

Linked Immunisation Action Network

Overcoming barriers to introduce and scale the HPV vaccine

Istanbul, Turkey

11-12 July 2023

DAY ONE



Welcome!!!!



Introductions

Icebreaker

- Please start by introducing yourselves
- Find a common preference across the following questions:
 - Do you prefer to drink tea or coffee?
 - When you go on holidays, do you prefer to go to the beach or the mountains? Adventure or relaxation?
 - Do you prefer dogs or cats?
 - Are you a night or morning person?
 - Are you messy or tidy?
 - Do you prefer paperback or ebooks?
 - Do you prefer airplanes or trains?

Have fun: get to know each other!

Workshop Agenda Day 1

Time	Length	Session Title	Presenter(s) and Facilitator(s)
9:00–10:00	60 min	Welcome, introductions, and framing	Elizabeth Ohadi, R4D, Priscilla Rouyer, R4D, Rebecca Casey, US CDC
10:00–11:00	60 min	Coffee break and poster walk	
11:00–11:50	50 min	Session 1: Country experiences	Country presentations from Mongolia, Vietnam
11:50–12:00	10 min	Group photo	
12:00–13:00	60 min	Lunch	
13:00–13:50	50 min	Session 2: Key success factors and learnings to successfully introduce the HPV vaccine	Country presentations from Philippines, Tunisia
13:50–15:00	70 min	Breakout room discussions	CIF
15:00–15:15	15 min	Coffee break	
15:15–15:30	15 min	Lessons learned and country examples on HPV introduction	Priscilla Rouyer, R4D
15:30–15:45	15 min	Lessons learned for HPV introduction in the EURO region	CIF
15:45–16:00	15 min	Question & Answer Discussion	CIF
16:00–16:30	30 min	Report-out activity	Elizabeth Ohadi, R4D
16:30–16:45	15 min	Closing	Elizabeth Ohadi, R4D
19:30		Gala Dinner	

Workshop Agenda Day 2

Time	Length	Session Title	Presenter(s) and Facilitator(s)
9:00–9:35	35 min	Opening and recap	Priscilla Rouyer, R4D, Miriam Faid, Gavi
9:35–10:35	60 min	Session 3: Collaborative problem-solving discussions on selected countries' challenges: Addressing vaccine hesitancy: demand generation communication strategies	Country presentation from the Philippines
10:35–10:50	15 min	Coffee break	
10:50–11:50	60 min	Session 3: Collaborative problem-solving discussions on selected countries' challenges: Service delivery strategies and implications on sustainable financing	Priscilla Rouyer, R4D
11:50–12:50	60 min	Lunch	
12:50–14:00	70 min	Session 4: Developing an action plan to accelerate the introduction and scale-up of the HPV vaccine	Priscilla Rouyer, R4D
14:00–15:00	60 min	Peer country break out session	
15:00–15:30	30 min	Coffee break	
15:30–16:00	30 min	Country presentation preparation	
16:00–17:00	60 min	Country action plan presentations	CIF
17:00		Closing	Elizabeth Ohadi, R4D

Rebecca Casey

Vaccine Introduction Team,
Global Immunization Division,
Centers for Disease Control &
Prevention
USA

HPV vaccination: Global policy update, programme opportunities and challenges

Rebecca Mary Casey, MBBS, MPH

Medical Epidemiologist

Vaccine Introduction Team

Strengthening Immunization Systems Branch

CDC Global Immunization Division, Atlanta, USA

New vaccine introduction in Middle Income Countries

Linked Immunisation Action Network

Istanbul, July 2023

Overview

- **HPV and the WHO Global Cervical Cancer Elimination Strategy**
- **Global progress and challenges for HPV vaccination programs**
- **Current HPV vaccination catalysts**
- **Single dose HPV vaccine schedule option**

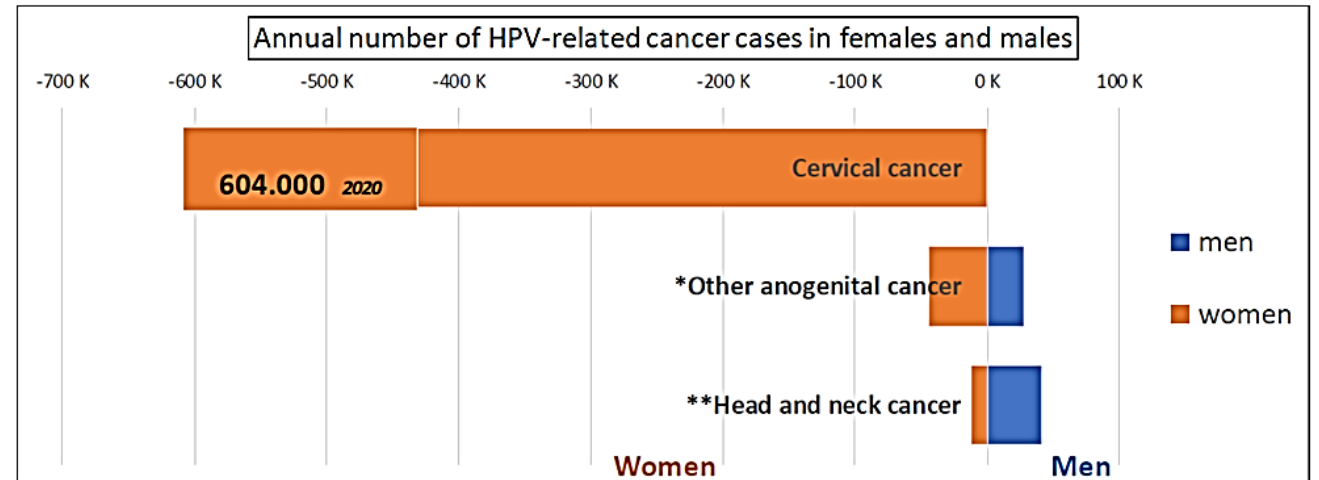
Disclaimer: The findings and conclusions in this presentation are those of the author(s) and do not necessarily represent the official position, policies, or views of the U.S. CDC or partners.

Human Papillomavirus (HPV)

- **Extremely common, small DNA virus that infects skin or mucosal cells**
- **At least 13 of 100+ known HPV genotypes cause cancer of the cervix and are associated with other cancers (anogenital, head and neck)**
 - Two most common "high-risk" genotypes (HPV 16 and 18) cause

Source: De Martel et al, Lancet Glob Health, 2020, (2018 data); Globocan

Epidemiology of HPV-related cancers



***Other anogenital cancers:**

- Anal
- Penile
- Vaginal, and
- Vulva cancer

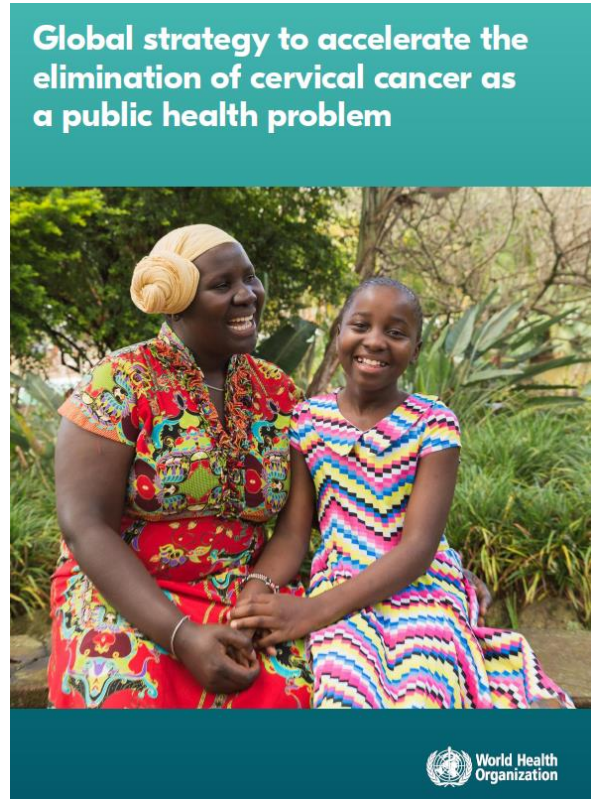
**** Head and neck cancers:**

- Oropharyngeal
- Oral cavity, and
- Larynx cancer

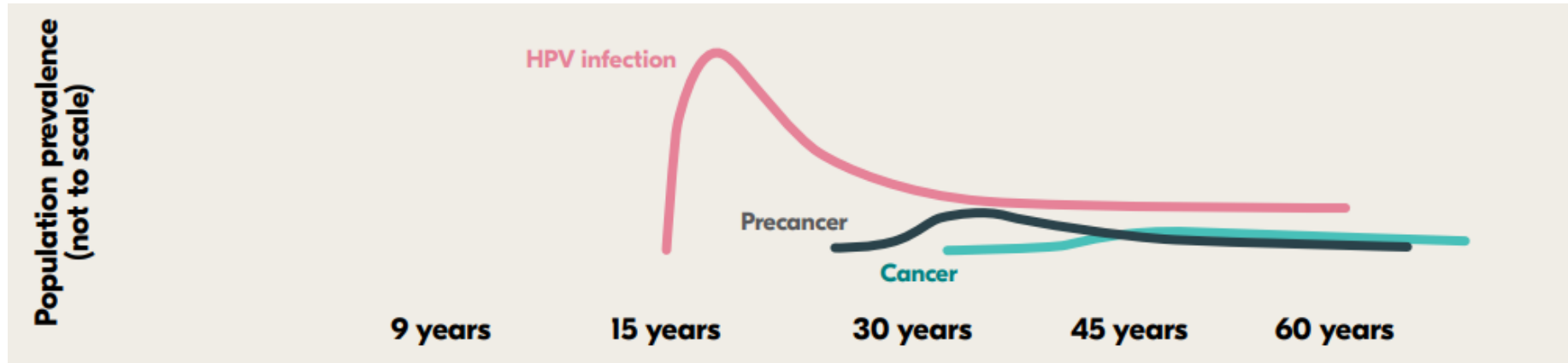
WHO Global Cervical Cancer Elimination Strategy

