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Comparing performance of year-round and campaign-mode influenza vaccination strategies among children aged 6–23 months in Kenya: 2019–2021

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: SSC has since left the US CDC and is currently an employee of Sanofi Vaccines, Lyon, France.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2023.11.036.

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Abstract

Introduction: In 2016, the Kenya National Immunization Technical Advisory Group requested additional programmatic and cost effectiveness data to inform the choice of strategy for a national influenza vaccination program among children aged 6–23 months of age. In response, we conducted an influenza vaccine demonstration project to compare the performance of a year-round versus campaign-mode vaccination strategy. Findings from this demonstration project will help identify essential learning lessons for a national program.

Methods: We compared two vaccine delivery strategies: (i) a year-round vaccination strategy where influenza vaccines were administered throughout the year at health facilities. This strategy was implemented in Njoro subcounty in Nakuru (November 2019 to October 2021) and Jomvu sub-county in Mombasa (December 2019 to October 2021), (ii) a campaign-mode vaccination strategy where vaccines were available at health facilities over four months. This strategy was implemented in Nakuru North sub-county in Nakuru (June to September 2021) and Likoni sub-county in Mombasa (July to October 2021). We assessed differences in coverage, dropout rates, vaccine wastage, and operational needs.

Results: We observed similar performance between strategies in coverage of the first dose of influenza vaccine (year-round strategy 59.7 %, campaign strategy 63.2 %). The coverage obtained in the year-round sub-counties was similar (Njoro 57.4 %; Jomvu 63.1 %); however, more marked differences between campaign sub-counties were observed (Nakuru North 73.4 %; Likoni 55.2 %). The campaign-mode strategy exceeded the cold chain capacity of participating health facilities, requiring thrice monthly instead of once monthly deliveries, and was associated with a two-fold increase in workload compared to the year-round strategy (168 vaccines administered per day in the campaign strategy versus 83 vaccines administered per day in the year-round strategy).

Conclusion: Although both strategies had similar coverage levels, the campaign-mode strategy was associated with considerable operational needs that could significantly impact the immunization program.

Keywords

Strategy; Target population; Coverage; Policy; Program; Infants; Influenza vaccine

1. Introduction

The decision as to whether to implement a year-round or campaignmode influenza vaccination strategy is not straightforward in tropical countries such as Kenya, where influenza circulates throughout the year and there is no defined primary peak in influenza activity [1].

Introduction of influenza vaccine into the national immunization program is currently under consideration – the Kenya National Immunization Technical Advisory Group (KENITAG) made a provisional recommendation in support of influenza vaccination of children <5 years of age, particularly those 6–23 months of age. This provisional recommendation was contingent on additional programmatic and cost effectiveness data being made available to inform a national vaccination program. The additional data would be used to determine the most appropriate strategy for vaccine delivery i.e., whether a year-round or campaign-mode vaccination strategy, provide cost-effectiveness estimates using local data, and evaluate the impact of influenza vaccine introduction on the broader immunisation program [2].

The implementation and performance of a nationwide influenza vaccine program in Kenya would differ from existing vaccine programs within the country and influenza vaccine programs in other countries in several ways. Firstly, unlike other vaccine-preventable diseases for which vaccines are included in the Kenya national immunisation program, influenza is often viewed as a mild illness by parents in Kenya, and the lack of perceived risk of severe outcomes could lead to low vaccine uptake among their children [3]. Secondly, unlike other vaccines in the routine immunisation schedule, the influenza vaccine has a considerably shorter shelf life. Each year, two formulations of the influenza vaccine are available. The Northern Hemisphere (NH) vaccine formulation is available in Kenya from October and expires in July of the following year. The Southern Hemisphere (SH) vaccine formulation is available from April and expires in December of the same year. The short shelf life of the vaccine presents unique challenges for the national program as it requires precise vaccine forecasting to avoid wastage. Lastly, while most countries worldwide have defined influenza seasons, there is significant year-round influenza virus circulation in Kenya [1,4]. While the best strategy for vaccination is established in countries with defined influenza seasons, in Kenya, there is no consensus on the most appropriate vaccination strategy to use [4–7]. Consequently, policy decisions as to which strategy to implement would be greatly influenced by real-world performance of the proposed strategies.

A well-designed demonstration project can test the performance and feasibility of different vaccination strategies to inform national expansion [8]. Indeed, based on costing and sustainability findings from a Human Papilloma Virus (HPV) vaccine demonstration project in Kenya, national roll-out among female adolescents in 2019 was implemented as a health facility-based strategy instead of a school-based strategy [9]. We therefore set out to compare the performance of a year-round versus a campaign-mode vaccination strategy during an influenza vaccine demonstration project among children 6–23 months of age in Kenya. Here we assessed differences in coverage, dropout rates (i.e. failure to get the booster dose), vaccine wastage, and operational needs.

