Community groups to increase Human papillomavirus (HPV) vaccination through Participatory Learning and Action, Reducing barriers and increasing community Mobilisation in Zambia (CHARMZ) project.

Katarina Hoemke (katarina.hoemke.19@ucl.ac.uk)
University College London

Methodology

Keywords: cervical cancer, human papillomavirus vaccination, participatory learning and action, community-based, behaviour change, theory of change, process evaluation

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Abstract

Background Zambia has a high incidence of cervical cancer. Uptake of the human papillomavirus (HPV) vaccine has been low since it first became available in Zambia in 2013. Community mobilisation and engagement with civil society has been identified as a key component of HPV vaccination programs in low and middle-income countries. Of the evidence available on community-based interventions in the context of HPV, participatory approaches which work closely with local stakeholders to identify and overcome barriers to HPV vaccination uptake have shown promising results. This is a proposal for a community-based cluster randomised controlled trial to increase HPV vaccination uptake in Zambia through a participatory learning and action (PLA) cycle approach in community groups. PLA is an approach in which participants identify and prioritise problems, and subsequently develop, implement and evaluate solutions to improve the health needs of their community. Key stakeholders to be engaged in this project include government members, policymakers, healthcare, donors and relevant non-governmental organisations (NGO), religious leaders, and civil society members. Formative research will be carried out with key stakeholders through semi-structured interviews and focus group discussions. The community group intervention will be facilitated by local healthcare workers from the cervical cancer prevention program in Zambia (CCPPZ).

Results Success will be indicated by an increase in HPV vaccination uptake. The primary outcome will be HPV vaccination rates measured quantitatively. Data will be gathered once at the start of the study, once midway through the PLA phase and once during the post-intervention phase. Questionnaires and semi-structured interviews will allow for measurement of secondary outcomes both quantitatively and qualitatively, including perceived (i) HPV vaccination and cervical cancer knowledge, (ii) acceptability, accessibility and equitability of the HPV vaccination, as well as (iii) attitudes of female group members towards other cervical cancer screening and treatment services.

Conclusions There is a need to address the high cervical cancer disease burden in Zambia. This would be the first intervention aiming to increase HPV vaccination uptake in Zambia through a low-cost, sustainable and scalable community-based participatory learning and action cycle approach.

Background

The global and national distribution of cervical cancer

Cervical cancer is the fourth most common female cancer across the world (1). Global distribution of the disease burden is starkly unequal, with 20% of cases found in sub-Saharan Africa (2, 3). The incidence of cervical cancer in Zambia is 66.4 per 100,000 women (4). Compared to the global average of 13.1 per 100,000 women (1), the World Health Organization's (WHO) goal to keep cervical cancer incidence below 4 in 100,000 may seem unattainable in Zambia (5). However, cervical cancer is, in fact, largely preventable. It is nearly always caused by an underlying infection with a high-risk strain of human papillomavirus (HPV).
papillomavirus (HPV), which is preventable through a vaccination able to reduce infection rates by up to 90% (6, 7).

The HPV vaccine's efficacy, low-cost and safety have led to its integration into national immunisation programs across the world (8). Primary prevention through vaccination appears to be more cost-effective and equitable, particularly in countries such as Zambia where a lack of access to screening and treatment services reduces the effectiveness of such secondary and tertiary prevention measures (3). Furthermore, insights from cervical screening programs suggest that cervical cancer screening tests are insufficient to curb rising rates of cervical cancer in countries without the financial resources to invest in the newest technologies (1).

**HPV vaccination in Zambia**

The HPV vaccine first became available in Zambia in 2013 through international donors and has since been integrated into the national immunisation program where it is given to 14 year old girls over “Child Health Week” once per year (9). Despite an increasing supply of the HPV vaccination in Zambia, uptake has been low (10). Available data from the first three years of the vaccination program showed that it failed to meet its target of vaccinating 50,000 girls every year (11). More recently, a study on Zambian parents in Lusaka found that 41% of their participants did not support the vaccination (12), and only 6.7% of participants in another study had vaccinated their daughters (13).

