

# A perspective on the novel pentavalent Men5CV (NmCV-5) meningitis vaccine and Nigeria's pioneering rollout campaign

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## SUMMARY

The burden of meningitis poses great challenges for neurology and global health, manifesting with a range of symptoms from mild fever and headaches, to severe long term complications such as paralysis and cognitive impairment. Unfortunately, those living in endemic regions, especially survivors, are often confronted with the harsh reality of reduced quality of life as measured by disability-adjusted life years. Meningitis is one of the leading causes of mortality and morbidity, especially in the meningitis belt of sub-Saharan Africa, with a recorded disease burden of over 2.5 million cases globally and children under five disproportionately impacted. This paper examines the global burden of meningitis, exploring its prevalence and impact across different regions. It further analyzes the evolution of vaccination strategies for meningitis prevention, emphasizing the recent development and introduction of the novel Men5CV meningococcal conjugate vaccine. Recurrent meningitis outbreaks across the meningitis belt have resulted in significant mortality over decades. A major turning point in the fight against the serogroup A epidemic was the development of the MenAfriVac vaccine, which resulted in declining cases. However, sero-

groups C, W, and X continue to pose problems. The novel pentavalent (Men5CV) vaccine has emerged as a remarkable advancement in the fight against meningitis, with its safety and effectiveness against a variety of serogroups, including the elusive serogroup X, demonstrated in clinical trials. Its prequalification by the World Health Organization (WHO), and subsequent recommendation for incorporation into routine immunization programs issued a new era with the potential for meningitis eradication. Nigeria now sets a benchmark for other nations in the meningitis zone, becoming the first country in the world to roll out the new Men5CV vaccines. Funding from organizations like Gavi, the Vaccine Alliance, highlights the importance of coordinated international efforts aligned with the WHO's roadmap for meningitis elimination by 2030. Stakeholder involvement, extensive immunization campaigns, and a strong healthcare infrastructure are all practical recommendations for public health integration.

*Keywords:* Meningitis, Men5CV, Vaccination, Meningococcal conjugate vaccine, Meningococcal disease.

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## INTRODUCTION

Meningitis, a pernicious inflammation of the central nervous system's protective layers, continues to pose a significant threat to public health, particularly in sub-Saharan Africa (SSA). The neurological sequelae are not limited to the

immediate – with fever, headache, photophobia, and terrifying neck stiffness – but extend far beyond, leaving a trail of long-term outcomes like cognitive decline, hearing loss, paralysis, seizure disorders, and even death [1, 2]. Although fungal, parasitic, and viral subtypes exist, occasionally with a fatal presentation, bacterial meningitis leads in terms of morbidity and mortality, historically causing devastating sporadic outbreaks across the African “meningitis belt” [3, 4]. This region has a population of approximately 400 million individuals in 26 countries, which extends from the Gambia, Guinea, and Senegal in West Africa to Ethiopia in East Africa [4].

The stark burden of meningitis becomes clear when examining the data from the Global Burden of Diseases, Injuries, and Risk Factors Study [5]. In 2019, a staggering 2.51 million cases were reported globally, with under-five children disproportionately affected, having about 50% of these cases [6]. Sub-Saharan Africa emerged as a hotspot, with the highest rates recorded in the Western region (105.8 cases per 100,000 population), followed by Eastern and Central SSA. This translates to a three-fold difference when compared to the global average incidence rate of 35.4 cases per 100,000 population, highlighting the troubling disparity between developed and developing nations [6]. Furthermore, the disease caused over 236,000 deaths, underlining the critical need for improved preventative measures [6].

Surveillance data indicates that three bacterial pathogens are notorious for outbreaks of meningitis: *Neisseria meningitidis*, *Streptococcus pneumoniae*, and *Haemophilus influenzae* type b (Hib) [7, 8]. In Africa’s meningitis belt, *Neisseria meningitidis* serogroup A (NmA) previously accounted for a bulk of the disease burden, while B, C, W, X, and Y strains were also implicated in invasive meningococcal disease (IMD) [9]. However, the 2010 introduction of the meningococcal serogroup A conjugate vaccine (MACV [MenAfriVac]) achieved near-eradication of NmA [10, 11]. This success has spurred the development of broader vaccine groups targeting additional strains (C, W, X, B) as outbreaks shifted. Today, over 53 countries use these new vaccines, with about 27 using quadrivalent (A, C, W, Y) vaccines and nine countries using meningococcal serogroup B vaccines, offering a multi-pronged attack on this devastating disease [12]. The journey to progress has not been without set-

backs as sporadic outbreaks of C and X strains continue, particularly in countries lacking vaccines for those specific strains. Nigeria’s recent serogroup C outbreak highlighted the need for broader vaccine development to achieve eradication targets by 2030 [13].

