

Vaccines and immunization services during the pandemic era and beyond

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Vaccines and immunization services during the pandemic era and beyond

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Editorial: Vaccines and immunization services during the pandemic era and beyond

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COVID-19, equity, vaccines, vaccine preventable diseases, immunization, pandemic

Editorial on the Research Topic

Vaccines and immunization services during the pandemic era and beyond

It is now well established that the COVID-19 pandemic caused by the SARS-CoV-2 virus significantly impacted immunization services, threatening to reverse the substantial gains made in the prevention and control of vaccine preventable diseases, globally. Consequently, an estimated 23–25 million children missed one or more of their scheduled vaccine doses at the height of the pandemic (1, 2). Foremost on the global health agenda is re-prioritizing immunization services to recover vaccine coverage rates and secure population health and well-being. While recovery is ongoing, progress has been suboptimal or inconsistent across countries. Robust interrogations into the disruptions caused by the pandemic at country and community levels are required to draw from lessons learned in enhancing the resilience and responsiveness of immunization systems globally. Paradoxically, the pandemic has also been a catalyst for innovations in the vaccine space. We are seeing a substantial shift in the vaccine landscape, from increased interest in vaccine discovery and development, to how policies are formulated and implemented, and how we conduct vaccine research and deliver immunization services (3–5).

To chart a sustainable way forward in the face of current epidemics and future pandemics, immunization services will need to be guided by reliable evidence generated to suit local contexts. Our goal for this research topic therefore was to collect a rich diversity of articles documenting how the COVID-19 pandemic influenced vaccines research and immunization services, with a focus on recovery and strengthening efforts at all levels and across the vaccinology cascade (from vaccine development through to policy formulation and access/delivery of essential vaccines, as well the barriers to implementation like vaccine hesitancy). The scope and themes of interest included, but were not limited to, original

research articles, brief research reports, study protocols, as well as opinion and perspective pieces covering the following topics:

1. Pandemic prevention and preparedness with a focus on innovations and advancements in the field;
2. Equitable access to vaccines and immunization services for underserved populations. These include hard-to-reach or hard-to-vaccinate populations, adolescents, pregnant women, the elderly, marginalized persons, and migrant populations;
3. Vaccine confidence, hesitancy, and acceptability;
4. Vaccine communication and demand generation;
5. Leveraging lessons learned from COVID-19 control efforts to improve prevention and control of existing and emerging vaccine preventable diseases;
6. Expansion of vaccinology expertise to support scale-up of immunization programs, particularly in low- and middle-income countries;
7. Advances in evidence-informed policy- and decision- making for vaccines and immunization services;
8. Implementation and integration of immunization programs into primary health care systems; and
9. The economics of vaccine preventable diseases, vaccines, and immunization services.

Overall, vaccine (in)equity emerged as a prominent theme across the collection of articles in this research topic, with a focus on advocating for inclusive, responsive, and fair access to immunization services. As a primary example, COVID-19 mitigation strategies including vaccination programs, have not always been responsive to the specific needs of underserved and marginalized populations. This was the case in a study conducted in Germany to assess the determinants of COVID-19 vaccine acceptance and access among people experiencing homelessness. In this study, [Grune et al.](#) found that vaccine acceptance within this population was influenced by their confidence in the vaccine, as well as the political and healthcare system. Their individual COVID-19 risk perceptions and a sense of collective responsibility also played a role. [Carol and Amro](#) found that inter-group dynamics and boundaries, as well as entrenched binary perceptions of “us” vs. “them” played a significant role in how minority groups (Bedouins and internally displaced Palestinians) and majority groups (non-refugees or non-Bedouins) living in the West Bank, prioritized COVID-19 booster vaccination. These dynamics can have potential negative consequences for the healthcare of minorities. In a study conducted in Slovakia by [Filakovska Bobakova et al.](#) marginalized Roma communities were reported to experience significant barriers when accessing vaccination services. These barriers include limited or disparate coverage by medical insurance companies for vaccines like the human papillomavirus (HPV) vaccine, health worker shortages, impaired relationships between health workers and Roma communities, and poor access to appropriate risk communication and health information. Improving fair and just access to immunization services for underserved populations should be a top priority in the public health agenda. This can be achieved through policy reforms and innovative interventions which carefully consider the lived experiences of specific population groups. In line with this, [Broach et al.](#) detail how a novel vaccine

delivery model, known as the Mobile Vaccine Equity Enhancement Program, successfully improved the rapid and equitable delivery of the COVID-19 vaccine among communities with high social vulnerability indices in Central Massachusetts. Similarly, [Skaathun et al.](#) propose Project 2VIDA! which is a community-based participatory research intervention aiming to address key barriers to access and acceptance of COVID-19 vaccines among African American and Latino communities living in Southern California. Taken together, these innovative interventions could provide crucial learnings for enhancing equitable delivery of immunization services for persistently underserved communities.

The contributions of vaccine inequity, or better yet vaccine apartheid, to growing sentiments of public mistrust in COVID-19 vaccines specifically, and vaccine hesitancy more broadly, during the pandemic era cannot be overstated. [Nkole et al.](#) offer pivotal perspectives on the importance of community experiences in better understanding how inequitable vaccine supply undermines demand generation, especially in the African context. Drawing on lessons learned from the COVID-19 experience, [Nkole et al.](#) further suggest the need for more equitable emergency response strategies, improved accountability of global health partners and relevant stakeholders, and the importance of applying a human rights-based approach to vaccine delivery, grounded in key principles such as equity, transparency, and community. To counter vaccine hesitancy and build back trust in immunization services, several countries have explored a myriad of interventions. One such intervention is the COVID-19 Vaccine Communication Campaign (CVCC) instituted by the Chinese state. A major finding of an evaluation conducted by [Yang and Han](#) to assess the vulnerabilities of the CVCC was the influence of top-down political pressure, leading the authors to propose broader stakeholder engagements and optimization of service provision to de-politicize COVID-19 vaccination programs if a successful vaccine communication campaign is to be achieved.

There were some useful insights into COVID-19 vaccine implementation strategies from various countries. [Chen et al.](#) evaluated selected COVID-19 vaccine clinics in the United States and found that sound communication systems, multidisciplinary leadership structures, and adoption of patient-centered engagement strategies were some of the strong drivers of implementation while vaccine scarcity posed significant challenges. In Nigeria, a government-sanctioned family-centered approach to increasing uptake of COVID-19 vaccines, known as the Whole Family Approach, showed promising findings. [Offor et al.](#) describe how this unique health promotion intervention draws on the high demand for other primary health services (e.g., malaria, diabetes, hypertension, and reproductive services) among families in Nigeria to increase demand for COVID-19 vaccines and routine immunization services in general. Recognizing the fact that trypanophobia or fear of needles could contribute to COVID-19 vaccine refusal or hesitancy, [Wang et al.](#) conducted a cross-sectional survey in China to assess perceptions and willingness towards other prospective modes of vaccine administration. Interestingly, the overwhelming majority indicated a preference for intramuscular injection compared to oral inhalation or intranasal spray, although the findings may have been influenced by a

low level of awareness about alternative routes of vaccine administration currently undergoing clinical trials (6).

It is also worth highlighting how other routine immunization services were impacted during the COVID-19 pandemic. Acute or prolonged disruptions have been observed more frequently in countries with suboptimal pre-pandemic vaccine coverage rates compared to those with stable immunization systems (1, 7–9). In a health facility-based study conducted in South Africa, Manan et al. found that routine childhood vaccine coverage rates fell below national targets with uncertainties about the risk of COVID-19 contributing to low clinic attendance. Positive vaccine seeking behavior was observed among caregivers with good family support and those who were beneficiaries of the national social welfare grant scheme. Such findings are critical to informing context-specific interventions aimed at generating vaccine demand. Anraad et al. in their paper detail the development of an online tailored decision aid coupled with an intervention to promote informed decision making on pertussis vaccination among pregnant women in the Netherlands. This intervention was informed by a preliminary needs assessment which showed that pregnant women tend to base their decisions on vaccinating during pregnancy on information accessed online in addition to discussions with their healthcare providers and social contacts. Given the heavy presence of anti-vaccine sentiments online bolstered during the COVID-19 pandemic, such intervention could only serve to reduce the devastating impact of mis- and dis-information on health outcomes. In Indonesia, the COVID-19 pandemic was reported to have dramatically impacted the performance of routine immunization services. Here, private health facilities were found to be adequately staffed, had fewer vaccine stock-outs, and provided sufficient time for essential childhood immunization services. As such, Suwantika et al. call for better coordination between public and private sectors, and an expansion of the role of private healthcare facilities in order to improve the performance of the national routine immunization program. The successful integration of immunization and other primary health services in Lebanon, amidst multiple, nested crises such as the COVID-19 pandemic, the economic collapse, fuel crisis, Beirut blast, and a large refugee presence, was attributed by Kapuria et al. to strong partnerships between government institutions and global health agencies.

Despite having the highest burden of cervical cancer, African countries experience significant challenges in implementing life-saving HPV vaccination programs, suggesting underlying health systems constraints which have been exacerbated by the COVID-19 pandemic (10). In Kenya, acceptance and uptake of the HPV vaccine has been negatively impacted by growing vaccine hesitancy at the community level following the COVID-19 pandemic. Umutesi et al. propose a study to assess barriers and facilitators to HPV vaccine delivery, and the acceptability of a single-dose strategy. It is anticipated that the findings will provide useful insights into the single-dose strategy aimed at enhancing uptake of the HPV vaccine among adolescent girls in Kenya. Strategies aimed at scaling-up HPV immunization programs should be informed by

the perceptions and opinions of adolescent girls themselves. To increase their knowledge and awareness of HPV vaccination and thereby improve acceptance and uptake, adolescents in Zambia who participated in a study by Lubeya et al. suggest making vaccine information more accessible within communities through social mobilization campaigns and school curricula, and also stress the importance of the active involvement of politicians in the country.

Finally, as Manga et al. point out, a well-trained workforce is crucial to getting immunization programs back on track for those who need them the most. In their article, the authors report on a proof-of-concept study assessing the training needs of alumni (policy makers, programme managers, immunization providers, and scientists working in the field of vaccinology) of the Annual African Vaccinology Course who required refresher training because of the rapid evolutions in the field and the challenges brought on by the COVID-19 pandemic. By tailoring a vaccinology webinar series to meet these needs, the authors were able to show the success of implementing a low-cost, widely accessible continuous health education program in the African context.

This research topic comprises 18 articles which contribute highly researched and thought-provoking findings on how the COVID-19 pandemic has influenced the vaccines and immunization landscape across various contexts, globally. These articles are an important contribution to the growing body of evidence required to inform immunization recovery strategies in the pandemic era and beyond. We anticipate that this research topic will stimulate further dialogue and inspire future research aimed at “pandemic-proofing” immunization services.

Author contributions

EA-D: Writing – review & editing, Writing – original draft, Conceptualization. AF: Writing – review & editing. AA: Writing – review & editing. SM: Writing – review & editing. OW: Writing – review & editing.

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Determinants of COVID-19 vaccine acceptance and access among people experiencing homelessness in Germany: A qualitative interview study

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Introduction: People experiencing homelessness face lower life expectancy, higher prevalence of somatic and mental diseases and a more difficult access to healthcare compared to people in secure living. During the COVID-19 pandemic transmission rates were higher among people experiencing homelessness and preventive public health measures were not properly adapted to the specific needs of people experiencing homelessness. Thus, goal of our study was understanding the determinants of acceptability and access of the COVID-19 vaccine.

Materials and methods: We conducted a qualitative interview study with twenty guideline interviews with adult people currently experiencing homelessness in Berlin, Germany (August 2021 – April 2022). Participants were approached in a purposive sampling strategy. The interviews were analyzed with qualitative content analysis according to Mayring.

Results: Acceptance and attitude toward the COVID-19 vaccine is influenced by confidence in the vaccine as well as in the political and healthcare system, the individual COVID-19 risk perception and sense of collective responsibility. Overall, the acceptance of the vaccine was high among our participants. Facilities offering low threshold COVID-19 vaccines for people experiencing homelessness were perceived as helpful. Language barriers and the need for identity documents were major barriers to access the COVID 19 vaccine.

Discussion: People experiencing homelessness are a marginalized and vulnerable group often underrepresented in the public and scientific discourse. During the COVID-19 pandemic, preventive public health measures, including the COVID-19 vaccine, failed to consider specific needs of people experiencing homelessness. Multidimensional strategy to enhance inclusive healthcare are needed to improve access and to reduce discrimination and stigmatization.

KEYWORDS

homelessness, prevention, vaccine acceptance, vaccine hesitancy, vaccine access, COVID-19, primary care, access to health care

1. Introduction

Homelessness is a multidimensional social and health state, often caused by a complex network of individual and structural circumstances (1).

The *European Typology of Homelessness and housing exclusion* (ETHOS) developed by the non-governmental organization *European Federation of National Organizations Working with the Homeless* (FEANTSA) uses the following categories to cover possible living situations subsumed as homelessness: *rooflessness* (living without shelter of any kind), *houselessness* (having a temporary place to sleep), *living in insecure housing* (living with the threat of eviction or domestic violence) and *living in inadequate housing* (for instance in caravans, on illegal campsites) (2). In this article we focus on people experiencing rooflessness as well as people experiencing houselessness and refer to them as people experiencing homelessness (PEH).

According to the *National Federation for the Homeless* (Bundesarbeitsgemeinschaft Wohnungslosenhilfe, BAG W), approximately 417.000 houseless people lived in Germany in 2020. Included in this number were around 41.000 roofless people (3).

Existing studies show stark health discrepancies of PEH when compared to people in secure living situations. For instance, a systematic review from 2020 reveals a higher prevalence of cardiovascular, musculoskeletal, and respiratory diseases among PEH compared to the population in secure housing in Germany (4). A meta-analysis from 2017 draws a similar picture: mental health problems among PEH are considerably higher as compared to people in secure housing. The major share of mental health burden can be attributed to alcohol dependency and substance use disorders, further anxiety disorders, affective disorders, drug dependence, and major depression (5). Similar results were described in the German-based National Survey on Psychiatric and Somatic Health of Homeless Individuals (6). Homelessness is not only associated with a higher prevalence of somatic and mental illness, but also with higher mortality rates. According to a literature review comparing data on mortality from the United States, Canada, Europe, Asia, and Australia, PEH are three to four times more likely to die prematurely than the general population and their life expectancy is reduced by 30 years (7).

At the same time, PEH face major barriers when seeking health care (6, 8). A qualitative study from Spain identified administrative, personal, and medical-professional barriers for PEH, demonstrating inequities in accessing healthcare. Personal barriers were based on experiences of poor service, discrimination, or unaffordable treatment (9). In a Canadian study, more than one-third of the included PEH reported unmet health needs (10). According to a survey from Hamburg (Germany), uninsured PEH (one-third of the included individuals), reported fewer physician visits, again indicating a lack of affordability of health care (11). Matching those findings, a facility enabling access to health care for people without health insurance in Berlin reports 50% of their clients to be home- or roofless (12).

In times of the COVID-19 pandemic general information, health regulations or disease control measures were often delivered online. This “digital gap” leads to reduced access of PEH to preventive services

(e.g., vaccination) and treatment which is enhanced by socio-economical barriers (13). Another barrier lies in the general practitioners (GPs) themselves. As shown in qualitative research among GPs in the United Kingdom, barriers to providing health service for PEH included insufficient training and inadequate consultation competences to address special needs of PEH (14). Further, PEH repeatedly experience stigmatization when accessing healthcare. Those experiences of stigma and shame may lead to avoidance of healthcare facilities (15, 16).

Access to health care is a human right (17) and is a frequently discussed and universal concern when it comes to equity in health. A broader approach to understanding access was given by Penchansky et al.: they describe access “as a concept representing the degree of “fit” between the clients and the system” including five different dimensions: *availability* (balanced supply and demand), *accessibility* (health service is within reach to the client in reasonable travel time and distance), *adequacy* or *accommodation* [fitting opening hours, appointment systems and facility structures (e.g., wheelchair access)], *affordability* (in means of financial and incidental costs for service providers and clients) and *acceptability* (relation between perception of social and cultural concerns of the provider and client) (18). Saurman modified that concept of access by adding a sixth dimension: *awareness*. As all other dimensions, *awareness* can be implied in both ways – meaning that it is important for health services to provide adequate information for possible clients in an appropriate way but also underline the significance of health services being aware of local context and population needs (19).

Beyond difficult access to preventive infection control measures PEH’s worse health state increased the likelihood to experience a severe course of COVID-19. Especially cardiovascular and respiratory diseases, disproportionately frequent among PEH increase the risk of severe COVID-19. PEH are confronted with higher transmission risks due to sleeping rough, lack of isolation possibilities in emergency or temporary shelters, and barriers to accessing adequate (health-)care and information (13, 20, 21). In addition to that, some non-pharmaceutical interventions – such as staying at home (without having a home), social distancing, and increased hygiene – are simply almost impossible to realize for PEH.

Vaccines are an important cost-effective public health measure (22) and can reduce incidences of different diseases (23). Vaccines work at both the individual and community levels since high vaccine coverage induces protection for the whole community and not only for vaccinated individuals (23). Therefore, vaccination programs and their success depend on a high uptake level. Increasing incidences of vaccine-preventable diseases like measles (24) and the not yet achieved eradication of poliomyelitis (25) have been linked to under or non-vaccinated communities (23). One factor reducing high vaccine uptake levels is vaccine hesitancy. Vaccines are very important in the context of homelessness: PEH are a particularly vulnerable group because their impaired health status compared to the general population and their difficulties in accessing the health care system. In this context, lower vaccination rates among PEH as compared to the general population is worrisome (26, 27). It is therefore of great importance to enhance the inclusion of PEH in vaccination strategies (28).

To understand the very complex composition of factors leading to vaccine-hesitant behavior, different approaches to examining determinants of vaccine hesitancy have been developed. Betsch et al.

Abbreviations: COSMO, COVID-19 Snapshot Monitoring; COVID-19, Coronavirus Disease 2019; COVIMO, COVID-19 Impfquoten Monitoring (COVID-19 vaccination rate monitoring); PEH, people experiencing homelessness.

developed the 5C *psychological antecedents of vaccination*, giving insights into individual and psychological factors. The 5C consists of five different dimensions influencing vaccine behavior: *confidence* (trust in the effectiveness of the vaccine, the delivering system, and the motivation of policy-makers), *complacency* (degree of risk perception related to a specific diseases), *constraints* (circumstances as physical availability, geographical accessibility, ability to understand consequences of a disease), *calculation* (engagement in information searching and evaluating pro and cons) and *collective responsibility* (will to protect others by vaccinating oneself) (29).

Monitoring COVID-19 vaccine uptake in Germany, the studies COSMO and COVIMO both identified safety concerns, low-risk perception of COVID-19, and distrust as the main reasons inhibiting the willingness to get vaccinated (30, 31). Similar reasons for vaccine-hesitant behavior among people in secure living situations were identified in international studies (32). Regarding determinants influencing vaccine uptake and access to the vaccine among PEH, a few studies have been conducted. Existing studies with a focus on PEH from Italy (33), France (34), and the United States (35) aim mostly at vaccine acceptance rates. Only a few studies address determinants for vaccine-hesitant attitude or access to the vaccine (36–38). To our best knowledge, no study explored such topics among PEH in Germany until today.

This study aims to gain insights into thoughts and experiences on access and acceptance of COVID-19 vaccination among PEH to inform policymakers and service providers. Thus, we had the following research question: What factors influence the access to and acceptance of the COVID-19 vaccine among PEH in Berlin?

2. Materials and methods

In reporting our methods, we followed the Consolidated Criteria for Reporting Qualitative Research (COREQ) (39) and the Standards for Reporting Qualitative Research (SRQR) (40).

2.1. Study design

To understand which determinants influenced the accessibility of the COVID-19 vaccination and its acceptance among PEH living in Berlin, we designed a qualitative study with semi-structured interviews methodologically orientated on Mayring's qualitative content analysis (41, 42). The qualitative study design was chosen because PEH have been under-researched so far and we had to assume that categories from frameworks may not be transferable to this group. In general, we aimed at identifying determinants of access and acceptance to COVID-19 vaccination, and in doing so, to test whether the models mentioned below are applicable to this.

Therefore, the interview guideline was developed theory-based by DS using the “5C psychological antecedents of vaccination” by Betsch (29) and the “Theory of Access” by Saurman (19). We did not take the questions directly from the frameworks but designed them more openly to be open to determinants outside of the frameworks. The interview guide was developed in German, Polish, and English and included open-ended questions about the persons experiences with access to the COVID-19 vaccination and factors influencing their motivation to get the vaccine. A selection of sample questions is provided in Table 1.

TABLE 1 Selection of interview guide questions.

Icebreaker
What do you think of when I mention the COVID-19 vaccination?
Acceptability of the COVID-19 vaccine
What motivated or stopped you to from getting vaccinated when you first heard of the COVID-19 vaccine?
Access to the COVID-19 vaccine
What made it easy or hard for you to get the COVID-19 vaccine?

2.2. Recruitment of participants

As PEH are often harder to reach or to find than people not experiencing homelessness, we chose to approach PEH in person and ask them about their availability for an interview. To include homeless and shelterless people (both included in the term PEH), we approached aid providers in emergency and temporary day or night shelters in Berlin. Six providers accepted our request to conduct our study in their facilities during opening hours. To ensure a safer environment during the interviews, we conducted the interviews inside facilities instead of interviewing on the streets. We performed convenience sampling at first approach and adopted a purposive sampling strategy further on, aiming for a heterogeneous sample (maximum variation sampling) in terms of sex, language, and attitude toward COVID-19 vaccination. Researchers were not previously known to the interviewed persons.

2.3. Data collection

The guideline-based interviews were conducted between August 2021 and April 2022. In total, 19 interviews with 20 interviewees were carried out. One interview was conducted with two PEH at once because of the personal preferences of the interviewees. All other interviews were carried out with one person.

Due to limited space in most facilities, only a part of interviews was held in private rooms. The others were conducted in common areas such as dining or sleeping rooms in presence of non-participants. To ensure privacy and a secure interview setting we carried out the interviews in private area in the communal rooms. If necessary, nearby PEH were asked to leave the interview area for the duration of the interview to provide privacy.

In the concrete interview setting, the interviewer first informed about the study and asked for written consent for participation and the audio recording from the interviewees. Additional field notes on paper were made if necessary. Interviews were carried out until data saturation was achieved. The researchers have recognized point of data saturation in joint discussion. Four interviews were transcribed verbatim by DS, all the remaining were transcribed verbatim by JG according to previously set transcription rules based on the simplified transcription rules by Dresing and Pehl (43). Reflection and interpretation took place through the supervision of AS and discussion of preliminary results in interdisciplinary researcher's workshops at the Institute of General Practice and Family Medicine and Institute of Medical Sociology, Epidemiology and Health Economics at Charité Berlin.

All interviews were conducted by DS, MK, and JG: five by DS in German or English, two by MK in Polish, and twelve by JG in German,

English, or Polish. DS is a male medical student. MK and JG are female medical students, both with Polish backgrounds. Primary responsible for data collection processes after the first interviews held by DS and MK and data analysis was JG. The study was accompanied and supervised by AS, WH, and AL. All researchers had training in qualitative study processes. AS and WH are engaged in a researchers' network working on health and homelessness. DS and JG were both engaged in the Berlin city mission during the process of the study; DS as the medical volunteer's coordinator, and JG as a medical volunteer.

2.4. Data analysis

For data analysis, we used Mayring's qualitative content analysis method. Using this method, we categorized the collected data and analyzed it subsequently (41, 42). Mayring's qualitative content analysis allowed an analysis of mechanisms and determinants of vaccination access and acceptance in PEH. The choice of method was adapted to the research project and discussed with the participating researchers in advance of the analysis.

Categories were developed inductively from the data to reduce masking of unexpected findings and afterward revised in a deductive manner using the theoretical frameworks mentioned above. The first draft of the codebook was developed using five transcripts and then discussed with an interdisciplinary group of researchers. Suggestions for modifications were implemented and the further developed codebook was tested on other transcripts. JG coded all 19 interviews twice to account for continuous iterative adaptation of the codebook, AS counter-coded two interviews and another doctoral student counter-coded three interviews. Again, suggestions for modifications were discussed and integrated with mutual consent.

To explore the credibility of the findings, JG conducted member checking. JG discussed preliminary results with twelve non-interviewed PEH during a PEH self-advocacy meeting. The preliminary findings were discussed in an open group evaluation (44). The importance of certain themes was underlined and suggestions for further data analysis were made by the participating PEH. This helped us focusing the analysis on issues that were considered as very important by the PEH participating in the discussion. We chose to include this procedure because it was not possible to reach out to the previously interviewed PEH. Further measures to enhance credibility of the findings included ongoing discourse on methods and main focuses of the analysis with other researchers.

Transcription of interviews, Coding and Data analysis was carried out using the qualitative data analysis software MAXQDA. The transcripts were not translated for analysis and the codebook was developed in German. For this article, JG translated non-English quotes into English.

The analytical lens of our analysis was to focus on inhibiting and promoting determinants of access and acceptance of COVID-19 vaccination among PEH in Berlin.

2.5. Ethics statement

The study received ethical approval from the Charité ethics committee (Number = EA2/168/21). Data safety was performed according to the current data safety regulations at Charité.

All interviewees provided informed written consent. Interviews were pseudonymized in the transcripts, full names were not recorded intentionally and identifying aspects were paraphrased according to their function.

All participants included in this study were assessed as sane and oriented by the interviewer. In some cases, this also applied to participants who had possibly consumed mind-bending substances such as alcohol prior the interview. In the specific setting, the interviewer asked whether the participant considered him or herself able to participate in the interview with a brief conversation and explored if the participants assessment matched with the impression of the interviewer. PEH who were unwilling or unable to participate were not included in this study. The consumption of alcohol and other substances is prohibited in all facilities visited, however consumption of mild stupefactors of the participants cannot be excluded. The decision to include PEH who could give consent but might have consumed alcohol or other substances was taken to prevent selection bias toward potentially healthier PEH.

3. Results

We carried out 19 interviews with 20 participants. The length of the interviews was between 13 to 88 min with a mean of 29 min. Of the 20 participants, 75% were male, the mean age was 55 years (IQR. 25 P – 75 P) and 75% have received at least one COVID-19 vaccination. Interviews were carried out in German (50%), Polish (20%), and English (30%). For a detailed overview of the participant's sociodemographic data, vaccination status, and interview language please consider Table 2.

The interview analysis focused on factors that contribute to understanding vaccination behavior and access to the COVID-19 vaccine among PEH. A deeper understanding of those aspects is relevant for future public health measures and better inclusion of PEH.

Table 3 shows a summary of inhibiting and enhancing factors for the acceptability of and access to the COVID-19 vaccine (Table 3).

3.1. Acceptance of the COVID-19 vaccine

We explored the acceptance of the COVID-19 vaccine among PEH using Betsch's 5C model (29). Overall, we found a high willingness to get vaccinated with the COVID-19 vaccine among most of our participants. This indicates a general acceptance of the vaccine as preventive measure.

"I indeed think the vaccination is good." (T7, male, 52 years).

Not everyone showed that willingness to get vaccinated: a few participants refused to accept the vaccine under any condition.

"I say it right away: I will never take this vaccine." (T12, male, 42 years).

3.1.1. Confidence in the safety and efficacy of the COVID-19 vaccine

The degree of acceptance toward COVID-19 vaccination of some participants was dominantly influenced by their trust or mistrust of

TABLE 2 Sociodemographic data of interviewees (N=20).

		<i>n</i>
Sex	Male	15
	Female	5
Age	< 30 years	2
	30–50 years	6
	> 50 years	12
COVID-19 vaccination status	Vaccinated*	15
	Not vaccinated	5
Interview language	German	10
	Polish	4
	English	6
Country of origin	Germany	6
	Poland	3
	Russia	2
	USA	1
	Great Britain	1
	Romania	1
	Italia	1
	Namibia	1
	Bulgaria	1
	Netherlands	1
	Mazedonia	1
	Ireland	1

*At least one COVID-19 vaccine received.

the vaccine. Especially the perception of the safety and effectiveness of the vaccine affected our participant's vaccination attitude.

Some participants expressed their trust in the vaccine and did not experience side effects which enforced their trust in this preventive measure.

"They say about Johnson & Johnson, you can have side effects. Honestly, I didn't have any either. I felt even better afterward. [...] So, I can't understand the others why they [didn't do vaccination], it's not so bad." (T3, male, 44 years).

Trust in the vaccine was also expressed by referring to the high safety and effectiveness of COVID-19 vaccines.

"Astra Zeneca and BioNTech [...], Johnson & Johnson and Moderna, they are all at 90%. That is highly effective." (T1, male, 84 years).

Other participants expressed concerns regarding safety and effectiveness. Worries or misconceptions about different short- or long-term side effects of the vaccine enhanced the mistrust in the vaccine itself.

"So, after the second injection I had extreme side effects [...]. But I'd say that if it's gene-modifying, then it doesn't happen overnight, then somehow it can be harmful for years." (T14, female, 38 years).

TABLE 3 Summary of categories.

Acceptability of the COVID-19 vaccine	
Inhibiting factors	<ul style="list-style-type: none"> • Fear of side effects caused by the vaccine • Mistrust in politics and the health system
Enhancing factors	<ul style="list-style-type: none"> • Trust in the safety and effectiveness of the vaccine • High-risk perception of COVID-19 • Protecting others from transmission • Taking part in daily life
Access to the COVID-19 vaccine	
Inhibiting factors	<ul style="list-style-type: none"> • Need for personal documents or health insurance for a vaccine appointment • Language barriers
Enhancing factors	<ul style="list-style-type: none"> • Information and assistance in getting the vaccine by facilities for PEH • Unbureaucratic vaccination offers

PEH are especially exposed to side effects such as fever and possibly must deal with them in extremely vulnerable situations while living on streets or in unstable shelters.

"I'm afraid of the side effects. [...] Imagine I get vaccinated tomorrow, I'm here and then I have to go out during the day and I'm lying in bed with a fever like this." (T11, male, 24 years).

3.1.2. Confidence in the political and healthcare system

Additional to the previous factors influencing confidence in the COVID-19 vaccine, some of the interviewed PEH mentioned aspects concerning politics and the healthcare system. Trust or mistrust in politics or the healthcare system can be interpreted from many statements. While some interviewees trusted the process of vaccine production and the involved healthcare system, others were skeptical.

"No, I trust the scientists. They did not do that many years of school to kill me, did they?" (T3, m, 44 years).

Reasons for not trusting the healthcare system in producing the vaccine were lack of time for proper research, assumptions on life- or health-threatening ingredients, and worries because of the development phase of the vaccine.

"Besides, this time for testing was too little, that's why I say: 'lab rabbit' because normally a drug is tested for 10 years before it gets the 'ok' at all." (T6, female, 49 years).

Another aspect leading to less trust in the healthcare system for some participants was their experience of stigmatization while seeking out help.

"If you go to a hospital, if you go to an emergency center and you say you have no permanent residence, then they act as if you are looking for an emergency overnight stay and do as little as possible at first." (T10, female, 57 years).

Some participants considered the entire health care system untrustworthy and criticized the heavy commercialization of the health care system.

"So complete trust in medicine [...] is not really there for me anyway. [...] I don't want to say that medicine is completely wrong, but I also know that the pharmaceutical industry makes a lot of money with pills and everything else." (T14, female, 38 years).

When it comes to politics, interestingly most of the participants expressed mistrust in either individual politicians or the whole system itself. This distrust of politicians and the political system, as well as a general skepticism, led to a hesitant attitude toward vaccines.

"So, if I let my trust in politics or politicians determine my vaccination decision, I wouldn't get vaccinated at all. [...] I would like to see information that is more independent of political moods and elections and things like that and how many doses of vaccine are there right now and what the variants are." (T10, female, 57 years).

Especially the communication of politicians gained negative attention and was linked to unreliability.

"This contradictory [name of politician] says this and that yes and every federal state [something different]. That worries me. What is it actually about? Germany can talk to us in straightforward language, can't it?" (T7, male, 52 years).

3.1.3. Complacency

The need for vaccination depended on the COVID-19 risk perception and the assessment of the person's resistance capacity.

"Terrible, I got COVID, so, and I am in shape. [...] And my immune system has always been good. But by God, COVID. [...] it attacked me with a vengeance. You know, flat out. [...] So, this is why I do not understand these people who do not get vaccinated." (T2, male, 63 years).

Others, however, did not feel at risk because of COVID-19 and therefore saw no need for a vaccine.

"How dangerous do I think it [COVID-19] is? Actually, not really dangerous. I think [my body is protected] quite well [also without the vaccination]." (T14, female, 38 years).

3.1.4. Collective responsibility and protection through COVID-19 vaccination

When trusting the effectiveness of the COVID-19 vaccine, some of the interviewed PEH aimed to protect themselves or others by getting vaccinated. For some participants not only their own protection played a role in the vaccination decision but also the protection of others. This behavior indicates a collective responsibility toward the community in protecting each other through accepting preventive offers such as the COVID-19 vaccine.

"When I'm sick [...], I want to protect others so that I don't infect them. And that they then infect other people. [...] you don't want to spread it." (T9, male, 55 years).

3.1.5. Calculation

The acceptance of the COVID-19 vaccine depended strongly on the individual benefit–risk weighing. One aspect that helped some participants in accepting the vaccine was their desire to take part in daily life. Many daily life activities were restricted due to infection control measures and sometimes required a COVID-19 vaccination or a current antigen test.

"So, I wanted to have my peace, I wanted to participate everywhere, I didn't want to be excluded, [...] I want to get into every shop." (T20, male, 62 years).

Therefore, the hope to reduce necessary COVID-19 tests because of prior vaccination was another motivator for some participants.

"Here today everyone was standing in line, [to get tested in their noses]. I got the vaccine, they left me in peace." (T4, male, 59 years).

Interestingly, some participants were skeptical concerning the benefits and the need for the COVID-19 vaccine compared to other vaccines.

"I'm skeptical [...]. I'll put it this way: there are vaccinations that people need [like against] tetanus, [...] or polio or something like that. But in general, with COVID-19 [vaccines] I am not sure." (T14, female, 38 years).

In general, it was important for some participants to inform themselves about the COVID-19 vaccine before getting vaccinated.

"I would like to inform myself about [...] what happens when I have recovered? And where does the protection come from and how long will it last - when does it wear off? [...] I'd like to get more objective information about that." (T10, female, 57 years).

3.1.6. Constraints

Constraints regarding the COVID-19 vaccine were often linked to factors that inhibited the accessibility of the vaccine in general. An in-depth discussion of such factors can be found below. For some participants, their daily life circumstances and barriers because of experiencing homelessness made it difficult to get vaccinated.

"I couldn't do [the COVID-19 vaccine] because I was on the street. [...], I slept on the benches and lost my health card and my ID. And I couldn't go anywhere because you need proof of who you are." (T3, male, 44 years).

3.2. Access to the COVID-19 vaccine

To understand perceptions and experiences of access to the COVID-19 vaccine among PEH, we based our analysis on Saurman's Theory of Access (19).

3.2.1. Availability and awareness of needs

The interviewed PEH mostly perceived support and assistance from facilities for PEH as very helpful. Facilities for PEH were aware of the special needs of PEH and some offered information on COVID-19 vaccines or appointments for a vaccine. Those services were additionally offered to the usual services like providing food and a place to sleep. Some participants underlined the importance of the employees and volunteers in facilities for PEH. If they are considered trustworthy, they can play an important role in some of the participant's decision-making.

"[I would have] rather not [taken the vaccine without information of people working in this night shelter], because I wouldn't have known where to go and stuff like that. And here they came, they came beautifully, nicely "do you want it?". We had a normal conversation because the Polish woman was also going around. They said, "do you want the vaccine?" and I said, "of course, yes". Normally, no." (T17, female, 56 years).

In addition to the information provided by staff and volunteers working in facilities for PEH, some PEH emphasized the importance of addressing language barriers.

"The problem here for foreigners is language." (T3, male, 44 years).

The inability to understand information about the vaccine was in line with lower acceptance rates. Therefore, translation by staff and volunteers at facilities was found to be very helpful.

"[Information is important for me, then one can learn.] And especially since there is another Polish woman working here, she will always translate." (T17, female, 56 years).

3.2.2. Accessibility and affordability

In terms of accessibility, many PEH considered COVID-19 vaccination offers from facilities for PEH as enhancing access to the vaccine. Many referred accessing the vaccine within such offers as easy and convenient.

"Now I came to the [name of provider for PEH], they made it easier for me to do it. They told me [about the vaccine,], I did it, that was the fastest. Before I couldn't do it because I was on the street." (T3, male, 44 years).

Compared to most participants' very positive opinions on vaccination offers assisted by facilities for PEH, their perception of

public vaccination offers differed strongly. A few gave a positive response to public vaccination offers in big vaccination centers and pointed out a good organization in Germany.

"All I can say is that Germany has done such a wonderful job about this." (T2, male, 63 years).

Nevertheless, many participants indicated a panoply of different barriers in the context of public vaccination offers. Some PEH had a negative experience with offers that were difficult to reach and going there required high transportation costs.

"What the price was - [...] you know, it's free, but almost 6 € I've got to pay for the metro ticket. I mean that's a bottle of wine or a couple of drinks [...]. Again, for the poor people, that is a lot of money." (T15, male, 59 years).

Secondly, some participants experienced a lack of appointments.

"An appointment [would make it easier for me to get vaccinated]." (T7, male, 52 years).

3.2.3. Acceptability and adequacy of service

In terms of acceptability and adequacy of service, conditions of public vaccination offers were considered unbearable by some participants. They referred to long waiting times and hard reachability.

"I twice went to [the COVID-19 vaccine center in] Tempelhof and once to the Messe Berlin. And you know, it takes me an hour to get there and then I have to wait in those inhumane conditions." (T15, male, 59 years).

Another aspect often perceived as a barrier to access to the COVID-19 vaccine was the need for identification documents for receiving a vaccine in public vaccination centers.

"For the homeless, [it is often difficult], because [identification] documents are often stolen [...] and if the vaccination fails because of that and then they say [...] "You'll get an appointment in five months", well, congratulations!" (T10, female, 57 years).

In summary, access to the COVID-19 vaccine was perceived as easier the lower the threshold. Many participants experienced low-threshold vaccination offers in facilities for PEH with a focus on the specific needs of PEH.

4. Discussion

Overall, the data indicate a positive attitude toward the COVID-19 vaccination among PEH. We were able to identify inhibiting and enhancing factors for the accessibility and acceptance of the COVID-19 vaccine. Interestingly, vaccine acceptance was found to be vaccine-specific: some participants rejected the COVID-19 vaccination while accepting other vaccines. We noticed this aspect outside of the theoretical frameworks. This observation matches studies indicating an overall decrease in vaccine confidence rates after the outbreak of

SARS-CoV-2 in comparison to pre-pandemic times (32). In addition to general vaccine hesitancy, the COVID-19 vaccine also worried people with safety concerns because of the quick development or perceived lack of efficiency of the vaccine. Vaccine hesitancy against the COVID-19 vaccine was also associated with a low-risk perception of COVID-19 (45).

We were able to identify the dimensions of the 5C model (confidence, complacency, constraints, calculation, and collective responsibility) in our findings (29). Acceptance of the COVID-19 vaccine was predominantly influenced by trust in the vaccine itself or mistrust in the politics and healthcare system. Confidence in the safety or efficacy of the vaccine was associated with a greater willingness to get vaccinated, while mistrust or misconceptions about the vaccine was linked to hesitant behavior. Fear of side effects caused by the vaccine or misconceptions about the vaccine played a role in some participants' vaccine attitudes. Interestingly, most participants clearly stated their mistrust of the political system. This mistrust, sometimes combined with mistrust of the healthcare system, was also associated with lower acceptance of the vaccine. Experienced stigmatization in the health and political system could be a reason for mistrust (15). A systematic review on improving vaccination rates in PEH also suggests providing clear and stringent information in order to tackle misinformation and mistrust (26). In accordance with our findings from this Germany-based study, prior international studies on the COVID-19 vaccine and PEH report safety concerns regarding the vaccine, distrust in the government, and vaccine manufacturers as enhancers for vaccine-hesitant attitude (36, 37). Similar results were also found in studies focusing on people in secure living situations (45). However, some participants, although distrusting the political or healthcare system, mentioned self-protection, protection of others, or the willingness to be part of social life as prevailing drivers to accept vaccination. Especially the willingness to be included into social life is an important aspect for PEH. Recent studies have shown that loneliness and social isolation among PEH can be considered a determinant for health (46, 47). The impact of loneliness on health is also well described for people in secure living situations (48). Considering that PEH are a marginalized group, this aspect is of great importance. Calculating risks and benefits and the willingness to prevent the spread of COVID-19 was also found among young PEH in a study from the United States. Interestingly, this study shows slightly lower vaccine acceptance which might be explained by the younger study population (38). Low-risk perception of COVID-19 was associated with vaccine-hesitant attitude among the participants of our study. A German study from 2021 indicated low fear of COVID-19 among PEH. They also described higher fear of COVID-19 among PEH aged 50 to 64 (49) which is the main age group in our cohort and might explain the mainly positive attitude toward the COVID-19 vaccination. That age might have a strong impact on the attitude toward vaccine attitude is also mentioned by a Danish study on COVID-19 vaccine coverage among PEH. PEH aged 18–24 years showed lower vaccination rates than older PEH (50). Constraints regarding the COVID-19 vaccine were often associated with other dimensions of acceptability as safety concerns or distrust in the political system. Overall, PEH who participated in our study perceived several life-circumstances-related barriers in accepting the vaccine, such as difficulties accessing public vaccination sites and everyday struggles that limited opportunities to get vaccinated.

To operationalize access to the COVID-19 vaccine, we were able to implement the Theory of Access (availability, accessibility, adequacy of service, affordability, acceptability, and awareness of needs) as the

analytical lens in our study (19). COVID-19 vaccination offers by facilities for PEH were considered as very helpful and matched PEH needs in terms of availability and awareness. Personal interaction and engagement of staff with PEH facilitated willingness for vaccination by providing trusted information or simply by answering open questions. A similar outcome was reported in studies from the United States. Low-barriers for testing for COVID-19 and vaccine offers facilitated by community health outreach workers were associated with higher vaccine uptake and better accessibility (36, 37). In addition of the benefits personal interaction mentioned in our study prior research highlights the positive effect of offering vaccines at sites already frequently visited by PEH (26). This aspect is not as evident in our data, but still fits with the overall positive response to vaccination offers at facilities for PEH. Another important inhibiting factor in accessing the COVID-19 vaccine were language barriers. Addressing language barriers through the provision of information in a variety of languages can enhance the participation of PEH and are important aspects of improving access to healthcare for PEH (13, 51). In terms of accessibility and affordability, the support and assistance of facilities for PEH in organizing vaccination or an appointment were again found to be very helpful. This enhancing factor was acknowledged by almost every participant and helped many of them to receive their vaccine. In our study, unbureaucratic vaccination offers were also linked to better accessibility for PEH, as many struggle with personal documents such as an ID card. Some participants experienced the publicly available COVID-19 vaccination sites as disappointing because they were considered as too bureaucratic, lacked appointments, or were hard to reach. Vaccine offers at general practitioners' practices were rarely mentioned among our participants, possibly because of avoidant behavior due to previous experiences of stigmatization in the healthcare system (15, 52).

There are several limitations to our study. The interviews were conducted at different periods due to organizational reasons and the seasonality of the shelters. Therefore, the circumstances of the COVID-19 pandemic as the availability of vaccines, current infection control measures, and political discourse differed. We also assume a selection bias toward PEH with positive vaccine attitudes and higher educated PEH, as our interview requests might have not caused interest by PEH with a negative attitude toward vaccinations or might have caused fears in less educated individuals. Furthermore, we did not include PEH who were unable to participate in the interviews because of substance abuse. This might have led to a selection bias toward healthier PEH. To address this limitation, we conducted maximum variation sampling based on theoretical criteria. The dimensions of access (19) are independent but interconnected. Therefore, the categorization of our participants' statements was not always clear. Further, to increase the validity of our results we conducted interviews in German, English as well as in Polish. However, the fact that we only included three languages in our interview study is also a limitation. It should also be considered that not all interviewees were native speakers of the respective language. This also applies to the interviewers. This might have been an obstacle for participants to fully articulate their ideas and feelings. Because we conducted the interviews in facilities with limited space, we could not provide private rooms for each interview. We were always seeking highest degree of privacy. Sometimes, non-participants were present in adequate distance. This might have had an influence on the openness of statements made in the respective interviews. We conducted one of our interviews with two participants at once. This might have influenced their perception of the interview

setting as a safe space to talk but also engaged them to think further on specific issues because of an ongoing interactive discussion. Through member checking with PEH community members (44) and representatives and interprofessional exchange with other researchers specialized in the subject matter and/or the subject methods we aimed to increase validity and credibility of our results.

Building a multidimensional strategy to better reach PEH is also recommended by the *National Federation for the Homeless* (Bundesarbeitsgemeinschaft Wohnungslosenhilfe, BAG W). Specifically, vaccination sites are suggested at locations that are already visited by PEH to ensure better integration into daily life, better accessibility, and less discrimination or experience of stigma. Furthermore, target-group-specific information given in different languages was recommended (26, 52, 53). Recommendations for a better vaccine uptake include a stronger and clearer promotion, development of interventions and stakeholder collaboration as PEH themselves might be interested in opportunities in being involved in preventive strategies for their community (26). Further, participatory health promotion involving PEH have been shown to be appropriate, acceptable and effective for community-based interventions (54). Our study contributes to understanding determinants of access and acceptance for preventive public health measures such as the COVID-19 vaccination among PEH in urban areas in Germany. Our findings are in line with prior international studies and add information on Germany in this context. We were able to identify determinants of vaccination access and acceptance using the 5C model and Theory of Access. Overall, our study suggests that vaccination acceptance is mainly influenced by psychological factors and depends in part on access factors. Further, the political discourse around COVID vaccination has shown to play an important role.

The identified fields for action offer important opportunities to steer vaccination offers for PEH in the future.

For future preventive public health measures, interest groups strongly recommend adapting prevention strategies to the special needs of vulnerable groups in society, especially for PEH (53, 55). Therefore, establishing target-group-oriented health care and public health strategies are crucial. Policymakers have recognized this gap and called for structural changes aiming at openness, accessibility, and reduced discrimination in the healthcare system in Germany (56). However, concrete steps to bring this aim further are currently lacking.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by Charité – Universitätsmedizin Berlin, Ethics Committee

(EA2/168/21). The patients/participants provided their written informed consent to participate in this study.

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Author contributions

JG, AS, and DS: study design. JG and DS: recruitment of participants. JG, DS, and MK: data collection. JG, AS, and MP: data analysis. JG: writing of original manuscript. JG, AS, and WH: revision and editing. AS, WH, and AL: supervision. All authors have read and agreed upon the published version of the manuscript.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Evidence for “Whole Family Approach” in accelerating uptake of COVID-19 and routine immunizations among integrated primary health services in Nigeria

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The family is the simplest unit but possesses the strongest bond in society. These qualities — bond and proximity — that exist both within and across neighboring families, according to our research, can be instrumental in shaping a new kind of health promotion strategy that can transform health behaviors in communities. The Whole Family Approach (WFA) is a government-sanctioned approach to increase uptake of COVID-19 vaccines in Nigeria. The approach entails leveraging the high family-based demand for some primary health services, such as malaria, diabetes, hypertension, and reproductive services, to generate demand for COVID-19 and routine immunizations. However, since the announcement in 2021, there has been no available evidence to show the impact of the approach on COVID-19 vaccine uptake, though global literature generally favors family-centered health approaches. This study tests the effectiveness of the approach in increasing the utilization of target services in a Nigerian community and further provides a theoretical framework for the strategy. Two primary healthcare facilities were selected in two communities located in Abuja in a quasi-experimental design. After a small-sample landscape assessment of the communities and the facilities, family-targeting health promotion activities were facilitated in the intervention community (integrated health education by trained community health influencers) and facility (opportunistic health promotion through in-facility referrals) for one month. Anonymized service utilization data were acquired from both facilities over a period of four months to analyze their respective month-by-month service utilization trends. Time trend analysis was conducted and revealed that WFA significantly increased service utilization ($N = 5870$; $p < 0.001$, $\alpha = 0.01$, 99% CI) across all the package services provided at the intervention facility. A supplementary Pearson's correlation analysis further presented a positive relationship ($r = 0.432-0.996$) among the services which favored the result. It can therefore be concluded that the “Whole Family Approach” of health promotion is efficacious in accelerating uptake of priority health services such as COVID-19 and routine immunizations. While there is more to be understood about this interesting approach, we recommend the improvement of communication and capacity gaps in Nigeria's primary healthcare system to ensure that promising strategies such as the WFA are adequately implemented at the community and facility levels.

KEYWORDS

Whole Family Approach, family-centred health promotion, covid-19 vaccination in Nigeria, routine immunization in Nigeria, integrated primary health services

1. Introduction

Nigeria's Ministry of Health, through the National Primary Health Care Development Agency, announced the adoption of the Whole Family Approach as a measure to increase uptake of the COVID-19 vaccine (1). The agency mentioned that it was to retain focus on the holistic health of individuals and their families while looking to improve the uptake of the vaccines in the second phase after a challenging first phase characterized by low uptake, even among health workers (2). The scope of the WFA was to integrate COVID-19 vaccination into primary health services, such as childhood routine immunization, hypertension, diabetes, malaria, reproductive health, and malnutrition, so that when people visited primary health care facilities, primarily for any of these services, they and their eligible family members could also receive their COVID-19 vaccines.

This family-centered care is an approach in healthcare delivery in which the services are planned around the family rather than an individual (3). The approach has existed for many decades but is mostly dominant in pediatric care, where it originated (4). The idea solidified after the realization that parents can equally contribute to medical decision-making over their children. Equally, the Institute for Patient- and Family-Centered Care defined the approach as a partnership between the health service providers, patients, and their families. In all the existing definitions, family-centered care is observed to be conceptualized around decision-making on treatment and patients' information management. In the Whole Family Approach, however, family-centered care manifests primarily in the domain of health promotion.

While existing literature affirms that family-oriented health promotion and disease prevention strategies improved treatment outcomes in patients (5), reduced clinical workload, and increased staff satisfaction (6), it is not yet understood whether the Whole Family Approach or Family-Centered Care could improve the uptake of health services within the Nigerian primary healthcare system context. It is important to note that Nigeria's primary healthcare system is mostly positioned to serve rural and semi-urban communities (7), which are occupied by the majority (64%) of Nigeria's population (8), of whom 96% access healthcare through out-of-pocket health spending (9). Thus, this research is poised to explore the potential of the Whole Family Approach in health promotion to improve health-seeking behavior in a Nigerian community setting. Following the demand and supply model of health systems, the Whole Family Approach is conceptualized to increase health-seeking behavior while optimizing the healthcare delivery system to provide family-centered care. Thus, the implementation strategy employed in this study involves the use of family-targeting health messages while working with health facilities to create a family-centered environment.

1.1. Theoretical bases of the implementation research

The Whole Family Approach aligns with four different theoretical models and emphasizes the attempt to increase uptake

of priority health services by simultaneously increasing key identified aspects of the factors of demand and supply. The models are the health-promoting family model (10), the Donabedian model (11), the health belief system (12), and Anderson's behavioral model for health services utilization (13). The health-promoting family model suggests that the family itself plays a critical role in the health promotion of its members. It suggests a new emphasis on the family's eco-cultural pathway (a range of activities that the family engages in which may affect the health of each family member), family health practices, and the family as actors (14). The Donabedian model underpins a method for the measurement of improvement in quality healthcare. The model is made up of four components: structure measures (these show the qualities of the staff/service to patient ratios and service hours), process measures (these show the way the structures and systems cooperate to deliver the intended outcomes), outcome measures (which measure the end result of quality care and if it achieved the aim it was set for), and balancing measures (these show the management of unforeseen or unintended positive or negative consequences and mitigates their impact if necessary) (15). The health belief model posits that the probability of individual adoption of a health behavior depends on the threat perception (susceptibility to and severity of a disease) and behavioral evaluation (concerning the efficacy and cost of adopting the health behavior) of the individual. Also, beyond the individual perception, individuals may need to be cued into successful adoption of a health behavior (12). The Anderson and Newman model for utilization of health services posits that the uptake of health services is a function of predisposing, enabling, and need factors. Need factors are a more immediate cause of healthcare service uptake and reflect the recognized or assessed health status of the individual. Enabling factors, such as individual or family income and wealth, refer to the resources and arrangements needed to acquire health treatments. Predisposing factors are an individual's socio-cultural features before illness, and they include culture, health beliefs, and demographic characteristics (13). These models are crucial to and play important parts in the formation of the strategies employed in this research. The adaptation of these models is illustrated below.

1.2. Description of intervention and the theory of change

In terms of poor uptake of health services, whether that is COVID-19 vaccines or childhood routine immunization, in developing countries, the challenges have been simplified along the lines of demand and supply (16). The demand side describes the choice of individuals or groups to seek health services, while the supply issues relate to accessibility, availability, and quality of health service delivery. Factors of demand are within the control of the individual or unit of individuals. They include household geographical location, indirect cost of care, ability to pay for services, individual and community attitude and perception towards healthcare/cultural preferences and norms

(1), and so on. Proximal factors are factors that directly affect the individual's choices, such as attitude towards healthcare and other preferences, while distal factors have intermediate effects and are further away from the individual, such as the individual's religious and traditional environment, social and economic status, gender power dynamics, and level of education (17).

Supply-related factors are service delivery factors that ultimately impact whether the clients can access, utilize, and continue the uptake of health services by the health system. They include the location of the healthcare service, attitude of the healthcare workers, staff management and effectiveness, direct cost of services, availability of drugs and related items, and functionality of payment systems (1). More frequently than not, the factors of demand and supply are dependent on each other and thus come together to influence the rate of uptake of health services.

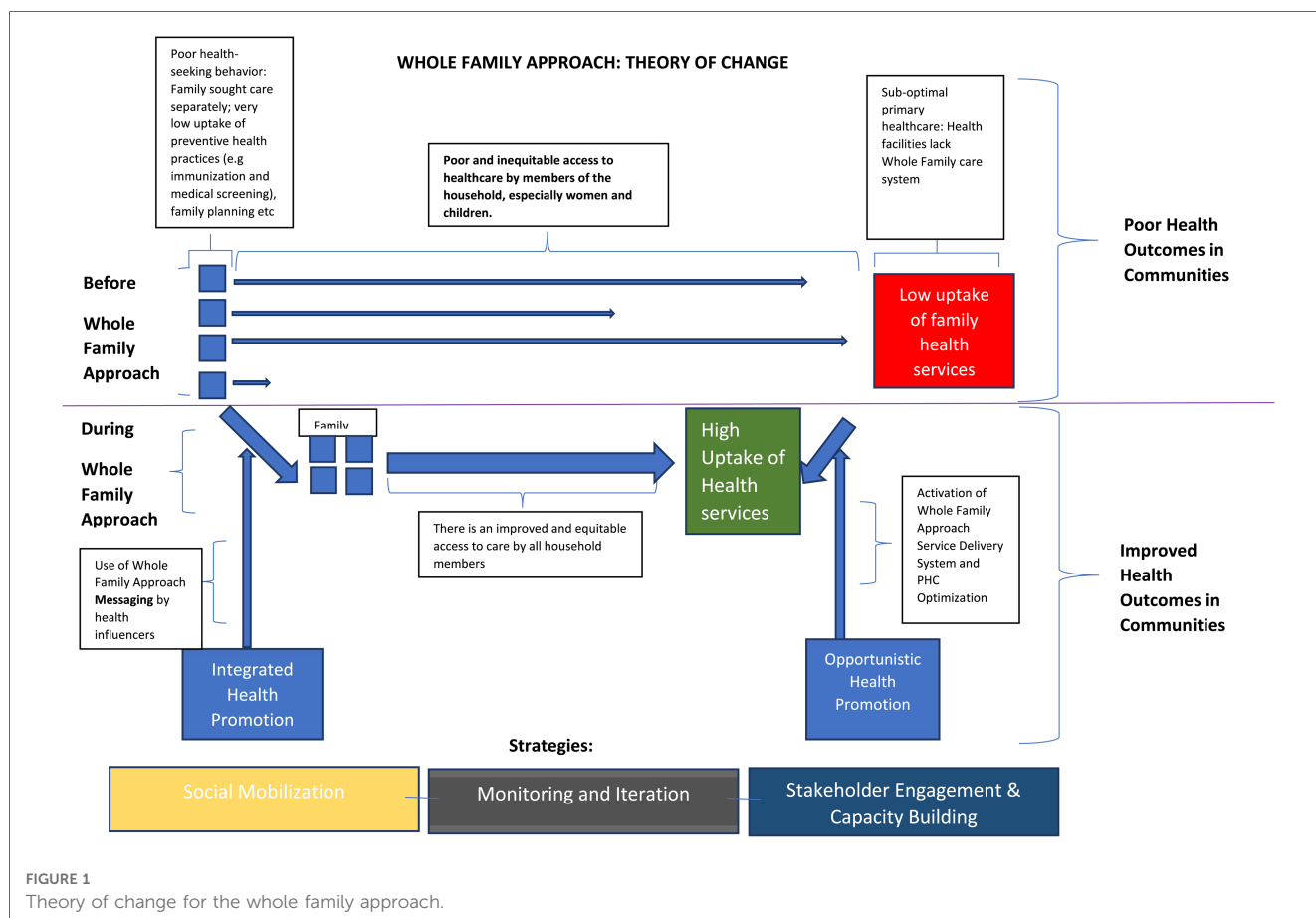
Therefore, in this study, the Whole Family Approach is deployed in the demand and supply components of family and community health. For the demand side, trackable Information Education and Communication (IEC) print materials are deployed through designated health announcers in each community and facility. On the supply end, facilities are primed with training and data collection tools to provide and document health services.

This approach aims to close the gap between people and health services through integrated health promotion in the communities and opportunistic health promotion in the facilities [see theory of

change]. Integrated health promotion programs combine two or more topics within health education or demand generation protocol and have been proven to improve health behavior (18). In this case, the services are outlined on a flier bearing a picture of parents and a child to depict the family-centeredness of the program at first glance. This aspect of health promotion is carried out by trained community health influencers who educate households on the benefits of the whole-family health service package at the primary health center located within their community.

The other strategic domain for health promotion is within the health facility, known as opportunistic health promotion. This form of health promotion is supported by a number of empirical studies in clinical setting (19, 20). Here, health service providers are primed to refer families of patients to services other than their sought-after health service. For instance, a parent who brings his or her child for routine immunization may be advised by the child immunization officer to consider taking their COVID-19 vaccine or receive counselling on family planning. Printed banners are also placed at conspicuous points in the facilities to opportunistically prompt health demand for the key services in the package. The alternative before Whole Family Approach illustrates theoretically poorer access to primary healthcare in an individualized approach to primary healthcare, leading to poor health outcomes in communities (see Figure 1).

The service package in this implementation research comprised reproductive health services, malaria, hypertension, diabetes,



childhood routine immunization, and COVID-19 vaccination. However, the approach itself can be employed to support a diverse health service package, including in an epidemic response setting such as COVID-19.

2. Method

2.1. Study design

This was a quantitative study based on a quasi-experimental design. Specifically, this design is defined by Miller et al. as pre-post with non-equivalent control group style (21). In this study, two facilities—one intervention, one control—with relative similarities are purposively selected for the study. This design is selected to compare mean differences using a time series analysis within and between the two facilities.

2.2. Study setting

The Federal Capital Territory (FCT), also known as Abuja, is the administrative capital of Nigeria. Located in the north-central geopolitical zone of Nigeria, it comprises six area councils and 62 (22) political wards. Abuja is inhabited by an estimate of 3,652,029 (23) people, of which the majority reside in its municipal area. The Abuja Municipal Council Area (AMAC) represents more than half of the FCT's population, while the rest is shared among the five other area councils: Kuje, Kwali, Bwari, Gwagwalada, and Abaji (see Figure 2). This research is geographically scoped within the municipal area as it provides a cross-sectional collection of most demographics (24, 25) not only in the FCT but in Nigeria. The key health services considered in this research are COVID-19 vaccination, routine immunization, nutrition, malaria, reproductive health services, and Non-Communicable Disease (NCD) screening services, especially Diabetes and Hypertension.

2.3. Study participants

The most crucial aspect of the study used the summary databases of the intervention and control facilities to measure the

utilization trend in the two facilities. In this process, the databases accounted for at least 8,339 participants—5,870 participants in the intervention facility, and 2,469 in the control facility. The research had no access to further demographic information on the participants who took up these services to avoid breach of patient data protection. In the small-sample landscape assessment, the non-probability sampling did not require calculating minimum sample size. For the study, 20 adult participants—10 female community members, six male community members, three female facility managers, and one male facility manager—were recruited to answer a survey on the knowledge, attitude, and practice of the Whole Family Approach in the intervention facility's community. Only community members who were adults (18 years and above) and resided in the community at the time of the study were eligible to participate in the survey.

2.4. Recruitment of community health influencers

Two community influencers (one male, one female) attached to the intervention facility were trained and recruited to carry out the awareness creation for this approach in the community.

2.5. Data collection

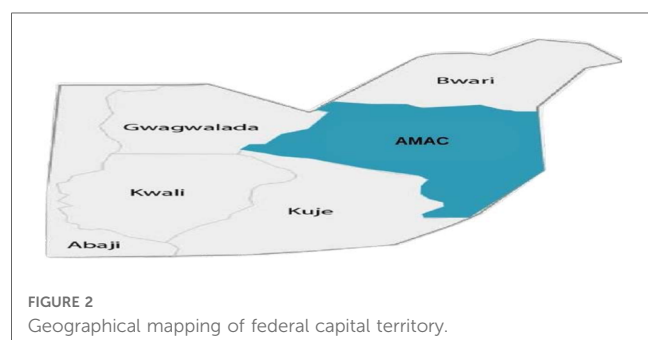
The data collection for this study spanned over a period of four months (May - August) in 2022. Data were collected in two stages: the landscape assessment and facility utilization data.

2.5.1. Landscape assessment

The landscape assessment was conducted in the intervention community for two days. Specifically, we were interested in understanding whether the participants were aware of the government's WFA program and if they were interested after a brief explanation of the approach by data collectors. Given that Hausa speakers predominate in the research areas, the surveys were written in English and facilitated in the local tongue for improved comprehension. Trained data collectors from the research team were responsible for collecting the data from each participant. Data were collected simultaneously in prepared google forms and paper questionnaires. The small-sample assessments were conducted to obtain a basic understanding of the level of awareness about the WFA as well as the readiness of the facility to provide the services. It provided context to the intervention research without forming the evidence basis for the impact of WFA in increasing uptake of primary health services.

2.5.2. Service utilization data

The end-line stage of the data collection involved collection of service utilization data from the facilities over a period of 4 months, inclusive of three months pre-intervention and one month of intervention. Routine data from the facility register was used to



capture service utilization data for this study instead of introducing an alternative data instrument at the facilities. The facility summary data provide utilization information of the facility without disclosing the private medical information of the patients. Kane et al (26). supported the use of routine facility data for most studies carried out within the clinical setting.

2.6. Data analysis

Following the validating of the data by comparing the paper-documented data with the electronically computed data, the landscape assessment and the service utilization data were analyzed using a set of data analysis tools, namely Microsoft Excel and IBM's Statistical Package for Social Sciences (SPSS). The landscape assessment data were represented in simple descriptive statistics while the service utilization data were processed through a few steps of data analysis to extract detailed understandings. The first analysis was to examine if there was a significant impact on the trend of service utilization in the intervention facility compared to the control facility. So, a chi-squared test was used to analyze a comparative time trend between data from intervention and control facilities. The data input across the four months of both facilities were converted to percentage. Therefore, the percentile distribution in the control facility was used to model the expected rates in the intervention dataset. The second step of analysis was to confirm that the first result was due only to the month of intervention (Month 4 or M4). To achieve this, pre-intervention percentile distribution in the control facility was used to model the expected rates of distribution in the intervention dataset. The third step of analysis was a Pearson's correlation analysis run across the services to test the relationship between the services.

2.7. Ethical consideration

The project team obtained ethical approval from the Research Ethics Committee of the Health and Human Services Secretariat (HHSS) of the Federal Capital Territory in Nigeria. During data collection for landscape assessment, oral consent was obtained from each participant using a standard verbal consent script that highlighted identity and confidentiality protection. Oral consent was also obtained in local languages where necessary.

3. Results

3.1. Landscape assessment

For the interviews, 16 randomly selected respondents were chosen. Families who had at least one of the criteria were included: they were married, had a pregnant woman, or had an child under the age of 5 in their household. The questions assessed the respondents' knowledge of and attitude to the whole family approach in the community. All participants were aware of

the location of primary health care centers in their communities and, upon further inquiry, used them for basic health care consultation and treatment. The majority of the respondents were unaware of the whole-family approach. 87.5% were aware of an integrated family approach, which entails individuals going along with their families to health centers for joint family care, but not specifically of the government's initiative to do so. The idea was widely accepted, with 81.3% of participants expressing a willingness to be a part of the integrated family approach if the opportunity arose. The rest expressed reluctance to participate in the idea, perhaps due to perceived barriers such as cost of the services, time availability, and documentation fatigue at primary health care centers (see [Table 1](#)).

The baseline facility assessment on the practice of WFA showed that three out of four managers were unaware of the whole-family approach. However, the two facilities were fully equipped and provided basic health care services (see [Table 2](#)).

3.2. Comparison of service utilization between intervention and control facilities

Month-by-month summary data was obtained from the intervention and control facilities (see [Table 2](#)) and was then subjected to a descriptive analysis presented in [Figure 3](#). Not that, because nutrition services are integrated with routine immunization services to children in facilities, the summary data obtained from the facilities yielded combined uptake rates for both services. The aim of collecting service utilization data is to determine if there will be a significant increase in the uptake of the WFA services in Month 4 at the intervention facility. To achieve this, therefore, percentile distribution of the month-by-month rates of total service uptake was analyzed for each facility. The control facility recorded 23.01%, 25.67%, 24.91% and 24.40%, while intervention facility recorded 22.47%, 23.75%, 22.33% and 31.45%. With the exception of the Month 4 ratio at the intervention facility (also known as Intervention M4 ratio), there is an observed evenness of +/-2% relative difference in successive ratios across the intervention and control facilities, showing an appreciable level of similarity enough to model one

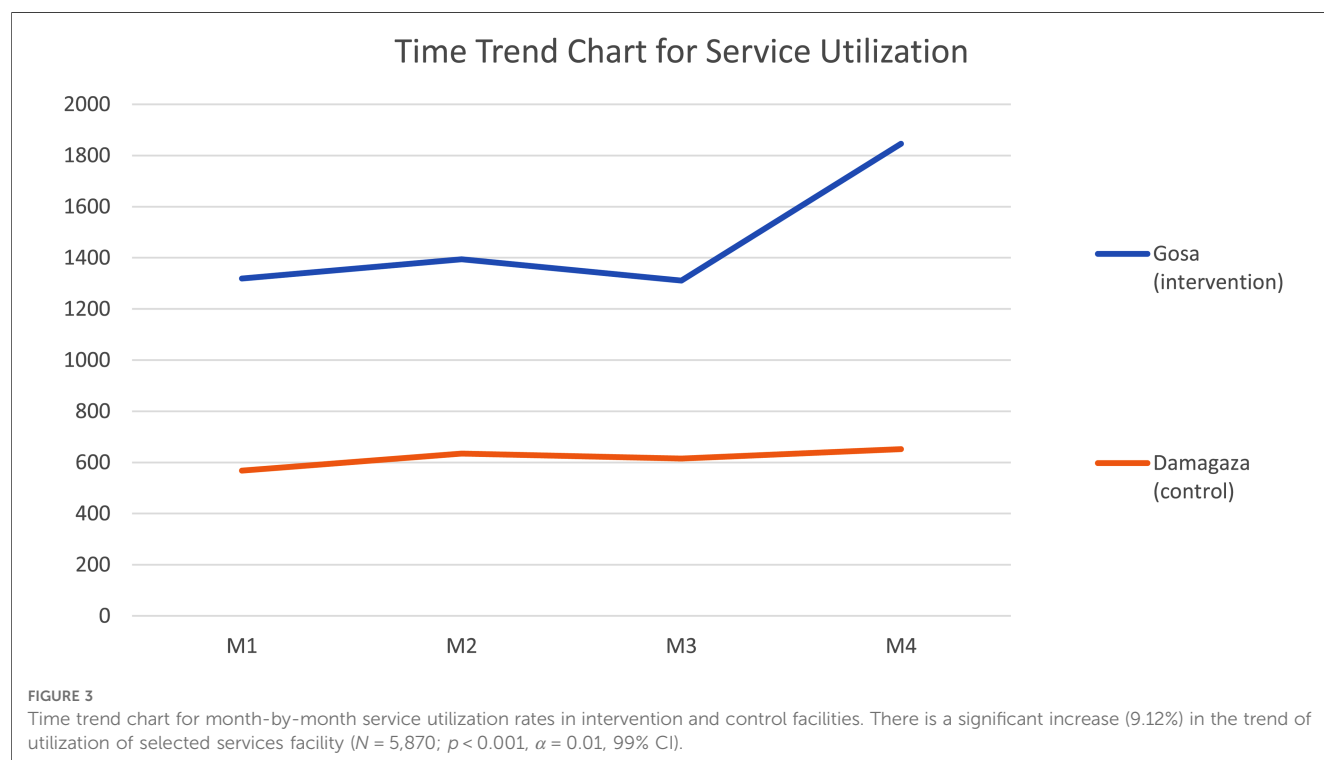
TABLE 1 Baseline assessment for level of knowledge and facility readiness.

Question	Yes % (n)	No % (n)
Community		
Men	37.5 (6)	62.4
Women	62.5 (10)	37.5
Do you know the PHC in your community?	100 (16)	0 (0)
Do you know about the WFA?	12.5 (2)	87.5 (14)
Would you be interested in the WFA?	81.3% (13)	17.7 (3)
Facility		
Men	25 (1)	
Women	75 (3)	
Do you know about the WFA?	25 (1)	75 (3)
Does your facility provide WFA package services?	100 (4)	0 (0)

TABLE 2 Month-by-month service utilization rates in intervention and control facilities.