The disconnect between supply and demand has been attributed to a lack of knowledge surrounding the vaccine’s indication, efficacy and safety (13), as well as a lack of community engagement to address concerns and misunderstandings, particularly in rural districts (11, 14). Women's limited decision-making power compared to their husbands regarding their daughters receiving the HPV vaccination, coupled with a lack of engagement with male community members during the vaccine's roll-out has also been attributed to low uptake (15, 16). A further barrier is cervical cancer's stigmatised association with sexual transmission, human immunodeficiency virus HIV and high mortality rates, as well as its sensitive anatomical location (17).

**Cervical cancer on the global and national health agendas**

Addressing the burden of cervical cancer is currently high on the national and international health agendas. The WHO (2013) has called for a 25% relative reduction of global non-communicable disease mortality by 2025 and the elimination of cervical cancer (5). The HPV vaccine has been identified as one of their cost-effective “best buy” interventions in helping to achieve these goals (19). Leaders at the 2019 African HPV summit also called for an increase in the number of HPV vaccinations, particularly through strengthening vaccination programs within communities (2). The Ministry of Health in Zambia (2016) has echoed the goals of the WHO with aims to reduce cervical cancer mortality by 25% by 2025, while stressing the importance of increased vaccination rates across the country. Furthermore, the HPV vaccine has been identified as an integral component to Zambia’s wider goal of achieving universal health coverage through a strong primary healthcare system (9).
A unifying element of these national and international calls for addressing the burden of cervical cancer has been the emphasis on strengthening collective efforts with key stakeholders and community members to improve prevention strategies (2, 5, 9). The low vaccination rates are problematic in the face of Zambia's high rates of cervical cancer. Addressing this large and complex burden of disease will require innovative interventions which engage with communities to better understand the contextual barriers limiting their uptake of the HPV vaccine in girls (5, 20).

**Existing evidence base for community groups and participatory learning and action cycles**

Community engagement and mobilisation is increasingly recognised as a central component of patient-centred primary healthcare (21, 22). Participatory learning and action (PLA) cycle is an approach in which participants identify and prioritise problems, and subsequently develop, implement and evaluate solutions to improve the health needs of their community (23, 24). PLA has the ability to facilitate health behaviour change by empowering a given community to identify, implement and evaluate approaches to address their health needs through active participation (21). Community group PLA has been researched most extensively in the context of women's groups, where they have been associated with a 20% reduction in neonatal mortality rates (23, 25). Their success, scalability and cost-effectiveness has led the WHO to recommend PLA with women's groups as an approach for improving neonatal health outcomes (26). Community-based PLA has more recently been explored in improving health in other contexts, such as the prevention of type-2 diabetes (27), violence against women (28) and adolescent mental health (29).

Community mobilisation and engagement with civil society has been identified as a key component of HPV vaccination programs in low and middle-income countries (30). Of the evidence available on community-based interventions in the context of HPV, participatory approaches which work closely with local stakeholders to identify and overcome barriers to HPV vaccination uptake have shown promising results (31, 32). This project targets communities over individuals with the aim of increasing collective health seeking behaviours which start at the community-level. A community group approach is predicted to be suitable in this context, as demonstrated by the high acceptability of a community group intervention recently trialled in Zambia as part of a sexual and reproductive health education initiative (33). Implementing the intervention as a cluster randomised controlled trial (CRCT) will allow for the reduction of possible confounding factors which influence the decision to vaccinate and make findings comparable to a control. Implementing the intervention as part of a study design also allows findings to add to the research on health beliefs and behaviours towards HPV vaccination in Zambia. Findings from this intervention will add value to the limited evidence of PLA community groups outside the context of maternal and neonatal health, as well as evidence on community groups which also include male community members (23, 34). This is important, as a lack of research on community based interventions for health promotion is limiting their widespread use in strengthening primary healthcare and global efforts towards universal health coverage (35).
Methods

Recruitment

Participants will be purposively sampled from communities in the district Chongwe in Lusaka province, as Lusaka has the highest incidence of cervical cancer compared to other provinces in Zambia (36) and most research on HPV vaccination hesitancy in Zambia has been conducted there (13, 14, 37). Furthermore, Chongwe was chosen for its rural setting, where community groups have been shown to be most effective (23). Community groups will meet monthly with around 30 members. Thirty villages in the rural district of Chongwe will be matched into 15 pairs and a cluster in each pair randomly allocated into an intervention arm and control arm. The estimated population of Chongwe is 188,091 (38). Each cluster will therefore have an average population of around 6,300 people, which is a similar number to previous studies on community groups (23). Participation in this intervention is voluntary and consent may be withdrawn at any time. While informed consent will be gained from all participants, written informed consent may be difficult in CRCTs where village leaders make decisions collectively on behalf of the group (39). Consent will therefore be gained from key stakeholders during the formative research phase, in case there are difficulties obtaining written consent from individual participants.

