Leveraging Traditional and Religious Leaders in Delivery Design and Demand Generation– Protocol for a living systematic review

Protocol information

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Introduction

Cervical cancer remains a devastating global health challenge, accounting for an estimated 661,021 new cases and 348,189 deaths globally in 2022 alone (Bray et al., 2024). Distinct global inequality characterises this health burden. While high-income regions such as North America, Australia/New Zealand and Western Asia have declining rates of cervical cancer due to reliable screening and vaccination, the highest mortality rate is concentrated in sub-Saharan Africa and Melanesia with some countries experiencing sharp increases in prevalence (WHO Regional Office for Africa, 2023). Often described as the 'disease of the poor', cervical cancer disproportionately affects women in settings with limited resources, where clinical interventions are sparse and preventive measures remain out of reach for the most marginalised (Knaul et al., 2019).

In the most isolated and marginalised communities of low- and middle-income countries (LMICs), structural and social barriers often obstruct access to preventive measures. A Cochrane review found that the role played by traditional and religious leaders can either increase or decrease acceptance of the human papillomavirus (HPV) vaccine (Cooper et al., 2025). Clinical availability, therefore, does not necessarily translate into cultural accessibility. Traditional and religious institutions offer a proven yet underutilised solution to these barriers by serving as the primary frameworks for community communication channels, governance and social legitimacy**.** To understand the role of these organised social establishments as potential solutions to vaccine inequity, hesitancy, and non-conformity, we must define these institutions by their dual capacity for administration and social influence (Logan, 2013).

In the African context, traditional leadership is a sophisticated system that is both symbolic and administrative. These authorities serve as an important administrative hub for rural communities, going beyond their ceremonial role. From managing communal resources to verifying residency for social grants and facilitating access to various social services, traditional institutions fill gaps where the formal state presence is thin (Delius, 2008; Comaroff & Comaroff, 2018). Customary institutions also act as the legitimising authority for a dynamic ecosystem of community actors. Home-based caregivers who provide essential health services to those who cannot readily access clinics are not formal traditional authorities themselves, yet they frequently operate only through the sanctioned authority and cooperation of the traditional leader (Moshabela et al., 2016). These customary institutions typically (but not exclusively) centre men in their overt structures, with older male title-holders governing them and operating on power imbalances. Community health intermediaries, who are predominantly women, must negotiate access to adolescent female vaccine recipients through a governing layer of male elders who police local sexual and reproductive health norms (Chigbu et al., 2023).

In a number of West African customary systems, particularly among the Akan/Asante and Krobo communities in Ghana, female traditional leaders, commonly referred to as 'Queen Mothers', 'ohemaa/obahemaa' or 'manye', are not merely informal advisors but recognised office holders with their own stools, courts, constituencies and lines of authority. Scholarship on Asante chieftaincy describes queen mothers as female leaders who function in parallel with chiefs in dual-gender political systems, while work on Akan succession shows that the ohemaa can be central to nominating a royal for enrolment, though her role in destoolment varies by customary area and may be exercised with kingmakers rather than unilaterally (Stoeltje, 1997; Asaanful, 2019). This review recognises that customary governance is not entirely monolithic; these male-dominated structures are frequently mediated by covert female power networks, including institutional figures such as ‘Queen Mothers’ or paternal female advisors, i.e. Rakgadi/Makhadzi (Oomen, 2005). Contemporary evidence shows that queen mothers are active in community development, women's and children's welfare and health-related mobilisation. For instance, studies of Ghanaian queen mothers document their roles in children’s education, women’s rights, community planning and development, while the Manya Krobo Queen Mothers Association has been described as a credible community actor in HIV/AIDS awareness, mobilisation, partnership building and vulnerability reduction (Brown, 2011; Boateng, 2017). While these internal dynamics heavily influence community consensus, the review focuses primarily on formal institutional gatekeepers, in order to maintain analytical manageability. Variation in the role of traditional leaders is evident across Africa. Nonetheless, in other parts of the continent (such as in Uganda, Malawi and Nigeria), where traditional leaders may have less formal administrative responsibility, their role in influencing the behaviour and the social acceptance of rural populations remains the primary determinant of an intervention’s success (Baldwin, 2016; Cammack et al., 2007; Englebert, 2000; Vaughan, 2006). The review will therefore not assume that engagement must always proceed first through male chiefs or elders. Instead, it will code the gender, title, level of authority and customary functions of the leader engaged, including whether women traditional leaders hold formal decision-making, advisory, mobilisation or gatekeeping roles within the intervention.

Elsewhere outside the African context, there is evidence that the role of traditional leaders has been formally incorporated into local governance structures. For example, in India the ‘Sarpanch’ (known with different names in different parts of the country such as Pradhan and Mukhiya) is the elected leader of the *Gram Panchayat* (village council) as part of a village governance system based on a council of elders dating back thousands of years (Mathew, 2000; Palanithurai, 2008). One example from East Asia is the village assembly (Sangguniang Barangay) in the Philippines. The modern system of barangays, in which a Barangay Captain (Punong Barangay) is elected is based on the pre-colonial village governance system operating under a chief or ‘Datu’ (Bueno, 2013;

Rojo, 2002). In China, local governance at the village level combines the role of the Party with traditional leaders represented by the elders of local clans or du lao (Tsai, 2007; Xu & Yao, 2015). Across all three contexts, the vast regional diversity introduces a critical linguistic and methodological consideration for this review: in empirical literature, customary leaders are often reported solely by their locally recognised titles rather than by generic administrative terms. This specificity is increasingly prominent in contemporary co-produced or decolonial research, where investigators deliberately utilise indigenous appellations out of institutional respect and as a practice of epistemic justice.

Drawing on Baldwin's (2020) conceptualisation, this project defines traditional leadership as an institution in which authority derives from customary conventions and hereditary legitimacy. It should be noted that traditional institutions are not undifferentiated systems of governance. Instead, these institutions exist in a state of legal hybridity, with the extent of recognition and incorporation into formal governance structures varying across region and country. Internal institutional power dynamics frequently face contestation, national courts redefine them, or local government acts integrate them (Oomen, 2005). Across various LMIC contexts, this dynamism creates a complex political landscape in which traditional councils, often comprising both hereditary figures and community representatives, must navigate shifting legal recognition while maintaining their local symbolic authority. This dynamism does not diminish the capacity of traditional leadership to mobilise collective action in ways that formal states cannot match.

In parallel with traditional institutions, religious leadership serves as a foundational institution that shapes shared norms and ethics. Melillo et al. (2022) noted that religious leaders can influence vaccination uptake for diseases. For example, several mechanisms such as facilitating communication, improving access to resources and shaping followers' beliefs, can influence Polio, HPV, and COVID-19 vaccine uptake. Conversely, vaccine hesitancy also often arises from religious beliefs and the perceived spiritual safety of medical interventions. The conflation of religious and ideological doctrines with vaccines as a mechanism for Western control further complicates the issue. This highlights a critical point: a vaccine may be physically available in a clinic but remain socially inaccessible if local governing structures have not legitimised its presence within the community's moral framework (Richard & Synthia, 2026).

Pfeiffer et al. (2002, 2011) suggest that while global definitions of religious leaders often focus on formal clergy: priests, imams, or bishops, they may overlook other important roles. However, in many African LMICs, this definition must be Africanised to include leaders of African Initiated Churches (AICs), such as the Zion Christian Church (ZCC), and practitioners of African spirituality, including traditional healers. These figures often serve as the primary point of medical and spiritual contact. Anderson (2018, 2023)

observes that within AICs, the theology of healing posits that spiritual and physical well-being are inseparable. In this integrated approach, the church functions as a holistic health system in which spiritual practices, such as the use of blessed elements or adherence to physical disciplines, are considered active medical interventions. Consequently, religious institutions operate extensive non-state social safety nets and possess a unique faith-based legitimacy that can reshape how people access health care, through sermons and community counselling (Olivier et al., 2015). For this review, religious leadership is defined not merely by ecclesiastical title but by the authority to mediate between the spiritual and the physical, thereby determining the cultural safety of vaccines like the HPV vaccine.

The same logic of broadening definitions of religious leadership applies across Asian contexts, where Buddhist monastic orders (Sangha) operate as comprehensive parallel institutions that are not limited to 'traditional and religious affairs' but transcend these domains and extend into the state. In Thailand the Sangha functions as a fully developed administrative system with legislative, executive and judicial branches that mirror secular governance structures at every level: regional, provincial, district and village (Kyaw, 1984). This integration with secular governance extends to public health: the Thai government has established a National Sangha Health Charter, issued monks national identification cards for universal healthcare access, and trained nursing monks through the Ministry of Public Health (National Health Commission Office, 2013; Yamada et al. 2025). In Bangladesh, the United Nations Population Fund (UNFPA) has formally partnered with thousands of imams as community health advocates, recognising their unique grassroots position to influence maternal and reproductive health outcomes (UNFPA, 2006).

In China, Traditional Chinese Medicine (TCM) remains widely practised and is often the preferred channel for health-seeking behaviour among many populations (Lau et al., 2001). Within the Chinese healthcare framework, TCM is institutionalised as complementary medicine alongside Western clinical practices, with both paradigms collaborating at all levels of the health system (Zhang et al., 2025). However, contrary to assumptions that institutional integration eliminates opposition, multiple studies have identified a robust association between TCM preference and vaccine hesitancy (Lan & Jin, 2024; Zhang et al., 2025). Because TCM practitioners nonetheless function as the primary, trusted point of medical and community contact for many populations (Lau et al., 2001), they occupy an influential gatekeeping role, making them crucial pathways for legitimising public health interventions and also potential sources of hesitancy (Lan & Jin, 2024).