2. Methods

2.1. Study sites and design

We assessed the performance of two influenza vaccination strategies, year-round and campaign, in Kenya's Nakuru and Mombasa counties. These counties were selected because of their participation in the national influenza sentinel surveillance program and their representation of diverse and largely distinct demographic and socio-cultural settings. Nakuru county is in the Rift Valley region of Kenya and has a population of 2.2 million persons, half of whom reside in rural areas and practice farming [10]. Most households are Christian [10]. Twenty-seven percent of residents are in the country's lowest wealth quintile [11], and three of every four children are fully vaccinated (at the time of the Demographic and Health Survey of 2014, a fully vaccinated child at one year of age was defined as having received the following vaccines: one dose of the bacille Calmette-Guerin vaccine, three doses of diphtheria, tetanus, pertussis, hepatitis B and Haemophilus influenzae type b vaccine, three doses of polio vaccines, three doses of pneumococcal vaccines, and one dose of a measles-containing-vaccine).

Mombasa county is in the coastal region and has a population of 1.2 million persons, all of whom reside in urban areas. It represents a more cosmopolitan mix of residents with a significant Muslim population [10]. Forty percent of residents are in the country's lowest wealth quintile [11]. Four of every five children are fully vaccinated [11].

In each county, two sub-counties were selected to participate in the study, Njoro and Nakuru North sub-counties in Nakuru county, and Jomvu and Likoni sub-counties in Mombasa County. These sub-counties were purposively selected based on ease of access and relatively lower risk of spillover of residents and project interventions between subcounties, thereby allowing concurrent assessment of two different vaccination strategies in each county (Fig. 1).

For the year-round strategy, influenza vaccines were available throughout the year at all health facilities that provide vaccination services as part of the national immunization programme, while for the campaign-mode strategy, vaccines were available at health facilities for four months. In both strategies, the vaccines were delivered alongside routine vaccines and other child health services within the health facility. The participating health facilities included facilities owned by the government, private entities, and faith-based organisations.

Preparation for and implementation of the demonstration project was similar across strategies and sub-counties; however, more intensive social mobilisation activities were conducted for the campaign-mode strategy sub-counties, and additional nurses were hired on short-term contracts to support high-volume health facilities for the duration of the campaign [12] (Supplementary information, section 1).

We used both the inactivated trivalent influenza vaccine (from 2019 to mid-2020) and inactivated quadrivalent influenza vaccine (from mid-2020 onwards when the trivalent influenza vaccine was no longer available in the Kenyan market). The inactivated influenza

vaccine which was produced by Sanofi Pasteur (brand name Vaxigrip®/VaxigripTetra®) was registered by the Pharmacy and Poison's Board in Kenya and had been available for use in the country for several years, largely limited to the private sector. Either the Southern Hemisphere or Northern Hemisphere formulation of the vaccine was supplied to health facilities depending on which vaccine formulation was most up to date at the time of the year. Vaccine purchase was planned twice yearly based on assumptions of vaccine uptake in the target population in the coming months. Top-up purchases were made as needed.

The influenza vaccine was available as a prefilled single-dose syringe, administered intramuscularly, to children 6–23 months of age. As per the manufacturer's instructions, children less than 9 years of age who had not previously received the influenza vaccine, should receive a second dose at least 4 weeks after the first dose is given [13]. The influenza vaccine is not widely available in Kenya so it was expected that nearly all children would require two doses of the inactivated influenza vaccine. Although the study was limited to the four sub-counties, children from other sub-counties who attended participating health facilities were also vaccinated and their parents were asked to indicate which sub-county they resided in during the medical visit. While the vaccine was provided at no cost in public health facilities, some non-public institutions charged a nominal fee (Kenya shillings [Kshs] 50–100 equivalent to United States Dollar [$] 0.5–0.9; at a mid-year exchange rate of $1 = 107.85 Kshs in 2021) to cover the costs incurred to administer the vaccine.

2.2. Data collection

Health facilities provided reports of any adverse event following immunization (AEFI) and monthly summaries of the vaccine doses used (i.e., vaccines administered and wasted) using the Ministry of Health vaccine monitoring tools. In addition, hard copy influenza vaccine registers, developed specifically for the project, were used to collect data on the child's particulars (i.e. sex, age, residence, date of vaccination) and whether any other vaccine or Vitamin A was given during the clinic visit. Pictures of handwritten data in the influenza registers (excluding personally identifiable information) were taken using a smartphone application and uploaded to a web server, where they were digitised using ScanForm software [14]. Field officers verified the uploaded digitised data at least thrice a week. These data were used to provide near real-time summaries of vaccination coverage per site.

