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Building HPV vaccine confidence through codesigned interventions with and for healthcare workers in Nigeria: protocol for a pilot cluster randomised controlled trial

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ABSTRACT

Introduction The human papillomavirus (HPV) vaccine can effectively prevent cervical cancer, yet HPV vaccine uptake is particularly low in some low-income settings, due to supply and vaccine confidence barriers. HPV vaccine confidence has also been found to be lacking among healthcare workers in some countries, including Nigeria. Nigeria has a long history of low vaccine confidence in some parts of the country. HPV vaccine rumours and concerns have been observed throughout the country, including among healthcare workers. Interventions that specifically address healthcare workers' vaccine confidence are limited, since vaccine confidence is often assumed among this group. The aim of our pilot cluster randomised control trial (cRCT) is to evaluate the feasibility of conducting a trial that evaluates codesigned interventions to improve HPV vaccine confidence in healthcare workers and the acceptability and feasibility of delivering this intervention.

Methods and analysis This is a 3-arm pilot cRCT, using a mixed-methods approach to assess the feasibility of the trial design, alongside the feasibility and acceptability of intervention delivery in two states in Nigeria (Jigawa and Oyo). We will implement two interventions: one with a focus on digital delivery, and one with an HPV champion present at a health facility. Both will be compared with a control arm, providing standard information on HPV vaccine only. Overall, 12 trial clusters (six in Jigawa and six in Oyo), defined as government primary healthcare facilities, will be randomised using a 1:1:1 ratio, stratified by state. All healthcare workers within these facilities will be eligible to take part in the intervention and evaluation. The primary outcome of interest will be intervention uptake, as a measure of subsequent trial feasibility given concerns around contamination in control clusters. This will be assessed through an endline healthcare worker survey. Intervention feasibility and acceptability will be assessed through quantitative intervention monitoring and qualitative interviews with healthcare workers.

Ethics and dissemination We received approval from Jigawa State Ethics Committee (ref: JGHREC/2023/151), Jigawa Ministry of Health (ref: MOH/PH/PHRAT/MN/23/003), Oyo State Research Ethics Review Committee (ref: AD/13/479/362A), The University of Ibandan and University College Hospital Research Ethics Committee (UI/UCH Ethics Committee) (ref: UI/EC/23/308) and from the Swedish National Ethics Review Board (2023-04772-01-471058). Data will be presented in manuscript form and submitted to relevant conferences for dissemination.

Registration details The pilot trial has been registered with ISRCTN—the UK's Clinical Study Registry, registration number ISRCTN37847119.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A key strength of the study is the codesigned intervention with healthcare workers (HCWs), and involvement of the Ministry of Health in the planning to implement the intervention to HCWs.
⇒ The pilot trial has been designed to assess our major methodological concern, around exposure to the intervention, both in the form of contamination in control clusters and uptake in intervention clusters.
⇒ Health system barriers to human papillomavirus (HPV) vaccine access are a major threat to the study, which is outside the scope or control of the study team to address.

BACKGROUND

The human papillomavirus (HPV) is a common sexually transmitted infection globally, with most sexually active individuals contracting the virus at some point in their lives.[1] HPV has direct causal links to cervical cancer.[2] There is strong evidence that an HPV vaccine, administered before onset of sexual debut (ie, during early adolescence), is associated with substantially reduced risk of invasive cervical cancer.[3] However, global uptake of HPV vaccination varies substantially, between 5% and 90%.[4] While progress to increase the rollout of the HPV has been made, some

countries lag behind.[4] This low uptake is associated with both limited HPV vaccine supply and demand, of which vaccine hesitancy plays an important role.[4]

