VACCINES FROM RESEARCH TO LICENSURE

LOW- AND MIDDLE-INCOME COUNTRY PERSPECTIVE

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MY PERSPECTIVE, BIAS AND INTERESTS

My perspective is based upon

- 30+ years in clinical, public health and PHC work in Asia and Africa, including health aid projects
- WHO engagement as chair of global Immunization Practices Advisory Committee (IPAC), chair of Western Pacific Regional Immunization TAG, core group attendee (not member) at SAGE, member of SAGE COVID Vaccines Working Group and other similar advisory committees for WHO and Unicef
- 2001-2020 work in Asia and Pacific for Burnet Institute and Nossal Institute, then
- 2020 - Aug 2026 for Jhpiego/Johns Hopkins University in 25+ countries in Africa, Asia, the Pacific

Bias

- Australian, male, non-indigenous, educated in PNG and Australia,
- Believer in multi-lateral institutions, value of country-led development assistance, integrated PHC

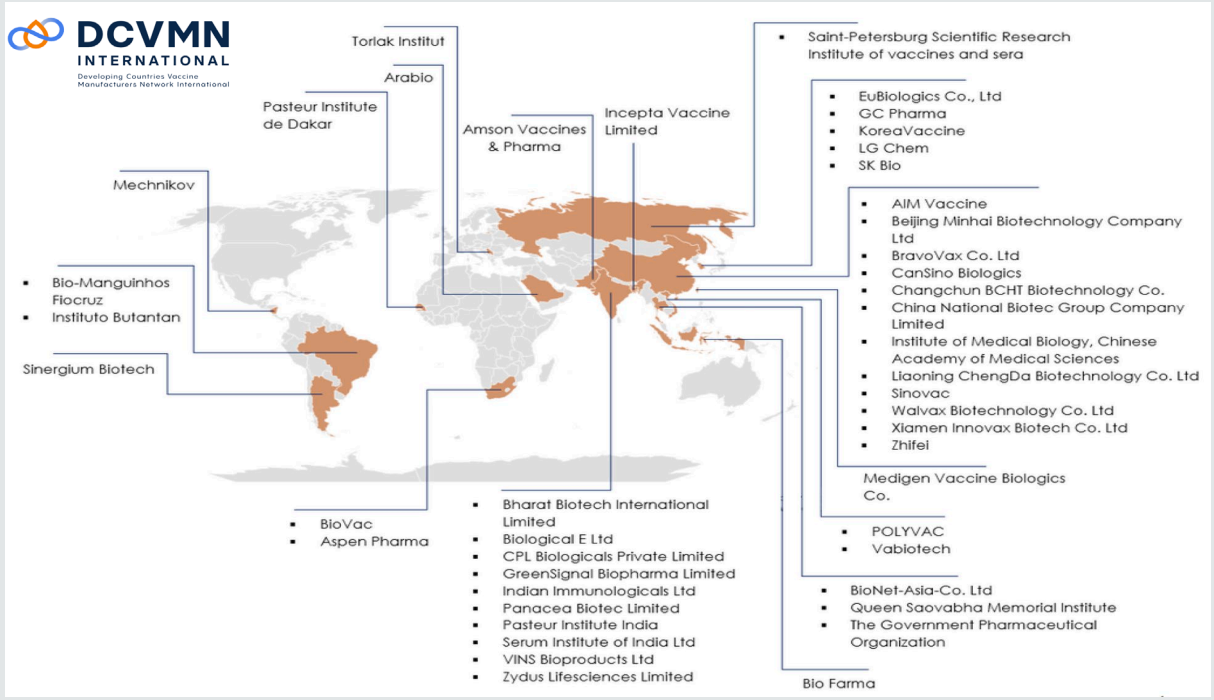
Interests

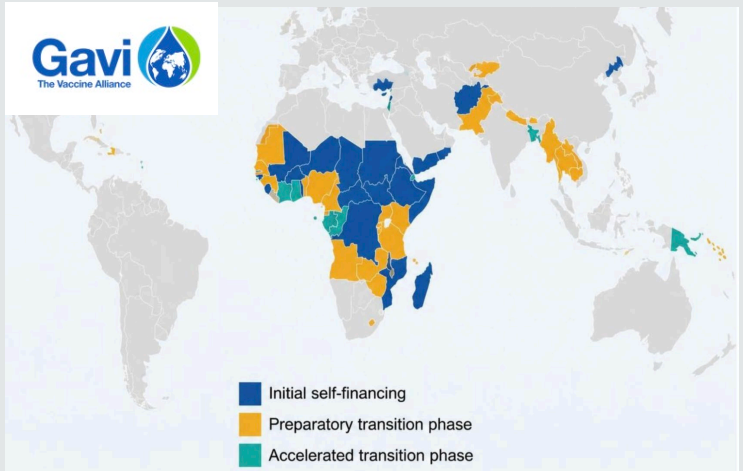
- Continuing consulting for Jhpiego and others, including a PNG program evaluation,
- Otherwise no commercial or personal interests to declare

