Cervical Cancer Prevention:
Practical Experience Series

Evaluating HPV vaccination pilots

PRACTICAL EXPERIENCE FROM PATH | 2012

PATH

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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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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 five 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 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 (this document) focuses on how program monitoring and evaluation can be accomplished within existing health infrastructures in an efficient manner.
5. **Cervical Cancer Screening and Treatment in Low-Resource Settings.** The fifth and final unit of this series examines the second component of a successful cervical cancer prevention program—screening and treatment of adult women for precancerous lesions.

For information about cervical precancer screening and treatment and related topics, visit the RHO Cervical Cancer Library (www.rho.org).

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.

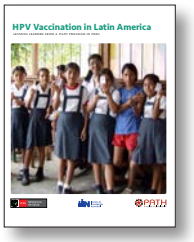
Information on cervical cancer

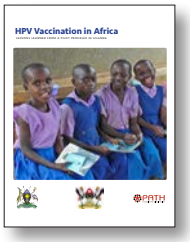
- The RHO Cervical Cancer Library is a comprehensive online source for detailed information about cervical cancer and how it can be prevented.
- *Outlook*: Progress in preventing cervical cancer: Updated evidence on vaccination and screening is a 12-page primer on all aspects of cervical cancer prevention,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

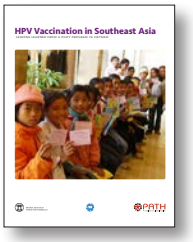
Results of the PATH demonstration projects

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.
- HPV Vaccination in Southeast Asia is a summary of lessons learned from the PATH demonstration project in Vietnam.







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ABBREVIATIONS/ACRONYMS

AIDS	**Acquired immune deficiency syndrome**
HIV	**Human immunodeficiency virus**
HPV	**Human papillomavirus**
NGO	**Nongovernmental organization**
PATH	**Program for Appropriate Technology in Health**
STI	**Sexually transmitted infection**
WHO	**World Health Organization**

Introduction

This unit presents experience from operations research evaluations of human papillomavirus (HPV) vaccination pilots, also called demonstration projects, in low-resource settings in India, Peru, Uganda, and Vietnam. It provides links to free online resources, such as questionnaires, checklists, interview guides, and data recording forms, useful to program managers, technical staff, and researchers planning to use operations research methods to evaluate an HPV vaccination pilot or demonstration project. Most of the resources come from a comprehensive research portfolio implemented by PATH and its partners: the Centre for Operations Research and Training (India), the Instituto Investigación Nutricional (Peru), and the Child Health and Development Centre at Makerere University (Uganda).

The objective of this unit is to offer methods and tools for designing and conducting an evaluation of an HPV vaccination pilot or demonstration project and to give practical examples of using the results to refine an HPV vaccine delivery strategy for national scale-up. Some of these resources may also be useful for evaluating aspects of a national HPV immunization program. Because the circumstances for each country will vary, a diverse set of examples and tools are included that can be adapted to local needs.

This document consists of four principal sections covering the primary outcomes that should be evaluated in an HPV vaccination pilot or demonstration project: coverage, acceptability, feasibility, and cost. For each outcome, the dimensions for evaluation, methodology and tools, and possible study populations are defined. Each section includes a case study that provides examples of how this outcome was evaluated and a summary of how the results were used to shape HPV vaccine delivery strategies. Depending upon the level of research rigor required for an individual country's evaluation needs, some components evaluated in the PATH HPV vaccine demonstration projects may not apply. Countries can adapt to fit their specific context.

The last section of the document summarizes which evaluation elements, methods, and tools were most useful for informing national decision-making, based on the PATH experience.

Rationale for evaluating HPV vaccination pilots

In its April 2009 publication Human Papillomavirus Vaccines: WHO Position Paper, the World Health Organization (WHO) recommended that countries should consider including HPV vaccine in their Expanded Programme on Immunization (EPI) for the prevention of HPV infection and its consequences, namely cervical precancer and cancer. Young adolescent girls, aged 9 to 13 years, were suggested as the primary target population, as they are the most likely to

benefit from the vaccine and the least likely to have been exposed previously to the human papillomavirus—the sexually transmitted virus that is the necessary cause of cervical cancer. However, with the exception of specialized campaigns for catch-up vaccinations, such as those for measles, or outbreak control, such as for polio, most national EPI programs do not routinely vaccinate girls aged 9 to 13 years.

Because HPV vaccine needs to reach a population not normally targeted for routine vaccination services and it is a new multi-dose vaccine for a disease that is not well-understood in communities, a phased approach to national introduction might be appropriate. Gaining HPV vaccine delivery experience through a small pilot or focused demonstration project can provide a rich opportunity for countries to design and shape a program prior to investing resources for full-scale implementation. Countries can gain insight into the design of, and components required for, an HPV vaccine demonstration project from other countries' experience and focused formative research. Two other Practical Experience units from PATH provide summaries of how to conduct formative research—Conducting Formative Research for HPV Vaccination Program Planning—and how to implement an HPV vaccine pilot or demonstration project—Implementing HPV Vaccination Programs.

Once an HPV vaccine demonstration project has been designed, it is important to develop an evaluation plan prior to program implementation. A systematic evaluation is a companion tool to routine program monitoring; it can identify programmatic aspects that were the most beneficial for program success and program weaknesses or barriers that could be mitigated. The results from such an evaluation can be used to refine program components and enable countries to capture the greatest value from their practical experience prior to national scale-up.

There are four overarching research questions that should be considered in the evaluation of each program outcome:

- Coverage: What level of vaccine coverage was achieved by the delivery strategy?
- Acceptability: Was the delivery strategy acceptable to communities?
- Feasibility: Was the delivery strategy feasible to implement?
- Cost: How much did it cost to implement the delivery strategy?

These questions will be explored in-depth in the following sections of this document. Tools and methodologies to explore, define, and assess the multiple dimensions of each program outcome are suggested, as well as study populations. Case studies are presented to illustrate how each research question was answered through the tools and methods provided and to summarize how the results were used to validate the HPV vaccine delivery strategy piloted or to refine the strategy for program sustainability and/or scale-up.

Coverage

Coverage is a defining measurement for any vaccination program. It is the indication of how well the program is reaching the target population. It is also used as a surrogate marker for both community acceptability and program feasibility. If a vaccination program reaches a large proportion of the target population, it implies that parents were accepting of the program and health workers could implement the program well.

The umbrella term coverage encompasses multiple dimensions. How coverage (i.e., which dimension) is calculated can influence the interpretation of the result.

Dimensions of coverage

Uptake

Uptake is the number of beneficiaries that received at least one dose of the vaccine. It often refers to the initiation of a vaccine series or first dose (if more than one dose is required). Uptake is usually expressed as a numeric value and often contains no denominator.

Uptake of HPV vaccine can count either the total number of girls who received the first dose or the number of eligible girls who received the first dose. For HPV vaccine, eligibility criteria have usually been established based on a girl's age or grade or class in school (for those attending). To evaluate a delivery strategy for uptake, definitions of uptake and eligibility should be specified in advance of implementing an HPV vaccination program (see Implementing HPV Vaccination Programs for discussion of target populations and coverage).

Example 1

- Eligibility: all girls aged 10 years.
- Uptake definition 1: all girls who received the first dose of HPV vaccine.
- Uptake definition 2: all girls aged 10 years who received the first dose of HPV vaccine.

Example 2

- Eligibility: all school-attending girls in primary grade 5 and all girls not attending school who are 10 years of age.
- Uptake definition 1: all girls who received the first dose of HPV vaccine.
- Uptake definition 2: all school-attending girls in primary grade 5 who received the first dose of HPV vaccine and all girls 10 years of age not attending school who received the first dose of HPV vaccine.

Continuation or completion

An additional dimension of coverage is continuation or completion of the vaccine series when more than one dose is required. It is recommended that girls receive three doses of HPV vaccine. To measure continuation or completion of the 3-dose series, initial data from uptake can be used to track progress for second and third dose such that the report of continuation or completion is done as a percentage of those who started the series (uptake). In this way, uptake becomes a denominator for continuation and completion.

Example

- Eligibility: all girls aged 10 years.
- Uptake: 4,250 girls aged 10 years who received the first dose.
- Continuation: number of 10-year-old girls who received the second dose divided by 4,250 (uptake), expressed as a percentage.
- Completion: number of 10-year-old girls who received the third dose divided by 4,250 (uptake), expressed as a percentage.

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Measuring coverage

Coverage is the proportion of eligible beneficiaries that completed all three doses of HPV vaccine divided by the number of girls eligible to receive HPV vaccine according to the delivery strategy and eligibility requirements of the program. Coverage is expressed as a percentage and is usually measured at the end of a program or calendar year. Coverage can be measured for each dose of vaccine delivered.

