The introduction of human papillomavirus (HPV) vaccine has the potential to save the lives of millions of women and girls worldwide. Based on a review conducted by the London School of Hygiene & Tropical Medicine and PATH, this brief highlights findings, key lessons and recommendations relevant to the theme of the value of HPV vaccine demonstration projects.

Findings and key lessons

BACKGROUND ON HPV VACCINE DEMONSTRATION PROJECTS
Prior to 2012, access to HPV vaccine for many low- and middle-income countries was limited to demonstration projects, through vaccine donations to the government, or via an external partner. Because of the high cost of the vaccine, national rollout was not an option for the vast majority of countries. In late 2012, access to HPV vaccine was made more widely available to low-income countries through support from Gavi, the Vaccine Alliance. The purpose of these demonstration projects was for countries to test the delivery of this new vaccine, which targeted a novel population (young adolescent girls), and to pave the way for countries to build the capacity and infrastructure needed to vaccinate girls nationwide.

This review focused on 46 low- and middle-income countries that conducted HPV vaccination demonstration projects or national programmes. Their cumulative experience is important for countries that are considering how to introduce HPV vaccination.

EXPERIENCE GAINED THROUGH DEMONSTRATION PROJECTS
Twenty-nine countries in the review reported opinions about the value of demonstration projects; in general they benefited from ‘learning by doing’. Demonstration projects allowed countries to gain knowledge and experience in planning and budgeting for various delivery strategies, calculating vaccine cold chain and transport requirements, enumerating the target population, using acceptable consent procedures for older children and adolescents, working with the ministry of education, developing and disseminating community education materials and in some cases assessing readiness for national introduction.

Value

Of the 20 demonstration projects supported by Gavi, only three took advantage of the opportunity to integrate HPV vaccine with other services. Significant barriers to integration were financing, lack of existing school health programmes, complexity of coordinating multipartner interventions, disruptions to classroom activities and national engagement.

Key lesson: Experiences from the last nine years of demonstration projects were generally consistent across countries. Early demonstration projects were critical for gaining experience and support for national implementation. Lessons from recent and ongoing projects have been consistent with those experiences.

Key lesson: Well-designed demonstration projects assessed different delivery strategies, tested how to achieve high coverage in populations and areas with specific challenges, and focused on integration with national systems.

Key lesson: Integration of HPV vaccine delivery with other services was operationally challenging.

LIMITATIONS OF DEMONSTRATION PROJECTS
By the very nature of their size and scope, projects have limitations which impact country learning. The small size of the HPV demonstrations meant that they were not necessarily representative of the wider country context. Their limited scale made it difficult to assess the impact of HPV vaccination on health system functioning and other primary health care services.
Several countries reported that the difference in funding strategies for demonstration projects and national programmes posed challenges. Many countries stated that the resource-intensive delivery strategies used during their demonstration projects might not be sustainable once the financial support provided by funders has ended. Among the 33 countries that shared opinions about future funding availability for HPV vaccines and their delivery, 23 stated either considerable uncertainty or a decision not to scale up.

Significant challenges exist in scaling up from a small demonstration project to a national programme. Some stakeholders signalled concerns that a ‘loss of momentum’ at the project’s end and the high costs of the demonstration projects may have deterred decision-makers. Expansion of HPV vaccine delivery after implementing demonstration projects has stalled in a number of countries; five countries that completed demonstration projects in 2010 or 2011 are no longer providing HPV vaccination. These countries reported valuable lessons learnt, but they have not yet taken action towards national introduction.

**Key lesson:** The small size of most demonstration projects limited learnings about cold chain capacity, impact on primary health care and integration with routine immunisations for national scale-up.

**Key lesson:** Demonstration projects using resource-intensive delivery strategies generated concerns about the sustainability of national HPV vaccination programmes. Alternative delivery strategies were rarely tested.

**Key lesson:** Demonstration projects had both positive and negative influences on the intention to introduce HPV vaccine nationally. In some countries, they increased the confidence of national implementers in the acceptability of vaccine delivery. In other countries, demonstration projects deterred policymakers from scaling up.

**INCREASING THE VALUE OF DEMONSTRATION PROJECTS**

Findings from the review suggested that the value of demonstration projects could be increased if countries used the opportunity to test different delivery strategies. This would help them to identify approaches that are sustainable and effective and to learn how to better provide vaccines to hard-to-reach populations. Only 7 of 44 countries purposefully selected areas that included challenging or hard-to-reach target groups or tested different delivery strategies or approaches.

The opportunity to test the delivery of combined interventions with HPV vaccine – such as tetanus toxoid vaccine, deworming or vitamin A supplementation – has largely been missed. Only a few countries reported implementing HPV vaccine delivery simultaneously with other interventions and/or testing combined vaccination with the delivery of health education messages.

**Key lesson:** Countries have not yet fully taken advantage of demonstration projects, which can be used to test different combinations of vaccination venues, timing, eligibility criteria in different populations and co-delivery of other health interventions.

**A NEW FUTURE FOR DEMONSTRATION PROJECTS**

In the context of increasing vaccine availability and wide sharing of lessons learnt, countries could consider foregoing HPV vaccine demonstration projects and instead opt for a phased national rollout. This approach could allow faster national introduction of vaccine, provide experience in social mobilisation and delivery while maintaining political commitment, and avoid the potential pitfall of being separated from the national immunisation programme, which has challenged some demonstration projects.
Recommendations

Based on country experience, funders supporting HPV vaccine programmes should:

1. **Regularly re-evaluate policy around assisting countries to gain HPV vaccine experience and ensure that policy is as flexible as possible.** Countries should consider leveraging the extensive lessons learnt to implement a phased national rollout.

2. **Consider a higher initial investment.** Start-up costs for a phased national rollout for HPV vaccine may be higher than other new vaccines, but recurring costs will reduce over time.

3. **Convert demonstration projects to a phased national rollout, which might accelerate decision-making for national introduction.** This approach may help maintain political commitment for HPV vaccination.

Based on country experience, decision-makers supporting HPV vaccine demonstration projects or national programmes should:

1. **Translate lessons learnt to inform a phased national rollout as the best method to gain experience for HPV vaccine introduction.** Given the increasing ability to learn from other countries’ experiences, countries should forego demonstration projects and instead conduct a phased national rollout.

2. **Be aware that introducing a new vaccine through a demonstration project creates distortions to normal procedures of the national immunisation programme because of the proportionally high investment made in developing, implementing and evaluating the project.** This tends to promote the establishment of vaccination approaches that operate separately from the national programme, which may not be easily scalable.

3. **Carefully plan and design a phased national scale-up strategy to gain lessons relevant for introduction.** Plans might include maximising opportunities to test different strategies or delivery to hard-to-reach populations, assessing integration with national immunisation programme processes and combining vaccination with other interventions.

4. **When designing a phased national scale-up strategy, anticipate and test aspects of delivery that are likely to create challenges, such as staff incentives or joint supply of HPV vaccines with other vaccines.**