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Lessons for strengthening childhood immunization in low- and middle-income countries from a successful public-private partnership in rural Nigeria

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Background: Immunization is a cost-effective public health strategy to reduce vaccine preventable disease, especially in childhood.

Methods: This paper reports the philosophy, service delivery, achievements and lessons learned from an immunization program in rural Nigeria privately financed via a corporate social responsibility initiative from GlaxoSmithKline Biologicals.

Results: The immunization program served the community for a 16-y period extending from 1998 until 2015, resulting in an increase in age-appropriate immunization coverage from 43% to 78%.

Conclusion: In its success, this immunization program exemplified the importance of early and sustained community engagement, integration of strategies to optimize implementation outcomes and effective team building well before some of these principles were accepted and codified in the literature. The project also underscores the important role that the private sector can bring to achieving critical immunization goals, especially among underserved populations and provides a model for successful public-private partnership.

Keywords: childhood immunization, immunization coverage, private sector, public-private partnership, vaccination.

Introduction

Immunization is consistently described as one of the great success stories of modern medicine. Childhood immunizations are estimated to prevent 2–3 million deaths per year and are not only cost-effective, but also cost-saving.¹ Among the world's most economically deprived countries, each 1US\$ investment in vaccination is associated with 16US\$ savings in healthcare costs, lost wages and lost productivity from illness or death.^{2,3} With a very early recognition of the potential importance of vaccines for all children, the WHO launched the expanded program on immunization (EPI) in 1974, and urged countries to ensure that chil-

dren across the globe would benefit from this life-saving preventive measure.⁴

Despite the numerous benefits of childhood immunization, coverage, especially in low- and middle-income countries (LMICs), remains low and vaccine-preventable diseases remain a foremost cause of under-five mortality in sub-Saharan Africa.⁵ In 2018, an estimated 19.4 million infants did not have access to routine immunization services worldwide, with 60% of them residing in 10 countries, namely, Angola, Brazil, the Democratic Republic of the Congo, Ethiopia, India, Indonesia, Iraq, Nigeria, Pakistan and South Africa.^{6,7} In the same year, Nigeria alone accounted for >25% of the world's unvaccinated children.⁶ The

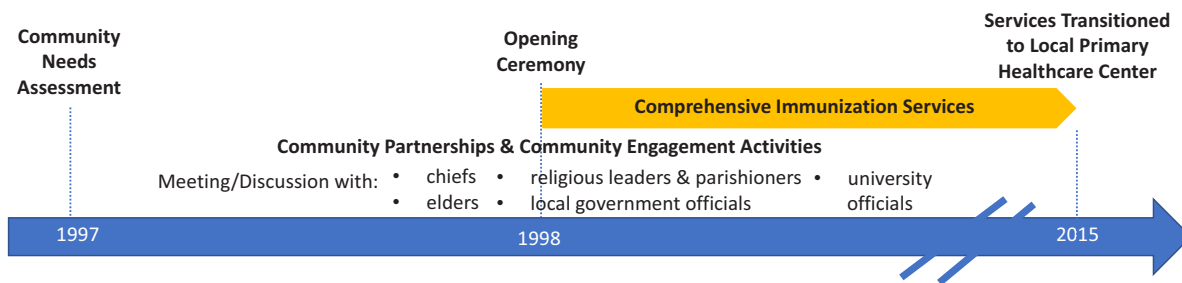


Figure 1. Timeline of pre-implementation, implementation and transition activities for the Sabongidda-Ora Vaccination Project.

Nigerian EPI commenced in 1979 with the aim to provide routine immunization to children aged >24 mo and to address high infant morbidity and mortality.^{8,9} Despite initial successes in the early 1990s, Nigeria has since experienced a consistent decrease in immunization coverage. In 1996, national data showed a decline to <30% immunization coverage for all age-appropriate antigens.⁸⁻¹¹ A number of individual, family, community and health-system factors likely contribute to low immunization coverage in Nigeria.^{1,9,12-15} Intertwined in each of these categories is Nigeria's political backdrop, which has demonstrated waxing and waning governmental commitment to reaching its EPI goals.^{9,12,13}