Theory of change

Two theories underpin the aim of this intervention to improve HPV vaccination uptake in this population through PLA community groups. Firstly, that an individual’s health behaviours are influenced by their social networks. And secondly, that PLA cycles increase community mobilisation to improve health outcomes. Rooted in behavioural science theories such as Bandura’s (1997) social learning theory and Bronfenbrenner’s (40) Ecological Framework for Human Development, a social ecological approach can be used to better understand health behaviours in the context of vaccinations. The social ecological model suggests that individual’s health behaviours are influenced by the health behaviours of their close social network and wider community members (41). Community groups are thought to allow individuals to collectively engage with these social and community-level influences. This has been witnessed in Zambia, where knowing someone in the community that vaccinated their daughter increased the likelihood that mothers would vaccinate their own daughters (13).

A key theory underlying this intervention is that health outcomes improve when communities are empowered to increase their health literacy, make decisions about resource allocation, and be involved in implementing solutions. PLA is thought to give agency to group members, empower marginalised communities and facilitate community mobilisation to address their own health needs (42). The value of community group PLA is thought to lie in the process of collectively reaching solutions, rather than solely the solutions themselves (21). In this context, PLA community groups are predicted to help communities identify factors which facilitate HPV uptake such as motivation, trust and social support (22) and address barriers such as lack of knowledge (13), concerns and misunderstandings (14), women’s limited decision-making power (15), social norms (15), stigma (17), religious beliefs (33) as well as financial and geographical barriers to access (22, 43).
The capability, opportunity, motivation, behaviour (COM-B) model can help identify, prioritise and better understand enabling factors and barriers to vaccination uptake. The COM-B model is a widely used framework for understanding a variety of health behaviours as a result of the interaction between the factors influencing an individual's capability, opportunity and motivation to act (44). Extensive research on theories underpinning health behaviours in the context of vaccine uptake has led to the development of a tailored COM-B model recommended as part of the WHO's (2019) Tailoring Immunisations Program (TIP). The TIP COM-B model expands on the original principles of COM-B so that Capability includes knowledge, skills and physical ability, Opportunity includes vaccine accessibility, affordability and social influences, and Motivation includes attitudes, emotions and beliefs surrounding the vaccine (45).

**Stakeholders**

Key stakeholders to be engaged in this project include government members (health minister and district government representatives), policymakers, healthcare workers (members of the cervical cancer prevention program in Zambia (CCPPZ) and community health workers), donors and relevant non-governmental organisations (NGO), religious leaders, and most importantly, civil society members including but not limited to mothers, fathers, grandparents and school teachers. These stakeholders have all been shown to influence collective health beliefs and behaviours surrounding the HPV vaccine in Zambia (15). There are several other stakeholders collaborating with the ministry of health to run the CCPPZ, which are not key stakeholders for this intervention but may require engagement throughout the project if necessary. These include the Centre for Infectious Disease Research in Zambia (CIDRZ), Lusaka University Teaching Hospital, a partner university in the U.S. (46), as well as the Ministries of Education, Chiefs and Traditional Affairs, Community Development and Social Welfare, Higher Education (9).

Formative research with key stakeholders through semi-structured interviews and focus group discussions will provide valuable insights into the acceptability and feasibility of the proposed intervention and can identify any required adaptations to the implementation process. The stakeholder meetings will allow for the project team to assess the readiness for change and engagement with community leaders. A pilot community group session will also be conducted to assess feasibility, acceptability and identify adaptations as needed. Community leaders will be engaged to lead a gradual introduction of the project into their community during the formative research phase. A sensitisation period such as this has been deemed an important missing component to previous HPV vaccination programs (15, 47–49).