	Intervention (GOSA)					Control (DAMAGAZA)				
Services	M1	M2	M3	M4	Total	M1	M2	M3	M4	Total
Covid-19	19	12	10	72	113	8	4	7	8	27
% Distribution	17	11	9	64		30	15	26	30	
% Change	-	-6	-2	55		-	-15	11	4	
RH	106	123	112	355	696	61	46	70	48	225
% Distribution	15	21	16	51		27	20	31	21	
% Change	-	4.8	-5	35		-	-7	9	-10	
Malaria	22	31	26	103	182	105	159	83	125	472
% Distribution	13	17	14	57		22	34	18	26	
% Change	-	4	-3	43		-	12	-16	8	
Diabetes	5	3	6	13	27	11	7	5	9	32
% Distribution	19	11	22	48		34	22	16	28	
% Change	-	-8	11	26		-	-12	-6	12	
Hypertension	6	6	6	16	34	88	90	51	98	327
% Distribution	18	18	18	47		27	28	16	30	
% Change	-	0	0	29		-	1	-12	14	
RI & Nutri	1,161	1,219	1,151	1,287	4,818	295	328	399	364	1,386
% Distribution	24	25	24	27		21	24	29	26	
% Change	-	1	-1	3		-	3	5	-3	
All Services	1,319	1,394	1,311	1,846	5870	568	634	615	652	2,469
	22.47	23.75	22.33	31.45		23.01	25.67	24.91	26.4	
	-	1.28	-1.42	9.12		-	2.66	-0.76	1.49	

M, Month; RH, Reproductive Health; RI, Routine Immunization; Nutri, Nutrition. Table 2 shows that the highest uptake of services across months was recorded in the month of the intervention (M4). Also, COVID-19 vaccine uptake increased by 55% against previous months where uptake declined by 2% and 6% respectively. The increase in percentages of 35%, 43%, 26%, 29%, and 3% were similarly observed for reproductive health, malaria, diabetes, hypertension and routine immunization services, respectively. [Note: Routine immunization and nutrition (vitamin A administration) are recorded combined in the facility Summary Data in Nigeria's public primary health facilities].



facility after the other and run a chi-square test. Although there is a seemingly significant difference (9.12%) between intervention M4 ratio when compared to its preceding month ratio (22.33%), chi-

square statistics helped to determine the statistical level of significance of this difference ($p < 0.001$, $\alpha = 0.01$) at 99% confidence interval (CI).

TABLE 3 Pearson's correlation analysis among the chosen services for the whole family approach testing.

	Covid-19	RH	Malaria	Diabetes	Hypertension	RI
Covid-19	1					
RH	.972*	1				
Malaria	.851	.949**	1			
Diabetes	.952**	.964*	.905**	1		
Hypertension	.961*	.996*	.962*	.974*	1	
RI	.432	.540	.707	.581	.611	1

There is a positive (+) correlation across all the services.

*Correlation is significant at the 0.01 level (2-tailed).

**Correlation is significant at the 0.05 level (2-tailed).

3.3. Relationship within the WFA services package

The third level of analysis in this study is testing the level of relationship within the services in the WFA package deployed in the intervention facility. The Pearson's correlation analysis of individual service ratios is presented in Table 3, indicates that, although there is generally a positive relationship among the services ($r = .452 - .949^{**}$), COVID-19, an adult (age 18 and above) health service in Nigeria, significantly correlated other services related to adults namely reproductive health ($r=.972^{*}$), malaria ($r=.851$), diabetes ($r=.952^{**}$), and hypertension (.961*), but not significantly with routine immunization and nutrition ($r=.432$) which are exclusively provided to children (0-5 year old).

4. Discussion

A small-sample landscape assessment informed the project team of the low level of awareness of the community members about the government-sanctioned approach. Most of the facility managers also had limited knowledge about the program despite offering the services required to implement the approach. The project team identified a communication gap between the facility managers and the agency leaders which motivated the team to organize a capacity-building program for all the facility managers with the attendance of the agency leaders to emphasize the need to strengthen top-bottom communications in the primary health system. The project team further visited the facility to train staff about the approach, especially the community health influencers. A 6 ft-by-5 ft flex-banner was erected at the entrance of the facility to facilitate in-facility referrals for the services.

At the end of the 1-month community sensitization using the 100 tracked fliers distributed by the community influencers, trend analysis from the 4-month facility utilization data harvested from the facility summary registers revealed that the Whole Family Approach significantly increased total uptake of services in the local primary health facility during the month of intervention. Similar results had been obtained using WFA to improve the weight profiles of children in a clinical study carried out in the United Kingdom (27). Health promotion activities are generally

expected to increase health service uptake whether in lowering blood pressure (28) or in improving health outcomes in adults with developmental disabilities (29). Some studies measured the impact of health promotion and education activities through behavioral changes before and after the intervention (30) while others measured impact through service utilization or both (31). Since health promotion activities in Nigeria are rarely measured and published with empirical data, it is difficult to compare this program's outcomes to other related programs.

The program was implemented on a small scale, influenced by limited availability of resources and administrative compliance. However, it manages to present evidence for the efficacy of the approach as well as establish a positive association in the package services selected for the study. The efficacy of the approach was ascertained through the pre-post non-equivalent control group design (Figure 3) while a Pearson's correlation analysis affirms that the incorporated services in this program were suitable for family-targeted health promotion (Table 3).

Although there is no significant level of correlation between the rates of uptake of COVID-19 and routine immunizations due to WFA, the positive association observed makes a moderate case for the integration of routine immunization and COVID-19 vaccination as Nigeria is faced with low rates of uptake of both services (32, 33). In addition, Nigeria in 2021 had an estimated 3.1 million (~14%) (34) zero-dose children, which may have been exacerbated by the COVID-19 pandemic (35), as well as other challenges such as insecurity (36)—both of which have disrupted health services in many affected areas. However, in the wake of efforts to integrate services to increase uptake of these essential immunization programs, the positive relationship in the uptake of these services among other primary health services occasioned by WFA can be effectively leveraged.

5. Limitations

The formative study was limited by funds, thereby limiting the number of facilities and communities included to test the approach. Beyond that, some implementation challenges were experienced in the team's objective to track the use of IEC material with the utilization of the services. Tracking the IEC material with details of households reached helped to ensure that

the contracted community health influencers actually achieved the target number of households. However, the project team could not fully measure how much of the increase in uptake can be attributed directly to either the community sensitization or the opportunistic health promotion within the facility.

Also, data collection for the service utilization data was limited to the facility summary data register which lacked demographic details such as sex- and age-disaggregated data.

6. Conclusion

The Whole Family Approach of integrated health promotion generated a significant increase in the utilization of six family-targeting services in a suburban community at the heart of Nigeria's federal capital territory. This study should inform intermediate adoption and expansion of the strategy based on the stated evidence and implementation guidelines. With respect to future need for the strategy, it is important to state that the whole-family approach is capable of a wide range of flexibility in the mix of services, however, standards for choosing a services package is yet to be established. Conclusively, it would be fulfilling to see future studies done to strengthen the developed framework and implementation steps, and also obtain results across a wider variety of facilities and communities with stronger arrangement with facilities to obtain demographic information without breaching patients' medical privacy.

Data availability statement

The original contributions presented in the study are included in the article, further inquiries can be directed to the corresponding author.

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Ethics statement

The studies involving human participants were reviewed and approved by Federal Capital Territory Health Research Ethics Committee. The patients/participants provided their written informed consent to participate in this study.

Author contributions

OA-B conceptualized the article and propounded its theoretical framework. CO and CN contributed to the conceptualization and methodology setting. GN, FA, and BE conducted data collection while. JO, CO, and MO analyzed the data. All authors proof-read and OA-B did the final review of article. All authors contributed to the article and approved the submitted version.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Evaluation of COVID-19 vaccine implementation in a large safety net health system

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Objectives: To evaluate rapid COVID-19 vaccine clinic implementation from January-April 2021 in the Los Angeles County Department of Health Services (LACDHS), the second-largest US safety net health system. During initial vaccine clinic implementation, LACDHS vaccinated 59,898 outpatients, 69% of whom were Latinx (exceeding the LA County Latinx population of 46%). LACDHS is a unique safety net setting to evaluate rapid vaccine implementation due to system size, geographic breadth, language/racial/ethnic diversity, limited health staffing resources, and socioeconomic complexity of patients.

Methods: Implementation factors were assessed through semi-structured interviews of staff from all twelve LACDHS vaccine clinics from August-November 2021 using the Consolidated Framework for Implementation Research (CFIR) and themes analyzed using rapid qualitative analysis.

Results: Of 40 potential participants, 25 health professionals completed an interview (27% clinical providers/medical directors, 23% pharmacist, 15% nursing staff, and 35% other). Qualitative analysis of participant interviews yielded ten narrative themes. Implementation facilitators included bidirectional communication between system leadership and clinics, multidisciplinary leadership and operations teams, expanded use of standing orders, teamwork culture, use of active and passive communication structures, and development of patient-centered engagement strategies. Barriers to implementation included vaccine scarcity, underestimation of resources needed for patient outreach, and numerous process challenges encountered.

Conclusion: Previous studies focused on robust advance planning as a facilitator and understaffing and high staff turnover as barriers to implementation in safety net health systems. This study found facilitators that can mitigate lack of advance planning and staffing challenges present during public health emergencies such as the COVID-19 pandemic. The ten identified themes may inform future implementations in safety net health systems.

KEYWORDS

COVID-19, vaccine, vaccine distribution, implementation, leadership, communication, integrated delivery of health care, equity

Introduction

When COVID-19 vaccines attained U.S. Food and Drug Administration Emergency Use Authorization (EUA) and were made available to U.S. health systems in December 2020, safety net health systems were challenged to implement widespread vaccination in resource-limited environments during a time of peak COVID-19 transmission (1, 2). Vaccination implementation entailed understanding the evolving regulations of vaccine eligibility and availability, then distributing vaccine accordingly to vulnerable communities experiencing significant racial and economic inequities due to the COVID-19 pandemic. Implementation of safety net initiatives has been associated with challenges including limited staffing, lack of organizational financial investment, and the need to address patients' biopsychosocial complexities. Facilitators to implementation have included advance planning, redundancy in communication, knowledge of patient needs, desire to perform well, personnel commitment to reducing health inequities, and multidisciplinary teams to drive implementation (3–6). More research is needed to understand the role of implementation factors in the safety net, particularly for primary care-led vaccine distribution approaches (7). To date, there are few published qualitative studies of COVID-19 vaccine delivery in safety net health systems (8, 9), and none in a large safety net health system with coordination across many sites.

The Los Angeles County Department of Health Services (LACDHS) faced challenges in rapid vaccine implementation due to the size of the system, geographic breadth, language/racial/ethnic diversity and socioeconomic complexity of patients (low-income, publicly insured, and/or uninsured). LACDHS is the second largest public health system in the United States, serving over half a million unique patients annually across eight health center groups and four hospitals (Figure 1). Facilities span a geographic area greater than 4,000 square miles, including rural, urban, suburban, and exurban populations. The LACDHS empaneled patient population comprises approximately 60% Latinx and 12% Black/African American patients, compared to the overall LA County population with 46% Latinx and 8% Black/African-American people (10, 11). These populations were disproportionately affected during the pandemic as Latinx and Black people living in LA County had death rates nearly twice that of non-Hispanic white people (12–14). Persons in extremely poor or high-poverty census tracts had the highest COVID-19 case and death rates in LA County (14, 15).

In January 2021, LACDHS launched twelve COVID-19 vaccine clinics at each hospital and health center group, geographically spread across the county (Figure 1). The goal of the LACDHS COVID-19 vaccine implementation was to vaccinate as many patients as quickly as possible in the setting of limited access to vaccines, rapidly evolving eligibility guidelines, and staffing shortages related to the concurrent COVID-19 surge. We aimed to identify determinants impacting implementation of a systemwide COVID-19 vaccine intervention using the Consolidated Framework for Implementation Research (CFIR) in

a safety net health system under circumstances where advance planning was limited. This evaluation could inform future population-level implementation efforts in safety net health systems, especially during public health emergencies.

Methods

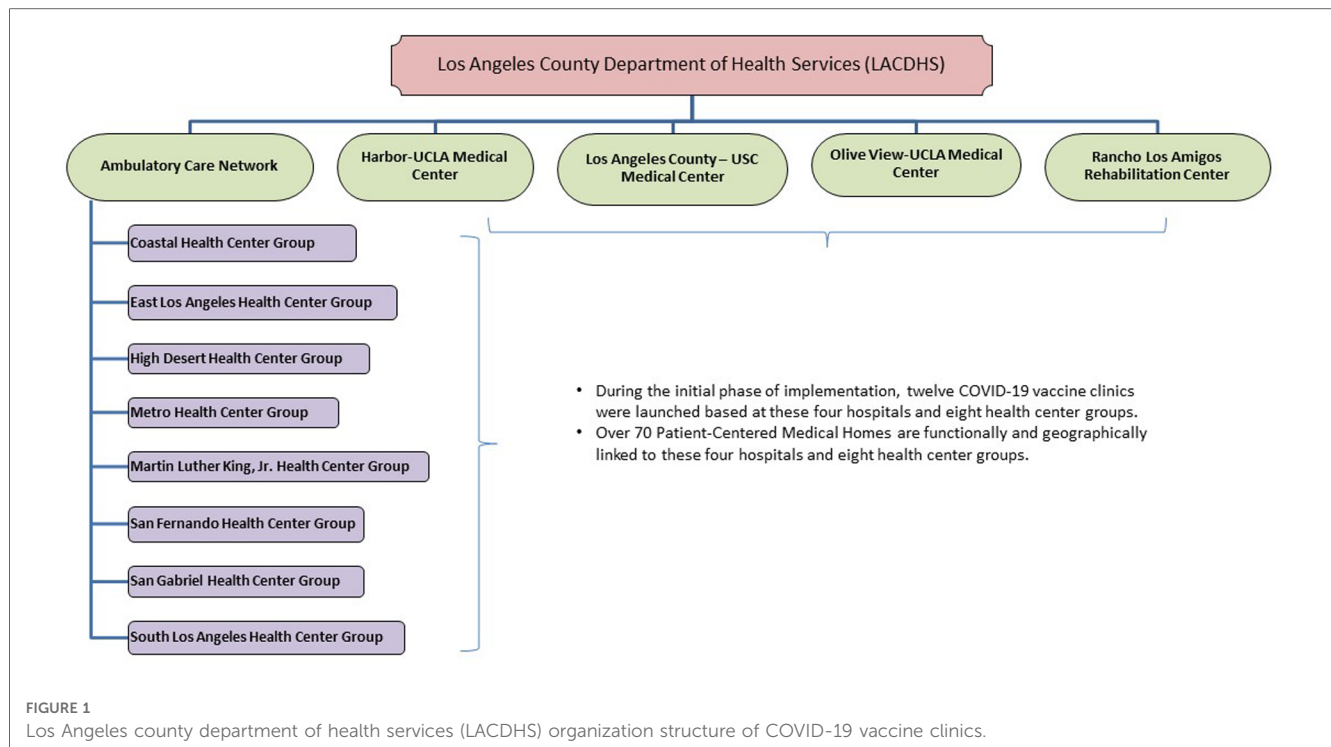
This qualitative study evaluated determinants of LACDHS COVID-19 vaccine clinic implementation during the initial period of phased vaccine availability from January 2021 to the end of April 2021. The LA County Department of Public Health (LACDPH) Institutional Review Board approved the study before the initiation of the research. We report our work using the Standards for Reporting Qualitative Research (16, 17).

Setting and organization of LACDHS COVID-19 vaccine clinics

In January 2021, LACDHS leveraged its experience with and infrastructure from prior dedicated influenza clinic implementation to set up twelve COVID-19 vaccine clinics geographically spread across the county (Figure 1). LACDHS convened a multidisciplinary vaccine steering committee and primary care vaccine strategy workgroup to engage key stakeholders across disciplines and sponsor systemwide vaccination planning (Figure 2 “Central Leadership”). Each clinic site formed multidisciplinary leadership teams (Figure 2 “Site Leadership”) to oversee local COVID-19 vaccine clinic implementation.

Central leadership determined which sites within LACDHS would house its limited supply of ultra-low temperature freezers and met regularly to decide on system-level strategies impacting COVID-19 vaccine allocation and administration (Figure 2). Central leadership also made the critical decision to focus initial vaccination efforts on LACDHS-empaneled patients rather than the general public. Given that empaneled patients are disproportionately Latinx and Black, low-income, and undocumented people compared to the general LA County population, this was an intentional system-level decision to combat inequities in COVID-19 care.

COVID-19 vaccine clinics offered appointment-based and walk-in access. Some sites also offered drive-up services. To target eligible patients most effectively during the early phases of CDC vaccine eligibility, data-driven patient outreach lists were generated based on patient age and information on chronic conditions from the EMR. Utilizing outreach lists and scheduling scripts, clinic and call center staff called patients to schedule vaccine appointments, using bilingual staff when available. Additional strategies to reach vulnerable patients included automated phone calls, texts, and emails for high-volume population outreach. Staff also scheduled vaccine clinic appointments when patients presented to clinic sites for other reasons (i.e., primary care appointments, pharmacy medication pick-ups, and laboratory testing). Vaccine clinics were mostly staffed using existing staffing resources, with little additional hiring of contractors.



Summary of LACDHS COVID-19 vaccine administration during implementation

From January 21, 2021, through April 30, 2021, LACDHS COVID-19 vaccine clinics administered 101,222 COVID-19 vaccinations. This number excludes doses administered in hospital inpatient wards, emergency departments, homeless sites, or correctional facilities not administrated by the COVID-19 vaccine clinics described herein. Of the 59,898 unique outpatients LACDHS vaccinated during this initial implementation period, 29.8% were aged 65 years or over, 69.7% were aged 18–64, and 0.5% were aged 16–17. 57.5% of vaccinated identified as female, 42.4% as male, and less than 0.1% as other or unknown. The race and ethnicity breakdown of those vaccinated during implementation was: Hispanic/Latinx 69.2%, Black/African American 8.1%, Asian 6.7%, White 3.6%, American Indian/Alaskan Native 0.1%, Native Hawaiian/Pacific Islander 0.1%, Multi-Race 0.3%, Other/Unknown 11.9%. The majority of COVID-19 vaccinations LACDHS administered (85%) went to individuals in the lowest two quartiles of the Healthy Places Index (accounting for social determinants of health including education, job opportunities, environmental factors) which surpassed overall LA County performance in this regard (18). Vaccine administration data and demographic information were gathered from the LACDHS electronic medical record and analyzed using Statistical Analysis Software.

Interview guide

We utilized the CFIR to design an interview guide for COVID-19 vaccine clinic stakeholders. CFIR domains covered included

inner setting, outer setting, individuals, process, and intervention characteristics (19, 20). The guide included open-ended primary questions and prompts to elicit thorough responses (see [Supplementary Material A](#) for the interview guide mapped to CFIR domains).

Interview recruitment and methods

From August 2021 through November 2021, potential participants were recruited *via* purposive sampling. The research team asked the twelve vaccine clinic directors to identify a cross-section of personnel who played integral roles in the planning, managing, and/or daily operations of the local vaccine clinic from January–April 2021. These potential participants were either members of “Site Leadership” or front-line staff in COVID-19 vaccine clinics. Each potential participant was emailed up to three times. Interested participants were sent an electronic pre-interview demographic survey and attitude questions (see [Supplementary Material B](#) for pre-survey) and scheduled for an interview. Participants provided written informed consent. Interviews were recorded *via* HIPAA-compliant internet phone or video call and lasted 30–45 min. A professional transcription service transcribed interview recordings and de-identified proper names, clinic names, and locations.

Rapid qualitative analysis

The research team applied a rapid analysis approach to analyzing all 25 stakeholder interviews (21–24). The team

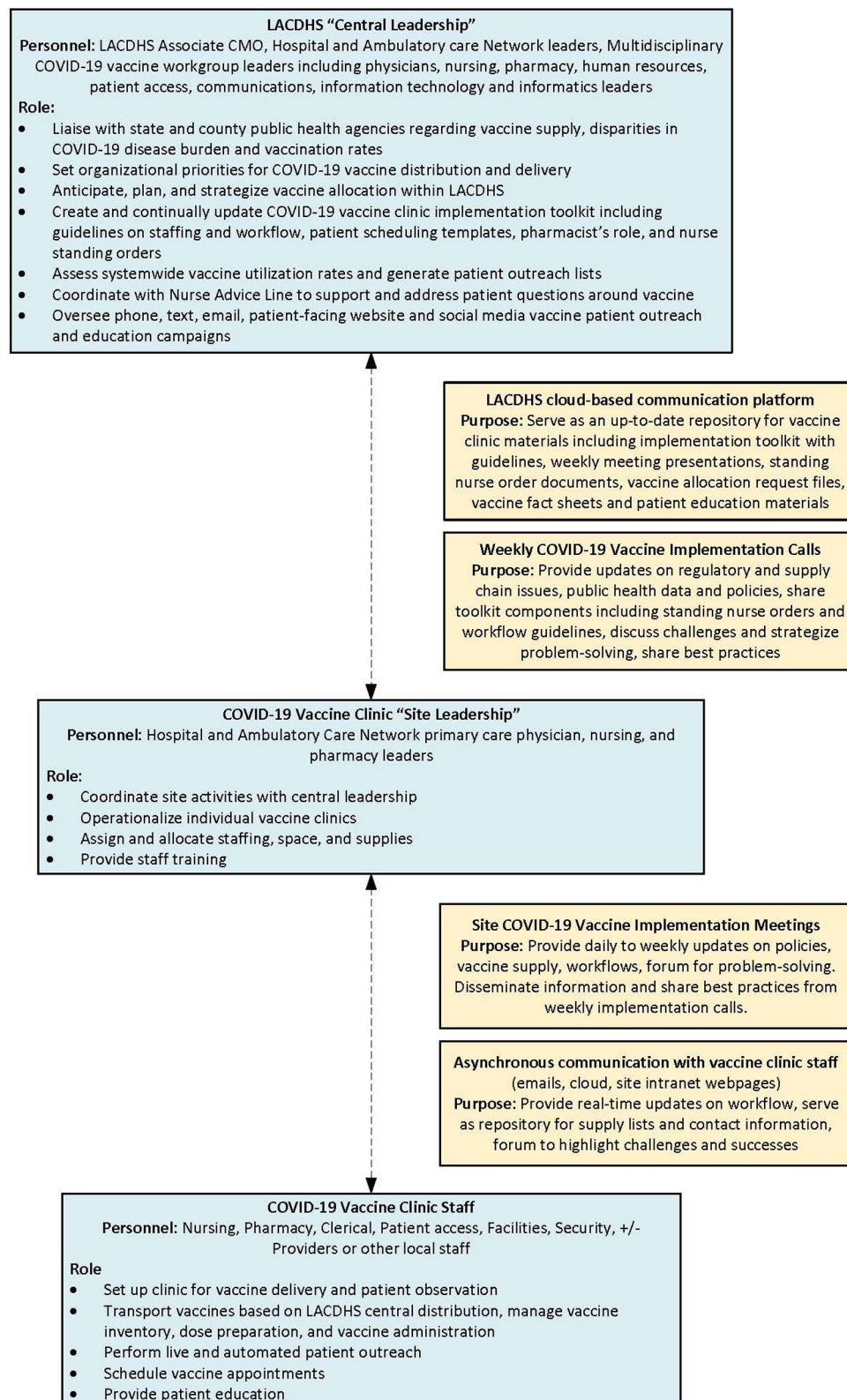


FIGURE 2
 LACDHS COVID-19 vaccine clinic implementation leadership and communications structure.
 Blue-shaded boxes summarize leadership infrastructure and yellow-shaded boxes summarize communications infrastructure.

developed a master transcript summary template based on the original interview guide. This template was adapted upon the team trialing the template with six transcripts to improve standardization of data entry until consensus was reached. Researcher pairs then independently took notes, selected exemplar quotations from each de-identified interview transcript, compared notes, and edited a single high-level summary for each interview. Researchers met weekly to discuss findings, resolve discrepancies, and build consensus on transcript summaries. Each transcript summary was entered into an Excel matrix (24–27). Each row captured an individual interview and each column represented a topic area from the summary template (see [Supplementary Material C](#) for the transcript summary template). Then, the team identified and summarized major themes and representative quotes across interviews, which mapped to four CFIR domains. A synthesized summary of findings was presented to participants for comment and correction. An audit trail was kept throughout the analysis,

including survey and interview guide drafts, scheduling logistics, raw data, field notes, rapid analysis summaries, weekly meeting minutes, and other process notes documenting key steps in methodological decision-making.

Results

Of 40 potential participants, 32 responded to initial email requests, 26 completed the participant demographic survey, and 25 ultimately completed an interview (see [Table 1](#) for Survey Participant demographics). The survey also included two questions related to the experience of participating in the implementation. When asked to rate the ease or difficulty of the COVID-19 vaccine implementation at their site on a Likert scale from 1 (easiest) to 5 (hardest), 31% ($n=8$) of participants indicated implementation was easy or very easy and 38% ($n=10$) participants indicated implementation was difficult or very difficult. Ninety-two percent of participants ($n=24$) endorsed they would agree to be part of the COVID-19 vaccine clinic if asked again.

Ten narrative themes emerged as determinants of the LACDHS COVID-19 vaccine implementation. These determinants are presented as they correspond to four CFIR domains: Innovation Characteristics, Outer Setting, Inner Setting, and Process. Themes and exemplar quotes are presented in [Table 2](#).

Innovation characteristics—implementation of COVID-19 vaccine clinics

Theme 1. LACDHS central leadership guidance and local site flexibility supported problem-solving during rapid implementation.

The LACDHS leadership communication infrastructure included structured weekly and *ad hoc* meetings between central and site leadership ([Figure 2](#)). This served as a platform for the bidirectional exchange of ideas between central and site leadership and across sites. These meetings provided a forum to clarify rapidly evolving information, coordinate and align around promoting health equity, and share best practices and lessons learned which site leaders could bring back to vaccine clinics to adapt local workflows quickly. Sites had leeway to adapt workflows based on local needs and resources while aligning with central guidelines. Participants viewed central leadership as informative and transparent, communicating regularly to inform clinics of the latest federal, state, and county policies.

Standardization worked effectively to an extent, but it was ultimately up to the clinics to adapt the implementation to best meet the needs of their local site and teams, particularly related to staffing and space availability. Participants described variations across vaccine clinics regarding infrastructure, demonstrating local flexibility in implementing central guidance. Sites strategized staffing solutions in the context of a concurrent winter COVID surge with nursing shortages due to frequent staff sick calls and redeployment of outpatient nursing to inpatient settings. As a result, some sites used staff from pandemic-closed

TABLE 1 Survey participant demographics*.

Role in LACDHS	% total surveyed ($n=26$)	Count
Clinical provider/medical director	26.9%	7
Pharmacist	23.1%	6
Nursing staff	15.4%	4
Other (administrative, scheduling, health education, physical therapy)	34.6%	9
Sex		
Female	50.0%	13
Male	50.0%	13
Age		
20–30 years	3.8%	1
31–40 years	34.6%	9
41–50 years	30.8%	8
51–60 years	26.9%	7
61–70 years	3.8%	1
Cultural background		
Asian	42.3%	11
Latinx	26.9%	7
Caucasian	15.4%	4
Black/African American	11.5%	3
Native American/Pacific Islander	3.8%	1
Years in current position		
<1 year	3.8%	1
1–5 years	57.7%	15
6–10 years	11.5%	3
11–15 years	15.4%	4
16–20 years	3.8%	1
21–25 years	3.8%	1
>25 years	3.8%	1
Vaccine clinic effort per week		
1–10 h	26.9%	7
11–20 h	34.6%	9
21–30 h	7.7%	2
31–40 h	11.5%	3
>40 h	19.2%	5

*26 staff completed the pre-interview demographics survey and 25 staff completed the interview.

TABLE 2 Themes and exemplar quotes from the Los Angeles County Department of Health Services COVID-19 vaccine implementation evaluation.

CFIR domain	Theme	Exemplar quotes from participants
Innovation characteristics	(1) LACDHS central leadership guidance coupled with local site flexibility supported problem-solving during rapid implementation.	<ul style="list-style-type: none"> • “DHS did a great job as far as giving us the guidelines and then what the facilities did was to take it and then make it their own. Like, we harmonized it.” (Clinical provider/medical director from Site 3) • “Everything was quite complicated. So, they took all those complex pieces and simplified it for us and made it into a workable system.” (Clinical provider/medical director from Site 1)
	(2) Multidisciplinary teams facilitated vaccine implementation and vaccine clinic activities.	<ul style="list-style-type: none"> • “... it was a lot of collaboration with nursing, with providers, with pharmacy, and even down to the different departments ... it was definitely a collaborative effort, and it was surprising how well it went in ... I was impressed with DHS, actually, because it seems like everyone got together quickly. (Nursing staff from Site 11) • “DHS pharmacy staff was very supportive ... if we needed to get more vaccine or get less vaccine, or swap vaccines, they were pretty open to it ... sometimes it would require our pharmacy staff to travel from X to really, really far away, to XX probably one of the farthest away locations”. (Clinical provider/medical director from Site 12)
Outer setting	(3) Initial COVID-19 vaccine scarcity and rigid eligibility tiers led to ethical dilemmas.	<ul style="list-style-type: none"> • “So it was great to see them come but it was also sad to see people that were, like, 64 with the same conditions. ‘But yes, I’m sorry I can’t vaccinate you right now, but you’re in the next tier. Keep calling us, we will call you when we’re ready.’ But telling that to the community when they’re saying ‘I want it, I want it,’ and it’s a free vaccine, but we’re still following the CDC guidelines of holding it out.” (Clinical provider/medical director from Site 3) • “[We] felt very strongly that given this small, scarce supply, it was irresponsible for us as healthcare providers to let a dose go to waste. And so, my entire objective and purpose from the onset and being involved was to try to ensure that no dose was wasted.” (Other staff (administrative, scheduling, health education, physical therapy) from Site 4)
	(4) Initial COVID-19 vaccine scarcity and infrastructure limitations made coordination of vaccine delivery across LACDHS complex.	<ul style="list-style-type: none"> • “Initially it was little aliquots of vaccine coming through in certain ways for certain groups, so very restrictive criteria. Everything was quite complicated.” (Clinical provider/medical director from Site 1) • “Because you have this whole thing going on where you’re trying to predict and project your vaccine usage ... So, I’m trying to project how many vaccines we’re going to do two weeks out, trying to make sure we’ve got the schedules and then trying see if we’re going to get full and actually use those. And we were routinely carrying over from one week to another because it just was impossible to hit it with the precision that they would have liked to” (Clinical provider/medical director from Site 10)
Inner setting	(5) Underestimated time and resources to overcome vaccine concerns and misinformation.	<ul style="list-style-type: none"> • “I discovered the amount of time required to engage with patients and incorporate the patient perspective, to understand where they’re coming from and to potentially get them to the point of being ready to get the vaccine. And so, to have these sensitive and challenging and energy-consuming conversations takes time. And I don’t think that there was space made for that adequately.” (Other staff from Site 4) • “... controversy with Johnson & Johnson came about and it was temporarily suspended and then it was restarted, but it was tough because people had already heard all this publicity and had concerns. But then you still had some people that were anxious to only have one shot. I mean we certainly tried to accommodate our patients as much as we could, but it’s a tough thing, overcoming vaccine hesitancy and not having the time to really work with all your outreach staff except at a very basic level on how to work with patients when they’re hesitant about being vaccinated.” (Clinical provider/medical director from Site 10)
	(6) Broader adoption and use of standing nurse order protocols enabled rapid capacity-building in COVID-19 vaccine clinics.	<ul style="list-style-type: none"> • “It was good ... when they started rolling it out to more people to be trained for the [standing protocol] then we have more vaccinators and more staff that can help us with the clinic.” (Nursing staff from Site 2) • [Standing protocols] made it “a lot easier to give the vaccine to people. And it avoided us having to use the providers, which allowed them to do other things; so that was a good one.” (Clinical provider/medical director from Site 6)
	(7) A shared sense of purpose fostered a positive team culture.	<ul style="list-style-type: none"> • “... That ... concept of ‘It takes a village’ and our administration, everyone enacted an approach and commitment to getting our patients vaccinated.” (Clinical provider/medical director from Site 3) • “Since we’re there every day and working long periods of time, we all got to know each other very well, and it was a good mini family/team kind of ambience or vibe.” (Nursing staff from Site 3) • “Neat to be living through and involved with something that’s so big, and really momentous.” (Clinical provider/medical director from Site 5)

(continued)

TABLE 2 Continued

CFIR domain	Theme	Exemplar quotes from participants
Process	(8) Active and passive communication structures enabled sites to adapt to evolving demands.	<ul style="list-style-type: none"> • “I had just an ongoing text message with the leads at the time just because you know, email was sometimes just not fast enough.” (Other staff from Site 7) • “At the end of the day we would also have a post-clinic huddle where we would talk about what went well today or what could have been improved or things that happened on that day, like, that clinic, and then ways we can improve them for tomorrow.” (Nursing staff from Site 1)
	(9) Developed patient-centered engagement strategies for COVID-19 vaccine clinic scheduling and vaccine administration.	<ul style="list-style-type: none"> • “So the patients who needed to be in their cars, so they were handicapped, they weren’t dressed for the weather, they had a child—and this are all that has happened—or they were helping someone who was not ambulatory or they themselves weren’t ambulatory. We set up, like, reserved parking spaces as close to the vaccine station as possible and they would just tell the registration staff when they drove in that they were not able to walk up.” (Other staff from Site 7) • “We were trying to spread the word that, hey, our site is offering COVID vaccines and ... that population where there’re a lot of African Americans. And I know based on the history, there’s a lot of resistance or hesitancy. So there was a lot of outreach done and I think that’s why a lot of the nurses, they continued to call the day before and the day of their vaccination appointment just to confirm that they’re going to keep it and also to answer any questions.” (Pharmacist from Site 9)
	(10) Sites encountered a variety of process challenges implementing COVID-19 vaccine clinics.	<ul style="list-style-type: none"> • “So the way that we had set up this clinic, it was actually in the older parking garage ... something so simple as that. That’s where we were actually stationed. But then if there was rain, we would feel the rain. So then, we would have to quickly shift somewhere else within the clinic. I mean, if we’re vaccinating ... 200 patients within a few hours, so of course it could be a little tight for spacing.” (Nursing staff from Site 11) • “... then you have this challenge of people working one list and then you get another list and a lot of it’s still duplicative and cumulative ... Then you have the other challenge of internally somebody having to take that list and put it on some sort of shared drive or something because you might have multiple people working the same list. And you get some feedback that patients are getting tired of getting calls about this ... so trying to document that this person doesn’t want any more calls ...” (Clinical provider/medical director from Site 10)

clinics (e.g., dentists), some paid overtime for staff to work additional hours, and others used registries, volunteers, or students to staff vaccine clinics. Some sites pulled staffing from primary care or urgent care clinics, leaving those clinics short-staffed, sometimes leading to staff resentment. Each site had different vaccine clinic floor plans with varying accessibility to host the vaccine clinics. Some sites held the vaccine clinics indoors in temporarily closed clinics or repurposed spaces, including lobbies and auditoriums, and others held clinics outdoors on sidewalks, patios, and in covered garages.

Theme 2. Multidisciplinary teams facilitated vaccine implementation and vaccine clinic activities.

LACDHS assembled a multidisciplinary leadership team at the central level which included physician, nursing, pharmacy, and patient access leadership (Figure 2). This team designed a vaccine implementation toolkit to provide integrated guidance for the vaccine clinics. For example, physician leadership digested and communicated clinical and public health updates, nursing leadership addressed workflow and informatics needs related to vaccine administration, and patient access leads designed scripts and workflows for outreach and patient registration. Due to the complexity of inventory and allocation, storage, handling, and preparation of the vaccines, pharmacy leadership coordinated the distribution of large direct vaccine shipments across the system and monitored utilization across vaccine

clinics. Pharmacy leads managed re-distribution of vaccine between sites to accommodate daily patient volume and minimize waste associated with short expiration dates.

Based on central leadership toolkit guidelines, site leadership assembled local multidisciplinary teams to problem solve and optimize workflows across staff types, and adapt workflows in real time. The strategic choice to designate a lead pharmacist role in the COVID-19 vaccine clinics was identified as an essential enabler of vaccine clinic efficiency as site pharmacists had knowledge of LACDHS vaccine resources and could mix, draw, administer, and counsel on the vaccine. Central leadership toolkit materials were designed to allow for workflow and role flexibility. For example, pharmacists could administer vaccine if there were nursing shortages, and nursing could register new patients when there was a clerical shortage.

Outer setting—macro-level factors that originate outside the LACDHS system

Theme 3. Initial COVID-19 vaccine scarcity and rigid eligibility tiers led to ethical dilemmas.

During the early weeks of vaccine scarcity and strict adherence to state and federal eligibility tiers, avoiding vaccine wastage was one of the participants’ most significant concerns and even a

source of anxiety. This felt most weighty at the end of a clinic session when the time came to draw the vaccine from the last multi-dose vial for the day, and there were more doses than patients remaining. Some participants expressed this as an ethical challenge: avoiding administering vaccines to patients outside the eligibility tiers meant doses might be wasted. Participants noted it was challenging to stay within eligibility tiers as tiers rapidly shifted. For example, at one point, there was discordance between the CDC and LACDPH guidance on the definition of chronic conditions and how to vet eligibility by occupation instead of age. Participants also experienced moral conflict when withholding vaccine from high-risk patients close to meeting eligibility criteria but did not fall into current eligibility tiers. Participants noted this was a tense time—balancing a reluctance to turn patients away with the risk of vaccine wastage resulted in extraordinary efforts to find patients to use the last remaining doses which could not be stored. One participant described this undertaking:

“We felt very strongly that given this small, scarce supply, it was irresponsible for us as healthcare providers to let a dose go to waste. And so, my entire objective and purpose from the onset and being involved was to try to ensure that no dose was wasted.”—Other staff member (administrative, scheduling, health education, physical therapy) from Site 4

To administer all remaining doses, participants performed last-minute outreach including overhead announcements, finding vulnerable staff such as environmental services and dietary workers to vaccinate, or going to Urgent Care and the emergency department to find patients before the vaccine had to be wasted.

Theme 4. Initial COVID-19 vaccine scarcity and infrastructure limitations made coordination of vaccine delivery across LACDHS complex.

Initial scarce COVID-19 vaccine supply necessitated complex coordination of vaccine distribution across our large health system. LACDHS received vaccine shipments weekly only at select sites with ultra-low temperature freezers. Vials then had to be re-distributed to sites without ultra-low freezers. Limited and variable weekly vaccine allocations restricted how far in advance patients could be scheduled. This resulted in complicated staffing and outreach planning, and sometimes led to site pharmacists driving long distances across the county to pick up doses from another LACDHS site. Participants also commented on the challenges of dealing with unpredictable and variable vaccine availability and the differences across multiple vaccine brands, including dosing intervals, expiration dates, and community preferences.

Inner setting—pertaining to the infrastructure, resources, and culture of the LACDHS system

Theme 5. Underestimated time and resources required to overcome vaccine concerns and misinformation.

Participants observed that additional time and resources were needed to overcome vaccine hesitancy and misinformation at all points of patient contact. This included encounters with the primary care provider, the nurse advice line, at the time of vaccine scheduling, while waiting in line at the vaccine clinic and at the time of vaccine administration. Local sites performed most of the patient-level vaccine outreach and scheduling mostly using non-clinical call center staff. However, non-clinical staff felt unprepared to answer vaccine questions from patients. Some sites reassigned clinical staff to make individualized calls to vaccine-hesitant patients or answer questions on-site at the vaccine clinics. Participants desired more community education and outreach and perceived a lack of consistent scripting for staff, especially in addressing complex vaccine conversations during a clinic visit with several competing priorities. Patients presenting to the vaccine clinic intending to get vaccinated still had questions about allergies, interactions, what to expect after the vaccine, and other concerns. Some sites created their own patient education and FAQ materials. It was viewed as a barrier that LACDHS central leadership did not provide more support in this area. A few staff expressed concern for their own safety from exposure to patients with COVID-19, and compared the COVID-19 pandemic to the HIV epidemic.

Theme 6. Broader adoption and use of standing nurse order protocols enabled rapid capacity-building in COVID-19 vaccine clinics.

Participants recognized that the urgency and breadth of COVID-19 vaccine implementation warranted a transformation of existing workflows to improve efficiency for widespread vaccination. A meaningful change was delegating provider vaccine ordering authority to nursing staff for quicker vaccine ordering. LACDHS had prior experience with standing nurse orders, however an important change was made to the nurse training process for the COVID-19 vaccine implementation. Training for the standing nurse orders shifted from periodic in-person training to on-demand recorded virtual training for nurse vaccinators, which allowed hundreds of vaccinators to be trained in a short amount of time. Additionally, electronic post-training proficiency testing allowed for real-time calculation of results, which were posted to the staff portal where an up-to-date master roster of staff ready to vaccinate was maintained. Participants thought completing the online training before arriving to work at the vaccine clinic facilitated orientation and same-day onboarding while staffing was in flux.

Theme 7. A shared sense of purpose fostered a positive team culture

Participants noted a fellowship with their vaccine clinic co-workers when asked about site-level engagement. Staff had a strong sense of purpose and a feeling of responsibility to match the moment and be a part of history fighting the pandemic. Participants agreed a robust process for communication and collaboration amongst the local site team was a key factor in success. Participants desired to reach as many patients as possible with an “all hands-on deck” approach and willingness to do whatever it took to “make it work.” One participant described the team approach:

“That ... concept of ‘It takes a village’ and our administration, everyone enacted an approach and commitment to getting our patients vaccinated.”—Clinical provider/medical director from Site 3

Multiple participants expressed feeling proud that they were making a difference. Openness to feedback and continuous improvement fostered a culture of multidisciplinary teamwork and collaboration, which stemmed from shared investment in the work. Sites were keenly aware of the safety net patient population, which led to many discussions at the local level about historical and contemporary marginalization and vaccine hesitancy as barriers to COVID-19 health equity. This strong sense of purpose facilitated buy-in for COVID-19 vaccine clinic implementation. Additionally, participants praised site leaders who showed gratitude and appreciation for vaccine clinic staff. Many leaders were present on the front lines to quickly address staffing and supply issues, effectively promoting a teamwork culture.

Process—means by which LACDHS COVID-19 vaccine clinics were implemented

Theme 8. Active and passive communication structures enabled sites to adapt to evolving demands.

Participants discussed the site-specific rapid decision-making related to implementation of brand-new vaccine clinic workflows and expressed the feeling that “we were building the plane as we flew it.” Site leaders realized they had to develop site-specific tools and infrastructure to support real-time communication between local team members. Debriefing with frontline staff promoted staff engagement in continuous improvement and enabled sites to walk back from stalled innovations. Sites with effective communication used various tools (e.g., emails and remote meeting platforms) and built redundancy in their communication structure (e.g., daily clinic huddles, weekly meetings, and workstations in proximity to leaders). Sites without timely, broad, and multidisciplinary communication structures felt challenged. Participants cited *ad hoc* meetings, frequent updates relaying messages from central leadership, and openness to feedback from frontline staff as effective communication methods used by site leaders.

Theme 9. Developed patient-centered engagement strategies for COVID-19 vaccine clinic scheduling and vaccine administration.

Participants enthusiastically described the novel ways their sites engaged patients to get vaccinated.

LACDHS central leadership created low-literacy vaccine Frequently Asked Questions documents in English and Spanish for use in the vaccine clinics. Site leaders were intentional about staffing vaccine clinics with diverse and multilingual staff and interpreters, along with providing appropriate educational materials when available. Sites used data-driven patient outreach lists provided by central leadership to schedule patients. Motivational interviewing, clinic staff sharing their vaccine stories, and face-to-face patient communication were important tools that helped engage patients. Sites prioritized direct patient education and communication; providers and clinic staff engaged

patients while waiting in line and during and after vaccine administration to answer questions.

Sites provided broad access to vaccine appointments by offering evening and weekend clinics, accepting walk-ins, and performing patient-centered scheduling to combine a vaccination visit with another clinic visit. Online self-scheduling was also available systemwide for first doses. Participants expressed a desire for expanded self-scheduling for subsequent vaccine doses. Efforts to recruit patients for vaccine scheduling extended beyond phone outreach to every touch patients had with the clinics, e.g., picking up medications at the pharmacy or getting labs done. Participants described strategies to meet limited-mobility patient needs by providing wheelchairs and walkers on-site, vaccinating at curbside, and coordinating home vaccination referrals. One participant described these efforts:

“So the patients who needed to be in their cars, so they were handicapped, they weren’t dressed for the weather, they had a child—and this are all that has happened—or they were helping someone who was not ambulatory or they themselves weren’t ambulatory. We set up, like, reserved parking spaces as close to the vaccine station as possible and they would just tell the registration staff when they drove in that they were not able to walk up.”—Other staff member from Site 7

Additionally, patient safety, comfort, and experience were of paramount importance. Participants reported designating places for patients to lie down, socially distanced observation areas, and providing free personal protective equipment and outdoor heating.

Theme 10. Sites encountered a variety of process challenges implementing COVID-19 vaccine clinics.

Central leadership designed social media and broadcast message campaigns in English and Spanish to encourage vaccination and created patient outreach lists stratified by language for sites to schedule eligible patients. While most sites agreed with this outreach approach, one site refrained from performing language-concordant outreach for fear of prioritizing that ethnic group over English-speaking patients. The live outreach calls required extensive effort, yielded mixed results, and sometimes seemed to be wasted effort. Non-clinical scheduling staff worked outreach lists that were thousands of patients long, making multiple attempts and leaving voicemail messages if patients did not initially answer. Site staff also leveraged previously infrequently used robocall technology to perform automated outreach. Staff accommodated variable incoming call volume by adjusting staffing shifts, modifying the interactive voice response (phone tree branching structure), and continuously monitoring calls. In addition to this outreach, sites fielded a high volume of incoming calls from patients requesting to schedule vaccine appointments, many of whom were not yet eligible per county eligibility tiers.

LACHDS COVID-19 vaccine clinics were based in primary care settings. The hospitals and larger health centers also deliver specialty care and varied in how much their vaccine clinic collaborated with specialty care. These sites varied in their workflows of how patients in specialty care were directed to vaccine clinics, and how limited staffing was distributed between

primary care, vaccine, and specialty care clinics. During the early phases of implementation in the setting of vaccine scarcity, central leadership focused initial vaccination efforts on LACDHS-empaneled primary care patients rather than the public to promote vaccine equity. This led to some confusion and tension at sites when non-empaneled patients receiving specialty care at LACDHS sites could not be vaccinated even when meeting vaccine eligibility criteria.

Participants were forthcoming that not all site-level operational decisions were adaptive. Examples of workflow decisions that were not sustained or served as barriers to efficient vaccination included: not hiring temporary nursing staff which resulted in staffing shortages, mixing vaccines in pharmacy hoods rather than at the vaccine clinic which required additional staff runners to transport vaccines, limiting Janssen vaccine administration for women over age 50 due to concern for thrombus despite no such FDA guideline, and not opening vaccine clinic on county holidays despite available staffing. Some participants noted that central leadership could have helped anticipate some logistical needs of the sites, such as coordinating bulk printing of vaccine clinic signage and purchasing of cold cubes for vaccine storage and tents for outdoor vaccine administration.

Discussion

Participants' experience of the LACDHS COVID-19 vaccine implementation converged on ten themes related to four CFIR domains: Innovation Characteristics, Inner Setting, Outer Setting, and Process. These themes illustrate how our large safety net health system rapidly mobilized to launch broad-scale COVID-19 vaccination during a public health emergency. Limited resources necessitated LACDHS leadership and staff to be resourceful by leveraging bi-directional communication, quickly adapting to local site and patient needs, and promoting teamwork, all while aligning work to evolving COVID-19 vaccine guidelines.

Our study adds to the literature by providing a qualitative assessment of a large-scale implementation in a safety net health system where coordination across many sites was a core feature. LACDHS had implemented systemwide programs in the past (28, 29); however, no previous intervention was as far-reaching or had to be rolled out as quickly under such a systemwide strain on resources. To date, there have been few publications detailing COVID-19 vaccine implementation in safety net systems. DiVirgilio et al. emphasized community education and targeting by zip code to focus on communities disproportionately affected by COVID-19 morbidity and mortality in their Chicago study (8). San Francisco's safety net health network highlighted drop-in hours as the most effective way to lower barriers to COVID-19 vaccine access (9). Both studies operated on a smaller scale (approximately 5,000 patients in the San Francisco study and 11,000 patients in the Chicago study), with less geographic breadth.

A key facilitator of implementation seen in some safety net health system studies is an emphasis on advance planning for implementation (5, 6). However, health systems did not have the luxury of advance planning with COVID-19 vaccine

implementation during the pandemic. The LACDHS case of COVID-19 vaccine clinic implementation under time pressure suggests that real-time frontline staff input into implementation design and balancing system standardization and local site adaptations are important facilitators in scenarios where advance planning is not possible. The rapid stand-up of LACDHS COVID-19 vaccine clinics demonstrates how a traditionally rigid system can be agile and adaptive to meet the moment.

A recent review of qualitative implementation studies in safety net settings found that understaffing and high staff turnover rates were the most common reason for the lack of acceptability of interventions (6). LACDHS, like other safety net systems, experienced high staff turnover and understaffing rates during the pandemic due to the inpatient COVID-19 surge and COVID-19-related sick callouts. Our study identified the use of multidisciplinary teams, bidirectional communication across leadership and sites, and the broad use of standing nurse orders as facilitators which helped overcome the barriers of staff turnover and understaffing. Similar to Crable's findings (3) where stakeholders' personal commitment to reduce health inequities was a facilitator of implementation, a takeaway of this evaluation is that a positive work culture and a clear shared goal helped mitigate a pressured work environment with high demands. Our themes of the importance of bidirectional and frequent communication and addressing patients' biopsychosocial complexities also aligned with previous studies of implementation in safety net settings (3).

The LACDHS vaccine clinic implementation deepened participants' and the research team's appreciation for the social complexity of the LA county safety net population. Frontline staff served as the best advocates for identifying and addressing social needs to lower barriers to patient vaccine access (30); however, beyond providing operational accommodations such as expanded vaccine clinic hours, bilingual staff, and assistance for those with limited mobility, sites had varying interpretations of how to promote health equity in vaccine clinics. Most sites and staff naturally focused on addressing the social needs of individual patients, rather than on the root causes of health inequities. Participants experienced moral discomfort when asked to focus on empanelment status and vaccine eligibility criteria, rather than vaccinating all-comers. These scenarios illustrate how additional training promoting a deeper understanding of health equity vs. equality is needed. To build on a commitment to inclusive care, LACDHS should offer staff training to further develop structural competency in health equity, an important step in the journey to advance health equity (31–33).

The LACDHS COVID-19 vaccine implementation experience highlighted the need to develop a comprehensive patient education strategy at the system level, encompassing outreach communications as well as education at the point of care. Safety net patient populations comprise diverse groups with different sociocultural, education, and outreach needs to combat vaccine misinformation and promote vaccine uptake (34–37). Participants expressed that central leadership did not provide enough support in patient education. LACDHS central leadership included low-literacy vaccine FAQ documents and scheduling scripts in its implementation toolkit, however, additional support and a robust infrastructure for patient education was needed.

Some sites opted to create their own scheduling scripts, FAQs, and signage, reallocated clinical staff to address questions, and attempted to use language-concordant and culturally concordant staff to promote optimal health communication. Additional patient education materials in the vaccine clinics and resources to address vaccine hesitancy might have increased vaccine acceptance and vaccination rates. Allocating funding for and investing resources in building patient education, engagement, and communications infrastructure as a core service for safety net systems would be an important step to laying the foundation for future successful safety net implementations.

Study limitations include potential participant recall bias. Interviews were conducted from September to November 2021, months after the defined early vaccine implementation period from January to April 2021. Interviews were intentionally conducted mainly with vaccine clinic team members rather than central leadership, leading to a perspective focused more on site and frontline experiences. Finally, this study lacked patient perspectives on the LACDHS vaccine clinic implementation.

This comprehensive qualitative analysis of the LACDHS rapid implementation of COVID-19 vaccine clinics yielded important lessons for safety net health systems caring for populations experiencing disproportionate disease burden due to societal inequities. This analysis fostered a deepened understanding of facilitators which can help overcome understaffing and a lack of advance planning. Key facilitators included using robust communication between all levels of the organization and balancing workflow standardization with local site flexibility. Additional lessons included the importance of building system capacity for health equity work and regarding patient engagement and communications infrastructure as a core necessity for safety net health systems. Applying these lessons in future implementations can benefit staff, patients, and safety net communities.

Data availability statement

The original contributions presented in the study are included in the article/[Supplementary Material](#), further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving human participants were reviewed and approved by Los Angeles County Public Health, Ambulatory Care Network and Health Services Administration Institutional Review Board. The participants provided their written informed consent to participate in this study.

Author contributions

JC and CZ conceived of the study design and developed the interview guide, with expert guidance from SC and review by JT, GG, AT, RK, and KK. RK conducted interviews and data

acquisition. JC, JT, GG, AT, KK, RK conducted data analysis and interpretation. JC, JT, GG, AT, and KK created tables and figures. SC provided expertise in qualitative research and rapid analysis techniques. AB provided expertise in qualitative research during conception and design of the research and funding for research support. JC, JT, GG, AT, KK, RK, CZ drafted sections of the paper, with SC and AB providing critical revisions, and JC and KK responsible overall for the paper's content and accuracy and responsibility for accuracy and integrity of all aspects of this research. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/frhs.2023.1152523/full#supplementary-material>.

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Assessment of childhood immunization services at private healthcare facilities in Indonesia: a case study in a highly-populated city

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Introduction: The need to enhance the utilization of the private sector for immunization programs in Indonesia while maintaining the high quality of services provided is evident. This study aimed to rapidly assess immunization services at private healthcare facilities in Indonesia by using Bandung, the most densely populated city, as the reference case.

Methods: Initially, a situation analysis was conducted by collecting data from selected healthcare facilities ($n=9$). Furthermore, a qualitative study was taken into account by developing framework approaches and conducting interviews with different layers, such as mid-level managers at healthcare facilities ($n=9$), professional organizations ($n=4$), and public stakeholders ($n=7$).

Results: The situation analysis showed that private healthcare facilities had provided sufficient time for essential childhood immunization services with adequate staff. Nevertheless, the number of limited staff the Ministry of Health (MoH) has trained remains a programmatic problem. Furthermore, private healthcare facilities have used the MoH guidelines and additional internal guidelines for immunization services as the primary reference, including in the efforts to provide complete and reliable equipment. Vaccine availability at private healthcare facilities is manageable with an acceptable out-of-stock level. The results of our interviews highlighted three key findings: the lack of coordination across public and private sectors, the need for immunization service delivery improvement at private healthcare facilities, and the urgency to strengthen institutional capacity for advocacy and immunization systems support.

Conclusion: Even though private healthcare facilities have been shown to make a modest contribution to childhood immunization services in Indonesia, efforts should be made to expand the role of private healthcare facilities in improving the performance of routine immunization programs.

KEYWORDS

vaccination, vaccine, situation analysis, qualitative, interview

1. Introduction

The Expanded Program for Immunization (EPI) in Indonesia is falling short of the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) target to reach 90% of children under the age of 1 nationwide and at least 80% in every province by 2020 (1, 2). The Coronavirus Diseases 2019 (COVID-19) pandemic has dramatically impacted routine immunization

performance in Indonesia (3, 4). The national immunization program data showed a decline in the coverage of basic immunization programs from 93.6% in 2020 to 84.5% in 2021, indicating that thousands of children will be at risk of increased morbidity and mortality from the outbreaks of vaccine-preventable diseases (VPDs) (5). Coverage of immunization is at risk because restrictions have already led to temporary closure and service suspensions among integrated public healthcare facilities as the backbone of routine maternal, newborn, and child services in Indonesia. On the other hand, subsequent reports showed that the proportion of immunization services at private healthcare facilities has been growing significantly (6, 7). Despite the transition to universal health coverage, private healthcare facilities still dominate Indonesia's healthcare system, where 64% of Indonesia's hospitals are private (8). A recent immunization perception survey in Indonesia showed a high demand for safe and timely vaccination services during the COVID-19 outbreak (5). Respondents strongly supported government policy to continue the immunization services with safety precautions, and private healthcare facilities are preferable places for getting immunization services (5). This preference for private healthcare facilities might be due to the proximity of private healthcare facilities to the people, the constant availability of healthcare professionals at private healthcare facilities, and poor services in some public healthcare facilities (9). This preference for healthcare facilities informed the need to enhance the utilization of the private sector in immunization programs while maintaining the high quality of services provided. In addition, from a global perspective, the private sector performs various tasks and activities to support national immunization programs. In low- and middle-income countries (LMICs), it supports the delivery of immunization services and promotes early acceptance of new vaccines before their introduction and widespread use by the public sector (10).

This study aimed to rapidly assess immunization services at private healthcare facilities in Indonesia using Bandung as the reference city. As the capital of West Java Province, Bandung is considered the most densely populated city in Indonesia, with a density of over 14,000 people per square kilometer (11). The latest basic health research conducted by the Ministry of Health (MoH) in 2018 reported that the complete basic immunization coverage for children aged 12–23 months in this region was only 58% (12). Compared with other regions, this coverage was lower, possibly caused by underreporting data from private healthcare facilities. Hence, the objectives of this exercise were to identify gaps, gather perceptions of relevant stakeholders, and prepare for the scale-up of immunization activities at private healthcare facilities.

2. Methods

A review of available data, existing policy, legal review, and published literature was applied as the initial step to analyze the situation of immunization services at private healthcare facilities. In addition, primary data were collected by identifying problems and gaps in vaccine service delivery, human resources, and supply chain management, and delivering questionnaires to 9 of 30 (30%) private healthcare facilities that deliver immunization services in Bandung (13). Applying WHO's guidelines on Service Availability and Readiness Assessment (SARA) to assess service readiness for childhood routine immunization services at private healthcare facilities, several significant variables were taken into account in the

questionnaire by focusing on basic amenities and equipment, such as general characteristics (e.g., service days per month, hours of service in a typical day, staff involved in vaccination, and outreach services available), staff and training (e.g., guidelines for EPI and staff trained in EPI), equipment (e.g., cold boxes/vaccine carriers with ice packs, refrigerators, sharp containers, single-use standard disposable or auto disposable syringes, continuous temperature monitoring devices in the refrigerators, energy sources and power supplies for vaccine refrigerators and immunization cards), and vaccine availability (e.g., current stock and stock-outs in the past 3 months) (14).

Furthermore, a qualitative study was considered by developing framework approaches and conducting interviews with different layers. Applying WHO's framework on monitoring the immunization system (15), in-depth interviews with mid-level managers were conducted in 9 selected private healthcare facilities, representing a type A hospital ($n=1$; TAH), type B hospital ($n=2$; TBH1 and TBH2), type C hospital ($n=2$; TCH1 and TCH2), vaccination house ($n=2$; VH1 and VH2), and private clinic ($n=2$; PC1 and PC2). These respondents comprise private-for-profit ($n=7$) and private-not-for-profit institutions ($n=2$). Questions focused on five components of the immunization system: service delivery, vaccine supply, quality, and logistics; surveillance and monitoring; advocacy and communication; and program management (15). Each component has different vital points to be explored during the interview process (see Table 1).

Following a framework by Tan et al. on the significant achievements related to immunization advocacy to strengthen the immunization outcomes in private sectors in Indonesia (6), in-depth interviews with healthcare professional organizations and public stakeholders were conducted, focusing on efforts to increase coordination across public and private sectors, to improve service delivery, and to strengthen institutional capacity for advocacy and immunization systems support. As an alternative to get some insights from professional organizations and public stakeholders on these three efforts, interviews were conducted with healthcare workers' organizations ($n=2$; Indonesian Doctor Association/IDA and Indonesian Pediatrician Association/IPA), hospital associations ($n=2$; Indonesian Hospital Association/IHA and Indonesian Private Hospital Association/IPHA), central government, which was represented by Indonesian MoH ($n=1$; Directorate of Immunization Management/DIM), and local government, which was represented by Bandung District of Health/DoH ($n=6$; Department of Disease Prevention and Control/DDPC, Department of Healthcare Services/DHS, Department of Human Resources/DHR, Department of Public Health/DPH, and two primary healthcare centers/PHC1 & PHC2).

3. Results

3.1. Situation analysis

The results showed that most private healthcare facilities (56%) provided essential immunization services for children at >6h per day and <25 days per month. The number of vaccination staff the MoH had trained varied from 2 to 16 members of staff. Most private healthcare facilities (67%) applied guidelines for immunization services and developed additional internal guidelines. Regarding vaccine availability, the majority of healthcare facilities confirmed that they have available vaccines (e.g., MR, BCG, polio, pentavalent, PCV, IPV, and hepatitis B

vaccine) for essential childhood immunization services at that moment. Only a few healthcare facilities confirmed that they did not have the MR (11%), PCV (11%), and IPV vaccine (33%). In the context of experiencing vaccines being out of stock in the last 12 months, all healthcare facilities mentioned that they had these experiences for MR (22%), BCG (44%), polio (33%), pentavalent (33%), PCV (22%), and IPV vaccines (22%). Most healthcare facilities applied self-procurement for PCV (67%), IPV (56%), and hepatitis B vaccines (56%). In particular, most of them (67%) applied a combination of self-procurement and government programs for MR, BCG, polio, and pentavalent vaccines (see Table 2).

3.2. In-depth interviews with mid-level managers in healthcare facilities

3.2.1. The lack of coordination across public and private sectors

- Underreporting immunization coverage data

“I think 58% is underrated. Many private hospitals might not report their data (TBH2).”

“This number is too low. The major possibility is data from independent medical practice have not been included (VH1).”

- Unclear report on vaccine utilization

“To our knowledge, there is no mandatory to report the use of vaccines to the DoH. (TCH1).”

“Regarding the use of vaccines that are self-procured and obtained from the government, reports have to be submitted routinely every month to the DoH (VH1).”

“We only report the use of vaccines procured by the government (PC2).”

- Various types of agreements between the government and private sectors allow private healthcare facilities to use vaccines procured by the government

“We have a written contract with the DoH to get vaccines from the primary healthcare center (PC2).”

“There is an official document, and we are also encouraged to send monthly report [sic] to the primary healthcare center that gives us vaccines (TBH1).”

“We do not have any contract or cooperation documents with the DoH or the primary healthcare center (TCH1).”

- Differences in the frequency of immunization services monitoring

“The DoH, through the primary healthcare center, conducted a routine monitoring of immunization services and vaccine supply chain in our healthcare facility (TBH2).”

TABLE 1 Framework approach for in-depth interviews with mid-level managers.

Components	Key points
Service delivery	<ul style="list-style-type: none"> • Coverage rate • Drop-out rate • Existence of a national plan for immunization
Vaccine supply, quality, and logistics	<ul style="list-style-type: none"> • Availability and continuity of services • Existence of guidelines on vaccine management, transport management, cold chain, and waste disposal and destruction • Cold-chain equipment operating and in good repair • Completion and display of cold-chain monitoring charts • Existence of inventory of immunization equipment that includes date-of-purchase, functional status, maintenance schedule, and evidence that equipment that has been maintained. • Availability and sustainable access to other immunization equipment • Vaccine forecasting, vaccine utilization, and wastage monitoring • Quality of vaccines, including fully functional National Regulatory Authority or other independent assessment of quality performed, manufacturer viable or vaccines procured from prequalified • Implementation of a multi-dose vial policy • Completion of a standardized immunization injection safety survey • Existence and implementation of policy, plan, and budget on injection safety assessment • Type of injection equipment in use • Method of injection equipment disposal
Surveillance and monitoring	<ul style="list-style-type: none"> • Completeness and timeliness of routine reporting • Completion and display of coverage/drop-out monitoring charts • Vaccine-preventable disease (VPD) incidence rate • Proportion of cases confirmed by laboratory • Mortality rate and case fatality rate • System for detecting, investigating, and reporting adverse events following immunization (AEFI) • Notified and investigated AEFI • Case/outbreak investigation initiated within 48 h of notification • Percentage of reported VPD cases with information on age and vaccination status • Feedback of data to sub-national levels • Supervisory checklists complete • Development of monitoring indicators • Staff monitor status and stock of supplies, equipment, and consumables

(Continued)

TABLE 1 (Continued)

Components	Key points
Advocacy and communication	<ul style="list-style-type: none"> • Availability of social mobilization, advocacy, or overall communication plan • Availability of specific strategy for hard-to-reach population in immunization policy • Existence of clinician advocacy and community mobilization • Existence of active community health committees • Planning meetings conducted with communities • Community mobilizers involved in immunization sessions and outreach • Engagement of sectors other than the MoH (e.g., Information, Education, Finance, Development, and Planning) • Commitment of a broad range of high-level decision makers (demonstrated by active support and public promotion) • Budget for activities, staffing, and materials • Availability of adequate and appropriate information, education, and communication (ICE) materials
Program management	<ul style="list-style-type: none"> • Government funding of vaccines for routine immunization and program-recurrent costs for supplies and operations • Multiple-year commitment to financing • Proportion of planned supportive supervision visits conducted • Adequacy of personnel to carry out tasks • Adequacy of personnel training • Reports on implementation of the plans • Assessment of services conducted

“The primary healthcare center supervised and monitored our immunization services and vaccine supply chain management only once at the beginning (VH2).”

“When the DoH visited our healthcare facility for supervision and monitoring, they only asked about immunization technicalities, such as the standard operating procedure of vaccine cold-chain (TCH1).”

- Various types of coverage, drop-out rate, and incidence of VPDs monitoring

“Monitoring coverage and the drop-out rate are done through the patients' vaccine books. We send parents a reminder of the vaccination schedule (PC1).”

“We use a vaccine diary or passport to maintain coverage and minimize drop-out rate. In particular, most doctors and their nurses have initiatives to ascertain patients' attendance for vaccination one day before the schedule of appointment (TAH).”

“We monitor the incidence of VPDs through updated news from media, data on the use of vaccines, and patient's medical record (TBH1).”

“We do routine monitoring related to the incidence of VPDs. We have an interesting story during the COVID-19 pandemic where we found a significant increase of PCV immunization requests from patients (TCH 2).”

3.2.2. The need for immunization service delivery improvement at private healthcare facilities

- Vaccine availability and the number of patients' visits are critical indicators of immunization services at private healthcare facilities

“All private healthcare facilities confirmed that there are two key indicators of their immunization services, such as vaccine availability and number of patients' visits.”

“We believe that our brand is strongly associated with good services, and it helps us deliver immunization services as well (TCH1).”

- Impact of the pandemic on routine immunization services

“The availability of vaccines is limited because of the pandemic, such as pentavalent and polio vaccine (PC1).”

“There is a significant decline in the number of hospital visits, possibly due to the stigma of visiting hospital is not safe, so many patients turned to private clinics for getting immunization services (TBH2).”

- Impact of national immunization plan, such as PCV, which will be included in the national program in 2024, on immunization services at private healthcare facilities

“It will have an impact on reducing our revenue, but we always commit to supporting the national immunization programs in achieving the targeted coverage (TBH1).”

“Depending on the parents' choices between getting the free vaccine from public healthcare facilities or visiting private healthcare facilities with additional costs for certain reasons (TBH2).”

- Availability and sustainability of public immunization services need to be improved

“Up to now, we can request routine vaccines from the DoH. If they have vaccines out of stock, we do self-procurement through official distributors (TAH).”

"Monitoring minimal stock is crucial to avoid out of stock (TCH2)."

"Patients make appointment [sic] first, and the availability of vaccines will be ascertained before they come (VH2)."

- Guidelines for vaccine management, transportation management, cold-chain, and waste disposal should be updated regularly

"We always follow the government guidelines (PC2)."

"We use a guideline developed by our central office (VH2)."

"We update our guidelines from materials we receive from related seminars (TCH2)."

"Evaluation and monitoring are based on daily usage data (TBH2)."

- Vaccine quality and safety should be monitored routinely

"Routine monitoring and evaluation from the DoH are important for us to maintain vaccine quality and safety (TCH2)."

"We do a daily refrigerator temperature monitoring twice a day (TBH1)."

"Refrigerator temperature is monitored by the engineering division three times a day (TAH)."

- Detection, investigation, and reporting of adverse events following immunization (AEFI) are important

"All private healthcare facilities confirmed that they do monitoring [sic] AEFI for 48 hours after immunization. All of them also confirmed that they had no experience on [sic] finding AEFI cases until now."

"To monitor AEFI, patients are asked to wait for 30 minutes after immunization and to do self-monitoring for 48 hours after that (TBH2)."

- The vaccine procurement plan and multi-dose vial policy should be evaluated

"The pharmacy unit performs a vaccine procurement plan using consumption method and considering safety stock (TBH1)."

"The vaccination unit conducts planning, and estimation is made by considering several existing customers (VH1)."

"Multi-dose is more wasted than single-dose, even though it can be anticipated (PC2)."

"Multi-dose is less efficient because of higher wastage rate. It is better to use single-dose (TAH)."

3.2.3. The urgency to strengthen institutional capacity for advocacy and immunization systems support

- Social mobilization, advocacy, and communication of immunization services need to be expanded on

"In addition, we have routine seminars as a media to promote our immunization services and to communicate with the society (TCH2)."

"To expand our communication with hard-to-reach population [sic], we are also active in social media and regular webinars or workshops in collaboration with the primary healthcare center and other stakeholders (TBH2)."

"Materials for social mobilization, advocacy, and communication of immunization services are arranged by immunization unit [sic] and supervised by medical doctors (VH2)."

- Different types of budgeting for social mobilization, advocacy, and communication of immunization services

"We do not have specific [sic] budget for social mobilization, advocacy, and communication of immunization services planning because it is already included in our routine activities (PC1)."

"There is a specific budget for social mobilization, advocacy, and communication of immunization services that is arranged by two divisions of marketing and public relations (TBH1)."

- Government supports social mobilization, advocacy, and communication of immunization services

"There is no direct involvement or support from the MoH, DoH, or primary healthcare centers for social mobilization, advocacy, and communication of immunization services in our healthcare facility (VH1)."

"The government only supports monitoring and procuring vaccines for the public program through the DoH and primary healthcare centers. Until now, no government supports for [sic] social mobilization, advocacy, and communication of immunization services (TCH1)."

- Government funding of vaccines for routine immunization and program-recurrent costs for supplies and operations

TABLE 2 Results of situation analysis.

