Decision making for vaccine policy - case study

Australian Vaccinology Course

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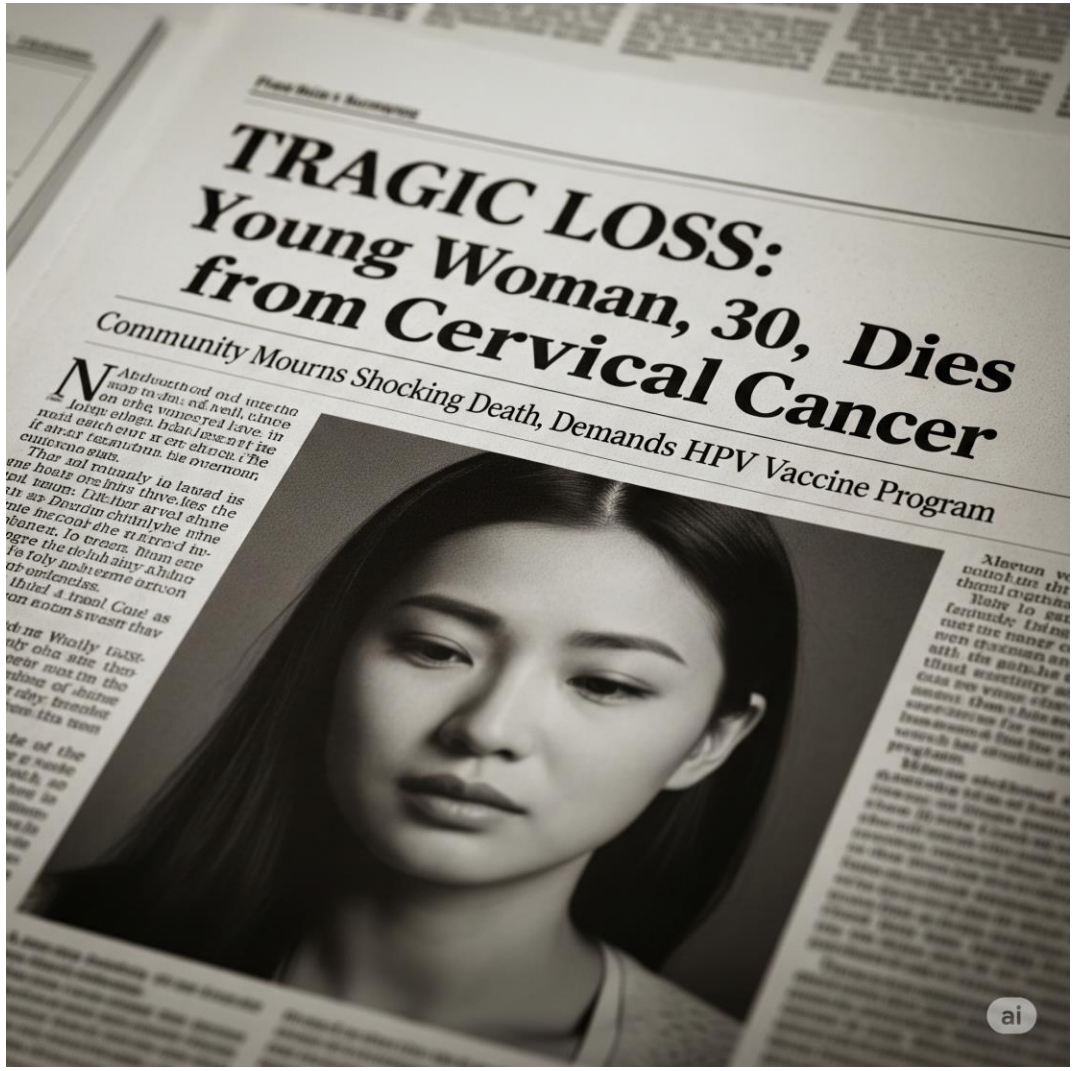
You work in the Ministry for Health in a medium income country…

- You arrive at work one morning to find a request from the Minister to know whether HPV vaccine could be introduced in your country before the next election in 6 months time….
- A young celebrity influencer has just died from cervical cancer at the age of 30, there is widespread media coverage and people are asking why the government is not acting to prevent further deaths.
- The Minister thinks there would be many votes in an election promise to start protecting people against cervical cancer.



1) What information would be needed to inform decision making about whether HPV vaccine

a) *could* be introduced

b) *should* be introduced

in 6 months time?

