World Health Organization | IVB

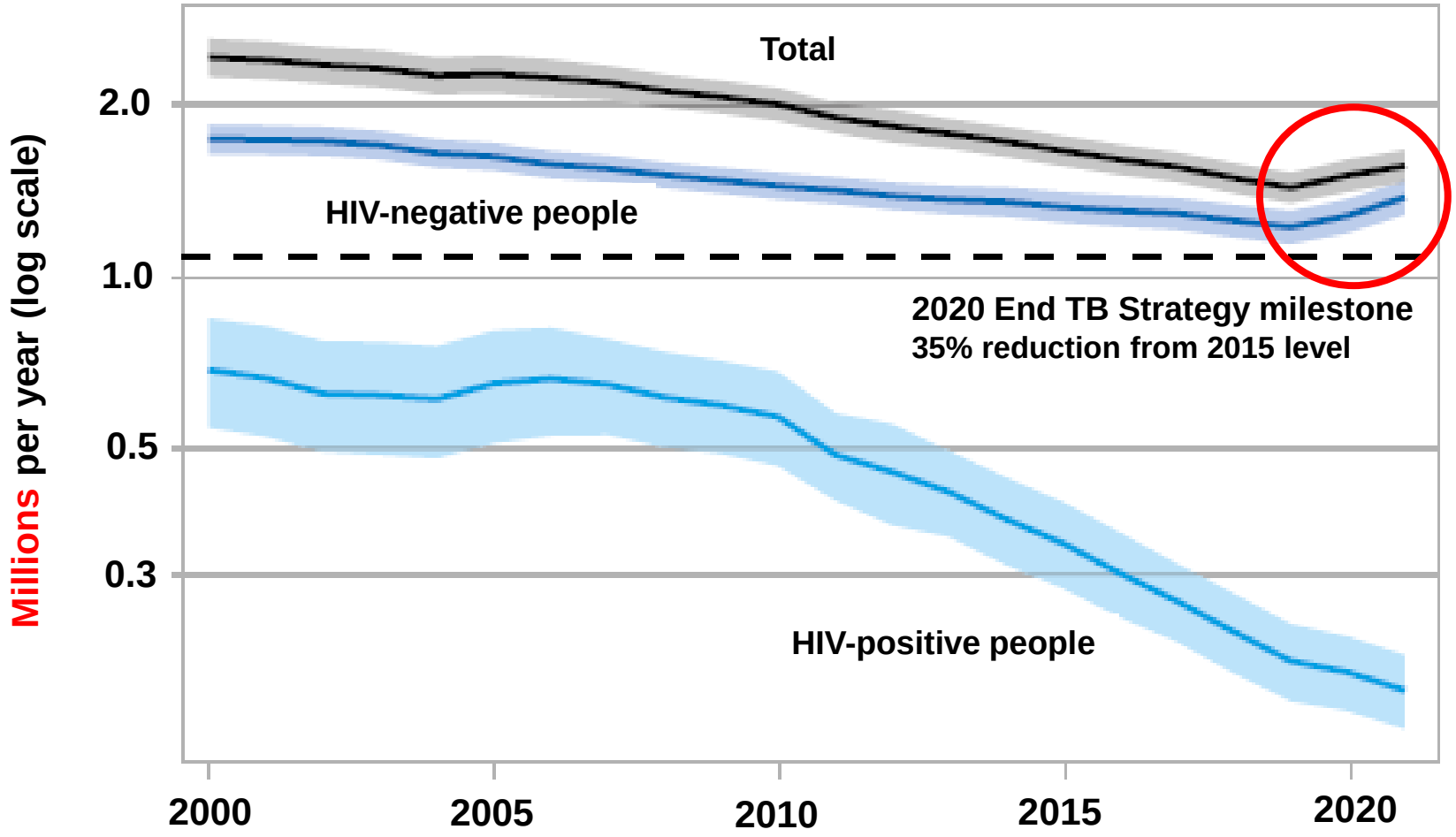
WHO activities to accelerate TB vaccine development and use

Birgitte Giersing, PhD
Dept of Immunizations, Vaccines and Biologicals

4th April 2023

Global number of TB deaths increased in 2020 and again in 2021, back to 2017 level

TB second only to COVID-19 as cause of death from single infectious agent



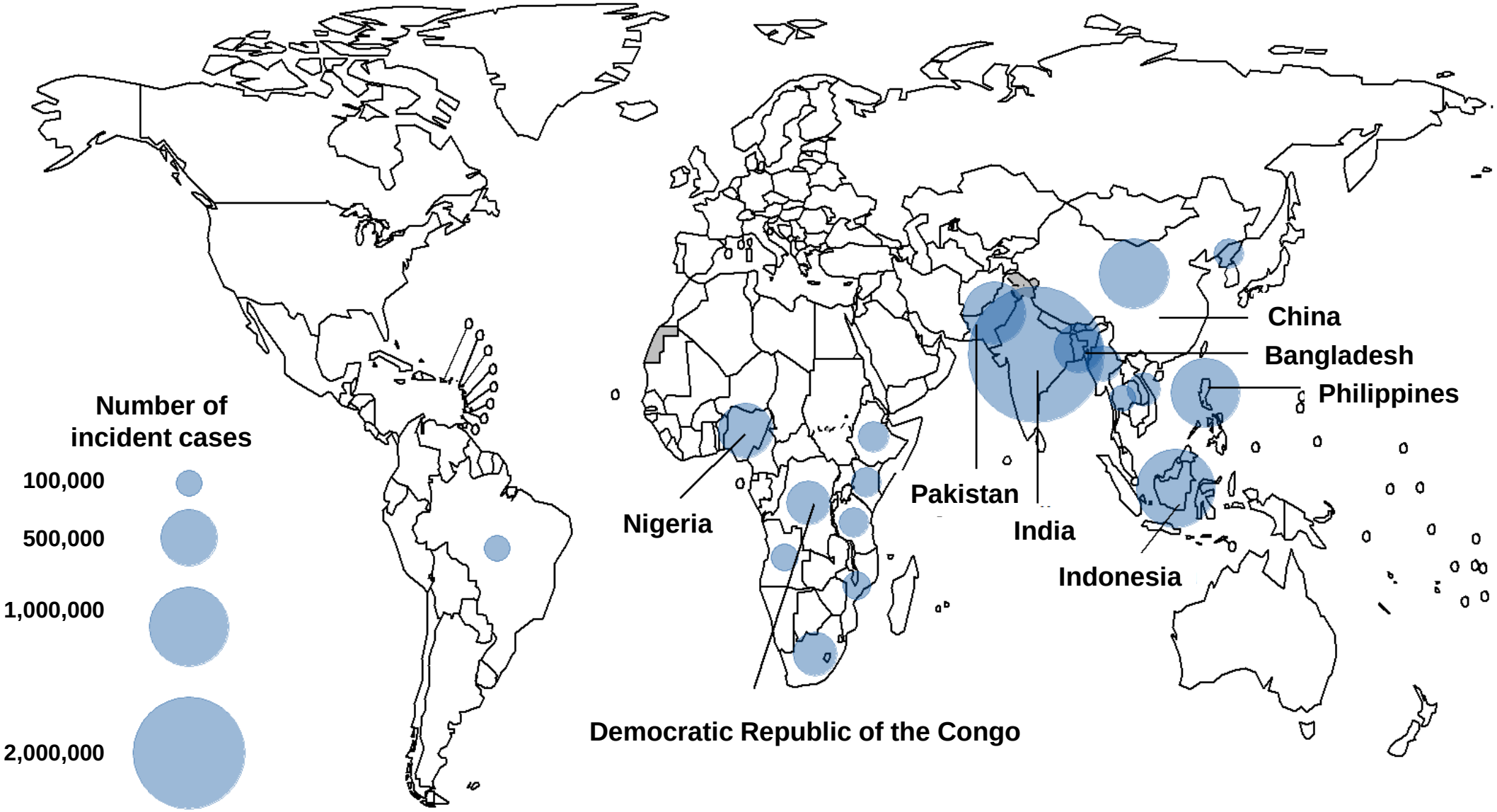
1.6 million in 2021, up from 1.5 million in 2020 and 1.4 million in 2019

