Implementing HPV Vaccination: A review of seven key themes for decision-makers

London School of Hygiene & Tropical Medicine, PATH

2016
Study objectives

1. Collate and synthesise lessons from completed HPV vaccine demonstration projects and national programmes.
   • Explore why some countries have not applied to Gavi, the Vaccine Alliance for HPV vaccine support.
2. Generate insights and recommendations on how HPV vaccine delivery can be successfully integrated into national immunisation programmes and on key drivers of costs.
3. Use creative mechanisms to disseminate the synthesised lessons/insights and best practices, both for HPV vaccine demonstration projects and national programmes.
HPV vaccine support

- **Merck & Co., Inc.**: Funded GARDASIL® Access Program and direct donations of vaccine (e.g., Rwanda).

- **GARDASIL® Access Program (GAP)**: 3 million doses of vaccine made freely available except funds for operational costs.

- **Gavi, the Vaccine Alliance**: Provided vaccine and financial support for implementing demonstration project and copay for vaccine and 1-year vaccine introduction grant for national programmes.

- **Australian Cervical Cancer Foundation**: NGO purchased vaccine or raised funds to buy vaccine in-country and provided implementation costs to Nepal, Kiribati, Vanuatu.

- **PATH (funded through Bill & Melinda Gates Foundation)**: Provided free vaccine and operational costs for 4 countries to conduct demonstration projects.
Study methods

This review included:

- 46 selected countries after mapping exercise.
- 3 data-collection approaches:
  - Systematic review (61 articles, 11 conference abstracts).
  - Review of unpublished literature (188 reports).
  - Key informant interviews (56 interviews).
- Data extraction based on the World Health Organization’s (WHO’s) new vaccine introduction guidelines.
- 9 countries that did not apply to Gavi (5 interviews).
- Approval by the Research Ethics Committee of the London School of Hygiene & Tropical Medicine.

Note: Demo = demonstration project; GAP = GARDASIL® Access Program; Gavi = Gavi, the Vaccine Alliance; National = national programme.
Study by numbers

- Data from 46 countries (18 LIC, 22 LMIC, 5 UMIC, 1 HIC):
  - 12 national introductions.
  - 66 demonstration projects.
- 92 distinct delivery experiences.
- 120 years of cumulative vaccination experience.
- >1,750,000 girls reached.
- >1,400,000 girls fully vaccinated.

Ninety-two distinct delivery experiences: defined by the vaccination venue and target population within a specific project/programme.

1Data was received from three countries planning to scale up to national rollout from their demonstration project in 2015–2016 and four other programmes which had planned to change delivery strategy in 2015–2016.
### Countries and financing sources

<table>
<thead>
<tr>
<th>Country</th>
<th>Type of financing</th>
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<td>15 Honduras</td>
<td>GAP demos and national</td>
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Note: ACCF = Australian Cervical Cancer Foundation; GAP = GARDASIL® Access Program; Gavi = Gavi, the Vaccine Alliance; MOH = ministry of health.
Key themes: Findings, lessons, recommendations

A four-page overview and a collection of two-page summaries detail findings, lessons learnt, and recommendations for decision-makers on seven themes:

- Preparation
- Communications
- Delivery
- Achievements
- Sustainability
- Value
- Pitfalls
Preparation
Decision-making and leadership

Findings

• Country motivators: high national cancer burdens, free vaccines/financing, successful implementation in other countries.
• Ensuring political will during preparation critical for gaining support at regional and district levels.
• Ministry of health (MOH) most common lead institutional decision-maker.
• Ministry of education (MOE) collaboration important for school-based initiatives. Ministry of finance (MOF) important for national programmes.

Lesson learnt

• Timely planning across sectors (health, education, finance) critical for implementation and sustainability.
National/local planning, integration with national immunisation programme

Findings

• 33 of 46 countries formed planning coordination committees (national and subnational).
• Subnational committees responsible for microplanning and fund requests.
• Most effective microplanning efforts marked by involvement of health and education sectors.
• HPV vaccination typically delivered through national immunisation programme and shared structures and resources.
• Processes for microplanning, communication, social mobilisation, training, and logistics were similar to those for the national immunisation programme (or the Expanded Programme on Immunization [EPI]).
• Several countries reported HPV vaccination required more ‘intense’ resource mobilisation and preparation.

