Cervical Cancer Prevention:
Practical Experience Series

Conducting Formative Research for HPV Vaccination Program Planning

PRACTICAL EXPERIENCE FROM PATH | 2012

PATH

ACKNOWLEDGMENTS

This document was compiled from research funded by the Bill & Melinda Gates Foundation and coordinated by PATH.

We would like to acknowledge the contributions of collaborating research institutions that informed this work: Child Health and Development Centre, Makerere University, Kampala, Uganda; Instituto de Investigación Nutricional, Lima, Peru; National AIDS Research Institute, Pune, India; National Institute of Hygiene and Epidemiology, Hanoi, Vietnam.

We thank former and current PATH staff who participated in the research that guided this document: Dr. Robin Biellik, Dr. Tenzing Donyo, Dr. Sanjay Gandhi, Ms. Michelle Gardner, Dr. Vu Minh Huong, Ms. Trinh Thu Huong, Dr. Martha Jacob, Dr. Satish Kaipilyawar, Dr. Carol Levin, Dr. Lysander Menezes, Dr. Emmanuel Mugisha, Dr. Manoj Patki, Ms. Mirriam Rafiq, Dr. Tilly Sellers, and Ms. Jennifer L. Winkler.

Dr. Allison Bingham, Dr. D. Scott LaMontagne, Ms. Proma Paul, Ms. Amynah Janmohamed, and Dr. Vivien D. Tsu were the principal authors of this document. The authors wish to thank Mr. Scott Wittet, Ms. Beth Balderston, Dr. Marjorie Murray, Ms. Colleen Kuehl, and Mr. Adam Drolet for editorial assistance in preparation of this document.

Finally, we acknowledge countless individuals, including country-level field researchers, community members, civic leaders, school and health personnel, and administrative leaders in India, Peru, Uganda, and Vietnam, who participated in the conduct of the research and for their support in cervical cancer prevention efforts.

The global *HPV Vaccines: Evidence for Impact* project is being implemented by PATH and our partners. This project is being funded in whole by a grant from the Bill & Melinda Gates Foundation. The views expressed herein are solely those of PATH and do not necessarily reflect the views of the Foundation.

ABOUT PATH

PATH is an international nonprofit organization that transforms global health through innovation. We take an entrepreneurial approach to developing and delivering high-impact, low-cost solutions, from lifesaving vaccines and devices to collaborative programs with communities. Through our work in more than 70 countries, PATH and our partners empower people to achieve their full potential.

Headquartered in Seattle, Washington, PATH operates offices in 33 cities in 22 countries. PATH currently works in the areas of health technologies, maternal and child health, reproductive health, vaccines and immunization, and emerging and epidemic diseases.

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Suggested citation: PATH. *Conducting Formative Research for HPV Vaccination Program Planning: Practical Experience from PATH.* Seattle: PATH; 2012. Cervical Cancer Prevention: Practical Experience Series. Available at: www.rho.org/files/PATH_HPV-conducting-formative-research_2012.pdf.

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INTRODUCTION TO THE CERVICAL CANCER PREVENTION: PRACTICAL EXPERIENCE SERIES

About the PATH HPV vaccination demonstration projects

From 2006 to 2011, PATH conducted HPV vaccination demonstration projects in four low- to middle-income countries—India, Peru, Uganda, and Vietnam—to provide evidence for decision-making about public-sector introduction of human papillomavirus (HPV) vaccines. The Cervical Cancer Prevention: Practical Experience Series of four units summarizes lessons learned that can help guide future cervical cancer prevention program planning, especially in low-resource settings around the globe.

In conducting the vaccination demonstration projects, PATH worked closely with ministries of health, civil society organizations, and other key stakeholders to carry out formative and operations research in each country. The studies looked at a variety of vaccine introduction questions, including how sociocultural barriers may impede acceptance of the vaccine; how the vaccine can be most effectively delivered to adolescent girls; how HPV vaccination can be integrated into (and strengthen) existing health programs; and what the cost of implementing HPV vaccinations might imply for health programs.

Each Practical Experience unit focuses on an important aspect of an HPV vaccination program:

1. **Strategic Planning and Situation Assessment for Cervical Cancer Prevention.** The first unit helps decision-makers and program planners focus on key "big picture" questions about cervical cancer prioritization and on opportunities and challenges for improved cancer prevention in their countries.
2. **Conducting Formative Research for HPV Vaccination.** The second unit (this document) demonstrates that preliminary formative research is a necessary component of overall planning, discusses formative research issues specific to cervical cancer, and explains how research results may be used for strategic planning within the cervical cancer context.
3. **Implementing HPV Vaccination Programs.** The third unit offers resources on general immunization topics such as how to set up an immunization site or to give a safe injection. However, the main focus is on practical issues relevant to HPV vaccination, such as working in school settings and developing effective messaging about the vaccine.
4. **Evaluating HPV Vaccination Programs.** The fourth unit focuses on how program monitoring and evaluation can be accomplished within existing health infrastructures in an efficient manner. [To be published in 2012.]

Check the RHO Cervical Cancer Practical Experience Series page (www.rho.org/HPV-practical-experience.htm) regularly for completed units.

For more information about PATH's cervical cancer vaccine project, visit: www.path.org/projects/cervical_cancer_vaccine.php or contact info@path.org.

PATH resources for information on cervical cancer and HPV vaccination

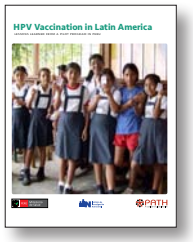
The resources below are available at www.rho.org.

The following three items provide an overview of the scientific literature on cervical cancer, current evidence on methods of prevention, and information for program planning:

- The RHO Cervical Cancer Library is a comprehensive online source for detailed information about cervical cancer and how it can be prevented.
- *Outlook*: Progress in preventing cervical cancer: Updated evidence on vaccination and screening is a 12-page primer on all aspects of cervical cancer prevention, published in 2010.
- PATH's Cervical Cancer Prevention Action Planner provides a wealth of information and interactive exercises to assist with program planning.

