

WHO global framework to prepare for country introduction of new tuberculosis vaccines for adults and adolescents

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After a health education session on the prevention of chronic otitis media for students who have a hearing impairment at Mandaka Deaf Primary School in Moshi Municipality, 8-year-old Baraka, a class 3 pupil who is deaf, leaves school with his mother, Theresia.

Contents

Acknowledgements ..... **iv**

Declarations of interest ..... **iv**

Abbreviations and acronyms ..... **v**

Executive summary ..... **vi**

1. Background and context **1**

2. Rationale for the framework **3**

3. Development process **5**

4. Structural elements **6**

5. Goals, key milestones and activities **7**

Goal 1: New vaccine available: sufficient, sustainable and timely supply 8

Goal 2: New vaccine accessible: equitable delivery aimed at all who could benefit 11

Goal 3: New vaccine accepted: policy-makers, end-users, and health system requirements met 13

6. Integration of goals, milestones and activities **15**

7. Global and regional enablers for the introduction **17**

8. What is needed next? **19**

References **20**

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Declarations of interest

Declarations of any competing interests were received and evaluated from all expert applicants as part of the working group recruitment process. None of the stakeholders was considered to have any relevant conflicts.

Abbreviations and acronyms

ADIPs	accelerated development and introduction plans
AIGHD	Amsterdam Institute for Global Health and Development
AMR	antimicrobial resistance
BCG	Bacille Calmette-Guérin
CHAI	Clinton Health Access Initiative
COVID-19	coronavirus disease of 2019
DR-TB	drug-resistant tuberculosis
ECVP	evidence considerations for vaccine policy
EDCTP	European and Developing Countries Clinical Trials Partnership
EPI	Essential Programme on Immunisation
FVVA	Full Value of Vaccines Assessment
Gavi	Gavi, the Vaccine Alliance
Hib	*Haemophilus influenzae* type B
HPV	human papillomavirus
IAVI	International AIDS Vaccine Initiative
IP	intellectual property
MoF	Ministry of Finance
MoH	Ministry of Health
MoI	Ministry of Industry
Mtb	Mycobacterium tuberculosis
NIS	national immunization strategy
NITAG	National Immunization Technical Advisory Group
PAHO	Pan American Health Organization
PDVAC	Product Development for Vaccines Advisory Committee
PHC	primary health care
PPCs	preferred product characteristics
R&D	research and development
RITAG	Regional Immunization Technical Advisory Group
SAGE	Strategic Advisory Group of Experts on Immunization
TB	tuberculosis
TPT	tuberculosis preventive treatment
UN	United Nations
UNICEF	United Nations Children's Fund
WHO	World Health Organization

Executive summary

Tuberculosis (TB) is a major cause of ill health and one of the leading causes of death worldwide. Member States adopted a political declaration at a High-Level Meeting of the United Nations General Assembly in 2018 that committed countries to accelerate efforts to end the TB epidemic, with TB vaccines as the cornerstone for reaching future targets.

In support of this commitment by Member States, WHO seeks to advance the development and deployment of **new TB vaccines to prevent TB disease, with a focus on adolescents and adults in whom 90% of TB disease occurs**. TB prevention in these populations, responsible for most of the transmission, will have a significant impact on reducing TB disease and incidence in those at risk, including unvaccinated infants, children, older adults and other key populations, such as people living with HIV. Most countries, however, do not have a well established immunization platform for vaccine delivery to adults and adolescents.

With new TB vaccines still in the development phase, their effectiveness and the strategy for their integration will need to be determined in the context of in-country epidemiology and existing national TB control interventions. Anticipating and addressing the opportunities and challenges of vaccine delivery in different country contexts must start now, in parallel, to the late stage of vaccine development, to ensure the implementation of successful vaccines as rapidly as possible.

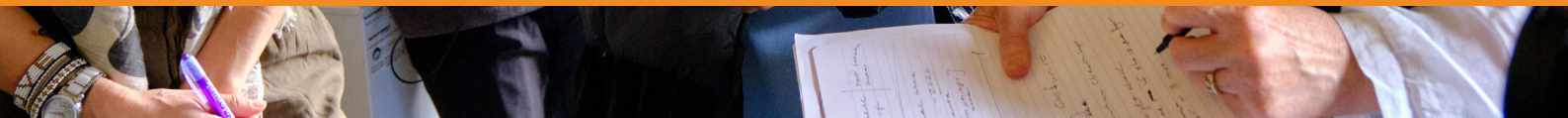
This framework intends to facilitate the planning, investments and preparation for the rapid introduction and scale-up of TB vaccines for adults and adolescents so that they are **available**, in that new vaccines are manufactured with sufficient, sustainable and timely supply; **accessible**, with equitable delivery aimed at all who could benefit; and **accepted**, so that end-users, health care workers, and policy-makers´ requirements are met. The framework supports and is aligned with the vision of the WHO's End TB Strategy to "achieve a world free of TB, with zero deaths, disease and suffering due to the disease" through rapid and equitable access to and distribution of new adolescent and adult TB vaccines.

This document intentionally focuses on activities at a national level, while also highlighting the global and regional activities that need to occur in tandem to accelerate equitable introduction and scale-up of new TB vaccines for adults and adolescents.

"This framework intends to facilitate the planning, investments and preparation for the rapid introduction and scale-up of TB vaccines for adults and adolescents"



WHO Technical Officer Kristen Kelleher (right) and community health worker Wezzie (centre) look over a child's vaccine passport in rural Lilongwe, Malawi, in this case as part of the WHO Malaria Vaccine Implementation Programme.
Photograph courtesy of WHO / Fanjan Combrink



1. Background and context

Approximately one quarter of the world's population, or 2 billion people, have been infected with Mycobacterium tuberculosis (Mtb). Of those infected, 5–10% will progress to active tuberculosis (TB) disease over their lifetimes. In 2021 alone, nearly 10.6 million people developed active TB disease, and 1.66 million died, with an estimated 1.4 million deaths among HIV-negative people and 18 000 deaths among HIV-positive people *(1)*.

TB is a disease mainly affecting people living in under-resourced conditions and is driven by health and socio-economic risk factors such as HIV infection, diabetes, smoking, undernutrition and poverty. Bacille Calmette-Guérin (BCG), the only available TB vaccine, is effective at preventing severe forms of TB disease in young children but has limited efficacy in preventing pulmonary TB disease in adolescents and adults, who are the main transmitters of Mtb. A world free of TB will only be achieved with the availability of new effective TB vaccines to complement improved preventative, diagnostic and curative tools.

In 2018, a United Nations High-Level Meeting set key targets and commitments to accelerate efforts to end the TB epidemic, which all Member States endorsed *(2)*. **To help achieve these targets, WHO seeks to advance the development and deployment of new TB vaccines to prevent TB disease in adolescents and adults in whom 90% of TB disease occurs.**[1] As several innovative TB vaccine candidates intended for use in adolescents and adults are either currently in or about to enter Phase 3 clinical trials *(1)*, **a vaccine for the prevention of TB disease in adolescents and adults could be available in the near term.**[2]

Preventing pulmonary TB disease in adolescents and adults, given their overwhelming contribution to Mtb transmission, is also likely to significantly impact the incidence of TB in those who are unvaccinated, including infants, children, older adults and other key populations, including people living with HIV and diabetes *(1)*. Vaccines for the prevention of pulmonary TB disease in adolescents and adults, with and without prior exposure to Mtb, are preferable, as screening for evidence of prior exposure before vaccination would likely be an impediment to efficient delivery and uptake *(3)*. New effective TB vaccines will also help decrease the use of antibiotics, circumvent the long-term effects of toxicity from current treatments, as well as reduce drug-resistant tuberculosis (DR–TB), which has become a significant public health crisis *(1)*. New vaccines can directly reduce the incidence of DR–TB and reduce the empiric use of antibiotic treatment for non-specific respiratory tract infections in people with undiagnosed TB *(4)*.

