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**CONDUCTING FORMATIVE RESEARCH FOR HPV VACCINATION PROGRAM PLANNING:
PRACTICAL EXPERIENCE FROM PATH**

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Assessing the Health Policy Arena

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Assessing the Health Policy Arena

Key policymakers and other stakeholders

Rationale

A critical first step is identifying national-level stakeholders and policy decision-makers. A stakeholder mapping exercise carried out at the project outset can identify key policymakers and other influencer leaders, with whom informal meetings or structured or semi-structured interviews should be carried out. During these meetings, other persons and groups in a country who play a major decision-making or influential role in the introduction of vaccines can also be identified. Critical information needs of policymakers to overcome potential obstacles can also be uncovered.^{1,2} In order to understand the best way to position new HPV vaccines within the health policy arena, it is important to identify who the primary individuals are that influence the public policy for immunizations, cancer control, and adolescent health. If school-based programs are being considered, individuals overseeing public education institutions should also be consulted.

Be sure to cover the following areas:

- Identity of those responsible for making new or adapting existing national health policy, specifically in the areas of immunizations, adolescent health, reproductive health, and cancer control. Describe their function and tasks with regard to policy, making sure national, regional, and district levels are appropriately represented.
- Identity of any additional critical individuals in the health care delivery system who are involved in the policy decision-making process. Describe their function and tasks with regard to policymaking.
- Identity of any government officials at the community level who will be involved in implementing the policy. Describe their function and tasks. Ask respondent to describe any previous experiences with implementing new government health policy.
- Any other external influencers or other issues that contribute to the government's decision to introduce a new vaccine

How national health policy on immunization is formed (decision-making process)

Rationale

The role of policy analysis to support the introduction of new vaccines in low-resource settings is well recognized.³ Based on pre-introduction studies for the HPV vaccine in four countries, national vaccine policy development occurs in four stages: raising awareness of a health issue or intervention; evaluation of scientific evidence; policy formulation and review; and policy approval.¹

This process is likely to be fairly consistent in different country settings. However, the individuals involved at each stage and how external influencers affect the process may vary by country. Therefore, detailing the exact decision-making process in the local context for health policy formation with regard to HPV vaccine introduction should be the primary focus for this area of inquiry.

Be sure to cover the following areas:

- The general steps for new health policy and/or new vaccine introduction. Provide a recent example whenever possible to outline clearly how the process works.
 - Describe how the policy development process starts. Is it usually need-based, data-based, media driven, etc.?
 - Describe the process of negotiation, legislation, and adoption
 - Describe how objectives are set
 - Describe how long it takes to get a policy adopted
- Differences between areas of immunizations, adolescent health, reproductive health, and cancer control policy
- Mechanisms that are used for influencing policy development at the regional and district levels—lobbying, negotiation, advocacy, etc.
- The type of cervical cancer prevention policy needed for HPV vaccine introduction
- How guidelines are developed after a new policy goes into effect and how these guidelines are disseminated

What vaccine-related information is needed to make HPV vaccine introduction decisions

Rationale

Although vaccines have been shown to be safe and protective in clinical trials, policymakers still may have doubts about whether a new vaccine should be introduced as part of a public health program.⁴ Addressing policymakers' needs for vaccine technical information, evaluations of cost and cost-effectiveness, and assessment of national capacity for introduction are key ingredients for successful introduction of a new vaccine.^{1,5,6} Specific issues such as vaccine financing, ongoing relationships with external influencers (e.g. WHO, GAVI Alliance, UNICEF, and scientific organizations), or characteristics specific to the vaccine should also be explored.¹ Information on cervical cancer burden, vaccine safety and efficacy, and cost-effectiveness and affordability are important to policymakers when deciding on HPV vaccine introduction.⁷⁻⁹ Additional information needs, such as flexibility in vaccine schedule, logistical and operational issues, and financing strategies not only contribute to decision-making for HPV vaccine introduction but also address critical sustainability issues.^{7,10} Any expectations or concerns of key policymakers need to be identified and understood at the outset.⁶ These pieces of information may be key for influencing policy decisions and should be part of the communications and advocacy strategies.¹