The critical difference between coverage and uptake is that coverage includes a denominator. The denominator is always defined as the total number of persons eligible to receive the vaccine according to prespecified eligibility criteria for the HPV vaccine delivery strategy.

Population-based coverage is most often measured through a survey of a representative sample of those eligible. Since the eligible population for HPV vaccination is young girls, the survey is usually administered to parents or guardians of the eligible population. Administrative records may be used to measure coverage if excellent and accurate census data and vaccination data (by age and dose) are available or the eligible population has been enumerated accurately prior to the initiation of a vaccination program. However, due to challenges with accurate tracking of doses delivered and robust, reliable estimates of denominators in routine immunization programs, a population-based coverage survey is usually the most accurate measure of vaccination coverage.

Example 1 (coverage only)

- Eligibility: all girls aged 10 years, regardless of school-attending status.
- Coverage: all girls aged 10 years (both in- and out-of-school) who were verified by a representative survey sample to have received all three doses of HPV vaccine divided by the total number of all girls aged 10 years included in the survey, expressed as a percentage.

Example 2 (coverage and uptake)

- Eligibility: all girls aged 10 years.
- Uptake among eligible girls: 5,000 girls received the first dose of HPV vaccine, of which 4,500 were aged 10 years and 500 were aged 11 years and older. Thus, uptake totaled 4,500 girls aged 10 years.
- Coverage: a representative sample of parents of 500 eligible girls aged 10 years was selected and surveyed, of which 450 were confirmed to have received all three doses of HPV vaccine. Thus, coverage was calculated at 90 percent.

Methods and tools

For all the measures of uptake, continuation, and completion, it is important to consider the eligibility criteria and to be able to collect, track, and tabulate vaccination data according to these criteria. If age or grade is a criterion, data collection forms need to record the grade in school and/or age of the girl vaccinated for each dose. If girls' attendance at school or not is a criterion, then this data point, too, needs to be recorded on vaccination tracking forms.

Most national EPI programs have established vaccination-recording tools available for infant immunizations. The PATH HPV vaccine demonstration projects adapted these existing forms to track HPV vaccine delivery. Annex 1 includes examples of tracking forms used during vaccination sessions for HPV vaccine [include tracking forms from India and Vietnam].

To measure coverage, WHO has provided a technical guidance document on designing and implementing vaccination coverage surveys, Immunization Coverage Cluster Survey—Reference Manual. This method utilizes a population-based representative sample of households with children eligible for a specific vaccine (or vaccines) based on the predefined criteria of the government program. The sample is drawn through a technique called two-stage cluster sampling. In the first stage, clusters are selected from the predefined area of the vaccination program. If the area is large enough, such as a district, clusters are often the census enumeration areas used by the national census bureau. Clusters need to have a fixed geographic boundary and be large enough to include the number of eligible vaccinees necessary for the sample size. The sample size is predetermined based on the estimate of coverage the survey team is expected to measure and the desired precision of the estimate. An excerpt from the WHO manual is provided in Table 1, which illustrates the number of vaccinees per cluster and number of clusters required to measure vaccination coverage at different levels. Once the number of clusters for the estimate of coverage is determined, then that number of clusters is selected proportion to population size from the total list of clusters available in the geographic area of the vaccination program. The second stage of the two-stage cluster sampling process is the random selection of households within the selected clusters. This two-stage process facilitates implementation without sacrificing statistical representativeness.

Table 1. Number of children per cluster, immunization coverage survey, precision ±5 percent*

DESIRED PRECISION ±5%		EXPECTED COVERAGE									
		50%	55%	60%	65%	70%	75%	80%	85%	90%	95%
NUMBER OF CLUSTERS	20	39	39	37	35	33	29	25	20	14	8
	21	37	37	36	34	31	28	24	19	14	7
	22	35	35	34	32	30	27	23	18	13	7
	23	34	34	33	31	29	26	22	18	13	7
	24	33	32	31	30	27	25	21	17	12	7
	25	31	31	30	28	26	24	20	16	12	7

* Adapted from WHO Immunization Coverage Cluster Survey—Reference Manual, Annex C: Determination of Sample Size.

It is important to note that the requisite sample size can be achieved either through a small number of large clusters or a large number of small clusters. For example, to estimate 70 percent coverage in Table 1, either 20 clusters of 33 eligible vaccinees or 25 clusters of 26 vaccinees can be selected (see shaded area). Both will result in the same precision of ±5 percent if coverage is expected to be 70 percent. Because coverage surveys measure receipt of all three doses of vaccine, they cannot be administered until the eligible population has had the opportunity to receive all three doses. Data on vaccine uptake and completion recorded during program implementation may provide insight into the level of

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coverage that the program may have achieved. These administrative records can be reviewed prior to establishing an estimate of vaccine coverage to measure through the coverage survey, provided that all persons who received the vaccine can be differentiated from those who met the predefined eligibility criteria of the delivery strategy in the administrative records.

If the objective of the coverage survey is to test whether coverage is significantly different between two areas, then the sample size needed for surveys in each area will be different and a different calculation is used (see Immunization Coverage Cluster Survey—Reference Manual, Table C-5). To apply this method, it is necessary to predetermine the difference in coverage expected between the two areas. In the PATH demonstration project, for example, one area implemented a school-based program for all 10-year-old girls with outreach to girls not in school, while a different area implemented a health center-based program where all 10-year-old girls (regardless of whether they attended school) were asked to come to the health center for HPV vaccine. The program's administrative records of vaccination sessions had indications that the health center-based program had reached 10 percent more of the eligible 10-year-old girls than the school-based program, so coverage surveys conducted in each area were powered to detect this difference in success and infer whether one strategy was more successful than the other.

The WHO immunization cluster survey methodology was adapted and field-tested for the first time on a population level in the PATH HPV vaccine demonstration projects. In all countries, the census enumeration area was used as the cluster; the census bureau in each country randomly selected the clusters needed for the specific survey based on the sample size projections calculated by the research team, using the WHO sample size matrix presented in Table 1. Only the point estimate for coverage within the selected strategy was measured, rather than doing comparative coverage surveys to detect differences. The

data collection tool or HPV vaccination survey was also adapted from a generic form available in the WHO Immunization Coverage Cluster Survey—Reference Manual, forms G-1 and G-2. Annex 2 provides copies of the HPV vaccination cluster surveys and the guides for survey administrators used in the PATH HPV vaccine demonstration projects.

Study populations

The study populations for evaluating uptake, continuation, and coverage are different because they are measuring different concepts using different tools. Table 2 summarizes the different tools and study populations appropriate for each dimension of coverage.

Table 2. Study populations and data collection tools to estimate HPV vaccine uptake, continuation, and coverage

DIMENSION	STUDY POPULATION	DATA COLLECTION TOOL
Uptake	1) All girls who received first dose of HPV vaccine, or 2) All girls who were eligible for the HPV vaccine program who received first dose of HPV vaccine	Routine tracking forms of vaccination sessions completed by health workers
Continuation	1) All girls who received second and/or third dose of HPV vaccine, or 2) All girls who were eligible for the HPV vaccine program who received second and/or third dose of HPV vaccine	Routine tracking forms of vaccination sessions completed by health workers
Coverage	Parents or guardians of girls who were eligible for the HPV vaccine program who received all three doses of HPV vaccine	Survey questionnaire administered at randomly selected households with girls who were eligible for the HPV vaccine program

Case Studies

Vietnam: multiuse coverage survey

Four districts in Vietnam implemented two different HPV vaccine delivery strategies: delivery to all girls in grade 6 through schools or delivery to all girls aged 11 years through health centers (1). A coverage survey was conducted for each strategy after each year of the two-year HPV vaccine demonstration project.

A representative sample of parents with daughters eligible for HPV vaccine was drawn for the coverage survey after the first year of implementation. The national EPI program had determined that it could leverage the opportunity of having this sample to do a population-based survey of knowledge, attitudes, and practices (KAP) among both parents and girls. The basic HPV vaccine coverage survey data collection tool was revised to include a comprehensive set of KAP questions and the sampling frame was revised to also invite the daughters of

parents who would complete the coverage survey to respond to the same KAP questions given to their parents [Annex 2]. The end result was a representative sample of parents and girls demonstrating their understanding of cervical cancer and HPV. The national EPI program was able to determine from these survey results that the level of knowledge about some dimensions of disease or the program among both girls and their parents were lower than they wanted. They therefore revised their educational materials and communication strategy for the second year of program implementation.

