

SCALING-UP

HPV

VACCINE
INTRODUCTION



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LIST OF ABBREVIATIONS

AEFI	adverse event following immunization
CIN	cervical intraepithelial neoplasia
cMYP	comprehensive multi-year plan for immunization
EPI	Expanded Programme on Immunization
Gavi	Gavi, the Vaccine Alliance
GVAP	Global Vaccine Action Plan 2011-2020
HIC	high-income country
HIV	human immunodeficiency virus
HIV+	human immunodeficiency virus positive
HPV	human papillomavirus
ICC	Interagency Coordinating Committee
KAP	knowledge, attitudes and practice study
LIC	low-income country
LMIC	low and middle-income country
LSHTM	London School of Hygiene and Tropical Medicine
MIC	middle-income country
MoH	Ministry of Health
MoE	Ministry of Education
MoF	Ministry of Finance
NCD	non communicable disease
NGO	non-governmental organization
NITAG	National Immunization Technical Advisory Group
UMIC	upper middle-income country
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
V3P	Vaccine Product, Price and Procurement platform
WHO	World Health Organization

PURPOSE OF THIS REPORT

This report is a companion to the World Health Organization's (WHO) 2016 guide for Introducing HPV Vaccine Into National Immunization Programmes.

This report primarily summarizes country-reported experiences introducing HPV vaccine and provides guidance to those involved in its introduction. Each chapter summarizes lessons learned in topics ranging from decision-making to financing and sustainability. These experiences can inform immunization, cancer, adolescent and reproductive health programme managers, together with decision makers in Ministries of Health, Education and Finance as a country strives to improve, scale-up or introduce HPV vaccine.

EXECUTIVE SUMMARY

The report should be considered a companion guide to WHO's guide for Introducing HPV Vaccine Into National Immunization Programmes.

Globally, there is almost a decade of HPV vaccine introduction experience from dozens of countries in all income groups. This report distills and shares information gathered and presented by WHO and partners at a Global Learning Meeting on HPV Vaccine Introduction in November 2015.

Specifically, this report offers experiences – many directly reported by country health managers - and implications for action in the main areas of vaccine introduction: decision-making, planning and coordination, delivery strategies, communication, crises management, monitoring and evaluation, costing and sustainability. This report also offers insights into reaching hard-to-reach populations and on integration of HPV vaccine in both a comprehensive cervical cancer prevention and control plan and into adolescent health programming.

Country experiences show that it is feasible to introduce and attain high-coverage of HPV vaccine in different country settings. Decision-making requires high-level political commitment. Coordination and sustainability demands a partnership spanning immunization, adolescent health, cancer programming, the Ministry of Education (MoE) and communities. Testing and selecting a cost-effective delivery strategy tailored to the community, health and education infrastructure– whether primarily school-based, facility based or a mixed strategy - will be key to both coverage and sustainability. Investment in an engagement and communication strategy, including effective consent processes, is essential to success. Countries must plan for crises and be flexible and tackle them rapidly when they occur.

Experiences also demonstrate the challenges and some remaining questions. Demonstration-programme countries could benefit from selecting districts that better represent the mix of urban and rural communities, including hard-to-reach girls, allowing a more realistic picture of the costs and resources required for scale-up. More work and time are required to integrate HPV vaccine with other adolescent health services and to document that work. Stronger bonds can be made between immunization and cancer programmes to strengthen cervical cancer prevention and control.

There is still more learning to come. Standardized monitoring indicators and reporting will help countries and partners better estimate coverage and pinpoint challenges. Support for impact monitoring and accurate costing analyses will be critical to advocate for sustainable national introduction. Vaccine cost remains an issue, particularly for middle-income countries. Low-income countries will have access to Gavi vaccine prices several years after graduation. Gavi should review demonstration programme requirements, including ensuring evaluations are feasible for countries to conclude in a reasonable timeframe.

This report concludes that the quest to prevent cervical cancer, which extracts an especially heavy toll on women in low-income countries, is more timely than ever as the health and wellbeing of women and girls are considered essential to ending extreme poverty, promoting development and resilience, and achieving the Sustainable Development Goals.

INFORMATION SOURCES AND STRUCTURE

INFORMATION SOURCES

This report represents an update on HPV vaccine delivery experiences as of December 2015. It builds on previous lessons learned from HPV vaccine delivery, including resources published by WHO and partners at <http://www.who.int/immunization/hpv/> and by PATH at www.rho.org. Specifically, this report draws from the following information sources:

1. Presentations and discussions at the **Global Learning Meeting on HPV vaccine introduction**, hosted by the World Health Organization in Geneva from November 10-12, 2015. The purposes of the meeting were first, to draw lessons learned from HPV vaccine introductions and demonstration programmes in high, middle and low-income countries; and second, to identify future resource development needs and research questions. The three-day meeting included participants and/or presentations from twenty countries, including three high-income: Argentina, Australia and Latvia; three upper-middle income: Fiji, Malaysia and South Africa; six lower-middle income: Bhutan, Cameroon, Ghana, Morocco, Senegal and Zambia; and eight low-income countries: The Gambia, Madagascar, Malawi, Mozambique, Niger, Rwanda, Senegal, United Republic of Tanzania and Zimbabwe; together with expert presentations on costing and sustainability, integration with cervical cancer and adolescent health services, and monitoring studies. The following partners were also present: Agence de Médecine Préventive, the Bill and Melinda Gates Foundation, the Centers for Disease Control and Prevention, Gavi, John Snow Inc., the London School of Hygiene and Tropical Medicine, PATH, UNFPA, UNICEF and WHO.
2. **Responses to Questionnaires** that were distributed prior to the 2015 Global Learning Meeting. These were completed by eight countries and sought to examine all aspects of HPV vaccine introduction and sustainability.
3. The results of **HPV Vaccine Lessons Learnt & Recommendations**, a 2015 PATH/LSHTM review of HPV vaccine delivery experiences in 37 low- and middle-income countries. This review details findings, key lessons and recommendations from eight national introductions and 55 demonstration projects or pilots, and analyses information across five key themes: preparation, communication, delivery, achievements and sustainability. Additional summaries address the value of demonstration projects and potential HPV vaccination pitfalls. The summaries are published here: www.rho.org.
4. Additional publicly available information from studies, assessments and evaluations of national and demonstration projects.

STRUCTURE

Almost every section of the report represents a general topic in guidance on HPV vaccine introduction (e.g. planning, coordination, delivery, monitoring).

- Each section begins with a short summary of the issue.
- This is followed by experiences reported by countries – both positive and challenging - from the sources listed above.
- Finally, based on the experiences, there is a list of implications for action, also summarized at the end of the document.

INTRODUCTION: THE PROMISE AND PROOF OF HPV VACCINE INTRODUCTION

The World Health Organization (WHO) recommends HPV vaccination for 9–14 year-old girls as the most cost-effective public health measure against cervical cancer, and a core strategy for primary prevention. WHO recommends introduction through national immunization systems where cervical cancer is a public health priority, vaccine introduction is feasible, sustainable financing can be secured and vaccines are considered cost-effective.¹

As of December 2015, more than 65 countries had introduced national HPV vaccine programmes and a number of others had introduced or planned to introduce pilot or demonstration programmes. The pace of introduction in low-income countries eligible for Gavi, the Vaccine Alliance support is increasing and Gavi aims to support vaccination of more than 30 million girls in 40 countries by 2020.

However, despite the progress, WHO estimates that in 2015 less than 5% of the age cohort of girls who could benefit from HPV vaccine world-wide were fully immunized with HPV vaccine. More than 130 countries have yet to introduce the vaccine. In 2012, an estimated 530,000 women developed cervical cancer, and 270 000 women died from the disease. More than 85% of these women lived in low and middle-income countries where access to screening and treatment can be limited.

Global momentum is growing to reverse the toll of cervical cancer and to improve adolescent health and well-being. The Sustainable Development Goals 2030 include a health target to reduce premature mortality from non-communicable diseases by one-third through prevention and treatment. The Global Strategy for Women's, Children's and Adolescents' Health (2016–2030) advocates a multisectoral approach to improving health over the life course, including immunization for adolescents and screening and management of cervical cancer for women. The Global Vaccine Action Plan (GVAP) 2011–2020 aims for all countries to have introduced and sustained use of one or more under-utilized vaccines, including HPV vaccine.


The bivalent (16,18) and quadrivalent HPV (16,18, 11, 6) vaccines currently most used in low and middle-income countries can prevent about 70% of cervical cancers by preventing infection with HPV types 16 and 18 (11 and 6 cause anogenital warts).

Countries that introduced HPV vaccine soon after it was licensed in 2006 have had time to measure the impact. Australia is an example.

Australia offered a catch-up opportunity for girls and women aged 12 – 26 from 2007–2009, and since then has provided the quadrivalent vaccine to all girls in the first year of high-school, mainly through school-based delivery. About 75% of girls aged 12–13 were fully vaccinated from April 2007 to mid-2015.

In addition, males in the first year of high school have also been included in the HPV vaccine program since 2013.

A 2014 Australian study found that 29% of women tested in the years prior to the HPV vaccine program were positive for the four genotypes targeted by the quadrivalent HPV vaccine (16,18,11,6) but just 7% of women in the vaccinated cohorts had a positive result.² A 2013 study showed that of



The survival, health and well-being of women, children and adolescents are essential to ending extreme poverty, promoting development and resilience, and achieving the SDGs.

- The Global Strategy for Women's, Children's and Adolescents' Health

¹ HPV vaccines can also prevent vulvar, vaginal, oropharyngeal, anal and penile cancers. WHO will be revising its HPV Vaccine Position Paper in 2017, in light of the SAGE October 2016 recommendations. The main changes will include a focus on 9–14 year olds and recommendation for vaccinating multiple age cohorts when HPV vaccine is first introduced to result in faster population impact.

² Tabrizi SN, Brotherton JM et al., *Assessment of herd immunity and cross-protection after a human papillomavirus vaccination programme in Australia: a repeat cross-sectional study*. The Lancet Infectious Diseases, Volume 14, Issue 10, October 2014, Pages 958–966.

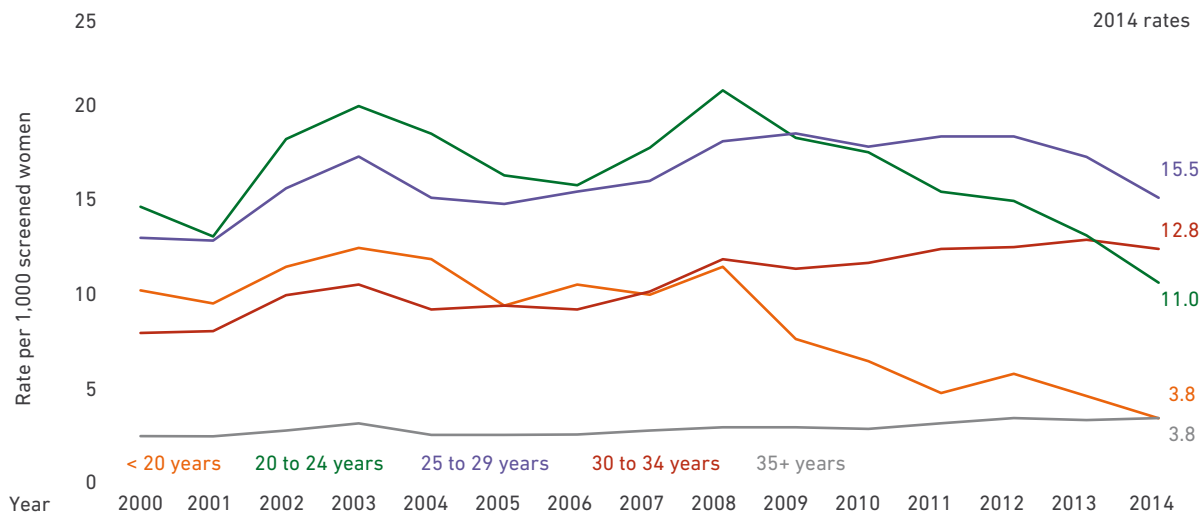
431 young Australian women tested, none had a positive swab for HPV types 18, 11 or 6, and HPV 16 was detected in just six, all of whom had sexual debut before they were vaccinated.³

Most encouragingly, an analysis of national cervical screening outcomes in Australia from 2005-2013 shows a reduction of 57% in high-grade cervical abnormalities amongst women under 20 (the group more likely to be immunized), and a 25% decrease in women aged 20-24. In the State of Victoria, cervical screening registry data shows that by the end of 2014 declines are also starting to occur amongst women aged 25-29 years.⁴

Australia has shown that scaling up HPV vaccination coverage of target-age girls reduces HPV infection and cervical pre-cancer, which strongly suggests that lesions that would otherwise have progressed to cervical cancer are being prevented. Similar findings were reported from Denmark where a reduced risk of cervical lesions was observed six years after licensure of the quadrivalent HPV vaccine.⁵

Several countries using the quadrivalent HPV vaccine have found significant declines in genital warts amongst women who were likely to be vaccinated including Australia, Denmark, New Zealand, Sweden and the United States, and some have also found a decline in men, likely due to herd immunity.⁶

► **Figure 1 Trends in rates of histologically-confirmed high-grade cervical abnormalities by age, 2000-2014, Victoria, Australia**



SOURCE: <http://www.vccr.org/data-research/statistical-reports/annual-statistical-reports>. Data presented by Assoc Prof. Julia Brotherton at the WHO Global Learning Meeting on HPV Vaccine Introduction, Geneva, November 2015. Australia introduced HPV vaccine in 2007, and soon after saw sharp declines in detection of high-grade cervical abnormalities amongst younger women who were likely vaccinated.

LEARNING TO SCALE-UP

The public health impact of HPV vaccination is continuing to be demonstrated as an effective preventer of HPV infection and disease and there is now almost a decade of HPV vaccine introduction experience from dozens of countries of all income groups. Learnings from each step of these experiences – from advocacy and decision-making, to planning and implementation – can help countries implement better programmes, overcome challenges and scale-up more effectively. Countries and partners have shared their experiences in published reports, with one another, with researchers, and at the November 2015 Global Learning Meeting on HPV Vaccine Introduction. These experiences and the implications for action are summarized in the pages that follow.