What unites these religious figures across both continents is that they operate within deeply male-centred frameworks that ultimately govern clinical interventions aimed at women, determining whose voice is heard, whose body is accessed, and which interventions move forward or stall (Arguedas et al., 2025; Dube & Chirongoma, 2025).

However, male authority often operates alongside authorised female actors. Traditional birth attendants (TBAs), for example, can play an important role because of their direct engagement in sexual and reproductive health and rights and simply because (unlike nearly all traditional and religious leaders) they are women. Research from Uganda confirms that men actively seek and trust TBA services, and TBAs in turn become allies with women in influencing male decision-makers to provide resources needed for maternity care (Turinawe et al., 2016). The same caution applies to traditional leadership: while many village councils and religious hierarchies are male-dominated, some customary systems include formally recognised women leaders, such as queen mothers, whose authority may be central to community legitimacy and whose omission could weaken the design of interventions. Traditional leaders and village councils are typically male elders; religious leaders are usually male, in most religions exclusively so (Dube & Chirongoma, 2025). Messaging via these channels therefore takes place within the larger context of the dominant ideology of sexual and reproductive health and rights promoted by these leaders, which may affect both how messages are conveyed and how they are received.

HPV vaccination is highly effective in preventing cervical cancer (Dorji et al., 2021; Han et al., 2025), yet uptake in LMICs remains suboptimal due to intersecting systemic, logistical, and social barriers (Waheed et al., 2023). These barriers range from supply chain constraints and inadequate infrastructure, to school absenteeism and challenges in ensuring multi-dose adherence (Aggarwal et al., 2024). Furthermore, persistent vaccine hesitancy, driven by gaps in health literacy and entrenched cultural norms, continues to hinder progress (Omohwovo et al., 2025). In some contexts, this hesitancy is exacerbated by historical medical trauma; for instance, the legacy of coercive sterilisation programs in India has fostered deep-seated suspicion toward clinical reproductive health initiatives, creating a significant, long-term barrier to HPV vaccine acceptance (Sur, 2021). Traditional and religious leaders can play a potentially important role in shaping trust, social norms, and community behaviour regarding HPV vaccination. However, their effects are likely to vary across settings depending on the specific socio-cultural context and the capacity of the health system to deliver the vaccine, especially in hard-to-reach populations. This protocol is designed to review evidence on whether, how, and under what conditions traditional and religious leaders can support HPV vaccine delivery and demand generation in LMICs.

Although the review focuses on traditional and religious leaders, it also recognises that HPV vaccine delivery and demand generation often depend on their interactions with health workers. Health workers are included only where their role is linked to, coordinated with, or helps explain traditional or religious leader engagement; the review will not assess health-worker-only interventions as a separate intervention category (Bakare et al., 2024; UNICEF Europe and Central Asia Regional Office, 2024). The expanded scope reflects the reality that community legitimacy and clinical delivery are mutually dependent. Traditional and religious leaders may shape whether HPV vaccination is perceived as culturally, morally and socially acceptable, while health

workers often provide the technical recommendation, counselling, vaccination service, recording and follow-up through which acceptance is translated into uptake and completion. This interaction is therefore examined as an implementation feature of traditional and religious leaders' engagement, rather than as a separate review of health worker-only interventions.

This living systematic review (LSR) is being produced for the HPV Living Evidence and Knowledge Partnership. Read more about the partnership here.

The partnership includes:

- The Alive team at the Future Evidence Foundation. The goal of Alive is to build innovative evidence systems that empower decision-makers to solve society's most pressing challenges.
- Elevate Evidence Hub (EEH) is the team that was commissioned to produce this review. EEH is a non-profit company based in Johannesburg, South Africa, and a woman-led pan-African organisation that is strongly committed to addressing health issues affecting women and girls in the developing world. Our evidence synthesis team is among the most experienced in decision-making evidence synthesis. Thus, we ensure that the leadership of African evidence synthesis remains firmly rooted on the continent and continues to drive equitable health outcomes globally.
- UCL EPPI Centre. The EPPI Centre aims for better evidence for better decision-making: robust and responsive reviews informing policy and practice
- The Research and Evaluation Centre, a global network of researchers with expertise in evidence synthesis across a wide range of subject areas
- Three structures represent the HPV vaccine delivery community: a Steering Group, a Tactical Group, and a Group of Advisors.

Why is it important to do this living systematic review?

Given the rapidly evolving, context-dependent nature of the evidence on the role of traditional and religious leaders in HPV vaccine delivery design and demand-generation activities, a static review would quickly become outdated. An LSR provides an approach that can continually incorporate new evidence, track emerging patterns, and support timely decision-making for countries introducing or scaling up HPV vaccination. This approach is particularly important because living systematic reviews are designed to preserve the rigour of systematic review methods while improving the currency and usefulness of evidence for decision-making in rapidly changing fields (Elliott et al., 2014; Akl et al., 2024). In the case of HPV vaccination, the evidence base is likely to evolve as countries introduce or expand HPV vaccination programmes, adjust delivery platforms, respond to misinformation, and refine strategies to reach out-of-school adolescents and marginalised communities. A living approach is therefore not only a technical updating

mechanism, but also a way of ensuring that evidence remains responsive to changes in vaccine delivery systems, community trust, and implementation realities.

In many LMICs settings, the role of traditional and religious leaders in health programming is not fixed or straightforward; it is constantly shaped by negotiations over authority, legitimacy and trust as well as the nature of gender relations. Traditional and religious leaders may act as intermediaries between households, health workers, schools, local government, and national programmes. Their influence is not simply inherited or doctrinal; it may depend on whether communities perceive them as accountable, effective, gender-sensitive, and aligned with local priorities. These leadership structures do not exist in isolation; changing legal frameworks, shifting political realities, and evolving state policies shape them (Logan, 2013; Baldwin, 2016). In many rural contexts, authority itself is fluid, particularly where customary systems coexist uneasily with democratic governance structures and where national courts continue to redefine the powers of traditional leadership (Comaroff & Comaroff, 2018). For this reason, a once-off or static review would struggle to capture the ongoing adjustments required for effective HPV vaccine delivery. An LSR approach becomes important precisely because it allows the review to follow these changing dynamics in real time, especially in contexts where community trust may already be shaped by local political tensions, resource conflicts or competing forms of authority (Logan, 2013). Empirical research indicates that interaction with traditional and religious leaders may encompass various avenues, including community mobilisation, message endorsement, involvement in planning, service monitoring, and collaboration with health workers. A cluster-randomised trial in Cross River State, Nigeria, investigated an intervention involving traditional and religious leaders in community decision-making and vaccination coverage efforts, demonstrating that these leaders can serve as both communicators and participants in planning and implementation (Oyo-Ita et al., 2021). Recent HPV-specific research from Kenya indicates that religious leaders may be inclined to advocate for HPV vaccination among their congregations, however their willingness and influence may be influenced by knowledge, misconceptions, doctrinal issues, and trust in health systems (Kaaria et al., 2024).

By continuously incorporating new evidence, the review is better positioned to observe how interventions adapt as the relationships between customary and elected structures shift over time, and to offer more grounded insights for programmes operating within these complex governance landscapes. The LSR design is particularly suitable for this subject as it can monitor not only the impact of traditional and religious leader engagement on HPV vaccine uptake, completion, acceptance, and equity, but also how these effects fluctuate with changes in governance structures, gender dynamics, religious narratives, misinformation contexts, and delivery mechanisms. This is crucial for preventing oversimplified conceptions that traditional or religious leaders are

invariably obstacles or consistently enablers. The evaluation will produce an ongoing account detailing when, how, for whom, and under what circumstances these leaders favourably or negatively influence HPV vaccine distribution and demand development.

In this protocol, we have considered PRISMA guidance established for living systematic reviews Akl EA, Khabsa J, Iannizzi C, Piechotta V, Kahale LA, Barker JM, McKenzie JE, Page MJ, Skoetz N. Extension of the PRISMA 2020 statement for living systematic reviews (PRISMA-LSR): checklist and explanation. BMJ 2024;387:e079183. doi: 10.1136/bmj-2024-079183.

Research questions

Primary Research Question

To assess the effects of engaging traditional and religious leaders in the design of HPV vaccine delivery and demand generation activities on uptake, completion, acceptance, and equity in LMICs.

Secondary Research Questions

1. To examine the extent to which effect estimates vary by intervention design, context, and substantive, methodological, and extrinsic study characteristics.
2. To assess the barriers and facilitators influencing the intervention's implementation and effects.

Definition of key concepts

a. Traditional leadership (customary institutions)

Definition: Local governance structures whose legitimacy is derived from customary conventions, hereditary succession and indigenous social systems.

Nominal variation: This review defines traditional leaders by what they do and not what they are called. Contemporary research increasingly avoids generic Western labels like 'traditional authority', and instead uses specific local titles out of respect and in adherence to what is epistemically just. In this case, if the institution functions as a custodian of local custom, a community asset or an arbiter of indigenous resources, it will be included in the review, despite the name that the original study might use.