- Cervical cancer is considered nearly completely preventable because of the highly effective primary (HPV vaccine) and secondary (screening) prevention measures.
- **WHO Global Cervical Cancer Elimination Strategy calls for:**
 - Vaccination of 90% of girls by age 15 years
 - Other targets: screening, treatment
- **Elimination:**
 - All countries to reach < 4 cases 100,000 women years

Source: World Health Organization. Cervical Cancer factsheet. Available online: <https://www.who.int/news-room/fact-sheets> (accessed February 2023)



The life-course approach for cervical cancer prevention



Primary Prevention

Girls 9–14 years

- HPV vaccination

Girls and boys, as appropriate

- Health information and warnings about tobacco use
- Sexuality education tailored to age and culture
- Condom promotion/provision for those engaged in sexual activity
- Male circumcision

Secondary Prevention

Women > 30 years of age

- Screening with a high-performance test equivalent to or better than HPV test
- Followed by immediate treatment or as quickly as possible, of precancerous lesions.

Tertiary Prevention

All women, as needed

Treatment of invasive cancer at any age

- Surgery
- Radiotherapy
- Chemotherapy
- Palliative care

WHO, Global cervical cancer elimination strategy

<https://www.who.int/publications/i/item/9789240014107>

Burden of cervical cancer is high and disproportionately affects low- and middle-income countries (LMICs)



4th

Cervical cancer is the fourth most common cancer among women worldwide



~342K

annual deaths caused by cervical cancer

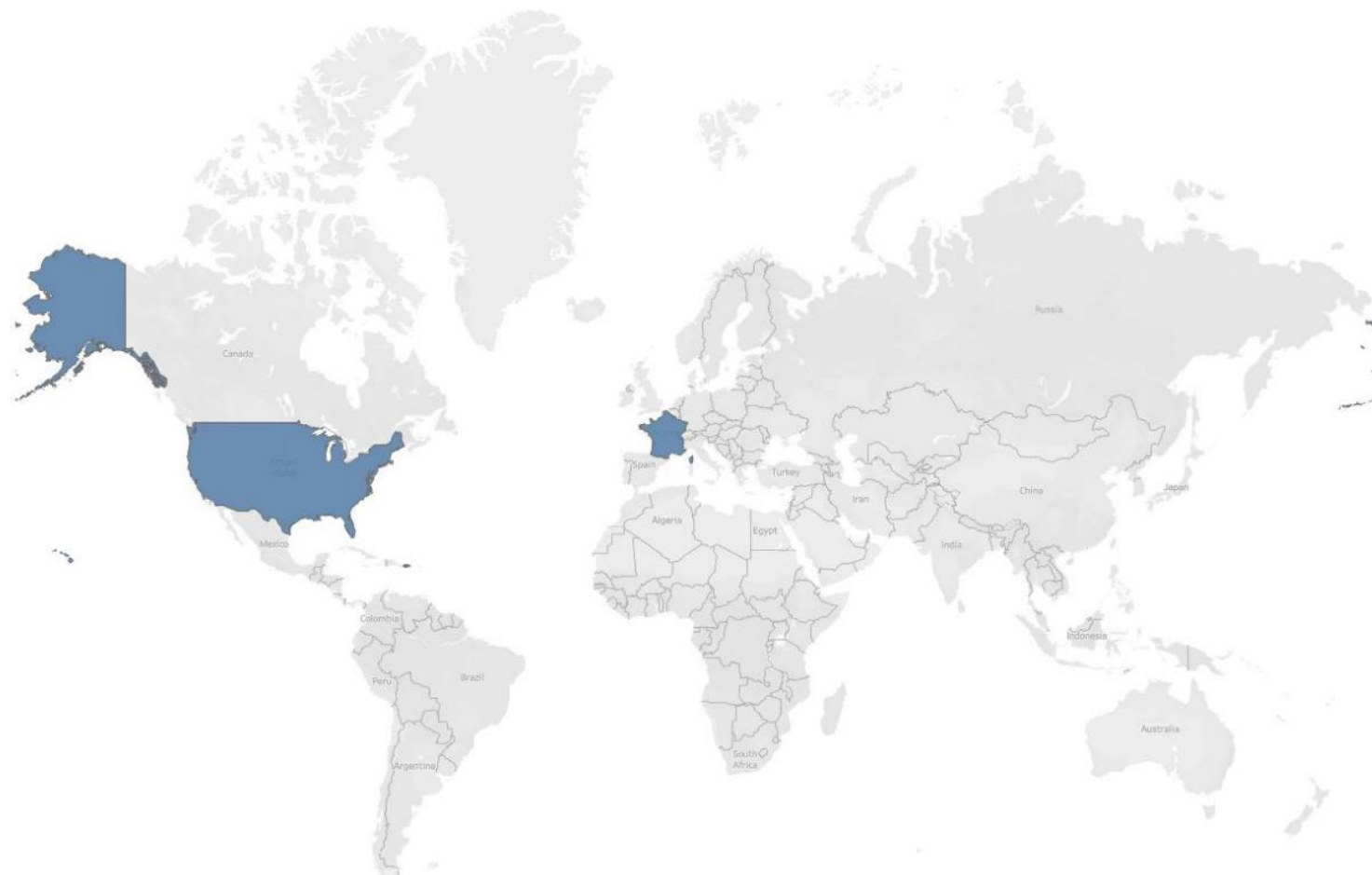


~90%

of those deaths happen in LMICs

Global progress: National HPV vaccination introduction status

Year:
2006

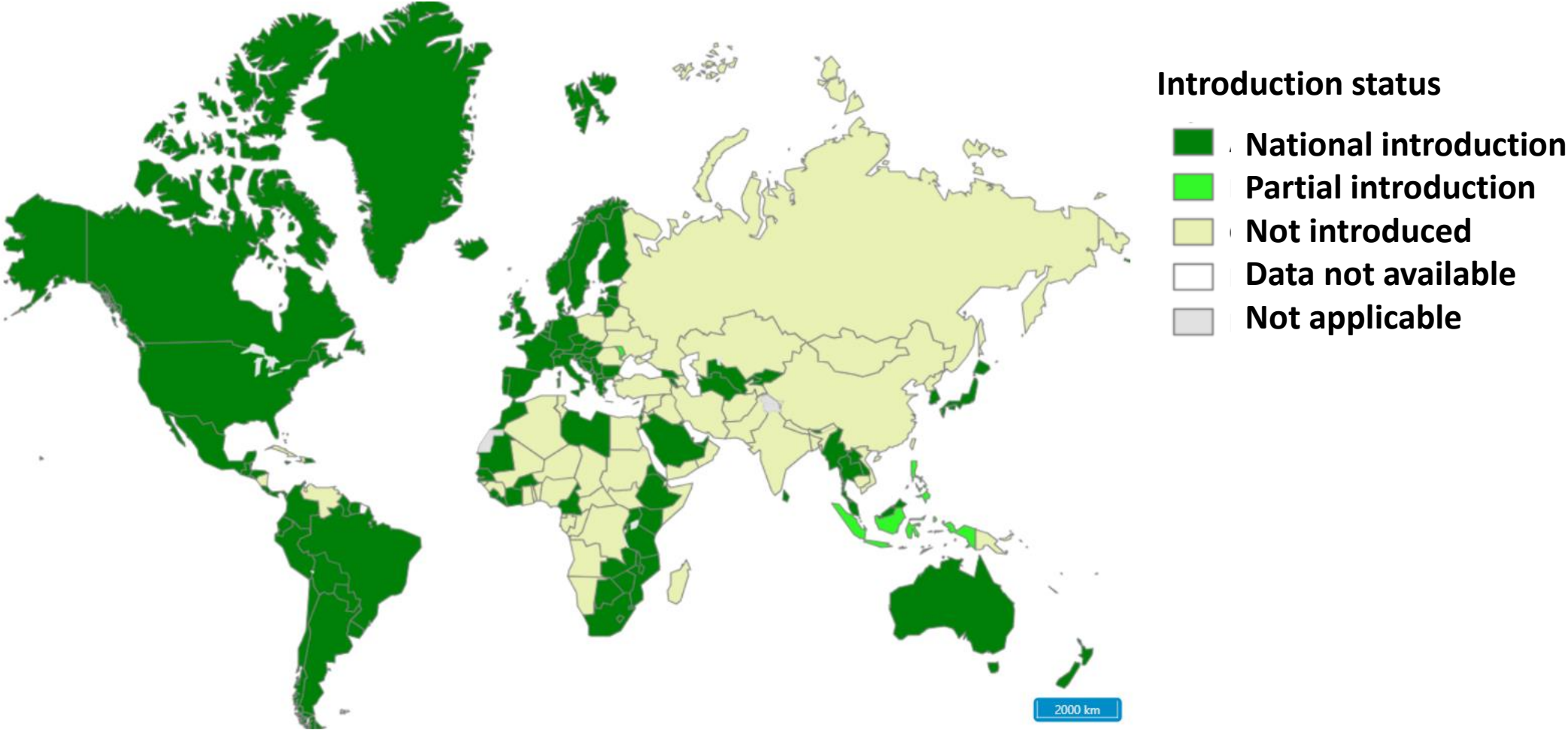


Introduction status

 National introduction

Global progress:

National HPV vaccination introduction status, 2023



Global HPV vaccination coverage is low; declined during 2020–2021

Category	Reported HPVc vaccination coverage by year		
	2019	2020	2021
Geography			
Global	54%	45%	44%
WHO Region			
AFR	62%	39%	39%
AMR	47%	33%	32%
EUR	60%	61%	60%
SEAR	54%	46%	45%
WPR	50%	47%	40%
Country income level			
High income	63%	57%	59%
Low and middle	47%	38%	33%
Country GAVI eligibility			
Non-GAVI	53%	44%	44%
GAVI	64%	47%	42%

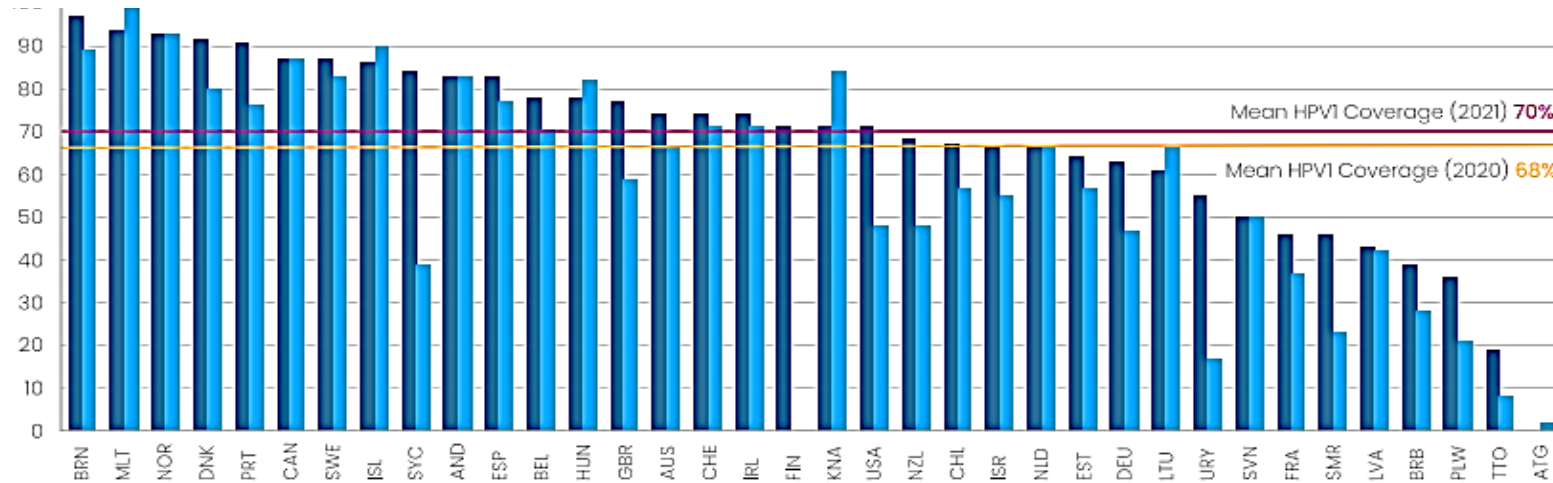
Note: HPVc coverage is HPV vaccination coverage of final dose in schedule

Source: World Health Organization. Human Papillomavirus (HPV) vaccination coverage. Available online:

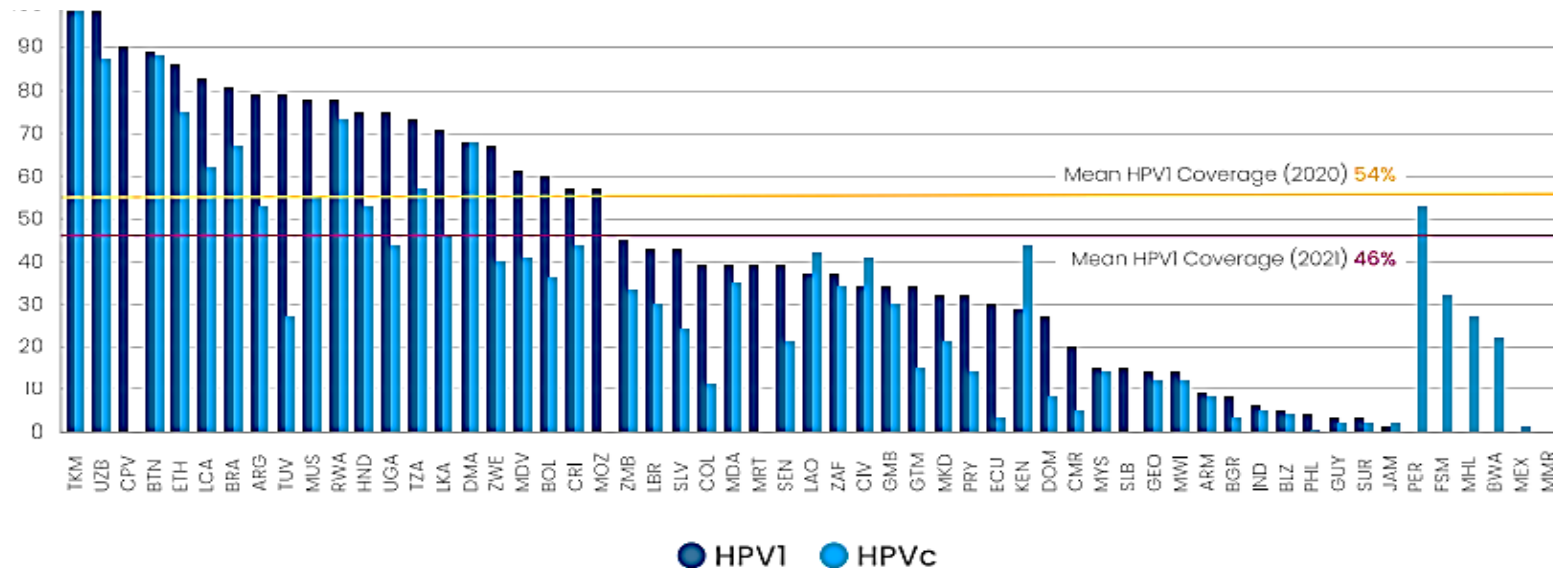
<https://immunizationdata.who.int/pages/coverage/hpv.html>. (accessed February 2023)

Global progress: HPV vaccination coverage (%) by country and income level, 2021

High income country HPV vaccination coverage (HPV1 and HPVc)

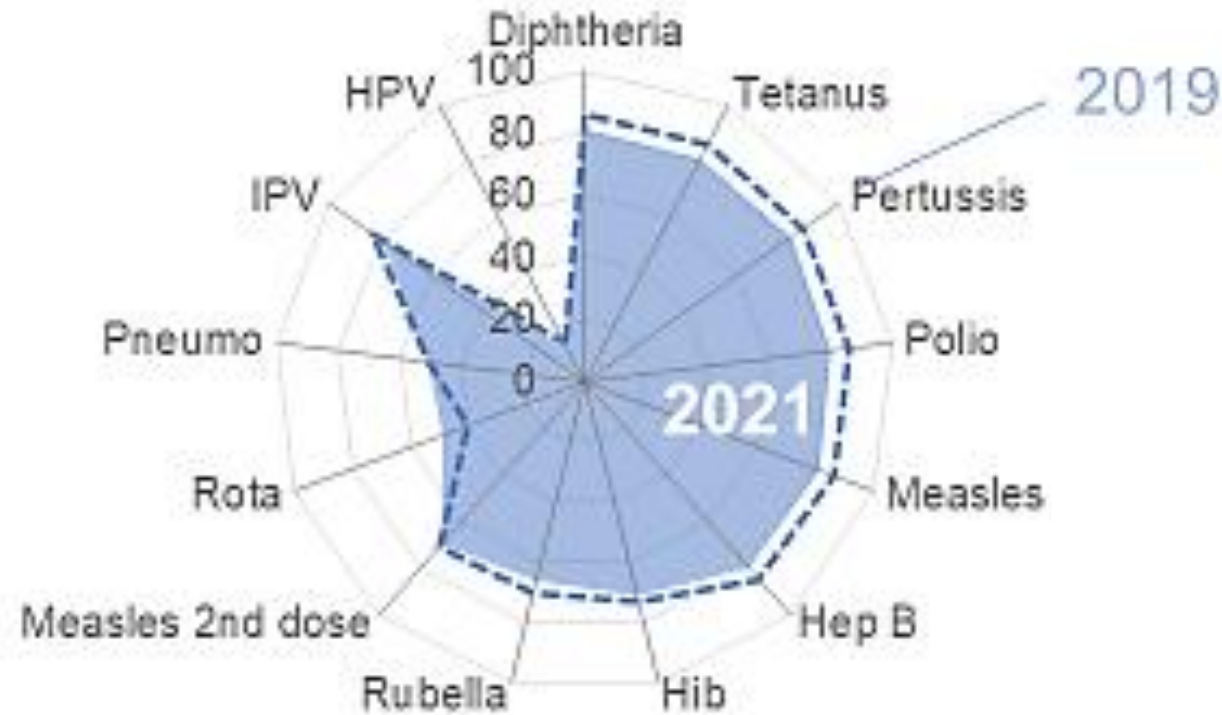


Low- and middle-income country HPV vaccination coverage (HPV1 and HPVc)