Given its contribution to antimicrobial resistance (AMR) and its impact on people living with HIV, TB is not just a public health emergency but also an economic one. The disease places a significant burden on health care systems and impedes economic development, particularly in low- and middle-income countries (LMICs). By investing in TB care, including new, effective TB vaccines, countries can reduce the burden of the disease and save lives while promoting economic growth and prosperity.

> "A world free of TB will only be achieved with the availability of new effective TB vaccines to complement improved preventative, diagnostic and curative tools."

Rapid introduction and coverage scale-up of new TB vaccines will require a significant upfront investment nationally, regionally and globally to capacitate the readiness, introduction, programme delivery platforms and monitoring in parallel with the planned or ongoing efficacy trials. Pivotal efficacy studies are conducted in high-burden countries, several of which are not dependent on funding from global donors for vaccine procurement. Stakeholders in these settings need to consider how to introduce new TB vaccines as they become available, potentially in parallel with the formulation of a WHO policy recommendation that will support global implementation. There may be other conditions that need to be met to enable vaccine introduction, such as in-country clinical studies and local vaccine production. In addition, vaccine manufacturers are seeking clarity on anticipated demand, priority populations, acceptability for TB vaccines for adults and adolescents, and guidance on the evidence that will need to be generated to facilitate vaccine uptake to inform their investment decisions.

This framework aims to guide countries and global stakeholders in preparing for the introduction and coverage scale-up of new TB vaccines for adolescent and adult populations as these new vaccines become available. It seeks to create a people-focused, country-owned and partnership-based approach to early collaboration. It leverages lessons from past experiences with new vaccine introductions (in particular, the *Haemophilus influenzae* type B (Hib), human papillomavirus (HPV) and COVID-19), and from the vaccines Accelerated Development and Introduction

[1] While adolescents include young people under 15 years of age, 12–15-year-olds are unlikely to be included in Phase 3 prevention of disease studies due to the low incidence of TB in this population *(3)*.

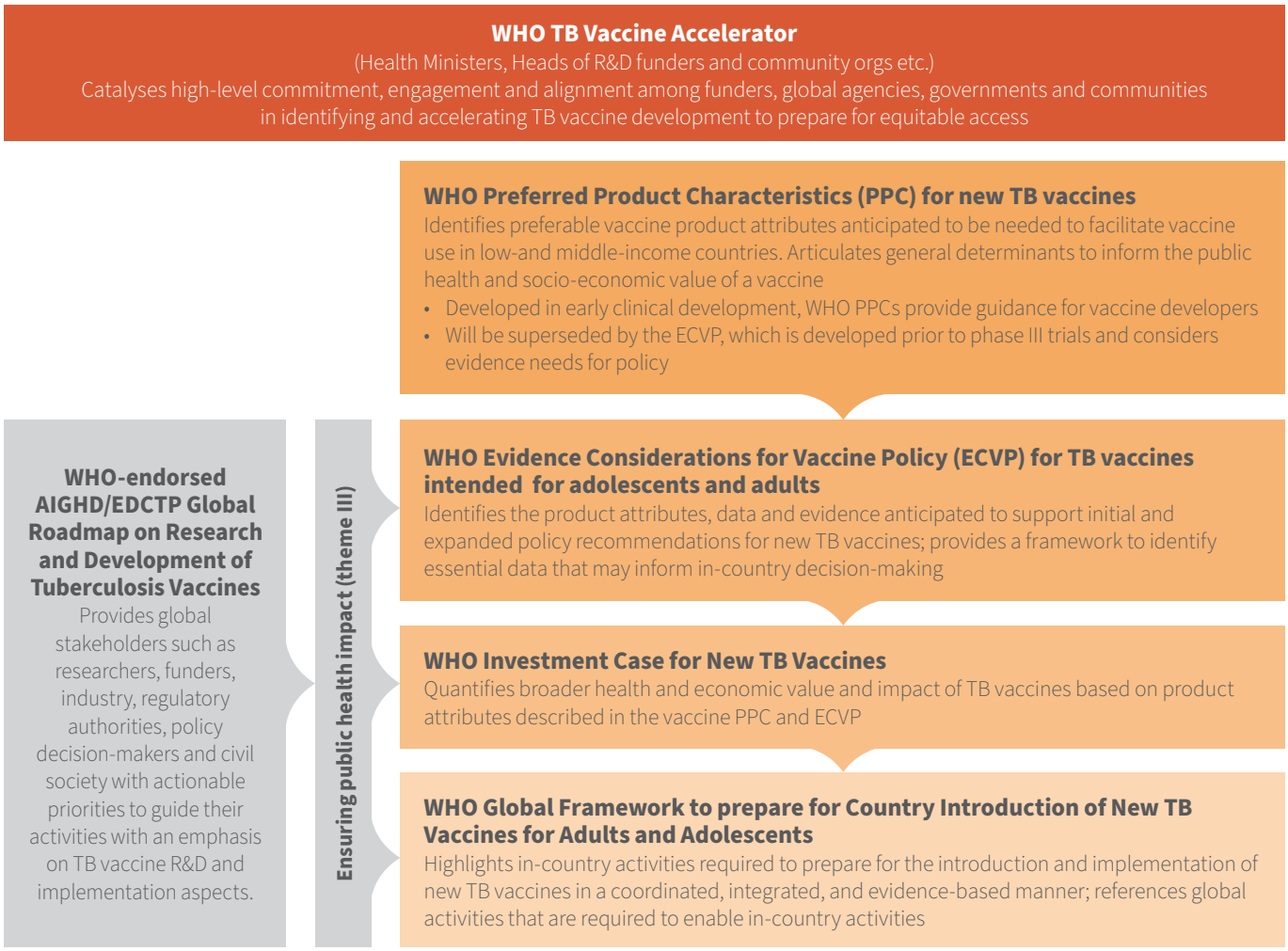
[2] Other priority populations important for service delivery platforms are discussed in detail in the WHO *Evidence considerations for vaccine policy (ECVP) TB vaccines intended for adolescents and adults (3)*.

Plans (ADIPs) for rotavirus and pneumococcal conjugate vaccines. These past experiences, as well as the MenAfriVac experience for meningococcal group A vaccine, have demonstrated that preparation and planning are essential to achieve rapid, effective and equitable vaccine rollout *(5)*.