Vietnam was able to use the results of the coverage survey completed after the second year of implementation to decide which strategy would be best, if they were to scale up nationally. These results indicated that coverage achieved through the school-based strategy was 96.1 percent (93.0–97.8) and through the health center-based strategy was 98.6 percent (95.7–99.6) (1). The overlapping confidence intervals on these coverage estimates indicated that there was no statistically significant difference in the coverage achieved by the two strategies. Therefore, the government of Vietnam can feel confident that either strategy could be successful upon scale-up.

Uganda: coverage versus uptake

In Uganda, as in Vietnam, a coverage survey was conducted after each year of HPV vaccine implementation. Two districts participated, each implementing a different delivery strategy. One district used schools as the vaccination venue, and eligible girls were those in primary grade 5. The other district delivered HPV vaccine as part of an existing health outreach program called Child Days Plus (CDP), and eligible girls were those aged 10 years. Both strategies included scheduled special sessions for girls absent on vaccination days due to illness, non-attendance, or other reasons. The results of the coverage survey showed that the school-based program resulted in approximately 90 percent of the eligible girls receiving all three doses of HPV vaccine, whereas the approach using CDP resulted in just over 60 percent of the eligible 10-year-old girls receiving all three doses (1). The latter result was surprising to the national EPI program, as uptake data from the area recorded 3,277 girls receiving the first dose and 73 percent of those completing the three-dose series, suggesting that more than just 10-year-old girls (the target population) were vaccinated. This highlighted the difference between uptake and coverage and the strengths and weaknesses of the methods used to calculate each.

The coverage survey also explored why some girls did not get vaccinated. The most frequent reasons stated by mothers were difficulty in determining age (exact birth dates are not always recorded) or not being aware of the program and who was eligible (1). These results were used by the Uganda EPI program to change the delivery strategy for HPV vaccine to a hybrid strategy: using the CDP program and selecting girls based on their grade in school. The national EPI program has used this hybrid strategy for two additional years in the districts that participated in the HPV vaccine demonstration projects. It has reported that about 80 percent of eligible girls have completed all three doses.

Acceptability

Even though coverage is the ultimate measure of vaccine acceptability, other dimensions of acceptability could provide additional insight as to why parents agreed (or did not agree) to have their daughter vaccinated with HPV vaccine. These considerations are important for community education and mobilization efforts and can provide useful insights for future national scale-up.

Dimensions of acceptability

Reasons to get or not to get vaccinated

Parents' motivation or reluctance to have their daughter vaccinated should be explored as they can contribute to program success or act as barriers to uptake of vaccine. Motivating factors to vaccinate can be leveraged in community outreach and education to foster an enabling environment for the vaccination program. Factors that may motivate parents to accept vaccination include feeling informed, being influenced by others they trust, or wishing to be compliant with health recommendations. Understanding barriers allows program managers to address them with the most appropriate and targeted responses. For example, it can help them to determine whether an obstacle is programmatic or personal, which could require different responses. These obstacles could be lack of information, lack of motivation, lack of opportunity, refusal (by parent or child), among others.

Influencers

The decision to have a child vaccinated or not can also be influenced by those around the parent, such as spouses, other family members, extended networks, or community leaders (2). Understanding whether a specific person, such as a religious leader, or type of person, such as health workers, played a role in the decision-making process of parents can be useful for an HPV vaccination program. If these persons or groups played facilitating roles in vaccine acceptance, program managers could use this information to more strategically disseminate information about the HPV vaccination program. If these persons or groups played a negative role in the community and helped shape parents' decisions not to vaccinate, immunization programs could use that information to consider how to address this negative influence. The most critical information to collect regarding this aspect of acceptability is which specific person or type of person shapes the opinions of parents. It is important to note that since the target age group for HPV vaccine is girls 9 to13 years old—ages when they could exert influence on decisions regarding their health—the influencer for parental decisions could be the girl herself.

Information, education, and communication materials

Comprehensive and relevant information about cervical cancer, HPV vaccine, and the HPV vaccination program is important for informed decision-making (3-6). Knowledge could be a factor that helps parents to accept or not accept vaccination for their daughters. However, there are many more facets of information, education, and communication (IEC) materials that may be of interest to program planners and managers: what materials were received, who delivered the materials, whether parents read the materials , whether the materials were comprehensible, whether the key messages in the material resonated with parents, and whether the information in the materials met the needs of the parents (i.e., were their questions answered through the materials and was the content of the materials presented in a visually appealing way). The collection of this information will also be important if a program had a prespecified target of what materials parents and/or girls should have received as a part of the communication strategy prior to HPV vaccination. Gathering this information could determine if this target was met.

Communication strategy/community sensitization

How parents receive information is often just as important as the information itself. Good plans for HPV vaccinations should outline a specific communication strategy for educating parents and communities and creating a positive environment for vaccine acceptance. It is also important to measure whether the communication strategy that was designed was actually implemented, and what aspects of that implementation were most relevant for vaccine acceptance.

The dynamics of the communication strategy include: what materials are disseminated (covered above); who disseminates the information (teachers, health workers, health communicators, and others); how the dissemination happens (such as parent-teacher meetings, educational sessions, home visits, via the radio or mass media, with posters or billboards, etc.); the frequency of the communications (e.g., every day, every week, the end of the school week, etc.); and the timing (three times a week, twice in the two weeks prior to the vaccination dates, etc.).

Methods and tools

A range of methods and tools can be employed to measure the dimensions of vaccine acceptability. Both quantitative and qualitative methods and tools are discussed in this section.

Quantitative methods utilize surveys, usually from a representative sample of the group being studied, such as parents. This approach has many advantages. Survey questionnaires provide an opportunity to standardize questions so that they are asked in the same way to all respondents. Questions can also be arranged in a specific order so that answers to questions in the beginning of a survey do not influence answers to subsequent questions. Surveys also have the advantage of being fairly easy to administer in the field, and their length can be fixed to facilitate efficient data collection. Quick and easy-to-administer questions that answer “what,” “when,” “who,” and “where” tend to

be well-suited to a quantitative survey. A quantitative approach can often make drawing a representative sample of the target population easier, thus increasing the possibility that the results could be inferred or generalized to the larger population.

There are limitations with this approach, as well. Surveys with fixed responses limit the types of questions that can be asked, such as yes/no or predefined response options. The information gathered tends to be descriptive—what was done or what was received. It can be difficult to collect more nuanced information or in-depth details that might describe why certain actions or decisions were taken, as the range of responses for these types of questions could be difficult to prespecify. Surveys also limit the interviewer's ability to ask follow-up questions that probe more deeply, due to the need to balance a questionnaire that could be easily and quickly administered and that has the level of detail that might be of interest. Lastly, depending on the timing of the survey, some data could be subject to higher rates of recall bias. For example, if the survey is administered many months after a communications strategy was employed, respondents may not be able to remember specifics, such as what material was received, who it was received from, and how often they were exposed to IEC messages.

In the PATH HPV vaccine demonstration projects, the data collection tool to measure HPV vaccine coverage was adapted to gather these additional dimensions of acceptability in a quantitative way. The generic form available in the WHO Immunization Coverage Cluster Survey—Reference Manual, Form G-2 provided a framework for collecting data related to reasons for children not being vaccinated. Response categories were organized around three themes: lack of information, lack of motivation, and obstacles. PATH built on this framework, adding questions about reasons parents accepted HPV vaccination and exploring any barriers with non-acceptors. Because the coverage survey used a representative sample of parents of girls eligible for vaccination, additional quantitative questions related to influencers for vaccination and exposure to IEC materials and the communication strategy were also included, keeping in mind the limits of parental recall as the survey was administered seven to nine months after parents may have received the original IEC information. Annex 2 provides copies of the HPV vaccination cluster surveys, which include these additional questions.

One additional issue to consider when collecting quantitative data for dimensions of acceptability is whether to ask open-ended questions or fixed-response questions. In open-ended questions, usually the interviewer asks the question and then records whatever response is made without prompting of prespecified choices. Categories for data recording of likely responses can be predefined and included on the data collection form; however, these are not read to the person being interviewed and are only used to organize and record responses more efficiently. In fixed-response questions, the interviewer reads all the answer options to the person being interviewed, then either directs them

PATH/Robin Biellik

to "select the one that fits best," or to "select all that apply," or to specifically answer "yes" or "no" to each individual response category. There are advantages and disadvantages with each type of question. There are trade-offs with both methods, as reading predefined categories might bias parents into selecting specific reasons, but open-ended questions may take more time during data collection and add complications for the field research team.

In the PATH HPV vaccine demonstration projects, open-ended questions were asked to obtain reasons to vaccinate or not vaccinate and the person(s) that might have influenced parental decision-making; all responses made by parents were recorded in prespecified categories of likely responses, with a further option of "other" where the exact response of the parent was written. Fixed-response questions were asked regarding information related to the IEC materials and the communications strategy, as it was important to know if the parents received each type of material or communication method used. These data were then used to refine the communications strategy in the following year to ensure those materials and methods that resonated most with parents were the ones replicated. Please refer to Annex 2 for examples.