Institutional structure: This review treats traditional leadership as an institutional entity (such as traditional councils) rather than as individual actors. This approach

acknowledges that authority is typically distributed across a representative body rather than a single person, although there may be a recognised leader of the council or other body.

Hierarchical sensitivity: The review recognises diverse levels of customary authority, ranging from recognised kingships and queenships to senior traditional leaders and village headmen/headwomen. It acknowledges that while these leaders hold significant symbolic and customary authority, their formal powers are exercised within the constitutional frameworks of their respective nations which reflect differing degrees of incorporation into formal governance structures.

Contested legitimacy: This review acknowledges that authority is often in flux. Legitimacy may be fractured by perceived mismanagement of communal resources (such as land or mining royalties) or by tensions between hereditary members and democratically elected representatives. In such contexts, community trust may shift toward elected structures that represent the community gaze.

Sanctioned agents: These are actors (i.e., community-based caregivers or village health committees) who do not hold formal titles themselves but whose operational license in the community is derived from the approval and legitimising authority of traditional leadership.

b. Religious leadership and faith-based organisations (FBOs)

Definition: Individuals or groups or organisations recognised as spiritual intermediaries or faith-based entities with the power to influence communal norms and health behaviours based on religious doctrine, spiritual authority or communal recognition

Scope: This definition includes three interconnected categories:

Formal denomination clergy: Priests, Imams, bishops, pastors, reverends, catechists, sheikhs, rabbis, deacons, ministers, chaplains and other recognised religious office-holders.

African Initiated Churches (AICs) and indigenous spiritual practitioners: Leaders of AICs (such as the Zion Christian Church), traditional healers, prophets and spiritualists whose authority derives from both Christian and indigenous cosmological frameworks. As Anderson (2018, 2023) observes, within AICs the theology of healing posits that spiritual and physical wellbeing are inseparable, meaning that these leaders function as holistic health authorities.

Faith-Based Organisations (FBOs): Following Song et al. (2024), FBOs are entities whose organisational control, expression of religion and program implementation are tied to values and beliefs belonging to specific religious identities. This includes

church-backed NGOs, faith-affiliated health networks, missionary health services, and religious charitable trusts.

Inclusive scope across formal and informal settings: For the purpose of this review, religious and spiritual leadership is defined inclusively to encompass both formal, ordained religious authorities and informal or community-recognised spiritual practitioners. This includes mosque elders, scripture teachers, spirit mediums, prophetesses and syncretic ritual leaders whose authority derives from community recognition rather than formal ordination. The definition is not limited to any single religious tradition and applies across Buddhist, Hindu, Muslim, Christian, indigenous and syncretic contexts in low- and middle-income countries.

Integrated framework of health: Religious leaders and FBOs are defined by their role within an integrated framework in which physical well-being and spiritual health are inseparable. Religious institutions operate extensive non-state social safety nets and possess a unique faith-based legitimacy that can reshape how people access health care, through sermons, community counselling, and institutional health programming (Olivier et al., 2015). Endorsement by a religious or spiritual authority is often a prerequisite for perceived cultural safety in clinical interventions.

Healthcare workers as complementary authority figures: This review recognises that religious leaders, FBOs, and healthcare workers do not operate in isolation. Evidence from a recent UNICEF multi-country faith survey suggests that these actors may influence vaccine acceptance through different, though potentially complementary, channels (UNICEF, 2023). While the survey does not explicitly distinguish between moral and practical forms of authority, its findings suggest that religious leaders may contribute to shaping the normative environment for vaccination decisions, while healthcare workers often play a more direct role in providing information, addressing concerns and facilitating access to services. Rather than operating independently, these forms of authority may reinforce one another. A vaccine may receive legitimacy through trusted faith networks while its uptake depends upon the technical expertise, recommendations, and service delivery provided by healthcare workers.

Relationship between religious leaders, FBOs and healthcare workers: The dynamic operates as follows: religious leaders and FBOs shape perceptions of vaccines, setting the normative framework for community acceptance. Healthcare workers exercise pragmatic authority that facilitates direct clinical uptake. A vaccine may receive moral validation from a religious leader but remain logistically inaccessible without the pragmatic execution of the healthcare worker. This review highlights the increasingly porous boundary between these roles, particularly in faith-based settings

where doctrinal and medical practices unify. We therefore seek to examine how these two forms of authority interact to shape vaccine demand.

This review examines the role of traditional and religious leaders in shaping HPV vaccine delivery design and demand generation. We recognise that traditional and religious authorities often operate alongside healthcare workers to influence outcomes. For the purpose of this review, healthcare workers are not being considered a primary leader category; however, they are included where their activities are linked or coordinated with traditional and religious authorities. Therefore, we will extract data on two forms of healthcare worker engagement:

- **Direct interaction:** Cases where traditional, religious or FBOs and healthcare workers collaborate in HPV vaccine delivery design or demand generation activities.
- **Comparative influence:** Studies that separately report outcomes for traditional, religious leader or FBO engagement versus healthcare worker engagement, allowing us to examine how these forms of authority complement or contradict each other.

This expanded scope is limited to understanding the interaction between these actors, not to reviewing healthcare worker interventions in isolation. Health workers are treated as complementary implementation actors, not as an independent leader category. Evidence on health workers will be included only where their activities are explicitly linked to traditional or religious leader engagement, faith-based organisations, customary institutions or community mobilisation structures. Studies focusing only on health-worker knowledge, attitudes, recommendation practices, training, counselling or service delivery, without any connection to traditional or religious leaders or institutions, will remain outside the scope of this review.

Description of the interventions

This protocol focuses exclusively on evidence related to the involvement of traditional and religious leaders in the design of HPV vaccine delivery and demand-generation activities in low- and middle-income countries. This intervention can be categorised into two primary streams:

Stream 1: Administrative Integration (The Structural Component). This component addresses the logistical (or structural) barriers to vaccine delivery by utilising the organisational capacity and physical infrastructure of traditional and religious institutions. Examples include using traditional council offices, community meeting grounds, or religious halls as vaccination sites. Furthermore, this stream includes integrating vaccine follow-up into existing administrative cycles, such as residency

verification, social service distribution meetings, or customary assemblies (traditional open gatherings for community consultation and information exchange).

Stream 2: Social Legitimisation (The Symbolic Component). This component leverages the institution's symbolic and moral authority to build community trust. Interventions include sermons, formal traditional proclamations, and the public vaccination of leaders or their family members. The objective is to establish the vaccine as a culturally and morally accepted community priority, thus addressing ingrained concerns regarding cultural safety and vaccine hesitancy. Activities under this component include those activities that build knowledge of and support for HPV vaccination among traditional and religious leaders.

Across both intervention streams, health workers may appear as linked implementation actors, working with traditional or religious leaders to support HPV vaccine delivery design, demand generation, counselling, referral, vaccination, follow-up, or misinformation management. Their inclusion is limited to interventions where they engage with traditional or religious leaders. The review will therefore not synthesise health-worker-only interventions but will extract and analyse health-worker roles that help explain how traditional and religious leader engagement is operationalised, strengthened, constrained, or translated into vaccination outcomes.

Engagement and reporting

The primary users of this LSR will be decision-makers and primarily their advisors in low- and middle-income countries (LMICs) involved in HPV vaccine delivery, including but not limited to: representatives from National Immunisation Technical Advisory Groups (NITAGs), EPI teams, Ministries of Health, Ministries of Education, Ministries of Finance, technical partners, academia, researchers, implementing partners, and civil society. However, this LSR also has application to policy, program design, and implementation decisions for normative and financing institutions, technical and learning partners, and evidence intermediaries at global and regional levels.

This review is not intended to replace national decision-making processes. Rather, it aims to strengthen evidence-informed deliberation by providing decision-makers at all levels with a continuously updated, contextually relevant synthesis of evidence on the effects of engaging traditional and religious leaders in HPV vaccine delivery design and demand-generation activities across multiple outcomes.

Alive, the partnership secretariat will facilitate and convene a community of users to engage with, support the dissemination of, and directly use evidence that emerges from this LSR. This community and engagement process will focus on collectively refining a

rigorous body of evidence to ensure that policy and practice questions receive timely, context-specific answers.

The community will be engaged through three structures.

- The Steering Group (SG) stewards the development of the living HPV vaccine delivery evidence base. It provides strategic direction and ensures that the living evidence serves the broader research and delivery community and meets end users' needs. See here for the involved individuals.
- The Tactical Group (TG) provides expert guidance and technical oversight to the Elevate Evidence Hub synthesis team, UCL, and Alive, which are the teams responsible for developing the LSR. Members of the TG will provide technical oversight to ensure the LSR is both methodologically sound and meets the needs of decision-makers. The TG will provide technical oversight to ensure the development of robust, high-quality living protocols, providing input on PICO frameworks, search strategies, and inclusion criteria. The Group of Advisors (AG) provides technical input and systems insight to inform the SG's strategic decisions.

Methods

This study is an LSR and will be updated continually. An LSR is a high-quality, up-to-date online synthesis of health research that is updated as new, relevant research data that meet the study inclusion criteria become available (Elliott et al., 2014). This means that, following an initial search from 2000 (GAVI Strategy 1.0) to [August 2026 for base review], repeat searches will be rerun monthly, any new studies will be incorporated into the review, and updates will be published regularly. Based on current funding, we anticipate the last update will be in February 2027, but options for sustainability beyond that are under exploration.