The framework also leverages and is linked to new recent WHO guidance called *Evidence considerations for vaccine policy (ECVP) for adult and adolescent TB vaccines (3)*. The ECVP describes attributes that are expected to optimize vaccine value, which are quantified in the WHO investment case for new TB vaccines *(6)*. It also addresses expectations for clinical and observational data that are anticipated to support the development of policy at a global level, as shown in Fig. 1. This WHO framework, the ECVP and investment case for new TB vaccines builds upon the *Global roadmap on research and development of tuberculosis vaccines (7)*, specifically expanding upon the theme related to "ensuring public health impact". These guidance documents also support the work of the new WHO TB Vaccine Accelerator Council, envisaged to serve as a coordinating body "to 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" *(8)*.

> "This framework aims to guide countries and global stakeholders in preparing for the introduction and coverage scale-up of new TB vaccines for adolescent and adult populations."

Fig. 1. WHO guidance to inform development and introduction of new TB vaccines[3]



Preferred product characteristics (PPCs); evidence characteristics for vaccine policy (ECVP); Amsterdam Institute for Global Health and Development/European and Developing Countries Clinical Trials Partnership (AIGHD/EDCTP)

[3] See WHO Preferred product characteristics (PPC) for new TB vaccines intended for adults and adolescents, 2018; AIGHD/EDCTP Global roadmap for research and development of tuberculosis vaccines, 2021; WHO Full value proposition for new TB vaccines, 2022; WHO Evidence Considerations for Vaccine Policy Development (ECVP) for Tuberculosis vaccines intended for Adults and Adolescents, 2024; WHO Principles and considerations for adding a vaccine to a national immunization programme: from a decision to implementation and monitoring, 2014.

2. Rationale for the framework

"The objective of this framework is to raise awareness of the potential impact of TB vaccines for adults and adolescents and to understand how they might be used in different contexts"

As vaccine candidates approach late-stage product development, preparing the pathway for rapid introduction, coverage, scale-up and impact of new TB vaccines is necessary. Regulatory approval and policy recommendations for programmatic use, and early engagement with and ownership by country-level stakeholders are therefore critically important. The following points are noteworthy.

- New TB vaccines that prevent disease in adults and adolescents could become available for use within the next 3–5 years.
- The potential impact of an effective vaccine for adults and adolescents needs to be assessed and communicated early *at both the individual and population levels*.
- It is important to assess the need for and potential use of new TB vaccines in the context of in-country epidemiology in order to identify priority groups for vaccination, strength of the immunization system, and effectiveness when integrated with existing, and potential future, TB control interventions.
- Consideration of how a new vaccine delivery could be integrated into existing strategies and interventions and contribute to TB prevention and control is essential, as is assessing cost-effectiveness, acceptability and programmatic readiness.
- Planning and preparation for TB vaccine introduction and scale-up for adolescents and adults will be complex, take time, and require adequate training and resourcing, particularly since there are few countries with established systems in place for delivery of vaccines to adults and adolescents.
- Producing adequate vaccine supply requires a robust assessment of country-level demand and available financing.

This framework supports and is aligned with the vision of WHO's End TB Strategy, to "achieve a world free of TB, with zero deaths, disease and suffering due to the disease" through rapid and equitable access to and distribution of new adolescent and adult TB vaccines *(9)*. It **intentionally focuses on activities at a national level while also highlighting the global and regional activities needed to accelerate equitable introduction and scale-up.**

The general considerations for national vaccine introduction are well-described in WHO's *Principles and considerations for adding a vaccine to a national immunization programme: from the decision to implementation and monitoring (10)*. However, the **public health need, infrastructure and processes for vaccine introduction vary by country and context,** including the regulatory, policy, financing and procurement environment. The framework thus identifies specific goals and milestones required to facilitate the rapid introduction and scale-up of new TB vaccines for adolescents and adults, aiming for an **accelerated, coordinated, integrated, people-centred, equity-driven and evidence-based approach.**

The objective of this framework is to raise awareness of the potential impact of TB vaccines for adults and adolescents and to understand how they might be used in different contexts when they become available. The primary stakeholders that need to be engaged at the national level include government ministries (in particular, health, finance, education, trade and industry) and parliamentarians and politicians (who appropriate budgets). It is also important to engage civil society (including those who represent TB patient and survivor groups), National Immunization Technical Advisory Groups (NITAGs), national TB programmes and national immunization programmes. Academic institutions, professional societies, and cultural and religious leaders where relevant should also be included in the process.

Importantly, the framework also seeks to guide global actors. These include product developers and manufacturers, nonprofit organizations, philanthropic organizations, donors and funders, academic institutions involved in TB vaccine research and implementation, UN agencies and the broader TB community.

The framework assumes new TB vaccines will meet the attributes and be supported by the evidence described in WHO's ECVP for new TB adult and adolescent vaccines to support equitable introduction in all countries, especially low- and middle-income settings*(3)*. Therefore, **this framework should be read in conjunction with the WHO ECVP document, which provides more guidance on priority populations, potential implementation strategies and regulatory processes.**



On 1 August 2023 Lillyan leads a training for community mobilizers about an upcoming vaccination campaign at Kariokor Social Hall in Kamukunji, Nairobi, in this case for oral cholera vaccine. Photograph courtesy of WHO / Billy Miaron

3. Development process

In response to the need for guidance to prepare for global access to new TB vaccines for adults and adolescents, WHO convened a series of five scoping workshops in 2022, which collectively included approximately 150 expert stakeholders. The workshops were convened around five proposed strategic pillars, as follows:

Pillar 1. Understanding the public health need for a new TB vaccine at the country level (including an exploratory discussion on evidence that could inform introduction decision-making)

Pillar 2. Regulatory strategy

Pillar 3. National, regional and global policy-making

Pillar 4. Manufacturing, scale-up and commercialization

Pillar 5. Financing, supply and access.

The workshops aimed to identify the key activities and additional research required to facilitate late-stage product development, commercialization, access and implementation of new TB vaccines for adolescents and adults. In the context and as an outcome of these workshops, the following WHO technical guidance documents are now publicly available:

- The WHO ECVP for tuberculosis vaccines intended for adults and adolescents *(3)* related to strategic Pillars 2 and 3.
- The WHO commissioned An investment case for new tuberculosis vaccines *(6)* related to strategic Pillars 1, 3 and 4.

Following the five workshops, a WHO Expert Advisory Group was established and convened at WHO Headquarters in December 2022 to review the outputs. The group prioritized the need for this country-level framework, which describes critical activities to prepare for decision-making and subsequent rapid introduction, scale-up and impact of new TB vaccines for adults and adolescents.

In addition to the work with the expert group to develop a draft framework, consultations were conducted in early 2023 for broader input from policy-makers at the national and regional level, civil society representatives, the vaccine industry and TB programme managers. A draft of the framework was issued for public consultation and sent to immunization and TB programme managers and advisory groups, as well as to WHO's Product Development for Vaccines Advisory Committee (PDVAC) and Strategic Advisory Group of Experts on Immunization (SAGE). This final version of the framework consolidates all inputs received.

"The scoping workshops aimed to identify the key activities and additional research required to facilitate late-stage product development, commercialization, access and implementation of new TB vaccines for adolescents and adults."

4. Structural elements

In alignment with the WHO End TB Strategy, this country-level framework envisions a world free of TB, with zero deaths, disease and suffering due to TB. **Through its three goals, each with three milestones (Section 4), it seeks to facilitate rapid introduction and scale-up of new TB vaccines for adults and adolescents.** The framework also outlines global and regional enabling activities (Section 5) that need to occur in parallel to the country-level activities described to ensure equitable introduction and scale-up (see Fig. 2 below).