Vaccine hesitancy is one of the top 10 public health threats according to the WHO. This is opposed to the concept of vaccine confidence—where individuals are confident in the safety, necessity and efficacy of a vaccine. HPV vaccine hesitancy—the refusal or delay of HPV vaccination even though the vaccine is available[5]—has been observed globally and to a greater extent in Colombia, Denmark and Japan where rumours regarding HPV vaccine side effects were circulating and significantly affected HPV vaccine confidence.[6] In recent years, HPV vaccine hesitancy has been widely found across Africa, including Nigeria.[7] In Nigeria, for example, reasons for low confidence in HPV vaccines have been linked to social media rumours (such as infertility rumours), the quantity and quality of information available about HPV vaccination, concerns about potential side effects of the vaccine and mistrust of health authorities and new vaccines.[8 9]

While healthcare workers (HCWs) remain among the most important and trusted sources of information for vaccination, HPV vaccine hesitancy has been observed among HCWs throughout the world.[10] The main barriers to recommending the HPV vaccine were concerns around safety and efficacy, cost, parental concerns and systemic barriers.[11] The results of a systematic review of HCWs' HPV vaccine confidence and concerns illustrate the importance of contextually adapted approaches to improving vaccine acceptance and recommendation.[10 11] Both digital and inperson interventions to build vaccine confidence have been implemented. Yet, the literature on interventions that specifically address HCWs is scarce, and there is a need for more research on the effectiveness of interventions through randomised controlled trials (RCTs).[11] The use of codesign methods to develop targeted interventions in collaboration with end-users has proven promising in a wide range of public health interventions, including in relation to vaccine confidence in a recent review on the use of codesign methods to address and build vaccine confidence.[12] Digital interventions are often a product of a codesign process for health interventions and have been successful in addressing vaccine hesitancy, in particular when combined with a series of interventions.[13]

Nigeria has a longstanding history of vaccine hesitancy, including towards the polio vaccine.[14 15] This hesitancy is deeply rooted in complex political and social factors, including mistrust surrounding the motives of vaccination programmes and a history of unethical vaccine testing.[16] Studies have also reported substantive COVID-19 vaccine hesitancy among HCWs.[17–19] Ongoing research on HCWs' views on new vaccines conducted by our team has highlighted similar concerns about the recently introduced HPV vaccine. These concerns are primarily linked to side effects and limited ease of access to new vaccines. Healthcare workers' distrust in government institutions remains a significant obstacle to the rollout of new health technologies such as vaccines.[19] This is especially concerning considering the crucial role that HCWs play in shaping public opinion on vaccine safety and efficacy as trusted sources of health information.[20]

Increasing trust among healthcare workers could have the positive effect of building trust and confidence in vaccines for the whole population. This is particularly relevant for settings like Nigeria where there is a history of vaccine hesitancy and a high burden of morbidity. The comparison of two distinct intervention approaches, digital delivery and a HPV champion, against the standard provision of HPV vaccine information, could offer valuable insights on the impact of each strategy. Therefore, the aim of this pilot trial is to understand whether a full trial that tests a codesigned intervention to build HCWs' HPV vaccine confidence is feasible and acceptable.

METHODS AND ANALYSIS

Setting

Nigeria is a West African country, and it is the most populous country in Africa with an estimated population of over 200 million.[21] The Nigerian population is growing at approximately 2.6% annually, and by 2050, the country is projected to have the third largest population in the world.[22]

Cervical cancer is the second leading cause of cancer-related deaths in Nigeria among women aged 15–44 years.[23] The HPV vaccination campaigns first began in October 2023 and aim to protect nearly 16 million Nigerian girls by 2025. The first phase of the HPV vaccine rollout included 15 states, while the second phase, which commenced in May 2024, included the remaining 21 states.[24] This initiative demonstrates a commitment to strengthening the nation's response to cancer and improving public health outcomes. According to Gavi, 5.3 million girls were vaccinated in the first phase and 7 million in the second phase.[25] However, some studies prior to the roll-out found low awareness and additional concerns around the HPV vaccine, beyond cost, that have impacted vaccine uptake.[26 27] A 2024 study of Nigerian caregivers showed that there is a complex interplay between motivation, knowledge, social factors and ability that impact caregivers' likelihood to have their child vaccinated.[28]

