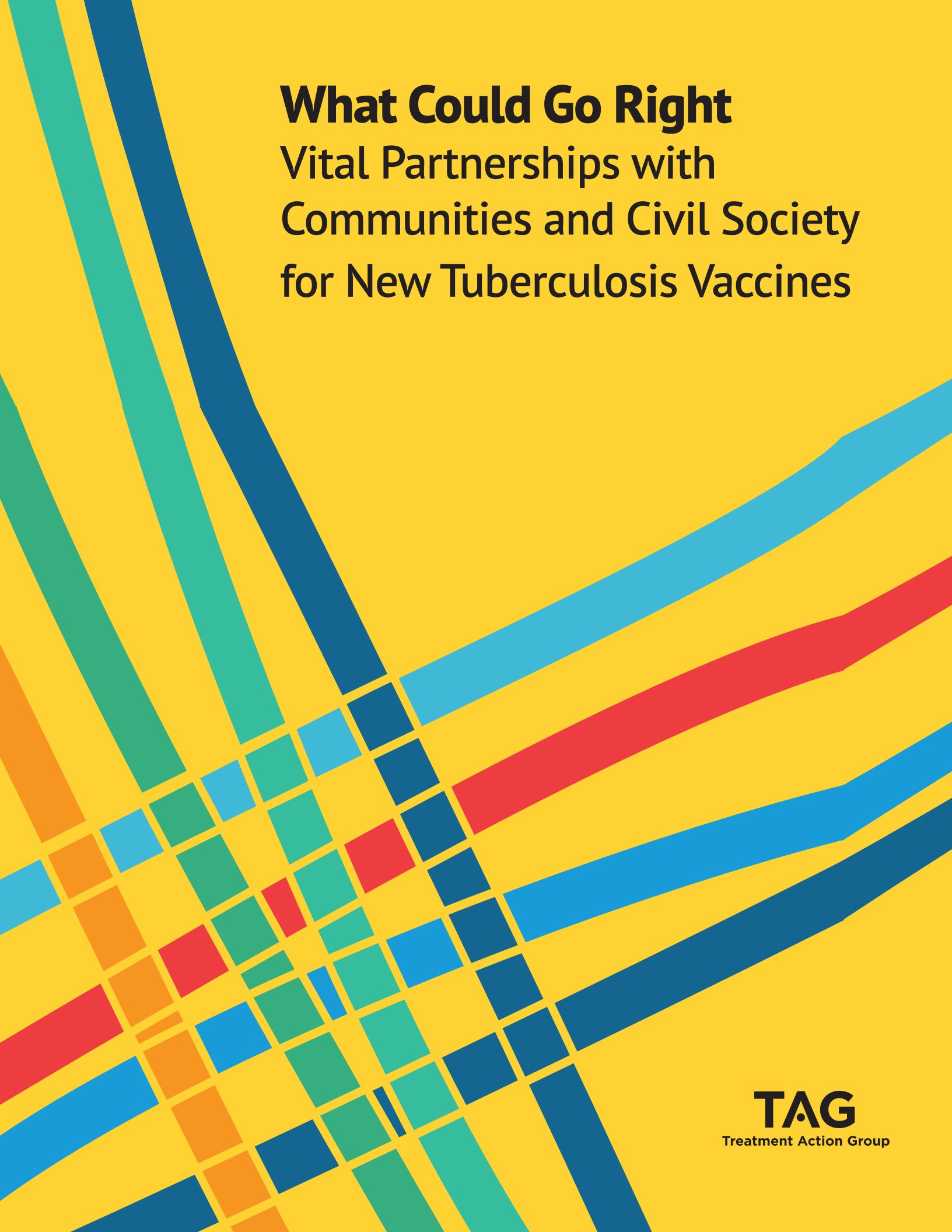
What Could Go Right

Vital Partnerships with Communities and Civil Society for New Tuberculosis Vaccines



TAG
Treatment Action Group

Acknowledgements

Treatment Action Group (TAG) is grateful to Wellcome for providing funding to research and publish this report and for offering consistent support and thought partnership along the way.

Veteran health activist Karyn Kaplan helped design the civil society landscape methodology, implement the online survey, and interpret its findings. Members of three regional community advisory boards — AFROCAB, APCASO, ECAT — authored the country policy portraits. Sergey Golovin wrote the access roadmap.

The Global TB Community Advisory Board provided advice throughout the project and reviewed components of the work.