187,000, down from 201,000 in 2020

World Health Organization

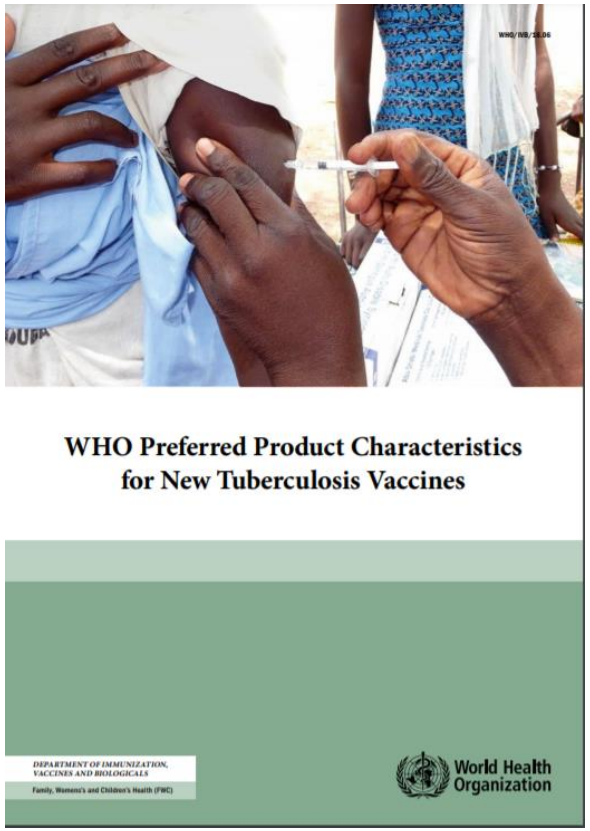
8 countries, 68% of global cases in 2021

87% in 30 high TB burden countries



World Health Organization

In 2014, WHO developed guidance on the preferred product characteristics for new vaccines to inform developers



The WHO PPC document captures most key clinical and regulatory considerations for TB vaccines:

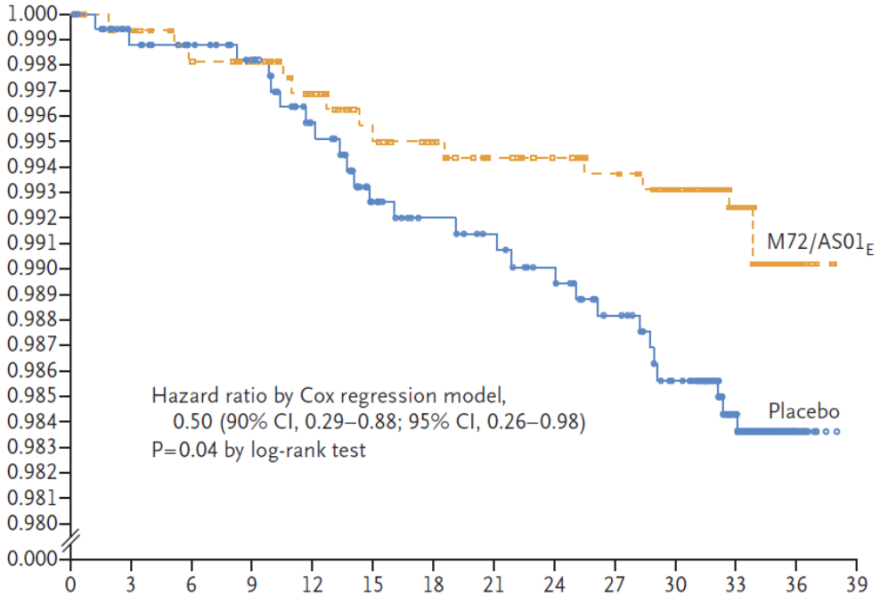
- ✓ Indication
- ✓ Target population
- ✓ Outcome measure; efficacy
- ✓ Duration of protection (at licensure; eventually)
- ✓ Safety
- ✓ Schedule
- ✓ Co-administration

Please see WHO vaccine PPC & Roadmap guidance documents under:
Product Development for Vaccines Advisory Committee and PPCs

One candidate, M72, has met the criteria of the WHO vaccine characteristics (and others are coming)