Fig. 2. Framework to facilitate the rapid introduction of new TB vaccines for adolescents and adults within countries

Vision & Purpose	**A world free of TB, with zero deaths, disease, and suffering due to TB**		
	Facilitate rapid introduction and coverage scale-up of new adult and adolescent TB vaccines		
Goals	**Available** Sufficient, sustainable, and timely supply	**Accessible** Equitable delivery aimed at all who could benefit	**Accepted** Policymakers, end-users and health systems requirements met
Milestones	• **Demand assessed** (e.g., no. of doses in short, medium and long term for priority populations; in context of other interventions; with country stakeholders engaged) • **Policy, evidence needs, and pathways defined** (e.g., safety and vaccine efficacy; regulatory approvals; specific populations; in-country trials; recommendations for use; import licensing) • **Procurement plans in place** (e.g., agreements with local, regional and global manufacturers, 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; with private providers and communities) • **Delivery systems in place** (capacity; infrastructure; supply chains; adequate numbers of trained health and community workers; data monitoring; pharmacovigilance; phase IV studies) • **Sustainable financing strategy in place** (e.g., national health sector strategy, external donors, private payers)	• **Value defined** (i.e., at individual and population levels and from perspective of health workers, policymakers, vaccinees) • **Communities engaged as partners in decision-making** (i.e., priority populations, TB survivors, health workers, community 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	• Appropriately designed phase III efficacy trials • Rapid, harmonized regulatory pathways to approval • WHO guidance/ recommendation on vaccine use, aligned with broader TB control efforts • 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)

Pan American Health Organization (PAHO)

5. Goals, key milestones and activities

The framework outlines three goals with milestones and activities required to facilitate readiness at the country level.

The activities identified are intended as illustrative (rather than exhaustive) and will differ by country, depending on factors such as disease burden, strength of the TB control programme, primary health care (PHC), and immunization systems. To enable **accelerated, coordinated, integrated, people-centred, equity-focused, and evidence-based introduction and scale-up, planning of activities at the country level needs to start early**, after clinical proof-of-concept has been demonstrated (therefore, after Phase 2b),[4] also in order to inform strategies for and investment in late-stage product development, regulatory approval and early implementation research (see Fig. 3).

Fig. 3. Approach to country introduction of new TB vaccines defined

Accelerated	Sufficient supply rapidly delivered to priority communities in the shortest possible time
Coordinated	Aligns actions to achieve a shared vision, shares knowledge, and builds and drives synergies across and between all stakeholders
Integrated	Considered in the context of TB, immunization, HIV, community health, and primary health care programs
People-centered	Driven by the needs of individuals and communities and owned by in-country stakeholders
Equity-driven	Focuses services to meet the needs of priority populations and those most at risk of TB disease
Evidence-based	Generates and uses the best available evidence and data to inform decision-making

[4] Phase 2b proof-of-concept trials are designed to demonstrate initial proof of efficacy of a vaccine, prior to Phase 3.

Goal 1: New vaccine available: sufficient, sustainable and timely supply

Rapid introduction and coverage scale-up require that any newly approved TB vaccine **be available** in the country with **sufficient, sustainable and timely supply.** Activities to guarantee vaccine availability must be initiated in advance of efficacy studies. This early planning helps to engage vaccine manufacturers, support regulatory approval, drive policy recommendations for use, create mechanisms for affordable procurement at the national level, and ensure that adequate and appropriate data are obtained as part of clinical trials or pre-implementation research (see Fig. 4).

Fig. 4. Milestones and illustrative activities to support Goal 1

Key milestones and illustrative activities	Potential stakeholders
M1.1 Robust vaccine estimates for country demand • Determine vaccine use case relative to other TB prevention tools including TB preventive treatment (e.g., based on vaccine and preventive treatment product attributes, comparative efficacy and safety, acceptability to specific groups, and cost of alternative interventions) • Conduct country-level modelling of demand based on a standardised approach and methodology (e.g., review of country TB epidemiological data, alignment on preferred/expected vaccine product attributes and potential use scenarios/delivery strategies) • Evaluate vaccine health and economic impact in priority and key populations (e.g., based on range of preferred/expected vaccine product attributes and anticipated delivery strategies, and with regard to other potential interventions, assessment of primary healthcare system to deliver vaccines to priority and key populations) • Based on above, engage TB and immunization advisors and other national stakeholders to define priority and key populations and develop a robust demand forecast	MoH NITAG National TB Control Programme Academic partners Civil society TB Community National Immunization Programme National Public Health Institutes
M1.2 National policy pathway for new TB vaccine defined and evidence gaps identified • Define data needs and processes for regulatory approval and licensing as required • Define data and evidence requirements to inform policy recommendations by NITAG / National TB Control Programme (in the context of data expected to be available for regulatory approval) • Where feasible, address evidence gaps for national policy in parallel with clinical development for inclusion in NITAG / National TB Control Programme review and streamline processes for rapid introduction • Conduct pre-implementation research to address evidence gaps to support introduction decision-making	National Regulatory Agency NITAG National TB Control Programme MoH Manufacturers Academic partners National Immunization Programme TB Community National Public Health Institutes
M1.3 Procurement plans in place • Facilitate dialogue between manufacturers, regulators, and procurement partners (e.g., UNICEF, PAHO, AFRIVAC, regional and national procurement entities) • Secure pricing and volume commitments from manufacturers • Assess the role of local and regional manufacturers	MoH MoF NITAG MoI Manufacturers Global Health Initiatives

Ministry of Health (MoH); Ministry of Finance (MoF); Ministry of Industry (MOI) National Immunization Technical Advisory Group (NITAG); Pan American Health Organization (PAHO)

M1.1 Robust vaccine estimates for country demand

Given that TB vaccines for adults and adolescents will rely on a novel delivery platform, the demand for such a vaccine at the country level is unclear. National epidemiological data should inform both the burden of disease and the size of priority and key populations, as well as drive alignment on the critical product attributes, such as expected efficacy and schedule and duration of protection (as described in ECVP). Assessments of potential demand will be informed by an early understanding of the vaccine use case. This is informed by: i) the acceptability, feasibility of delivery and prioritization of new TB vaccines relative to alternative prevention tools for TB, for example, TB preventive treatment (TPT); ii) the potential to take advantage of existing vaccination or PHC programmes for other diseases or interventions to deliver new TB vaccines (including the possibility of co-administration or using the PHC system); and iii) the epidemiological context.

> "National epidemiological data should inform both the burden of disease and the size of priority and key populations"

For each use case, modelling of impact and prediction of demand must be quantified in terms of the number of doses needed in the short, medium and long term. The demand assessment should be based on the preferred vaccine attributes that impact the ease of delivery and cost-effectiveness within the country's delivery system. These modelled outcomes need to be discussed in the context of anticipated product attributes and implementation strategies with country TB and immunization programmes and other stakeholders to determine potential demand forecasts for vaccines.