Variables							Number (n)							Percentage (%)							
Type of private healthcare facilities																					
Hospital							5							56%							
Non-hospital							4							44%							
Immunization service																					
Per day		Per month					Per day			Per month				Per day			Per month				
3–6 h		<25 days					4			5				44%			56%				
>6 h		> = 25 days					5			4				56%			44%				
Staffs in vaccination unit																					
Number of staffs		Trained staffs by MoH					Number of staffs			Trained staffs by MoH				Number of staffs			Trained staffs by MoH				
<6 staffs		<6 staffs					3			6				33%			67%				
6–10 staffs		6–10 staffs					3			3				33%			33%				
>10 staffs		>10 staffs					3			0				33%			0%				
Guideline for immunization services																					
Using guideline		Type of guideline					Using guideline			Type of guideline				Using guideline			Type of guideline				
No		Internal guideline					3			4				33%			67%				
Yes		MoH’s guideline					6			2				67%			33%				
Vaccine availability																					
MR	BCG	Polio	Penta	PCV	IPV	HepB	MR	BCG	Polio	Penta	PCV	IPV	HepB	MR	BCG	Polio	Penta	PCV	IPV	HepB	
Yes	Yes	Yes	Yes	Yes	Yes	Yes	8	9	9	9	8	6	9	89%	100%	100%	100%	89%	67%	100%	
No	No	No	No	No	No	No	1	0	0	0	1	3	0	11%	0%	0%	0%	11%	33%	0%	
Vaccine stock out in the last 12 months																					
MR	BCG	Polio	Penta	PCV	IPV	HepB	MR	BCG	Polio	Penta	PCV	IPV	HepB	MR	BCG	Polio	Penta	PCV	IPV	HepB	
Yes	Yes	Yes	Yes	Yes	Yes	Yes	2	4	3	3	2	2	0	22%	44%	33%	33%	22%	22%	0%	
No	No	No	No	No	No	No	7	5	6	6	7	7	9	78%	56%	67%	67%	78%	78%	100%	
Vaccine procurement																					
MR	BCG	Polio	Penta	PCV	IPV	HepB	MR	BCG	Polio	Penta	PCV	IPV	HepB	MR	BCG	Polio	Penta	PCV	IPV	HepB	
SP	SP	SP	SP	SP	SP	SP	2	2	2	2	6	5	5	22%	22%	22%	22%	67%	56%	56%	
GP	GP	GP	GP	GP	GP	GP	1	1	1	1	0	1	0	11%	11%	11%	11%	0%	11%	0%	
C	C	C	C	C	C	C	6	6	6	6	3	3	4	67%	67%	67%	67%	33%	33%	44%	

(Continued)

TABLE 2 (Continued)

Equipment		
<i>Cold box/vaccine carrier with ice packs</i>		
Yes	9	100%
No	0	0%
<i>Refrigerator</i>		
Yes	9	100%
No	0	0%
<i>Sharp container</i>		
Yes	7	78%
No	2	22%
<i>Single use standard/auto disposable syringe</i>		
Yes	8	89%
No	1	11%
<i>Continuous temperature monitoring device</i>		
Yes	9	100%
No	0	0%
<i>Energy source and power supply</i>		
Yes	7	78%
No	2	22%
<i>Immunization card</i>		
Yes	9	100%
No	0	0%

MoH, Ministry of Health; MR, Measles Rubella; BCG, Bacillus Calmette–Guérin/TB vaccine; PCV, Pneumococcal Conjugate Vaccine; IPV, Inactivated Poliovirus Vaccine; HepB, Hepatitis B; SP, self-procurement; GP, government program; and C, combination of self-procurement and government program.

“There is no special funding from the government because all vaccines in our healthcare facility are self-procured independently (VH2).”

“We apply a combination of self-procurement and government programs for childhood vaccination programs. We request some vaccines from the DoH. When our requested vaccines are out of stock in the primary healthcare center, we should have active initiatives to follow up until these vaccines are ready in stock (TBH1).”

- Adequacy of personnel to carry out tasks and personnel training

“We sent human resources to join the training organized by the MoH approximately 2-3 years ago (PC2).”

“Our healthcare facility has the initiative to conduct regular in-house training for immunization services led by a medical doctor (TAH).”

- Regular reports on the implementation of the plans and assessment of services conducted

“There is no direct support from the government to our healthcare facility on vaccine procurement planning. The only support is when they confirm the availability of our requested vaccines (PC1).”

“Regarding immunization services' plans in our healthcare facility, including vaccine procurement, no DoH involvement exists. In addition, they never ask for reports on implementing plans (TCH2).”

“Since we also request several vaccines to the primary healthcare centers, it is important for them to ascertain vaccine availability and to minimize potential out-of-stock (TAH).”

3.3. In-depth interviews with professional organizations and public stakeholders

3.3.1. Coordination across public and private sectors needs To Be increased

“It is crucial to have a legal agreement between the government and private sectors, which will facilitate private healthcare facilities to get vaccines from the government. This agreement should cover the mandatory of private healthcare facilities to submit a monthly report on the utilization of vaccines for self-procurement and government programs. AEFI reporting should also be considered, including the flow to report AEFI (IHA).”

“Reporting the use of vaccines to the government is mandatory for all healthcare facilities. In the context of government support to

private facilities on immunization services, the DOH should provide regular training programs that focus on the distribution, supply chain, and procurement of vaccines. Monitoring of the implementation of vaccinations at private facilities should also be routinely conducted (IPHA).”

“For general practitioners or pediatricians who practice independently and carry out vaccination programs, we encourage them to submit regular reports to the DoH regarding the utilization of vaccines. The government should have specific standard operating procedures and reporting formats to create a more practical reporting system than the current situation. Providing a user-friendly online platform also will be an additional benefit (IDA).”

“The MoH should have a clear regulation on whether private healthcare facilities should communicate with the DoH or with the nearest primary healthcare center to get vaccines and report the use of vaccines. The possibility that routine vaccinations are not fully reported because of unclear regulations can be minimized. Additionally, there is an urgent need for more comprehensive standard operating procedures for vaccine distribution, implementation, and administration of childhood vaccinations at private healthcare facilities (IPA).”

“To increase coordination across public and private sectors, the technical guideline of immunization services at private healthcare facilities will be published soon. This guideline is based on the Minister of Health Regulation number 12 of 2017 concerning immunization. The MoH also will increase the number of vaccination training and intensify monitoring-supervision for private healthcare facilities (DIM).”

“In the contract document between the primary healthcare center and private healthcare facility, it has been mentioned that one of the private healthcare facility's obligations is reporting the utilization of vaccines regularly every month, and one of their rights is receiving vaccines from the primary healthcare center. We supervise and monitor at least once a year for private clinics only. For hospitals, we only do if there are major issues or concerns (PHC1).”

“To our knowledge, we only receive reports on the use of vaccines from clinics and midwives. For private hospitals, they send the report to the DoH directly. We supervise and monitor private healthcare facilities, if required only, based on an assignment order from the DoH. The contract document between the primary healthcare center and private healthcare facility is crucial as the legal form of our cooperation, and it should be managed by the DoH (PHC2).”

“In the local government regulation, it has been stated that all private healthcare facilities have to report the use of vaccines to the DoH through the primary healthcare center. Both private hospitals and clinics should follow this point in Bandung. For better

coordination across public and private sectors, all healthcare facilities must have a contract document with the DoH (DHS)."

"Following Mayor's regulation number 1 of 2020 concerning regional health systems, article 47 mentioned that private healthcare facilities must report immunization activities to the DoH as the consequence of receiving DoH's support in vaccines (DPH)."

3.3.2. Service delivery should be improved significantly

"To improve immunization service delivery, private hospitals can apply several efforts. Firstly, the quality of vaccination data should be improved. Secondly, an automatic system of vaccination schedule reminders is important to maintain coverage and minimize drop-out rates. Last, information about common AEFI cases, such as low-grade fever, should be delivered clearly to the parents (IHA)."

"Most private hospitals have realized that vaccination is one of the main good services. They already have initiatives to optimize this potential revenue to provide optimal immunization services through several innovative approaches (IPHA)."

"The success story of our social insurance program, BPJS P-Care, can be adopted for vaccination programs. Developing a one-stop-service application is important to improve service delivery for immunization programs in public and private healthcare facilities (IDA)."

"Currently, patients have two alternatives to obtain immunization services from public or private healthcare facilities. They can choose their preference based on their needs and economic factors. In this case, the government has the same responsibilities to improve the service delivery of immunization programs in public and private healthcare facilities (IPA)."

"Private healthcare facilities are encouraged to apply lean management, which is an approach to create additional values by optimizing resources, such as creating a stable inventory workflow to ascertain vaccine availability and to avoid out-of-stock. Moreover, an information technology system can be considered as the major supporting system (DIM)."

3.3.3. Institutional capacity for advocacy and immunization systems support is required to be strengthened

"There should be comprehensive monitoring and supervision from the DoH to healthcare facilities, such as detailed SOPs to maintain the quality, safety, and efficacy/effectiveness of vaccines.

Additionally, healthcare facilities should provide regular education programs to the patients and communities about the importance of vaccinations and potential AEFI. The latest recommendation from the Indonesian Doctor Association and the Indonesian Pediatrician Association can be used as the major references (IHA)."

"Strengthening institutional capacity for advocacy and immunization systems support can be initiated by enhancing the private hospitals' awareness to regularly report the use of vaccines. Under-reported data from private hospitals may cause low vaccination coverage. On the other hand, the government should conduct routine supervision and monitoring of these facilities (IPHA)."

"Even though private healthcare facilities have followed technical guidelines arranged by the MoH, a comprehensive mapping of their resources and needs is necessary to be conducted by the DoH to strengthen institutional capacity for advocacy and immunization systems support effectively. In particular, the development of online vaccination reporting platform for private healthcare facilities should be accelerated (IDA)."

"Series of training for vaccinators at private healthcare facilities are important to improve their competence following the MoH's regulation. This approach can strengthen institutional capacity for advocacy and immunization systems support. A comprehensive monitoring system is also crucial to avoid the misuse of vaccines (IPA)."

"Ideally, supervision and monitoring of private healthcare facilities are routinely conducted through face-to-face visits. Nevertheless, the pandemic has impacted intensifying these activities (DIM)."

"Before the pandemic, supervision and monitoring were routinely carried out with limited human resources, specifically for vaccine cold chain. The urgency of contract documents between private healthcare facilities with the DoH should be reviewed because childhood immunization is a national program. Implementation of COVID-19 vaccination can be used as a reference case when contract document was not required (DDPC)."

"Given limited human resources in routine immunization programs, it is crucial to develop an application that can assist healthcare facilities in reporting data and the DoH officers to supervise and monitor (DHR)."

4. Discussion

Immunization services at public healthcare facilities in Indonesia were disrupted at 65–90% because of the pandemic (3). In contrast

with public healthcare facilities, the demand for immunization services at private healthcare facilities has been increasing significantly in the last 2 years. This situation occurred in many countries, highlighting the need for various contributions from the private sector, including private healthcare facilities. In Indonesia, childhood immunizations are a package of essential health services provided and financed by the government. The government's ability to deliver these services is directly affected by governance, administrative capacity, and economic factors (10). In particular, health financing, infrastructure, and competing health priorities challenge the desire to provide more comprehensive immunization services (16). Hence, the role of private healthcare facilities in vaccination coverage and practices should be accelerated by enhancing interaction between public and private sectors, the level of monitoring, and the degree of regulations imposed on private healthcare facilities (17).

Our study is the first to assess immunization services at private healthcare facilities in Indonesia. Nevertheless, it has several limitations, and one of the significant limitations is about setting of the study. Firstly, we only considered one respondent from one institution in our in-depth interviews. To ascertain that the critical person is enough to give a complete account of the situation of interest, we listed and ranked potential participants who could meet our purposes. Secondly, we focused our study on Bandung, the capital of West Java Province, the most populous province in Indonesia with a relatively low childhood vaccination coverage (12). Using this such a region as the case study, we expect the results of this study to be one of the references to enhance the role of private healthcare facilities in delivering immunization services. The situation analysis showed that private healthcare facilities had provided sufficient time for essential childhood immunization services with adequate staff. However, the limited staff the MoH has trained remains a programmatic problem. Furthermore, private healthcare facilities have used the MoH's guidelines and additional internal guidelines for immunization services as the primary references, such as providing complete and reliable equipment. Vaccine availability at private healthcare facilities is manageable, with the out-of-stock vaccine level remaining acceptable.

The qualitative evaluation provided a critical view of immunization services at private healthcare facilities by gathering perceptions of healthcare workers and other relevant stakeholders. Applying WHO's framework for monitoring the immunization system (14), we collected information from mid-level managers at private healthcare facilities by focusing on service delivery, vaccine supply, quality, and logistics; surveillance and monitoring; advocacy and communication; and program management. This evaluation highlighted three key findings: the lack of coordination across public and private sectors, the need for immunization service delivery improvement at private healthcare facilities, and the urgency to strengthen institutional capacity for advocacy and immunization systems support. In the context of coordination across public and private sectors, we found several interesting findings, such as the importance of legal agreements between the DoH and private healthcare facilities and the urgency for private healthcare facilities to report the use of vaccines from self-procurement and government programs. Another critical issue is immunization service delivery at private healthcare facilities. All private healthcare facilities confirmed that there are two critical indicators of their immunization services, such as vaccine availability and the number of patient visits. As most

private healthcare facilities apply a combination of vaccine self-procurement and government programs, support from the government in terms of vaccine availability is significant. When private healthcare facilities can avoid out-of-stock vaccines, the performance of immunization services can be maintained, and the number of patient visits can be increased simultaneously. The last concern is about institutional capacity for advocacy and immunization systems support. Private healthcare facilities require regular DoH supervision and monitoring to improve immunization services, including vaccine supply chain management continuously.

By conducting in-depth interviews, we gathered insights from healthcare workers' organizations, hospital associations, and both central and local government. Feedback from professional organizations and public stakeholders is required to find out solutions related to those findings. Several promising alternatives could be identified. Firstly, the government should publish a comprehensive technical guideline for immunization services at private healthcare facilities immediately to increase coordination across public and private sectors (18, 19). Even though several central and local government regulations have been launched, they should have considered technical and practical issues. Secondly, technology interventions to develop one-stop-service applications can be used as an alternative to improve service delivery for immunization programs in public and private healthcare facilities (20, 21). Lastly, comprehensive monitoring and supervision must be conducted regularly through more detailed SOPs to maintain the quality, safety, and efficacy/effectiveness of vaccines. Given limited human resources, the Internet of Things can assist healthcare facilities in reporting data and the DoH officers in supervision and monitoring (22, 23).

All countries worldwide have variable degrees of government engagement with the private sector to deliver immunization services. In most LMICs, publicly funded immunization services are mainly provided by public healthcare facilities, but the more significant contribution from private healthcare facilities to deliver these services is essential (24, 25). It has been known that private sector engagement can add value to the health system at various levels, including increased access to skills and expertise, operational efficiencies, increased innovation, shared risk, and allowing the government to focus on its core competencies (24, 26). This engagement is significant for Indonesia as a country with limited resources to achieve national health and vaccination goals (24). More effective engagement between the public and private healthcare sectors could improve the performance of health systems by providing better policies, regulations, information sharing, and financing mechanisms (27). If private healthcare facilities already provide a significant proportion of childhood vaccinations, engagement should be focused on service quality issues. If they do not contribute a significant proportion of vaccinations, a potential role for them to expand the reach of public healthcare facilities should be accelerated. Hopefully, this study could assist the stakeholders in the decision-making process related to improving immunization services in Indonesia.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Author contributions

AS and AD: conceptualization. AS and RA: methodology. AS and NZ: software, formal analysis, investigation, writing—original draft preparation, and project administration. NZ and RA: validation. RA and AD: resources, writing—review and editing, and supervision. All authors contributed to the article and approved the submitted version.

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HPV vaccination in Kenya: a study protocol to assess stakeholders' perspectives on implementation drivers of HPV vaccination and the acceptability of the reduced dose strategy among providers

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Background: Cervical cancer is the leading cause of cancer-related deaths among Kenyan women. Persistent infection with high-risk oncogenic Human papillomavirus (HPV) genotypes is a necessary cause of cervical cancer. HPV vaccines are safe, durable, and efficacious in preventing incident HPV infections. In Kenya, despite efforts to increase HPV vaccination, coverage remains low. We sought to assess: (1) barriers and facilitators of HPV vaccination from the perspective of adolescent girls and young women (AGYW), their guardians as well as stakeholders involved in HPV vaccine delivery, and (2) the acceptability of the single dose of the HPV vaccination among healthcare providers (HCPs).

Methods: Our study is nested within the KENya Single-dose HPV-vaccine Efficacy study (KEN SHE) that sought to test the efficacy of single-dose bivalent (HPV 16/18) and single-dose nonavalent (HPV 16/18/31/33/45/52/58/6/11) vaccination. We are conducting this study in Kiambu, Nairobi, and Kisumu counties. In these counties, we are interviewing stakeholders ($n = \sim 25$), selected based on their role in HPV vaccination at the county and national levels. Interviews are audio recorded and conducted in English or Swahili. The semi-structured interview guides were designed based on: (1) the Theoretical Domains Framework (TDF) for AGYW and guardians and (2) the Consolidated Framework for Implementation Research (CFIR) for other stakeholders. The Theoretical Framework of Acceptability (TFA) was leveraged to design the survey administered to HCPs ($n = \sim 309$) involved in HPV vaccination. We will develop a codebook based on emerging codes from the transcripts and constructs from the TDF and CFIR. Emerging themes will be summarized highlighting similarities and differences between and within the different stakeholder groups and counties. Descriptive statistics and a χ^2 test will be used to assess the distribution of responses between the different sites and regression analysis will be used to assess factors associated with high acceptability of the single-dose strategy while controlling for confounding variables.

Discussion: Our study will describe key barriers and facilitators that affect HPV vaccination from the perspective of multiple stakeholders as well as insights on the perspective of HCPs towards the single-dose strategy to inform the designing of strategies to increase HPV vaccination uptake in Kenya and comparable settings.

KEYWORDS

cervical cancer prevention, human papillomavirus vaccine, Kenya, consolidated framework for implementation research, theoretical domain framework, theoretical framework for acceptability, implementation science

Introduction

Cervical cancer is the fourth leading cause of death among women (1). In 2020, the burden of new cases and deaths due to cervical cancer was concentrated in low-and-middle-income countries (LMIC), accounting for 90% of the global cancer incidence and mortalities (2). Sub-Saharan Africa bears a high prevalence of cervical cancer with a mortality rate of 94.1 per 100,000 in 2018 (2, 3). Invasive cervical cancer (ICC) is one of the few cancers with a known infectious etiology, and persistent infection with high-risk oncogenic human papillomavirus (HPV) is a necessary cause for ICC (4). However, HPV vaccines are safe, durable, and efficacious in preventing incident HPV infections that lead to cervical cancer (5, 6). The World Health Organization (WHO)'s Global Cervical Cancer Elimination Strategy has three pillars, one of which is achieving 90% HPV vaccination coverage for age-eligible girls. Unfortunately, the global HPV vaccination coverage for age-eligible adolescent girls remains low where it was estimated at 15% in 2019 (5, 7, 8).

In Kenya, cervical cancer is the leading cause of cancer-related deaths among women, resulting in approximately 3,400 deaths annually (9). In accordance with the recommendations from the WHO, a two-dose schedule for HPV vaccination was introduced in Kenya in 2019 targeting 10-year-old adolescent girls through facility-based delivery (10). At the time of the HPV vaccination launch, social mobilization, and community education efforts were conducted to raise awareness and ignite vaccine uptake (11, 12). Since the national introduction, the HPV vaccination coverage in Kenya has been suboptimal where 33% of eligible AGYW received the first doses in 2020 and this estimate increased to 77% in 2021 but only 31% of targeted AGYW had received 2 doses of the HPV vaccine in 2021 (9, 13). In Kenya, HPV vaccination coverage has been adversely impacted by delivery processes and vaccine hesitancy among healthcare providers (HCPs) and at the community level. Additionally, the global COVID-19 pandemic increased vaccine hesitancy at the community level, the lack of confidence among HCPs sparked their reluctance to promote HPV vaccination, and the lack of community engagement and education after the initial launch of the program resulted in knowledge gaps that fueled HPV vaccination refusals (11, 12, 14, 15).

These implementation-related challenges highlight the need for comprehensive evidence from stakeholders on factors that facilitate or impede the delivery and uptake of HPV vaccination. The overall objective of this study is to understand why HPV vaccination coverage remains low for AGYW in Kenya, despite

evidence endorsing the crucial role of HPV vaccination in cervical cancer prevention. This study aims to generate knowledge on implementation drivers of HPV vaccination in Kiambu, Nairobi, and Kisumu County. Our specific aims are to (1) assess barriers and facilitators to HPV vaccination delivery in the three counties, and (2) assess the acceptability of the single dose of HPV vaccination among HCPs. Findings from this study will be shared with the Kenyan Ministry of Health and they will potentially contribute to informing the design of the national guideline for HPV vaccination and generate evidence for decision-makers.

Methods and analysis

This study is nested within the KENya Single-dose HPV-vaccine Efficacy study (KEN SHE, ClinicalTrials.gov number NCT03675256). The KEN SHE study is a randomized, multicenter, double-blind, three-arm, controlled trial that sought to test the efficacy of single-dose bivalent (HPV 16/18) and single-dose nonavalent (HPV 16/18/31/33/45/52/58/6/11) HPV vaccination compared with meningococcal vaccine among Kenyan women of 15–20 years of age (16). Interim data analysis done at 18 months of the KEN SHE study showed that the HPV vaccines were highly effective with a vaccine efficacy of 97.5% to prevent incident persistent HPV 16/18 infection.

Aim 1: assessing barriers and facilitators to HPV vaccination delivery in three Kenyan counties

Study design and study population

We are leveraging a qualitative study design to assess barriers and facilitators to HPV vaccination delivery. Study participants are stakeholders involved in HPV vaccination delivery program at the national, county, sub-county, and community levels. Study participants are being selected based on their position and role in the delivery of HPV vaccination for AGYW in Kenya. They include:

- (1) From the central government: staff from the National Immunization Program and the Reproductive Health Division at the Ministry of Health (MOH); staff from the Ministry of Education (MOE); national implementing partners (NGOs, advocacy groups, etc.)
- (2) From the county level: the health minister or coordinator at county level, heads of county hospitals, other local implementing partners.

- (3) From the delivery level: heads of hospitals where HPV vaccines are delivered, the nurse in charge of immunization at the health facility; healthcare frontline vaccine providers at facilities; clinical or medical officers where applicable; principals and teachers as well as opinion leaders (including religious leaders and area chiefs).

Adolescents, girls, and young women (AGYW) aged 10 years and older who were vaccinated and those who were not vaccinated along with their guardians, are also being interviewed to capture details on implementation drivers and barriers from the AGYW and guardians' perspective.

Sample size determination

Study participants are purposefully sampled based on their involvement in the delivery of HPV vaccination. Eligible participants are enrolled and interviewed until saturation is reached for each participant category. We estimate that in each of the three counties, we will interview ~5 participants from each category and 10 from the national level, however, more participants are being recruited and interviewed when saturation is not reached after interviewing the estimated number of participants.

Recruitment procedures

The KEN SHE study team has engaged the Ministry of Health, Ministry of Education, and other relevant implementers at the national and county levels to recruit relevant study participants for interviews. Identification of eligible key informants is done in liaison with county managers and the target group includes teachers, religious leaders, and healthcare providers. Additionally, a list of key informants specific to each county is being supplemented with a list of AGYW and guardians (both vaccinated and unvaccinated). AGYW aged 10 years and older are being recruited from the parent study, health facilities, the community, schools, and colleges. The identification of unvaccinated AGYW is done by community health workers (CHWs) with experience in research recruitment, and who have been involved in the parent study, the KEN SHE trial. Parents or guardians approached for permission before speaking to AGYW and their consent is sought before interviewing AGYW under the age of 18. Informed assents are being obtained for all study participants before enrolment. All interviews are being held in an environment that is convenient for participants. This includes clinics for providers, offices for implementers and decision makers, churches, schools, or other community settings for opinion leaders, AGYW, and guardians.

Data analysis and management

Data collection tools

To select constructs relevant to this study, we mapped out each construct from the Theoretical Domain Framework (TDF) and the Consolidated Framework for Implementation Research (CFIR) to the KEN SHE study setting (17–19). Constructs that matched the study setting and local context were leveraged to design the semi-structured interview guide to capture information on the

selected TDF and CFIR constructs. We used the TDF to design the interview guide for AGYWs and their guardians. This approach ensured that the interview guide accounted for the characteristics of the implementation environment and determinants of behavior ([Supplementary Appendix I](#)). Additionally, the CFIR served as a guide to design the interview guide for opinion leaders and decision-makers since CFIR focuses more on aspects of the health system and it is more appropriate in contexts where the individual domain or determinants of behavior are less relevant ([Supplementary Appendix II](#)). This interview guide was also adapted from a CFIR-guided tool that was used in Mozambique for similar purposes (20). Both interview guides were pilot tested and refined prior to conducting the interviews with targeted study participants. Domains and constructs captured in each interview guide as well as sample questions are illustrated in [Table 1](#).

Data analysis

We will use constructs of the TDF and the adapted CFIR to guide the analysis of interview transcripts. A codebook will be developed based on emerging codes from the transcripts and the interview guide developed using TDF and CFIR. Once consensus on the codebook has been reached; the remaining interviews will be coded, and appropriate measures will be used to ensure that the coding approach is reliable. Regular coding checking will be performed to ensure that the coding strategy used is reliable. Field notes will be used to inform the interpretation of findings and all coding work will be done with Atlas.ti version 9. Participants' demographics will be summarized in a table detailing the distribution of key characteristics of each targeted group, the number of participants interviewed in total, and for each group. Emerging codes will be used to identify key themes that will be categorized within constructs and domains of the appropriate framework. Themes that do not fit within constructs and domains of the TDF or CFIR will also be listed as new insights that emerged from the interviews. We will summarize similarities and differences of key themes between and within groups.

Aim 2: assess the acceptability of the single dose of HPV vaccination among healthcare providers

Study design and study population

We are using a concurrent mixed-methods study design to assess the acceptability of the single-dose strategy among healthcare providers. Study participants are healthcare providers involved in the HPV vaccination delivery at different levels of the health system. This includes nurses, clinical officers, pharmacists, pharmacy technicians, medical officers, and other relevant healthcare providers.

Sample size determination

Based on the assumption that each health facility has at least one healthcare provider responsible for HPV vaccination with a total of 1,568 health facilities in the three counties (Kiambu: 364, Nairobi ~1,000, Kisumu ~200), we estimated the total number of

TABLE 1 Example of questions from the interview guides for AGYW, parents, opinion leaders and decision makers.

Framework	Domain	Construct	Example of questions
Theoretical Domain Framework (TDF) ^a	Intervention	Relative advantage	Do you feel HPV vaccine is better than the existing system of screening for and identifying cervical cancer in women in Kenya?
		Adaptability	Are there alterations that should be implemented to improve uptake of HPV vaccine? If yes, which ones
		Cost	What is the cost that you have incurred for you/your daughter to receive a full HPV vaccination?
	Outer setting	Cosmopolitanism	Is there networking happening between AGYW/their parents regarding HPV vaccine? or with AGYW/parents from other settings?
		Peer Pressure	To what extent have other AGYW in your setting received the HPV vaccine?
		External Policy & Incentives	What kind of financial or other incentives influenced your decision to receive/allow your daughter to receive the HPV vaccine?
	Implementation context (Inner Setting)	Structural Characteristics	Where do most adolescents receive the HPV vaccine in your community? How is their experience in general?
		Implementation climate	To what extent does the implementation of HPV vaccination take a backseat to other high-priority initiatives going on now in your community?
		Readiness for implementation	What kind of support or actions are needed to make HPV vaccine delivery successful in your community/setting?
	Characteristics of individuals	Knowledge and Belief about HPV vaccine	How do you feel about the HPV vaccine being delivered to AGYW in your setting?
Consolidated Framework for Implementation Research (CFIR) ^b		Self-efficacy	How confident are you that you/your community will be able to use the intervention (agree to receive HPV vaccine)?
	Process	Planning	How was planning for implementation of the HPV vaccination carried out in your community?
		Engaging	Who are the key people who have been engaged in the HPV vaccine delivery in your community/setting?
	The health system and policy context	Health systems context	In your opinion, what knowledge and beliefs about the HPV vaccine impacted implementation? At the community and individual level?
		Policies and guidelines	Are there any policies, programs, or guidelines that might affect the delivery and uptake of HPV vaccines in your community/setting?
	Intervention characteristics	Evidence strength and quality	To what extent were you provided with or made aware of the evidence supporting the introduction of the HPV vaccine?
		Adaptability	In your opinion, what alterations should be implemented to improve uptake of HPV vaccine?
		Design Quality & Packaging	How is public health education on the importance of the HPV vaccine undertaken?
		Cost	Are you aware of the estimated cost of implementing HPV vaccination in government health facilities/your area?
	Outer Setting	AGYW Needs & Resources	In your opinion, to what extent are implementers aware of the needs and preferences of AGYWs?
		Cosmopolitanism	Is there networking happening between the Kenyan MOH and other MOHs during the HPV roll out? or with other county managers?
		External Policy & Incentives	What kind of international policies, mandates have influenced the decision to roll out the HPV vaccine in Kenya/your setting?
	Implementation context (Inner Setting)	Network & Communications	What was the structure of the network of stakeholders for HPV delivery in Kenya/your setting?
		Implementation climate	[Compatibility sub-construct] How well does the HPV vaccination fit with existing work processes and practices in Kenya/your setting?
		Readiness for implementation	[Leadership Engagement sub-construct] What has been the level of support from leaders?
	Process	Planning	How was planning for implementation of the HPV vaccination carried out at your facility, district, county, nationally?
		Engaging	Who are the key people who have been engaged in the HPV vaccine delivery in your setting/nationally?
		Executing	Has the HPV vaccination delivery been implemented according to the implementation plan?
		Reflecting and evaluating	How has the national rollout of HPV vaccination been monitored and evaluated?
	The health system and policy context	Health systems context	How do you think the rollout of the HPV vaccination is going in your area/community/the health system?
		Policies and guidelines	Are there any policies, programs, or guidelines that might affect the delivery and uptake of HPV vaccines?

^aleveraged to interview AGYW and guardians.^bleveraged to capture insights from opinion leaders and decision makers.

healthcare providers responsible for HPV vaccination to be ~1,568. Assuming that 50% of healthcare providers in the three countries are involved in HPV vaccination, at least 309 health healthcare providers will need to complete the 10-item survey to assess the acceptability of the reduced dose strategy among providers in the three counties with a 95% confidence interval that the real value is within a $\pm 5\%$ of the survey results (Table 2).

Recruitment procedures

The study coordinator collaborated with County Immunization Managers to map health facilities where providers are being recruited to participate in a survey that assesses their acceptability of the single-dose strategy. To minimize selection bias and obtain diverse perspectives, the survey link is being shared among providers at different levels of the healthcare system and *via* healthcare providers' WhatsApp groups to capture insights from providers at various levels of the health system, including private, public, and missionary health facilities, as well as different administrative levels such as county, sub-county, and health center.

Data analysis and management

Data collection tools

We used the theoretical framework for acceptability (TFA) to design the survey focusing on questions that are relevant to Kenya and the KEN SHE study sites (21). Survey responses include qualitative data from free-text responses to the survey and quantitative data from selected responses to the survey.

Data analysis

We will employ constructs of the TFA to guide the analysis of text responses from the survey. A codebook will be developed inductively based on emerging codes from these responses and deductively from the TFA. Once consensus on the codebook has been reached, all text responses from the survey will be coded, and appropriate measures will be used to ensure that the coding approach is reliable. Participant demographics will be summarized in a table detailing the distribution of key characteristics, similar codes will be merged into key themes and categorized into

domains of the TFA where applicable. Themes that do not fit within constructs and domains of the TFA will also be listed as new insights that emerged from the survey. All qualitative analyses will be conducted in Atlas.ti version 9. Additionally, descriptive statistics and a χ^2 test will be used to assess the distribution of survey responses between the different sites. A multinomial logistic regression analysis will be used to assess the factors associated with the acceptability of the single-dose among healthcare providers controlling for confounding variables. All quantitative analyses will be performed in R-4.3.1. A joint display approach will be leveraged to mix qualitative and quantitative results to facilitate a mixed-method interpretation of findings.

Confidentiality and data storage

Trained study staff are conducting all study procedures in private and protecting the privacy and confidentiality of study participants. Study-related information are being stored securely at the study clinic. Study records that contain names or other personal identifiers, such as the informed consent forms, are being maintained separately and securely with limited access. Forms, lists, and any other listings that link participant numbers to identifying information are being secured in a separate locked file area. Data collection and administrative forms are being identified only by coded numbers and kept secure, with access limited to authorized study staff. Audio-recorded interviews and interview transcripts are labeled with a study ID-specific site for each site and study participant (e.g., NBO/HCW/KI001—Nairobi/Healthcare worker/key informant#1) and stored securely. All study databases are being protected with password access systems and all datasets including interview transcripts and the survey responses will be stored in a password-protected SharePoint folder managed by the KEMRI team.

Informed consent processes

Informed written consents are being sought and obtained from all study participants and parents or guardians where applicable. For illiterate study participants, the consent form is being read out loud for them and their signature or thumbprint is being obtained for those who agree to participate in the study. All study participation is strictly voluntary, and participants can refuse study participation at any time.

All participants will go through an informed consent process and assent is being obtained from parents or guardians for all minor AGYW. All materials used in providing informed consent, including consent forms, were reviewed, and approved by the ethics committees.

Discussion

Achieving WHO cervical cancer elimination goals requires understanding context-specific bottlenecks, factors that contribute to increasing HPV vaccination coverages, and uptake to protect as many women as possible from HPV infections and future cervical cancer incidences. Findings from this study will generate insights on barriers and facilitators that affect HPV vaccination from the perspective of a diversity of stakeholders at different levels of the

TABLE 2 Summary of study participants for each aim.

Study aim	Study participant category	Number of participants	Comment
Aim 1 (KIIs)	AGYWs	15	~5/county
	Parents/Guardians	15	~5/county
	Community leaders/ Opinion leaders	15	~5/county
	Healthcare providers	15	~5/county
	Ministry of Health/ Education (National & County) and Implementing partners	10	
Aim 2	Healthcare providers	309	<ul style="list-style-type: none"> • ~100/county • Including 15 from aim 1
Total		364	

health system (providers, opinion leaders, funders, implementers, AGYWs, and their parents) in Kenya. A variation of factors is expected between and within settings and other key characteristics of participants (gender, location of residence, level of training, role in the community, etc). Additionally, the acceptability of the single-dose strategy will vary depending on the providers' awareness of existing evidence on this new recommended vaccination schedule, their location, and level within the healthcare system. We do not expect the acceptability to vary among providers based on their demographic characteristics or education.

Insights from this study will contribute evidence to support the Kenya HPV vaccination delivery and uptake. Additionally, these findings will contribute to the development of setting-specific outreach, educational and training materials to disseminate evidence among different stakeholders which will contribute to increasing the HPV vaccination coverage in Kenya.

Dissemination policy

The study team is committed to public dissemination of results of the formative research to participants, local stakeholders and policy makers in Kenya, the global scientific community. Dissemination of study results will follow principles of good participatory practice. Results will be published in conference abstracts and peer-reviewed journals. Study results will be disseminated through presentations to local stakeholders and policymakers in Kenya, including the Ministry of Health.

Ethics statement

This study involves human participants and it was approved by the Kenya Medical Research Institute's Scientific Ethics Review Unit (KEMRI - SERU, reference number/ID: KEMRI/SERU/CCR/0283/4546), the Massachusetts General Hospital's Institutional Review Board (IRB) (Protocol number: 2022P002863) and an IRB exemption was obtained from the University of Washington's Human Subject Division. Written informed consents to participate in this study were provided by the participants or their guardians where applicable.

Author contributions

All the listed author contributions include the conception and design, drafting the article or revising it critically for important intellectual content, and final approval of the version published. Regarding responsibility for overall content, the lead author, GU is the guarantor. GU and LO had the idea for this article and wrote the first draft. BJW, EB, MO, BN, LM, KN, RVB and NRM wrote additional section and suggested additional changes. All authors revised the article and approved the final version. As the guarantor, GU affirm that the manuscript provides an honest, accurate, and

transparent account of the issues covered, that there are no important omissions, and that there are no discrepancies between what was planned and the final version. All authors contributed to the article and approved the submitted version.

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Conflict of interest

RVB reports Regeneron Pharmaceuticals provided abstract and manuscript writing support outside this study. KN and NRM report research funding from the Merck Investigator Studies Program, outside this study. All reported funders were not involved in the study design, data collection, analysis, interpretation, the writing of this article, or the decision to submit it for publication.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/frhs.2023.1233923/full#supplementary-material>

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Expanding the reach of vaccinology training in Africa: leveraging the success of the Annual African Vaccinology Course

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Introduction: It is estimated that one in five African children lack access to recommended life-saving vaccines. This situation has been exacerbated by the COVID-19 pandemic which disrupted routine immunization services in several parts of the region. To better support recovery efforts and get immunization programmes back on track, policy makers, programme managers, immunization providers and academics need continuous upskilling. Unfortunately, the vaccinology training needed by these cadres remains limited and oftentimes inaccessible within our context. In addition, cadres should be continuously updated on advances in vaccinology so as to keep abreast with this rapidly evolving field. This calls for new and accessible approaches to training vaccinologists in Africa where the demand is high.

Methods: The aim of this proof-of-concept study was to ascertain the training needs of alumni of the Annual African Vaccinology Course and assess the effectiveness of an online webinar series in meeting those needs.

Results: We found that alumni from across Africa required refresher training to gain up-to-date information about new developments in vaccinology, leverage opportunities to reinforce and consolidate their knowledge, and exchange country-specific experiences with their counterparts. A prominent motivation for refresher training was the rapid developments and challenges brought on by the COVID-19 pandemic. Drawing on the expressed needs of our alumni, we developed a webinar training series. This series aimed to provide participants with training on current and emerging trends in vaccinology with a focus on the regional context. Online participation in the webinar series was found to be comparable to previous in-person training, reaching a diverse group of cadres, and allowing for participation of a richer global faculty due to fewer cost constraints. Further to this, a post-training survey indicated that generally, alumni training needs were successfully met.

Discussion: The findings suggest that an online approach can be used to expand the reach of vaccinology training in Africa.

KEYWORDS

vaccines, vaccinology, health education, online training, COVID-19, Africa

1. Introduction

The Annual African Vaccinology Course (AAVC) is a five-day in-person course which was developed in 2005 by the Vaccines for Africa Initiative (VACFA) based at the University of Cape Town in South Africa, in response to the growing demand for vaccinology training in Africa (1, 2). Each year since then, an average of 60 participants comprising of members of

National Immunization Technical Advisory Groups (NITAGs), immunization programme managers from national, sub-national and district levels, immunization providers from both private and public health sectors, scientists, postgraduate students and postdoctoral research fellows, as well as individuals working with non-governmental or not-for-profit agencies, and the pharmaceutical industry, have been trained through the AAVC. Notably, this has amounted to an alumni pool of 992 individuals from 44 of the 54 African countries who have received vaccinology training through the AAVC between 2005 and 2020 (1, 2). The broader goal of the AAVC is to empower African vaccinologists to be directly involved in the design and implementation of home-grown solutions to the local challenges facing immunization programmes across the continent.

Despite the remarkable efforts of the AAVC and other training initiatives elsewhere, a 2019 landscape analysis of vaccinology research and training in sub-Saharan Africa found that training opportunities for vaccinologists in the region remains limited (3). This study identified only ten vaccinology courses, including the AAVC. The courses identified vary in duration, content and level depending on the target audience, and are mainly delivered through an in-person format with fewer opportunities for distance or remote learning (3). Evidently, there is a need for expanding vaccinology training opportunities in Africa, while simultaneously adapting and synergizing existing efforts in order to meet the evolving needs of vaccinologists and the immunization systems they work in (3, 4).

In addition to the limited availability of vaccinology education for first-time trainees, Duclos et al. (5), report that alumni (vaccinologists who have received training previously) encounter challenges with keeping their knowledge updated due to time, availability, and financial constraints. In addition to this, very few vaccinology courses offer refresher training or support for their alumni. Ensuring that alumni remain engaged and continue their training in vaccinology has become crucial due to the introduction of new vaccine technologies over time, the resurgence of previously controlled vaccine preventable diseases (VPDs), the emergence of new VPDs like COVID-19, and growing needs for countering vaccine mis- and dis-information. Empowering vaccinologists with up-to-date knowledge ensures that immunization programmes are appropriately and competently administered and monitored (5, 6). This can be achieved by providing alumni with refresher vaccinology training through online approaches such as massive open online courses, permanent access to online repositories with continuously updated training resources, and regular meetings or workshops delivered through webinar formats.

In 2020, the 16th edition of the AAVC was delivered in a hybrid format for the very first time, allowing for limited in-person attendance ($n=34$) and complemented by online participation ($n=54$) due to COVID-19 restrictions on social gatherings that year (2). This hybrid format allowed for a larger number of participants to attend this popular course, prompting the AAVC conveners to start exploring online vaccinology training as a strategy to make vaccinology training more accessible on the continent. Further to this, conveners noted a

trend of an increasing number of AAVC alumni applying to re-attend the course. In response to this, the conveners of the AAVC sought to develop a refresher vaccinology training course as an avenue to keep its alumni updated with new developments in the field and to foster opportunities for meaningful engagement and collaboration. This study aimed to (a) ascertain the vaccinology refresher training needs of AAVC alumni; (b) develop a cost-effective and widely accessible refresher vaccinology webinar-based course tailored to the African context; and (c) provide proof-of-concept evidence by investigating the success of this training as perceived by participants.

2. Methods

2.1. Assessing the vaccinology training needs of AAVC alumni

A questionnaire was devised to survey AAVC alumni about the need for a refresher training course. This questionnaire was reviewed and piloted among AAVC organizing committee and faculty members who were also alumni but were not selected as part of the participants for this study. The study population consisted of alumni who attended the AAVC in 2011 and 2013 to 2020. Cohorts who attended from 2005 to 2010 were excluded because many of their contact details were outdated. The 2012 cohort was excluded because the 2012 AAVC was held back-to-back with the First International African Vaccinology Conference with some participants attending both events (7). A Google form survey consisting of 8 closed-ended and 2 open-ended questions (Supplementary File S1) was devised to ascertain the vaccinology refresher training needs of AAVC alumni. An invitation with a link to the survey was emailed to each alumnus on 9 February 2022. Data from the responses received by 20 February 2023 were entered into a Microsoft Excel® (Version 2205 Build 16.0.15225.20368) form designed for this study and analyzed independently by two researchers (NM and EA-D) using inductive descriptive analysis to identify thematic categories.

2.2. Refresher vaccinology training webinar series

Drawing on the findings of the survey, we developed a five-part vaccinology training programme tailored to the expressed needs of alumni and delivered via a webinar format on Zoom—an innovative video conferencing platform—between 22 April and 27 May 2022. A copy of the detailed programme for this webinar series is provided in Supplementary File S2. All participants were requested to register for each webinar via the VACFA website (www.vacfa.uct.ac.za), indicating the year they last attended the AAVC, their current occupation or role, email address and whether they wanted to be added to an AAVC alumni email group. While the webinar series was targeted at AAVC alumni, it was not restricted to them and was made available to anyone who would benefit. As such the programme

was distributed via email among AAVC alumni, as well as the broader VACFA network, and uploaded onto the VACFA website. Registered participants were provided a link to each webinar in the series. The registration and attendee data were entered in Microsoft Excel® (Version 2205 Build 16.0.15225.20368) for basic descriptive analysis.

2.3. Post-training survey and feedback assessment

To determine whether the objectives of the webinar series were met, participants were requested to provide feedback via email after each webinar. Unfortunately, the response rate was dismal. Therefore, a post-training questionnaire was devised, and the registrants sent an email containing a link to the survey on Google Forms ([Supplementary File S3](#)). Participants were requested to complete the survey from 6 to 14 June 2022. The data from the survey responses were then entered into Microsoft Excel® (Version 2205 Build 16.0.15225.20368) and analyzed using inductive descriptive analysis to identify thematic categories.

2.4. Ethical considerations

Although this study involved human participants, it is categorized as a quality improvement audit of educational interventions, thus formal approval from an Institutional Ethics Committee was not required. In addition, written informed consent was not required in order to participate in this study in accordance with the national legislation and the institutional requirements.

3. Results

3.1. Outcomes of the alumni training needs assessment survey

3.1.1. Survey response rate

A total of 547 alumni from our 2011 and 2013–2020 AAVC cohorts for whom email addresses were available were invited to complete the online survey. Of these, 101 (18.5%) survey responses were received. One duplicate response was detected by cross-referencing email addresses with responses and thus was not included in the final analysis. Therefore, 100 unique responses were analyzed which equates to an 18.3% (100/547) response rate.

Six respondents indicated that they had attended the course more than once, five had attended twice and one attended five times. [Table 1](#) shows the responses by cohort based on the year of attending the AAVC. Most of the responses were received from those who attended the recent editions of the course; 23% (17/74) in 2017, 26.7% (16/60) in 2019, and 25.6% (20/78) in 2020. Fewer responses were received from alumni who attended earlier offerings of the AAVC.

TABLE 1 Response rate for the AAVC alumni training needs survey per participating year.

AAVC Cohort ^a	Number of alumni surveyed	Number of responses received	Response rate
2011	58	7	12.1%
2013	50	6	12.0%
2014	63	7	11.1%
2015	54	11	20.4%
2016	50	7	14.0%
2017	74	16	21.6%
2018	60	10	16.7%
2019	60	16	26.7%
2020	78	20	25.6%
Total	547	100	18.3%

^aParticipants who indicated attending the AAVC more than once were assigned to the first year they attended the course.

3.1.2. Vaccinology refresher training needs of AAVC alumni

Of all respondents, 93% (93/100) answered “yes” when asked “Do you think there is a need for refresher training?” ([Figure 1A](#)). Of the seven respondents who did not see the need for a refresher, six opted not to provide reasons for their response. However, one respondent did state that: “*I think people should be given access to online modules. Anyone who needs a refresher should take the online course*” [AAVC 2018 alumnus]. Three main themes emerged from the reasons given by respondents who indicated needing a refresher course.

3.1.2.1. Theme 1: need to obtain up-to-date training on new developments in vaccinology

Firstly, 80% (80/100) of the respondents indicated that they wanted to attend the refresher in order to obtain up-to-date information about new developments in vaccinology, including concepts related to policies, immunization programmes, vaccines, vaccination trials and technology. For example, one of the respondents stated: “*So many things have changed in the immunization landscape since we last attended the course*” [AAVC 2016 alumnus].

A prominent motivation for the need to be updated was the rapid developments and challenges brought on by the COVID-19 pandemic. Alumni wanted to learn about the development of new COVID-19 vaccines and the implementation and roll-out of COVID-19 vaccination programmes in Africa: “*Especially with Covid-19 there has [sic] been advances in the vaccine field that would be most helpful to learn of*” [AAVC 2017 alumnus] and “*Vaccinology is a rapidly changing field especially with the emergence of COVID-19*” [AAVC 2017 alumnus]. They were also interested in learning about managing immunization programmes during the pandemic in the context of lockdown restrictions: “*To have new ideas on how to implement during Covid-19 Pandemic*” [AAVC 2019 alumnus] and “*the context of the Covid19 pandemic requires a new way of managing vaccines*” [AAVC 2013 alumnus].

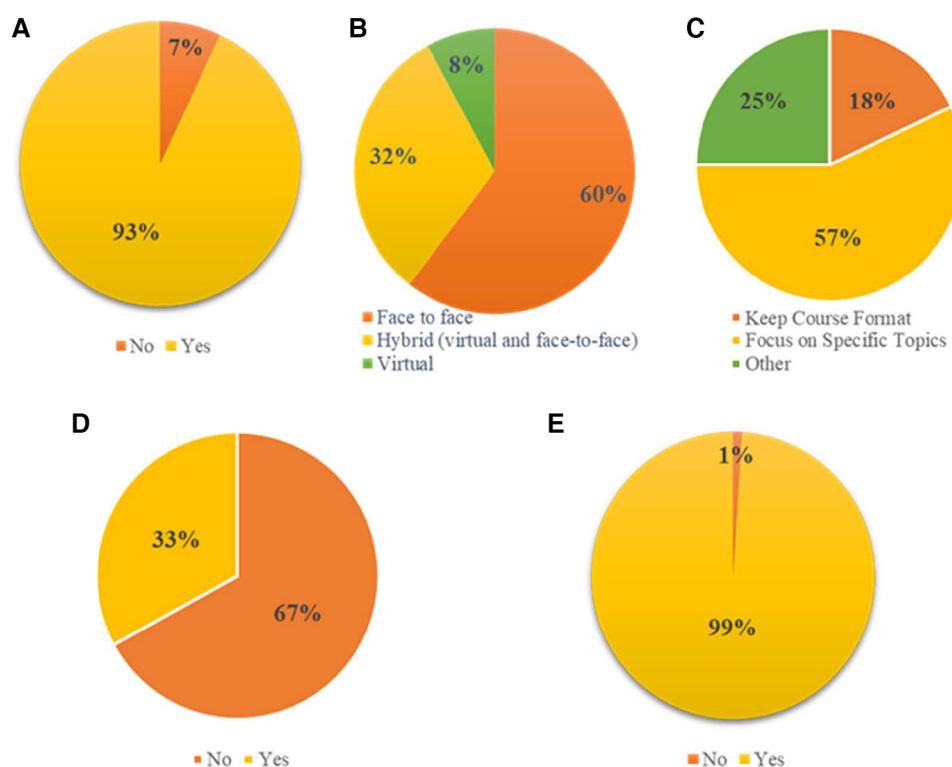


FIGURE 1

Distribution of responses to the alumni training needs assessment survey. (A) The need for a refresher in vaccinology training. (B) Course delivery preference. (C) Course organisation. (D) Attendance of other vaccinology course after AAVC. (E) Willingness to attend online vaccinology course as refresher training.

The need for refresher training was also due to concerns about emerging diseases that would require vaccination: “*New pathogens e.g., COVID -19 (Emerging)*” [AAVC 2011 alumnus], and “*The occurrence of new diseases like Ebola and corona, the vaccine knowledge to the community is very much needed*” [AAVC 2014 alumnus]. Information was also needed about issues which were becoming more prominent and concerning during the COVID-19 pandemic, such as vaccine hesitancy and the consequent need for greater advocacy: “*I need knowledge on vaccine hesitancy (vaccine preventable diseases) and the emergence of new diseases (COVID-19) and what needs to be done to curtail it especially in [a] country like mine*” [AAVC 2019 alumnus], “*News [sic] challenges on immunisation field: infodemics, hesitancy, anti-vax*” [AAVC 2011 alumnus] and “*vaccines [sic] hesitancy knowledge to the community*” [AAVC 2019 alumnus].

3.1.2.2. Theme 2: need to reinforce and consolidate knowledge in vaccinology

Another prominent theme identified among 22% (22/100) of respondents was the anticipated benefits of attending refresher training. Alumni expressed that a refresher course would give them the opportunity to reinforce and consolidate their knowledge. Here, it was considered that a refresher course would be of benefit to those attending as they had gained more experience since they last attended the course and could glean more from the refresher:

“*Some of [us] attended the course in our early carrier [sic] stage, when not many things were fully understood and appreciated. With more experience in the field of Immunisation and vaccination, the course will be more helpful*” [AAVC 2014 alumnus]

and,

“*Participation in the NITAG [National Immunization Technical Advisory Group] makes me see the relevance; I could benefit more now*” [AAVC 2018 alumnus].

In addition, the need for obtaining reliable scientific evidence was raised as shown by one response:

“*COVID-19 Pandemic alongside with it vaccine production brought about conflicting Scientific data and information perspectives. Attending a new vaccinology workshop session may assist us [to] have a clear scientific perspective on COVID-19 vaccine development, and booster information. Moreover we may refresh our skills in vaccine development in general*” [AAVC 2015 alumnus].

Alumni thought that a refresher course would help bring them up to date with new developments and thereby strengthen their capacity to execute their roles:

"I work as a stock control pharmacist at a wholesaler and have to have most answers when my clients ask me about vaccines that I store. The course [AAVC in 2017] helped to improve how we manage our inventory and lastly helped with distribution patterns to our clients that is maintaining of temperature from our stores to end users" [AAVC 2017 alumnus].

3.1.2.3. Theme 3: need for networking and knowledge exchange

The final emergent theme was related to the perceived opportunity for networking and strengthening of collaborations among African vaccinologists which was expressed by 32% (32/100) of respondents: "refresh networks; share information" [AAVC 2019 alumnus], "To share knowledge and network with other African vaccinologists" [AAVC 2011 alumnus], and "Strengthen network with other vaccinologists in Africa" [AAVC 2017 alumnus].

When it came to alumni's preference for the delivery of refresher training (Figure 1B), 60% (60/100) indicated that they preferred a face-to-face mode of delivery, 32% (32/100) preferred a hybrid format, while only 8% (8/100) preferred a virtual mode of delivery. Further to this, when alumni were asked how the course conveners could best meet their needs, 57% (57/100) preferred that the refresher be focussed on specific topics determined by both alumni and conveners (Figure 1C). In ascertaining whether alumni had sought additional training since attending the AAVC, we found that 67% (67/100) had not attended another vaccinology course (Figure 1D). Alumni were then informed that AAVC conveners had partnered with other global vaccinology course conveners to meet the growing demand for vaccinology training in Africa as well as other regions and were asked if as an alternative to returning to the 5-day, in-person AAVC format for refresher training, they would be open to attend any other online vaccinology course as a strategy for refresher training. The overwhelming majority, 99% (99/100), were in favour of this option (Figure 1E).

3.2. Development and uptake of the refresher vaccinology training webinar series

The overarching aim of the webinar series was to address the training needs of the AAVC alumni as ascertained in the survey. In this regard, the primary objectives of the webinar series were to, (i) provide participants with up-to-date information about new

developments in vaccinology, (ii) reinforce and consolidate participants' knowledge, (iii) provide an opportunity for networking and strengthening collaborations especially in the African context, and (iv) broaden the understanding of the challenges and opportunities in vaccinology at regional and global levels.

The series consisted of five webinars held via Zoom. All presentations were delivered in English. Generally, the format of the webinars was 3–4 keynote presentations followed by a moderated discussion for 50 min. The webinar series covered topics such as the Immunization Agenda 2030, basic principles of immunology, history and rationale of vaccination schedules, developing vaccines for pandemic preparedness, surveillance of VPDs and other infectious diseases, and the application of human centred design principles in vaccinology. Key action points for the Immunization Agenda 2030 focussed on successes and challenges of National Immunization Programmes (NIPs) in Africa. The impact of the COVID-19 pandemic was discussed in the context of NIPs in Africa. Emerging trends in immunology and vaccinology were also discussed in addition to the vaccine manufacturing capacity for Africa. Issues around generating demand for vaccination to increase vaccine confidence were also addressed. A Human Centred Design (HCD) consultant facilitated the final webinar on the application of HCD in improving access and acceptability of immunization services (Supplementary File S2). This HCD session was designed to expose participants to tools they can use to foster innovations in addressing key immunization challenges unique to the African context.

Table 2 provides a summary of the number of registrants, and attendees. Unfortunately, registration and attendee data for the third webinar was lost due to changes to the online registration platform. On average, 86.3% (272/315) of registrants were AAVC alumni and 52 individuals attended each webinar in the series. Overall, 176 individuals attended at least one webinar and participants were from 40 different African countries.

A diverse pool of 16 local, regional, and international faculty members delivered talks and moderated discussions during the webinar series. Faculty members were representatives from academia, global health agencies, non-governmental organizations, and the vaccine industry.

3.3. Feedback from the post-training survey

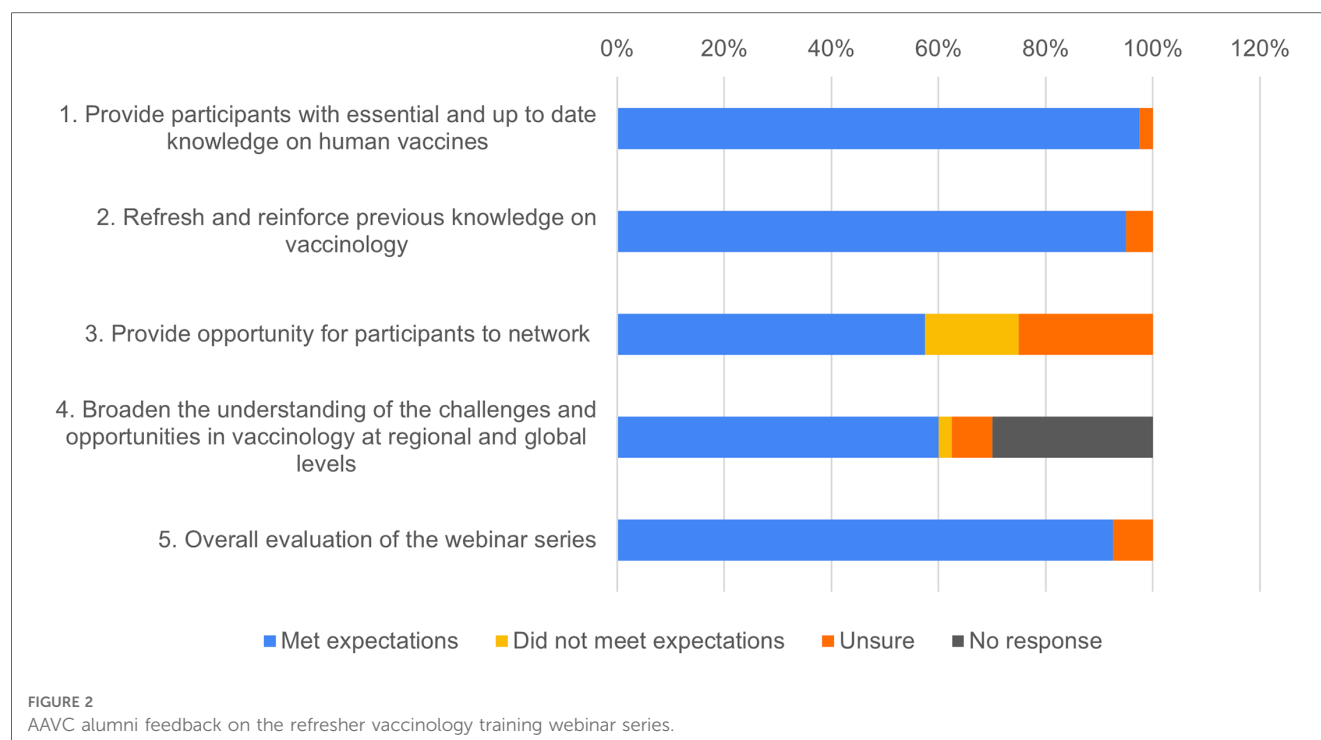
Of the 176 individuals who attended at least one webinar during the five-part series, 22.7% (40/176) responded to the post-

TABLE 2 Registration and uptake of the refresher vaccinology training webinar series.

Webinar series no.	Number of registrations	Number of registrants who were AAVC alumni ^b (%)	Number of attendees ^b (%)	Number of African countries represented
1	80	71 (88.8%)	64 (80%)	30
2	73	67 (91.8%)	49 (67.1%)	22
3 ^a	—	—	—	—
4	104	86 (82.7%)	61 (58.7%)	28
5	58	48 (82.8%)	33 (56.9%)	22

^aData could not be retrieved for webinar #3 due to changes in the online registration platform.

^bThe denominator is the number of registrations per webinar.



webinar series survey. Eighty percent (32/40) of those surveyed attended two or more webinars in the series while 18% (7/40) attended all five webinars. When asked the extent to which the webinar series met its first two objectives, 97.5% (39/40) and 95% (38/40) of respondents respectively, indicated that their need for (1) essential and up to date knowledge on human vaccines, and (2) reinforcing previous knowledge on vaccinology was successfully met (Figure 2). In relation to networking opportunities, 57.5% (23/40) of respondents indicated that the webinar series met their expectations while 25% (10/40) and 17.5% (7/40) were unsure or did not agree that this objective was met, respectively. Sixty percent (24/40) expressed that the webinar series broadened their understanding of the challenges and opportunities in vaccinology from both regional and global perspectives (Figure 2). Finally, when asked about their overall evaluation of the webinar series, 93% (37/40) indicated that their expectations had been met.

3.3.1. Theme 1: need for inclusive training formats

Alumni expressed that the refresher vaccinology training webinar series was a good initiative and wanted it to be rolled out regularly with broadened participation including making the webinars more accessible to other participants as well as making presentations available to those unable to attend due to work commitments or other constraints. While some respondents stated that the online format allowed more people to attend, one respondent raised the challenge of internet access: “*what are the initiatives put in place to accommodate potential participants from some countries without internet connection or access?*” [Respondent #21]. Another expressed the need to make the training more inclusive by providing language translations: “*we would like this*

course to be translated into other languages such as French and Portuguese because this will facilitate deep understanding and good assimilation of the courses” [Respondent #11].

Additional feedback related to the format or structure of the webinars which in some instances interfered with work commitments: “*please avoid long sessions IN a day, one that goes longer than 2 h becomes difficult to actively participate in due to work and other commitments*” [Respondent #24].

3.3.2. Theme 2: need for training environments that foster meaningful collaboration

One respondent suggested that future webinars provide more opportunities to network and establish collaborations: “*I think the coming webinar should increase the environment for researchers to network and establish collaborations*” [Respondent #35]. This gap in opportunities to actively network emerged as a key theme among alumni who participated in the webinar series. To help bridge this gap, alumni were asked if they wanted to be part of an AAVC alumni group that VACFA was establishing. In response to this, 94% (167/176) of the registrants indicated that they would like to be part of the group. The contact details of those who responded affirmatively were collated for the formation of a mailing list. This group was also invited to access a resource repository on the VACFA website containing e-resources which have been assembled to supplement the webinar series.

4. Discussion

In 2018, the World Health Organization reported that one in five African children still lack access to recommended life-saving

vaccines (8). Since then, immunization gaps within the African region have been amplified following disruptions to routine services brought on by the COVID-19 pandemic (9, 10). A capable health workforce will be an integral health systems resource for recovery efforts aimed at getting immunization programmes back on track. It is not surprising then that the primary motivation for refresher vaccinology training among alumni of our AAVC was the COVID-19 pandemic and its influence on the rapid developments within the immunization landscape. In addition, alumni sought opportunities to reinforce and consolidate their knowledge having had further experience in the field since they last attended the AAVC, as well as an environment that fostered networking and collaboration with their counterparts across the continent. In response to this, we developed a refresher vaccinology training series, delivered in a webinar format to enhance the accessibility of the course. The findings from our post-training survey indicate that overall, the webinar training series was an overwhelming success, having met the expectations of 93% of alumni surveyed.

At a 2018 workshop, leaders of 26 advanced vaccinology courses conducted an extensive review of vaccinology courses available globally (5). One of the conclusions of this review was that there was a need to facilitate post-course cascade training for alumni. Further to this, online approaches to adult education were proposed as efficient and cost-effective strategies for providing accessible refresher training. Such an approach would also negate the necessity for participants to attend multiple courses or to attend the same course again, thus allowing for a greater number of individuals to have access to vaccinology training (5). It is with this in mind that we sought to build on the success of the AAVC which has been at the forefront of vaccinology training in Africa for the past 16 years, amassing an alumni pool of 992 NITAG members, immunization programme managers and providers, academics, and individuals from relevant non-governmental or not-for-profit agencies, and the pharmaceutical industry (1, 2). Generally, the reach of the refresher webinar training series was found to be comparable to the in-person format of the AAVC. Conveners were able to leverage the faculty of the AAVC, with the added benefit of including a richer and more internationally representative faculty membership without the travel and logistics cost limitations imposed by in-person training.

Two key themes emerged from the post-webinar training survey, the first being the need for inclusive refresher vaccinology training webinar series. While the webinar format may allow for wider participation, settings with unstable internet access may not be conducive for online training. To mitigate this challenge, we created a repository accessible via the VACFA website where recordings and slide presentations were made available soon after the series to broaden the reach of the training materials for those who were unable to attend or access the live webinars. Analysis of web traffic on this site going forward will give an indication of the reach and usefulness of this information to AAVC alumni. Translation of the webinars into French and Portuguese would also make the information more accessible to a greater African audience. The second theme was on the need for an

environment that fosters meaningful collaboration among African vaccinologists. This emerged as a critical limitation of the webinar format. Future refresher training initiatives will have to explore the usefulness of discussion groups or breakout rooms as an avenue for further interaction and improved engagement among alumni.

The findings of this study should be interpreted with careful consideration of some limitations. First, the response rates of the needs assessment and the post-webinar surveys were sub-optimal. While we attempted to survey our large pool of alumni, deactivated or unmonitored email addresses meant that we could not reach most of them. With the establishment of alumni groups and mailing lists, it is anticipated that contact details will be maintained and regularly updated. While findings may be unique to alumni from the African context, this study does provide significant lessons for guiding other training initiatives intending to implement continuous vaccinology training.

5. Conclusion

Addressing the gaps and growing demand for vaccinology training in Africa relative to the rest of the world requires more than the provision of once-off training. Alumni of vaccinology courses require regular upskilling in order to strengthen their capacity to execute their roles and make lifesaving vaccines accessible to those who need them the most. This study supports the use of an online approach for providing cadres working in the immunization space with continuous vaccinology training. The findings suggest that online training is a practical and cost-effective approach to expanding vaccinology expertise in Africa.

Data availability statement

The datasets presented in this study can be found in online repositories. The names of the repositories can be found in the article/[Supplementary Material](#).

Ethics statement

This study was conducted in accordance with the local legislation and institutional requirements. None of the AAVC alumni invited to participate in the survey were minors. Written informed consent was not required in order to participate in this study in accordance with the national legislation and the institutional requirements.

Author contributions

This article was conceptualized by NM and BMK. NM and EA-D were involved in data curation and formal analysis, and

drafted the original manuscript. BMK validated the data. RM, GH and BMK reviewed and edited the final draft of the manuscript. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The reviewer VVN declared a past co-authorship with the author EA-D to the handling editor. The author BMK declared that they were an editorial board member of Frontiers at the

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The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

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"When you get the HPV vaccine, it will prevent cervical cancer; it will act as a shield": adolescent girls' knowledge and perceptions regarding the human papillomavirus vaccine in Zambia

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Introduction: The human papillomavirus (HPV) vaccination is an important preventive measure for HPV-related conditions such as cervical cancer. In 2019, Zambia introduced a free national HPV vaccination program for 14-year-old girls. However, the adolescents' knowledge and perceptions regarding the HPV vaccine are not well understood. Therefore, this study aimed to understand adolescent girls' knowledge and perceptions regarding the HPV vaccine and discuss its acceptability and uptake implications.

Methods: We conducted a qualitative study in the Lusaka district between June 2021 and November 2021 using semi-structured interviews with adolescent girls aged 15–18 years regardless of their HPV vaccination status. Interviews were transcribed verbatim, and NVIVO 12 was used for data management and analysis. We coded transcripts deductively and inductively based on emerging themes. Perceptions were coded using the health belief model constructs.

Results: We interviewed 30 adolescent girls to reach saturation. Seventeen girls reported having received at least one dose of the HPV vaccine. Participants expressed variable knowledge and awareness about HPV and the HPV vaccine. Participants exhibited positive attitudes towards the HPV vaccine and perceived it as beneficial. However, there were multiple perceived barriers to vaccination, such as the need for parental consent, not being in school, concerns about vaccine side effects, and belief in myths and misinformation.

Conclusion: The adolescent girls in this study showed variable knowledge and positive attitudes toward the HPV vaccine despite the many perceived barriers. To support increased HPV vaccine acceptability and uptake among adolescent girls in Zambia, it is critical to actively engage stakeholders involved in HPV vaccination, such as adolescents and their parents, and debunk myths and misconceptions about HPV vaccination. Health education in schools and communities should be implemented to increase knowledge about HPV and HPV vaccination among adolescents and their parents.

KEYWORDS

HPV vaccine acceptability, HPV vaccine uptake, COVID-19 vaccine, health belief model, parental consent, myths and misinformation, cervical cancer

Background

The World Health Organization (WHO) recommends that the human papillomavirus (HPV) vaccine be included in national vaccination programs to prevent cervical cancer and other HPV-related conditions (1). Persistent infection with HPV causes benign conditions such as genital warts and malignancies such as cervical cancer, anogenital cancers (anal, vulva, penile), and head and neck cancers. HPV is a risk factor for the development of cervical cancer, with types 16 and 18 commonly identified in approximately 70% of all cervical cancers (2). By far, cervical cancer is most common in Low and Middle-Income Countries (LMICs), with a disproportionately larger burden in sub-Saharan Africa (SSA) (1). In 2020, there were over 600,000 new cases of cervical cancer globally, with approximately 330,000 related deaths, most of which were reported from LMICs (1).

Like many other SSA countries, Zambia has one of the highest cervical cancer incidences and mortality rates in the world (2) and faces many challenges in treating those diagnosed with the disease since most of them present in late stages (3). According to the Global Cancer Observatory, Zambia cervical cancer-related incidences and mortality stand at 65.5 and 43.4 per 100,000 (1) making it one of the most common cancers in the country.

Persistent infection with HPV and rapid progression to malignancy is characteristic in women co-infected with the Human Immunodeficiency Virus (HIV), especially in high epidemic regions like Zambia (4–6). Women living with HIV are six times more likely to have cervical cancer than those without HIV with about 63.8% of women with cervical cancer and HIV residing in Southern Africa (7). The 2021 Zambia Population-based HIV/AIDS Impact Assessment (ZAMPHIA) reported a National HIV prevalence of 11% among people aged 15 years and older, however, when disaggregated by sex, women bear a higher prevalence of 13.9% while it is 8% in males (8). This further puts women at an increased risk of having persistent infection with HPV leading to cervical cancer.

In 2018, the WHO recognized cervical cancer as a public health problem and announced a strategy for its elimination by setting triple targets to be achieved by 2030 (9). According to this strategy, the first target entails that 90% of girls should be fully vaccinated against HPV by age 15 years and this is the focus of this paper. There is overwhelming evidence of the safety and effectiveness of the HPV vaccine as a primary prevention for cervical cancer (10).

The HPV vaccine is primarily recommended for adolescents aged 9–14 years (11), however, most countries in SSA are currently implementing girls-only programs (12). In contrast, high-income countries (HIC) have commenced gender-neutral programs for both girls and boys as the HPV vaccine is more accessible (11). Countries that have implemented national HPV vaccination programs, deliver vaccinations in various settings such as schools, health facilities, community outreach posts, or a combination of different platforms (13, 14).

Since 2019, Zambia has been offering the two-dose HPV vaccine to 14-year-old girls 12 months apart, following a demonstration project done between 2013 and 2017 in Lusaka Province (15). The national HPV vaccination program is campaign-based, conducted annually during the first round of Child Health Week (CHWk1), lasting six days from Monday to Saturday, after which walk-in vaccinations are at the health facilities for those who could have missed out during the campaign. The primary vaccination platforms include static at health facilities and outreach at schools and other community points. However, uptake has been low owing to different factors such as parental refusal, beliefs in myths and misinformation, school closures due to the COVID-19 pandemic and its prevention measures (15). Zambia's reported coverage for dose one in 2019 was 75%, which dropped to 39% in 2021 owing to some of these highlighted factors (16, 17).