Issues to consider…

- **Disease burden and epidemiology** – is there a problem? How large is it? Who does it effect?
- **Vaccination as a possible solution** – Effective? Safe? Available? Timeline? Piloted in country/existing experience? Alternatives? Any other impacts of this vaccine?
- **Infrastructure and capacity of current National Immunisation Program**
- **Resources** – Sufficient? Available? Opportunity cost?
- **Politics, existing stakeholder and community buy in** (or not)

2) Who should be involved in this decision making?
What do you think about the role of politics in shaping vaccine policy and programs – what are the positives and negatives of this?

Introduction of the Australian HPV vaccination program 2007

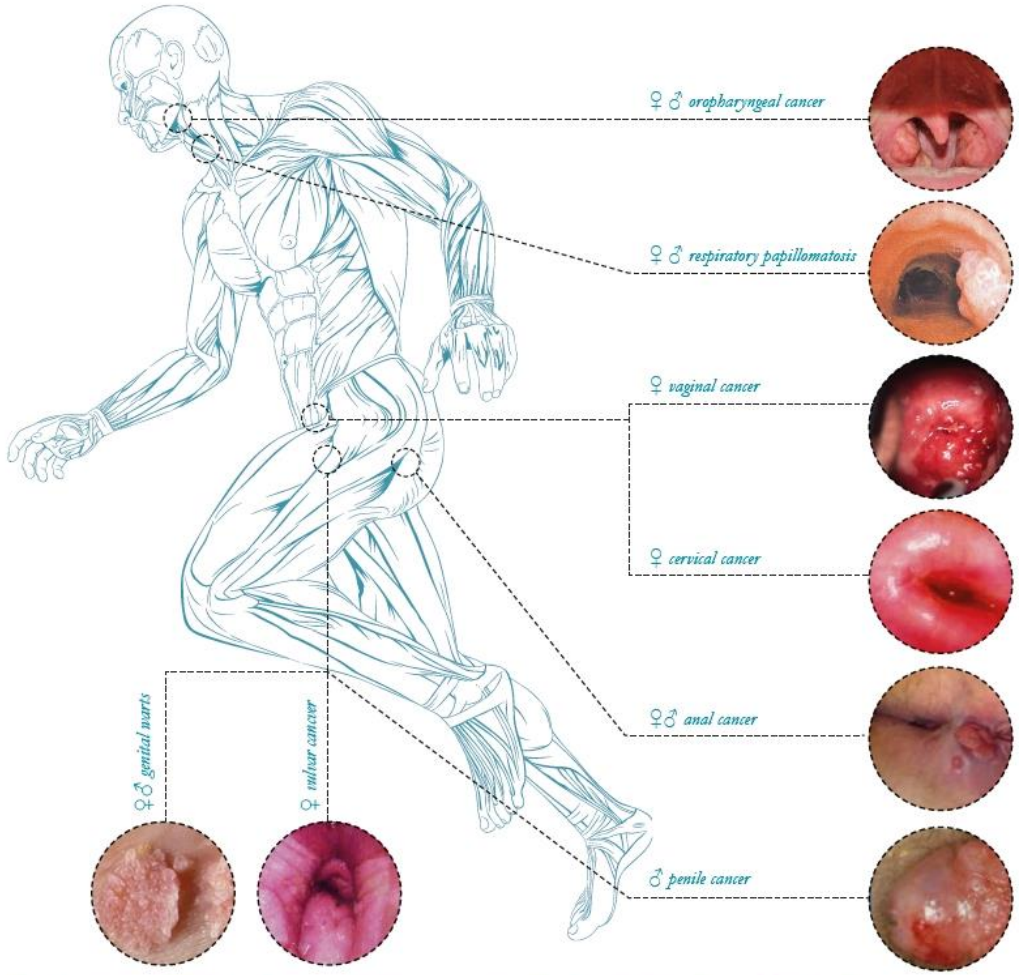
TIMELINE FROM ANNOUCEMENT TO PROGRAM START 4 MONTHS!

- 29 November 2006 – Australian Government announces Program
- 1 April 2007 – Program start! Target 2.4 million girls/women!

**Koutsky 2005, Garland 2007, FUTURE study group 2007*

Let’s talk about HPV vaccine….