VI. PPC FOR NEW TUBERCULOSIS VACCINES: USE IN ADOLESCENTS AND ADULTS

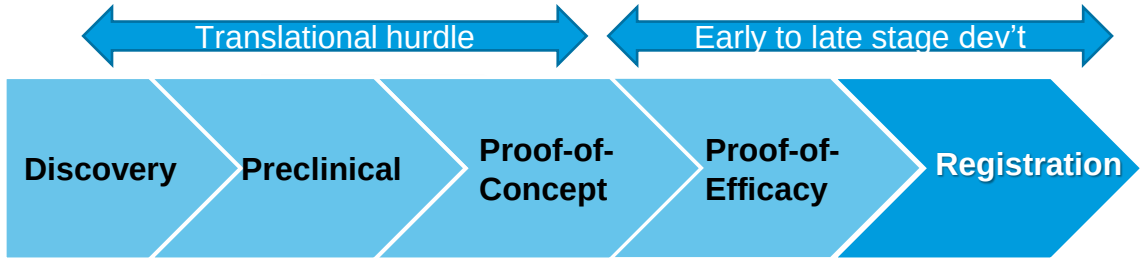
Parameter	Preferred Characteristic	Comments
Indication	Immunization for prevention of active pulmonary TB disease.	
Target population	Adolescents and adults.	Adolescents and adults with TB disease represent the most common sources of *Mtb* spread and are therefore the WHO priority target for TB vaccine development. Demographic changes in some high endemicity countries justify inclusion of older adults in the target population. The optimal timing for paediatric evaluation should be discussed with regulators and policy makers but a paediatric clinical development program should certainly be considered when proof of concept is established in adolescents and adults.
Outcome measure and efficacy	50% or greater efficacy in preventing confirmed pulmonary TB.	A vaccine with lesser vaccine efficacy against confirmed TB in adolescents and adults, if widely used in areas of high TB endemicity, may still prove valuable and contribute to reducing the spread of *Mtb* in a cost-effective way *(4)*, but this would fall short of the requirements necessary to meet the End TB goals by the 2035 target date.
Schedule	A minimal number of doses and boosters required.	A requirement for more than three doses to achieve primary immunization would not be desirable due to logistical and cost concerns.

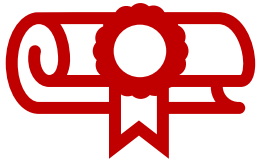


- **M72/AS01$_{E-4}$ met key criteria** of the WHO PPC for adult/adolescent TB vaccines.
- The phase III efficacy study will begin in Q1 2024

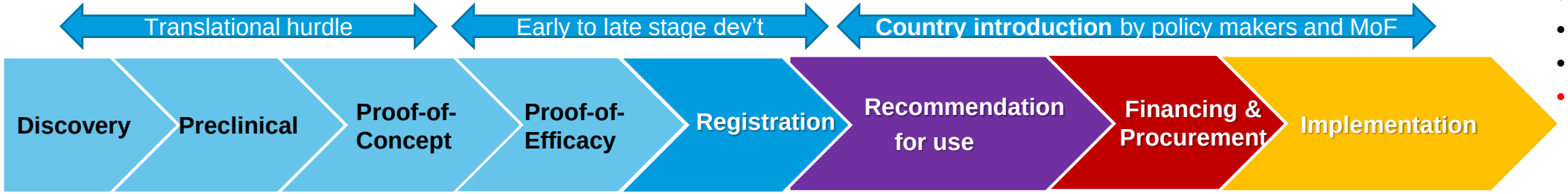
http://apps.who.int/iris/bitstream/handle/10665/273089/WHO-IVB-18.06-eng.pdf5

Steps along the pathway to vaccine licensure- **and use**

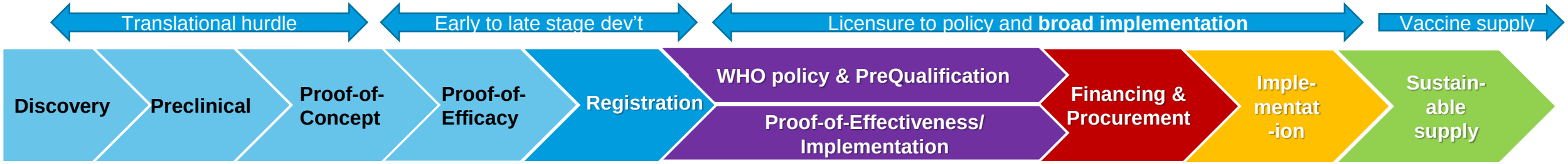




Regulatory approval:
- Safety
- Quality
- Efficacy

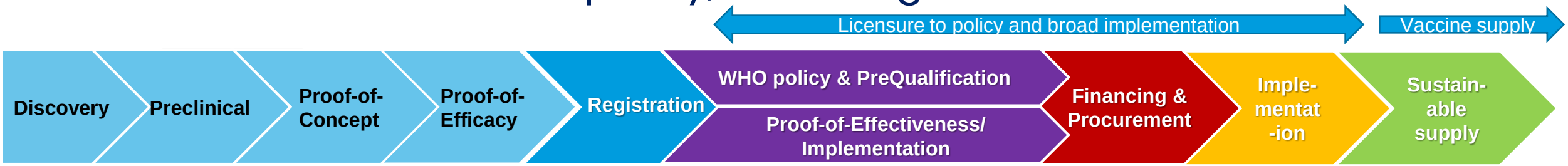


In countries
- Feasibility,
- Acceptability,
- Cost effectiveness
- Cost benefit
- Self procuring countries could be early adopters



Globally:
- Data related to programmatic fit
- Data from sufficiently diverse and representative disease contexts
- ….and populations

The data expectations for decision-making become more complex as a vaccine advances to policy, financing and introduction



