



HPV Vaccine Lessons Learnt

Human papillomavirus (HPV) vaccination experience in 45 low and middle-income countries: lessons learnt

Katherine Gallagher (LSHTM)

Deborah Watson-Jones (LSHTM; MITU, Tanzania), Severin Kabakama (MITU, Tanzania), Natasha Howard & Sandra Mounier-Jack & Ulla Griffiths & Helen Burchett (LSHTM); D. Scott LaMontagne & Marta Feletto & Beth Balderston (PATH)

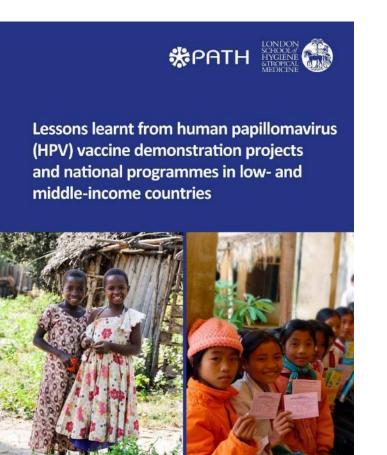
HPV prevention and control Board meetingBarriers in HPV vaccination & cervical screening programmes.27-28 June 2016, Antwerp, Belgium





Study objectives

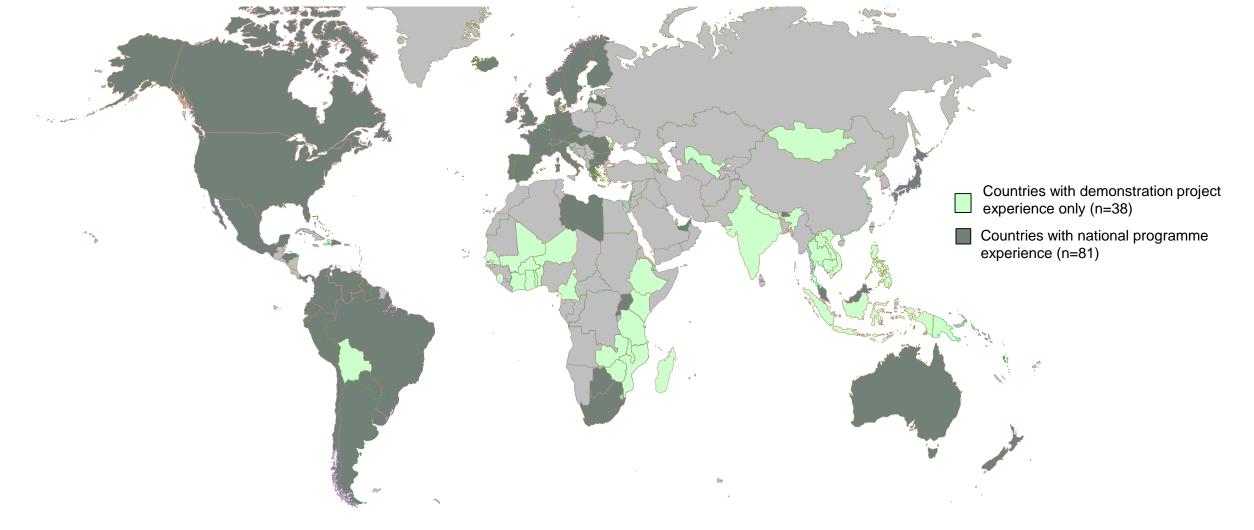
- 1. Collate and synthesize lessons from completed HPV vaccine demonstration projects and national programmes (*LSHTM*).
 - Explore why some countries have not applied to Gavi, the Vaccine Alliance, for HPV vaccine support.
- 2. Generate recommendations on how HPV vaccine delivery can be successfully integrated into national immunisation programmes and on key drivers of costs (*LSHTM*).
- 3. Use creative mechanisms to disseminate the synthesized lessons and best practices, for HPV vaccine demonstration projects and national programmes (*PATH*).