Qualitative methods, such as focus group discussions or semi-structured interviews, provide an opportunity for in-depth exploration of "why" and "how." These techniques encourage free expression of ideas about the topics and full understanding of the range of views, experiences, and attitudes that may exist within different groups that might participate.

Focus group discussions (FGDs) can provide information and cross-validation through group interaction. FGDs can be used to elicit normative data on

attitudes, perceptions, and practices. Sample FGD guides used in acceptability research with girls and parents are provided in Annex 3.

Semi-structured interviews (SSI), including with key informants in 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 method can also be used if it is difficult to gather enough participants for a focus group discussion or if the target population is too small to build a representative sample. In both Uganda and Vietnam, very few girls did not get vaccinated, making it difficult to gather a large enough group of parents to explore in-depth reasons for non-vaccination and the details of the communications strategy. Instead, a purposive group of parents of girls who did not get vaccinated were identified from the health worker records and invited to participate in the SSI. Examples of these interview guides can be found in Annex 3.

In India, exit interviews were conducted with girls after they received doses one and two of HPV vaccine. These interviews complemented surveys of parents, exploring the vaccine recipients' reasons for accepting vaccine. This approach was unique to the India project, where girls in the target age group of 9 to 13 years old were frequently involved in deciding for themselves whether to get vaccinated. A sample exit interview form is also included in Annex 3.

Study populations

The principal study populations for vaccine acceptability are those most directly impacted—girls, as beneficiaries, and their parents or guardians, as decision-makers. Table 3 provides a summary of study populations and data collection tools as they relate to the different dimensions of HPV vaccine acceptability.

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Table 3. Study populations and data collection tools to measure dimensions of HPV vaccine acceptability

DIMENSION	STUDY POPULATION	DATA COLLECTION TOOL
Reasons to vaccinate/ not vaccinate	Parents or guardians of girls eligible for HPV vaccine	Coverage survey questionnaire Focus group discussion guide Semi-structured interview
	Girls eligible for HPV vaccine	Coverage survey questionnaire Focus group discussion guide Exit interview
Influencers	Parents or guardians of girls eligible for HPV vaccine	Coverage survey questionnaire Focus group discussion guide Semi-structured interview
IEC materials	Parents or guardians of girls eligible for HPV vaccine	Coverage survey questionnaire Focus group discussion guide Semi-structured interview
	Girls eligible for HPV vaccine	Coverage survey questionnaire Focus group discussion guide Exit interview
Communication strategy/ community sensitization	Parents or guardians of girls eligible for HPV vaccine	Coverage survey questionnaire Focus group discussion guide Semi-structured interview
	Girls eligible for HPV vaccine	Coverage survey questionnaire Focus group discussion guide Exit interview

Case study

India: using multiple data sources to create a richer picture of community sensitization

In all four demonstration project countries, researchers measuring HPV vaccine acceptability and its dimensions utilized multiple data collection techniques with different populations to leverage the strengths that each provided. In India, the two state governments implementing the vaccination strategy wanted to learn about the diffusion of the IEC materials on cervical cancer and HPV vaccine, any influence of the communication methods used to disseminate information, and whether there was active interaction among parents and health workers, teachers, and others who were involved in delivering key messages. To assess these dynamics comprehensively, both qualitative and quantitative techniques were employed.

The HPV vaccine coverage survey included specific questions on the IEC materials parents received to determine whether they read and understood the materials and found them beneficial (Annex 2). Exposure to other community sensitization activities, such as talks by health workers, the identities of others with whom parents generally spoke regarding HPV vaccine, and who delivered which aspect of the communication strategy were also assessed in this survey. These quantitative data were complemented with qualitative data collected in a different survey administered to a different study population of parents (Annex 3). The results of analysis of both sets of data highlighted similarities in the materials and messages that parents received, as well as key information related to who delivered the message and the influence this person had on parental decision-making to accept HPV vaccine for their daughter. For example, the IEC pamphlet was the most frequently received written material by parents, but the factors that were strongly related to vaccine uptake were the delivery of this information by trained personnel, such as the health worker, and the one-to-one communication that this opportunity provided (7). This information was used to refine and optimize the communications strategy by utilizing methods and messages that were most influential with parents.

Feasibility

Achieving high coverage in a vaccination program can also be a surrogate indicator of its feasibility. However, as with acceptability, there are many dimensions to what makes a program feasible to implement and sustain. Understanding how program components worked in the context of a demonstration project can reveal how well implementation went according to

the plan, easy and difficult aspects, unexpected barriers, and the programmatic resources used. Taken together, this information can be used by program planners and managers to design a national scale-up plan that leverages the things that worked well and incorporates improvements needed to address those things that did not work well.

Dimensions of feasibility

Collaboration/cooperation

Because HPV vaccine crosses several programmatic domains, especially if schools are used as a location for vaccinations, implementing the delivery strategy may require collaboration across sectors that may not have strong working relationships. Collaboration is the degree to which the principal players in the vaccination program performed their preassigned roles and the cooperation achieved across sectors to support successful implementation. This information is used to understand how these linkages functioned and where breakdowns impeding implementation may have occurred. This dimension tries to understand the mechanisms employed at all levels of the health system to foster the cooperation needed in program delivery, so it is important to measure this at national, state, provincial, district, and local levels.

Workload/human resources

The human resource requirements to deliver HPV vaccine to young adolescent girls may be different from those employed in immunization programs targeting infants. Understanding the level of effort that was employed will facilitate country planning on resource needs if national rollout is planned. This information can also be used to understand what additional time and labor effort might be required to add HPV vaccine to existing duties of personnel working in the routine immunization program. This dimension is the number and types of personnel needed for planning, implementing, and monitoring HPV vaccinations and the time requirements of such for each dose of delivery and by all levels of the health system involved. If a school-based delivery strategy is used or if schools are used to facilitate community sensitization, then the human resources utilized in schools should also be measured.

Training

The feasibility aspect of training covers a wide range of topics from content and materials to training methods and audiences, as well as the resources required to develop, implement, and evaluate the training activities. Assessing these on a small training program conducted prior to implementation of an HPV vaccine demonstration project provides an opportunity to ascertain the scope, depth, and breadth of such an activity that may be required when taking the vaccination program to scale. This dimension should measure who was trained, by whom, on what aspects of the program, for how long, the resources used to

develop the training curriculum and implement the training, and the adequacy of the training to prepare trainees to perform their assigned functions in the vaccination program.

Cold chain system

Cold chain capacity and management is a cornerstone of any vaccination program. Like training, there are myriad details about the cold chain that could be evaluated to understand how feasible it is to include HPV vaccine into the current system. Storage space at national, regional, provincial, and district levels; availability of vaccine carriers and icepacks for carriers at the local level; adequate distribution and transportation systems; and vaccine supply should all be assessed before and during delivery of HPV vaccine. The maintenance of the required temperatures within the system should also be monitored. Lapses in any of these aspects of the cold chain system during an HPV vaccination pilot could indicate critical areas to strengthen prior to national introduction.

Supply chain

In addition to the vaccine supply, adequate availability of other supplies that are necessary for immunizations should be assessed before and after program implementation. Quantities of syringes, cotton swabs, sharps boxes, medical waste containers, anaphylaxis kits, and other supplies should be inventoried. The assessment helps programs ensure that their projections of supply needs are based on the target population to vaccinate. Assessing the supplies used at the end of program implementation allows for reflection on how well the projected supply met the needs and to uncover any barriers related to supply distribution (timing and delivery) so that program improvements can be made for subsequent rounds of vaccination.

Transport

There are several transport needs for vaccine delivery. Transporting the vaccines and supplies has been discussed above. Transporting health workers is another critical need, especially for routine outreach vaccination sessions or for school-based delivery. Transport should include number of people transported, by what means, and for what distance and time. These data can be used to compare the microplan for vaccine delivery and human resource with that actually implemented in the program. Estimates of time and human resources for transport could then be figured into any calculation of these needs to bring HPV vaccination to scale. Considerations of the transport used in urban, rural, and remote settings should be a part of this assessment.

Mobilization

The activities involved in mobilization are complementary to those involved in community sensitization. Mobilization activities are often done the day before or day of vaccination to ensure the target population and community at-large are sufficiently aware of the impending vaccinations. As with transport, the

human resources used to mobilize, how the mobilization was carried out, the time and travel requirements, and the geographic area of mobilization (urban, rural, remote) should be tabulated and described when evaluating this dimension of feasibility. Characterization of the activities and resources utilized will allow programs to qualify and quantify mobilization activities, relate these to the vaccine coverage achieved, assess which might be most relevant for scaling up, and determine if changes will be needed during subsequent vaccination rounds.