Globally, successful immunization initiatives have been made possible through collaborations between governmental and non-governmental organizations, international and multilateral donor agencies and the private sector.^{16,17} In the vast majority of LMICs, publicly funded immunization services are provided solely by public providers.¹⁶ Private sector-supported immunization services have generally favored more resourced individuals in access to immunization programs, thus exacerbating inequities.^{16,17} However, the private sector has also been seen to play a vital role in reducing inequities in vaccine access, especially in hard-to-reach or conflict-affected areas and among marginalized populations.^{16,17} International organizations or initiatives, like the Global Alliance for Vaccines and Immunization (GAVI), have established effective partnership models to both drive down the cost of vaccines and promote vaccine delivery to partner countries.¹⁸ Another area that has received growing attention is corporate social responsibility (CSR), defined as 'the overall contribution of a business to sustainable development'.¹⁹ CSR rests on the premise that many companies have at least some negative impact on their consuming communities and should offset some of the negative impact with intentional, positive acts.¹⁹⁻²¹ Pharmaceutical companies are in a particularly unique position in this regard because their company decisions have direct impacts on human health, some of which have been harshly criticized.²⁰⁻²² In the last 20 y or so, CSR efforts have increased greatly, especially in LMICs.²²

In this paper we describe a public-private partnership, supported by CSR, which successfully administered a childhood immunization program in rural Nigeria from 1998 to 2015. The program's explicit goal was to provide free, comprehensive immunization services for children without routine access until government-sponsored services were made available. We summarize key steps in the program development, including conducting a baseline needs assessment, identifying community part-

ners, engaging key stakeholders in the community, delivering the program and measuring its effectiveness (Figure 1). We highlight important lessons learned—which are ever more relevant with the current, unprecedented global spread of the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)—and may serve as a model that can inform the development of successful CSR-driven partnerships for critical health services and the scaling up of novel vaccines.

Methods

Project setting: rural Nigeria

At a time of economic stagnation and increasing unmet health needs in Nigeria in the 1990s, the prospects for addressing the weak public health system seemed bleak. The picture was even more dire in Nigeria's rural communities. Our program site, Sabongidda-Ora, is one of six local communities, with a combined estimated population of 70 000. Without a substantial local industry, employment or revenue base, the primary occupations are subsistence farming and simple artisan work, and the average annual income was US\$302-837 (1997). About 60% of the households used a pit latrine and there was no communal solid waste disposal system. Reliable health statistics were unavailable on the prevalence of communicable diseases among <5-y-old children. We suspected low vaccine coverage rates (this was later confirmed during our baseline assessment, where only 43% of children had complete, age-appropriate coverage).

Community assessment: defining the need

To assess the need for a vaccination intervention in Sabongidda-Ora, we conducted a needs assessment informed by in-depth interviews with three populations: (1) community representatives in the church and local government (n=10); (2) medical directors at the healthcare facilities in the community (n=3); and (3) mothers of children aged <5 y (52 mothers of 82 children in the target age group). Key informants were interviewed to better understand community characteristics, current availability and the scope of general health services, current health-related practices of the target population (children aged <5 y) and awareness and attitudes towards immunization.

Our community assessment revealed several key findings. Community members had been well educated on the EPI's efforts, and mothers were very interested in immunizing their

children, but the availability of immunizations was poor. The community was served by a 30-bed general hospital, primary healthcare center and one private clinic. Only the primary healthcare center offered routine childhood immunization, but the clinic experienced shortages and reported an ineffective back-up power generator system for vaccine storage. There was concern about both the timeliness and effectiveness of vaccines. Of all the children represented in the survey (n=82), 38% had been diagnosed with measles in the past. Among them, 17% reported not having received a measles vaccine, while 21% reported contracting measles before and 62% after vaccination. Accordingly, based on their anecdotal experience, medical providers at the general health hospital cited measles as one of the top five presenting diagnoses for children aged <5 y.

Aligning priorities for a public-private partnership

Our needs assessment provided clear support for an initiative focused on strengthening childhood immunization. This focus was a strategic fit for GlaxoSmithKline Biologicals (GSKBio) as a leading manufacturer and supplier of vaccines worldwide. In 1995, the worldwide clinical working group of GSKBio, tasked with global vaccine clinical development, unanimously embraced the mantra of CSR. The working group subsequently committed to promote community partnership initiatives in three geographic regions within its areas of operation. We submitted a proposal to provide affordable childhood immunization services in Sabongidda-Ora, to fill a needed gap in health services, and provide capacity building and local support to facilitate the establishment of a public primary healthcare service to which we would transition this care. Our proposed Sabongidda-Ora Vaccination Project was selected as an inaugural project of this initiative with funding, operational and logistical support provided by GSKBio and its subsidiary, GSK Nigeria Plc. The project management team included company leaders in the USA, Belgium and Nigeria.