The following "lessons learned" reports summarize results from the HPV vaccination programs implemented through the PATH *HPV Vaccines: Evidence for Impact* project. The reports will be useful for policymakers and program managers around the world who are designing public-sector HPV vaccination programs.

- HPV Vaccination in Latin America is a summary of lessons learned from the PATH demonstration project in Peru.
- HPV Vaccination in Africa is a summary of lessons learned from the PATH demonstration project in Uganda.



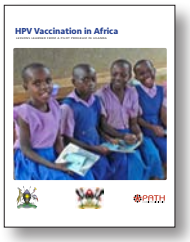


TABLE OF CONTENTS

ABBREVIATIONS/ACRONYMS

AIDS	**Acquired Immune Deficiency Syndrome**
HPV	**Human papillomavirus**
HIV	**Human immunodeficiency virus**
NGO	**Nongovernmental organization**
PATH	**Program for Appropriate Technologies in Health**
STI	**Sexually transmitted infection**
WHO	**World Health Organization**

Introduction

The objective of this unit is to assist teams that are planning cervical cancer prevention programs and want to learn more about their key audiences and existing operational systems. Collecting this information is often called "formative research"—research conducted to help formulate a policy, strategy, or message. The material in this unit is based on many years of PATH's experience working with ministries of health and nongovernmental organizations (NGOs) in the field and especially recent experience conducting formative research in preparation for human papillomavirus (HPV) vaccination in Africa, Asia, and Latin America.[1-4]

In addition to health program teams, other key stakeholders such as community partners, women's health care advocates, and health care advocates of all kinds can benefit from formative research. They can use it to design programs people are more likely to value and use, to answer critical questions and shape advocacy efforts, and to ensure that communication materials provide information audiences can understand.

Individual program teams will have different research interests and varying levels of resources (both human resources and funding), so a single design for formative research will not work. Instead, this unit encourages teams to do as much formative research as possible with the resources at hand to generate the information they need, as even modest effort can yield great strategic and programmatic benefits.

Free resources such as training manuals, sample questionnaires, and study guides are featured throughout this unit and are linked directly to the online version. Users of a printed copy will find all resources at www.rho.org.

Although this unit focuses on HPV vaccine introduction, it also may be helpful for programs introducing other new vaccines in low-resource settings and those seeking to increase access to cervical screening and precancer treatment. For more information about screening and treatment, visit the Screening section of the RHO Cervical Cancer Library (www.rho.org/screening.htm).

PATH/Amynah Janmohamed

Cervical cancer and HPV vaccination

Cervical cancer is the second most common cancer in women in the developing world. More than one-half million new cases of invasive cervical cancer are estimated to occur globally each year, and more than 275,000 women die annually from the disease. It is a leading cause of cancer mortality in women in developing countries, and 88 percent of women who die of cervical cancer reside in low-resource settings.[5] In large part, this inequity is due to the lack of resources for cervical screening and precancer treatment in the developing world.[6,7]

The sexually transmitted human papillomavirus is the primary cause of cervical cancer,[8] with two HPV types (16 and 18) accounting for about 70 percent of cervical cancer cases worldwide.[9,10] Routine HPV vaccination offers a new prevention strategy in the fight against cervical cancer that could be especially useful in the developing world, where it could reduce cervical cancer rates to the very low levels now observed in many developed countries, especially when combined with simple, evidence-based cervical screening and treatment approaches.[11]

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The two currently available HPV vaccines, Gardasil® (Merck & Co., Inc.) and Cervarix® (GlaxoSmithKline), have been shown to be safe and effective against HPV types 16 and 18 when administered prior to infection.[12-14] The World Health Organization (WHO) recommended that in 2009 the ideal group for receiving the vaccine are females between the ages of 9 or 10 to 13 years old, before they are likely to be infected with the virus through sexual contact.[15]

Since the approval of the first HPV vaccine in 2006, countries have taken strategic steps to prepare for the introduction of the vaccine as a means of primary prevention for cervical cancer, to complement their efforts in secondary prevention through screening of adult women for precancerous lesions. Formative research is an important initial step in the country planning process and will lead to an understanding of the broader issues of cervical cancer and its prevention for a variety of populations at all levels of society, from community members to policymakers.

Formative research in action—the PATH experience

In preparation for designing HPV vaccine demonstration projects in 2006, PATH began conducting careful formative research in each study area to identify the best ways to communicate about vaccination, deliver the vaccine, and advocate for it. A central focus of the approach was to understand and address community concerns and potential institutional and policy barriers in advance. The research teams used a variety of methods to collect information from various audiences and applied the findings to develop strategies for communication, vaccine delivery, and advocacy in each country.

An example of how formative research benefitted the HPV demonstration programs can be seen in the development of communication strategies. PATH and its partners in India, Peru, Uganda, and Vietnam together made strategic decisions to emphasize certain factors when educating community members about cervical cancer and HPV vaccines. Some of these messages would have been obvious without any formative research (it was important to explain the purpose, safety, and efficacy of the vaccine), but many other decisions were strongly influenced by the research. One of the most important findings, which was an open question prior to conducting the formative research, was how to describe the vaccine to non-specialist—and sometimes low-literate—community members.

Research results clearly documented that communities were worried about cancer and the findings suggested that emphasizing how the vaccine protects against cancer, rather than the mode of transmission (sexual activity) or the disease agent (HPV), was preferred by communities and was most understandable to them. Therefore, in all four countries, posters, local radio spots, brochures, and other mass media promoted a "cervical cancer vaccine" (not an "HPV vaccine" or a "vaccine that protects against a sexually transmitted infection"). Later, during educational outreach prior to vaccination, health workers added details to this headline message by explaining that not all cancer, and not all cervical cancer, would be prevented by the vaccine, but that girls would be protected against infections that cause a high proportion of cervical cancer cases. In those interactions, they also explained the sexual mode of transmission, along with many other topics needed by parents to make an informed decision to vaccinate their daughter or not.