³ Osborne SL et al., *Assessing genital human papillomavirus genoprevalence in young Australian women following the introduction of a national vaccination program*. *Vaccine*. 2015 Jan 1;33(1):201-8.

⁴ Brotherton JM, et al., *HPV vaccine impact in Australian women: ready for an HPV-based screening program*. *Med J Aust* 2016; 204 (5): 184.

⁵ Baldur-Felskov B, et al., *Early impact of human papillomavirus vaccination on cervical neoplasia – nationwide follow-up of young Danish Women*. *J Natl Cancer Inst*. 2014. Mar;106(3):djt460.

⁶ Mariani L et al., *Early Direct and Indirect Impact of Quadrivalent HPV (4HPV) Vaccine on Genital Warts: a Systematic Review*. *Advances in Therapy*. 2015;32:10-30.



THE DECISION TO INTRODUCE



THE ISSUES

Given the multitude of partners with an interest in HPV vaccine and cervical cancer control, decision-making can be complex and time consuming, but securing the right buy-in from the right partners can make a difference for both introduction and sustainability.



THE EXPERIENCES

Many countries report that **high-level support by political figures**, such as the **First Lady** was a key driver in decision-making. In several countries, the First Lady had attended a regional or global meeting on cancer, learned about the cervical cancer burden and the role of HPV vaccine, and upon her return asked the country to strengthen cervical cancer programming including by introducing HPV vaccine.

Many countries want to be seen to be **doing more for women's health** and HPV vaccine introduction places them as a frontrunner.

The **disease burden** and access to screening and treatment is another driver. Several countries had analysed the cervical cancer burden and found it to be a leading cancer and cause of cancer deaths amongst women.

Programme initiative to collect evidence is a factor. In several countries, women's health, the Expanded Programme on Immunization (EPI) or cancer programmes collected the information about cervical cancer and advocated for HPV vaccine inclusion in the country health programme. In the Americas for example, cancer programmes collected cervical cancer evidence and advocated to introduce HPV



vaccine. A handful of countries had a cancer registry which also provided evidence. Some countries had conducted feasibility and acceptability surveys.

A policy recommendation from the National Immunization Technical Advisory Group (NITAG) or equivalent independent entity is a key driver for decision-making, given its influence as a credible scientific opinion and its influence on the MoH.

Vaccine donations were a motivating factor in some countries, as was the **opportunity** to apply to Gavi for HPV vaccine introduction, demonstration programmes and subsidized vaccine prices.¹

Some countries reported a confluence of factors: For example, the Ministry of Health and/or NGOs had collected disease burden information and were proposing to strengthen cervical cancer programming; the First Lady advocated for stronger cervical cancer programming upon her return from a meeting; and a donation or Gavi funding presented the opportunity to introduce the vaccine.

However, in some countries, **there was insufficient coordination between the cancer and EPI programmes, or no coordination with the Ministry of Finance (MoF)**, and decisions were made without including all stakeholders. This led to complications – including funding shortages – later.

Middle and high-income countries that have introduced HPV vaccine nationally report that **decision-making follows a lengthy process** that includes: advocacy for inclusion by experts and civil society; data analyses (e.g. disease burden, access to and usage of screening, cost-effectiveness); regulatory steps (e.g. licensing, listing HPV vaccine in national schedule); decision-making by committees (e.g. health, education) and then a cabinet or parliamentary decision, which ideally – but not always – results in secure long-term funding.

Country snapshots:

First Lady support makes a difference

Zambia's First Lady, who was an obstetrician/gynecologist, attended a regional First Ladies meeting where cervical cancer was on the agenda. There, she learned that cervical cancer was a major issue for Zambian women and became convinced it could be prevented. Upon her return, she advocated for introduction of HPV vaccine. A non-governmental organization (NGO) involved in cervical cancer screening had advocated for HPV vaccine given Zambia has the 2nd highest burden of cervical cancer in Africa and that it accounts for 40% of hospital admissions for cancer treatment. The First Lady's advocacy tipped the decision in favour of HPV vaccine introduction. Zambia applied for a donation from a vaccine manufacturer and implemented a pilot programme in 2013/2014 and is now exploring national scale-up.

Following national processes

Fiji first introduced HPV vaccine with a donation from a manufacturer in 2008/2009. As it was a single donation, the programme ended when the vaccine doses were finished. Fiji then underwent a rigorous decision-making process to introduce the vaccine nationally. The Family Health Unit made the proposal, based on data that showed the cervical cancer burden was very high, at 42.4 per 100,000 women. Next, the National Health Executive Committee endorsed the proposal to include HPV vaccine in the national immunization schedule. In May 2011, the Cabinet approved a submission to implement an HPV vaccination programme. The Family Health Unit then consulted widely with stakeholders to prepare for introduction, including close collaboration with the School Health Programme. However, there was no budget allocated at the time. Therefore, the Family

¹ For UNICEF/WHO guidance to help achieve good vaccine donations practice see this Joint Statement: http://www.who.int/immunization/hpv/plan/who_unicef_joint_statement_on_vaccine_donations_who_unicef_2011.pdf

Health Unit advocated to successfully secure donor funding and re-introduced in 2013 as part of the School Health Programme. Fiji continues to seek donor assistance to sustain the programme.

Decision-making: Implications for Action

- ✓ **Gaining the support of high-level advocates**, such as First Ladies, can have a major impact on the decision to introduce HPV vaccine.
- ✓ **Prepare evidence:** Investigating and reporting on the cervical cancer burden; cost-effectiveness, feasibility and acceptability provides important information for decision-makers.
- ✓ **Coordination with the right stakeholders** from the beginning will ensure all the players are at the table when it's time to make decisions and implement. The Health, Education and Finance Ministries are particularly important.
- ✓ **Prepare for a process involving the policy committees, regulatory bodies, political and financial processes** to ensure the decision is anchored in country policies and budget.
- ✓ **Consider sustainable funding.** Donations and external support can help a country introduce HPV vaccine in the short-term, but countries will need to contribute a portion of funding, and advocates should have a plan to secure funding for longer-term sustainability.





TIMELY PLANNING &
COORDINATION WITH
THE RIGHT PARTNERS



THE ISSUES

Like the decision-making process, coordination and planning for implementation will involve many partners, including partners who may not have worked closely together in the past. To increase the chance of successful HPV vaccine delivery, EPI managers - the traditional “owners” of vaccination programming - may need to adjust their ways of working to forge a successful, productive partnership with new stakeholders in cancer control, women’s and reproductive health as well as adolescent health, the education sector and others.



THE EXPERIENCES

COORDINATION

HPV vaccine countries generally have worked with an oversight committee (such as the Inter-agency Coordinating Committee (ICC)), and a national level planning committee which is led by the Ministry of Health/EPI in close coordination with the Ministry of Education (for school-based programming).

It has been beneficial to create a series of sub-committees, including for communication, training, vaccine management and logistics, and monitoring and evaluation. Countries report that regular meetings of these committees (e.g. weekly) helps to keep work-plans on track.

For a school-based HPV vaccination strategy, countries stressed the importance of coordination between the Ministry of Health and Ministry of Education at national, state/province, district and local levels. Several countries highlighted the importance of involving Parent-Teacher Associations locally.

Countries included other non traditional EPI partners in the planning, including cancer/non communicable diseases (NCDs), adolescent health, women’s health, gender, professional associations of oncologists, gynecologists, pediatricians and general practitioners at all levels. Close coordination with technical and financing partners including Gavi, the Clinton Health Access Initiative, PATH, UNFPA, UNICEF, and WHO was important.

Countries discussed the difference between including partners for planning, versus those for advocacy and community engagement. For example, one country included a national religious council on the planning committee, while others generally include religious organizations as part of advocacy and community engagement efforts.

Countries either used EPI structures and processes to deliver HPV vaccine, or, when available, the school health programme (particularly in middle-income countries). Strong existing EPI or school programmes led to good HPV vaccine coverage.

“By switching from a separate campaign-style school-based delivery to EPI programme structures, including human resources, vaccine management and cold chain, training, transport and monitoring, we reduced our operational costs from \$193,000 to \$ 22,000 per round.” – Rwanda, reporting >95% HPV vaccine coverage.

“Because of our established school health programme our only added costs for HPV are for vaccines, some cold chain and communication.” – Malaysia, reporting >95% HPV vaccine coverage.

DENOMINATORS PROVED DIFFICULT

Determining the denominator is a major issue for countries, particularly for those without birth registers or identity cards, or with high numbers of girls out-of-school. Various sources of data exist – some more reliable than others. Countries generally used school registrations for school-based delivery, and relied on community health volunteers to register out-of-school girls. Other sources of information include municipal data, national census, UNESCO estimates, mini-census and headcounts. Each of these sources can have challenges.

“We relied on school registration from the previous years, but ran into challenges when girls repeated the year or changed schools,” reported one western African country. Other countries reported similar problems when girls moved districts and changed schools mid-year, affecting the denominator and ability to record whether girls had received all doses.

“We could never be sure if community health workers were able to register all out-of-school girls,” said one demonstration country. “Or sometimes there was duplication of names,” said another.

“The UNESCO estimates were 50% too high in one area, and 50% too low in another,” reported a western African country that conducted a mini-census and registration for HPV vaccine as a result.

Countries also reported challenges with grade-based versus age-based denominators. Age-based can be simpler if girls have identity cards or other proof-of-age, and is easier to explain to communities. However, some countries reported that it can be disruptive in schools if girls from different grades have to be gathered for vaccination (while this hasn't been disruptive in other countries). Grade-based can be easier to manage at the school. However grade-based can also be challenging if there are girls older (or younger) than the recommended 9-14-years in the grade.

When school headmasters and teachers of all schools are involved and coordinate with the school health team in areas where school enrollment is high, denominators can be very accurate.

“We check enrollment with the headmasters of all public, private and religious schools,” said one middle-income country with a school health programme and >95% HPV vaccine coverage, “and the school health team verifies the numbers.”

Countries also report that timing enumeration a few weeks after the school term begins is important as school enrollments will be more accurate once pupils have had time to settle into their schools and grades.

Timing

Time, or the lack of it, was an issue for countries. Countries noted success when work plans and timelines were respected by everyone, and when arrangements ensured planned funds were released on time.

Microplanning

Countries that conducted **facility-based microplanning** with local stakeholders including schools and the community had more success.

Training

Countries generally used a **cascade approach** to training, from national to sub-national, districts and local levels. Trainees included health managers, supervisors, health workers, health educators, school health teams, pharmacists, headmasters, teachers, and community health workers.

Training was considered successful when **standardised guides and sufficient IEC materials** were available, and when everyone's roles and responsibilities were clear.

Countries cited **insufficient training time as a common problem**. Several countries noted they would have planned for longer training sessions (e.g. two days as opposed to one) for health workers. Some countries, health workers and/or teachers agreed their training was too short.

For at least part of the allocated training time, some countries **trained health workers and teachers together and found teachers could be a big help** to health workers in planning, mobilization and implementation. Others provided training to health workers and separate orientations for teachers depending on their roles and responsibilities.

Regarding **training content**, one country stressed that "health workers really need to understand cervical cancer and its prevalence in the country, the link to HPV, and the role of the vaccine to prevent HPV infection and the normal side effects. **The more health workers know, the more they can advocate for the vaccine.**"

Coordination and Planning: Implications for Action

- ✓ Establish a **national planning committee and sub-committees**, and meet regularly to monitor progress and adjust plans.
- ✓ For school-based programmes, the **Ministries of Health and Education should coordinate early and closely at all levels** – from Ministry level to teachers, parent-teacher associations and community health workers.
- ✓ **Use existing platforms** whether EPI or school health programmes to deliver HPV vaccine.
- ✓ **Map out and coordinate with non-traditional partners** - who may be the strongest advocates - including cancer/NCDs, adolescent health, women's health, professional associations (gynecologists, oncologists, general practitioners, pediatricians), parent-teacher and in some countries, religious associations.
- ✓ Take the opportunity to explore how **vaccination could be coordinated with other cervical cancer prevention activities during and post-introduction**.
- ✓ **Spend adequate time and resources to double-check denominators** through reliable sources including education-sector statistics on school enrollments and with headmasters, but consider how to account for girls who are repeating a grade or change schools. Enumerating and registering out-of-school girls will take time and should involve the health facility, community health workers, community-based NGOs and leaders.
- ✓ **Identify, list and contact all schools** – including private and religious schools – and **coordinate activities to avoid coinciding with school holidays and exams**.
- ✓ **Allow at least six months** for planning, community- based microplanning and training including preparation of standardized training materials.
- ✓ **Ensure planning includes the necessary processes for timely release of funds**.
- ✓ **Consider who needs to be trained and oriented** and ensure **enough time** is allocated to teach the training curriculum. A few hours is not enough. It can be helpful to train health workers and teachers together for at least part of the time. Ensure all trainees have a thorough understanding of cervical cancer, the links to HPV, the protective benefits and side effects of the vaccine, as well as their role in crisis communication and rumor management.



DELIVERY STRATEGIES



THE ISSUES

Choosing a cost-effective delivery strategy is one of the most important success factors for sustainable HPV vaccine introduction. The strategy will have an impact on costs, human resources, monitoring, acceptability, coverage and ultimately on sustainability.



THE EXPERIENCES


SCHOOL-BASED DELIVERY

Demonstration programmes have almost all focused on school-based delivery as the primary strategy to reach target-age girls, with opportunities for out-of-school girls to be vaccinated in outreach services or at the health facility. For girls who are sick or otherwise miss a dose, countries have either returned to schools for mop-ups (an expensive strategy), asked the girl to visit the health centre, or vaccinated them during the next scheduled school visit.



Country views on the pros of school-based delivery:


- Coverage can be very good when the EPI and/or school health programme is strong, school enrollment is high, there is good coordination with the Ministry of Education, health workers, teachers and parents.
- Headmasters and teachers – often influential and respected – can be involved in mobilizing communities, registering girls, coordinating consent, providing a space (library or classroom) for the immunization session, reinforcing or assisting with health education. They can also follow-up with girls who were absent on vaccination day.
- HPV vaccination is an opportunity to provide other adolescent interventions such as additional vaccines, deworming tablets, menstrual hygiene and life skills education.
 - Some countries are asking teachers to provide deworming tablets during or shortly after HPV vaccine immunization sessions.



