HAPPI
PARTNERSHIP FOR ACCELERATING HPV VACCINATION

Evidence-based summary of lessons learned in HPV vaccine program implementation in LMICs:

SUSTAINING PROGRAMS

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A review of diverse program implementation experiences globally shows remarkable consistency in outlining enablers and obstacles for a sustainable national HPV vaccination program.

THE CHALLENGE OF DEFINING SUSTAINED PROGRAMS

HPV vaccination programs in low- and middle-income countries (LMICs) have been operational for more than a decade. In Africa, Rwanda was the first country to introduce HPV vaccines in 2011, and first dose HPV vaccination coverage has averaged around 80% every year since 2016. Many other countries have similarly been operating programs continuously since the initial introduction year.

However, there is not an agreed-upon definition for program sustainability for HPV vaccinations. Some have suggested consistent high coverage as a proxy measure, though "high" is also not defined. The WHO cervical cancer elimination strategy sets a target of 90% for HPV vaccination coverage. By this definition of "high coverage," only a handful of countries have "sustained" their program continuously for more than three years: Bhutan, Cape Verde, Iceland, Niue, Norway, Portugal, Spain, Sweden, Turkmenistan, and Uzbekistan. Others have suggested funding and affordability as key indicators of sustainability; again, "sufficient funding" and "affordable" have not been defined. Recently, Waheed et al. characterized sustainability as "the ability to sustain high coverage within a smoothly running program," with neither "high coverage" nor "smoothly running" defined.

PROGRAM ACTIVITIES

Despite the absence of precise definitions, recent studies have summarized the operations of ongoing national HPV vaccinations programs in a variety of country settings. These studies augment a prior review of HPV vaccination experiences in 45 LMICs, representing 12 national programs and 60 pilot or demonstration programs. As all of these countries continue to provide HPV vaccines (with the exception of the global interruptions due to the COVID-19 pandemic), they are clearly sustaining their HPV vaccination programs.

The collective findings from the evaluations of global HPV vaccine introductions and programs in LMICs, which summarized experiences, operations, and facilitators needed to maintain a competently run program, can arguably serve as a proxy for understanding the elements of a "smoothly running program".

These program activities are broadly aligned with the areas of program operations that WHO recommends when evaluating any vaccination program. Table 1 summarizes the operational components that need to be conducted and maintained every year of ongoing HPV vaccination programs and elements that facilitate success. While reducing the two-dose schedule to a single dose may result in fewer financial expenditures, most elements of successful HPV vaccination programs need to be maintained regardless of dosing schedule.

COSTS OF HPV INTRODUCTION AND ONGOING ROUTINE HPV PROGRAMS

A recent systematic review of HPV vaccine delivery costs found wide variation in the cost estimations. With the exception of the HPV demonstration program in Zimbabwe as an outlier, the financial costs per dose ranged from US$0.27 (routine school-based delivery in Sri Lanka) to US$6.07 (national program in Mozambique), and the economic costs per dose ranged from US$1.31 (Zimbabwe national program) to US$17.20 (Guyana national program). The wide variability in cost estimates was due to study design, sample size, inclusion criteria for different cost components, stage of the country program (demonstration, introduction year, years after introduction), dosing schedule, locations and volume of vaccines

delivered at sessions, types of activities allocated financial resources, and the share of the financial resources spent by cost category.

Illustrative information on what the recurrent economic costs are to sustain an HPV vaccination program in LMICs is provided in Figure 1. The cost of human resources for both health workers and non-health workers (such as teachers, administrator, managers, volunteers, etc.) is the largest expense incurred by national HPV vaccination programs. This calls into the question the oft-cited notion that "school-based delivery" for HPV vaccines is expensive in and of itself. Health worker time is agnostic to the location of vaccination. These data also illustrate the variability in the expenses that countries incur and which of these can be adjusted or reduced. With the exception of Uganda, the financial costs of HPV vaccine delivery in LMICs is a small fraction—ranging from 7% to 32%—of the overall economic cost, demonstrating that no two countries spent financial resources on the same activities or to the same degree.