Global HPV vaccination coverage

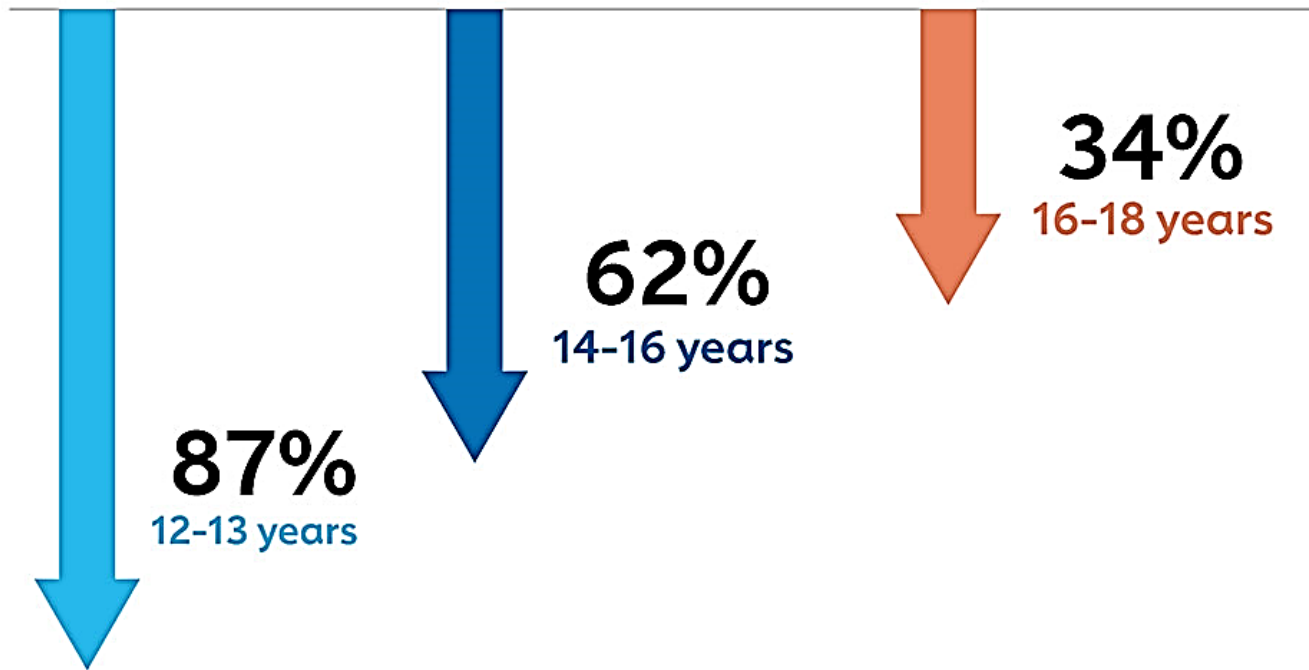
— lower than all other recommended antigens



Source: World Health Organization. Immunization data vaccination coverage. Available online: [https://immunizationdata.who.int/listing.html?topic=&location=.](https://immunizationdata.who.int/listing.html?topic=&location=) (accessed February 2023)

HPV vaccine is highly effective

Estimated relative reduction in cervical cancer rates
compared with the unvaccinated cohort



Source: Falcaro, M., Castañon, A., Ndlela, B., Checchi, M., Soldan, K., Lopez-Bernal, J., ... & Sasieni, P. (2021). The effects of the national HPV vaccination programme in England, UK, on cervical cancer and grade 3 cervical intraepithelial neoplasia incidence: a register-based observational study. *The Lancet*, 398(10316), 2084-2092.

HPV vaccine is safe

>500 M doses used
Globally by 2022

“Excellent Safety profile”

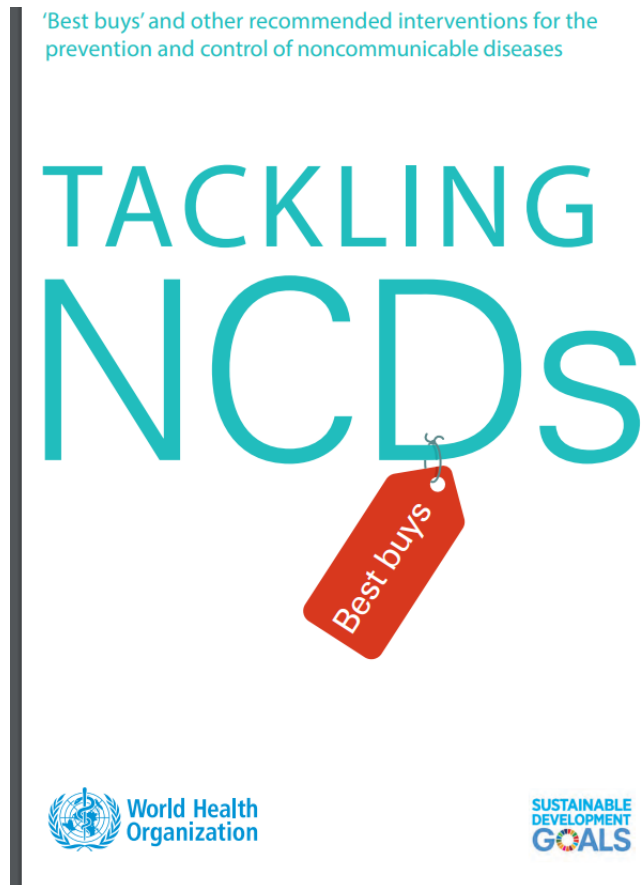
WHO Global Advisory Committee on Vaccine Safety (GACVS)
Statement on the continued safety of HPV vaccination (2017)

"Since licensure of HPV vaccines, GACVS has found no new adverse events of concern based on many very large, high-quality studies. The new data presented at this meeting have strengthened this position." *

Safety of HPV further confirmed in 2022 Systematic Review on safety of HPV vaccines by Cochrane Review)
-see WHO Position Paper (Dec 2022)

* <https://www.who.int/groups/global-advisory-committee-on-vaccine-safety/topics/human-papillomavirus-vaccines>

HPV vaccination is one of 16 “Best Buys”



Increasing HPV coverage in girls will avert more deaths per person vaccinated than any other immunization activity

Estimating the health impact of vaccination against ten pathogens in 98 low-income and middle-income countries from 2000 to 2030: a modelling study

Xiang Li*, Christinah Mukandavire*, Zulma M Cucunub, Susy Echeverria Londano, Kaja Abbas†, Hannah E Clapham†, Mark Jit†, Hope J Johnson†, Timos Pappadopoulos†, Emilia Vynnycky†, Marc Brisson, Emily D Carter, Andrew Clark, Margaret J de Villiers, Kirsten Ellertson, Matthew J Ferrari, Ivane Gamkrelidze, Katy A M Gaythorpe, Nicholas C Grassly, Timothy B Hallett, Wes Hinsley, Michael I Jackson, Kevin Jean, Andromachi Karachaliou, Petra Klepac, Justin Lessler, Xi Li, Sean M Moore, Shevanthi Nayagam, Duy Manh Nguyen, Hamie Razzavi, Devin Razzavi-Shearer, Stephen Resch, Colin Sanderson, Steven Sweet, Stephen Sy, Yvonne Tam, Hira Tanvir, Quan Minh Tran, Caroline L Trotter, Shaun Truelove, Kevin van Zandvoort, Stéphane Verguet, Neff Walker, Amy Winter, Kim Woodruff, Neil M Ferguson, Tini Garske, for the Vaccine Impact Modelling Consortium

Summary
Background The past two decades have seen expansion of childhood vaccination programmes in low-income and middle-income countries (LMICs). We quantify the health impact of these programmes by estimating the deaths and disability-adjusted life-years (DALYs) averted by vaccination against ten pathogens in 98 LMICs between 2000 and 2030.

Methods 16 independent research groups provided model-based disease burden estimates under a range of vaccination coverage scenarios for ten pathogens: hepatitis B virus, *Haemophilus influenzae* type B, human papillomavirus, Japanese encephalitis, measles, *Neisseria meningitidis* serogroup A, *Streptococcus pneumoniae*, rotavirus, rubella, and yellow fever. Using standardised demographic data and vaccine coverage, the impact of vaccination programmes was determined by comparing model estimates from a no-vaccination counterfactual scenario with those from a reported and projected vaccination scenario. We present deaths and DALYs averted between 2000 and 2030 by calendar year and by annual birth cohort.

Findings We estimate that vaccination of the ten selected pathogens will have averted 69 million (95% credible interval 52–88) deaths between 2000 and 2030, of which 37 million (30–48) were averted between 2000 and 2019. From 2000 to 2019, this represents a 45% (36–58) reduction in deaths compared with the counterfactual scenario of no vaccination. Most of this impact is concentrated in a reduction in mortality among children younger than 5 years (57% reduction [52–66]), most notably from measles. Over the lifetime of birth cohorts born between 2000 and 2030, we predict that 120 million (93–150) deaths will be averted by vaccination, of which 58 million (39–76) are due to measles vaccination and 38 million (25–52) are due to hepatitis B vaccination. We estimate that increases in vaccine coverage and introductions of additional vaccines will result in a 72% (59–81) reduction in lifetime mortality in the 2019 birth cohort.

Interpretation Increases in vaccine coverage and the introduction of new vaccines into LMICs have had a major impact in reducing mortality. These public health gains are predicted to increase in coming decades if progress in increasing coverage is sustained.

Funding Gavi, the Vaccine Alliance and the Bill & Melinda Gates Foundation.

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Source:

World Health Organization. Tackling NCDs. Available online: <https://apps.who.int/iris/bitstream/handle/10665/259232/WHO-NMH-NVI-17.9-eng.pdf> (accessed February 2023)

Li X, Mukandavire C, et al; Vaccine Impact Modelling Consortium. Estimating the health impact of vaccination against ten pathogens in 98 low-income and middle-income countries from 2000 to 2030: a modelling study. *Lancet*. 2021;397(10272):398-408.