The number of children vaccinated from the ScanForm database was considered the true record of vaccinated children as the influenza register was the primary verifiable vaccine administration record. Data from ScanForm database were cleaned – duplicate entries, incompatible entries e.g., invalid ages and vaccination dates, and entries of children vaccinated outside the target age group were not included in the analysis. Field officers recorded the number of times a health facility received influenza vaccine stock each month for the duration of the demonstration project. The number of influenza vaccines delivered was dependent on the availability of space within the vaccine fridge at the health facility and projected consumption for the month. Ideally, all vaccines for use within a health facility, including influenza vaccines, should be delivered once a month in keeping with national immunization programme guidelines. Where cold chain capacity was limited or

consumption was higher than expected, more frequent deliveries of influenza vaccine were made and recorded.

2.3. Definition of terms

The **target population** refers to children 6–23 months of age who resided in the study sub-county and were eligible to receive the influenza vaccine. As the size of the population changes over time, the target population was specifically calculated for the period when the first dose of influenza vaccine was available in each sub-county. A detailed description of how the target population was derived is provided in the supplementary text section 2. **Coverage** refers to the percentage of the target population that received the influenza vaccine. It was calculated separately for the first and second doses of the influenza vaccine. It did not include vaccinated children who (i) did not reside in the targeted sub-counties, (ii) were <6 months or ≥24 months of age at the time they were administered the first dose of influenza vaccine, or (iii) were <7 months or ≥25 months of age when they received the second dose of influenza vaccine. Records of children aged ≥25 months when they received the second dose of influenza vaccine were only retained if we could confirm that the child was aged 6–23 months at the time the first dose of influenza vaccine was administered. **The dropout rate** refers to the percentage of children who received the first dose of influenza vaccine and not the second dose, i.e. did not receive the booster dose at 4 weeks. **Wastage rate** refers to the percentage of vaccines used at the health facility level that were not administered to children due to breakage, expiry, cold chain issues, or failure to document vaccine administration.

2.4. Data analysis

The annual target population of eligible children 6–23 months of age for both strategies was obtained from yearly projections for the years 2019–2021 provided by the National Vaccines and Immunization Program (NVIP). NVIP determines the target population in an area using previous years' vaccine consumption rates. The wastage rate for the duration of each vaccination strategy was determined per strategy and sub-county based on health facility reports of vaccines used and administered. Dropout and AEFI rates were calculated for each strategy and sub-county. All other indicators were summarized as means, proportions, or rates.

In our comparison of strategies, we use data from the first year of the year-round vaccination strategy (first 365 days of implementation in each sub county between 2019 and 2020) to compare performance with the first year of the campaign-mode strategy (which occurred in 2021). A comparison of costs between strategies and a qualitative assessment of factors influencing influenza vaccine uptake and refusal are reported separately.

2.5. Ethical approval

Administrative approval to conduct the demonstration project was received from the Office of the Director General, Ministry of Health, Kenya and the Nakuru and Mombasa County health departments through the national council of governors. This activity was also reviewed by U.S. CDC and was conducted consistent with applicable federal law and CDC

policy.[2] Health care workers obtained verbal consent to administer the vaccine from parents before administering the influenza vaccine to their children.

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3. Results

3.1. Summary of the influenza vaccine demonstration project

The year-round strategy ran for 705 days in 37 health facilities in Njoro from November 2019 through October 2021 and 685 days in 13 health facilities in Jomvu from December 2019 through October 2021. The campaign strategy ran for 120 days in 24 facilities in Nakuru North from June to September 2021 and 114 days in 17 facilities in Likoni from July to October 2021. Public health facilities accounted for half of all health facilities in the demonstration project and administered nearly three quarters of all vaccines administered (Supplementary information, Fig. 1). One hundred and twelve thousand vaccine doses were procured for the demonstration project, while health facilities reported administering 83,829 (74.8 %) vaccine doses. Of these administered doses, only 77,277 (92.1 %) doses could be accounted for through ScanForm records (Fig. 2).

During the demonstration project, batches of procured vaccines were due for expiry in July 2020, December 2020 and July 2021. Given that only 74.8 % of procured vaccines were utilised in the demonstration project, there were significant numbers of influenza vaccine still in stock in July 2020 and July 2021. These vaccine doses were considered unutilized vaccines and were offered to other priority groups including healthcare workers at the direction of the Ministry of Health. No vaccine due for expiry was in stock in December 2020 – this period had been preceded by a vaccine stock out.

3.2. Comparison of year-round versus campaign-mode strategies in their first year of implementation

This section compares performance of the first year of the year-round strategy conducted between 2019 and 2020, with the first year of the campaign-mode strategy conducted in 2021.