The race to eradicate meningitis by 2030 is gaining momentum. The World Health Organization’s roadmap provides a strategic framework with three ambitious objectives: eradicating bacterial meningitis epidemics, achieving a 50% reduction in vaccine-preventable bacterial meningitis cases and a 70% decrease in mortality rates, and minimizing meningitis-associated disabilities to improve quality of life [14]. This ambitious plan prioritizes prevention and epidemic control, and recent breakthroughs in vaccine technology are fueling optimism. The introduction of the novel Men5CV strengthens the fight against serogroups A, C, W, X, and Y. Moreover, a significant leap of progress came on April 16, 2024, when the Serum Institute of India signed a technological agreement with the University of Oxford to produce the Meningitis-B (Men-B) vaccines [15]. This collaboration paves the way for a complete vaccine series targeting all six IMD strains, offering hope for eliminating the disease. With an emphasis on the global burden of the disease, recent developments in vaccine technology, and efforts toward disease eradication by 2030, this paper aims to thoroughly examine the historical perspectives of meningitis vaccination, the novel Men5CV vaccine development, and recommendations for public health interventions as Nigeria takes the lead.

## ■ HISTORICAL PERSPECTIVES

The documented history of invasive meningitis dates back to 1805 in Geneva, Switzerland; however, the first epidemic was reported in Africa in 1840. By the early 20th century, the West African region grappled with recurring epidemics, culminating in a devastating peak within Africa in 1996. Over 184,487 documented cases and 16,000 deaths exemplified the difficulties Africa faced [16, 17]. From 1928 to 2018, the continent witnessed a formidable and ever-changing meningitis epidemic, registering 2.6 million cases and exceeding 150,000 deaths. This translated to 216 cases per 100,000 people, highlighting the continent’s long-standing yet often under-recognized battle with meningitis

[7, 10]. Nigeria stands out as a front-line fighter in the meningitis belt, bearing the brunt of over 552,821 cases. However, the threat extended beyond this region, with Egypt, Ghana, and the Democratic Republic of Congo facing their battles. Historically, *Neisseria meningitidis* serogroup A (NmA) is responsible for 80-85% of cases found in the meningitis belt [18]. Globally, meningococcal meningitis claimed approximately 54,400 deaths in 2019 [19].

Recognizing the limitations of the initial polysaccharide vaccines, PATH and WHO established the Meningitis Vaccine Project (MVP) in 2000 [17, 20]. PATH (Program for Appropriate Technology in Health) is an international nonprofit organization that drives transformative innovations in healthcare, partnering with governments and stakeholders to achieve universal health coverage. They focus on four platforms - vaccines and drugs development, diagnostics and devices, health systems, and integrated service innovations - and leverage their scientific and public health expertise to deliver people-centered primary healthcare [12]. The MVP aimed to develop a safe, immunogenic, and affordable NmA conjugate vaccine (MenACV) to address epidemics in the meningitis belt. The Serum Institute of India produced the resultant MenAfriVac (MenACV), demonstrating safety and efficacy through extensive clinical trials conducted in India and Africa [17, 21]. Approved by the WHO in June 2010, MenAfriVac's regional rollout marked a major public health advancement. Subsequently, mass MenACV vaccination campaigns targeted persons aged 1-29 years across 24 nations in the meningitis belt. Remarkably, 15 countries integrated MenAfriVac into their routine childhood immunization programs [22]. This intervention has yielded a success story in public health. Since its introduction, serogroup A epidemics have been contained, with a drastic reduction in cases within the region [20, 22]. By 2021, eight of twelve meningitis belt nations had vaccination coverage rates exceeding 60%, with Burkina Faso leading at 87.3%. Interestingly, Ghana, Sudan, Eritrea, Côte d'Ivoire, the Gambia, Niger, and Mali have crossed 60% coverage rates. Guinea's coverage has remained below 40%, while Nigeria, Chad, and the Central African Republic require further improvement, with projected coverage ranging from 40-60% [11].

The successful eradication of the serogroup A epidemic has not eliminated the threat of meningitis in Africa, as serogroups C, W, and X continue to pose health risks, causing sporadic outbreaks. Serogroup C is implicated in outbreaks, such as 14,000 suspected cases of meningitis in Nigeria in 2017, the recurrent epidemics in Niger between 2020 and 2023, and a current epidemic in Nigeria [23]. In response to this evolving threat, the Serum Research Institute of India developed the pentavalent meningococcal conjugate vaccine (Men5CV) [24].