Project implementation

Community engagement

Our community-engaged approach included outreach to leaders across several community layers. Multiple consultations were organized to galvanize alignment with the traditional rulers of Sabongidda-Ora first, and subsequently with the six neighboring communities. The traditional rulers understood and agreed with the need for childhood vaccination services; and in their capacity as key influencers, they helped to create awareness of the new program and encouraged mothers of young children to receive vaccination for their babies. Further consultations led to approvals from the local government authority and the Edo State Ministry of Health. This elaborate series of consultations fostered a collaborative and supportive relationship with stakeholders who represented a community advisory board that advised on pre-implementation, facilitated recruitment and provided ongoing program support. Involvement of the local, state and federal health authorities was critical for the development of a transition plan that was articulated very early in the planning process.

We assembled a cohesive, multidisciplinary team that had expertise in public health nursing, family medicine, vaccinology and pharmaceutical medicine. Importantly, several team members, including one of the international program leaders, a family

Table 1. Vaccination schedule

Age	Vaccines administered
Birth	BCG, OPV0, HBV1
6 wk	DPT1, OPV1, HBV2
10 wk	DPT2, OPV2
14 wk	DPT3, OPV3, HBV3
9 mo	Measles, yellow fever

Abbreviations: BCG, Bacillus Calmette-Guerin; DPT, diphtheria-pertussis/whole cell-tetanus; HBV, hepatitis B vaccine; OPV, trivalent oral polio vaccine.

physician, a public health nurse, a clerk and a security guard, were also members of the community we served. Their knowledge of local tradition and culture, combined with their commitment to the health of the community, were very helpful in maximizing program delivery by allowing us to foster ongoing community-engaged strategies to facilitate program success.

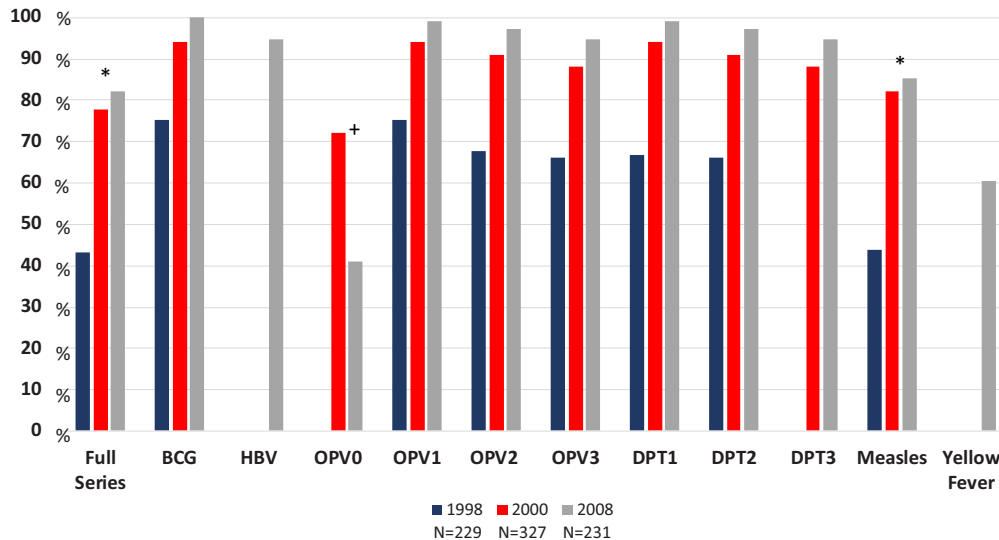
Immunization services

One important objective of the project was to raise childhood immunization levels to WHO EPI-recommended targets. The vaccines were Bacillus Calmette-Guerin (BCG), trivalent oral polio vaccine (OPV), hepatitis B vaccine (HBV), diphtheria-pertussis/whole cell-tetanus (DPT), measles and yellow fever. DPT and HBV were provided as a combined formulation (TritanrixHB) at 6, 10 and 14 wk of age. Vaccines were provided according to the schedule outlined in Table 1. The clinic operated Monday through Friday with vaccines administered thrice weekly, and served an average of 150 children monthly. We engaged our program staff, community leaders and key informants as local experts, and were committed to being responsive to the needs raised by them about program services. Based on their feedback, in addition to comprehensive vaccine services, our program also provided basic health and hygiene education to the young mothers, both at the program facility and through outreach to nearby communities. Vaccine days started with health education talks, weight checking, growth monitoring and nutrition lessons. We also provided treatment of common ailments and twice-weekly home visits. After-hours medical services were made available in a nearby private hospital for babies with possible vaccine-associated complaints or concerns.