We observed similar performance in coverage between strategies. The first year of the year-round strategy achieved dose 1 coverage of 59.7 %, while the campaign strategy achieved slightly higher coverage at 63.2 % (Table 1). Of note, sub-counties implementing the year-round strategy did not have as marked differences in coverage between sub-counties (63.1 % Jomvu, 57.4 % Njoro) as compared to the sub-counties implementing the campaign strategy (Nakuru North 73.4 %, Likoni 55.2 %) (Supplementary information). Less than five percent of children received the first dose of influenza vaccine at less than 6 months of age in either strategy (Table 1). The median age of children who received the influenza vaccine

[2]See e.g., 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C. §3501 et seq.

outside the recommended age was 5.95 months for dose 1 influenza vaccine (n = 1361) and 6.90 months for dose 2 influenza vaccine (n = 1308). The largest proportion of children who received influenza vaccine at too young an age (i.e., off label use), were vaccinated in Njoro sub- county (Supplementary information).

The dropout rate was more marked in the year-round strategy (26.5 %) compared to the campaign strategy (19.9 %). The occurrence of AEFIs was rare; however, rates of AEFIs reported in campaign sub-counties (15.7 [95 % CI 5.0–43.2] per 100,000 doses administered) were twice as high as that observed in the year-round sub-counties (6.6 [95 % CI 1.1–26.5] per 100,000 doses administered) but not significantly different (Table 1). AEFIs included reports of fever and convulsions post vaccination, with one child requiring hospital admission. All affected children recovered following the AEFI.

Wastage was higher in the year-round strategy (2.3 %) as compared to the campaign strategy (0.6 %). For the duration of the demonstration project, delivery of influenza vaccines to health facilities in campaign sub-counties occurred 3 times a month as opposed to once a month (Table 1). In addition, sub-counties that implemented the campaign strategy vaccinated children at a rate that was 2 times higher than in the year-round sub-counties (168 vaccines administered per day in the campaign strategy versus 83 vaccines administered per day in the year-round strategy).

The median duration between receiving the first and second dose of influenza vaccine was slightly longer in the year-round sub-counties (median 33 days, IQR 29–50) compared to the campaign sub-counties (median 31 days, IQR 28–34) (Table 1).

4. Discussion

We observed similar coverage rates between year-round and campaign-mode influenza vaccine delivery strategies, although there was a substantial difference in performance between sub-counties implementing the campaign strategy. We documented rare occurrences of AEFIs, with higher but not significantly different rates in the campaign versus the year-round strategy, which may reflect heightened awareness or increased capacity to report AEFIs because of hiring additional vaccinators, as opposed to actual differences in incidence rates. Operational challenges included limited cold chain capacity, evidenced by the need for more frequent vaccine deliveries (specific to the campaign strategy) and large numbers of unutilized vaccines.

The coverage levels of influenza vaccine during the demonstration project were not as high as the coverage of routine vaccines in the national program, where up to three of every four children in Kenya are fully vaccinated [11]. The lower coverage achieved by the demonstration project as compared to performance of routine antigens in the national immunization program may be explained by the fact that during the demonstration project, children who were near the upper limit of the target population would have had to receive the influenza vaccine as soon as it became available to avoid aging out of the target population and becoming ineligible to receive the vaccine. Whereas in the national immunization program, more time is available to vaccinate children who delay receiving

their vaccines, which would explain the relatively higher coverage of routine childhood vaccines.

There were also several other factors that could have affected the performance of the demonstration project. Government-led COVID-19 mitigation measures were put in place soon after the start of influenza vaccination and continued in varying intensity throughout the demonstration project. Some of the COVID-19 mitigation measures that could have affected immunization services were travel restrictions, the directive for clients to wear face masks within health facilities, and dusk to dawn curfews. In Njoro sub-county, additional movement restrictions within the sub-county were implemented in July 2020 in response to local insecurity because of conflicts between residents. The insecurity was due to long-standing conflict between communities and was unrelated to the demonstration project. There were nationwide industrial actions, such as strikes and go-slows, by healthcare workers from November 2020 to December 2020. In addition, Mombasa county had several more healthcare worker industrial actions from November 2020 to January 2021 and from September 2021 to November 2021 because of delayed payment of salaries to public employees, including healthcare workers.

A study conducted between 2010 and 2012 evaluating influenza vaccine uptake in Kenya did not achieve high coverage rates. In this previous study, the influenza vaccine was offered for free at fixed delivery points for 2–3 months each year, and dose one coverage among children 6 months–2 years of age ranged between 42 and 46 % [15]. Similar coverage levels have been reported elsewhere during the first few years of influenza vaccine introduction among young children [16–20]. Notably, more established influenza vaccination programs, such as in the United States, have achieved coverage levels of 64–75 % among children 6 months–4 years of age in the past decade [21].