Lessons learnt

• Cooperation between local representatives from health and education sectors facilitated effective microplanning.
• Where EPI led HPV vaccine demonstration projects, integration with routine activities was generally strong and existing infrastructure was utilised.
Staff capacity, training, remuneration, and workload

Findings

• Team size: among 29 countries, the most common vaccination team size was 3 to 4 persons.

• Staff training: 26 of 30 countries used a ‘cascade’ training and supervision model. Training duration varied from <1 day to 3 days and covered all aspects of routine immunisation with HPV-specific topics.

• Impact on routine service provision: 10 countries reported no impact (5 had mitigation strategies in place) while 10 countries reported impact.

• Allowances: 29 of 32 projects/programmes used allowances to pay health workers for outreach or other activities outside health facilities, posing challenges in demonstration projects not integrated with routine activities.

Lessons learnt

• Cascade approach was the most common staff training and supervision method. Supervision of training was critical to preparing vaccination teams.

• When HPV vaccination training was combined with training for another vaccine, inadequate emphasis on each vaccine compromised quality.

• Staff allowances and transport to schools tended to be expensive; these costs were a key planning consideration.
Vaccine management

Findings

• Routine immunisation programme systems were used to transport HPV vaccine in 49 experiences across 35 countries.

• Separate transport was arranged for HPV vaccines in projects where timetables differed from other vaccines.

Lesson learnt

• Coordinating transportation of HPV vaccines with routine vaccines reduced logistical challenges and costs.
Additional lessons learnt

• For demonstration projects, those that were small-scale were difficult to integrate with routine EPI; those run by non-MOH groups showed minimal or no integration with routine services; limited lessons about scalability.

• Several countries intended to test combined HPV vaccination with other interventions, but few have implemented and none have formally evaluated.

• Health workers and teachers must be trained on HPV vaccine, cervical cancer, and eligibility to answer questions from community and mobilise girls.

• Novel aspects of HPV vaccines require specific training; could be integrated into national immunisation programme in the future.
Recommendations

1. Ensure the national planning process includes leadership/endorsement from ministries of health, education, and finance. Allow at least nine months.
2. Ensure that national immunisation programme feels ownership and is involved in each phase.
3. Conduct a human resources capacity assessment to determine vaccination team size.
4. Ensure adequate supervision when adding HPV vaccine to health workers’ training and workload.
5. Carefully consider whether and how to allocate allowances during planning.
6. Plan HPV vaccine management closely and well in advance with the broader national immunisation system.
7. Conduct training for all health workers at least two months before delivery.
Countries that have not yet applied for Gavi HPV vaccine support

- National immunisation team representatives from five countries (of nine) were contactable for interview.
- All five felt cervical cancer was a public health problem and were aware of Gavi funding for HPV vaccine introduction.
- Two countries were aiming to submit applications for funding within the next year.
- Two countries prioritised other new vaccine introductions; an application for HPV vaccine support was thought to be planned for some point in the future.
- One country felt there was not enough country-specific data on HPV epidemiology or funding to warrant starting an HPV vaccination project/programme.

<table>
<thead>
<tr>
<th>Country</th>
<th>World Bank classification of country economy</th>
<th>Data collection</th>
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<tbody>
<tr>
<td>Comoros</td>
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<td>Djibouti</td>
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<tr>
<td>Nigeria</td>
<td>LMIC</td>
<td>Interview</td>
</tr>
</tbody>
</table>

1World Bank classification 2014.

Note: LIC = low-income country; LMIC = lower-middle-income country.
Communications
Formative research and messages

Findings

• Knowledge of HPV and the vaccine was generally low across countries.
• Nearly all countries messaged the vaccine as preventing cancer rather than sexually transmitted infections.
• Secondary messages: vaccine safety and efficacy, where and how it would be delivered, information about consent, and messages to counter rumours.
• Rumour type was limited to alleged effects on fertility or adverse events.
• Rumour mitigation: tailored communication messages, endorsements by officials, and dissemination of WHO or national safety statements.

