An Approach to Formative Research in HPV Vaccine Introduction Planning in Low-Resource Settings

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Abstract: *Introduction*: Formative research can inform country-level HPV vaccine delivery strategies, communication messages, and advocacy plans. This paper describes our formative research's conceptual framework; details our applied methodology; summarizes our field experience and challenges; and outlines best practices for formative research in vaccine introduction.

Methods: From 2006–2008, literature reviews, stakeholder mapping, sociocultural studies, health system assessments, and policy reviews were conducted. Data collection at individual, interpersonal, community, institutional, and policy levels included in-depth interviews, focus groups, surveys, observations, secondary data, and facility audits. Data were analyzed thematically using an iterative process.

Discussion: Integrated formative research can be implemented in low-resource settings, but may require overcoming operational challenges. Best practices in applied formative research include a conceptual framework, multidisciplinary approach, and rapid dissemination of results.

Conclusions: Formative research informs effective health program planning by examining complex and interrelated factors surrounding vaccination. Methodologically sound formative research provides valid and reliable evidence for country-level vaccine introduction.

Key Words: Formative research, vaccine introduction planning, HPV vaccine, cervical cancer, screening, immunization, team-based research, conceptual framework.

INTRODUCTION

Cervical cancer is the second most common cancer in women worldwide. Approximately one-half million new cases of invasive cervical cancer are diagnosed each year, resulting in more than 270, 000 deaths [1]. It is the leading cause of cancer mortality in women in developing countries and 85 percent of women who die of cervical cancer reside in these regions [1]. In large part, this inequity is due to the lack of resources for secondary prevention screening and treatment of precancer in the developing world [2, 3].

The sexually transmitted human papillomavirus (HPV) is the primary cause of cervical cancer [4]. Two HPV types (16 and 18) account for 70 percent of cervical cancer cases worldwide [5]. Routine HPV vaccination offers a new primary prevention strategy in the global fight against cervical cancer that could be especially useful in the developing world, where women have poor access to screening and treatment. HPV vaccination could reduce developing-country cervical cancer to the very low levels currently observed in many developed countries, especially when combined with simple, evidence-based cervical screening and treatment approaches [6]. The two currently available HPV vaccines, Gardasil® (Merck & Co.) and Cervarix™ (GlaxoSmithKline), have been shown to be safe and effective against HPV types 16 and 18 when administered prior to infection [7, 8]. The Advisory Committee for Immunization Practices (ACIP) recommends the ideal group to receive the vaccine are young females between 11 and 12 years of age, well before they are likely to be infected with the virus through sexual contact, although administration of the vaccine can occur among females as young as 9 years of age [9].

Delivering the HPV vaccine to girls in this age group requires innovative approaches that depart from traditional infant and child immunization program models. The vaccine is administered by intramuscular injection, and the recommended schedule is a 3-dose series over a 6-month period [9]. This dosage schedule presents unique challenges for a number of reasons. The sociodemographic characteristics of eligible HPV vaccine recipients vary widely and can strongly influence vaccine program coverage [10]. School enrollment status, household and family composition, roles young girls are expected to play in the household, and the degree of autonomy girls may have in their own health decision-making are important considerations that may also influence vaccine coverage [10-12]. In the developing world, preteens and adolescents rarely access health services unless they are

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ill. Although young adolescence is marked by relatively good health, this group is typically neglected for targeted health interventions and tends to fall through the cracks in the health-delivery system at a time of vulnerability and intense transition [10, 13]. Only a few developing countries have included adolescent immunizations in their routine schedules (e.g., those countries with anti-tetanus campaigns), which poses considerable challenges for introducing a vaccine for this age group in such a policy environment [12, 14]. Even in those countries where tetanus toxoid is given routinely through schools, programs may not perform well.

Successful planning for HPV vaccine introduction in developing-country settings requires an integrated and comprehensive approach that addresses factors influencing acceptance or willingness to support the vaccine and delivery mechanisms at multiple levels [15]. Information on the potential impact of the vaccine on existing, and often overburdened, health systems is also needed. Well-designed formative studies are a critical first step for effective HPV vaccine introduction, given that so little is known about how to best deliver health interventions to this age group [11, 16, 17].

HPV Vaccines: Evidence for Impact, a five-year funded project led by PATH, aims to identify information needs and generate evidence for decision-making and operational planning relevant to vaccine introduction in low-resource settings. Four countries were selected to participate in this project: India, Peru, Uganda, and Vietnam. Through a combination of formative research and vaccination demonstration projects in all four countries, PATH is facilitating more rapid introduction of this new vaccine to places that need it most.

This paper departs from a more standard scientific reporting format and focuses primarily on a description of research methods. The process of designing and implementing complex multidisciplinary research is rarely documented in the peer-reviewed literature, to the detriment of the field, as often lessons learned from the actual scientific process can be just as powerful as the scientific result itself. The reporting of research methods is increasingly being recognized for its importance in vaccine introduction work [18]. We believe the benefit of this type of documentation for our peer community of scientists outweighs the non-standard approach of our manuscript in scientific report writing. For readers more results-oriented, country-specific and global findings from this research are extensive and are either in preparation or reported elsewhere [19-21].

In the following pages, we describe the ecological conceptual framework that is the foundation of our formative research; detail the development, structure, and process of our research using this theoretical framework; summarize the implications of our experience with this methodology within the larger context of health services research; reflect on challenges faced in implementing this methodology for a relatively unknown health problem; and outline the best practices for, and contribution of, rigorous formative research for vaccine introduction.

METHODS

Project Background: The HPV Vaccine Project Planning Model

The formative research represents the first of four stages in the HPV vaccine project planning model (Fig. **1**). In the preparatory phase, stage 1 includes the five levels of inquiry for the formative research. Stage 2 represents the application of the formative research findings to the design of a vaccine delivery strategy, a communication strategy, and an advocacy strategy. During stage 3, the subsequent testing phase (demonstration project) of the project, these three outputs