TAG thanks the 125 organizations that responded to the online survey, and the over 30 TB and immunization experts who participated in key informant interviews.

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Executive Summary

Executive Summary

The promise of new safe and effective TB vaccines may be realized as soon as 2028. Multiple vaccine candidates are undergoing or preparing for phase III trials, giving momentum to the prospect of eliminating TB, the leading cause of death from an infectious disease globally. Ending the TB epidemic by 2030 is among the health targets of the United Nations (UN) Sustainable Development Goals (SDGs) and an aspiration reaffirmed by governments at two UN General Assembly high-level meetings on tuberculosis in 2018 and 2023.

New vaccines that can safely and effectively prevent TB disease in adolescents and adults would save millions of lives and radically bolster the chance to eliminate the disease as a public health threat.[1] The only existing TB vaccine — bacillus Calmette-Guérin (BCG) — was introduced over a century ago, in 1921, and although it keeps infants and young children safe from the most severe forms of TB, it offers limited protection to adolescents and adults, who account for the majority of TB morbidity, mortality, and transmission.

Vaccines have been called a "great equalizer" that, where available, consistently lead to improvements in life expectancy, economic stability, and upward mobility.[2] At the same time, access to vaccination has never been equal: 14 million "zero-dose" children never received a dose of any vaccine in 2024, over a million more than in 2019.[3] Grave disparities in timely access to COVID-19 vaccines between high- and low-income countries were responsible for the loss of millions of lives that could have been saved through more equitable distribution.[4,5] Scarce availability of new vaccines at launch has forced global institutions and national governments to make wrenching ethical tradeoffs, such as decisions about how to allocate limited doses of RTS,S, the world's first malaria vaccine, in 2021 and 2022.[6]

The transformative potential of vaccines to improve health and well-being is not only undermined by persistent structural inequalities. A cultural sphere that amplifies mis-/disinformation about the risks and benefits of vaccination, coupled with rising vaccine antipathy in some political systems, presents a profound challenge to the integrity of vaccine science and evidence-based

policy making. As long as vaccines have existed, vaccine hesitancy has existed. But the antivaccine turn evident in so many quarters today means that the risk to public and political support for immunization is unignorable for anyone working to prepare for new TB vaccines. If "immunity is a public space," as the writer Eula Biss has described it, then vaccines need supportive publics to live up to their scientific promise.[7]

For this reason, communities affected by TB and their allies in civil society will be vital partners in ensuring the success of new TB vaccines. Communities and civil society (collectively referred to as CSOs here) are integral to building what the Equity-First Vaccination Initiative has called the "infrastructures of trust" that support vaccination, increase health equity, and meet the information needs of diverse constituencies. CSOs are uniquely positioned to address the intersectional drivers of vaccine demand and overcome the structural, institutional, and cultural failures that hamper it.[8]

This report, produced by Treatment Action Group (TAG) in concert with community partners and with support from Wellcome, explores community partnerships and interventions to support new TB vaccines. The findings of this three-pronged project, "Scoping Community Interventions to Support New TB Vaccine Introduction: From Grassroots Partnerships to Global Policy Making," suggest proactive investments Wellcome and other funders can make to support a key element in ensuring the right to new TB vaccines: community and civil society engagement for optimum impact. The first study of its kind, the report weaves together three substudies with distinct aims:

- No Vaccines Without Us: A Global Landscape Analysis of Civil Society Engagement in TB Vaccine Preparedness, based on a global survey of 125 civil society organizations active in the TB response and nine key informant interviews. The survey documents the readiness of CSOs to engage in new TB vaccine policymaking, demand creation, and implementation.
- Seven Country Policy Portraits illustrating how immunization policy is made in each country and detailing potential community and civil society points of intervention. Written by local advocates, the portraits represent different archetypes of high-TB-burden countries — Bangladesh, Kazakhstan, Kenya, Malawi, Mongolia, South Africa, and Vietnam — chosen to represent a mix of settings with respect to Gavi and Global Fund eligibility; World Bank country income level; TB epidemiology; and history of state-civil society relations.
- TB Vaccine Access in "4D": A Roadmap Charting Civil Society Actions for Equitable Access outlines a series of recommended actions to be undertaken by civil society with the support of other key stakeholders. The actions are organized into four areas — development, delivery, demand, and data — to offer a "4D" view of interventions to secure equitable access to new TB vaccines.