- Extremely effective and safe prophylactic vaccines in use since 2006 (over 500 million doses…)
- Proven to prevent cervical cancer
- Originally trialed in women 15-26 as 3 dose schedule, immunobridged to 2 doses in 10-14 year olds, then (off label) single dose per WHO Dec 2022
- WHO states *“The priority purpose of HPV immunization is the prevention of cervical cancer”* Recommends vaccination of 9-14 year old girls, with an initial multi-age cohort catch up at commencement where possible *‘for faster and greater population impact.’*
- *Vaccination of secondary target populations, e.g. females aged ≥15 years, boys, older males or MSM, is recommended only if this is feasible and affordable, and does not divert resources from vaccination of the primary target population or effective cervical cancer screening programmes.*

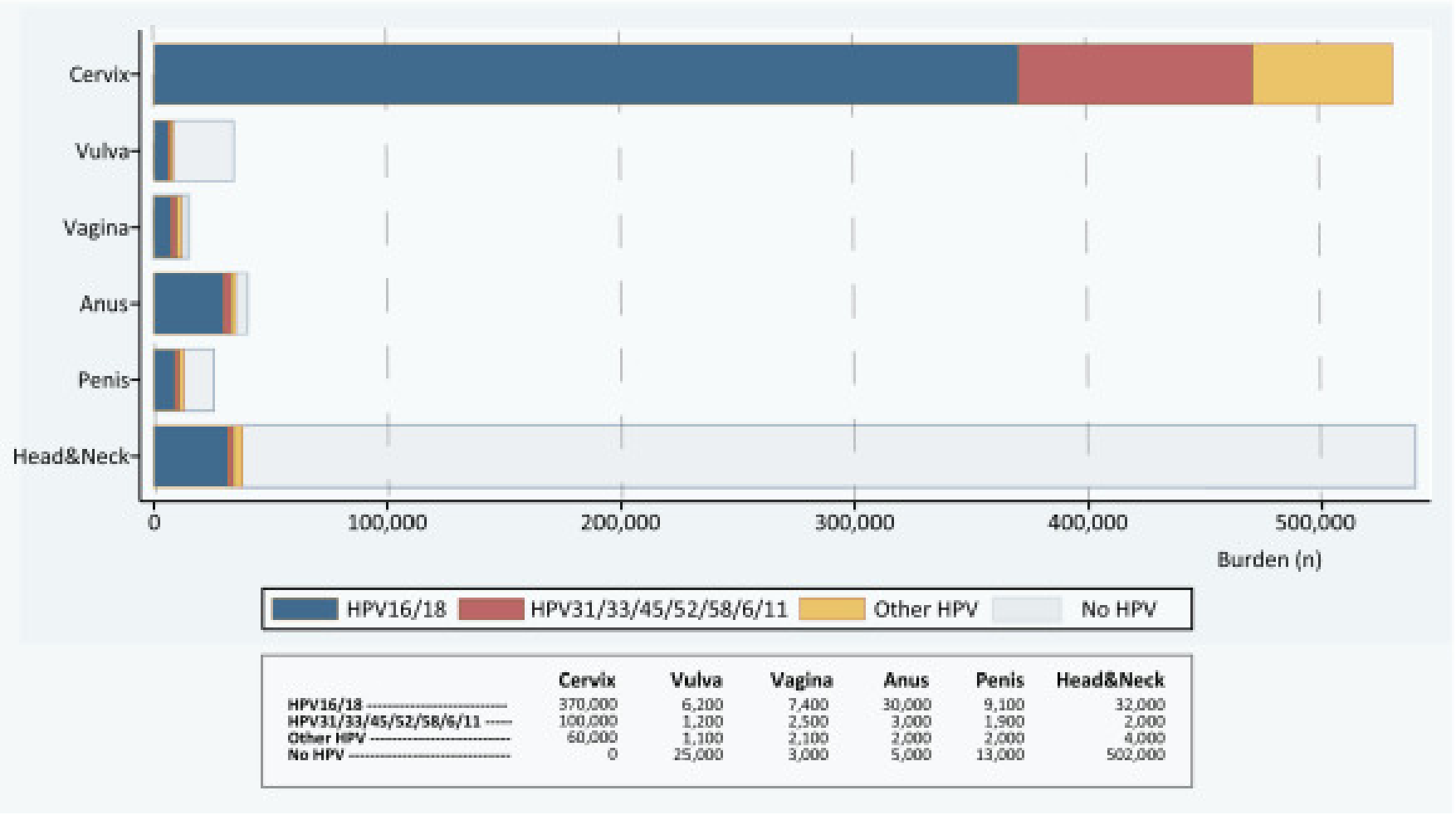


Annually, in women HPV infections cause 530,000 cancer cases in the cervix, 18,000 in the anus, 8,500 in the vulva, 12,000 in the vagina and 5,500 in the oropharynx. In men, HPV infections cause 17,000 cancer cases in the anus, 13,000 in the penis and 24,000 in the oropharynx. Ref. (1)