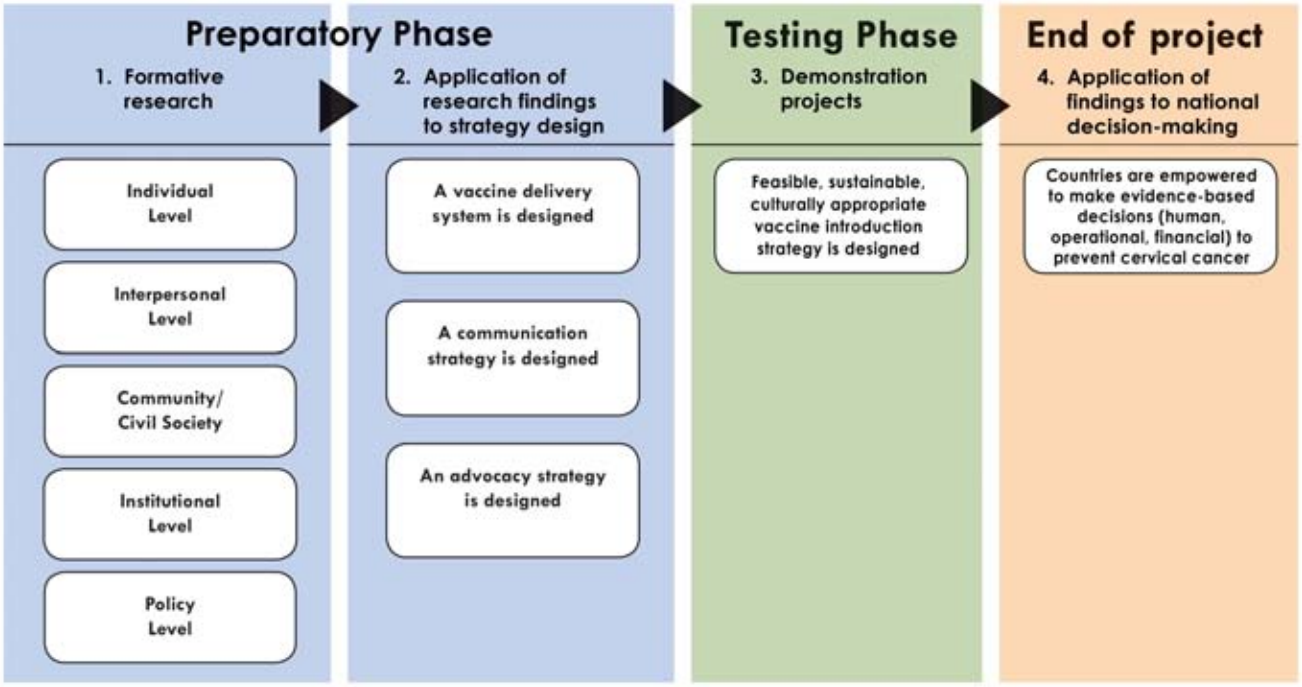

Fig. (1). HPV vaccine project planning model.

will be evaluated for their effectiveness (coverage), cultural appropriateness (acceptability), impact on health and education systems (feasibility) and affordability (costs).

In stage 4, the findings from the demonstration project can be applied to address key questions and enable country-level policymakers to make evidence-based decisions about programs to prevent cervical cancer. The evidence base will specify the human, operational, and financial inputs necessary for adding the HPV vaccine to other existing or planned cervical cancer prevention activities.

Formative research is the first step in our new vaccine introduction studies planning model. It is a recognized activity in the World Health Organization's framework for new vaccine introduction; however, little guidance is actually provided on how to structure the research [15]. We needed an approach that would enable information generated from all of the study levels to inform each of the three study outputs. The research covered a variety of topics, therefore our research teams needed to be interdisciplinary. To this end, we followed general methods outlined by Guest and MacQueen for conducting interdisciplinary team-based qualitative research [22]. Moreover, work carried out on cervical cancer prevention through the Alliance for Cervical Cancer Prevention has shown that in these settings (especially in Peru, India, and Vietnam) awareness about, and knowledge of, cervical cancer varied considerably [23]. Since little is known about how to deliver services—or even a vaccine—to this age group, we needed an exploratory research approach.

COUNTRY SELECTION

Our four project countries were selected during the proposal-writing phase based on an array of factors, including disease burden, performance of the national Expanded Programme on Immunization (EPI), regional representation, and political commitment to cervical cancer prevention. Furthermore, experience suggested vaccine demonstration projects could be effectively undertaken in these countries and there was a strong likelihood that lessons learned from these projects could be applied to larger-scale introduction and inform policy, program, and funding decisions for other countries in the respective regions.

RESEARCH AIMS

Two general questions guided our formative research: What factors are most likely to result in a young adolescent girl receiving the complete doses of the HPV vaccine? What factors are most likely to foster institutional decisions resulting in successful HPV vaccine delivery? We had four research objectives: 1) determine information needs of various stakeholders regarding cervical cancer, HPV, and the vaccine; 2) identify key sociocultural factors that could influence acceptance of the HPV vaccine; 3) assess health system capacity for introduction; and 4) review the current health policy environment. Research objectives were shaped in part by the World Health Organization's vaccine introduction guidelines and PATH's new technology introduction framework [15, 24]. Information generated from the formative research was designed to inform the development of three specific outputs for vaccine demonstration projects: 1) an HPV vaccine delivery strategy appropriate to the target age group—young adolescents; 2) a communication strategy and materials to support a positive environment and positive individual attitudes to vaccine administration at the community level; and 3) a national advocacy plan to achieve awareness and support for cervical cancer prevention among policymakers and key stakeholders at regional and national levels.

Our assumption was that if we answered the research questions and followed our project planning model for utilizing the information effectively, this would lead to a more effective vaccine demonstration project. Since demonstration projects are currently underway, this assumption will be examined during subsequent phases of the project.

Research Planning Workshop

A workshop was convened in November 2006 that brought together program staff from PATH, project managers, and lead investigators from each country.[1] A general orientation to the project was provided to attendees, including a review and discussion of the overall project objectives. The workshop helped further develop and refine the overall global approach to the formative research. Critical country-level research planning took place. Country teams worked with the global PATH staff to further develop and refine country-level key research questions. At the workshop, a working draft of a global conceptual framework (discussed below) was reviewed and refined. Local country experiences, variations, and differing research priorities were discussed.

AN ECOLOGICAL CONCEPTUAL FRAMEWORK

An ecological conceptual framework was employed in the study (Fig. **2**). A conceptual framework is an organizing tool for research and provides an immediate link from the study's research aims to a larger evidence base [25]. It also provides the necessary platform for carrying out a cross-country comparative analysis where multiple research methods are employed, where multiple units of analysis are being examined, and where local context may prohibit complete standardization of key measures and indicators.

An ecological framework recognizes that individual health behaviors are influenced at different levels within a complex environment [16]. This framework is commonly used in health-program planning, as it illustrates these different levels as embedded health planning systems which are interrelated and not mutually exclusive. The ecological framework adapted for HPV vaccine introduction consisted of five levels of influence that formed the basic units of analysis and defined the key target groups to be included in the formative research. The important attributes and rationale defined at each level shaped the topics and research questions explored in the study. The outcomes of interest within each level were behaviors (individual or collective decision-making) that would either support a girl receiving the HPV vaccine, or foster institutional decisions that would result in successful HPV vaccine delivery. Each level is discussed in more detail below.

Individual Level

Units of Analysis (Target Audience)

- Girls between 10 and 14 years of age.

[1] Because of project scheduling, the Peru formative research was well underway at the time of the workshop; researchers were able to provide useful feedback on their work to other teams.