Our study will take place in Oyo and Jigawa states from May 2025 to December 2025. Oyo State is one of the six states in the Southwest geopolitical zone of Nigeria with Ibadan as its capital. Oyo State has an estimated population of over 7 million people,[29] across 33 local government areas (LGAs) and three senatorial districts. Yoruba is the major ethnic group in the state.[23] The most common occupations in Oyo State include agriculture, small and medium scale entrepreneurship and civil service.[29] In 2018, the under-five mortality rate in Oyo State was estimated to be 60 deaths per 1000 live births. However, the state is underperforming in immunisation coverage; of

the children aged 12–23 months, 39.7% did not receive all the basic vaccines, while 10.7% had no vaccinations.[29]

Jigawa State is in the Northwest geopolitical zone of Nigeria and its capital is Dutse. It has 27 LGAs and three senatorial districts. It is an agrarian region with over 80% of its populace practising subsistence agriculture.[29] Hausa and Fulani are the major ethnic groups in Jigawa, and about 99% of the population practises Islam.[29] The under-five mortality rate in Jigawa is high, at 179 deaths per 1000 live births, with low but improving vaccine coverage. The proportion of children aged 12–23 months that received all basic vaccines has increased from 3.9% in 2013 to 56.9% in 2024, and the proportion of children with no vaccination has decreased from 29.9% in 2013 to 26.9% in 2024.[29] Currently, there are no good data on HPV vaccination rates by state in Nigeria.

Study design

We will conduct a 3-arm pilot cluster RCT (cRCT) in 12 primary healthcare facilities (six in Jigawa and six in Oyo), using an embedded mixed-methods approach to assess the feasibility of the trial methodology, and feasibility and acceptability of intervention implementation in Oyo and Jigawa States. The clusters are primary healthcare facilities, with a cluster trial design chosen given the nature of the intervention and the facility being the unit of implementation.

We will focus on primary healthcare facilities because they are situated within communities and accessible to most of the population. Primary HCWs play a major role in vaccine delivery efforts as they foster trust and encourage community participation in vaccination programmes. The vaccination services rendered at these facilities extend beyond routine immunisation and HPV vaccination at the facilities; they also include health education and community outreach programmes.

The intervention, being piloted, will be developed through a codesign process, and we anticipate this will result in two intervention implementation approaches in each state. We will therefore plan for two intervention arms and one control arm. The pilot cRCT will be conducted for 3 months, with a baseline facility survey focused on HPV vaccination programme information, an endline HCW survey to capture intervention exposure and the trial outcome and process data collected throughout the pilot period (figure 1).

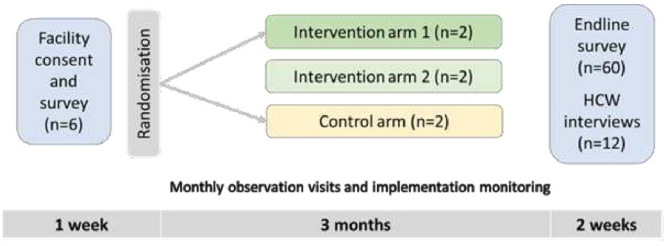

Figure 1 Pilot trial schematic for each state.

Clusters and participants

Clusters are defined as government primary healthcare facilities, with the following eligibility criteria: (1) the facility is scheduled to be operational throughout the pilot trial period; (2) a minimum of 5 HCWs that provide direct patient care are employed at the facility; (3) the facility is a designated HPV vaccination service according to the Ministry of Health.

Within eligible facilities, all HCWs who are employed within the facility are aged 18 years and older and can provide informed consent will be eligible to take part in both the intervention and evaluation. HCWs are defined as those who provide direct clinical services and include community HCWs and assistants.