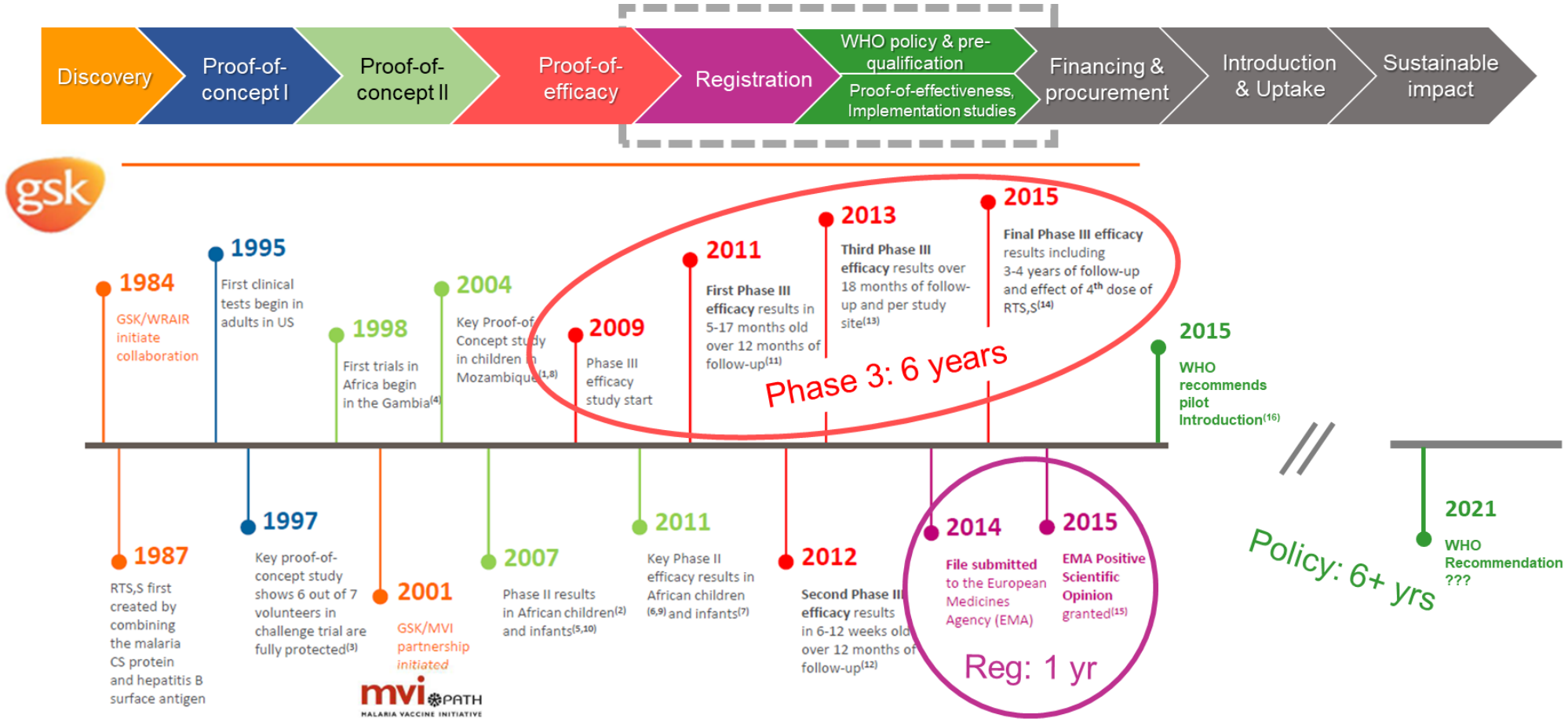
PPC Parameter	WHO Policy Recommendation parameter	Gavi Vaccine Investment Strategy (VIS) Parameter
Indication for use, Target population, Contraindications	Recommendation(s) for use (Burden / recommended targeted risk population(s) by epi setting(s); other populations (permissive /contraindicated); geographies (regional, national, subnational), etc)	
Efficacy Durability of protection	Benefits (pre-clinical and clinical; *direct*: effectiveness / preventable disease, and duration of protection; *indirect:* herd effect; etc)	**Health impact** Broader health system benefits
Safety & reactogenicity	Harm (pre-clinical and clinical; safety/ tolerability; benefit-harm-acceptance assessment; etc)	
Dose regimen, Route of administration, Co-administration, Formulation/presentation Product stability and storage	Feasibility (implementation considerations: regimen, route, setting(s); storage, delivery, etc.) Resource Use (*Costs:* illness; product & implementation; *Cost-effectiveness*; *Supply and wastage*: vaccine & delivery considerations; etc.)	Implementation feasibility
Accessibility	Values & Preferences (related to intervention & comparative health outcomes) Equity (Vaccine access; health, social, economic security, human rights/civil liberties, etc.) Acceptability (by stakeholders; affordability, etc)	Vaccine cost **Value for money** Operational cost **Equity & social protection impact** **Economic impact** Additional implementation costs Global health security impact Gavi comparative advantage

Source: WHO TPP for COVID-19 vaccines

Source: SAGE Guidelines development recommendations

Source: Gavi Vaccine Investment Strategy

Timelines for the malaria vaccine RTS,S (Mosquirix) from concept to the point of consideration for global policy recommendation



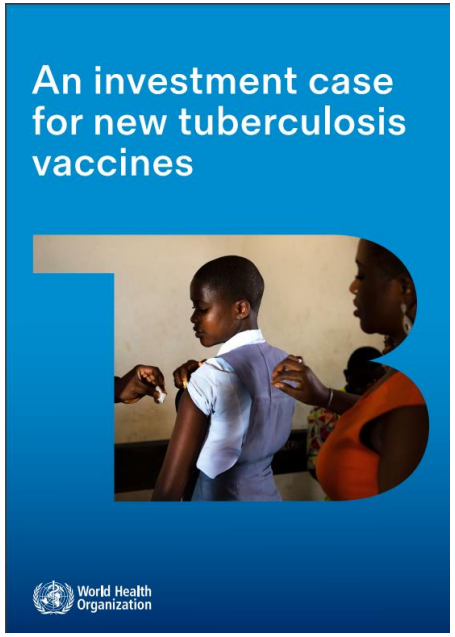
(1) Alonso P et al. Lancet 2004; (2) Aponte J et al. Lancet 2007; (3) Stoute J et al. NEJM 1997; (4) Doherty J et al. AJTMH 1999; (5) Bejon P et al. NEJM 2008; (6) Olotu A et al. Lancet ID 2011; (7) Asante KP et al. Lancet ID 2011; (8) Sacarlal J et al. JID 2009; (9) Agnandji ST et al. JID 2010; (10) Abdulla S et al. NEJM 2008; (11) RTS,S Clinical Trials Partnership. NEJM 2011; (12) RTS,S Clinical Trials Partnership. NEJM 2012; (13) RTS,S Clinical Trials Partnership, PLoS Med 2014; (14) RTS,S Clinical Trials Partnership, Lancet 2015; (15) www.ema.europa.eu; (16) www.who.int/immunization/research/development/malaria_vaccine_qa/en/

https://www.sciencedirect.com/science/article/pii/S0264410X21013955?via%3Dihub

Alignment and co-ordination of stakeholders is crucial to achieving access and impact of new TB vaccines

Extensive work on assessing the ‘full’ value of new TB vaccines by LSHTM and Harvard, under WHO framework

- Articulates the full value of new TB vaccines from the perspectives of multiple stakeholders
- Serves as an **end-to-end** compendium of available **evidence** to support advocacy and inform **decision making** at **various stages** of **product development**