Lesson learnt

• Key messages: HPV vaccine prevents cervical cancer, is safe, will not harm future fertility, and is endorsed by government and WHO.
Materials and tactics

Findings

• Common interactive methods: in-person meetings, direct contact with teachers or health workers.
• Noninteractive tactics: leaflets, posters, radio, television, community announcements, social media.
• Most effective communication from ‘credible influencers’: health workers, teachers, community/religious leaders.
• Most parents reported first learning about the vaccine from in-person communication and meetings.

Lessons learnt

• Face-to-face interaction is the most effective way to mobilise parents and the community, especially if exposed to antivaccination rumours.
• Most effective influencers: health workers, teachers, community leaders.
Social mobilisation timing and sequencing

Findings

- Most countries initiated activities at least one month before vaccination.
- Greatest success reported when activities were coordinated with health, education, and community leaders.
- Projects reporting delays also reported additional difficulties with social mobilisation.

Lesson learnt

- Community sensitisation and mobilisation activities conducted at least one month prior to vaccination were most effective.
Acceptability and consent

Findings

• Reasons parents accepted: vaccines seen as good for health and to protect child from cancer/infection/disease.
• Persistent sensitisation through community influencers increased vaccine acceptability.
• 37 delivery experiences in 28 countries reported information related to acceptance or refusal.
• A few projects experienced institutional/group refusals: private schools (8 projects), religious/antivaccine groups (7 projects), health workers (4 projects).
• Reasons parents did not accept: fear of adverse effects, lack of awareness of programme, absenteeism.
• 71 of 92 delivery experiences reported consent procedures:
  • Nearly 50% used ‘opt-in’.
  • 27% used ‘opt-out’.
  • 15% used combination of opt-in and opt-out.
  • 10% switched from opt-in to opt-out.

Lessons learnt

• Logistical challenges (lack of awareness of vaccine availability and school absenteeism or transfers) were common reasons for nonvaccination and incomplete vaccination.
• Vaccine safety concerns, rumours, and attending a private school were associated with nonvaccination.
• Opt-in consent (where not standard practice) increased rumours.
• Lengthy consent procedures decreased uptake.
Additional lessons learnt

• Further formative research may not be necessary due to consistency in messages across high-coverage projects.

• Training of influential stakeholders/spokespersons and health workers necessary at all levels.

• Social mobilisation activities can be reduced after the first few years of a national programme as the vaccine becomes ‘normalised’.

• Urban and private-school parents often require more information and time for consideration compared with other people.
Recommendations

1. Develop a communications plan to inform social mobilisation.
2. Engage early with community groups, including schools (public and private) and churches.
3. Focus messages on cervical cancer prevention, vaccine safety and efficacy, government endorsement, and the timing and venues for delivery.
4. Tackle emerging rumours as soon as possible.
5. Begin social mobilisation at least one month before vaccination.
6. Ensure consistency with existing consent policy, and where possible, use opt-out consent. Determine if modification of consent process is needed for private schools.
Delivery strategy and population selection

Findings

- Most common delivery strategy: strategies using schools plus health facilities/outreach for out-of-school girls (87%); required additional resources.
- Some countries used community health workers and reported better access to hard-to-reach groups and reduction in health worker workloads.
- District selection criteria: conditions constituting ‘typical’ district, convenience/practicality, variable conditions, challenges requiring additional testing.
- Defining population among strategies using schools: 52% by age, 31% by grade, 17% by age within grade.
- Common enumeration methods: school registers, MOE enrolment data, census data, and survey estimates.
- Most countries took head count of eligible girls before vaccine delivery/during first dose to adjust estimates.

Lessons learnt

- Delivery strategies including a school component effectively captured most 9- to 13-year-old girls but were resource intensive.
- Engaging community health workers increased acceptance and helped identify girls who missed doses or were out of school.
- Grade-based delivery strategy was easier to implement on vaccination days. Age-based strategy was easier to explain but posed challenges and could cause greater disruption in school.
- Estimating target population for demonstration projects posed challenges.
- Scope of ‘mop-up’ activities was governed by country-specific factors like absenteeism and resources.
- Microplanning included establishing reliable registers validated during first-dose delivery.
Duration

Findings

• One week was most common duration for each dose.
• Common follow-up strategies for girls missing initial dose: directing girls to health facility, returning to schools for second dose, starting dose 1 at time of dose 2, or visiting girls at home.