Sampling

Facilities will be purposefully selected to take part in the pilot trial, in close coordination with the Ministry of Health in each state. Key considerations for selecting facilities to take part will include vaccination coverage rates in the region, geographical setting (rural, periurban, urban) and ease of access and feasibility for intervention delivery. Facilities will be matched into two sets of trios based on geographical proximity—with the closest three facilities grouped together. Given that contamination is a major concern, randomising by proximity should allow us to explore whether buffer zones or a 'fried-egg' design would be needed in a full trial. HCWs will be recruited using a census approach, where all eligible HCWs will be invited to take part.

Randomisation

Randomisation will be done at the facility level, with a 1:1:1 randomisation (n=6 per state, n=12). The intervention and control clinics will be randomised within their geographical strata. Randomisation will be done separately in each state, after all six facilities have agreed to participate, using a random number generator. Randomisation will be done by an external statistician at Karolinska Institutet, and the randomisation sequence will be shared directly with the research team in Nigeria. Due to the nature of the intervention, participants and data collectors will not be blinded to the intervention allocation, but the analysis will be done blinded.

Intervention details

The intervention will be a series of activities or information sessions focused on building HCW confidence in the HPV vaccine. The intervention is currently being codesigned by the team and is expected to be finalised by May 2025, at the beginning of the pilot trial. The mode of delivery and content of the intervention will be developed using a codesign process with HCWs, based on the IDEAS approach.[20] IDEAS is comprised of 10 phases (empathise, specify, ground, ideate, prototype, gather, build, pilot, evaluate, and share), grouped into four overarching stages: integrate, design, assess and share (IDEAS).[30] Each of these phases is described, and

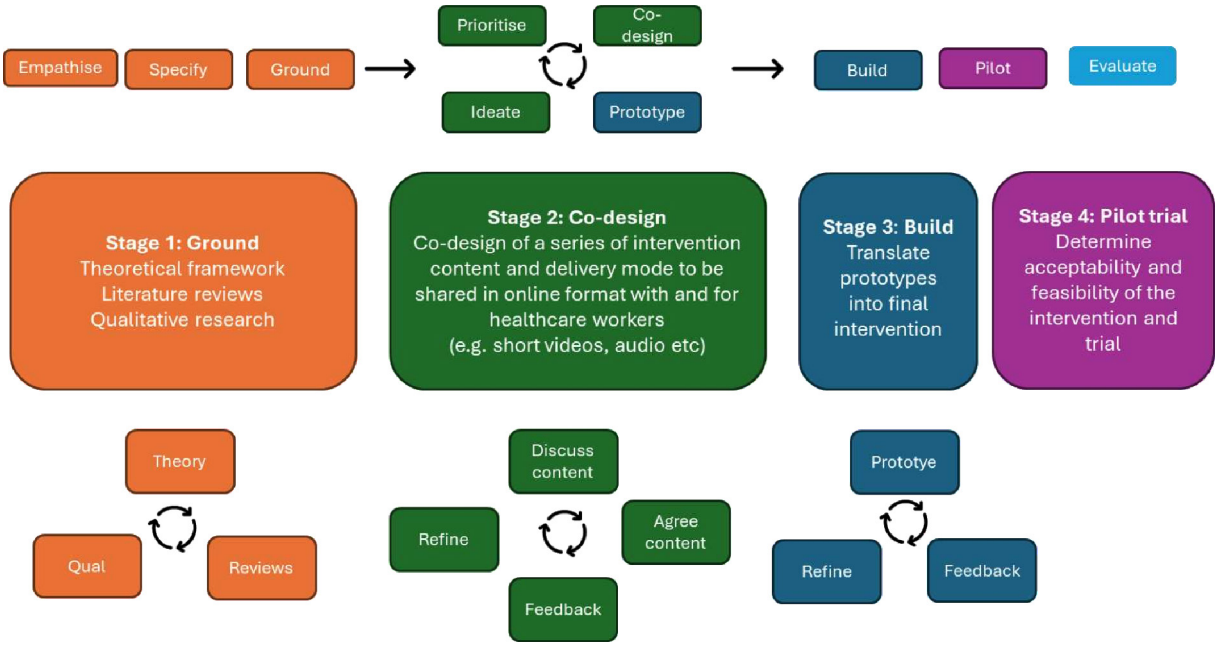

Figure 2 Development stages for codesigned interventions as per the adapted IDEAS (integrate, design, assess and share).