Identifying target population

Without an existing registry of girls in the target group for vaccination, identification poses a challenge for HPV vaccine delivery. Understanding the mechanism to identify eligible girls and assessing whether in fact the correct girls were identified and offered HPV vaccine are critical aspects of the feasibility of program delivery. This dimension measures the process by which the target population was identified, and the ease or difficulty of completing this activity. Human resource effort to accomplish this in terms of both time and type of personnel should also be considered.

Location of vaccinations

The vaccine delivery microplan will outline the locations for vaccination and the vaccination schedule for each dose, as well as assign staff to implement the program. This evaluation dimension compares the plan for locations of vaccination with the actual locations used during the program for each dose. It should also describe which girls (e.g., those in school/out of school) and how many were captured at each type of vaccination location (e.g., schools, health centers, routine outreaches, etc.). The data generated will be important for planning of national delivery and human resource requirements by giving an understanding of what proportion of the eligible population could be targeted through each vaccination location and where any gaps in population coverage occurred.

Record keeping

Routine data collection provides valuable information to program planners and managers on vaccine delivery and system performance. These data confirm whether the correct target population has been served, the quality of the service delivery, the adequacy of the supplies, the performance of the cold chain system, the monitoring of adverse events, and the monitoring and supervision provided for the program. The data recorded should be checked for completeness, accuracy, and timeliness.

Adverse events and their monitoring

Monitoring of adverse events following immunization (AEFIs) is used to assess continued safety of the vaccine and uncover serious, unexpected, or rare events that might not have been observed during vaccine clinical trials. The ongoing validation of vaccine safety provides reassurance to the community and fosters

trust in the immunization program more broadly. Standard definitions of adverse events are provided by WHO(8):

- An adverse event is any untoward medical occurrence among beneficiaries, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.
- A serious adverse event (SAE) is any untoward medical occurrence that: results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or is a congenital anomaly/birth defect in the offspring of a vaccine recipient.

Each vaccine will have specific morbidities that might be particular to that vaccine (e.g., injection site pain, nausea, light-headedness, etc). If these are known, they should be monitored by type. The AEFI reporting system should be assessed for the events reported, time of report, health worker action, appropriateness of the response, and proper recording and reporting of the event to the required health authorities.

Vaccine wastage

Vaccine wastage is the amount of vaccine lost, damaged, or misused during the storage, transport, or use of the vaccine. It is usually calculated from the vaccine usage rate based on doses issued and administered, as described in the WHO manual Monitoring Vaccine Wastage at Country Level. The number of doses issued, allocated to a specific facility, or distributed to a specific health worker is recorded. During implementation of vaccinations, all doses used are recorded; any vials that are broken, dropped, determined to have been exposed to freezing (shake test), expired, or otherwise cannot be used for immunizing the target population are recorded as wasted doses. The wastage rate is the inverse of vaccine usage and is calculated as the number of doses issued minus the number of doses administered divided by the number of doses issued (times 100 to get a percentage). Standards for allowable wastage rates have been set by WHO (9). The resulting figure from an evaluation of vaccine wastage in an HPV vaccination pilot can be compared to these standards.

Supportive supervision

Supportive supervision involves working with health staff to establish goals, monitor performance, identify and correct problems, and proactively improve the quality of service. Prior to vaccination implementation, a supportive supervision plan may be established. The assessment of the feasibility of supportive supervision entails reviewing the plan compared to what was actually implemented, reviewing health worker performance and any corrective action taken, and describing follow-up for improved performance. The number of supportive supervision visits made and the number of health workers and/or vaccination sessions where supportive supervision was provided should be tallied and reported. A description of how well the plan performed can be used to inform a national scale-up plan, and weaknesses identified can be used to provide

refresher training on vaccination for health workers that might be needed to make national scale-up feasible.

Methods and tools

As with acceptability, methods and tools to assess the feasibility of HPV vaccine pilots are numerous and diverse, utilizing both quantitative and qualitative techniques. Most of the dimensions of feasibility are common to any immunization program, so there is a plethora of tools available to, and in use by, countries that would require only small adaptations to assess HPV vaccination feasibility.

Structured or semi-structured questionnaires (referring to the degree to which open-ended questions are used) can be administered with a variety of populations who are involved in program preparations or delivery. These tools are suited well to health workers and others implementing the program. Questions can be crafted to explore their direct involvement and facilitate easy recall, and to collect data in a timely manner. The type of person sampled to complete such a questionnaire influences the type of interviewing technique conducted and whether a structured or semi-structured questionnaire is appropriate. These interviews are often called "key informant" or "in-depth" interviews, where key informant refers to the respondent and in-depth refers to the breadth and depth of the scope of the interview.

Key informants tend to be purposively selected based on their specific role in the program, which would be different from other respondents. Questions included in their interview usually probe program aspects in more depth. For example, interviewing the senior health worker in charge at a specific facility as a key informant may elicit details on program administration that may not be reflected in comments from a more general health worker. The dimensions of training, workload, mobilization, identifying the target population, AEFI, and supportive supervision may be covered in these interviews. Examples of different interview guides used with different groups are provided in Annex 4.

Focus group discussions with groups of health workers or others involved in program preparations or delivery could be a valuable method to use to collect richer data that describe the "how" and "why" related to different aspects of feasibility. Dimensions of collaboration, human resources, transport, and supportive supervision might be well-suited to this methodology. Annex 4 has some examples.

Quantitative tools such as facility observations using checklists or time-motion assessments are appropriate for data that are easily tabulated. Questions related to "how much," "how long," quantities and volumes, distance, and resources expended are well-suited to quantitative measurement. The dimensions of workload, human resources, cold chain, supplies, transport, mobilization, location of vaccinations, record keeping, AEFI monitoring, and vaccine wastage

are often captured using these tools and techniques. Because these aspects are common to all immunization programs, the tools for monitoring and evaluating them are already largely available and widely used. Examples of tools adapted for the HPV vaccine demonstration projects by PATH are provided in Annex 4. A review of existing tools used by the national EPI program could uncover local tools that could be easily modified for HPV vaccine delivery.

The advantages and disadvantages of using each of these techniques and tools to measure feasibility are the same as those described in the acceptability section of this document.

Study populations

The principal study populations for feasibility are those who were directly involved in the planning and implementation: primarily health workers and district and/or regional EPI leaders. If schools or the education structures are used for sensitization, mobilization, or vaccination, then teachers and school headmasters are an important population to include.

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Table 4. Study populations and data collection tools to measure dimensions of HPV vaccine feasibility

DIMENSION	STUDY POPULATION	DATA COLLECTION TOOL
Collaboration/ cooperation	Health workers Teachers/school leaders Other EPI personnel, such as cold chain managers District health and education leaders	Semi-structured or key informant interviews Reports from routine supervision visits
Workload/ human resources	Health workers IEC workers/ community sensitizers Teachers Mobilizers District EPI leaders	Vaccination tally sheets Semi-structured or key informant interviews Attendance logs for training or microplanning exercises Time-motion assessments Vaccination observations
Training	Health workers IEC workers/ community sensitizers Teachers Mobilizers District EPI leaders	Attendance logs for training exercises Semi-structured or key informant interviews Pre/post-training evaluation survey
Cold chain system	Health facilities EPI cold chain managers	Existing cold storage logs UNICEF cold chain monitoring tools Existing vaccine storage requirements calculator Existing vaccine supply and distribution logs Existing temperature tracking sheets Semi-structured or key informant interviews
Supply chain	Health facilities District EPI leaders	Existing supplies and distribution logs Semi-structured or key informant interviews
Transport	Health workers IEC workers/ community sensitizers Mobilizers District EPI leaders	Existing transport tracking sheets for supplies and vaccine distribution Existing district records on transport requirements and use Vaccination tally sheets by health workers, linking health center with location of vaccinations to calculate distance Semi-structured or key informant interviews Adaptation of microcosting data collection tools from facilities

DIMENSION	STUDY POPULATION	DATA COLLECTION TOOL
Mobilization	Health workers Teachers Mobilizers	Existing mobilization tracking sheets Existing district records on mobilization activities, transport, and time spent Semi-structured or key informant interviews Adaptation of microcosting data collection tools from facilities
Identifying target population	Health workers Teachers District EPI leaders	Vaccination tally sheets and/or registers Semi-structured or key informant interviews
Location of vaccinations	Health workers Teachers District EPI leaders	Vaccination tally sheets and/or registers Semi-structured or key informant interviews
Record keeping	Health workers District EPI leaders	Desk review of existing record keeping forms Semi-structured or key informant interviews
Adverse events and their monitoring	Health workers District EPI leaders	Existing AEFI monitoring reports Coverage survey data from parents Semi-structured or key informant interviews
Vaccine wastage	Health workers District EPI leaders	Vaccination tally sheets Existing vaccine supply, distribution, and return receipt logs
Supportive supervision	Health workers District EPI leaders	Checklist/vaccination observations Reports from routine supervision visits Semi-structured or key informant interviews

Case study

Uganda: determining which delivery strategy is most feasible

Uganda implemented two different vaccine delivery strategies in two different districts. A school-based program was used in a district that had not previously used schools routinely to deliver immunization, requiring new coordination and collaborations with the local education system and schools. This strategy selected all girls in primary grade 5 as eligible for vaccination. If girls were not enrolled in school, they received outreach and the eligibility criterion was being 10 years of age.