Lessons learnt

• Scope of follow-up activities governed by country factors such as school absenteeism, perceived ‘adequate’ coverage, and available resources.
• Delivery of all doses within one school year minimised dropouts and facilitated tracking of all doses.
• When resources allowed, second opportunity reached girls/parents who initially refused.
• Two-dose schedule easier/cheaper than three doses.
Adverse events following immunisation

Findings

• Most adverse events following immunisation were minor and temporary, requiring observation but no or minimal treatment.
• Most countries indicated availability of injection safety guidelines and/or training procedures.
• Parents and teachers were useful in monitoring and reporting AEFIs.

Lessons learnt

• Adverse event training, monitoring, and response procedures were acceptable and consistent with other vaccines.
Additional lessons learnt

- Two-stage delivery of each dose can reach girls who initially refused, *but* providing the first dose to unvaccinated girls during second-dose delivery can create tracking and reporting challenges.
- Strategies to reach out-of-school girls was difficult to evaluate without specific coverage data.
Recommendations

1. Target schools as an effective way to reach most 9- to 13-year-olds.
2. Consider a range of factors, such as cost and sustainability, when selecting a delivery strategy.
3. Clearly define eligible populations.
4. Implement a specific mobilisation strategy for out-of-school girls.
5. Implement a two-dose vaccination schedule, as it is easier than a three-dose schedule.
6. Assess cost-effectiveness of follow-up activities, such as return visits to schools with low coverage rates.
7. Vaccinate all 9- to 13-year-old girls in first year of national rollout to act as catch-up.
8. Have standardised national guidelines and training for reporting/responding to adverse events.
Achievements
Vaccine coverage

Findings
• Coverage data available from 60 of 92 distinct experiences.
• 50 used 3-dose schedule, 10 used 2-dose schedule.
• 83% of delivery experiences reported coverage of 70% or higher.
• Minimal data from health-facility-only strategies.

Lessons learnt
• Achieving high HPV vaccine coverage is feasible in low-income and lower-middle-income countries.
• Strategies with a school-based component achieved generally high coverage.
• Insufficient data was available from strategies that did not include schools to draw key lessons.
Uptake and dropout

Findings

• Among 56 experiences, first-dose coverage ranged from 64% to >100%.
• Among 31 out of 54 delivery experiences, dropout rate was 10% or less.
• Factors reported to reduce dropout: vaccination registers, immunisation cards, involvement by school staff, reminders through health workers, churches, and community forums.

Lesson learnt

• Vaccination registers, immunisation cards, and community members facilitated tracking to ensure completion of all doses.
Factors correlated with high/low coverage

Factors correlated with **high** coverage:

- Strategies using schools and collaboration with education sector at national and local levels.
- Programmes and projects led by national immunisation programme.
- Inclusion of approaches to also reach out-of-school girls.
- Comprehensive social mobilisation, including use of ‘credible influencers’.
- Use of vaccination registers and cards.
- Both two-dose and three-dose schedules achieved similar high coverage, but two-dose schedules were easier to deliver.

Factors correlated with **low** coverage:

- Health-facility-only delivery strategies.
- Ineffective coordination and planning with schools.
- Rumours that caused schools to refuse vaccinators.
- Urban areas (more exposure to negative media, greater population mobility, difficulty in enumeration compared with rural areas).
- Other factors: delay in receipt of social mobilisation and school-delivery funds; not providing a second opportunity for girls who missed the first dose.
## HPV vaccination final-dose coverage

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Number of experiences with data</th>
<th>Number (%) with final dose coverage:</th>
<th>≥90%</th>
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<tr>
<td>School + health facility +/- outreach</td>
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<td></td>
<td>15 (43)</td>
<td>13 (37)</td>
<td>7 (20)</td>
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HPV vaccine coverage data collection and reporting

Findings

• Accuracy of coverage data was variable and only 60 of 92 delivery experiences reported data.
• Understanding of eligibility criteria by health workers, teachers, and parents influenced data quality.
• Only 17 delivery experiences in 13 countries reported coverage data from population-based surveys.
• Reporting challenges: unique population, tracking multiple doses, lack of standardised and harmonised forms, difficulties collecting and recording age, variable requirements by donors for grade and age data.

