

WHO TB Vaccine Accelerator Forum



Vaccine Implementation and Research Task force in South Africa

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health

Department:
Health
REPUBLIC OF SOUTH AFRICA



NAGI TB Vaccine Working Group



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South African National Advisory Group on Immunisation (NAGI)

Year established: 1993

No. of current members: 14

Working groups: 10

- COVID, PCV, Hep B, HPV, Polio, Rubella, Mpox, RSV, Rotavirus
- TB vaccine June 2024
- Vaccine confidence 2026

RSV: Use of the bivalent RSV vaccine (Abrysvo™ Pfizer) during pregnancy for the prevention of RSV-associated lower respiratory tract disease in infants

SAGE recommendation Sep 2024

WHO PQ Mar 2025

NAGI recommendation Apr 2025

NAGI CEA and budget impact assessment 2026

No MoH adoption as yet



Strategic Advisory Group of Experts on Immunization

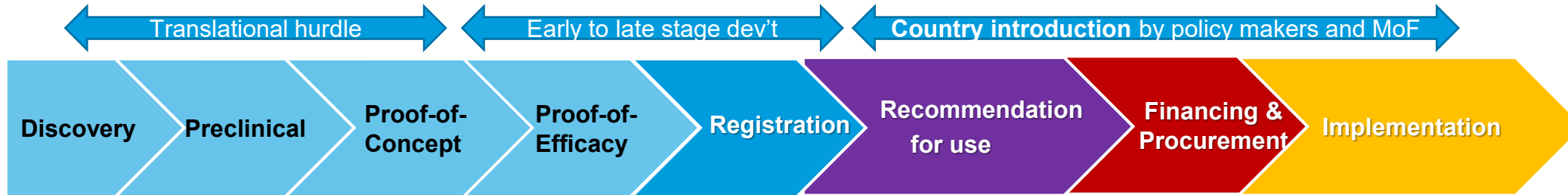


News

GNN monthly update:
March/April 26

<https://www.health.gov.za/nagi/>

Coordination between NAGI and NTP/EPI is essential to avoid delays

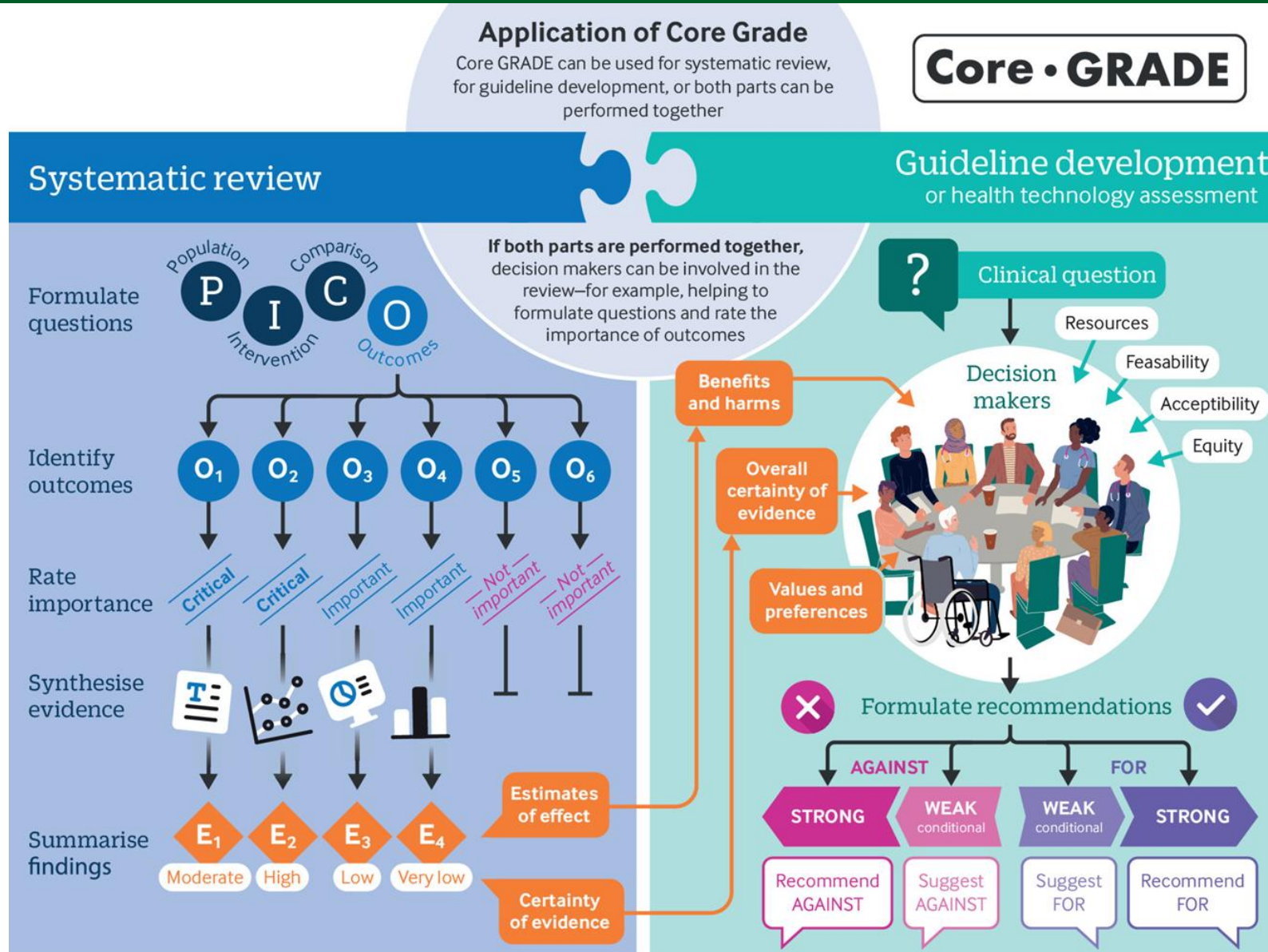


Country (**NITAG**) and/or regional (**RITAG**) policy-makers and **NTP** interpret global policy in relation to the regional context to inform local policy and introduction decisions

NTP and EPI plan for introduction and implementation

South Africa preparedness has begun ahead of Phase 3 results

NAGI structured Evidence-to-Decision logic



Evidence required for GRADE EtD



EtD Domain	What Data in This Domain Will Evaluate
Problem Priority	TB incidence, mortality, notification trends, subnational burden distribution
Benefits & Harms	Vaccine efficacy from trials, safety data, duration of protection, population impact
Values & Preferences	Household costs, care-seeking behaviour, socio-economic burden of TB
Resource Requirements	Health system capacity requirements (HR, cold chain, service delivery platforms, vaccine doses)
Cost-effectiveness	Vaccine price, programme costs, healthcare utilization, ICER
Equity	TB burden by age, sex, HIV status, geography, and vulnerable populations (guide prioritisation of high-burden and underserved populations)
Acceptability	Community perceptions, vaccine hesitancy patterns, provider attitudes
Feasibility	Delivery platforms, service readiness, implementation constraints

TB Vaccine Implementation Roadmap

National Department of
Health &
World Health Organization

Roadmap for Accelerated
Implementation of Novel
TB Vaccines for Adults and
Adolescents in South Africa



Vision: Initiation of nationwide implementation of TB vaccines for adults and adolescents within one year of regulatory approval			
