DECISION MAKING FOR VACCINE POLICY

LOW- AND MIDDLE-INCOME COUNTRY PERSPECTIVE

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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 Characteristics**
- Rapid revision or adaptation of existing vaccines, and adaptive research during outbreaks
  - Ebola responses
  - Influenza and DNA technologies
- Re-examined Phase III and 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

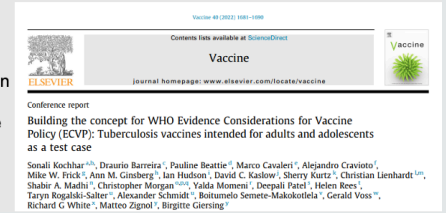
SAGE Evidence to Recommendation framework

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

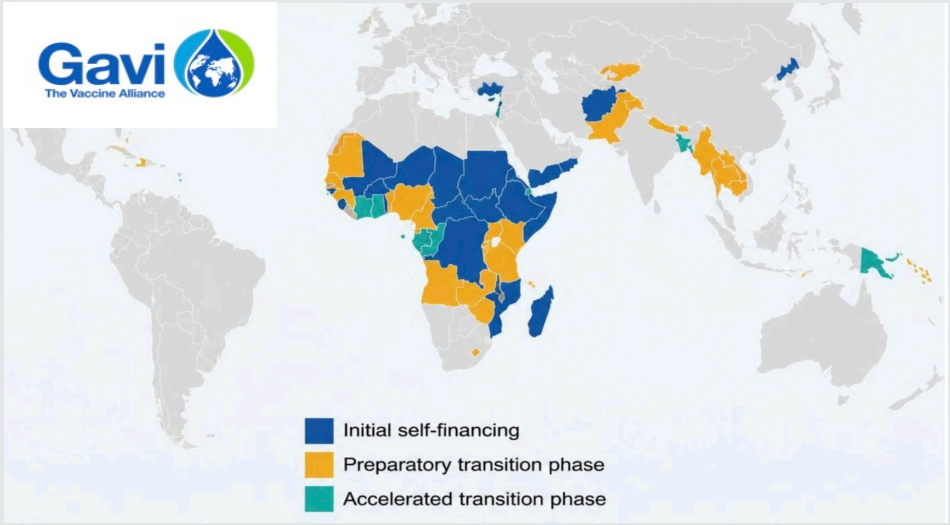

Vaccine

Conference report

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

DECISION MAKING IN LMIC, ALSO DOMINATED BY WHO, GAVI ETC.

- For low-income countries, Gavi supply dominates discussion.
  - Gavi use WHO processes as their policy reference.
- For middle-income countries, WHO processes are important to a varying degree
- In this ecosystem, traditionally:
  - WHO SAGE assesses evidence, issues global guidance
  - WHO RITAGs support regional implementation
  - Unicef Supply Division and PAHO's revolving fund support procurement
  - Country advisory bodies reference WHO SAGE and/or RITAGs, often through national immunization programs
- For many LMICs, WHO policy (guided by SAGE) and Unicef SD determine product choice options





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UNICEF staff unloading emergency supplies in Port Moresby, Papua new Guinea for earthquake response efforts, in March 2018.

SAGE





- An exemplar of global health policy setting
- Transparent and rigorous
- Working group study topics in depth
- Vaccine position papers summarize research to implementation
- Willingness to provide “off-label” recommendations when needed
- Other products on program issues

Strategic Advisory Group of Experts on Immunization (SAGE) – October 2026

5 – 8 October 2026 |Reading time: Less than a minute (26 words)

This meeting for the Strategic Advisory Group of Experts on Im tion (SAGE) wa held from Monday to Thursday.

