

# Linked Immunisation Action Network

*Overcoming barriers to introduce and scale the HPV vaccine*

Istanbul, Turkey

11-12 July 2023

DAY ONE



# MICs NVI Support

# Gavi Middle-Income Country Approach: Overview

July 2023

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# Countries and economies eligible under the MICs Approach as of July 2022

Former-Gavi eligible countries			Never-Gavi eligible countries*		
Angola	Guyana	Sri Lanka	Algeria	Kosovo	Saint Lucia
Armenia	Honduras	Timor-Leste	Belize	Lebanon	Saint Vincent and the Grenadines
Azerbaijan	Indonesia	Ukraine	Cabo Verde	Maldives	Samoa
Bhutan	Kiribati	Uzbekistan	Dominica	Marshall Islands	Tonga
Bolivia	Moldova	<b>Viet Nam</b>	Egypt	Micronesia	<b>Tunisia</b>
Cuba	<b>Mongolia</b>		El Salvador	<b>Morocco</b>	Tuvalu
Georgia	Nicaragua		Eswatini	Occupied Palestinian territory	Vanuatu
			Fiji	<b>Philippines</b>	Venezuela
			Grenada		
			Iran		

# The MICs Approach addresses key threats to equity and sustainability

## Problem statement

## Objectives



MICs are lagging behind in introducing critical vaccines, presenting a threat to inter-country equity

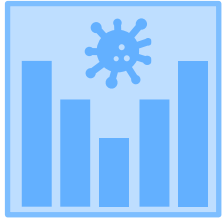
Drive the sustainable introduction of PCV, rotavirus, and HPV vaccines in former- and select never-Gavi eligible countries



Risk of backsliding, heightened by the pandemic, exacerbates intra-country inequities and jeopardises the legacy of Gavi investments

Prevent and mitigate backsliding in vaccine coverage in former-Gavi eligible countries

# The MICs Approach is guided by explicit outcomes, reflecting its clear focus on results



**90%** of former-Gavi countries with **>90%** pre-COVID DTP3 coverage restore coverage back above this threshold & remaining countries **arrest the decline** and begin an **upward trajectory**



Reduce the number of zero-dose children by **230,000** in former-Gavi countries



Introduce **8-10** new vaccines and reach **4M-6M** children/adolescents



# Foundational building blocks



# Addressing systemic issues across middle-income countries

Gavi works hand-in-hand with **core and expanded partners to strengthen the enabling environment** for new vaccine introductions and sustainable

immun



Providing regional and multi-country

ing:



Supporting

platforms



Galvanising

# Responsive & catalytic tools

# Responsive & catalytic tools: Addressing country-specific needs to **introduce new vaccines**

- A suite of targeted and catalytic tools helps drive the sustainable and equitable introduction of PCV, rotavirus, and HPV vaccines in both former- and never-Gavi eligible countries:



## **Technical assistance**

Support via relevant core and expanded partners to drive forward sustainable and equitable new vaccine introductions



## **Flexible funding for one-off costs**

Funding to help cover one-off costs related to new vaccine introductions that are traditionally unfunded or challenging to fund



## **Vaccine catalytic financing**

Vaccine financing equivalent to half the first birth (or target) cohort for a new vaccine introduction



## **Pooled procurement mechanisms**

Assistance accessing pooled procurement mechanisms in collaboration with UNICEF Supply Division

# New vaccine introduction support

Scope, eligibility and entitlements, timing of support

Suite of support	Description	Timing of support
<b>Technical Assistance from in-country partners</b>	<i>Support via relevant in-country and national partners (CSOs, academic institutions etc) to drive forward sustainable and equitable new vaccine introductions</i>	Support can be requested from Gavi to cover the cost of activities that take place by <b>the 31 December 2025</b>
<b>One-off support for vaccine introduction costs</b>	<i>Funding to help cover specific one-off costs directly related to ensuring the success and equity of a new vaccine introduction</i>	Support can be requested from Gavi to cover the cost of activities that take place by <b>the 31 December 2025</b>
<b>Vaccine Catalytic Financing</b>	<i>One-off vaccine financing for doses to cover half of the first single-age target cohort for a new vaccine introduction where this has a meaningful and positive impact on a new vaccine introduction.</i>	Funding for VCF can be requested to fund the costs of eligible vaccine doses if these vaccines have been committed on Purchase Order by one of Gavi's approved procurement partners (UNICEF SD and PAHO RF) by <b>31 December 2025</b>