The campaign strategy was characterized by more intensive social mobilization activities and short-term hires of additional nurses to assist with vaccination. This could have contributed to better performance in the campaign sub-counties, particularly, Nakuru North sub-county. Conversely, Likoni, having been provided with the same degree and, in some cases, more intensive preparatory interventions than those provided in Nakuru North [12], did not achieve the same coverage rates. The difference in performance between these two sub-counties highlights the challenge with short-term campaigns in quickly recovering from contextual factors that affect performance. Contextual factors occurring in Likoni at the time of the campaign included local resistance to the COVID-19 vaccine coupled to misconceptions that the influenza vaccine was the COVID-19 vaccine, community expectations that the influenza vaccine would be administered door-to-door similar to the ongoing polio vaccine campaign in Mombasa, and healthcare workers' strikes [12], all of which could have contributed to the substantial difference in performance. Notably, Nakuru North did not experience most of these challenges. The year-round strategy sub-counties did not show as substantial a difference in influenza vaccine coverage as was observed between Nakuru North (73.4 % dose 1 coverage) and Likoni (55.2 %), which may point towards greater resilience within a year-round strategy to make up for disruptions in service delivery.

We also observed more operational demands within a short period of time during the campaign strategy. Apart from the need to hire additional staff and conduct more intensive social mobilization activities, there was insufficient cold chain capacity within health facilities to hold a month's supply of the influenza vaccine leading to more frequent influenza vaccine deliveries. During national expansion, this could potentially increase the risk of vaccine stockouts at the health facility level if vaccines were not replenished in time and contribute to higher vaccine delivery costs. The recent introduction of HPV vaccine into the national immunization program and the bulky nature of the influenza vaccine formulation used in the demonstration project strongly suggest that a nationwide cold chain capacity assessment and switch to a multidose vial formulation of the influenza vaccine would be necessary before national roll-out. Campaign strategy sub-counties were also vaccinating children at twice the rate of the year-round strategy sub-counties, which points to a more substantial increase in workload for the duration of the demonstration project. Health facilities in Kenya are already understaffed, requiring five times the current number of nurses to address the population's health needs [22]. The increased demands of a campaign strategy, if no additional human resources are hired, could negatively impact existing health services.

The short shelf life of the influenza vaccine was a crucial operational consideration in both strategies. This has implications for procurement and stock management. In the year-round strategy, switching from NH to SH vaccine and vice versa would require accurate vaccine use projections with little room for error. Similarly, in the campaign strategy, any vaccine not utilized during the campaign period could not be used in the next campaign in the following year because of vaccine expiry, leading to high wastage. We demonstrated low wastage rates during vaccine administration at the health facility level (<3%) but up to a quarter of vaccines purchased were unutilized because of lower-than-expected demand. Given the short shelf life of the influenza vaccine, most of these unutilized vaccines would have expired in storage if they had not been redirected to vaccination of other priority groups.

The development of next-generation influenza vaccines with long-term immunity and reduced need for annual revaccination would have operational benefits, especially decreased wastage because of expiry [23]. The expiry dates currently applied to influenza vaccines are dictated by the semiannual release of more up-to-date vaccine formulations that better match circulating influenza strains and are not because of an intrinsic loss of safety or lack of ability to elicit an immune response. Influenza vaccines with long-term protection would reduce the likelihood of wastage because these could have a longer shelf life. Nonetheless, in the absence of longer shelf-life vaccines, a national program may consider forecasting consumption using lower vaccine demand estimates. Although this would reduce wastage, it carries the risk of influenza vaccine stockouts and lower vaccine coverage. Importantly, vaccine stock-outs of any antigens, including new vaccines, can negatively impact the uptake of other vaccine antigens given to children [24], so this option should not be adopted lightly. It has been shown that when there is a stock out of one vaccine, the community may believe that all vaccines are not in stock [24] or alternatively, may delay bringing their child for vaccination until all the vaccines are available and thus avoid the need for a second visit to receive the out-of-stock vaccine.

Our AEFI rates were in keeping with rates of influenza vaccine adverse events observed during passive influenza vaccine AEFI surveillance [25], although we did not distinguish whether the adverse event occurred during co-administration of the influenza vaccine with other vaccines. It is important to note that the occurrence of AEFIs can lead to vaccine refusals and nearly one-third of infants who experience an AEFI will not report for their next vaccination [26]. The occurrence of AEFIs can also influence vaccine uptake by other community members. Because of this, a health system response is required for AEFIs to investigate the cause of the AEFI and reassure healthcare workers and community members of the continued benefit of vaccination. The rates of AEFIs observed in our study were 2–3 times higher in campaign sub-counties compared to year-round sub-counties, suggesting the need to allocate more resources to respond to AEFI signals in campaigns as opposed to year-round strategies. Nonetheless, we propose that the differences between AEFI rates in the campaign and year-round strategies were because of differences in reporting rather than actual differences in occurrence. The difference in reporting rates between strategies highlights the gaps in AEFI signal generation frequently observed in Kenya [27].