Lessons learnt

• Data collection and data accuracy posed challenges based on a range of factors specific to HPV vaccination.
Additional lessons learnt

• Specific strategies are needed to identify and mobilise out-of-school girls.

• Simultaneous delivery with another health service did not seem to affect coverage rates (only six projects/programmes with joint delivery and coverage data).

• Electronic monitoring and reporting systems reduced errors and simplified recording.

• Not providing comprehensive training on data collection to health workers caused difficulties in timeliness and accuracy.
Recommendations

1. Conduct joint planning in collaboration with the national immunisation programme and education sector at national and local levels.
2. Distribute funds early for planning, mobilisation, and implementation activities.
3. Offer vaccination in schools because it is likely to maximise coverage.
4. Clearly define eligibility criteria for efficient delivery in schools: grade-based eligibility is easier to implement; age-based eligibility is easier for calculating coverage.
5. Engage teachers, community health workers, and community to identify out-of-school girls and track girls between doses.
6. Carefully monitor and evaluate coverage, including target numbers, doses delivered, and age of the girl.
Sustainability
Financing and costs

Findings

• 66 demonstration projects in 44 countries had delivery costs fully or partially financed by donors.
• Primary financing for national programmes provided by a range of donors or national governments.
• Financial delivery costs in early pilot projects: US$1.11 to $2.10 per dose.
• Mean delivery cost in seven GAP pilots: US$2.74 per dose.
• Financial delivery costs in six Gavi-funded projects: US$2.24 to $9.21 per dose.

Lessons learnt

• Financial costs perceived as high by implementers and driven by allowances and transport costs for health workers/supervisors and social mobilisation.
• Funding provided for implementation covered some delivery costs, though many countries reported it was inadequate.
• Annualised start-up costs represented on average 50% of financial/economic costs and were challenging to finance.
• Underestimating start-up costs led to activity disruption.
Factors influencing scale-up

Findings

• Information on cost drivers influenced countries. Of 34 countries, 10 scaled up nationally, 11 not planning to scale up due to perceived cost of programme (delivery + vaccine), 13 planned to apply to Gavi for a national HPV grant.
• Of 10 countries that scaled up, 6 noted experience from demonstration projects provided important insights.
• Uncertain funding remained a concern for countries.

Lessons learnt

• Costs for start-up and delivery caused concern about securing resources for scale-up.
• Vaccine costs considered significant issue for sustainability in countries currently eligible or graduating from Gavi support.
• Estimates of delivery costs were important to inform country planning to secure financial resources for introduction.

How vaccine cofinancing increases as countries’ economies grow

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

1. Use available tools to model the costs of different strategies for national scale-up.
2. Share operational costs with the national immunisation programme to reduce costs of implementation.
3. Explore sustainable funding options and expand the funding base beyond Gavi.
4. Call for and facilitate additional research on scale-up experiences.
5. Test different delivery strategies, if implementing a demonstration project, to compare implementation costs and identify a sustainable option.
Value
Experience gained from demonstration projects

Findings

- Countries report benefits from ‘learning by doing’ during demonstration projects.
- Experience gained: planning and budgeting, cold chain and transport, population enumeration, consent procedures, working with MOE, developing materials.
- Barriers to integration of HPV vaccine with other services: financing (vertical and/or uncertain), lack of school health programme platform, complexity coordinating delivery of different interventions, disruption at school, national engagement of stakeholders with different priorities.

Lessons learnt

- Lessons from nine years of demonstration project experience was consistent across countries and time.
- Well-designed demonstration projects assessed delivery strategies, tested how to achieve high coverage in challenging populations and areas, and focused on integration with national systems.
- Integrating delivery with other services was operationally challenging.
Limitations of demonstration projects

Findings

• Nature of demonstration projects has meant they are not always nationally representative.
• Small scale prevented some countries from assessing impact on cold chain, impact on primary health care, and integration with routine immunisations.
• Resource-intensive delivery strategies used in demonstration projects may not be financially sustainable at national level.
• Some countries reported that ‘loss of momentum’ and perceived high costs of demonstration projects may have deterred decision-makers from national scale-up.