Be sure to cover the following areas:

- Data needs regarding vaccine efficacy, duration of protection, and other issues of vaccine performance
- Data needs regarding the safety of HPV vaccines and their availability
- Cost-data needs and budgetary concerns regarding HPV vaccines. Discuss the immediate affordability and sustainability of an HPV vaccination program versus the long-term cost-effectiveness of the HPV vaccine. Describe the importance of cervical cancer disease burden versus likely health impact of vaccination.
- The priority of cervical cancer prevention and HPV vaccines compared to other preventative initiatives/programs
- The importance of having country-level large-scale trials before a decision about HPV vaccine introduction can be made
- The need for having international consensus and recommended guidelines before a decision about the HPV vaccine introduction can be made
- Any other expectations or concerns key policymakers may have about the HPV vaccine or its introduction

How the HPV vaccine fits within existing cervical cancer control efforts

Rationale

How a new vaccine fits into existing disease control priorities of policymakers in low-resource settings and how a new vaccine fits within existing priorities are questions that need to be answered early in the formulation of a new vaccine initiative.² For example, recent research from the HPV Vaccines: Evidence for Impact project found that competing priorities for different health initiatives was an underlying theme in all four countries.¹ An understanding of these issues at the outset will help planners shape the dialogue with policymakers to position cervical cancer and introduction of HPV vaccines for the prevention of cervical cancer within the context of these other priorities.^{1,11}

Be sure to cover the following areas:

- Any current health policies regarding cervical cancer control
- Any national cervical cancer control efforts, including their institutional structure, capacity, existing efforts, and partnerships
- The viability/feasibility of accommodating HPV vaccination among children 10 to 14 years old in current cervical cancer control policies

How HPV vaccine can be positioned to support or strengthen other health interventions

Effective partnerships between programs and interventions are critical ingredients for a successful introduction strategy. In the WHO guidelines, preparing for the introduction of HPV vaccines, the following is recommended:

“Programme approaches will need to be planned and organized, making the most cost-efficient use of existing or, where necessary, strengthened services. HPV vaccine delivery should be built on structures already in place at the national level.”⁶

These partnerships necessarily include ongoing interventions in other sectors. Formative results from the HPV vaccine: Evidence for Impact project confirmed this recommendation, since partnerships were emphasized by policymakers in all four countries as critical to success.¹ Key partners may include ministries of health, education, gender, and finance. During the formative phase it will be important to uncover any potential for promoting other immunization or adolescent health interventions through the introduction of a cervical cancer vaccine.

Be sure to cover the following areas:

- How HPV vaccine introduction can benefit and potentially change existing health programs and immunization services. Identify any likely negative impacts to existing immunization services.

What vaccine delivery strategy is considered feasible or is preferred

Rationale

An important set of HPV vaccine-related issues focuses on implementation. Policymakers will likely have specific ideas and preferences regarding the vaccine delivery strategy and process. It will be important to understand these views at the outset and regard them as guideposts or starting points for planning discussions. An example from the HPV Vaccine: Evidence for Impact project illustrates the importance of this key area of inquiry. Formative research results found that policymakers in all countries had clear ideas about different vaccine delivery options and their strengths and weaknesses, management processes, partnerships needed, and the age range to target. Concerns about the acceptability of the different delivery options and the impact a new vaccine would have on existing immunization services were voiced by policymakers in several countries.¹

Be sure to cover the following areas:

- What vaccine delivery strategies are being considered?
- Why are certain strategies being considered? Explore the following: venue, cost, vaccine packaging, existing partnerships and other coordinating efforts, desired management structures, delivery mechanisms, and community mobilization strategies.
- Is there a possibility for integration with existing efforts or are completely new approaches being considered?
- What are the strengths and weaknesses of each strategy (school-, health facility- or community-based)?
- What additional concerns do policymakers have regarding different options?

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