On the other hand, for health professionals and other highly educated audiences, materials used the phrase "HPV vaccine," since these individuals were more likely to understand that term. This strategic approach seems to have been successful, as community understanding and acceptance of the vaccine was much higher than expected for a new vaccine that had never been part of the routine government immunization program.[16]

Educational challenges remain—lack of complete and up-to-date knowledge about cervical cancer and HPV still is common even in the medical community, and more so among civic leaders, parents, and girls eligible for the vaccine. Unanswered scientific questions also remain. Because the vaccine is relatively new, no one knows the number of years it will provide protection or the extent of protection against HPV types other than those specifically targeted by the vaccine.[17] Not having all the answers can cause some decision-makers to wonder if they should delay introduction, even though some of those answers will not be known for 20 to 30 years. Formative research helps program planners anticipate such concerns and develop appropriate responses in advance.

HPV vaccination also presents new challenges for immunization services. For example, while all countries are familiar with infant immunization, which is often conducted in a clinical setting, they may lack experience in vaccinating older children and adolescents and they may not have systems for coordinating vaccination sessions in schools. Focus groups or in-depth interviews with health teams and school administrators can help clarify logistic and functional problems and opportunities in advance. Another example of the potential benefit of formative research comes from assessment of the cold chain. Because three doses of HPV vaccine are required for full protection and each dose is packaged in its own vial, there are implications for cold chain storage space. Assessments of cold stores and clinics can provide crucial information for planning and implementing immunization system upgrades.

The success of the PATH HPV vaccine demonstration projects in terms of high acceptability and high coverage suggests that such formative research guidance was extremely helpful for designing communication, vaccine delivery, and advocacy strategies.

PATH formative research reports on cervical cancer and HPV vaccines

Shaping a Strategy to Introduce HPV Vaccines in India

Shaping a Strategy to Introduce HPV Vaccines in Peru

Shaping a Strategy to Introduce HPV Vaccines in Uganda

Shaping a Strategy to Introduce HPV Vaccines in Vietnam

Formative research overview

Characteristics

Formative research seeks to gather information on a target audience's beliefs, values, attitudes, knowledge, and behaviors, and to answer questions about the context that influences, and is influenced by, those factors.[18] Formative research may also focus on system or operational issues. In both cases, the research provides a solid evidence base for designing meaningful and realistic implementation plans. New HPV vaccination programs especially stand to benefit from audience and systems research conducted well in advance of vaccine launch.[19-21]

Choosing an approach based on available resources

Resources available for formative research and the level of evidence required for planning a vaccination program will vary by country and program. The depth and breadth of research can range from a basic design requiring a low level of resources to a resource-intensive study design. The quality of the research can be high at all levels, provided that the design is appropriate to the objectives, with a sound methodology, adequate sampling, robust data analysis, and implementation by a team whose skills match the needs of the study.

Trade-offs must be examined when choosing the research approach that is best for a country or program, and this provides an opportunity to critically assess the specific objectives, level of scientific rigor desired, the design that is best for achieving those objectives, and the resources that will be needed for that design. Areas to consider when making choices based on resources are the study populations to include, their representativeness of the overall population, the

PATH/Aisha Jumaan

sample size requirements, the type of information that can be collected, the analysis required for the data, and the expertise needed to complete the study activities. These should be balanced against the resources available. For example, if the research design calls for focus group discussions, in-depth interviews, or other data collection methods that use large amounts of qualitative data, the expertise needed to analyze the textual data should be included in the study team. If, however, only a more quantitatively trained data analyst is available, the study may need to shift to data collection and design strategies that use quantitative data instead. Throughout the planning process, it will be important to consider and clearly state these trade-offs between resources available and the possible formative research designs.

Topic areas for investigation

PATH used formative research to investigate three main topic areas—the sociocultural environment, health system structures, and policy pathways. Each domain is geared toward a specific outcome, or strategy, that is instrumental for new vaccine introduction (Table 1). An assessment of the sociocultural environment is critical for identifying the information needs of parents and for designing a communication strategy. Understanding the structures of the health system can guide the vaccine delivery strategy and illustrate components of that system that can facilitate or hinder delivery. Mapping policy pathways can lead to a strategy for advocacy to ensure that policymakers have the information they need to formulate vaccine policy and endorse the vaccine delivery strategy recommended. The strategies generated from the results of formative research may be embedded in comprehensive implementation plans for an HPV vaccination program.

Table 1. Formative research

TOPIC AREAS		STRATEGIES
Sociocultural environment	→	Health communication strategy
Health system structures	→	Vaccine delivery strategy
Policy pathways	→	Advocacy strategy

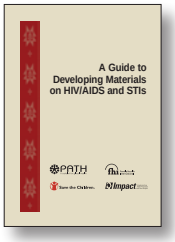
PATH employed this general framework of topic areas when conducting formative research for HPV vaccination programs in India, Peru, Uganda, and Vietnam. The remaining sections of this document will guide the reader through the components and the activities recommended for each area of research, providing examples and tools for adaptation to local needs.

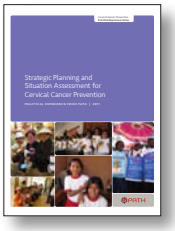
Key formative research activities

Define objectives

A first step in planning formative research is to define clearly the objectives of the research, including listing milestones for achieving the objectives, identifying key deliverables (a report on lessons learned, for example), and articulating how the research will be evaluated (to determine if the project was a success).

Objectives must be in line with available resources and level of scientific evidence required. For example, a resource-intensive study may gather data useful only for the local project, or may include findings that are generalizable to a wider population and therefore contribute to the global scientific literature. The latter objective requires more time-consuming and expensive research methods than a more basic research design. PATH's Immunization and Child Health Materials Development Guide and A Guide to Developing Materials on HIV/AIDS and STIs provide guidance for developing objectives and overall qualitative research planning. See also the general resources listed after of the Conclusion section of this unit.





Review existing information

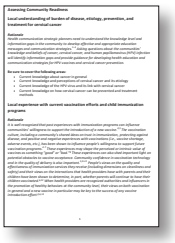
Key background information in each country, such as cervical cancer burden, the age of initiation of sexual activity, and knowledge about cancer, can help determine the strategic direction that formative research should take in each setting. Country-specific survey data on cervical cancer, adolescent immunization, status of the existing immunization program, and school-based vaccination may be available from the government, United Nations agencies, or NGOs. The WHO/ICO (Institut Català d'Oncologia) Information Centre on HPV and Cervical Cancer has data and statistics for analysis and comparison for HPV and related cancers at country, regional, and global levels. PATH's Strategic Planning and Situation Assessment for Cervical Cancer Prevention, the first unit in this series, includes links to information sources that may help.