For a further discussion on delivery strategies see also WHO's 2016 guide for *Introducing HPV Vaccine Into National Immunization Programmes*, Chapter 2.

Country views on the challenges of school-based delivery:

- Can be expensive, particularly if implemented in “campaign mode” or treated as special outreach for which per diems and transport costs are required for health workers to travel to schools.
- Must include all schools – including private, religious and special schools – which may not be under the jurisdiction of the Ministry of Education or part of the school health programme.
- Insufficient coordination, mobilization, engagement and awareness, particularly at private and religious schools can lead to resistance such as school authorities withholding authorization to vaccinate or parents not providing consent.
- HPV vaccine delivery must be coordinated with school holidays and exams.
- Can be onerous for health workers to plan and implement, potentially take time from their other work, and may affect the continuity of service delivery.
- Schools may not welcome the class time lost to HPV vaccination.
- Can be difficult to fully vaccinate girls if they're absent, change schools or drop out. The evidence for the best ways to reach these girls is, so far, fairly scarce. Many countries report that community health workers can be very helpful to mobilize out-of-school girls.



The PATH/LSHTM review found that delivery of all doses within one school year minimised drop-outs and facilitated tracking girls to complete all doses.

HEALTH FACILITY-BASED DELIVERY

In contrast to high-income countries, very few low- or middle- income countries have tried to deliver HPV vaccine solely through a routine health-facility approach and there are only a couple of examples to report. Several high-income countries with facility-based delivery record lower coverage. In 2014 for example, full coverage was 39.7% in the USA; and 54% in Latvia¹. Some other countries managed to achieve coverage above 80% (Denmark; Portugal².)

¹ USA coverage figures are reported here: <http://www.cdc.gov/vaccines/who/teens/vaccination-coverage.html> and Latvia coverage figures were reported by the country at the 2015 Lessons Learned Meeting.

² Brotherton JM., Bloem P. *HPV Vaccination: Current Global Status*. *Curr Obstet Gynecol Rep* (2015) 4:220–233.

Bhutan switched from a school-based delivery programme, to routine health-facility delivery and then back again. In 2010 Bhutan delivered a catch-up campaign for girls aged 12-18 in schools, and achieved HPV3 91% administrative coverage. However, Bhutan found school-based delivery to be costly, and so it switched to facility-based delivery for 12-year old girls from 2011-2013. HPV3 coverage dropped to about 70% in this period. So, Bhutan switched the strategy back to school based for grade 6 girls, and HPV3 coverage in 2014 increased to 94%. Currently, the Ministry of Health with support from WHO is conducting an economic analysis in Bhutan to understand the cost-effectiveness of school-based and health facility routine strategies. Bhutan continues to determine the optimal mix of delivery strategies throughout the country in order to sustain the programme in the long-term. Programme managers are looking at areas where they might gain efficiencies such as co-delivery of tetanus vaccine with HPV.

Tanzania is testing a routine immunization strategy in Year 2 of its Gavi-supported demonstration programme. In 2014 (Year 1), Tanzania delivered two rounds of HPV vaccine targeted at 9-year old girls in a 1-week “campaign-mode” to schools spaced six months apart. A coverage survey showed 94% coverage. However, this proved to be more expensive than anticipated, so in Year 2 Tanzania switched to routine based vaccination – a mix of facility-based delivery with routine outreach including to schools and communities. The country reports that health facilities are generally quite close to schools, and that health workers will coordinate closely with schools to mobilize girls for vaccination. Once Year 2 results are known, the Tanzania experience will provide an excellent opportunity for learning about different HPV vaccine delivery strategies.

Delivery Strategies: Implications for Action

- ✓ In order to understand the trade-offs between reaching high coverage and the related impact on coverage, cost, human resources, logistics and other factors, **countries implementing demonstration projects might consider testing and evaluating more than one type of delivery strategy**. This could even be done in two different districts in the same year.
- ✓ Countries should **analyse multiple delivery options** to determine how they can achieve the highest coverage at an affordable cost. Strategies may need to vary in different parts of the country (e.g. in districts with high number of out-of-school girls), and they may be changed over time as the programme matures.
- ✓ Countries **may be able to achieve high coverage with a school-based strategy, but may not be able to afford to sustain it** due to costs.
- ✓ School based delivery may be **more efficient and affordable** if other interventions – such as tetanus vaccine or deworming – are **integrated with HPV vaccine delivery**, allowing some of the delivery costs to be shared among programmes.
- ✓ Countries should consider the added costs associated with campaign-style approaches and assess the option to use routine approaches including health facility and regular outreach.
- ✓ **Routine delivery through the health facility will likely require more resources for communication and social mobilization** so that girls and their caregivers know when and where the vaccine is available, especially in countries where health facilities may not offer services during weekends and outside of school hours.
- ✓ **WHO and partners will continue to update and advise countries** on costing analyses and coverage studies to help countries make decisions on sustainable delivery strategies. **Analysis of cost data and coverage levels are key** for countries to make decisions on sustainable delivery strategies, including several years after introduction when countries may wish to review and fine-tune strategies.



REACHING
HARD-TO-REACH
GIRLS



THE ISSUES

Reaching the hard-to-reach is a matter of equity and a guiding principle of the Global Vaccine Action Plan. These girls are often at higher risk of HPV infection and cervical cancer, particularly if they are human immunodeficiency virus (HIV) positive, yet registering and following-up with them can be a challenge. Hard-to-reach girls can include those who are not enrolled in, or rarely attend school; girls living in zones affected by conflict; girls living in challenging terrain or in dense urban settings; girls who are part of a minority community; girls who are working in the informal sector; girls with disabilities; are HIV+; girls who move frequently (e.g. nomadic communities); and girls whose caregivers are vaccine-hesitant. The number of hard-to-reach girls can be very large: for example, an average of 1 in 4 primary-school aged girls are out-of-school in Gavi-eligible countries. Amongst the poorest quintile, that number rises to 4 in 10 girls.¹



THE EXPERIENCES

Many countries have recently introduced HPV vaccine and haven't yet focused on hard-to-reach girls. Experience reported so far indicates mixed results.

Countries report that it can be expensive to locate, register and follow-up hard-to-reach girls for vaccination.

Some countries report that the proportion of out-of-school girls is very low (e.g. <3%), and so they don't focus on reaching them. One middle-income country noted their programme only covered

¹ Based on an analysis of UNESCO's Institute for Statistics database: <http://data.uis.unesco.org/>.





girls registered in public and special schools but agreed it should start considering ways to reach out-of-school girls.

One middle-income country reported that it had a very good community nursing system that had the capacity to enumerate, register and support out-of-school girls to be fully vaccinated.

Two Latin American countries have introduced nominal HPV vaccination registries which help to identify and follow-up with hard-to-reach girls.

Countries have used different strategies for hard-to-reach girls:

- The most common is for **community health workers to connect with local leaders to enumerate and mobilize out-of-school girls** wherever they are – at home, on the farm, the market, or transit points.
- Countries generally pick one age for out-of-school girls – aged 9 or 10 for example.
- Challenges include difficulties in assessing the girl's age, and being certain that every girl has been located and registered.
- Another challenge presents in countries where it's illegal for girls of this age to be out-of-school – in these cases caregivers may be reluctant to identify their girls and they may not come forward for vaccination.
- **Very few countries disaggregate and report vaccination coverage for out-of-school girls** and those that do have challenges with denominators.
- Countries generally **translate materials into local languages** for minority communities.
- **When caregivers are vaccine-hesitant**, countries work with trusted influencers such as religious and traditional leaders or school headmasters to speak with the caregivers.

Ideas to improve coverage of hard-to-reach girls include:

- **Invest in strengthening ties between communities and health facilities** by:
 - increasing community mobilization to increase demand;
 - investing in women peer leaders from the community;
 - investing in champions at the health facility;
 - strengthening links with local community and faith-based organizations.
- **Use practical EPI and other public health tools and lessons** such as:
 - Add HPV vaccine to regular routine outreach;
 - Ask community health workers to conduct an annual census in their zone;
 - Use lessons and data from the polio eradication programme;
 - Map where girls congregate;
 - Provide integrated services to hard-to-reach girls and include additional health interventions such as vaccines, bednets, deworming tablets, menstrual hygiene or referrals to school vouchers;

Girls who are HIV+ can also be hard-to-reach. Protecting these girls with three doses rather than only two dose of vaccine is important as evidence shows they are at greater risk of cervical cancer disease progression to high grade and invasive lesions. In 2012, there were approximately 2.1 million adolescents living with HIV and about one-seventh of all new HIV infections occur during adolescence. Many do not know their status. The incidence of CIN, as confirmed by colposcopy, is four to five times higher in HIV-positive women and adolescents compared to HIV-negative women and adolescents with high-risk sexual behaviors. It can take only 5 to 10 years in women with weakened immune systems, such as those with untreated HIV infection, to develop cervical cancer. More work is required to reach these girls – already potentially facing stigma, discrimination, and low access to testing and treatment - while preserving their confidentiality.

- Provide small incentives to girls such as small foodstuffs, or simple bracelets.
- **Use laws and policies** such as the Social Welfare Act.
- **Ensure parents and girls will not be punished** for identifying out-of-school girls in countries where being out-of-school is against the law.
- Understand hard-to-reach girls and how to reach them better **through anthropological and other socio-behavioural studies**
- Understand costs and benefits of reaching hard-to-reach populations through **cost-effectiveness studies** and modelling.

In the longer term, countries agreed that **higher school enrollment, birth registration and more financing** would all be required to reduce the numbers of hard-to-reach girls.

Hard-to-reach girls: Implications for Action

- ✓ **To achieve equity, plan for more time and resources** for enumeration, registration and coverage of hard-to-reach girls.
- ✓ **Monitor registration and coverage of hard-to-reach girls.**
- ✓ **Invest in strengthened ties between health facilities and communities** including through HPV vaccine microplanning with community leaders.
- ✓ **Consider adding HPV vaccine to routine outreach services.**
- ✓ **Train health workers to welcome and not report or punish hard-to-reach girls, whatever their school or other status.**
- ✓ **Ensure communication strategies that will reach and mobilize hard-to-reach girls;** including by engaging trusted influencers and media; and producing accessible IEC materials that are literacy and language appropriate.
- ✓ **Consider**
 - **integrated services for hard to reach communities.**
 - **small incentives for girls who visit the health facility.**
 - **how HPV vaccine opportunity could connect hard to reach girls with the education system.**
- ✓ **Invest in studies that will help to understand behaviours, risks, motivations and movements of hard-to-reach girls and their caregivers.**





DEMONSTRATIONS AND PHASED INTRODUCTIONS

THE ISSUES

Demonstration programmes and phased introductions give countries the opportunity to learn by doing, and understand how to achieve high coverage sustainably. To date, 30 countries have either begun, or will soon begin, demonstration projects supported by Gavi. They have tested ways to conduct effective demonstration programmes and have a lot of advice to share, though some are taking more time to find the ideal delivery strategy. Many more countries have done pilots of varying scale. Some countries are phasing in national introductions in a step-wise manner over a few years in order to design affordable delivery strategies for different settings.

THE EXPERIENCES

Countries generally agreed the demonstration projects and small pilots have been valuable to gain experience with:

- a new vaccine for a new female-only target group.
- enumerating, registering, securing consent for, and vaccinating a new target population.
- testing and evaluating different delivery strategies.
- gathering data to inform budget decisions.
- handling communication for a vaccine that is known to present challenges with rumours and misunderstandings.
- working with new stakeholders, including the Ministry of Education, cancer control, school health, and adolescent health programmes.
- strengthening health worker capacity and building their confidence.





- strengthening ties to the community including with religious leaders and teachers.
- developing the communication, training, and monitoring tools required.

Some countries also felt demonstration programmes helped to trigger momentum and demand for a national introduction.

Countries also spoke of challenges to demonstration and pilot programmes. These included:

- Gavi demonstrations were considered a lot of work for a small population – including the planning, implementation and evaluations.
- demonstration districts were often selected based on the potential to achieve good coverage (e.g. easy-to-access area with very high school enrollment) – so that lessons learnt from the districts may not be apply to nationwide roll-out
- not taking the opportunity to test different delivery strategies and challenging districts.
 - PATH/LSHTM lessons learnt review found that only 5 of the 36 countries they reviewed had purposefully selected areas that included challenging or hard-to-reach target groups, or tested and compared different delivery strategies.
- countries have mainly delivered in “campaign mode” to reach high coverage– which is resource-intensive and not always feasible for a sustained national programme.
- countries may apply for or repeat demonstration programmes to respond to political pressure to introduce HPV vaccine, without strong political commitment for national scale-up; and prolonging HPV vaccination in demonstration or pilot settings may reduce momentum for national introduction.
- the Gavi-suggested timeline for evaluations in years 1 and 2 followed by national introduction was not realistic (note that Gavi does consider a 3rd year to “bridge” from the demonstration o national introduction).
- some countries said the word “demo” triggered fears of “vaccine trials” in the population.
- difficulties communicating why a “demo” was only taking place in a select number of districts.
- political pressure to extend a demo to specific or additional districts.

The PATH/LSHTM review found that “well-designed demonstration programmes assessed different delivery strategies, tested how to achieve high coverage in populations and areas with specific challenges and focused on integration with national systems.”

Some demo countries discussed what they might do differently in hindsight. These included:

- conduct a costing analysis before applying for the demonstration.
- work with partners well in advance to more clearly assess key issues (such as budget, delivery).
- encouraging partners to conduct more orientation meetings with potential demonstration countries to share lessons learned.
- test and evaluate different strategies in Year 1.
- select more challenging districts including those with more hard-to-reach communities.
- considering a phased national introduction instead of a demo. This was also one of the recommendations made by the researchers in the PATH LSHTM Lessons learnt project.

A handful of countries said they would have preferred not to have demonstration programmes and would instead have liked to introduce nationally.