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2 Presentation Footer

# A Note on Gavi Support for HPV 2 Dose vs Single Dose Vaccination

# Summary of WHO position on HPV vaccines (Dec 2022)

Primary target group		Girls, 9-14 years old	
Vaccination Schedule  (F = M)	Any age $\geq$ 9 years	2 doses, <i>min interval 6m, 12 recommended, no maximum interval*</i>	
	9-20 years old	1-dose*	
	Immuno-compromised & HIV+ individuals ( <i>any age</i> )	Minimum 2 doses*, ideally 3 doses	
Vaccination prioritization	Multi Age Cohort Catch-up	<ul style="list-style-type: none"> <li>• Prioritize multi-age cohort (MAC) vaccination at introduction or catch-up missed girls through 18 years of age</li> <li>• Offer multiple opportunities to receive at least 1 dose before age 15</li> </ul>	
	Immunocompromised /HIV+ and sexually abused individuals	<ul style="list-style-type: none"> <li>• Prioritize vaccination of immunocompromised/ PLWHIV and children or adolescents who faced sexual abuse</li> </ul>	
	Boys	<ul style="list-style-type: none"> <li>• Introducing the vaccination of boys and older females should be carefully managed until the global supply situation is fully unconstrained.</li> </ul>	
	Older age cohorts		

\* Off-label recommendations

# Vaccines recommended for 1 dose HPV schedule

Not all Products have efficacy data for 1-dose - immunobridging for new products

- “A single-dose schedule should be considered for those HPV vaccine products\* for which data on efficacy or immunobridging to vaccines with proven single-dose efficacy are available.”

\*As per Dec 2022, products for which efficacy and immunogenicity data support use in a single-dose schedule include [Cervarix, Gardasil and Gardasil9](#)

- “Immunobridging refers to evidence that peak and 24-month plateau antibody levels for a vaccine are comparable to those of vaccines with proven single-dose efficacy.”

New vaccines will require immunobridging studies:

- |                  |             |                           |                             |
|------------------|-------------|---------------------------|-----------------------------|
| ➤ Cocolin (2V)   | Innovax     | (WHO PQ'ed)               | 1-dose Trial ongoing        |
| ➤ Walrinvax (2V) | Wallvax     | (Licensed 2022, under PQ) | No information              |
| ➤ Cervavac, (4V) | Serum Inst. | (Licensed 2022 )          | 1-dose Trial in preparation |

# Current policy on 1 dose (per WHO guidelines)

Gavi provides support for HPV vaccination with either a 2-dose schedule or 1-dose off-label alternative schedule

For 1-dose off-label use, countries should carefully review and consider WHO guidance

Countries are encouraged to inform their national regulatory authority (or equivalent) of a programmatic decision of the 1-dose off-label schedule

Technical guidance documents and evidence summaries available to guide country decisions

## Resources for HPV vaccination schedule

- [Human papillomavirus vaccines: WHO position paper, December 2022](#)
- HPV vaccine technical partners: [HPV Vaccine Schedule Optimization](#)
- WHO: [CAPACITI decision support tool manual](#)
- [PATH summaries of HPV vaccine single-dose evidence](#)
- Financial planning tool for delivery strategies: [WHO Cervical Cancer Prevention and Control Costing tool: human papillomavirus vaccination module \(C4P-HPV tool\)](#)
- [WHO tool to assess the cost-effectiveness of HPV vaccination](#)
- PATH: [HPV vaccine cost calculator](#)



# Programmatic considerations for 1 dose schedule

## Considerations for decision on 1-dose schedule option

- ❑ “ The *off-label* single-dose option for routine and MAC catch-up vaccination is recommended from a public health perspective based on comparable levels of individual protection, while being more cost-effective, efficient (fewer doses per cancer case prevented), and providing more programmatic flexibility.”