Resources, equipment and supplies

Program costs were supported via GSKBio's CSR initiative. Start-up costs (approximately US\$22 000) covered building remodeling, furnishing and clinic supplies (both vaccine and non-vaccine), and annual operational costs averaged US\$14 000–18 000 per year. The clinic facility was spacious, in a building centrally located and easily accessible. While GSKBio supplied the vaccines and serology assays, non-vaccine supplies, such as multivitamins, antipyretic syrups and general equipment (clinic and administrative), were sourced locally from vetted, reliable vendors. Ensuring a consistent supply chain for supplies was an important priority for the program, both from the perspective of project leaders

Figure 2: Percent Immunization Coverage before, 2, and 8 years after initiation of the Sabongidda-Ora Vaccination Project



All changes from 1998 to 2002, and 2002 to 2008 statistically significant ($p < 0.01$) unless marked. Full series = fully immunized (7 diseases) * No statistically significant change from 2002 to 2008. + Statistically significant decrease from 2002 to 2008 ($p < 0.01$)

Figure 2. Percentage of immunization coverage before, 2 and 8 y after initiation of the Sabongidda-Ora Vaccination Project. BCG, Bacillus Calmette-Guerin; DPT, diphtheria-pertussis/whole cell-tetanus; HBV, hepatitis B vaccine; OPV, trivalent oral polio vaccine.

and community members who expressed concerns about inconsistent availability of vaccines during our needs assessment. The lack of a consistent electrical supply represented a major obstacle to vaccine cold-chain maintenance and raised concerns regarding the program's feasibility. Because diesel-fueled electricity generators were prohibitively expensive to purchase and maintain, we utilized simple, lower-cost kerosene-fueled refrigerators and freezers to maintain the cold-chain. The cold-chain system was checked twice-daily as part of quality assurance.

Maintenance and transition

The project was judged by stakeholders to be very successful, and it accomplished its stated goal, which was to avail the community of cost-free access to primary healthcare and comprehensive immunization services for children without access to services. It operated fully from inception in 1998 until 2015, when services were transitioned to a newly built government-supported primary healthcare center. Once the center began to offer routine childhood immunization services (in addition to inpatient and outpatient care), patients were counseled about the transition process and referred to the new center with updated immunization cards (Figure 1). Program equipment and supplies were donated to the new primary healthcare center and our program was dissolved.

Results

Improved immunization coverage

During the 17 y of the program, our primary mission was to provide no-cost immunization to our target community. Consequently, we witnessed a marked improvement in age-appropriate vaccine coverage, as illustrated in Figure 2. The

proportion of children immunized improved for all vaccines administered from 1998 to 2002 ($p < 0.01$) based on comprehensive household sampling of all children aged 0–2 y residing in Sabongidda Ora.^{14,23,24} This decline was likely attributable to a stock-out or shortage in the hospital supply chain during that period. Improvement persisted was sustained for all others, except for OPV0, which declined from 2002 to 2008 ($p < 0.01$). Our program was associated with a 30-fold increased chance of complete, age-appropriate vaccination relative to other programs in the community.¹⁴

Innovation in vaccine delivery

While our program generally took the approach of aligning vaccine services with Nigeria's EPI program, we did take advantage of the tremendous opportunity to introduce a new vaccine, HBV, into Nigeria's public health service. Because HBV was available in the private sector, and we had the opportunity to offer HBV in a combined formulation of DPT/HBV (TritanrixHB) at little extra cost to the funder, we made this formulation available to the children we served. This immunization innovation conferred the benefits of expanding the spectrum of diseases against which infants would be protected. Immunologic studies from our community cohorts underscored the critical nature of this intervention, as HBV infection (HepB surface antigen positivity) was prevalent in 12% of unvaccinated children compared with only 2% in the vaccinated group.^{15,25}