To date, vaccine impact modelling of new TB vaccines based on WHO-preferred product characteristics has been conducted at a global level and for priority populations in selected countries, where robust epidemiology data are available (14). As more country-specific epidemiology data become available, this modelling can be expanded and refined. The vaccine impact models commissioned by WHO are open source and are available to countries for their use (15). Where resources or data are inadequate to conduct modelling, countries may consider using neighbouring countries or regional data to infer demand.

M1.2 National policy pathway for new TB vaccine defined and evidence gaps identified

Policy pathways for new adult and adolescent TB vaccines and priority populations, including people living with HIV, should be determined during, but ideally before, Phase 3 studies. This is in order to identify the key stakeholders who must be engaged, and who will help set the "goal post", including identifying the data and evidence that are anticipated to be needed to enable rapid decision-making on adoption. The WHO ECVP for TB vaccines describes the considerations for policy at a global level, and can serve as a framework for policy recommendation by NITAGs, TB programmes and other stakeholders within the PHC system. It is critical to determine what evidence is required for policy recommendation at the country level, and to assess how this aligns with the data that will be generated as part of the regulatory package. This is in order to avoid a delay in the recommendation for use following regulatory approval.

Any critical evidence gaps could be addressed through manufacturer-, sponsor- or donor-funded parallel clinical studies and through early implementation research in a few pilot/early adopter countries, particularly as initial efficacy data may be limited to older adolescents and adults. Data to expand the indications to younger adults, and other key populations (older adults, people with diabetes, people with malnutrition) will also be required as part of the global development plan. In addition, forming part of the plan will be local studies to assess the feasibility of deploying vaccines for adults through the TB control programme, HIV control programmes, antenatal clinics or workplaces. Decision-making on TB vaccine introduction will also need to be taken in the context of immunization and national health strategies.

"Policy pathways for new adult and adolescent TB vaccines and priority populations, including people living with HIV, should be determined during, but ideally before, Phase 3 studies."

M1.3 Procurement plans in place

The timely introduction of new TB vaccines for adults and adolescents requires anticipation and dialogue between manufacturers and procurers on mechanisms, expected volumes and pricing before regulatory approval so that procurement can be rapidly executed once the decision to introduce a vaccine is in place.

In the case of self-financing countries, procurement agreements will be heavily influenced by vaccine prices, vaccine availability, national tendering processes and regional pooled procurement mechanisms where they exist. They may also be influenced by whether there is a requirement for in-country efficacy data or a preference for new TB vaccines to be manufactured in-country. The concepts and considerations described in the WHO *Investment case for new tuberculosis vaccines* and ECVP may assist countries in determining prioritization of new TB vaccines. This process can be helped by taking into consideration the benefits that would accrue from vaccination, such as health impact; value for money; equity and social impact; economic impact; and implementation feasibility. If a country aims to engage a global or regional procurement partner, like UNICEF Supply Division or Pan American Health Organization (PAHO) Revolving Fund, procurement principles also need to be determined upfront.

There is a global shift in vaccine production towards less reliance on global mechanisms and a greater focus on regional and national manufacturing *(11)*. Countries may seek to leverage these developments to provide greater flexibility and control over procuring new TB vaccines.

> "...procurement can be rapidly executed once the decision to introduce a vaccine is in place."



EPI (Expanded Programme on Immunization) centre in Rural Health Centre (RHC) in Raju Nazamani.
Photograph courtesy of WHO / Asad Zaidi

Goal 2: New vaccine accessible: equitable delivery aimed at all who could benefit

The decision to adopt a new vaccine and enabling its regulatory approval in a country is a critical step for vaccine access. **Rapid introduction and rollout require that a country has a clear plan for how that vaccine will be delivered to those most in need**, regardless of socio-economic status, location or other factors that may limit access. The most viable and cost-effective delivery strategies will likely differ by country, and they will need to be individually determined while being mindful of financing requirements (see Fig. 5).

Fig. 5. Milestones and illustrative activities to support Goal 2

Key milestones and illustrative activities	Potential stakeholders
M 2.1 Vaccine implementation strategy defined • Considering priority and key populations, agree on interaction/roles between stakeholders within primary health care, e.g., TB, HIV and EPI, and school health programs • Assess health system readiness and address context-specific gaps in implementation and access • Apply lessons learned from COVID-19 and other vaccines including human papilloma virus (HPV) vaccine strategies to reach adolescents and adults • Plan and conduct implementation research/pilot studies to inform vaccine rollout in different contexts/using different strategies	MoH NITAG Civil society Academic partners Private health institutions NGOs TB Community
M 2.2 Delivery systems in place • Assess the requirements for infrastructure and supply chain, including the in-country delivery strategies for priority and key populations • Work with manufacturers to put in place post-licensure surveillance (including risk-management plans, pharmacovigilance and vaccine effectiveness studies)	MoH NITAG Manufacturers Civil society TB Community
M 2.3 Sustained financing strategy in place • Assess the willingness to pay for new TB vaccines • Secure budget/ for procurement and delivery, including by identifying innovative financing solutions • Engage with potential donors/financiers and the private healthcare sector	MoH, MoF Global Health Financing Institutes In-country donors Private sector providers Researchers TB Community

Ministry of Health (MoH); Ministry of Finance (MoF); Ministry of Industry (MOI); National Immunization Technical Advisory Group (NITAG); human papillomavirus (HPV)

M2.1 Vaccine implementation strategy defined

Routine immunization programmes were established 50 years ago to vaccinate young children and have evolved considerably since then to include older children, adolescents, pregnant women, other adults and the elderly. However, in many countries established immunization platforms or implementation strategies for delivering vaccines to adolescents and adults remain limited or weak. For example, countries may choose to deliver TB vaccines through the PHC system or focus on delivery through Essential Programme on Immunisation (EPI) clinics, child and adolescent primary care programmes, workplaces or schools.

It is essential to establish clear expectations about which government department(s) are responsible for leading TB vaccine introduction and coverage scale-up. To determine the optimal delivery strategies for the country, there needs to be engagement and coordination with multiple parts of the health care system, other ministries (for example, education) and a range of stakeholders. These include affected communities, civil society organizations and health care workers, and this all needs to happen long before the vaccine is considered for implementation. The optimal delivery strategy (for example, routine immunization, campaign approach, school vaccination, TB programme, PHC services or HIV programme) will be based on the defined priority population and the vaccine characteristics, including cold-chain requirements and the number of doses required.

> "It is essential to establish clear expectations about which government department(s) are responsible for leading TB vaccine introduction and coverage scale-up."

The most relevant product development and vaccine delivery experience to adults and adolescents is with COVID-19 vaccines *(12)* for adults and adolescents, and HPV vaccines for adolescents. As such, countries should review what lessons can be applied to TB vaccine implementation from these programmes. While adolescents are a priority population, adult vaccine introduction will likely occur first, as there may be limited safety and efficacy data on young adolescents (under 15 years) at the time of first implementation.

In cases where anticipated demand may overwhelm supply, consideration should be given to manage this by using step-wise introduction of vaccines according to priority groups for vaccination. The WHO ECVP for TB vaccines identifies populations that could be prioritized initially, based on data expected to be included in the regulatory dossier, followed by safety and immunogenicity and/or effectiveness studies in other populations to support expanded policy. Therefore, countries will need short-, mid- and longer-term strategies to ensure equitable vaccination of all priority populations, and to conduct robust implementation research that may include pilot implementation and studies to establish acceptability, achievable coverage and potential impact to inform current and future strategies.