Demonstrations and Phased Introductions: Implications for Action

- ✓ Countries considering demonstration programmes could work closely with partners in advance to assess potential delivery strategies, integration with EPI, costing and other implications of the demonstration and national roll-out.
- ✓ Countries might consider **testing two different primary delivery strategies**, even in Year 1.
- ✓ Countries should **select demonstration districts that are more representative** of country conditions and test the potential to deliver hard-to-reach populations.
- ✓ Countries should **assess whether the word “demo” will trigger rumours and misunderstandings** about the programme, and choose alternate ways to describe it.
- ✓ Countries might **consider phased national roll-outs** rather than a demonstration project as this provides the opportunity to secure budgets and build political momentum while learning lessons that can be applied nation-wide.
- ✓ **Donors can assess and update requirements** for demonstration programmes based on learnings to date.
- ✓ **Technical partners should provide more timely orientation meetings** to share lessons with countries considering demonstration programmes or national roll-out.





COMMUNICATION



THE ISSUES

Global experience with HPV vaccine underscores the value of investing in communication. It is a unique vaccine, targeting young adolescent girls to prevent a sexually transmitted infection, and its full and major benefit will not be seen for decades. Rumours and misunderstandings are common in HPV vaccine introductions. Poor communication planning, new consent processes, and slow response to rumours in some countries has led to poor acceptance and coverage. Reassuringly, investing in communication with the right stakeholders, early community mobilization and engagement, combined with a rapid response to any rumours has shown achieving high coverage is possible.



THE EXPERIENCES

Countries advised to start early and build on existing platforms and communication lessons acquired in polio eradication, tetanus, measles and routine immunization programming.

One middle-income country negotiated to include support for communication programming as part of their vaccine procurement process.

Several countries and partners suggested gathering data before, during and after to measure the impact of communication. This includes Knowledge, Attitudes and Practice (KAP) studies, smaller surveys, monitoring during implementation (including for rumours) and evaluating for impact.

“Our KAP study told us there was potential for HPV and HIV to be confused,” reports one country. “So we took this into account in our communication plan.” An eastern African country said: “We did a KAP study and found that different language communities use different words for ‘cervical cancer’, so we tailored the messages so they would be understood by all.”

Several countries reported problems if they didn’t work with the right stakeholders early enough

“We engaged the Chief of the district to bring his community for vaccination and he did. We had very high coverage in that community,” reported one central African country. “But we didn’t mobilize a leader from a different religious tradition in the same district, and his people didn’t come out.”

“Shortly before introduction, a human-rights organization threatened to sue the government as it assumed we were conducting a trial. We had to work quickly to meet with this organization, listen to them and put their fears to rest,” reported one eastern African country.

“We found that working with parent-teacher organizations was absolutely critical,” said one southern African country, and many others agreed.

“To ensure HPV vaccine was acceptable culturally, our religious leaders issued a *fatwa* for girls to be vaccinated,” reports one country with a majority Muslim population that achieved near universal acceptance and sustained high coverage levels.



For more on HPV vaccine communication, see WHO’s *HPV Vaccine Communication: Special Considerations for a Unique Vaccine* (2016) at <http://www.who.int/immunization/hpv/communicate/en/>

Countries advise to prepare for and respond rapidly to common types of rumours and questions about HPV vaccine:

“Will this sterilize my daughter?” “Why should she have this vaccine now when she isn’t yet sexually active?” “Will this make her sexually active?” “What are the side effects?” “I heard it makes girls paralysed. “Why can’t I/my daughter/my mother have the vaccine too?” “Why the girls and not the boys?””

Consent was an issue for some countries especially if they introduced unfamiliar processes. Consent in private and boarding schools often had to be handled differently than in public schools.

“We don’t have formal consent for other vaccines. But we introduced one for HPV. When caregivers saw this, they started to doubt the safety of the HPV vaccine. Huge numbers in urban areas didn’t allow the girls to get vaccinated. We had to make a rapid decision to withdraw the consent forms.”¹

“Headmasters in private schools will not allow girls to be vaccinated without consent. So, coordinate with these schools to ensure acceptable consent processes are in order,” advised one country.

Different audiences, including the media, out-of-school girls and decision-makers will need different packages of information, ranging from simple to the sophisticated. They will also respond to different influencers. The PATH/LSTHM study found the main messages to include are cervical cancer prevention, vaccine safety and efficacy, government endorsement, and where and when to get vaccinated.

“We kept the messages simple for girls and their caregivers,” said one demonstration country. “But we need more scientific responses and messages for those who are taking a deeper look or have questions based on what they are reading on the internet,” said another country.

“Be sure the media have a comprehensive package of information and receive a briefing early,” advised another. “If they report the facts wrong there will be a lot of trouble. Call media right away and ask for corrections if they make any mistakes.”

“The First Lady can be a wonderful champion to mobilize high-level stakeholders as well as the country,” advises one eastern African country. “But girls will also respond to celebrities,” noted another.

Countries find that language consistency really matters.

“We have so many minority languages with different nuances in each,” said one Pacific Island country. “But everyone understands English, and so we maintained all materials in English so the messages would be standardized and understood by all in the same way.”

“We must translate all of our materials into the main languages,” reported one western African country. “Our people believe that ‘if it’s not in my language, it’s not for me.’” Another country reminded that “it’s important to test translations and ensure they are accurate and understood.”

Social media makes a difference to the target audience – in communicating messages, and in spreading and managing rumours.

“Girls love social media, so we use Twitter, Facebook and other social media,” reports one south-east Asian country. “This platform allows us to engage girls directly in a way they can relate with.”

“Once it’s on social media it’s everywhere,” stressed one southern African country.

¹ For more on consent see WHO’s “Considerations regarding consent in vaccinating children and adolescent between 6 and 17 years old.” http://www.who.int/immunization/programmes_systems/policies_strategies/consent_note_en.pdf

Experienced countries advise to plan for a longer-term investment in communication.

“You can plan for a big push at the beginning but there will be a new cohort of girls and parents who need to understand HPV vaccine every year,” advises a country that introduced the vaccine several years ago. “So plan to invest in ongoing communication.”

Communication: Implications for Action

- ✓ Start early to map and begin work with the right stakeholders. These can include Ministries and groups not usually involved in immunization including the MoE, adolescent health, gynecologists, NCDs specialists, religious groups, parent-teacher organizations, private schools, and various community-based organizations.
- ✓ If procuring vaccine with a manufacturer, consider requesting support for communication as part of the procurement package.
- ✓ Plan strategies to **proactively address and rapidly respond to common questions and rumours** about demos being mistaken for “trials”, vaccine safety, target population, sexual activity, fertility, and side effects.
- ✓ Consider gathering **additional information through small surveys or even a KAP study** to determine the level of understanding and language used amongst different stakeholders concerning cervical cancer, HPV, HPV vaccine and immunization. In addition to helping a country create an evidence-based communication strategy, this information will provide a baseline from which to measure progress.
- ✓ **Tailor strategies, messages and materials** for specific audiences, including girls, caregivers, teachers, health workers, media and professional organizations or other specialists who need sophisticated information.
- ✓ **Messages** work effectively when they promote the vaccine as cancer vaccine, its safety, efficacy, and include details about who, where and when to receive it.
- ✓ Materials should make clear that the government endorses the vaccine - through use of a logo for example.
- ✓ Decide whether to use **one language, or several** – and if materials are translated ensure they’re consistent and appropriate for the language groups.
- ✓ **Ensure media are oriented early with clear materials.** Ask for corrections immediately if media make any errors or unfounded allegations.
- ✓ **Take care when choosing the consent process to avoid the suggestion that HPV vaccination is part of a research project; while also balancing caregivers and girls’ rights to provide informed consent.** Some schools, particularly private schools may require a specific consent process.
- ✓ **Include a system to monitor for rumours and problems and respond to them very rapidly.**
- ✓ Use **monitoring and evaluation** to determine the impact of communication on HPV vaccine programming, and adjust the communication plan as necessary.
- ✓ **Invest in a long term** communication strategy that offers updated information for stakeholders every year, including about the HPV vaccine’s impact on infection and disease.



MANAGING CRISES



THE ISSUES

Crises can take many forms- from a vaccine stock-out to AEFI rumours to a natural disaster. Some can be avoided through planning while others are out of a country's control. Crises can result in lost time, money, low coverage and sustained damage to a vaccination programme.



THE EXPERIENCES

Countries reported a variety of types of crises. These included:

Managerial crises occurred when funds weren't released on time, insufficient vaccine was delivered, or health staff took strike action.

Middle-income countries that manage their **own vaccine procurement talk about the importance of including strict vaccine management and distribution clauses in the contracts**, with penalties for non-adherence.

Some countries mentioned the importance of creating a **checklist of items that need to be procured and bundled**. Vaccine without safety boxes or syringes for example can cause a big problem.

One south-east Asian country had major problems the year of national introduction. Funds were released late, there weren't enough fridges in the cold chain, and the manufacturer had insufficient vaccine supplies. So they worked quickly to change the plan, and split the provinces into two groups so they could phase the national introduction over the year.

Pacific Island countries are challenged by logistics, with the need to deliver vaccines to islands that might require days of travel by boat or irregular flight schedules. **When flights are cancelled or boats don't arrive on time**, these countries need to act quickly to get vaccines delivered, but this can result in extremely expensive charter flights.

In one western African country, **some schools were missed during pre-registration**. When vaccinators discovered a school not included in their list, the headmaster was furious and demanded the girls be vaccinated on the spot. The vaccination teams agreed, but this meant they had to return back to their base for supplies in order to complete the vaccinations scheduled for that day.

In one eastern African country, partners didn't release funds on time. As campaign dates were set and communities mobilized, health workers proceeded using their own funds.

Some countries warned about **the need to manage expectations concerning incentives**. One eastern African country had provided small incentives to community leaders to mobilize their populations. Coverage was good in the first round. For the second, the girls did not return. Community leaders said it was due to not being paid. The health teams subsequently had to meet with the community leaders to ask them to mobilize the girls for all three rounds. They did, but it required extra unplanned work.

Communication Crises occur when there is a gap in stakeholder involvement, poor choice of messaging, rumours in a community (including those spread by anti-vaccination groups), slow response to an adverse event following immunization (AEFI) or other problem.

One eastern African country didn't plan adequately to **engage with religious leaders in the original communication plan**. They encountered major problems as girls refused to be vaccinated. The country worked with health professionals of the same faith to interact with the leaders. This resulted in success but took additional time and resources.

Crises in another country can cause a crisis at home. **Days before launching in Bhutan**, media reports indicated neighbouring India's HPV pilot was being suspended for safety reasons. The Bhutan Ministry of Health rapidly invited experts to sit together and review the vaccine safety record, and reaffirmed that it was indeed safe. The Ministry then invited all stakeholders and explained its views on HPV vaccine safety, and all agreed with its intention to proceed with the national introduction. The Minister made a public announcement and held a panel discussion with media present to ensure the correct messages about the vaccine's safety and introduction. Within a few days the issue had been addressed and resolved. Bhutan achieved very high coverage in that first year.

"Demo crisis": A few countries discussed the **challenges of the word "demo" and how it in itself caused problems**. Several countries said the word "demo" implied HPV vaccine was a trial. Others encountered additional demand – and talked about the challenges of selecting one district over another as neighbouring districts also wanted HPV vaccine for their girls.

Unforeseen crises out of the control of EPI staff were mentioned by several countries, including natural disasters and strikes. One western African country encountered teacher strikes during the HPV vaccination campaign. Many of the girls were still at school, so the health teams visited the schools and asked the girls to get their friends. The health teams ended up travelling door to door to reach some girls. Another western African country encountered a strike when the per diems were deemed too low.

Managing Crises – Implications for Action

- ✓ **Be prepared**: Being aware of common pitfalls with HPV vaccine, countries can plan to avoid crises as much as possible: by early thorough planning that anticipates risks and potential problems, engagement of the right stakeholders, work plan oversight and accountability, an investment in communication and training.
- ✓ Create a risk mitigation plan.
- ✓ When making decisions, ask: "if we take X action, do the benefits outweigh the risks? How can we mitigate the risks?"
- ✓ **Act quickly** When a crisis does occur, and be sure the right people make and communicate decisions.
- ✓ **Public safety is not negotiable** and is the primary goal. On other issues **be nimble and flexible** to find solutions that will be acceptable.





RECORDING, MONITORING AND EVALUATION

THE ISSUES

As a new vaccine targeting different age cohorts or entire grades, HPV vaccination has seen a wider range of recording methods and indicators than for infant vaccines. As a result data have not always been comparable.


THE EXPERIENCES

Globally, WHO and UNICEF have not yet started to report HPV vaccine coverage estimates based on data countries provide through the Joint Reporting Form. This work is in process as more countries start reporting and data quality improves. Regular reporting of HPV coverage estimates should start in 2017.

To establish target sizes and to register girls, countries have generally enumerated girls in school and out-of-school, and kept clinic- and/or school-based registers. Some countries store and report them together with EPI records, while others (primarily the demo countries) have not yet integrated data reporting.

Most countries have developed HPV vaccination cards for girls. Many leave these in the care of the school and give them to girls once their doses are complete or if they transfer schools. Some countries have added messages to the cards about cervical cancer, the benefits, target age and doses required.

► Figure 2 South Africa’s HPV vaccine card includes messages about HPV.