Outline key areas of inquiry

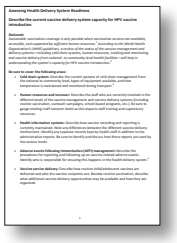
As illustrated in Table 1, formative research to help with HPV vaccination program design should investigate sociocultural issues, health systems issues (and education system issues related to in-school vaccination), and policy-related issues. Table 2 gives detailed components of each of these domains that can be explored.

Sociocultural issues. 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 vaccine delivery at multiple levels. Understanding local perceptions of need, the way

people make decisions about health matters, and locally acceptable vaccine delivery practices are key components for vaccine introduction. Sociocultural assessments can also clarify the information needs of parents, girls, local health care providers, and the wider community for vaccine decision-making. This information will be important in designing educational materials and communication strategies to sensitize communities prior to beginning a new vaccination program. Failure to design effective materials may result in low acceptability of vaccine and suboptimal vaccine coverage. Assessing Community Readiness, from the PATH HPV vaccine project, outlines the research domains to explore, the rationale behind each, and a list of references in the published literature to aid in understanding the sociocultural environment.



Health systems issues. A review of vaccine management and delivery systems should include areas such as cold chain systems, human resources, vaccination tracking and monitoring, adverse event monitoring, injection safety, and access points for vaccine delivery (such as schools), from the national level to the community level (Table 2). Identifying all the services available for health education, cancer prevention, immunization, and adolescent health will help to determine key groups with whom to coordinate activities. It will also help to identify key target audiences and potential communication strategies. These data will clarify the systems' capacity for HPV vaccine introduction and highlight potential gaps or challenges. Assessing Health Delivery System Readiness from PATH outlines the research domains to explore, the rationale behind each, and a list of references in the published literature to aid in understanding the current delivery capacity and structures.



Policy issues. Understanding the processes involved in the development and enactment of new vaccine policies may prevent some of the delays experienced with vaccine introduction in the past. To ensure that decisions to introduce new vaccines have the greatest impact, three critical factors must be considered: 1) deliberation must include a broad range of stakeholders; 2) in most cases, decisions must apply to the entire country; and 3) infrastructure must be in place to support national policy. Furthermore, development of new vaccine policy often entails ongoing exchange of information between scientific and medical communities and policymakers, comprehensive assessment of new vaccine introduction capacity, and multiple iterations during policy formulation. Information to characterize the decision-making process related to new vaccine introduction should be gathered from several different sources. The PATH resource Assessing the Health Policy Arena outlines the research domains to explore, the rationale behind each, and a list of references in the published literature to aid in understanding. The document also highlights critical information needs of policymakers and areas to leverage for policymaking.

Table 2. Formative research key topic areas of inquiry for HPV vaccine introduction

SOCIOCULTURAL ENVIRONMENT: ASSESSING COMMUNITY READINESS
• Understanding of burden of disease, etiology, prevention, and treatment
• Experience with current vaccination efforts and child immunization programs
• Role of key authority figures in health-related issues for children and adolescents
• Community awareness about health-related and immunization issues
• Social context of decision-making for child well-being and vaccination
• Living circumstances of out-of-school girls
• Utilization of health services by adolescent girls
• Perceptions and experiences with cervical and other cancers
• Local terms for referring to children 10 to 14 years old
HEALTH SYSTEM STRUCTURES: ASSESSING HEALTH DELIVERY SYSTEM READINESS
• Current vaccine delivery system capacity for HPV vaccine introduction
• Feasible options for HPV vaccine delivery
• Future needs of the vaccine delivery system to support added HPV vaccinations
• Future needs of the health communication system to support added HPV vaccinations
• Political and technical dynamics that influence the vaccine delivery system
• Existing health and education services
POLICY PATHWAY: ASSESSING POLICY READINESS
• Key policymakers and other stakeholders
• National health policy decision-making process
• Information needed to make HPV vaccine introduction decisions
• Integrating HPV vaccination into existing cervical cancer control efforts
• Feasible or preferred vaccine delivery strategies
• Positioning HPV vaccination to support or strengthen other health interventions

Define study populations

Once specific objectives have been identified and defined, and key areas of inquiry clarified, a usual next step is to identify the study populations to include in the formative research. Health program planning often uses an "ecological framework" to illustrate the different levels and actors in a health planning system. These levels are interrelated and are not mutually exclusive. An ecological framework recognizes that individual health behaviors are influenced at different levels within a complex environment.[20] An example of this type of framework is provided in the resource An Ecological Framework, which shows how to use this method for HPV vaccine introduction. It can guide the selection of study populations to include in formative research.

To the extent possible considering available resources, participant selection at each site should cover a variety of stakeholders who reflect the different populations and types of data required (Table 3). Depending on the objectives, the list may include any of the following:

- Girls eligible for vaccination.
- Parents or caregivers of eligible girls.
- Health workers, especially those who either make immunization referrals or who vaccinate.
- Health program managers.
- Ministry of health decision-makers.
- Ministry of education decision-makers or staff, school administrators, and teachers.
- Community-based development and social workers.
- Women's groups.
- NGOs that deliver reproductive health services.

Careful site selection in the country also is critical when conducting formative research. Strategies in each country should be designed to achieve broad representation in terms of rural/urban and inland/coastal/highland locations, cultural differences (including religious, ethnic, and language diversity), and exposure to ongoing cervical cancer prevention interventions, if any exist.

The study population for each area of inquiry must be selected carefully. Participants should be selected who are knowledgeable about or have experience with the key area of inquiry being explored so that the information they provide is valid and believable. The formative research populations from PATH's experience are summarized in Table 3. Note that the populations listed in the table represent the different levels of a health planning system, which follows directly from the conceptual framework used in that research and included in the ecological framework resource provided above.