Source: Sanjose & Tsu. Spectrum of HPV related diseases, HPV world no.36

See: Human papillomavirus vaccines: WHO position paper, December 2022. Weekly Epidemiological Record No 50, 2022, 97, 645–672

Global HPV related cancer burden by HPV type



	Cervix	Vulva	Vagina	Anus	Penis	Head&Neck
HPV16/18	370,000	6,200	7,400	30,000	9,100	32,000
HPV31/33/45/52/58/6/11	100,000	1,200	2,500	3,000	1,900	2,000
Other HPV	60,000	1,100	2,100	2,000	2,000	4,000
No HPV	0	25,000	3,000	5,000	13,000	502,000

- Very cost effective in almost all settings
- Supply constraints now easing
- New vaccines entering market from India and China
- GLOBAL: 2vHPV (Cervarix), 4vHPV (Gardasil), 9vHPV (Gardasil9)
- CHINA: 2vHPV (Cecolin), 2vHPV (Walrinvax)
- INDIA: 4vHPV (Cervavac)
- 5 prequalified by WHO
- 4 for use as single dose

Serrano et al 2018

‘Low risk’ types HPV6 and 11 cause anogenital warts and recurrent respiratory papillomatosis

3) If the decision is made to proceed, choices will need to be made about:

- which vaccine to use
- how many doses to give
- girls only or all children
- what age to vaccinate and how many cohorts
- how best to deliver the vaccine?

What information will you need to inform these decisions?

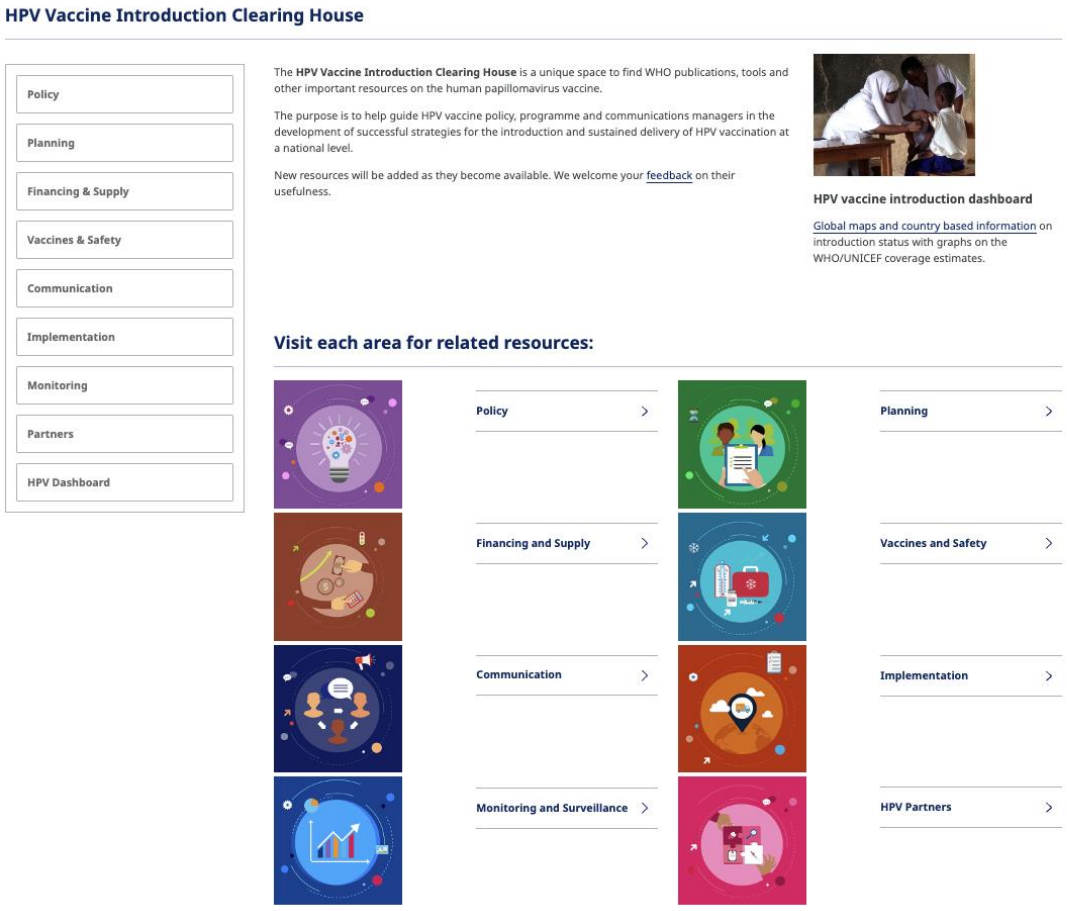
4) Who would be the key stakeholders to consult with before an HPV Vaccine program was rolled out?