Local and national recognition

In 2005 and 2007, the Director of National Program on Immunization and the Executive Director of the National Primary Health

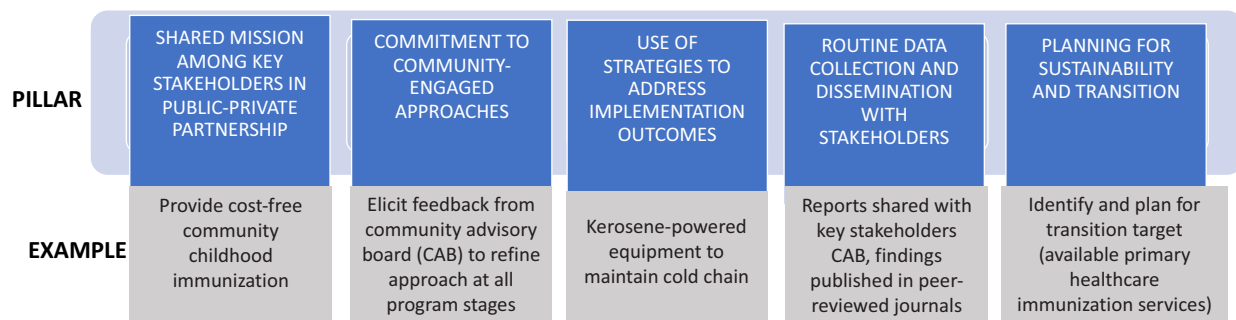


Figure 3. Key pillars of the program's success.

Care Development Agency, respectively, ranked the project as of the highest standard among donor-sponsored health initiatives in Nigeria.

A further testimony of success was the unanticipated number of visitors and guests who toured or inspected our project facilities and operations.

The impact of the program in the local community was similarly profound. Traditional rulers of the Sabongidda-Ora community relayed to us an outcome that they considered important: 'Ai ki che h'owa oimi fieo a' they said in the local language, Ora ('no more look away, an infant corpse is approaching the grave'). According to them, the ceremonial foot traffic to and from the children's cemetery substantially diminished once the project started. While a soft metric, this observation, which was eloquently expressed in the native dialect, was quite significant to them and noteworthy to us. Further, community observations were consistent with the published literature on the estimated mortality impact of childhood vaccinations.²⁶ Indeed, one comprehensive report from the GAVI suggests that routine HBV alone, a vaccine that was newly introduced into the community under this program, averts an estimated 8.3 deaths per 1000 persons vaccinated and, in Nigeria as a whole, nearly 10% of deaths were averted by routine immunization.²⁶

Contribution to public health research and knowledge

Although we were operating in a rural resource-limited community, we were keen to establish and maintain international standards and, in particular, disseminate our experience in appropriate scientific and community venues, documenting the steps from our theory of change to actualization and impact. We reported our work in scientific congresses and conferences as abstracts or podium presentations and published our results in peer-reviewed scientific journals.^{14,15,23-25} Locally, we shared monthly and quarterly reports with the local government authority immunization office.

Discussion

The Sabongidda-Ora Vaccination Project represents a successful public-private partnership that was funded through a CSR initia-

tive by GSKBio. At the start of the project, the team of local leaders vested in the community and international leaders committed to the ethos of the CSR initiative envisioned success to be instituting cost-free community childhood immunization to fill a gaping void in the health system of a rural community until the government established a functioning primary healthcare clinic with the capacity to provide affordable, efficient and reliable services to the community. Achieving this objective took 17 y, rather than 5 to 7 years that we had projected. Nonetheless, the project registered a continuous streak of important successes over the course of its operation. This was evidenced by important public health outcomes, such as substantially increased age-appropriate childhood immunization levels, renewing the community's faith and trust in these critical preventive services, attracting the interest and ongoing support of key stakeholders, as well as disseminating our experience through reports to local and national government officials, along with scientific publications.^{14,15,23-25}

The underpinning for the success of our program were key basic principles, among which were conducting a comprehensive needs assessment, collaborative engagement with the community, identification of strategies that would meaningfully address important implementation outcomes (including, but not limited to program effectiveness) and development of a plan for program maintenance and ultimately transition (Figure 3).