PATH/Nga Le Thi

Table 3. Areas of inquiry and suggested target populations for HPV vaccine formative research

	INDIVIDUAL	INTERPERSONAL	CIVIL SOCIETY	INSTITUTIONAL	POLICY
AREA OF INQUIRY	GIRLS AGED 10 TO 14 YEARS	PARENTS, CAREGIVERS, TEACHERS, HEALTH CARE PROVIDERS	FAITH GROUPS, CIVIC GROUPS, UNIONS, NGOS, LOCAL MEDIA	EDUCATIONAL AND HEALTH CARE INSTITUTIONS, HEALTH CARE ADMINISTRATORS	DISTRICT, REGIONAL, NATIONAL POLICYMAKERS; MINISTRY HEADS
Community readiness					
Understanding of burden of disease, etiology, prevention, and treatment		✓			✓
Experience with current vaccination efforts and child immunization programs		✓	✓	✓	✓
Role of key authority figures in health-related issues for children and adolescents		✓			
Community awareness about health-related and immunization issues		✓			✓
Social context of decision-making for child well-being and vaccination	✓	✓	✓		
Living circumstances of out-of-school girls	✓	✓	✓		
Utilization of health services by adolescent girls	✓	✓			
Perceptions and experiences with cervical and other cancers	✓	✓	✓	✓	✓
Local terms for referring to children 10 to 14 years old	✓	✓			

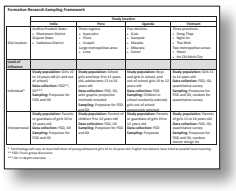
	INDIVIDUAL	INTERPERSONAL	CIVIL SOCIETY	INSTITUTIONAL	POLICY
AREA OF INQUIRY	GIRLS AGED 10 TO 14 YEARS	PARENTS, CAREGIVERS, TEACHERS, HEALTH CARE PROVIDERS	FAITH GROUPS, CIVIC GROUPS, UNIONS, NGOS, LOCAL MEDIA	EDUCATIONAL AND HEALTH CARE INSTITUTIONS, HEALTH CARE ADMINISTRATORS	DISTRICT, REGIONAL, NATIONAL POLICYMAKERS; MINISTRY HEADS
Health delivery system readiness					
Current vaccine delivery system capacity for HPV vaccine introduction		✓		✓	✓
Feasible options for HPV vaccine delivery		✓	✓	✓	✓
Future needs of the vaccine delivery and health communication systems to support added HPV vaccinations		✓		✓	
Political and technical dynamics that influence the vaccine delivery system		✓		✓	✓
Existing health and education services		✓		✓	✓
Policy readiness					
Key policymakers and other stakeholders				✓	✓
National health policy decision-making process					✓
Information needed to make HPV vaccine introduction decisions					✓
Integrating HPV vaccination into existing cervical cancer control efforts				✓	✓
Feasible or preferred vaccine delivery strategies		✓		✓	✓
Positioning HPV vaccination to support or strengthen other health interventions				✓	✓

Determine appropriate sample sizes

The sample size required from each of the study populations depends on many factors, including the methodological approach used, budgets, and deadlines. There will be trade-offs between depth and breadth when using a basic approach, but in general, high-quality research can still be accomplished if several considerations are kept in mind during the planning process.

First, it is better to talk to a few people than to none, and it is better to visit a few facilities to observe immunization systems than to rely only on verbal reports. However, it also is crucial to maximize the potential that respondents or sites approximately represent the broader population. For example, visiting only a few clinics near the capital might be misleading if the team wishes to understand the situation in more remote areas or among diverse cultural groups. It is critical that site and participant selection and sampling strategies in each country be designed to obtain a wide range of experiences and informational richness with enough variability to achieve the study objectives. A general rule for a basic study that has limited resources is to keep listening to key study populations or keep visiting facilities until new insights are no longer gained or until this part of the budget is exhausted.

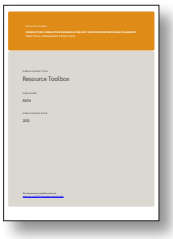
When resources allow for more comprehensive canvassing during formative research, it is important to keep several considerations in mind for target populations and sample sizes. Formative research generally involves a descriptive study rather than one testing a hypothesis or estimating precise outcomes. Data collection in formative research is usually limited to small samples chosen for specific purposes, since generalizing the findings from sample to population with statistical certainty is not the aim.[22] If additional resources are available for a population-based survey, standard sampling rules to avoid bias and assure generalizability would, of course, apply. Formative studies should also include separate data analyses for different target populations, to see if results differ across groups.[14] As indicated earlier, teams should try to engage participants who represent the different levels of influencers outlined in the ecological framework resource. The resource Formative Research Sampling Framework presents PATH's experience with study populations, data collection methods, and sampling procedures for each country where HPV vaccine formative research was conducted.



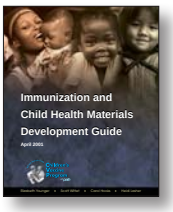
Decide on data collection methods

Suggested methodologies for collecting formative research data include the use of semi-structured and unstructured questionnaires and study guides, as well as other participatory methods that are exploratory in design, in order to encourage free expression of ideas about the topics and full understanding of the range of views, experiences, and attitudes that exist within each study population. Methods should be flexible to enable researchers to adjust their line of questioning as new information emerges in the field. Depending on the objectives, methods could include the following:

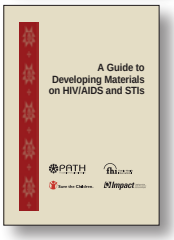
- A review of country documents such as guidelines, strategy frameworks, and program reports related to women's sexual and reproductive health can be helpful. A Desk Review Strategy from the PATH HPV vaccine project in Uganda offers suggestions for this research. This and other formative research tools used in the PATH HPV vaccine project countries can be found in the Resource Toolbox.
- Focus group discussions can provide information and cross-validation through group interaction. These discussions can be used to reveal the most common attitudes, perceptions, and practices in a population. Two focus group discussion guides, one for use with parents and one with out-of-school girls, are provided as resources to illustrate how this technique can be used.