Our research reveals that communities and civil society organizations are poised to play an indispensable role in new TB vaccine introduction but require immediate investment to be optimally activated. Findings from the landscape assess-

ment demonstrated a stark paradox: 97% of surveyed organizations express interest in TB vaccine preparedness, yet only 19% feel "fully prepared" to engage in vaccine work. This readiness gap exists despite organizations possessing strong foundations — 80% have more than five years of TB experience, 88% have conducted TB prevention activities, and 92% work directly with TB survivors and people at risk.

CSOs show proven capabilities essential for vaccine rollout and implementation success: 44% have experience in community-led monitoring, 40% provide direct services to TB-affected communities, and 77% work with people living with HIV (PLHIV), for example. However, their potential remains untapped due to critical gaps in vaccine-specific capacitation. With 85% scoring low or medium on vaccine policy knowledge and only 17% having engaged with National Immunization Technical Advisory Groups (NITAGs), the path forward is clear: strategic investment in capacity and relationship building, sustained funding, and formal inclusion in decision-making processes will strengthen community and civil society's role as the essential bridge between vaccine development and community uptake.

Across the three studies, a consistent theme emerged: CSOs possess unique capabilities that formal health systems cannot replicate. These include deep community trust, cultural competency, the ability to reach marginalized populations, and expertise in bridging technical knowledge with grassroots mobilization. For example, our seven country policy portraits show how CSOs serve as trusted intermediaries who can combat misinformation, build vaccine acceptance, and ensure equitable access — particularly for key populations such as people using drugs, migrants, prisoners, and PLHIV.

However, civil society infrastructure faces three intersecting crises: 1) drastic foreign aid cuts disrupting health systems and community organizations; 2) shrinking civic space constraining CSO operations; and 3) profound threats to trust in vaccines and scientific integrity. With the right investments, CSOs are poised to play an integral role in resisting and overcoming these threats and contributing meaningfully at each point of the vaccine policymaking-to-implementation process.

Rising vaccine skepticism and refusal is a crisis with deep attitudinal roots. Addressing vaccine acceptance and demand is therefore a society-wide challenge that necessitates significant investment in community systems. It also requires policy and regulatory adjustments, as well as a sustained commitment to building trust, enhancing health equity, and fulfilling the information needs of diverse communities.[9] Our research finds that while 83% of surveyed organizations identify funding as their top support need, and 80% require technical assistance and training, current funding models — characterized by fragmented, short-term, project-based support — are inadequate to sustain the comprehensive, long-term community engagement required for successful vaccine introduction.

Our country policy portraits reveal that most NITAGs lack formal structures for civil society engagement, contrasting sharply with the rich tradition of community participation in national TB program policymaking. Organizations report being largely excluded from vaccine decision-making spaces. This represents a missed opportunity, as meaningful civil society engagement from the outset of planning is fundamental to sustaining demand beyond initial launch phases and extending access to all populations in need. Community engagement is in the groundwater of the TB response, detectable to some degree in all levels and spaces, and is also discernible in vaccine delivery, but does not appear as prominently in immunization policymaking.

It is prime time for community engagement in national, regional, and global readiness activities to optimize the context for imminent vaccine introduction and scale-up. To ensure meaningful community engagement, viewed as essential by the World Health Organization[10] and representing ethical and rights-based practice, communities will require the means and opportunities to do this work. The findings across all three of our studies point to four interconnected areas where investment can activate civil society's essential role in TB vaccine introduction:

Transform Funding from Fragmented Projects to Sustainable Infrastructure

Current funding models inadequately support sustained engagement, with 83% of organizations identifying funding as their top support need. Piecemeal, project-based funding cannot sustain the comprehensive community engagement required for successful new TB vaccine introduction. Funders should:

- Establish dedicated, multiyear funding streams specifically for TB vaccine preparedness activities among civil society at all levels (global, regional, national, local).
- Create "guardrails" within consolidated funding mechanisms to ensure community engagement resources reach grassroots organizations (and not only larger, well-connected international nongovernmental organizations) and "set asides" for CSOs within larger TB vaccine investments.
- Develop sustainable financing that extends beyond vaccine introduction to cover long-term investments in community engagement across all aspects of TB vaccine work — from development through delivery, demand creation, and data monitoring.