So why aren't we doing better?

- **Often no standard answers for efficient HPV vaccine delivery**
- **Target population not routinely reached in many countries**
- **May be a new immunization/adolescent health platform**
- **Challenges with reaching out-of-school girls**
- **Vaccine hesitancy leading to disrupted introductions or declining coverage**
 - **Demand/ vaccine confidence related challenges in many countries**
- **Global vaccine supply shortages**

New opportunities: Global HPV vaccination catalysts

Single dose
schedule
recommendation

Improving HPV
vaccine supply

Funding support

Accelerate WHO's cervical cancer elimination initiative:

- accelerate national HPV vaccine introductions
 - improve HPV vaccination coverage

Summary of 2017 WHO position compared to the current WHO position (December 2022)

		Previous WHO position (2017)	Current WHO position (December 2022)
Primary target group		Girls aged 9–14 years old	Girls aged 9–14 years old
Vaccination Schedule by age (years)	9–14	2-dose schedule	Either a 1-dose* or a 2-dose vaccination schedule
	15–20	3-dose schedule	Either a 1-dose* or a 2-dose* vaccination schedule
	≥21	3-dose schedule	2-dose schedule can be used*
	Immuno-compromised, including people living with HIV (any age)	3-dose schedule	Should be prioritized and should receive <u>at least 2 doses*</u> but <u>ideally 3 doses</u> , if programmatically feasible.

Summary of trials with data on single-dose vaccination

Trial/Country Vaccine Sex/Age	Key findings
CVT ¹² Costa Rica 2vHPV Females 18–25	<ul style="list-style-type: none"> • Protection after 1, 2 or 3 doses of 2vHPV through 11 years - persistent HPV 16/18 infection among single dose recipients was 1.8% (95% confidence interval (CI) 0.3–5.8; n=112) compared to 1.6% (95%CI 0.1–7.7; n=62) among 2-dose recipients and 2% (1.3–2.8; n=1365) among 3-dose recipients. Vaccine efficacy (VE) was 82.1%, 83.8% and 80% among recipients of 1,2,and 3 doses respectively. • Sixteen years after HPV vaccination, HPV16 and 18 seropositivity was almost 100% among HPV-vaccinated women remained seropositive irrespective of the number of HPV vaccine doses received. • Minimal decline in the antibody concentration was observed over time, especially for the single-dose HPV vaccine group.
India IARC ^{3,4} India 4vHPV Females 10–18	<ul style="list-style-type: none"> • Protection after 1, 2 or 3 doses of 4vHPV through 10 years - persistent HPV 16/18 infection among single dose recipients was 0% (95% CI 0–0.3; n=2454) compared to 0.1% (95%CI 0–0.4; n=1685) among 2-dose recipients and 0.1% (0–0.4; n=) among 3-dose recipients. Vaccine efficacy was 94.2%, 94.5% and 91.2% among recipients of 1,2,and 3 doses respectively compared to control group. • Ten years after vaccination, the antibody levels were at least two times higher in single dose recipients compared to those following natural infection. • No HPV16/18-related CIN2/3 detected in vaccinated women.
KEN SHE^{5,6} Kenya 2vHPV, 9vHPV Females 15–20	<ul style="list-style-type: none"> • Single-dose HPV vaccination was highly efficacious (>95%) over 3 years; • 9vHPV vaccine efficacy (VE) was 98.8% (95%CI 91.3–99.8%, p<0.0001); • 2vHPV VE was 97.5% (95%CI 90.0–99.4%, p<0.0001).
DoRIS ⁷ Tanzania 2vHPV, 9vHPV Females 9–14	<ul style="list-style-type: none"> • Immunogenicity: Seropositivity >97.5% for all dose groups for both vaccines • Immunobridging showed that 1-dose responses were non-inferior in DoRIS compared with those in studies where 1-dose efficacy observed (CVT, India IARC)

Opportunity:

Single-Dose HPV Vaccination could...



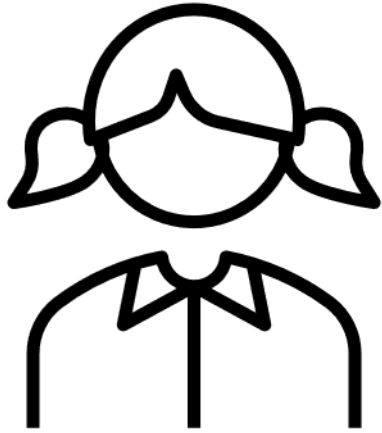
Image: PATH

- **simplify delivery**
- **provide new integration opportunities**
- **lower costs**
- **create new opportunities with resources saved**
 - **adolescent/school health platform**
 - **multi-age cohort catch-up strategies**
 - **cervical cancer screening and treatment**

Country-led decision-making process

- Systematic, accountable, evidence-based decision-making, planning and prioritization process
 - often by NITAG or appropriate decision-making body
- Coordinated with other components of the health system
- Some factors may outweigh and override others, depending on the specific circumstances.

simplify delivery



Less inconvenience for caregiver/girl

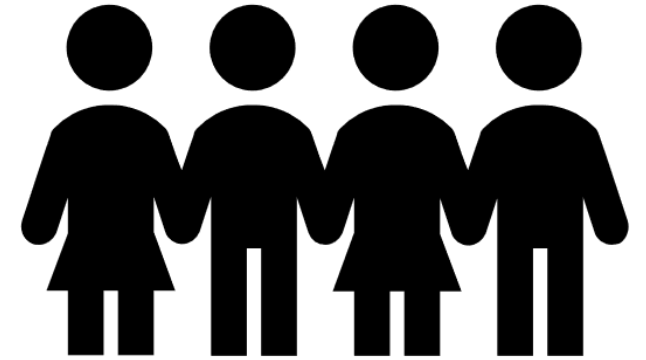
Less perceived or actual expenditures or adverse events relating to immunization



Reduced time burden for healthcare worker

Fewer outreach visits to schools

Reduced catch-up activities



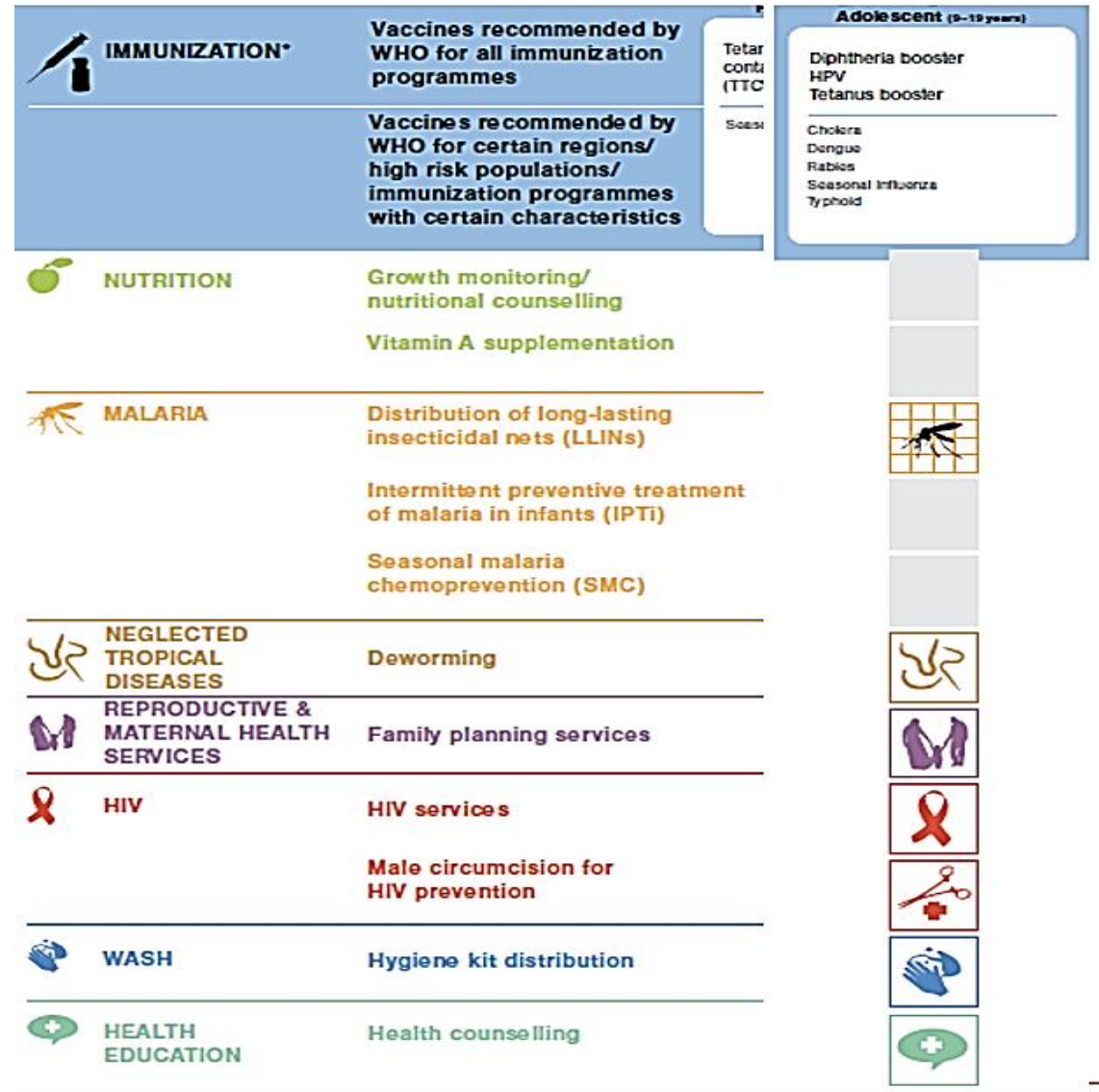
Less time commitment for other key stakeholders e.g., teachers