Understanding adolescents' knowledge and perceptions of the HPV vaccine is critical. Despite adolescents being the primary recipients (18), they are frequently left out in decision-making and research. In Zambia, most research has focused on other stakeholders, such as parents (6, 17, 19–22) and healthcare workers (22, 23) with very few studies focusing on adolescent girls as participants (24), despite being important stakeholders. The available literature has scanty information on adolescent girls' knowledge and perceptions regarding the HPV vaccine and this is likely to impact acceptability and uptake (25).

Therefore, adolescents' attitudes regarding the vaccine should be explored as a first step, to ensure the success of the HPV vaccination program as they are key stakeholders. This study is partly framed within the health belief model (HBM), a well-known and frequently used theory commonly used for exploring perceptions that may influence health-seeking behaviour such as HPV vaccine acceptability and uptake (26–29).

Methods

Study design and setting

We conducted an exploratory qualitative study using semi-structured interviews with adolescent girls between June 2021 and November 2021 within selected schools and health facilities of Lusaka district, the capital city of Zambia. The primary site for HPV vaccination is the school, as most adolescents within the target age group are found in schools. The Ministries of Health and General Education collaborate in implementing the HPV vaccination program. The number of eligible girls is determined using school registers, headcount, and Central Statistics Office figures (Now Zambia Statistics Office). At the same time, community health workers identify out-of-school girls in a door-to-door fashion or through civil societies and these girls receive the vaccine from health facilities or community outreach points.

Sampling

In the first stage, schools enrolling adolescent girls aged 15–18 years within the subdistricts of Lusaka were sampled purposively as those participating in the HPV vaccination program. Thereafter, girls aged 15–18 years were selected based on their eligibility to receive the HPV vaccine, regardless of their vaccination status. The selection of this age group was based on Zambia's national HPV vaccination policy rolled out in 2019, which currently targets 14-year-old girls for dose one (30), which was preceded by a demonstration project between 2013 and 2017 targeting 9- and 10-year-old girls out of school or school grade 4 pupils (31). The included schools were sampled conveniently with a combination of public, community, and private schools. The communities served by the various schools are primarily urban either in low, medium, or high-density areas.

Eleven schools were included with a minimum of two eligible girls per school selected to participate in the study. Although participants in our study were not asked about their socioeconomic status, a recent study within the same setting which focused on parents showed that most participants were either in the middle or lower wealth quintiles (17). The researchers met the headteachers to get access to the schools to sample eligible girls. Adolescent girls were identified either through the class teacher or the focal point teacher for school health-related activities. The potentially eligible girls were met during class break times slated at different times of the day.

Out-of-school girls were identified with the help of community health volunteers. Information about the study was given to the girls, and if they were willing to participate, information sheets and consent forms were presented in English or Local language in a sealed envelope for the girls to deliver to their parents for consent purposes. The girls were asked to return the forms once the parents reviewed them, and those who agreed to participate signed the informed consent form. Assent to participate in the study and interview audio recordings were obtained from the adolescent girls after parental consent.

Data collection

The semi-structured interview guide consisted of questions and probes that focused on socio-demographics; knowledge of HPV and the HPV vaccine, perceptions regarding the HPV vaccine, vaccination status (whether they had received at least one dose of the HPV vaccine), willingness to vaccinate for those not vaccinated or motivation for those vaccinated, and suggestions related to increasing HPV vaccine uptake. We explored knowledge and awareness by asking participants what they knew about HPV, what type of conditions it causes, if they knew about cervical cancer or genital warts and how they can be prevented, and how to prevent transmission. The questions regarding the HPV vaccine were whether they have heard about it, when it is given and how, and its purpose. To assess perceptions regarding the HPV vaccine, we used the HBM.

The HBM was developed in the early 1950s as a cognitive theory to predict health-seeking behavior (32). The original HBM postulates that for an individual to take a health-related action, they should perceive the disease as severe, perceive their susceptibility to the disease, believe that it is beneficial to take preventative action (HPV vaccination, in this case), and not perceive significant barriers to taking the health action (32). Two other constructs were added; self-efficacy (one's own confidence to engage in the behavior) and cues to action (specific triggers to action). Cues to action may be internal such as experiencing symptoms, or external such as receiving advice from friends, family members, or health care providers (32).

Some of the questions asked to the participants based on the HBM included; how likely are you to get infected with HPV, how severe would the HPV infection be if you got infected, what do you think are the benefits of getting the HPV vaccine, and what are the barriers to getting the HPV vaccine. See Table 1 for details.

An iterative process was used to develop and refine the interview guide. The guide was initially piloted using two interviews, after which edits were made to increase comprehension of the questions and improve clarity. Interviews took place in a private room on school premises for school girls and within health facilities for out-of-school girls. Interviews were conducted by one of the authors (MKL), experienced in conducting qualitative interviews and research related to HPV and HPV vaccination.

The interviewer's identity (MKL) as a medical doctor at the highest-level referral hospital in Lusaka could have potentially influenced the mutual relationship with participants and could have influenced how questions were asked. Further, the adolescents could easily feel the power difference and withhold information thinking the interviewer knows it all. The interviewer tried as much as possible to explain her current role as a researcher with a primary role in collecting data. To help the interviewer to be neutral, a reflexivity journal was maintained. Interviews were conducted in the local language, Cinyanja, or English, depending on the participants' preference.

TABLE 1 Examples of questions asked under each of the health belief model constructs.

HBM construct	Example question
Perceived susceptibility to HPV infection	How likely do you think are you to get infected with HPV?
Perceived severity of HPV infection	How severe would the HPV infection be if you got infected?
Perceived benefits of HPV vaccination	What do you think are the benefits of getting the HPV vaccine?
Perceived barriers to HPV vaccination	What are the possible things that can prevent you from receiving the HPV vaccine?
Cues to receive the HPV vaccine	What motivated you to get the HPV vaccine or why do you intend to get the HPV vaccine? (Depending on vaccination status or willingness to vaccinate)
Self-efficacy on getting the HPV vaccine	Could you please tell me more about your belief in your ability to receive the HPV vaccine?

All interviews were audio recorded using a voice recorder and transcribed verbatim.

Participants were allocated unique identification numbers to ensure anonymity during data analysis and discussion of results. All data were anonymized and kept securely. Data were collected until saturation was achieved. Saturation in this case was defined as a point where no additional data was obtained (33). This rigorous data collection process was used to assure dependability.

Data management and analysis

All interviews were transcribed verbatim by trained research assistants shortly after the interview; each transcript was checked for accuracy by one of the authors by listening to segments of the audio recording. Demographic data were collected to record the characteristics of the girls. Completed and final transcripts were imported into NVIVO 12.0 for data management and analysis.

Thematic analysis was used to identify emerging themes using a six-step approach: (a) familiarisation with the data through close reading of transcripts and memoing, (b) generating initial codes and developing a codebook, (c) searching for themes, (d) reviewing themes, (e) defining and naming themes, and (f) writing up the findings (34). Even though the study was framed within the HBM, thematic analysis was the most ideal approach to capture all aspects of data deductively and inductively. Other studies using the HBM as the guiding framework have used thematic analysis (35).

Transcripts were read thoroughly to understand what the adolescent girls were expressing, and memoing was used to reflect on the data and the analysis process. To assure confirmability, data was checked and rechecked throughout data collection and analysis. The initial codebook was developed (based on the HBM constructs for perceptions deductively) and codes were derived from the memoing process. Coding is an important step in data analysis, as it adds meaning to the data. Initially, one co-author (MKL) coded four transcripts to pilot the codebook, and a second co-author (SF) reviewed the transcripts, any disagreements in coding were discussed until consensus was reached or with a third co-author (MK), this member checking was done to ensure credibility of the data analysis.

The codebook was further refined through this iterative process until it was stable. Health belief model constructs were used as deductive codes. Using the finalised codebook, the rest of the transcripts were coded by MKL. Coded excerpts were then arranged into sub-themes and later themes. Data related to HBM constructs were coded deductively, while other emerging themes were coded inductively (34).

The standards for reporting qualitative research have been followed in the writing of this manuscript (36).

Ethical considerations

The study was conducted as per the national and international ethical principles in dealing with minors in research. Ethics approval was obtained from the University of Zambia Biomedical Research Ethics Committee (UNZABREC) Ref: 1609-2021, University of the Witwatersrand University Health Research Ethics Committee (HREC Medical) Ref: M21/04/73. A waiver was obtained from the University of North Carolina (UNC) Ethics Committee. Permission was sought from the Ministries of Health and General education and the heads of institutions for the study sites. The study was further registered with the Zambia National Health Research Authority (NHRA). Minors were only allowed to give assent and participate in the study after informed parental consent. Compensation of \$5 was given to all participants for their time. The completed assent and parental informed consent forms and interview transcripts were stored separately. Participants were free to withdraw from the study without repercussions, and confidentiality was observed.

Results

We invited 35 girls to participate in the study. Four girls were ineligible to participate due to lack of parental consent, and one girl was ineligible due to her age (<14 years old, invited by error) and we reached saturation at 30 participants. Of the 30 participants interviewed (age range: 15–18 years old), 17 had received at least one dose of HPV vaccine and 27 were enrolled in school (Table 2). We categorized findings related to the following themes: knowledge about HPV and HPV vaccination, perceived susceptibility to HPV infection, perceived severity of HPV infection, perceived benefits of HPV vaccination, perceived barriers to HPV vaccination, cues to HPV vaccine uptake, self-efficacy, and participants' suggestions to improve HPV vaccine uptake.

Knowledge about HPV and HPV vaccine

Participants displayed varying knowledge about HPV and HPV vaccination. Some were knowledgeable about HPV, its consequences, and the role of vaccination. However, some were not aware or knew very little, especially the unvaccinated girls:

What I know about the HPV vaccine is that it can protect me from having cervical cancer. A7, vaccinated

One unvaccinated girl mentioned having easy access to a health facility, but had no information about the HPV vaccine:

The place to access the vaccine is quite near, but I don't know anything about the HPV vaccine. A8, unvaccinated

TABLE 2 Participants characteristics.

Participant ID	Sub-district	Age	School	School grade	School type	Vaccinated?
A1	Kanyama	17	Yes	8	Public	No
A2	Matero	15	Yes	9	Public	Yes
A3	Matero	15	Yes	7	Public	Yes
A4	Chelston	18	Yes	12	Public	Yes
A5	Chelston	16	Yes	7	Public	No
A6	Chilenje	15	Yes	11	Private	No
A7	Chelston	15	Yes	9	Quasi	Yes
A8	Chelston	15	Yes	9	Public	No
A9	Kanyama	16	Yes	9	Private	Yes
A10	Chelston	16	Yes	8	Private	Yes
A11	Chelston	16	Yes	7	Public	No
A12	Chawama	16	Yes	8	Private	Yes
A13	Chelston	15	Yes	9	Public	Yes
A14	Kanyama	17	Yes	8	Public	Yes
A15	Chawama	15	Yes	7	Community	Yes
A16	Chawama	15	Yes	7	Community	Yes
A17	Chawama	15	Yes	8	Private	Yes
A18	Chawama	16	Yes	10	Public	No
A19	Chawama	15	Yes	7	Community	Yes
A20	Chilenje	16	Yes	8	Private	No
A21	Chawama	17	Yes	11	Public	No
A22	Chawama	17	Yes	11	Public	Yes
A23	Chawama	16	Yes	10	Public	Yes
A24	Chipata	18	Yes	10	Public	No
A25	Chipata	17	Yes	9	Public	No
A26	Chipata	15	Yes	6	Public	No
A27	Chilenje	16	No	NA	NA	No
A28	Chilenje	16	No	NA	NA	No
A29	Chilenje	15	No	NA	NA	Yes
A30	Chipata	15	Yes	8	Public	Yes

While another unvaccinated girl expressed fear due to a lack of awareness:

We (adolescent girls) are all scared... because we don't really know what the vaccine is really about. A27, unvaccinated

Both vaccinated and unvaccinated participants discussed HPV as a sexually transmitted infection. They also discussed the increased risk of cervical cancer for those who are unvaccinated:

I know that uh it's transmitted through sexual intercourse (...) it is found on the foreskin like those men who are not circumcised yet do have sex, and I know that it attacks the cervix of the womb (...) I knew that this is a virus that usually comes from men and I learnt that it is usually on the foreskin of the penis (...) when it comes to a woman it is something some kind like it is foreign, so it reacts. But what I know is that it doesn't usually react, first takes some time and then it is going to develop into cervical cancer. A21, unvaccinated

This virus is usually found in men at the foreskin, and it is transmitted sexually into the vagina. It won't react that much the same that day, but it will maybe some years (...) that's where cervical cancer comes in. A22, vaccinated

Perceived susceptibility

Adolescent girls who reported that they were not sexually active but were thinking about future sexual encounters such as marriage or non-consensual sex such as rape were more conscious about the dangers of HPV and so believed they were more vulnerable to HPV infection. However, some girls felt they were not susceptible to HPV infection as they were not sexually active, hence did not feel the need to take the HPV vaccine until they were older and sexually active. Adolescent girls discussed circumstances beyond their control, such as being raped, which could put them at risk of infection with HPV. Further, there was an inclination towards men being carriers of HPV and not women.

There are so many ways in which us girls can get the virus (...) like if we get raped, and you (we) can get the virus. So, it is very important that we get the vaccine so that even when I get the devastating news that I have been raped, at least I will not get the HPV. A14, vaccinated

Because if I am not really on the safe side, I can get married to someone who has got that HPV because from what I know is that it is coming from men. So, for example, my husband

might have it if I do not have any knowledge about It, and I might end up having cervical cancer. A21, unvaccinated

However, when an unvaccinated girl was asked about her risk of being infected with HPV, she said she would not get the virus “because I am not sexually active.” A28, **unvaccinated**.

While a vaccinated girl had this to say:

Abstinence is the best way, that's what I'm practicing so that I can't get the HPV and maybe others can use condoms if they are married. A13, vaccinated

Perceived severity of HPV infection

Some adolescents reported a higher perception of the severity of HPV infection especially when they were aware of its negative repercussions such as someone getting cervical cancer or experiencing other related health problems including death. Additionally, some perceived that their performance and participation in academic and career-related activities may be affected hence impacting their future professional prospects. Participants reported that their sense of self-worth may suffer as a result of worries about potential health effects and career progression.

It will affect me as I have a dream of becoming an engineer, but if I have this disease (cervical cancer), I can't go further in achieving my goals. A23, vaccinated

We were told not to sleep with boys as we would get the virus which doesn't go away until you die. A1, unvaccinated

Perceived benefits of HPV vaccination

Adolescent girls, regardless of their vaccination status, perceived HPV vaccination as being beneficial. Protection against cervical cancer was the primary benefit that participants discussed. Participants reported that the benefits of the HPV vaccine provided one with a feeling of safety, especially that the vaccine was known to be safe and effective.

The vaccine is very important to us, it prevents us from getting the cervical cancer. At some point we can be sexually active but if we never had that vaccine, HPV can be easily transmitted into us coz (sic) it comes as a foreign material. So as for that when you get the (HPV) vaccine it will prevent cervical cancer (hmm), it will act as a shield of course. A22, vaccinated

I can say I have not seen any bad side with these uh vaccinations coz (sic) it is just there to prevent those diseases that I might have in future, like cervical cancer, so just better to secure the future. A21, unvaccinated

Perceived barriers to HPV vaccination

There were several barriers reportedly experienced by both vaccinated and unvaccinated. These were coded as subthemes, namely: parental refusal to give consent, belief in myths and misconceptions, negative peer influence, being out of school, and perceived vaccine side effects.

Parents play a key role in the vaccination of their children, as they must consent for them due to their age. Even when adolescent girls may want to get the vaccine, the final decision comes from the parents. Participants reported conflict between mothers and daughters, as some adolescents were willing to receive the vaccine but were discouraged or stopped by parents, especially mothers.

Some (adolescents) think it's good, but their parents don't. So, there may be a bit of conflict between the two owing to the fact that most of my friend's parents are not educated and hence don't understand the importance of the vaccine, unlike us students who come here and understand the advantage of getting the vaccine. So, others think it's good while others don't. A13, vaccinated

My mum just refused me from getting the vaccine but I really wanted to get the vaccine I heard the effects of this disease (cervical cancer) and really wanted to get the vaccine, but my mum refused. A20, unvaccinated

In addition, participants reported that peers also influenced their reactions to the vaccine:

Well, at my previous school, I was willing to get injected, but after I transferred to this school, I started getting discouraged because of the comments they (peers) used to make such as they are just collecting your blood to take it elsewhere. A17, vaccinated

One participant indicated that some adolescent girls choose not to vaccinate because their peers say that one might get other diseases: “you will be opening the door to other illnesses.” A27, **unvaccinated**.

Belief in myths and misinformation were reported amongst both the vaccinated and unvaccinated girls. These myths seem to be perpetuated by different members of the community (including parents and peers) sharing false information, instilling fear in some girls. The most common myth was that the vaccine is meant to sterilize girls.

Then there some who say you are not supposed to get the vaccine because you will never have children, you will be barren for the rest of your life. A7, vaccinated

They get wrong information from the community. Some say you may die after taking the vaccine (...) they are told that they have

just come to kill us all because there are a lot of females in our population. A27, unvaccinated

The misinformation was worsened by the introduction of the COVID-19 vaccine, where the community assumed that adolescents were secretly being inoculated with the COVID-19 vaccine within the pretext of administering the HPV vaccine.

Others are scared of the injections they think it's the COVID vaccine. A2, unvaccinated

They think it is expired, harmful, and that it's the corona vaccine (...) that it's harmful because they have seen fake information on the internet, that the vaccine can kill, the whites want to kill Africans (...). A13, vaccinated

Other myths included the belief that the vaccine can cause illness or death:

Some were saying that oh maybe these people they are just here to get the blood for this what uh witchcraft activities so they want us to donate our blood. There will be that, they will put us into satanism. A22, vaccinated

I think there may be effects like paralysis of my arm or falling ill, or that I may have a sore at the site of injection that won't go away and later turn into a cancer (...). They (adolescents) get wrong information from the community. Some say you may die after taking the vaccine... they are told that they have just come to kill us all because there are a lot of females in our population. A27, unvaccinated

Another barrier expressed by adolescents was that the vaccination program was biased toward school-going girls:

They (out-of-school girls) cannot have anyone to go and educate them about the HPV virus that's the disadvantage for most of them. They are taken into early marriages without consent so that can also prevent them from learning about it (HPV vaccine), and there is no one to educate them. A13, vaccinated

Perceived side effects of HPV vaccine

Some adolescent girls perceived that the HPV vaccine had variable side effects some of which could lead to permanent dysfunction of some body parts which discouraged some from receiving the vaccine.

It was painful at first then I was uh something was itching so yeah it was very painful at first and then it stopped in three to two days. A23, vaccinated

Then also that you may experience headaches and stomach-aches (...) generally feeling ill. A8, unvaccinated

Cues to HPV vaccination

Participants mentioned getting a recommendation from parents and friends to receive the HPV vaccine. These served an important role as they helped ease and allay fears that eligible adolescents could have.

I went home to ask my mum if I could get the vaccine, then she said go back! Go and take the vaccine coz (sic) it may protect you somehow as you are growing (...) I was encouraged by my mum to say the vaccine is good that's how I got motivated. I know since mum is concerned about this let me just do it. A22, vaccinated

My friend is the one who told me to say, next time when they come (vaccinators) you just have to do it, she (a friend) has been encouraging me (...). A21, unvaccinated

Self-efficacy in getting the HPV vaccine

Adolescents showed willingness to take the necessary steps to get the vaccine, and expressed confidence in their own abilities to get vaccinated:

I think it just with my own motivation coz (sic) I think the health post they are always open (uh hmm) so any day I can just go there (and get the vaccine) yes, coz (sic) even now so I am out of class I have knocked off, I can go and get the vaccine. A21, unvaccinated

I was strongly encouraged and I have that boldness that's how I got the vaccine. A22, vaccinated

Participants' suggestions for increasing HPV vaccine uptake

Adolescents had several suggestions for increasing HPV vaccination amidst mixed messages. Some suggestions related to increasing knowledge and awareness of HPV vaccination by making information about HPV vaccination more accessible within communities through social mobilization campaigns, including information on HPV within the school curriculum and active involvement of politicians:

It should be more like a topic. They should put in a subject like science. Teachers make us understand coz (sic) me I have heard of it and many grade 11s have heard of it. But what of these grade 4s? They only know STIs like HIV. If you ask any child to say what kind of STI do you know, they mention HIV. A21, unvaccinated

Even the vice president needs to say something about the vaccine, encourage the young girls to get the vaccine so that they don't get diseases such as cervical cancer. A15, vaccinated

Some adolescents felt that parents and out-of-school girls should be educated more about the HPV vaccine:

Well, maybe talking to parents about the benefits of the vaccine, and assure them that nothing bad will happen when their daughters take it. A15, vaccinated

(...) they (Out of school) can be informed by community sensitisation on the advantages of being vaccinated. A28, unvaccinated

Discussion

This study set out to understand adolescent girls' knowledge and perceptions regarding HPV and the HPV vaccine and discuss its acceptability and uptake implications. The adolescent girls showed variable knowledge of HPV and HPV vaccination as more vaccinated girls were aware of HPV, its transmission route, and the outcome of infection. The attitudes towards the vaccine were generally positive among our study participants. The adolescent girls generally perceived the HPV vaccine as beneficial to limit the spread of HPV and prevent conditions like cervical cancer.

However, several barriers to receiving the HPV vaccine were highlighted, such as lack of parental consent, negative peer influence, belief in myths and misinformation, confusion, and misconceptions around the relationship of the HPV vaccine to the COVID-19 vaccine. Knowledge levels and positive perceptions play an important role in the acceptability of HPV vaccination, however, strategies to overcome the perceived barriers should be identified and implemented to actualize a high uptake (37, 38).

We found that adolescent girls in our study had positive perceptions towards the HPV vaccine, which is likely to increase its acceptability and uptake. Similarly, a qualitative inquiry conducted in Uganda found that girls with good attitudes towards the HPV vaccine widely accepted it despite most of them not having been vaccinated (39). This finding of positive perceptions regarding the HPV vaccine among Zambian adolescent girls holds promise as it could be used to reinforce positive messages about the vaccine to improve future uptake. HPV vaccine uptake remains low in Zambia, for 2021, only 39% and 31% of the eligible girls had received dose one and dose two respectively (16). Therefore, much effort is required to ride on these positive attitudes, because previous studies showed that in some instances, high acceptability did not translate into high HPV vaccine uptake (40, 41).

There was variable knowledge about HPV in general, the route of HPV transmission, and the HPV vaccine itself. Some girls were knowledgeable, while others were not even aware of HPV and its vaccine. In the extant literature, low levels of knowledge (42)

have been found in different settings and many times have contributed to low HPV vaccine uptake (43). Similarly, a qualitative study done in the UK early into the HPV vaccination program showed low levels of HPV vaccine knowledge among the recipients (44). Within SSA, a recent study done in Tanzania found low levels of knowledge among adolescents, parents, and teachers, especially before the HPV vaccine was integrated with other health programs (45). Additionally, a quantitative study among Brazilian adolescent girls (46) and a systematic review among European adolescents (47) showed low levels of knowledge.

Therefore, low knowledge of HPV and HPV vaccine is a common feature in different parts of the world and is implicated as one of the contributors to low global HPV vaccination (40). For Zambia, these findings of mixed knowledge among participants in the capital city could be explained by the program being in its infancy, and hopefully, as it matures, more people may be aware through access to information about the HPV vaccine. Therefore, in our study context, culturally appropriate and contextualized strategies could be implemented with the aim of raising awareness and improving knowledge, and subsequently improving HPV vaccine uptake (37).

Examples of strategies include messages around the HPV vaccine packaged in an easy-to-understand format and language using the most accessible platforms: door-to-door campaigns, churches, markets, schools, and health facilities to ensure widespread information sharing. We also suggest that a quantitative inquiry be conducted to measure the actual levels of knowledge using validated tools.

While our participants expressed willingness to recommend the vaccine or intent to get vaccinated, there were some perceived barriers such as lack of parental consent, belief in myths and misconceptions, and negative peer influence. While parental support was viewed as an enabling factor for adolescent girls to receive HPV vaccination, parental refusal to consent was perceived as a significant barrier.

These findings align with other studies showing that parents, specifically mothers, play a key role in influencing the health-related behavior of their daughters (48). When mothers said no, girls did not get the vaccine. In this study, parental refusal superseded the final decision even when girls were willing to receive the vaccine. However, daughters' parental consent for HPV vaccination in the Zambian context is implied with an opt-out approach, there are no legal requirements for vaccination. Therefore, in a situation where the adolescent insists on receiving the vaccine in the absence of parental consent, the vaccine is given (49).

Our study also showed that when mothers expressed support or encouragement, there was no resistance by the girls. This indicates that mothers would be an essential target group for strategies aiming to increase HPV vaccine uptake in our study setting. Parents and elders in general are held in high esteem, especially in conservative cultures in the African context, and decisions regarding their children are usually final without any further discussion as they are perceived to be in the best interest of the child (50, 51).

Contrary to these findings within the HPV vaccination space, parents in Zambia have actively vaccinated their infants with

other childhood vaccines such as oral polio vaccine, Diphtheria, and tetanus vaccines. There has been a gradual increase and sustainable coverage in the period 2000–2018 owing to strong communication, collaboration, and coordination in the background of strong health systems (52). Therefore, considering the relative novelty of the HPV vaccine in Zambia, applying strategies that have been used to improve other vaccine coverage may be necessary (38, 52). Additionally, further studies to understand factors influencing parental decision-making for their daughter's vaccination should be considered to aid in mitigating experienced barriers (17).

There were several myths about the HPV vaccine discussed by adolescent girls in our study, some of which have been reported frequently in the literature. These myths included the vaccine causing infertility (53) and (54) the Western world attempting to eliminate the African population, vaccines being experimental and not safe (44), and the COVID-19 vaccine being given to adolescent girls instead of the HPV vaccine (16). Beliefs in vaccine myths are rampant globally and the HPV vaccine has not been spared (54, 55). Parents who hold fast to myths and misconceptions coupled with low education levels are more likely to decline vaccinating their daughters (56), and as reported in our study, beliefs in myths and misinformation discourage adolescent girls from adopting preventive interventions.

Such findings are worsened by anti-vaccine movements present among society, healthcare workers, and various media platforms misleading many citizens (57). Counter and positive context-specific messages are key in ensuring constant debunking of these myths and misconceptions such as the HPV vaccine does not cause ovarian insufficiency as early claims were based on case reports (58). Dispelling myths and misinformation is, however, not easy, and health education alone is not sufficient, implementing multiple context specific strategies is of paramount importance (37).

In our study, peers were reported to have mixed roles to encourage or discourage vaccination most probably due to the variations in levels of knowledge. These findings on the role of peer influence are not unique to our study but have been elicited elsewhere (59, 60). Adolescence is a period where there is a lot of succumbing to “peer pressure” as adolescents seek a sense of belonging and validation by peers. In some instances, school vaccination programs have led to mass psychogenic effects and this has negatively affected the vaccination programs (61). Therefore, with active engagement and education, peers can play a critical role in increasing HPV vaccine uptake if they are knowledgeable and they themselves have experienced vaccination.

Some of our participants had a low perceived risk and susceptibility to HPV infection, which appears to be a common finding for people who are not sexually active (35). The asymptomatic nature of early HPV infection and marketing of the vaccine as a prevention for sexually transmitted disease in contrast with other childhood vaccines could contribute to this perception. A study in Ghana on risk perception for developing cervical cancer also showed lower risk perception compared to the actual risk (62). Therefore, ongoing education for adolescent

girls and parents on HPV virus infection disease progression is of paramount importance. These key stakeholders must be educated on the importance of the HPV vaccine being given before they become sexually active.

Strengths and limitations

This study has some strengths in that the voices of the primary HPV vaccine recipients have been illuminated. Out-of-school adolescents and those in hard-to-reach areas are rarely included in studies. We included out-of-school girls hence increasing the transferability of our findings in situations with in-school and out-of-school girls.

The use of the HBM as a guiding framework could be a basis for future quantitative research among adolescent girls with a view to ascertain whether some of the perceptions and experienced barriers are associated with HPV vaccine uptake and how they could be mitigated. Further, even though the current national guidelines entail a girls-only vaccination program, a future study involving boys is necessary because as the vaccine becomes more available, gender-neutral HPV vaccination will become policy.

To the best of our knowledge, this is the first study exploring knowledge, perceptions, and suggestions to increase the HPV vaccine from the perspective of adolescent girls in Zambia since the launch of the national program in 2019. It reinforces the earlier findings by other researchers among multiple stakeholders of low to moderate knowledge, positive attitudes, and perceived barriers amid high acceptability and low HPV vaccine uptake. It is important for policymakers to consider suggestions made by adolescent girls for the continued program implementation.

Our study is not without limitations. This study is qualitative and the participants were purposively sampled, therefore our results may vary with other settings if we randomly sampled a higher number of adolescent girls. This study enrolled participants in a single setting (Lusaka, Zambia), further investigation may be needed to confirm whether findings are generalizable to other settings, hence may affect transferability. These findings are however, still relevant within the Zambian context, and could still be useful in other sub-Saharan African countries.

Further, this study did not ask the girls what their HIV status was, therefore there is no information that is specifically about HIV keeping in mind the increased risk of HPV acquisition and cervical cancer development among people living with HIV.

We do not report differences in health beliefs between subgroups as our goal was not to achieve saturation in the subgroups of vaccinated and unvaccinated, as well as in-school and out-of-school girls. We focused on the emerging themes from the whole data set other than the disaggregated data as girls were not sampled in that way. Additionally, there were only three out-of-school girls.

To address these limitations, we have included a thorough explanation of the sampling methods, discussed our findings

within the context of existing literature, supported findings with quotes from our interviews reached saturation within our sample, and engaged in an iterative data collection and analysis process, thus increasing the dependability and transferability of findings.

Conclusion

For the first time since the nationwide roll out of the HPV vaccination program in Zambia we have highlighted the knowledge and perceptions of adolescent girls regarding the HPV vaccine, illuminating factors that may influence HPV vaccine acceptability and uptake in Zambia, from the perspective of adolescent girls. Our findings on adolescent perceptions are similar to those other earlier studies in Zambia have found with different stakeholders.

The knowledge that the HPV vaccine can provide long-term protection may improve uptake. There are still urgent issues that need to be addressed such as myths and misinformation, and lack of parental consent to vaccinate daughters. To promote greater knowledge and boost vaccination uptake, ongoing efforts must be made to offer correct information, address misinformation, and improve understanding by adolescents and parents on HPV infection and the advantages of HPV vaccination.

Additionally, we recommend that future studies enroll adolescent girls based on school status and to reach saturation considering that out-of-school girls are difficult to just as has been shown in this study, despite their high vulnerability to HPV infection and its consequences.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving humans were approved by University of Zambia Biomedical Research Ethics Committee (UNZABREC) Ref: 1609-2021, University of the Witwatersrand University Health Research Ethics Committee (HREC Medical) Ref: M21/04/73. A waiver was obtained from the University of North Carolina (UNC) Ethics Committee. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation in this study was provided by the participants' legal guardians/next of kin. Written informed consent was obtained from the individual(s), and minor(s)' legal guardian/next of kin, for the publication of any potentially identifiable images or data included in this article.

Author contributions

Conceptualization, ML, MK, MMw, CC; methodology, ML, MK, MMw, MMu, SF, and CC; formal analysis, ML, MK, and SF; data curation, ML, MK, and SF; writing—original draft preparation, ML; writing—review and editing, ML, MK, MMw, SF, MMu, and CC; funding acquisition, ML and CC; project administration, ML. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Perception and willingness toward various immunization routes for COVID-19 vaccines: a cross-sectional survey in China

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Background: To date, most vaccines, including the COVID-19 vaccine, are mainly administered by intramuscular injection, which might lead to vaccine hesitancy in some populations due to needle fear. Alternatively, needle-free immunization technology is extensively developed to improve the efficacy and acceptance of vaccination. However, there is no study to report the perception and willingness toward various immunization routes of the COVID-19 vaccine in the general population.

Methods: A cross-sectional survey was conducted nationwide using an online questionnaire. Bivariate analyses were undertaken to assess variable associations among the participants who reported a hesitancy to receive the COVID-19 booster vaccination. Multivariable logistic regression with a backward step-wise approach was used to analyze the predicted factors associated with the willingness to receive the COVID-19 booster vaccination.

Results: A total of 3,244 valid respondents were included in this survey, and 63.2% of participants thought they had a good understanding of intramuscular injection, but only 20.7, 9.2, 9.4, and 6.0% of participants had a self-perceived good understanding of inhalation vaccine, nasal spray vaccine, oral vaccine, and microneedle patch vaccine. Correspondingly, there was high acceptance for intramuscular injection (76.5%), followed by oral inhalation (64.4%) and nasal spray (43.0%). Those participants who were only willing to receive an intramuscular vaccine had less vaccine knowledge (OR = 0.78; 95% CI: 0.65–0.94) than those who were willing to receive a needle-free vaccine (OR = 1.97; 95% CI: 1.52–2.57). Some factors were found to be associated with vaccine hesitancy toward booster COVID-19 vaccination.

Conclusion: Needle-free vaccination is a promising technology for the next generation of vaccines, but we found that intramuscular injection was still the most acceptable immunization route in this survey. One major reason might be that most people lack knowledge about needle-free vaccination. We should strengthen the publicity of needle-free vaccination technology, and thus improve the acceptance and coverage of vaccination in different populations.

KEYWORDS

COVID-19 vaccine, immunization route, booster, needle fear, vaccine hesitancy

1. Introduction

The coronavirus disease 2019 (COVID-19) pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is still a serious challenge for global public health (1). To eventually control this pandemic, mass vaccination of the general population is extensively considered the most cost-effective intervention. As of 1 March 2023, more than 13.32 billion doses of COVID-19 vaccines had been used worldwide, of which the top three countries in terms of cumulative doses were China (3.49 billion), India (2.21 billion), and the United States (672 million) (2).

A variety of COVID-19 vaccines, including inactivated vaccines, protein subunit-based vaccines, mRNA-based vaccines, and recombinant viral vector-based vaccines, have been well-developed over the last 3 years. These vaccines are safe and effective in the early stages of the pandemic against SARS-CoV-2 infections and their related clinical symptoms (3, 4). However, the effectiveness of existing COVID-19 vaccines has waned due to the emerging SARS-CoV-2 variants (5, 6), especially for the omicron variants and their sub-lineages, including BA.5.2, BF.7, BQ.1.1, XBB.1.5, and CH.1.1 (7, 8). To promote the efficacy of the next generation of COVID-19 vaccines, various strategies are being extensively developed, including novel antigen design, prime/boost immunization, and induction of mucosal immunity with needle-free vaccination (oral inhalation, nasal spray, and oral capsule) (9–11). In addition, as a result of the government's effective control of the pandemic, there has been a decrease in people's acceptance of the COVID-19 vaccine when compared with the initial stages of the COVID-19 outbreak. Therefore, it is of great importance to enhance the public's willingness to vaccinate for the long-term prevention of the COVID-19 pandemic (12).

Currently, at least 15 kinds of COVID-19 vaccines have been approved by the WHO for human use, and most of these vaccines are administered via the intramuscular route. However, there are some limitations to intramuscular injection-based vaccination, including a relatively weak mucosal immunity against SARS-CoV-2, medical personnel, and cold-chain equipment requirements. More importantly, some people might have needle fear or needle phobia due to the trauma and pain of intramuscular injection, which may cause vaccine hesitancy (13, 14). Needle-free technology has the potential to increase the willingness and availability of vaccinations by eliminating the fear and discomfort associated with needles.

However, the public may not appropriately have access to these advantages and thus have limited knowledge or misunderstandings about needle-free vaccines, which can hinder people's acceptance of vaccination, particularly when faced with novel vaccine (15). A previous study has shown that if a vaccine is recommended by the government or officials, it can effectively increase the public's willingness to be vaccinated. Therefore, disseminating precise and timely information about novel vaccine technology by a highly trusted government might contribute to improving vaccination coverage (16). To date, there is no study to report the knowledge and willingness toward various immunization routes of COVID-19 vaccines among the general population in China. Therefore, we conducted this study to address this issue in Chinese citizens, and we also investigated how people choose the various

immunization routes of COVID-19 vaccines and the potential factors that contribute to vaccine hesitancy for multiple boosters of COVID-19 vaccination.

2. Methods

2.1. Study design

We conducted a cross-sectional study using an anonymous online questionnaire from 34 provincial administrative regions in China between 16 November 2022 and 5 December 2022. During this period, booster doses of COVID-19 vaccines were available to the adult population that had received the basic two doses of COVID-19 vaccines over 6 months. The secondary booster dose of COVID-19 was also recommended for the susceptible population.

2.2. Participants' recruitment

Individuals were recruited as participants if they were: (1) able to read and complete the online self-administered questionnaire independently; (2) informed consent to participate in the study. In addition, participants who had incorrect quality control question answers were excluded. The participants' recruitment relied on convenience sampling by disseminating the study questionnaire's URL link or quick response (QR) code on WeChat (<https://weixin.qq.com/>), which is currently regarded as the most popular instant messaging platform in China.

The sample size was calculated using PASS 21.0.3 (<https://www.ncss.com/>). A sample size of 789 was produced by a two-sided 95% confidence interval (CI) with a width equal to 0.04, and the proportion of participants with a hesitancy to receive a COVID-19 booster vaccine was estimated as 0.084 according to a recent study (17–19). The formula is as follows:

$$N = \left[\frac{Z_{1-\frac{\alpha}{2}}^2}{\left(\frac{\varepsilon}{2}\right)^2} \right] \times p \times (1 - p)$$

N is the sample size. Z is the Z-score corresponding to the desired level of confidence. For a two-sided 95% CI, the Z-score is ~ 1.96 . $\alpha = 0.05$. p is the estimated proportion of participants with a characteristic of interest. ε is the width of CI equal to 0.04. When p is unknown, we can set $p = 0.5$, and N is equal to 2,401.

2.3. Measurement and data collection

The questionnaire used in this study consists of four structures (Supplementary material): (1) Basic demographic information and health condition; (2) pandemic experiences and vaccination status; (3) participants' knowledge and attitudes regarding different immunization routes of COVID-19 vaccination; and (4) the modified Vaccine Hesitancy Scale (VHS).

2.4. Cognition on vaccine knowledge

Considering that limited knowledge or misunderstanding about needle-free vaccination might be a barrier for people to access needle-free vaccination (20), we therefore investigated the cognition of these participants toward self-perceived advantages and disadvantages between intramuscular injection and needle-free vaccination. As we know, healthy adult populations who have completed regular immunization are recommended to vaccinate with the orally aerosolized Ad5-nCoV (Convidecia Air), which is the first needle-free COVID-19 vaccine approved for emergency use by the China government in September 2022. Based on recent knowledge (21, 22), incorrect options were intentionally set in our questionnaire with reverse scoring, which are: (1) advantages: “Needle-free vaccines usually last a longer immune response” and “Needle-free vaccines usually have less side effects” (Actually, there were comparable immune duration and side effects between orally aerosolized Ad5-nCoV vaccine and intramuscularly injected Ad5-nCoV vaccine); and (2) disadvantages: “The time for needle-free vaccines to induce immune response is more slower” and “Needle-free vaccines are inconvenient to administer” (Actually, compared with the traditional intramuscularly injected vaccine, the time for this vaccine to induce an immune response is similar, and the administration of needle-free vaccines is more convenient). Participants who self-reported unawareness of needle-free vaccines or got a zero scores were identified as the incorrect understanding group, and the other participants were identified as the correct understanding group.

2.5. Vaccine hesitancy

In this study, we used the Vaccine Hesitancy Scale (VHS), which was developed by the WHO Strategic Advisory Group on Experts (SAGE) Working Group (23), to quantify participants' hesitancy to COVID-19 booster vaccination. The terms in the original VHS were modified by our experienced researchers in order to fit the latest Chinese COVID-19 epidemic situation and vaccine development. The modified scale had 10 items, and each item was asked on a 5-point Likert scale (strongly disagree, disagree, neither agree nor disagree, agree, and strongly agree). Hesitancy to receive a COVID-19 booster vaccine was defined as individuals with 30 scores or less of a total of 50 scores using the hesitancy scale. Exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) indicated that this scale had good reliability and validity (Supplementary Tables 2, 3), consistent with our previous studies (24–26).

2.6. Statistical analysis

Descriptive analyses were conducted to describe the involved participants. Frequencies and proportions were calculated for categorical variables, and continuous variables were summarized by mean and standard deviation. Bivariate analyses were then undertaken to assess variable associations in the group of respondents who reported a hesitancy to receive a COVID-19

booster vaccine. To determine which factors might be associated with this hesitancy, we then conducted a multivariate logistic regression to estimate odds ratios (ORs) with 95% confidence intervals (CIs) with a backward step-wise approach. Factors with a $P < 0.2$ in the bivariate analyses for hesitancy were included in the logistic regression model. Data were analyzed using R 4.1.3 and SPSS 26.0 (IBM). Statistical significance was set at a $P < 0.05$.

2.7. Ethics approval and consent to participate

The protocol for this study was approved by the Ethics Committee of the School of Public Health (Shenzhen), Sun Yat-sen University (approval number: SYSU-PHS-IACUC-2022-065). Participation was voluntary, and informed consent was obtained at the beginning of the questionnaire.

3. Result

3.1. Participants' characteristics and their status of vaccine hesitancy

A total of 3,244 (82.9%) of the 3,911 respondents recruited in this survey were considered valid. Participants' mean (\pm SD) age was 31.81 (\pm 8.88) years, and 91.6% of them were aged between 18 and 44 years old. For the educational level, 66% of the participants had reached a bachelor's degree or even a higher degree. In addition, 151 (4.7%) participants suffered from various chronic diseases (Table 1).

Consistent with the recommended vaccination procedures at the time of our investigation, 3,059 (94.3%) of participants had received the regular two doses of COVID-19 vaccines, and 2,314 (71.3%) of participants had received another booster dose of COVID-19 vaccines.

According to the score of the VHS and its classified criteria, 2,868 (88.4%) of participants were positive for COVID-19 vaccination, while 376 (11.6%) of participants were verified to be in a state of vaccine hesitancy. The further chi-square test showed that participants of different sexes, educational levels, occupations, and monthly incomes had different levels of vaccine hesitancy.

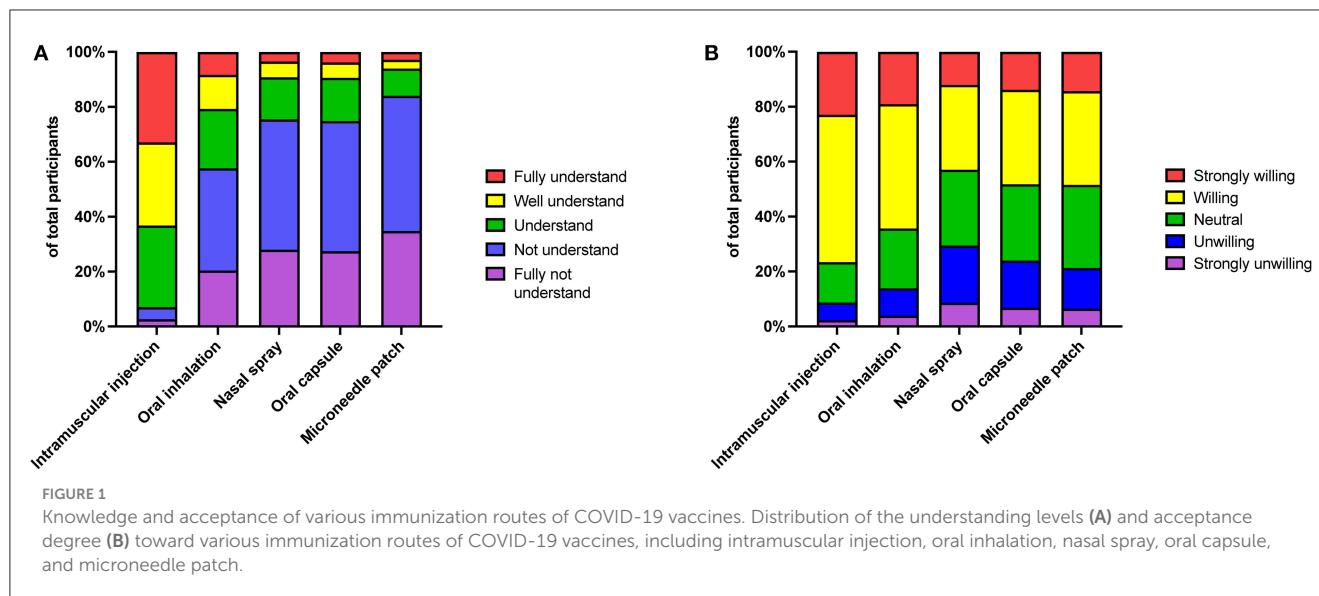
3.2. Knowledge and acceptance of various immunization routes of COVID-19 vaccines

Among different immunization routes of COVID-19 vaccines, 63.2% of participants thought they had a good understanding (fully understood or well-understood) of the immunization route of intramuscular injection. By contrast, there were only 20.7, 9.2, 9.4, and 6.0% of participants had a self-perceived good understanding of inhalation vaccine, nasal spray vaccine, oral vaccine, and microneedle patch vaccine, respectively (Figure 1A). Consistent with the level of understanding toward various immunization routes of vaccination, there was the strongest acceptance for intramuscular injection (76.5%), followed by oral inhalation

TABLE 1 Descriptive characteristics of populations by hesitancy to receive COVID-19 vaccine booster doses in China.

Variables	Total [<i>n</i> (%)]	Vaccine hesitancy		<i>p</i>
		Hesitancy [<i>n</i> (%)]	Non-hesitancy [<i>n</i> (%)]	
Sample size	3,244 (100)	376 (11.6)	2,868 (88.4)	
Age, year [mean (SD)]	31.81 (8.88)	31.92 (8.82)	31.79 (8.89)	0.789
Sex				
Male	754 (23.2)	109 (29.0)	645 (22.5)	0.006*
Female	2,490 (76.8)	267 (71.0)	2,223 (77.5)	
Marriage and bearing				
Single	594 (18.3)	77 (20.5)	517 (18.0)	0.278
Married and without children	51 (1.6)	6 (1.6)	45 (1.6)	
Married and keeping children	2,579 (79.5)	293 (77.9)	2,286 (79.7)	
Others	20 (0.6)	0 (0.0)	20 (0.7)	
Educational level				
≤Junior high school	411 (12.7)	43 (11.4)	368 (12.8)	0.001*
Senior high school	694 (21.4)	74 (19.7)	620 (21.6)	
Bachelor	1,974 (60.9)	224 (59.6)	1,750 (61.0)	
≥Master	165 (5.1)	35 (9.3)	130 (4.5)	
Occupation				
Businessman	238 (7.3)	32 (8.5)	206 (7.2)	0.016*
Farmer	46 (1.4)	5 (1.3)	41 (1.4)	
Healthcare worker	109 (3.4)	10 (2.7)	99 (3.5)	
Company employee or professional technician	954 (29.4)	127 (33.8)	827 (28.8)	
Public servant	202 (6.2)	25 (6.6)	177 (6.2)	
Student	526 (16.2)	68 (18.1)	458 (16.0)	
Teacher	146 (4.5)	12 (3.2)	134 (4.7)	
Unemployment or housework	65 (2.0)	4 (1.1)	61 (2.1)	
Ordinary worker/farm laborer	200 (6.2)	31 (8.2)	169 (5.9)	
Others	758 (23.4)	62 (16.5)	696 (24.3)	
Area				
Urban	3,054 (94.1)	349 (92.8)	2,705 (94.3)	0.296
Rural	190 (5.9)	27 (7.2)	163 (5.7)	
Monthly income (RMB)				
≤5,000	1,337 (41.2)	146 (38.8)	1,191 (41.5)	0.006*
5,001–10,000	1,201 (37.0)	138 (36.7)	1,063 (37.1)	
10,001–15,000	404 (12.5)	39 (10.4)	365 (12.7)	
≥15,001	302 (9.3)	53 (14.1)	249 (8.7)	
Chronic diseases				
No	3,093 (95.3)	353 (93.9)	2,740 (95.5)	0.193
Yes	151 (4.7)	23 (6.1)	128 (4.5)	

**p* < 0.05.



(64.4%), nasal spray (43.0%), oral capsule (48.2%), and microneedle patch (48.4%; [Figure 1B](#)).

We then investigated the participants' cognition about the advantages and disadvantages of traditional intramuscular injection vaccines and burgeoning needle-free vaccines. The majority (43.3%) thought that the main advantage of needle-free immunization was "no injection/no pain," 24.0% thought that the main advantage was "reduce medical waste," and 20.5% thought that needle-free immunization could be "self-service and save medical resources." By contrast, only 13.0% of participants chose the induction of mucosal immunity, and 7.4% chose "More effectively block virus infection." On the other side, the top three options for disadvantages for participants were "Not sure/I don't know" (29.3%), "Not easy to control the doses" (25.7%), and "Vulnerable to external influences (such as cough and sneeze)" (23.7%). Of note, as for these incorrect options, ~15% of participants chose at least one incorrect answer for each question, implying that these participants had limited knowledge and misunderstandings about needle-free immunization ([Figures 2A, B](#)).

Considering that needle-free vaccines are likely to be the most promising immunization routine in future, we specifically investigated people's knowledge about needle-free immunization and the associated factors. In our survey, we found that 47.3% of participants acquired vaccine knowledge from internet websites, 37.0% from popular science propaganda at workplaces or schools, and 25.0% from telecasts ([Figure 2C](#)). Of note, 20.6% of participants chose "never heard it," indicating that this population did care about vaccine-related information. In addition, most participants regarded safety (94.0%) and vaccine efficacy (87.1%) as the main factors when receiving a vaccination, followed by "easy to gain and vaccination" (43.2%), "National recommendations" (31.7%), and "price" (22.5%; [Figure 2D](#)).

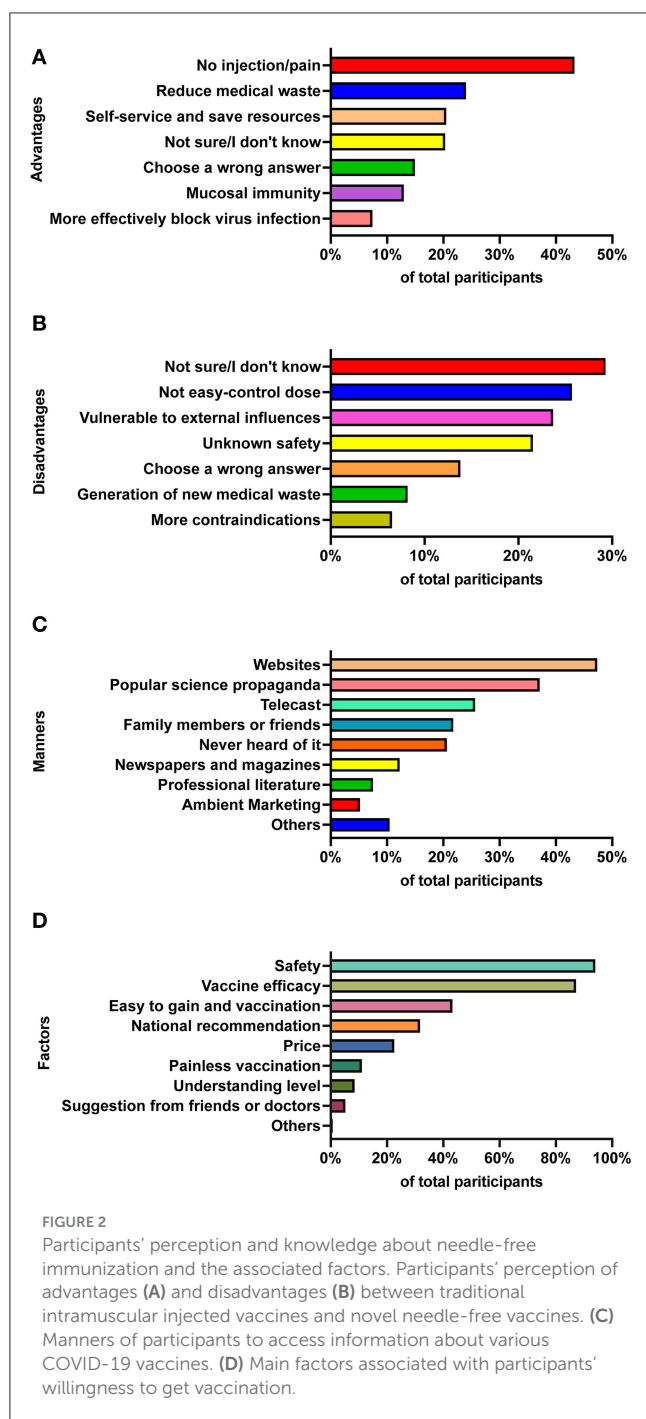
Further analysis demonstrated that there was a statistical correlation between the participants' vaccine knowledge level and

the ways to access vaccine information. Those who obtained vaccine information through websites, newspapers, magazines, telecasts, and professional literature had a higher score than those who obtained it in other unofficial ways or never cared about the vaccine information ([Table 2](#) and [Supplementary Table 4](#)). Interestingly, those participants who were only willing to receive an intramuscular vaccine had a lower cognition score (incorrect understanding) than those who were willing to receive a needle-free vaccine. As expected, participants with a higher education level had a higher frequency of acquiring the correct vaccine information.

3.3. Factors associated with vaccine hesitancy toward booster COVID-19 vaccination

Previous studies showed that needle phobia ("Afraid of needles") might be a factor associated with vaccine hesitancy ([27–29](#)), and we thus investigated this topic in this study. In our questionnaire, we defined those participants as having "Potential needle-phobia" if they were: (1) not vaccinated due to fear of needles or (2) regarded the pain as the main factor to affect whether receiving vaccination. However, Pearson's chi-square test analysis showed that participants who were considered "potential needle-phobia" had no statistical difference between other participants on the status of vaccine hesitancy, indicating that injection fear may not be a major factor that led to vaccine hesitancy in the Chinese population ([Supplementary Table 1](#)).

We further found that these people who had gotten at least one dose of the COVID-19 vaccine, willing to receive an intramuscular injection/inhalation or oral vaccine, were more likely to accept the COVID-19 booster vaccination. Participants who chose "not sure or didn't know about the advantages of needle-free vaccine" were less likely to accept



the COVID-19 booster vaccination (Table 3). In addition, these people who had a high education level (graduate student or above) and a high income (15,000 RMB and above/per month) were also less likely to accept the COVID-19 booster vaccination. However, sex, occupation, age, residence place, or chronic disease condition were not significantly correlated with vaccine hesitancy toward COVID-19 booster vaccination (Supplementary Table 5).

4. Discussion

Previous studies suggested that the needle fear due to intramuscular injection might play a role in vaccine hesitancy in some countries. For example, a survey conducted among 15,014 UK adults revealed that 3,927 (26.2%) were positive for blood-injection-injury phobia (14). A meta-analysis including 35 studies also yielded similar results, estimating that the prevalence of needle fear ranged from 20 to 50% in adolescents and 20–30% in young adults (13). However, in the present study, there were only 11.1% of participants identified “potential needle phobia,” and we also found that needle fear might not be the primary factor leading to vaccine hesitancy in the Chinese population, since there was no statistical correlation between the potential needle-phobia participants and their status of vaccine hesitancy. One potential reason for this difference might be the Chinese government's and medical personnel's vigorous promotion of the COVID-19 vaccines since the start of the COVID-19 epidemic. As a result, Chinese people are willing to believe that COVID-19 vaccination is beneficial to protect themselves and control the pandemic, resulting in high COVID-19 vaccination coverage and effective control of the COVID-19 pandemic (30, 31). The second reason for this observation might be that most people have insufficient knowledge and cognition about various immunization routes, especially for these novel needle-free vaccination technologies, including inhalation vaccine, nasal spray vaccine, oral vaccine, and microneedle patch vaccine. Consequently, intramuscular injection is still the most acceptable immunization route in this survey, mainly because most participants thought they had a better understanding of intramuscular injection than that of other needle-free vaccines. Thus, it is necessary to promote public cognition about the advantages and disadvantages of intramuscular injection-based vaccines and needle-free vaccines.

Recent studies have demonstrated that these needle-free vaccines are more efficacious against pathogen infection when compared with traditional intramuscular vaccines (32–34). However, there were only a few participants who chose the advantage of needle-free immunization as “induction of mucosal immunity” (13.0%), and “more effectively block virus infection” (7.4%).” Instead, many participants in our investigation thought that the main advantages of needle-free immunization were “no injection/no pain” (43.3%), “reduce medical waste (24.0%),” and “self-service and save medical resources (20.5%).” Thus, approximately half of the participants did not understand well or had limited knowledge and misunderstandings about the efficacy of needle-free vaccines (Figures 1, 2). This is interesting to note because “induction of mucosal immunity” and “more effectively block virus infection” might not be easily understood by the general public, but the explanations of “no injection/no pain” and “reduce medical waste” can be easily understood. Therefore, we should optimize some options in future research to make them easier to understand for the public.

The mindsponge theory, an emerging theory to illustrate how the human mind receives and filters information, and accepts or

TABLE 2 Multivariate logistic regression of vaccine knowledge level and information acquisition about intramuscular injection vaccine and needle-free vaccine.

Variables	Incorrect understanding	Correct understanding	Multivariate	<i>p</i>
	(<i>n</i> = 1,644, %)	(<i>n</i> = 1,600, %)	aOR [#] (95%CI)	
Age, year [mean (SD)]	32.65 (8.34)	30.94 (9.33)	0.99 [0.98, 1.00]	0.114
Sex				
Male	341 (20.7)	413 (25.8)	1 (ref.)	
Female	1,303 (79.3)	1,187 (74.2)	0.84 [0.69, 1.03]	0.095
Education level				
≤Junior high school	258 (15.7)	153 (9.6)	1 (ref.)	
Senior high school	383 (23.3)	311 (19.4)	1.40 [1.05, 1.86]	0.022*
Bachelor	952 (57.9)	1,022 (63.9)	1.60 [1.23, 2.09]	0.001*
≥Master	51 (3.1)	114 (7.1)	2.55 [1.57, 4.18]	<0.001*
Occupation				
Company employee or professional technician	553 (33.6)	401 (25.1)	1 (ref.)	
Student	160 (9.7)	366 (22.9)	2.20 [1.61, 3.01]	<0.001*
Businessman	121 (7.4)	117 (7.3)	1.27 [0.92, 1.76]	0.150
Public servant	116 (7.1)	86 (5.4)	1.09 [0.77, 1.56]	0.628
Ordinary worker/farm laborer	101 (6.1)	99 (6.2)	1.70 [1.19, 2.44]	0.004*
Teacher	59 (3.6)	87 (5.4)	1.90 [1.28, 2.85]	0.002*
Healthcare worker	22 (1.3)	87 (5.4)	4.51 [2.62, 8.06]	<0.001*
Unemployment or housework	36 (2.2)	29 (1.8)	1.33 [0.74, 2.39]	0.345
Farmer	35 (2.1)	11 (0.7)	0.52 [0.24, 1.07]	0.088
Others	441 (26.8)	317 (19.8)	1.14 [0.91, 1.43]	0.256
Way to access information about needle-free vaccines for COVID-19				
Websites				
No	1,067 (64.9)	641 (40.1)	1 (ref.)	
Yes	577 (35.1)	959 (59.9)	1.25 [1.05, 1.50]	0.013*
Newspapers and magazines				
No	1,527 (92.9)	1,320 (82.5)	1 (ref.)	
Yes	117 (7.1)	280 (17.5)	1.56 [1.22, 2.01]	<0.001*
Telecast				
No	1,358 (82.6)	1,054 (65.9)	1 (ref.)	
Yes	286 (17.4)	546 (34.1)	1.47 [1.23, 1.78]	<0.001*
Professional literature				
No	1,580 (96.1)	1,421 (88.8)	1 (ref.)	
Yes	64 (3.9)	179 (11.2)	1.57 [1.14, 2.18]	0.007*
Never heard of it				
No	1,045 (63.6)	1,530 (95.6)	1 (ref.)	
Yes	599 (36.4)	70 (4.4)	0.12 [0.09, 0.16]	<0.001*
Others				
No	1,464 (89.1)	1,441 (90.1)	1 (ref.)	
Yes	180 (10.9)	159 (9.9)	0.73 [0.57, 0.95]	0.018*

(Continued)

TABLE 2 (Continued)

Variables	Incorrect understanding (<i>n</i> = 1,644, %)	Correct understanding (<i>n</i> = 1,600, %)	Multivariate aOR [#] (95%CI)	<i>p</i>
Willingness on another booster vaccination against COVID-19				
All vaccination methods are acceptable	680 (41.4)	647 (40.4)	1 (ref.)	
Intramuscular injection	603 (36.7)	473 (29.6)	0.78 [0.65, 0.94]	0.008*
Needle-free vaccine	137 (8.3)	307 (19.2)	1.97 [1.52, 2.57]	<0.001*
Other routes of vaccination	68 (4.1)	91 (5.7)	1.23 [0.85, 1.80]	0.274
Unwilling to be vaccinated again	130 (7.9)	61 (3.8)	0.58 [0.40, 0.84]	0.004*
Not vaccinated yet	26 (1.6)	21 (1.3)	1.06 [0.54, 2.07]	0.866
Frequency of attention to news reports about COVID-19 vaccines				
≥Once a day	473 (28.8)	509 (31.8)	1.18 [0.97, 1.44]	0.093
≥Once a week	503 (30.6)	639 (39.9)	0.69 [0.56, 0.85]	0.001*
Community education or message prompt	573 (34.9)	416 (26.0)	0.34 [0.21, 0.55]	<0.001*
Never care	95 (5.8)	36 (2.2)	1.18 [0.97, 1.44]	0.093

**p* < 0.05; [#]aOR, adjusted odd ratio; ref, reference. Bivariate analysis is presented in [Supplementary Table 4](#).

rejects values (35), may provide a framework to explain our above results. According to this theory, the emerging values are compared with the existing values in an individual's core mindset by a multi-filtering system, and then the advantages and disadvantages of accepting or rejecting the emerging values are assessed. Therefore, people's cognition of intramuscular injection-based vaccines and trust in the government can be thought of as existing values in an individual's core mindset, which will affect the evaluation and acceptance of emerging information regarding needle-free vaccines. In our study, ~20% of participants expressed concern regarding the safety of needle-free vaccines. Considering that most participants regarded safety (94.0%) and vaccine efficacy (87.1%) as the main factors when receiving vaccination, the limited knowledge and misunderstanding about needle-free immunization might be the main factor to hinder the implementation of the needle-free COVID-19 vaccines. Previous survey showed that Chinese people had a high proportion (83.7%) of positive responses when they were asked if they would accept a vaccine recommended by the government (36), which was consistent with our result in this study (87.3%, 2,835 of 3,244). According to the mindsponge theory, people will be inclined to accept emerging information provided by an existing value of a highly trusted government. Thus, we also emphasize the importance for people to obtain vaccine information from official channels instead of other ways, since inaccurate information from unreliable sources may affect people's cognition of COVID-19 vaccines (20, 37). As a result, the government and authoritative social media should strengthen the publicity of needle-free vaccination technology, and thus improve the acceptance and coverage of vaccination in different populations.

Our study has limitations. First, this is a cross-sectional study, and we could not conclude the causal relationship between vaccine hesitancy and knowledge of various immunization routes. Therefore, more similar studies are needed to further clarify how people's perceptions of different routes of vaccination affect vaccination intentions. Second, our questionnaire's participants relied on convenience sampling through social media, which has inherent recruitment biases. As a result, it may be challenging to generalize the findings to different populations. However, this limitation could be partially addressed by using directed invitations to specific population groups. To obtain a more precise assessment of the population's perception and willingness, additional studies using more representative sampling methods are needed. Therefore, while our study provides valuable insights, these results should be interpreted with caution.

5. Conclusion

Overall, needle fear may not be the primary factor causing vaccine hesitancy in the Chinese population, and intramuscular injection remains the most acceptable immunization route in this survey, mainly because most people lack knowledge about needle-free vaccination. Additionally, it is of great importance for the public to obtain correct information about novel vaccination technology from reliable sources. We should strengthen the publicity of needle-free vaccination technology, and thus improve the acceptance and coverage of vaccination in different populations.

TABLE 3 Multivariate logistic regression of factors associated with vaccine hesitancy toward booster COVID-19 vaccination.

Variables	Non-hesitancy (<i>n</i> = 2,868, 100%)	Hesitancy (<i>n</i> = 376, 100%)	Multivariate aOR [#] (95%CI)	<i>p</i>
Sex				
Male	645 (22.5)	109 (29.0)	1 (ref.)	
Female	2,223 (77.5)	267 (71.0)	0.73 [0.57, 0.95]	0.017*
Marriage and bearing				
Single	517 (18.0)	77 (20.5)	1 (ref.)	
Married and without children	45 (1.6)	6 (1.6)	0.64 [0.23, 1.54]	0.358
Married and keeping children	2,286 (79.7)	293 (77.9)	0.80 [0.56, 1.14]	0.212
Others	20 (0.7)	0 (0.0)	0.00 [NA, 97.24]	0.965
Educational level				
≤Junior high school	368 (12.8)	43 (11.4)	1 (ref.)	
Senior high school	620 (21.6)	74 (19.7)	1.07 [0.71, 1.63]	0.744
Bachelor	1,750 (61.0)	224 (59.6)	1.12 [0.78, 1.64]	0.555
≥Master	130 (4.5)	35 (9.3)	2.36 [1.35, 4.09]	0.002*
Area				
Urban	2,705 (94.3)	349 (92.8)	1 (ref.)	
Rural	163 (5.7)	27 (7.2)	1.43 [0.89, 2.25]	0.130
Monthly income (RMB)				
≤5,000	1,191 (41.5)	146 (38.8)	1 (ref.)	
5,001–10,000	1,063 (37.1)	138 (36.7)	1.16 [0.87, 1.55]	0.311
10,001–15,000	365 (12.7)	39 (10.4)	0.94 [0.61, 1.42]	0.769
≥15,001	249 (8.7)	53 (14.1)	1.74 [1.16, 2.58]	0.006*
Vaccination procedure				
Unvaccinated	64 (2.2)	23 (6.1)	1 (ref.)	
Partial	87 (3.0)	11 (2.9)	0.32 [0.14, 0.71]	0.006*
Regular	645 (22.5)	100 (26.6)	0.44 [0.26, 0.77]	0.003*
One dose booster	2,029 (70.7)	235 (62.5)	0.30 [0.18, 0.51]	<0.001*
Two doses or more booster	43 (1.5)	7 (1.9)	0.42 [0.15, 1.08]	0.085*
Willingness of various COVID-19 vaccines				
Intramuscular injection				
No	614 (21.4)	147 (39.1)	1 (ref.)	
Yes	2,254 (78.6)	229 (60.9)	0.56 [0.44, 0.72]	<0.001*
Oral capsule				
No	962 (33.5)	194 (51.6)	1 (ref.)	
Yes	1,906 (66.5)	182 (48.4)	0.71 [0.52, 0.95]	0.021*
Oral inhalation				
No	1,428 (49.8)	252 (67.0)	1 (ref.)	
Yes	1,440 (50.2)	124 (33.0)	0.67 [0.49, 0.91]	0.011*
Know about advantages of needle-free vaccine				
No	1,504 (52.4)	234 (62.2)	1 (ref.)	
Yes	1,364 (47.6)	142 (37.8)	0.75 [0.59, 0.96]	0.022*

**p* < 0.05; [#]aOR, adjusted odd ratio; ref, reference. Bivariate analysis is presented in [Supplementary Table 5](#).

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by Ethics Committee of the School of Public Health (Shenzhen), Sun Yat-sen University (Approval number: SYSU-PHS-IACUC-2022-065). The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

CS conceived and designed this project and revised and edited the manuscript. HW, MC, SL, and FW performed this project, analyzed the data, and drafted the manuscript. SJ, HC, and JY contributed resources and discussion. All authors have read and agreed to the published version of the manuscript.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fpubh.2023.1192709/full#supplementary-material>

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COVID-19 booster prioritization in the West Bank: a survey experiment among Bedouins, refugees, and the majority group

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Introduction: Our main aim is to understand to what extent Bedouins, internally displaced Palestinians (refugees) and majority-group members (non-refugees, non-Bedouins, settled) in the West Bank prioritize COVID-19 booster shots for their own group over other groups.

Methods: We conducted a survey experiment (face-to-face) among 678 Palestinians living in the West Bank. Participants randomly received a description of an older man (Bedouin, refugee, settled) and were asked to indicate to what extent this person should be prioritized for the booster shot. Respondents belonging to a minority saw the profile of an in-group member or a majority-group member, whereas majority-group members would see the profile of an in-group or one out-group member (Bedouin, Palestinian refugee).

Results: We found slightly higher in-group preferences for Palestinian refugees when it came to vaccination, whereas majority-group members were less inclined to support a prioritization of Palestinian refugees but equally prioritized their group and Bedouins. For Bedouins, we did not find strong in-group preferences.

Discussion: Our study reveals the salience of group boundaries during the COVID-19 pandemic with potentially adverse effects on the health care of minorities.

KEYWORDS

COVID-19, vaccination, West Bank, solidarity, religion, intergroup attitudes

Introduction

Across the globe, we saw an unequal access to vaccines. On top of this disadvantage that many countries in the Global South experience, comes inequality in the prioritization for vaccination, potentially placing minorities within these countries lower in the queue. The vast amount of studies did not center on minorities when investigating vaccination priorities [e.g., (1–4)]. Yet, previous articles have highlighted the relevance of prioritizing vulnerable groups such as refugees, as overcrowded living conditions accelerate the spread of COVID-19 (5). However, is this view also supported within the population? When resources are scarce, such as a shortage in medical services and vaccines, the question of eligibility arises. A newly introduced term for this is vaccine chauvinism. The concept of vaccine chauvinism is derived from the concept of welfare chauvinism, which describes the idea that a group sees its members as more eligible for these resources. In the context of migration, those who have contributed to the

welfare state for a longer time and/or have contributed more (mostly majority-group members) perceive themselves to be also more entitled to welfare support compared to immigrants (6). However, in this case, these perceived differences in deservingness concern vaccination, rather than welfare support more generally.

We argue that the extent to which individuals display vaccine chauvinism will depend on the group belonging. We hypothesize that the majority displays higher levels of in-group favoritism, as they have on average a higher social status than minorities. Minorities are more often deprived and might have therefore contributed less to the welfare system. Previous research has shown that in-group and out-group boundaries in terms of national belonging were reinforced during the pandemic when it came to pro-social intentions (7, 8). Along these lines, immigrants were generally prioritized less (6, 9).