Meeting materials

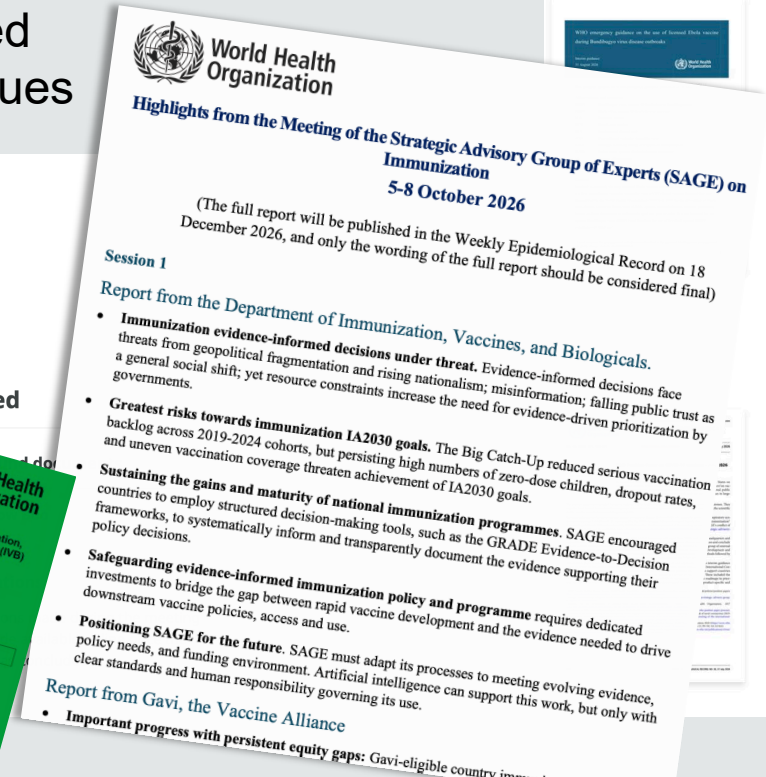
Agenda

Declaration of Interest

Meeting highlights

Related





World Health Organization

Highlights from the Meeting of the Strategic Advisory Group of Experts (SAGE) on Immunization
5-8 October 2026

(The full report will be published in the Weekly Epidemiological Record on 18 December 2026, and only the wording of the full report should be considered final)

Session 1

Report from the Department of Immunization, Vaccines, and Biologicals.

- **Immunization evidence-informed decisions under threat.** Evidence-informed decisions face threats from geopolitical fragmentation and rising nationalism; misinformation; falling public trust as a general social shift; yet resource constraints increase the need for evidence-driven prioritization by governments.
- **Greatest risks towards immunization IA2030 goals.** The Big Catch-Up reduced serious vaccination backlog across 2019-2024 cohorts, but persisting high numbers of zero-dose children, dropout rates, and uneven vaccination coverage threaten achievement of IA2030 goals.
- **Sustaining the gains and maturity of national immunization programmes**. SAGE encouraged countries to employ structured decision-making tools, such as the GRADE Evidence-to-Decision frameworks, to systematically inform and transparently document the evidence supporting their policy decisions.
- **Safeguarding evidence-informed immunization policy and programme** requires dedicated investments to bridge the gap between rapid vaccine development and the evidence needed to drive downstream vaccine policies, access and use.
- **Positioning SAGE for the future**. SAGE must adapt its processes to meeting evolving evidence, policy needs, and funding environment. Artificial intelligence can support this work, but only with clear standards and human responsibility governing its use.

Report from Gavi, the Vaccine Alliance

- **Important progress with persistent equity gaps:** Gavi-eligible country

Latest SAGE news and publications

1 SEPTEMBER 2026

WHO emergency guidance on the use of licensed Ebola vaccine during Bundibugyo virus...

The guidance outlines the benefits, risks and unknowns associated with off-label use of Ervebo® during the ongoing BDBV outbreak and recommends that the...

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31 JULY 2026

WHO position paper on COVID-19 vaccines - July 2026

Weekly epidemiological record

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18 AUGUST 2026

WHO position paper on typhoid vaccines, August 2026

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28 MAY 2026

WHO emergency guidance on the use of licensed Ebola virus vaccine during Bundibugyo...

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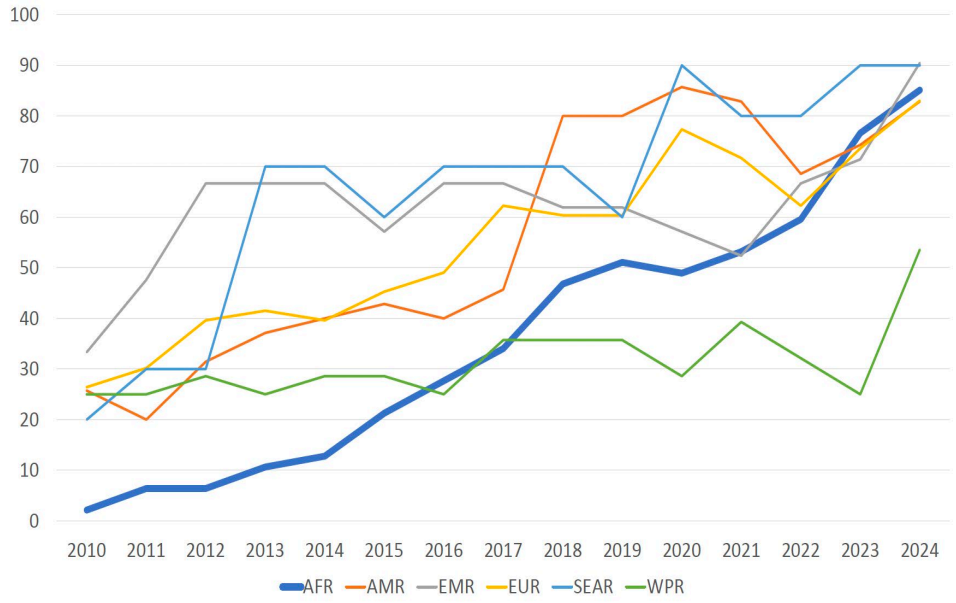
Read More