### ■ THE NOVEL MEN5CV VACCINE: A COLLABORATIVE EFFORT TOWARDS THE DEVELOPMENT

To circumvent the limitations of the monovalent meningococcal MenAfriVac (serogroup A) vaccine and logistic challenges with integrating quadrivalent vaccines (A, C, W, and Y), researchers explored pentavalent options. The outcome of these efforts is the development and rollout of the Men5CV (NmCV-5) vaccine, which holds immense potential for further mitigating the burden of meningitis. The conjugate meningitis vaccine (Men5CV) is the product of a 13-year collaborative effort between PATH and the Serum Institute of India Pvt. Ltd (SIPL), a research project funded by the WHO and the UK government's Foreign, Commonwealth and Development Office (FCDO) [25]. Men5CV is a pentavalent meningococcal vaccine designed to protect against five serogroups of *Neisseria meningitidis*. Unlike previous vaccines with limited strain coverage, the novel Men5CV confers immunity against the five major meningococcal serogroups: A, C, W, X, and Y [25]. The safety, immunogenicity, and efficacy of Men5CV were evaluated through series of clinical trials conducted across African countries, including Burkina Faso, Ghana, and Mali. Phase 1 results demonstrated promising safety and immune response among adults aged 18 to 45 years in the United States [26]. Phase 2 trials supported the effectiveness and safety in pediatric populations aged 12 to 16 months [27]. The Phase 3 trials compared the Men5CV to a previously WHO-prequalified and licensed quadrivalent MenACWY-D vaccine in Mali and Gambia among those aged 2 to 29 years of age [28]. The trial reported a seroconversion rate exceeding 97.2% for serogroup X, with se-

ro-response for other subgroups (A, C, W, Y) ranging from 50% to 97.4% [28]. Notably, the NmCV-5 had mild to moderate adverse events ranging from injection-site reactions and pain, with less than 10% experiencing infrequent events such as upper respiratory tract infection, malaria, and pharyngitis [28].

A Phase 3 trial of the Men5CV vaccine among healthy 9 to 15-month-old Malians is currently underway by researchers at the University of Maryland School of Medicine's (UMSOM) Center for Vaccine Development and Global Health (CVD) [8, 9]. This study, set to be completed in July 2025, aims to evaluate and assess the safety, immunogenicity, use, and non-interference of the Men5CV with routine rubella and yellow fever vaccines [29, 30]. The Infectious Diseases Clinical Research Consortium (IDCRC), in collaboration with the National Institutes of Health's (NIH) National Institute of Allergy and Infectious Diseases, is conducting this final and pivotal trial, where infants will be randomly assigned to receive either the meningococcal vaccine at 9 months or 15 months with a 2:1 ratio favouring the experimental meningococcal vaccine (NmCV-5) over the comparator meningococcal vaccine (MenACWY-TT, Nimenrix) [29, 30].

These trials paved the way for the Men5CV's prequalification by the WHO in July 2023, a crucial step for global access [25]. In addition to being the only meningococcal conjugate vaccine protecting against five meningococcal serogroups A, C, W, X, and Y, it is the first vaccine globally that combats the serogroup X [25]. This prequalification preceded the long-awaited change in meningitis prevention when the World Health Organization's Strategic Advisory Group of Experts on Immunization (SAGE) announced in September 2023 that all 26 countries within the meningitis belt update their routine childhood immunization programs [10]. The recommendation calls for replacing the MenACV vaccine with a newer pentavalent meningococcal Men5CV conjugate vaccine.

### ■ LAUNCH AND APPROVAL: NIGERIA TAKES THE LEAD

Nigeria, being one of the 26 African countries in the African meningitis belt, has taken the lead to become the first country in the world to introduce the Men5CV vaccine in March 2024 [13]. The deci-

sion to implement a new meningitis vaccination program was driven by Nigeria's substantial burden of meningococcal meningitis outbreaks. Between October 1st, 2023, and March 11<sup>th</sup>, 2024, seven Nigerian states reported over 1,742 suspected and confirmed cases of *Neisseria meningitidis* serogroup C meningitis, tragically resulting in 153 deaths [13].

This recent upsurge in cases and the urgency for a broader-spectrum vaccine with increased coverage led the Nigerian government to adopt the Men5CV vaccine, which now tackles all five of six major infectious strains of *Neisseria meningitidis*. This strategic step saw a large-scale vaccination campaign with a rollout of the Men5CV across Nigerian states between 25<sup>th</sup> and 28<sup>th</sup> March 2024. The campaign achieved coverage of over one million individuals within the target age group of 1-29-year-olds [32]. This proactive approach has set the pace for other countries within the meningitis belt, and further mirrors Nigeria's commitment to public health development and its leadership's dedication to tackling meningitis in the country.