Build Systematic Capacity to Activate Civil Society Across the Vaccine Development-to-Delivery Timeline

The second-highest support need, registered by 80% of organizations, was technical assistance and training extending beyond basic vaccine information to broader technical competencies enabling meaningful policy engagement and implementation. Organizations are ready to engage but require capacitation to do so effectively. Funders should:

- Develop structured training programs covering vaccine literacy, including updates on the pipeline of vaccines in development, TB vaccine science and clinical trials, policy and regulatory analysis, and immunization policy engagement skills.
- Support the development of gender- and culturally sensitive communication strategies that also address religious concerns and community misconceptions to generate demand and inoculate against misinformation.

- Create mentorship networks pairing experienced vaccine advocates with TB CSOs eager to engage but newer to immunization work to build capacity for evidence-based advocacy.

Normalize, Formalize, and Institutionalize Civil Society Participation in Vaccine Decision-Making

The need to normalize, formalize, and institutionalize community and civil society engagement in vaccine decision making — from development through implementation — was stressed across all findings. Most immunization technical advisory groups lack formal structures for civil society engagement and have underestimated the contributions civil society can make to vaccine policy making. Policy makers, governments, funders, and other stakeholders should:

- Advocate for explicit inclusion of CSO representatives in advisory and decision-making spaces at all levels, promoting policies that protect civic space and enable CSO participation in health policy making.
- Support the inclusion of civil society representatives as voting members of NITAGs and the establishment of national-level groups, committees, or boards composed of CSO representatives.
- Enable early and sustained CSO engagement in vaccine development processes as co-owners, not just implementers, so that communities shape vaccine development from the outset and are prepared to lead demand generation upon approval.

Invest in Community-Led Monitoring as Essential Infrastructure Supporting Vaccine Access

Evidence shows that community-led monitoring improves the effectiveness, quality, and accessibility of health programs as well as empowers communities affected by TB by enabling people to demand high-quality services by appealing to locally relevant data. Funders should:

- Designate community-led monitoring as a specific funding track in calls for proposals for community projects, alongside service delivery, awareness raising, and demand promotion.
- Support CSO-led research and advocacy in the fields of pricing, intellectual property, and procurement and supply to generate real-time data on the determinants of access to inform policy and implementation adjustments.
- Fund development and adaptation of community-led monitoring and research tools for new TB vaccines, with particular focus on monitoring vaccine access for specific key groups that can be better reached by community organizations: adolescents, people using drugs, migrants, prisoners, and PLHIV.

The pathway from vaccine development to community uptake runs directly through civil society organizations that are, by their own assessment, underresourced, undertrained, and underengaged in preparedness activities, yet ideally positioned and galvanized to take a leading role for optimal rollout. With most (97%) surveyed organizations expressing interest in vaccine preparedness but only a fraction (20%) feeling fully prepared, the opportunity and need for transformative investment is compelling. Strategic investment will activate civil society to fulfill its essential role across the vaccine timeline — from development to policy readiness to demand generation to post-market monitoring.

At a moment when so much of the progress made in vaccine science and access over the past decades appears at risk of backsliding, this report encourages funders and other stakeholders in the TB and immunization fields to ask: What could go right?

- What could go right if we invest in communities and provide them with the information and resources they need to play an active role in TB vaccine delivery?
- What could go right if we open policy-making spaces to voices from community actors closest to the beneficiaries of vaccination and invite their perspectives when plans are being made?
- What could go right if communities take those opportunities to build the infrastructures of trust that convert new vaccines into vaccinations and ensure access for all?

The central challenge before us is to bring more people and resources into a community-led movement for new TB vaccines. Communities and civil society are ready and willing; what they require is adequate resourcing, systematic capacitation, and formal inclusion in decision making to unleash their full potential.

No Vaccines Without Us:
A Global Landscape Analysis of Civil Society Engagement in TB Vaccine Preparedness

No Vaccines Without Us

Tuberculosis (TB) vaccines for adults and adolescents, a key missing piece in the United Nations' 2030 End TB agenda, are on track to emerge from the research and development (R&D) pipeline in a matter of years. Preparedness work required for a new vaccine to "deliver on its potential (reaching those who need it, when they need it)"[11] demands urgent attention and acceleration. Civil society and community-based organizations are raring to engage in preparations for new TB vaccines but need the opportunities and adequate resources to optimally play their part.

New TB vaccines are "critical to achieve annual global and national reductions in TB incidence and mortality that are much faster than those achieved historically."[12] The End TB targets endorsed by governments at two United Nations General Assembly high-level meetings on tuberculosis in 2018 and 2023 will not be met without new TB vaccines. Despite demonstrable scientific progress, the transformative potential of new TB vaccines to accelerate TB elimination is now at risk from three intersecting crises.