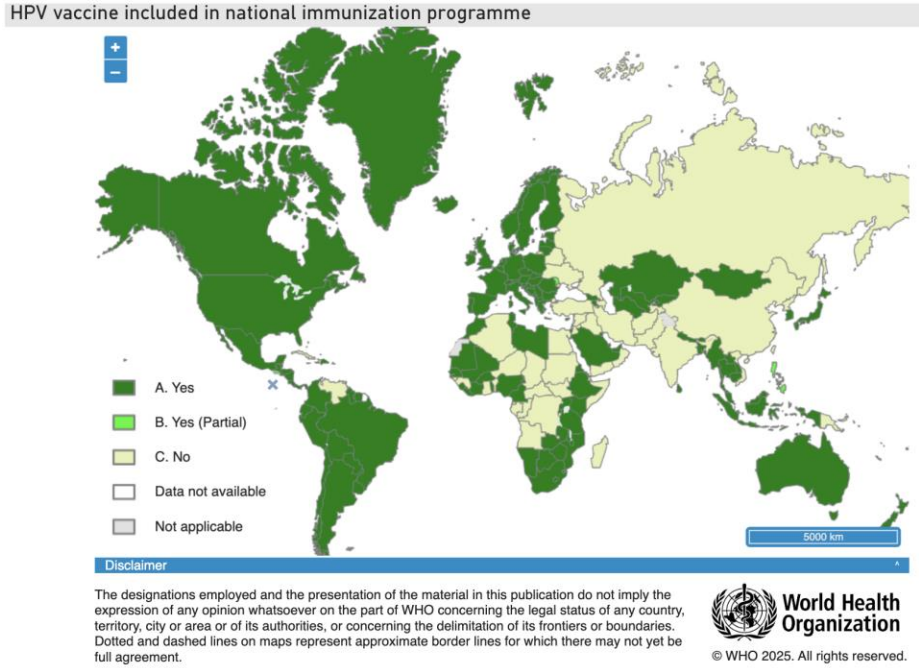
Diverse stakeholders for this particular vaccine…

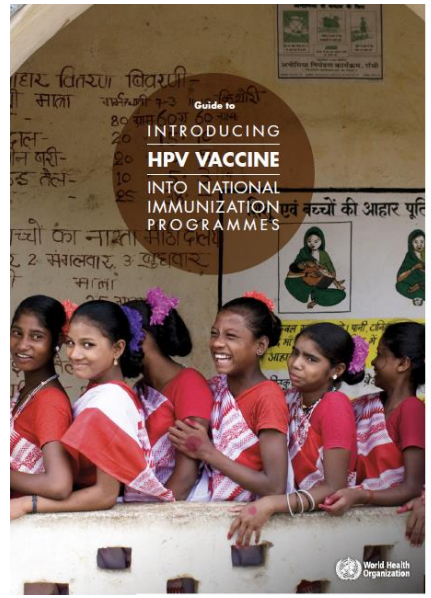
- Ministry of Health and National Immunisation Program lead
  - Health system from national to regional to local levels including community health
- Ministry of Education and education stakeholders at all levels (national, regional, local) including teachers. Across sectors (public and private)
- Ministry of Finance, Prime Minister's office – aim for bipartisan support
- Cancer stakeholders across spectrum from prevention (screening) to treatment to palliative care
- Sexual health
- Adolescent health
- Obstetricians and gynaecologists
- Women's health advocates
- Primary care
- Religious and community leaders
- Media

Extensive experience and documentation of HPV vaccine implementation

https://www.who.int/teams/immunization-vaccines-and-biologicals/diseases/human-papillomavirus-vaccines-(HPV)/hpv-clearing-house







WHO Cervical Cancer Prevention and Control Costing (C4P) Tool

WHO C4P tool has been developed specifically to assist low- and middle-income countries in planning and costing cervical cancer control strategies.