More than a third of all children who received the first dose of the influenza vaccine also received Vitamin A or another vaccine during the clinic visit. This may suggest that clinic visits for other vaccines such as measles vaccine (offered at 9 and 18 months) or vitamin A (offered routinely in Kenya from 6 months of age at 6-month intervals) were an opportunity to receive the influenza vaccine, or that children who had defaulted other vaccines were identified as they came to receive influenza vaccine. Between 14 weeks and 9 months of age, only vitamin A and monthly growth monitoring are offered to healthy children. These interventions are often not viewed as importantly as vaccination appointments. The introduction of influenza vaccination at 6 months may have improved clinic attendance and Vitamin A uptake; however additional investigation is required to systematically document such unintended influenza vaccine program benefits. While the introduction of new vaccines can lead to the detection of defaulters of routine vaccines and/or improved “well-baby” clinic attendance, previous findings suggest that these effects are often neither significant nor sustained, as was reported with the introduction of the pneumococcal vaccine in Kenya, Ethiopia, Cameroon and Mali [24]. On the other hand, introducing influenza vaccine in Kenya at 6 months of age, which is a time point when no other injectable vaccine is provided, could lead to a more sustained improvement in clinic attendance as opposed to the pneumococcal vaccine which was integrated into the existing pentavalent vaccine dosing schedule of 6, 10 and 14 weeks of age.

4.1. Limitations

The first year of the year-round strategy and first year of the campaign strategy were not conducted concurrently, and differences in contextual factors, such as the impact of the COVID-19 pandemic, could have led to the observed differences in performance. The demonstration project was initially intended to run for one year, with the year-round strategy beginning in the last quarter of 2019 and running for 12 months, and the campaign-mode strategy starting in mid-2020 for four months. With concurrent implementation, contextual factors within the country likely to affect performance would have been similar for both vaccine delivery strategies, but the detection of the first COVID-19 case in Kenya in March

2020 disrupted these plans. In line with government directives to avoid large gatherings of individuals, the campaign-mode strategy was postponed to 2021, and the year-round strategy was extended for an additional year. In addition, experiences and lessons learned from the year-round strategy between 2019 and 2020, and applied to the campaign strategy in 2021, could have led to better performance in the campaign strategy. For example, greater emphasis by supervisors on ensuring documentation after vaccinating a child in the campaign strategy could have contributed to the lower wastage rate - we had noted missed documentation as one of the main reasons for wastage in the year-round strategy which in the first months of implementation led to high wastage rates as compared to the later months when corrective action was taken. Furthermore, our coverage rates were determined based on parents'/caregivers' self-report of residency in the target sub-county. Although vaccines were administered to both residents and non-residents, social desirability bias may have occurred if parents thought that the vaccine was only to be given to residents of the sub-county, thereby leading to skewed coverage results. A coverage survey of residents could have validated our findings to confirm actual coverage during the demonstration project.

Finally, it is not a requirement for every country to conduct a demonstration project before introducing the influenza vaccine. After several demonstration projects are completed, a point of saturation may be reached, where no new information is obtained from further demonstration projects in additional countries. In these circumstances, lessons from countries with similar settings could be sufficient to inform future national programs [8]. To our knowledge, there are few published accounts of influenza vaccine demonstration projects in low and lower-middle-income countries [28]. Moreover, few countries with year-round influenza activity have a national vaccination strategy that could inform Kenya's implementation process, which highlights the utility of our work.

Aside from the programmatic findings presented here, the choice of which strategy to utilise is greatly influenced by several other elements including the cost and cost effectiveness of each vaccination strategy. We do not present the costs of each strategy in this paper. However, we previously modelled the cost effectiveness of different vaccination strategies across children's age groups in Kenya and found that once yearly vaccination had the highest incremental net monetary benefit as compared to other vaccination strategies including year-round vaccination, yet none of these vaccination strategies were likely to be cost effective given national willingness to pay thresholds [5]. Notably, we modelled much lower coverage rates with the campaign strategy as compared to what we achieved in the demonstration project which could influence the cost-effective estimates [5]. Modelling the potential health benefits of influenza vaccination with the coverage levels we attained from the demonstration project, could be a useful tool to identify the more effective strategy in averting influenza disease. As our findings do not address all the components required to make a final recommendation as to which strategy is best, we do not do so here. Nevertheless, we note that although the year-round strategy did not achieve as high coverage as the campaign strategy, its implementation was less disruptive to the immunization program and a year-round strategy may be better placed to recover from disruptions in health service delivery as compared to short term campaigns.

5. Conclusion

The demonstration project achieved modest coverage levels, which were similar across strategies. The campaign strategy was characterized by more marked differences in coverage between sub-counties and considerable operational needs (workload and cold chain capacity) compared to the year-round strategy. These operational challenges could have significant consequences on the broader immunization program. Regardless of the choice of strategy, vaccine forecasting and the risk of large numbers of unused vaccines that quickly expire are essential considerations for a national influenza vaccination program and require careful planning to avoid significant financial losses.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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All authors attest they meet the ICMJE criteria for authorship.

Data availability

The data that support the findings of this study are available from the corresponding author, JD, upon reasonable request.