LMIC MANUFACTURERS PRODUCE THE MAJORITY OF GLOBALLY USED VACCINES

- The Developing Country *(sic)* Manufacturers Network (DCVMN) lists 42 manufacturers who provide
  - 60% of global vaccine production
  - 70% of vaccines provided through Unicef Supply Division or PAHO, including those for Gavi, under WHO Pre-qualification
- WHO, Unicef, Gavi form a critical ecosystem for LMIC immunization, along with key donors/partners such as the Gates Foundation
- Also a useful lens for examining research to licensure to use in LMICs

Do we need to discuss LMIC term?





WHO Vaccine market report 2025

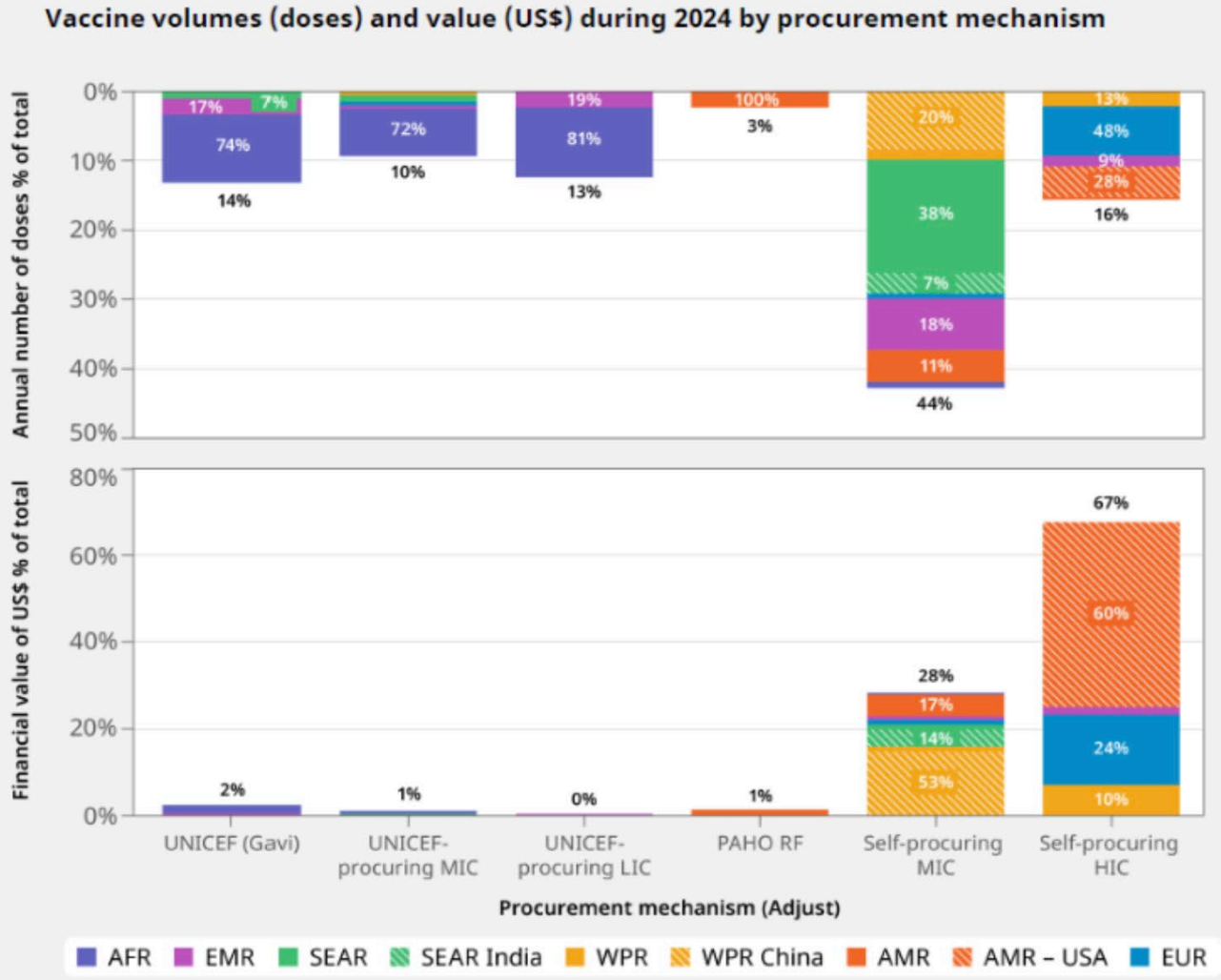
Procurement and pricing

Self-procuring MICs led volumes in 2024, followed by UNICEF SD

- Volume distribution was similar to 2023 with the exception of UNICEF (Gavi) which included an additional ~541 million doses of nOPV2 in 2024, which adds ~US$111 million of value
- MIC volume was dominated by China (23% of self-procuring volume) and India (45% of self-procuring volume) who together accounted for about 25% of the global 2024 volume
- UNICEF procurement of some vaccines (OCV, DTwP primary, Ebola, M-containing, OPV, typhoid, and YF) was ≥50% of global volume for each vaccine
- Self-procuring HIC represented 67% of value, down from 72% in 2023 due to less COVID-19 procurement in 2024. Greater value in HIC than in other income groups was driven by higher prices and procurement of vaccines for older adults