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

The impact of alternative delivery strategies for novel tuberculosis vaccines in low-income and middle-income countries: a modelling study

Rebecca A Clark, Christinah Mukandavire, Allison Portnoy, Chathika K Weerasuriya, Arminder Deol, Danny Scarponi, Andrew Iskauskas, Roel Bakker, Matthew Quaife, Shelly Malhotra, Nebiat Gebreselassie, Matteo Zignol, Raymond C W Hutubessy, Birgitte Giersing, Mark Jit, Rebecca C Harris, Nicolas A Menzies, Richard G White

PLOS MEDICINE

RESEARCH ARTICLE

The cost and cost-effectiveness of novel tuberculosis vaccines in low- and middle-income countries: A modeling study

Allison Portnoy[1*], Rebecca A. Clark[2,3,4], Matthew Quaife[2,3,4], Chathika K. Weerasuriya[2,3,4], Christinah Mukandavire[2,3,4], Roel Bakker[2,3,4,5], Arminder K. Deol[2,3,4,6], Shelly Malhotra[7,8], Nebiat Gebreselassie[9], Matteo Zignol[9], So Yoon Sim[10], Raymond C. W. Hutubessy[10], Inés Garcia Baena[9], Nobuyuki Nishikiori[9], Mark Jit[3,4,11], Richard G. White[2,3,4‡], Nicolas A. Menzies[1,12‡]

Category	Needs
Health gains	Estimated potential impact of new TB vaccines on disease burden and transmission (including drug-resistant TB (DR-TB) and co-infection with HIV), as measured by incidence, mortality and morbidity (in the context of alternative strategies)
Value for money	Estimated societal cost-effectiveness/cost-utility and return on investment for new TB vaccines from the perspective of both the healthcare payer and society
Equity and financial risk protection impact	Estimated impact of a new TB vaccine on equity (in the context of health gains by income distribution and vulnerability) and reduced household financial vulnerability (catastrophic costs and impoverishment)
Economic impact	Estimated impact of new TB vaccines on medical and other expenses, as well as on gross domestic product and its rate of growth; estimated impact of new TB vaccines on government expenditure (including expenditure through the HIV response, as applicable) and on sustainability of financing over the long term
Global health security impact	An estimated impact of a new TB vaccine on antimicrobial stewardship (reducing antibiotic use, mitigating the reduced effectiveness of antimicrobials from continued use, reducing DR-TB disease incidence, reducing human and programmatic costs of DR-TB management, and improving health outcomes)
Market	Estimated potential demand for new TB vaccines
Vaccine characteristics and implementation scenario assumptions	The various parameters above should be evaluated under different vaccine characteristics and implementation scenario assumptions (target population, geographical scope and vaccine characteristics) In addition, the interaction between a new vaccine and alternative strategies (optimal use of current and future alternative interventions) on key outputs should be considered

European Respiratory Journal 2020 55: 1902414; **DOI:** 10.1183/13993003.02414-2019

WHO covened a series of workshops in 2021-22 to map what is needed

1. Public health need for a new TB vaccine at the country level
considers the disease burden, existing interventions and criteria for decision-making, i.e. what data is needed?

2.Regulatory Strategy
outlines the proposed licensure pathway for first licensure and subsequent regulatory approvals including in additonal key populations

3. National/Global Policy Making
evaluates the potential vaccine impact and cost-effectiveness , based on anticipated use case

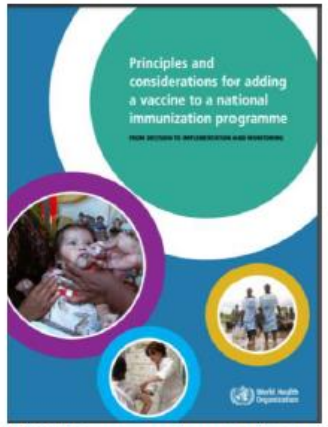
4. Manufacturing Scale up & Commercialization
considers the global market, potential scale and price, manufacturing capacity

WHO PQ

5. Financing, Supply, & Access
considers the potential financing and procurement mechanisms to ensure access to LMICs

Self-procuring countries

Country, regional and global implementation of new TB Vaccines



Source:
https://apps.who.int/iris/bitstream/handle/10665/111548/9789241506892_eng.pdf;sequence=1

WHO covened a series of workshops in 2021-22 to map what is needed

1. Public health need for a new TB vaccine at the country level
considers the disease burden, existing interventions and criteria for decision-making, i.e. what data is needed?

2.Regulatory Strategy
outlines the proposed licensure pathway for first licensure and subsequent regulatory approvals including in additonal key populations

3. National/Global Policy Making
evaluates the potential vaccine impact and cost-effectiveness , based on anticipated use case

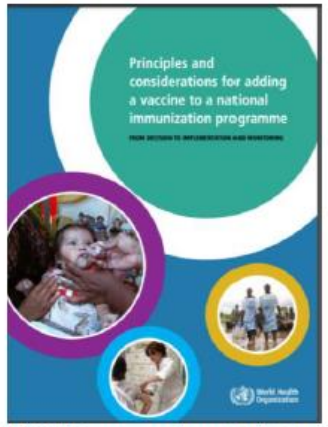
4. Manufacturing Scale up & Commercialization
considers the global market, potential scale and price, manufacturing capacity

WHO PQ

5. Financing, Supply, & Access
considers the potential financing and procurement mechanisms to ensure access to LMICs

Self-procuring countries

Country, regional and global implementation of new TB Vaccines



Source:
https://apps.who.int/iris/bitstream/handle/10665/111548/9789241506892_eng.pdf;sequence=1

Key variables to consider for the development of M72/AS01E demand forecast scena

MMGH CONSULTING

Country scope and pace of introduction	Scope of vaccination (national/subnational)	Booster dose requirements	Availability of vaccine supply
Which countries will introduce the vaccine?	Will introduction be done at a national or subnational scale?	Will booster doses be required?	How much vaccine supply will be available?
For countries electing to introduce, what will be the year of introduction?	Will all populations be targeted or only risk groups?	What is the frequency of boosters? Which populations are eligible?	How quickly will supply reach maximum volumes?

Vaccination coverage

- Vaccination coverage is a key variable, if anticipated to vary significantly (e.g., 10-80%)
- This forecast is aimed at understanding influence of other key programmatic variables that could cause large variance in demand, assuming narrower ranges in vaccination coverage

Slide courtesy of MMGH

WHO covened a series of workshops in 2021-22 to map what is needed

1. Public health need for a new TB vaccine at the country level
considers the disease burden, existing interventions and criteria for decision-making, i.e. what data is needed?