The protocol will be registered on PROSPERO. In this protocol, we have followed the PRISMA guidance for LSRs (Akl et al., 2024). All the data and analyses compiled and generated by the project will be stored at data.evidence-repository.org.

Eligibility criteria

Study types

Inclusion

- Randomised controlled trials

- Case studies
- Cross-sectional studies
- Surveys
- Qualitative studies
- Mixed-methods studies
- Controlled before and after studies
- Difference-in-differences
- Regression discontinuity
- Natural experiment
- Propensity score matching

Exclusion

- Opinion pieces
- Framework/conceptual
- Commentaries
- Editorials
- Policy analyses
- Methodological studies and guidelines
- Protocols

Publication status

Inclusion

- Peer-reviewed journal articles
- Preprints
- Working papers
- Government reports

- NGO or donor reports
- Technical briefs
- Theses/dissertations
- Unpublished data/evaluations

Exclusion

- Press releases
- Abstracts
- On-going studies

Concepts

Inclusion

- Co-design of HPV vaccine delivery programs involving traditional and religious leaders
- Community sensitisation and mobilisation involving traditional and religious leaders
- Communication through messaging, sermons, and mass media
- Outreach campaign strategies, such as community meetings
- Collaborative delivery of HPV vaccine programs
- Advocacy and endorsement of HPV vaccine programs
- Addressing misinformation
- Addressing vaccine hesitancy
- Partnerships with health departments or local NGOs
- Interventions in which healthcare workers collaborate with, are supported by, or operate through traditional or religious leaders, faith-based organisations, customary institutions or community authority structures in HPV vaccine delivery design or demand-generation activities

Exclusion

- Studies that do not include traditional or religious leader interventions
- Studies that focus on the non-HPV vaccine programs
- Studies on HPV vaccine efficacy, safety, or immunogenicity, such as pre-clinical or clinical trials
- Studies on reproductive health that don't include the HPV vaccination
- Health-worker-only interventions, including studies focused solely on provider recommendation, provider knowledge, clinical counselling, health-worker training or service delivery, unless these are explicitly linked to traditional or religious leader engagement

Participants

Inclusion

- Adolescents eligible for vaccination, including boys and girls
- Traditional leaders such as Kings, village chiefs, clan heads, and traditional healers
- Religious leaders such as priests, pastors, catechists, Reverends, and Bishops, Imams, Sheikhs
- Parents and caregivers
- Healthcare stakeholders such as nurses, doctors, and immunisation officers who work with traditional and religious leaders
- Healthcare leaders who work with traditional and religious leaders

Exclusion

- Individuals not involved in HPV vaccine programs

Geographical context

Inclusion

- Low and middle-income countries based on the World Bank's fiscal year 2026 (base data for calendar year 2024), World Bank Country and Lending Groups – World Bank Data Help Desk
- Venezuela and Ethiopia will also be included, even though they are currently unclassified

Exclusion

- High-income countries only

Language

Inclusion

- English

Exclusion

- Languages other than English

Year

Inclusion

- Studies published from 2000 (GAVI strategy 1.0)

Exclusion

- Studies published before 2000

Search and screening

Search strategy

A comprehensive search strategy will be developed in collaboration with an information specialist. The search strategy will aim to locate both published and unpublished studies from 2000 onwards, the year the HPV vaccine was introduced. Searches will be performed in the following electronic databases: [Medline via PubMed, Embase, CINAHL, CABI, Scopus, Web of Science; Social sciences, PsycINFO, Global Index Medicus and ERIC]. The search will combine MeSH terms (controlled vocabulary) with free-text keywords to account for evolving terminology in research on how traditional and religious leaders shape HPV vaccination. The strategy will incorporate truncation, wildcards, and proximity operators where supported and will be adapted for each database. The search strategy will include the HPV vaccine, traditional and religious leaders; faith communities; healthcare workers and LMICs terms. This strategy is presented in Appendix 1 and Table A3 provides a comprehensive list of academic and grey literature sources of the evidence for this review.

A grey literature search of umbrella organisations with broad knowledge repositories will be conducted. These organisations include the World Bank Knowledge Hub, World Bank Documents and Reports, UNICEF, and UNESCO; evidence repositories such as the International Initiative for Impact Evaluation (3ie) Development Evidence Portal (DEP) and the Cochrane and Campbell Collaboration Libraries; as well as specialised organisations focused on sub-areas relevant to the review question, for example, Gavi - the Vaccine Alliance, WHO IRIS, PATH, MSI Reproductive Choices (formerly Marie Stopes), Girl Effect, and UNFPA. The snowballing search will include backward citation searches (i.e., searching the reference lists of included studies and seminal papers) and forward citation searches (i.e., using Google Scholar to identify papers that cite the included studies).

Title and abstract screening

Following the search, all identified citations will be collated and uploaded into EPPI Reviewer, a web application that enables researchers to manage the entire lifecycle of a review in a single location (Thomas et al., 2023), and duplicates will be removed. A pilot test will be conducted on titles and abstracts, which will be screened by two independent reviewers to assess compliance with the review's inclusion criteria. Any disagreements will be resolved by a third reviewer or through team discussions. After achieving high agreement (80% or above), a further subset of references will be single-screened, with a 10% check-in by the team lead.

The double-screened references will be divided into 10% subsets. These subsets will be used to iteratively develop and test the use of Large Language Models (LLMs) for screening. Prompts will be developed using the inclusion and exclusion criteria for the review and run in EPPI Reviewer using the integrated OpenAI GPT-4.1 model on the first 10%. The performance of the LLM will be evaluated by comparing it against the gold-standard human reviewer judgements to determine the model's accuracy in correctly including and excluding citations. Once the prompt has been refined and evaluated to achieve a recall above 0.95, it will be deployed to all remaining unscreened citations. The team lead will then screen a random 10% sample of records to assess agreement with the LLM.

Full text screening

Reviewers will independently assess the full text of studies retained after title and abstract screening. Discrepancies will be resolved by a third reviewer or through team discussions. Reasons for exclusion will be documented. The results of the search and the selection process will be illustrated on a PRISMA flow diagram.

Data extraction

Data will be extracted using a standardised form (see Appendix 2 for the data extraction form). For each study retained after full-text screening, one reviewer will extract the data, and a second reviewer will verify its accuracy and completeness.

Using a subset of studies with data extraction verified by two reviewers, LLM prompts will be iteratively developed and tested for all items on the data extraction form using the integrated OpenAI GPT-4.1 model within EPPI Reviewer. The prompts will be applied to all studies included in the full text, with a 10% random subset double-screened by a human reviewer. If the agreement is above 95%, the LLM will extract the remaining studies, which will then be verified by a human reviewer for accuracy and completeness.

The extraction form will include details on the following areas, with details provided in Appendix 2.

- General characteristics: author and year of publication, study type.
- Study characteristics: start and end dates of the study, follow-up period, funding sources, and contextual information, including country or regional focus, continent, World Bank region, and World Bank income group;
- Intervention description: engaging traditional and religious leaders in the delivery design, mobilisation, messaging or delivery of HPV vaccination, target audience and activities;
- Comparison where applicable: standard of care;
- Target population information: age, gender, income;
- Outcomes: Uptake, completion, acceptance, equity, trust, knowledge misinformation reduction, cost, and sustainability;
- Delivery location of the intervention: school, community;
- Outcome data: means and standard deviations, sample size in each intervention group, test statistics (e.g. t-test, F-test, p-values, 95% confidence intervals).
- Barriers and facilitators to programme participation for (i) traditional and religious leaders, (ii) healthcare workers, and (iiI) target women for vaccination
- Barriers and facilitators to successful programme implementation
- Barriers and facilitators to achieving outcomes
- Gender relations, the extent to which intervention design or implementation explicitly adopt a gender-informed perspective.

For studies involving healthcare workers, we will extract whether their role was linked to traditional or religious leader engagement; the type of health worker involved; the nature of collaboration with traditional or religious leaders; whether health workers provided training, counselling, technical information, vaccination services, referral or follow-up;

and whether the study reports how this interaction influenced trust, acceptance, uptake, completion, equity or implementation.

Risk of bias (RoB) assessment

We will use the Cochrane risk of bias tool (RoB 2) to assess the risk of bias for included randomised studies and the ROBINS-I tool for included non-randomised studies of interventions (Sterne et al., 2019), with adaptations to our context, drawing on (Waddington et al. 2021). Two reviewers will independently conduct the appraisal, with any disagreements resolved through discussion or consultation with a third reviewer. For this LSR, RoB assessments will be updated as new studies are incorporated. The results will be presented in summary tables and will inform the interpretation of findings and the overall confidence placed in the body of evidence. The domain-based risk of bias tool covers the following six indications of trustworthiness:

- Selection bias
- Confounding bias
- Bias due to departures from applied interventions
- Bias due to missing data
- Bias due to the measurement of outcomes
- Bias due to the selection of reported results.

For each study, each domain of bias will be given a low, moderate, high, or critical risk-of-bias rating, enabling a transparent calculation of the overall risk-of-bias score. Studies with a critical risk of bias will be included in the review but excluded from the synthesis.