M2.2 Delivery systems in place

Once an implementation strategy is proposed and selected, as described in M2.1, countries will need to define and cost delivery, including the number of health care workers needed, training, data monitoring and recording systems, pharmacovigilance, infrastructure, logistics and supply chain requirements.

Selected countries will also need to work with manufacturers to put in place Phase 4 surveillance systems and impact evaluations, including for post-implementation vaccine effectiveness studies. Pharmacovigilance plans will need to be developed before implementation to establish a baseline against which vaccine safety assessment can be meaningfully measured. Risk management plans should also be developed to address regulatory and public concerns and provide early awareness regarding any evolution in the safety profile of new TB vaccines.

M2.3 Sustainable financing strategy in place

Countries' decision to introduce TB vaccines should be included in their National Immunization Strategy (NIS), which identifies sources of financing for the immunization programmes.

Significant financing, including funding for vaccine procurement and the in-country costs for the delivery, will be required for national introduction and continuous scaled-up rollout of new TB vaccines, particularly for a novel priority population. Allocation of additional resources to the PHC system or the essential package of services may be required for effective and sustained delivery of the vaccines to a new population. The financial case for investment in establishing a new TB vaccine for adults and adolescents within the health care system, so-called "willingness-to-pay", will require that countries assess the full value that encompasses the vaccine price and projected costs of introduction and rollout. These costs should be compared to public health, economic and broader benefits at both an individual and population level, and viewed in the context of other interventions for TB control as well as other vaccines that could be introduced. The allocation of resources for TB vaccines should be decided as part of both the national immunisation and TB control strategies and within the context of the national health strategy.

Policy-makers and budget holders will need to be engaged early in evaluating and assessing evidence needed for decision-making on vaccine introduction and deployment. For countries unable to finance TB vaccines from their national budgets alone, a dialogue will need to take place with potential external donors, such as Gavi, the Vaccine Alliance; the Global Fund, the World Bank; and bilateral aid agencies such as USAID. Countries may need to consider and plan for the private sector health care system's role in financing procurement and delivery, as well as its role in financing technical assistance and other forms of support required to implement any policy changes.

"Countries may need to consider and plan for the private sector health care system's role in financing procurement and delivery"

Goal 3: New vaccine accepted: policy-makers, end-users, and health system requirements met

COVID-19 has shown that unless and until the vaccines are accepted by the people who are expected to deliver and receive them, scaling up coverage in an equitable manner will not be possible. **Having a vaccine available and accessible does not mean it will be adopted by communities or populations at risk, particularly in the case of a vaccine intended for a new priority population.** For that reason, much work needs to be done upfront with a full range of stakeholders, from policy-makers to health workers, TB survivors and eligible patient groups (including in- and out-of-school adolescents) to position these vaccines for uptake. New TB vaccines must "fit" within health systems and be wanted by the people they serve. The country's PHC and HIV systems, for example, should be leveraged, and affected communities should be engaged in decision-making.

Scaling demand will also require addressing vaccine confidence, which significantly hindered COVID-19 vaccine uptake in many countries and communities. **National programmes will need to work closely with all stakeholders to anticipate and address specific areas of concern**, including through robust and focused communication strategies (see Fig. 6 below).

> "Scaling demand will also require addressing vaccine confidence"

Fig. 6. Milestones and illustrative activities to support Goal 3

Key milestones and illustrative activities	Potential stakeholders
M 3.1 Vaccine value defined, at individual and community levels • Conduct in-depth analysis by stakeholder group to assess perceived value (benefit and concern), decision drivers and acceptability of new TB vaccines for adults and adolescents, with respect to their individual and population level effects • Articulate benefits and potential concerns to anticipate hesitancy, raise stakeholder awareness and increase buy-in	MoH, MoF Academic partners TB community Stakeholders (policy-makers, health workers, vaccinees, community groups, opinion leaders, TB survivors)
M 3.2 Communities engaged as partners in decision-making • Conduct stakeholder identification mapping • Assess knowledge, awareness, and perceptions around TB and TB adult and adolescent vaccination through focus groups and community outreach in partnership with community leadership • Use information gathered to inform communications strategy (see below) • Provide support and information to promote engagement and coordination of stakeholders	MoH Academic partners TB community Stakeholders (TB survivors; patient groups; health workers; policymakers; private sector providers; professional associations)
M 3.3 Robust communication strategy in place • Identify key audiences and champions to deliver and amplify messages (e.g., public health experts, TB survivors, adolescents, religious and community leaders) • Develop targeted materials (appropriate and accessible to different stakeholder groups and informed by focus groups with and/or led by communities) to support the introduction, promote demand, and address vaccine hesitancy/stigma, mis- and dis-information campaigns • Integrate communication strategies with data-generating activities such as pre-and post-licensure clinical trials and pharmacovigilance activities	MoH Advocacy groups Civil society Stakeholders (Health care workers, traditional and social media, opinion leaders)

Ministry of Health (MoH); Ministry of Finance (MoF)

M3.1 Vaccine value defined at individual and community levels

Adopting new TB vaccines for adults and adolescents and building vaccine confidence will require "buy-in" from all stakeholders, from political leadership and policy-makers to front-line health workers, priority populations and TB survivors. Ensuring uptake and increasing coverage will require clearly articulating vaccine safety and efficacy at the individual level, as well as the public health and socio-economic benefits of an additional intervention, which is over and above what is already available, at the population level. For this reason, it is critical to involve communities from the beginning, including their involvement in all decision-making processes. Health care workers must also be confident that delivering this vaccine is worth the effort.

At a community level, new TB vaccines for adults and adolescents will reduce transmission and therefore risk of infection and disease, as well as potentially have other impacts, such as reducing antimicrobial resistance.

Policy-makers and donors will need to understand and quantify how these benefits trade-off against the cost of procuring and delivering the vaccine in a "value-for-money" assessment. This assessment should also consider the investment in alternative interventions for TB, other vaccines or other health issues. Assessing "vaccine value" will require an in-depth analysis of the drivers and trade-offs specific to each group of stakeholders.

"Ensuring uptake and increasing coverage will require clearly articulating vaccine safety and efficacy at the individual level"

M3.2 Community engaged as partners in decision-making

Engaging the range of stakeholders within a country, from community groups to professional associations, private providers and opinion leaders, begins before the planning of Phase 3 studies. In this way gaps in knowledge, awareness, preferences and perception of TB vaccines can be identified and addressed, including in pivotal studies. People- and user-centred design is an effective strategy to enable better programming, and community-based champions can engage in discussions on clinical design, promote vaccine acceptability, combat hesitancy, build demand and deliver vaccines to hard-to-reach groups or places if empowered to do so.

Building on successful experience with HIV medicines, it has been shown that engagement can include developing community advisory boards focused on national adoption and, in addition, engaging priority populations, particularly adolescents and their parents and caregivers. The COVID-19 experience underscored that engagement of health workers from the start is crucial.