Potential programme benefits: integrated delivery

Increase available resources

Leverage other single visit interventions

Leverage existing platforms
e.g., Child Health Days



Source: Working Together. An integration resource guide for immunization services throughout the life course. WHO, 2018

Implications of off-label usage

An off-label vaccine recommendation generally refers to a difference between the labelled instructions by the regulatory authorities (or “label”), vs. the recommendations for use issued by public health advisory bodies

Examples of off-label use: PCV schedule, fractional dosing (YF, IPV), use of influenza vaccines during pregnancy

As with any other off-label vaccination use – country needs to understand considerations, including liability, in their context

Source: Public Health England. Off-label vaccine: leaflets - GOV.UK (www.gov.uk). (accessed February 2023)

This leaflet from Public Health England explains why a child might be offered an off-label vaccine. It states that all medicines, including vaccines, must have a license or authorization before being offered to the public. Sometimes, however, healthcare professionals offer a vaccine that is slightly different from the strict terms laid down in its license. The leaflet describes the circumstances that can lead to vaccines being used 'off-label' and the reasons why this may be recommended.

Why is my child being offered an "off label" vaccine?
A guide for parents

Why do medicines have to have a license or authorisation before being offered to members of the public. Sometimes, however, healthcare professionals offer a vaccine that your child is being offered is 'off-label' - what this term means and why it's important that the vaccine is still recommended.

What is a licence?
All medicines authorised by the Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA). Vaccines will only be authorised for use in humans if they have been tested by the manufacturers on their target population (children or adults) and fully tested to see that they are safe and effective.

Why are off-label vaccines used?
Not all medicines are authorised for use in children. Some medicines are authorised for use in children but not for the specific age group or condition. Only when this information has been reviewed and accepted by the MHRA or EMA, will the vaccine be given a license and be produced and promoted by the manufacturers for general use. Amongst other things, the license specifies who can receive the vaccine, how many doses are required, what side effects may occur and how the vaccine should be handled and stored.

How does a vaccine get a licence?
All vaccines have to be authorised by the UK Medicines and Healthcare products Regulatory Agency (MHRA), or the equivalent agency for Europe – the European Medicines Agency (EMA), before they can be placed on the UK market and advertised or promoted for use by the manufacturer. Vaccines are only submitted for licensing to the EMA or MHRA after they have been tested in the target population (children or adults), and fully tested to ensure that they are:

- **acceptably safe**
- **able to provide protection** against the disease they are designed to protect against, and
- **manufactured** to a high standard of quality.

This extensive testing process – from the first batch of a vaccine being made in a laboratory to its use in the general population – can take more than ten years. The detailed information on the results of testing in the laboratory and from clinical trials is then submitted for independent evaluation by the experts at the MHRA or EMA. Only when these agencies are entirely happy with this information will the company be granted a license to place the product on the market and to advertise or promote its use. Amongst other things, the license specifies who can receive the vaccine, how many doses are required, what side effects may occur and how the vaccine should be handled and stored.

Children are being vaccinated in a laboratory to ensure that the vaccine is safe and effective.

This leaflet from Public Health England provides an introductory guide for healthcare professionals regarding off-label vaccines. It explains that all medicines, including vaccines, must have a license (marketing authorisation) for use in humans. Sometimes, however, it is necessary to offer a vaccine that is 'off-label'. This means that, although the vaccine is authorised for use, it's being used in a way that is slightly different from the strict terms laid down in its license. The leaflet describes the circumstances that can lead to vaccines being used 'off-label' and the reasons why this may be recommended.

Off-label vaccines
An introductory guide for healthcare professionals

Before they can be placed on the market, all medicines, including vaccines, have to have a license (marketing authorisation) for use in humans. Sometimes, however, it is necessary to offer a vaccine that is 'off-label'. This means that, although the vaccine is authorised for use, it's being used in a way that is slightly different from the strict terms laid down in its license. This leaflet describes the circumstances that can lead to vaccines being used 'off-label' and the reasons why this may be recommended.

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introduction: strengthening the system

- **Opportunity to improve the programme and health system.**
- **Option to conduct a situation analysis of the immunization programme to identify weak areas that could be strengthened before/during the intro/switch:**
 - safe immunization practices, adverse event surveillance and reporting
 - monitoring and evaluation of programme performance, including disease surveillance/registry and immunization data quality
 - communication strategy and crisis communication plan
- **Regular monitoring of progress or barriers to reaching targets should be conducted, and documentation of lessons learned**

Summary

- **Cervical cancer burden remains high, especially in LMICs**
- **Safe, highly effective HPV vaccine, available > 15 years**
- **New opportunities:**
 - **Single dose schedule option**
 - **Improving vaccine supply**
 - **Donor funding**

Thank you

Acknowledgements

- **Paul Bloem, WHO HQ**
- **Hiroki Akaba, WHO HQ**
- **Terri Hyde, Vaccination Introduction Team Lead, CDC HQ**

Poster walk

Poster walk guidance

***You have 60 minutes to observe the posters of peer countries and find out:

- *What are common themes, challenges or learnings you can identify with other peer countries?*
- *What experience or tool can you share that could be helpful to this country in addressing one of its challenges?*



Coverage & Key Indicators				
General	19	20	21	22
Coverage with the first DPT dose under 12 m.(%)				
Coverage DTP3 vaccine by 12 months (%)				
Drop-out rate between the first and third dose of DPT vaccine under 12 m. (%)				
Are vaccines or health interventions delivered to the same target population as HPV vaccine (whether or not the vaccine has been introduced)?				
Cervical Cancer				
Total number of cervical cancer cases				
Total number of deaths from cervical cancer				
Cervical cancer incidence rate per 100,000 women				
Mortality rate per 100,000 women OR % from all deaths				
If HPV vaccine is already provided by the private sector please provide the HPV vaccine full coverage (%) from the national sample				
Existence of a National Cancer (or Cervical Cancer) Strategic Plan (yes/no)				
Do you have a cervical cancer screening program in place? (Please describe the program: age cohort, coverage, methodology)				
HPV Vaccine – Plans for Introduction				
Plans for HPV vaccine introduction – if pilot please specify at what level and geographic coverage				
Planned vaccine product and number of dose strategy (one dose OR two doses)				
Age cohort (year)				
Mass campaign (yes/no)				
Facility-based (yes/no)				
School-based (yes/no)				
% of girls who are not currently enrolled in or attending school				
Mixed (yes/no)				
Will the HPV vaccine be integrated with other vaccines or health intervention for the same target population?				
Key Challenges and Strategies				
Strengths	Decision making	Challenges	Explaining Factors	Possible Strategies

Notes:

1. One representative from each country remains at their poster to interact with peers and answer questions.
2. Each country is required to prepare 1-2 questions to ask peers during the panel discussions.

Country presentations

Mongolia & Vietnam

Country presentations

Philippines & Tunisia

Country breakout–Situational analysis

Objective:

- Please summarize your country's objective for the introduction/scale up of the HPV vaccine: coverage, pilot/nation wide, timeline, cohort

1 Context

- What steps have you already taken to prepare for the HPV introduction?
- What political priority has been granted for the HPV vaccine?
- NITAG status

2 Key decisions steps

- What are the next important decision steps to introduce/scale up HPV vaccine?

3 Scope

- Are you looking to pilot the introduction – if so, where? - or introduce nation-wide?

4 Constraints

- What constraints could hinder your efforts? (e.g., concurring introduction of another vaccine, outbreak, covid-19 efforts, financial sustainability...)

5 Stakeholders

- Who are your key allies?
- Who are your champions?
- Who needs to be rallied to your objectives?

6 Your levers of influence

- How would you rate your level of influence over this decision-making process? (H/M/L)
- Where do you have influence? What would you need to exercise more of your influence?

Country breakout rooms

Country	Breakout room
Mongolia	
Philippines	
Tunisia	
Vietnam	

Lessons learned and country examples on HPV introduction

HPV Vaccine introduction: selected country examples & lessons learned

Linked HPV vaccine workshop, July 11-12th, Istanbul

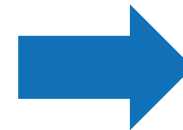
Priscilla Rouyer
Consultant, Results for Development



What do we know about HPV vaccine introduction across the world?

Global reviews of HPV programs identified key lessons learned

- [A review of 72 different programs from 60 countries](#) was done between LSHTM and PATH in 2015/2016
- The work of the LSHTM was revalidated [with a review of national introduction evaluations from 17 LMICs in 2022](#)
- A recent study of the delivery approaches and cost for ongoing HPV vaccination programs, to be published by Path (to be published soon)



One takeaway

- These reviews have led to a strong understanding of what works and what doesn't for HPV introduction.
- The challenge is in **“how”** these lessons learned are adapted to your country context

HPV vaccine lessons learned (1/3)

Preparation

- High-level political commitment led to more effective projects and national programmes
- Timely intersectoral planning and coordination – across health, education, and finance (particularly for national programmes) – was critical to successful implementation and sustainability
- Integrating HPV vaccine with routine vaccination programme models and resources created efficiencies



Malawi: Three departments in the Ministry of Health (Non-Communicable Diseases, Expanded Programme on Immunisation, Reproductive Health) worked collaboratively to plan and implement an HPV vaccine delivery programme with a high level of political commitment from the government



Botswana: conducted two demonstration projects prior to national introduction and directly incorporated lessons learnt from the projects into the national scale-up implementation plan.