A second district combined HPV vaccine delivery with the existing CDP community outreach program that brought health interventions, such as deworming and vitamin A distribution, to large segments of the population less than 18 years old. CDP is implemented twice a year at 6-month intervals, which matches the dose schedule for doses 1 and 3 of HPV vaccine. Dose 2 was administered as a separate outreach campaign. This strategy selected all girls aged 10 years in the entire district, regardless of whether they were enrolled in

school. Two features of the CDP program were of interest to the Uganda Ministry of Health for possible leveraging:

- The program was already funding health workers to leave the health post and go out into communities. Adding HPV vaccination therefore might not require additional resources for transport or supply distribution.
- The program largely used schools to gather children together to receive deworming, vitamin A, or other health interventions that were planned. The Uganda EPI could capitalize on the existing concentration of the target population to deliver HPV vaccine, and thus reduce mobilization needs.

Each of these delivery strategies had possible advantages and disadvantages. The results of the feasibility assessment of these programs revealed notable similarities and differences, which informed district and national EPI leaders as to the strategy that would work best (1;10). A key programmatic similarity between the two was the use of schools as a location for vaccinations. Even though the CDP program was community-based, health workers in this district had already been coordinating with schools to use their facility as a gathering place for children to receive the CDP program services. Thus, the relationships had already been established and planning exercises to determine dates of delivery were familiar to both teachers and health workers. The routine vaccination tally sheets used in both strategies revealed that nearly all girls who were eligible for HPV vaccination were enrolled in school, principally due to the establishment of free universal primary education in Uganda in 1997. Existing tracking forms for vaccine supply, cold chain, AEFI, and vaccination tally sheets showed that each district performed similarly in these aspects.

The critical difference picked up in the feasibility assessment, through the vaccination tally sheets, interviews with health workers and teachers, and even the coverage survey administered to parents, was the challenge with identifying the target population eligible for vaccinations—those girls aged 10 years. The recording of age or date of birth on health or school records was largely absent and there was variability in how girls themselves perceived their own age. Birth certificates were rare and baptismal records often were incomplete or inaccurate. It was inefficient to go to each and every home and ask parents. By contrast, in the school-based delivery program, every teacher knew who was in their primary grade 5 class, and most people in the community (and the girls themselves) knew the grade in which they were enrolled. This finding, combined with the result of the cost analysis done for each delivery strategy (see following section), resulted in the national EPI program adopting a delivery strategy that utilized the CDP mechanism for delivery, and eligibility was based on grade in school (lowered to primary grade 4, as

this grade largely held girls aged 10 years). Since over 99 percent of girls in these areas were found to be attending primary school, the extra burden to extensively implement an outreach program for girls not in school was greatly reduced.

Cost

The cost of delivering HPV vaccine to young adolescent girls is the last domain of critical importance. The economic and financial costs associated with the HPV vaccination demonstration projects can be used to evaluate affordability, sustainability and cost-effectiveness of future scale-up of HPV vaccinations. Specifically, cost and cost-effectiveness analysis can guide decisions about the most appropriate mix of strategies and the best way to allocate scarce resources, as well as to provide information on the level of resources that will be needed to start or expand a project. Additionally, cost data can assist managers in deciding on the most appropriate way to deliver HPV vaccination strategies for their country setting.

The implementation of the cost analysis in the PATH demonstration projects was integrated with other evaluation activities that assessed the acceptability and feasibility of introducing HPV vaccines to young adolescent girls. In this way, a final evaluation can address coverage, feasibility, and costs among the same set of facilities or schools and reflect the resources used to achieve the observed participation and HPV vaccination coverage among a demonstration project population.

Each analysis was from a government cost perspective and was associated with HPV vaccine services offered through public-sector health facilities. Since HPV vaccination activities were integrated into national immunization programs, each cost analysis estimates the incremental delivery costs and considers the value of all program resources used for start-up and recurrent activities to deliver HPV vaccine to the target population.

Dimensions of cost

Economic

The economic costs capture both the additional program implementation expenses to introduce the HPV vaccine, as well as costs of shared resources, reflecting the opportunity cost of all resources used to vaccinate girls with the HPV vaccine. Both the costs funded by the HPV vaccination pilot and those contributed by the routine EPI are included. Economic costs also include the value of any goods or services that may have been donated or that may not have been captured in the project or government budgets.

Financial

Financial costs capture the actual financial expenditures that would be needed to deliver HPV vaccine according to the vaccination strategies of the demonstration project. The financial costs omit the capital depreciation and salary costs that were already paid for by ministries of health and that are shared with existing immunization or other health services. Financial data can be used to estimate scenarios that scale up HPV vaccination beyond the scope of the pilot.

Start-up and recurrent

For both economic and financial costs, there are expenses that are incurred usually once at the beginning of a program (start-up) and those that need ongoing financing as they will be required each year the program is implemented (recurrent).

Activities included in start-up costs are microplanning, social mobilization and community sensitization, IEC activities, training, and capital equipment. These costs are treated as fixed costs because they typically occur only in the first or second year of introduction, or are at least at a much reduced level in subsequent years. Start-up costs should be estimated at each level of the system.

Activities included in recurrent costs are HPV vaccination-related staff time, salaries, and allowances; injection devices and supplies; waste disposal and management; vaccine transport, storage, and distribution; and depreciation.

Methods and tools

Activity-based microcosting and an expenditure ingredients approach are two common methods used to estimate economic and financial costs of vaccine delivery, as detailed in the WHO Guidelines for Estimating Costs of Introducing New Vaccines into the National Immunization System. Data collection can be through observation, interviews with project staff, and review of budget expenditure data from the ministry of health to gather information on the quantities of inputs and resources for specific activities. Different tools can be used for different activities or for the same activity for cross-verification purposes (Table 5). For example, key informant interviews with health workers about the time and resources used to vaccinate can be complemented with direct observation of health worker time and resource use during vaccine administration. Additionally, inputs, such as supplies and equipment, observed during vaccinations can be cross-verified by regional or national expenditure reports. Annex 5 provides examples of different data collection tools for microcosting.

Data from each level of the health system must be collected to assess the contribution of each, as the activities to support HPV vaccination are likely to vary by level. For example, training is typically paid for at the national level and occurs at subnational administrative levels, such as provinces or districts. Meanwhile, vaccine supply chain costs may occur at each level of the system

where vaccines are stored and transported. Service delivery typically occurs at lower levels of the health system through district or community level health facilities. To estimate recurrent unit costs per dose, data can be collected from key informants after the second or third round of HPV vaccination about resource use for the most recent round of vaccinations completed.

Table 5. Cost components and data collection tools to measure resource use and costs of HPV vaccine delivery strategies

DIMENSION	COST COMPONENT	DATA COLLECTION TOOL
Start-up costs	Microplanning Training IEC materials development and printing Social mobilization and community sensitization	Expenditure reports Key informant interviews Direct observation
Recurrent costs	HPV vaccination-related staff time Salaries and allowances Injection devices and supplies Operational costs for vaccine transport, storage, and distribution Depreciation on capital equipment (vehicles, cold chain equipment) Waste disposal and management	Expenditure reports Key informant interviews Direct observation

Cost indicators

Cost data can be analyzed in Microsoft Excel to estimate the following indicators for costs associated with reaching the vaccine coverage levels in each country setting:

- Total incremental costs for each strategy.
- Incremental cost per dose of HPV vaccine delivered.
- Incremental cost per fully immunized girl.

These same indicators can be measured for both economic and financial costs, as was done in several countries that estimated scenarios for projecting costs of a typical program that may be scaled up nationally.