INCREASING FOCUS ON, AND EXPECTATIONS OF, NITAGS

- Policy and practice increasingly devolving to countries (as it should?)
- A 10 year program by WHO to build the Global NITAG Network and standardize what NITAGs can/should do
- Draws heavily on partners and ‘mature’ TAGs such as ATAGI, Canada, NCIRS etc

Systems strengthening | Vaccine introduction & optimization progress, benefiting from 15 yrs of NITAG ecosystem strengthening.

Regional trends for functional* NITAGs (2010-25)



- By 2024, over 90% (178) of countries have a NITAG, and around 80% (155) have a functional* NITAG.
- Largest improvement in the African Region: 2% in 2010 to 85% in 2025.

IVB Director's Report to SAGE

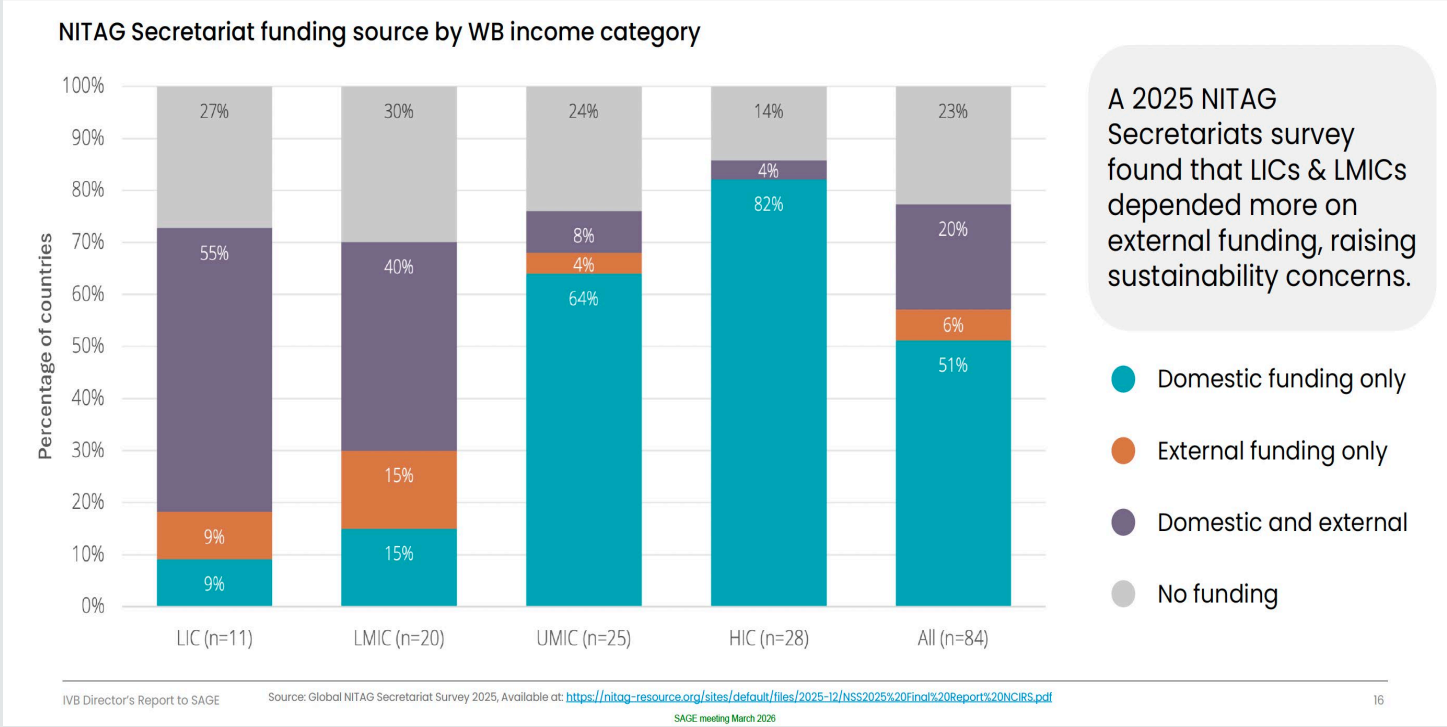
*Note: Based on meeting the six functionality criteria.: 1) legal or administrative basis, 2) formal terms of reference, 3) Disclosure of interests, 4) 5 areas of expertise, 5) One meeting a year, 6) Agenda circulated one week before meeting, Sources: WHO-IVB Database. Cleaned data reported by Member States through the WHO/UNICEF Joint Reporting Form, as at 30th June 2025.