Qualitative studies will be appraised using an adapted version of the CASP tool. The appraisal will assess six areas: clarity of the methodology, appropriateness of recruitment and sampling, consideration of researcher reflexivity, ethical standards, transparency of data collection methods, and rigour of data analysis. Each domain will be rated as 'Yes', 'Partly', 'No', or 'Insufficient detail', with supporting page references or quotations recorded for transparency. An overall judgement will then be assigned to each study using a “weakest link” approach, and results will be presented in summary tables or figures. Studies will not be excluded solely on the basis of appraisal, but the findings will be used to inform interpretation and confidence in the evidence.

Analysis

Measurement of the effect of treatment

We will calculate the standardised treatment effect using the quantitative outcome data extracted from the relevant included study. A standardised mean difference (SMD) or

Cohen's *d* will be calculated for continuous outcomes (where group means are being compared), using formulae reported in Boreistein et al., 2009 or the Campbell Collaboration's effect size calculator, Effect Size Calculator – Campbell Collaboration. Because Cohen's d can be biased in studies with small sample sizes, it will be adjusted to Hedge's g using the formula provided by Ellis 2010. Appropriate formulae will be used depending on the study's effect size. A Cox-transformed log-odds ratio effect size will be calculated for outcomes reported as proportions (Sánchez- Meca et al., 2003). Effect size calculations will be done from Excel spreadsheets, and if carried out using Campbell Collaboration's effect size calculator, the output will be copied into the Excel spreadsheets.

Unit of analysis issues

The main unit of analysis will usually be individual adolescents eligible for HPV vaccination, but we will also include studies that report outcomes at the levels of parents or caregivers, households, schools, health facilities, religious congregations, traditional authority areas, villages, or wider communities. Because interventions involving traditional and religious leaders are often delivered at the cluster level while outcomes such as uptake, completion, acceptance, trust, or misinformation are measured at the individual level, we will use study estimates that appropriately account for clustering where available. If a cluster-randomised or cluster-assigned study analyses individuals as independent observations, we will correct for the unit-of-analysis error by adjusting the effective sample size or inflating the variance using an intra-cluster correlation coefficient, drawing on reported ICCs where available or plausible external values tested through sensitivity analysis (Higgins et al., 2023). This adjustment will not be applied where the outcome is genuinely measured at the cluster level. For studies with multiple eligible intervention arms, such as separate engagement of traditional leaders, religious leaders, or combined leader engagement, we will include only relevant comparisons and avoid double-counting by combining conceptually similar arms where appropriate or splitting shared control groups across comparisons (Borenstein et al., 2009). Multiple reports from the same intervention or dataset will be linked before analysis, with one primary report used for effect-size extraction and companion reports used to obtain supplementary information. Where studies report multiple outcomes or time points, we will retain distinct outcome constructs separately, such as initiation, completion, acceptance and equity, while avoiding duplicate inclusion of the same participants for the same outcome in the same meta-analysis.

Dealing with missing data

In cases of missing data in any included study, we will contact the study's first author. If efforts to contact the author are unsuccessful, we will report those outcomes as missing. For continuous outcomes, in which standard deviations are not reported, standard

errors, confidence intervals, or probability values will be utilised to calculate them using appropriate formulae.

Synthesis and reporting

This review will adopt a mixed-methods evidence synthesis approach to answer both the effectiveness question of what works and the implementation-related question of how, why, for whom, and under what conditions interventions work. To answer the first question, where possible, a meta-analysis of studies that are sufficiently comparable[1] in terms of interventions and outcomes will be performed. Separate meta-analyses will be conducted for each intervention and outcome type, using standardised effect sizes where appropriate. The results of meta-analyses will be presented as forest plots. We aim to use Stata packages for meta-analysis and meta-regression and will consider alternative software and machine learning (ML) languages, such as R and Python. Where meta-analysis is not possible due to heterogeneity, limited numbers of studies, or insufficient reporting of effect estimates, we will conduct a structured narrative synthesis to summarise the direction, strength, and consistency of findings across studies. Where effect estimates are reported, they will be presented in summary tables and discussed in terms of their direction, magnitude, precision, and risk of bias, rather than relying on simple vote-counting based on statistical significance. We will also explore whether variation in findings can be explained by differences in intervention design, implementation intensity, population characteristics, comparator conditions, follow-up duration, or contextual factors.Two

This approach is consistent with guidance on the conduct of systematic reviews where statistical pooling is inappropriate, which recommends transparent, structured synthesis of findings and careful attention to heterogeneity, effect direction, effect size, and study quality (Popay et al., 2006; Campbell et al., 2020; Higgins et al., 2023)

To complement the quantitative synthesis, we will also synthesise qualitative and mixed-methods evidence on barriers, facilitators, acceptability, trust, implementation processes, and socio-cultural context. Qualitative studies, mixed-methods studies with extractable qualitative components, process evaluations, and relevant descriptive material reported alongside quantitative studies will be coded thematically. Coding will follow an abductive framework that classifies evidence according to whether factors operate as barriers or facilitators, whether they relate to implementation, diffusion, or effectiveness, and whether they are primarily individual, institutional, or contextual. The authors or participants will mostly report these data as commentaries. Within this structure, we will use an inductive approach to allow the evidence to reveal more specific themes. This review will capture how factors such as trust, legitimacy, local

[1] Two or more studies are considered sufficient for meta-analysis.

authority structures, gender norms, religious influence, misinformation, service access, and delivery context shape the success or failure of interventions across LMIC settings. The qualitative synthesis findings will be combined with the quantitative results to better understand what is likely to work, for whom, and in what contexts.

Where relevant, the synthesis will examine health-worker involvement as an implementation feature rather than a standalone intervention category. We will explore whether and how the interaction between health workers and traditional or religious leaders shapes intervention effects, acceptability, feasibility and implementation. This will allow the review to distinguish between the social legitimisation functions of traditional and religious leaders and the technical, counselling and service-delivery functions of health workers, while recognising that these functions may reinforce or undermine each other in practice.

Assessment of heterogeneity and subgroup analyses

Statistical heterogeneity will be assessed separately for each meta-analysis using appropriate heterogeneity statistics, including Cochran's Q-test, Tau (τ^2), and I^2, and visually examined through forest plots. Where sufficient data are available, we will explore potential sources of heterogeneity through subgroup analyses and meta-regression, considering substantive, methodological, and extrinsic study characteristics. In this review, likely sources of heterogeneity will include the type of traditional or religious leader engaged, the role they are assigned within the intervention, the delivery platform through which HPV vaccination is provided, the main demand-side barriers being addressed, the socio-cultural and geographic setting, and the institutional arrangements through which the intervention is implemented. This will help identify whether variation in effects is associated with differences in intervention type, population group, setting, study design, or other contextual factors relevant to HPV vaccine delivery and demand generation. For example, effects may differ depending on whether leaders are engaged primarily as trusted messengers or involved in mobilisation, consent processes, or follow-up for dose completion and whether interventions target school-going girls or out-of-school adolescents.

Certainty assessment

The certainty of the evidence for intervention effects will be assessed using the (Grading of Recommendations Assessment, Development and Evaluation) approach. GRADE provides a transparent and structured framework for rating the certainty of a body of evidence for each outcome, rather than assessing individual studies in isolation

(Guyatt et al., 2011; Schünemann et al., 2024). It is distinct from risk-of-bias assessment: while risk of bias focuses on the internal validity of individual studies, GRADE considers the overall trustworthiness of the evidence across studies, including risk of bias, inconsistency, indirectness, imprecision and publication or dissemination bias (Guyatt et al., 2011; GRADE Working Group, 2024).

Certainty will be rated as high, moderate, low or very low for each priority outcome and, where appropriate, by intervention type or comparison. Where meta-analysis is possible, GRADE assessments will be informed by pooled effect estimates, confidence intervals and heterogeneity. Where meta-analysis is not possible, and findings are synthesised narratively, GRADE will still be applied to the body of quantitative evidence, with judgements based on the direction and magnitude of effects across studies, consistency of findings, precision of reported estimates, applicability to the review question and the risk of selective reporting (Murad et al., 2017; Campbell et al., 2020). The rationale for all downgrading or upgrading decisions will be documented transparently and presented in evidence profile tables and Summary of Findings tables, following GRADE guidance (Schünemann et al., 2024).