Average delivery cost per dose of HPV vaccination can be estimated for each country, strategy, and geographic or administrative location. While the analytical methods used in the PATH projects are beyond the scope of this guide, all data were analyzed using Microsoft Excel. In each setting, a Microsoft Excel model was used to calculate the average cost per dose incurred for the health-center level. The average health center cost per dose was then added to the cost per dose at each higher-level tier of the system (national, state or region, block or province, district, health center) by geographic region. To estimate total economic costs, a weighted average cost per dose was calculated and multiplied by the total number of doses delivered.

The incremental cost per fully immunized girl is the total economic cost divided by the number of girls who received all three doses of the HPV vaccine.

Annex 5 provides one example of a plan for this type of analysis.

Study populations

Health facilities at local, district, provincial, regional and national levels make up the study population for a microcosting study of HPV vaccine implementation. The selection of facilities and the number of each should be based on criteria relevant to understanding differing capacities or structures, such as size of the facility, number of girls in the eligible population, geographic area (e.g., urban, rural), number of schools in the facility's catchment area (for school-based delivery), the overall EPI performance of the facility as represented by infant immunization coverage rates, and the performance of the facility during the HPV vaccination pilot as represented by estimates of HPV vaccine coverage. Criteria-based purposive sampling for the number of facilities at each level should be used to ensure that the widest diversity of facilities is included to represent the breadth of the system and costs incurred. Examples of different facility samples for cost studies done in the PATH HPV demonstration projects are provided in Annex 5.

Case study

Peru: using cost data to revise program delivery

In 2009, Peru implemented HPV vaccination using school-based delivery to all girls in the fifth grade covering two-thirds of the large northwestern region of Piura. Over 8,000 girls were eligible for vaccination and the program achieved 82 percent coverage for all three doses. This region is comprised of a unique topography of a few urban centers, large swaths of rural farmland, and a few more remote rural locations often in mountainous areas. The national EPI program presumed that it would be more expensive to implement HPV vaccinations in areas that were hard to reach. This consideration was factored into the design of the microcosting study to estimate economic and financial costs of delivery, and facilities from each of these distinct areas were included in the sampling frame.

The average economic cost of HPV vaccine delivery for all three doses (achieving 82 percent coverage) was US$11.64 per girl and varied widely across these three areas. In urban areas where schools and health centers were relatively close together, the economic cost was $8.52 per girl, and in rural areas it was $11.19 per girl; this contrasts markedly with $31.13 per dose observed to reach remote rural areas (due to high transportation costs). Focusing on financial costs only (not including shared program costs associated with health workers' salaries and depreciation for capital equipment such as cold chain and vehicles), the average total incremental cost per fully immunized girl with the HPV vaccine decreased to $6.09, with higher costs for reaching remote areas.

These data suggested that school-based delivery, generally, and school-based delivery in remote rural areas was more expensive than the government of Peru would be able to afford when scaling up vaccinations nationally. When the results of this study were reported to the Ministry of Health and the national EPI program, deliberations ensued, which resulted in a second demonstration project that delivered HPV vaccine using health facilities, in the hopes that delivery costs would be less. Because coverage with this facility-based strategy was lower than expected, the government created a hybrid strategy for national introduction that combined elements of the school- and facility-based strategies.

Applying the framework

As reflected in the case studies presented in each of the sections, the data generated from the operations research methods and tools used in the PATH experience informed a variety of decisions related to program implementation and improvements, including the decision by the government of Peru to

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introduce HPV vaccine nationally. The results from these assessments are used by countries in conjunction with additional evidence, as is done for vaccine policymaking more generally (11). However, there were particular methods, tools, and outputs that were found to be universally beneficial for all the countries that participated in these HPV vaccine demonstration projects. The most useful are discussed below with their potential relevance for countries that may apply to the GAVI Alliance HPV Vaccination Demonstration Programme.

Vaccine coverage validates acceptability and feasibility

A population-based survey with a representative sample of parents of girls eligible for HPV vaccine was perceived as the most systematic and reliable methodology to accurately measure the percentage of the target population reached by the HPV vaccine delivery strategy employed. All of the government immunization programs involved had previous experience with this methodology for infant immunizations. Governments recognized WHO as a leading expert in the field and endorsed the rigor of the approach usually applied to infant immunization surveys.

The coverage results were also used to highlight what level of coverage could be achieved by the strategy the government had employed. This illustrated whether the work asked of the health workers and the preparations made for the vaccination program could result in reaching the target population. If so, the approach was deemed feasible, based on the efforts put in for the program delivery. The details of what worked well and what didn't were not captured in the measurement of coverage, but the result was used as a barometer of what

was possible. The case study from Uganda highlighted the use of coverage survey results to understand feasible delivery strategies (page 8).

Governments interpreted the coverage result to be a direct measure of vaccine acceptability to parents; if parents were not sure of the program or did not feel they wanted their daughter vaccinated, they would not have had their child vaccinated. A higher proportion of unvaccinated girls would have been the result—the opposite of the country experiences in these demonstration projects. Most countries and strategies achieved greater than 75 percent coverage of the eligible population, and some approached near 100 percent coverage (1). This signaled to the government broad community support for HPV vaccine. Indeed, this support was validated by parental responses on the coverage survey as to why they had their daughter vaccinated—critical data to understand what motivators for parental acceptance were important to leverage.

Finally, the coverage survey, as a trusted, credible methodology, provided an additional opportunity for governments to learn more from parents about the program's implementation. Additional questions were included in the survey about the educational messages and activities carried out to sensitize and mobilize communities; parents' knowledge of different aspects of cervical cancer, HPV vaccine, and the program components; and the influence that others might have exerted in the parents' decision-making process. Vietnam used the coverage survey to assess knowledge levels of HPV among parents (page 7). Survey implementers did not incur extra expense for collecting these additional data, and it generated a wealth of information used by governments to understand what messages were most critical and relevant to parents, how parents understood the program, and which people helped shape the parent's decision for vaccination. Understanding these aspects has allowed the governments that implemented these demonstration projects to revise their communication strategy for HPV vaccination to focus on key messages, optimal means to disseminate those messages, and channels through which parents receive these messages. This process resulted in a more streamlined communications strategy that maximized the impact while using minimum resources with the most influential aspects of the strategy. This approach may be easier and more sustainable when programs are scaled up nationally.

A generic coverage survey protocol adapted from the PATH experience can be found in Annex 6 and is complementary to the coverage survey data collection tool and interviewing guide found in Annex 2. WHO is planning to release guidelines for an HPV cluster survey in 2013, which would provide countries with an additional resource.

Assessing implementation costs informs financial resource needs and affordability

As with the coverage survey, the microcosting studies of economic and financial costs of HPV vaccine implementation were similar across all four demonstration project countries. The data collected consisted of all resource inputs to help

understand the full economic costs of implementation but financial costs were also calculated, since these may reflect more broadly additional or new expenses that may be incurred by governments when taking their HPV vaccination program to scale. All governments were keenly interested in the results of these studies and were eager to learn how to interpret these data and how to use them for financial forecasting and budget planning. Even though the general result was average cost per girl fully immunized, the variability in costs by other parameters, such as geographic area or type of delivery strategy, was also demonstrated. The use of this was highlighted in the case study from Peru (page 24).

The microcosting study methodology was also adapted from an immunization program costing methodology recommended by WHO. The governments perceived the method to be rigorous and credible, as they did the coverage survey. As such, the method supported the soundness and validity of the results. The outputs from these studies were also used to project scenarios of what additional expenses might be incurred for national introduction. This information was used to inform discussions of resource requirements for different program components and affordability, in addition to the budget that might be necessary to cover such expenses.

WHO and international collaborators have been developing a costing tool that governments could use to plan possible budgetary needs for national introduction of HPV vaccines. The WHO Cervical Cancer Prevention and Control Costing (C4P) Tool User Guide is available and provides another resource for countries when planning national introduction of HPV vaccine.

Routine monitoring tools can inform feasibility

The PATH demonstration projects utilized a comprehensive mixed method approach to assess feasibility. The dynamics of program planning, preparation, implementation, and monitoring for HPV vaccinations were complex and ground-breaking, as implementation in low-resource settings for this new vaccine had not yet occurred. Due to the new target population and new delivery modality for a disease not well understood by communities, it was important for governments to gain detailed insight into perspectives of a wide spectrum of stakeholders involved in this program. Which elements were most feasible or most difficult was not known. In previous new vaccine introductions, the cold chain and its capacity was a major consideration. Did that still apply for HPV vaccine, especially as a single-dose vial? Would school-based delivery raise insurmountable challenges, or were there ways to implement such an approach that utilized resources efficiently and with minimal impact?