 <p>Basic Education Health</p> <p>Human Papillomavirus (HPV) Vaccination Card</p> <p>Keep this card in a safe place. Bring this card along for the next dose.</p>	<p>Parent please complete and return to school</p> <p>ID. No. _____</p> <p>Name: _____</p> <p>Surname: _____</p> <p>Date of birth: _____</p> <p>Name of School: _____</p> <p>Grade: _____ Date: _____</p> <p>Name of parent/guardian _____</p> <p>_____ hereby grant permission for my daughter _____ (Name of daughter) to receive the HPV vaccination.</p> <p>_____ Signature Date: _____</p>	<table border="1"> <tr> <td>Parent please complete</td> <td>Y/N</td> </tr> <tr> <td>Allergic to any vaccine</td> <td></td> </tr> <tr> <td>Severe illness in the last 7 days</td> <td></td> </tr> <tr> <td colspan="2">Any other medical condition: _____</td> </tr> </table> <p>For official use only</p> <table border="1"> <tr> <td>Signature of Vaccinator</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Date</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Batch no.</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Dose</td> <td>HPV 1</td> <td>HPV 2</td> <td></td> </tr> </table>	Parent please complete	Y/N	Allergic to any vaccine		Severe illness in the last 7 days		Any other medical condition: _____		Signature of Vaccinator				Date				Batch no.				Dose	HPV 1	HPV 2		<p>Why HPV Vaccine?</p> <p>Cervical cancer</p> <ul style="list-style-type: none"> ➤ HPV is a viral infection that can cause cervical cancer <p>HPV vaccine</p> <ul style="list-style-type: none"> ➤ Reduces your chances of developing cervical cancer <p>Who gets the HPV vaccine?</p> <ul style="list-style-type: none"> ➤ Given to all girls in Grade 4 that are over 9 years <p>Who should not get vaccinated?</p> <ul style="list-style-type: none"> ➤ Girls under 9 years ➤ Girls who had a severe illness recently or are very ill now <p>How is it given?</p> <ul style="list-style-type: none"> ➤ Injection in 2 doses ➤ Second dose given 6 months after first dose <p>For official use only</p> <table border="1"> <tr> <td colspan="2">Date of Next Vaccine</td> </tr> <tr> <td></td> <td>HPV 2</td> </tr> </table>	Date of Next Vaccine			HPV 2
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Countries delivering through school-based health programmes often have or are planning more integrated “school health records”, where HPV vaccination is recorded with other health data and interventions.

A few countries briefly mentioned **supervisory visits**, but did not offer much detail. While some funds are available for supervision in demos, countries were concerned these funds were insufficient.

Countries generally report results with the same frequency and in the same manner as other vaccines, collating information from local to district to national levels. A handful of countries delivering in “**campaign mode**” **monitored and reported daily**.

Countries use a variety of indicators suggesting the need to harmonize global indicators. For example:

- ▶ Total coverage for each dose
- ▶ Total coverage for 1st dose
- ▶ Coverage for each dose for out-of-school girls (2 countries)
- ▶ Drop-out rate
- ▶ Completeness of reporting
- ▶ Acceptance rate (% of caregivers giving written consent)
- ▶ Vaccine wastage
- ▶ Number and types of AEFI


For **AEFIs**, countries generally relied on their **AEFI reporting systems**, and very few AEFIs were identified.

As a precautionary measure to maintain trust in the HPV vaccine programme, Malaysia has a unique system of active AEFI surveillance. They send minor AEFI reporting forms home with girls and ask parents to fill them and return them to school. This way, they can record the proportion of minor AEFIs ranging from pain at the injection site, to body aches and weakness. Compared with other vaccines, they record more HPV vaccine-related AEFIs as a result of the active surveillance, but the country also has ample data to show the types and normal frequency of AEFIs, which helps allay any concerns.

Countries did not report on any communication indicators, but some reported “**rumours monitoring**” mechanisms, picking up rumours and concerns in communities and media so they could respond quickly. A handful of countries had conducted KAP surveys to get a baseline on cervical cancer, HPV and HPV vaccine.

The challenges in defining accurate denominators pose a challenge for monitoring:

Age versus grade monitoring: Several countries reported that monitoring grades could be challenging when there was a range of girls in any given grade. For example, the equivalent of Class 5 may have girls aged 8 – 15 or older, with many target age girls in Class 6. Some countries (e.g. Rwanda) have switched from grade-based to age-based for this reason.



For more on age versus grade-based target populations, see the WHO HPV Vaccine Introduction Guide.

Denominator for the second dose: some countries calculate the coverage of the second dose based on those girls who received the first dose, failing to acknowledge all eligible girls for the denominator.

Monitoring out-of-school girls could also be a challenge as some countries were not sure if the denominators were correct. **Most countries did not monitor coverage of out-of-school girls at all.**

While HIV+ women have a 4-5 times greater risk of developing cervical cancer, **no countries reported on monitoring for coverage of immunocompromised girls** who require three doses of vaccine.

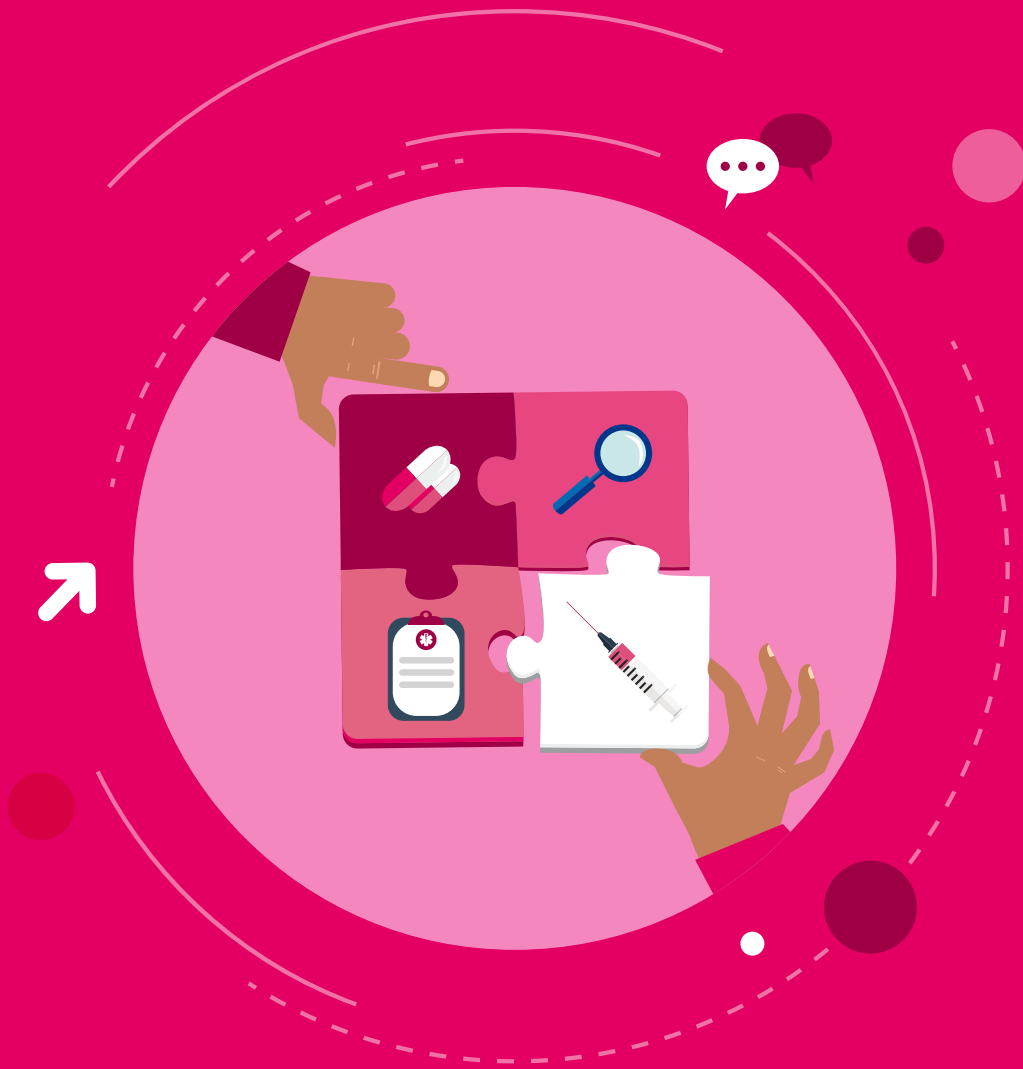
Some national programmes reported they are undertaking evaluations. For example, Fiji reports that two national studies of long-term protection are underway - one immunological and one for infections. **Australian** researchers have completed multiple impact studies on infections and cervical lesions. With WHO IARC support, Rwanda and Bhutan are involved in **impact studies using urine samples** to test for HPV prevalence and types.

HPV vaccine demo programmes had conducted Gavi-required evaluations, including the Post-Introduction Evaluation; a costing analysis; and coverage survey using the standard WHO cluster survey methodology. Countries report the Gavi-supported evaluations are helpful to find strengths and weaknesses, improve programming, and determine the costs for scaling up nationally. On the other hand, some countries also found these evaluations too labour-intensive and the time to conduct them between Year 1 and Year 2 too short, particularly when other new vaccine introductions do not have similar requirements. Gavi also reports some challenges – evaluations may cost more than anticipated, or funds intended for evaluation were spent on implementation and countries had to seek evaluation funds from other partners.

Reporting, Monitoring and Evaluation: Implications for Action

- ✓ WHO and UNICEF to provide guidance on monitoring HPV vaccination.
- ✓ WHO and UNICEF to start reporting on country estimates for HPV vaccine coverage.
- ✓ Gavi to re-consider its evaluation requirements given funding and workload for current evaluations.
- ✓ Countries introducing HPV vaccine to consider:
 - how to better integrate and monitor the frequency and quality of supervision.
 - ensuring coverage is calculated based on the total denominator, not the number of girls receiving the first dose.
 - how to use HPV vaccine introduction to improve AEFI reporting.
 - age versus grade based delivery and the implications for monitoring.
 - determining the target and monitoring coverage of out-of-school girls.
 - monitoring coverage of immunocompromised girls in collaboration with HIV programmes.
 - conducting more baseline communication-related surveys; including communication indicators for hesitancy and for determining the impact of communication activities.





INTEGRATION



THE ISSUES

Countries have an opportunity to integrate planning, offer existing and new services and gain efficiencies and better outcomes in comprehensive cervical cancer prevention and control and adolescent health. Countries are now exploring how, when and how much to integrate, balancing the challenges of working across programmes and sectors with the benefits of integrated services and the potential to save costs and gain efficiencies.



THE EXPERIENCES

CERVICAL CANCER PROGRAMMING

Many countries report that they have integrated or intend to integrate HPV vaccination as a primary prevention strategy in cervical cancer programming. Gavi-supported countries are creating draft national cervical cancer strategies and plans as part of the Gavi agreement.

A common way to integrate is to use the HPV vaccine opportunity to **raise awareness about cervical cancer, both with health workers and the public**. Countries have developed IEC materials and messages aimed at both adolescents and their female caregivers that promote **“vaccine for protection tomorrow, and cervical cancer screening today”**, particularly in countries where access to screening is higher.

A challenge with this approach is the **lack of cervical cancer screening in many low-income countries**.

However, some countries say that **HPV vaccine helps to create awareness and momentum to strengthen cervical cancer programming**. Often the impetus and evidence to introduce HPV




vaccine originates with the cancer programmes. Countries note that HPV vaccine planning and orientation meetings are increasingly bringing together immunization and cancer departments, though countries report that it can be challenging to continue coordination once the EPI programme becomes the lead implementer.



«..everybody talks about integrated approaches. Now [with the SDGs] the time has come for integration.»
- Dr. Margaret Chan, WHO Director General, 7 Oct 2015.

ADOLESCENT HEALTH PROGRAMMING

There are many opportunities for linking HPV vaccination to other adolescent health interventions.¹ For example, **coverage of chemotherapy for soil-transmitted helminthes is often low**, and deworming tablets can be integrated fairly simply with HPV vaccine delivery. Many countries **are already delivering other vaccines (e.g. Td) at schools but have not integrated with HPV vaccine delivery to gain efficiencies**. Some of the LMIC countries that have introduced HPV vaccine have started to integrate, but these experiences have not been fully documented. A lack of systematic data collection and research means there is very limited evidence of the potential benefits in contrast to integration of childhood vaccines for which more evidence has been collected.²



For more see WHO's *Options for Linking Health Interventions for Adolescents with HPV Vaccine*.

Gavi-supported demonstration countries are conducting adolescent health intervention assessments to determine which interventions might be co-delivered in Year 2 of programmes and beyond. For most countries, it is **still too early to introduce and evaluate interventions and more information will be forthcoming**. Common options discussed by some countries include health information or life skills sessions including information on menstrual hygiene, HIV prevention, deworming tablets, tetanus vaccine, or referrals to adolescent-friendly health services. A common concern is **how countries can mobilize resources for these interventions**. Another concern regards any potential side effects of co-delivery (e.g. with deworming), and the misattribution of side effects to HPV vaccine, underscoring the importance of evidence-gathering.

Some countries said the timeline for the adolescent health assessment was too close to Year 2 delivery in Gavi-supported countries, making it difficult to deliver additional services. Given this learning, **Bangladesh and Nepal are getting a head start by conducting their adolescent health assessments earlier or even before the start of vaccination in the demos**.

Rwanda regularly integrates additional services as part of a "Health Week." Rwanda now promotes hygiene, nutrition, addresses infectious disease and reproductive health when it provides the HPV vaccine. In an earlier year, Rwanda linked HPV vaccination and a measles vaccination campaign.

In middle and high-income countries, It's more common for countries to **deliver HPV vaccine as part of the School Health Programme**, integrating the vaccine with a range of other interventions provided to school children throughout their education. Some countries report they provide short (e.g. 30 minute) health information sessions to students prior to receiving the HPV vaccine.

¹ See http://www.who.int/immunization/diseases/hpv/linking_h_interventions/en/

² The Journal of Infectious Diseases discusses integration in a supplement : *Building on Success: Should Other Health Services be Integrated into the Immunization Platform?*, JID Volume 205 suppl 1 March 1, 2012.

Further, a USA-based study provides preliminary evidence that pairing the HPV vaccine with one or more co-vaccines may yield a higher HPV vaccination completion rate among adolescents age 9–18. See Keim-Malpass J et al, *HPV vaccination series completion and co-vaccination: Pairing vaccines may matter for adolescents*; Vaccine Vol. 33, Issue 43, Pages 5729-5888; 26 October 2015.