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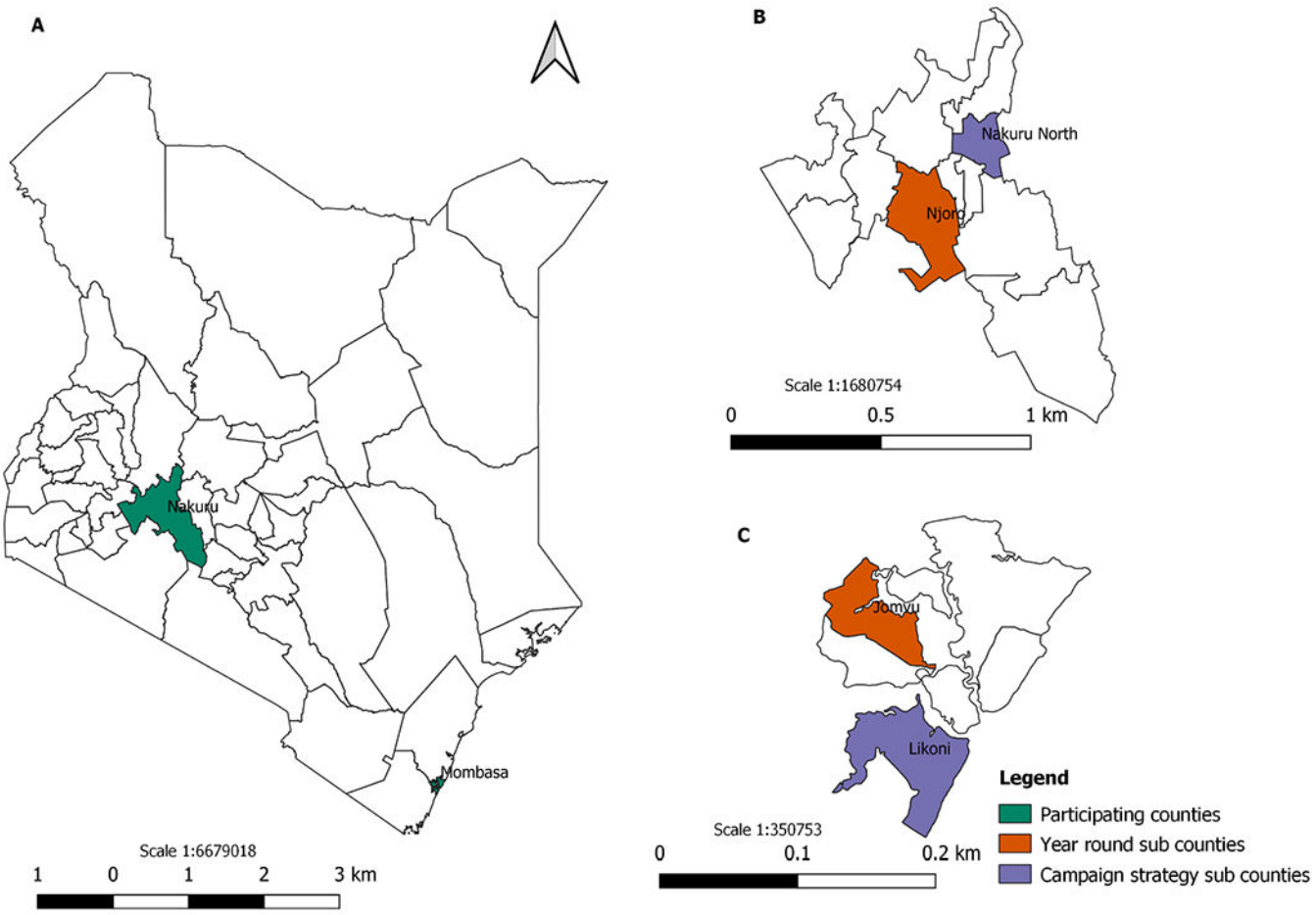

Fig. 1.

A. Map of Kenya showing Nakuru and Mombasa counties. B. Map of Nakuru county showing Njoro and Nakuru North sub-counties. C. Map of Mombasa County showing Likoni and Jomvu sub-counties. The green color in map A indicates the participating counties. The orange color in maps B and C indicates sub-counties where the year-round vaccination strategy was implemented. The purple color in maps B and C indicates sub-counties where the campaign vaccination strategy was implemented. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