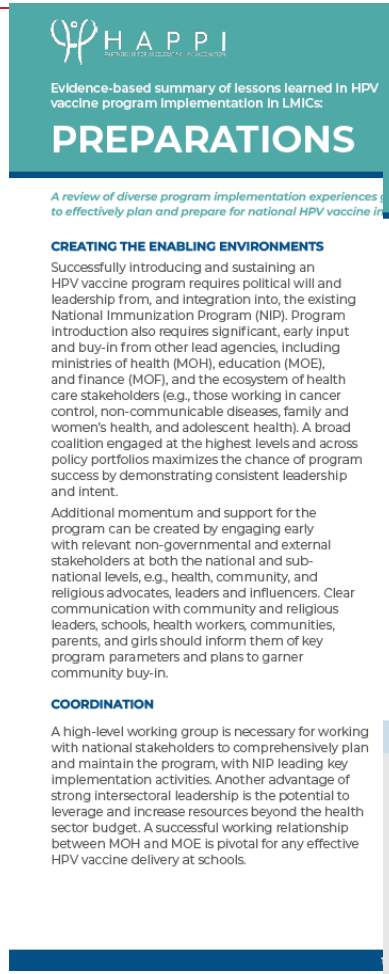
HPV introduction - toolbox

This toolbox on the TechNet-21 website contains practical tools often developed by EPI programmes and partners and is regularly updated.

HPV vaccine introduction dashboard

This dashboard contains both introduction status data and coverage data.

Updated Evidence Briefs (JSI/HAPPI)– five themes


HAPPI

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

PREPARATIONS

A review of diverse program implementation experiences g… to effectively plan and prepare for national HPV vaccine in…

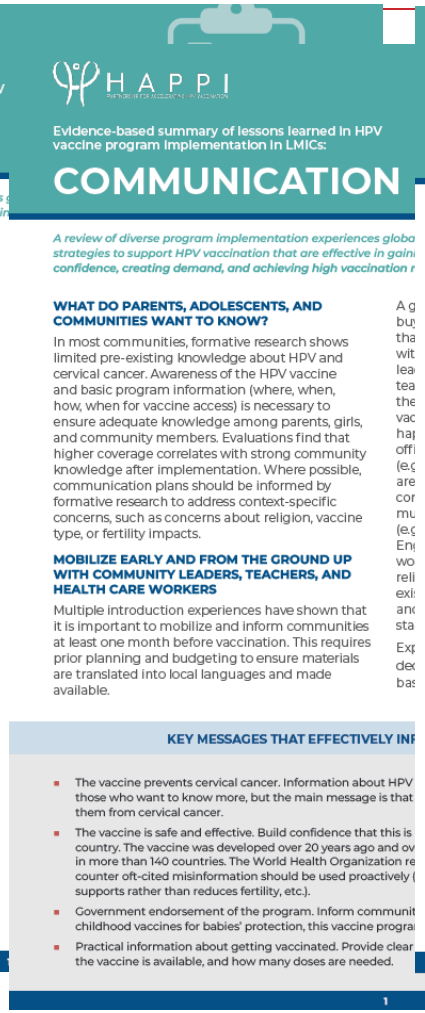
CREATING THE ENABLING ENVIRONMENTS

Successfully introducing and sustaining an HPV vaccine program requires political will and leadership from, and integration into, the existing National Immunization Program (NIP). Program introduction also requires significant, early input and buy-in from other lead agencies, including ministries of health (MOH), education (MOE), and finance (MOF), and the ecosystem of health care stakeholders (e.g., those working in cancer control, non-communicable diseases, family and women's health, and adolescent health). A broad coalition engaged at the highest levels and across policy portfolios maximizes the chance of program success by demonstrating consistent leadership and intent.

Additional momentum and support for the program can be created by engaging early with relevant non-governmental and external stakeholders at both the national and sub-national levels, e.g., health, community, and religious advocates, leaders and influencers. Clear communication with community and religious leaders, schools, health workers, communities, parents, and girls should inform them of key program parameters and plans to garner community buy-in.

COORDINATION

A high-level working group is necessary for working with national stakeholders to comprehensively plan and maintain the program, with NIP leading key implementation activities. Another advantage of strong intersectoral leadership is the potential to leverage and increase resources beyond the health sector budget. A successful working relationship between MOH and MOE is pivotal for any effective HPV vaccine delivery at schools.


HAPPI

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

COMMUNICATION

A review of diverse program implementation experiences globa… strategies to support HPV vaccination that are effective in gain… confidence, creating demand, and achieving high vaccination r…

WHAT DO PARENTS, ADOLESCENTS, AND COMMUNITIES WANT TO KNOW?