Madagascar Integrated training and delivery

Madagascar made efforts to integrate adolescent health services with HPV vaccination. First, Madagascar decided to provide deworming tablets together with HPV vaccine, because it was an established, trusted programme and there would be cost savings. Second, Madagascar trained health workers on adolescent health in conjunction with the HPV vaccine training, with a view to providing the skills to establish more adolescent friendly services in health clinics. Third, teachers were trained on how to give life skills education that could be taught to children in school. In total, more than 11,500 target age boys and girls received deworming in the two demonstration districts, and more than 1,000 teachers were trained on life skills education. A follow-up survey in 24 schools showed that all health workers and teachers had discussed adolescent health issues as per the curriculum with students. Madagascar also reports progress establishing 12 new adolescent friendly health service centres in the demo districts.



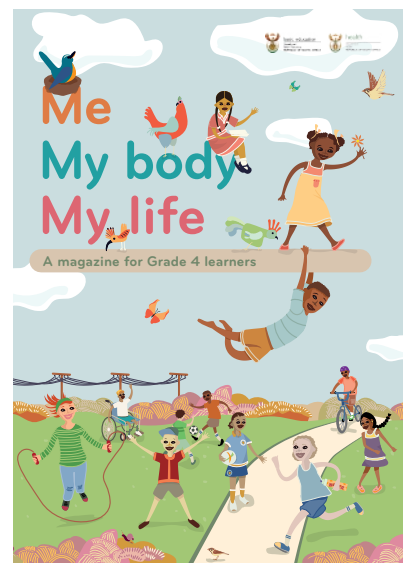
South Africa's Adolescent Health Workbook

HPV vaccine delivery was integrated nationwide into its public school health programme in March 2014, targeting Primary or Grade 4 students who are typically 9 years of age. In the school health programme, health teams travel to each school to provide a package for students in designated age groups (ages 5-8, 9-12, 13-15, 16-18). Interventions address barriers to learning and range from screening for vision, hearing, nutrition and oral health for younger pupils to sexual and reproductive health education for older students.

“With HPV vaccine, we wanted to provide an additional intervention for girls and boys so no one was left out,” says Dr. Nonhlanhla Dlamini, the Chief of child, adolescent and school health. “We developed a resource called *Me, My Body, My Life*. It is a workbook that provides Year 4 students the chance to learn and engage with information that will help to keep them and their communities physically and mentally healthy.”

The workbook presents colourful, hand-drawn child and adult characters in typical surroundings, discussing everything from puberty, to nutrition, healthy friendships and bullying, vaccines including HPV vaccine, tuberculosis, and unhealthy behaviours such as alcohol use. Students can answer quizzes, draw pictures, write journal entries and complete puzzles as they work through each page.

At the HPV vaccine session, the school health team distributes a copy of the the workbook to every Year 4 girl and boy and explains how to use it. Students then get started and work through the book while girls are called in for their HPV vaccine. “It’s a wonderful way for kids to learn about important issues in a fun, age-appropriate way,” says Dr. Dlamini. South Africa has more plans for integration. Next year, it intends to add deworming to its HPV vaccine sessions as well.

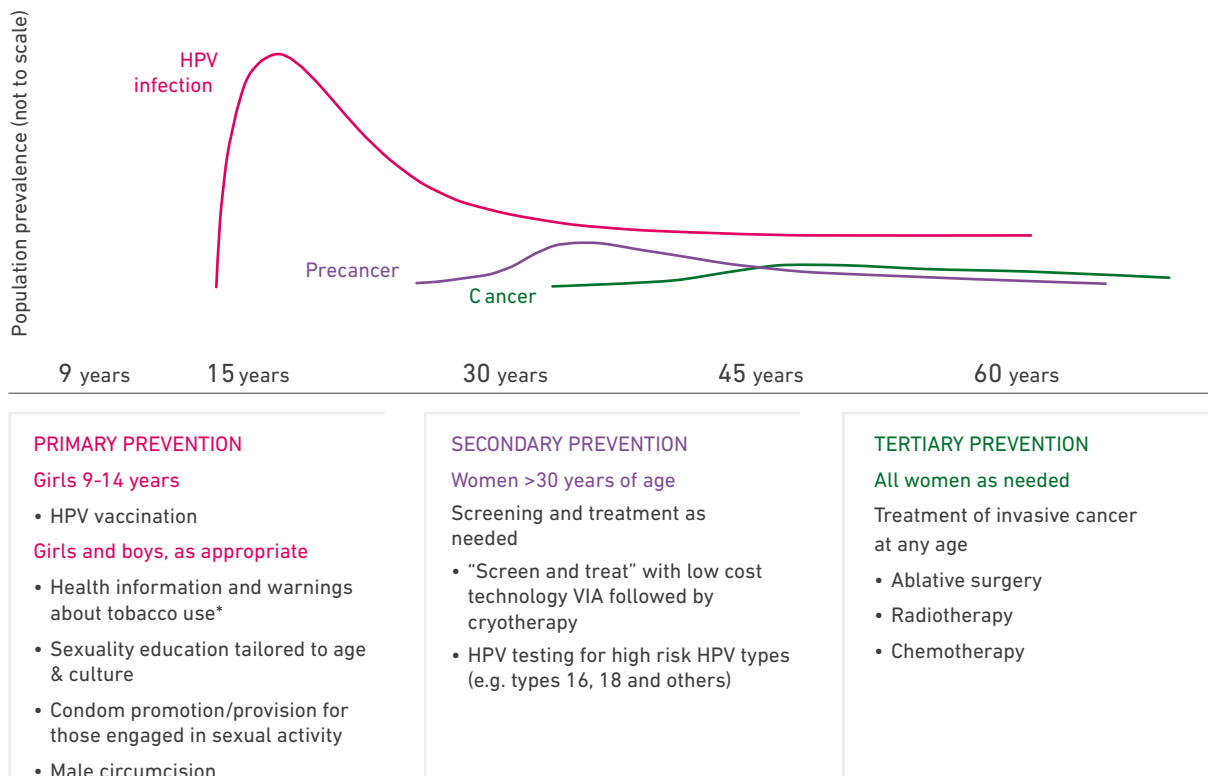


Integration: Implications for Action

For cervical cancer:

- ✓ Countries are encouraged to continue to build comprehensive cervical cancer prevention programming, with education, HPV vaccine, screening and treatment as key interventions through the life course. This will involve close coordination between EPI, NCDs and other departments. Countries can learn more in WHO’s **Comprehensive Cervical Cancer Control: A Guide to Essential Practice** (<http://bit.ly/WHOcervicalcancer>)
- ✓ Countries can use the opportunity of HPV vaccine to **increase knowledge, awareness, momentum and resources for cervical cancer** screening and treatment amongst decision makers, health workers, teachers, and communities, in women in particular.
- ✓ Countries should continue to use communication messages to promote HPV vaccine for girls and screening for mothers/female caregivers where screening is available.

► **Figure 3 from WHO Guidance Note Comprehensive cervical cancer prevention and control: a healthier future for girls and women, 2013**



* Tobacco use is an additional risk factor for cervical cancer.

For adolescent health:

- ✓ Countries are encouraged to **assess opportunities to integrate adolescent health services with HPV vaccine** where they will have a public health impact, are age-appropriate, and help to gain efficiencies.
- ✓ WHO has identified evidence-based options for integration as outlined in the table below.
- ✓ Coordination between EPI, adolescent health, school health, the education sector, and other groups may be challenging at first, but it holds the promise of contributing to better health outcomes for adolescents and more sustainable HPV vaccination through integration.

For both:

- ✓ Countries and partners need to better document integration efforts including studies on costs, impact on the health system and health outcomes, and to continue to share lessons.
- ✓ WHO and partners are developing costing tools for adolescent health programmes to foster integration.

► Figure 4 From WHO's Options for Linking Health Interventions for Adolescents with HPV Vaccinations, 2014.



TYPE	POSSIBLE HEALTH INTERVENTIONS
Screening	<ul style="list-style-type: none"> • Vision screening, if referral and glasses available and affordable
Commodities and treatment	<ul style="list-style-type: none"> • Anthelmintic treatment for schistosomiasis and soil-transmitted helminths (STH) • Insecticide-treated bednet for malaria prevention • Iron and folic acid supplementation
Information and life skills	<ul style="list-style-type: none"> • Promotion of physical activity • Prevention of mosquito-borne diseases • Menstrual hygiene education • Sexual and reproductive health education, HIV prevention and condom promotion
Other vaccines	<ul style="list-style-type: none"> • Td, Hep B, co-administration with other vaccines under investigation





COSTING, FINANCING AND SUSTAINABILITY



THE ISSUES

Economic and financial issues can be barriers to HPV vaccine introduction. As countries decide whether to introduce HPV vaccine nationally, decision-makers will want to know the approximate costs required to sustain the programme. Ministries of Health will need to convince the Ministry of Finance that there is a return on investment on HPV vaccine introduction. The PATH/LSHTM review found that most countries were uncertain about ongoing political commitment and future financing. The issue is particularly challenging for Gavi-supported countries that will eventually graduate and no longer receive funding.



THE EXPERIENCES

Based on initial assessments, Gavi estimated an eligible country would require US\$6 per girl to start-up an HPV vaccine demonstration programme in the first year, and US\$ 3 per girl each year to sustain the programme, excluding vaccine costs. Gavi has secured a vaccine price of US\$4.50 - US\$4.60 (depending on the vaccine) for each dose.

WHO has created a number of analytical decision making tools to assist countries with the introduction and scaling up of HPV vaccination programmes and cervical cancer screening and treatment. The following tools can be used in setting priorities for programming, financial planning and sustainability:

The PRIME modelling tool (Papillomavirus Rapid Interface for Modelling Estimates) assesses cost-effectiveness and health effects of vaccination of girls against HPV before sexual debut in terms of burden of cervical cancer and mortality. A 2014 PRIME study projected outcomes for 179 countries, and found HPV vaccination “very cost-effective” in 156 countries (87%) using global data bases for costs and epidemiology of HPV infections and cervical cancer cases and deaths.¹ The study models that vaccination of a cohort of 58 million 12-year-old girls in 179 countries prevented 690 000 cases of cervical cancer and 420 000 deaths during their lifetime (mostly in low-income or middle-income countries), The study also found that if 71 phase 2 GAVI-eligible countries adopt vaccination according to Gavi forecasts, then Gavi-funded vaccination could prevent 200 000 cases of cervical cancer and 100 000 deaths ever year in some of the highest-burden countries.² In 2015 the PRIME tool was introduced to national decision makers and academia using country-level data in Madagascar, Vietnam and Bhutan and results are expected in early 2016.³

The “C4P” tool, or Cervical Cancer Prevention and Control Costing and Planning Tool⁴ assists country managers and planners to assess affordability and sustainability of their national comprehensive cervical cancer prevention and control programme including HPV vaccine and cervical cancer screening and treatment. There is currently an HPV vaccination first year introduction and 5-year scale-up module that helps countries to assess the economic and financial costs for start-up and recurring annual programming. The tool has been primarily used in Gavi demonstration countries and in some middle and upper-middle income countries. WHO is now developing an integrated C4P tool to cost integrated delivery of HPV vaccine

¹ Jit, Mark et al. *Cost-effectiveness of female human papillomavirus vaccination in 179 countries: a PRIME modelling study*, The Lancet Global Health, Volume 2, Issue 7, e406 - e414

² These results would be achieved by 2070. Knowledge that protecting girls today will result in a national introduction of HPV vaccine therefore represent longer case studies.

³ For more on PRIME, see: <http://www.primetool.org/>. WHO also has plans to support PRIME studies in Sri Lanka, Madagascar and Uzbekistan. Note that PRIME does not model for more complex scenarios, including catch-up campaigns for older girls, comparing different vaccine valencies, male vaccination, assessing herd immunity or assessing impact on cervical cancer screening.

⁴ WHO Cervical cancer prevention and control costing (C4P) tool user guide. Geneva, Switzerland, 2012

with other interventions, such as the cervical cancer screening and treatment module and adolescent health programmes.⁵ The screening and treatment module has been piloted in Zambia and is to be rolled-out in more countries in Africa in 2016 while the adolescent health programme costing is still under development and to be tested in two countries in mid-2016. WHO also incorporated C4P in OneHealth for wider health sector planning and return of investment analysis and suggests ways in which the assessments can be linked to a country's comprehensive Multi-Year Plan for Immunization (cMYP).⁶

A preliminary C4P costing analysis conducted by WHO shows a range of financial costs per fully immunized girl (FIG) in demonstration countries including vaccine costs. Of seven countries examined, two were under US\$ 15 per FIG, four were between US\$ 15 – US\$ 25, and one was US\$ 25 – US\$ 35. Financial cost drivers include the number of doses, per diems, transport, training, microplanning, cold chain, communication/social mobilization, supervision, monitoring and evaluation.

Some preliminary key findings of the WHO C4P global costing analysis are:

- School delivery costs are higher than facility- based delivery particularly when the target population is small.
- High coverage is associated with high school delivery costs.
- Costs calculated in demonstration programmes per FIG are considerably higher (up to twice as high in some countries) than in 5 year scale-up scenarios.
- Facility delivery could reduce costs by 1/3 in countries with high per diems.

As C4P assessments are completed for more countries in 2016 and beyond, WHO will have more data to help better answer key questions, including whether different delivery strategies are more suitable to different settings, and the degree to which demonstration projects are indicative of national scale-up costs. In addition, further analysis will suggest country profiles based on common population demographics and density, economic development status, health systems infrastructure, school health programme infrastructure and other factors in order to assist countries to identify the optimal delivery strategy from a costing perspective.

The PATH/LSHTM review showed economic delivery costs including staff time in demonstration/ pilot countries ranged from US\$ 1.44 - \$3.88 per dose and that **key cost drivers are per diems and transport**. It also found that annualized start-up costs represented up to 50% of all financial and economic costs.

Reports from countries that have integrated HPV vaccine into their EPI or school health programmes show that costs can be reduced. Rwanda, for example, reported that it switched from a campaign with intensive supervision involving extensive staff travel (including from other programmes) and intensive media attention to a low-key, routine biannual outreach delivery to schools by the EPI programme. Although no formal costing study was done, operational costs were reportedly reduced by more than 80%.⁷

Countries and partners suggest that countries implementing a demonstration programme test different delivery strategies, including areas where efficiencies may be gained, and compare implementation costs to identify a sustainable option.