SAGE meeting March 2026

15

FUNCTIONAL COUNTRY DECISION-MAKING CRITERIA

- Minimum expectation is to adapt WHO policy, or another agency
- Biggest gap for LMICs is national resourcing of this function
- Functional NITAG, in WHO's maturity scale have:
  - Are established and compose of an effective mix of expertise (vaccines, economics, health specialties)
  - Independent, transparent and not biased (eg by industry)
  - Resourced and supported by an effective secretariat
  - Use effective processes to develop the policy question, collate and consider evidence, balance competing priorities
  - Make clear actionable recommendations
  - Are integrated into policy-making
  - Are recognized as expert body for vaccines



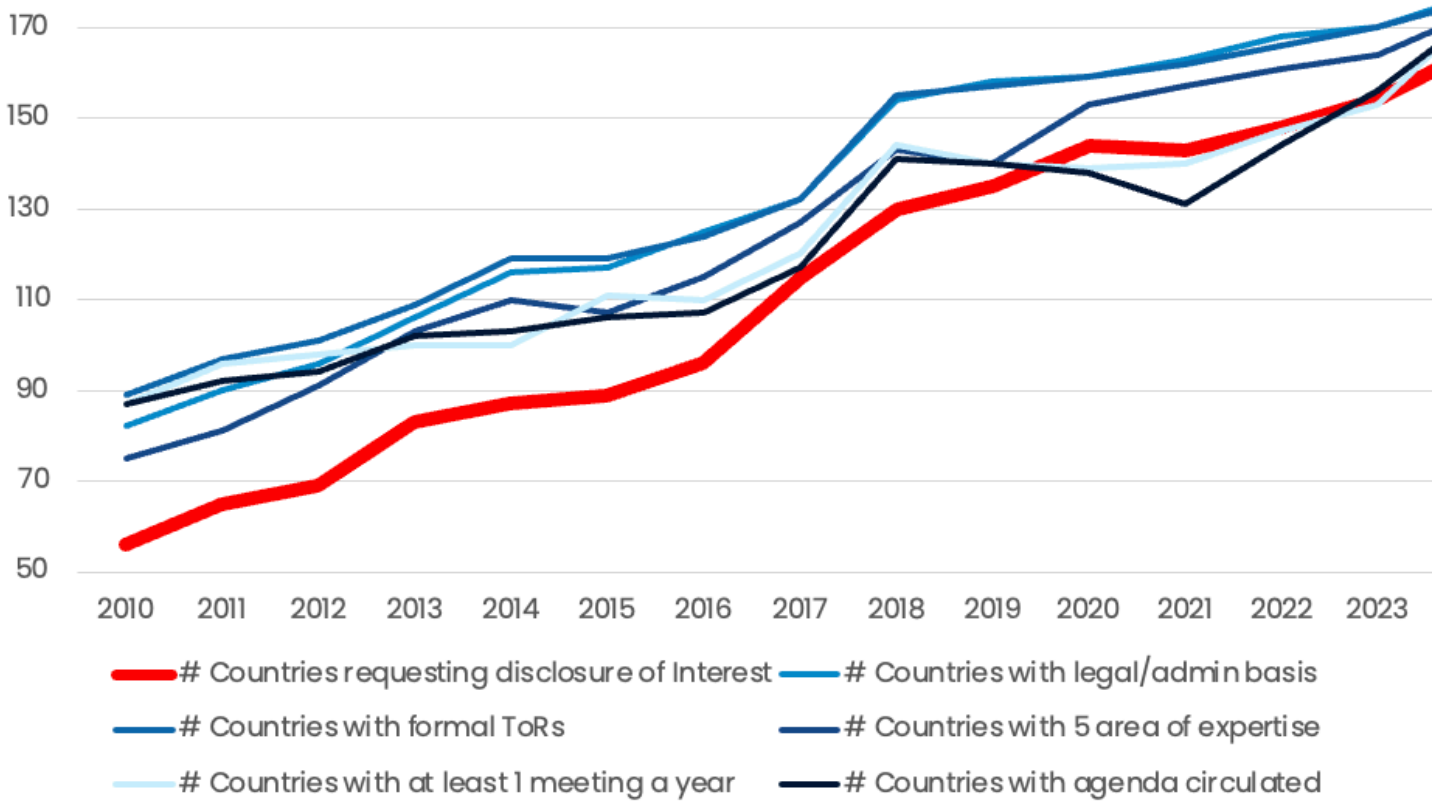
NITAGs in WPRO

By my rough count, of 35 WPR jurisdictions:

- 19 have both advisory committee and NITAG,
- 6 have an advisory committee but no NITAG, and
- 10 have neither.