The feasibility assessment employed by PATH included qualitative interviews, vaccine observations, system checklists, quantitative surveys, and focus group discussions. It generated a large and complex body of data to synthesize. The feasibility assessment cast a wide net to ensure that all voices were heard and no perspective or learning was lost. In addition, forms and tools already used

by immunization programs were adapted to accommodate HPV vaccine. This was a large-scale endeavor seeking to provide a comprehensive framework for the assessment and may not be easily replicated in all contexts. However, our experience suggests that the level of effort invested can range from basic to complex and still provide valuable and valid information about the feasibility of HPV vaccine delivery.

In general, the majority of the dimensions of feasibility outlined on pages 14–17 were captured in routine monitoring forms adapted for HPV vaccine. These forms included training attendance logs, supply logs for IEC materials, vaccine and related supplies received and distributed, cold chain temperature monitoring logs and storage space capacity assessments, routine vaccine tally sheets, routine reports of adverse events, and routine reports from monitoring and supervision visits. The vaccine tally sheets were particularly important as they tabulated the number, location, and type of sessions conducted; number and type of health workers at each session; logged time in/time out; recorded vaccine vial use for wastage; and tabulated number of doses administered for each dose. These data are core elements in understanding the activities of health workers and the feasibility and reach of the vaccination strategy. Strengthening the collection and use of routine immunization data can facilitate more reliable and robust data for decision-making on HPV vaccine delivery. The WHO New Vaccine Post-Introduction Evaluation (PIE) Tool can be a useful reference for countries on how to leverage existing data collection activities of routine EPI programs to assess aspects of program feasibility.

For countries with additional resources, interviewing local health workers and allied staff who supported HPV vaccine delivery can be beneficial to understanding dynamic aspects of implementation that are more challenging to quantify. These supplemental interviews need not include a large number of respondents but do need to include the key respondents, such as implementers (e.g., health workers, mobilizers, teachers, community leaders) at district and local levels. These participants should reflect the diverse conditions of the pilot's implementation, such as rural and urban areas; locations that experienced high uptake of vaccine and those that did not; and areas with strong infrastructure for vaccine delivery and those that needed more support. In-depth or key informant interviews can explore the dynamics, challenges, and opportunities afforded by collaboration, along with the areas of program planning, preparations, or implementation that worked well and those that were challenging. This information can provide insight into the positive aspects of program delivery to leverage and replicate for success, as well as an understanding of some of the challenges that need to be resolved prior to scaling up HPV vaccine delivery nationally.

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Conclusion

Countries may gain great benefit from piloting HPV vaccine delivery prior to national introduction. The decisions made during the design and implementation of a pilot require critical evaluation to generate the data required for future decision-making. A well-designed and well-implemented evaluation strategy can ensure that these data are robust, reliable, and valid.

This document has outlined recommendations based on the PATH experience in evaluating HPV vaccination pilots. It has presented a variety of methodologies and tools used, and given examples from four low-resource settings for other countries to adapt for their circumstances. These tools are non-proprietary and we encourage countries to use and adapt those that will be most beneficial. Lastly, this document summarized the methods and tools that countries deemed provided the greatest benefit for understanding which HPV vaccine delivery strategy was acceptable to communities, feasible to implement, and able to achieve high coverage.

Country applications to the GAVI Alliance for support of an HPV vaccination pilot will require a robust evaluation framework. The tools and methods highlighted here can help countries meet those evaluation expectations by providing a strong foundation to adapt to their specific needs.

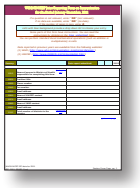
Resources

All resources can be accessed online at www.rho.org/HPV-evaluating-programs.htm.

Print resources

Immunization coverage cluster survey—Reference manual.

World Health Organization, 2005



National HPV Vaccine Coverage, WHO-UNICEF Joint Reporting Form

WHO/UNICEF, 2011

Module 7: The EPI coverage survey. Training for mid-level managers (MLM).

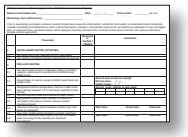
World Health Organization, 2008

Implementing HPV Vaccination Programs

PATH, 2011

New Vaccine Post-Introduction Evaluation (PIE) Tool

World Health Organization, 2010



HPV Vaccination Monitoring Tool for PATH Demonstration Projects

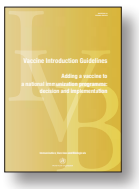
PATH, 2008

Sample Vaccination Cards and Registers

PATH, 2008

WHO Best Practices for Injections and Related Procedures Toolkit

World Health Organization, 2010



Vaccine Introduction Guidelines. Adding a Vaccine to a National Immunization Programme: Decision and Implementation

World Health Organization, 2005

Adverse Events Following Immunization (AEFI): Causality Assessment

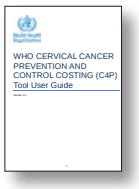
World Health Organization, 2005

Immunization in Practice, a Practical Resource Guide for Health Workers. Module 7: Monitoring and Using Your Data

World Health Organization, 2004

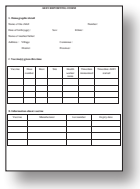
Immunization Safety Surveillance: Guidelines for Managers of Immunization Programmes on Reporting and Investigating Adverse Events Following Immunization

World Health Organization, 1999



WHO Cervical Cancer Prevention and Control Costing (C4P) Tool User Guide

World Health Organization, 2012



AEFI Reporting Form

PATH, 2008

Online resources

Vaccine Volume Calculator

World Health Organization

HPV Vaccine Delivery Costing Tool

ProVac, Pan American Health Organization/World Health Organization

New and Under-utilized Vaccines Implementation

World Health Organization

WHO/ICO Information Centre on Human Papilloma Virus (HPV) and Cervical Cancer

World Health Organization/ Institut Català d'Oncologia

Vaccine Resource Library

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Papers published in peer-reviewed journals presenting evaluation methods and results from HPV vaccination pilots in low-resource settings.

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;89:821–830B. Available at: www.who.int/bulletin/volumes/89/11/en/index.html.

Penny ME, Bartolini R, Mosqueira NR, et al. Strategies to vaccinate against cancer of the cervix: feasibility of school-based HPV vaccination program in Peru. Vaccine. 2011;29(31):5022–5030. Available at: www.sciencedirect.com/science/journal/0264410X/29/31.

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3. 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.
4. Nguyen NQ, LaMontagne DS, Bingham A, et al. Human papillomavirus vaccine introduction in Vietnam: formative research findings. *Sexual Health*. 2010;7(3):262–270.
5. 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.
6. 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.
7. Paul P, Menezes L, LaMontagne DS. Communication approaches to mobilizing communities for HPV vaccination. In press.
8. World Health Organization. *Adverse Events Following Immunization (AEFI): Causality Assessment*. WHO/Department of Immunization, Vaccines and Biologicals. Geneva: WHO; 2005.
9. World Health Organization. Projected Vaccine Wastage. WHO website. Available at: www.who.int/immunization_delivery/systems_policy/logistics_projected_wastage/en/index.html. Accessed June 20, 2012.
10. PATH, Child Health and Development Centre (CHDC), and the Uganda National Expanded Program on Immunization (UNEPI). *HPV Vaccination in Africa: Lessons Learned From a Pilot Program in Uganda*. Seattle: PATH; 2011.
11. Tsui J, LaMontagne D, Levin C, et al. Policy development for human papillomavirus vaccine introduction in low-resource settings. *The Open Vaccine Journal*. 2009;2:113-22.

Annexes

Annex 1 – Vaccination tracking forms

- Vaccine uptake reporting and tracking forms—India
- Health center vaccination register form—Vietnam
- Vaccination Register (School Form)—India

Annex 2 – Coverage survey tools and resources

- Coverage survey form and interviewer guide—India Year 1
- Coverage survey form and interviewer guide—Uganda Year 1
- Coverage survey form and interviewer guide—Vietnam Year 1
- Coverage survey form and interviewer guide—Uganda Year 2

Annex 3 – Acceptability study tools and resources

- Exit interview for girls—India
- Focus group discussion guide fully vaccinated girls—Uganda
- Semi-structured interview with parents of nonvaccinated girls—Vietnam

Annex 4 – Feasibility study tools and resources

- Key informant interview guide community leaders—Vietnam
- Key informant interview guide education staff—Vietnam
- Key informant interview guide HCW—Vietnam
- Key informant interview guide IEC—Vietnam
- Semi-structured interview guide ANMs vaccinators—India
- Time motion tool—Uganda
- Vaccination session observation checklist—India

Annex 5 – Cost study tools and resources

- Economic evaluation of HPV vaccine introduction
- HPV vaccine cost delivery forms
- Cost data collection tool—district level
- Cost data collection tool—health facility level
- Facility level cost data collection tool—India

Annex 6 – HPV vaccine coverage survey – generic protocol

- HPV vaccine coverage survey protocol—Uganda

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