But does this also extend to native minorities? This is an interesting question, as native minorities are citizens, but we further argue that salient group boundaries oftentimes go beyond citizenship. Native minorities across the world struggle with equal rights and accommodation [e.g., (10)]. A non-experimental study in the US revealed prioritization of Black, Hispanic, Native American, and other communities that have been disproportionately affected by COVID-19 (11). A follow-up study discovered that this was conditional on the risk status. A slight majority would toss a coin if the minority and non-minority member had an identical risk of severe COVID-19 (12).

To gauge the risk people are exposed to, we take into consideration if they classify themselves as belonging to the at-risk group, their previous vaccinations and deaths related to COVID-19 within their networks. A high number of deaths related to COVID-19 within one's networks suggests increased exposure to the virus. In addition to group belonging based on migration experience and minority status, we also investigate the role of religiosity in vaccine chauvinism. Several studies have suggested that more religious individuals tend to hold more pro-social attitudes (13, 14), as they stress creed of brotherhood (15). Hence, more religious individuals regardless of their religion should therefore be more willing to prioritize others. However, prior research on the relationship between religiosity or religious affiliation on the one hand and attitudes toward out-groups on the other hand also revealed a negative relationship (16–19).

To understand vaccine chauvinism and individuals' preferences for prioritization in COVID-19 vaccination, we conducted a survey experiment among 678 respondents living in the West Bank (area A under the Palestinian Authority). Our sample is composed of Bedouins, internally displaced individuals (in the following abbreviated as refugees) and majority-group members (non-refugees and non-Bedouins). Survey experiments provide a unique opportunity to approximate average causal effects of how belonging to a group influences attitudes toward other groups. While those experiments have been implemented in the Western hemisphere [e.g., (6)], they are very rare in countries shaken by instability in health care provision, and to the best of our knowledge focus more on immigrants than native minorities. Hence, our study attempts to fill a research gap.

The West Bank constitutes a highly relevant case, as the responsibility for health care is divided between the Palestinian Authority, Israel and the United Nations Relief and Works Agency for Palestine Refugees in the Near East (UNWRA), which complicates health care services. Existing studies point out the deficits in health care infrastructures (20). We focus on Bedouins and refugees, as they belong to the biggest native minorities in the West

Bank and are one of the most vulnerable populations in Palestine (21). Palestinian refugees in the 19 camps within the West Bank are supported almost exclusively by the UNWRA, as their legal status means they either cannot access government health care or cannot afford to pay for alternatives (22). Access to health care and medication is said to have worsened throughout the pandemic for all groups in the West Bank, but particularly for Bedouins and Palestinian refugees (23). Living in overcrowded camps, Palestinian refugees contracted COVID-19 more often than other groups (24). Yet, they did not belong to the prioritized groups for vaccination. As in other countries, medical staff, chronically ill, and older people were prioritized (25). However, non-representative online surveys indicate a relatively high willingness to get vaccinated (26), but the actual numbers are low (27). This speaks to other studies suggesting a lower willingness among health-care workers to get vaccinated (28). About one third is estimated to have received a vaccine at the time of our survey (29).

By presenting novel data on a research context and a research design less frequently covered in public health, we contribute to the existing state-of-the-art. Our main argument is that group boundaries are a salient factor when investigating health care and vaccination. If groups have strong perceptions of 'us' vs. 'them', these boundaries will be stronger and will explain why individuals do not support the health care of minorities. The study can inform us beyond COVID-19, as findings also bear implications for minorities' health care more generally.

Data and methods

Participants

The Palestinian population is estimated to be 5.35 million (30). The number of Bedouins is approximately 40,000 people (21). The population size of the refugee camps is based on estimates from UNRWA with the following numbers (West Bank Field Monitoring and Evaluation Office 2022): Alfawar (12,203), Dheisheh (18,558), Aqbat Jaber (10,033), Alamari (14,882), and Balata (31,791).

In our data, we analyzed 678 valid cases that were collected between October 2021 and February 2022. Among those are 125 Bedouins from the Jahaleen tribe (east of Jerusalem), Ka'abneh tribe (Jordan valley), and Rashaydeh tribe (southeast of Bethlehem) (31), 210 internally displaced individuals from the West Bank (from the Alfawar, Dheisheh, Aqbat Jaber, Alamari, and Balata camps), and 343 Palestinians who are neither Bedouins nor refugees and are called majority-group members in this study. We employed community-based sampling to gain access to the camps and tribes. Fieldworkers and volunteers from the Palestinian refugee camps and Bedouin tribes were trained and conducted pretests. At the time of the survey, fieldworkers were holding a Master or a doctoral degree. Volunteers are university students in their third or last year and all of them were supervised by the project leader. For the data collection, the team rented a car and visited the camps along with paper and pencil questionnaires, which were later manually entered. Respondents were interviewed in standard Arabic. Participants provided written consent. We incentivized the more vulnerable and hard-to-reach-populations of Bedouins and internally displaced Palestinians with a small amount (approximately €2,50).

Tools

Each respondent randomly saw one of those scenarios where the group belonging was signaled. Each minority group saw the description of a man belonging to their group or the majority group, whereas majority-group members also saw the profiles of a Palestinian refugee and Bedouin in addition to their own group. The treatment was balanced, and profiles nearly equally distributed within groups, as [Table 1](#) illustrates.

The outbreak of COVID-19 has placed an immense burden on societies and individuals who have become more isolated. Over the past months, countries have started to vaccinate its population against COVID-19. However, vaccines against COVID-19 are more effective with a booster shot. Imagine the case of a 70-year old [man who is a Palestinian refugee (Palestinian refugee, majority)/Bedouin man (Bedouin, majority)/Palestinian man who has lived in his house his entire life (all groups)]. Do you think that he should be prioritized when the vaccination booster shots are given? Please answer on a scale from 1 “Disagree strongly” to 5 “Agree strongly.”

In an additional analysis, we include a number of socio-demographic control variables ([Table 2](#), Model 2) such as sex (0 “male,” 1 “female”), education (0 “no education,” 1 “Elementary School,” 2 “Secondary School,” 3 “Vocational Training,” 4 “Bachelor,” 5 “Master,” 6 “Doctorate”). In addition, we controlled if participants have been fully vaccinated, if they count as an at-risk group for COVID-19-complications, and if they knew anyone who died of

COVID-19 in person (0 “no,” 1 “yes”). *Religiosity* was measured with the question “Regardless of whether you belong to a particular religion, how religious would you say you are on a scale from 0 “not religious at all” to 10 “very religious?” Respondents were also asked what their religious denomination is. We recoded the variable to distinguish only between Sunni Muslims (0) and non-Muslims (Christians/others) (1). Given the smaller sample sizes, we merged Catholic, Protestant and Christian Orthodox into one category, and added those who categorized themselves as none’s or other religion (7 respondents). Perceived *discrimination* was an additive index, adding up the number of discrimination experiences (0 “no,” 1 “yes”) in different places of public life (Shops, bank or restaurant; Public areas such as parks and streets; Internet, social media; Work, job market; Public transport or taxis; School; Police; Housing; Courts; Border; Health care). [Table 1](#) displays the descriptive statistics for these variables.

Statistical analyses

To obtain estimates, we ran ordinary least square regressions in STATA. Model 1 ([Table 2](#)) contains estimates from the net model including only the profile respondents saw interacted with their group belonging (majority, Bedouin, refugee). In a subsequent step ([Table 2](#), Model 2), we include control variables. Some of these variables contain missing values (due to refusal or not knowing an answer). Missing

TABLE 1 Sample characteristics.

Total		Majority					Refugees					Bedouins				
	n	n	Mean	p50	SD	IQR	n	Mean	p50	SD	IQR	n	Mean	p50	SD	IQR
Dependent variable																
Prioritization	678	343	3.19	4	1.16	1	210	2.99 ⁺	3	1.22	2	125	2.77***	3	1.22	2
Age	567	281	24.9	20	13.3	4	178	26.5	22	10.7	8	108	32.0***	28	12.7	18
Religiosity	605	301	6.68	7	2.37	4	185	6.66	7	2.17	3	119	6.51	7	2.10	3
Perceived discrimination	678	343	1.45	0	2.41	2	210	1.95*	1	2.73	3	125	3.22***	4	2.59	5
	n	n	%				n	%				n	%			
Treatment	678	343					210					125				
Profile Majority			34					49					50			
Profile Bedouin			31					0					50			
Profile Refugee			35					51					0			
Education	651	327					204					120				
No education			2					5					6 ⁺			
Elementary School			5					1 ⁺					14***			
Secondary School			19					10*					34***			
Vocational training			5					14**					13**			
Bachelor			62					64					28***			
Master			5					5					3			
Doctorate			2					0					1			
Female	636	312	57				201	49 ⁺				123	33***			
COVID-related variables																
Fully vaccinated	609	303	77				191	73				115	80			
At risk	524	276	58				156	60				92	60			
COVID-related deaths	577	292	67				181	75				104	66			
Sunni	658	329	83				204	96***				125	95***			

Significant differences compared to majority-group members, * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$, **** $p < 0.001$. p50 (Median), IQR (Interquartile Range), SD (Standard Deviation).

TABLE 2 Deservingness of booster shot (ordinary least squares regression).

	(1)	(2)
<i>Interactions group # profile</i>		
Majority → Majority (ref.)		
Refugees → Majority	−0.443**	−0.425**
	(0.161)	(0.163)
Bedouins → Majority	−0.435*	−0.345+
	(0.185)	(0.198)
Majority → Bedouin	0.0297	0.157
	(0.158)	(0.158)
Majority → Refugee	−0.267+	−0.0920
	(0.155)	(0.158)
Refugees → Refugees	0.573*	0.345
	(0.225)	(0.230)
Bedouins → Bedouins	−0.177	−0.289
	(0.265)	(0.264)
<i>Education</i>		
No education (ref.)		
Elementary School		−0.284
		(0.308)
Secondary School		0.143
		(0.264)
Vocational training		0.537+
		(0.288)
Bachelor		0.271
		(0.254)
Master		0.176
		(0.318)
Doctorate		−0.132
		(0.469)
<i>Age (centered)</i>		
		0.0115*
		(0.00492)
<i>Female</i>		
		−0.0182
		(0.0963)
<i>Perceived discrimination</i>		
		−0.0417*
		(0.0185)
<i>Fully vaccinated</i>		
		0.131
		(0.110)
<i>At risk</i>		
		0.195+
		(0.117)
<i>COVID-related death in network</i>		
		0.0585
		(0.106)
<i>Religion</i>		
Religiosity		0.0474+
		(0.0248)
Non-Muslims (Christian/others) vs. Sunni Muslims		−0.437**
		(0.167)
Constant	3.276***	2.555***
	(0.110)	(0.319)
Observations	678	678

Standard errors in parentheses, + $p < 0.10$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.

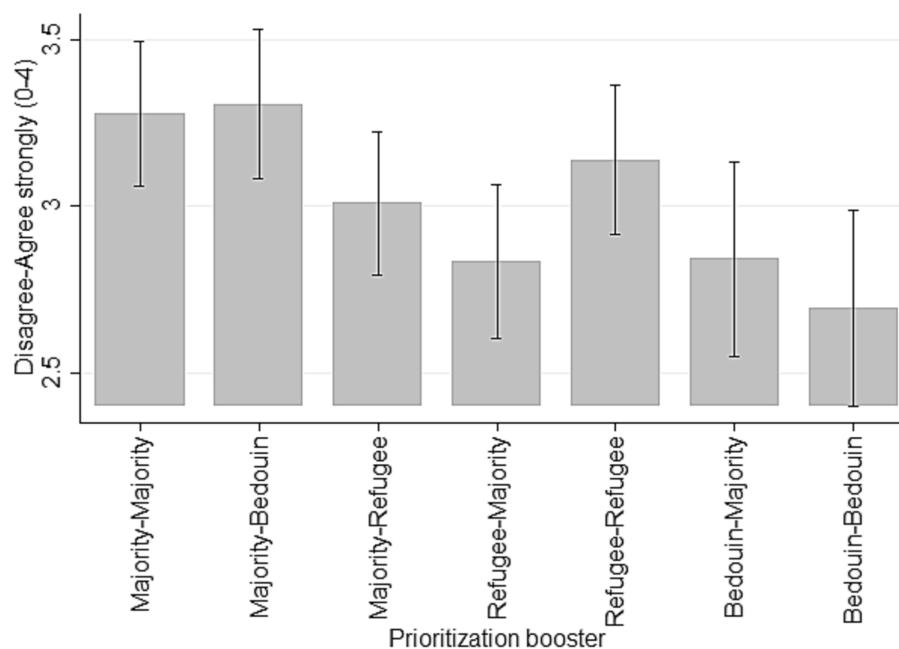


FIGURE 1
Deservingness of booster shot (marginal effects).

values were replaced after 20 multiple imputations using Markov Chain Monte Carlo. AIC values to compare the quality of models are not displayed, as the criterion cannot be estimated for the model with imputed values.

Results

The survey experiment reveals three key results. First, Bedouins show significantly less in-group favoritism than refugees and majority, they make no significant difference between them and the majority. We observe the same result for majority-group members. They prioritize the booster for an older man belonging to their group as much as they support the booster for a Bedouin older man (Figure 1). However, Bedouins' overall level of support for a prioritization of a majority-group member is significantly lower than the majority's level of support for a prioritization of another majority-group member ($b = -0.435$; 95% CI: $-0.799, -0.0705$). Second, majority-group members support the prioritization of a booster for a refugee marginally less than for non-refugees ($b = -0.267$; 95% CI: $-0.571, 0.0361$). Third, refugees in turn prioritize majority-group members significantly less than the majority themselves ($b = -0.443$; 95% CI: $-0.758, -0.127$) and prioritize their own group more ($b = 0.573$; 95% CI: $0.131, 1.015$).

Visible in a drop of significance levels, these differences are largely explained by socio-demographic variables such as sex and education, COVID-related variables, perceived discrimination, and religiosity (Table 2). These variables can explain how the majority thinks about the prioritization of an older refugee man, and how refugees evaluate the prioritization of another refugee. Moreover, Bedouins' stance toward prioritization of a majority-group member can partly be explained by these variables.

While education makes surprisingly little difference, age goes along with more empathy toward an older man to be prioritized for the booster shot. This is visible in an increasing support of prioritization with age ($b = 0.0115$, $p < 0.05$). Moreover, we observe that inequality measured through perceived discrimination is significantly linked to the extent to which citizens support prioritization ($b = -0.0417$, $p < 0.05$). The more perceived discrimination, the lower the likelihood to support the prioritization of other groups. From the descriptive statistics (Table 1), we see that perceived discrimination is higher among minorities, particularly among Bedouins compared to majority-group members. This finding is significant (Bedouins $p < 0.001$, Refugees $p < 0.05$).

COVID-19 related factors matter only little if other factors are controlled for. Persons categorizing oneself to be at risk, are marginally more likely to prioritize an older man, thus showing more empathy. However, being fully vaccinated, or having experienced COVID-related deaths in the personal network was not significantly associated with the prioritization of an older man. Lastly, in line with theories suggesting higher levels of pro-sociality among religious individuals, we see that more religious individuals are marginally more in favor of prioritizing an older man than less religious individuals ($b = 0.0474$, $p < 0.10$). In addition, we see that religious minorities in Palestine (Christians/others) are significantly less likely to prioritize.

Discussion

What have we learned from this study that we did not learn from other studies? As outlined at the beginning of this paper, the few studies that dedicated attention to citizenship found that immigrants were rated lower in the vaccine preference queue [e.g., (6, 9)]. However, we wanted to see if this pattern also extends to native minorities, as they might

be perceived as an out-group as well. However, we find that Bedouins who constitute a salient minority within Palestine are not placed lower in the vaccine preference queue. Geographically and medically, many Bedouins live rather secluded (31), which might explain the lower level of prioritization of any group in the survey experiment.

However, Palestinian refugees tend to be placed a bit lower in the vaccine preference queue. This is a striking finding, as it underlines that the boundary runs along migration rather than citizenship or minority status. Even more striking is that the type of migration we see in Palestine arises primarily from internal displacement due to occupation and does not entail a different cultural background as it is the case for migration in the Western hemisphere. Hence, migration does matter, even on a regional level, and might further contribute to exclusion. Previous studies have shown that even internal migration can have consequences for socio-economic integration [e.g., (32)]. In a case study on the Balata camp, interviewees reported tensions with residents from surrounding areas, experiences of discrimination, isolation, and socio-economic cleavages (33, 34). On top of that, political tensions with the Israeli army frequently center on refugee camps with the situation escalating again shortly after we finished the field work [e.g., (35)].

While the role of religiosity in solidarity has been controversially discussed in prior research, we find that religious individuals tend to be more supportive of prioritization for booster shots overall. This is line with the higher benevolence found in previous studies [e.g., (14)] and it does not result from scepticism toward vaccination for their own group, as found, for instance, in the United States [e.g., (36)]. The question of why religiosity and spirituality have such fundamentally different cross-national effects on vaccination is an interesting endeavor for future research. A previous study using data from the United Kingdom argued that the relationship between spirituality and vaccination preferences was explained by a low trust into science (37). It is possible that higher levels of trust into Palestinian public institutions prevented the rise of skepticism toward vaccination among more religious individuals. However, we see denominational differences. Those not identifying as Sunni Muslims were significantly less likely to approve of the prioritization of an older man. It is possible that their status hampers their level of solidarity. Unfortunately, we were not able to estimate any interactions given their small sample size. Future research may use more scenarios and draw a larger sample in a representative fashion. Given the pandemic restrictions, the current study drew on a community-based sample and descriptive statistics should therefore be interpreted with caution given selection biases regarding an underrepresentation of female and illiterate Bedouins. Moreover, we have to keep in mind that sensitive questions (e.g., out-group attitudes, religion) are more prone to social desirability in face-to-face interviews. Atheists, for instance, might be less willing to identify themselves and express their views openly (38).

As this might have not been the last pandemic, and access to vaccination against COVID-19 will most likely remain a salient issue for the next years, this study has important societal implications. To change individual's perceptions of deservingness, it would be first of all important to emphasize in the public debate that all residents need equal access to vaccination irrespective of their ethnic and social origin. Given the vulnerability of refugees and living circumstances making them more prone to contract the virus, we strongly recommend a prioritization of refugees from a humanitarian and empirical perspective. Palestinian refugees

reported more deaths within the personal network (24). A prioritization for future vaccinations can help to protect refugees from more severe consequences.

In addition, perceived discrimination experiences among minorities, particularly among Bedouins are salient and can explain some of the majority-minority differences. Astonishingly, there was no in-group favoritism among Bedouins despite reporting higher levels of discrimination experiences. Nevertheless, on average, reduced discrimination in the public sphere but particularly the health sector will also likely affect the solidarity between citizens within and between groups. This deems the eradication of discrimination on grounds of origin to be relevant for future research and political implementation.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation on request.

Ethics statement

The studies involving humans were approved by the Research Ethics Committee of Al-Quds University (Ref No: 200/REC/2021). The studies were conducted in accordance with the local legislation and institutional requirements. The ethics committee/institutional review board waived the requirement of written informed consent for participation from the participants or the participants' legal guardians/next of kin because interviews were conducted in the presence of guardians and verbal consent was sought. Participants provided written consent.

Author contributions

SC and AA designed the study and the questionnaire. SC drafted the manuscript and conducted the analyses. AA coordinated the data collection, wrote and commented on the draft. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fpubh.2023.1227559/full#supplementary-material>

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The mobile vaccine equity enhancement program—a model program for enhancing equity in vaccine availability based at a large health care system

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The SARS CoV-2 (COVID-19) pandemic presented unprecedented challenges as communities attempted to respond to the administration of a novel vaccine that faced cold chain logistical requirements and vaccine hesitancy among many, as well as complicated phased rollout plans that changed frequently as availability of the vaccine waxed and waned. The COVID-19 pandemic also disproportionately affected communities of color and communities with barriers to accessing healthcare. In the setting of these difficulties, a program was created specifically to address inequity in vaccine administration with a focus on communities of color and linguistic diversity as well as those who had technological barriers to online sign-up processes common at mass vaccination sites. This effort, the Mobile Vaccine Equity Enhancement Program (MVeeP), delivered over 12,000 vaccines in 24 months through a reproducible set of practices that can inform equity-driven vaccine efforts in future pandemics.

KEYWORDS

vaccine, COVID, pandemic (COVID19), equity, mobile healthcare application

Introduction

As of March of 2023, the COVID-19 pandemic caused over 676 million documented cases worldwide resulting in at least 6,881,000 deaths (1). In the US alone, there have been over 100 million cases of COVID-19 and, prior to the availability of the first COVID-19 vaccine in late 2020, over 800 thousand Americans had died from the infection (2–4). Due to the incredible burden of this disease, and its disproportionate impact on communities of color, older populations, and those with limited English proficiency, it was apparent that once a life-saving vaccine was available, it would be important to ensure that it was made available in an equitable fashion. Mass vaccination sites were a critical component of early vaccine distribution, especially as states tried to achieve vaccination rates as high as possible as early as possible in 2021 (5, 6). While these sites were efficient at providing large numbers of vaccines, many people found it challenging to use the internet-based scheduling system, to find appointments, and to find transportation to those appointments. Indeed, some individuals at greatest risk, such as the older adult and homebound, were completely unable to access vaccines (7–9). Beyond technological challenges, equity in vaccine distribution suffered as well, partially related to mass vaccination sites favoring those with access to transportation, those who lived near the vaccination centers, and those without socioeconomic barriers to seeking care at these facilities (10–14). While Massachusetts was successful in vaccinating a large percentage of its population, a need clearly existed to extend vaccine capability to those with difficulty accessing mass vaccination sites and to ensure equitable distribution of this life-saving measure.

Tertiary care medical centers are uniquely positioned with medical assets and community connections and were partners in numerous COVID-19 mitigation efforts. The vaccine effort described here, known as the Mobile Vaccine Equity Enhancement Program (MVeEP), was a program created by one such institution, UMass Memorial Health, Inc., in order to enhance the equitable availability of the COVID-19 vaccine in its community.

Context

After the first COVID-19 vaccine became available in December of 2020, work began to create a mobile and community-focused vaccine effort with the capability to provide vaccinations in community settings and in the homes of patients who could not easily access other sites. The concept of operations for our program was a mobile service, capable of administering vaccines at community sites or in the homes of individuals, and which focused on accessing individuals with barriers to other sites. Several factors were considered when determining the best sites to target for vaccination clinics including the need to make the service available to individuals who did not speak English as a primary language, had barriers to transportation, were at particularly high risk for severe COVID-19 infection, and communities of color. In particular, at the time of this intervention and since, African American and Latinx individuals were underrepresented among the vaccinated population, and particular attention is required to ensure that vaccination is made available in an equitable manner (15). It was also recognized that a number of high-risk individuals with advanced age and multiple comorbidities might have difficulty accessing the standard online sign-up portals for mass

vaccination sites and, indeed, were more likely to be home-bound or to have challenges with reliable transportation.

The MVeEP effort was undertaken in the larger context of a health-system-wide approach to ensure vaccination for the patients in our catchment area of Central Massachusetts. This meant that this mobile, equity-focused intervention was coupled with a strategy to vaccinate caregivers, provide vaccinations for existing patients who could attend their in-office PCP appointments or present to one of the system hospitals for vaccination or receive it as part of an Emergency Department or hospital stay. Several of the specific considerations for vaccine roll-out and site selection, along with the response posture adopted by MVeEP are described below.

Phased vaccine roll out

Throughout this effort, several factors influenced target populations and the operational plan including: vaccine availability, community engagement and outreach, administration reporting requirements, administration regulations, and storage and logistics.

The State of Massachusetts proceeded during early vaccine distribution with a phased rollout of eligibility similar to other states (Table 1). All vaccine providers were required to comply with this eligibility schedule and to attest to the fact that the individuals being vaccinated were appropriate at the time that their dose was being given. As the MVeEP program selected sites and engaged with community leaders, these eligibility criteria were strictly adhered to.

In the State of Massachusetts, registered vaccine administrations are tracked according to an organizational personal identification number (PIN) and logged into the Massachusetts Immunization Information System (MIIS). Each dose is ordered and delivered to the PIN holder and that entity is responsible for ensuring that each vaccine administration is accurately entered into the online system. Requirements for PIN holders include verification of the ability to receive and store vaccines, as well as an authorized ordering provider. Early in the vaccine effort, it was clear that health centers would play a role in distribution but it was unclear how large a role or how many doses they would be allotted. Numerous locales used a wide variety of vaccine deployment strategies in the U.S. These included partnerships with health systems, programs managed by municipalities, towns, counties, etc. and others focused primarily on state-sponsored programs (16–18). Our program was able to use the PIN associated with the UMass Memorial Medical Center; its pharmacy ordered vaccines based on perceived demand across a number of vaccine efforts including this program, inpatient vaccination efforts, employee vaccination efforts, and large scale vaccination efforts.

Detail to understand key programmatic elements

Vaccine scarcity management

In the early phases of vaccine administration, drug supply and allocation played a significant role in guiding prioritization efforts. In addition, vaccine scarcity meant that any vaccine-administering organization in Massachusetts was held accountable for each dose

TABLE 1 Initial COVID-19 Vaccine Phased Rollout Schedule – Massachusetts Department of Public Health.

Phase	Date	Group
1	12/15/20	Clinical and non-clinical healthcare workers doing direct and COVID-facing care
	12/28/20	Long-term care facilities, rest homes, and assisted living facilities
	1/11/21	First responders
	1/18/21	Congregate care settings
	1/21/21	Home-based healthcare workers Healthcare workers doing non-COVID-facing care
2	2/1/21	People who are 75 or older
	2/18/21	People who are 65 or older People with 2 or more certain medical conditions People who live or work in low-income and affordable senior housing
	3/11/21	K-12 educators, K-12 school staff, and childcare workers
	3/22/21	People who are 60 or older Workers in certain categories
	4/5/21	People who are 55 or older People with 1 or more certain medical conditions
3	4/19/21	People age 16 and older who live, work or study in Massachusetts
	5/12/21	People age 12 and older who live, work or study in Massachusetts
4	11/3/21	Children age 5–11 who live or study in Massachusetts
5	6/20/22	Children ages 6 months to 4 years old who live or study in Massachusetts

<https://www.mass.gov/info-details/massachusetts-covid-19-vaccination-phases#phase-1->

given and were entrusted to ensure that no doses were wasted. Complicating this further was the fact that each vaccine vial had a predicted number of doses contained within, yet the vials were frequently found to have a small amount of overfill that allowed some providers to obtain an extra dose from some vials if the medication was drawn up carefully.

Vaccine draw logistics and scheduling

For events at which hundreds or thousands of recipients were expected, these overages and accidental wastage could be balanced over the course of multiple vials. However, for small, targeted community events at which individuals with difficult access were targeted, this reality meant that a sophisticated system was needed to ensure that each dose was allotted and that no doses were wasted. Adding to the challenge was the fact that, once removed from storage, each dose was only usable for 2 h, meaning that not all vaccines could be drawn up at the beginning of the event in order to have a single starting count since it was common to have extra doses obtained as the vaccines were being drawn from the vials. It was also the case that, as numerous cases of COVID-19 were occurring during the vaccine administration timeframe, it was not uncommon to have patients signed up for the vaccine, who then had to withdraw. This created a situation where the MVeeP team had to plan on a certain number of vaccines being available, overbook the event to some extent based on local prevalence, and also have a roster of “stand-by” individuals available to quickly come to the site or who lived within a certain radius to ensure that extra doses if available, could be administered in the allotted time frame after they were drawn out of the vial. Key to this system was the role of the *Vaccine Navigator*. This role was a

critical intervention that contributed to the success of the effort and is discussed in more detail below.

Vaccine scheduling and walk-ins

The purpose of this program was to accommodate individuals who had barriers to or challenges with accessing an existing mass vaccination site. For this reason, MVeeP clinics were run with partner agencies at various locations in the community. The program evolved as vaccines became more available to accommodate walk-in participants but, early on, visits were scheduled ahead of time so that vaccine availability could be assured. In order to schedule visits, we worked closely with our community partners to ensure that the events were scheduled at times that made it easy for people to access them (i.e., change of shift at employer-based clinics to accommodate both off-going and oncoming workers). In addition, each partner helped provide a list of eligible individuals ahead of time. A customized Epic EHR software module was used to document the clinical process from scheduling appointments to the completion of vaccination. Epic EHR software also permitted on-site registration to accommodate walk-in patients and stand-by patients who were called to fill in when extra doses of vaccine were available.

Vaccine navigator

The *Vaccine Navigator* role was established to ensure that the MVeeP program both had success in accessing communities that were underrepresented in vaccine administration as well as developing, maintaining and utilizing a list of “stand-by” patients. The Navigator

was engaged in both the initial community outreach as the vaccine events were being organized and then was present for the entire vaccine event. During the event these individuals monitored the vaccine distribution, contacted patients that did not show up as planned, and when it was likely that extra vaccine doses would be available, contacted stand-by patients. Stand-by patients still needed to meet criteria for vaccine administration in a given phase and a specific point in time in the vaccine phase timeline. A running count of vaccine availability and the number of remaining scheduled patients were closely monitored to ensure that no dose was left ungiven, and no scheduled patient was denied a vaccine.

Vaccine administration

On each vaccine clinic day, both administrative and clinical staff and volunteers were present. In general, registration and other administrative staff ensured that all patients were checked in, that they had all information correctly documented in the EHR, and that they had any questions answered. They were also supplied with information about the vaccine so that they had an opportunity to review it and ask questions of the clinical staff. Unlike other mass vaccination efforts where patients walked through various stations to have different parts of the check in, information dissemination, vaccine administration, and observation period performed, our program recognized that this would likely pose a challenge to mobility impaired individuals. For this reason, individuals were seated after check-in and all subsequent steps were completed in their seat. Documentation was completed in a mobile fashion using smart devices on which the Rover application had been installed. Once the vaccine was administered, the patient was given a piece of colored paper with the time at which their observation period would end. Staff were moving continuously throughout the area to monitor these times and to be alert for vaccine reactions. When it was noted that a patient had completed the observation period they were guided to the exit with assistance as needed and the surfaces of their seat were cleaned by staff prior to the next patient. In this way, efficient flow of patients could be maintained through the vaccination site. [Figure 1](#) represents a schematic view and photographic representation of the important components of the mobile vaccine.

Vaccines administered

The MVeeP had its first vaccination clinic on February 5, 2021 and concluded its operation on January 30, 2023. During these 24 months of operation, the program administered 12,117 vaccine doses to 8,545 unique individuals who received at least one dose of a two-dose vaccine (Moderna or Pfizer) or the single dose Janssen vaccination. We found that a significant percentage of patients had more than one vaccine administered by MVeeP with 36% receiving at least two doses and 5% receiving three or more. In this program, single dose vaccines were offered as well as initial two dose series, monovalent boosters, and bivalent boosters depending upon CDC and State of Massachusetts DPH recommendations at the time of administration.

In-home vaccinations were provided to 593 individuals who received a total of 748 vaccine doses. The 12,117 doses administered by MVeeP accounted for 11.9% of the total vaccines administered by the UMass Memorial Health system as of March, 2023. Data was

pulled from the electronic health record and checked against both encounters for vaccination and actual administration of vaccination.

A total of 302 vaccine events were held with an average number of encounters at each event being 40 and the largest event providing vaccination to 328 patients in a single day.

An overview of the vaccine program is presented as [Table 2](#).

Diversity, equity, and inclusion mission

The stated goal of the MVeeP was to enhance equity in vaccine delivery. Over the 24 months of operation, the program vaccinated a higher percentage of black and hispanic patients and a significant percentage of patients for whom English was not their primary language, indicating effectiveness of the MVeeP focus. These results are represented in [Table 3](#).

[Figure 2](#) demonstrates the geographic locations of MVeeP clinics with overlaid census tract social determinants of health data. Census tracts are shaded in maroon if they have Social Vulnerability Indices (SVIs) in the 90th percentile and are therefore considered “most vulnerable” and shaded in beige if they have SVIs in the 75th to 89th percentiles (considered “very vulnerable”). The numbers on the map represent the number of patients who live in each tract who were served by our program.

Site/partner selection

The MVeeP program was managed by the Office of Community Health Transformation & Community Benefits (CB) department of our Health System. The CB team used their contacts in the community to identify individuals who had challenges accessing vaccines. The team also identified suitable sites and times to facilitate easy patient access to clinics being held. MVeeP considered its service area to be the entire region of Massachusetts served by UMass Memorial Health (i.e., Massachusetts DPH Region 2). Sites were selected with as much lead time as possible, based on the following considerations: community interest, availability of vaccine, the State’s guidance for vaccine eligibility, consideration of maximal benefit among those with barriers to vaccines, and the factors of Social Determinants of Health (SDoH). Once sites were selected, MVeeP team members partnered with trusted community spokespeople to answer questions about vaccination and to provide information so that individuals were able to make an informed decision about vaccination. Specific foci for MVeeP were those with limited language proficiency, undocumented individuals, people of color, and those with mobility or technological barriers. Within this construct, five general types of events emerged: Community Site Events, Residential Site Events, Employment Events, Testing Site Events, and Mobile Events. Most vaccination events comprised more than one type of intervention and each are described below:

1. Community Site Events – Community events relied on centrally located community spaces such as town halls, places of worship, schools, etc. to host vaccination clinics that were publicized to a specific community. All events were open to the general public according to Massachusetts DPH mandate but focused publicity prior to each event helped to ensure that the maximum impact was directed at the community of interest.

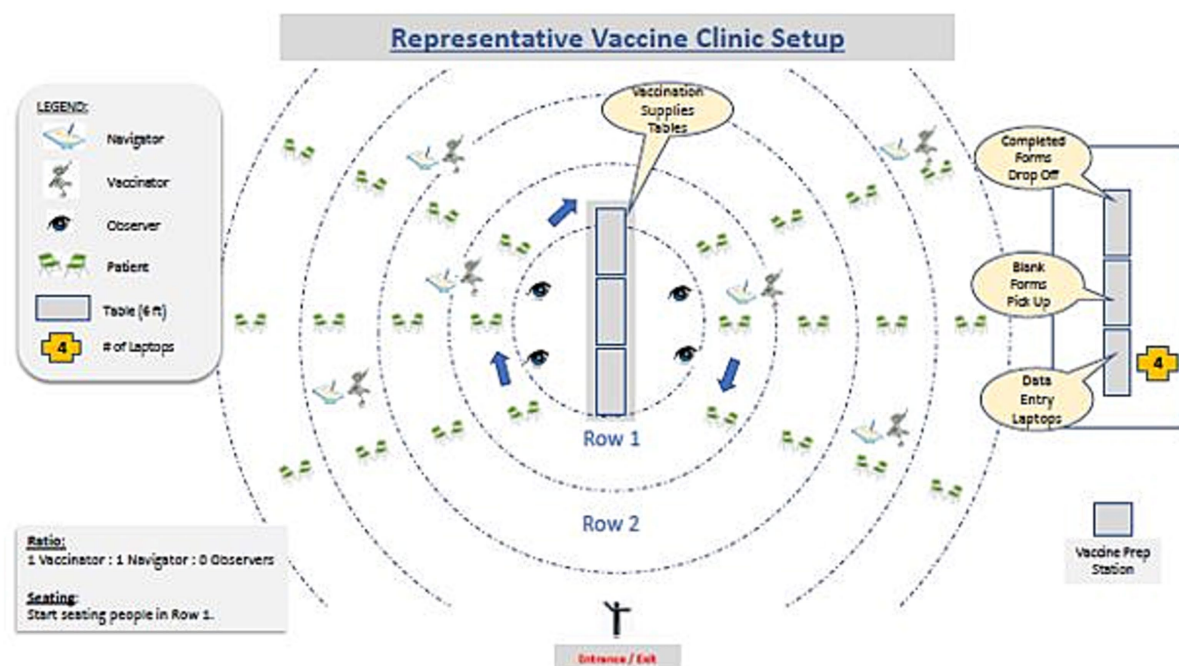


FIGURE 1

Typical MVeeP event set up schematic with representative photo of an event held in Clinton, MA.

2. Residential Events – Especially early in the vaccination program, much of the emphasis was understandably placed on older adult patients. In order to accommodate those that might have difficulty traveling from a senior living facility, especially those classified as senior affordable housing by the State of Massachusetts, special effort was made to work with these facilities in order to vaccinate their residents.
3. Employment Events – In a number of cases, the program engaged with employers to make vaccination clinics available on site at the place of work. This was a useful strategy not only because it allowed access to a large number of individuals and in certain worker categories that were high priority for vaccination but also because it allowed the program to address those who had long

TABLE 2 MVEEP vaccine encounters.

Mobile vaccine equity enhancement program overview		
Total vaccine encounters		
Number of encounters for COVID vaccination with MVEEP	Number of patients	Percentage of Total
1	5,469	64.00%
2	2,639	30.88%
3	366	4.28%
4	44	0.51%
5	26	0.30%
6	1	0.01%
Total	8,545	100.00%
Homebound vaccine encounters		
1	456	76.90%
2	119	20.07%
3+	18	3.04%
Total	593	100.00%
Number of vaccine doses by age		
Patient age at time of vaccine	Number of vaccines administered	Percentage of total
0–4	45	0.37%
5–11	342	2.82%
12–19	871	7.19%
20–29	1,384	11.42%
30–39	1,634	13.49%
40–49	1,598	13.19%
50–59	2,057	16.98%
60–69	2,134	17.61%
70–79	1,218	10.05%
80+	834	6.88%
Total	12,117	100.00%

In Worcester County, persons 65 years and older represent 17.3% of the population (19).

commutes and who could not afford to take time off of work to get vaccinated.

- Testing Site Events – UMass Memorial Health also worked collaboratively with the State of Massachusetts to operate one of the Commonwealth's Stop The Spread (STS) testing centers. This venue, located in downtown Worcester, Massachusetts, was another ideal venue for vaccination delivery.
- Mobile Events – The MVEEP program recognized that the primary barrier for a number of patients who wanted to be vaccinated were mobility limitations and lack of access to transportation. For this reason, a priority of our program was to make vaccination available to homebound individuals and to those with mobility limitations in their homes. At each event, “strike teams” were used to perform vaccinations for patients who lived in a reasonable radius from the main location of the event. Prior to each event, a list of home-based visits was generated and sufficient two-person “strike teams” were created

TABLE 3 MVEEP vaccine recipient race, ethnicity, and preferred language.

Vaccine administrations by patient reported ethnicity			
Ethnicity	Vaccine doses administered	Percentage of total	Worcester county data*
Asian	546	5%	5.6
Black/African American	1,276	11%	6.6
Hispanic	3,546	29%	12.8
White	5,000	41%	74.5**
Other and Unknown	1,749	14%	
	12,117	100%	

# Of vaccines administered by language spoken by patient	
Primary language spoken by patient	Number of vaccine doses (% of total)
English	9,015 (77)
Spanish	1,946 (17)
Portuguese	437 (4)
Vietnamese	104 (1)
Albanian	25 (0.2)
Arabic	80 (1)
Chinese (Mandarin)	1 (0)
Not reported	122 (1)

*Source: <https://www.census.gov/quickfacts/worcestercountymassachusetts> accessed on 3/17/23. ** “White alone” as reported by the US Census Bureau.

from among available MVEEP staff to complete these visits. The locations were plotted on a map and then the list of patients divided among the strike teams, roughly by sector and reasonable travel routes. This was accomplished prior to the event so that each team knew the addresses and patients that they were responsible for vaccinating. Just prior to departing, teams were supplied with adequate vaccines to accomplish their administrations while ensuring that all vaccines could be given within the allotted time since the vaccine vial was punctured.

Toward the end of many vaccine clinics, members of the MVEEP staff would also be dispatched to local neighborhoods to find individuals that qualified for vaccination. All necessary equipment was taken with them so that vaccinations could be delivered at the locations in which willing patients were found. All locations were used with the consent of their owners and included but were not limited to; barber shops, nail salons, homeless shelters, store fronts, city busses, private residences, and restaurants.

Acquisition, transportation, cold chain, and distribution logistics

In order to ensure that sufficient vaccine was obtained prior to each event, members of the MVEEP team communicated the day

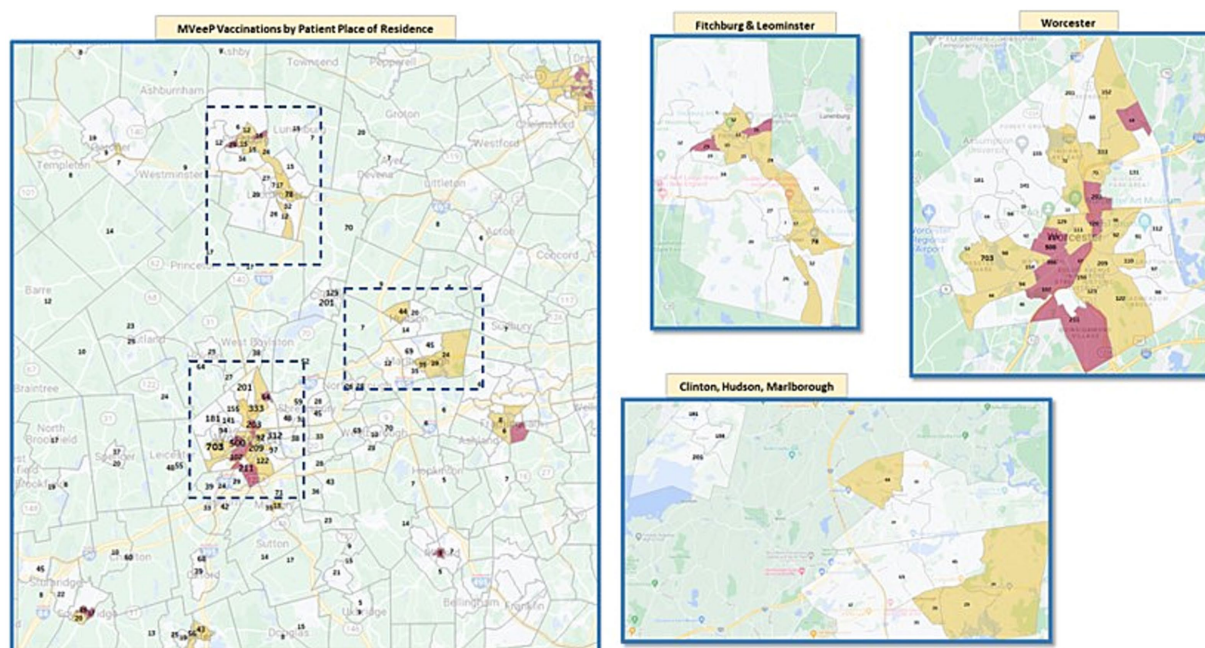


FIGURE 2
MVeeP vaccinations delivery cross referenced with Social Vulnerability Index.

before each event with the pharmacy staff at the Medical Center and requested a number of doses sufficient to complete the event. Confirmation was sent establishing that sufficient quantities would be made available. Each vaccine type used in this intervention (Moderna, Pfizer, and Johnson and Johnson) had different short term and long term storage requirements (20, 21). Long term cold chain storage requirements were maintained by the medical center pharmacy and, once thawed, short term requirements were maintained by the MVeeP team during vaccine events. On the morning of each vaccine event a member of the MVeeP team would go to the Medical Center and retrieve the vaccine doses contained in a specialized cooler that had been validated for 12 h of continuous temperature control within a certain range. Pick up time for each event was coordinated with the pharmacy on the day prior to the event. A continuous temperature reading was accomplished using a temperature probe that was monitored throughout each event by MVeeP staff. Because the vaccine was maintained at this temperature, it allowed unused vials to be returned to the pharmacy at the end of the event in the unlikely event that there were unexpectedly low numbers of patients at the community vaccine event. This ensured that no vials of vaccine were ever wasted or were out of temperature range and could not be administered. During the intervention, there were no unacceptable temperature excursions measured in the vaccine storage device and all unused vaccines were returned to the pharmacy in usable condition if not administered. Supplies required to administer the vaccines, including syringes, needles, and vaccine cards were supplied with the doses at the time of pick up. The pharmacy also supplies epi-pens and benadryl for use in the event of a vaccine reaction.

For each event, in addition to the vaccine doses themselves, significant amounts of supplies and infrastructure were required. As each event included between 30 and several hundred participants,

items such as radios, tables, chairs, disposable medical supplies, IT equipment, hand sanitizer, etc. were required to be delivered to each site. This was accomplished using a dedicated 15-foot moving van and supply crew that traveled with the MVeeP program for its duration. These individuals were assigned from the Medical Center facilities staff and were permanent members of the MVeeP team. Before and after each event they assisted with delivery of supplies, unloading, set up, and retrieval of all logistical items needed to make the program successful.

It infrastructure and mandatory reporting through MIIS

In order to ensure accurate tracking of patients who had received a vaccine, to ensure appropriate follow up if a vaccine reaction occurred, and to comply with the State of Massachusetts requirement that all vaccine administrations were logged into the MIIS system, a robust IT infrastructure was required to manage the MVeeP program. For this reason, MVeeP used the Epic Rover module in an innovative fashion in order to enable on site documentation of vaccine administration. To our knowledge, this was the first such use of Epic Rover in this fashion. Enabling this was a separate instance of the Epic EHR that was modified specifically for this use. Our Epic module communicated directly with the MIIS system, and therefore using it satisfied all documentation and reporting requirements for safe vaccine administration.

In addition to the EHR infrastructure, laptop computers and air cards were deployed with each MVeeP mission in order to ensure adequate connectivity. Air cards from multiple cellular carriers were used to ensure that in any given location adequate coverage could be achieved.

Staffing—volunteers, EMS personnel, employed staff

Throughout the course of the pandemic, the State of Massachusetts adopted a progressive policy of allowing allied health disciplines authorization to administer vaccinations. Our program made special use of dentists, dental hygienists, EMT-Basics and EMT-Paramedics, physicians, and nurses. Because the MVeeP program was being rolled out simultaneously with other large vaccination efforts statewide, and because many health professionals were already deployed to front line and patient facing locations, volunteers (fully onboarded and background checked at the Medical Center) were used as vaccinators. All vaccinators received specialized training and were supervised by core members of the MVeeP staff. Finally, the City of Worcester, the home city of the UMass Memorial Medical Center, also collaborated on a number of vaccine events, supplying staffing and capabilities at these co-run events.

Project management

Through its Center for Innovation and Transformational Change (CITC), project management support was provided to the MVeeP effort and was integral in the planning, resourcing, and execution of all aspects of the vaccination effort. This group also provided a critical link with the larger vaccination effort being undertaken by the Health System to ensure vaccine availability for all of its patients. Following Lean methodology, the CITC staff organized and streamlined the MVeeP effort to reduce waste and to increase efficiency of the effort.

Interpreter services

Given the mission of MVeeP in providing more equitable access to COVID-19 vaccination, we worked closely with the UMass Memorial Medical Center Interpreter Services Department to ensure several countermeasures designed to provide adequate interpretation capability. First, vaccine information packets were created in English as well as the five other most commonly spoken languages in our area (Spanish, Portuguese, Albanian, Vietnamese, and Arabic). These included Emergency Use Authorization (EUA) material required for distribution with the vaccine from the Food and Drug Administration (FDA) as well as a number of other documents and resources created by our program that were professionally translated by the Medical Center Interpreter Services Department. Second, the Medical Center provided its interpreter hotline for both audio and video translators during all MVeeP events. In addition, as many of the MVeeP staff were employed by the UMass Memorial Medical Center Ronald McDonald Care Mobile, many had multiple language fluencies. During this intervention, based on the countermeasures above, we did not encounter any individuals that were not able to be consented and vaccinated safely due to language barriers.

Medical support (hotline, on site and in home support)

As the program began, the MVeeP team recognized that many patients who would be served by this effort would not have easy

access to medical follow-up or primary care physicians. This was due in part to the difficulty in accessing outpatient care during this time, that was itself a product of decreased staffing and office hours in the throes of the pandemic and partly due to the fact that many of our patients were undocumented or simply did not have well-established primary care. Recognizing this, the MVeeP team worked with local EMS agencies and the program leadership to ensure that not only were there physicians and Nurse Practitioners trained in emergency response on scene for each vaccination event but that a hotline number was provided to the patients as a part of each patient's vaccine information packet. This hotline was staffed 24 h per day, 7 days per week by an Emergency Physician and was available for any patient who had questions regarding the vaccine or any side effects or symptoms following its administration.

Adverse events

During the course of the entire first 12 months of the vaccine program, until vaccine scarcity was no longer a consideration, zero doses of COVID-19 vaccine were wasted or given to non-qualifying individuals. In fact, due to overfills of vaccine vials, many more vaccine doses were given out over the course of the program than would have been expected if the standard number of vaccines were drawn from each vial. In addition, no serious reactions occurred during the observation period after vaccine administration and during only two instances was Benadryl given for minor vaccine reactions. Zero patients required epinephrine.

Discussion

The described vaccine effort was intended as an effort to enhance equity in vaccine delivery in a specific community of Central Massachusetts during the COVID-19 pandemic. This model provides several useful lessons learned for future pandemics that may require mass vaccination efforts, and also demonstrates some of the challenges inherent in providing a new type of vaccine to a population with myriad barriers to accessing it.

First, our program did demonstrate that mobile vaccination, even with vaccines that require specialized cold-chain logistics like the FDA approved vaccines, can be done safely. All vaccines were maintained within acceptable temperature ranges and no vaccine was wasted due to breakdown in cold-chain logistics. It is noteworthy that support from the medical center, which had access to extensive freezer capacity, allowed access to vaccine that was safely stored for longer periods of time prior to each event according to manufacturers guidelines. This was key to the success of the intervention. The program maintained strict adherence to vaccination guidelines and had no serious adverse events. Presence of on-site medical support and a medical hotline were important to ensuring that vaccines were delivered safely and that community members felt safe receiving the vaccine and supported thereafter.

Importantly, due to the logistical complexity of this vaccination program, and the challenges associated with doing it

in a mobile fashion, a health center or other institutional partner is key to success. Our home institution supplied multiple infrastructural resources as described above in order to ensure safe and effective program administration. Clear direction from health system leaders is also required to marshal and maintain this support.

The existence of the Office of Community Health Transformation & Community Benefits, and specifically the staff of the UMass Memorial Medical Center Ronald McDonald Care Mobile as the home department for such an intervention, was incredibly important to the success of the initiative. Critical in this respect were the deep connections that this office and program had with community and city leaders. This was important not only as the program sought to select sites but also as it worked collaboratively with these leaders to encourage vaccinations and to allay fears that some in the community had expressed. In addition to the CB office, the Corporate Relations and Concierge Medicine Department of the UMass Memorial Health CarePath Program was critical in accessing employers that represented hundreds of employees in our region.

The role of the *Vaccine Navigator* was a crucial intervention that we feel played an outsized role in the success of our program. These staff members formed a vital link to the community and were able to contact patients in real time and to quickly ensure that all available slots on a given day were filled.

The program was especially well positioned to address vaccine distribution inequity and succeed in its goal of focusing on non-white and non-English speaking populations. African-American and Hispanic populations made up 11 and 29% of individuals who received vaccines through our program while only representing 6.6 and 12.8% of the population of Central Massachusetts, respectively (22). In addition, as demonstrated in Figure 2, our program was highly effective at providing access for patients who live in communities with high Social Vulnerability Indices. Other programs focused on mobile vaccine delivery have demonstrated success in vaccinating hard to reach populations. Given the importance of local specificity when it comes to targeting these communities, direct comparisons of success are difficult, but this intervention joins a small list of published literature detailed successful methods of ensuring equitable access to vaccination (9).

While no structured assessment of feedback such as survey or focus group was employed, the program received outstanding anecdotal feedback from our partners. Numerous community organizations expressed support for the approach and many requested multiple return visits and subsequent vaccine clinics due to the success of previous events. In addition, we were pleased that several thousand participants chose to receive second doses through our program despite expanding access through other sites throughout the period of intervention.

Direction of future investigation in this area should include standardizing metrics for success of mobile vaccine programs, and development of best practices for program administration. Although assessment of domains such as community engagement can be difficult to measure precisely, ensuring ways of ongoing assessment of success during a vaccine program are critically important. During future pandemics and smaller level vaccine-amenable disease outbreaks (e.g., Mpox) it will be vitally important to ensure equity in designing vaccine distribution.

Acknowledgement of limitations

The program did experience difficulties, especially early on, with patient scheduling and the process of monitoring arrivals to ensure that all vaccine doses could be administered at each event. This was largely combated by the work of the *Vaccine Navigators* and program staff actively monitoring vaccine dose administration and remaining dose availability. In addition, by comparison to the larger mass vaccination sites in the State of Massachusetts and elsewhere, the scalability of our program was limited by the significant investment of time and resources in the administration of each vaccine dose. While this meant that the program was less efficient on a strictly dollar-per-dose basis, it is also acknowledged that many of the patients vaccinated by this program had significant difficulty accessing mass vaccination sites and many patients noted that the MVeeP program was their only opportunity to receive the vaccine. Many of these patients were either at very high risk of severe COVID-19 infection by virtue of age or comorbidity (i.e., the older adult and multiply comorbid patients with COVID-19 risk factors) or were members of groups that experienced higher than expected morbidity and mortality during the early phases of the COVID-19 pandemic – especially among communities of color. One limitation in terms of data collection in this intervention was that no specific data was recorded related to the percentage of patients with mobility challenges and their use of the service. Although this is captured to some extent in the number of home-bound visits that were performed, a more specific accounting of these patients and specific challenges involved would improve future interventions.

Despite significant effort to reach all communities it is acknowledged that some individuals in our service area were likely missed. Our approach depended upon engagement from community organizations and individuals without connections to these partners may have been less likely to receive notification of our events and to access the vaccine. The team attempted to mitigate this by incorporate a system of on-site registration to allow neighborhood residents to be vaccinated even if they had not been aware of the event prior. We used social media, communications such as newsletters and fliers, and word of mouth advertising to make as many people aware of the process as possible. However, future work should focus on the best ways to ensure maximum engagement, especially among isolated community members to ensure the greatest equity possible in terms of access.

In conclusion, the Mobile Vaccine Equity Enhancement Program (MVeeP) demonstrates one successful model for meaningful community engagement and the deployment of medical countermeasures in the midst of a global pandemic in a way that was specifically designed to address equity.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by UMass Chan Medical School Human Subjects Institutional Review Board. The

studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation was not required from the participants or the participants' legal guardians/next of kin in accordance with the national legislation and institutional requirements.

Author contributions

JB: Conceptualization, Project administration, Resources, Supervision, Writing – original draft, Writing – review & editing. OB: Conceptualization, Data curation, Formal analysis, Resources, Writing – original draft, Project administration, Supervision, Writing – review & editing. CaiM: Methodology, Project administration, Supervision, Writing – review & editing. JF: Investigation, Resources, Supervision, Writing – review & editing. PL: Resources, Methodology, Supervision, Writing – review & editing. NS: Project administration, Validation, Supervision, Writing – review & editing. JI: Project administration, Resources, Validation, Supervision, Writing – review & editing. RK: Methodology, Supervision, Writing – review & editing. ST: Conceptualization, Supervision, Writing – review & editing. AH: Visualization, Writing – original draft, Methodology, Supervision, Writing – review & editing. PM: Methodology, Resources, Supervision, Writing – review & editing. RB: Data curation, Methodology, Project administration, Writing – review & editing. GD: Supervision, Resources, Writing – review & editing. MG: Methodology, Resources, Writing – review & editing. CC: Resources, Supervision, Methodology, Writing – review & editing. JS: Methodology, Data curation, Formal analysis, Visualization, Resources, Supervision, Writing – review & editing. KE: Supervision, Conceptualization, Methodology, Resources, Writing – review & editing. NV: Project administration, Resources, Writing – review & editing. SH: Resources, Supervision, Writing – review & editing. KF: Writing – review & editing, Project administration, Supervision. RG: Resources, Writing – review & editing, Supervision. TH: Resources, Writing – review & editing, Methodology. VM: Project administration, Supervision, Writing – review & editing. TV: Writing – review & editing, Formal analysis, Software, Validation, Visualization. MB: Resources, Writing – review & editing, Project administration. TJ: Resources, Writing – review & editing, Software. CatM: Software, Writing – review & editing, Resources. WS: Project administration, Resources, Writing – review & editing. IP: Resources, Writing – review & editing, Project administration, Methodology. MR: Resources, Writing – review & editing, Project administration. CL: Project administration, Resources, Writing – review & editing. ML: Project administration, Resources, Writing – review & editing. ER: Project administration, Resources, Supervision, Writing – review & editing. LG: Project administration, Resources, Writing – review & editing, Methodology. AG: Project administration, Resources, Writing – review & editing, Supervision. SB: Project administration, Resources, Supervision, Writing – review & editing. ED: Project administration, Resources, Supervision, Writing – review & editing. MM: Project administration, Resources, Supervision, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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How a community-led understanding of access and uptake barriers and enablers informs better vaccination programs

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Introduction

Interventions to increase timely and equitable access to life-saving diagnostics and medicines for Africa must address the root causes of inequality and prioritize meeting communities at their point of need. Current donor funding for vaccination initiatives and voluntary licensing largely remains at the discretion of those in the global north, curtailing the agency of African countries, their pandemic preparedness, and the need for decolonization of research and development, i.e., free intellectual property provisions that benefit the pharmaceutical industry's profit over people's lives (1).

The most recent example of this schism is the COVID-19 pandemic. COVID-19 vaccine distribution was extremely inequitable from the outset, with low- and middle-income countries (LMICs) left waiting at the back of the global vaccine line. Despite the efforts of bodies like COVAX (2), who dedicated significant financial resources towards sending vaccines to LMICs, only 512 million or 4% of the 13.5 billion doses administered worldwide, were given to people in LMICs (most of which are in Africa) (3). Meanwhile, countries like Israel, the United States, Canada, the United Kingdom, and many others have administered multiple booster shots to their populations, making pharmaceutical companies billions (3). Additionally, the approval of second-generation COVID-19 vaccines that offer better protection against SARS-Cov-2 variants of concern such as Omicron and Delta, has added another layer of inequity, with countries in the global north procuring these vaccines. In contrast, less effective first-generation vaccines continue to be delivered to LMICs. This extreme inequality in vaccine access is due to the prioritization by vaccine manufacturers of bilateral deals with rich countries i.e., profit over the health needs of the global population—including African countries—and vaccine nationalism, where many global north countries stocked up on vaccine supplies even while others (mainly in the global south) had very limited supply.

While the supply of COVID-19 vaccines, tests and treatment on the continent may have increased since the initial global vaccination effort, challenges persist concerning the distribution and administration of these medical interventions in-country, i.e., getting them from the ports they arrive at, into communities to access in a timely and

coordinated way. These range from the logistics of delivering diagnostics and medicines in rural areas (physical infrastructure and access) to inadequate cold chain equipment and protocols to mis/disinformation and hesitancy fueled by unverified information shared across social media and by prominent public figures (4).

Underpinning these specific challenges is the already overburdened, under-resourced healthcare systems across Africa, undermining the continent's ability to prevent, prepare for and respond to pandemics—those that came before COVID-19 and those that will come after.

A community-led approach that can identify the specific barriers to a proposed response, in this case, a successful vaccination program, identify and promote enablers to access, and pair this approach with local advocacy linked to civil society preparedness, has the potential to increase communities' sense of agency, build confidence and trust in state-designed health emergency response.

The current top-down approach, driven by international agendas, has undermined public trust in African governments' health responses and led to vaccine hesitancy, fueled by a lack of information and effective awareness interventions. This contributed to wasting essential medicines and further mistrust in public health responses and resourcing. More evidence is urgently needed from a community perspective, i.e., those who continue to be most affected, on how the COVID-19 pandemic impacted public health systems, and how governments prepared for and responded to COVID-19, including their vaccine rollout strategies.

What could a community-led vaccination rollout look like?

In mid-2021, a concept for public health accountability, “Ports2Arms”, was developed. This project recognized that, even in the early days of the COVID-19 pandemic, global efforts to distribute vaccines to developing countries and monitor these through various public health tracking mechanisms had little oversight of the specific barriers and enablers on the ground to equitable vaccine distribution and uptake. Such tracking would ensure that vaccines reach ports and are distributed in a way that recognizes and can respond to the realities of already strained public health systems, significant disease burdens, geographically dispersed communities, and inequitable access to public goods and services (5). Ultimately, these warnings were borne out with gross vaccine inequality still evident between developing countries in places like Africa, and the rest of the world (6).

Through a community-led monitoring (CLM) approach, Ports2Arms works with national partners using a combination of media monitoring (TV, radio, newspapers, websites and social media); COVID-19 information availability in communities; the extent to which civil society was given advanced notice of incoming vaccine shipments and could prepare communities for uptake; and the specific vulnerabilities of underserved and marginalized populations, including the LGBTIQ+ community, sex workers, people who use drugs, people living with HIV,

people in detention, adolescent girls and young women, older people, and those living with a disability, among others. A story-gathering process enabled qualitative data collection to support mapping COVID-19 cases and vaccine rates and bring a human face to the data and other narratives captured through media monitoring. A co-analysis process with affected communities who had participated in the data collection sought to inform evidence-based advocacy, which for the pilot, saw a series of radio talkback shows hosted in each community during the pilot. Through this kind of multi-layered community-led monitoring (CLM) process, Ports2Arms aimed to ensure that, by learning from the South African COVID-19 vaccination experience at the community level, African communities and governments can be better prepared for and respond to future pandemics, incorporating better implementation of associated vaccination programs.

Monitoring barriers and enablers as potential sites for action

When the first COVID-19 vaccines became available, it brought hope for many devastated by the pandemic, its ongoing socio-economic effects, and its high death rate. The vaccines symbolized a solution to national and global struggles. However, over time, tensions arose regarding safety, accessibility, equitable distribution, and supply challenges. Specific barriers to vaccine distribution, as defined by the Ports2Arms project, include:

- *Supply chain bottlenecks*: any issue along the ports-to-arms pathway occurring on the supply side which prevents vaccine doses from becoming readily utilized for individuals willing to be vaccinated (e.g., cold chain issues, vaccines received close to expiry, lack of healthcare workers)
- *Health workforce*: In the context of the COVID-19 response, this refers to inadequate or non-existent training, discrimination of some population groups (people are turned away) or equipment shortages [e.g., syringes, personal protective equipment (PPE)].

Barriers to vaccine access and uptake include:

- *Vaccine hesitancy*: factors that prevent an individual from wanting to become vaccinated (e.g., lack of trust in the government, misinformation)
- *Vaccine access (poverty)*: barriers that hinder an individual from getting vaccinated. This encompasses any structural or social inequities that exist that actively or passively exclude certain people or groups within a population (e.g., Transportation costs, technological barriers).

Political instability, conflict, and unrest due to the disrupting effects of the COVID-19 response and caused by events such as local/national elections; protests (service delivery or other) and civil unrest related to the impact of COVID-19 on livelihoods cuts across both distribution and access barrier definitions.

The specific enablers of vaccine distribution and access can be defined as:

- *Training and skills development*: any initiatives focused on developing vaccine competencies.
- *Community outreach*: efforts to take Vaccines to communities to minimize associated access costs and challenges.
- *Multisectoral collaboration*: coordinated efforts of various sectors/organizations of a community that combine their resources/knowledge to deliver and encourage vaccination (e.g., government working with businesses or communities to promote vaccination or create vaccination sites).
- *Community engagement*: initiatives that mobilize community members to encourage vaccine uptake within their communities (e.g., local leaders' engagement and community vaccination initiatives).
- *Accountable leadership*: competent, timely, and responsible leadership that creates effective structures/programs/plans that encourage vaccination of their constituencies (e.g., creating a national vaccine strategy, creating programs to improve vaccine access).
- *International collaborative efforts*: any assistance from international organizations/countries to improve a country's capacity for vaccine absorption (e.g., donation of ultra-cold freezers, healthcare worker training).
- *Use of technology*: examples of innovation in the digital and technology spaces to facilitate vaccine access.
- *Incentives*: examples of incentives to facilitate access to vaccines (e.g., cash to cover associated costs or food vouchers as an incentive).

This diverse set of barriers— from vaccine hesitancy to lack of transportation—commonly hinders vaccination efforts, having the greatest ramifications in the countries suffering most from vaccine inequity. If these barriers are to be overcome, it is critical that they be well understood and that the approaches taken to mitigate them be clearly identified. Monitoring enablers or good practices also supports this by identifying local solutions that facilitate a more equitable response. Such community-led mapping of barriers and enablers allows countries and communities to use effective solutions and discard unhelpful approaches, based on the lived experiences of the communities they are meant to service—hence increasing the speed and number of vaccines that travel from ports to arms.

Why community-led monitoring?

CLM approaches have been particularly critical in contexts with weak health systems, where communities, on the one hand, experience health system failings (lack of personal protective and other equipment or stockouts), stigma and discrimination, and inadequate infrastructure, and on the other hand, lack the structures and ability to raise grievances due to cultural norms, power imbalances, and fear of reprisal. Despite this, community actions have been critical in securing political will and funding for HIV research, prevention, care, and treatment (7) and the evidence of CLM having delivered benefits to communities through policy and practice change at the local and national levels is a key driver in the recent mainstream attention brought to the approach by global agencies such as PEPFAR, Global Fund and UNAIDS. This was perhaps triggered by the COVID-19

pandemic's highlighting the impact of high levels of treatment interruptions for people living with HIV, but also recognizes the way CLM can identify specific barriers to services (access and uptake) and facilitate evidence-based community engagement and risk communication strategies to build individual confidence and trust in government public health guidance. There is also recognition of its broader applicability, for example, in humanitarian situations—to improve preparedness and response (for future pandemics) (8)—and other challenging environments to monitor related societal and structural interventions, including improving the legal environment, Human Rights promotion and protection, or action against stigma and discrimination.

However, while communities have provided feedback on the quality of health service provision since the early days of the HIV epidemic, the gathering, collation, and use of such data has not always been systematic or widespread, resulting in an evidence gap in terms of its efficacy for other kinds of public health crises, such as pandemics. There is also a significant gap in understanding how underserved and vulnerable populations are particularly affected (9).

Conclusion

In conclusion, in the context of the lessons learnt from COVID-19 pandemic, which continues to impact communities on the continent, there is an urgent need for future emergency vaccination programs to consider:

- how to ensure a more equitable emergency response that includes visible global manufacturing and distribution plans for vaccines, other medical interventions and technologies, and a regular public reporting mechanism with meaningful civil society oversight.
- improved accountability, including a commitment from global leaders and bodies, including Gavi, the African Union, Africa Centre for Disease Control and the World Health Organization, to ensure consistent, meaningful and independent access for civil society and community observers from the onset of widespread vaccination initiatives.
- addressing roots of systemic and inequitable access, where any pandemic or widespread vaccination response must be grounded in the principles of community, equity, transparency and Accountability, for example, all clinical research conducted in Africa implemented with resourced community engagement plans that span all phases of research, from protocol development to dissemination and access. Research must include women, transgender women, and other marginalized groups, such as people living with HIV.

A CLM approach like Ports2Arms is by no means a panacea, but its focus on identifying locally grounded realities and its ability to offer solutions through identifying barriers, highlighting enablers and using the data for evidence-based advocacy at grassroots community level, national and regional levels, and globally have the potential to take us much closer to achieving, at the least, the COVID-19 vaccination targets for the continent than the current strategies that have been employed, and lay a solid foundation

for using similar approaches to guide future pandemic and emergency responses and related vaccination programmes.

Author contributions

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Immunization as an entry point for primary health care and beyond healthcare interventions—process and insights from an integrated approach in Lebanon

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Integrated healthcare systems are continually pitched as major contributors towards better distribution of health outcomes and enhanced well-being. Under emergency conditions, integrated healthcare services can guarantee better access to the target population. In recent years, several crises, i.e., economic collapse, the fuel crisis, the Beirut blast, a large refugee population, and the COVID-19 pandemic, in Lebanon have led to a major shift in the health-seeking behavior of the communities, with preventive services being downprioritized despite being available and curative healthcare services being sought out as late as possible. An extensive drop in immunization coverage and an overstretched public health system presents the risk of Vaccine-Preventable Disease outbreaks and urgent intervention is needed to bridge the immunity gap. The Ministry of Public Health, Lebanon, and UNICEF Lebanon successfully demonstrated the use of an immunization platform as an entry point to reach communities for service delivery, identification and referral, screening, awareness generation, and a host of other services that can be copied for other programs including but not limited to those for Maternal and Child health, nutrition, early childhood development, COVID-19, children with disabilities, social protection, education, health emergencies like cholera, etc., and these can provide bi-directional support to each other. UNICEF along with the MoPH (Ministry of Public Health) has been working towards reaching the most vulnerable population with a bouquet of services through existing immunization touchpoints for favorable healthcare outcomes.

KEYWORDS

immunization, integration, outreach, comprehensive healthcare, primary healthcare
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1. Introduction

Health systems combine both integrated and individual interventions. Integration is best seen as a continuum rather than as the two extremes of integrated or not integrated. Routine immunization has a long history of integration with multiple programs, like vitamin A supplementation, growth monitoring, deworming, or insecticide-treated bed nets (1). The

importance of integration, both in health systems in general and within immunization programs more specifically, has been continually growing, and this is reflected in a broad range of global policies and strategies.

There has been much interest in using immunization as a platform for other interventions since immunization coverage is relatively high in most countries compared to other interventions along the continuum of care (1). In addition, childhood immunization organizes regular immunization contact at set intervals, such as five contact moments in the first year of life and additional contact during the second year of life, school age, and adolescence depending on the national immunization schedule. Immunization is a global health and development success story, saving millions of lives every year. Immunization is the foundation of the primary health care system. However, it is important that the scheduling of integrated services is assessed to determine their feasibility based on the human and material resources needed vs. those available.

A life course approach to immunization can facilitate integration opportunities. For example, the delivery of a birth dose of the Hepatitis B vaccine could be provided alongside other postnatal care and be used as a key advocacy opportunity to inform the parents about the national immunization schedule and provide them with a home-based record for their child. The need to identify all newborns in the community to provide the birth dose vaccinations could also strengthen systems for civil registration and vital statistics, which could in turn improve the denominators used to monitor immunization coverage rates.