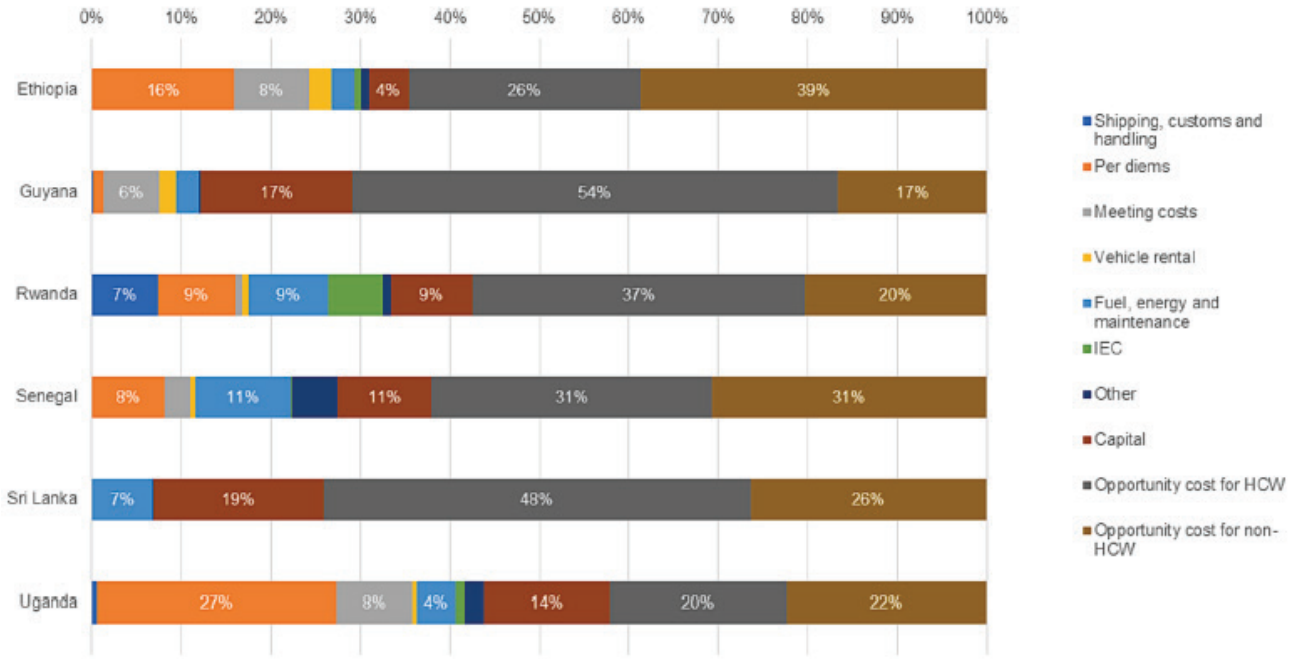
With data now available about the financial and economic costs of delivery from national HPV vaccine programs in 11 LMICs, with seven evaluations published in 2023-4, it is likely that the evidence base will continue to grow.

FINANCIAL SUSTAINABILITY

Given the large variability in cost of HPV vaccine delivery by country and stage of introduction, gathering evidence about the types of activities required and by whom, including frequency and intensity required for ongoing operations, can inform estimates of whether the program can be financially sustained

Following costing of these estimates, countries should outline the financial requirements of their annual operating plan for HPV vaccine delivery, map the available funding resources in country from all sources (e.g., domestic financing, World Bank loans, Gavi health system strengthening grants, bilateral funds, etc.), and then assess if the available resources cover the planned financial outlays. Where budget gaps exist, the country could either adjust the activities to lower the budget or increase the allocations from the available resources.

Figure 1*. Proportion of the aggregated mean economic cost per HPV vaccine dose delivered by cost type



* adapted from Mvundura M., et al. Vaccine. 2023 Nov 30;41(49):7435-7443.