SAGE April 2022

### Considerations for NITAG deliberations to decide on *off-label* single-dose use:

- Funding: easier to introduce/sustain or extend programme
- Extend MAC: Same resources can prevent up to 2x as many Cx cases in catch-up strategies (introduction MAC or COVID recovery)
- Performance of ongoing HPV programme: Coverage high (>80%) or not? Drop-out?
- Perceived capacity of single dose strategies to boost coverage – Innovative strategies?
- HIV+ epidemiology: capacity to provide 2/3 dose when young women test+
- Efficiency of resource allocation within national cervical cancer elimination strategy
  - Reallocating \$\$ to strengthen screening & treatment may prevent more cervical cancer cases in short term<sup>21</sup>

Resource: HPV vaccine technical partners: [HPV Vaccine Schedule Optimization](#)




# Country adoption of 1 dose HPV schedule

## Countries that switched to 1-dose HPV schedule or 2-dose vaccination schedule in secondary targets

Region	Country (intro year)	WB group	Policy change
AFR	<ul style="list-style-type: none"> <li>Cap Verde (2021)</li> </ul>	LMIC	<ul style="list-style-type: none"> <li>Switch to 1-dose, <b>extended MAC to 14 yr old girls</b></li> </ul>
AMR	<ul style="list-style-type: none"> <li>Bolivia (2017)</li> <li>Guatemala (2018)</li> <li>Guyana (2011)</li> <li>Jamaica (2017)</li> <li>Mexico (2008)</li> <li>Peru (2015)</li> </ul>	LMIC UMIC UMIC UMIC UMIC UMIC	<ul style="list-style-type: none"> <li>Switch to 1-dose in routine programme</li> <li>Switch to 1-dose in routine programme</li> <li>Switch to 1-dose in routine programme ♀</li> <li>Switch to 1-dose in routine programme ♀</li> <li>Switch to 1-dose in routine programme ♀</li> <li>Switch to 1-dose in routine programme</li> </ul>
	<ul style="list-style-type: none"> <li>UK (2008)</li> <li>Ireland (2009)</li> <li>Albania(2022)</li> <li>Netherlands (2008)</li> <li>Sweden (2010)</li> </ul>	HIC HIC LMIC HIC HIC	<ul style="list-style-type: none"> <li>Switch to 1-dose, 9 - 25 year old ♀ ; <b>MSM&gt;25yr: 2 doses</b></li> <li>Switch to 1-dose, 9 - 25 year old ♀ ; <b>MSM&gt;25yr: 2 doses</b></li> <li>Introduction with 1-dose in 13-year-old girls</li> <li><b>15-26 year ♀ in catch-up 2-doses</b></li> <li><b>15 year and older females in catch-up 2-doses</b></li> </ul>
WPR	<ul style="list-style-type: none"> <li>Tonga (2022)</li> <li>Australia (2007)</li> </ul>	LMIC HIC	<ul style="list-style-type: none"> <li>Introduction with 1-dose in girls, <b>extended MAC to 14 year</b></li> <li>Switch to 1-dose dose in routine programme ♀</li> </ul>
<b>GAVI Countries</b>	<i>NITAGs in several GAVI-supported countries (LMICs) have recommended 1-dose HPV schedule</i>		<ul style="list-style-type: none"> <li>Bangladesh (2023/24)</li> <li>Nigeria (2023/24)</li> <li>India (2023/24)</li> </ul>