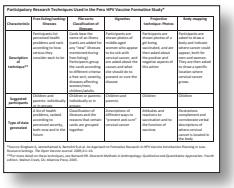
- Unstructured in-depth interviews, including key informant interviews with key target groups, can be used to explore specific topics in more detail and to gather information about individual practices, health-seeking behaviors, or potentially sensitive information. This is an appropriate means for gathering information among national policymakers or busy institutional administrators who also wish to maintain confidentiality. In-depth interview guides can assist planners using this method for gathering information from health care policymakers and health providers.
- Investigation of ongoing immunization programs can also yield useful information. A combination of tools used to assess a Peruvian immunization campaign for rubella[23] is provided to illustrate how this technique can be used. A checklist for assessing health facility equipment, cold chain, and supplies from the HPV vaccine demonstration project in Uganda is another useful tool.



- The Immunization and Child Health Materials Development Guide and A Guide to Developing Materials on HIV/AIDS and STIs from PATH also give detailed instructions for conducting focus group discussions and in-depth interviews.



- Participatory research techniques during group discussions and individual interviews have proven useful in improving the overall data collection process. These might include free lists, pile sorting, interactive games, mapping exercises, vignettes, and photo or illustrative projective techniques. The resource Participatory Research Techniques presents a summary of these procedures with suggestions of the appropriate target audience, the types of data that can be generated, and how to use the data. Investing When it Counts, from the Population Council, discusses research methods and tools that can be used with children and young adolescents.



Identify experienced field researchers and train the team

A strong study team will have expertise in community-based social science research, public health, qualitative research methods, health communications, national health policy, vaccine delivery and expanded program on immunization (EPI), child health, and immunization. The team configuration should be based on the study design and is dependent on available resources, time, and capacity.

The team does not need to be large but should consist of the right expertise to conduct the study, to ensure that resources are used efficiently. This is especially important for programs that want to do high-quality research using a more basic approach.

If the formative research design uses qualitative data collection techniques that produce textual data, the study team should include someone who has skills in analyzing large amounts of textual data. In situations where more checklists, surveys, or other fixed-response tools are used, persons trained in classic epidemiology or behavioral scientists with a quantitative research background (e.g., in demography, economics, or education) will be more appropriate. The team should also include people with strong language skills for the locales selected for the study. A good plan may be to forge strategic partnerships with institutions experienced in community-based social science research, health systems research, and policy research.

Once the study team is organized, it is ready to be trained. The team should first review the objectives of the study. In addition to learning the basics about cervical cancer epidemiology and current cervical cancer control and immunization programs, the team should complete a thorough review of study instruments, such as the guides and checklists provided in this unit, to understand the rationale behind the questions or key areas of inquiry. This will also allow the team to discuss whether the terminology used and data collection processes are appropriate or need to be refined. Use of the instruments is recommended during training, practice sessions, or role plays.

Develop well-designed and tested research tools

It is always best to start with tools that have been tested and provided by a credible source (e.g., WHO or another well-known NGO) and that can be adapted for individual programs. Teams embarking on formative research should be mindful of the tools they use, their source, and their limitations even if they have been previously validated.

Engage a broad array of relevant stakeholders in formative research

Delivering the HPV vaccine to young adolescent girls will require innovative strategies that depart from traditional infant and child immunization program models. Decisions about vaccine introduction (and ultimately its success) require the input and collaboration of many individuals. These are likely to include administrative officials from different health departments (immunization, cancer control, and reproductive and adolescent health) and from other sectors of government, such as education (because schools often are used as immunization venues), as well as community stakeholders (civic leaders, girls eligible for the vaccine, and their primary caregivers). These groups are a part of the ecological framework for health program planning, as explained earlier, and they can become credible sources of information.

Regardless of whether the study design is more basic or more intensive, getting the support and cooperation of individuals most relevant for study outcomes will help ensure that the research runs smoothly and meets the needs of potential users of the results. It will also engender feelings of ownership among various stakeholders.

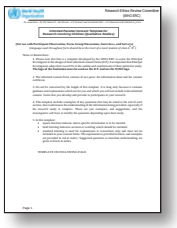
Follow age-specific ethical guidelines for research

While all research should follow internationally accepted ethical principles, research involving older children and young adolescents requires special considerations. Investing When it Counts, from the Population Council, discusses the ethical use of research methods for children and young adolescents. Researchers from the Child Health and Development Centre at Makerere! University's College of Health Sciences in Uganda have outlined age-specific ethical guidelines for research, which include the following:

- Always put the best interests of children and adolescents first by promoting and protecting their rights.
- Children and adolescents require special protection because they are vulnerable to exploitation and have less power than adults.
- Researchers should always be sensitive to the presence of parents, siblings, and classmates, and respondent concerns about privacy.

Studies to prepare for HPV vaccine introduction will likely include girls 10 to 14 years old among research respondents. Because they are minors, special protection must be accorded to them following the guidelines stipulated in the Helsinki Declaration of 1964, most recently revised in 2008, which state that: "...when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation."[23] Due to their legal status as minors and the implied vulnerability this status confers, the research team will need to negotiate access to girls through their parents or guardians. In the case of those in school, access also will need to go through appropriate administrators and teachers who, through their relationship with the girls, are assumed to have a protective role. All research should adopt this principle to ensure maximum protection of privacy, confidentiality, and autonomy of the girls as study respondents.

A sample Verbal Consent Form used in the PATH HPV vaccine project in Uganda for parents or guardians of children participating in formative research is provided as a resource. An Informed Parental Consent Template for Research Involving Children from WHO is also available.

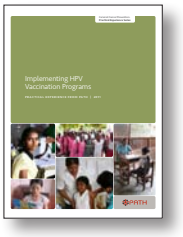


Analyze the data with planning needs in mind

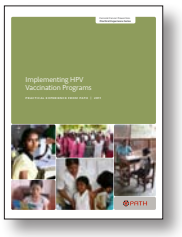
As mentioned earlier, formative research can be used to guide development of a communication strategy (for outreach to communities), a vaccine delivery strategy (to fit within the health system), and an advocacy strategy (for outreach

to policymakers). Once data have been gathered, analysis by qualified researchers should focus primarily on generating findings relevant to the specific objectives of the research and the planned outputs, as outlined below.