a summary of theory-based behavioural strategies that may inform intervention design is provided. We have organised our codesign stages within the wider IDEAS framework phases. The formative work, which includes systematic reviews, qualitative research with HCWs and a tool adaptation and validation, is within the integrate phase of empathise and specify. The main codesign takes place within the design phase. The development stages and the corresponding IDEAS phases are illustrated in figure 2.

The intervention entails tailored and concrete strategies to build vaccine confidence among Nigerian HCWs. The intervention aims to use information sharing strategies to increase Nigerian HCWs' knowledge, understanding and skills around the HPV vaccine and how to address questions and concerns from the community.

The specific interventions will be codesigned with HCWs prior to beginning the pilot trial. They will be digital in nature and will include different types of videos. The codesign process involves four stages: (1) team brainstorming and training, (2) codesign workshops with a core group of HCWs developing the materials and strategies with additional inputs from a sense check group, (3) draft material development and (4) feedback on the draft material using focus group discussions and finalisation of the intervention material and strategies. During this process, HCWs will be closely consulted in each state to have strategies and materials that suit their needs.

A digital intervention will be developed for one arm and an inperson intervention for the second arm in both Oyo and Jigawa. The content of the materials will be as similar as possible across the two different delivery mechanisms and states, but the content specifics may be different in the two states. For both digital and inperson interventions, there will be a minimum of 6 interactions (between the intervention team and each HCW) over the course of the 3-month pilot trial. The delivery mechanisms and specific content will be determined during the codesign process. For the digital delivery mechanisms, these may include videos, podcasts, email chains or posts in health facility-specific social media groups (WhatsApp, Facebook, etc). For the inperson interventions, this could include workshops with a HPV vaccine champion, facilitated discussions, flip chart discussions or similar strategies. The content of both the digital and inperson interventions may include a variety of topics such as: explanations of HPV manufacturing, descriptions of typical side effects, tutorials on how to discuss with hesitant parents, how to ensure good cold chain management, pharmacovigilance strategies in Nigeria and globally and many more.

For example, the digital intervention could include two educational videos per month and an inperson intervention that includes three initial workshops over 1 week with an HPV champion in the clinic with three shorter follow-up sessions. Both the videos and workshops would focus on three core topics, such as HPV vaccine side effects, discussing with hesitant parents and long-term benefits of HPV vaccine.

Control

Control facilities will receive standard information about HPV vaccination, in line with information made available by the National Primary Health Care Development Agency (NPHCDA), in the form of information leaflets or posters.

Outcomes and exposure

The primary outcome of the pilot trial is the proportion of HCWs who self-report engaging with the intervention content—either receiving information through

Table 1 A summary of exposure and outcome variables

Exposure	Employment at an intervention or control clinic (categorical variable, control =0, intervention arm 1 =1, intervention arm 2 =2)	
	Digital intervention	Inperson intervention
Acceptability of intervention	a. Proportion of HCWs employed in intervention facilities who have viewed at least one digital message (HCW endline survey) b. Mean number of digital messages that HCWs employed at intervention facilities have viewed (HCW endline survey) c. The number of views/likes that individual digital messages receive (implementation monitoring) d. The number and content of messages sent in digital discussions (implementation monitoring) e. Reasons for not engaging with the intervention (qualitative) f. Perceptions of the intervention (qualitative)	a. Proportion of HCWs employed in intervention facilities who have taken part in an intervention session (HCW endline survey) b. Mean number of sessions attended by HCWs employed at intervention facilities (HCW endline survey) c. Participatory engagement with the intervention session (implementation monitoring) d. Content of intervention sessions (implementation monitoring) e. Reasons for not engaging with the intervention (qualitative) f. Perceptions of the intervention (qualitative)
Feasibility of intervention	a. Proportion of HCWs that own a phone that can support the digital intervention (HCW endline survey) b. Proportion of HCWs in intervention and control facilities that have the digital delivery platform installed on their phone (HCW endline survey)	
	a. Extra HCW time needed to engage in the intervention (HCW endline survey) b. Perception of the intervention burden, including network cost, compensation and task shifting (qualitative)	
Feasibility of cRCT design	a. Proportion of facilities that consent to the randomisation process (study records) b. Vaccine availability (baseline facility survey) c. Proportion of HCW who are employed in study facilities for a minimum duration of 3 months (HCW endline survey) d. Proportion of HCW in control facilities who report viewing any digital messages (HCW endline survey) e. Proportion of HCW in control facilities who report hearing about the intervention content (HCW endline survey)—primary outcome f. Social desirability in reporting vaccine confidence (qualitative)	