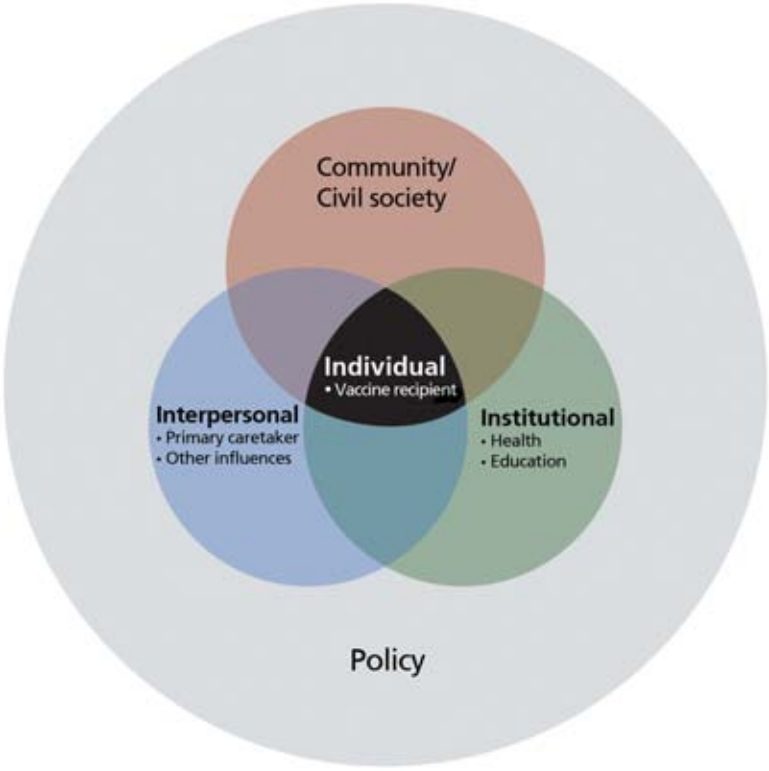

Fig. (2). An ecological framework for guiding formative research about vaccine introduction.

Behavioral Outcome of Interest

- Participation in the HPV vaccine program.

The individual level centers on the vaccine recipient, a young adolescent female of 10 to 14 years of age. The formative research sought to explore the extent to which a girl has decision-making authority for vaccination, or whether the locus of decision-making resides elsewhere, such as with one or both parents or others in the family or extended household (see interpersonal level below) or with an institution (the assumption being that teachers and health workers can be very influential on a girl's decision). The formative assessment sought to better understand any relevant developmental factors that might influence whether a girl assents or dissents. Research has shown that these can include peer influences, concrete versus abstract levels of thinking, and anticipated or relevant sexual maturation or experience [11].

Interpersonal Level

Units of Analysis (Target Audience)

- Decision-makers and influencers in the family, household, or other authority figures in a vaccine recipient's social network.

Behavioral Outcome of Interest

- Provide positive support that contributes to the decision for a girl to receive the HPV vaccine.

This level emphasizes important interpersonal relationships that may influence whether a girl receives a vaccine. Social scientists recognize that individual health decision-making and health behavior must be viewed within a broader social context, and that healthcare-related decisions are also negotiated in broader social networks that may extend beyond the primary household [26, 27]. This level includes persons who have direct authority to make decisions on behalf of the girl and others who have an influence on the girl's well-being. The nuclear family, extended household, work groups, or friendship networks may influence or even dictate a young girl's patterned behavior [10, 28].

Community/Civil Society Level

Units of Analysis (Target Audience)

- Civil society organizations, religious institutions, local media outlets or geographically-bound units such as towns or cities.

Behavioral Outcomes of Interest

- Provide positive support, either collectively or organizationally, for individual participation in HPV vaccination programs.
- Foster decisions related to successful HPV vaccine delivery.

This level refers to the broader societal networks, communities, and civil society organizations that vaccine recipients, households, and other key authority figures are connected to, and that may influence health decision-making for a girl. The media is an important normative influence at this level. These various societal networks recognize and share norms, regulations, and standards and draw upon these standards when making health-related decisions [28]. These standards and practices may either promote or discourage what Obrist van Eeuwijk refers to as "health-sustaining practices" such as vaccination programs [28].

Institutional Level

Units of Analysis (Target Audience)

- Individuals in the health delivery system and school system.
- Institutional policy environment.

Behavioral Outcomes of Interest

- Provide positive support and institutional capacity for individual participation in HPV vaccination programs.
- Foster decisions related to successful HPV vaccine delivery.

Individuals in the health and school systems (especially if school-based vaccination is conducted) would play a key role in facilitating access to HPV vaccine and can have considerable influence in shaping normative values related to vaccine acceptance. It is therefore important to understand whether cervical cancer is viewed by these individuals as a priority health issue and whether they see themselves playing a role in HPV vaccination and the prevention of cervical cancer. In addition, the health system must have the resource capacity (human, financial, cold chain) to support introduction of the vaccine. It is important to understand what the impact of providing a new service will likely have on an existing system.

Public Policy Level

Units of Analysis (Target Audience)

- Individual policymakers and national stakeholders, national media outlets, professional organizations, government agencies, or other identified entities which influence policymakers.

Behavioral Outcomes of Interest

- Create policies favorable for HPV vaccination introduction activities.
- Demonstrate financial commitment for HPV vaccine introduction.

This level includes national policymakers and organizations, agencies, and entities that influence them. Health policymakers who need to endorse HPV vaccine introduction may include legislators, ministry of health officials (including heads of epidemiology, gynecology, maternal and child health, cancer control, and immunization), and key officials in finance and planning ministries. Leaders of medical/health professional associations, cancer/health institutes, heads of nongovernmental organizations, and women's health advocates are also important units of analysis at this level. This level covers a broad range of public policy factors that directly affect access to, and availability, delivery, and affordability of the vaccine [29]. Most health policymakers are generally not experts in the area of cervical cancer prevention and it is therefore important to pinpoint specific information needs as part of a formative assessment [30]. Exploring these questions becomes increasingly important as governments juggle competing health priorities within a context of acute budgetary constraints [31].

KEY RESEARCH TOPICS COVERED IN THE STUDY

Each ecological level included salient research topics that were appropriate for the overall study objectives. Research topics were identified in a number of ways. A review of literature was carried out as part of the conceptual framework development. Researchers and practitioners with expertise in the different areas of inquiry were also consulted. For operational purposes, the study consisted of three components: sociocultural research, a health system assessment, and a policy review.

The sociocultural research explored understanding of cervical cancer, its causes and cures, perceptions about and previous experiences involving vaccination, and HPV vaccine acceptance at the individual, interpersonal, community, institutional, and policy levels. The health-system assessment sought to evaluate the readiness of health systems to introduce and sustain delivery of the HPV vaccine. The policy review examined factors impacting vaccine decision-making at national and subnational levels. Table **1** presents the key areas of inquiry or research topics explored within each study component and the corresponding ecological levels contained in the conceptual framework.

A NOTE ON TERMINOLOGY FOR HPV VACCINE STUDIES

The World Health Organization defines an individual between the ages of 10 and 19 as an "adolescent" [32]. However, this terminology was not necessarily effective in describing the target group for HPV vaccination. Each country research team decided on nomenclature that was locally customary to describe this target group and that would ensure optimal communication and appropriateness during the research: adolescent girls (India), children/girls (Peru), girls (Uganda, Vietnam).

In Peru, the term "adolescent" refers to children of 12 years and older. Health services for adolescents are associated with the promotion of reproductive and sexual health and the prevention of reproductive and sexual diseases. It was not appropriate to position vaccination this way, so the focus was on girls 9 to 12 years of age.