The project will require political support with coordination between the project team, Ministry of Health and district level government members to ensure institutional support, adequate and equitable allocation of resources. This would involve collaborating on a detailed budget distribution plan for the program's duration (30). Engaging with NGOs which have mutual health agendas has been shown to increase uptake of HPV vaccination (50). The CCPPZ works closely with HIV programs, through which they receive a significant portion of donor funding (46). This project will coordinate with NGOs to ensure funding is
maintained and prevent parallel programs interfering with one another. Joining efforts and utilising any ongoing positive social movements can increase community support as well (22).

The community groups will be facilitated by local CCPPZ members. The CCPPZ has an existing network of volunteers who facilitate community-based teaching to increase cervical cancer awareness (46). These facilitators will be recruited and trained in the PLA approach to facilitate the community group meetings. They will be central to the success of the community groups as being members of the local community will increase acceptability and possibly sustainability of the intervention beyond the timeframe of this project. Their knowledge on cervical cancer and the HPV vaccine will allow them to address concerns and misconceptions of the group when needed, in a dynamic and participatory way.

This project aims to serve as a platform for strengthening partnerships between stakeholders in order to make a lasting impact beyond the scope of this project. If successful, this project will work closely with the ministry of health, district governments and the CCPPZ to integrate community groups and the PLA approach into their existing cervical cancer prevention program.

Results

Indicators of success

Success will be indicated by an increase in HPV vaccination uptake during Child Health Week. The primary outcome will be HPV vaccination rates measured quantitatively. Data will be gathered once at the start of the study, once midway through the PLA phase and once during the post-intervention phase (see Fig. 4). Qualitative semi-structured interviews and focus group discussions with a small, purposively sampled group of participants from each cluster will occur at 12 monthly intervals during Child Health Week. Participants with daughters will be asked whether they were vaccinated. They will also be asked about the perceived change in health beliefs and behaviours towards HPV vaccination uptake in other community members. These insights will give context to the primary outcomes measured quantitatively. Questionnaires and semi-structured interviews will allow for measurement of secondary outcomes both quantitatively and qualitatively, including perceived (i) HPV vaccination and cervical cancer knowledge, (ii) acceptability, accessibility and equitability of the HPV vaccination, as well as (iii) attitudes of female group members towards other cervical cancer screening and treatment services.

Evaluation Outcomes

This intervention targets a wide range of factors influencing health beliefs and behaviours at the community level and requires a detailed evaluation plan to capture the complexity of the various causal pathways underpinning the outcomes. It will evaluate the theory, delivery and effectiveness of the intervention through process evaluation using the guidance by Moore et al. (51). Process evaluation has been shown to be especially useful in understanding the processes involved in community-level interventions (25). It will provide insights into how the intervention was implemented, as well as the
contextual factors affecting its implementation and outcomes. It will also be used to assess the extent to which the intervention was implemented as designed and whether the intended participants were reached. Furthermore, the PLA community group approach has been adapted for implementation into a context and health outcome not yet explored in the literature. A process evaluation is therefore useful for recording adaptations for future study replication.

The process evaluation team will consist of members from the project research team and community group facilitators. The team will receive training on the principles of process evaluation. Measurement of primary and secondary outcomes will occur separately from the process evaluation, however, the teams will work together as part of a larger integrated team. This will make most use of available resources and reduce duplication of results. It will also allow for the process evaluation to help inform the type of qualitative insights required from the outcome team to be able to compare the theory of change with the implementation process. Evaluations of the project itself will be nested within the study, with acceptability and feasibility assessed by facilitators during the formative and post-intervention phase. Participants of the community groups will be involved in these evaluations. The results of the intervention and process evaluation will be disseminated to participants, policymakers and key stakeholders, such as community leaders, healthcare workers and the Ministry of Health.

Discussion

This will be the first intervention to use PLA community groups in the context of cervical cancer prevention in Zambia. There is a risk that the adaptations made from previous PLA community group interventions are not adequate or appropriately suited to the local context. Continuous engagement with stakeholders and a thorough process evaluation with nested evaluations will help identify necessary adaptations to be implemented.

Behaviour change influenced by a complex interaction of personal, sociocultural and economic factors can be difficult to attribute to an intervention such as this one. Use of a CRCT, and incorporating the process evaluation into the implementation process from the beginning stages of the study design, including a detailed theory of change, will help highlight the mechanisms underlying the outcomes of this intervention.