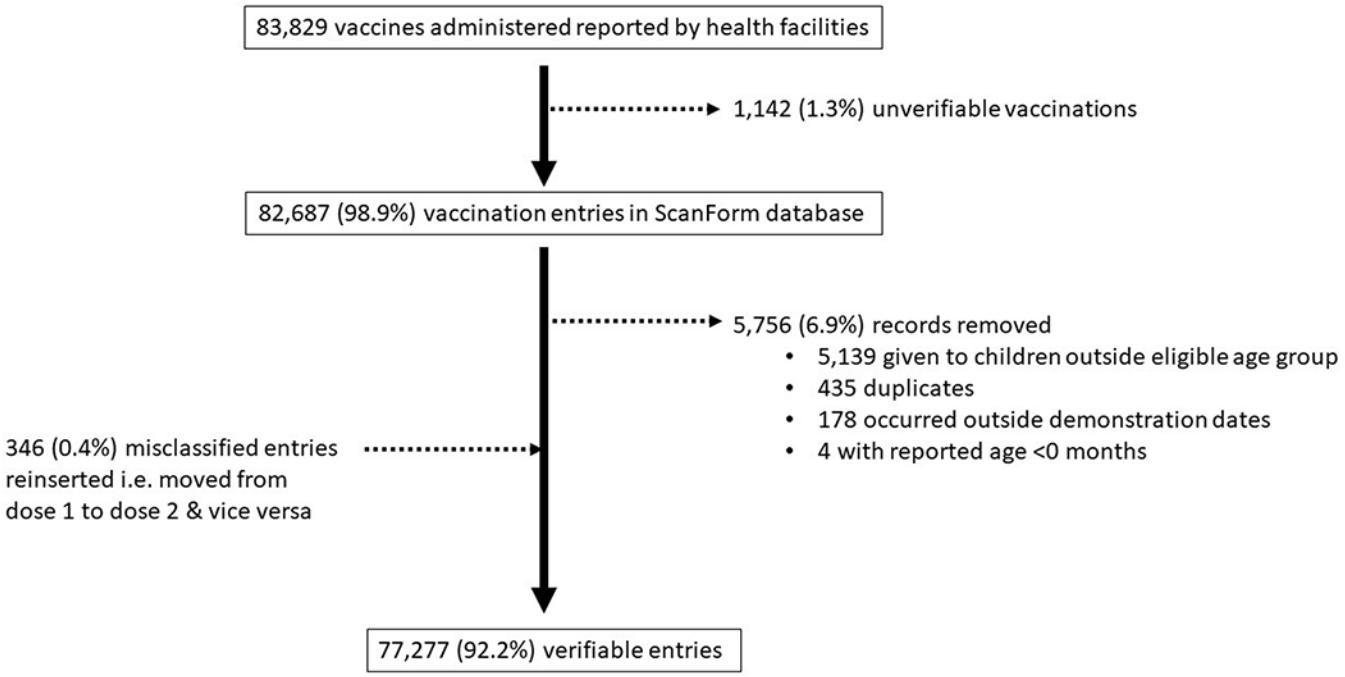

Fig. 2.

Vaccine doses purchased and administered during influenza vaccine demonstration project in Nakuru and Mombasa counties, Kenya, 2019–2021.

Table 1

Indicators of performance of influenza vaccine demonstration project per vaccination strategy in Nakuru and Mombasa counties in Kenya (2019 – 2021).

Indicator	Year-round strategy	Campaign strategy
	Njoro and Jomvu sub-counties	Nakuru North and Likoni sub-counties
Target population	28,234	21,565
Number of influenza vaccine dose 1 administered	17,517	14,104
Number of influenza vaccine dose 2 administered	12,880	11,300
Number (%) of children who received the first dose of influenza vaccine at <6 months of age	716 (4.1 %)	533 (3.8 %)
Number (%) of children who received the first dose of influenza vaccine at ≥24 months of age	55 (0.3 %)	57 (0.4 %)
Vaccine dose 1 administered to children from target sub-county (%)	96.2 %	96.7 %
Coverage dose 1 (%)	59.7 %	63.2 %
Coverage dose 2 (%)	43.9 %	50.6 %
Dropout rate	26.5 %	19.9 %
Wastage rate	2.3 %	0.6 %
AEFIs per 100,000 vaccine doses administered	6.6 (1.1–26.5)	15.7 (5.0–43.2)
Median age in months of children receiving the first dose of influenza vaccine (IQR)	9.6 (6.9–15.7)	12.9 (8.9–17.7)
Number of children (%) receiving Vitamin A or other vaccines when receiving the first dose of influenza vaccine[#]	7989 (46 %)	4849 (34 %)
Number of dose 1 records (%) with a linked dose 2 entry (%)	8443 (48 %)	8379 (59 %)
Number of children (%) who received dose 1 and dose 2 in the same facility (%)	7793 (92 %)	7933 (95 %)
Median duration in days between dose 1 and dose 2 among children with linked dose 1 and 2 records (IQR)	33 (29–50)	31 (28–34)
Minimum and maximum duration in days between dose 1 and dose 2 among children with linked dose 1 and 2 records	1–698	1–117
Median number of times each health facility received the influenza vaccine in a month (IQR)	1 (1–1)	3 (1–4)
Number of vaccines administered per day	83	168

[#]Less than 2 % of entries had no data recorded for this variable.