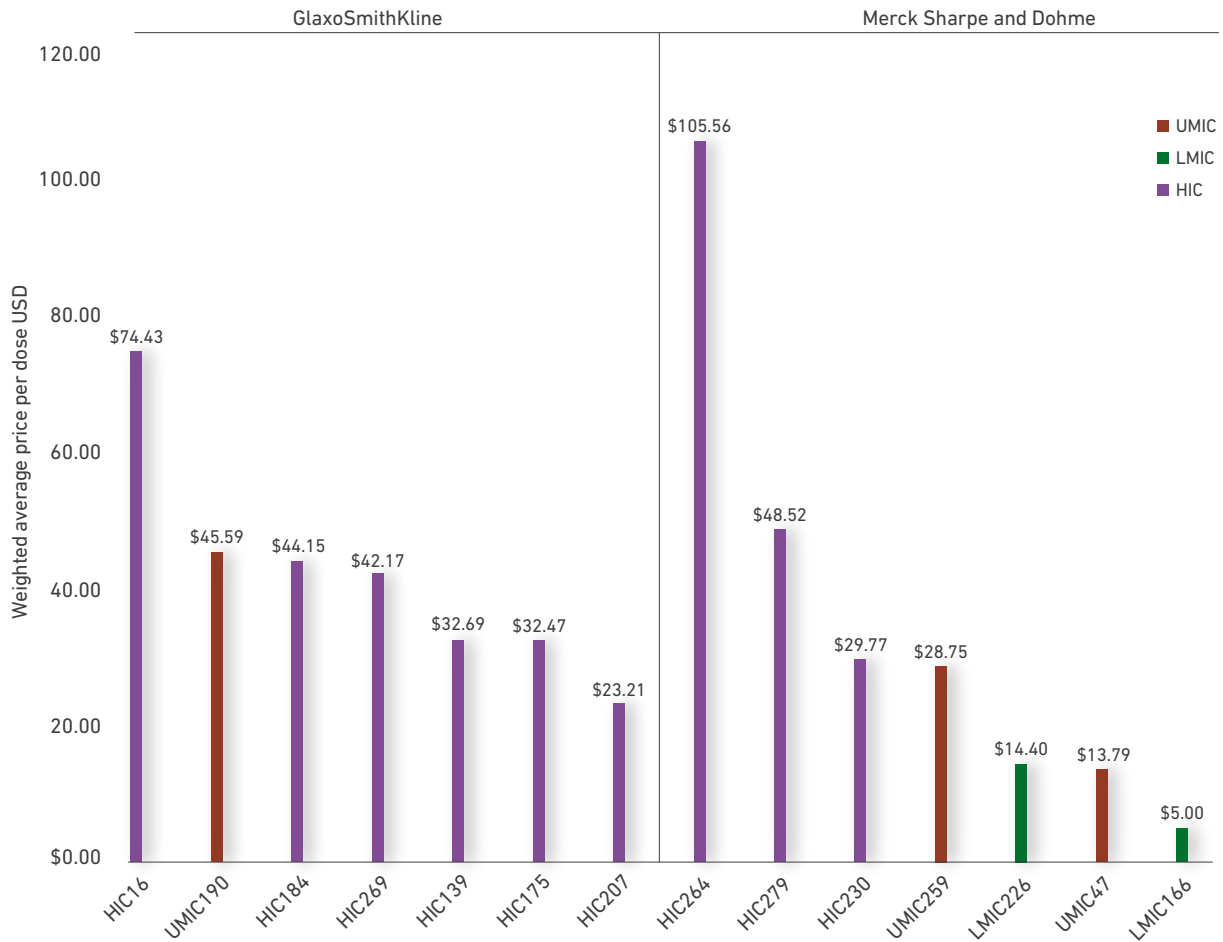
⁵ For the C4P modules see: http://www.who.int/immunization/diseases/hpv/cervical_cancer_costing_tool/en/.

⁶ OneHealth is a UN Inter-agency group tool that attempts to link strategic objectives and targets of disease control and prevention programmes to the required investments in health systems. The tool provides planners with a single framework for scenario analysis, costing, health impact analysis, budgeting and financing of strategies for all major diseases and health system components. It is thus primarily intended to inform sector wide national strategic health plans and policies. See: <http://www.who.int/choice/onehealthtool/en/>.

⁷ For more on Rwanda's initial costing see Ngabo F, et al., *A cost comparison of introducing and delivering pneumococcal, rotavirus and human papillomavirus vaccines in Rwanda*. Vaccine, 2015 Dec 16;33(51).

There are many issues for countries in transition from Gavi-support, including advocacy to continue (or begin) HPV vaccination; the proportion of cost compared with other EPI vaccines and competing health priorities; and securing funding from government and other internal sources. Countries transitioning from Gavi-support have the opportunity to access Gavi prices for several years after graduation, though different conditions apply depending on the country and manufacturer.

► Figure 5 Weighted average price per dose of HPV vaccines in countries of different income groups.



WHO can support countries in transition to develop cost and economic analyses in order to strengthen advocacy activities for increased immunization financing and create a financing strategy to mobilize additional financial resources for immunization.

Many middle-income countries (MICs), which never benefitted from Gavi support or the PAHO revolving fund, negotiate HPV vaccine prices directly with the manufacturers and do not benefit from an HPV vaccine access scheme. WHO observes a large variation in the prices these countries secure. For example, data shows a three-fold difference between the lowest and highest price paid by MICs (see figure 5). While clear national policy and planning processes, such as the cMYP, are helping countries to access these important vaccines, sustainability is at risk for some. A recent study shows that opportunities exist to lower HPV prices with manufacturers who are receiving economic returns worth five times their original investment in HPV vaccine development.⁸

⁸ Hertihy N, Hutubessy R, Jit M. *Current Global Pricing For Human Papillomavirus Vaccines Brings The Greatest Economic Benefits To Rich Countries*. Health Aff (Millwood). 2016 Feb 1;35(2):227-34.

To assist countries gain access to up-to-date vaccine product, price and procurement information, WHO has created a “one-stop-shop” **V3P** platform (Vaccine Product, Price and Procurement). To date, there are 40 countries participating (15 HICs, 24 MICs, 1 LIC); with data available on around 200 vaccines. The database is freely accessible.⁹

Given the cost of screening and treatment and the burden of HPV-related cancers in men, **Australia found that it is cost-effective for the country to vaccinate boys** in order to extend protection of females and directly prevent cancers in males including penile, anal, mouth and throat cancers. **Argentina** has had access to the PAHO Revolving Fund price, and is now implementing a technology transfer to **begin manufacturing HPV vaccine locally**.¹⁰

Costing, Financing and Sustainability: Implications for Action

- ✓ **Countries with Gavi-support can take several measures** to improve the chance of scaling-up and sustaining HPV vaccination programmes:
 - Involve key decision-makers from the Ministry of Health, Education and Finance early to secure advice and buy-in.
 - Using information and tools available to date, conduct a preliminary cost analysis before beginning the demonstration programme, modelling different delivery strategies and integration with other adolescent health interventions. Select delivery strategies that are likely to strike a balance between high coverage and sustainable cost.
 - Build HPV vaccine programming and costing into the cMYP financial plan.
 - Continue to strengthen the coalition of champions for HPV vaccine from EPI, cancer, women’s health, gynecology, adolescent health, education and other areas who can help to advocate for budgeting HPV vaccine as part of a comprehensive cervical cancer prevention and control strategy.
- ✓ **All countries** can continue to publish and exchange information on how they are achieving cost-effective and sustainable HPV vaccine programming.
- ✓ **All countries can contribute to and consult WHO’s V3P tool**, which will help improve price transparency and increase the knowledge base on costs and other information on all available vaccines.
- ✓ **WHO and partners must:**
 - Support countries to use the available tools, including cMYP and annual workplan, C4P, PRIME and V3P tools and platforms.
 - Continue to analyze HPV delivery costs in order to better understand cost drivers and optimal delivery strategies from a cost perspective.
 - Build and share more knowledge about the best mix of delivery strategies to achieve cost-effective, sustainable HPV vaccine programmes.
 - Complete the costing tool on adolescent health interventions that can be integrated with HPV vaccination as well as the cervical cancer prevention and screening costing module and promote their use.

⁹ For more see: www.who.int/immunization/v3p.

¹⁰ For more on the PAHO Revolving Fund see: http://www.paho.org/hq/index.php?option=com_content&view=article&id=1864&Itemid=40713&lang=en



OPPORTUNITIES AND WHAT WE HAVE YET TO LEARN

The experiences and lessons in this document underscore the immense amount of learning countries and partners have collected on HPV vaccine in a relatively short amount of time. They also point to the areas where we need to gather more experience and evidence. These include:

Achieving high coverage for an affordable cost: The GVAP 2020 goal is to achieve 90% national coverage, and 80% in every district or equivalent, of all vaccines in the national immunization schedule. Throughout this document, countries and partners have referenced the need to achieve high coverage, but also note that high coverage is associated with higher costs. Demonstration countries, for example, aim to achieve at least 50% coverage in order to secure support for national scale-up and very few countries reported a coverage target. One country achieved just over 50% coverage, while others have achieved more than 90%. Countries with a high proportion of hard-to-reach girls, or with costly campaign strategies including high per diems, will probably spend more per girl to achieve high coverage. Countries and technical partners will continue to work to find the optimal balancing of reaching high coverage at a sustainable cost.

Reaching the hard-to-reach: In general, countries have not gathered much evidence about how to reach hard-to-reach girls. These girls are likely at greater risk of developing cervical cancer in the future due to the potential for risk factors and poor access to screening and treatment. In Gavi-eligible countries for example, an average of 1 of 4 primary school girls is out of school, and the proportion is higher for several of those countries. What are the most effective strategies to reach these girls? What other interventions could be bundled to serve the population and achieve efficiencies? This report contains several suggestions to enumerate and reach these girls. If countries began to monitor and report enumeration and coverage, countries and partners could better predict costs and implement strategies to reach them.

Reaching the immunocompromised: WHO continues to recommend that girls who are immunocompromised receive three doses of HPV vaccine within a six-month interval (at 0, 1-2 and 6 months). HIV positivity, for example, is associated with increased prevalence of cervical HPV infection, greater prevalence of cervical intraepithelial neoplasia (CIN), and a higher grade of CIN. The strength of these associations increases with diminished immune status.¹ Of the countries represented at the HPV Global Learning Meeting on HPV Vaccine Introduction, only Argentina reported that it was offering HPV vaccine to boys and girls aged 11-26 who were HIV+ or had received tissue transplants. One other country said that while it had high HIV prevalence, it had to be mindful of protecting confidentiality of HIV+ girls and had not begun to monitor coverage. Therefore questions remain. How can countries reach and monitor immunocompromised girls with three doses while protecting their confidentiality? Could HPV vaccines be integrated with HIV testing and treatment? How could immunocompromised populations be made aware and mobilized to receive three doses of HPV vaccine? Linked to this issue, **note that the Global Fund is accepting applications for funding for cervical cancer screening in countries with high HIV prevalence.**

Opportunities to monitor Impact: The more evidence of the impact of HPV vaccine, the better the case for sustainable national scale-up. **One important step is for countries to establish national cancer registries**, which will help establish baseline information and monitor ongoing cancer prevention and

¹ M Palefsky, ML Gillison, HD Strickler. Chapter 16: HPV vaccines in immunocompromised women and men. *Vaccine* 2006; 24: S140-6. In addition, a recent US-IARC study showed that about 40% of cancers in HIV-positive people (men and women) in the US were caused by infections, compared with only 4% in the general population. HPV was a leading infectious cause of cancer. See De Martel C, Shiels MS, Franceschi S, Simard EP, Vignat J, Hall HI, Engels EA, Plummer M (2015). *Cancers attributable to infections among adults with HIV in the United States*. *AIDS*. 29(16):2173-2181.

control efforts. Measuring short-term impact is also difficult, due to the costs, privacy and practicality of performing cytology testing on young women in low-resource settings. New techniques may start to change this. For example, IARC has begun testing the impact of HPV vaccine through a new urine test that can be simply administered. In a supervised process, young women who have likely become sexually active (e.g. aged 17-21) can collect their own urine specimens using an inexpensive specially designed funnel-type device. They also answer a short questionnaire including questions on sexual activity, which is transmitted directly to IARC. The samples are then sent to a laboratory for DNA extraction, HPV testing, and genotyping. IARC has already tested the methodology in Bhutan and Rwanda where high coverage of HPV vaccination has been reported. Amongst those tested, infection with HPV 6,11,16 or 18 was much lower amongst those who had been vaccinated. IARC reports the test is affordable, appropriate to the age group, and easily transferable to low income countries.²

The nine-valent vaccine: An HPV vaccine that prevents against 9 HPV types (6, 11, 16, 18, 31, 33, 45, 52, 58) was licensed in the US in December 2014 and implemented in February 2015. Several high-income countries quickly followed suit. In April 2016, it was licensed for 2 dose schedule. WHO pre-qualification of the vaccine is under review (September 2016). In the US the additional HPV vaccine types are found to prevent an additional 15% of cervical cancer cases. For low-income countries there are outstanding issues related to the vaccine including cost and how switching to 9vHPV vaccine would impact on the production and availability of the other HPV vaccine products.

Vaccinating boys: Several high-income countries recommend and provide free HPV vaccination for boys, as a preventive measure against anogenital warts and other HPV related cancers such as oropharyngeal cancers, for which men who have sex with men (MSM) and HIV+ men are particularly at risk. Given the costs of treatment, and as MSM do not generally benefit from the herd immunity that results from vaccinating girls, countries including the US and Australia have found vaccinating boys to be a cost-effective public health measure. **Given the current cost of the HPV vaccine and the public health impact of preventing cervical cancer, WHO recommends that low-income countries prioritize the vaccination of girls aged 9-14 years.**

Doses and dosing schedule: The revision in WHO's recommendation from a three-dose to a two-dose schedule offers the potential for increased coverage of HPV vaccine as countries reduce vaccine and delivery costs. In addition, the recommendation that doses could be given up to 15 months apart offers new opportunities for vaccine delivery – including, a single, yearly vaccination round in which target girls can get their first or second dose.