Kate Gallagher, Severin Kabakama, Natasha Howard, Ulla Griffiths, Sandra Mounier-Jack, Marta Feletto, Scott LaMontagne, Helen Burchett, Deborah Watson-Jones

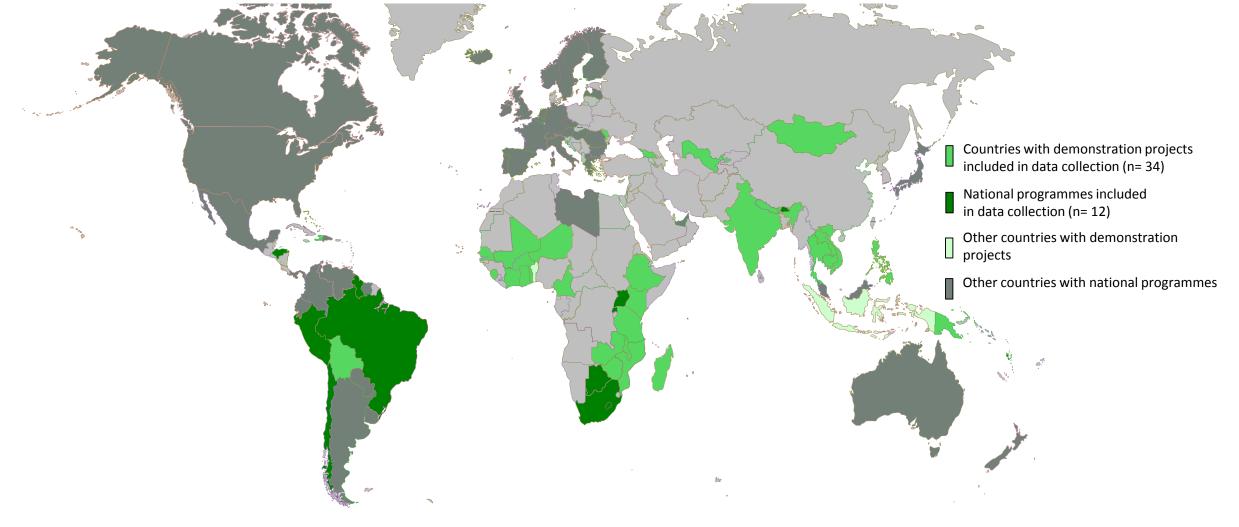


Global HPV vaccination experience – May 2016





Study countries – May 2016





HPV vaccine support

- Merck & Co., Inc.: Funded direct donations of vaccine (e.g. Rwanda) and GARDASIL® Access Program.
- GARDASIL[®] Access Program (GAP): 3 million doses of vaccine freely available; no operational costs.
- **Gavi:** vaccine and financial support for demonstration projects, and co-pay for vaccine and 1-year vaccine introduction grant for national programmes.
- Australian Cervical Cancer Foundation: Purchased vaccine or raised funds to buy vaccine and provided implementation costs for 3 countries.
- **PATH (funded by BMGF):** Provided free vaccine and operational costs for 4 countries to conduct demonstration projects.



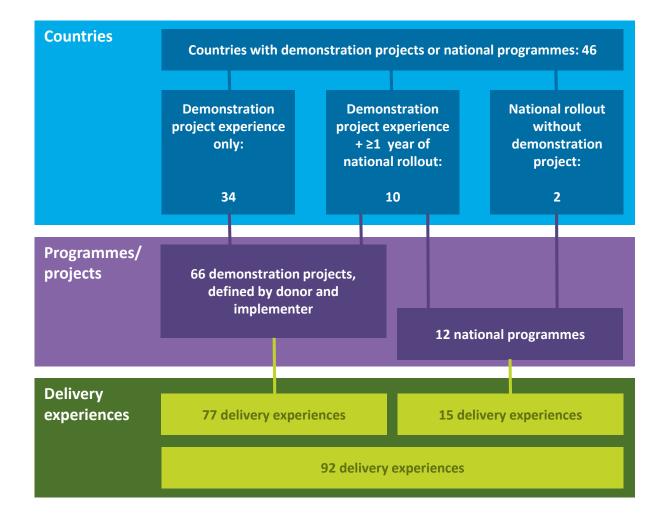
PATH/Amynah Janmohamed



Study by numbers

- 45 low- and middle-income countries (18 LIC, 22 LMIC, 5 UMIC, 1 HIC)
 - 12 national introductions.
 - 66 demonstration projects: Gavi (n=20), GAP (n=30), PATH (n=4), other (n=12).
- 3 data-collection approaches:
 - 1. Systematic review (61 articles, 11 abstracts)
 - 2. Review of unpublished literature (188 reports)
 - 3. Key informant interviews (56 interviews)
- Extraction on themes in WHO's NVI guidelines.