World Health Organization | MI'A

Global Vaccine Market Report 2025



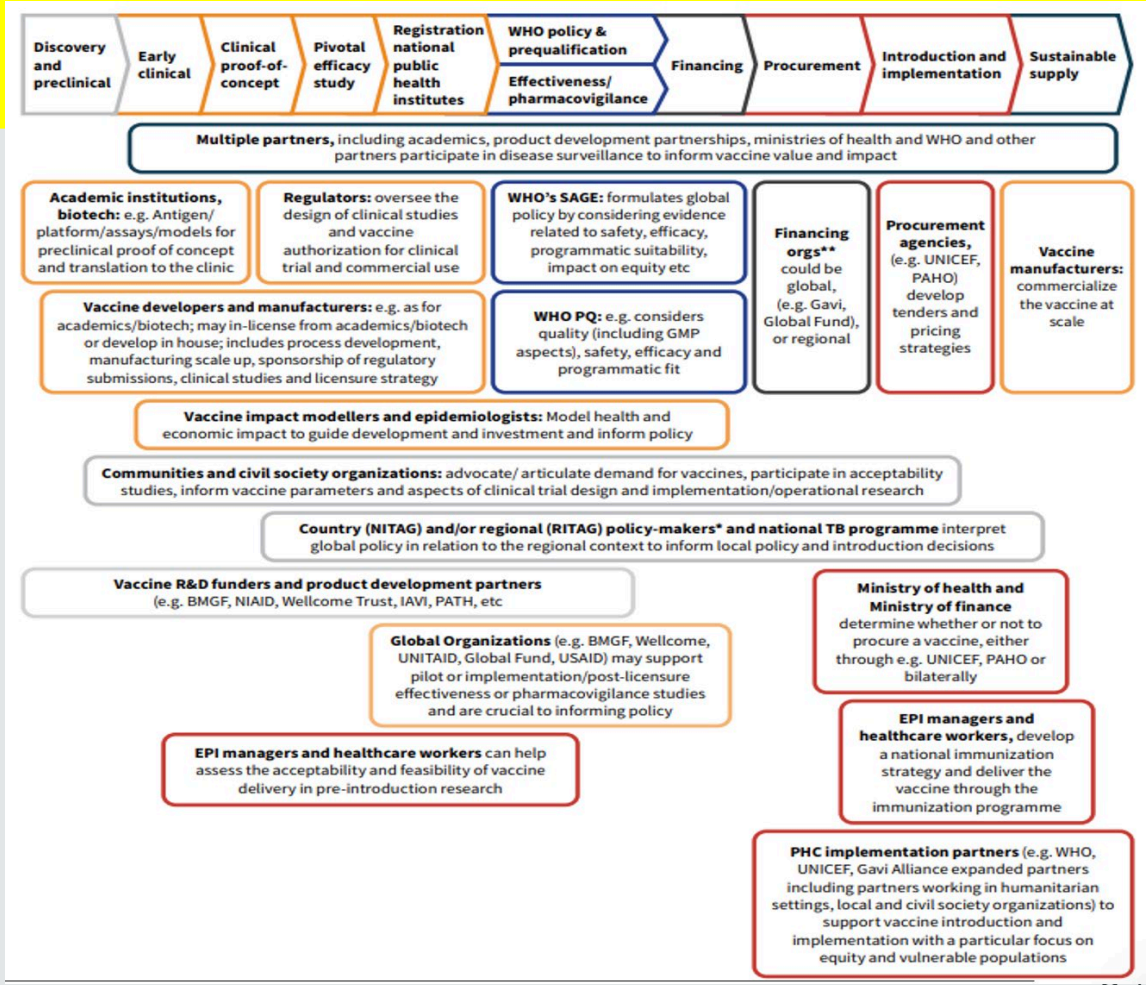
Overview of Analysis

207 | 115 | 137 | 6

2025 WHO Global Vaccine Market Report

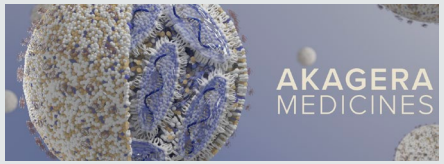
WHO AND LMIC COUNTRIES NEED A PROGRAMMATIC LENS ON THE RESEARCH TO LICENSURE TO USE CHAIN