cRCT, cluster randomised control trial; HCW, healthcare worker.

digital channels or taking part in face to face sessions. We have selected this to give a measure of contamination in control clusters, but also coverage in intervention clusters. The exposure is trial arm allocation. Other outcomes, assessing acceptability and feasibility of the intervention and feasibility of conducting a full trial, are presented in table 1.

Sample size

The sample size for the pilot trial is based on the outcome which we are most concerned about—the proportion of HCW in control facilities that have heard any of the intervention messages (either from the digital or inperson arms). Recruiting an average of nine HCWs per control facility (n=35) will allow us to measure 10% of these HCWs being exposed to intervention messages, with a 10% precision (ie, 0–20%) and 95% confidence, pooled across both states. The 10% proportion was selected as a methodologically relevant number, and if the true value is >20%, this will call into question the trial feasibility.

Quantitative data collection

There will be four different sources of quantitative data collected for the pilot trial: (1) baseline facility survey; (2) endline HCW survey; (3) intervention delivery monitoring; (4) facility records of HPV vaccine stocks and population coverage.

1. Baseline facility survey: at the point of recruitment of facilities, we will conduct a baseline facility survey to assess access to uninterrupted cold chain, outreach and catch-up vaccination programmes, youth-friendly initiatives and vaccine supply and stock-outs over the prior 12 months. The survey will be conducted using ODK Collect on an Android tablet and completed by the study data collector, together with the facility in-charge. Where possible, data should be validated with visual inspections.
2. Endline HCW survey: a survey will be conducted with all eligible HCWs in all study facilities after the 3-month pilot intervention implementation period. The survey will be conducted using ODK Collect on an Android tablet with inbuilt skip patterns and cleaning rules. A study data collector will gain consent from the HCW and then administer the questionnaire, finding a private space within the facility. The survey will include the following topics: demographics and employment, validated vaccine confidence tool, vaccination status and intervention exposure. The vaccine confidence tool will be a validated and adapted version of the Pro-VC-Be tool, which a systematic review tool illustrated to be the most well validated.[31] The survey should not take more than 20 min to complete and will be administered within the health facility at a convenient time during the workday. The data will be uploaded to a secure server at the end of each day. Vaccine confidence and intervention exposure will be summarised using means and SD and proportions and 95% CIs.

3. Digital intervention implementation monitoring: for the intervention delivered through a digital platform, we will monitor engagement. At the start of the intervention, members of closed digital platform groups (eg, a WhatsApp group) will be asked for their consent to observe and analyse the conversations they share in this group. We will extract data on the number of messages read, the number of HCWs who read each message, the number of HCWs who actively post messages and the content of these messages.
4. Monthly facility monitoring: each month, a study data collector will visit all the study facilities to observe routine practice, especially focused on vaccine services. During these visits, they will extract information from routine facility registers on vaccine stocks, Diphtheria, Pertussis, Tetanus, Hepatitis B, and Haemophilus influenzae type B (DPT-Penta) and HPV vaccine coverage, and observe any changes to the wider infrastructure or functioning of the facility. This will be collected on an ODK form, and for facilities in the inperson intervention arm, we will aim to visit on days when these intervention sessions are happening and will therefore collect information on this as well.