Funding from Gavi, the Vaccine Alliance, played a pivotal role in facilitating the vaccine's rollout in Nigeria in December 2023. In addition, relevant regional stakeholders such as the Nigeria Centre for Disease Control and Prevention (NCDC) have been invaluable in the campaign, supporting health promotion, health workers training, and public sensitization and awareness. Further roll-outs are now expected across the regions following Nigeria's strategic lead.

### ■ RECOMMENDATION FOR PUBLIC HEALTH INTEGRATION

To achieve the ambitious goal of epidemic control of IMD and elimination of bacterial meningitis by 2030, a multi-pronged approach is needed [14]. Aligning national strategies with WHO's roadmap requires rapid deployment of Men5CV. Integrating this vaccine into routine immunization programs and targeted campaigns is paramount to reducing meningitis incidence and preventing future outbreaks. The extensive MenAfriVac adoption across Africa reduced meningococcal meningitis cases drastically [22], demonstrating the potential for the novel Men5CV vaccine to achieve eradication. To ramp up ongoing preven-

tive efforts and further align with the WHO's eradication plans, integrating the Men5CV into expanded immunization programs across the meningitis belt becomes imperative. In a move to drive increasing awareness, Men5CV catch-up campaigns in high-risk areas, particularly in the meningitis belt, should be prioritized.

Beyond regional focus, ensuring travelers to and from endemic countries are vaccinated against all major serogroups of IMD with valid proof is crucial to accelerate the current campaigns and prevent international disease spread. Travel medicine physicians and practitioners play a crucial role in educating travelers about meningitis risks and prevention, potential complications, and the promising efficacy of the Men5CV vaccine. Incorporating them into meningitis prevention strategies will ultimately reduce the global burden of the disease. Furthermore, efforts should be made towards recruiting and training community healthcare workers in endemic areas on appropriate vaccination shot delivery, campaign implementation, and community outreach strategies. This will involve prioritizing financial investment in healthcare infrastructure to support these initiatives and reduce the knowledge gaps among healthcare workers regarding meningococcal disease and vaccine recommendations [33].

Technological advancements, particularly Geographic Information Systems (GIS), along with skilled GIS experts, are essential for identifying and mapping isolated and remote populations, ensuring their inclusion in vaccination campaigns. This targeted approach enhances vaccination coverage, overall effectiveness, and reach to frequently overlooked communities.

Elimination efforts cannot succeed without robust community management. Stakeholder engagement at all cadres, including the involvement of community leaders, town criers, community residents, and community instructors, will be essential for information dissemination addressing vaccine hesitancy and promoting widespread participation in prevention efforts. Furthermore, optimizing vaccine supply chains by involving logistics experts will minimize waste while ensuring equitable distribution across regions. Health systems must design and adhere to an approved distribution matrix to ensure early deployment and widespread accessibility. Investing in a robust cold chain infrastructure is equal-

ly needed to maintain vaccine viability and efficacy in the long term, particularly during storage and transportation. The use of artificial intelligence and machine learning algorithms to forecast and predict clustering patterns, especially in new endemic areas outside the meningitis belt for massive vaccination, will be an advanced and proactive approach. Finally, fostering continuous international collaboration with epidemiologic specialists, funding bodies, and health policy implementation agencies is essential for sustainability. This will ensure timely vaccine production during stockouts, enhance disease mapping and epidemic response, and will support global meningitis eradication.

## ■ CONCLUSIONS

Meningitis epidemics persist in Africa's "meningitis belt," with sporadic upsurges across various regions, leading to increased case fatalities and disproportionately impacting children. However, a new hope for elimination has emerged with the development of the Men5CV vaccine. The novel pentavalent Men5CV vaccine developed as a result of a 13-year collaboration between PATH, SIIPL, WHO, and the UK Government, has shown potential to build on the successes of the monovalent MenAfriVac in eradicating meningitis by 2030. Several rounds of clinical trials have confirmed the safety, immunogenicity, and effectiveness; an impressive 97% immunogenicity for the challenging serogroup X strain has been reported, with mild and manageable side effects. Following the WHO's prequalification in July 2023 and the SAGE's recommendation for integration in September 2023, Nigeria has led the charge as the first country to carry out a massive rollout campaign with over a million vaccines distributed. This feat has set the pace for other countries in the meningitis belt to incorporate the Men5CV into their expanded programs for immunization (EPI). We recommend rapid deployment of vaccines, utilization of GIS technology and machine learning, and health system structures to ensure equitable distribution and large-scale reach. Swift action by key stakeholders, including field experts, logistics and supply chain professionals, governments, funding agencies, and policy-implementing organizations, assures sustainable, rapid, and scalable vaccine distribution.

**Conflicts of interest**

None to declare.

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**Authors contributions**

All authors contributed equally to the writing of this manuscript, and I've read and approved the final draft.

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