Among the 6 functionality process criteria, which one is the most difficult to meet?

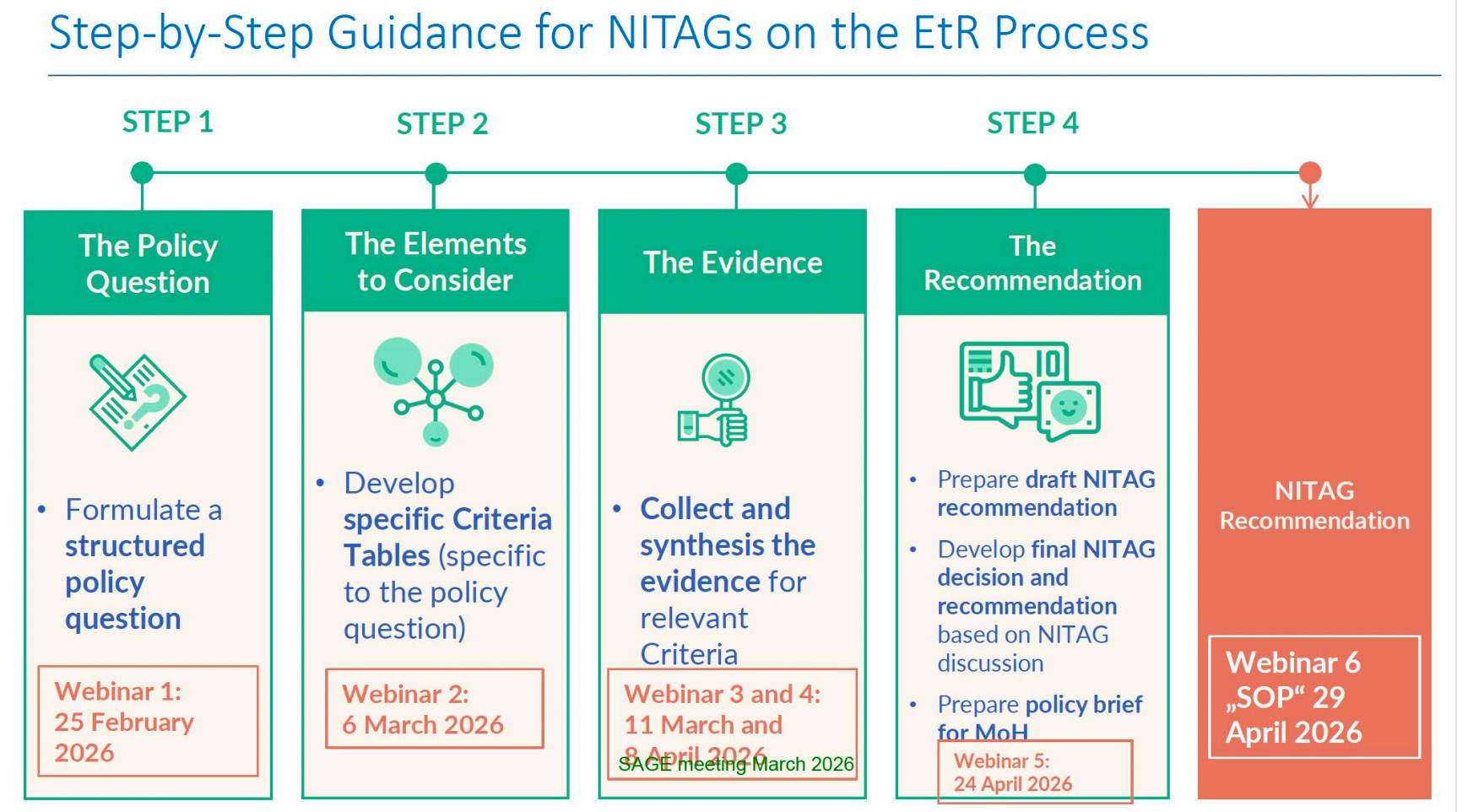