- Often lack control of research priorities
- Around 50 low-income countries highly dependent on WHO, Unicef and Gavi for new product choices
- Other lower- and upper-middle income often squeezed for resources
- So the partner map is complex and engagement throughout the chain often mediated by WHO



LMIC NATIONAL INTERESTS AND PATHOGENS

- Market forces do drive some research, *modulated by:*
- National interest, and self-sufficiency
  - more in Asia than Africa at present
- Local epidemiology,
  - such as dengue vaccine in Brazil (albeit challenges this year) Ebola in Africa
- Outbreaks with national, regional and global significance
  - LMICs have particular risks
  - PHEICs affect everyone
- Prioritization of pathogens and new products
  - WHO PDVAC
  - Regional pathogen prioritization work
    - Hasso-Agopsowicz M, *et al* EBioMedicine. 2024 Dec 1;110.



One Rwanda example cites their “moral purpose” as an African-owned solution to African diseases

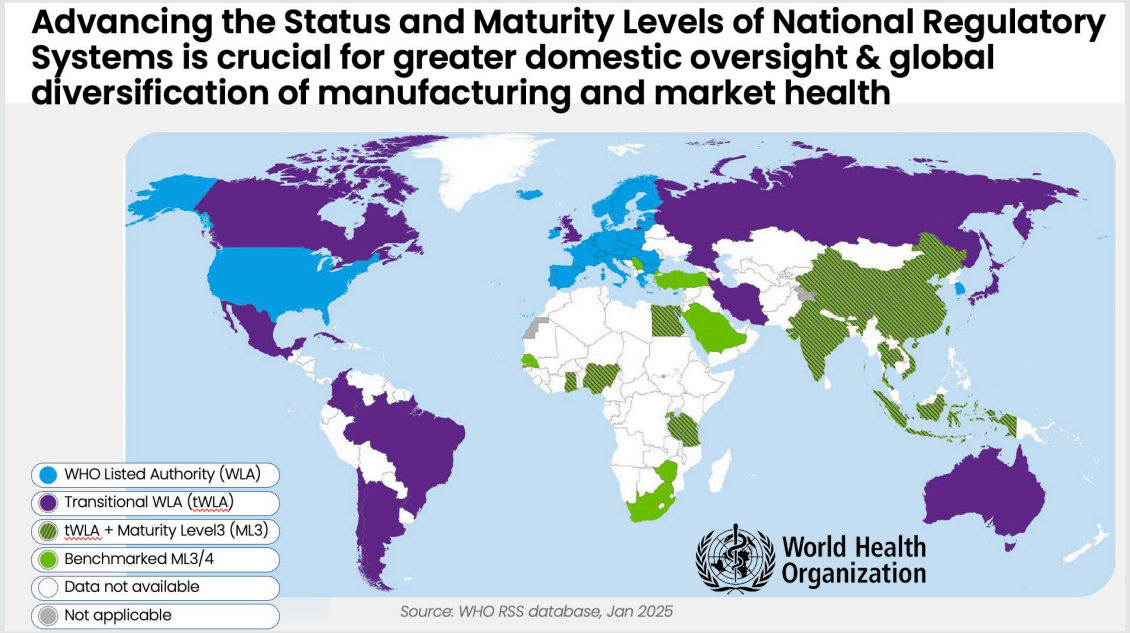


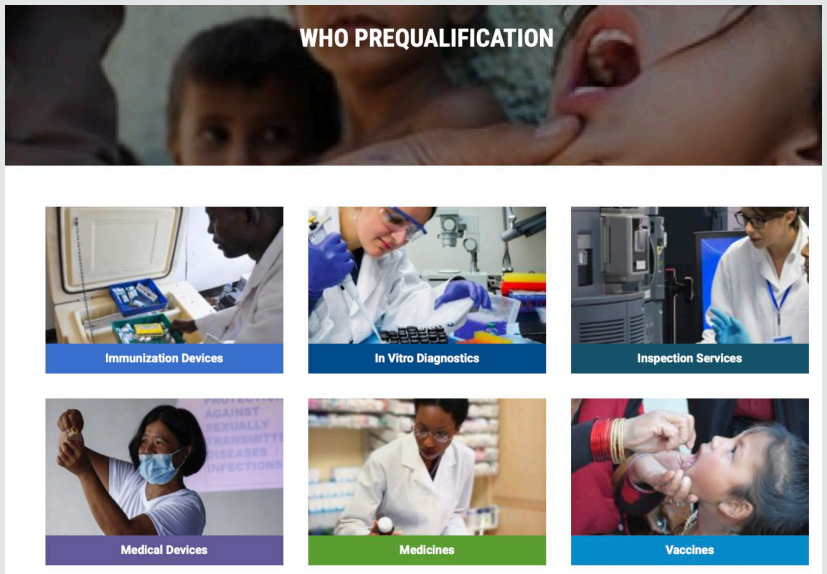
World Health Organization

Pathogen or Vaccine Area	PPC / TPP	VVP	FVVA	Roadmap	ECVP	Other
Generic	√		Concept paper		√	
TB	Therapeutic Vaccines (2019) Prophylactic vaccines (2018)	Development in progress	An investment case for new tuberculosis vaccines (WHO) -2022	AIGHD /EDCTP global TB vaccine R&D roadmap 2021	Publication of WHO ECVP for vaccines for adults and adolescents in progress	WHO Framework for Rapid Introduction and Impact of New TB Vaccines for Adults and Adolescents – in development
HIV	mAb for HIV prevention (2022)	Review in progress				
Shigella	√ (2021)	Publication in progress				
Gonococcus	√ (2021)	Publication in progress				
RSV	Vaccines (2017)	Publication in progress (Vx and mAbs)				
ETEC	√ (2021)	Publication in progress		Publication on Research gaps (2021)		
HSV	√ (2019)	Publication in progress				STI vaccine roadmap (2016)
GAS	√ (2018)	Publication in progress	In progress*	√		