HPV vaccine lessons learned (2/3)

Communications

- Effective community mobilisation activities were conducted at least one month prior to vaccination, used multiple methods, and were carried out by health workers and community leaders
- The most effective messages were: HPV vaccine prevents cervical cancer, is safe, will not harm future fertility, and is endorsed by the government and the World Health Organization
- Face-to-face communication with parents and communities enhanced support and mitigated spread of rumours
- Opt-in consent, where not used for routine vaccines, increased rumours. An opt-out approach was acceptable where implemented



Bolivia: carried out comprehensive community sensitisation using multiple modalities, including local media, well in advance of vaccination days.

HPV vaccine lessons learned (3/3)

Delivery

- Including schools in the strategy attained the highest coverage
- Enumerating the population before vaccination proved challenging and expensive but useful in developing vaccine registers and planning vaccine stock for future years
- In schools, grade-based eligibility was logistically easier to implement than age-based eligibility
- Utilizing a two-dose vaccination schedule was easier and cheaper than a three-dose schedule
- Delivery of all doses within one school year minimised dropout and resulted in higher coverage
- Use of community health workers assisted in identifying out-of-school girls and those who missed doses
- Providing a second opportunity for vaccination was successful in reaching girls and parents who initially refused and those who were absent or out of school



Laos PDR: Achieved greater than 90% coverage in urban and peri-urban districts through school-based delivery



Bhutan: School-based and health facility-based delivery were implemented nationally in 2010 and 2011–2013, respectively. School-based delivery resulted in 20% higher coverage, so the country decided to use this approach from 2014 onward.



Tanzania: Successfully used schools for vaccine delivery & is testing healthfacility-based delivery with outreach to schools and communities in 2015–2016.

Delivery approaches and cost

- Path will release this summer a recent study of the delivery approaches and cost for ongoing HPV vaccination programs
- Countries in focus: Guyana, Rwanda, Senegal, Sri Lanka, Uganda, and Ethiopia
- Early takeaways:
 - Schools are the primary location for HPV vaccinations, even in “mixed” strategies
 - Drivers of sustainability costs include: vaccine product (# of doses), delivery mode and # of sessions: what are the levers you would like to use and sustain in the next few years?

Table 1. Key program characteristics of HPV vaccine delivery in six low- and middle-income countries, 2019.

	Ethiopia	Guyana	Rwanda	Senegal	Sri Lanka	Uganda	
Month and year of introduction	Dec. 2018	Jan. 2017	Apr. 2011	Oct. 2018	Jan. 2017	Oct. 2015	
Year of study*	2019	2019	2019	2019	2020	2019	2019
National coverage (2019)†	94% HPV1 84% HPVc	42% HPV1 20% HPVc	97% HPV1 94% HPVc	86% HPV1 25% HPVc	45% HPV1 31% HPVc	99% HPV1 82% HPVc	99% HPV1 64% HPVc
WHO classified delivery strategy	School-based	School-based	School-based	Facility-based	Facility-based	Mixed	School-based
Eligible population	14-year-old girls	9- to 16-year-old girls and boys	12-year-old girls (grade 6)	9-year-old girls	Grade 6 girls (at least 10 years old)	Grade 6 girls (at least 10 years old)	10-year-old girls
Number of facilities in study	60	43	42	56	56	30	66
Number (%) of facilities vaccinating in study year	51 (85%)	40 (93%)	41 (98%)	55 (98%)	46 (82%)	30 (100%)	52 (79%)
Average number of sessions / facility / year	4.0	5.4	9.5	11.0	8.1	25.6	6.4
Average number of doses / facility / year	410.9	169.7	612.7	226.5	152.0	760.7	162.3
Location of HPV vaccinations	Schools	Mixed	Schools	Mixed	Mixed	Schools	Mixed
Frequency of vaccination sessions	Twice, fixed months	Continuous	Twice, fixed months	Continuous	Continuous	Continuous	Continuous (2 peaks)
Financial cost (USD) per dose‡	\$2.23	\$2.10	\$1.03	\$2.50§	\$1.73§	\$0.27	\$3.23

What's next?

- Share ideas and experiences with your peers on how to apply these lessons learned into your own journey
- Ask questions to clarify anything you don't understand or where you need additional support
- Reflect on the influence you and other stakeholders have over how HPV vaccine is introduced: where do you have most influence? Where can you extend your influence through building allies?

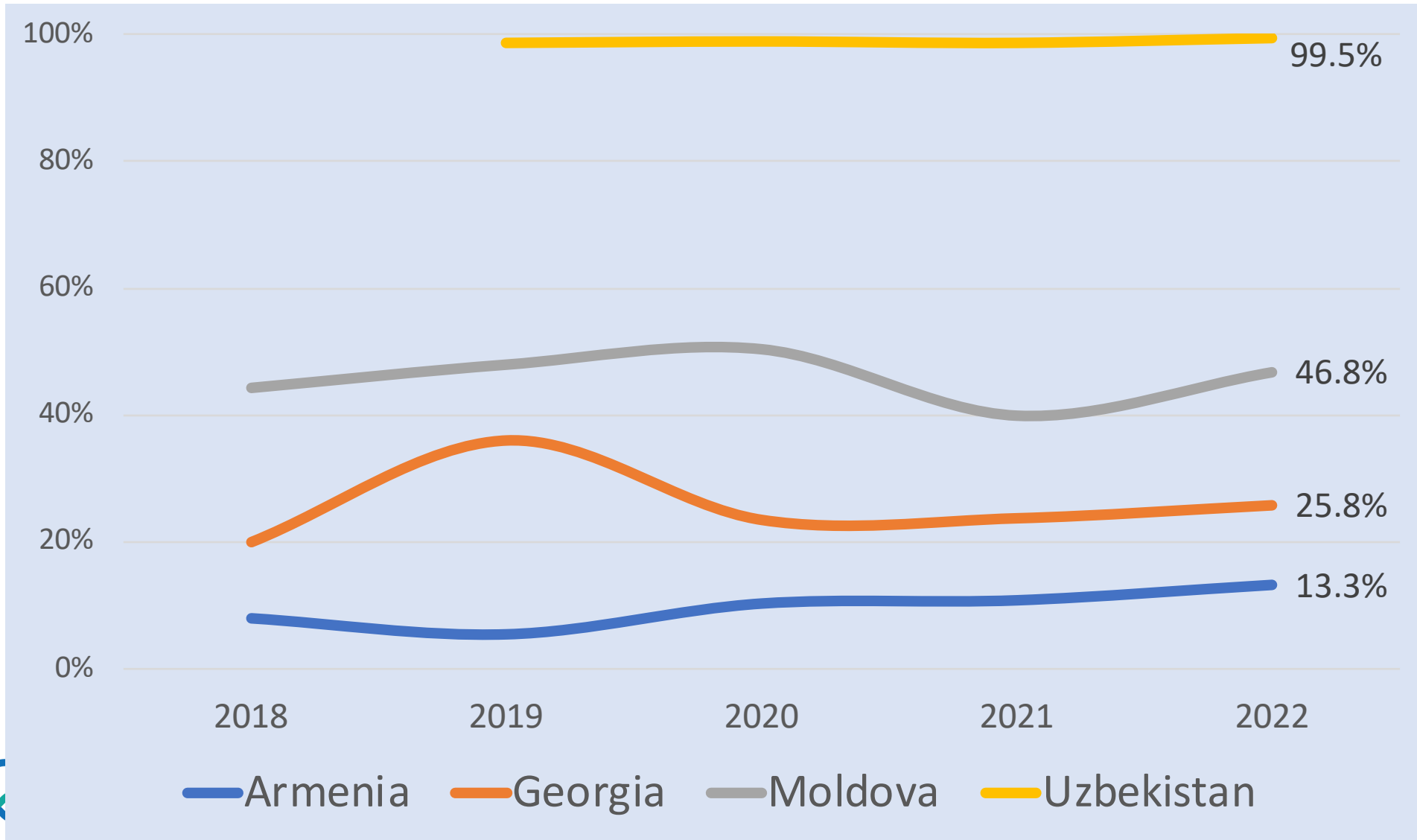
Lessons learned for HPV introduction in the EURO region