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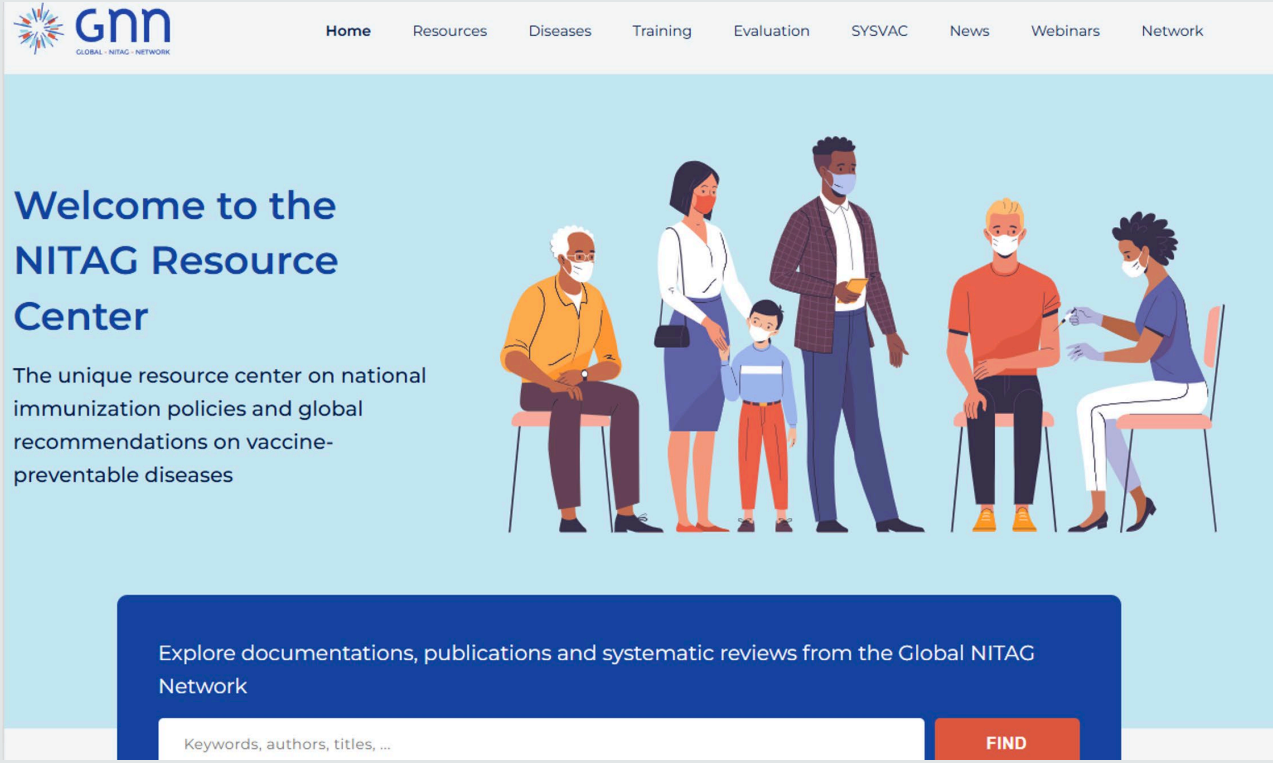
NITAG SUPPORT IS INCREASINGLY HORIZONTAL THROUGH TWINNING OR PEER LEARNING