Globally there have been multiple efforts to sync immunization services with other country-specific domains or areas of concern in many countries, such as the United States Agency for International Development's Maternal and Child Survival Program (MCSP) supported the Liberia Ministry of Health to scale up integrated family planning and immunization services as part of a broader service delivery and health systems recovery program after the Ebola epidemic (2). The Government of Malawi's *Health Sector Strategic Plan II* highlights the importance of service integration and systematically implemented integrated family planning and immunization services in all health facilities and associated community sites in the Ntchisi and Dowa districts during the period June 2016–September 2017; results indicated statistically significant increases in family planning users and shifts in the use of family planning services from health facilities to community sites (3). In an assessment in Rwanda, 98% of women interviewed supported the idea of integrating family planning service components into infant immunization services (4). Additionally, a study conducted in two northwest Ethiopian districts and another study conducted with survey data from Ethiopia, Malawi, and Nigeria found an association between contraceptive use and child immunization (5, 6). In Lao PDR, the use of this integrated approach compared with the implementation of the vertical deworming campaign alone allowed a reduction of the individual cost of deworming by 10 times (from US\$0.23 in the vertical deworming campaign to US\$0.03 in the integrated campaign). The burden on health workers by the integration process was perceived as minimal and

manageable. Moreover, delivery of anthelmintic drugs during immunization campaigns enabled campaign teams to observe drug intake directly, which ensured safety (7).

The Global Routine Immunization Strategies and Practices (GRISP) document includes “integrating the routine immunization program through comprehensive approaches and joint service delivery” (8) as one of the key strategies to maximize the reach of routine immunization and mentions placing vaccines into the context of comprehensive approaches to disease control, delivering other key preventive maternal and child health interventions during vaccination visits where appropriate and starting immunization program tracking with pregnant women and during antenatal care, as key interventions. The provision of outreach services is advocated to be a central strategy in countries where fixed sites are inadequate for regular provision of preventive health services to all targeted individuals (9).

Immunization is the most strategic component of primary health care aimed at preventing diseases through primary healthcare (10), and it is also one of the best health investments money can buy. Vaccines are also critical to the prevention and control of infectious disease outbreaks. Researchers from Gavi and the Federal University of Pelotas, Brazil, investigated the overlap between not being vaccinated with routine immunizations and failing to receive other primary healthcare services. They analyzed data from more than 200,000 infants aged 12 to 23 months between 2010 and 2019 from 92 LMICs. They found that unvaccinated children and their mothers were systematically less likely to receive other primary healthcare interventions, particularly for antenatal visits, and access institutional delivery. Families whose children have no access to vaccination are missing out on crucial primary healthcare services that affect both mothers and children and offer an opportunity for integrated service delivery to reduce inequity. Identifying and reaching zero-dose children is likely to be critical to tapping into families who are missing out on important primary healthcare interventions (11).

Integration of CoVID-19 Vaccination delivery into routine immunization services has yielded favorable outcomes across many countries. The initial arrangement of COVID-19 vaccination campaigns, i.e., mass-level vaccinations, was deemed a non-sustainable model in terms of finances as well as human resources; there was also an increasing risk of adverse effects on routine immunization services, leading to increased interest from other countries and efforts toward integration of the COVID-19 immunization services with the routine immunization.

Outreach services (an extension of facility-based primary care services used to reach the underserved), campaigns, and outbreak responses are key interventions deployed to increase immunization coverage, reduce the risk of outbreaks, and address the barrier to access. Outreach often plays an important role in systematically delivering immunization services to a large proportion of the population—in some cases reaching >50% of the target population. In addition to providing routine immunizations, outreach sessions present opportunities to provide women, children, and their families with other vital interventions, such as vitamin A supplementation, deworming

tablets, and insecticide-treated nets (ITNs). “Reaching every district” (RED) is a strategy to achieve the goal of 80% immunization coverage in all districts and 90% nationally in the WHO member states. Outreach sessions have been recognized as a key activity for WHO’s RED strategy. Outreach sessions, especially mobile teams, present opportunities to provide other interventions along with immunization (12).

Lebanon has traditionally been an upper middle-income country and has had a significant share of the private healthcare sector for both preventive as well as curative services but is now facing a cascade of crises. The Lebanon financial and economic crisis is likely to rank in the top 10, possibly top 3, most severe crises globally since the mid-19th century. This is a conclusion of the Spring 2021 Lebanon Economic Monitor (LEM) in which the Lebanon crisis is contrasted with the most severe global crises as observed by Reinhart and Rogoff (2014) (13) over the 1857–2013 period. In July 2022, the World Bank reclassified Lebanon as a lower-middle income country (LMIC), down from an upper-middle income country (UMIC) (14). Amid its worst socioeconomic crisis in decades, Lebanon has a unique situation in hosting the highest number of refugees per capita worldwide. The Government estimates that there are 1.5 million Syrian refugees and 13,715 refugees of other nationalities; 90% of Syrian refugees are living in extreme poverty (15).

Lebanon’s once robust healthcare system has buckled under the weight of the economic collapse and COVID-19. Hundreds of healthcare workers have fled the country in “a mass exodus” unable to withstand the chronic shortages of staff, basic medical supplies, and pay. The August 2020 explosion damaged 292 health facilities. As the economy has deteriorated and poverty has risen, private health care has become unaffordable for many, increasing the strain on the depleted public health sector. The healthcare system has been battling with poor healthcare outcomes since 2020, and Lebanon is witnessing an extensive drop in immunization coverage with only 67% of children receiving the initial doses of basic vaccination. Various factors contribute to the drop in immunization coverage with non-affordability of the private sector, challenges in accessing public health facilities due to rising transportation cost, and the shrinking value of income coupled with low priority at the family level to spend precious and limited time and resources on getting a child vaccinated leading to delays and postponement.

Furthermore, the IPC (Integrated food security Phase Classification) Acute Food Insecurity analysis carried out in all 26 districts showed that 33% of the Lebanese resident population and 46% of the Syrian refugee population (16) were estimated to be in IPC Phase 3 (Crisis) or above, requiring urgent humanitarian action to reduce food gaps, protect and restore livelihoods, and prevent acute malnutrition. The rising food insecurity is a major threat to the nutritional status of the country. From being the first country to achieve SDG goals for the last two decades, Lebanon had been known to maintain stable maternal mortality rates, however maternal mortality rates tripled between 2019 and 2021 from 13.9/1,000 to 47.6/1,000. Likewise a three-times rise in neonatal deaths, especially among Syrian refugees, within the span of 2 years (2019–2021) has

been observed. All the above factors highlight a need for multi-dimensional integration of methods to address various ongoing as well as underlying crises.

UNICEF, along with the MoPH and locally active NGOs, is working towards interventions to not only ensure uptake of immunization but also explore arrays of integration—to use the opportunities of immunization interventions as a platform to provide impetus to efforts directed at multi-dimensional health and well-being efforts for children. Immunization has a long history of integration with a broad range of other health services delivered using both routine and campaign-based delivery strategies.

2. Materials and methods

Post identifications of factors like economic and fuel crises, which were the major barriers to seeking immunization, it was deemed appropriate to move from the existing facility-based approach towards the community-based service through outreach sessions. The transportation affordability was a major cause of the continuously dropping rate of immunization, leading to a mammoth rise in unvaccinated as well as under-vaccinated children in the country. Following the COVID-19 pandemic, 1 in every 3 children born are estimated to be missing either one or more vaccines, while 1 in every 10 children are part of a zero dose children cohort. Nearly one-third of the children are subjected to a risk of measles, and because of the overall compromised scenario, Lebanon has faced its first devastating outbreak of Cholera in 29 years. Cumulatively, the country stands vulnerable to multiple VPD (Vaccine Preventable Disease) outbreaks, including polio, measles, etc.

To minimize the risk of VPD outbreaks and make immunization more accessible, the MoPH, UNICEF, and the Lebanese Red Cross (LRC) have joined hands to identify high-risk areas, i.e., areas with a high number of missed or dropped out children. Nine priority districts were identified initially in early 2022; to further intensify the efforts in consultation with district officers, pockets with more urgent need of interventions were identified within these nine districts to ensure that the immunization services are delivered closer to the most vulnerable populations.

Before the commencement of each outreach session, LRC through its network of Volunteers on a national scale, would create awareness of and involvement in activities through house-to-house/door-to-door visits by informing and mobilizing parents and engaging with community leaders, municipalities, schools, religious leaders, etc.

In order to utilize immunization as an entry point for the delivery of a diverse range of healthcare and additional services, a multifaceted coordination strategy was put in place under the aegis of the Ministry of Public Health (MoPH). This involved formalizing a technical and financial collaborative agreement between UNICEF and the Lebanese Red Cross (LRC). Additionally, the MoPH spearheaded the creation of a working group comprising representatives from each participating

organization. This group was involved in the ongoing monitoring of the initiative's implementation, identification of operational challenges, and the generation of monthly progress reports. Adaptation plans were formulated as needed based on these assessments. To further support the endeavor, UNICEF conducted periodic field visits to furnish on-site assistance as necessary. This systematic approach was designed to ensure the seamless integration and success of the initiative.

In the development of the integration plan, the Ministry of Public Health (MoPH) collaborated closely with UNICEF and the Lebanese Red Cross (LRC), as UNICEF is the lead partner to MoPH on immunization with a focus on strengthening primary healthcare services in Lebanon. Additionally, the organization leads the education sector in Lebanon and implements various initiatives for child protection, WASH, and other interventions around mothers and children in Lebanon. On the other hand, the LRC is distinguished as one of Lebanon's most trusted non-governmental organizations and is renowned for its emergency response capabilities. With a robust network of over 12,000 community-based volunteers, the LRC serves as the first responders in times of emergencies. Moreover, the organization also operates the majority of the ambulance services in the country, further solidifying its credibility among local communities. Therefore, the collaborative efforts leveraged the unique strengths of each partner to develop a comprehensive approach to integration of healthcare and other services in Lebanon.

The main aim of using 'Immunization as an Entry Point (IaEP)' during these visits was to utilize the available resources to create awareness and linkages to other healthcare services than immunization. This was done by providing integrated and age-appropriate MNCH messages beyond mobilization for the upcoming immunization session. COVID-19- and Cholera prevention-related messaging and promotion of COVID-19 vaccination became an integral part of the entire intervention as standalone COVID-19 interventions were not being received well by the community. The same visits were also used during the cholera outbreak to sensitize the community on prevention, early detection, and care seeking behavior.

The approach was to use 'Immunization as an Entry Point (IaEP)' for other health and beyond-health interventions during the time available when parents/caregivers and children were at a session site. The pre-vaccination waiting time, during immunization time, and post-immunization observation time were key opportunities identified to provide other services and open doorways for referral and linkages. In a regular outreach session, the pre-vaccination waiting time averaged 15 min followed by 5–10 min of time for vaccination (depending on the number of vaccines to be administered) and followed by a post-vaccination observation time ranging 20–30 min. Overall, every parent/caregiver was at the session site for 45–60 min, and we managed to use this time for IaEP. It is important to state that the intervention was designed with a clear understanding that all services of PHC or comprehensive interventions of each program cannot be provided at the immunization session, and the intention was only to create 'Entry Points' so that linkage to

other services can be established. It is essential to note that ensuring parents/caregivers stay at a session beyond 45–60 min becomes challenging and leads to a drop in participation. Another important fact to note is that post-vaccination, children and young infants often cry, and parents/caregivers are engaged in calming the child. Therefore, a delicate balance of limited information, messaging, and interventions needs to be planned to ensure effective uptake. We used this opportunity to discuss and screen children and identify challenges in the domains of education, malnutrition, and maternal and child health and finally link the identified beneficiaries to relevant departments and child welfare schemes. UNICEF has a child-centric approach and multiple levels of intervention for various domains ranging from health to education, child and social protection, disability, and gender inclusion, and it has become an effective platform for integration and linkage.

Integration of the other services with immunization can help to address the major challenges faced by communities, i.e., access to health facilities due to the total absence of public transport and the high cost of travel within the context of shrinking income. Also, the rising trust in the public routine immunization system of parents can further add impetus to other initiatives adopted by these families if these services are advocated for through immunization service delivery platforms. The domains mentioned below were explored for possible integration with the immunization services either for delivery of service, creating awareness advocacy, or for screening purposes.

2.1. Registration of missed children

Lebanon maintains digital health records for every child seeking services from the public health system. The immunization status of every child is entered in the PHENICS (Primary HealthCare Network Information and Communication System) or its mobile program MERA (Mobile EPI Registry Application). During outreach intervention, all children missing from the database were entered and their vaccination records were updated. Once the child is part of the database, it becomes easier for the PHCC to follow up with parents for the next vaccination, identify drop-out cases, and plan interventions. The MoPH and UNICEF also developed a mobile application for parents called 'Sohatona' to track the vaccination status of their children, and this is linked to a PHENICS/MERA database. During the vaccination session, parents were informed about the Sohataona application and were updated about the PHCC network, the nearest PHCC, and the services offered. All PHCC-related details, including geo-locations on the map, are also available in the Sohataona application for easy navigation by parents/caregivers.

2.2. Malnutrition

Healthcare workers and volunteers involved in outreach immunization activities were trained in using MUAC

(Mid-Upper Arm Circumference) tape to screen children between 6 and 59 months of age. During the screening process, children identified as malnourished were referred to the ongoing malnutrition management program by the MoPH and supported by UNICEF. The screening was done when the child reached the session site and occurred during the process of registration. The result of the screening was added to the individual digital database along with vaccination details using the MERA application. Children were also provided with micronutrient supplements and parents/caregivers were oriented on frequency and administration.

2.3. COVID-19

With the multiple ongoing crises, discussions related to COVID-19 in 2022–23 became a low priority for individuals and communities and attempts to create exclusive COVID-19-related interventions, including COVID-19 vaccination, were not gaining any traction from the community. We integrated COVID-19 prevention with motivation for getting a COVID-19 vaccine and facilitating registration and referrals for vaccination, and this became a part of the integrated outreach intervention. This led to the preservation of pandemic-related intervention, mobilizing the community for the purpose of COVID-19 vaccination and better acceptance of continuous dialogue around COVID-19 as part of the overall preventive-promotive health discussion.

2.4. Education

One of the major priorities and commitments for UNICEF is school education for all children. The outreach immunization program provided a noteworthy prospect to identify the out-of-school children when they come for vaccination thus acting as an 'Entry Point'. Identification of areas with large numbers of out-of-school children is also supported in the prioritization of education-related interventions. The out-of-school children were connected to various ongoing interventions by UNICEF and other stakeholders to facilitate school enrolment and other interventions to facilitate children in need of support.

2.5. Child welfare

UNICEF closely works with communities to ensure that the most vulnerable children are supported and protected. UNICEF's cash incentive scheme "Haddi" for the most vulnerable children became a proxy indicator to check if outreach sessions are reaching the most vulnerable areas while ensuring the most marginalized children are vaccinated and protected from deadly disease. Families enrolled under the "Haddi" scheme were informed about the upcoming sessions in their area and were motivated to take their children for vaccination thus protecting them from diseases.

2.5.1. Children with disability/es

Children with any form of disability often face challenges in getting vaccinated due to issues related to access as well as prioritization. The integrated outreach intervention focused on identifying children with special needs and motivating their parents to get them vaccinated. The activity supported reaching out to a large number of missing children with disabilities. Although the intervention did not create a separate indicator to document the number of "children with special needs" getting vaccinated, the on-ground implementation indicated successful outreach to many such children. Immunization can also become an entry point to link children with special needs to relevant intervention and support schemes by the Government and partners.

2.6. Maternal and child health

Parents and caregivers attending immunization sessions were provided with context and audience-specific integrated messaging around breastfeeding, weaning, childcare, identification and timely health seeking for basic child health disease, etc. This integrated messaging focused on updating mothers with age-specific preventive and promotive behaviors for the betterment of their own health as well as that of their children, key awareness generation, and information related to health-seeking behaviors for PHCs.

2.7. Management of other disease outbreaks

During the intervention, Lebanon witnessed a rapidly spreading Cholera outbreak 29 years after the last reported case. Immunization sessions were used as an entry point to address the cholera outbreak as well. While engaging with the community for immunization, awareness generation on cholera was incorporated to make the community aware of prevention, symptoms, and the need to seek immediate care. The community engagement team also carried ORS sachet and an additional screening questionnaire was added to identify any family member suffering from symptoms of Acute Watery Diarrhea (AWD). For any symptomatic individual, five ORS sachets were provided, and family members were oriented on the creation and use of ORS solutions along with information related to health facilities managing cholera cases. The information on potential cases was also shared with the surveillance and health teams for follow-up.

The integrated approach identifies indicators for each of the domain areas, and the absolute numbers of beneficiaries reached against each indicator, and this will support the quantification of the efforts made to provide comprehensive services to children, using immunization as an entry point.

3. Results

The efforts to reach and vaccinate missed children resulted in vaccination of >200,000 children and adolescents from Dec 2021

to March 2023, during the phased scale-up approach. In addition, as reflected in [Table 1](#), the supplementary activities added after September 2022 resulted in reaching out to nearly 798,125 caregivers for MNCH-related services, making this the domain's biggest beneficiary from the integration efforts. Other noteworthy results were reaching 363,926 individuals with cholera prevention information, and 322,284 individuals were reached for COVID-19-related messages. A lot of effort was put into integrating education, child protection, and nutrition linkages, and analysis shows that although considerable reach could be attained through an integration approach, more strategies and implementation methodologies can be looked into for further reach.

4. Discussion

Compared to Lebanon, many countries face the challenge of limited healthcare resources, and many policy- and decision-makers are faced with decisions on where and how to prioritize resources for certain healthcare services and technologies for different groups in an equitable manner to achieve more effective care. In these scenarios, using an immunization platform to develop a minimum package of essential healthcare and child welfare services, ensuring availability and accessibility for the beneficiaries, can contribute to improving the overall childcare spectrum.

Providing additional integrated services (such as bed nets/hygiene kits or other relevant commodities) may provide increased motivation to caregivers to fully immunize their

children. Integrated service delivery may help to increase efficiency as operational costs are shared across programs and could therefore contribute to their long-term sustainability.

Improving links between immunization programs and other services (nutrition, education, ECD, MNCH) can help ensure that each contact with a child for immunization acts as an 'entry point' for multiple other interventions in health and beyond health domains. Similarly, cross-linkage between other interventions interacting with children and adolescents can be used to screen and improve immunization coverage, especially for booster dose vaccination.

Integrated service delivery may reduce the costs of reaching hard-to-reach populations in the future. The global approach of "life-course vaccination" and with introduction of new vaccines targeting extended age groups, such as HPV vaccine for adolescents, provide an opportunity to reach these populations with broader health interventions (such as deworming, sexual, and reproductive health education, etc.), which may, in turn, also increase demand for vaccination. Ongoing scientific advancement in new ways of vaccine delivery, for example, microarray patches or compact prefilled auto-disable devices, will simplify the delivery of immunizations in the future and may further facilitate integrated service delivery at the facility and community level.

It is important to note that under the concept of "integration", services cannot and should not be packed in one service delivery model or intervention, especially at community-level intervention. Every intervention has some unique pre-requisite to successfully reach the desired output, however, attempts should be made to create inter-linkages and gateways to connect the beneficiary with a host of other interventions benefiting children, adolescents, women, and the community at large. This approach supports the identification of individuals and populations in need of specific services and facilitates better distribution of limited resources to already identified individuals rather than starting afresh, e.g., screening children for malnutrition during the immunization session supports identification of malnourished children and directly connects them with nutrition-led intervention to treat these children without additional financial investment in screening thus effectively utilizing nutrition funding. In addition, geographies reporting a high number of malnourished children could be a focus area for detailed nutrition intervention.

Lack of integration among existing healthcare systems may serve as a major limiting factor in future pandemics, as an unintegrated system does not have the capacity to prevent cases from spreading rapidly and converting into an outbreak or potential epidemic or even pandemic.¹ Well-integrated healthcare systems are people-centric responsive units that can be easily leveraged for better outcomes during future pandemics through expanded surveillance through existing systems using digital technology to identify and communicate epidemiological changes and trends. Integration can be key for better outbreak responses in the future through leveraging of existing linkages among different healthcare delivery systems. With immunization programs being one of the most cost-effective public health interventions reaching a maximum number of people and families at the community level and vaccination now being an integral component of any future

TABLE 1 Outcome of integration activities.

Domain	Indicators	Number
Immunization	Number of missed children and adolescents reached with vaccination	2,24,574
	Number of missed children receiving first dose of DPT-containing vaccine as per the national dropout protocol	25,219
	Number of missed children receiving the first dose of Measles vaccine	14,070
	Number of children receiving their first dose of IPV (Injectable Polio Vaccine)	11,933
Nutrition	Children screened with MUAC tape	87,724
	Children identified with moderate malnutrition and referred to Health Facilities for management of malnutrition	297
	Children identified with severe malnutrition and referred to Health Facilities for management of malnutrition	42
	Children provided with micronutrient supplements	5,691
Education	Identified and referred out of school children	2,482
Child protection	Number of vulnerable children enrolled under cash incentive scheme reached and vaccinated	6,482
Maternal and child health	Number of parents/caregivers reached with integrated MNCH messaging	7,98,125
COVID-19	Number of individual reached with awareness generation related to prevention of COVID-19 and promotion of COVID-19 vaccination	3,22,284
Cholera outbreak	Number of individuals reached with information related to Cholera prevention and control	3,63,926

pandemic response, using immunization as an entry point for regular public health programs as well as an effective route for pandemic/epidemic/emergency responses is well demonstrated through intervention.

Successful integration of other health and non-health interventions with immunization requires a series of carefully planned and implemented steps, including “selecting interventions that can be feasibly integrated; instituting intersectoral coordination at all program levels; exploring funding for integrated interventions; conducting joint training and supervision of health workers and program managers; ensuring the participation of community based organizations, leaders, and volunteers; and establishing a robust monitoring and review mechanism”.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

On behalf of UNICEF Lebanon, ethical approval or specific consent procedures were not required for conducting or reporting the data from this study. The authors endorse that the study does not involve clinical interventions or the use of human identifier data, nor does it involve direct interventions or the use of personal data that may have probable ethical considerations, such as privacy, confidentiality, informed consent on participants or communities involved.

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Author contributions

BK, RSH, and SS contributed to the conception and design of the study. FM, KC, and DK organized the database. WK and FM compiled the statistical information. SS wrote the first draft of the manuscript. BK, KA, EH, TT, and CEK contributed to writing different sections of the manuscript. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Routine immunization experience and practices during the COVID-19 pandemic of caregivers attending a tertiary hospital in Cape Town

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Introduction: Immunizations are successful, cost-effective interventions for the control of infectious diseases and preventing mortality. Lockdown restrictions during the COVID-19 pandemic had adverse effects on child-health including access to immunizations. Our study aimed to document immunization status, describe caregiver experiences around accessing immunizations during the COVID-19 pandemic and identify any significant factors associated with immunization status.

Methods: Caregivers, with children between the ages of 10 to 33 months, attending Tygerberg Hospital Paediatric Department were invited to complete an anonymous survey from 15th September–15th December 2022. Data was captured using a REDCap questionnaire and analysed using Stata Version 17.

Results: 171 caregivers completed the survey. Immunizations were up to date in 81%. Most (155, 88%) agreed it was important to immunize their child. A third of caregivers (55) felt it was unsafe to attend the clinic and 37% (62) agreed it was difficult to attend. Caregivers receiving a social grant ($p = 0.023$) or who felt safe attending clinic ($p = 0.053$) were more likely to be up to date with immunizations. Three-quarters (128, 78%) were aware of recommendations to continue immunization. These caregivers were more likely to think it was important to immunize on time ($p = 0.003$) and to receive family encouragement ($p = 0.001$). Caregivers were more likely to attend clinic if they felt it was important to vaccinate on time ($p < 0.001$) or felt safe attending clinic ($p = 0.036$).

Conclusion: Immunization rates were higher than expected but below global targets. Although caregivers feel immunizations are important, unknowns still instilled fear of attending clinics. Social factors such as family support and social grants improve vaccine seeking behaviour.

KEYWORDS

childhood immunizations, immunization practices, caregiver experiences, COVID-19, pandemic

1. Introduction

Immunizations are recognized globally as one of the most successful and cost-effective interventions for the control of infectious diseases. Annually immunizations prevent 2–3 million deaths in children under five years of age (1, 2). They improve health equity across low-, middle- and high-income countries by reducing disability and mortality (3). Immunization programs have been implemented worldwide to ensure immunizations at every contact with the healthcare system (4, 5).

Fifty-six percent of global deaths in children under five years of age occur in Africa (1, 3), many of which could be prevented by immunizations. While overall global immunization rates reach 86%, Africa lags behind with the lowest rate of 76% (1, 3). In South Africa, the 2016 Demographic and Health Survey (DHS) revealed that up to 40% of the country's children are not fully immunized for their age (5).

The COVID-19 pandemic increased the burden on healthcare systems and had severe consequences related to rigid lockdown restrictions, social distancing, and prolonged school closures resulting in adverse effects on the pediatric population (6, 7). One of the consequences of lockdown restrictions was a decrease in childhood immunization rates. A recent systematic review showed a relative median decline of 11%, affecting upper and lower-middle income countries (decline of 14% and 18% respectively) more than low-income countries (decline of 3%) (8). It is estimated that during 2020, 30 million children missed their third diphtheria-tetanus-pertussis vaccine, and 27 million children missed their measles vaccines (9). The United States and Singapore documented a drop in measles vaccination, whilst 40 million children in Pakistan missed their polio immunization due to the cessation of vaccination campaigns in April 2020 (10–12).

In South Africa various levels of public restrictions were implemented from March 2020. These levels varied according to the prevalence of COVID-19 infections and included evening curfews, restrictions of public events and gatherings as well as alcohol and tobacco sales. Mask wearing was compulsory, and citizens were requested to limit movement and only leave their house for emergencies. Government recommendations were that childhood vaccination should continue (13). Despite this South Africa also reported a decrease in immunization rates. The National Department of Health reported a decrease in national immunization coverage from 82% in April 2019 to 61% in April 2020 during high levels of restriction. Most concerning was the sharp decrease in second dose measles vaccine coverage rates from 77% in April 2019 to 55% in April 2020 with the Western Cape Province dropping to a low of 48% during that period (14).

Reasons for low immunization rates prior to the COVID-19 pandemic have been well documented and are largely related to sociodemographic factors, including extremes of maternal age, limited education, single parents, and low family income (1). Limited parental knowledge about immunization benefits is the most frequently reported factor that influenced childhood immunization uptake (1, 3, 5). In South Africa lack of parental awareness of immunization schedules, inadequate training of healthcare workers and the high workload of women have been identified as negative influencers of immunization coverage (15, 16).

Fear of acquiring COVID-19 infections has been reported as a significant factor behind falling immunization rates during the pandemic (17–20). Whilst parental perspectives on the importance and effectiveness of childhood immunizations remained unchanged, they experienced many barriers during

lockdown periods that influenced their motivation and the opportunity to vaccinate their children (18, 19, 21). These barriers included uncertainties about operational hours of clinics as well as uncertainties around booking vaccination appointments (18, 19).

Whilst there has been data published on parental experiences and perceptions around accessing immunizations during the COVID-19 pandemic in other countries, none have been published in the South African setting. This study aimed to document immunization rates within our setting and describe caregiver experiences around accessing immunizations during the COVID-19 pandemic. In addition, it aimed to identify any risk factors pertaining to a lack of knowledge of government recommendations as well as immunizations not being up to date.

2. Materials and methods

This was an explorative descriptive study undertaken at Tygerberg Hospital, a tertiary referral hospital in the Cape Town metropole. The paediatric department provides varying levels of care to half of the Western Cape Province's paediatric population <14 years, estimated at 787 000 in 2016 (22). Approximately 8 500 admissions and 1 400 ambulatory patients were seen in the wards surveyed during 2022 (23).

We surveyed caregivers with children between the ages of 10 and 33 months attending the emergency, ambulatory services and paediatric wards over a 3-month period starting on 15 September to 15 December 2022. Age was calculated to include children requiring immunization during the COVID-19 pandemic starting from March 2020 to December 2021, when lockdown restrictions were eased. Caregivers of children admitted to high care and intensive care areas were excluded due to severity of disease and parental concern.

Data was collected by trained medical students or the principal investigator using an anonymous structured questionnaire administered electronically in the language of their choice to caregivers accompanying their children to the wards. A REDCap survey link provided access to the questionnaire and data was saved automatically.

2.1. Data collection tool

The anonymous survey consisted of four sections: compulsory informed consent; a research questionnaire consisting of demographic details such as age, sex, education, employment status and family size; questions centred around immunization experiences and perceptions which were structured in a 5-point Likert question format (strongly agree to strongly disagree) and finally information around immunization status obtained from the road to health booklet (RTHB). The RTHB is a handheld booklet given at birth to all caregivers in South Africa to record their child's growth parameters, receipt of immunizations and other healthcare interventions.

The questionnaire was adapted for our South African setting from a previously validated questionnaire which assessed the impact of COVID-19 lockdown on immunization behaviour in caregivers living in London ([Supplementary Data Sheet S1](#)). Consent for use was obtained from the author (19).

2.2. Sample size calculation and data analysis

Sample size was calculated based on the reported data suggesting a drop in the second-dose measles coverage in the Western Cape to 48% (14). A sample size of 160 participants was required to achieve a desired precision of $\pm 8\%$ for a 95% confidence interval. Sample size estimation was done using WINPEPI (www.brixtonhealth.com/pepi4windows.html).

Data was extracted from REDCap and analysed using Stata 17 (College Station, Texas 77845 USA). For associations the Likert score was condensed for ease of analysis into agree (strongly agree and agree) and did not agree (neutral, disagree, strongly disagree) for ease of analysis.

Continuous variables were summarised using mean (standard deviation) and compared using a t-test. Categorical variables were summarised using count (percent) and compared using chi-squared test or Fisher's exact test. We report immunization rate with the corresponding 95% confidence interval. Immunizations up to date were defined as children who had received all their vaccinations on time during the pandemic as well as those who had delayed immunizations but had now caught up the required schedule for their age. A p value < 0.05 was considered statistically significant.

We tested the association between binary outcome variables and exposure of interest using univariate and multivariate binomial regression and reported relative risks as measures of association.

Approval from the Human Research Ethics Committee (HREC) at Stellenbosch University was obtained. HREC S22/06/013_COVID-19.

3. Results

171 caregivers completed the survey over the three-month period. There were 10 incomplete responses but entered data was included in the analysis. Demographic details of caregivers are shown in [Table 1](#). The majority 159 (93%) of caregivers were female and had a mean age of 30.4 (± 8.3) years. One hundred and forty-five (88%) caregivers had their RTHB present, and 132, 81% (95% CI 74%–86%) children's immunizations were up to date at the time of the study ([Table 1](#)). Three quarters (128, 78%) of caregivers were aware of the government recommendation to continue routine immunizations during the COVID-19 pandemic.

3.1. Caregiver experiences

Caregiver experiences during the COVID-19 pandemic and periods of restriction are shown in [Figure 1](#). Caregiver

TABLE 1 Demographic details of caregivers and immunization status of children.

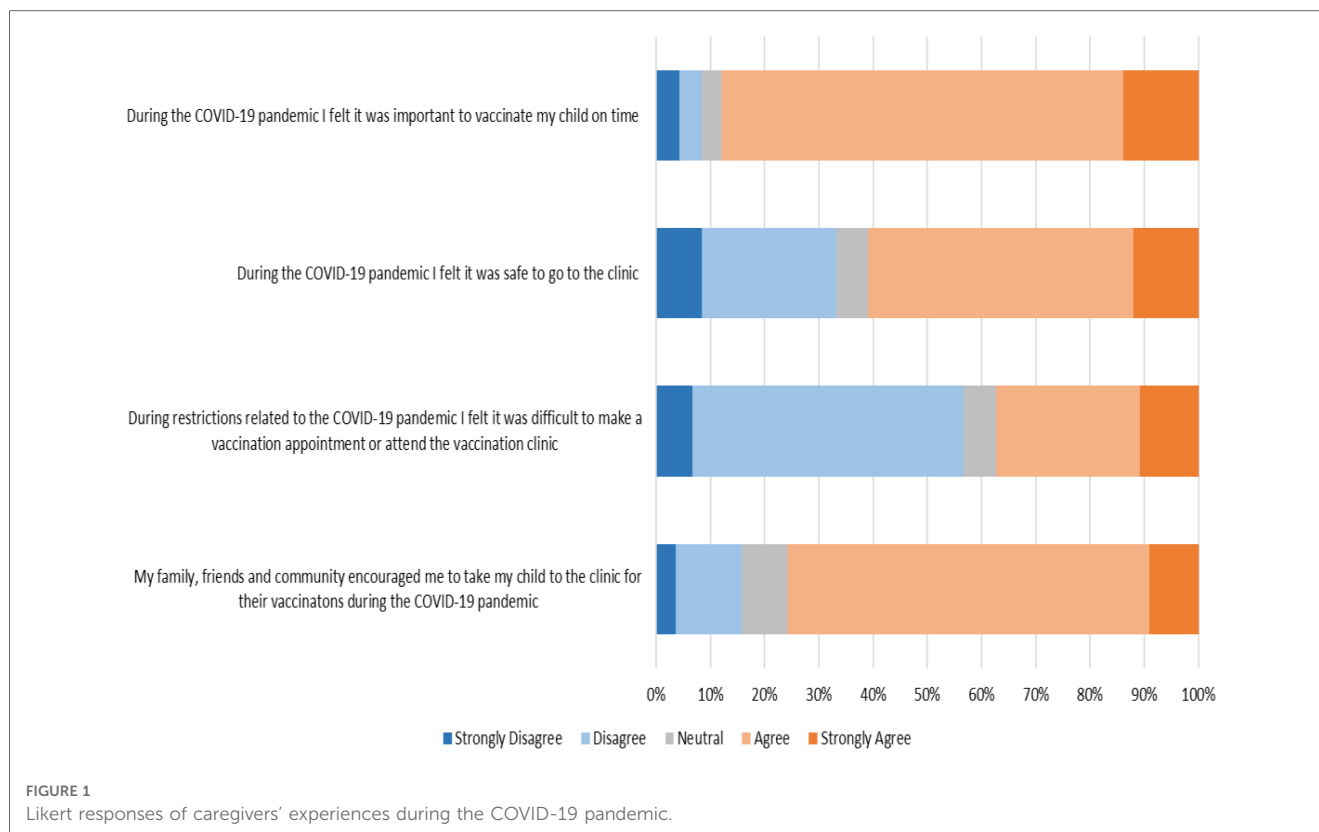
		<i>n</i> (%)
Sex (<i>n</i> = 171)	Female	159 (93.02%)
	Male	12 (6.98%)
Residence (<i>n</i> = 171)	Within Cape Metro	144 (84.21%)
	Outside Cape Metro	27 (15.79%)
Level of Education (<i>n</i> = 170)	Junior (Grade 1–7)	9 (5.29%)
	High School (Grade 8–11)	76 (44.71%)
	Grade 12	64 (37.65%)
	Tertiary diploma or degree	21 (12.35%)
Relationship Status (<i>n</i> = 168)	With a partner	100 (59.52%)
	Single parent	46 (27.38%)
	Raising my grandchild	14 (8.33%)
	Raising a family member	3 (1.79%)
	Foster parent	2 (1.19%)
	Other	3 (1.79%)
Employment (<i>n</i> = 168)	Fulltime	48 (28.57%)
	Part-time	29 (17.26%)
	Unemployed with partner support	43 (25.60%)
	Unemployed with family support	23 (13.69%)
	Unemployed with no support	11 (6.55%)
	Other	14 (8.33%)
Government Grant (<i>n</i> = 168)	Yes	99 (58.93%)
	No	69 (41.07%)
Number of Children (<i>n</i> = 168)	One	50 (29.76%)
	Two	61 (36.32%)
	Three	37 (22.02%)
	Four or more	20 (11.90%)
RTHB present (<i>n</i> = 164)	Yes	145 (88.4%)
	No	145 (88.4%)
Immunisations status (<i>n</i> = 162)	Always up to date	129 (79.63%)
	Delayed but catch up complete	3 (1.85%)
	Delayed catch up in progress	10 (6.17%)
	Not up to date	17 (10.49%)
	Unable to recall	3 (1.85%)

RTHB, road to health booklet.

experiences were mostly positive with 153 (88%) of caregivers who either agreed or strongly agreed that it was important to take their child to the clinic for immunizations. Caregivers felt that family members encouraged them to take their child to the clinic, 125 (75%) agreed or strongly agreed with the statement. A third of patients (55, 33%) did not feel it was safe to attend the clinic and 62 (37%) either agreed or strongly agreed that it was difficult to make an appointment or attend the vaccination clinic over the lockdown period.

3.2. Risk factors for immunization

When trying to identify risk factors for immunizations not being up to date, we looked at demographic factors, caregiver experiences, knowledge of governmental recommendations and whether the RTHB was present ([Table 2](#)). Receiving a government support grant was the only significant factor, caregivers receiving a grant were more likely to be up to date with immunizations than those who did not (79, 88% vs. 50, 72%; $p = 0.023$). Other factors



associated with immunizations being up to date was caregivers who felt safe to attend the clinic ($p = 0.053$), caregivers with lower education level ($p = 0.055$) and caregivers with less than four children ($p = 0.052$), these however did not reach significance.

Receiving a social support grant reach significance on both univariate, relative risk 1.2 (95% CI 1.02–1.42) and multivariate analysis, after adjusting for age, gender, and employment status, RR 1.22 (95% CI 1.05 to 1.42), $p = 0.001$.

3.3. Influence of caregiver experiences on taking children to the clinic

Caregivers who agreed that it was important to immunize on time were more likely take their children to the clinic (139, 97% vs. 12, 60% $p < 0.000$). Those caregivers who felt safe were also more likely to take their child to the clinic (95, 96% vs. 56, 86% $p = 0.036$). Other caregiver experiences did not influence whether they took their child to the clinic (Table 3).

3.4. Influence of knowledge of government recommendations

Caregivers who felt it was important to immunize their children on time and who received family encouragement were more likely to know the government recommendations to continue vaccination ($p = 0.003$ and $p = 0.001$). Other factors did not reach significance (Supplementary Table S1).

Only 13 (7%) of caregivers did not attempt to go to the clinic during the COVID-19 pandemic. Over half of these caregivers (10, 60%) reported feeling scared of contracting COVID-19. Half (7, 53%) of the caregivers who did not attend the clinic caught up their immunizations after restrictions were lifted. Seventy percent (5) of these caregivers agreed that it was easy to start the catch-up process at the clinic. Only 5 (50%) caregivers who did not catch up responded to the reasons they felt it was difficult, of these 3 caregivers (60%) felt the waiting queue was too long, the rest did not disclose reasons for difficulty catching up immunizations.

4. Discussion

To our knowledge, this is the first study that describes routine immunization experiences and practices of South African caregivers during the COVID-19 pandemic.

We found that 81% of caregiver's immunizations were up to date which was higher than the Western Cape provincial average of 48% for measles vaccinations, as reported in the press during the beginning of the pandemic (14). Our results are in keeping with other studies which found that disruptions to childhood immunizations were higher in the first months of the pandemic and normalized towards the end of 2020 (5, 8, 23). Data from the Western Cape Provincial Annual Health report documents immunization coverage under one year of age in 2019/2020 as 82.2% and 2020/2021 as 82.9% (24), showing that overall immunization rates were maintained in the province during the pandemic.

TABLE 2 Risk factors for not having immunizations up to date.

		Immunisations up to date		
		No n (%)	Yes n (%)	p-Value
Age (years)	Mean (std.deviation)	29.9 (\pm 5.4)	30 (\pm 8.2)	0.860
Sex	Male	1 (8.33%)	11 (1.670%)	0.466
	Female	29 (19.72%)	118 (80.20%)	
No. of children	One	5 (10.20%)	44 (89.80%)	0.052
	Two	13 (22.41%)	45 (77.59%)	
	Three	3 (8.82%)	31 (91.18%)	
	Four/more	6 (33.33%)	12 (66.67%)	
Education	School	20 (14.49%)	118 (85.51%)	0.055
	Diploma/Postgraduate	7 (33.30%)	14 (66.67%)	
Relationship status	Raising child with partner	15 (15.79%)	80 (84.21%)	0.416
	Single parent	10 (22.73%)	34 (77.27%)	
	Raising someone else's child (grandchild, foster etc.)	2 (10.00%)	18 (90.00%)	
Employment	Employed	14 (18.92%)	60 (81.08%)	0.544
	Unemployed	13 (15.29%)	72 (84.71%)	
Government Grant	Yes	11 (12.22%)	79 (87.78%)	0.023
	No	19 (27.54%)	50 (72.46%)	
Area of residence	Inside Metro	22 (16.54%)	111 (83.46%)	0.463
	Outside Metro	5 (19.23%)	21 (80.77%)	
Aware of Recommendation	Aware	21 (17.07%)	102 (82.93%)	1
	Not Aware	6 (16.67%)	30 (83.33%)	
Felt safe to go to the clinic	Disagree	15 (24.19%)	47 (75.81%)	0.053
	Agree	12 (12.37%)	85 (87.63%)	
Important to Immunise on time	Disagree	3 (15.00%)	17 (85.00%)	1
	Agree	24 (17.27%)	115 (82.73%)	
Difficult to make an appointment	Disagree	14 (14.00%)	86 (86.00%)	0.192
	Agree	13 (22.03%)	46 (77.97%)	
Encouraged by Family	Disagree	7 (18.92%)	30 (81.08%)	0.803
	Agree	20 (16.39%)	102 (83.61%)	
Has RTHB with them	Yes	24 (16.90%)	118 (83.10%)	1
	No	3 (17.65%)	14 (82.35%)	

RTHB, road to health booklet.

P-values in bold indicate reached significance.

TABLE 3 Experiences, perceptions and if they took the child to the clinic.

		Took child to the clinic		
		Yes	No	p-value
Parents felt safe	Disagree	56 (86.15%)	9 (13.85%)	0.036
	Agree	95 (95.96%)	4 (4.00%)	
Important to vaccinate on time	Disagree	12 (60%)	8 (40.00%)	0.000
	Agree	139 (96.53%)	5 (3.47%)	
Encouraged by family	Disagree	33 (84.62%)	6 (15.38%)	0.082
	Agree	151 (92.07)	13 (7.93%)	
Difficult to make an appointment	Disagree	97 (94.17%)	6 (5.83%)	0.236
	Agree	54 (88.52%)	7 (11.48%)	
Aware of Government Recommendation	Yes	120 (93.75%)	8 (6.25%)	0.162
	No	31 (86.11%)	5 (13.89%)	

P-values in bold indicate reached significance.

The service team responsible for the Expanded Programme on Immunizations (EPI) maintained immunization coverage even with the added COVID-19 challenges. This was after the Western Cape implemented strategies to improve the immunization services at the facilities and to enhance safety for caregivers by minimising the risk of acquiring infection.

These measures included appointment systems to minimise waiting time and the creation of secondary sites where “healthy” clients could receive preventative services such as immunizations (Sonia Botha, Provincial EPI co-ordinator, 24/05/23) (25).

The Western Cape EPI task team undertook various campaigns to maintain immunization rates and services within the province. These included regular printed media as well as social media and radio adverts highlighting the importance of attendance and immunizations. The public-private partnerships were enhanced, and child health services were prioritized and protected (25).

Other strategies included recalling caregivers and outreach for catch up-immunizations with assistance of community-based services (Sonia Botha, Provincial EPI co-ordinator, 24/05/23) (25). These strategies are likely to have contributed to the high rate of awareness of the government recommendations to continue vaccination during the lockdown period. More than three-quarters of caregivers were aware of the recommendations, which is in keeping with data from the United Kingdom where 74.4% of survey respondents were

aware of their national recommendations to continue routine vaccination practices (19).

Despite our higher-than-expected immunization rates, it is important to note that these figures still fail to meet the global EPI targets of 90% nor the Western Cape EPI targets of 86% (24). The recent measles outbreak in South Africa which started in October 2022 suggests that immunization rates remain suboptimal (26). Strengthening of EPI services is needed via improved healthcare strategies to raise awareness and promote access to vaccinations.

4.1. Caregiver experiences

4.1.1. Safety

A third of caregivers in our study did not feel it was safe to attend the clinic. A systematic review examining reasons for reduced uptake of routine immunizations in low-middle income countries, reported fear of contracting the COVID-19, was the primary reason affecting health seeking behavior (27). Eighty percent of caregivers in India and 61% of Saudi Arabian caregivers reported fear of contracting COVID-19 during the pandemic (27, 28). High income countries including the UK and the USA also reported that parental hesitancy to visit immunization facilities was due to perceived fear and risk of acquiring COVID-19 infection (17–20).

As expected, there was a trend that caregivers who felt safe to attend the clinic were more likely to have their children's immunizations up to date although this did not reach statistical significance. Mishra et al. found that 83% of caregivers in Eastern India felt that safety was more important than vaccination (27). Although 72% of survey respondents in England felt it was safe to attend the clinic, these caregivers reported to have delayed immunizations initially but once attending the facility reported positive experiences (19). In these specific studies safety measures were in place, such as screens between patients, social distancing, donning of protective gear by staff and the availability of hand sanitisers.

Prior to the pandemic and currently, there are various safety concerns of caregivers and their children attending primary care facilities in South Africa. These range from exposure to other infectious agents such as Tuberculosis, the lack of child friendly spaces as well as exposure to violence in the community (29). Thus, it is imperative to prioritise the safety of caregivers and children, in order to improve access to immunizations and other primary health care services.

4.1.2. Importance

Over 80% caregivers agreed that it was important to take their child to the clinic for immunizations on time, 85% of parents in the UK felt similarly (19). Literature suggests that parental perspectives on the importance of immunizations remained the same before and after the pandemic (18, 19, 21, 30). Caregivers deliberately delayed routine immunization out of fear of exposure to COVID-19 infection, rather than a change of attitude towards vaccination (17, 18, 20). Caregivers

understood the importance of vaccinations in preventing disease, but it was weighed up against perceived risks of contracting the COVID-19 virus. While there was fear of acquiring COVID-19, caregivers felt that acquiring a vaccine preventable disease would be less likely during periods of restriction as children were isolated from others (19).

We did not look at specific barriers that influenced caregiver motivation to immunize their children however over a third strongly agreed that it was difficult to make an appointment or attend the immunization clinics over the lockdown period. These have previously been reported in the UK and Saudi Arabia as barriers to accessing immunizations (18, 19).

Family encouragement to take children to the clinic during the lockdown period was high. It is evident that family plays a role in decision making around seeking health services. A study in Indonesia showed that lack of support from parents, husbands, and friends led to caregivers not seeking to provide complete primary immunizations to their children (31). Family support and encouragement are critical factors for enabling completion of the immunization schedule. In South Africa, cultural norms are that the family participates in caring for and raising a child, thus having a great influence on decisions around immunizations (31). Forty one percent of households in South Africa are headed by women, with the lack of partner support particularly identified as a reason for children missing immunizations (5, 15, 32). Supportive partners can greatly enhance knowledge around immunizations as partners jointly improve health seeking behaviour for their offspring (1, 31).

4.2. Factors associated with immunization rates

Caregivers who received social support grants were more likely to be up to date with immunizations on multivariate analysis. South African children under the age of 18 qualify for a social support grant that is paid to the primary caregiver provided they pass the means test (33). The means test determines whether a person qualifies to receive a grant by evaluating income and assets (33). Social support grants have been shown to increase likelihood of clinic visits for monitoring of weight, nutrition, and health (34). They help alleviate poverty and improve nutritional and health outcomes as grants are spent on food, education, and basic services. This is especially impactful in female-headed households (35, 36). Caregivers responsible for children who qualify for a social support grant should be encouraged to apply to improve quality of life and healthcare outcomes.

Family size has previously been shown to influence immunization with support for both large and small families having better immunization rates (1, 37). Our study did not reach significance but there was a trend that families with four or more children were less likely to be immunized, supporting the notion that parents of larger families may have more daily tasks causing missed vaccinations (18, 28, 38). Our study showed that there was a trend that caregivers with post-secondary school

education were less likely to have immunizations up to date. This is in contrast to other studies in Africa which showed that parents with at least a primary or secondary school education, were more likely to fully immunize their children compared to parents with no formal education (1, 3, 5). We did not look specifically at no education in our study and post-secondary education numbers were low. Caregivers with a diploma and postgraduate degrees may have better access to growing social media influence on vaccine hesitancy and therefore choose to not take children for routine immunizations. An online survey conducted in China showed that parents with higher education levels were more likely to hesitate to immunize their children against COVID-19 (39). In India and Chennai there was increased vaccine hesitancy among parents belonging to an educated population, social media and television was the source for vaccine-related misinformation (40).

There was no difference in immunization rates within or outside the metro despite previous studies suggesting that distance to clinic may influence immunization rates (6). The Western Cape Province has an efficient community-based service in remote areas which includes home visits and encouragement of good healthcare practices and routine immunizations in children (41). These services may help improve immunization rates in hard to reach areas. There was no difference in immunization status according to knowledge of government recommendations around immunizations, previous studies showed increased immunization rates in those that knew the recommendations (19, 23). Parents in the UK were more likely to be aware of the government recommendation after an announcement by the public health emergency unit later in 2020 (19). Research by the South African department of Planning, Monitoring and Evaluation in 2021 highlights deep levels of distrust by the public in Government and public services (42). Despite this, regular presidential press statements and social media campaigns raised awareness around the pandemic regulations (43). Caregiver recall may have been influenced by the timing of our study which took place towards the end of the pandemic.

Few caregivers answered questions around not catching up their child's immunizations and we were therefore unable to make informed inferences, however caregivers who attempted catch up after delayed immunization felt that long waiting queues made the process difficult. This was previously identified as a barrier to routine immunization uptake (44).

5. Limitations

Our study has a number of limitations. The sample size was calculated from data at the time of the pandemic which suggested that immunization rates had dropped significantly, considering the higher vaccination rates we found, a larger sample size may have provided more accurate results.

This study was undertaken two years after the start of the COVID-19 pandemic, which may have recall bias from caregivers who had forgotten true perceptions at the time of COVID-19 lockdown. Although the study was done at a hospital which provides all levels of care, these caregivers were already in a

healthcare facility and may have better health seeking behaviours than caregivers in the community leading to an inflated immunization rate.

Despite these limitations our immunization rate was similar to the official rates reported by the provincial healthcare systems. Lastly, we used a quantitative survey to evaluate caregiver perceptions, the addition of a qualitative component may have given additional insights into parental perceptions and experiences.

6. Conclusion

We found an immunization rate of 81% which was higher than expected but below global targets. Although caregivers may feel that immunizations are important, unknown factors such as the COVID-19 pandemic may still instill fear of attending clinics, steps should be taken to mitigate perceived dangers at primary care facilities. Social factors such as family support and access to a social grant are likely to improve immunization seeking behaviour. There should be focussed efforts on improving social support of caregivers as well as providing clear information on clinic activities. Further studies examining caregivers' perceptions and practices when accessing routine immunization are needed to address lack of knowledge around immunization services and guide improved immunization targets.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

Approval from the Human Research Ethics Committee (HREC) at Stellenbosch University was obtained: HREC S22/06/013_COVID-19. The patients/participants provided their electronic informed consent to participate in this study.

Author contributions

HF and AM: came up with the concept. HF, AM, and TW: helped with the design of the study. HF: designed the database. AM: wrote the initial draft, HF and TW helped with manuscript revision and approved manuscript submission. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/frhs.2023.1242796/full#supplementary-material>

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Unfolding COVID-19 vaccine communication campaigns in China's neighborhoods: a qualitative study of stakeholders' narratives

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Introduction: The Chinese state has recently implemented the COVID-19 Vaccine Communication Campaign (CVCC) to counter vaccine hesitancy. Nonetheless, the extant literature that examines COVID-19 vaccine acceptance has less represented COVID-19 vaccine communication efforts.

Methods: To address this lacuna, we qualitatively explored how CVCCs were organized in Chinese communities by investigating 54 Chinese stakeholders.

Results: This study indicates that the CVCC was sustained by top-down political pressure. CVCCs' components involve ideological education among politically affiliated health workers, expanding health worker networks, training health workers, implementing media promotion, communicating with residents using persuasive and explanatory techniques, encouraging multistakeholder partnerships, and using public opinion-steered and coercive approaches. While CVCCs significantly enhanced COVID-19 vaccine acceptance, lacking open communication, stigmatizing vaccine refusers, insufficient stakeholder collaboration, and low trust in the COVID-19 vaccination program (CVP) eroded the validity of CVCCs.

Discussion: To promote the continuity of CVCCs in China, CVCC performers are expected to conduct open and inclusive communication with residents. Furthermore, CVP planners should create robust partnerships among health workers by ensuring their agreements on strategies for implementing CVCCs and optimize COVID-19 immunization service provision to depoliticize CVPs. Our study will not only deepen global audiences' understanding of CVCCs in authoritarian China but also offer potential neighborhood-level solutions for implementing local and global public health communication efforts.

KEYWORDS

COVID-19 vaccine, communication campaign, neighborhood, political pressure, continuity

1 Introduction

The COVID-19 vaccination plays a vital role in containing virus spread, protecting personal health, and preventing the collapse of healthcare systems and the economy from shutting down to contain the pandemic outbreak (1). To roll out the COVID-19 vaccination program (CVP) across the country, the Chinese state created a series of policies, such as “Technical Guidelines for COVID-19 Vaccination” issued in March 2021, “Notice on Further Optimizing the Implementing of COVID-19 Prevention Measures” and “Implementation Plan for Second Dose of COVID-19 Vaccine” issued in December 2022, and “Vaccination Work Plan for Response to Recent COVID-19 Infection” issued in April 2023 (2), to provide policy support for COVID-19 vaccinations.

In academia, mainstream scholarship related to COVID-19 vaccination centers on the willingness, attitudes, confidence, and acceptance of the COVID-19 vaccine among different groups, such as healthcare workers, patients living with chronic diseases, college students, older adults, and vaccine hesitators, and their determinants (3, 4), and strategies for implementing CVPs, such as social campaigns, incentives, and science popularization (5, 6). However, COVID-19 vaccine communication has been less explored in China. In reality, influenced by the principle of “informed, consented and voluntary” created by the central state in 2022, many citizens chose not to be vaccinated or not to be fully vaccinated. To swiftly achieve a high vaccination rate and reach herd immunity as quickly as possible to contain virus spread, local states implemented COVID-19 vaccine communication efforts to deter vaccine misinformation, eliminate citizens’ negative attitudes toward COVID-19 vaccination, and address vaccine hesitancy (7, 8). Informed by these analyzes above, we explore how COVID-19 vaccine communication programs are organized in China.

To further confirm the research lacuna, we traced academic debates on vaccine communication activities in China. Extant research has primarily explored the routine science-based popularization of vaccines, doctor–patient communication on vaccines and patients, and risk communication during vaccine incidents. For instance, Yang et al. (9) indicated that many Chinese citizens with insufficient scientific literacy are easily misled by vaccine disinformation, necessitating vaccination science popularization among citizens. Therefore, Ren and Zhai (10) and Li et al. (11) explored diverse media tools of science popularization, such as speeches, broadcasts, exhibitions and periodicals, magazines, mass media, and media convergence. Hou et al. (12) and Hu et al. (13) demonstrated that doctor–patient communication on vaccines helps to significantly increase vaccine acceptance since physicians possess professional knowledge and their recommendations are considered by the public to be reliable. Following a vaccine crisis, governments should carry out risk communication with citizens swiftly and maintain transparency to reduce the negative consequences caused by this crisis and regain public confidence in vaccination (1, 14). Therefore, Ma et al. (15) argued that governments must accurately identify and respond to public demands and sentiments to dispel fear and anxiety in vaccine crises. To ensure the reliability of information sources, authoritative professionals should steer risk communication following vaccine crises (16). In addition, given that a single stakeholder is generally unable to effectively address fragmented public needs, creating a multi-stakeholder partnership in risk communication during vaccine incidents is also necessary (17).

In summary, previous studies have explored strategies for implementing immunization promotion efforts in routine times, risk communication during vaccine incidents, and doctor–patient interactions in informing vaccination hesitancy. However, these studies have not focused on campaign strategies for implementing vaccine communication programs in emergencies. The mobilization campaign, which originated in military affairs, refers to the launch of a series of actions or events launched to gain public support and achieve a particular goal (18). The elements of a campaign involve creating campaign goals, defining and engaging with target audiences, offering key information that induces changes, and distributing campaigns via multiple media (19). In the context of public health emergencies, such as epidemics and widespread vaccine hesitancy, conventional means fail to effectively promote public acceptance of vaccines. In this case, deploying an immunization campaign helps create a favorable information environment, reach a wide audience, boost vaccine acceptance, and swiftly achieve vaccination goals. As such, the Chinese state launched the COVID-19 Vaccine Communication Campaign (CVCC) in neighborhoods to convince citizens to accept COVID-19 vaccines.

Therefore, we explored how CVCCs were organized in communities. Specifically, this study interrogated the drivers, strategies, and vulnerabilities of CVCCs in Chinese communities. Investigating CVCCs in China helps identify the specific risks associated with CVCCs and offers countermeasures to increase the resilience of CVCCs in China. These findings could also enrich international debates about COVID-19 vaccine communication, deepen global audiences’ understanding of COVID-19 vaccine communication in an authoritarian regime, and offer potential neighborhood-level solutions for implementing local and global public health communication efforts. In the following sections, we present the methods through which we achieved this and their results, discuss the findings, and offer contributions that can inform policy agenda setting in China and international debates.

2 Methodology

2.1 Research design

In this study, we adopted qualitative methods to gain insight into the scenarios, elements, and risks of CVCCs in Chinese communities. We conducted semi-structured interviews with Chinese stakeholders to gather data in an exploratory way. We interviewed respondents via face-to-face interaction, telephone, and video calls on WeChat (akin to WhatsApp) between July 2022 and December 2022. To incentivize participation, we offered gifts to respondents interviewed offline and 50–150 RMB (6.56–19.67 €) to those interviewed remotely. Participant recruitment procedures were aligned to the specific Chinese context: selection started through informal, personal networks, and continued through snowballing to include participants’ colleagues. For instance, we first interviewed staff of the resident’s committee we were familiar with and recruited more participants via referrals from acquaintances. Subsequently, we identified other potential subjects via these enrolled participants. These sampling methods generated enough data for analysis. Prior to the interviews, we obtained oral informed consent from participants after sharing with them the research goals, methods,

expected outcomes, anticipated impacts, and rights and responsibilities of participants and after ensuring their anonymity.

2.2 Data collection and analysis

We interviewed 54 respondents in Beijing, Guangzhou, Shanghai, Wuhan, and Changshang to reach data saturation (20). The research population included 5 directors, 5 secretaries, 10 staff of the neighborhood committee, 6 doctors in the community public healthcare center, 17 community residents, and 6 members of the homeowner association. These participants were approached because of their knowledge of and experiences with CVCCs (Table 1).

We did not record the interviews at the respondents' requests and avoided taking notes in front of participants to mitigate their guardedness and encourage them to express their opinions freely. Gathering data without records are considered unconventional, but we created detailed transcriptions from memory immediately afterwards. Meanwhile, to ensure that we would do justice to original intentions and connotations and the correctness of quotes, in some cases we verified these via WeChat (9). Subsequent thematic analysis was conducted to inductively analyze the transcripts of the interview. Specifically, we first coded the data relevant to the research questions using a semantic approach to gain a condensed overview of the main points that recur throughout the data. Next, we identified sub-themes among these codes and reviewed these sub-themes to ensure their accurate representations of the data. Subsequently, we conceptualized themes among these sub-themes. Finally, to conduct a credible qualitative analysis, two professionals engaged in reviewing each phase of thematic analysis. In that way, sub-themes we identified in this study include the dynamics of CVCCs' emergence, the driving forces of CVCCs' continuity, ideological education among politically affiliated health workers, expanding health worker networks, training health workers, implementing media promotion, confirming communication tactics between community health workers and residents, and identifying risks in CVCCs. Important themes identified were the dynamics of CVCCs' development, organizations, and the risks of CVCCs. Finally, we selected exemplary data extracts from the key themes for inclusion as quotes (21). This qualitative study has followed standards for reporting qualitative research.

3 Results

3.1 CVCCs in the neighborhood

In this section, we presented the scenario of CVCCs, the dynamics of CVCCs' emergence, and the continuity and risks in CVCCs.

3.1.1 Scenario of community CVCCs

In November 2022, in a community in Shanghai, we observed that a group of community health workers, wearing uniform red jackets and holding COVID-19 vaccination brochures, were actively communicating with residents to promote the benefits of vaccination. They informed residents of the procedures, sites, and times of COVID-19 vaccination, promoted the benefits of vaccination, discussed vaccination precautions, and taught residents how to make an appointment for COVID-19 vaccination via the workers'

vaccination service application on WeChat. Several community health workers were also posting on community bulletin boards and hanging up banners at the entrance to the community to advertise the importance and urgency of the COVID-19 vaccination. A cluster of health workers, led by the secretary of the neighborhood committee, visited residents' homes to investigate their attitudes toward vaccination, address their vaccine concerns, and encourage residents eligible for vaccination to get the COVID-19 vaccine. Furthermore, some community health workers communicated with residents who were waiting in line for COVID-19 vaccination at the community site about precautions after vaccination. COVID-19 vaccination became a main theme of Chinese neighborhood governance in 2022, and sparked massive media coverage.

The foregoing scenario reflects a typical Chinese COVID-19 vaccination campaign in a neighborhood. These campaigns were not exclusive to certain communities or neighborhoods; instead, they occurred in most urban communities in China (ID1-4). The CVCC, a key component of the COVID-19 vaccine campaign involving top-level policy designs and grassroots-level policy implementation, refers to various activities health workers carry out with target audiences. Health workers addressed vaccine-related concerns to change citizens' knowledge, beliefs, opinions, and behavior regarding vaccination in the direction desired by these health workers.

3.1.2 Dynamics of community CVCCs' development

In this section, we explore the dynamics of CVCC's emergence and continuity. The emergence of CVCCs is attributed to the advantage of social campaigns in reaching vaccination goals, to the voluntary vaccination policy, and to state reliance on the campaign paradigm in authoritarian China. Compared to routine strategies, mobilization campaigns help prioritize CVPs, tweak the bureaucratic system, and accumulate resources underpinned by the principle of handling special matters with special arrangements to achieve political goals effectively (ID 5-9). Under the principle of voluntary vaccination, mandatory measures are more likely to induce media exposure and public criticism, damage the government's reputation, and trigger public accountability (ID 10-11). The social mobilization approach encourages voluntary vaccination via tactical communications with citizens, aligning with the voluntary immunization policy. Additionally, given the successful experience of social mobilization in the past and the current political structure, the Chinese government would conventionally deploy mobilization campaigns to address complex governance problems after routine means fail (22).

The continuity of CVCCs is attributed to top-down political pressure. CVCCs that emphasize extensive tweaks to the bureaucratic system cannot be sustained in the long run without external forces (ID 17-20). To ensure the continuity of CVCCs, the top-level government constantly exerts pressure on lower-level states via a series of measures such as accountability, incentives, and political mobilization to promote states' active performance of duties and efficiently achieve political goals. Political pressures in relation to the COVID-19 vaccine campaign were exerted with the aim of achieving a high vaccination rate. Therefore, the central state conceptualized COVID-19 vaccination as a "major political task" in April 2022 and adopted a series of measures, such as setting specific goals, issuing various policies, and intensifying the supervision and accountability of local

TABLE 1 Participants' demographic characteristics.

Participant ID	Description of function	Gender	Location
ID1	Director of Yanxi resident's committee	Female	Shanghai
ID2	Director of Baohuiyuan resident's committee	Male	Beijing
ID3	Director of Baiyue resident's committee	Male	Guangzhou
ID4	Director of Huiyuetiandi resident's committee	Female	Wuhan
ID5	Director of Runzeyuan resident's committee	Male	Changsha
ID6	Secretary of Yanxi resident's committee	Female	Shanghai
ID7	Secretary of Baohuiyuan resident's committee	Male	Beijing
ID8	Secretary of Beiyue resident's committee	Male	Guangzhou
ID9	Secretary of Huiyuetiandi resident's committee	Female	Wuhan
ID10	Secretary of Runzeyuan resident's committee	Male	Changsha
ID11	Staff in Yanxi resident's committee	Female	Shanghai
ID12	Staff in Yanxi resident's committee	Female	Shanghai
ID13	Staff in Baohuiyuan resident's committee	Male	Beijing
ID14	Staff in Baohuiyuan resident's committee	Female	Beijing
ID15	Staff in Beiyue resident's committee	Male	Guangzhou
ID16	Staff in Baiyue resident's committee	Female	Guangzhou
ID17	Staff in Huiyuetiandi resident's committee	Female	Wuhan
ID18	Staff in Huiyuetiandi resident's committee	Male	Wuhan
ID19	Staff in Runzeyuan resident's committee	Male	Changsha
ID20	Staff in Runzeyuan resident's committee	Male	Changsha
ID21	Resident in Yanxi community	Female	Shanghai
ID22	Resident in Yanxi community	Male	Shanghai
ID23	Resident in Yanxi community	Female	Shanghai
ID24	Resident in Meishumingjia community	Female	Shanghai
ID25	Resident in Meishumingjia community	Male	Shanghai
ID26	Resident in Baohuiyuan community	Male	Beijing
ID27	Resident in Baohuiyuan community	Male	Beijing
ID28	Resident in Baohuiyuan community	Male	Beijing
ID29	Resident in Baiyue community	Male	Guangzhou
ID30	Resident in Baiyue community	Female	Guangzhou
ID31	Resident in Baiyue community	Female	Guangzhou
ID32	Resident in Huiyuetiandi community	Female	Wuhan
ID33	Resident in Huiyuetiandi community	Male	Wuhan
ID34	Resident in Huiyuetiandi community	Female	Wuhan
ID35	Resident in Runzeyuan community	Male	Changsha
ID36	Resident in Runzeyuan community	Male	Changsha
ID37	Resident in Runzeyuan community	Male	Changsha
ID38	Doctor in Changning district public healthcare center	Female	Shanghai
ID39	Doctor in Xinjinzhen community public healthcare center	Male	Shanghai
ID40	Doctor in Baohuiyuan community healthcare center	Male	Beijing
ID41	Doctor in Baiyue Community Healthcare center	Male	Guangzhou
ID42	Doctor in Manchun street Healthcare center	Female	Wuhan
ID43	Doctor in Yuelu district public healthcare center	Male	Changsha
ID44	Property manager in Yanxi community	Female	Shanghai
ID45	Property manager in Baohuiyuan community	Male	Beijing

(Continued)

TABLE 1 (Continued)

Participant ID	Description of function	Gender	Location
ID46	Property manager in Baiyue community	Male	Guangzhou
ID47	Property manager in Huiyuetiandi community	Female	Wuhan
ID48	Property manager in Runzeyuan community	Male	Changsha
ID49	Staff of homeowner association in Yanxi community	Female	Shanghai
D50	Staff of homeowner association in Meishumingjia community	Female	Shanghai
ID51	Staff of homeowner association in Baohuiyuan community	Male	Beijing
ID52	Staff of homeowner association in Baiyue community	Male	Guangzhou
ID53	Staff of homeowner association in Huiyuetiandi community	Female	Wuhan
ID54	Staff of homeowner association in Runzeyuan community	Male	Changsha

officials, to stimulate the implementation of CVPs at the local level (ID 1–3). One respondent we interviewed argued that,

In 2022, the central government has promulgated a total of 18 vaccination-related policies, and inspection teams delegated by the central state conducted more than 100 inspections of vaccination work in local areas (ID 1).

Correspondingly, local governments outlined the responsibilities of various grassroot-level government agencies, conducted political mobilization among local officials, and established accountability and incentive mechanisms to stimulate healthcare workers to actively perform their duties (ID 8). Under top-down pressure, community healthcare workers initiated CVCCs to increase residents' acceptance of vaccination (ID 24).

3.2 Organization of community CVCCs

The elements of CVCCs in the community involve conducting ideological education among politically affiliated health workers, expanding the network of health workers, training health workers, and communication between health workers and residents.

3.2.1 Ideological education among politically affiliated health workers

In an authoritarian regime, ideological education refers to a social practice in which states or social groups indoctrinate political ideas, beliefs, and moral norms to improve their political identity and compliance, enhance social solidarity, and enable the bureaucratic system to manage threats (23). During the CVCCs, the party-state carried out intensive ideological education among politically affiliated health workers composed of members of the neighborhood committee and of the Chinese Communist Party (CCP) branch in the community to improve their political identity with and loyalty to the CCP. These educational campaigns also enhanced health workers' sense of serving the people and ensured the pragmatic implementation of COVID-19 vaccination policies. Meanwhile, ideological education also helped eliminate disagreements and conflicts among politically affiliated health workers, create a consensus on strategies for implementing CVPs among them, and increased their sense of solidarity and collaboration (ID 9, 21).

In practice, community managers performed ideological education activities by holding mobilization meetings and CCP meetings, inviting senior officials to engage in community-based activities, and conducting COVID-19 vaccination online education programs. Specifically, neighborhood committee leaders frequently organized vaccination mobilization meetings to convey the spirit and intent of the central leadership's important speeches on COVID-19 vaccination and to organize politically affiliated health workers to study COVID-19 vaccine-related policy documents, aiming to deepen their understanding of agreement with these vaccination policies (ID 16–19). One of the our respondents indicated that,

The secretary of the neighborhood committee announced at the community mobilization meeting: We must thoroughly perform COVID-19 vaccination tasks assigned by the higher-level government, enhance our sense of political responsibility, adhere to the strategy of “people first, life first” and the principle of “ensuring all people eligible for vaccination have access to it” created by the central state, and do our damndest to implement vaccine communication activities (ID 18).

Senior officials, such as leaders of the municipal government and the sub-district office, were also invited to participate in the community mobilization meetings to provide institutional support for CVPs, signaling that senior governments attached great importance to CVPs. These who perfunctorily implemented CVPs were considered disloyal and disobeying a superior's orders, and they will be accountable (ID 4, 5). Community CCP branches regularly held meetings as well, encouraging their members to practice self-reflection on their previous immunization work, and learn the CCP's principles and regulations and COVID-19 immunization policies, reinforcing CCP members' political obedience and awareness of serving the people, and ensure standardized implementation of CVPs. These efforts shaped CCP members' initiatives in implementing community CVCCs (ID 9–11).

3.2.2 Expanding health worker networks

Merely relying on state forces cannot lead to successfully implementing CVCCs, and partnering with multiple stakeholders is therefore necessary. In doing so, neighborhood committees expanded health worker networks by absorbing members of the grid-based governance system, including property managers, members of

homeowner associations and healthcare practitioners of the community public health service center. They also recruited volunteers (ID1-3, 11-14). A director of the neighborhood committee argued that,

The grid management model has been widely deployed by governments to optimize public service provision in communities. As members of the grid-based governance system, property managers, owners committees, and community public health service centers are responsible for assisting neighborhood committees in delivering public services. Therefore, these stakeholders are easily mobilized by neighborhood committees to participate in implementing CVCCs (ID 2).