Goals	Available Sufficient, sustainable and timely supply	Accessible Equitable, affordable delivery to all who could benefit	Acceptable Aligned with expectations of end-users and recipients
Milestone 1	Policy Alignment	Hybrid Delivery	Value Proposition
Milestone 2	Regulatory Harmonization	Health System Resilience	Community Partnership
Milestone 3	Supply & Market Security	Innovative Finance	Transparent Communication

Availability	Evidence and policy alignment	Regulatory Harmonization	Supply & Manufacturing Security
	Develop Phase 3b/4 & Demonstration Site Proposals (secure funding)	Activate SAHPRA Review Pathway	Develop Scenario-Based Demand Forecasts
	Conduct Implementation Research Landscape Analysis	Activate Regional Regulatory Reliance	Finalize Advance Purchase Agreements
Accessibility	Implementation & Delivery Strategy	Health System Resilience	Innovative Financing & Access
	Identify Target Groups and Delivery Platforms	Implement Facility Readiness, Policy and Guidelines, HCW Training	Establish Multi-Sectoral Financing Task Force
	Finalize Tiered Rollout Sequencing Plan	Upgrade Digital and AEFI Systems	Develop TB Vaccine Investment Case and Dedicated Funding
Acceptability	Value & Trust Foundation	Community Co-creation	Transparent Communication
	Conduct Acceptability Studies	Formalize Civil Society Inclusion in Policy Dialogues	Establish a National Stigma-Reduction Messaging Framework
	Develop TB-Specific "Vaccine Value" Briefs	Co-design "Trusted Space" Delivery Pilots	Deploy Culturally Adapted Digital Media Strategies

Evidence Gaps

Evidence Gaps	Description & Rationale
Sub-Population Effectiveness	Effectiveness in well-controlled PLHIV and IGRA negative (25-60% of South Africans).
Sub-Population Safety & Efficacy	Safety and effectiveness data for groups often excluded from primary trials, including 2.3 million uncontrolled PLHIV, pregnant/lactating women, elderly.
Previous TB Disease	Safety and duration of protection for the 15–20% of South Africans with a history of previous TB
IGRA Positivity & Mapping	Mapping latent TB infection (LTBI) rates across provinces to define the eligible population and refine targeting.
Asymptomatic TB	Determining vaccine performance in individuals with subclinical/asymptomatic TB at the time of vaccination.
Acceptability & Behavioral Insights	Identifying end-user preferences, optimal messaging, and potential barriers to uptake among adolescents and adult men.
Delivery Feasibility	Testing the "Fixed + Outreach" hybrid model in real-world settings to identify cold chain or human resource bottlenecks.
Economic Modeling & Scenarios	SA-specific CEA, absolute costs and budget impact analysis based on various efficacy levels and implementation scenarios (e.g., adolescent vs. catch-up).