Data for developing a communication strategy. Addressing community issues and concerns prior to introduction of a new vaccine is the overall goal of a comprehensive communication strategy, which must build trust in vaccination and highlight important characteristics of a new vaccine. Data on community readiness should identify target audiences, information channels, and key messages that address both information needs and factors that motivate or constrain new vaccine acceptance. Differences among study groups and research sites should be highlighted. The information gathered should also determine the appropriate person or means for delivering key messages, because effective communication is essential to building trust in vaccination. Data gathered during formative research can also provide valuable information for shaping a plan for emergency response to any adverse events during vaccine introduction. Results should be carefully reviewed for sensitivities, social responses, and key communication channels that will be important. Communication strategies are available on pages 16–18 in another unit of this series, Implementing HPV Vaccination Programs.

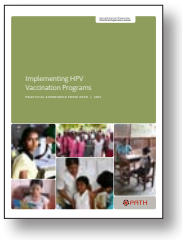


Data for developing a vaccine delivery strategy. Analysis of data from assessments of the health system and immunization financing mechanisms should focus at minimum on six key topics for identifying appropriate and effective strategies for HPV vaccine delivery: 1) health services for young adolescents, 2) current immunization systems, 3) immunization financing, 4) vaccine logistics and cold chain systems, 5) health information systems and associated human resources, and 6) effective delivery strategies for the HPV vaccine. Opportunities and challenges for each strategy option should be highlighted. The feasibility and sustainability of each proposed strategy also should be considered. Finally, any financial and institutional barriers need to be critically examined. HPV vaccination delivery strategies are illustrated on pages 6–9 in Implementing HPV Vaccination Programs.



Data for developing an advocacy strategy. The main purpose of an advocacy strategy for immunization is to generate and maintain support of vaccine programs among health policymakers and other national leaders. Several specific areas should guide the analysis of data: descriptions of the existing policy environment, the policy development process, and HPV vaccine-specific issues. Analysis of the policy environment should focus on the information needs of policymakers, such as cervical cancer burden and control, adolescent health services, and immunization programs. A closer analysis of the policy process could focus on how health policy is developed for new vaccine introduction, critical actors and external influencers, vaccine financing, and how policy is implemented. The data should be examined for any HPV vaccine-specific issues, which might include questions about vaccine characteristics, economic evaluation, and any social concerns. Information needs of policymakers, effective

strategies to generate and maintain support for vaccine policy, or crucial collaborations for introduction and financial commitments also should be summarized. Examples of stakeholders and their roles can be found on pages 19–20 in Implementing HPV Vaccination Programs.



Plan for data packaging and dissemination

Formative research findings will provide critical information for a variety of audiences, including key stakeholders invested in introducing the new HPV vaccine. It is important to make sure that all relevant audiences receive and understand the findings so they can make informed decisions.

A good dissemination strategy uses a variety of packaging and channels to reach diverse audiences effectively. Discussion about dissemination plans should begin early in the research process because distributing the information can have important implications for budget, timelines, and staff capacity. Some dissemination activities are relatively inexpensive, but others, such as national dissemination workshops, publication preparation, and attendance at national and international conferences, have significant cost implications. Some of the activities may require help from people with expertise beyond the capacity of the team, such as meeting organizers, graphic artists, or web page designers.

Dissemination packages may differ in content, style, and delivery in different country settings and for different audiences within the country and may include the following:

- Detailed technical report for health program managers.
- Two-page executive summary for busy policymakers.
- Slides for a workshop discussion.
- Manuscript for submission to a peer-reviewed journal for scientific audiences.

Regardless of the format, content should be tailored to each audience, with clear and simple language to present key findings and recommendations. Illustrations, charts, and other visual elements are powerful means of synthesizing complex

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findings. Illustrative examples drawn from narratives, observations, or other data sources make findings even more compelling.

Table 4 presents various types of dissemination activities and can be used as a template for developing country-specific distribution plans.

Table 4. Recommended dissemination activities for formative research results

TYPE OF ACTIVITY	AUDIENCES	COMMENTS
Workshops	Local NGOs, participating communities, national- or district-level administrators (school, health, etc.), scientific community, local and national press	Allow significant, high-quality time to engage with partners and stakeholders Often expensive May be difficult to organize
Conferences	Scientific community, policy decision-makers	Reach many people at one time; publish information in conference proceedings Others may organize Travel and registration may be expensive
Print media/research briefs	Donors or funders, national-level administrative agencies, advocacy groups, policy decision-makers, community	Necessary as handouts at workshops and conferences Can be produced in more or less expensive ways Can be electronically published and offered online at little expense
Scientific publications	Scientific or practitioner community at global, regional, or national levels	Provide good credibility for findings Restrictions on format and use of illustrations and captions; requires more formal writing Some journals available for free online, others only available to subscribers Can take a long time for publication
Mass media (TV, radio, and the web)	Policy decision-makers, advocacy groups, general public	Can offer many things; on the web: photos, films, audio, interactive games Can be inexpensive (simple web page) or very expensive (TV slot during prime time) May reach many individuals, but can be difficult and expensive to evaluate

Conclusion

As countries begin to develop strategic plans for the prevention of cervical cancer through HPV vaccination, understanding the sociocultural environment, health system capacity, and policy pathways will be critical to laying a solid foundation for the design of programs to reach young adolescent girls. Decisions for vaccination at the individual level are made within a larger context of the parent-child relationship, familial structure, community influence, infrastructure of the health system, and the policies created at the national level that foster and support such decisions.

Formative research can assist countries in mapping the dynamics of decision-making at the individual level, the systems to leverage for HPV vaccination, and the policies that provide a supportive framework. This document provides an overall structure and examples of tools from PATH's experience in conducting formative research for HPV vaccine introduction in India, Peru, Uganda, and Vietnam. The results of this work led to the design of communication strategies for vaccine acceptability, vaccine delivery strategies that were feasible to implement and that could achieve high coverage, and an advocacy strategy to engage policymakers in the critical decision process for HPV vaccine introduction. Countries can draw on this experience to develop a formative research strategy that is tailored to their needs and the resources available to them.

PATH/Nga Le Thi

General resources for conducting formative research

This list includes some books and articles that have been cited in the text, but they are included again here because they offer a broad perspective on formative research, in addition to information for which they were noted in the text.