92 delivery experiences: defined by the vaccination venue and target population within a specific project/programme (defined by funding source).





Key Themes: Findings, Lessons, Recommendations

Findings, lessons learnt, and recommendations for decision-makers on seven themes:

- Preparation
- Communications
- Delivery
- Achievements
- Sustainability
- Pitfalls
- Value



PATH/Jacqueline Sherris





HPV Vaccine Lessons Learnt & Recommendations

Key Findings: Barriers to introduce, deliver, achieve good coverage and sustain HPV vaccination







Key findings: The decision to introduce HPV vaccine

- Drivers of the decision to introduce: 29/40 countries with HPV vaccine experience mentioned cervical cancer burden, 15/40 mentioned availability of free vaccine.
- 5/ 9 countries eligible for Gavi support but had not applied by May 2015 were contactable for interview:
 - All five aware of Gavi funding for HPV vaccine
 - Two countries planned to submit applications;
 - Two countries prioritised other new vaccine introductions (no natl. capacity for others);
 - One country felt there was not enough funding to warrant starting an HPV vaccination project/programme.

Countries that have not yet applied for Gavi HPV vaccine support	World Bank income group	Data Collection
Comoros	LIC	Unavailable
Congo, DR	LIC	Unavailable
Djibouti	LMIC	Unavailable
Eritrea	LIC	Interview
Guinea-Bissau	LIC	Interview
Kyrgyz Republic	LIC	Interview
Mauritania	LIC	Interview
Nicaragua	LMIC	Unavailable
Nigeria	LMIC	Interview





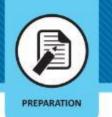
Key findings: preparation

Decision-making and leadership

- Lead department within the MOH varied (e.g. EPI/ SHP/ RH/ NCD).
- Political commitment ensured support from all levels of health/education sectors.
- MOE collaboration important for school-based delivery.
- MOF important for planning national programmes.







Key findings: preparation

Staff capacity, training, remuneration and workload

- Most common team size was 3-4 persons.
- Community health workers accessed hard-to-reach groups and reduce heath worker workloads.
- Novel aspects of HPV vaccine required specific training. 26/ 30 countries used 'cascade' training.
- Remuneration: Health worker & supervisor allowances were paid for outreach/school delivery.
- Additional transport to the routine EPI transport had to be arranged when HPV demonstration project timing differed from routine EPI vaccine delivery.
- Vaccine, health worker, supervisor transport and health worker and supervisor per diems were reported key drivers of delivery cost.



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Key findings: communications

Social mobilisation

- Low HPV knowledge in the community.
- Social mobilisation was effective with interactive methods delivered by 'credible influencers': health workers, teachers, community leaders.
- Rumours limited to alleged effects on fertility.
- Key messages: cervical cancer vaccine, is safe, will not harm fertility, endorsed by government, neighbouring countries delivering vaccine.
- Rumour mitigation: Tailored communication messages, endorsements by government officials, and dissemination of WHO safety statements.

"Recovering trust is proving extremely challenging, despite involvement of national figures in medicine and entertainment" KI Country 4 after a rumour on social media.









Key findings: communications

Social mobilisation timing

Problems reported if social mobilisation was initiated • less than a month before vaccination.

Top 3 reasons for acceptance	Score	Surveys
Vaccine is "good for health"	31	12
Protection from cancer	30	12
Protection from infection	16	9
Top 3 reasons for non-vaccination		
Not aware of the programme	<mark>25</mark>	<mark>10</mark>
Absenteeism	<mark>21</mark>	<mark>11</mark>
Fear of adverse effects	<mark>16</mark>	<mark>9</mark>

Acceptability

- Refusals: Private schools, religious groups, anti-٠ vaccine groups (8 projects/programmes each).
- HW hesitancy contributed to parental refusal to uptake in 4 countries.

Consent

- 71/92 delivery experiences reported on consent procedures: 50% used opt-in and 30% used opt-out; some used a mixture or changed process.
- 7 projects changed opt-in to opt-out: opt-in (where not standard EPI practice) increased rumours; lengthy consent decreased uptake.