The main risks to success of this project include a lack of engagement, inadequate local adaptations and the complex nature of drawing conclusions regarding health behaviour change from a single intervention. Lack of engagement by an adequate proportion of participants can lead to insignificant effects of PLA community groups on health outcomes (23). The sensitisation period with community leaders aims to increase engagement to ensure that the community groups have an adequate population coverage. The groups will also be called “child health groups” which aligns with the efforts of the CCPPZ to reduce stigmatisation by calling themselves the “cervical health program.” Avoiding the use of the word “cancer” and rather focusing on the health of the community’s children is also in keeping with the Child Health Week campaign during which the vaccination is administered.
Limitations

A CRCT design is useful when there are multiple possible confounding factors which could influence the outcomes of this intervention. While the CRCT design of the study allows for comparisons to be made between groups, there is still a risk of contamination between intervention and control arm participants from paired villages biasing the results (52). The quantitative data on vaccination rates will therefore be balanced with qualitative insights and a thorough process evaluation. Careful consideration of geographical location of the selected villages will be considered before randomisation to reduce this risk.

This project’s three-year duration is insufficient for a comprehensive long-term follow up to determine the sustainability of the intervention’s effect. Close collaboration with stakeholders and a comprehensive handover between the research team and the communities at the end of the project aims to promote lasting benefits of the intervention.

A limitation of the integrated process and outcome team is that findings from the process evaluation may increase bias of the outcome analysis (51). It can also limit the feedback to the process evaluation team from participants regarding concerns or complaints directed towards the outcome team (51). The training sessions will provide the team with clear guidance on how to limit introducing bias whilst still working together.

Although the TIP COM-B model was adapted for health behaviours specific to vaccines and does recognise social influences, it places much emphasis on individual health beliefs. This tendency of health behaviour theories has been criticised for its failure to acknowledge wider determinants of health (53). This project has tried to overcome this by utilising a community-based approach throughout the project, from implementation to evaluation.

Measuring effectiveness of this intervention by HPV vaccination rates relies heavily on an adequate vaccine supply. Engagement with the ministry of health, CCPPZ, local NGOs and donors will ensure that the vaccine supply is maintained throughout the project.

Another potential issue in this project is the lack of involvement with the girls receiving the HPV vaccine. Previous studies suggest they have little decision-making power regarding whether they receive the vaccine (15). This is the justification for directing community groups towards adults. However, the girls’ perceptions, beliefs and attitudes towards the HPV vaccine are important and more research into this area is required.

Participants willing to partake in the intervention may have higher acceptability of the HPV vaccine and may not be the sample of the population which requires a change in health beliefs and behaviours. Evaluation of outcomes at a community level, rather than only those in the intervention arm will help combat this. Community engagement led by village leaders during the formative research phase aims to expand the reach of the study.
The control group must also benefit from this intervention and will therefore continue to receive the educational sessions offered by the CCPPZ volunteers, who would be able to share the knowledge and skills gained from the PLA training and community group facilitation.

**Conclusions**

The need for low-cost, sustainable and scalable approaches to addressing the high cervical cancer rates in Zambia is evident. The CHARMZ project offers a promising community-based participatory learning and action cycle approach to help increase uptake of the HPV vaccination amongst girls in Zambia, significantly reducing the disease burden of cervical cancer.

**Abbreviations**

| Abbreviation | Description |
|--------------|-------------|
| HPV          | Human papillomavirus |
| PLA          | Participatory learning and action |
| CRCT         | Cluster randomised controlled trial |
| CCPPZ        | The cervical cancer prevention program in Zambia |
| CHARMZ       | the Community groups to increase Human papillomavirus (HPV) vaccination through Participatory Learning and Action, Reducing barriers and increasing community Mobilisation in Zambia |

**Declarations**

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Figures
Figure 1

Participatory learning and action cycle for community groups addressing HPV uptake. Adapted from: Morrison et al. (2019).
Figure 2

Topic guide designed for community group facilitators to prompt discussion and help identify, prioritise and categorise barriers and facilitators to HPV vaccination uptake through a COM-B approach. Adapted from: WHO Tailoring Immunization Programmes (TIP) (45)
Figure 3

Theory of change how community groups increase HPV vaccination uptake through PLA

Figure 4

CHARMZ project timeline