Purposeful collaboration with the community and relevant stakeholders to promote the health of its members has been a cornerstone of public health efforts for decades. This collaboration, now appreciated as a fundamental principle of research and public health practice called community engagement, was formally recognized by the Centers for Disease Control (CDC) in the USA in 1995. The CDC's initial primer defined community engagement as 'the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting their well-being'. The approach relies on building partnerships and coalitions that can serve as important catalysts to mobilize resource and influence change.²⁷ The community engagement continuum describes five steps of increasing engagement, which have been shown to positively impact research partnerships in general and immunization programs in particular. The steps consist of outreach, consultation, involvement, collaboration and shared leadership. Community engagement was a fundamental pillar

in the GSKBio Vaccination Program even before it was a named methodologic approach. Indeed, a community engagement approach will be critical to the successful adoption of new vaccine programs, including the present-day roll-out of the SARS-CoV-2 vaccine.

In addition to the incorporation of a community-engaged approach, another important part of our program's success was the use of important principles codified in a now widely employed implementation framework. RE-AIM was clearly articulated in 1999 to guide the effective implementation of evidence-based interventions by promoting successful Reach, Effectiveness, Adoption, Implementation and Maintenance.²⁸ Although not named as such at a time that predated this nomenclature, our implementation strategies incorporated several approaches to optimize these implementation outcomes (including feasibility, acceptability and appropriateness). Our approach included a detailed community engagement plan, as described above, which directly impacted our ability to extend the reach and influence the adoption, acceptability and maintenance of the program at the patient and community levels.²⁸ Careful consideration of logistical facilitators and barriers for provision, storage and the use of equipment and supplies addressed important feasibility issues, and our holistic approach to service provision promoted the adoption and acceptability of the program.

Challenges and lessons learned

Important contextual factors arose and impacted critical implementation outcomes. In this resource-constrained rural community, maintaining a cold chain for vaccine storage was essential. We chose to use kerosene-powered equipment, including refrigerators and freezers, an affordable but not a widely used approach. Fortunately, the equipment performed well throughout and needed only occasional minor servicing, but we were prepared to deploy other affordable strategies if needed. An uninterrupted supply chain was another program priority that allowed us to gain the trust and confidence of the community we served, while also maximizing our ability to administer vaccines according to schedule. The vaccines were imported from Belgium through the Nigerian port city of Lagos, and port customs clearance sometimes caused substantial delivery delays. We arranged to receive interim supplies from GSKBio's country office inventory in Lagos and occasionally from local government supplies. Importantly, these were challenges that were anticipated by our robust program team and the community collaborators, and thus we were able to identify strategies to address them.

While our program represented a success, and had several strengths as enumerated, it also had some weaknesses. While we were fortunate to have gained support from GSKBio for the duration of the program, we did rely on them as our single financial benefactor, which was potentially risky for both short- and long-term financial sustainability. To that end, the community did not engage materially. Another weakness of this report is the limited availability of follow-up immunization coverage data. Although high coverage was maintained, subsequent reports were merged with the local government data, which were not readily available for this article.

The Sabongidda-Ora Vaccination Project offered cost-free access to childhood primary healthcare and an immunization

program that was otherwise unavailable to an underserved, rural Nigerian population. The project was developed and administered within a strategy encompassing evidence-based goal-setting, building of purposeful collaboration, resource mobilization and measuring performance and impact. In addition, before these principles were widely lauded for public health and other interventions, the project also demonstrated key principles of community engagement and implementation science while leveraging a CSR initiative from GSKBio, which also fueled its success. The project delivered its major goals, including raising childhood vaccination rates, contributing to public health research and the transfer of services to a newly constructed government facility. The project represents a successful model for a public-private partnership and highlights how CSR initiatives can be utilized to maximize benefit to the community for critical public health interventions.

Authors' contributions: VIA conceived the manuscript. AAA, OOO and TOD drafted the initial manuscript. LJP and VIA refined the manuscript. EFA, RC and FPM provided critical revisions to the manuscript. All the authors read and approved the final version of the manuscript.

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Ethical approval: Ethical approval was obtained from the Ethics Committee of the Ambrose Alli University College of Medicine, Vanderbilt University Medical Center (protocol no. 211864), and from the community leaders.

Competing interests: FPM was a director at GSK Vaccines until February 2021 and is now an invited professor of vaccinology at the University of Namur, Belgium. The other authors have nothing to disclose.

Data availability: No new data were generated or in support of this research. All original data sources have been cited in this manuscript.

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