To stimulate community volunteers to join health worker networks, neighborhood committees massively advertised the importance and urgency of the COVID-19 vaccination and volunteerism and altruism via diverse media channels, such as community bulletin boards, WeChat public accounts, and TikTok (ID 22-25). Additionally, CCP organizations at all levels required their members to actively join health worker networks in their communities to assist neighborhood committees in implementing CVCCs (ID 26-29).

3.2.3 Training community health workers

Most health workers, composed of non-professionals, did not possess abundant scientific knowledge, so they failed to deliver accurate information about the COVID-19 vaccination to residents. Meanwhile, health workers who lacked proper communication skills and failed to collaborate with other stakeholders reduced the effectiveness of vaccine communication activities. Specialized training was thus expected to enhance health workers' knowledge of vaccination, and boost their skills in collaboration and communication with residents (ID 5-8). A secretary of the neighborhood committee argued the following:

Many health workers did not have professional knowledge of vaccines, and were unclear about the safety, efficacy, procedures and precautions of COVID-19 vaccination, failing to respond to residents' inquiries accurately. That reduced public trust in CVPs, and a professional training on these health workers is imperative (ID 7).

In response, CVP managers enhanced health workers' communication skills via strategies such as routine professional training conducted by health experts, practical guidance, and online education programs. Specifically, neighborhood committees invited local public health experts to conduct COVID-19 vaccination training and offer practical guidance to ensure that health workers had the knowledge and skills required to implement CVCCs (ID 19, 20). Neighborhood committees also organized health workers to participate in COVID-19 vaccination online education seminars held by the district office to deepen their understanding of the laws and regulations surrounding COVID-19 vaccination to promote standardized policy implementation. This also allowed them to acquire the techniques to interact with residents. These training activities helped deter the illegal administration of CVPs and promote the efficiency of COVID-19 vaccine communication (ID 14, 15).

3.2.4 Implementing media promotion

Media promotion, defined by Kabakama et al. (24) as a one-way communication approach, refers to leveraging the power of popular media tools to achieve marketing goals. Media promotion helps massively in disseminating positive information regarding a product or a behavior, to create a favorable information context and alter target populations' attitudes and behaviors in a desirable way. Neighborhood committees, managers of community CVPs, primarily advertised COVID-19 vaccination via online and offline platforms. On the one hand, neighborhood committees hung up banners, posted on community propaganda boards, and distributed pamphlets to residents in communities to ensure widespread awareness of the importance and urgency of COVID-19 vaccination and enhance their vaccine acceptance (ID 27-30). A resident we interviewed indicated that,

Banners hung in communities claimed that: To protect your family members, please get fully vaccinated; COVID-19 vaccination benefits other people as well as oneself; vaccination helps construct herd immunity (ID 30).

On the other hand, neighborhood committees utilized multiple social media tools, such as WeChat groups, WeChat public accounts, TikTok, WeChat videos, and Sina Weibo, to massively advertise COVID-19 vaccines and ensure that residents were exposed to a huge amount of positive information related to COVID-19 vaccines, thereby increasing their willingness to get vaccinated (ID 49, 50).

3.2.5 Communications between health workers and residents

COVID-19 vaccine communications between health workers and residents in the neighborhood involve persuasive, coercive, explanatory, public opinion-steered, and stakeholder collaborative patterns.

3.2.5.1 Persuasive communication

Persuasive communication centers on confirming what most appeals to target audiences and then adopting tailored tactics to convince them of something. During the CVCC, the persuasive approach played an indispensable role in addressing vaccine hesitancy, and it involved logical and empathic models. The logical model highlights the use of facts, accurate evidence, and logical reasoning to create persuasive messages. In the CVCCs, health workers quoted expert opinions, statistical data, and clinic trial data to increase the credibility of arguments, curb misinformation and increase residents' rational perception of vaccination, thereby easing vaccine concerns (ID 38-41). A doctor in the community public healthcare center noted that,

To dispel public concerns that COVID-19 vaccinations may cause leukemia and diabetes, I explained: The domestically produced vaccine is safe and has been verified by international official organizations. Meanwhile, clinical monitoring and statistical data show that in the four years before and after the COVID-19 pandemic, the number of visits and hospitalizations for diabetes and leukemia has not significantly changed, indicating that COVID-19 vaccination has not yet caused leukemia and diabetes (ID 40).

Nonetheless, the logical approach, often involving a high degree of assertiveness and aggressiveness, is not effective in all situations. Complementing the logical approach, the empathetic model also plays a critical role in persuading target people to get vaccinated. Empathetic persuasion refers to listening to target audiences' narratives, understanding their feelings, supporting their perspectives, and reassuring their concerns in an empathetic way for behavior change. During such interactions, health workers attentively listened to residents' narratives, shared their perspectives with residents in an empathetic way, and sincerely recommended that they get vaccinated to protect their personal health. This approach resonated with residents and enhanced public trust in CVPs, thereby decreasing vaccine hesitancy (ID 32–37). In fact, health workers employed hybrid strategies to communicate with residents about vaccine concerns instead of using a singular approach, given their respective pros and cons (ID 5).

3.2.5.2 Explanatory communication

Explanatory communication, similar to question-and-answer format communication, entails that utterers respond to specific questions raised by audiences in detail to deepen their understanding of something. During the vaccine communication efforts, health workers primarily employed the explanatory model to interact with residents cautious about the COVID-19 vaccination. This approach helped increase health workers' responsiveness to public demands, deepen residents' understanding of the necessity, safety, efficacy, and procedures of the COVID-19 vaccination, and eventually gain residents' trust in CVPs. In communities, health workers mainly responded to residents' concerns about the safety, efficacy, procedures (e.g., walk-in sites, working hours, and appointments), necessity, contraindications, possible side effects, and precautions of COVID-19 vaccination via diverse media platforms such as WeChat groups, telephone, and community temporary vaccination sites. They also answered questions from residents with limited mobility in their homes (ID 45–50). For instance, one respondent we interviewed narrated that there were over 7,000 residents in my community, disabling health workers from responding to everyone's questions offline. As such, we established more than 100 WeChat groups to answer residents' questions about COVID-19 vaccinations. During peak hours, each health worker answered at least 400 questions from residents every day (ID 46).

3.2.5.3 Coercive communication

Coercive communication, a means of communication that exerts pressure on target audiences, members implies the adverse consequence of non-compliance to force them to act in the direction desired by the utterer. Coercive strategies are primarily applied in industries with extensive safety or operational regulations, such as the manufacturing and medical industries, to ensure that employees follow rules and stay safe, to decrease employee deviation, and to increase productivity (25). Facing top-down political pressure and influenced by the traditional governance idea of resorting to forces after courteous measures fail, some neighborhood committee members responsible for allocating community public resources probably employed coercive tactics, such as implicitly or explicitly threatening that vaccine refusers would only be able to access limited portions of community medical care facilities, year-end benefits, and

educational resources, to compel them to get vaccinated after persuasive tactics failed (ID28–31). A resident we interviewed argued that,

The medical insurance, pension and year-end benefits of vaccine refusers were canceled by some neighborhood committees. Meanwhile, vaccine refusers' children were forced to delay school enrollment (ID 31).

Coercive measures encouraged vaccine refusers to get vaccinated to a certain extent. Nonetheless, this approach violated the voluntary vaccination policy and incurred negative media reports, public criticism, mistrust in local CVPs, and public accountability for health workers who were exposed by the media to impose coercive measures. Given the pros and cons of coercive tactics, most health workers were cautious about this approach (ID 4).

3.2.5.4 Public opinion-steered communication

Public opinion-guided communication is a means of communication that follows a public opinion event that emerges on social media. Media regulators control and steer the flow of public opinions in line with their governance values and expectations to avoid trust-destroying events and elicit positive sentiment expressions on social media (26). During CVCCs, health workers also emphasized managing public opinions in communities to erase citizens' negative perceptions of COVID-19 vaccines (ID 5). In the self-media era, everyone can be a producer and disseminator of information, causing a large amount of unverified information to be disseminated on social media. The dissemination of negative vaccine information increased residents' vaccine concerns in online communities. For instance, vaccine concerns expressed in WeChat groups involve that domestically produced vaccines are unsafe; mutations in the virus make vaccines ineffective; and vaccination induces leukemia and cancer (ID 7).

In such a case, health workers engaged in evidence-based interactions with residents, disseminated scientific evidence via diverse media tools, such as WeChat public accounts and official websites, and forwarded them expert opinions via WeChat groups to mitigate negative sentiments toward vaccination. They also advertised the hazards of rumors and the benefits of trust in science for personal health to enhance vaccine trust (ID 8–15). A health worker we interviewed argued that to allay public concerns about the effectiveness of domestically produced vaccines, we cited the results of clinical trials: Sinovac vaccine offers 64–75% protection for older adults, and Sinovac boosters have increased the protection to 98% (ID 10).

3.2.5.5 Stakeholder collaboration model

Stakeholder collaboration persuasion refers to the idea that multistakeholders work together to interact with target audiences to alter their attitudes and behaviors in a desired way. According to Honora health workers with high charisma and social influence, extensive professional knowledge, and strong communication skills were more likely to persuade refusers to get vaccinated (27). Merely relying on a single stakeholder cannot successfully convince vaccine hesitant to get vaccinated. Connecting with health workers with different knowledge, skills, resources, and relationship networks, such as medical professionals, clinicians, neighborhood committee leaders,

local celebrities, and acquaintances of target people, to jointly persuade residents to vaccinate is thus expected. In practice, the leaders of the neighborhood committee worked with doctors at the community healthcare center, acquaintances of residents who refused to get vaccinated, and so on to urge refusers to get vaccinated (ID 8–10). This stakeholder collaborative approach to vaccine communication was demonstrated to be effective (ID 9).

3.3 Risks in community CVCCs

According to Wang, Chinese CVCCs underpinned by the principle of “informed, consented and voluntary” that connects institutional efficiency and humanity have dispelled citizens’ misconceptions about vaccines, refuted rumors, increased the public’s scientific knowledge about vaccines, and boosted the public willingness to vaccinate (28). However, risks of CVCC have been identified, such as stigmatizing vaccine refusers, poor communication, insufficient stakeholder collaboration, and low trust in state-sponsored CVCCs.

3.3.1 Stigmatizing vaccine refusers

Some neighborhood committee members constructed moral norms, promoting collectivism and community spirits, to mobilize residents to get vaccinated. Vaccine refusers were criticized by health workers as selfish, immoral, without a sense of social responsibility, violating community conventions jointly created by residents, and endangering collective security. Vaccine refusers’ medical care, pension, and year-end benefits were canceled by neighborhood committees, and property managers limited their ability to enter and exit the community freely (ID 29, 30). One of the our respondents argued that,

Some community health workers advertised that immunization is the greatest contribution to the family and the country; those who not vaccinate are selfish and immoral (ID 30).

Meanwhile, affected by cyber-nationalism and patriotism, some health workers believed that vaccination helped prevent virus spread in the country and ensure the stability and security of the country (ID 37). Those who were not vaccinated are treated as unpatriotic and as requiring punishment. Stigmatizing vaccine refusers and moral hijacking, which refers to occupying the moral ground to condemn someone and to dictate what others should do, sparked media coverage and public outrage, inducing distrust in local CVPs (29).

3.3.2 Lack of transparency in communication

A lack of open communication means that health workers did not properly respond to tricky questions raised by residents, such as what are the negative effects of vaccination, why foreign-produced vaccines are not allowed, hindering the diversity of vaccine choices in China, and whether COVID-19 vaccinations were still effective as the virus mutated (ID 49, 50). A respondent elucidated that,

Vaccination’s principle is to implant the virus into the human body. While vaccination could develop immunity, it has also negative effects on human body. However, health workers convey these negative messages to citizens (ID 49).

The reasons for the lack of transparent COVID-19 vaccine communication are that health workers’ limited expertise hinders them from professionally responding to residents’ questions. Additionally, to construct the political discourse surrounding COVID-19 vaccination, grassroots-level health workers were required by governments to avoid responding to politically sensitive questions and involving themselves in topics prone to raising public controversies (ID 38–40, 51–53).

3.3.3 Insufficient collaboration among health workers

Although multiple health workers banded together to a certain extent to conduct CVCCs, multistakeholder collaboration was insufficient, decreasing CVCCs’ efficiency. In practice, health workers were used to conducting CVCCs independently and only cooperated with other health workers in special situations, such as top-down political pressure for cooperation and the failure of vaccine communication led by a single stakeholder (ID 32–37). A member of the neighborhood committee argued that,

We usually work independently, and will only collaborate with others to conduct vaccine communication required by the sub-district office, or when we failed to persuade residents to get vaccinated (ID 37).

Insufficient stakeholder collaboration is attributed to health workers’ disagreements regarding strategies for implementing CVCCs and a lack of collaboration. Health workers disagreed with the schedule and strategies for implementing CVCCs based on their availability and values, perceptions, and experiences of the COVID-19 vaccination. Failure to tackle and address these disagreements reduced health workers’ willingness to cooperate. Consequently, instead of diverse stakeholder collaboration, community health workers preferred to clearly define their respective responsibilities to facilitate the independent performance of CVCCs rather than teamwork (ID 42–49).

3.3.4 Distrust in state-sponsored CVCCs

The political tendency of CVCCs and low trust in neighborhood committees caused some residents to express their distrust and even resistance to CVCCs. To complete the political tasks assigned by the higher state and obtain a good performance appraisal, neighborhood committees adopted various measures to endlessly pressure residents to ensure compliance, arousing public disgust (ID 24–28). A resident argued that,

Neighborhood committees competitively conducted vaccination campaigns to achieve a high vaccination rate and get rewards from senior governments rather than to serve the people and protect personal health (ID 25).

Low trust in neighborhood committees also bred distrust in community CVPs. Neighborhood committees, although legally deployed to represent and serve public interests in communities, function as an extension of the government apparatus in reality to implement administrative tasks assigned by states and are less responsive to public demands. The bureaucratisation of public service provision, neighborhood committees’ weak sense of serving the

people, and unfair public resource distribution have greatly reduced public trust in the neighborhood committee. Meanwhile, members of neighborhood committees lack vaccination-related expertise, reducing the credibility of CVCCs initiated by neighborhood committees. During the CVCCs, neighborhood committees primarily marketed the safety, necessity, and urgency of COVID-19 vaccination to mobilize residents to get vaccinated. However, they failed to answer residents' questions professionally, arousing public skepticism.

To ensure the continuity of CVCCs in modern China, health workers are expected to maintain more open communication with residents and be inclusive of vaccine refusers. Furthermore, CVP managers should create robust partnerships among health workers by ensuring their agreement on strategies for implementing CVCCs and optimize COVID-19 immunization service delivery to depoliticize community CVPs.

4 Discussion

This analysis shows that CVCCs were driven by top-down political pressure. The components of CVCCs involved ideological education among politically affiliated health workers, expanding health worker networks and training health workers, communicating with residents using persuasive and explanatory techniques, encouraging stakeholder collaboration, and using public opinion-steered and coercive approaches. While CVCCs significantly enhanced COVID-19 vaccine acceptance, a lack of open communication, the stigmatization of vaccine refusers, and low trust in CVCCs eroded CVCCs' validity. To promote the continuity of CVPs in modern China, community health workers must communicate with residents in a more open and inclusive way. Furthermore, CVP managers should create robust partnerships among health workers by ensuring their agreements on strategies for implementing CVCCs and optimizing COVID-19 immunization service delivery to depoliticize CVPs (Figure 1).

COVID-19 vaccine hesitancy has raised scholarly attention to COVID-19 vaccine communication efforts. Extant research illustrates the principles and strategies of COVID-19 vaccine communication (30). COVID-19 vaccine communication principles involve transparency, intelligibility, and consistency of information delivery and the inclusiveness of interaction to avoid negative assumptions or stereotyping associated with ethnicity (31, 32). COVID-19 vaccine communication tactics include rational persuasion, emotional appeals, message framing, A social marketing mix, contextualized models, mass media campaigns, construction of trusted networks, and stakeholder collaboration. Rational persuasion highlights that health workers provide credible information such as statistical data, clinical trial data, and expert opinions to address citizens' specific concerns, neutralize misinformation, and strengthen vaccine-supporting voices (1, 33, 34). Emotional appeals entail that health workers empathetically respond to vaccine concerns and strengthen individuals' moral norms to raise vaccination intention (35–37). Message framing includes gain-framed and loss-framed messages. The former highlights the benefits of adopting a recommended behavior, while the latter underlines the losses stemming from not adopting a recommended behavior. Given this, health practitioners must communicate the societal and individual benefits of COVID-19 vaccinations and the risks of vaccine refusal to citizens (35, 38). The social marketing mix, demonstrated by Hong as an effective COVID-19 vaccination approach in South Korea, involves

product communication, highlighting the community and individual benefits of vaccination; price communication, referring to the drivers of COVID-19 vaccination such as self-efficacy, personal health, and rewards; place communication, denoting informing residents timely of the schedule and sites of COVID-19 vaccination service delivery; and promotion communication, entailing delivering clear, accurate, and coherent information via trusted media outlets (39). Constructing a trusted network helps incorporate influencers of vaccination decisions, such as medical professionals, celebrities, opinion leaders, and acquaintances, into CVCCs to deliver pro-vaccine messages and enhance public trust in COVID-19 vaccines (32, 40). Reinforcing partnerships among health workers supports connecting various stakeholders' knowledge, experience, and resources and increases the accuracy and receptivity of information delivered. Therefore, Gao et al. (41) propose creating collaborations involving local governments, doctors, and universities to communicate with vaccine-hesitant students. Chou et al. (1) also suggested a contextualized communication model tailored to a community's culture, values, concerns, and information needs. Similarly to previous studies, our study also highlighted the efficacy of reliable collaboration networks, rational persuasion, emotional appeals, and coordinated COVID-19 vaccination communication approaches. Building upon previous studies, our study revealed the political context of CVCCs in China, ideological education among politically affiliated health workers, coercive and public opinion-steered communication tactics, and the risks of CVCCs in an authoritarian regime. Interestingly, our analysis indicated that CVCCs exhibited a stress-response pattern in China. The CVCC was sustained by political forces and was significantly affected or even disrupted by top-down political pressure. In this context, community health workers were less responsive to public concerns about vaccines and increased vaccine hesitancy. To achieve a high vaccination rate, top-level governments had to continuously exert political pressure on grassroots-level governments to sustain CVCC practices in China.

The Chinese government deployed the mobilization campaign to roll out CVPs across the country to reach herd immunity. The central state conceptualized COVID-19 vaccination as a "major political task," enacting political pressure and ideological education and creating accountability and incentive systems to promote the political loyalty of local officials and ensure that they actively performed their duties (42). Local states, based on the principle of handling special matters with special arrangements, prioritized vaccination tasks, tweaked the bureaucratic system, and accumulated social capital, aiming to achieve a high vaccination rate swiftly. At the neighborhood level, health workers advertised collectivist values and socialist morality, oriented public opinions, and constructed favorable information contexts to raise public acceptance of the COVID-19 vaccination. They coercive adopted deterrent strategies to compel public obedience (43). This reflects the institutional characteristics of CVCCs in authoritarian China. Although vaccine mobilization practices significantly increased Chinese COVID-19 vaccination rates, the inappropriate organization of CVCCs eroded the legitimacy of vaccinations. Politicization of CVCCs bred distrust in CVPs, local coercive styles of vaccine communication induced media exposure and public criticism, and vaccine communication activities underpinned by collectivism and patriotism stigmatized vaccine refusers. Therefore, counteracting the political tendencies of and reconciling government–market–society forces in immunization campaigns in modern China warrants further research.

Dynamics of CVCCs' emergence	Drivers of CVCCs' development	CVCCs' elements	Risks in CVCCs	Policy implications
<ul style="list-style-type: none"> ● The advantage of campaign approaches in reaching political goals ● Path dependence of governments in tackling tricky governance issues 	<ul style="list-style-type: none"> ● Persistent political pressure 	<ul style="list-style-type: none"> ● Ideological education among politically affiliated health workers ● Expanding health worker networks ● Training community health workers ● Implementing media promotion ● Communication patterns between health workers and residents: persuasive and explanatory techniques, multi-stakeholder partnerships, public opinion-steered and more or less coercive approaches 	<ul style="list-style-type: none"> ● Stigmatising vaccine refusers ● Lack of transparency in communication ● Insufficient collaboration among health workers ● Distrust in state-sponsored CVCCs 	<ul style="list-style-type: none"> ● Open and inclusive communication approaches ● Constructing robust partnerships among health workers via ensuring their agreements on strategies for implementing CVCCs ● Optimising COVID-19 immunisation service delivery

FIGURE 1
Organization of CVCCs in Chinese communities.

4.1 Limitation of this research

This qualitative study deepened our understanding of CVCCs in Chinese grassroots society. Nonetheless, this research must be considered against the background of its limitations. First, we selected participants using an informal and snowballing approach instead of a scientific sampling method to align with China's highly relationship-oriented society (44). However, data gleaned by snowballing in this study conformed to the principle of data saturation. Second, although two professionals are involved in reviewing each phase of data analysis, a more rigorous thematic analysis (e.g., researcher triangulation, description of audit trails, peer debriefing, and member checking) is expected to be conducted to establish trustworthiness in qualitative research. Finally, this study centers on CVCCs in urban communities, but not yet on CVCCs in rural China. According to Zhao, China's urban-rural divide, with a focus on constraining rural-to-urban mobilization by a household registration system instituted by the government in 1958 and differentiated resource input between rural and urban areas, induced

urban-rural differences in the contexts, strategies, and risks of COVID-19 vaccine communication activities (45). Future research is thus expected to explore the CVCC in rural China.

5 Conclusion

The continuity of CVCCs was driven by top-down political pressure. The components of CVCCs involve conducting ideological education among politically affiliated health workers, expanding health worker networks, training health workers, implementing media promotion, communicating with residents using persuasive and explanatory techniques, encouraging stakeholder collaboration, and using public opinion-steered and coercive approaches. While CVCCs significantly enhanced COVID-19 vaccine acceptance, inadequate openness in communication, stigmatizing vaccine refusers, insufficient stakeholder collaboration, and low trust in CVPs eroded CVCCs'

validity. To favor the continuity of CVCCs in China, CVCC performers are expected to conduct more open and inclusive communication with residents. Furthermore, CVP planners should also create robust partnerships among health workers by ensuring stakeholders' agreements on strategies for implementing CVCCs and optimize COVID-19 immunization service provision to depoliticize CVPs.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

Ethical approval was not required for this study. The studies presented in this article were conducted in accordance with local legislation and institutional requirements.

Author contributions

RY: Investigation, Resources, Data curation, Formal analysis, Methodology, Writing – original draft, Funding acquisition. YH:

Conceptualization, Methodology, Formal analysis, Writing – review & editing, Supervision, Validation, Visualization.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Barriers to HPV vaccination in marginalized Roma communities in Slovakia

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Introduction: Limited access to healthcare services leads to lower vaccination rates in marginalized Roma communities (MRCs). This study aimed to explore health system barriers to HPV vaccination faced by people from MRCs from multiple perspectives.

Methods: The qualitative study was conducted in Slovakia in 2021/22 with 43 community members and health professionals. Data were analyzed using a combination of content analysis and consensual qualitative research.

Results: A substantial barrier to vaccination is limited coverage of vaccination expenses for certain age categories by health insurance. Moreover, Slovakia faces a significant shortage of healthcare personnel, leading to work overload and a lack of capacity and motivation to address HPV vaccination. Impaired relationships between health care providers and people from MRCs lead to the avoidance of healthcare services, which contributes to insufficient delivery of information and a lack of awareness regarding HPV-related diseases and vaccination.

Conclusion: Strengthening the capacities of health care providers, expanding the age group covered by health insurance and providing tailored information to people from MRCs are necessary prerequisites to increase the availability of HPV vaccination and enable people to make informed decisions about HPV vaccination.

KEYWORDS

marginalized Roma communities, ethnic minority, HPV vaccination, health system barriers, access to health care

1 Introduction

Human papillomavirus (HPV) is one of the most potent viruses associated with multiple cancer incidences (1) and genital warts (2). Although HPV vaccination has the potential to prevent HPV-associated diseases which pose a significant risk to health and constitute a healthcare burden (1, 3), HPV vaccination programs largely differ across the countries and achieving the desired vaccination rates remains a challenge in many of them (4), including Slovakia (5). In Slovakia, HPV vaccination with the bivalent vaccine has been fully covered by health insurance for 12-year-old girls and boys since January 2019 and with the nonavalent vaccine since May 2022 (5). For older age groups, health insurance companies offer benefit programs for optional vaccinations for their clients in which the costs can, under certain conditions, be partially reimbursed (for those 13–18 years old); otherwise, costs for the vaccine have to be fully covered by the recipients (those

18+). In Slovakia, the vaccination coverage rate for 12 years olds in 2021 was 25% for girls and 8% for boys which is less than half compared to neighboring countries such as Hungary or the Czech Republic and far from the desired 90% vaccination coverage rate which was successfully achieved for example in Denmark or Norway (5).

Roma, particularly those living in marginalized Roma communities (MRCs), are among the underserved groups facing limited access to health care and vaccination services, which leads to lower vaccination rates compared to the general population (6). Although there are no data on HPV vaccination rates among Roma, given the low HPV vaccination uptake in the general Slovak population (5) and the lower uptake of other vaccinations in the Roma (6–8), it can be assumed that HPV vaccination rates among Roma living in MRCs are very low. Regions with the lowest HPV vaccination coverage (5) are those with the highest share of Roma population (9).

Lower vaccination rates among Roma can be attributed to discrimination, socioeconomic deprivation, limited access to health care, language barrier, low literacy and low awareness of vaccination as a preventive measure (8, 10). Concerning HPV vaccination specifically, cultural beliefs (no sex before marriage), safety concerns (10), lack of knowledge and poor attitudes and perceptions of HPV vaccination (11), patient-provider relationships and active community health workers, such as community nurses or Roma health mediators (12, 13), might also affect decision-making and uptake in Roma. However, evidence on barriers to HPV vaccination in Roma is scarce and focuses rather on the barriers on the side of Roma than on health system barriers. In a broader sense, however, access to health care is not solely a result of a person's ability to identify healthcare needs or to seek, reach and obtain healthcare services which is highly influenced by the abovementioned factors. Access to health care results from the interface between these characteristics and the characteristics of health systems, organizations and providers such as approachability, acceptability, availability and accommodation, affordability and appropriateness as described by the conceptual framework of access to health care (14). In European countries with a significant Roma population, including Slovakia, evidence describing health system barriers to HPV vaccination that would inform public health policies and help tackle the vaccination gap is fully lacking.

Therefore, this study aimed to explore health system barriers to HPV vaccination faced by Roma living in MRCs from multiple perspectives. Our objectives were to include perspectives of both healthcare providers and community members and to collect in-depth information about health system determinants of low vaccine uptake (barriers/obstacles) among underserved marginalized Roma communities that could inform the development of new system-level intervention tailored to underserved communities and targeting individual or multiple WHO health system building blocks.

2 Materials and methods

2.1 Design

A qualitative study exploring health system barriers to HPV vaccination faced by Roma living in MRCs in Slovakia was conducted

as a part of the RIVER-EU project (Reducing Inequalities in Vaccine Uptake in the European Region—Engaging Underserved Communities).

2.2 Study settings

The study was conducted between October 2021 and May 2022. To capture a wide spectrum of perspectives, participants of multiple expertise were recruited. Purposive sampling was used to involve community members (parents and daughters from MRCs) and health professionals from different backgrounds with a deep understanding of the topic of interest.

A qualitative study with community members was conducted in the Košice district, which has the highest share of marginalized Roma population in Slovakia (9) characterized by high unemployment rates and low educational levels. Three different towns/villages were selected to capture the variation in the share of the Roma population (50–100%), the number (2–10) and size of communities (2,000–7,000 inhabitants), the level of urbanization and separation from the majority population (9).

2.3 Sample and procedure

The recruitment of participants was organized in cooperation with Roma health mediators from the national Healthy Communities project using purposive sampling techniques. Roma health mediators are of Roma origin; they live and work in the target communities, know the social structures and local families and have the trust of community members which enabled us to enter the communities and recruit a variety of participants who met the selection criteria. Roma health mediators identified families with girls between 12 and 15 years old and invited eligible parents (both mothers and fathers with different educational levels and employment status) and daughters to participate in the interview with researchers. Semi-structured interviews with participants from the community sample were conducted face-to-face at the community center, or in respondents' homes.

Purposive sampling techniques were used to recruit professionals involved with the topic of HPV vaccination and working with marginalized Roma communities from Slovakia, preferably from the Košice district, across these categories: general practitioners for children and adolescents, gynecologists, Roma health mediators, public health authorities and policymakers. Participants from the healthcare system could choose the form (face to face, online by Zoom or Teams) of the interviews and where they took place (their office, our office).

Written informed consent was obtained before each interview after a detailed explanation of the project aims and how the data will be treated. In the case of children participating, their parents signed the consent form on behalf of the children. Children were allowed to refuse participation regardless of parental consent. Participants were informed in advance that they are not obliged to answer all the questions and that they can withdraw their consent at any stage.

Participants who agreed to participate were interviewed individually or in groups. The interviews covered topics such as general access to health services, knowledge and attitudes toward

Abbreviations: HPV, human papillomavirus; MRCs, marginalized Roma communities.

vaccination, sources of information, experiences with vaccination, perceived barriers to vaccination and suggestions for improving vaccination services.

2.4 Analyses

The transcripts of the interviews processed by a trained research assistant were checked for accuracy and compared with the audio recordings by one of the researchers, who also anonymized the data. We approached the acquired data using a consensual qualitative research (CQR) methodology (15), which requires researchers to reach an agreement on identified topics and interpretations to avoid subjectivity, as different team members performing the analysis provided various perspectives. Data were analyzed on an ongoing basis using a combination of conventional and directed content analysis (16). During data collection, we reached a point of saturation, where no new themes occurred.

The analyses of qualitative data were performed by a team of three researchers with different backgrounds (health psychology, public health, and social work) and different levels of experience in conducting research with marginalized Roma and with content analyses. Prior to analyses, researchers shared their professional background and personal perspectives and assumptions that might influence their approach to data to acknowledge their subjectivity. Each team member read the transcripts of the interviews and created codes for parts of the interviews independently. Then, the team members met and shared their codes and interpretations to achieve consensus. In the case of differing opinions, the discussion continued until a consensus was reached. We used the MAXQDA software for the coding and analysis process. Based on the codes produced in this data handling, we conducted a content analysis (16). We did this by clustering codes regarding the reported barriers to health care and HPV vaccination. We first read all the codes and sorted them into groups (subthemes) based on the topic they were covering. Afterwards, we created themes by searching for an umbrella concept for the subthemes.

As a last step, the identified themes covering different health system barriers were then sorted depending on how they corresponded with six core components or “building blocks” of the WHO health systems framework (17): (1) service delivery, (2) health workforce, (3) information, (4) medical products, (5) vaccines and technologies, (6) financing and leadership/governance. This framework was identified as being suitable for organizing the identified health system barriers, as it was designed to address monitoring and evaluation needs for different users and multiple purposes (17).

3 Results

The sample consisted of three groups of respondents with different perceptions of the studied topic. We interviewed 13 teenage girls, 17 parents (mostly mothers) and 13 professionals with various expertise at different levels of the work hierarchy. Most of the respondents (28) were interviewed individually. Fifteen respondents were interviewed in small groups or couples. The girls and their parents were all residents of MRCs. Also, six professionals were of Roma origin. The background characteristics of the sample can be found in Table 1.

The following sections describe the main themes regarding health system barriers to HPV vaccination according to WHO building blocks. An overview of the identified barriers per health system building block can be found in Table 2.

3.1 Leadership and governance

3.1.1 Insufficient coordination between stakeholders engaged in vaccination

A lack of coordination between different organizations delivering vaccines and/or a lack of coordination between different elements of the healthcare system pose a significant barrier according to the respondents. Roma health mediators are perceived as an essential bridge between the community and health services, yet coordination between the mediators and healthcare workers is not optimal.

“I think that they [doctors] need really, very, very good cooperation with those Roma health mediators. [...] Those Roma health mediators, I know it’s difficult, but in my opinion, they should be educated at a slightly higher level about some activities. So, I would call it something between, um, between the nurse and the social worker directly in the community, who then cooperates with that doctor. Right? So, if this were the case, then the cooperation and also the health care in those communities would be, um, much better in my opinion.”

(primary paediatrician)

3.1.2 No awareness raising of HPV

The healthcare system is not able to reach MRCs with relevant and sufficiently formulated information about HPV infection, HPV-related cancer and HPV vaccination. People from MRCs are not reached by media campaigns. Also, schools, municipalities or health insurance companies are not involved in providing tailored information to relevant age groups, and the topic of HPV is not on the agenda of Roma health mediators.

TABLE 1 Background characteristics of the sample.

	Daughters (N = 13)	Parents (N = 17)	Professionals (N = 13)	Total (N = 43)
Gender	N (%)	N (%)	N (%)	N (%)
Male	0 (0)	2 (11.8)	5 (38.5)	7 (16.3)
Female	13 (100)	15 (88.2)	8 (61.5)	36 (83.7)
Age	Mean (range)	Mean (range)	Mean (range)	Mean (range)
	13.9 (12–15)	41.4 (33–54)	46.9 (30–68)	34.7 (12–68)

TABLE 2 An overview of identified barriers per health system building block.

Health system building block	Identified barriers
Leadership and governance	(a) Insufficient coordination between stakeholders engaged in vaccination
	(b) No awareness-raising of HPV
	(c) Lack of government intervention to address the influence of anti-vaccination movements
	(d) Unresponsiveness and passivity of the system
Health workforce	(a) Healthcare professionals are insufficiently trained and skilled to provide tailored information about vaccination
	(b) Discrimination against target population
Service delivery	(a) Insufficient access to services
	(b) Insufficient resources to deliver all vaccines
	(c) Lack of, insufficient or inadequate delivery of information
	(d) Language barriers
Financing	(a) Costs to the systems
	(b) Costs to the patients
Medical products	(a) Optional status of HPV vaccine
Health information systems	NA

“Insurance companies should promote this vaccination; it should be talked about everywhere, on the radio and TV, maybe even in those children’s programmes. [...] It’s definitely not talked about much, it’s not talked about, it’s not written about, and it’s not in the media, so push it in that direction. And mainly push it to those people that it’s already paid for, that it’s free.”

(gynaecologist)

“Well, HPV is, let’s say in general, very little talked about, very little communicated in the Roma population in the localities. [...] I would welcome more such education and training. First of all, I would like our workers to know more about it, so that they could inform, talk to and advise people in their localities about what and how so that they would not underestimate it.”

(coordinator of Roma health mediators)

3.1.3 Lack of government intervention to address the influence of anti-vaccination movements

The healthcare system is not able to fill the space with relevant information, and more space is given to anti-vaccination movements and the dissemination of false and contradictory information on the Internet, social media and among the lay public. Knowledge and attitudes of people from MRCs are largely influenced by information that reaches them from various sources.

“I perceive from my experience that there is a certain gap in the healthcare ‘market’, which is then filled by all kinds of charlatans and spreaders of various delusions, I’ll put it bluntly. [...] it’s not systematically covered or covered enough, and to be fair, either it creates that gap that isn’t filled with anything – that information doesn’t come – or it will be filled willingly and gladly simply by those who benefit from it in some way. [...] They are very successful and therefore one of the effects is absolute distrust in science as such and in scientists, which is a disaster.”

(public health authority)

3.1.4 Unresponsiveness and passivity of the system

Respondents suggested that underserved populations require proactive, tailored approaches for vaccination. In Slovakia, health care providers are mostly convinced that the healthcare system is built and functional, and the only thing people need to do is to come and engage with it. A lack of engagement from people living in MRCs is perceived as a barrier to access rather on their side than on the side of the healthcare system.

“I think that the barrier is mutual, that it is literally some kind of ‘ditch’, where on the part of the system there is such a deep conviction that it is enough if the system is technically built. That is, there will be some network of buildings, which is filled with outpatient departments; there are doctors in those departments; those doctors have opening hours; those opening hours are best posted on the door and you just have to come there and things will happen. [...] Probably the most common thing I heard was: ‘We are here and they have no other task but to come and participate in those processes, and they are not willing to do this either’. [...] And all the rest is already on the side of the recipient of that ‘service’ because, from the provider’s side, it is a done deal.”

(public health authority)

3.2 Health workforce

3.2.1 Healthcare professionals are insufficiently trained and skilled to provide tailored information about vaccination

Insufficient training and skills of health care providers as a barrier concern their knowledge about HPV and HPV vaccination, their cultural competency and their assumptions about the target population. Vaccine hesitancy on the part of health care providers or their non-participation/inactivity in HPV vaccination is, according to some of our respondents, influenced by the religious beliefs of health care providers, their preference for other means of

prevention (sexual restraint), the influence of hoaxes, insufficient information about HPV vaccination among health care providers and their lack of motivation to discuss and offer HPV vaccination to patients.

"I don't know what percentage are of retirement age. So, they are happy to be able to handle the basics and maybe because they are older, maybe because of the HPV vaccine, which is a relatively new thing and modern, so maybe they don't believe it. So, they do not devote themselves to it and do not act actively in this area to somehow actively persuade those people. [...] Maybe they don't have enough knowledge about the vaccination, what it actually is and why and how and that the insurance company already covers it. [...] But some are anti-vaxxers against it."

(gynaecologist)

"And then we have those in the population who say there is another way of protection; let's call it sexual restraint, and regular preventive examinations, so many paediatricians have the same opinion, huh? [...] That they are, let's say, I will call it more religious because I encounter it the most, so they are so reserved that they may not actively offer it [the HPV vaccine]."

(primary paediatrician)

Health care providers are not providing detailed information humanly but are talking rather technically, which might have an impact on decision-making.

"They [Roma] have distrust; they are afraid. [...] I think that [because of] the approach of doctors, because they are not given the exact information, hey, what is it actually about, that it can't cause anything bad, only good. [...] Because you need to pay a little more attention to the Roma so they understand what it is all about. [...] Because most Roma won't understand technical words, right? So they don't know what it's about and say 'No, we don't want to.' Right? Maybe she would go for it or he would go for it, but it wasn't explained in detail, it wasn't said humanly, hey, but professionally."

(Roma health mediator)

3.2.2 Discrimination against the target population

An impaired relationship and insufficient or inappropriate way of communication between health care providers and patients from MRCs is burdened by prejudices, impersonal attitudes and double-standards. This was indicated by respondents from each group. According to health professionals, this creates a barrier for marginalized Roma in access to health care and has an impact on the perceived quality of health care. Many professionals, but also mothers from MRCs, indicated that it might lead to avoidance of health care.

"People from the socially weaker strata have very bad experiences with doctors, because those doctors are sometimes literally arrogant; they are not at all interested in the person who has a problem; they

also have bad experiences with nurses who beat them back very quickly, forcefully and literally brutally."

(Roma health mediator)

"Um, what would help me? What would help me? So, that they respect us and our children, and they should also consider our children. No, no offence, ma'am, but you shouldn't judge what a white child is like and this is a Romani child. They should deal with and take children the same way whether he or she is white or black; that's all I'd like, that they have respect for our children as well."

(mother from an MRC)

"She [the doctor] is rude to some people, but sometimes she is also rude to her nurse. Her mood changes."

(girl from MRC)

Both mothers and daughters from MRCs described situations of interactions with their doctors as unpleasant. As a reason for that, they often provided their opinion that doctors have negative attitudes toward them because of their origin. Racism was explicitly mentioned several times.

"Well, the doctor is good, but the nurse, I don't even know how to tell you. [...] She doesn't know ... she doesn't know how to deal with people. [...] Maybe she's racist or I don't know what she is."

(mother from an MRC)

"Because I'm a Roma woman, because we're Roma, but because they put us aside, sit down away from whites. I also had personal experience with it, and they knew that I was employed; they saw that I was clean, that I was decent, I have a card [health insurance], I can express myself, and I also had such a problem. That I say from my own experience."

(Roma health Mediator)

3.3 Service delivery

3.3.1 Insufficient access to services

According to our participants, access to healthcare services is limited due to various reasons, including physical access and the complexity of navigating the system and booking appointments. Primary care outpatient clinics are often several kilometers from MRCs and with bad traffic connections.

"So, well, if I were to take the bus, it would be at eight o'clock and I would wait there until half past twelve before going home."

(mother from an MRC)

"Where should she put the seven children when she needs to go 40 km or more to the nearest workplace? What will she do with them and where will she get the money? And another thing, she

has to get off somewhere at a station in a city she has never been to in her life, she has to find her way there, she has to know how to get on the right train or bus, and she has no idea how to do it, she doesn't know where to buy tickets. These are things that are completely legitimate."

(public health authority)

The process of HPV vaccination generates major logistical barriers, as it requires parental consent, the presence of a legal guardian during vaccination, a prescription from a pediatrician, ordering the vaccine from a supplier and the patient picking up the vaccine him/herself at the pharmacy before bringing it back to the health center. The whole process is repeated for the second dose. This process is even more complicated in rural areas where pharmacies are not present in each village.

"The vaccination procedure [...] can't be done that way. Not only that you have the prescription and you need to go 20 km to the pharmacy with the prescription and they say they don't have it."

(public health authority)

3.3.2 Insufficient resources to deliver all vaccines

Health care providers highlighted their restricted capacity and the high number of patients per pediatrician, leading to a lack of pediatricians' time, energy and motivation to address unnecessary or non-compulsory tasks, such as HPV vaccination and prioritizing acute management of ill children, mandatory preventive check-ups and vaccinations which take up all their capacities.

"Before the pandemic [...] I myself had the energy to talk to people about optional vaccinations at my clinic, but now I'm changing my mind and saying that it's not possible, right? By the paediatrician. I don't have the time, space, energy, or motivation to argue with them, do I? I just don't have the drive for it anymore, right? And that's why, with the workload that the paediatricians have [...] I'd rather examine 5 more sick children because I don't have time for those either."

(primary paediatrician)

"You know what? I don't really offer it [HPV vaccine], because I have so many children that I have a problem vaccinating them with mandatory vaccinations."

(primary paediatrician)

This lack of capacity was also reported by community members.

"We don't have a normal doctor, that we go to the doctor's office, that we sit down, that we talk, like about children. When we go there, everything is fast, because we don't have a doctor in the village [...]. She doesn't have the time to communicate with us. [...] She keeps saying that she has many patients."

(mother from an MRC)

Moreover, a large proportion of doctors are of retirement age, which might cause the situation to be even worse in the upcoming years. The insufficient capacity was compounded by the difficulty in attracting new health care providers to the catchment areas with MRCs, because of insufficient support, financial motivation and salary conditions.

"I see the care of MRCs as a huge problem also from the perspective that there is a huge shortage of primary paediatricians. Fifty percent of primary paediatricians are of retirement age, and the young ones will simply not go to those villages and those MRCs voluntarily to become doctors. [...] Given the conditions that the doctors have there, I mean the overall conditions, hey? Not only financially, but also mentally, including the number of children, payment mechanisms, and the difficulty of the work and communication with different types of people, so they are undervalued and, in my opinion, they are doing their best."

(primary paediatrician)

3.3.3 Lack of, insufficient or inadequate delivery of information

The previously mentioned restricted capacities of health care providers are leading to a situation in which people from MRCs are not informed about HPV infections by their doctors and are not offered HPV vaccination. The information does not reach them from any other source either, and as a result, they are unaware of HPV infections and its association with cancer, or of how vaccination (not only HPV but generally) works and whether it is effective.

"Doctors don't even talk about it [HPV]; they don't talk about it in the news or outside, that's why [people do not know about it]."

(girl from MRC)

"He [the doctor] is the main one, yeah, who is supposed to provide information or tell them that 'this will help you', 'that will help you'; he should do all that, but it's not like that, because the district physician will say: 'I still have 20 patients outside, yeah, I won't deal with you.'"

(Roma health mediator)

At the same time, both parents and girls often indicated that their doctor is the most reliable source of information for them and if they would like to get more information about cervical cancer or HPV vaccination, they would most likely approach their doctor.

"I would go to the doctor to find out what it is and how it can be treated and so on. Only them, because they [doctors] know more than Google, Facebook, or friends."

(girl from MRC)

According to our participants from the group of professionals, the existing field services providing health mediation in MRCs have insufficient personal capacities to be able to cover the topic

of HPV prevention on top of more pressing issues related to the health of people living in MRCs. Also, the coverage of these services is limited, as they are not available to all people in need of such services.

“So, I think there is a need to increase the number of Roma health mediators in the given communities. So, one paediatrician usually cooperates with one such Roma health mediator; they should actually have one in every marginalized community.”

(primary paediatrician)

“Rather, we are focusing on ensuring that children are vaccinated [with mandatory vaccines], and we are trying to ensure that the gynaecological check-ups are carried out, that women go to them regularly and that they also have a preventive check-up at the district doctor and so on, hey? That’s enough; we have enough to do.”

(Roma health mediator)

3.3.4 Language barriers

Language as a barrier includes difficulties in communication during consultations as well as the unavailability of information in the preferred language. Respondents mentioned that leaflets and health care providers use language and expressions which are hard to understand, and information materials do not align sufficiently with the needs of the people from MRCs. Information is tailored to middle/higher class educated women.

“Well, they also write something like that, as you say, uterus, to vaccinate, or whatever the substance is there. Well, sometimes I don’t understand at all what it is about. [...] Sometimes they also write in Latin, so we won’t understand what is there at all.”

(mother from MRC)

“Well, the difference is that if a non-Roma comes to talk to them [Roma] about it [HPV], in most cases 50% of those people will not know what they were talking about, or they will not understand what they were talking about. And the difference is that they have a little more trust in me, and I can say it in both the Romani language and the Slovak language.”

(Roma health mediator)

Several respondents indicated that people with lower literacy and limited capacity for understanding information related to health might confuse the abbreviation “HPV” with “HIV.” The translation may not be the right solution, as for many expressions there are no alternatives in the Romani language, as the vocabulary is limited.

“Once I read about vaccination against jaundice, then that there is a vaccination against HIV positive, that is the AIDS I mentioned before. Yeah. I read about several, yeah, but ... as one says to himself, hey, it doesn’t concern me yet, so...”

(mother from MRC)

3.4 Medical products

3.4.1 Optional status of the HPV vaccine

Mothers from MRCs differentiated between routine vaccines, such as MMR, and “optional” ones, such as HPV. “Optional” vaccines were viewed by them as inferior and somehow suspicious. Once the vaccination is optional, many people do not even consider it.

“I am not at all interested in optional vaccinations, nor would I have children vaccinated at all. If it is not mandatory, I will not vaccinate them. I wouldn’t even vaccinate myself. [...] I don’t know, maybe it’s not even explained well.”

(mother from MRC)

Healthcare professionals reported that people from Roma communities are not able to understand the meaning of vaccination as a means of prevention, and the optional status of HPV vaccination is a barrier.

“It’s as if they can’t fully evaluate the benefit in advance. [...] when you inject their child, who according to them is completely healthy, and you say that you are doing it so that something will not happen to him in 10 or 15 years, it is as if they have a problem evaluating why. So, the barrier is huge there. So, in my opinion, the only thing that would help there would be if the vaccination were mandatory, nothing else would help there.”

(primary paediatrician)

3.5 Financing

3.5.1 Costs to the system

Another substantial health system barrier to vaccination mentioned by respondents is the high cost of the HPV vaccine and the limited coverage of vaccination expenses from health insurance. This is likely to be caused by the high price of the vaccine and the willingness of health insurance companies to reimburse high costs.

“They [health insurance companies] are aware of the need (HPV vaccination) and what it is against, but then when the economic side comes into play, they look at it differently. [...] On the one hand, they know that it is necessary, on the other hand, it really costs a lot of money, because it is really one of the most expensive vaccines, right?”

(primary paediatrician)

3.5.2 Costs to patients

HPV vaccination is fully covered by health insurance companies only for 12-year-old girls and boys. This interval is perceived by respondents to be very short for people from MRCs to be able to organize vaccination fully covered by health insurance for their children in case of interest. Out-of-pocket payment to obtain vaccination outside of the regular reimbursed scheme and to cover travel costs pose an additional financial barrier for people from MRCs.

"Since it is paid out of pocket [in adulthood] and not covered by public insurance somehow, these marginalized groups are not interested in such vaccinations because it is very expensive."

(gynaecologist)

"For example, there are families that do not work. They only have those social benefits in material need and they have several children, so they also have to feed the children and clothes, and everything, and if the woman needs the vaccination and has nothing to pay for it, what is she supposed to do?"

(mother from MRC)

"It would be better to give ... I don't know how to say it ... this reimbursement [full coverage of the vaccine from health insurance], or whatever you call it. This, for all girls to have. Both adults and children."

(girl from MRC)

4 Discussion

This study aimed to explore health system barriers to HPV vaccination faced by Roma living in MRCs in Slovakia from multiple perspectives. The identified health system barriers seem to be related to the utilization of health care in general, as well as to the HPV vaccination specifically.

4.1 Leadership and governance

The current state of the health system and its approach to HPV vaccination requires quite proactive attitudes of health care users to obtain information, make a decision and get vaccinated against HPV. Insufficient regulation of information on the Internet and social media gives space to anti-vaccination movements which encourage mistrust of vaccination as a tool for prevention. Although media campaigns have recently relaxed since the nonavalent vaccine began to be fully covered by health insurance for 12-year-old boys and girls, these target the general public and information provided in the limited space of ads in public and social media is not sufficient to make an informed decision and require a further active search for information. This is not likely to be efficient in settings with limited resources and limited access to information, health care and low health literacy, causing a limited ability to understand and evaluate health-related information, which is a characteristic often associated with Roma, as has been described by health professionals in our research as well as elsewhere (18). Underserved populations require more proactive, tailored approaches for vaccination; however, the responsiveness of the healthcare system seems to be low toward people living in MRCs.

4.2 Health workforce and service delivery

Generally, access to health care was considered to be limited; however, perceptions of the causes differed among the groups.

People from MRCs are affected by the restricted capacities of primary care providers and perceive the tension it causes. Moreover, they also perceive the healthcare system as unfriendly and interaction with health care providers often as unpleasant due to their attitudes and behaviors influenced by prejudices and racism. Impaired relationships with health care providers contribute to the avoidance of healthcare services, which was similarly described by previous research (19, 20). More equitable access for Roma could be ensured by establishing a respectful and understanding relationship between health care providers and their Roma patients (21).

According to health professionals, the network of primary health care providers, including the number of primary care pediatricians, is insufficient. Many of them are of retirement age, and the number of patients per pediatrician is high. This is consistent with the findings of a spending review (22), according to which primary care is underfunded and less developed at the expense of specialized care. The availability of primary health care in Slovakia is poor and less effective also due to insufficient competencies, capacities and the structure of staffing (22). Restricted capacities cause pressure on the outpatient departments and limit access to health care, which was viewed as a universal problem concerning all patients, not only those from MRCs. However, this problem is more prominent in rural areas (22–24), especially in areas with a higher proportion of MRCs (24). The healthcare system is unable to attract a new healthcare workforce to such areas and offer the conditions and support (not only in terms of finances) needed to overcome difficulties connected to the demanding work with the target population and the administrative burden. Attracted by higher wages abroad, students in medical fields, including nurses, leave Slovakia after graduation to pursue their careers elsewhere (23). This complex situation leads to work overload and a lack of capacity and motivation to address HPV vaccination in primary care pediatricians.

Roma health mediators in MRCs focus on awareness-raising activities, serve as a bridge between health care and MRCs and help to overcome barriers in access to health care (25). Although the number of Roma health mediators and the number of communities in which they are operating is gradually increasing, this support is not available to all communities in need of such services, and the capacities of Roma health mediators are greatly utilized by helping to ensure basic health care, mandatory preventive examinations and mandatory vaccinations of children, acute health conditions and outbreaks (26). According to the Annual Report of Healthy Regions (26), which operates the health mediation program in Slovakia, educational activities mainly focus on child care and women's health as well as hygiene and prevention of infectious diseases causing outbreaks; thus, HPV is not yet on the agenda of Roma health mediators.

Lack of capacities and motivation of health care providers who are perceived as the most important source of information to address HPV vaccination leads to a lack of awareness about HPV-related cancer and its prevention among community members. This is in line with recent findings on barriers to HPV vaccination experienced by racial/ethnic minority groups indicating that HPV vaccine uptake is associated with a lack of recommendations for HPV vaccination from health care providers, mistrust toward healthcare professionals and low awareness of HPV and HPV vaccination (27, 28). Moreover, the process between the decision to vaccinate and the actual vaccination

is complicated for people with lower literacy, given the number of steps that separate them. Problems with navigation in the healthcare system occur in people with lower health literacy in vulnerable and underserved populations (29) such as Roma (18, 20).

4.3 Medical products and financing

Another group of barriers results from the way HPV vaccination is organized and financed. As many Roma living in MRCs suffer from financial hardship, those who are not eligible to have HPV vaccination fully covered by health insurance cannot afford it. The price of the vaccine leads to the hesitancy of health insurance companies to widen the age interval for free vaccination from 12-year-old to 9–15-year-old boys and girls despite pressure from the Ministry of Health and recommendations of health care providers (5). Although the vaccine itself is free for 12-year-old boys and girls, many primary pediatricians charged patients a fee for administering the vaccine, which was heavily criticized by health professionals, the public and the media (23). Such additional costs, together with travel costs, pose another barrier in access to HPV vaccination. However, from April 2023, all health insurance companies now reimburse the performance of HPV vaccination of 12-year-old children, which should lead to the cancelation of the fee for the administration of the vaccine by primary pediatricians. This measure has the potential to improve the affordability of HPV vaccination by eliminating out-of-pocket payments. If people from the MRCs were better informed about the possibility of getting vaccinated for free, it could support the acceptance of the HPV vaccine. However, without improving awareness, this measure by itself is unlikely to have much effect in marginalized Roma communities.

4.4 Strengths and limitations

The strength of this study can be seen in the diversity of the sample involving a range of stakeholders from community members to health care providers and policymakers with different perspectives on the studied topic, thus ensuring a rich spectrum of viewpoints. Moreover, following the principles of the Consensual Qualitative Research (CQR) methodology (15) was an important step in avoiding the subjectivity of researchers and improving the reliability of the results and interpretations. The use of the WHO health system building blocks framework allowed us to focus on health system barriers and organize them accordingly to highlight the essential components of a health system in which barriers are operating and need to be addressed.

A limitation of this study may be seen in the purposive sample consisting mostly of women. This limitation may be attributable to the fact that the expert field concerning the topic of interest is limited and feminized in Slovakia, and the HPV vaccination is mostly viewed as a prevention of cervical cancer and consequently as concerning more women than men. Moreover, in marginalized Roma communities, it is usually mothers who are responsible for dealing with issues related to health, and thus, they are more willing to participate in discussions concerning health. Another limitation of the study is that it was conducted in one specific region. MRCs in Slovakia are very

heterogeneous; thus, the results should be generalized with caution. The selected region is the one with the highest share of the Roma population and at the same time the lowest HPV vaccination rates, which is a good prerequisite for obtaining relevant data about barriers to HPV vaccination in MRCs. However, in other regions with varying demographics and healthcare resources, the barriers to HPV vaccination might occur to a lesser extent.

4.5 Implications

Identified health system barriers related to the utilization of health care, in general, are essentially connected with financial and legislative frameworks. It is necessary to increase the number of primary care providers, improve the system of financing and reimbursement of their services, provide them with sufficient support and secure decent working conditions, reduce the administrative burden associated with operating clinics and attract primary health care providers to less attractive regions. Increased capacities and motivation of primary care providers to address HPV vaccination are essential to increase vaccination rates not only in MRCs but in the whole population. Training of healthcare professionals might be needed in the area of communicating with people with lower health literacy, as the provision of tailored and understandable information has an impact on decision-making. The HPV vaccine fully covered by health insurance can be currently prescribed only by primary pediatricians. Relaxation of this restriction, optimally without limitation, might add some capacities of other health care providers, such as gynecologists.

Underserved groups, such as Roma, require special attention and proactive outreach to provide vaccination (6). Increasing the capacities of Roma health mediators, extending their scope to other communities in need of such services and providing them with training on HPV vaccination might partially take the burden off the shoulders of health care providers and help to overcome the language barrier. Roma health mediators can provide Roma living in MRCs with tailored and understandable information and help people navigate the complicated vaccination process. It would also be appropriate to consider how this process can be simplified. Expanding the age group for which the vaccine would be covered by health insurance and distributing the vaccine from the pharmacy to the care provider without involving parents or establishing school vaccination programs would contribute to simplifying the vaccination process and increasing the availability of the vaccine. These changes are of a legislative nature and create pressure on the Ministry of Health and health insurance companies, but pressure should also be exerted on pharmaceutical companies, too, as the price of the HPV vaccine is high and its reduction would mean better accessibility for several socioeconomic and age groups that are not covered by health insurance.

Future research should focus on the development and evaluation of tailored interventions for underserved groups, including communication strategies to foster their positive attitudes toward vaccination care as a means of prevention. Moreover, it is necessary to assess the needs of health care providers to enable them to communicate the topic of HPV and provide high-quality health care to patients with different needs.

5 Conclusion

Our results suggest that the healthcare system is not able to provide high-quality services to people with different needs, and their overall access to health care is limited. Slovakia faces a significant shortage of healthcare personnel, leading to work overload and a lack of capacity and motivation to address HPV vaccination. Impaired relationships between health care providers and their patients from MRCs lead to the avoidance of healthcare services. Moreover, the healthcare system fails to reach MRCs with appropriate and understandable information about HPV-associated diseases and HPV vaccination, which contributes to extremely low awareness of HPV, related cancer and possible prevention strategies. Limited coverage of vaccination expenses from health insurance makes HPV vaccination inaccessible for people from a disadvantaged background, which is often the case for Roma living in MRCs. Strengthening the capacities of health care providers, expanding the age group covered by health insurance to at least 9–15 years and providing tailored information to people from MRCs are necessary prerequisites to increase the availability of HPV vaccination and enable people to make informed decisions about HPV vaccination.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by Ethics Committee of the Faculty of Medicine at PJ Safarik University under number 11N/2021 and Ethics Committee of Košice Self-governing Region under the protocol identifier “H2020 RIVER-EU.” The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation in this study was provided by the participants’ legal guardians/next of kin.

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DF, DJ, and ME: conceptualization. DJ and ME: methodology. DF, ZD, JP, and IU: formal analysis, investigation. DF: writing—original draft preparation and writing—review and editing. ZD, DJ, and ME: supervision. All authors have read and agreed to the published version of the manuscript.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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From Ports2Arms: reimagining demand creation for the African context

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COVID-19, vaccines, demand creation, inequity, Africa, health rights, accountability, community-led monitoring

Introduction

The advent of the COVID-19 vaccine was seen as a silver bullet to end the pandemic by many, yet from the outset, African countries faced significant barriers to its effective distribution, access, and uptake. This was compounded by vaccine hoarding and nationalism by global north governments, making procurement difficult. Attempts to “equalise supply access” through global mechanisms like COVAX and bilateral vaccine donations from G7 and EU members (1, 2) (often of expired or close to expired stock) ultimately impeded efficient vaccine distribution and only added to historical mistrust of global north government agendas, with supply continuing to be erratic. As the pandemic progressed, the narrative soon shifted from one of a supply issue to that of distribution and demand, with “demand creation” becoming the central challenge—framed as “Africans don’t want vaccines” (3). Yet, in the context of erratic supply, what can demand creation mean for African communities whose experiences are often left out of vaccine rollout decisions, even when they put their bodies on the line for the research and development of these medical commodities.

Demand creation in the business marketing context refers to the creation of desire or motivation on the part of a consumer to buy a given good or service (4). In the public health context, the product or service is medicine or healthcare, such as a vaccine or medical procedure. In this context, demand creation or generation can be defined as “increas[ing] awareness of, and demand for, health products or services among a particular target audience through social and behavior change communication and social marketing techniques” (5).

What is missing in both the business and public health definitions of demand creation is a nuance that reflects historical legacy and local context. Any successful African vaccination demand creation strategy must be informed by lessons and mistakes from the recent past. Too often awareness is raised for new medical products, for example, new HIV medications in South Africa, resulting in the creation of community-level demand, only to result in a lack of supply when communities ultimately try to access these products. Similar issues occurred with the COVID-19 vaccine as African countries initially faced significant supply shortages, despite the global community touting the importance of the vaccine and the dangers of remaining unvaccinated. This unstable supply created hesitancy and mistrust, ultimately undermining effective demand creation (6). In addition, architects of demand creation strategies must consider any biases they may harbour. As an example, in 2001, Andrew Natsios, then-USAID

administrator, claimed that antiretroviral therapy for HIV should not be given to African communities because those “[p]eople do not know what watches and clocks are” and therefore would not be able to take the medications at the right times (7). Not only was this clearly proven false, but evidence demonstrating that Africans are not only more adherent to antiretroviral therapy than North Americans but actively engage with researchers and scientists to ensure that any research or public health intervention considers the local context and community realities so that such processes do not harm communities in the way they are rolled out (8, 9).

In the case of COVID-19, despite millions of vaccines coming in, there is a significant historical legacy to contend with, compounded by overburdened and under-resourced public health systems. Therefore, It is fundamentally immoral to position communities to demand a product before it is provided and before they have received adequate information to make a decision about its use. Communities need accurate and regularly updated information in accessible formats; steady and accessible vaccine supply; and meaningful engagement to better build trust between themselves, government, and vaccine distributors.

While some may argue that to increase vaccination in a time of crisis—like a global pandemic—certain coercive measures are justified (such as mandatory vaccination and associated penalties for unvaccinated workers), community agency in any vaccine rollout is critical for any vaccination program to be successful. The problem with directives regarding preventative measures being exerted in a top-down manner, is that they undermine the trust required for community engagement and can result in decreased demand and potentially less engagement with government, and the research and science community. Indeed, in the face of inconsistent and unreliable COVID-19 vaccine supply, demand decreased, fuelled by mistrust (10). Building agency around demand creation through skills strengthening, access to credible information and ensuring meaningful feedback loops goes hand in hand with community mobilisation; when given the tools, communities will find creative ways to get information out to support vaccination and other preventative measures, but if coercive measures are used, suspicion and resentment may increase, resulting in resistance to vaccination and decreased mobilisation efforts.

Contextual realities

The community perspective and experience of the COVID-19 pandemic is critical to understanding the role of supply-side inequity in undermining vaccine demand and to chart a more equitable practice for the next pandemic. We need to elevate local voices so we don’t replicate the mistakes of the past. A successful demand creation strategy in Africa must come from Africans—grounded in unique national contexts and community realities.

As soon as the COVID-19 vaccine became available, we saw a clear erosion of global solidarity. While African bodies were put on the line as part of fast-tracked clinical trials in South Africa, the subsequent rollout was marked by extreme inequity (11, 12). Individuals in Global North countries received second and third

doses well before most Africans received their first vaccine (13). Many African countries were reliant on donations from governments in the Global North, who often provided vaccines based on their own interests and priorities, resulting in a bizarre, disjointed vaccine rollout. Vaccines would arrive with little notice [and often close to expiry (14)], meaning national governments, healthcare workers, and communities had little time to prepare.

In South Africa, disapproval, and mistrust of the government alongside concerns about the effectiveness and potential adverse effects of the vaccine were critical obstacles to the vaccination rollout (15). Rumours contributed to vaccine hesitancy, including those that suggested vaccines were intended by Western countries to “kill Africans”.¹ Similarly, in Rwanda, some religious communities were said to believe vaccines were an attempt by Westerners to hurt Africans (16). This kind of misinformation, which emerged in the context of doubts about the safety of the AstraZeneca and Johnson and Johnson vaccines, strongly impacted the public perception of COVID-19 vaccines on the continent, casting doubt on the safety of the vaccines in general (17).

Competing priorities also affected community members’ desire or willingness to access the vaccine. In the context of climate change and related food insecurity, the costs of travelling to vaccine sites compared to the lost work opportunity costs are significant barriers to getting vaccinated (18). Yet even where vaccines were available, long lines inhibited uptake, or people would get to the end of the queue only to be told that supply had run out. All this led to increasing distrust of the vaccine rollout, and the vaccine itself.

Additionally, in countries like the Democratic Republic of the Congo or on the borders of countries in East Africa, frequent conflict and mass displacement affect people’s ability and desire to get vaccinated (19). These access and uptake challenges have been repeatedly compounded by inequitable vaccine supply dynamics globally, leading to confusion around the availability of different vaccine types in which countries, and cynicism and mistrust due to repeated reports of vaccines being delivered close to expiry and having to be destroyed (6). As a result, it is no surprise that this uncertainty and lack of accountability to effective vaccine distribution has significantly limited demand.

Reimagining demand creation: a rights-based approach

A lack of community ownership was highly evident in vaccine rollout on the continent. Large international bodies with no real contextual experience or understanding made assumptive decisions about local vaccine delivery. For the most part, communities did not have their concerns addressed or have control over when, how, and where vaccines were delivered. In addition, when vaccines were available, many historical and on-

¹The African Alliance (2023) Semi-structured conversation with communities in Gauteng [transcript]. South Africa.

the-ground realities resulted in limited uptake and vaccine hesitancy. As a result, effective demand creation must differ from traditional demand creation which often sees communities as passive actors to traditional social marketing techniques. Conversely, a rights-based approach encourages and engages active participation from communities, and recognises that for people to fully realise their right to health, they also must be in the position to claim and realise other rights, such as the right to information and education, and the right to equality under the law and non-discrimination in terms of access. These are expressed through the International Covenant on Economic, Social and Cultural Rights provisions that State parties are obliged to satisfy at minimum essential levels (20):²

1. Access to health facilities, goods and services;
2. Access to minimum essential food to ensure freedom from hunger;
3. Access to basic shelter, housing and sanitation;
4. Provision of essential drugs;
5. Equitable distribution of all health facilities, goods and services;
6. Adoption and implementation of a national public health strategy and plan of action based on epidemiological evidence, that addresses the health concerns of the whole population, periodically reviewed in a participatory and transparent process.

In the context of a pandemic, this means that all people at all times have the right to access services and commodities, such as the COVID-19 vaccine, to prevent the exposure to and transmission of a virus like COVID-19, as well as to treatment, care and support services. A community-led approach to demand creation grounded in human rights would first carefully listen to and consider the concerns and needs of community members in its design, seeking to inform them about the benefits of vaccination and provide meaningful, practical support in getting vaccinated, while also acknowledging that every person has a right to make autonomous decisions regarding their health.

This approach differs from the traditional view of demand creation in that, while it encourages vaccination, it does not seek to increase vaccination by *any* means but rather puts agency strengthening and recognition of basic human rights at its centre. To increase demand, communities must regain ownership over the COVID-19 vaccination rollout and general pandemic response, and be supported with accurate information, reliable supply and communication that meets them where they are, as well as allowing for feedback loops to key stakeholders in planning and response. This will better promote trust between communities and vaccine distributors, increasing local motivation and mobilisation efforts for vaccination. Only then can community agency and vaccine confidence be strengthened, and demand creation be truly promoted.

Concretely, what does community ownership of health look like? Our Ports2Arms project seeks to ensure that African communities in

all their diversity are meaningfully engaged in monitoring their lived experiences of public health crises, and their documented experiences and advocacy responses inform a shift to local ownership of future prevention, preparedness and response strategies for public health emergencies. This includes local ownership of healthcare delivery in the context of pandemics like COVID-19 (21). It is important to note that this approach does not imply that communities are entirely responsible for vaccination; the state must ensure vaccine availability. It is the role of communities to hold state actors accountable and ensure the vaccine rollout is equitable, just, and accessible to vulnerable populations. This model of community-led monitoring allows for the discussion and integration of various stakeholders and opinions to create effective strategies to improve vaccine uptake.

Doing better next time

Despite the devastation of the pandemic on the continent and globally, significant good, local practices have emerged to build on to inform future pandemic responses. For instance, in South Africa, local community members rallied to bring vaccines — as well as accurate information — straight to people's homes (22). Pop up vaccination clinics as part of a larger health roadshow have also been a successful initiative. Preparation and local mobilisation must occur *before* the crisis strikes, otherwise it may be too late. Practically, this means learning from COVID-19 — for instance, identifying barriers and enablers to COVID-19 vaccine uptake — so communities can be ready to quickly and efficiently roll out the next vaccine for the next pathogen (21). Focused and locally-tailored interventions are vital to ensure an equitable, rights-based response to the next pandemic or health emergency. What is needed is a constant effort to support communities in taking control over all aspects of their health. When communities lead the response, local agency is strengthened, and the trust that is built creates demand. Only when demand is created within a human rights framework will vaccines be efficiently and equitably transported from “ports to arms”.

Author contributions

PN: Writing – review & editing. FA: Writing – review & editing, Conceptualization, Supervision, Writing – original draft. AS: Conceptualization, Data curation, Formal Analysis, Investigation, Writing – original draft. LY: Conceptualization, Data curation, Formal Analysis, Investigation, Writing – original draft. AM: Funding acquisition, Supervision, Writing – review & editing, Project administration. TJ: Funding acquisition, Supervision, Writing – review & editing, Conceptualization, Validation.

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²Internationally, standards for good healthcare commonly use a framework of availability, accessibility, acceptability (including acceptable standards of quality), affordability and accountability.

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Promoting informed decision making about maternal pertussis vaccination: the systematic development of an online tailored decision aid and a centering-based group antenatal care intervention

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Introduction: Maintaining and enhancing vaccine confidence continues to be a challenge. Making an informed decision not only helps to avoid potential future regret but also reduces susceptibility to misinformation. There is an urgent need for interventions that facilitate informed decision-making about vaccines. This paper describes the systematic development of two interventions designed to promote informed decision making and indirectly, acceptance of maternal pertussis vaccination (MPV) in the Netherlands.

Materials and methods: The 6-step Intervention Mapping (IM) protocol was used for the development of an online tailored decision aid and Centering Pregnancy-based Group Antenatal Care (CP) intervention. A needs assessment was done using empirical literature and conducting a survey and focus groups (1), intervention objectives were formulated at the behavior and determinants levels (2), theoretical methods of behavior change were selected and translated into practical applications (3), which were further developed into the two interventions using user-centered design (4). Finally, plans were developed for implementation (5), and evaluation (6) of the interventions.

Results: The needs assessment showed that pregnant women often based their decision about MPV on information sourced online and conversations with their partners, obstetric care providers, and peers. Responding to these findings, we systematically developed two interactive, theory-based interventions. We created an online tailored decision aid, subjecting it to four iterations of testing among pregnant women, including those with low literacy levels. Participants evaluated prototypes of the intervention positively on relevance and usability. In addition, a CP intervention was developed with midwives.

Conclusion: Using IM resulted in the creation of an online decision aid and CP intervention to promote informed decision making regarding MPV. This description of the systematic development of the interventions not only serves to illustrate design rationales, it will also aid the interpretation of the evaluation of

the interventions, the development of future interventions promoting informed decision and acceptance of vaccines, and comparisons with other interventions.