Terminology used in the study to describe the HPV vaccine and cervical cancer varied from its commercial name and medical nomenclature. Country research teams opted to use the name "cervical cancer vaccine." In Peru, HPV was almost unknown, even by health personnel, so the vaccine was referred to as "protecting against cervical cancer" rather than its commercial name. It was assumed at project onset that this term would better help people to understand that the vaccine was ultimately for preventing cervical cancer. Country teams in general preferred using "cervical cancer vaccine" because people are more likely to be familiar with "cancer, " "cancer of the cervix, " or "cancer of womb" (terms commonly used in low-resource settings) even though cancer implies "death" or is a "death sentence" [23, 33]. (Note: Early detection and treatment services simply are not available or easily accessible in low-resource settings [34].) In Uganda, for example, the exploratory study findings confirmed that both the public and health providers (including

Table 1. Areas of Inquiry (Research Topics) by Study Component and Ecological Level

Area of Inquiry	Ecological Level*				
Sociocultural component	ID	IP	C	I	P
Local understanding of cervical cancer, HPV, burden of disease, prevention, and treatment	X	X	X	X	X
Local experience with vaccination and perceived benefits or concerns about vaccines in general and specific for HPV	X	X	X	X	X
Importance of key authority figures	X	X	X	X	
Strategies for awareness raising	X	X	X	X	
Girls' understanding about well-being/motivators for health care	X	X	X	X	
Health decision-making for girls	X	X	X	X	
Health service utilization by girls	X	X	X	X	
Local terms for referring to children this age	X	X	X	X	
Roles that girls play in family, household, society	X	X	X		
Family and household living arrangements	X	X	X		
Living circumstances of out of school girls	X	X	X		X
Health system component	ID	IP	C	I	P
Current capacity for HPV vaccine introduction (logistics, cold chain, human resources, training, health management information services, adverse events following immunization, among others)				X	
Current services to reach young adolescents		X		X	X
Feasible vaccine delivery strategy options, including target population and venues for vaccination				X	X
Future needs to support HPV vaccine introduction (logistics, cold chain, human resources, training, Health Management Information Services, adverse events following immunization, among others)				X	
Epidemiological, demographic, vaccine-specific data that influence design of vaccine delivery system				X	
Political and technical dynamics that influence vaccine delivery system				X	X
Impact of adding the HPV vaccine to existing services				X	
Current services to reach young adolescents		X		X	X
Policy review component	ID	IP	C	I	P
Identifying the key stakeholders and policy decision-makers					X
How national health policy is formed (decision-making processes)					X
Factors influencing decisions to introduce a new vaccine					X
Information needs to make a decision about HPV vaccine introduction					X
How cervical cancer is perceived against other health concerns					X
How HPV vaccine fits within existing cervical cancer control efforts					X
Preferred vaccine delivery strategy or process					X
How HPV vaccine can be positioned to support or strengthen other health interventions					X

*ID (individual); IP (interpersonal); C (community); I (institutional); P (policy).

gynecologists participating in the study) knew little to nothing about HPV. Despite this, most people knew the term "cancer" and the fact that it is fatal.

RESEARCH TEAM COMPOSITION AND TRAINING

The formative studies were conducted in collaboration with in-country research partners. Multidisciplinary research teams were assembled to leverage the expertise required for the different study components [35]. Teams consisted of social scientists (anthropologists, sociologists, health economists, health communication specialists, social psychologists, policy researchers), clinical practitioners (gynecologists, pharmacists, nurses, clinical laboratory staff), and public health specialists (epidemiologists, vaccine and health systems specialists). Teams organized themselves according to the main study components and included researchers or practitioners knowledgeable in each content area: sociocultural research (social scientists, including health communications specialists), health system assessment (medical researchers, epidemiologists, health practitioners, health

economists, and vaccine delivery specialists), and policy review (social scientists, health policy analysts). Field worker training was conducted by the research institution in each country with technical assistance provided by PATH. In India, the training was jointly conducted by PATH and the in-country research partner, the National AIDS Research Institute. In India, Vietnam, and Uganda, training averaged between 4 to 5 days and in Peru it was approximately 12 days. Training involved classroom sessions covering HPV disease etiology, vaccinology, qualitative research principles, simulated focus group discussion and interview scenarios, note-taking exercises, and field practice involving the pretesting of research instruments. It is worth noting that in Uganda, preliminary findings from questions about local terminology and nomenclature for cervical cancer and related issues influenced the recomposition of the research team to ensure appropriate languages and disciplines were represented. Field researchers in each country were fluent in the local languages.

PARTICIPANT INCLUSION CRITERIA AND SAMPLING

The sampling strategies were designed in all countries to engage a variety of stakeholders who reflected the different ecological levels or inputs required to meet the objectives of the formative research (Table **2**). Teams sought to obtain a wide range of experiences and informational richness in order to capture the greatest variability, since a classic representative sample is neither appropriate nor feasible with this type of study design [36]. Criteria used to select participants appropriate for the local context were developed by the local research teams and are being reported elsewhere [20, 21]. This was especially important at the community, institutional, and public policy levels where participant selection varied across countries. The age range for the individual level (potential vaccine recipients) also varied by country. In Peru, girls as young as 9 years of age were included in the study because the vaccine is licensed for girls this age. Once the study groups were identified, combined randomized and purposive sampling strategies were used to select informants at each level of influence. This combined approach was used because it was necessary to select parents with girls of target ages; health professionals working in vaccination programs, reproductive health, adolescent health, and/or cancer prevention and treatment; teachers of target age children; and well respected and influential community and religious leaders. The complex policy environment varied somewhat across countries and necessitated a mapping of the policy pathway in each country to identify potential key informants involved in decision-making related to vaccine introduction, or those who could potentially influence this process. This involved consulting with authorities in the ministries of health, education, finance, and planning, as well as members of advisory groups to these institutions.

DATA COLLECTION INSTRUMENTS

Instrument development was a collaborative process in each country. Local research teams identified key research topics and appropriate content based on research objectives and local contexts. For specific question development, teams reviewed the key topic areas in the conceptual framework and the global HPV vaccine project work plan (Table **1**). A comprehensive literature review was also conducted in each country that included: peer-reviewed publications; various national public policy guidelines (e.g., women's health, immunization, cancer control); other informal sources of information; review of country immunization strategic plans and EPI reports; women's health, reproductive health, adolescent health, and school health policies; and other strategic and technical documents. Local teams also identified topics relevant to the particular local setting based on their own experience and understanding of local context. In Uganda, for example, questions exploring local terminology and nomenclature for cervical cancer and related issues were important since the country does not have any organized cervical cancer prevention efforts.

In Peru and Vietnam, instruments were initially developed in the local language and translated into English to facilitate review by English-speaking collaborators. Instruments were first developed in English and then translated into four languages in Uganda (Runyankole, Luo, Luganda, Ateso) and two in India (Telugu in Andhra Pradesh and Gujarati in Gujarat). Instruments were pretested among different target populations and then back-translated into English in three countries, whereas in India local language versions were reviewed and then revised and certified by language experts in the local state university. In Peru, interviews were conducted in Quechua and Shipibo and translated when necessary.