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Appendices

Appendix 1. Search Strategy

Table A1: MeSH Terms

Category	**MeSH Terms**
HPV vaccines	"Papillomavirus infections"[Mesh]; "Human papillomaviruses"[Mesh]; "Human Papillomavirus Recombinant Vaccine Quadrivalent, Types 6, 11, 16, 18"[Mesh]
Traditional and religious leaders	"Religious personnel"[Mesh]; "Traditional medicine practitioners"[Mesh]
Healthcare workers	"Health personnel"[Mesh]

Search terms

HPV vaccines terms

HPV vaccines: "human papillomavirus*", "human papilloma virus*", hpv*, (vaccin*, shot*, injection*, jab*, dose*, booster*, immunization*, immuniz*, immunisation*, immunis*, inoculat*

Traditional and religious leaders terms

Traditional and religious leaders: traditional, village*, trib*, clan*, religious, church, spiritual, faith) adj2 (leader*, chief*, head, heads, healer*, headman, headmen, headwoman, headwomen, headperson, elder, elders), "faith leader*", "faith-based leader*", king*, queen*, priest*, imam*, bishop*, pastor, pastors, catechist*, reverend*, sheikh*, clergy, cleric, rabbi*, deacon*, minister*, chaplain*, "council of elders", "gram pradhan", "gram panchayat", sarpanch, mukhiya, "village assembly", "sangguiniang barangay", "barangay council", shaman*, sangoma*, inyanga*, babalawo, dibia, marabout*, mullah*, mufti*, ayatollah*, ulema, ulama, qadi, archbishop*, cantor*, monk*, nun*, guru*, swami*, pandit*, pujari*, granthi*, lama*, rinpoche*, bonze*, sultan*, oba, emir*, "medicine man", matai, sadhu, mahant

Faith community terms
church*, mosque, temple, (religion* ,religious, faith*, spiritual, spirituality) adj2 (communit*, organization*, organisation*, group*, network*, association*, institution*, actor*, representative*) congregation*, parish*, parishioner*, masjid*, synagogue*, gurdwara*)

Health worker terms
Healthcare workers: (health*, medical, clinical) adj (worker*, personnel, professional*, staff, practitioner*, provider*), physician* ,doctor*, clinician*, nurs*, midwi*

LMIC terms

afghanistan OR albania OR algeria OR angola OR argentina OR armenia OR azerbaijan OR bahrain OR bangladesh OR "republic of belarus" OR belarus OR byelarus OR belorussia OR byelorussia OR belize OR "british honduras" OR benin OR dahomey OR bhutan OR bolivia OR "bosnia and herzegovina" OR bosnia OR herzegovina OR botswana OR bechuanaland OR brazil OR brasil OR "burkina faso" OR "burkina fasso" OR "upper volta" OR burundi OR urundi OR "cabo verde" OR "cape verde" OR cambodia OR kampuchea OR "khmer republic" OR cameroon OR cameron OR cameroun OR "central african republic" OR "ubangi shari" OR chad OR china OR colombia OR comoros OR "comoro islands" OR "iles comores" OR mayotte OR "democratic republic of the congo" OR "democratic republic congo" OR congo OR zaire OR "cote d'ivoire" OR "cote d ivoire" OR "cote divoire" OR "ivory coast" OR cuba OR cyprus OR djibouti OR "french somaliland" OR dominica OR "dominican republic" OR ecuador OR egypt OR "united arab republic" OR "el salvador" OR "equatorial guinea" OR "spanish guinea" OR eritrea OR eswatini OR swaziland OR ethiopia OR fiji OR gabon OR "gabonese republic" OR gambia OR "georgia republic" OR ghana OR "gold coast" OR grenada OR guatemala OR guinea OR "guinea bissau" OR "british guiana" OR haiti OR hispaniola OR honduras OR india OR indonesia OR timor OR iran OR iraq OR "isle of man" OR jamaica OR jordan OR kazakhstan OR kazakh OR kenya OR "north korea" OR "south korea" OR korea OR kosovo OR kyrgyzstan OR kirghizia OR kirgizstan OR "kyrgyz republic" OR kirghiz OR laos OR "lao pdr" OR "lao people's democratic republic" OR lebanon OR "lebanese republic" OR lesotho OR basutoland OR liberia OR libya OR "libyan arab jamahiriya" OR "republic of north macedonia" OR macedonia OR madagascar OR "malagasy republic" OR malawi OR nyasaland OR malaysia OR "malay federation" OR "malaya federation" OR maldives OR "indian ocean islands" OR "indian ocean" OR mali OR micronesia OR "federated states of micronesia" OR kiribati OR "marshall islands" OR "northern mariana islands" OR palau OR tuvalu OR mauritania OR mauritius OR mexico OR moldova OR moldovian OR mongolia OR montenegro OR morocco OR ifni OR mozambique OR "portuguese east africa" OR myanmar OR burma OR namibia OR nepal OR "netherlands antilles" OR nicaragua OR niger OR nigeria OR muscat OR pakistan OR "papua new guinea" OR "new guinea" OR paraguay OR peru OR philippines OR philipines OR phillipines OR phillippines OR rwanda OR ruanda OR samoa OR "pacific islands" OR polynesia OR "samoan islands" OR "navigator island" OR "navigator islands" OR "sao tome and principe" OR "saudi arabia" OR senegal OR serbia OR seychelles OR "sierra leone" OR melanesia OR "solomon island" OR "solomon islands" OR "norfolk island" OR "norfolk islands" OR somalia OR "south africa" OR "south sudan" OR "sri lanka" OR ceylon OR "saint lucia" OR

"st lucia" OR "st. lucia" OR "saint vincent and the grenadines" OR "saint vincent" OR "st vincent" OR "st. vincent" OR grenadines OR sudan OR suriname OR surinam OR "dutch guiana" OR "netherlands guiana" OR syria OR "syrian arab republic" OR tajikistan OR tadjikistan OR tadzhikistan OR tadzhik OR tanzania OR tanganyika OR thailand OR siam OR "timor leste" OR "east timor" OR togo OR "togolese republic" OR tonga OR tunisia OR turkey OR turkmenistan OR turkmen OR uganda OR ukraine OR uzbekistan OR uzbek OR vanuatu OR "new hebrides" OR venezuela OR vietnam OR "viet nam" OR "middle east" OR "west bank" OR gaza OR palestine OR yemen OR zambia OR zimbabwe OR "northern rhodesia" OR "global south" OR "africa south of the sahara" OR "sub-saharan africa" OR "subsaharan africa" OR "central africa" OR "north africa" OR "northern africa" OR magreb OR maghrib OR sahara OR "southern africa" OR "east africa" OR "eastern africa" OR "west africa" OR "western africa" OR "west indies" OR caribbean OR "central america" OR "latin america" OR "south and central america" OR "south america" OR "central asia" OR "north asia" OR "northern asia" OR "southeastern asia" OR "south eastern asia" OR "southeast asia" OR "south east asia" OR "western asia" OR "east europe" OR "eastern europe" OR "developing country" OR "developing countries" OR "developing nation*" OR "developing population*" OR "developing world" OR "less developed countr*" OR "less developed nation*" OR "less developed population*" OR "less developed world" OR "lesser developed countr*" OR "lesser developed nation*" OR "lesser developed population*" OR "lesser developed world" OR "under developed countr*" OR "under developed nation*" OR "under developed population*" OR "under developed world" OR "underdeveloped countr*" OR "underdeveloped nation*" OR "underdeveloped population*" OR "underdeveloped world" OR "middle income countr*" OR "middle income nation*" OR "middle income population*" OR "low income countr*" OR "low income nation*" OR "low income population*" OR "lower income countr*" OR "lower income nation*" OR "lower income population*" OR "underserved countr*" OR "underserved nation*" OR "underserved population*" OR "underserved world" OR "under served countr*" OR "under served nation*" OR "under served population*" OR "under served world" OR "deprived countr*" OR "deprived nation*" OR "deprived population*" OR "deprived world" OR "poor countr*" OR "poor nation*" OR "poor population*" OR "poor world" OR "poorer countr*" OR "poorer nation*" OR "poorer population*" OR "poorer world" OR "developing econom*" OR "less developed econom*" OR "lesser developed econom*" OR "under developed econom*" OR "underdeveloped econom*" OR "middle income econom*" OR "low income econom*" OR "lower income econom*" OR "low gdp" OR "low gnp" OR "low gross domestic" OR "low gross national" OR "lower gdp" OR "lower gnp" OR "lower gross domestic" OR "lower gross national" OR lmic OR lmics OR lmic* OR "third world" OR "lami countr*" OR "transitional countr*" OR "emerging economies" OR "emerging nation*" OR afghan* OR afghani OR albanian* OR algerian* OR "american samoan*" OR angolan* OR antiguan* OR barbudan* OR argentine* OR argentinian* OR argentinean* OR armenian* OR azerbaijani* OR bahraini* OR bangladeshi* OR bangalee* OR bajan* OR belarusian* OR byelorussian* OR belizean* OR beninese* OR bhutanese OR bolivian* OR bosnian* OR batswana OR brazilian* OR brasilian* OR bulgarian* OR burkinabe OR burkinese OR burundian* OR "cape verdean*" OR "cabo verdean*" OR cambodian* OR khmer OR cameroonian* OR "central african*" OR chadian* OR chilean* OR chinese OR colombian* OR comorian* OR congolese OR "costa rican*" OR ivorian* OR croatian* OR cuban* OR cypriot* OR czech* OR djiboutian* OR dominican* OR ecuadorian* OR egyptian* OR salvadoran* OR "equatorial guinean*" OR equatoguinean* OR