Up to date info on GAVI country switches in next PPT by GAVI

# Gavi country updates on 1-dose schedule

 <p><i>Switch decision pending / under discussion</i> Currently on 2-dose schedule</p>	 <p><i>Switch decision made, implementation planned</i></p>	 <p><i>Switched schedule</i></p>
<ul style="list-style-type: none"> <li>Cambodia</li> <li>• Cote d'Ivoire</li> <li>Ethiopia</li> <li>Eritrea</li> <li>The Gambia</li> <li>Kenya</li> <li>Kyrgyzstan</li> <li>Lao PDR</li> <li>Lesotho</li> <li>Liberia</li> <li>Mali (<i>new intro</i>)</li> </ul> <ul style="list-style-type: none"> <li>Myanmar</li> <li>Mauritania</li> <li>Mozambique</li> <li>Uganda</li> <li>Rwanda</li> <li>Sao Tome &amp; Principe</li> <li>Senegal</li> <li>Zimbabwe</li> </ul>	<ul style="list-style-type: none"> <li>Bangladesh (<i>new intro</i>)</li> <li>• Burkina Faso</li> <li>Cameroon</li> <li>• India* (<i>new intro</i>)</li> <li>• Malawi</li> <li>• Nigeria (<i>new intro</i>)</li> <li>• Sierra Leone</li> <li>• Tanzania</li> <li>Togo (<i>new intro</i>)</li> <li>• Zambia</li> </ul> <p><small>* Dosing schedule is state-specific in India.</small></p>	<ul style="list-style-type: none"> <li>Guyana (<i>transitioned</i>)</li> <li>Solomon Islands</li> </ul>

# Gender neutral HPV vaccination

**Gavi** follows WHO guidelines for HPV vaccine procurement and policy.

Primary target group is girls aged 9 to 14 years.

Countries can consider vaccination for secondary populations if feasible, affordable, and doses do not divert resources from vaccinating the primary population (WHO position paper, 2022, p.670).

Gavi / Unicef HPV vaccine tender comes up for renewal in 2025, at which time global supply, WHO policy, and vaccine prices may shift to allow gender neutral vaccinations in Gavi-eligible **countries.**

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	Older age cohorts	

\* Off-label recommendations

# Thank you

# Addressing vaccine hesitancy: demand generation communication strategies

# Service delivery strategies and implications on sustainable financing

# Country action planning



# Country action planning

**Main objective of action planning** – Identify activities to accelerate the introduction OR scale-up of the HPV vaccine:

## Steps:

- Identify key barriers, enablers, opportunities for accelerating OR scale-up of the HPV vaccine
- Identify key stakeholders to be engaged to support the introduction and roll-out
- Think of one or more **good practice or lessons learned** discussed at the workshop
- Identify objective: New or from your program/operational plans
- Identify activities:
  - new activities **inspired by the learnings**
  - existing activities from your country operational plans **inspired by learnings**
  - Mention ongoing activities relevant to the topic
- Identify **learning needs** to support your activities – they will be addressed during further learning engagements

# Country action planning

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## Criteria to consider for activity identification

- **Feasible, realistic** to have control over implementation, accomplish with existing resources and indicated time-frame
- **Relevant** – to HPV vaccine introduction OR scale-up
- Try **not to choose very ambitious actions** that require a long-term implementation timeline (e.g., 2+ years).
- Consider **What activity, good practice, or lesson learned through this workshop might be useful to ensuring effective implementation of these activities or to achieve objectives?**

# Country action planning

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- The facilitators (in-country partners) will help Country teams to develop the plans (general guidance, data entry in the template)
- The Country teams have *full ownership* on the action plan – **activities are identified by you**
- As practiced Linked will be following-up on the progress –**routine calls** with the country teams, **virtual twinning calls** between the peer countries

# Country action planning - 1

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Country	Breakout Room
Tunisia	
Mongolia	
Vietnam	
Philippines	

# Country action planning - 2

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Country pairs	Breakout room
Tunisia & Mongolia	Main plenary room
Vietnam & Philippines	

- Each country team presents action plan to a peer country (15 min)
- Country receives peer country's feedback. (15 min)
- Countries change

# Country action planning - 3

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Country	Breakout Room
Tunisia	
Mongolia	
Vietnam	
Philippines	

# Action plan template

Main Objective: to accelerate the introduction <b>OR</b> scale-up of the HPV vaccine								
Implementation Roadmap: 1 - 1.5-year period								
Objective	Activity (new/ongoing)	New learning	Responsible	Completion Date	Expected Outcome	Learning Needs	Risks	Progress/ Status / Note
Objective 1:								
Objective 2:								

**Other Learning Needs:** *(add rows as needed)*

1)

2)

# Conclusion