DATA COLLECTION PROCEDURES

Data collection methods were selected for their appropriateness in each research setting, and were fairly consistent across the four countries. All research teams carried out *desk reviews* of health statistics, school attendance data, existing health policies, and vaccine delivery information. *Focus group discussions* (FGD) were used to gather data from young adolescents, their parents, teachers, health workers, and community leaders. In person *in-depth interviews* (IDI) were conducted at all levels and were the primary means of data collection for policymakers at national and subnational levels. FGD and IDI guides were exploratory in their design to encourage a free expression of ideas about roles, understanding, perspectives, and experiences related to general health and well-being, vaccines, and cervical cancer. *Observations* of routine immunization services were carried out in all countries except Vietnam, and a measles and rubella vaccination campaign was observed in Peru. Each country conducted *health facility audits* using observations and checklists, informal consultations, health facility record reviews, and/or exit interviews with users of immunization services to gather information on health and vaccine delivery system readiness. Teams used both structured and unstructured data collection methods to carry out facility audits. *Stakeholder consultative workshops* and *individual consultations* were held with leading immunization experts at the country level to gather information on health-system readiness and vaccine delivery capacity.

Additional research activities took place according to local contexts. In Vietnam, at the request of the National Institute of Health and Epidemiology, a *knowledge, attitudes, practices* (KAP) survey was administered to randomly selected 11- to 14-year-old girls and their parents to complement the qualitative sociocultural study. The survey con-

Table 2. Sampling Design

Level of influence/ Study group	Study Location			
	India	**Peru**	**Uganda**	**Vietnam**
	Andhra Pradesh State: • Khammam District Gujarat State: • Vadodara District	Three regions: • Ayacucho • Piura • Ucayali Large metropolitan area: • Lima	Five districts: • Gulu • Kampala • Masaka • Mbarara • Soroti	Three provinces: • Dong Thap • Nghe An • Thai Binh Two large metropolitan areas: • Hanoi • Ho Chi Minh City
Individual*	**Study population:** 10–14 year old girls (in and out of school) **Data collection:** FGD**, IDI*** **Sampling:** Purposive for FGD and IDI	**Study population:** School girls and boys 9–12, adolescents 13–16 **Data collection:** FGD, IDI, with graphic projection methods included **Sampling:** Purposive for FGD and IDI	**Study population:** Children in school (boys and girls) and out of school (girls) 10–12 years **Data collection:** FGD **Sampling:** Children in school randomly selected, girls out of school purposively selected	**Study population:** Girls 11–14 **Data collection:** FGD, IDI, quantitative survey **Sampling:** Purposive for FGD and IDI, random for quantitative survey
Interpersonal	**Study population:** Parents/guardians of 10–14 year old girls **Data collection:** FGD, IDI **Sampling:** Purposive for FGD and IDI	**Study population:** Parents of children 9–12 **Data collection:** FGD, IDI **Sampling:** Purposive for FGD and IDI	**Study population:** Parents/guardians of girls 10–12 years **Data collection:** FGD **Sampling:** Purposive	**Study population:** Parents of 11–14 year old girls **Data collection:** FGD, IDI, quantitative survey **Sampling:** Purposive for FGD and IDI, random cluster design for quantitative survey
Community/Civil society	**Study population:** Community leaders, NGOs, elected ward and village and religious leaders, local leaders **Data collection:** FGD, IDI **Sampling:** Purposive for FGD and IDI	**Study population:** NGOs, churches, media **Data collection:** IDI **Sampling:** Purposive	**Study population:** Community leaders, religious leaders, NGOs **Data collection:** FGD for community and religious leaders; IDI for NGOs **Sampling:** Purposive for FGD and IDI	**Study population:** Community leaders (provincial, district, commune levels); members of women's and youth unions **Data collection:** IDI **Sampling:** Purposive for IDI
Institutional	**Study population:** Education and health personnel (local, state, national); teachers, headmasters, health workers including community health workers, immunization experts (state and national) **Data collection:** FGD, IDI, expert consultation **Sampling:** Purposive for FGD, IDI, expert consultation	**Study population:** Health managers/administrators, health workers, teachers, immunization experts **Data collection:** FGD for teachers, IDI for health authorities, health workers, teachers **Sampling:** Purposive for FGD and IDI	**Study population:** Immunization experts, managers of district health services, health workers, teachers and head teachers **Data collection:** FGD for teachers; IDI for immunization experts, health managers, and health workers **Sampling:** Purposive for FGD and IDI	**Study population:** Immunization experts, health program managers, health workers, secondary school teachers **Data collection:** FGD, IDI **Sampling:** Purposive for FGD, IDI and expert consultation
Policy	**Study population:** Local, state, and national policymakers and policy and project implementers **Data collection:** IDI **Sampling:** Purposive for IDI	**Study population:** Local, regional, national government representatives **Data collection:** IDI **Sampling:** Purposive	**Study population:** District and national policymakers **Data collection:** IDI **Sampling:** Purposive	**Study population:** Health and education personnel at provincial level **Data collection:** IDI **Sampling:** Purposive for IDI

* Terminology varies on what young adolescent girls aged 10–14 are called. English translations have tried to be consistent with their original meaning.
** FGD: Focus group discussion.
*** IDI: In-depth interview.

tained questions about knowledge of cervical cancer, decision-making for young girls, and access to health information. Researchers in India and Peru used various participatory techniques during focus groups and IDIs with young girls and parents, including *body mapping exercises* to explore and corroborate knowledge and understanding of the human body, reproductive organs, and what vaccines do. Other techniques included *free listing, pile sorting, sociodramas, role playing, interactive games*, and *vignettes* of hypothetical scenarios. Table **3** provides more detail on the different interactive techniques used by the Peru team and their utility for this type of research.

After preliminary analysis of the FGDs and IDIs in Peru, follow-up meetings were held with girls, parents, institutional level health personnel and teachers, and several central-level health administrators to present the findings and discuss them using participatory and ludic methodology [37]. These meetings confirmed the findings and provided further ideas for the pilot vaccination.

Table 3. Peru Formative Research: Complementary Qualitative Research Techniques Used During FGDs

Characteristic	Free Listing/Ranking: Illnesses	Pile Sorts: Classification of Illnesses	Vignettes	Projective Technique: Photos	Body Mapping
Description of technique	Participants list perceived health problems and rank according to how serious they consider each to be.	Cards bear the name of an illness (cards are added for any "new" illnesses mentioned during free-listing). Participants group the cards according to different criteria: a free sort, severity, diseases affecting women/men, children/adults.	Participants are shown photos of middle-aged women who appear to be sick with cervical cancer, and are asked about the causes and what she should do to prevent or cure the disease.	Participants are shown photos of a girl being vaccinated, and are then asked about the positive and negative aspects of this action.	Participants are asked to draw a body and indicate where cancer could appear, both for men and women. They are then asked to show a specific location where cervical cancer grows.
Suggested group	Children and parents: individually or in groups.	Children (or parents): individually or in groups.	Children and parents	Children	Children
Type of data generated	A list of health problems, ranked according to perceived severity, both now and in the future.	Classification of illnesses and the reasons that certain cards are grouped together.	Descriptions of different ways to "prevent and cure" cervical cancer.	Attitudes and reactions to vaccination and to the function of vaccines.	Illustrations complement and corroborate verbal descriptions of where cervical cancer is located in the body.
Uses of the data	To determine whether cervical cancer is or is not in the spectrum of known, possible illnesses.	To determine understanding of cervical cancer in relation to other illnesses in terms of severity and importance, grouped by age and sex.	To further corroborate across groups the perceived causes and cures of cervical cancer. To provide descriptive narratives for use in developing communication campaign.	To clarify how people perceive and value vaccination in order to develop communication campaign.	To clarify what people understand about cervical cancer in order to develop communication campaign.
How technique can improve the data collection process	Facilitate the introduction of a discussion about illnesses in general, to collect information on perceived spectrum of illnesses.	Facilitate initial discussion of cervical cancer through the grouping of the cards.	Facilitate identification and corroboration of causality and what cancers are present in the life of a woman.	Facilitate the exploration of the vaccination process and what is known about it.	Facilitate literal understanding of where cervical cancer is located in the body; allows deeper probing of cervical cancer if topic hasn't been mentioned.