eritrean* OR estonian* OR swazi* OR swati* OR ethiopian* OR fijian OR gabonese OR gabonaise OR gambian* OR georgian* OR ghanaian* OR gibraltarian* OR greek* OR grenadian* OR guamanian* OR guatemalan* OR guinean* OR "bissau guinean*" OR guyanese OR haitian* OR honduran* OR indian* OR indonesian* OR iranian* OR iraqian* OR iraqi* OR manx OR jamaican* OR jordanian* OR kazakhstani* OR kenyan* OR kiribati OR kiribatian* OR "north korean*" OR kosovar* OR kosovan* OR kyrgyz* OR lao OR laotian* OR latvian* OR lebanese OR lesothan* OR lesothonian* OR mosotho OR basotho OR liberian* OR libyan* OR lithuanian* OR macanese OR macedonian* OR malagasy OR madagascan* OR malawian* OR malaysian* OR maldivian* OR malian* OR maltese OR marshallese* OR mauritanian* OR mauritian* OR mexican* OR micronesian* OR moldovan* OR mongolian* OR mongol OR montenegrin* OR moroccan* OR mozambican* OR burmese OR myanma OR namibian* OR nauruan* OR nepali OR nepalese OR "netherlands antillean*" OR nicaraguan* OR nigerien* OR nigerian* OR "northern mariana islander*" OR mariana* OR omani* OR pakistani* OR palauan* OR "papua new guinean*" OR paraguayan* OR peruvian* OR philippine* OR philipine* OR phillipine* OR phillippine* OR filipino* OR filipina* OR rwandan* OR rwandese OR ruandan* OR ruandese OR samoan* OR "sao tomean*" OR santomean* OR "saudi arabian*" OR saudi* OR senegalese OR serbian* OR seychellois OR seychelloise* OR "sierra leonean*" OR slovak* OR slovene* OR "solomon islander*" OR somali* OR "south african*" OR "south sudanese" OR "sri lankan*" OR ceylonese OR "saint lucian*" OR vincentian* OR sudanese OR surinamese* OR syrian* OR tajik* OR tajikistani* OR tanzanian* OR tanganyikan* OR thai OR timorese* OR togolese OR tongan* OR trinidadian* OR tobagonian* OR tunisian* OR turk* OR turkish OR turkmen* OR tuvaluan* OR ugandan* OR ukrainian* OR uruguayan* OR uzbek* OR vanuatu* OR venezuelan* OR vietnamese OR yemeni* OR yemenite* OR yemenese OR zambian* OR zimbabwean* OR african* OR asian* OR "pacific islander*" OR "latin american*" OR "central american*" OR "south american*" OR caribbean* OR "west indian*" OR iberoamerican* OR "middle eastern*"

Search records.

Table A2: Search results (Medline/Ovid).

1 HPV vaccine	exp Papillomavirus Infections/ OR exp Human Papillomavirus Viruses/ OR Human Papillomavirus Recombinant Vaccine Quadrivalent, Types 6, 11, 16, 18/ OR (("human papillomavirus*" OR "human papilloma virus*" OR hpv*) AND (vaccin* OR shot* OR injection* OR jab* OR dose* OR booster* OR immunization* OR immuniz* OR immunisation* OR immunis* OR inoculat*)).ti,ab,kf,ot,oa.
2 Traditional and religious leaders	exp Religious personnel/ OR Traditional Medicine Practitioners/ OR (((traditional OR village* OR trib* OR clan* OR religious OR church OR spiritual OR faith) adj2 (leader* OR chief* OR head OR heads OR healer* OR headman OR headmen OR headwoman OR headwomen OR headperson OR elder OR elders)) OR "faith leader*" OR "faith-based leader*" OR king* OR queen* OR priest*

	OR imam* OR bishop* OR pastor OR pastors OR catechist* OR reverend* OR sheikh* OR clergy OR cleric OR rabbi* OR deacon* OR minister* OR chaplain* OR "council of elders" OR "gram pradhan" OR "gram panchayat" OR sarpanch OR mukhiya OR "village assembly" OR "sangguiniang barangay" OR "barangay council" OR shaman* OR sangoma* OR inyanga* OR babalawo OR dibia OR marabout* OR mullah* OR mufti* OR ayatollah* OR ulema OR ulama OR qadi OR archbishop* OR cantor* OR monk* OR nun* OR guru* OR swami* OR pandit* OR pujari* OR granthi* OR lama* OR rinpoche* OR bonze* OR sultan* OR oba OR emir* OR "medicine man" OR matai OR sadhu OR mahant).ti,ab,kf,ot,oa.
3 Faith community	(church* OR mosque OR temple OR ((religion* OR religious OR faith* OR spiritual OR spirituality) adj2 (communit* OR organization* OR organisation* OR group* OR network* OR association* OR institution* OR actor* OR representative*)) OR congregation* OR parish* OR parishioner* OR masjid* OR synagogue* OR gurdwara*).ti,ab,kf,ot,oa.
4 Healthcare workers	exp Health personnel/ OR (((health* OR medical OR clinical) adj (worker* OR personnel OR professional* OR staff OR practitioner* OR provider*)) OR physician* OR doctor* OR clinician* OR nurs* OR midwi*).ti,ab,kf,ot,oa.
5	2 OR 3 OR 4
6 LMICs	(afghanistan or albania or algeria or angola or argentina or armenia or armenian or azerbaijan or bahrain or bangladesh or republic of belarus or belarus or byelarus or belorussia or byelorussian or belize or british honduras or benin or dahomey or bhutan or bolivia or "bosnia and herzegovina" or bosnia or herzegovina or botswana or bechuanaland or brazil or brasil or burkina faso or burkina fasso or upper volta or burundi or urundi or cabo verde or cape verde or cambodia or kampuchea or khmer republic or cameroon or cameron or cameroun or central african republic or ubangi shari or chad or china or colombia or comoros or comoro islands or iles comores or mayotte or democratic republic of the congo or democratic republic congo or congo or zaire or "cote d'ivoire" or "cote d' ivoire" or cote divoire or cote d ivoire or ivory coast or cuba or cyprus or djibouti or french somaliland or dominica or dominican republic or ecuador or egypt or united arab republic or el salvador or equatorial guinea or spanish guinea or eritrea or eswatini or swaziland or ethiopia or fiji or gabon or gabonese republic or gambia or "georgia (republic)" or georgian or ghana or gold coast or grenada or guatemala or guinea or guinea bissau or british guiana or haiti or hispaniola or honduras or india or indonesia or timor or iran or iraq or isle of man or jamaica or jordan or kazakhstan or kazakh or kenya or

	north korea or south korea or korea or kosovo or kyrgyzstan or kirghizia or kirgizstan or kyrgyz republic or kirghiz or laos or lao pdr or "lao people's democratic republic" or lebanon or lebanese republic or lesotho or basutoland or liberia or libya or libyan arab jamahiriya or republic of north macedonia or macedonia or madagascar or malagasy republic or malawi or nyasaland or malaysia or malay federation or malaya federation or maldives or indian ocean islands or indian ocean or mali or micronesia or federated states of micronesia or kiribati or marshall islands or northern mariana islands or palau or tuvalu or mauritania or mauritius or mexico or moldova or moldovian or mongolia or montenegro or morocco or ifni or mozambique or portuguese east africa or myanmar or burma or namibia or nepal or netherlands antilles or nicaragua or niger or nigeria or muscat or pakistan or papua new guinea or new guinea or paraguay or peru or philippines or philipines or phillipines or phillippines or rwanda or ruanda or samoa or pacific islands or polynesia or samoan islands or navigator island or navigator islands or "sao tome and principe" or saudi arabia or senegal or serbia or seychelles or sierra leone or melanesia or solomon island or solomon islands or norfolk island or norfolk islands or somalia or south africa or south sudan or sri lanka or ceylon or saint lucia or "st. lucia" or "saint vincent and the grenadines" or saint vincent or "st. vincent" or grenadines or sudan or suriname or surinam or dutch guiana or netherlands guiana or syria or syrian arab republic or tajikistan or tadjikistan or tadzhikistan or tadzhik or tanzania or tanganyika or thailand or siam or timor leste or east timor or togo or togolese republic or tonga or tunisia or turkey or turkmenistan or turkmen or uganda or ukraine or uzbekistan or uzbek or vanuatu or new hebrides or venezuela or vietnam or viet nam or middle east or west bank or gaza or palestine or yemen or zambia or zimbabwe or northern rhodesia or global south or africa south of the sahara or sub-saharan africa or subsaharan africa or africa, central or central africa or africa, northern or north africa or northern africa or magreb or maghrib or sahara or africa, southern or southern africa or africa, eastern or east africa or eastern africa or africa, western or west africa or western africa or west indies or indian ocean islands or caribbean or central america or latin america or "south and central america" or south america or asia, central or central asia or asia, northern or north asia or northern asia or asia, southeastern or southeastern asia or south eastern asia or southeast asia or south east asia or asia, western or western asia or europe, eastern or east europe or eastern europe or developing country or developing countries or developing nation? or developing population? or developing world or less developed countr* or less developed nation? or less developed population? or less developed world or lesser developed countr* or lesser developed nation? or lesser developed population? or lesser developed world or under developed countr* or under developed nation? or under developed population? or under developed world or underdeveloped countr* or underdeveloped nation? or