Qualitative data collection

For the qualitative data analysis, we will interview two health workers from each intervention facility and a facility manager (n=12). We will apply a mixture of purposive and convenience sampling, where we will aim to interview a male and a female HCW in the intervention facility to allow for exploration of possible gender differences. We will ask the facility manager to help with this recruitment process by asking the manager to randomly pick two HCWs. The interview guide includes a series of questions about the HCWs' views on HPV vaccination as well as their views on their access and exposure to the intervention materials.

Analysis

The primary analysis will be estimating the proportion of HCWs who have been exposed to intervention messages in intervention and control facilities, using counts and 95% CIs and comparing these using a χ^2 test. Other quantitative data will be summarised using proportions, 95% CIs, means and medians. Free text entries in facility monitoring and digital intervention observations will be analysed qualitatively—through summaries in quarterly process reports. Intervention delivery data will be summarised using counts and proportions. Qualitative data will be analysed using qualitative thematic analysis. Quantitative and qualitative data will be analysed separately and then triangulated under the domains of intervention acceptability; intervention feasibility; feasibility of cRCT design.

ETHICS AND DISSEMINATION

The study follows the ethical principles laid out in the Helsinki Declaration. This includes informed consent and protection of study participants' anonymity. All data are being stored at Oxygen for Life Initiative per data management regulations. Data will be accessible to the main research team members. The final data set will be accessible to the principal investigator in Nigeria and the principal investigator in Sweden. We received approval from Jigawa State Ethics Committee (ref: JGHREC/2023/151), Jigawa Ministry of Health (ref: MOH/PH/PHRAT/MN/23/003), Oyo State Research Ethics Review Committee (ref: AD/13/479/362A), UI/UCH Ethics Committee (ref: UI/EC/23/308) and from the Swedish National Ethics Review Board (2023-04772-01-471058).

As the trial is a cluster pilot trial, consent for participation in different parts of the study will take place at different levels. Consent for randomisation and participation in the pilot trial will be obtained from the facility in charge. This will include consent to collect the baseline facility survey and monthly facility visit data. Individual consent will be sought from HCWs for the endline HCW survey, qualitative interviews and to enrol them within the digital intervention groups. An example of a participant consent form for the qualitative interviews with HCWs can be found in the Supplementary material, with other consent forms following a similar format (online supplemental appendix 1).

There are two ethical problems that might arise during this pilot. First, since we are targeting HCWs to actively take part, we expect them to take time from their usual practice. HCWs can be scarce and overburdened in these settings. This is something that will be raised during the codesign with HCWs and in the qualitative interviews conducted during the pilot trial, to explore whether the burden is too much for HCWs. HCWs will also receive a small incentive for taking part in research interviews and surveys, to acknowledge the time they are giving.

Second, a HCW might spread misinformation about HPV, using this study as a platform for sharing these views. To counter this, we will do quality controls on all health messages and get health workers who participate in this trial to comply with a set of rules and regulations (eg, we stick to the messages we developed for the purpose of this trial). We will also offer ongoing support to peer leaders if they encounter the emergence of rumours or misinformation. We will advise on how to counter such situations. Monitoring and advice will be guided through a data monitoring and safety board and a trial steering committee, who will have oversight over the trial management and safety concerns. The committee will consist of an independent group of Nigerian public health experts. Protocol amendments will be carefully documented using version control. The version is V.5.0 as per 28 March 2025. Any changes, for example, to inclusion criteria or analyses, will be communicated to relevant independent review committees (IRCs) and the ISRCTN registry. We

do not anticipate the qualitative aspects of this study will cause any significant risks to participants; however, we will inform all participants before collecting any data that they are free to leave at any point during the process. We do not anticipate any major risks to the researchers in this project; however, we will ensure full risk assessments are conducted prior to any field visits and that all researchers are fully covered by insurance and meet recommendations for vaccinations. Interim monitoring and discussions with the external monitoring committee will allow us to identify any challenges, which could lead us to stop the pilot trial. This will be decided by the external monitoring committee.