KEYWORDS

intervention mapping, vaccination uptake, decision aid, informed decision making, maternal pertussis vaccination, centering pregnancy

Introduction

With pertussis, commonly known as whooping cough, still prevalent in the Netherlands [36.8 cases per 100,000 in 2019 (1)], newborn infants who are not yet vaccinated are exposed to its health risks, potentially leading to hospitalization and, in rare cases, death (1, 2). To prevent pertussis in newborn infants, maternal pertussis vaccination (MPV) was introduced in the National Immunization Programme (NIP) in 2019 (3, 4). This vaccination is administered during pregnancy at 22 weeks of pregnancy, providing direct protection for infants immediately after birth until they can receive their first vaccination. In the Netherlands, pregnant women have the opportunity to receive MPV free of charge at or after 22 weeks of pregnancy at a youth health center, where the child vaccinations in the NIP are also administered. They receive an invitation letter and brochure about MPV from their obstetric caregiver (5). The current uptake of MPV in the Netherlands was estimated to be 70% in 2020 (1).

Currently, there are no studies done on the characteristics of those who accepted MPV versus those who did not accept MPV in the Netherlands. During the current project, MPV was introduced in the Netherlands. Prior to the introduction, our earlier study looked at determinants of the intention to accept MPV, giving us an idea of which factors are at play in the decision making process about MPV (6). This study included mothers and prospective parents with differing attitudes and intentions regarding MPV. Among others, beliefs about safety and effectiveness, moral and social norms, as well as anticipated regret were positively associated with vaccination intention. We will go into these determinants further in the results section.

In the Netherlands, in the decade prior to the COVID-19 pandemic, a decrease in vaccine uptake in the NIP over time (for example of recommended vaccinations for children), and a lower uptake of newly introduced vaccines in the NIP than expected were observed (1). Making informed decisions ensures that patients' choice align with their values, helps prevent future feelings of regret, and reduces susceptibility to misinformation (7, 8). This can potentially result in higher vaccination rates, given that level of knowledge about a vaccine is often associated with a higher level of uptake of that vaccine (9). Given that MPV is a relatively new vaccination in the NIP, making it likely that people have questions about it, and the uptake is estimated to be 70% at the start of this study, we argue that it would be beneficial to promote informed decision making about MPV. In addition, for first-time parents, the MPV is the first vaccination decision in a series of vaccination decisions for their future child, making it especially relevant to ensure a positive experience (10).

This paper describes the systematic development of two interventions aimed at promoting informed decision-making about and uptake of MPV in the Netherlands. We used the Intervention

Mapping (IM) framework to describe each step of the interventions' development (11). IM provides a framework for using theory and empirical evidence to systematically develop behavior change interventions from a problem-based and participatory perspective. Interventions grounded in strong theoretical and empirical foundations tend to be more effective (12, 13). We advocate for transparent descriptions of health promotion interventions and their designs so that health promoters can replicate studies, and identify the conditions under which an intervention was (in)effective (14). Therefore, this paper describes our decision-making process and rationale at each step of the IM development process of the two interventions.

Materials and methods

IM is an approach designed for the systematic development of health promotion and behavior change programs. It offers a framework that facilitates the design, planning, implementation, and evaluation of health promotion interventions.

IM consists of six steps. Step 1 entails constructing a logic model of the problem. In this step, we identify the behavioral and environmental causes of the problem, and the underlying determinants reflected as cognitions, beliefs, and feelings of members of the at-risk population and environmental decision-makers. To accomplish this, we reviewed literature, conducted a survey study [$n = 611$, described at (6, 15)] and a focus-group study. We conducted four focus-group interviews involving a total of 19 pregnant women who were aged 25–37, and recruited at midwife clinics. In the Netherlands, midwifery practices are the standard care option for prenatal care. In case of a complicated pregnancy, pregnant individuals go to a gynecologist instead. As 90% of pregnant individuals start their prenatal care at a midwifery clinic (16), recruitment at a midwifery clinic includes a wide range of members of the target group. Among the 19 participants, four already had a child. Nine were college or university-level educated, ten had a vocational or practical education. Four had already received the vaccination, and seven already had the intention to get the vaccination prior to the interview. The 1.5-h focus-groups were semi-structured and focused on factors associated with the decision to accept or refuse MPV, how pregnant individuals perceive the decision-making process, and their evaluation of sample information about MPV. The focus-groups were transcribed and analyzed using thematic coding.

In Step 2 of the IM protocol, performance objectives (POs) are formulated. These POs represent the (sub)behaviors that must be performed by the target group in order to reach the intervention goal. Also, for each PO and its determinants, change objectives are formulated. This results in a matrix outlining pathways for change in informed decision making and acceptance of MPV, serving as the core

rationale for the intervention design. Step 3 concerns the design of the intervention program and its themes, components, scope, and sequence. This step includes the selection of theory-based intervention methods and the translation of these methods into practical applications, taking into account the parameters for the effectiveness of these methods. In Step 4, the methods and practical applications are being creatively translated into a cohesive intervention during the production phase, including pretesting of prototypes. In Step 5, the use of the intervention in real-life settings is carefully planned to ensure that the intervention will be adopted by the intended users and implemented according to the protocol to ensure sustained, long-term use of the intervention. The work done to ensure implementation does not take place after the development of the interventions, but takes place in parallel with the other steps. Finally, Step 6 concerns the planning of the process and effect evaluation of the intervention to measure program implementation and outcomes (11). Although the steps are presented as a linear process and outcomes of earlier steps inform later ones, it is important to note that IM is completed in an iterative way.

Results

IM step 1—needs assessment/logic model of the problem

Aims of the needs assessment

The needs assessment aimed to identify factors associated with the intention to accept MPV, and questions and information needs of pregnant individuals. This was examined with a qualitative study, conducting focus-group interviews with pregnant women ($n=19$), a survey study ($n=611$), and by reviewing literature (cited below).

Factors associated with the intention to accept MPV

The participants of the focus-group study indicated that reasons for accepting MPV included protection of their child, vaccine safety in the short and long term, recommendation from their GP or obstetric care provider, and the child being able to skip their first vaccination at 6 weeks of age. Additionally, they indicated that support from their partners and experiences from other women in their circles were important for their decision; some experienced social pressure when someone important to them opposed their decision. Conversely, reasons for refusing MPV were doubt, religious beliefs, a lack of trust in the NIP and feeling overwhelmed with the high amount of preventive or care interventions during pregnancy. These results were also found in the Dutch context in our previous survey study, where we studied determinants of the intention to accept MPV within the framework of the Theory of Planned Behavior and the Health Belief Model (6, 15, 17). Beliefs that the vaccine might cause harm was associated with a low vaccination intention, while beliefs that the vaccine was effective, safe, and beneficial for both mother and child were factors associated with a higher vaccination intention and uptake. Additionally, perceived susceptibility to infection and perceived severity of infection were related to a higher vaccination intention and uptake. Social norms, anticipated regret of accepting the vaccine, fear of the vaccine and of whooping cough, and decisional certainty were found to influence MPV intention. Under low levels of

decisional certainty, intention to accept MPV was low, indicating that an ambivalent attitude about the vaccine leads to a lower uptake. Instead, promoting a robust, informed decision is likely to lead to a higher uptake of MPV (6). Our results are in line with findings from a systematic review by Kilich et al. (18). From this review, recommendation from a health-care professional to get vaccinated was also found to be of importance (13). Additionally, knowledge is considered a prerequisite for making an informed decision (8), and perceived control is thought to be of influence based on the theory of planned behavior (19). Finally, affect, in addition to cognitive factors, is thought to be of influence on vaccine-decision making (20). The factors listed about are also covered in models that specifically describe vaccine hesitancy. For example in the 3C model of vaccine hesitancy by the SAGE working group on vaccine hesitancy, in which determinants are categorized into confidence, complacency, and constraints (21).

Information needs

Participants in our focus-group study frequently sought online information about pregnancy and health, primarily on websites and social media. Another important source of information was other (previously) pregnant women. When presented with examples of information about MPV targeted at pregnant women, participants positively evaluated materials with a clean layout, a moderate amount of text with clear sub-headings, a reliable source, personal experiences of other women, and relevant images and explanatory videos. Conversely, information that was perceived as patronizing or condescending was evaluated negatively.

Among pregnant participants in our survey study ($n=202$) (15), 55% a desire for assistance in making a decision about MPV (15). Of this group, 60% preferred a conversation with a healthcare professional, and 42% wanted to use an online decision aid. Most participants preferred to be informed by their obstetric caregiver. Information was desired about risks of side-effects in the mother and the baby, of the baby getting whooping cough, about the effectiveness of the vaccine, the symptoms of whooping cough, and possible alternatives for the vaccine. Information was preferably received through a brochure or letter (70%) or a website (49%).

IM step 2—program outcomes and objectives—logic model of change

Program outcomes and objectives

Building on the identified problem and needs we formulated the following primary program outcome: pregnant women make an informed decision about MPV-uptake, and act upon that decision. The associated behavioral outcome is as follows: pregnant women make an informed decision about MPV-uptake and experience low or no decisional conflict. To achieve these outcomes, we have formulated the following performance objectives: (PO1) the pregnant women make an informed decision about the MPV, (PO2) make an appointment to get MPV, (PO3) ask questions about MPV if one has any, and (PO4) go to the Youth Health Centre to get MPV.

Behavioral determinants

Next, we identified the behavioral determinants that could potentially mediate a change in the specified performance objective,

based on a review of existing literature (18) and our survey study (6). We selected all determinants deemed important based on the needs assessment and then selected those that were changeable. For example, for PO1 (making an informed decision), the selected determinants are: knowledge, attitude toward MPV, beliefs about safety, decisional certainty, injunctive norm, anticipated regret of vaccinating, beliefs about the effectiveness of MPV, negative and positive outcome expectancies of accepting MPV, social pressure, perceived control, positive and negative affect, risk perceptions and trust in the (provider of the) NIP (6, 18). For PO2, regarding making an appointment to get MPV, the selected determinants are knowledge, attitude, and perceived control about making the appointment. For PO3, regarding asking questions about MPV, the selected determinants are perceived control and trust in the (provider of) the NIP. For PO4, going to the Youth Health Centre to get the vaccine, selected determinants were knowledge, attitude, and perceived control. [Supplementary Table S1](#) shows a complete overview of the performance objectives and the determinants targeted.

Change objectives

Change Objectives (COs) were subsequently formulated based on the intersecting of determinants with the performance objectives. Change objectives specify what the target audience should learn in relation to a determinant to fulfill the performance objective. [Table 1](#) shows a sample of change objectives (for a complete overview, see [Supplementary Table S1](#)).

IM step 3—program design

This step describes the rationale of the intervention types chosen, based on the needs assessment and proximal program outcomes (change objectives). The selection of theoretical methods and their applications is based on the identified determinants and change objectives.

Because in the needs assessment pregnant women indicated searching for information online, and 42% in the survey indicated wanting to use an online decision aid, we decided to develop an online, tailored decision aid. Online interventions have the potential

to reach large audiences at a low cost. Online tailoring is “a combination of strategies and information intended to reach one specific person based on characteristics that are unique to that person, related to the outcome of interest, and derived from an individual assessment” (22). Online tailored interventions have demonstrated great effectiveness to change health behavior than generic interventions (23).

However, even though online interventions can be effective, the reach of at-risk populations (i.e., those with low (health) literacy and socio-economic status) is more challenging (23, 24). Therefore, aside from making the online intervention as easily accessible as possible, we additionally developed an intervention based on the Centering methodology, a method that has become more common in the context of pregnancy (Centering Pregnancy; CP). CP is group-based prenatal care where individual consultations are replaced with group sessions, led by a midwife or other obstetric-care provider (25). Additionally, healthcare professionals play a potentially pivotal role in the decision making about vaccinations, and therefore an intervention where they are closely involved may have the potential to be effective (13). Because the group sessions are much longer (90–120 min) compared to individual sessions, there is more time for education, self-management, skills building, and building trust between caregiver and clients (26–28).

CP is associated with better pregnancy outcomes and an increase the initiation of breastfeeding compared to individual care. Pregnant women felt more empowered to voice opinions about care and indicated that they were more likely to feel that their wishes were listened to by care providers (29). Currently, CP has been adopted in approximately 35% of midwifery clinics in the Netherlands and has proven to be an effective strategy for reaching at-risk populations (29–31).

Theoretical methods and practical applications

For each determinant, we identified theory-based methods of change with the help of the taxonomy of behavior change methods of Kok et al. (32).

Knowledge and outcome expectancies were targeted using consciousness-raising (17, 33) about the MPV and pertussis in babies. Active learning (34, 35), feedback (36), and belief selection

TABLE 1 Examples of change objectives, grouped per determinant.

Performance objectives	Determinants				
Pregnant women...	Knowledge	Attitude	Decisional certainty	Risk perceptions	Perceived control
PO1. Make an informed decision about the MPV	Recognize that MPV serves the purpose to protect her child once it's born for several months until it can be vaccinated itself	Evaluate MPV positively. They recognize the health benefits of MPV for themselves and their unborn child	Feel on balance positively about the decision	Acknowledge the risk of side-effects of MPV, such as a painful arm, a red injection spot, body ache, fatigue or fever	Describe feeling in control of processing information about MPV
PO2. make an appointment to get MPV		Evaluate making the appointment as smoothly and positively			Describe feeling in control of making an appointment at the JGZ

A complete overview can be found in [Supplementary Table S1](#).

(19) were used to enhance the processing of information by participants. They answered questions about their beliefs before being given tailored feedback. Chunking (37) was applied to avoid information overload. In the CP intervention facilitative discussion were applied, encouraging participants to deliberate on the information, and encourage active participation, asking questions, in order to get to the issues that were most relevant for participants. Within CP, questions and concerns of pregnant women are leading for the conversation. Learning from other pregnant women by sharing and discussing experiences and considerations is encouraged (25).

To target attitude, we applied “feedback on benefits and barriers” (38) to help participants draw up a balance of their considerations. Furthermore in CP, arguments for and against MPV were discussed. For example, this was done by letting participants formulate questions and facilitating the group to find the answers.

Risk perception was targeted using scenario-based risk information (39). Risk information was presented using natural frequencies (e.g., 1 out of 100) to enhance the understandability of probabilities (40).

To target perceived control, injunctive norm, and social pressure, we used the methods “resistance to social pressure” (19) and “information about others approval” (41, 42). Participants were facilitated to prepare conversations and questions about MPV for important others or healthcare providers. Furthermore, we used modeling (36, 43), allowing participants to read about or talk about other’s experiences about how to deal with making the decision.

Details about how the methods and applications were used in the interventions are described in IM step 4. [Supplementary Table S2](#) specifies which methods were used in each component of both interventions. [Supplementary Table S3](#) provides a comprehensive overview of the theories selected for each determinant and their practical applications.

IM step 4—program production

Theme, components, scope, and sequence

The online tailored decision aid and CP intervention were created in parallel. Both interventions can be used separately or combined. This section outlines the operationalization of the methods in both interventions.

The online decision aid

The online decision aid was created mobile-first in the form of a progressive web app because participants in the qualitative study (IM step 1) indicated a preference for using their mobile telephones most to search for pregnancy-related information online. During the development process, we aimed to meet the International Patient Decision Aid Standards (IPDAS) criteria for decision aids (44).

The online decision aid consisted of three main components: (1) information tiles, (2) a module called “my choice,” and (3) a “make an appointment” module. [Figure 1](#) presents screenshots of selected pages in the different components of the intervention. Participants were directed or “tunneled” from one page to the next, encouraging them to explore more components. They could also use the menu for navigation (45). Participants could visit the intervention as many times as they wished.

Participants were led, if they chose to follow the offered sequence, to the information component first (see [Figure 1A](#)). Because information is evaluated as more comprehensive when offered in the preferred mode (46), participants could choose if they preferred to watch a video, read text, or have the text read aloud. The text was chunked into basic information, automatically displayed, and “more information,” to prevent information overload (37). Sources of information were also provided, in line with the International Patient Decision Aid Standards (47). Videos showed a dialog between a pregnant woman and a midwife, along with visual organizers to explain concepts such as “how does the vaccine work?” and the rationale for administering MPV during pregnancy. The information pages stimulated active learning by providing “test your knowledge” questions. Participants could answer questions with true or false, and immediate feedback was provided (34–36, 48). The information provided on the information pages was checked for quality by a medical advisor of the National Institute for Public Health and the Environment, the RIVM.

The “my choice” component was divided into three submodules. The first, “test your knowledge” ([Figure 1B](#)), uses active learning and feedback to provide the most basic and relevant information about the vaccine (34–36, 48). The second, “weighing pros and cons” ([Figure 1C](#)), was aimed at improving decisional certainty by providing a tailored overview of the participants’ considerations about the MPV using a decisional balance (49). This exercise allows listing potential worries and feelings about MPV. Participants were presented with possible pros and cons of MPV and could indicate the extent to which these applied to them. Subsequently, participants were shown a customized overview of their results, without imposing a final judgment or recommendation. We did not include such a recommendation because some focus-group participants (IM step 1) negatively assessed materials that pressured them or directed them toward a specific choice. The third exercise was called “prepare a conversation about the vaccine” ([Figure 1D](#)). In this chat-like conversational module participants prepared for a conversation with a significant other, indicating what they wanted to gain from a conversation with an important social referent or health care provider, and what their feelings, needs, and questions were with regard to MPV. The module targeted dealing with social pressure and injunctive norm with regard to MPV by applying resistance to social pressure (19) and using non-violent communication (50). Participants received a customized overview of their responses that could be used in a conversation with an important other or healthcare provider.

The third component of the intervention was the “make an appointment” feature ([Figure 1E](#)). We included this to simplify the process of scheduling an MPV appointment, aiming to lower barriers for those who had decided in favor of the vaccine. We provided a postcode-based location finder where participants could make an appointment.

The DA meets the six qualifying criteria as defined by the IPDASi v4.0 guidelines (44). Aside from qualifying criteria, the IPDAS guidelines also contain certification criteria, quality criteria and evaluation criteria. The DA complies with five out of six certification criteria (four additional criteria that are only applicable to DAs about screening tests are not relevant for our DA). The certification criterion that our DA does not comply with, is the inclusion of author information and credentials in the DA. Out of 23 quality criteria

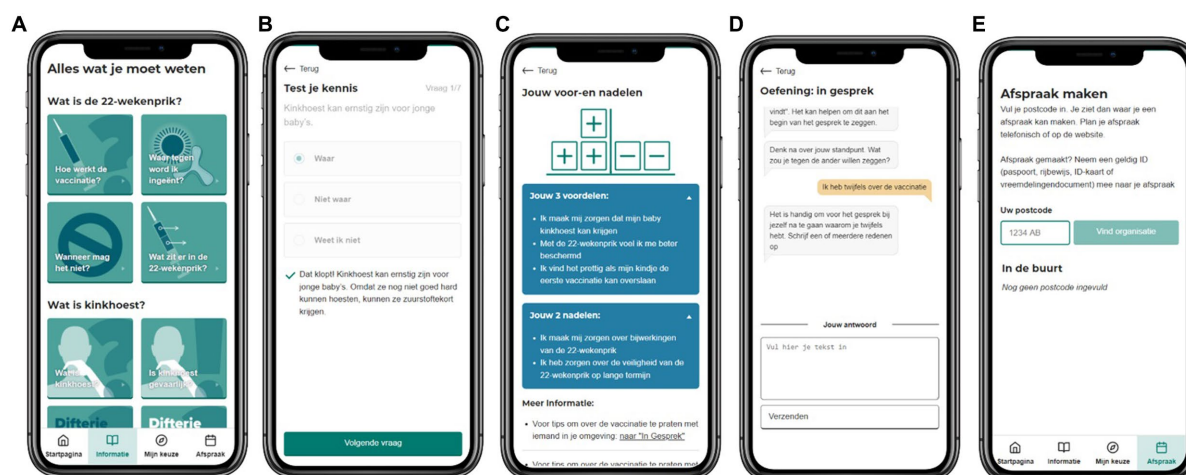


FIGURE 1

Screenshots of a selection of the website components: an overview of the information topics (A), an example of a “test your knowledge” question and tailored feedback (B), an overview page of the decisional balance with tailored pros and cons (C), the “prepare a conversation” exercise (D), the “make an appointment” page (E).

(excluding the criteria for screening test DAs), the DA meets 18. A criterion that was not met was “The patient DA (or associated documentation) describes the quality of the research evidence used.” We did not do this in order not to overwhelm participants with information, especially since we aimed to make the DA inclusive for low-literate users. We did include references to the research evidence used. Another unmet criterion was “The patient DA includes authors'/developers' credentials or qualifications.” The DA did include organizational credentials, but not that of the authors themselves. In addition, the DA did not report readability levels, but was instead tested with low-literate users to ensure readability. We also included a read-aloud option to improve readability. Whether the DA meets the evaluation quality criteria is assessed in the evaluation study. All other criteria with regard to development (the inclusion of users and professionals in the development process), evidence, guidance, values, probabilities and (balance of) information were met (44).

The centering pregnancy MPV information and decision making module

Within CP sessions participants are gathered in a circle. There are 10 sessions in total. Each session has an overall plan, but emphases may differ based on the group's needs. Because of the long sessions (90 min) and the opportunity to socialize, group cohesion takes shape in which women feel supported and safe. The leadership of the midwife is transparent and facilitative. Women are empowered by being involved in check-ups and self-care activities, so they learn to understand how their body is changing during pregnancy. These principles of CP are founded by the Midwifery Model of Care, and derived from social-cognitive theory, targeting social support and self-efficacy enhancement (51). During each session, issues are discussed in an interactive way.

Within existing CP groups, the possibility to get the MPV is discussed during the second CP meeting, around 16 or 20 weeks of pregnancy. First, the midwife identifies the group needs, by asking participants about what they already know and think of MPV.

Second, the midwife decides which CP method to apply in order to convey information about MPV. Examples of CP methods, incorporating active learning, included quizzes that required participants to determine the accuracy of statements about MPV, followed by immediate feedback. Another method involved participants formulating questions and encouraging group discussions, all in line with principles that centered on questioning, reflection, and autonomy. Participants were facilitated to arrive to their own answers, a process during which the midwife guides the conversation and summarizes learning points by asking questions and encouraging participants to draw conclusions, based on the facts that were provided. Depending on the input of the participants, specific topics were further explored. The consequences of vaccinating versus not vaccinating are discussed, incorrect beliefs about safety and effectiveness of MPV are deconstructed, and correct beliefs about safety and effectiveness are strengthened, confirmed, or if needed, introduced.

Third, upon having discussed some of the facts around MPV, participants are encouraged to actively think about what the information they received means for their decision about MPV, and share this with the group if they wish to. Participants are further encouraged to voice any potential concerns and considerations. A method used to do this is to collectively make a list of pros and cons of getting the MPV and to individually write down those that are evaluated as most personally relevant. Participants share their thoughts on the MPV, and learn how to address these through discussing the MPV and voicing their concerns and beliefs, and seeing other participants do this.

Fourth, participants who are still in doubt about MPV are encouraged to contemplate, express, and pursue what they need to make a decision that they felt comfortable with. This might involve seeking individual consultation with the doctor providing the vaccine, or a conversation with the partner or other important person. Participants are then provided with practical information about how to get the vaccine, to make it as easy as possible to get MPV if they chose to do so.

Pre-testing intervention prototypes

We used user-centered design to create the online decision aid, aiming to meet the needs and user preferences of the target group. We involved the target group in four iterations during the development process. In all pre-tests, we involved pregnant women of diverse ages and backgrounds. The aim of the pre-tests was to get participants' feedback on the intervention's clarity, relevance, usability, and overall structure.

In the initial pre-test, a focus group consisting of six pregnant women was presented with a static intervention prototype. The prototype featured a feedback system where participants were first to answer a question before receiving tailored feedback. However, participants expressed a preference for immediate access to the information without the initial question. They also preferred not having to indicate in which form they wanted to see information: video or text, but to have both options directly available. Participants further wanted to have more control over the information they received.

In the second iteration, five pregnant women individually used an interactive prototype of the intervention during think-aloud sessions. Participants generally evaluated the intervention positively and found it relevant. Based on their feedback, we made several improvements, including shortening and chunking the texts, refining sub-topic divisions, incorporating more sub-headings, and consulting a text-writer specialized in writing health-information texts suitable for both low-literate and high-literate users.

The third iteration featured a full, interactive version of the intervention, with six pregnant women individually using the intervention individually during a think-aloud session. Participants indicated wanting to have more explanatory and guiding text in the intervention. We incorporated this feedback and included an introduction video on the homepage that explains the purpose of the web app. Participants further indicated a preference for direct feedback during the knowledge quiz, which we implemented. To improve usability, alterations in wording and placement of buttons were made based on the evaluation of the participants.

The fourth iteration was a usability test with four low-literate users in individual think-aloud sessions. These participants were not pregnant. The aim of the test was to evaluate the usability of the intervention for low-literate users, whether the intervention was easy to understand and navigate for them, and whether the core message of the intervention was understood. Participants indicated that they were still interested to learn more about the vaccination, but were discouraged to pursue this on the web app because of the amount of text. Therefore, we included the option to have the text read aloud using *Readspeaker*®. Additionally, we made several adjustments to icons and images used based on participants' feedback to increase understanding.

After the final iteration, the intervention was tested further by members of the project group on various devices to ensure usability.

The CP intervention was developed by and in collaboration with midwives with extensive experience in applying CP methods and discussing vaccination in CP groups. The training was piloted with midwives trained to deliver CP. This process was embedded in a training for midwives that is part of the implementation and is described under IM step 5.

IM step 5—program implementation plan

Implementation of a program happens at the end of the development process. However, planning for the implementation happens throughout the entire development. This paragraph describes the steps we took to *plan* the implementation, and make sure that the interventions aligned with the needs of potential implementation partners.

To implement the CP intervention, midwives already practicing CP are trained to deliver the CP-MPV intervention. During a 3-h training in groups of 12 midwives, the following steps are taken. First, midwives are invited to complete a self-evaluation form, to foster awareness about their own opinions about the MPV. Second, to start a conversation about vaccinations, an "across the line" exercise is done, where everyone indicates for example whether they ever had doubts about getting a vaccine, followed by a short discussion. Third, midwives are invited to adapt an interactive CP method for the context of MPV. The aim is to educate pregnant women about the immune system and the MPV, where to find and how to judge information about vaccines, and how to make the decision about MPV. Fourth, executing this was practiced in the plenary group, with participating midwives assuming roles with varying perspectives on MPV. This helps to enhance awareness of the perspectives of participants in CP groups. Furthermore, creating a safe environment to discussing the MPV, sources of information for midwives, and logistical matters such as the timing of the session are discussed.

The training was tested with a group of midwives ($n = 12$), after which the training was made more interactive, and exercises were included where midwives could apply their preferred CP-method on MPV, and practice this. After the first full training, participating midwives were consulted for feedback, and small adjustments were made to the training information materials, and timing of the exercises. After each subsequent training, feedback from participating midwives was gathered and where needed, adjustments were made.

To further optimize the implementation of the interventions upon evaluation, we formed a linkage group with stakeholders at the start of the project. This group included representatives from the National Institute for Public Health and the Environment, RIVM (the provider of the National Immunization Program), the Royal Dutch Organisation of Midwives (KNOV), the organization training for Centering based CP (CenteringZorg) the overarching organization of direct providers of the MPV to pregnant women (Dutch Youth Health Centre, NCJ), Radboud University, physicians from preventive Youth Health Care responsible for administering child and maternal vaccinations, and the Netherlands Patients Federation. Representatives of these institutions and groups advised on the qualitative study in the needs assessment, theme and scope of the interventions during the development, the interactive elements, the practicability, usability, flexibility of the interventions, the planned effect-evaluation, and the implementation plans. They were consulted at every step of the process, and provided, e.g., suggestions for which information examples to test in the focus-groups, which topics to prioritize in the interventions, etc. During the needs-assessment, this was done with a group meeting. For the other steps in the development, individual meetings were held between each advisor and one of the authors (CA), during which work was presented and feedback was collected. Feedback from the advisors was then discussed within the author team and integrated in the intervention.

The RIVM will get full control and management over the online decision aid if it turns out to be effective. They have been involved in the development phase to ensure a successful implementation. The CP intervention is owned and managed by CenteringZorg, who are also a member of the project team. The CP intervention is in line with existing CP care, also to ensure a successful implementation.

IM step 6—evaluation plan

We planned to test the interventions in a semi-randomized controlled trial in order to assess their effects on informed decision-making, determinants of MPV uptake, and to check whether they influenced MPV uptake. In addition, we aimed to assess participants' subjective evaluations of the interventions. The outcomes of the trial will be published separately. The study has been approved by the TNO Institutional Review Board (2018-050). The trial registration is available at <https://www.onderzoekmetmensen.nl/en/trial/25018>. This trial registration describes the initial trial design.

We planned to use a semi-randomized design because participating midwifery clinics could not be randomly assigned to the CP or control condition, as CP care is only offered in a limited number of clinics. However, due to the COVID-19 pandemic and the associated social-distancing measures in place at the time of the data collection, CP group-care could not safely take place and could therefore not be included in the large-scale trial. We then used a randomized controlled design for the evaluation of the online decision aid. We recruited pregnant individuals in the Netherlands through midwifery clinics and social media. Baseline measurements were conducted via questionnaires upon enrolment in the study (before or at 16 weeks of pregnancy). The intervention group was granted access to the decision aid in addition to standard information between 16 and 20 weeks of pregnancy, while the control group received only standard information. At 20 to 22 weeks of pregnancy, a follow-up questionnaire was conducted, including measures of informed decision making, decisional certainty, and acceptance and usability of the intervention. Vaccination status was derived from Praeventis, the National Immunization Register. Data were analyzed using an intention-to-treat approach, using mixed regression models for longitudinal data and logistic regression for vaccination uptake data.

When it became possible to resume CP group-care, we conducted a small-scale study to evaluate the feasibility and acceptability of the CP intervention. We interviewed midwives and participants who were involved in a CP session about MPV, and additionally administered questionnaires offered to all participants who participated in the sessions about MPV.

Discussion

In this article, we have provided a detailed description of the systematic development of two complementary interventions promoting informed decision making about MPV during pregnancy. We created an online tailored decision aid for MPV decision-making. This included the provision of information using tailored feedback to existing beliefs, weighing pros and cons about the MPV, and a module to prepare a conversation about the MPV. Additionally, a CP session was developed that can be implemented in existing CP care settings.

We applied a user-centered, iterative design to meet the needs of the target group, and participants evaluated the intervention positively. Although the interventions are designed to complement each other, especially to ensure targeting all sub-groups of the population of pregnant women, the interventions can easily be used independently and are not reliant on each other.

Vaccination programs still have lower uptake among lower-educated compared to higher-educated people (52, 53), and many (online) health interventions do not sufficiently reach at-risk populations such as those with low socioeconomic status (SES) and low literacy (24, 54, 55). We aimed to make the interventions suitable for those with low (health) literacy by involving low-literate users in the development of the online tailored decision aid, and by using a CP approach that has proven to be suitable for these populations.

Midwives play an important role as facilitators in the CP intervention. Therefore, it is important to note that their personal attitudes toward vaccination may impact the potential effectiveness of the intervention. Although we are not aware of studies in the Netherlands on attitudes about vaccination among midwives, a 2018 review of global literature on the topic shows that the majority of midwives supports vaccinations (56). However, there is a spectrum of beliefs present among midwives. The training that we have developed may help to deconstruct incorrect beliefs, but midwives who are critical of vaccination may be less inclined to follow the training. It is important that this is taken into account in the evaluation of the study.

We used IM to systematically develop the interventions, offering insight in the underlying rationales, and behavioral theories that informed their design. The IM intervention blueprint described in this article provides insight into the theories used in the different intervention components, helping to interpret the results of our evaluation study, aiming to identify causal mechanisms that contribute to intervention effects. Furthermore, this blueprint provides the opportunity to compare the interventions to other interventions on a theoretical level, for example in reviews or replication of studies in different contexts (12, 57). IM is a time-consuming process. But the blueprint created for the interventions can also advise the development of similar interventions for other vaccines or behaviors.

Limitations

The small sample sizes in this study do not serve to evaluate the effectiveness of the intervention. They merely served to improve the intervention during the development process. We aimed to include a diverse group of pregnant individuals in terms of educational and cultural background. However, it is difficult to comment on generalizability of such a small sample. The larger evaluation study that was described under IM step 6 will provide statistically more robust data on use, acceptance and effectiveness of the interventions.

During the development of the interventions, we chose to target informed decision making rather than vaccination uptake. In addition, we aimed to reduce barriers to vaccination uptake once a decision had been made, and had the indirect aim to enhance vaccination uptake. This could be interpreted as conflicting with the decisional autonomy that a DA should respect and facilitate. The user-tests enabled us to guard a suitable balance of two-sided information for informed decision making. User input helped us redress the balance when a prototype of the DA was too favorable toward one decisional outcome.

Conclusion

We developed two interventions aiming to promote informed decision making and to decrease decisional conflict about MPV. These interventions were developed using the IM framework, incorporating behavioral change methods from various theories. This systematic approach to intervention development will aid the interpretation of the process and effect evaluations of the interventions.

Data availability statement

The datasets presented in this article are not readily available because participants did not consent to their data being shared. Requests to access the datasets should be directed to charlotte.anraad@maastrichtuniversity.nl.

Ethics statement

The studies involving humans were approved by TNO Institutional Review Board (Reference number 2018-01). The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

CA: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Writing – original draft, Writing – review & editing. PvE: Conceptualization, Funding acquisition, Investigation, Methodology, Supervision, Writing – review & editing. RR: Conceptualization, Funding acquisition, Investigation, Methodology, Supervision, Writing – review & editing. MR: Investigation, Supervision,

Writing – review & editing. KvG: Investigation, Validation, Writing – review & editing. HvK: Conceptualization, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Supervision, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fpubh.2024.1256337/full#supplementary-material>

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Study protocol: Project 2VIDA! SARS-CoV-2 vaccine intervention delivery for adults in Southern California

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Background: To date, the United States (US) leads the world in the number of infections and deaths due to the Coronavirus Disease 2019 (COVID-19). Racial and ethnic disparities in COVID-19 morbidity and mortality are staggering. Age-adjusted data show that AA and Latino individuals have had higher rates of death over most of the pandemic and during surges. Project 2VIDA! is community-based participatory research (CBPR) that was developed to address individual, social, and contextual factors related to access and acceptance of the COVID-19 vaccine among African American and Latino communities in Southern California. This paper describes the study protocol and overarching objectives.

Methods and design: Project 2VIDA! is a multilevel intervention that builds on the principals of CBPR and is designed to increase uptake of the COVID-19 vaccine among African American and Latino individuals (≥16 years and older) in San Diego County. The intervention was developed with a working group comprised of representatives from community and academia and centers on targeted COVID-19 individual awareness and education, linkage to medical and supportive services, COVID-19 community outreach and health promotion and offering the COVID-19 vaccine through community pop-up clinics.

Discussion: Findings from 2VIDA! will provide data on the impact, feasibility, and acceptability of the intervention which are all crucial for the adaptation, refinement, and improvement of vaccine outreach interventions for COVID-19 and other vaccine preventable infectious diseases that severely impact African American and Latino communities.

Clinical trial registration: <https://clinicaltrials.gov/ct2/show/NCT05022472?term=Project+2VIDA&draw=2&rank=1>, NCT05022472.

KEYWORDS

COVID-19, African American, Latino (Hispanic), vaccine hesitancy, community-based participatory research

Introduction

To date, the United States (US) leads the world in the number of infections and deaths due to the Coronavirus Disease 2019 (COVID-19), with 103 million infections and 1.1 million deaths (1). Racial and ethnic disparities in COVID-19 morbidity and mortality are staggering. Early in the pandemic, there were large racial disparities in COVID-19 cases, however, age-adjusted data show that African American, Latino and American Indians and Alaska Natives individuals have had higher rates of death compared with White individuals over most of the pandemic and during surges. Further, research indicates that pre-existing conditions such as diabetes, hypertension, and obesity increase a patient's risk for severe COVID-19 disease and mortality (2–4). African American and Latino individuals have a disproportionately high prevalence of such comorbidities that are compounded by social and contextual factors such as lower access to healthcare and higher rates of poverty (5–7). Racial and ethnic minority groups also comprised a disproportionate percentage of workers in essential industries (e.g., “front line” employees such as caregivers in nursing homes, transportation, food service) making it more likely for these communities to acquire and transmit the virus as they had limited opportunities to work remotely (8–10). These occupational hazards were intensified for those in the hospitality industry, as only 55% of those workers have access to paid sick leave (10). Within communities of color, there is often higher housing density, more housing insecurity, increased exposure to air pollution, and a greater number of multigenerational households which makes physical distancing harder, thereby increasing the risk of COVID-19 acquisition and transmission (6, 11). These important medical, social, economic, environmental, and political contexts predate and were exacerbated by the pandemic, contributing to disproportionate infections and deaths among African American and Latino individuals in the United States (12, 13).

Furthermore, public confidence in COVID-19 vaccines has been a complex and evolving issue since the vaccines were first developed and rolled out. Several factors have influenced public perception and confidence in these vaccines, including the unprecedented speed at which COVID-19 vaccines were developed, safety and efficacy concerns, vaccine misinformation, and mistrust in the healthcare system and government, among others (14–16). Early in the COVID-19 pandemic, the vaccination rates among African American and Latino individuals lagged well behind that of White individuals (17). Disparities in the uptake of at least one COVID-19 vaccination dose have narrowed over time. According to the CDC, over 8 in 10 people had received at least one COVID-19 vaccination dose as of February 23, 2023 (18). Despite this progress, a vaccination gap persists, particularly among African American individuals. Approximately half (59%) of African American individuals had received at least one dose compared with 64% of White individuals, and 67% of Latino individuals (19–21). Overall, few people have received the updated bivalent booster vaccine dose. Likewise, African American and Latino individuals are about half as likely as White individuals to have received this booster.

Since the onset of the pandemic, a variety of approaches have been employed to improve COVID-19 vaccination rates among racial/ethnic minorities and vulnerable populations, including provider delivered educational interventions (22); patient education, incentives, reminders (e.g., text messaging), motivational interviewing (23);

digital interventions (24); community-based approaches (25, 26) and provision of vaccines in settings serving high risk populations (27). However, these studies have yield mixed findings, noting that some interventions had no notable change in COVID-19 vaccine uptake (23). To effectively address vaccine hesitancy among African American and Latino communities, strategies should be culturally sensitive, community-centered, and built on trust. Engaging with trusted community leaders, healthcare providers, and organizations is essential. Additionally, providing accurate information about vaccine safety and efficacy, addressing concerns, and acknowledging historical injustices are key components of any effort to increase vaccination rates among communities of color. Ultimately, promoting vaccine confidence within the African American and Latino community is a crucial step toward controlling the spread of COVID-19 and advancing health equity in the U.S. Building on the lessons learned from the previously described efforts, in December of 2020, utilizing the principals of community based participatory research (CBPR), we formed an intervention working group comprised of representatives from community and academic organizations to address challenges in COVID-19 vaccination uptake among African American and Latino communities in Southern California by using a community-based participatory research (CBPR) approach. Specifically, we have developed Project 2VIDA! (SARS-CoV-2 Vaccine Intervention Delivery for Adults in Southern California), a multilevel intervention, to combat COVID-19 health misinformation and address individual, social, and contextual factors related to access, acceptance, uptake, and series completion of the COVID-19 vaccine among African American and Latino individuals (≥ 16 years old) in Southern California. The overall aim of the study is to assess the impact of an intervention known as Project 2VIDA! focused on addressing vaccine hesitancy and increasing access, acceptance, uptake, and series completion of the COVID-19 vaccine per CDC recommendations among African American and Latino individuals (≥ 16 years and older) across six communities in Southern California. More specifically, the study will: (1) Assess intervention effects on COVID-19 vaccination rates and series completion among African American and Latino individuals (≥ 16 years old) living in San Diego County; (2) Determine feasibility and acceptability of the 2VIDA! intervention among African American and Latino individuals (≥ 16 years old) living in San Diego County; (3) Examine individual and structural barriers to COVID-19 vaccination among African American and Latino and AA individuals (≥ 16 years old) living in San Diego County; and (4) Identify the main sources of COVID-19 information that African American and Latino individuals (≥ 16 years old) trust and are utilizing, to inform efforts to combat health misinformation related to COVID-19 as well as future public health emergencies.

Methods

Study design

This is a multicentric cluster randomized controlled trial with a control group and an intervention group, with participant blinding. This protocol has been written according to the recommendations of the SPIRIT 2013 statement, a guideline that provides evidence-based recommendations for a clinical trial protocol, including

recommendations for intervention trials. Additionally, the design of this clinical trial follows the requirements of the CONSORT statement.

Participants, recruitment, and study settings

With a population of 39.2 million people (28), California is home to a many distinct communities. Though all of these communities are the supposed equal beneficiaries of the state public health system, appreciable inequity is evident. In mid-2020, one of the most salient factors dividing local communities, unfortunately, remains racial composition. Southern California is one of the most ethnically diverse areas that was hit the hardest during the pandemic (29, 30). However, in San Diego County, the impact of the virus varied dramatically depending on ZIP code. For example, population and case-rate data indicate that individuals that lived in zip codes associated to more affluent neighborhoods such as Carmel Valley (located 30 miles north from San Ysidro), were nearly 60 times less likely to live next to someone who tested positive for COVID. Compared to individuals in San Ysidro, were one in every 10 individuals tested positive (31). These ZIP codes were concentrated in Southeast San Diego and home to predominantly racial and ethnic minorities who are uninsured and live below the federal poverty line (32). Participants were recruited from the zip codes that reported the highest number of cases in San Diego County, that include the communities of National City, Logan

Heights, Lincoln Park, Valencia Park, Chula Vista, and San Ysidro (Figure 1).

Participants from both intervention ($n=500$) and control sites ($n=500$) were recruited using multipronged recruitment strategies including the use of trusted community partners, social media platforms, and flyer distribution within the selected health centers and the selected communities in highly trafficked and readily visible areas where eligible participants frequent (e.g., grocery stores, local community-based organizations [CBOs], faith-based organizations, parks, food banks, gyms, local restaurants). Flyers include study and contact information for study staff. Likewise, project staff publicize the community pop-up clinics by posting flyers that note locations, dates, and times of vaccine distribution and through presentations about the project at community meetings. Project staffing, training, and support, including the selection of nurses and outreach staff (e.g., peer-health educators and research assistants) with complementary research skills and personal knowledge of the community were key to the success of the project. Bilingual outreach workers trained in research ethics and protocols, and familiar with the target population, approached individuals who appear to be eligible at the health center, and community pop-up clinics in the participating sites.

Research assistants approached potential eligible participants from the waiting rooms of the health centers and at the community pop-up clinics and assessed whether or not they met the inclusion

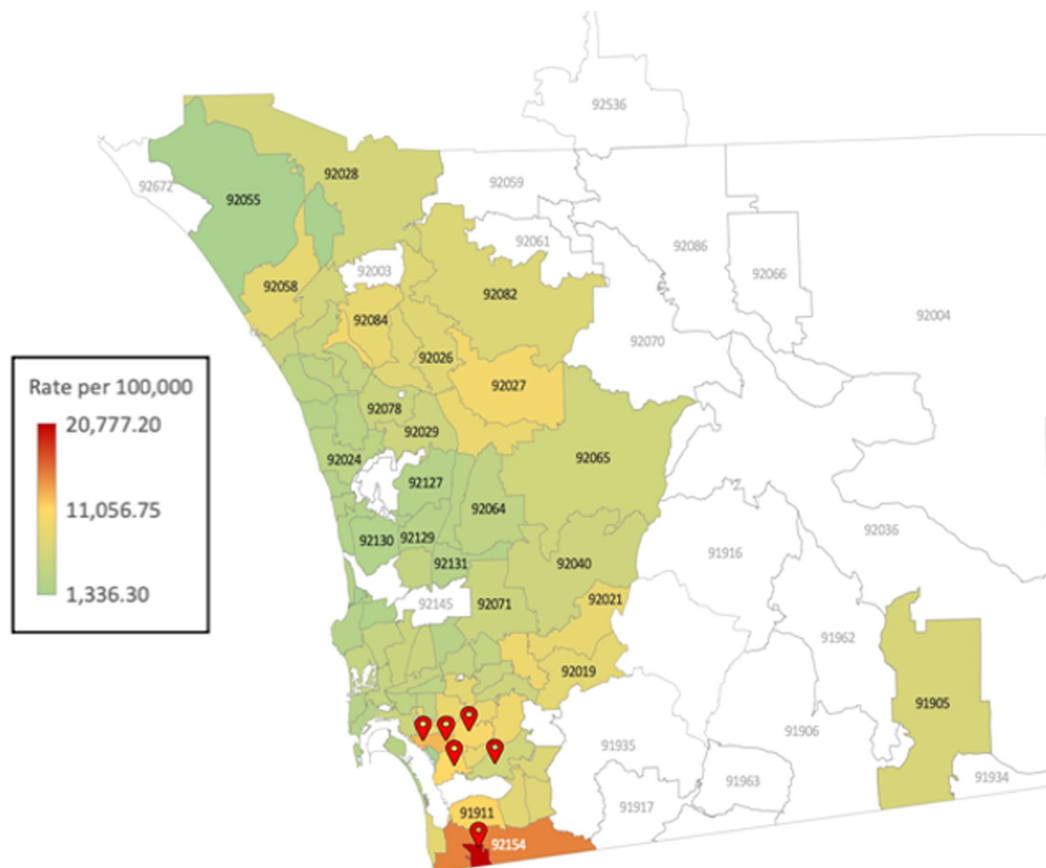


FIGURE 1
Map of San Diego County with the daily Coronavirus Disease (COVID-19) summary of cases by zip code of residence (data from 01/28/2021) and Project 2VIDA sites.

criteria described below; they explained the purpose of the study including its risk and benefits. They were also reminded that participation in the study was voluntary and if they declined to participate, they would not lose access to care or any other service they were currently receiving or eligible to receive. Research assistants recorded data regarding eligibility and reasons for non-participation where applicable, however, no personal identifying information was collected. These data were recorded in the form of a Client Recruitment Log. Those agreeing to participate were escorted to a private room within the participating health center or at the community pop-up clinic and provided verbal consent and completed the survey via a tablet (self-administered). Extensive efforts were made to have a study sample that represented the racial and ethnic composition of San Diego County, and at least 40% women. Participants received a \$20 VISA gift card for completing the baseline survey and additional \$20 VISA gift card for completing the follow-up survey.

Inclusion criteria

(i) age 16 years or older, (ii) identify as Latinx and/or AA, (iii) biologically male or female, (iv) be a resident of one of the six communities selected for this study (National City, Lincoln Park, Logan Heights, Valencia Park, Chula Vista or San Ysidro), (v) literate in English or Spanish, (vi) no known history of severe allergic reactions to any components of the vaccine, (vii) no history of immune disease, (viii) not currently pregnant, (ix) no plans to move from the area in the following 30 days, (x) able to provide voluntary informed consent, and (xi) able to provide complete contact information for themselves (for follow-up survey, 2nd vaccine and booster shot).

Exclusion criteria

(i) under 16 years old, (ii) pregnant women, (iii) adults unable to consent. Although pregnancy is not a contraindication for COVID-19 vaccination, working group members decided that vaccinating pregnant women, especially at the beginning of the pandemic, would not be well received in the target communities.

Randomization of sites

Prior to intervention piloting, the six participating communities were randomized to either the intervention (e.g., pop-up community clinic) or control condition (e.g., health center) using a computer-generated random sequence. Community-level randomization was selected to minimize between-arm contamination of intervention and control conditions. Additionally, these communities were at least 10–20 miles apart from each other to further minimize contamination. Sites matched to the control condition were briefly trained in process evaluation and quality assurance procedures. All sites will participate in process and outcome evaluation protocols. Data collection began June 16, 2021 and is expected to be completed in Fall 2023.

Description of the intervention

2VIDA! is a multilevel intervention informed by the National Institute on Minority Health and Health Disparities (NIMHD) research framework (33) and the principles of CBPR (34, 35). *2VIDA!* centers on COVID-19 individual awareness and education, linkage to medical and supportive services, COVID-19 community outreach and health promotion and offering the COVID-19 vaccine through

community pop-up clinics targeting African American and Latino individuals across six communities in San Diego County (See Figure 2 Study Design). *2VIDA!* is grounded in the NIMHD framework (Figure 3) as it seeks to understand and address health disparities from a multilevel approach by examining individual, social, and contextual factors related to access to, and acceptance of, the COVID-19 vaccine, as well as CBPR. CBPR offers an opportunity to amend health disparities in communities of color. It requires an equitable involvement of researchers and the members of a community that are affected in all aspects of a research process, aiming to improve health, generate knowledge and effect social change. Utilizing the principles of CBPR, we aim to reduce such disparities in health literacy and access to COVID-19 vaccine by addressing the specific challenges of the African American and Latino communities in South San Diego with practical, sustainable, culturally appropriate solutions that utilize the community's strengths, and test the effectiveness of the intervention by utilizing rigorous research methods. We expect *2VIDA!* to improve health literacy, feasibility, acceptance, and uptake of COVID-19 vaccine among African American and Latino individuals (≥ 16 years old) in the target communities. The *2VIDA!* intervention has two phases.

Phase 1

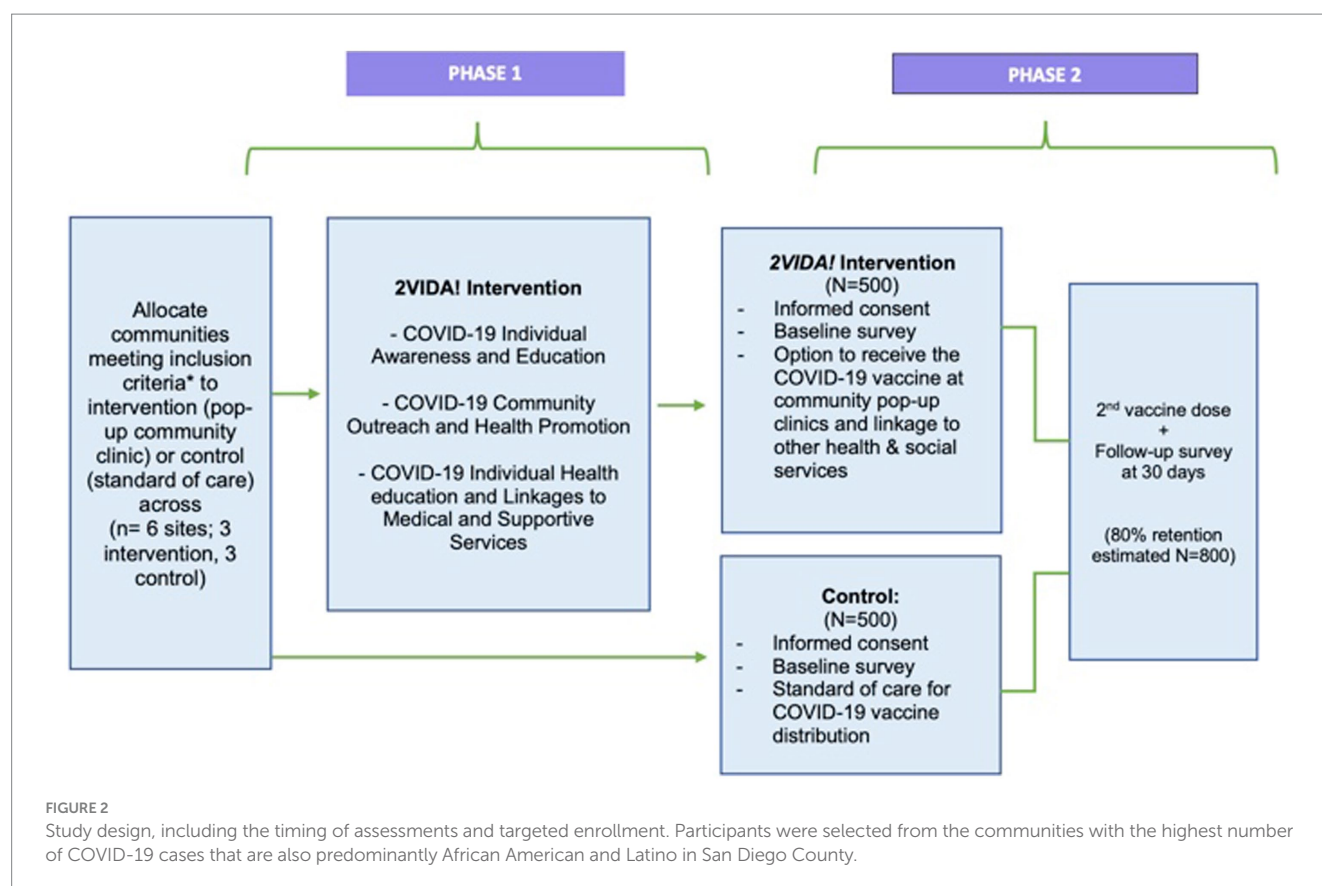
The phase 1 of the *2VIDA!* intervention has three components outlined below.

COVID-19 individual awareness and education

2VIDA! formed a CBPR working group that developed culturally competent COVID-19 educational and outreach materials (available in print and digitally) in English and Spanish that were written at an 8th grade reading level (the average reading level of adults in the United States). Peer-health educators distributed to community members during their visits to the participating sites, door-to-door, local supermarkets, and CBOs in the selected communities. These materials have general information on COVID-19 as well as educational information and resources regarding COVID-19 prevention, symptoms, testing, contact tracing, COVID-19 vaccine (how it works, technology used, administration, importance of vaccine series completion and booster), safety concerns, benefits, risks, dispelling common misconceptions and misinformation, and potential side effects, and other topics identified based on community needs. This information is updated on a weekly basis to ensure the most accurate and recent information is provided. Approximately 50,000 printed educational and outreach materials were distributed across the intervention sites.

COVID-19 community outreach and health promotion

Peer-health educators worked with local CBOs to facilitate a combination of targeted live radio broadcast sessions, town hall meetings, power-point presentations in the community and via Zoom, pre-recorded webinars, social media posts, and other outreach activities in English and Spanish in different community settings. These activities engaged community members with information on COVID-19 related topics as the pandemic evolved, as well as other identified needs such as what to do if a family member is infected and where they can get the COVID-19 vaccine. The goal is to reach 10,000 viewers (per session) in the across the social media platforms in the selected intervention communities.



COVID-19 individual health education and linkages to medical and supportive services

A COVID-19 Resource Center has been established to serve the intervention sites providing individual COVID-19 related health education and linkages to medical and supportive services for participants and community members in need of additional education and support regarding COVID-19 disease and COVID-19 vaccine.

Phase 2

During Phase 2, the COVID-19 vaccine and other health and social are offered through community pop-up clinics that are set-up in the targeted communities as part of our efforts to address some of the barriers Latino and African American communities have to accessing the COVID-19 vaccine. The community pop-up clinics take place in various open spaces such as public parks, parking lots, grocery stores, community recreation centers, swap meets, faith-based organizations, and food banks in these communities.

Control group (standard of care)





Participants in the control group receive the standard of care for COVID-19 vaccine distribution. As previously mentioned, in order to minimize the occurrence of contamination, randomization occurred at the community level and the intervention sites are located at least 10–15 miles or more apart from each other. Data collection surveys to assess individual, social, and contextual factors related to access,

acceptance, and uptake of the COVID-19 vaccine be administered at baseline and follow-up.

Data collection

The baseline survey lasts approximately 20 min and is self-administered via tablet in either English and Spanish. The baseline survey assesses individual, social, and contextual factors related to access, acceptance, and uptake of the COVID-19 vaccine including: (a) sociodemographic characteristics; (b) characteristics associated with social marginalization (e.g., homelessness, food insecurity); (c) access to and utilization of health care; (d) vaccination history, interest, hesitancy and uptake; (e) perceptions of the COVID-19 vaccine (e.g., fears, myths, etc.); (f) general health; (g) trust in government, research, and social agencies; and (h) satisfaction with 2VIDA! Following participation in the intervention and completion of baseline survey, participants are eligible to receive the COVID-19 vaccine if they are interested and provided informed consent. Participants are also asked to complete a follow-up survey when they receive the second dose or booster. The follow-up survey takes approximately 8 min to complete and assessed changes in (a) access to and utilization of health care; (b) vaccination history, interest, hesitancy and uptake; (c) perceptions of the COVID-19 vaccine (e.g., fears, myths, etc.); (d) trust in government, research, and social agencies; and (e) satisfaction with 2VIDA! The research staff are always available in case questions arise or help is needed with any aspect of the survey.

National Institute on Minority Health and Health Disparities Research Framework

		Levels of Influence*			
		Individual	Interpersonal	Community	Societal
Domains of Influence (Over the Lifecourse)	Biological	Biological Vulnerability and Mechanisms	Caregiver–Child Interaction Family Microbiome	Community Illness Exposure Herd Immunity	Sanitation Immunization Pathogen Exposure
	Behavioral	Health Behaviors Coping Strategies	Family Functioning School/Work Functioning	Community Functioning	Policies and Laws
	Physical/Built Environment	Personal Environment	Household Environment School/Work Environment	Community Environment Community Resources	Societal Structure
	Sociocultural Environment	Sociodemographics Limited English Cultural Identity Response to Discrimination	Social Networks Family/Peer Norms Interpersonal Discrimination	Community Norms Local Structural Discrimination	Social Norms Societal Structural Discrimination
	Health Care System	Insurance Coverage Health Literacy Treatment Preferences	Patient–Clinician Relationship Medical Decision-Making	Availability of Services Safety Net Services	Quality of Care Health Care Policies
Health Outcomes		 Individual Health	 Family/ Organizational Health	 Community Health	 Population Health

National Institute on Minority Health and Health Disparities, 2018

*Health Disparity Populations: Racial and Ethnic Minority Groups (defined by OMB Directive 15), People with Lower Socioeconomic Status, Underserved Rural Communities, Sexual and Gender Minority Groups, People with Disabilities
Other Fundamental Characteristics: Sex and Gender, Disability, Geographic Region

FIGURE 3

Project 2VIDA! is a multilevel intervention informed by the National Institute on Minority Health and Health Disparities research framework (33) and the principles of community-based participatory research.

Outcome measures

Primary outcome measurement

Vaccination hesitancy and distrust

Based on the SAGE Working Group on Vaccine Hesitancy, vaccine hesitancy is defined as “delay in acceptance or refusal of vaccination despite availability of vaccination services” (36).

Vaccination interest, uptake, and series completion

Interest in vaccination which is assessed in the survey through the question, “Are you interested in taking a vaccine against COVID-19?”; uptake of COVID-19 which will be recorded as “yes” if they receive the COVID-19 vaccine that day; vaccine series completion will be assessed based on them receiving having completed the series per recommendations by the CDC’s Advisory Committee on Immunization Practices (37) and confirmed through the California Immunization Registry (CAIR).

Receipt and acceptability of 2VIDA! intervention

Receipt and acceptability of the intervention was assessed utilizing the Treatment Acceptability and Preferences (TAP) measure tool (38) that contains 4 items scored on a 5-point Likert scale.

Secondary outcomes measurement

Differences between both groups with respect to the following items:

Sociodemographic outcomes

Age (assessed as a continuous measure); sex assigned at birth (male, female, intersex); gender identity (agender, genderqueer or genderfluid, man, non-binary, woman); race/ethnicity (American Indian or Alaska Native, Black or African American, Hispanic or Latino, Native Hawaiian or other Pacific Islander, White, Multiracial/more than one race; other); education (never attended school, elementary, some high school, high school graduate, some college or technical school, graduated from college or technical school, postgraduate school); country of origin (this was an open ended question); marital status (single, married, living with a partner, divorced, widow), employment status (employed full time, employed part-time, unemployed, retired, student/currently in school), household income for the past 12 months (less than \$5,000, \$5,000–\$19,999, \$20,000 – \$49,000, \$50,000–\$99,999, \$100,000–\$149,999, More than \$150,000), living situation (own, rent, live with friends, live with family, no permanent residence, live at a shelter/currently

homeless), household composition (assessed by the question: how many people are currently living in your household. By “living” in your household we mean that they spend more than 2 nights a week in your house).

Characteristics associated with social marginalization

Measured by 5 items: Recent and lifetime homelessness, substance abuse, engagement in commercial sex work, food insecurity (adapted from the (39)), and intimate-partner violence (IPV).

Medical history

History of having COVID-19 (yes/no) and/or medical conditions (yes/no) that could exacerbate COVID-19 infection including type 1 and type 2 diabetes mellitus, hypertension, heart conditions (e.g., coronary artery disease), obesity (e.g., body mass index of 30 kg/m² or higher but <40 kg/m²), mental health (depression, anxiety, post-traumatic stress disorder), asthma, chronic obstructive pulmonary disease (COPD), and smoking.

Access to and utilization of health care

Assessed by 5 items: Insurance status, type of insurance, regularity, and location of access to health care, receipt of services from government or community agencies (adapted from the National Health Interview Survey) (37).

Mistrust of COVID-19 vaccine effectiveness

This was assessed by the question “I believe a vaccine can help control the spread of COVID-19,” modeled from the WHO survey (40). This survey item was measured ordinally as a range from “Strongly Agree” to “Strongly Disagree.”

Perception of COVID-19 media hype

Using a survey item adapted from the WHO survey (40) participants were asked to rate their perception of COVID-19 being media hyped. Participants’ perceived level of media hype surrounding COVID-19 was measured ordinally along a 7-point rating scale (Strongly Media Hyped to No Media Hype).

Frequency of use and level of trust in COVID-19 sources of information

The variables *Level of Trust* and *Frequency of Use* assessed participants’ engagement with several media sources (i.e., Television, Newspapers, Health Workers, Social Media, Radio, Health Departments, the CDC, Celebrities/Influencers, the WHO, COVID-19 Hotlines, National COVID-19 Websites) in relation to COVID-19 information. *Level of Trust* was measured ordinally for each media source as a range from “Very Little Trust” to “A Great Deal of Trust.” *Frequency of Use* was also measured ordinally for each media source from “Never Use” to “Use Very Often” (40).

Ease of finding, judging, understanding, and following COVID-19 recommendation

Participants were asked to rate the difficulty level of understanding, judging and following COVID-19 recommendations such as when to stay home, if they needed to get the booster, what symptoms they should look for, etc. These variables were measured ordinally from “Very Difficult” to “Very Easy.”

Attitude toward COVID-19 vaccine policies

Participants were asked their attitudes toward public vaccine policies were assessed as categorical variables. Participants were asked to indicate their sentiment toward receiving the vaccine if everyone else was already vaccinated, attitudes toward the national vaccine schedule, and whether they agreed all should follow the recommended guidelines by the government and organizations such as the WHO and the FDA.

Withdrawal

Participants may withdraw from the study at any time and by any given reasons. Reasons for withdrawal will be recorded for further study. The participants who withdraw from the study will not be replaced.

Adverse events

Any adverse events are currently not foreseen, due to the study and intervention’s nature will be reported accordingly to the IRB and the vaccine adverse event reporting system (VAERS).

Data analysis

As a feasibility study, the analyses will primarily involve simple univariate and bivariate analyses, with additional logistic and linear regression analyses to explore time x treatment effects from baseline to follow-up. Adjusted regression models will be created to assess whether intervention effects on specified outcomes are maintained subsequent to controlling for potential confounders selected based on baseline treatment group differences in demographics and reported risk factors (e.g., pre-existing conditions, mistrust in government or healthcare system). Findings will receive extensive investigative team and community review to assist with interpretation of findings. The primary outcome of the study is vaccination rate, which is dichotomous. Comparison between the intervention and control arms will be compared using a Fisher’s exact test for proportions. Differences in the rates between the two groups, along with the OR and their 95% CI will be reported. Missing data considerations: Data will be routinely monitored by the study team to ensure completeness. Entered data will be reviewed routinely and inspected for errors, and omissions. A CONSORT diagram will be produced at the end of the study that will show the participant flow in the study, including numbers screened, enrolled, withdrawals, and completers. We expect that the amount of missing data for the primary assessment will be minimal (<15%). Substantial efforts will be made to ensure complete follow-up. Rates of missing data and loss to follow-up will be reported. Missing strategies, such as sensitivity analyses, missing data imputation or propensity weighting, will be considered based on the degree of missingness in the data. Under these various missing data strategies, the statistical analysis will be run and compared for consistency.

Anticipated results

Results on Project 2VIDA! feasibility, acceptability, and efficacy to improve COVID-19 vaccination rates and address vaccine hesitancy among African American and Latino individuals (≥16 years old) in San Diego, California will be shared with the scientific community

and our community leaders and partners that work with predominately African American and Latino individuals in this region. We anticipate that findings from this study will provide insight on factors that have driven vaccine hesitancy and impacted perceptions of COVID-19, including identifying main trusted sources of COVID-19 information and understanding the individual and structural barriers to accessing the COVID-19 vaccine among African American and Latino communities in Southern California. Furthermore, this data will aid in designing future interventions preventing the spread of misinformation about COVID-19 and how to best communicate and engage with our community to prevent health misinformation. Overall, findings will present key details to assist in preventing the disproportionate and ongoing prevalence of COVID-19 infection as we transition to this endemic phase, as well as prevent long term chronic health implications among African American and Latino communities.

Additionally, a key strength of this intervention is the robust support and involvement of representatives from community and academic organizations. These community-based collaborations allow for sustainability and can be replicated in other settings, ensuring generalizability. Likewise, this collaboration offers expertise in CBPR, health disparities research, and provides systems for disseminating results. All partners will participate in interpretation of findings and dissemination planning, including use of national newsletters and listservs, participation in conferences and trainings, and creation of presentations and reports for communication to multiple classes of stakeholders. All partners have demonstrated a strong commitment to the proposed study from its inception and will work collaboratively to ensure wide dissemination of the findings of this community practice-based demonstration. Further, publications will be open-access and available after publication under the NIH Public Access Policy in the digital archive PubMed Central. The information derived from *Project 2VIDA!* is expected to offer valuable perspectives for enhancing strategies aimed at addressing COVID-19 vaccine hesitancy and increasing COVID-19 vaccine uptake among our communities of color and the use of CBPR. Lastly, findings can also be applicable to aid in national public health vaccination initiatives to prevent future outbreaks or for other vaccine preventable diseases that significantly impact African American and Latino communities.

Discussion

The COVID-19 pandemic highlighted racial and ethnic disparities in both infection rates and vaccination coverage, mirroring longstanding health inequities in the United States (2, 41). Tackling this issue amid the urgency of a public health emergency, such as COVID-19, posed numerous challenges, requiring rapid efforts to address decades of unequal healthcare access and the resulting distrust among vulnerable populations. Our strategy was grounded in the principles of CBPR and involved the establishment of a working intervention group comprised of representatives from community, academia, and public health organizations and together we developed *Project 2VIDA!* The response to the project was overwhelmingly positive within the local communities (intervention sites), and community members expressed eagerness to participate in the study (e.g., attend a community engagement forum, a meet the expert Q&A session, receive information about the vaccine in their preferred language) or to be a site for a community pop-up clinic. Previous

research has documented the crucial role that community leaders and community-based organizations play in both public health campaigns and vaccination initiatives, contributing significantly to fostering high vaccine uptake and confidence, particularly among racial/ethnic minorities and vulnerable populations (42–44). Likewise, our multilevel intervention integrated COVID-19 educational and outreach materials (printed and digital), utilized different communication channels, community engagement efforts, health promotion, and healthcare provider involvement to combat COVID-19 health misinformation and address individual, social, and contextual factors related to access, acceptance, uptake, and series completion of the COVID-19 vaccine among African American and Latino individuals (≥ 16 years old) in Southern California. This multifaceted approach has been found effective in enhancing the overall impact on vaccine intervention delivery for adults for other vaccine preventable diseases such as influenza (45, 46).

Although the aim of this project was to target undeserved African American and Latino communities, project staff distributed the vaccine to all interested and eligible persons at the community pop-up clinics, irrespective of individual characteristics. Because the targeted neighborhoods were low-income and many lacked access to healthcare, widespread distribution was warranted.

Our study has several limitations. Data collection efforts began in June 2021, during the period of general eligibility and experiences may have differed compared to when the vaccine first became available to only certain groups. However, this can also be seen as a strength, as the findings are applicable to the present vaccine scenario, where the supply exceeds demand, and everyone is eligible for the vaccine and/or booster. It is also important to acknowledge this study only sampled African American and Latino individuals in San Diego (Southern California), and therefore are not generalizable to other settings, however, the fundamental pillars of the intervention can be adapted to other local contexts.

Conclusion

The COVID-19 pandemic has been an unprecedented global crisis that has deeply impacted the healthcare sector and revealed several important lessons. Although the WHO ended the public health emergency on May 11, 2023, at the writing of this publication, there has been a significant increase in COVID-19 cases and hospitalization due to the JN.1 variant in the United States and globally (47, 48). With the rise of the JN.1 variant and as we enter winter season when respiratory viruses are known to have a high incidence of infection (49), it is ever more critical to have clear, transparent, and tailored messages regarding the importance of receiving the COVID-19 vaccine and/or booster and addressing vaccine hesitancy. *Project 2VIDA!* is a multipronged intervention aimed at addressing this gap in the Southern regions of San Diego which have been heavily impacted by COVID-19. As previously mentioned, *Project 2VIDA!* intervention uses evidence-based, CBPR approaches to increase equitable access to COVID-19 information, resources, and pop-up community clinics that provide the vaccine and linkage to healthcare and social services to African American and Latino communities. *2VIDA!* addresses the various limitations of current interventions through the strategic design and implementation grounded in CBPR. Evidence from this intervention will inform efforts to address vaccine hesitancy for COVID-19 and other vaccine

preventable infections particularly among communities of color. Vaccination efforts must be multifaceted, responding not only to the culture, history, and values of minoritized communities, but also addressing their concerns by providing reliable information and access to healthcare.

Ethics statement

The studies involving humans were approved by Human Research Protections Program (HRPP) at the University of California, San Diego (UCSD) and the *Ad hoc* Institutional Review Board (IRB) from San Ysidro Health (SYH). The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation in this study was provided by the participants' legal guardians/next of kin.

Author contributions

BS: Investigation, Methodology, Writing – original draft, Writing – review & editing, Data curation. LS: Conceptualization, Methodology, Writing – review & editing. FM: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Writing – review & editing. GT: Conceptualization, Investigation, Writing – review & editing. DS: Conceptualization, Funding acquisition, Investigation, Methodology, Project administration, Writing – review & editing. JS: Conceptualization, Investigation, Writing – review & editing. SO'B: Project administration, Resources, Supervision, Writing – review & editing. DR: Project administration, Resources, Supervision, Writing – review & editing. CJ-P: Project administration, Resources, Visualization, Writing – review & editing. AS: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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