M3.3 Robust communication strategy in place

Introduction and coverage scale-up requires that early identification and addressing of gaps in knowledge, awareness and perception of TB vaccines happens across the range of stakeholders who need to be engaged in the policy and implementation process. On the policy front, analyses should be developed on the burden of TB within a country in order to identify the priority populations and potential delivery strategies, and to assess the potential impact a new TB vaccine could have at an individual and societal level, both on the health care system and on the economy more broadly. At the individual and community levels, communication messages should be developed, based on evidence, to address and alleviate specific concerns, including vaccine hesitancy. The messages should highlight the attributes judged to have the highest value.

Some audiences may have limited knowledge of TB and, in particular, the need and potential benefit of a vaccine for adults and adolescents, or of the imminent availability of these vaccines as an essential method of TB control. Therefore it is vital that, even before Phase 3 studies, materials addressing their specific questions and concerns are developed and made accessible to multiple audiences at different levels, such as senior policy-makers, health care workers, schools and workplaces, and broader communities. Some of the concerns that may require communication could include the exclusion of some groups from late-phase clinical studies and how this is being addressed, or the impact a new TB vaccine may have on other ongoing TB control efforts such as TPT.

Regarding communication strategies, countries can leverage their experience with COVID-19 vaccination. Particularly important will be identifying and addressing the issues that led to vaccine hesitancy, and engaging early in the development process to pre-emptively address misconceptions as they start circulating. Robust, quickly reactive communication strategies are also essential during the implementation of the vaccine, including explaining any emerging safety issues that may become evident after the vaccine has been introduced and is being widely used.

"At the individual and community levels, communication messages should be developed, based on evidence, to address and alleviate specific concerns, including vaccine hesitancy."

6. Integration of goals, milestones and activities

Each milestone described in section 5 is underpinned by multiple activities, some of which are supporting other goals and milestones (see Fig. 7). Many of these activities are inter-related; for example, assessing demand will require a clear understanding of perceived value and acceptability by the community, and early implementation research will inform both the policy pathway and the implementation strategy.

Reading across the activities (left to right) informs how each activity will support each of the three goals. Reading across the goals and milestones (top to bottom) highlights the multiple and related activities that contribute to each goal and milestone.

Fig. 7. Interlinkages between the goals, milestones and illustrative activities

		Goal 1: Available			Goal 2: Accessible			Goal 3: Accepted			Timeframe (Short, Medium)
		M1.1 Demand assessed	M1.2 Policy/ evidence needs/ pathways defined	M1.3 Procurement plans in place	M2.1 Implementation strategy defined	M2.2 Delivery system in place	M2.3 Sustainable financing strategy in place	M3.1 Value defined	M3.2 Communities engaged	M3.3 Robust communications strategy in place	
Activities: Available	**M1.1 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
	M1.2 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
	M1.3 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

		Goal 1: Available			Goal 2: Accessible			Goal 3: Accepted			Timeframe (Short, Medium)
		M1.1 Demand assessed	M1.2 Policy/ evidence needs/ pathways defined	M1.3 Procurement plans in place	M2.1 Implementation strategy defined	M2.2 Delivery system in place	M2.3 Sustainable financing strategy in place	M3.1 Value defined	M3.2 Communities engaged	M3.3 Robust communications strategy in place	
Activities: Accessible	**M2.1 Vaccine implementation strategy defined**										
	Define at-risk/priority populations	✓	✓		✓			✓	✓	✓	S
	Agree on interaction/roles between primary health care, TB, HIV and EPI, and school health programs		✓		✓					✓	S
	Assess health system readiness and address context-specific gaps in implementation and access				✓	✓					M
	Build on lessons learned from strategies from COVID-19 and HPV				✓	✓			✓		M
	Plan and conduct pre-implementation research/pilot studies to inform vaccine rollout		✓		✓				✓		S, M
	M2.2 Delivery systems in place										
	Define milestones/criteria for data and evidence requirements to inform policy decisions					✓			✓		M
	Gather evidence needs for policy in parallel with clinical development for inclusion in regulatory dossier, streamline processes for rapid approval		✓			✓					M
	M2.3 Sustained financing strategy in place										
	Assess the willingness to pay for new TB vaccines	✓			✓		✓	✓	✓		S
	Secure budget/financing for procurement and delivery						✓	✓		✓	M
	Engage with financiers and the private sector	✓	✓		✓		✓	✓		✓	M
	Identify innovative financing solutions	✓			✓		✓			✓	M
Activities: Accepted	**M3.1 Vaccine value defined, at individual and community levels**										
	Assess perceived value and acceptability	✓			✓			✓	✓	✓	S, M
	Articulate benefits and potential concerns to anticipate hesitancy, raise stakeholder buy-in		✓					✓		✓	M
	M3.2 Communities engaged as partners in decision-making										
	Conduct stakeholder identification mapping				✓			✓	✓		S
	Assess knowledge and perceptions through focus groups and other community outreach				✓			✓	✓		S, M
	Use information gathered to inform communications strategy				✓			✓	✓	✓	S, M
	Provide support and information to promote engagement and partnership				✓				✓	✓	M
	M3.3 Robust communication strategy in place										
	Identify key audiences and champions							✓	✓	✓	S, M
	Develop targeted materials; address vaccine hesitancy/stigma, mis/ dis-information campaigns							✓	✓	✓	S, M
	Integrate communication strategies with data-generating activities such as pre-and post-licensure clinical trials and pharmacovigilance activities				✓					✓	S, M

Human papillomavirus (HVP); Expanded Programme on Immunisation (EPI)

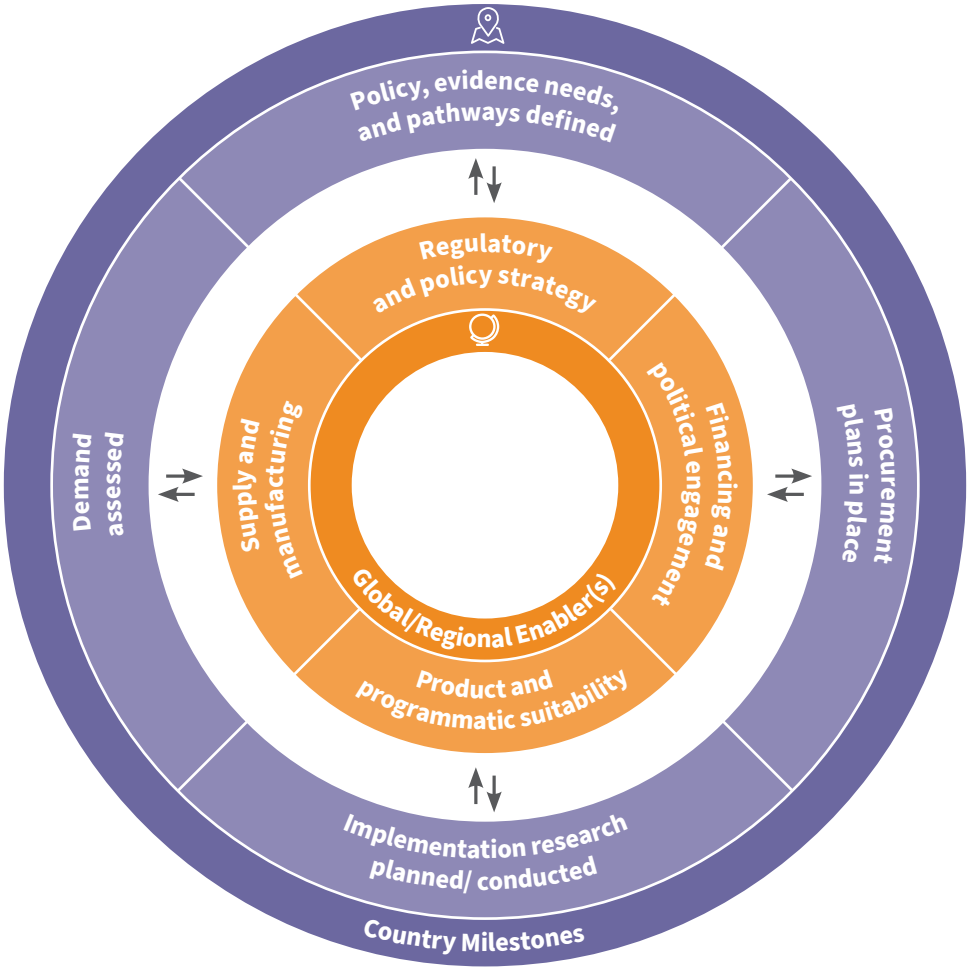
7. Global and regional enablers for the introduction