Table 1. Requisite components for continuity of HPV vaccination programs in LMICs

	OPERATIONAL COMPONENT	ENABLERS FOR SUCCESS
Policy Environment	**Political will, commitment**	☐ There is a written national vaccination policy that includes adolescents to normalize HPV vaccine as a routine vaccine ☐ The annual EPI program operating plan includes HPV vaccine as a routine vaccine
	Advocacy, stakeholder engagement	☐ EPI engages with MOH, MOE and other ministries, e.g., Women's Affairs, Youth, Sports, Religion, Finance, etc. through existing coordination and management mechanisms ☐ EPI actively collaborates with a variety of key stakeholders – medical and nursing associations, advocacy groups, community support organizations, cancer prevention programs, adolescent health care providers, religious leaders – to maintain trust, awareness, and demand for HPV vaccines
Financing	**Funding, financing, vaccine procurement**	☐ Sufficient allocation of financial resources for HPV vaccination efforts at all levels is maintained and distributed in a timely manner ☐ Clear demarcation of annual financial resources needed to maintain HPV vaccinations is a regular part of the annual budgeting cycle of the EPI program with the MOH and MOF ☐ Annual EPI program budget includes HPV vaccine as a regular vaccine in EPI
Planning & Management	**Cross-sectoral and coordination MOH, MOE + others**	☐ EPI coordinates with Ministry of Education (primary and secondary), the broader education system, and all schools, including public, private, and religious schools ☐ EPI actively coordinates HPV vaccination efforts with key community stakeholders – community support organizations, subnational and local religious leaders, community leaders and influencers – to maintain trust, awareness, and demand for HPV vaccines
	Annual microplanning	☐ An annual operating plan for HPV vaccinations (either separately or as part of the annual operational national and subnational EPI plans) is written and available
	Eligibility and estimating target population	☐ The best estimate of the target population for HPV vaccines is triangulated with data from the census office and Ministry of Education every year ☐ Program managers, health workers, education staff, parents, and communities are made aware of the age(s) of the target population who should receive HPV vaccine that year
	Vaccine procurement	☐ EPI budget includes the cost of procuring HPV vaccines, e.g., PAHO revolving fund, bilateral tender, Gavi co-financing, UNICEF procurement, etc. ☐ Established channels, such as national tenders, pooled procurement, or UNICEF Supply Division for Gavi-eligible countries, are used to secure affordable access for HPV vaccine
	Human Resources	☐ Sufficient allocation of human resources for HPV vaccination efforts at all levels is maintained
Communications	**Communication, social mobilization, demand generation**	☐ HPV vaccine communication activities to raise awareness and mitigate rumors are conducted using effective key messages, trusted sources of information (including religious leaders), and multiple channels to foster acceptance by parents, girls, and communities ☐ EPI immediately and effectively responds to rumors, hesitancy, and community concerns, leveraging an established, written crisis communication plan ☐ A clear and consistent consenting process is implemented with parents, ensuring adequate time and resources for teachers and schools every year, as applicable
	Crisis management, response	☐ Crisis communication plan exists with clear demarcation of process of responding to rumors and other crises .
Training	**Training**	☐ Adequate training on HPV vaccines and the vaccination program for new cadres of health workers in response to staff turnover is conducted ☐ Ongoing orientation for teachers and school staff on HPV vaccines and the vaccination program is provided when schools are used as a location for vaccination
Logistics & Delivery	**Coordinated vaccine delivery at schools, other locations, mop-ups**	☐ Districts and facilities are conducting HPV vaccinations at least once a year at schools, as in-school vaccination has demonstrated on-average higher coverage and lower costs per girl reached due to vaccinating a large number of girls in a short amount of time ☐ HPV vaccination at facilities and through outreach is also provided a part of the service delivery mix to provide additional opportunities to reach out of school girls, mop-ups, and other missed populations ☐ Microplanning is done to support the estimation of the target population, coordination with schools (if using schools as a vaccination site), reaffirmation of eligibility criteria, and identification of when and where HPV vaccines will be provided ☐ Program managers, health workers, education staff, parents, and communities are made aware of the age(s) of the target population who should receive HPV vaccine that year
	Vaccine management, transport, logistics	☐ HPV vaccine supply uses the same supply management system and are distributed using the same channels, processes, and timing with infant vaccines ☐ HPV vaccine supply is onsite at local facilities in line with the timing and locations planned for HPV vaccinations
	Cold chain management	☐ If conducting time-bound HPV vaccinations, such as campaign-like or PIRI approaches, cold chain capacity and vaccine supply have been assessed to be sufficient at subnational, district, and facility levels ☐ Existing RI mechanisms are used to estimate vaccine supply requirements and to improve the planning and management of HPV vaccines
	Waste management, injection safety	☐ HPV vaccine waste management and injection safety procedures are embedded within RI processes and procedures
Monitoring	**HPV vaccine uptake, schedule, coverage**	☐ Electronic data reporting systems, such as HMIS or DHIS2, reflect the current dosing schedule and include routine reporting of age of vaccine recipient and location of vaccination and allow for recording of multiple doses for special populations, such as immunocompromised or living with HIV
	Supervision	☐ Supervision visits are budgeted for and conducted as an opportunity to monitor program implementation, problem solve concerns from health workers, and foster the normalization of HPV vaccine as a routine vaccine, supporting program sustainability
	Vaccine wastage	☐ AEFIs for HPV vaccine are always monitored and addressed to mitigate safety concerns
	Monitoring AEFIs	☐ AEFIs for HPV vaccine are always monitored and addressed to mitigate safety concerns
	Data recording, reporting	☐ Data system infrastructure of EPI, such as DHIS2, includes recording of HPV vaccination activities: doses, recipient age, location of vaccination, and other relevant data ☐ Data recording tools, including tally sheets, vaccination cards, and registers, are printed and made available in all facilities every year, to foster accurate tracking of vaccinations and reporting coverage