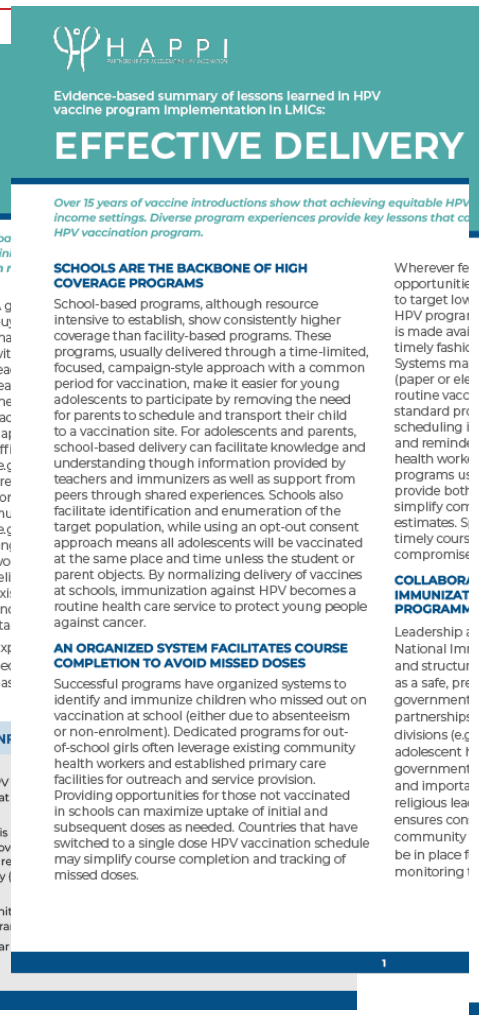
In most communities, formative research shows limited pre-existing knowledge about HPV and cervical cancer. Awareness of the HPV vaccine and basic program information (where, when, how, when for vaccine access) is necessary to ensure adequate knowledge among parents, girls, and community members. Evaluations find that higher coverage correlates with strong community knowledge after implementation. Where possible, communication plans should be informed by formative research to address context-specific concerns, such as concerns about religion, vaccine type, or fertility impacts.

MOBILIZE EARLY AND FROM THE GROUND UP WITH COMMUNITY LEADERS, TEACHERS, AND HEALTH CARE WORKERS

Multiple introduction experiences have shown that it is important to mobilize and inform communities at least one month before vaccination. This requires prior planning and budgeting to ensure materials are translated into local languages and made available.

KEY MESSAGES THAT EFFECTIVELY INF…

- The vaccine prevents cervical cancer. Information about HPV … those who want to know more, but the main message is that … them from cervical cancer.
- The vaccine is safe and effective. Build confidence that this is … country. The vaccine was developed over 20 years ago and ov… in more than 140 countries. The World Health Organization re… counter oft-cited misinformation should be used proactively (… supports rather than reduces fertility, etc.).
- Government endorsement of the program. Inform communit… childhood vaccines for babies' protection, this vaccine progra…
- Practical information about getting vaccinated. Provide clear … the vaccine is available, and how many doses are needed.


HAPPI

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

EFFECTIVE DELIVERY

Over 15 years of vaccine introductions show that achieving equitable HPV… income settings. Diverse program experiences provide key lessons that c… HPV vaccination program.

SCHOOLS ARE THE BACKBONE OF HIGH COVERAGE PROGRAMS

School-based programs, although resource intensive to establish, show consistently higher coverage than facility-based programs. These programs, usually delivered through a time-limited, focused, campaign-style approach with a common period for vaccination, make it easier for young adolescents to participate by removing the need for parents to schedule and transport their child to a vaccination site. For adolescents and parents, school-based delivery can facilitate knowledge and understanding though information provided by teachers and immunizers as well as support from peers through shared experiences. Schools also facilitate identification and enumeration of the target population, while using an opt-out consent approach means all adolescents will be vaccinated at the same place and time unless the student or parent objects. By normalizing delivery of vaccines at schools, immunization against HPV becomes a routine health care service to protect young people against cancer.

AN ORGANIZED SYSTEM FACILITATES COURSE COMPLETION TO AVOID MISSED DOSES

Successful programs have organized systems to identify and immunize children who missed out on vaccination at school (either due to absenteeism or non-enrolment). Dedicated programs for out-of-school girls often leverage existing community health workers and established primary care facilities for outreach and service provision. Providing opportunities for those not vaccinated in schools can maximize uptake of initial and subsequent doses as needed. Countries that have switched to a single dose HPV vaccination schedule may simplify course completion and tracking of missed doses.