One example from a regional program led by WHO EURO in 2026 also shows an effective sequence in applying evidence to formulate recommendations



GLOBAL NITAG NETWORK

- https://www.nitag-resource.org
- Has grown into one of the key global resources for majority world decision-making for vaccine policy
- Tools for
  - Assessing new vaccines,
  - Developing briefs,
  - Health economics
  - Modelling
  - Optimisation of programs and schedules
  - twinning with other NITAGs



EVIDENCE APPLIED TO GIVE POLICY OPTIONS

- In a Canadian survey, around 2/3 of NITAGs provided “off-label” recommendations
- Some examples:
  - Yellow Fever dosing
  - HPV vaccine dosing
  - HPV vaccine age groups
- Re-examined Phase III and post-licensure research with major program implications that needs regulators to update policy – the “off-label” debate
- HTAC may differ from NITAGs (and WHO) on this
- MR campaigns
  - Adjusting age group targets
  - Deciding whether local data allows targeted or selective campaigns


Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Exploring off-label vaccine use: a survey of the global national immunization technical advisory group network

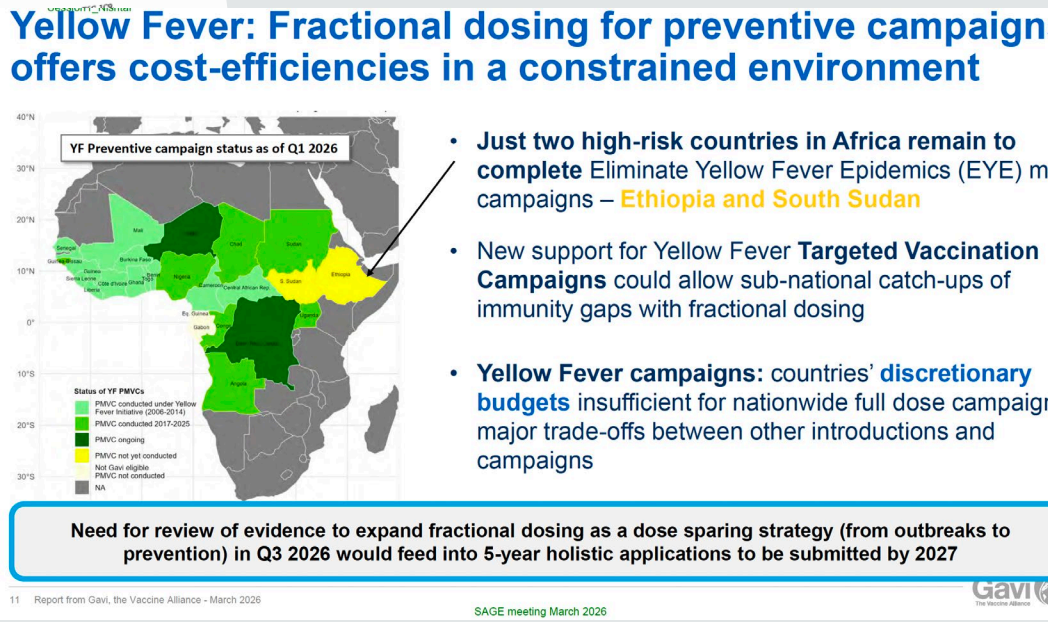
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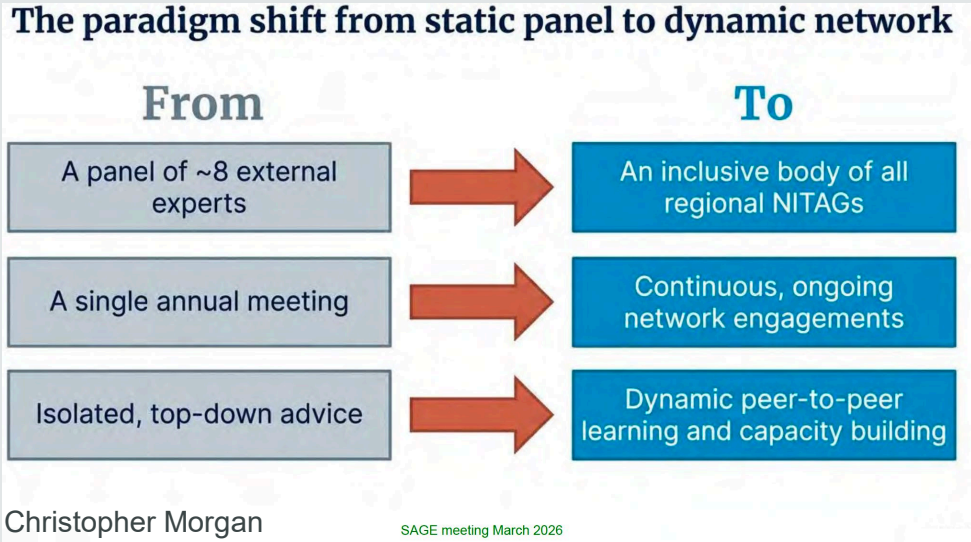
ABSTRACT





A TRANSFORMED RITAG TO PUT NATIONAL PROGRAMMES AND NITAGS AT THE CENTRE





WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTÉ

REGIONAL OFFICE FOR THE WESTERN PACIFIC
BUREAU RÉGIONAL DU PACIFIQUE OCCIDENTAL

REGIONAL COMMITTEE

Seventy-seventh session
Manila, Philippines
19–22 October 2026

Provisional agenda item 11

WPR/RC77/8

22 September 2026

ORIGINAL: ENGLISH

Immunization a major agenda item at this week's RCM, featuring: zero dose; measles/rubella; life-course vaccines; data for action and stronger evidence to policy.

Strong national advisory mechanisms, particularly functional national immunization technical advisory groups (NITAGs), are essential to accelerate progress across the three regional priorities for strengthening immunization programmes.