Note: Solid color boxes are program components that require targeted effort to sustain HPV vaccinations
Note: Outlined boxes are program components that get absorbed over time into routine EPI process, procedures, and structures

ENABLERS	
✓	Annual budgeting for known financial expenses that will be incurred each year
✓	Timely disbursement of funds to local levels
✓	Capitalizing on existing structures for vaccine delivery to reduce transport and distribution costs
✓	Integration of HPV vaccines into routine program activities of EPI to foster sustainability
✓	Explicit sustainability plan for continuing HPV vaccinations
✓	Low-cost models of HPV vaccine delivery, based on frequency, timing, and location of vaccinations and the number of girls vaccinated at a single session
✓	Funding to continue vaccination strategies that result in high coverage, e.g., outreach activities or campaigns
✓	Programmatically and financially sound plan to sustain HPV vaccinations year-on-year after the initial introduction
✓	Political will to secure funding for strategies that are effective and result in high coverage, e.g., outreach at schools or annual fixed-time delivery
✓	Financial plan and cost-effectiveness analysis at the national level

OBSTACLES	
X	Not treating HPV vaccines and vaccinations as a regular part of the routine program, functions, and responsibility of health workers at the local level, program coordinators at the subnational level, and the management at national level
X	Inadequately planned financial needs, budgeting, and delays in distribution funds to lower levels
X	Financing delays or shortages are reasons for suboptimal implementation
X	Unanticipated travel and printing costs
X	Inadequate funds devoted to social mobilization/ communications activities needed to sustain program activities

A comprehensive list of references can be found in a separate document, available here.

This material was produced by the HPV Vaccine Acceleration Program Partners Initiative (HAPPI) Consortium and may be used freely. The HAPPI Consortium is managed by JSI together with our esteemed partners Clinton Health Access Initiative (CHAI), the International Vaccine Access Center (IVAC) at the Johns Hopkins Bloomberg School of Public Health, Jhpiego, and PATH.