Influenza	√ (2017; update in progress)	Special issue in progress	In progress			
GBS	√ (2017)	Publication in progress	√ 2021	√ (2017)	Planned 2024	
Malaria	vaccines (2015) mAbs in progress	Publication in progress (Vx and mAbs)				
MR-MAPs*	√ (2019)		Initial FVVA in progress			VIPS action plan for MAPs (2021)

RESOURCE LIMITATIONS

- Development of new vaccines for diseases of the less-resourced majority world have benefited from philanthropic investment
  - Malaria and TB vaccine collaborations for example
- Adaptations to allow local research (such as immuno-bridging) and manufacture (such as technology transfer or final steps in country)
- Reliance on WHO and Unicef for guidance on regulation to support under-resourced local registration and licensure processes, including WHO Prequalification



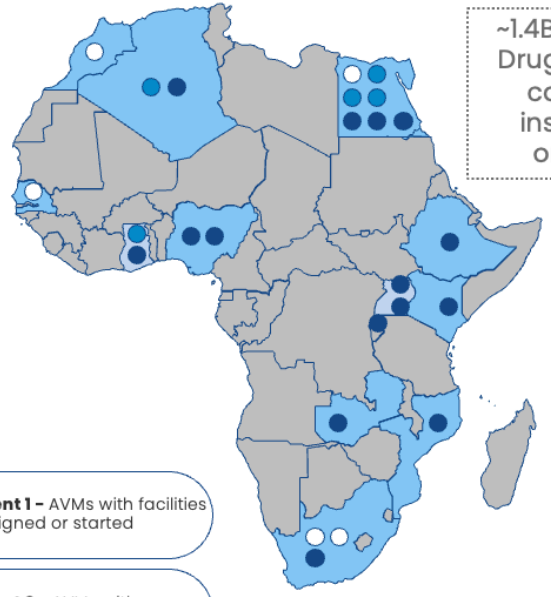


Regionalization of vaccine manufacturing, including WHO mRNA Technology Transfer Programme

Prior to 2020, there were 3 mfcts. capable of commercial-scale* vaccine manufacturing, across all technologies



....While in 2024, there are 25 African vaccine manufacturing projects with commercial-scale* ambitions in the pipeline



- **Segment 1 -** AVMs with facilities & TTs signed or started
- **Segment 2 -** AVMs with facilities awaiting TT initiation
- **Segment 3 -** AVMs with facilities in development

mRNA Technology Transfer Programme



Guidance for best practices for clinical trials

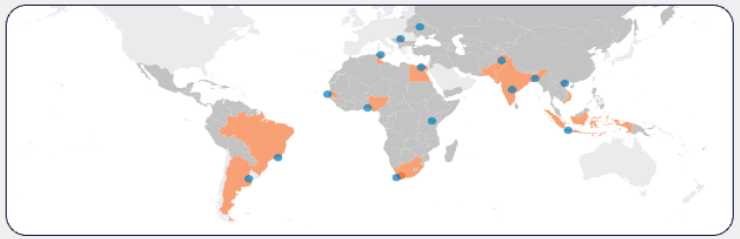
WHOSAGE

Prequalification of Medical Products
IVDs, Medicines, Vaccines & Immunization Devices, Vector Control

GTH-B Global Training Hub for Biomanufacturing

WHO Health Technology Access Program (HTAP)

WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory system of medical products



13 partner manufacturers trained

11 manufacturers could produce mRNA vax for human use by 2030

* Commercial-scale defined as production scale of 1Mn+ doses/year; mapping courtesy of CHAI, PATH & Africa CDC