2.Regulatory Strategy
outlines the proposed licensure pathway for first licensure and subsequent regulatory approvals including in additonal key populations

3. National/Global Policy Making
evaluates the potential vaccine impact and cost-effectiveness , based on anticipated use case

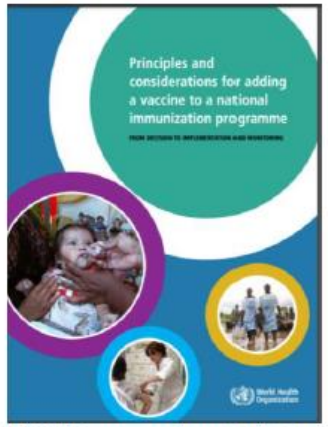
4. Manufacturing Scale up & Commercialization
considers the global market, potential scale and price, manufacturing capacity

WHO PQ

5. Financing, Supply, & Access
considers the potential financing and procurement mechanisms to ensure access to LMICs

Self-procuring countries

Country, regional and global implementation of new TB Vaccines



Source:
https://apps.who.int/iris/bitstream/handle/10665/111548/9789241506892_eng.pdf;sequence=1

WHO is attempting to articulate the needs for global policy recommendations NOW, so that that data and evidence can be generated

PPC Parameter	WHO Policy Recommendation parameter	Gavi Vaccine Investment Strategy (VIS) Parameter
Indication for use, Target population, Contraindications	Recommendation(s) for use (Burden / recommended targeted risk population(s) by epi setting(s); other populations (permissive /contraindicated); geographies (regional, national, subnational), etc)	
Efficacy Durability of protection	Benefits (pre-clinical and clinical; *direct*: effectiveness / preventable disease, and duration of protection; *indirect:* herd effect; etc)	**Health impact** Broader health system benefits
Safety & reactogenicity	Harm (pre-clinical and clinical; safety/ tolerability; benefit-harm-acceptance assessment; etc)	
Dose regimen, Route of administration, Co-administration, Formulation/presentation Product stability and storage	Feasibility (implementation considerations: regimen, route, setting(s); storage, delivery, etc.) Resource Use (*Costs:* illness; product & implementation; *Cost-effectiveness*; *Supply and wastage*: vaccine & delivery considerations; etc.)	Implementation feasibility
Accessibility	Values & Preferences (related to intervention & comparative health outcomes) Equity (Vaccine access; health, social, economic security, human rights/civil liberties, etc.) Acceptability (by stakeholders; affordability, etc)	Vaccine cost **Value for money** Operational cost **Equity & social protection impact** **Economic impact** Additional implementation costs Global health security impact Gavi comparative advantage

Source: WHO TPP for COVID-19 vaccines

Source: SAGE Guidelines development recommendations

17

Source: Gavi Vaccine Investment Strategy

Structure of the ECVP guidance

The ECVP is based on SAGE's **Evidence to Recommendation** framework and includes five tables:

- Table 1: Vaccine Product Related Parameters for priority populations
- Table 2: Vaccine Delivery related Parameters for the priority populations, including delivery strategy/setting
- Table 3: Vaccination of other target populations (clinical and delivery considerations)
- Table 4: Regulatory Strategy Considerations to facilitate policy review
- Table 5: Implementation Considerations (data for decision making e.g. used in Gavi VIS)

Tables 1,2 and 3 identify evidence needs for **initial (IP) and expanded (EP) policy** recommendations

Each section identifies:

o **High Priority** parameters in red: expected to be critical for SAGE and other policy bodies at the regional and country level;

o **Medium Priority** parameters in blue: for which data and evidence are likely to be beneficial for policy recommendation.

Where are we now, with the ECVP tool and the TB vaccine ECVP?

World Health Organization

Health Topics | Countries | Newsroom | Emergencies | Data | A

Home / Publications / Overview / WHO Evidence Considerations for Vaccine Policy Development (ECVP)

WHO Evidence Considerations for Vaccine Policy Development (ECVP)

Draft document

22 August 2022 | Technical document

Download (603.2 kB)

Overview

WHO's IVB department has developed a novel kind of guidance for vaccine development stakeholders, referred
Evidence Considerations for Vaccine Policy, or ECVP. The ECVP document aims to provide early information o
data and evidence that is likely to be required to support WHO policy recommendations. The original concept o
ECVP was developed through a global stakeholder meeting (published here), after which both a generic ECVP
framework (posted on this page) and subsequently the first ECVP exemplar has been drafted for new Tuberculo
(TB) vaccines intended for adults and adolescents in collaboration with a global expert technical working group.
link to the TB vaccine ECVP can be found here:

Public consultation of ECVP for TB vaccines intended for adults and adolescents.

Generic ECVP framework is available on IVB website

World Health Organization

Health Topics | Countries | Newsroom | Emergencies | Data | A

Home / Publications / Overview / Public consultation of ECVP for TB vaccines intended for adults and adolescents

Public consultation of ECVP for TB vaccines intended for adults and adolescents

25 September 2022 | Technical document

Download (1.2 MB)

Overview

WHO's IVB department has developed a novel kind of guidance for vaccine development stakeholders, referred to as Evidence Considerations for Vaccine Policy, or ECVP. The ECVP document aims to provide early information on the data and evidence that is likely to be required to support WHO policy recommendations. The first ECVP exemplar has been drafted for new Tuberculosis (TB) vaccines intended for adults and adolescents, in collaboration with a global expert technical advisory group.

The primary audience for this TB vaccine ECVP includes all stakeholders intending to support the product development, regulatory approval, introduction and widespread use of new TB vaccines intended for adults and adolescents, in low- and middle-income countries, with the aim of reducing delays between vaccine regulatory approval and vaccine introduction.

We invite all those interested in the ECVP for new Tuberculosis (TB) vaccines intended for adults and adolescents to review this draft document and provide comments on both the general utility of the document, and the specific guidance developed for new TB vaccine. Please use the comment form to capture your comments and return to: vaccines@who.int. **Please use the term "TB vaccine ECVP" in the subject line, otherwise your comments will not be received.** The document will be posted until the **28th October 2022** for comment.

ECVP for TB vaccines intended for adults and adolescent vaccines has been through public consultation and is being finalized.