DATA MANAGEMENT AND ANALYSIS

Textual and numerical data were collected during the research, and in some countries in different languages (e.g., India and Uganda). Overall, teams used a team-based iterative research design during all phases of the research. This consisted of multiple iterations of data synthesis, interpretation, and summarization methods found to be useful not only for conducting qualitative, clinically-based research, but also in community settings [22, 38, 39]. Using a reflective process, each iteration included a critical team review, debate, and discussion of emerging findings, followed by further refinement and synthesis of data. This iterative process was carried out during data collection, and once teams returned from the field, during subsequent data processing, organizing, synthesizing, interpreting, and writing up of findings. As data were further organized and synthesized, teams would continue to meet and discuss the findings and ongoing analysis. The iterative process continued as data summaries were prepared and as interpretation of findings was carried out.

The data were also being used for a variety of purposes and different analyses were required. Therefore data management practices and analysis had to be flexible in order to achieve the following goals: 1) to answer country-specific research questions posed by each country team; 2) to inform development of the three study outputs to be tested in a demonstration project: a vaccine delivery strategy, a communication plan, and an advocacy strategy; and 3) to answer specific research questions posed by the overall project objectives and conceptual framework as part of a four-country comparative analysis of findings.

Textual Data

Textual data originated primarily from key informant interviews, FGDs and some data gathered as part of the health systems assessments. The four project countries utilized similar processes for management and analysis of textual data, although this process varied according to the different capacity, time, and resource levels in each country. In all countries, different kinds of data were collected (qualitative and quantitative) and in some countries data were collected in different languages. In Peru, Uganda, and Vietnam, FGDs and IDIs at the community and facility levels were tape-recorded. In India, due to time constraints, researchers used an expanded field note method for FGD data; all IDIs were tape-recorded. Policy interviews were recorded where appropriate. (In general, the tape recording of high-level administrators was not considered appropriate in all research settings.) In Peru and India, tapes and raw field notes were entered into an electronic format and used as the primary

data for analysis. In Peru and Vietnam, analysis was carried out in the local language, while in Uganda and India teams translated the transcripts into English for analysis, since the field research was conducted in several different languages.

The primary textual data were reviewed for data cleaning and then for identification of emergent themes. Units of analysis were identified according to the five levels of influence outlined in the conceptual framework, for study sites, for data type (e.g., FGD or IDI), and for other specific socio-demographic characteristics as needed (e.g., gender, rural vs. urban). For example, in Uganda, FGD data from parents in each of the five study sites constituted a separate unit of analysis.

Due to the large volume of raw textual data and different types of textual data collected, all four teams used a template or matrix organizing style to carry further synthesizing, analysis, and interpretation [38, 39]. Text matrices with manual sorting, processing, and synthesizing were used in Peru to organize the data [39]. Researchers in India, Uganda, and Vietnam used a team-based approach to develop a formal codebook and used either NVivo© or Atlas.ti© electronic textual management software to organize, sort, and synthesize information into textual matrices for analysis and interpretation [40-42].

Codebook Development and Coding

Teams that developed codebooks to analyze textual data used a similar approach which combined both inductive and deductive processes and several cross-mapping exercises to link codes (representing key themes), research questions, ecological levels in the conceptual framework, and research outputs [38]. The codebook development process actually began in the field through regular reviews and daily debriefing. As new themes emerged, if they encompassed new domains, these were noted and the codebook revised, making the codebook a dynamic and flexible tool. This iterative process continued through the analysis portion of the research [38, 39]. Table **4** illustrates elements of the codebook used in India. The first three columns constitute the codebook contents (code number, theme represented, and definition of code). Column 4 highlights the data sources where corresponding text information was likely to be found. Column 5 identifies the associated ecological level, and column 6 identifies the corresponding study output—essentially what the data would be used to inform.

In all four countries, data were coded either manually or electronically using recognized coding reliability checks [39, 43]. Reports for FGDs and IDIs were generated separately and information was later synthesized by thematic area. These reports pulled together coded text that contained relevant data needed to answer each research question. Additional analysis techniques included use of table summaries, diagrams, narratives, and conceptual mapping [39].

Multiple iterations of data synthesis, interpretation, and summarization were carried out. Using a reflective process, each iteration included a critical team review and discussion

Table 4. India Codebook Linked with Conceptual Framework Ecological Levels and Study Output

Code	Themes	Definition of Code	Data Source/s*	Ecological Level	Output
1	Free time (School-going girls and non-school girls)	Free time (time when girls are not busy in any household chores or studies, including summer holiday and festivals).	• FGD adolescent girls, parents, teachers	Individual Interpersonal	Vaccine delivery strategy
2	Decision-makers' influencers	People who influence the decision or help those who make decisions regarding adolescent girls' health, provide them information or help them seek information related to the adolescent girls' health and related aspects.	• FGD adolescent girls, parents, teachers • IDI community opinion leaders	Individual Interpersonal	Communication strategy
3	Knowledge and attitude towards general vaccination	Attitudes, views, concerns, myths, and misconceptions; perception of quality, factors, and reasons influencing acceptance or non-acceptance of vaccination from adolescent girls and adults group; service providers.	• FGD adolescent girls, parents • IDI service providers	Individual Interpersonal Institutional	Communication strategy
4	Health system preparedness for HPV vaccine delivery	Strength of the existing system to be able to cope with the introduction of cervical cancer vaccine, including staff, infrastructure, supply, and logistics.	• IDI health administrators • Health system assessments	Institutional	Vaccine delivery strategy
5	Resources needed to cope with the addition of HPV vaccine	The gaps identified within existing system to introduce HPV vaccine in terms of storage, supply, infrastructure, staff, and training; the ways to close the gaps.	• IDI health administrators • Health system assessments	Institutional	Vaccine delivery strategy
6	Policy-making process and key people involved	The various steps, agencies, and people involved in the health policy formation process.	• IDI policy stakeholders	Policy	Advocacy strategy
7	Facilitators for HPV vaccine policy	Policies, people, and factors that might pose as facilitators to the introduction of HPV vaccine.	• IDI policy stakeholders	Policy	Advocacy strategy

*FGD: Focus group discussion, IDI: In-depth interview.

of emerging findings to further verify the data findings, followed by further refinement and synthesis of data [39].

The data interpretation process involved linking findings to questions posed in the conceptual framework and the primary research objectives, and the translation of findings to inform the formative research outputs—the backbone for planning the HPV vaccine demonstration activities in each country. Table **4** illustrates how this was carried out.