RESEARCH LINKED TO POLICY AND USE

- Need to smooth pathways to regulatory approval, especially vaccines lacking commercial drivers
  - Contrast of malaria vaccines and new TB vaccines
- Bringing programmatic considerations and the eventual use-case into research efforts
  - Evidence Considerations for Vaccine Policy
  - **Target Product Profiles and Preferred Product Characterics**
- Rapid revision or adaptation of existing vaccines, and adaptive research during outbreaks
  - Ebola responses
  - Influenza and DNA technologies
- Post-licensure research with major program implications that needs regulators to update policy – the “off-label” debate





Evidence Considerations for Vaccine Policy



Preferred Product Characteristics: (PPC): defines product attributes for LMIC use

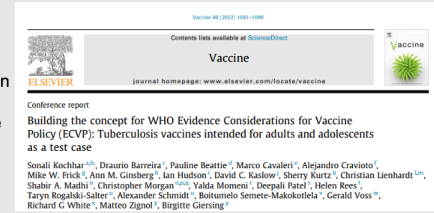
SAGE Evidence to Recommendation framework

WHO Position paper: summarize essential background information on diseases and vaccines, and the current WHO position on the use of vaccines worldwide

Financing & procurement criteria

Scientific advice meetings: Data on safety, quality and efficacy for licensure

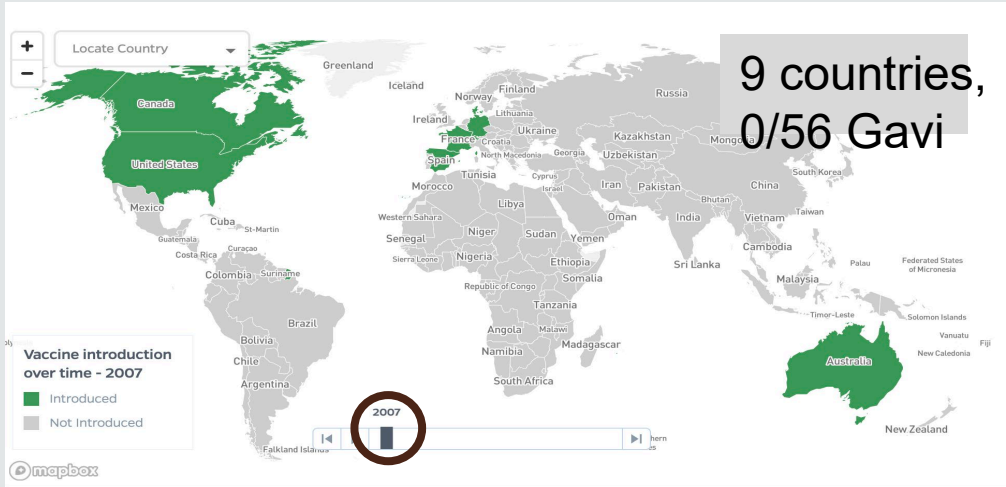
ttps://www.who.int/publications/i/item/9789240064690


Vaccine

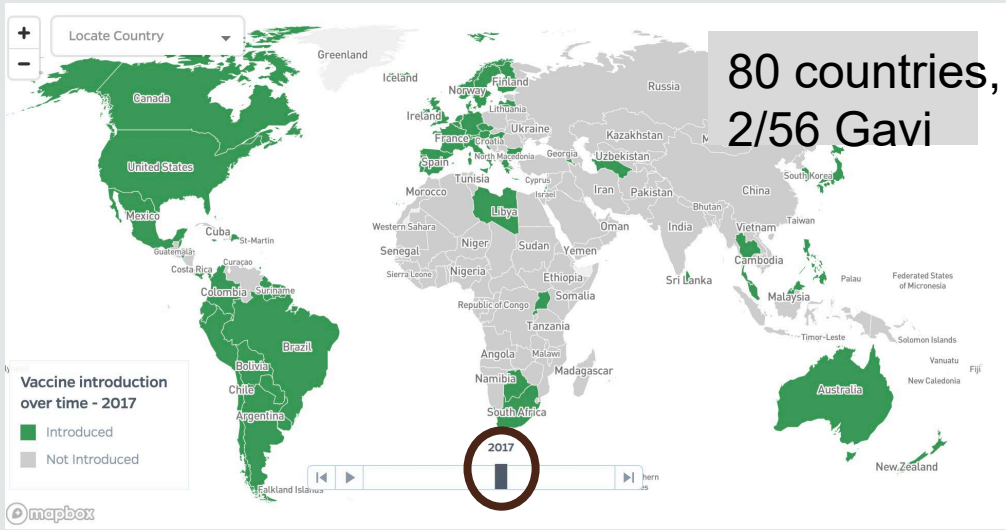
Conference report

Building the concept for WHO Evidence Considerations for Vaccine Policy (ECVP): Tuberculosis vaccines intended for adults and adolescents as a test case