Target groups?



Population	No. of people in the country in 2023	TB burden in 2023 (incidence)
Adolescents (12-17 years)	5.3 million (UN Population)	427 in 100k population ¹
Adults (18-64 years)	37.4 million (UN Population)	427 in 100k population ¹
People living with HIV	10.2 million (IHME)	4200 per 100,000 population ⁶
Household contacts	0.26 million (WHO TB Report)	1300 per 100,000 population ⁶
Healthcare workers	0.2 million (WHO)	1470 per 100,000 population ⁶
People living with diabetes	4.5 million (Diabetes Atlas)	1240 per 100,000 population ⁶
Informal settlements	5.5-6 million (Statistics South Africa)	4500 per 100,000 population ⁶
Inmates	157,000 (RSA Dept of Correctional Services)	3900 per 100,000 population ⁶
Miners	471,882 (Statistics South Africa)	3000 per 100,000 population ⁶

Vaccine cost and supply uncertainty necessitates targeted roll-out
Permissive labelling important
Phased expansion as supply improves

Rollout plan?



Target groups	PLHIV cost-effective and efficient Adolescents greatest impact and highly cost-effective General population (irrespective of HIV) broader population-level impact at a higher cost	
Geographic	5 metropolitan districts accounting for 35% of national TB cases Informal settlements with documented high transmission rates	
Low Availability	Medium Availability	High Availability
Goal: Maximise impact per dose	Goal: Balance risk and transmission	Goal: Population-level impact
Priority: PLHIV, HCWs Focus on high-burden districts	Expand to informal settlements, inmates, miners Adolescents in high-burden districts	All high-risk groups + adolescents + adults
Delivery: ART clinics, occupational health	Delivery: PHC, schools, workplaces	Delivery: 3-year PHC campaign plus school-based adolescent immunization

Vaccine Hesitancy?

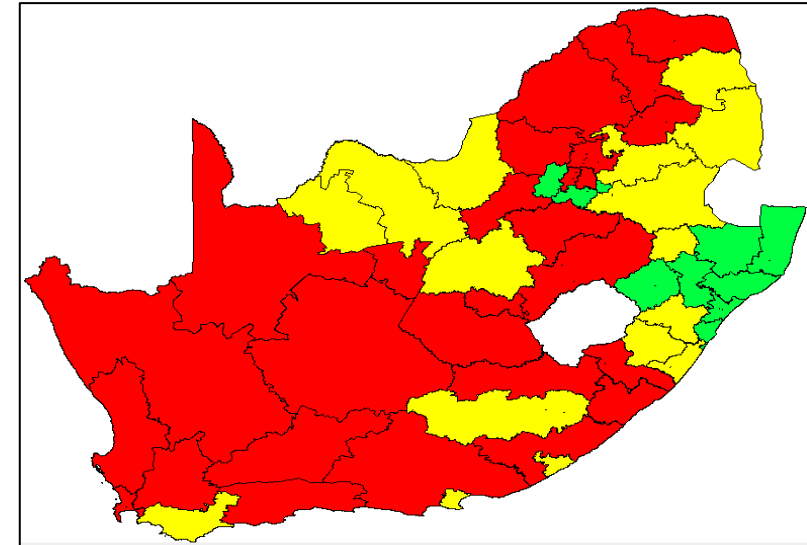
- Routine immunization coverage declining, especially post-COVID (trust deficits, product confidence, misinformation)
 - Institutional trust
 - Access barriers
 - Social perceptions
 - Information ecosystems
- Low public awareness of TB vaccine development and benefits
- Concerns around HCW confidence in TB vaccines



"I will not take the TB vaccine. If a patient comes to my clinic and requests it, I will vaccinate them. But if they ask me if I think they should take the TB vaccine, I will say no."

TB nurse (Mpumalanga)

IMMUNISED COVERAGE <1YEAR



LEGEND		NO. OF DISTRICTS
	≥ 90.0%	9
	80% - 89.9%	16
	< 80.0%	27

TB Vaccine Technical Support and Research Ecosystem

TB Think Tank Prevention Task

Team: Engage stakeholders and provide guidance to NDoH



Wellcome Trust/ UCT VACFA: **TIMBER Study:**
NITAG-led Co-development of Model-Based
Recommendations for Introduction and
Implementation of New TB Vaccines (SA, Gambia,
Kenya). Research fellow to support NAGI



<https://health.uct.ac.za/vacfa/timber-study>

South African TB vaccine readiness consortium:

- Post-licensure studies and demonstration sites
- Communication strategies



Vaccine acceptability studies

Integrated model of delivery

WellmodTB (Aurum/ LSHTM):

- latent TB prevalence study
- Modelling potential cost, budget and epidemiological impact
- Develop a TB vaccine demand forecast

Wellcome Trust/CHAI: potential demand and introduction scenarios

Thank you