Numerical Data

Numerical data included information gathered from checklists used in the health system capacity assessments, and information gathered on the vaccine delivery system, cold chain, transport and logistics, as well as facility storage capacity. Data from a KAP survey conducted in Vietnam were entered as numeric data.

Numerical data obtained from the health system assessments were entered into Excel 2003©, Epi Info™ 6, or Access 2003©. Data were analyzed using Excel 2003© spreadsheets, SPSS 14.0©, or Access 2003© [44-47]. Data elements were analyzed descriptively according to the key areas of inquiry and research questions relevant for each country setting. KAP survey analysis included univariate statistical analysis to describe sample characteristics, and frequency tables, cross tabulations, and relevant statistical parameters to examine variable associations.

The data interpretation process also involved linking findings to address key issues outlined in the conceptual framework, research questions specific to each country, and the application of findings to inform the formative research outputs. Results from the Vietnam KAP survey were fed into the advocacy work being carried out among health policy decision makers; results also provided baseline data for the Phase II demonstration projects.

Research Results Workshop

A second global researchers' workshop held in November 2007 brought country teams together to share experiences, identify cross-cutting themes, explore how the formative research was being used, revisit the conceptual framework for its relevance and utility, identify appropriate methods and tools for use by other countries for vaccine introduction and planning, and to identify themes and research processes that teams had shared in common as well as to identify differences. Teams also shared ways the research findings are being used to inform vaccine introduction planning (developing instruction, education and communication materials, communication/advocacy, and vaccine delivery options) and ideas about ongoing data management, analysis, and interpretation of data results.

QUALITY ASSURANCE PROCEDURES

Country research teams employed a series of measures to ensure the highest standards of rigor for qualitative research [39, 48-50]. The use of a conceptual framework and stated research objectives guided the development of sampling strategies and data collection instruments to ensure data dependability (the equivalent of reliability for qualitative data). The multidisciplinary teams received intensive training in qualitative research, including data-elicitation methods, clarity on information that would not be gathered, documentation and recording, and procedures for conducting quality-control checks during data collection. Pretesting of data-collection tools and methods was also carried out. Considerable field planning informed the selection of study participants likely to provide the most relevant information on the identified research topics. This included a stakeholder-mapping exercise to identify appropriate key informants for the policy review study. Regular debriefings among team members were held in the field and throughout the data analysis process to check the validity of the data and enable researchers to make corrections in the field as needed [51].

Teams were constructed to ensure that data were gathered, prepared, and analyzed by researchers familiar with the different research topics covered in the study, and who were familiar with local languages and communities. Teams followed an iterative process for data reduction and synthesis, verification of study results, and identification and treatment of any biases entered into the data [38]. In all countries, quality-control checks were conducted during the data reduction and synthesis by the senior investigators. The use of a team-based codebook approach to data organization and analysis further ensured that the analysis was systematic and stayed aligned with the study objectives and conceptual framework, increasing research transparency and ensuring the study is replicable [39, 40]. The use of software to conduct further quality-control checks on the data coding process and management of the various data sets also ensured maximum utilization of the data in a systematic way [35, 43].

CONSENT AND ETHICS REVIEW

Approval to conduct the formative research was obtained from the respective ethical review committee in each country. Research staff received training in informed consent and principles of ethical research. Oral or written consent was secured from all participants in accordance with local requirements, including parental consent for the participation of young adolescents. Permission was obtained from respondents to tape-record focus group discussions and interviews, with provisions and assurances made for confidentiality. Requiring written consent proved to be problematic in India among the few policymakers who were willing to participate, and who did so through verbal consent. In Peru, researchers documented institutional consent as well as verbal consent at each health facility where a measles and rubella vaccination campaign was being carried out.

DISSEMINATION AND USE OF THE RESULTS

A comprehensive dissemination plan was also included in our project planning model. Country teams have disseminated formative research findings to key stakeholder audiences who were identified as important players in the planning and execution of the vaccine demonstration activities through community, regional, national, and international dissemination workshops. These workshops have also served as opportunities to validate study findings and obtain input into the demonstration project planning process. In addition, research teams and PATH staff are presenting findings and discussing key components of the vaccine delivery, communication, and advocacy strategies in smaller venues with various ministry- and community-level officials.

As of this writing, HPV vaccine demonstration projects informed by the results of the formative studies in Peru, Uganda, and Vietnam are underway. Results are currently being used to design demonstration projects in India. In all countries, informational, educational, and counseling materials have been or will be developed and pretested based on the formative research findings. Materials will be further evaluated after use in the demonstration projects. Plans for national policy–level advocacy activities are also being formulated, drawing upon the stakeholder mapping and exploration of information needs at national and subnational levels. Publications for individual country-level data findings are also underway [20, 21] and papers covering cross-site synthesized findings from the sociocultural [19], health systems readiness, and policy research components are in preparation.

DISCUSSION

Implications for Health Services Research

Health program planners around the world recognize the importance of engaging in a process that is grounded in specific goals and principles, and that is applicable to the local context [16, 52]. The value of formative research in this process is well recognized in the international development sector [16, 53, 54]. It is becoming an increasingly funded type of public-health research used to inform the development of health communication and advocacy interventions, and as a basis for implementation of new health interventions, including vaccines [15, 55-57].

While the importance of formative research in planning for vaccine introduction is recognized in the literature, little exists in the way of specific guidance on how to structure a qualitative exploration of factors impacting vaccination through the use of a theory-based conceptual framework. A review of immunization introduction literature suggests that formative research is often undertaken haphazardly, is loosely tied to a broader vaccine introduction model (*e.g.*, the Health Technology Assessment [58]), if at all, and may consist of several mini-studies that are not embedded into a cohesive framework. Some notable exceptions involve the work of the Diseases of the Most Impoverished (DOMI) project, led by the International Vaccine Institute, which has utilized theory-driven conceptual frameworks to guide formative sociobehavioral and policy studies that inform planning for enteric vaccine introduction (shigella, cholera, typhoid) [18, 31, 59, 60]. A distinguishing feature of the DOMI model is the use of different conceptual frameworks designed for each country setting.

Applied research aims to provide answers to real-world questions. That being said, how, and even whether, formative research is used in the real world to encourage innovation and change has not been a major focus of attention in the public health research and implementation community [61]. The steps to actually collect and then utilize research findings to inform decision-making, program planning, and implementation are poorly understood by many researchers and program planners alike, and many barriers exist that may impede the process. Gold and Taylor, for example, identify key factors that facilitate the implementation of research to practice, including having a demand-driven approach, the right team configuration, and a focus on disseminating findings to key stakeholders [61].

CHALLENGES IN THE FIELD

Developing a Conceptual Framework Requires Special Expertise

Social scientists will likely have the special expertise needed for developing a sound conceptual framework for this type of research study and should be included on vaccine research teams. Additional time, resources, and planning had to be built into a work plan. Facilitating an in-depth orientation of program and research staff to the conceptual approach also required extra effort.

Several versions of a conceptual framework may be needed in order to ensure that it is appropriately flexible and can be used or modified for different purposes. The first may be a more formal version, that is, written using language reflecting the disciplines from which different concepts have originated. A second, less technical version that focuses more on specific programmatic actions could enable trained field teams with a variety of professional and educational background to access and incorporate the basic tenets of the framework into project work plans.

