway, from research to manufacturing. Countries such as Egypt, Ethiopia, Nigeria, and Rwanda have developed some capacity but face gaps in research funding. Most trials conducted in Africa reflect the continent's disease burden, focusing primarily on HIV/AIDS, malaria, tuberculosis, and Ebola. However, many high-burden diseases, including several neglected and endemic diseases

(Lassa fever, Marburg virus disease, yellow fever, and meningitis), remain under-researched. This analysis integrates multiple data sources to provide a more complete picture of how different components of the vaccine ecosystem fit together, though gaps in available data limit what can be assessed. For example, much of the funding data focuses on diseases that primarily affect LMICs, meaning funding for vaccines such as influenza or RSV may not be captured, even when trials are conducted in Africa. Findings highlight an opportunity to advocate for more equitable vaccine research and development funding and to build on existing strengths across Africa.

## **Additional Articles of Interest**

- 1 Knowledge, attitudes, and practices (KAP) of the Philippine general public towards human mpox (hMPX): a cross-sectional study. {Full Article}
- 2 Knowledge, perceptions and acceptance of COVID-19 Vaccine in Plateau States, Nigeria: A Qualitative Study. {Full Article}
- 3 Determinants of uptake of childhood immunization in Gboko, Benue State, Nigeria. {Full Article}
- 4 Strengthening the mpox response: how do we balance pragmatism and equity in resource-constrained settings? {Full Article}
- 5 Off-Label use of vaccines may save lives and money: lessons from the province of Quebec, Canada. {Full Article}
- 6 Parental Vaccine Hesitancy, Awareness, and Attitudes Toward Childhood Vaccination in Saudi Arabia. {Full Article}
- 7 Immunization data management practices and data quality in Ethiopia. {Full Article}
- 8 Human papillomavirus infection and vaccination among young females in rural Uganda. {Full Article}
- 9 Health-resilient frameworks and their impact on routine immunisation and Maternal, Neonatal and Child Health services during pandemics in sub-Saharan Africa: a scoping review protocol. {Full Article}
- 10 Health system and caregiver related factors influencing measles vaccination uptake: perspectives of Chadibe village, Botswana. {Full Article}
- 11 BCG Vaccination Coverage and Determinants Among Children in Somalia: A Nationwide Survey Study. {Full Article}
- 12 Barriers and Disparities in Maternal and Child Vaccination Coverage in Galmudug State, Somalia: A Descriptive Study. {Full Article}
- 13 Systems-Integrated Thermostable Vaccine Delivery: Converging Cold-Chain-Free Design, Al-Augmented Formulation, and Climate-Resilient Infrastructure. {Full Article}
- 14 Artificial Intelligence in Vaccine Communication. {Full Article}
- 15 Reducing vaccination pain using a multidermatomal or deltoid region buzzy® applications versus control: A randomized controlled study. {Full Article}
- 16 Health System Determinants of Delivery and Uptake of HPV Vaccination Services Among Involuntary Migrant Populations: A Qualitative Systematic Review. {Full Article}
- 17 Factors contributing to compliance with Expanded Programme on Immunization and RTS, S/AS01 schedules among children aged 24-40 months in Central Tongu District of Ghana. {Full Article}
- 18 Real-world vaccine effectiveness of typhoid conjugate vaccine in children and adolescents: a systematic review and meta-analysis. {Full Article}

- 19 Associations of socioeconomic factors with parents' awareness and acceptability of HPV vaccination in sub-Saharan Africa a systematic review and meta-analysis. {Full Article}
- 20 Physicians' knowledge of, and willingness to encourage caregivers to partake in the RTS S/AS01 and R21 matrix M malaria vaccines roll out a national survey in Nigeria. {Full Article}

## **Appendix**

The literature search for the August 2025 Vaccine Delivery Research Digest was conducted on September 24, 2025. We searched English language articles indexed by the US National Library of Medicine and published between August 15, 2025 and September 14, 2025. The search resulted in 488 items.

#### **SEARCH TERMS**

(((("vaccine"[tiab] OR "vaccines"[tiab] OR "vaccination"[tiab] OR "immunization"[tiab] OR "immunisation"[tiab] OR "vaccines"[MeSH Terms] OR ("vaccination"[MeSH Terms] OR "immunization"[MeSH Terms])) AND ("logistics"[tiab] OR "supply"[tiab] OR "supply chain"[tiab] OR "implementation"[tiab] OR "expenditures"[tiab] OR "financing"[tiab] OR "economics"[tiab] OR "Cost effectiveness"[tiab] OR "coverage"[tiab] OR "attitudes"[tiab] OR "belief"[tiab] OR "beliefs"[tiab] OR "refusal"[tiab] OR "Procurement"[tiab] OR "timeliness"[tiab] OR "systems"[tiab])) OR "vaccine delivery"[tiab] OR "vaccination refusal"[MeSH Terms] OR "immunization programs"[MeSH Terms] OR "zero dose"[tiab] OR "unvaccinated children"[tiab] OR "gavi"[tiab]) NOT ("in vitro"[tiab] OR "immune response"[tiab] OR "gene"[tiab] OR "chemistry"[tiab] OR "genotox"[tiab] OR "sequencing"[tiab] OR "nanoparticle"[tiab] OR "bacteriophage"[tiab] OR "exome"[tiab] OR "exome"[tiab] OR "exogenous"[tiab] OR "electropor\*"[tiab] OR "systems biology"[tiab] OR "animal model"[tiab] OR "cattle"[tiab] OR "sheep"[tiab] OR "goat"[tiab] OR "rat"[tiab] OR "pig"[tiab] OR "mice"[tiab] OR "mouse"[tiab] OR "murine"[tiab] OR "porcine"[tiab] OR "ovine"[tiab] OR "rodent"[tiab] OR "fish"[tiab])) AND "English"[Language] AND 2025/10/15:2025/11/14[Date - Publication]