First, drastic foreign aid funding cuts implemented by the United States and other Western countries are disrupting health systems, jeopardizing access to services for people with and at risk for TB.[13,14,15] Funding cuts are undermining decades of progress, including the essential work of many community-based organizations (CBOs) and nongovernmental organizations (NGOs), particularly in high-TB-burden countries.[16,17] The WHO considers this an existential threat to the global TB response — saying that abrupt funding cuts will "cripple TB prevention and treatment," "endanger millions of lives," and have "devastating and often fatal consequences for millions worldwide," potentially undoing progress that has saved more than 79 million lives in the past two decades.[18,19]

Second, civic space is shrinking in tandem with funding evaporating. Civil society groups that have been essential to TB service delivery are facing financial constriction from donor cuts and operational restrictions from policy encroachments on civic space — both nega-

tively impacting the health of people worldwide.[20, 21] The United Nations Office of the High Commissioner for Human Rights has warned that civic space is under pressure and declining in every region.[22] To achieve the Sustainable Development Goals, including an end to the TB epidemic, governments must establish positive engagement frameworks with civil society actors that foster dialogue and debate, inform policy making, and shape health practices, behaviors, and social norms.

Third, public trust in vaccines, and in the very integrity of vaccine science, is under profound threat. In the United States — historically the largest funder of TB vaccine research and a major contributor to global immunization programs — attacks on vaccine science and political interference in vaccine policy making risk turbocharging antivaccine movements with ramifications that would be felt around the world.[23]

Investing in and centering community and civil society engagement is an effective public health strategy that continues to bear fruit. It is crucial for protecting vulnerable populations, ensuring equitable access to resources, and fostering community resilience to overcome multiple and compounding crises.[24] This section presents a first-of-its-kind landscape analysis of TB community and civil society groups working across global, regional, and national/local levels in relation to their readiness to engage in new TB vaccine policy making, demand creation, and implementation. It offers key recommendations for how funders can support civil society and mobilize its unique strengths, skills, and connections to ensure the success of new TB vaccines. It concludes with examples of funding structures from the TB, immunization, and human rights fields that could be adapted to respond to identified resource needs for TB vaccines.

Survey Methodology

This landscape analysis addresses a critical gap in understanding of community capacity, interests, and needs by systematically mapping TB community and civil society organizations and their readiness to engage in vaccine preparedness activities. Collectively, we refer to community and civil society organizations as CSOs, though more specific terms —CBOs, NGOs — appear when referring to specific types of survey respondents. The study identifies specific intervention points where CSOs can contribute to vaccine literacy, policy development, demand creation, implementation, planning, and equity promotion. The analysis spans the following geographical levels:

- **Global organizations** that influence international TB policy and resource allocation;
- **Regional platforms and networks** that coordinate across multiple countries and facilitate knowledge exchange;
- **National and local groups** that directly serve affected communities and interface with country-level health systems.

To create the landscape analysis, TAG employed a mixed-methods approach, combining an online survey questionnaire (see online Appendix) with semistructured key informant interviews to capture both the breadth and depth of CSO engagement in TB vaccine preparedness.

Community Consultation

In November 2024, TAG convened a project kickoff meeting and consultation in Bali, Indonesia, where this landscaping project plan was introduced to key community partners: members of the Global TB Community Advisory Board (Global TB CAB) and three regional community advisory boards (rCABs) representing Africa (AFROCAB), Asia-Pacific (APCASO), and Eastern Europe/Central Asia (ECAT). The Global TB CAB acted as an external advisory board by providing high-level input on activities and outputs. rCAB partners worked closely with TAG to produce the country policy portraits and access roadmap sections that appear later in this report. Participants were invited to further input into the survey design, and comments were incorporated along with post-meeting feedback solicited by TAG over subsequent e-mails and on virtual meetings. Community partners also helped TAG identify survey translators and electronically distribute the survey questionnaire.