Results will be disseminated using a variety of formats including in written form through the publication of a manuscript and policy briefs. We will also aim to disseminate the results in suitable conferences and meetings with key local stakeholders.

Compensation of participants

Participants will be compensated for time and efforts for participating in this study. This will be provided in alignment with ethical guidelines and will not serve as an undue inducement. Each participant will receive monetary payment on completing all required study activities. Participants who withdraw from the study prior to completing all study activities will receive prorated compensation based on the duration of their participation.

Patient and public involvement

HCWs—the study subjects—have been involved in the development of the interventions for the study, through a process of codesign. HCWs were also involved in the cultural adaptation of data collection tools about vaccine confidence for the setting. The ministry of health and regional authorities—future executers of the intervention—have been involved in reviewing intervention development content and will be involved in the implementation of the intervention.

DISCUSSION

When conceptualising a full cRCT, our main concern has been contamination. HCWs in this setting are frequently reassigned between facilities and take part in professional social media groups that include HCWs from a wide geographical scope. Therefore, information shared with one group of HCWs in a facility can reasonably be expected to be shared beyond their facility. While this is not necessarily a problem for the intervention itself and provides a clear route to scale-up for a digital intervention—it is problematic from the perspective of trial design. As information is commonly shared through WhatsApp groups, the common solution of applying a 'fried-egg' approach in cluster trials would not work. We therefore chose contamination as our primary outcome for the pilot trial, powering the pilot to detect 10% (±10%) contamination within the control facilities. Realistically, contamination above this would threaten the ability to measure a difference in a full trial and would therefore deem it an unviable evaluation approach.

Another potential source of bias in our pilot trial design is the lack of blinding. Due to the nature of the intervention, we will be unable to blind HCWs to their allocation. While researchers will not be informed of facility allocation during quantitative and qualitative data collection, it will be challenging to mask allocation from them due to the nature of questioning and expected responses. Finally, a major threat we see to a full trial is the unpredictable and limited funding and supply of HPV vaccines. HPV vaccination is primarily rolled out through campaigns at certain points in the school year. In the main trial, increased coverage of HPV would be the outcome, and lack of supply would limit our ability to measure any difference in HCW motivation and practices around HPV vaccinations. While we are measuring vaccine availability, it is likely that this will not reflect the supply at the time of a full trial.

By conducting a pilot cRCT, we aim to evaluate the feasibility of a trial that assesses the effectiveness of codesigned interventions to improve HPV vaccine confidence among HCWs in Nigeria. The main challenge we anticipate with this trial design and aim to assess with this pilot trial is the risk of contamination. We aim to disseminate the findings from this study in a publication and to use the learnings in a full trial. The learnings will help to inform a future wider RCT to examine the effectiveness of the codesign interventions on HCWs' HPV vaccine confidence and recommendation behaviour. HCWs are trusted sources of information and a vital resource for enabling HPV vaccine acceptability and uptake. This pilot trial is essential to help inform the future research direction of this project. It will both help to understand whether a full RCT is feasible but also build on our theory of how different intervention strategies may be effective in improving HPV vaccine uptake in different settings in Nigeria.

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Contributors All authors have read and agree to the finalised submitted version of the manuscript. Conceptualisation: SHvW, CK, AAB and AGF. Methodology: CK, SHvW, AAB and AGF. Writing—original draft preparation: SHvW, CK, AAB and AGF. Writing—review and editing: all authors. Visualisation: all authors. Project administration: AAB, KOA, JS, DB and EG. Guarantor: SHvW. Data monitoring committee: To be recruited. 2 Nigerian vaccine experts and 1 external expert also contributed to the study.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, conduct, reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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