HPV VACCINE AS AN EXAMPLE OF ITERATIVE EVIDENCE AND REGULATORY UPDATES

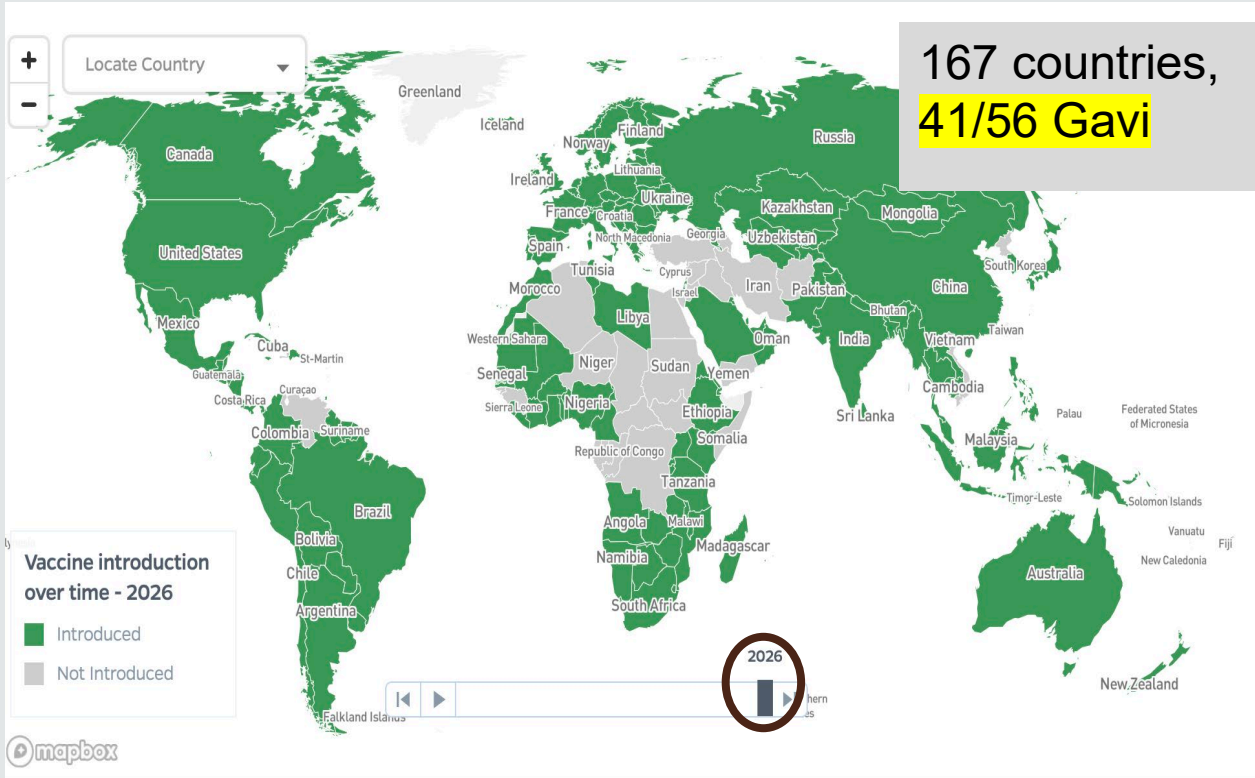


9 countries, 0/56 Gavi



80 countries, 2/56 Gavi

HPV Vaccine introductions over 20 years



167 countries, 41/56 Gavi

Graphics from JHU/IVAC View Hub www.view-hub.org

GAVI'S 2025 TARGET WAS 86 MILLION GIRLS. WAS IT MET?

Gavi The Vaccine Alliance

About us | Our work | Partner countries | Investing in Gavi | News & insights

Home > News releases

2022

Immunisation partners outline ambitious plan to protect millions of girls in lower- and middle-income countries against cervical cancer



Three years ago we made a promise to girls around the world to help end the scourge of cervical cancer. Today we have honoured it.

In December 2022 Gavi set an ambitious target of reaching 86 million girls with the HPV vaccine by the end of 2025. We have met it ahead of schedule.

21 November 2025 • 3 min read • **by** Sania Nishtar Add as preferred Google source



UNICEF/ANG-2025/Carlos Cesar

HOW WAS THIS TARGET MET, AND EXCEEDED?