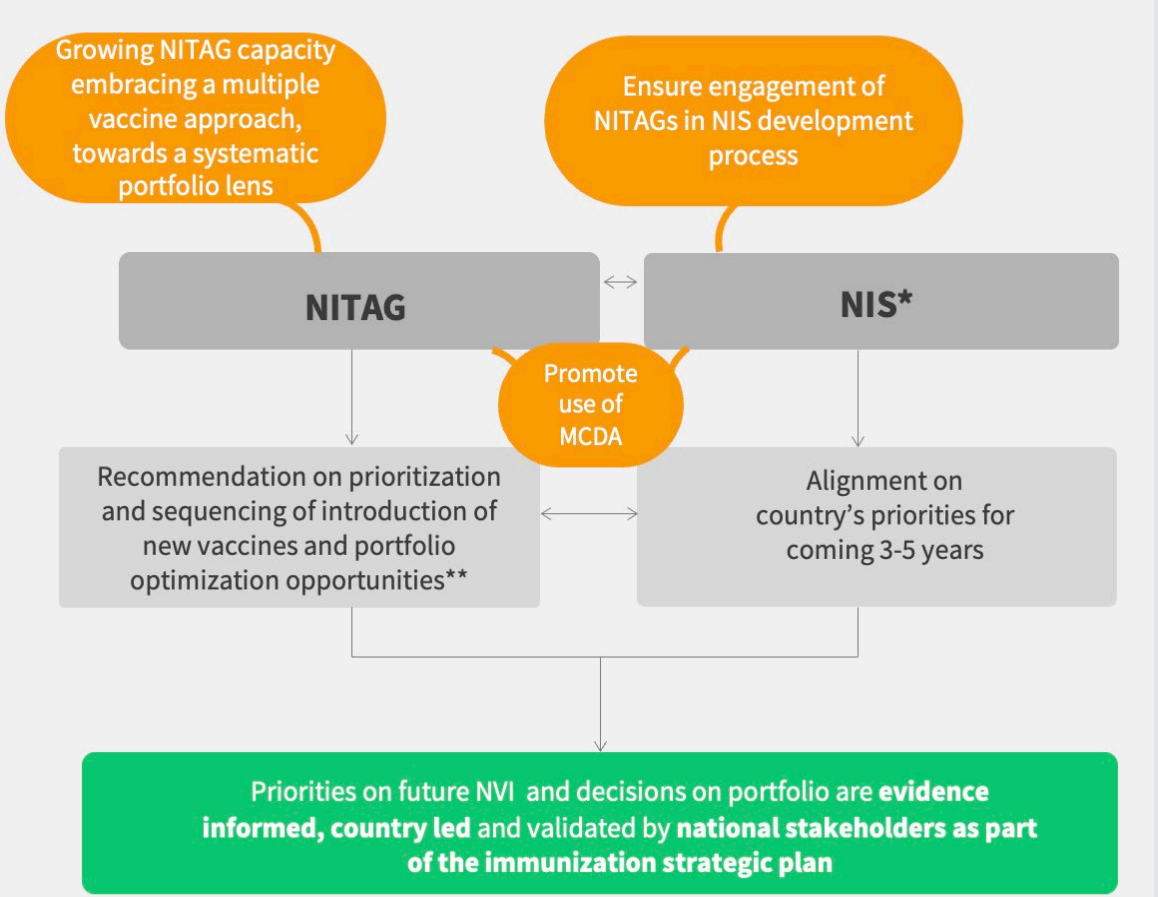
- They provide independent, evidence-based guidance on programme priorities, vaccine policy, disease burden assessments, economic evaluations and product optimization. They also help countries strengthen equity, achieve measles elimination goals and expand immunization platforms across the life course.
- Functional NITAGs, or equivalent advisory bodies, can support governments to make evidence-informed decisions on new vaccines and strategies, while regional collaboration can facilitate technical exchange and adaptation of global recommendations to country contexts.

- **Transform the Regional Immunization Technical Advisory Group** (RITAG) into a more responsive and country-led regional advisory network, with stronger participation from NITAGs and equivalent advisory bodies. The transformed RITAG will strengthen peer learning and technical exchange, support countries to adapt global recommendations to national contexts, and strengthen two-way links between national, regional and global immunization policy processes, including the WHO Strategic Advisory Group of Experts.

More on this tomorrow

NEW DEMANDS ON NITAGS TO SUPPORT DECISIONS IN STRATEGY, PRIORITIZATION AND OPTIMIZATION

- Desire for more evidence-based approach to
  - national strategy development
  - **prioritisation** of which new vaccines to introduce, when
  - **optimization** of the program in terms of vaccine schedules, vaccine products, service delivery options
- Pressure is being directed to NITAGs to undertake this, making the need for capacity development that much more important
- Gavi is now requiring all countries to undertake formal prioritisation and optimization (VPOP) using WHO tools
- At the same time, countries are seeing up to a 2/3 reduction in operational budgets, and a cap on Gavi-supported budgets for vaccines.



WHO presentation to GNN. MCDA = Multi-criteria decision analysis

Definitions: Vaccine Prioritization and Optimization

Maximize the present

Vaccine Optimisation:

Assessing new products, presentations, schedules, or uses and switch to more suitable ones *(e.g. PCV product switch or schedule change).*

Anticipate the future

Vaccine prioritisation:

Deciding which new vaccine introductions programmes should invest in, when and in what order *(e.g. Malaria vs RotaVirus introduction)*

Maximizing health impact within available resource

Shifting towards a systematic, portfolio lens, process led by national stakeholders

World Health Organization

THANK YOU

<CHRISTOHER.MORGAN@IMMUNIZATIONPLUS.ORG>