Initial policy considerations outlined in ECVP for TB vaccines for adults and adolescents

- Data demonstrating **prevention of pulmonary TB disease** as the primary endpoint, to ensure the most rapid impact on the TB epidemic due by reducing transmission.
- Data demonstrating safety and 50% or greater efficacy in preventing confirmed pulmonary TB
- **Efficacy data in adults with evidence of prior Mtb infection**
- **Safety and immunogenicity data** in adults **without evidence of prior Mtb infection**, to avoid the need for screening prior to vaccination.
- Safety and immunogenicity data from **people living with HIV**.
- Efficacy data from sufficiently **diverse representative geographies** to support global policymaking.
- A safety and reactogenicity profile supportive of widespread use of a preventive vaccine.
- Data demonstrating **duration of protection** for the disease indication of at least **2 years**.
- Dosing regimens, schedule and **delivery** strategy designed for optimal cost-effectiveness and to achieve equitable impact, **integrated within primary healthcare delivery systems**
- Data relating to end-user acceptability, based on community engagement to ensure **vaccine acceptance**.

WHO covened a series of workshops in 2021-22 to map what is needed

1. Public health need for a new TB vaccine at the country level
considers the disease burden, existing interventions and criteria for decision-making, i.e. what data is needed?

2.Regulatory Strategy
outlines the proposed licensure pathway for first licensure and subsequent regulatory approvals including in additonal key populations

3. National/Global Policy Making
evaluates the potential vaccine impact and cost-effectiveness , based on anticipated use case

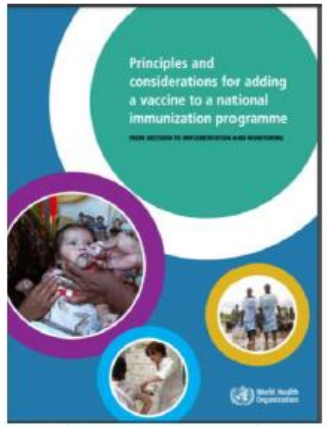
4. Manufacturing Scale up & Commercialization
considers the global market, potential scale and price, manufacturing capacity

WHO PQ

5. Financing, Supply, & Access
considers the potential financing and procurement mechanisms to ensure access to LMICs

Self-procuring countries

Country, regional and global implementation of new TB Vaccines



Source:
https://apps.who.int/iris/bitstream/handle/10665/111548/9789241506892_eng.pdf;sequence=1

WHO developing a global framework for country introduction of new adolescent and adult TB vaccines

Vision & Purpose

A world free of TB, with zero deaths, disease, and suffering due to TB

Facilitate rapid introduction and scale up of new adult and adolescent TB vaccines

Goals

Available	Accessible	Accepted
Sufficient, sustainable, and timely supply	Equitable delivery aimed at all who could benefit	Policymakers, end-users and health system requirements met

Milestones

Available	Accessible	Accepted
• **Demand assessed** (for short, medium and long term for priority populations; with regard to other interventions) • **Policy, evidence needs, and pathways defined** (e.g., approvals, recommendations, efficacy, and safety data required, specific populations; country testing) • **Procurement plans in place** (e.g., agreements with local and global manufactures, including on price, quantity and timing)	• **Implementation strategy defined** (for priority populations; vis-á-vis interaction between primary health care, TB, HIV, school health, EPI programs; private providers) • **Delivery systems in place** (capacity; infrastructure; supply chains; pharmacovigilance; vaccine efficacy; phase IV studies) • **Sustainable financing strategy in place** (e.g., national health sector strategy, the Global Fund, Gavi, private pay)	• **Value defined** (i.e., at individual and population levels and from perspective of health workers, policy makers, vaccinees; vis-á-vis safety and efficacy) • **Community engaged** (i.e., priority populations, TB survivors, health workers, advocates, policymakers) • **Robust communications strategy in place** (e.g., localized; responsive to community concerns and priorities)

Approach

Accelerated, Coordinated, Integrated, People-centred, Equity-driven, Evidence-based