HPV Vaccination in Linked EURO countries: Key challenges and learnings

Linked HPV workshop, July 11, Istanbul

Ivdivy Chikovani, Eka Paatashvili
Curatio International Foundation

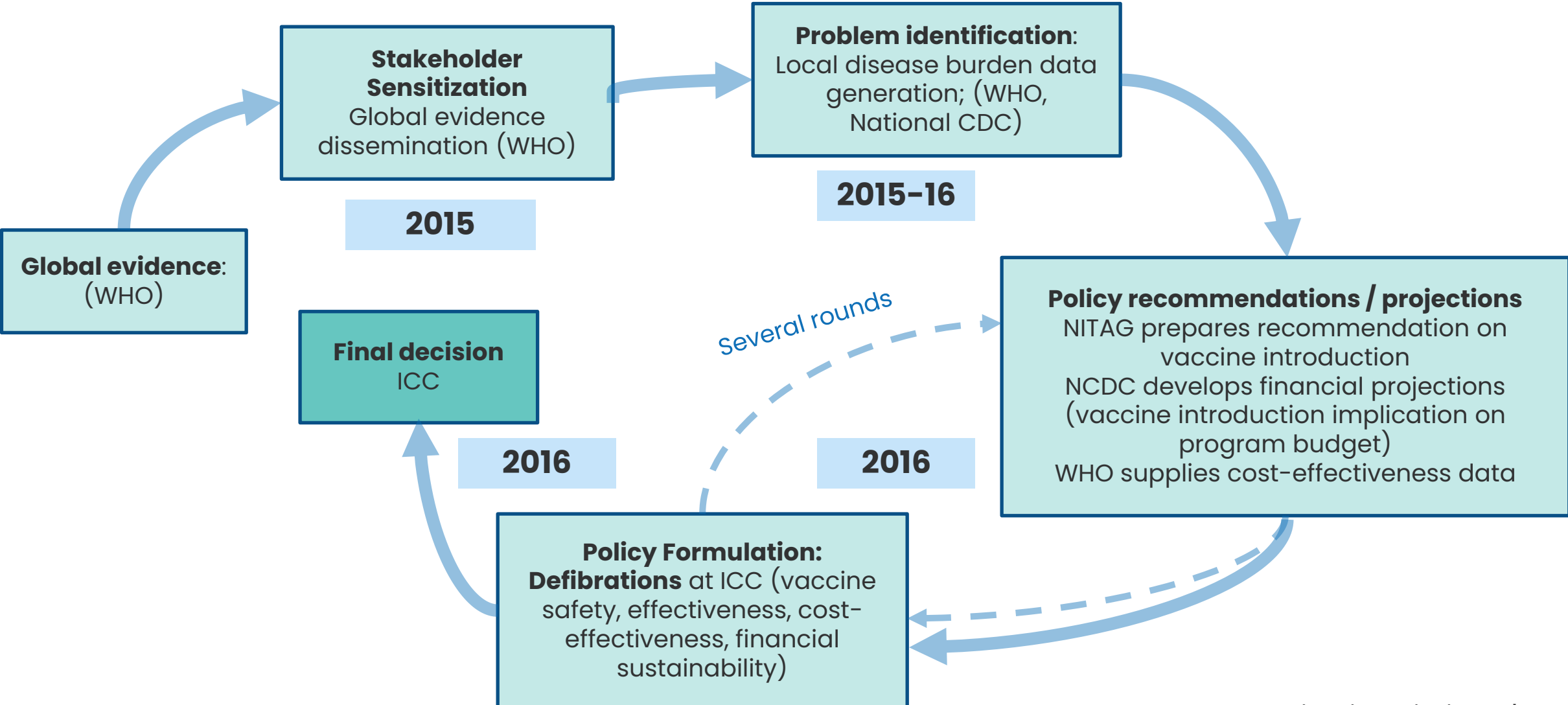
HPV full coverage



From early experience to Decision-making

	Armenia	Georgia	Moldova	Uzbekistan
Pre Gavi	High burden of cervical cancer, sub-optimal screening programs			
		Pilot humanitarian project (capital city 2010-12) failed - poor planning & communication	<ul style="list-style-type: none"> • Pilot through donation (2011-12) – poor coverage • Negative experience with other vaccines hesitancy 	<ul style="list-style-type: none"> • Pilot through Gardasil Access Program (2009-11)
<i>2015 Gavi HPV window opened, last opportunity for transitioning countries, access to vaccine fixed price for 10 y.</i>				
Data generation / advocacy	<ul style="list-style-type: none"> • WHO-Euro support: supply with global evidence on vaccine effectiveness, safety, efficacy; advocacy work • Professional groups involvement (champions) • NITAG recommendations 			
			<ul style="list-style-type: none"> • Intensive preparatory work • HPV cost-effectiveness study • Denmark, Ireland, Japan experience learned 	<ul style="list-style-type: none"> • HPV cost-effectiveness study
Decision making	<ul style="list-style-type: none"> • ICC decision on Introduction • MoH/ Cabinet of Minister's decision on Introduction (domestic financial resource allocations) 			
Applying to Gavi	2016	2016	2016	<ul style="list-style-type: none"> • First 2014 (postponed due to other vaccine introduction) • Second 2017

NVI National Decision-making – Georgia example



MoF role in decision-making – Georgia example

- **Role** – Member of ICC, participatory of all Gavi/ WHO /Sabin organised regional or local meetings dedicated to NVI & financial sustainability
- **Criteria for decision-making** on New Vaccine Introduction:
 - The disease burden is significant
 - The vaccine effectiveness is proved
 - The vaccine is available at competitive and stable prices: **4.50 USD for 10 years vs 14.34 USD market price**
 - Evidence on vaccine cost-effectiveness is available (desirable national)
 - Previous vaccine introductions were successful
 - Public sector budget projections allow introduction

Preparation

	Armenia	Georgia	Moldova	Uzbekistan
Introduction	<ul style="list-style-type: none"> • Demo project (countrywide)– 2017 • Post introduction evaluation (PIE)-2018 • Nationwide intro – 2019 	<ul style="list-style-type: none"> • Demo project (regional)- 2017 • PIE -2018 • Nationwide intro – 2019 	<ul style="list-style-type: none"> • Demo project (countrywide)–2017 • PIE -2018 • Nationwide intro – 2020 	<ul style="list-style-type: none"> • No Demo project • Nationwide intro delayed to 2019 (vaccine global shortage)
Age-groups	<ul style="list-style-type: none"> • Demo:– 13 y girls • Nationwide: - 13–45 y 	<ul style="list-style-type: none"> • Demo: 9–10 girls • Nationwide: -10-12 y 	<ul style="list-style-type: none"> • Demo: 10 y girls 	<ul style="list-style-type: none"> • Nationwide: 9 y girls • From 2nd year up to 14 y
Preparation	<ul style="list-style-type: none"> • Formative research: <ul style="list-style-type: none"> • explored barriers and drivers for positive HPV vaccination behaviors among target groups • Informed communication strategies • Communication strategy and crises communication plan development 			
	<ul style="list-style-type: none"> ▪ Trainings of HWs 	<ul style="list-style-type: none"> ▪ Trainings of HWs 	<ul style="list-style-type: none"> ▪ Trainings of HWs (Communication component integrated) 	<ul style="list-style-type: none"> • More time for preparation • Study visit to Moldova • Roadmap with the MoE on introduction and joint working schedule • Trainings of HWs

Communication / demand generation

	Armenia	Georgia	Moldova	Uzbekistan
Communication in practice	<ul style="list-style-type: none"> • Communication plan NOT fully implemented • Crisis communication plan not completed & implemented • Vaccination became highly politicized topic 	<ul style="list-style-type: none"> • Communication plan NOT fully implemented • Activities not aligned with communication plan • SCO low involvement • Information camp & media engagement lacked intensity and consistency • Weak engagement with Education sector 	<ul style="list-style-type: none"> • Communication plan implemented in practice • Social media monitoring • Webpage and platforms for interaction • Engagement of parents • Media engagement • Strong engagement with Education system 	<ul style="list-style-type: none"> • Comprehensive Communication plan & crises communication plan implemented in practice: • Social media campaigns and monitoring • Webpage for interaction • Parents' platform • Engagement with parents, NGOs • consistent media activities (talk-shows, • Strong engagement with Education system

Service Delivery

	Armenia	Georgia	Moldova	Uzbekistan
Platforms & related factors	<ul style="list-style-type: none"> Public clinics School-vaccination services in 4 regions 	<ul style="list-style-type: none"> Private for-profit clinics (95%) – poor dedication to immunisation services Village doctors Poor integration with adolescent services 	<ul style="list-style-type: none"> Public clinics 	<ul style="list-style-type: none"> Public clinics School-based vaccination services countrywide through campaigns
Age groups & adjustments	<ul style="list-style-type: none"> Demo: – 13 y girls Nationwide: – 13–45 y (to increase uptake and eliminate wrong perceptions about age) 	<ul style="list-style-type: none"> Demo: 9–10 girls Nationwide: –10–12 y To increase uptake gradually up to 18 y and 26 y, >27 based on clinician’s decision 	<ul style="list-style-type: none"> Demo: 10 y girls 	<ul style="list-style-type: none"> Nationwide: 9 y girls ‘increase 9–14 y
Coverage 1st year	<ul style="list-style-type: none"> 2018 – 8% 	<ul style="list-style-type: none"> 2018 – 20% 	<ul style="list-style-type: none"> 2018 – 44% 	<ul style="list-style-type: none"> 2019 – 98% (after 1 month)

Lessons Learned – what worked well

Decision-making

- Strong justifications for decision-makers (cervical cancer disease burden, vaccine efficacy, safety, economic evaluations – global and/or national)
- Advocacy work (involvement of partners, sensitisation meetings, sharing of evidences, discussions, continuous work)
- Involvement of MoF early on in the discussions
- Champions among professional groups, gov structures

Lessons learned

Critical challenges during introduction

- Vaccine safety concerns among
 - health workers including specialists
 - parents
 - school teachers
- Anti vaccination movements mainly through social media
- Religious groups

Lessons learned

Preparatory stage

- Thorough planning
- More intensified preparatory work compared to other routine vaccines (1-2 years)
- Strong communication campaign based on research of public concerns and health workers knowledge and attitudes
- Continuous training of health workers (primary care)
- Training of specialists (gynaecologists particularly)

Lessons learned

Service delivery

- Integration with preventive services (screening, adolescent health)
- School-based where possible
- Continuous on-the-job training of HW to increase their confidence

“Building a mountain”

Report out activity

- Each country team contributes a new insight, observation, impression, or question (**cannot repeat what another team contributes**) from the day’s discussions.
- Teams are selected at random.
- Each contribution builds upon the others...to build a mountain
- 15 mins of team discussion
- 15 mins for exercise.

Conclusion