Bernard HR. *Research Methods in Anthropology: Qualitative and Quantitative Approaches*. Fourth Edition. Walnut Creek, CA: AltaMira Press; 2005.

Bingham A, Janmohamed A, Bartolini R, et al. An approach to formative research in HPV vaccine introduction planning in low-resource settings. *The Open Vaccine Journal*. 2009;2:1–16.

Chong E, Hallman K, Brady M. *Investing When it Counts: Generating the Evidence Base for Policies and Programmes for Very Young Adolescents: Guide and Tool Kit*. New York, NY: United Nations Population Fund and Population Council; 2006. Available at: http://www.popcouncil.org/pdfs/InvestingWhenItCounts.pdf.

Green LW, Kreuter MW. *Health Program Planning: An Educational and Ecological Approach*. New York, NY: McGraw-Hill; 2005.

Mack N, Woodsong C, MacQueen A, Guest G, Namey E. *Qualitative Research Methods: A Data Collector's Field Guide*. Research Triangle Park, NC: Family Health International and US Agency for International Development; 2005.

Van den Akker J, Gravemeijer K, McKenney S, Nieveen N. *Educational Design Research*. New York, NY: Routledge Press; 2006.

Zimet GD, Liddon N, Rosenthal SL, Lazcano-Ponce E, Allen B. Chapter 24: Psychosocial aspects of vaccine acceptability. *Vaccine*. 2006;24:(Suppl. 3)S201–S209.

References

1. Katahoire RA, Jitta J, Kivumbi G, et al. An assessment of the readiness for introduction of the HPV vaccine in Uganda. *African Journal of Reproductive Health*. 2008;12(3): 159–172.
2. Jacob M, Mawar N, Menezes L, et al. Assessing the environment for introduction of human papillomavirus vaccine in India. *The Open Vaccine Journal*. 2010;3:96–107.
3. Nguyen NQ, LaMontagne DS, Bingham A, et al. Human papillomavirus vaccine introduction in Vietnam: formative research findings. *Sexual Health*. 2010;7(3):262–270.
4. Bartolini R, Drake JK, Creed-Kanashiro HM, et al. Formative research to shape HPV vaccine introduction strategies in Peru. *Salud Pública de México*. 2010;52(3):226–233.
5. Ferlay J, Shin HR, Bray F, Forman D, Mathers C, Parkin DM. GLOBOCAN 2008 V1.2, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 10. International Agency for Research on Cancer ebsite. 2010. Available at: globocan.iarc.fr/. Accessed April 25, 2012
6. World Health Organization (WHO). Virus Cancers: Human Papillomavirus. WHO website. 2010. Available at: www.who.int/vaccine_research/diseases/viral_cancers/en/index3.html. Accessed February 21, 2010.
7. Sankaranarayanan R. Overview of cervical cancer in the developing world. *International Journal of Gynaecology and Obstetrics*. 2006;95(1):S205–S210.
8. Bosch FX, Lorincz A, Munoz N, Meijer CJ, Shah KV. The causal relation between human papillomavirus and cervical cancer. *Journal of Clinical Pathology.* 2002;55(4):244–265.
9. Clifford G, Franceschi S, Diaz M, Munoz N, Villa LL. Chapter 3: HPV type-distribution in women with and without cervical neoplastic diseases. *Vaccine*. 2006;24(3):S26–S34.
10. Smith JS, Lindsay L, Hoots B, et al. Human papillomavirus type distribution in invasive cervical cancer and high-grade cervical lesions: a meta-analysis update. *International Journal of Cancer*. 2007;121(3):621–632.
11. Franceschi S, Denny L, Irwin KL, et al. Eurogin 2010 roadmap on cervical cancer prevention. *International Journal of Cancer*. 2011;128(12):2765–2774.
12. Paavonen J, Naud P, Salmeron J, et al. Efficacy of human papillomavirus (HPV)-16/18 AS04-adjuvanted vaccine against cervical infection and precancer caused by oncogenic HPV types (PATRICIA): final analysis of a double-blind, randomised study in young women. *The Lancet*. 2009;374(9686):301–314.
13. The FUTURE II Study Group. Quadrivalent vaccine against human papillomavirus to prevent high-grade cervical lesions. *The New England Journal of Medicine*. 2007;356(19):1915–1927.
14. Garland SM, Hernandez-Avila M, Wheeler CM, et al. Quadrivalent vaccine against human papillomavirus to prevent anogenital diseases. *The New England Journal of Medicine*. 2007;356(19):1928–1943.
15. World Health Organization (WHO). Human papillomavirus vaccines. WHO position paper. *Weekly Epidemiological Record.* 2009;84(15):118–131.
16. LaMontagne DS, Barge S, Le NT, et al. Human papillomavirus vaccine delivery strategies that achieved high coverage in low- and middle-income countries. *Bulletin of the World Health Organization*. 2011;89(11):821–830B.

17. Murray M. Progress in preventing cervical cancer: updated evidence on vaccination and screening. *Outlook*. 2010;27(2).

18. Newes-Adeyi G, Helitzer DL, Caulfield LE, Bronner Y. Theory and practice: applying the ecological model to formative research for a WIC training program in New York State. *Health Education Research*. 2000;15(3):283–291.

19. Breinbauer C, Maddaleno H. *Youth Choices and Change: Promoting Healthy Behaviors in Adolescents*. Washington, DC: Pan American Health Organization; 2005.

20. Green LW, Kreuter MW. *Health Program Planning: An Educational and Ecological Approach*. New York, NY: McGraw-Hill; 2005.

21. Zimet GD, Liddon N, Rosenthal SL, Lazcano-Ponce E, Allen B. Chapter 24: Psychosocial aspects of vaccine acceptability. *Vaccine*. 2006;24(Suppl. 3):S201–S209.

22. Van den Akker J, Gravemeijer K, McKenney S, Nieveen N. *Educational Design Research*. New York, NY: Routledge Press; 2006.

23. World Medical Association (WMA). WMA Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. WMA website. 2012. Available at: www.wma.net/en/30publications/10policies/b3/. Accessed April 25, 2012.

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