Beyond the goals and milestones described to accelerate country introduction and scale-up, several factors are influenced by the regional and global environment. A series of "enablers" need to be coordinated and integrated to achieve global supply, policy, financing and procurement to support introduction *across all countries that choose to introduce new TB vaccines for adults and adolescents* (see Fig. 8).

Rapid and equitable introduction and rollout of new TB vaccines across multiple countries cannot occur without: i) ensuring that vaccines are designed to "fit" within the programmes that are intended to deploy them; ii) alignment on the expectations for data to support regulatory approval and policy recommendations; iii) adequate supply and manufacturing capacity; and iv) sustained global/regional financing and political engagement. These global and regional factors facilitate (or hinder) countries to achieve accelerated, integrated, coordinated, people-centred, equity-driven and evidence-based TB vaccine introduction and scale-up, and are particularly important in supporting implementation in low-income settings.

> "A series of "enablers" need to be coordinated and integrated to achieve global supply, policy, financing and procurement to support introduction *across all countries*"

Fig. 8. Example of interplay between country milestones and global/regional enablers to achieve implementation of new TB vaccines across all countries



i) Product and programmatic suitability

Early consensus on the anticipated delivery strategies for vaccines informs the criteria for optimal vaccine presentation. It also enables manufacturers to develop a vaccine that is acceptable for use by national programmes. In this regard, country preferences, driven by the initial assessment of a country delivery system and preliminary implementation plans, need to feed into the vaccine development process. These attributes are described in the WHO PPC *(13)*, the WHO ECVP for a TB vaccine intended for adults and adolescents *(3)*, and guidance on requirements for WHO prequalification *(14)* to guide vaccine manufacturers. Furthermore, early implementation research is vital in helping understand the "real-life" use of the vaccine in a range of contexts that countries have regarding prioritized populations, TB and immunization programmes, and health systems.

ii) Regulatory and policy strategy

"Harmonized regulatory pathways are key enablers to accelerating a TB vaccine supply."

Some countries' national regulatory authorities may have specific requirements for population-specific data, such as country-, sex-, and age-specific data, and data on women and adolescents. Therefore it is important that early engagement between national programmes, national regulatory authorities and manufacturers takes place at the appropriate time in relation to the pivotal efficacy studies; good timing will ensure informed study design and rollout. Harmonized regulatory pathways are key enablers to accelerating TB vaccine supply. They align data expectations, approval processes, and timelines across the national regulatory agencies of multiple priority countries. Synchronizing a collective regulatory review entails clarity on the roles and timing of entities responsible for safety and efficacy reviews and licensing at the global and regional level, particularly for high-burden countries.

Notably, the data required by global policy-makers and financing agencies for introduction are usually beyond the requirements for regulatory approval and rely heavily on factors such as cost-effectiveness and feasibility of use. The evidence needed for global policy bodies, such as WHO's SAGE and financing agencies, must be clarified and data collected, either as part of the pivotal efficacy study or generated in parallel to accelerate introduction.

iii) Supply and manufacturing

An affordable, reliable and sufficient supply of TB vaccines is a prerequisite for effective vaccine introduction and scale-up at the country level. To this end, diversified vaccine production, including regional manufacturing capacity, is important in lowering the risk of supply shortages and securing equitable distribution. Overall, early collaboration is needed between regulators, regional and global policy-makers, manufacturers, potential regional and global procurement agencies (such as PAHO and UNICEF), and vaccine and TB procurement and programme financiers (such as Gavi and the Global Fund). This collaboration can facilitate the development of initial access, intellectual property (IP), procurement agreements, and pooled procurement arrangements to enable country preparedness and equal distribution of vaccines. In the case of constrained supply, WHO's SAGE may develop guidance on priority populations in the form of a vaccine allocation framework *(15)* or vaccine prioritization roadmap *(16)*.

iv) Financing and political engagement

To progress from vaccine development to country implementation, strong political will and buy-in across the stakeholders are drivers of success and enable the availability of adequate funding. Achieving universal access will require sufficient and sustained public sector investments in research and development to lower end-user costs. To this end, high-level advocacy, including engagement of G7 and G20 countries, is critical for equitable TB vaccine introduction. Furthermore, early clarity is needed on the roles of funding partners (such as Gavi, the Global Fund, the World Bank, Unitaid and bilateral donors); procurement partners (such as PAHO and UNICEF); their potential financing instruments (such as advance market commitments, volume guarantees and vaccine independence initiative); and potentially other sources of domestic and donor funding. This is to enable countries to define the priority populations and plan the procurement and delivery while also providing manufacturers with risk mitigation measures for investment.

"To progress from vaccine development to country implementation, strong political will and buy-in across the stakeholders are drivers of success and enable the availability of adequate funding."

8. What is needed next?

This framework identifies the essential activities and considerations that will apply to every country as it evaluates the potential impact and feasibility of deploying new TB vaccines for adults and adolescents.

The work at the country, regional and global levels is intrinsically linked; the end-user preferences, anticipated implementation strategy and political will at the national level all shape investment in product development and the policy and procurement strategies at the regional and global levels. Country-level demand for a new TB vaccine will vary according to epidemiological and programmatic context as well as socio-economic status. Partnership with community and policy stakeholders is therefore fundamental to identify what evidence and stakeholder alignment is needed to ensure expeditious decision-making, vaccine uptake and to guide global initiatives.

If implemented, this framework will enable integrated and evidence-based decision-making to optimize resources, align stakeholders and accelerate the pathway to available, accessible and acceptable new TB vaccines for adults and adolescents.

In parallel, at the global level, WHO will take a leading role in creating the strategic and technical guidance, through broad stakeholder engagement, to support and leverage the WHO TB Vaccine Accelerator Council and identify resources and partners to work together to achieve the goals described in the framework.

"Partnership with community and policy stakeholders is therefore fundamental to identify what evidence and stakeholder alignment is needed to ensure expeditious decision-making, vaccine uptake and to guide global initiatives."



WHO Director-General, Dr Tedros Adhanom Ghebreyesus talks to WHO consultant, Aicha Taybi, recruited to support vaccine preparedness activities, in this case for Ebola. Photograph courtesy of WHO / Paul Lorgerie

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