Key findings: delivery

Delivery strategy and population selection

- 88% experiences involved schools; *resource-intensive*.
- Targeting a grade simpler to implement than age, but can be challenging to communicate and calculate coverage.
- Estimating target population for delivery challenging.
- Common enumeration methods: school registers, MOE enrolment data, census data or survey estimates.
- Uncertainty re: how to vaccinate HIV+ girls with 3 doses and HIV- with just 2 doses (19 countries).

"HIV positive girls are vaccinated with 2 doses alongside all other girls – we can't separate them" Country 16

Delivery strategy for in-school and out-of- school girls	Experiences (N=89)	
School only	<mark>24</mark>	27%
School + health facility	<mark>21</mark>	24%
School + health facility + outreach	<mark>25</mark>	28%
School + outreach	<mark>8</mark>	9%
Health facility only	<mark>6</mark>	7%
Health facility + outreach	<mark>5</mark>	6%
Target population in school	(N:	=75)
Age	<mark>39</mark>	52%
Grade	<mark>23</mark>	31%
Age within a school grade(s)	<mark>13</mark>	17%







Key findings: delivery

Duration

- Vaccine most commonly delivered over 1 week. •
- Common mop-up strategies for girls: directing girls to • health facility, returning to schools for second vaccination, offering dose 1 at dose 2 visit for those who missed dose 1 initially.
- Impact on routine service provision: 10 countries ٠ reported no impact, 10 countries reported impact.

Adverse events (AEs) following immunisation/ safety

- Most AEs were minor and temporary, requiring ٠ observation but no or minimal treatment.
- Most countries reported availability of injection safety ٠ guidelines and/or training procedures.



LSHTM/ Deborah Watson-Jones

"We have a national policy for waste management, but don't have funding to implement it. So waste is just burned in secured tanks because we don't have funding for incinerators" KI Country 17.





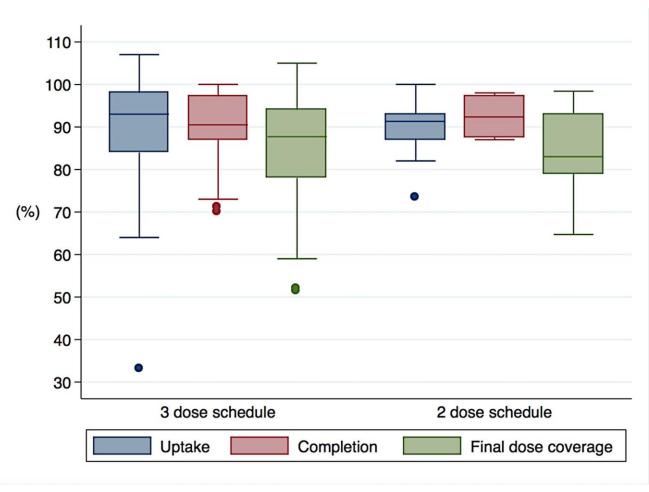
Key findings: achievements

Vaccine coverage

- Coverage data available from 60 of 92 experiences: 50 used 3-dose schedule, 10 used 2-dose.
- 83% reported final dose coverage of <a>70%.
- Minimal data from health facility strategies (5 experiences; 65-96%).

Uptake and dropout

- First-dose coverage: 64- 100%.
- Completion: 70-99%.
- Majority reported drop-out rate of 10% or less.







Key findings: achievements

Factors correlated with **high** coverage experiences:

- Strategies using schools incl. good collaboration with education sector at national and local levels (limited data on health facility only strategies).
- Involvement of national immunisation programme in planning and implementation.
- Targeted social mobilisation of out-of-school girls achieved uptake in this group.
- Comprehensive social mobilisation, including use of 'credible influencers'.
- Use of vaccination registers and cards.
- Delivering vaccine on schedule and within 1 school year.

Factors correlated with **low** coverage:

- Ineffective coordination and planning with schools.
- Rumours that caused schools to refuse vaccinators.
- Urban areas with high exposure to negative media/ mobile populations.
- Other factors: Delay in receipt of social mobilisation and school-delivery funds, not providing a second opportunity for girls who missed the first dose.





Key findings: achievements

HPV vaccine coverage data collection and reporting

- 17 delivery experiences in 13 countries had data from coverage surveys (reliable).
- 43 experiences in 32 countries only reported administrative coverage in literature (quality highly variable).
- Understanding/ implementation eligibility criteria by health workers, teachers, parents influenced data quality.