Lessons learnt

• Small size of demonstration projects limited learning on cold chain procedure, impact on primary health care, and integration with routine immunisations for national scale-up.
• Demonstration projects that used resource-intensive strategies generated concerns about sustainability of a national programme.
• Demonstration projects had both positive and negative influence on national introduction. In some countries they increased the confidence of national implementers; in others, they deterred policymakers from scaling up.
Increasing the value of demonstration projects

Findings
Value could be increased by:

• Testing different delivery strategies to identify sustainable approaches.

• Testing the delivery of combined interventions with HPV vaccine—tetanus toxoid vaccine, deworming, or vitamin A supplementation.

Lessons learnt

• Countries have not yet fully taken advantage of opportunities to test different combinations of vaccination venues, timing, and eligibility criteria in different populations and codelivery with other health interventions.
A new future for demonstration projects

Findings

• Data from 46 countries suggest the value of demonstration projects has decreased.

• Countries should consider a phased national rollout in place of demonstration projects due to increasing vaccine availability and access to lessons learnt.

• Phased rollout could allow faster national introduction, provide experience in social mobilisation and integration, and avoid separation from national immunisation programme.
Recommendations for funders

1. Regularly reevaluate policy around assisting countries to gain HPV vaccine experience and ensure that policy is as flexible as possible.

2. Consider a higher initial investment for national programme start-up costs to enable development and evaluation of integration with another service and testing/evaluation of delivery strategies.

3. Convert demonstration projects to a phased national rollout, which might accelerate decision-making for national introduction.
Recommendations for decision-makers

1. Translate lessons learnt to inform a phased national rollout as the best method to gain experience for HPV vaccine introduction.

2. Be aware that introducing a new vaccine through a demonstration project creates distortions because of the proportionally high investment made in developing, implementing, and evaluating the project.

3. Carefully plan and design phased national rollout to gain lessons relevant for introduction.

4. When designing phased national rollout, anticipate areas that could create challenges, such as staff allowances or joint supply of HPV vaccines with other vaccines.
Pitfalls
Planning and coordination

Findings

• Lack of political commitment created delays in vaccine importation and funds disbursement.
• Lack of initial involvement by health and education sectors created difficulties in planning and implementation.
• Lack of strong involvement by the national immunisation programme caused problems with systems, transportation, and human resources.
• Weak supervision of training created challenges; resulted in inadequate knowledge transfer.
• Insufficient time for planning posed a challenge to implementation.

Lessons learnt

• Lack of political commitment early in the process caused delays later in the programme.
• Failure to coordinate early with national immunisation programme staff, MOE, and MOF led to planning, social mobilisation, and delivery problems.
• Not allowing enough time for planning led to poor decision-making, lack of availability of funds, and untimely disbursement.
Communication and social mobilisation

Findings

• Gaps in communications training for school staff, teachers, and community leaders allowed rumours to take hold when questions could not be answered.

• Some countries underestimated the power of negative media exposure, including social media.

• Several countries faced challenges with HPV vaccine acceptance in private schools if they were not engaged early in social mobilisation.

Lessons learnt

• Not engaging, or engaging too late, with local community leaders derailed social mobilisation efforts in some cases.

• Insufficient training of school staff/teachers and lack of a crisis communications plan perpetuated rumours.

• Failure to engage sufficiently or early enough with private schools led to resistance by school leaders and parents.
Delivery

Findings

• Specific strategies are needed to reach out-of-school girls and those without them often saw low coverage in this group.

• Strategies that did not clearly define, implement, or train health workers on eligibility criteria faced challenges in enumeration and calculation of coverage.

Lessons learnt

• Limited focus on strategies to deliver HPV vaccine to out-of-school girls led to low coverage in that group.

• Failure to understand and implement eligibility criteria during enumeration and vaccine delivery created difficulties estimating coverage.
Recommendations

1. Secure political commitment early in the planning process.
2. Closely coordinate planning and delivery with national immunisation programme, schools, ministry of education, and ministry of finance.
3. Train teachers and community leaders to answer questions and combat rumours.
4. Develop a crisis communications plan to address rumours in communities and media.
5. Allow adequate time for private-school coordination.
6. Develop additional delivery strategies to reach out-of-school girls.
7. Clearly define eligibility criteria in advance.
8. Ensure adequate time, capacity, and funding to conduct proper enumeration.
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Thank you