	underdeveloped population? or underdeveloped world or middle income countr* or middle income nation? or middle income population? or low income countr* or low income nation? or low income population? or lower income countr* or lower income nation? or lower income population? or underserved countr* or underserved nation? or underserved population? or underserved world or under served countr* or under served nation? or under served population? or under served world or deprived countr* or deprived nation? or deprived population? or deprived world or poor countr* or poor nation? or poor population? or poor world or poorer countr* or poorer nation? or poorer population? or poorer world or developing econom* or less developed econom* or lesser developed econom* or under developed econom* or underdeveloped econom* or middle income econom* or low income econom* or lower income econom* or low gdp or low gnp or low gross domestic or low gross national or lower gdp or lower gnp or lower gross domestic or lower gross national or lmic or lmics or third world or lami countr* or transitional countr* or emerging economies or emerging nation?).ti,ab,hw
7 LMICs	(afghan or afghans or afghani or albanian? or algerian? or american samoan? or angolan? or antiguan? or barbudan? or argentine? or argentinian? or argentinean? or armenian? or azerbaijani? or bahraini? or bangladeshi? or bangalees or bajan? or belarusian? or byelorussian? or belizean? or beninese? or bhutanese or bolivian? or bosnian? or botswana or batswana or brazilian? or brasilian? or bulgarian? or burkinabe or burkinese or burundian? or cape verdean? or cabo verdean? or cambodian? or khmer or cameroonian? or central african? or chadian? or chilean? or chinese or colombian? or comorian? or congolese or costa rican? or ivorian? or croatian? or cuban? or cypriot? or czech? or djiboutian? or dominican? or ecuadorian? or egyptian? or salvadoran? or equatorial guinean? or equatoguinean? or eritrean? or estonian? or swazi? or swati? or ethiopian? or fijian or gabonese or gabonaise or gambian? or georgian? or ghanaian? or gibraltarian? or greek? or grenadian? or guamanian? or guatemalan? or guinean? or bissau guinean? or guyanese or haitian? or honduran? or indian? or indonesian? or iranian? or iraqian? or iraqi? or manx or jamaican? or jordanian? or kazakhstani? or kenyan? or kirabati or kirabatian? or north korean? or kosovar? or kosovan? or kyrgyz* or lao or laotian? or latvian? or lebanese or lesothan? or lesothonian? or mosotho or basotho or liberian? or libyan? or lithuanian? or macanese or macedonian? or malagasy or madagascan? or malawian? or malaysian? or maldivian? or malian? or maltese or marshallese? or mauritanian? or mauritian? or mexican? or micronesian? or moldovan? or mongolian? or mongol or montenegrin? or moroccan? or mozambican? or burmese or myanma or namibian? or nauruan? or nepali or nepalese or netherlands antillean? or nicaraguan? or nigerien? or nigerian? or northern mariana islander? or mariana? or omani? or pakistani? or palauan? or papua new guinean? or paraguayan? or peruvian? or philippine?

	or philipine? or phillipine? or phillippine? or filipino? or filipina? or rwandan? or rwandese or ruandan? or ruandese or samoan? or sao tomean? or santomean? or saudi arabian? or saudi? or senegalese or serbian? or montenegrin? or seychellois or seychelloise? or sierra leonean? or slovak? or slovene? or solomon islander? or somali? or south african? or south sudanese or sri lankan? or ceylonese or saint lucian? or vincentian? or sudanese or surinamese? or syrian? or tajik? or tajikistani? or tanzanian? or tanganyikan? or thai or timorese? or togolese or tongan? or trinidadian? or tobagonian? or tunisian? or turk? or turkish or turkmen? or tuvaluan? or ugandan? or ukrainian? or uruguayan? or uzbek? or vanuatu* or venezuelan? or vietnamese or yemeni? or yemenite? or yemenese or zambian? or zimbabwean? or african? or asian? or pacific islander? or latin american? or central american? or south american? or caribbean? or west indian? or iberoamerican? or middle eastern?).ti,ab,hw
8	6 OR 7
9	1 AND 5 AND 8
10 Publication date	2000-present

Table A3: List of targeted databases and grey literature sources

Database Type	**Name of Database**
Academic	1. Medline via PubMed
	2. Embase
	3. CINAHL
	4. Centre for Agricultural Bioscience International (CABI)
	5. Scopus
	6. Web of Science (Social Science Citation Index, Science Citation Index Expanded, Emerging Sources Citation Index)
	7. PsycINFO
	8. Global Index Medicus
	9. ERIC
Grey Literature	1. World Bank Knowledge Hub

	2. World Bank Documents and Report
	3. UNICEF
	4. UNESCO
	5. International Initiative for Impact Evaluation (3ie)
	6. Development Evidence Portal (DEP)
	7. Cochrane and Campbell Collaboration Libraries
	8. Gavi, the Vaccine Alliance
	9. WHO IRIS
	10. PATH
	11. MSI Reproductive Choices (formerly Marie Stopes)
	12. Girl Effect
	13. UNFPA
	14. Google Scholar

Appendix 2. Data Extraction Form

Description	**Question**
Publication author	*Surname of the first author*
Publication date	*Year when the study was published*
Publication type	*What type of publication is it?*
Funding agency	*Who funded the intervention/study?*
Country	*Select*
Detailed location	*Describe the location where the study took place*
World Bank region	*Select region(s) in which the study was conducted according to the World Bank.*
World Bank income category	*Select the World Bank income classification of the country at the time of the study*
Study design	*Choose the type of study design*
Program name	*Name of the program as reported by the author/s*
Program description	*Short description of the program*
Description of the intervention	*Describe the intervention*
Number of intervention components	*Select the number of components of the intervention*
Description of the intervention components	*Brief description of intervention components*
Type of leader/institution/organisation involved in the intervention	☐ *Traditional* ☐ *Religious* ☐ *Faith-based organisation/NGO* ☐ *Healthcare worker* ☐ *Other*
Gender	☐ *Male* ☐ *Female*
Type of traditional leader engaged	*Specify the type of traditional leader engaged*
Type of religious leader engaged	*Specify the type of religious leader engaged*
Type of Faith-based organisation/NGO involved	*Specify Faith-based organisation/NGO involved/engaged*

Traditional, religious leader or faith-based organisation/NGO engagement role	*Leader engagement role/Level of authority within the intervention.* ☐ *Vaccine delivery program co-design* ☐ *Mobilisation* ☐ *Formal decision-making* ☐ *Messaging/communication* ☐ *Consultation* ☐ *Vaccination delivery* ☐ *Endorsement* ☐ *Health education* ☐ *Other*
Health-worker linkage to traditional or religious leader engagement	*Record whether the health worker role was explicitly linked to traditional or religious leader engagement, and describe the nature of this linkage.*
Nature of collaboration with traditional or religious leaders	*Describe how health workers collaborated with traditional or religious leaders, faith-based organisations, customary institutions or other community authority structures.*
Health-worker functions within the intervention	*Select and describe any health-worker functions reported: training, counselling, technical information, vaccination services, referral, follow-up, misinformation response, or other relevant activities.*
Influence of health-worker and leader interaction on outcomes or implementation	*Extract whether and how the interaction between health workers and traditional or religious leaders influenced trust, acceptance, uptake, completion, equity or implementation.*
Intervention target group	*Describe the group that received the intervention*
Target population's living environment	*Select the target population's living environment* ☐ *Rural* ☐ *Urban* ☐ *Mixed*
Target population gender	*Select the gender-targeted population* ☐ *Male* ☐ *Female*
Target population age	*Indicate the age*
Target population school attendance status	☐ *Attend school* ☐ *Out of school*
Income of the target population	*Indicate the target population income*
Delivery location of the intervention	*Select the delivery location of the intervention*

	☐ *School* ☐ *Community* ☐ *Health facility* ☐ *Mobile/outreach* ☐ *Other*
Intervention start and end date	*When did the intervention start and end*
Period of follow-up	*From the start of the intervention, how long was the follow-up period?*
Comparison	*What was the comparison group?*
Consideration of equity	*Has the study considered any form of equity?*
Equity dimension	*What dimension does the study consider?*
Cost	*Report any cost data provided or comments on cost effectiveness of the Intervention, include the authors' comments on cost data even if quantifications are not provided.*
Outcome type	*Define the outcome(s)* ☐ *Uptake* ☐ *Completion* ☐ *Acceptance* ☐ *Equity* ☐ *Trust* ☐ *Misinformation reduction* ☐ *Intention to vaccinate* ☐ *Other*
Methods	*Description of how the outcome was estimated*
Were there any differences in the measurement of this outcome between the treatment group participants and the comparison group?	☐ *Yes* ☐ *No*
Was the effect significant?	☐ *Yes* ☐ *No*
Treatment sample size	*Input a numerical value*
Control sample size	*Input a numerical value*
Type of outcome measure	☐ *Continuous* ☐ *Dichotomous*
The questions below are applicable to continuous outcomes	

Treatment group mean	*Input a numerical value*
Comparison group mean	*Input a numerical value*
Treatment group standard deviation	*Input a numerical value*
Comparison group standard deviation	*Input a numerical value*
Treatment group standard error	*Input a numerical value*
Comparison group standard error	*Input a numerical value*
T-value from the independent t-test	*Input a numerical value*
The questions below are applicable to dichotomous outcomes	
Number of participants in the treatment group who experienced a change	*Input a numerical value*
Number of participants in the comparison group who experienced a change	*Input a numerical value*
Proportion of the treatment group who experienced a change	*Input a numerical value*
Proportion of the comparison group who experienced a change	*Input a numerical value*
Adjustment of proportions	☐ *Yes* ☐ *No*
Log odds ratio	*Input a numerical value*
Standard error of the log odds ratio	*Input a numerical value*
Log odds ratio adjusted?	☐ *Yes* ☐ *No*
The questions below are applicable to regression data	
Regression coefficient (beta)	*Input a numerical value*
Standard error of beta	*Input a numerical value*
CI (lower bound) of beta	*Input a numerical value*
CI (upper bound) of beta	*Input a numerical value*
T stat	*Input a numerical value*

P value	*Input a numerical value*
Source of the data	*Include source of the data: Table, row, column and page number*
Barriers and facilitators	
Facilitators	*a) Short copied passage from text with page number* *b) Summarised in own words*
Barriers	*a) Short copied passage from text with page number* *b) Summarised in own words*