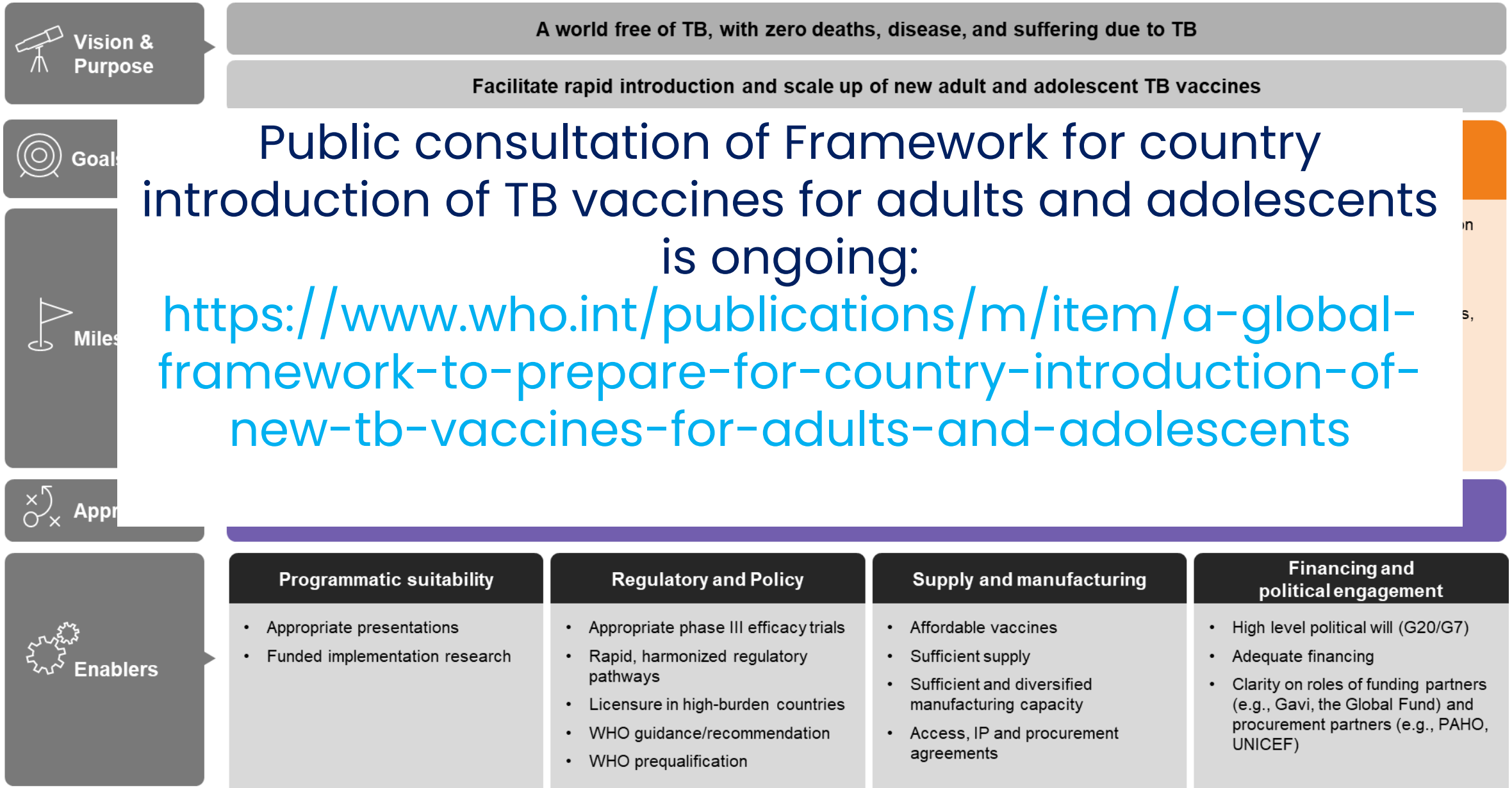
Enablers

Programmatic suitability	Regulatory and Policy	Supply and manufacturing	Financing and political engagement
• Appropriate presentations • Funded implementation research	• Appropriate phase III efficacy trials • Rapid, harmonized regulatory pathways • Licensure in high-burden countries • WHO guidance/recommendation • WHO prequalification	• Affordable vaccines • Sufficient supply • Sufficient and diversified manufacturing capacity • Access, IP and procurement agreements	• High level political will (G20/G7) • Adequate financing • Clarity on roles of funding partners (e.g., Gavi, the Global Fund) and procurement partners (e.g., PAHO, UNICEF)

Some activities under the different goals are related and should be tackled collectively

		Available			Accessible			Accepted			Timeframe (Short, Medium)
		Demand assessed	Policy/evidence needs/pathways defined	Procurement plans in place	Implementation strategy defined	Delivery system in place	Sustainable financing strategy in place	Value defined	Community engaged	Robust communications strategy in place	
Available	**Robust vaccine estimates for country demand**										
	Country-level modelling of demand	✓			✓				✓		S, M
	Evaluate vaccine health and economic impact	✓			✓				✓		S, M
	Engage TB programs and other national stakeholders to develop a robust demand forecast	✓								✓	S, M
	National policy pathway defined, and evidence gaps identified										
	Define milestones/criteria for data and evidence requirements to inform policy decisions		✓							✓	S
	Gather evidence needs for policy in parallel with clinical development for inclusion in regulatory dossier, streamline processes for rapid approval		✓								S
	Conduct pre-implementation research		✓		✓						S, M
	Procurement plans in place										
	Facilitate dialogue between manufacturers, regulators, and procurement partners	✓		✓				✓		✓	S
	Secure pricing and volume commitments from manufacturers	✓		✓						✓	M
	Assess the role of local and regional manufacturers	✓		✓						✓	M

WHO developing a global framework for country introduction of new adolescent and adult TB vaccines



Public consultation of Framework for country introduction of TB vaccines for adults and adolescents is ongoing:

https://www.who.int/publications/m/item/a-global-framework-to-prepare-for-country-introduction-of-new-tb-vaccines-for-adults-and-adolescents

UN high-level meeting on TB, 2023

LEADERSHIP:
OFFICE OF THE PRESIDENT OF THE GENERAL ASSEMBLY with UNSG and WHO
H.E. Mr Csaba Kőrösi, President of the UN General Assembly

Date: **22 September, 2023**
Where: UN Headquarters, New York

Co-facilitators:
Uzbekistan and Poland

HLM outcome: **concise and action-oriented political declaration, agreed in advance by consensus through intergovernmental negotiations**

CIVIL SOCIETY HEARING: 8-9 May, 2023

Participants:
UN Member States at the highest possible level, preferably at the level of Heads of State and Government; observers of the General Assembly; NGOs, civil society organizations, academic institutions and the private sector

World Health Organization

WHO announces plans to establish a TB Vaccine Accelerator Council

17 January | Davos - The adverse impact of the COVID-19 pandemic on tuberculosis (TB) services has brought the urgency of vaccine development efforts into sharp focus. Speaking earlier today at a high-level panel on TB at the World Economic Forum, Dr Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization, announced plans to establish a new TB Vaccine Accelerator Council.

The Council will facilitate the licensing and use of effective novel TB vaccines catalysing high-level alignment between funders, global agencies, governments and end users in identifying and overcoming barriers to TB vaccine development.

"One of the most important lessons from the response to the COVID-19 pandemic is

Acknowledgements – many!

- **ECVP working group members** (alphabetical order):
- ECVP working group chairs**:** Sonali Kochhar & Helen Rees
- Marco Cavaleri - EMA
- Huang Fei – China CDC
- Mike Frick - Treatment Action Group
- Gagandeep Kang – CMC Vellore/SEARO RITAG
- Noni McDonald - Dalhousie University
- Yalda Momeni - UNICEF
- Andrew Pollard – University of Oxford
- Richard White - LSHTM
- Yauba Saidu – CHAI/ Cameroon NITAG

Observers:

- Ann Ginsberg – BMGF (TB)
- Ian Hudson – BMGF (DAC)
- Shelley Malhotra – IAVI
- Alexander Schmidt - GMRI
- Marta Tufet/Cate Bennett - Gavi
- Susan Wang – US CDC
- Charlie Weller – Wellcome Trust
- Matteo Zignol, Nebiat Gebresselassie (WHO GTB)
- Sparks Street Advisors

Country Introduction Framework WG members:

- Babik Javid - UCSF
- Bader Al Ruwahi - Ministry of Health, Oman
- Carlos Martin - Universidad de Zaragoza
- David Lewinsohn . - OHSU Center for Global Child Health Research
- Gagandeep Kang - CMC, Vellore
- Gerald Voss – TBVI
- Jimmy Galarza –
- Kawser Choudhury – SEARO RITAG
- Muluken Melese Aseresa – MSH
- Patrick Agbassi – Village Reach
- Peter Smith – LSHTM
- Puck Pelzer – KNVC
- Richard White – LSHTM
- Shelly Malhotra - IAVI
- Yanfeng Lim - CHAI
- MMGH consulting