Global health coordination

- Global policy and practice coordination: the ‘subteam’
- Role of WHO, Unicef, Gavi and other multilaterals plus other development partners
- Mobilised resources and commitment – donors & governments
- Overcame politics and culture – work by governments & all partners

Evidence for revising regulation and policy

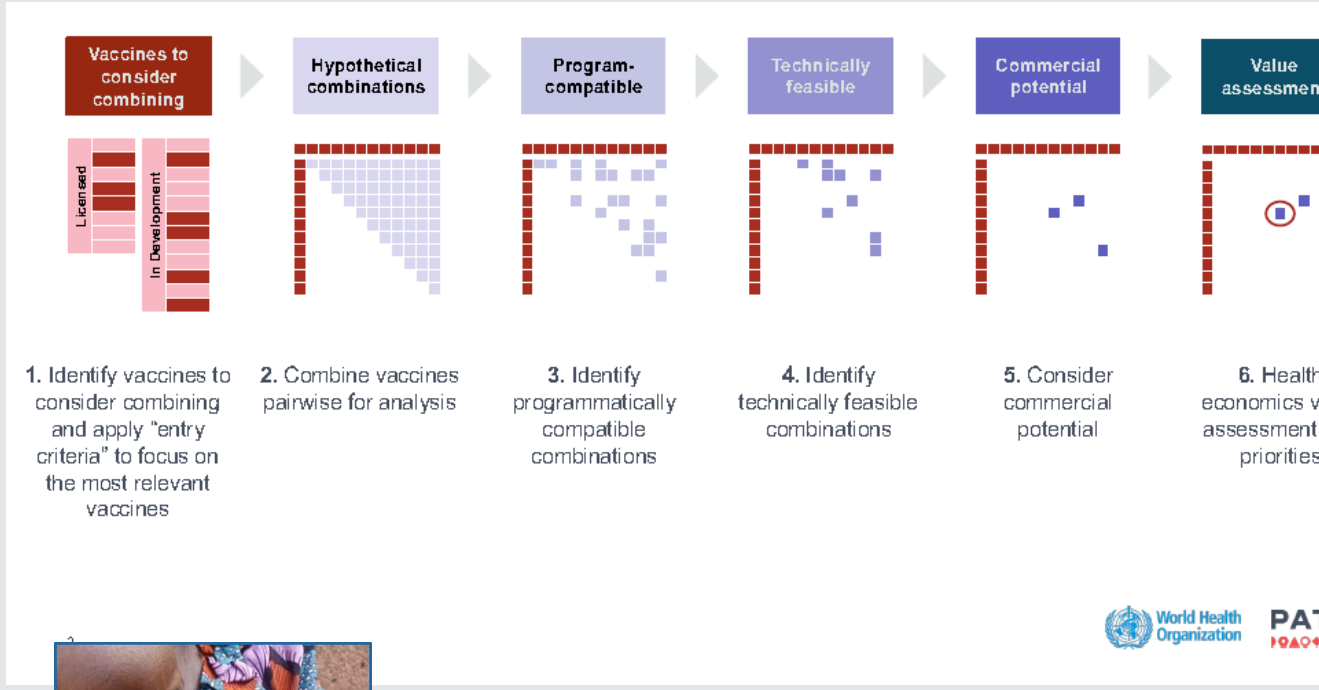
- Applied evidence to deal with limited supply
- Modified licensing recommendations as new evidence on schedule/efficacy became available, most recent updates Oct 2026
- Modified further as new products that varied in valency, price and schedule became available, especially from LMIC mfrs

Vaccine	Bivalent			Quadrivalent	Nonavalent
Trade name	Cecolin®	Cervarix™	Walrinvax®	Gardasil®	Gardasil-9®
Manufacturer	Xiamen Innovax Biotech Co. Ltd.	GlaxoSmithKline Biologicals SA	Walvax Biotechnology Co. Ltd.	Merck Vaccines	Merck Vaccines
Date of WHO prequalification	14 October 2021	08 July 2009	02 August 2024	20 May 2009	09 February 2018
Antigens (VLP types)	HPV 16 HPV 18	HPV 16 HPV 18	HPV 16 HPV 18	HPV 16 HPV 18 HPV 6* HPV 11*	HPV 16, HPV 18, HPV 31, HPV 33, HPV 45, HPV 52, HPV 58, HPV 6*, HPV 11*

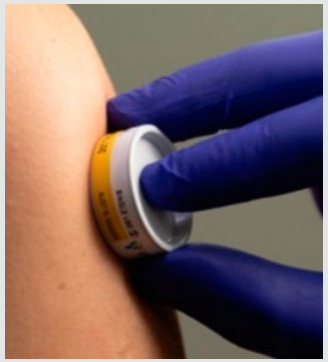
WHO 2024 Considerations for human papillomavirus vaccine product choice, second edition
ISBN 978-92-4-010093-0

OTHER CRITICAL TOPICS IN LMIC RESEARCH TO LICENSURE

- Combination vaccines
  - Pentavalent a game-changer 20 years ago
  - Hexavalent with inactivated poliovirus vaccine
  - Future choices complex, but research underway
- Novel administration options
  - Uniject – Compact Pre-filled Autodisable Devices
  - Needle-free jet injectors
  - Measles-rubella micro-array patches
- Implementation research
  - Critical to HPV and malaria so far, will be very important for maternal RSV vaccination, MR MAPs and others







THANK YOU

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