² Franceschi S et al., *Urine testing to monitor the impact of HPV vaccination in Bhutan and Rwanda*. Int J Cancer. March 17 2016.



CONCLUSION

Experience to date in dozens of countries provides good news about the potential of HPV vaccination. Globally, advocacy and resources to protect the health of women, girls and adolescents has never been stronger. There is growing momentum to prevent and treat non-communicable diseases, including cervical cancer. Evidence shows that girls who are protected with HPV vaccine have a dramatically reduced incidence of genital warts and lower rates of high grade cervical lesions (CIN2+). Increasing numbers of countries, including about 30 low income countries are demonstrating how to successfully reach and fully vaccinate a high-proportion of target-age girls with HPV vaccine.

Significant programmatic experience and evidence has accumulated about costing, effective planning, delivery and monitoring of HPV vaccination. Countries are learning by doing, and from one another. Lessons from countries, as captured in country reports, the PATH/LSHTM HPV vaccine lessons learnt review, and this document, can help countries design and implement effective HPV vaccine programmes. The PRIME modelling study of 179 countries shows that HPV vaccination is very cost effective in most of them, and that high coverage can prevent 200,000 cases, and 100,000 deaths every year in LICs alone.

Given this momentum and clear evidence of the benefits to health and wellbeing, now is the time for more countries to introduce HPV vaccine and to scale-up nationally as part of comprehensive cervical cancer prevention and control plans. The strengthened ties between immunization, cancer programmes and the education sector is a platform to further mobilize communities to not only accept, but expect HPV vaccine as a key intervention for adolescent girls and to understand and demand cervical cancer screening for women.

Challenges remain. Two-thirds of countries globally, mostly lower and middle-income countries, have not yet introduced HPV vaccine. To scale-up HPV vaccine introduction, global and country partners must work together to build country-specific evidence to advocate for the inclusion of comprehensive cervical cancer programming in medium and long-term national policy and budgets. Many countries need to work to find the appropriate delivery strategies that attain and sustain high coverage at an affordable cost. Communication and acceptance issues demand effort and vigilance. Monitoring indicators and reporting require more standardization. More focus and resources will be required to introduce cancer registries and increase access to cervical cancer screening and treatment, and to use the opportunity to integrate additional adolescent health services with HPV vaccination.

There are outstanding questions that research can address. How best to reach hard-to-reach girls, including those who are immunocompromised? What interventions can countries most successfully integrate with HPV vaccine to improve adolescent health and gain efficiencies? Can countries fully immunize girls by offering an HPV vaccine opportunity once per year? What is the most cost-effective way to deliver HPV vaccine, while achieving maximum coverage in different settings?

These questions should not delay scale-up. Protecting girls today is an important step towards realizing the health and wellbeing of girls and women everywhere, essential to ending extreme poverty, promoting development and resilience, and achieving the Sustainable Development Goals.

Despite progress, only an estimated 5% of eligible girls globally have been fully-vaccinated against HPV. Applying current knowledge and experience, countries can continue to work to advocate for, plan and implement national introduction of HPV vaccine delivery.

SUMMARY OF IMPLICATIONS FOR ACTION

AREA	IMPLICATION FOR ACTION
Decision-making	<ul style="list-style-type: none"> ✓ Gaining the support of high-level advocates, such as First Ladies, can have a major impact on the decision to introduce HPV vaccine. ✓ Prepare evidence: Investigating and reporting on the cervical cancer burden; cost-effectiveness, feasibility and acceptability is important for decision-makers. ✓ Coordinate early with the right stakeholders including the MoH, MoE, MoF. ✓ Prepare for a process involving the policy committees, regulatory bodies, political and financial processes to ensure the decision is anchored in country policies and budget. ✓ Consider sustainable funding. Advocates should have a plan to secure funding for longer-term sustainability.
Planning & Coordination	<ul style="list-style-type: none"> ✓ Establish a national planning committee and sub-committees, and meet regularly to monitor progress and adjust plans. ✓ For school-based programmes, the MoH and MoE should coordinate early and closely at all levels. ✓ Use existing platforms - EPI or school health programmes to deliver HPV vaccine. ✓ Map out and coordinate with non-traditional partners including cancer/NCDs, adolescent health, women's health, professional associations (gynecologists, oncologists, general practitioners, pediatricians), parent-teacher and in some countries, religious associations. ✓ Take the opportunity to explore how vaccination could be coordinated with other cervical cancer prevention activities during and post-introduction. ✓ Spend adequate time and resources to double-check denominators through reliable sources for in-school and out-of-school girls. ✓ Identify, list and contact all schools – including private and religious schools – and coordinate activities to avoid coinciding with school holidays and exams. ✓ Allow at least six months for planning, community-based microplanning and training including preparation of standardized training materials. ✓ Ensure planning includes the necessary processes for timely release of funds. ✓ Consider who needs to be trained and oriented. Ensure enough time is allocated. It can be helpful to train health workers and teachers together for some of the time.
Delivery Strategies	<ul style="list-style-type: none"> ✓ Countries implementing demonstration projects might consider testing and evaluating more than one type of delivery strategy in different districts so that delivery and costs can be compared. ✓ Strategies may need to vary in different parts of the country (e.g. in districts with high number of out-of-school girls), and they may change over time as the programme matures. ✓ Countries may be able to achieve high coverage with a school-based strategy, but may not be able to afford to sustain it due to costs. ✓ School based delivery may be more efficient and affordable if other interventions – such as tetanus vaccine or deworming – are integrated with HPV vaccine delivery, allowing some of the delivery costs to be shared among programmes. ✓ Countries should consider the added costs associated with campaign-style approaches and assess the option to use routine approaches including health facility and regular outreach. ✓ Routine delivery through the health facility will likely require more resources for communication and social mobilization so that girls and their caregivers know when and where the vaccine is available, especially in countries where health facilities may not offer services during weekends and outside of school hours. ✓ WHO and partners will continue to update and advise countries on costing analyses and coverage studies to help countries make decisions on sustainable delivery strategies, key for countries to make decisions on sustainable delivery strategies.

AREA	IMPLICATION FOR ACTION
Hard-to-Reach Girls	<ul style="list-style-type: none"> ✓ To achieve equity plan for more time and resources for enumeration, registration and coverage of hard-to-reach girls. ✓ Monitor registration and coverage of hard to reach girls. ✓ Invest in strengthened ties between health facilities and communities including through HPV vaccine microplanning with community leaders. ✓ Consider adding HPV vaccine to routine outreach services. ✓ Train health workers to welcome hard-to-reach girls, whatever their status. ✓ Ensure communication strategies that will reach and mobilize hard-to-reach girls through trusted channels and with appropriate materials. ✓ Consider <ul style="list-style-type: none"> ▸ integrated services for hard to reach communities. ▸ small incentives for girls who visit the health facility. ▸ how the HPV vaccine opportunity could connect hard-to-reach girls with the education system. ✓ Invest in studies that will help to understand behaviours, risks, motivations and movements of hard-to-reach girls and their caregivers.
Demonstrations and Phased Introductions	<ul style="list-style-type: none"> ✓ Countries could work closely with partners in advance to assess potential delivery strategies, integration with EPI, costing and other implications of HPV vaccine roll-out. ✓ Countries might consider testing two different primary delivery strategies even in Year 1. ✓ Countries should select demonstration districts that are more representative of country conditions and test the potential to deliver to hard-to-reach populations ✓ Countries should assess whether the word “demo” will trigger rumours and misunderstandings about the programme, and choose alternate ways to describe it. ✓ Countries might consider phased national roll-outs rather than demonstration project as this provides the opportunity to secure budgets and build political momentum while learning lessons that can be applied nation-wide. ✓ Donors can assess and update requirements for demonstration programmes based on learnings to date. ✓ Technical partners should provide more timely orientation meetings to share lessons with countries considering demonstration programmes or national roll-out.
Communication	<ul style="list-style-type: none"> ✓ Start early to map and begin work with the right stakeholders. ✓ If procuring vaccine with a manufacturer, consider requesting support for communication as part of the procurement package. ✓ Plan strategies to proactively address and rapidly respond to common questions and rumours about demos being mistaken for “trials”, vaccine safety, target population, sexual activity, fertility, and side effects. ✓ Consider gathering additional information through small surveys or even a KAP study to prepare the communication strategy. ✓ Tailor strategies, messages and materials for specific audiences, including girls, caregivers, teachers, health workers, media and professional organizations or other specialists. ✓ Messages work effectively when they promote the vaccine as a cancer vaccine, its safety, efficacy, and include details about who, where and when to receive it. <ul style="list-style-type: none"> ▸ Materials should make clear that the government endorses the vaccine.

AREA	IMPLICATION FOR ACTION
Communication	<ul style="list-style-type: none"> ✓ Decide whether to use one language, or several – and if materials are translated ensure they're consistent and appropriate for the language groups. ✓ Ensure media are oriented early with clear materials. Ask for corrections immediately if media make any errors or unfounded allegations. ✓ Take care when choosing the consent process to avoid the suggestion that HPV vaccination is part of a research project; while also balancing caregivers and girls' rights to provide informed consent. ✓ Some schools, particularly private schools may require a specific consent process. ✓ Include a system to monitor for rumours and problems, and respond to them rapidly. ✓ Use monitoring and evaluation to determine the impact of communication on HPV vaccine programming, and adjust the communication plan as necessary. ✓ Invest in a long term communication strategy that offers updated information for stakeholders every year.
Managing Crises	<ul style="list-style-type: none"> ✓ Be prepared: By being aware of common pitfalls with HPV vaccine, countries can plan to avoid crises as much as possible. ✓ Create a risk mitigation plan. ✓ When making decisions ask "if we take X action, do the benefits outweigh the risks? How can we mitigate the risks?" ✓ Act quickly when a crisis does occur. Be sure the right people make and communicate decisions. ✓ Public safety is not negotiable and is the primary goal. On other issues be nimble and flexible to find acceptable solutions.
Recording, Monitoring and Evaluation	<ul style="list-style-type: none"> ✓ WHO and UNICEF to provide guidance on monitoring HPV vaccination. ✓ WHO and UNICEF to start reporting on country estimates for HPV vaccine coverage. ✓ Gavi to re-consider its evaluation requirements given funding and workload for current evaluations. ✓ Countries introducing HPV vaccine to consider: <ul style="list-style-type: none"> ▸ how to better integrate and monitor the frequency and quality of supervision. ▸ ensuring coverage is calculated based on the total denominator, not the number of girls receiving the first dose. ▸ how to use HPV vaccine introduction to improve AEFI reporting. ▸ age versus grade based delivery and the implications for monitoring. ▸ determining the target and monitoring coverage of out-of-school girls. ▸ monitoring coverage of immunocompromised girls in collaboration with HIV programmes. ▸ conducting more baseline communication-related surveys; including communication indicators for hesitancy and for determining the impact of communication activities.
Integration	<ul style="list-style-type: none"> ✓ countries and partners need to better document integration efforts including studies on costs, impact on the health system and health outcomes, and to continue to share lessons. ✓ WHO and partners are developing costing tools for adolescent health programmes to foster integration.

AREA	IMPLICATION FOR ACTION
Integration with Cervical Cancer Programming	<ul style="list-style-type: none"> ✓ Countries are encouraged to continue to build comprehensive cervical cancer prevention programming, with education, HPV vaccine, screening and treatment as key interventions through the life course. This will involve close coordination between EPI, NCDs and other departments. Countries can learn more in WHO's Comprehensive Cervical Cancer Control: A Guide to Essential Practice (http://bit.ly/WHOcervicalcancer) ✓ Countries can use the opportunity of HPV vaccine to increase knowledge, awareness, momentum and resources for cervical cancer screening and treatment amongst decision makers, health workers, teachers, and communities, in women in particular. ✓ Countries should continue to use communication messages to promote HPV vaccine for girls and screening for mothers/female caregivers where screening is available.
Integration with Adolescent health programming	<ul style="list-style-type: none"> ✓ Countries are encouraged to assess opportunities to integrate adolescent health services with HPV vaccine where they will have a public health impact, are age-appropriate, and help to gain efficiencies. ✓ WHO has identified evidence-based options for integration. ✓ Coordination between EPI, adolescent health, school health, the education sector, and other groups may be challenging at first, but it holds the promise of contributing to better health outcomes for adolescents and more sustainable HPV vaccination through integration.
Costing, Financing and Sustainability	<ul style="list-style-type: none"> ✓ Countries with GAVI-support can take several measures to improve the chance of scaling-up and sustaining HPV vaccination programmes: <ul style="list-style-type: none"> ▸ Involve key decision-makers from the MoH, MoE and MoF to secure buy-in. ▸ Using information and tools available to date, conduct a preliminary cost analysis before beginning the demonstration programme, modelling different delivery strategies and integration with other adolescent health interventions. ▸ Select delivery strategies that are likely to strike a balance between high coverage and sustainable cost. ▸ Build HPV vaccine programming and costing into the cMYP financial plan. ▸ Continue to strengthen the coalition of champions for HPV vaccine from EPI, cancer, women's health, gynecology, adolescent health, education and other areas who can help to advocate for HPV vaccine. ✓ All countries can continue to publish and exchange information on how they are achieving cost-effective and sustainable HPV vaccine programming. ✓ All countries can contribute to and consult WHO's V3P tool, which will help improve price transparency and increase the knowledge base on costs on all available vaccines. ✓ WHO and partners must: <ul style="list-style-type: none"> ▸ Support countries to use the available tools, including cMYP and annual workplan, C4P, PRIME and V3P tools and platforms. ▸ Continue to analyze HPV delivery costs in order to better understand cost drivers and optimal delivery strategies from a cost perspective. ▸ Build and share more knowledge about the best mix of delivery strategies to achieve cost-effective, sustainable HPV vaccine programmes. ▸ Complete the costing tool on adolescent health interventions that can be integrated with HPV vaccination as well as the cervical cancer prevention and screening costing module and promote their use.

FURTHER READING AND RESOURCES

For more HPV vaccine resources, see the WHO's HPV Vaccine Introduction Clearing House: <http://www.who.int/immunization/hpv/en/>, the PATH resources at www.rho.org, and consult the documents listed in footnotes throughout this document.