Using Our Approach Under Time and Resource Constraints

In Peru, there was a need to collect and analyze data quickly in order to develop the research outputs in time for school-based vaccinations that had been previously scheduled. Innovative and creative flexibility was necessary in order to maintain rigor, produce utilizable data, and carry out sufficient dissemination activities. Formative research at the level and rigor implemented in this project, particularly the development of a conceptual framework unique to each project, may simply not be feasible or practical in other contexts. Therefore some flexibility and creativity will be required as countries assess what they can do prior to the introduction of any new health intervention. The context of local constraints, including varying research capacity, time, funding, and lack of national political will can also influence the approach taken. Creative and flexible responses may be needed to adapt existing planning models or conceptual frameworks that have been tested elsewhere. Another approach might be to partner with in-country or even international academic research institutions with existing collaborative ties to government to assist with formative research activities. Key research topics should be prioritized in circumstances where capacity, resource, or time constraints are a reality.

Unfamiliar Research Topics Require Methodological Flexibility

Field researchers also faced the challenge of exploring subjects little known to the community—HPV and cervical cancer—which were key lines of inquiry. This was especially true in India and Uganda, as well as more remote regions of Peru where no cervical cancer prevention activities exist and there is limited awareness about the disease. In some respects the exercise was hypothetical. Teams had to use different techniques in order to approach subjects in a

more open-ended fashion, such as exploring the meaning of "cancer" in general (e.g., what causes cancer, who gets it, etc.). Through the global interactive process, techniques and ideas were shared across teams, thereby strengthening the overall methodology. It is noteworthy that findings from all countries clearly show that conducting HPV research in developing countries poses special challenges, and therefore special techniques may be needed for eliciting meaningful information.

BEST PRACTICES OF OUR APPROACH

Using a Conceptual Framework

One of the important benefits we found was the use of an ecological conceptual framework to provide a theory-driven blueprint for transforming large data sets into application. The framework proved to be a simple and practical way to represent the interrelationships of the three study components, and constituted a basis for integrating them into a "road map" to guide the multidisciplinary teams in cohesive processes for data collection, analysis, interpretation, and dissemination. The framework provides a platform for the standardization of thematic areas, depth of exploration, and common definitions to ensure comparability across research sites. Using a coding scheme also provides a replicable process for how to turn results into concrete action plans.

Research Team Configuration and Stakeholder Involvement

In studies where research is intended to lead to action, it is critical to link researchers with intended users of the research, with the optimal scenario being researchers housed in the operational system [61]. Research teams were multidisciplinary and PATH staff with expertise in these areas also provided technical assistance in drafting scopes of work for each of the study outputs. In India and Vietnam, PATH staff participated in the entire process, including study design, field-based data collection, and analysis and interpretation of those data. As the formative research was intended to inform the development of demonstration projects in each country, ministry of health officials and key policy stakeholders were also involved at various stages of the research process. For example, in Peru, the Ministry of Health's technical and consultative committee on immunization was regularly consulted. Technical advisory groups comprised of senior government officials, heads of medical professional organizations, and clinical experts were formed in two research settings (India and Uganda) to oversee and provide input into research activities.

Team-Based Approach

The benefits of a team-based and interactive research process were also clear. The team-based approach is arguably the best means for ensuring that the formative research approach can be easily transferable, and for optimizing programmatic utility [49]. This approach clearly built in a layer of methodological rigor that made our results more valid and reliable. The team-based process also enabled teams to conduct the research in a more concentrated period of time, and to cover a wide array of topics in a more integrated fashion. This has facilitated the process of translating results into concrete programmatic activities.

An interactive process among the country teams began with the initial global researchers' workshop and continued throughout the project. This made the overall global research approach stronger, more verifiable, and more confirmable. Because many aspects of the research were exploratory, it was critical that throughout the project, research teams be kept informed about each other's activities, and to share tools, ideas and techniques.

For example, in previous research with young adolescents, the Peruvian researchers discovered that IDIs are inadequate for obtaining detailed information. The key challenge was establishing a quick rapport, and special techniques during FGDs were developed to address this, including games and interactive play [37, 62]. Children are often timid and sensitive when discussing certain or unfamiliar issues (e.g., reproductive organs or body image). These methods boosted the confidence of informants and helped them to focus more clearly on the subject. The techniques were shared with other country research teams and then further refined. Integrated data-management practices and the team-based codebook development process were initially developed in Peru, adapted for electronic data manipulation by Ugandan researchers, and then further adopted for use by both Vietnam and India teams. A similar process occurred with the use and refinement of health systems assessment tools; the second global research workshop was especially helpful with this process as teams met to discuss their ongoing research and shared ideas and techniques for ongoing data management and analysis.

A Demand-Driven Approach

A common feature of successful applied research projects is a clear focus on user needs, because it makes it easier to move from research to implementation [61]. This research was designed to address needs of program planners and policymakers for information on factors relevant to acceptance and support of the HPV vaccine, as well as the institutional resources needed for HPV vaccine introduction in these country settings.

Additionally, our planning model is clearly demand-driven and dictates that findings from this formative research feed into our three outputs which then directly inform the planning for our demonstration activities. Our conceptual framework also linked the three research outputs, which also helped ensure that data would be transformed into utilizable segments of information. Finally, research priorities and specific research topics were developed using a collaborative process involving end users of the information (ministries of health, local research partners, PATH, the vaccine producers) that further verified the utility of the data.

Dissemination of Findings

Our approach considers the often neglected role of dissemination, which increases the likelihood that research findings will result in action. In their own analysis, Gold and Taylor revealed sizeable barriers to the dissemination and use of research findings that included competing and more immediate operational needs as well as the lack of credibility in research findings [61]. Limited funding for dissemination

is also common, although dissemination activities are an important means of moving from research to action in each project setting.

A strong new vaccine introduction planning model should actively incorporate research results dissemination as a key activity, accompanied by thoughtful planning and ample funding. In the HPV vaccine study, dissemination of results is an amply funded priority, and both global- and country-level plans have been developed. The need to share research findings with informants on a larger scale was recognized as an important means of moving research to implementation and a variety of dissemination activities are either underway or have been recently completed in each country. In addition, all country project managers established regular communication with top officials in the ministry of health and national-level immunization programs at the onset of the project, and advocacy will play an ongoing role throughout all project phases. And lastly, as noted earlier, scientific articles covering country-level and global results are in preparation.

CONCLUSION

The new HPV vaccines offer unprecedented potential for reducing the burden of cervical cancer if appropriate and sustainable strategies can be identified for delivering them to young adolescents, a traditionally underserved population in the developing world. The most effective health program planning does require attention to structure and process, keeps in line specific goals and principles, and is applicable to the local context. The application of formative research in examining the complex and interrelated factors surrounding vaccination can help to achieve this level of planning. Program planners and researchers should also be aware of the challenges that may facilitate and impede the application of formative research findings.

The processes outlined in this paper worked well and produced the information needed to achieve our formative research objectives. Overall, the benefits gained from this approach—rigorous yet flexible, comprehensive, and integrated—have outweighed the challenges. Our experience to date supports our contention that theory-driven and methodologically sound formative studies provide a valid and reliable contribution to the evidence base for effective country-level vaccine introduction.

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