Wherever fe… opportunitie… to target low… HPV progra… is made avai… timely fashi… Systems ma… (paper or ele… routine vacc… standard pr… scheduling i… and reminde… health work… programs us… provide both… simplify com… estimates. S… timely cours… compromise…

COLLABORA… IMMUNIZAT… PROGRAMM…

Leadership … National Imm… and structur… as a safe, pre… government… partnerships… divisions (e.g… adolescent h… government… and importa… religious lea… ensures con… community… be in place f… monitoring t…


HAPPI

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

SUSTAINING PROGRAMS

A review of diverse program implementation experiences globally shows remarkable … 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), th… their HPV vaccination pr…

The collective findings f… global HPV vaccine intro… LMICs, which summariz… and facilitators needed t… run program, can argua… understanding the elem… running program".

These program activities … with the areas of progra… recommends when eval… program. Table 1 summa… components that need t… maintained every year o… programs and elements … While reducing the two-… dose may result in fewe… most elements of succe… programs need to be mi… dosing schedule.

COSTS OF HPV INTROD… ROUTINE HPV PROGRA…

A recent systematic revi… costs found wide variati… With the exception of th… program in Zimbabwe a… costs per dose ranged fr… school-based delivery in… (national program in Mo… economic costs per dos… (Zimbabwe national pro… national program). The v… estimates was due to stu… inclusion criteria for diffe… stage of the country pro… introduction year, years … schedule, locations and …


HAPPI

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

PITFALLS

A review of diverse program implementation experiences globally provide lessons on how previous programs can be improved upon. Learning from others' experiences can help low- and middle-income countries avoid common pitfalls and maximize their chance of success when introducing and sustaining HPV vaccinations for adolescent girls between the ages of 9 and 14 years.

PITFALLS TO AVOID IN PLANNING AND PREPARATION

Some delays are inevitable when coordinating a vaccine introduction across multiple sectors and levels. However, experience shows that delays in planning affect both the timing and quality of introduction activities. It is critical to avoid protracted delays in obtaining memoranda of understanding (MOUs) and funding, including funding distribution to lower levels, to avoid further delays across planning activities. Clear communication at all levels is vital to avoid mistimed implementation activities and loss of trust.

Low coverage is common in countries that did not undertake a successful planning process (i.e., failure to design detailed plans, microplanning activities, stakeholder consultation and coordination). Similarly low coverage is associated with countries that have struggled to create an enabling environment through demonstrable political will, creation of a strong National Immunization Program (NIP)-led multisectoral implementation committee, clear communication, and strong community engagement.

Clear leadership and communication are vital to ensure that all stakeholders are aware of and understand the plan for HPV vaccine delivery. Limitations in program reach are inevitable if vaccines are only provided once or at a single location, and the delivery plan should address this. The ministry of education's (MOE) leadership and support at the highest level needs to be communicated across all levels of the education sector.

PITFALLS TO AVOID IN COMMUNICATIONS

When IEC materials are delayed, rushed, or not effectively disseminated (including in local languages), misinformation and rumors can arise and result in hesitancy. Local communications should be disseminated and reinforced by trusted voices, such as health workers, schools, community leaders, or religious leaders.

Failure to anticipate and manage rumors at all levels, including in schools, will result in hesitancy and low coverage or pockets of low coverage.

Regaining trust is far more challenging than implementing a proactive communications approach that anticipates and preempts potential rumors, including a plan for their immediate and ongoing management.

Community trust in the vaccine can be lost during an uncoordinated and poor response to crisis in the absence of an effective crisis communication plan.

PITFALLS TO AVOID IN EFFECTIVE DELIVERY

Failure to leverage existing health care and vaccination delivery mechanisms at the local level frequently results in missed opportunities, lack of confidence in the program, and poor coverage. Using these mechanisms well can include assigning community health care workers to reach out-of-school girls, assigning village health teams to conduct immunization sessions, and using existing vaccine transport systems and schedules. Consent procedures that do not align with those implemented for infant vaccines creates mistrust.

Not adequately coordinating vaccine delivery with school breaks or other known events (e.g., school holidays, rainy season, or exam periods) can lead to low coverage and less support for future vaccine rounds.

Vaccination eligibility and how this is determined should be clearly communicated with school staff, parents, and health care workers. Failure to do so can lead to missed vaccinations and vaccine leakage into the non-target population. Similarly, adequate planning for and communication about out-of-school vaccination sessions, especially for those who missed in-school sessions, is vital.

Available on TechNet at: https://www.technet-21.org/en/hpv-vaccine-introduction