"There was no way of verifying age; many more could present on vaccination day and were vaccinated than were actually eligible" KI Country H

• Target population estimates affected by estimates from multiple data sources (basis for denominator unclear).



PATH/Amynah Janmohamed





Key findings: sustainability

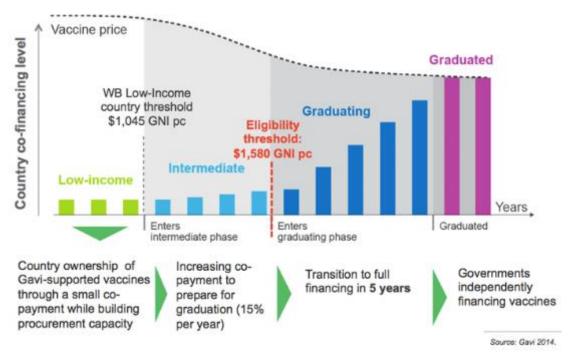
Financing and costs

- 66 demonstration projects in 44 countries received vaccine and/or funding for delivery from GAP (n=30), Gavi (n=20), PATH (n=4), ACCF (n=3), other (n=9).
- Financing for national programmes provided by Merck, Gavi, ACCF or national governments.
- Recurrent financial costs per dose:
 - 5 initial demos: US\$ 1.11 -2.10
 - 7 GAP demos: US\$ 2.74 (mean)
 - 5 Gavi demos: US\$ 3.1 9.21

Factors influencing scale-up

- Uncertainty about future financing and on-going political commitment; 11/24 may not scale up.
- Ineligibility for Gavi support is major barrier for some countries.

How vaccine co-financing increases as countries' economies grow



Note: Gavi=Gavi, the Vaccine Alliance; GNI pc=gross national income per capita; WB=World Bank.







- Lessons learnt from 2007-2016 (9 years) of demonstration projects consistent across countries/ time.
- Vaccine delivery can achieve as good coverage as successful programmes in HIC e.g. Australia, England
- Well-designed demonstration projects can be used to assess different delivery strategies, how to achieve high coverage in challenging areas, and learn about integration with national systems; to-date many countries have missed this opportunity.
- Demos using resource-intensive delivery strategies have generated sustainability concerns.
- Demonstration projects may have decreased momentum, or intention, in some countries to introduce HPV vaccine nationally.



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PATH/Robin Biellik



Conclusions: Barriers to introduce, deliver, achieve and sustain

Table: Challenges identified in the literature (2006-2013)¹

Sociocultural	Logistical	Political
Low HPV knowledge	Infrastructure and human resources	Lack of political will
	Financing mechanisms/ cost	Coordination of diverse stakeholders
Parental concerns of side effects, infertility, sexual promiscuity	Reaching out-of-school girls	Competing priorities on capacity
Vaccine target age and group	Timetabling	
Community sensitisation	Delivery strategies	

¹Wigle J, Coast E, Watson-Jones D. Human papillomavirus (HPV) vaccine implementation in low and middle-income countries (LMICs): health system experiences and prospects. *Vaccine* 2013;**31**(37):3811-7.



Resources available to everyone – Recommendations

- All materials in English, French, Spanish (forthcoming)
- Information packet
 - 1. 4-page high level summary
 - 2. 2-page detailed briefs by theme:
 - Preparation
 - Communications
 - > Delivery
 - Achievements
 - Sustainability
 - Benefits
 - Pitfalls
 - 3. 1-page "Steps for Success" poster
 - 4. Peer-reviewed manuscripts:
 - Value of demonstration projects (Human Vaccines & Immunotherapeutics; 2016)
 - Social Mobilisation, consent and acceptability (accepted; BMC PH 2016)
 - General lessons learnt (*submitted;* WHO Bulletin)

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- All programmes, nongovernmental organisations and partners that implemented the HPV vaccine pilots, demonstration projects and national introductions.
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The views expressed herein are solely those of the authors and do not necessarily reflect the views of PATH; the London School of Hygiene & Tropical Medicine; Axios International; Gavi, the Vaccine Alliance; or the Bill & Melinda Gates Foundation.

Thank you

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PATH/Le Thi Nga