Online Survey Implementation

We developed an English-language online survey instrument; translated it into French, Russian, and Spanish; and had it reviewed and beta tested by Global TB CAB members. The online survey was open for participation in March and April 2025; an extension through May 2025 was provided and led to an additional 72 completed surveys. CSOs working at the national level, operating regionally across multiple countries, and working at the global level were encouraged to complete the survey by submitting one response per organization. Unaffiliated activists could respond as an "individual." TAG distributed the survey electronically through targeted, purposive outreach to established TB civil society networks, including:

- TB civil society listserv (tb-civil-society@googlegroups.com)
- Stop TB Partnership's Challenge Facility for Civil Society Fund and TB REACH implementing partners
- The Global Fund's Community, Rights and Gender platform
- Gavi's CSO constituency
- Global TB CAB and rCAB partners' networks

Recruitment also leveraged TAG's extensive partner network, supplemented by snowball sampling through regional platforms and direct outreach to organizations serving marginalized communities, including young people, people living with HIV (PLHIV), Indigenous/tribal people, and people who use drugs.

The survey contained both closed and open-ended questions addressing the following domains:

- Organizational characteristics and target populations
- Current TB-related activities and intervention areas, including policy/advocacy
- Awareness and interest in TB vaccine policy and preparedness
- Perceptions of challenges and opportunities to engage in TB vaccines
- Resource and capacity needs
- Existing partnerships and collaboration patterns

TAG received 125 survey responses representing diverse geographic regions, organizational types, and target populations. Thirty responses were from individual advocates. Of 125 completed surveys, 93 responses were in English, 17 in Russian, eight in Spanish, and seven in French. All responses were translated individually by Yandex Translate and compiled and reviewed by TAG staff. Multiple-choice questions were standardized with text from the English-language survey to facilitate analysis.

Key Informant Interviews

TAG conducted nine key informant interviews with community representatives from high-TB-burden settings, CSO leaders with experience in vaccine introduction, vaccine policy advocates and program managers, and representatives from both global and national immunization technical advisory groups. Four respondents were selected from among survey respondents, and five external respondents were contacted for an interview based on their unique expertise. Interview topics included the current space for CSO engagement in vaccine preparedness, barriers and facilitators to meaningful community participation, insights and lessons learned from other TB prevention and vaccine introduction experiences, and recommendations for strengthening CSO involvement. Each interview lasted between 30 and 60 minutes, was audio-recorded, and was automatically transcribed using Otter.ai service. The interviewer cleaned and reviewed interview transcripts for themes.

Data Analysis

Survey data were analyzed in Excel using descriptive statistics to characterize the landscape of organizations, their capacities, and their needs. For a deeper dive into survey data, TAG conducted exploratory analyses to identify relationships, patterns, and trends in TB vaccine readiness and policy familiarity in CSO networks across local, national, regional, and global communities. To assess respondents' readiness to engage TB vaccine work, we developed several composite scores by combining responses to multiple survey items, weighted to capture important aspects of readiness capacities and needs. Qualitative data from open-ended survey questions and interviews were analyzed thematically to identify patterns, including challenges, opportunities, and recommendations.

Limitations

This analysis faced several inherent limitations:

- **Geographic scope:** Despite efforts to ensure global representation, including through extending the deadline and conducting direct outreach to underrepresented regions, some regions and contexts are underrepresented (North and South America, Middle East and North Africa).
- **Language barriers:** The survey was available in English, French, Russian, and Spanish, and interviews were conducted in English, thereby limiting responses to people proficient in these languages.
- **Selection bias:** Our sampling strategy was directed toward organizations already engaged in TB work or connected to existing networks. The survey was electronic and accessible only to people with internet access.
- **Temporal constraints:** The rapidly evolving vaccine development landscape, combined with unprecedented disruptions to foreign aid and changing civil society dynamics, means findings represent a snapshot in time and the perspective of organizations with capacity to respond during this tumultuous period.

Survey Results

CSO Characteristics

A total of 125 respondents from 42 countries completed the survey. Based on WHO region classifications, most respondents were in the African (41%), Southeast Asian (27%), and European (11%) regions (Figure 1). Eighty percent of responding organizations reported working in TB for more than five years. Half of respondents (47%) identified as national NGOs and around one-third as CBOs (29%). Regional networks and international NGOs (INGOs) each made up 6% of the sample (Figure 2). Ninety-four percent of respondent organizations were legally registered. The median staff size was 11 and ranged from 2 to 432.

Respondents reported working with a wide range of key and vulnerable populations, the most-mentioned groups being "TB survivors/people living with TB/people at risk of TB" (92% of respondents), "people living with HIV" (77%), and "women and girls" (58%).

When asked to indicate their primary area of focus (respondents could select three), the most frequently selected were "community-led monitoring" (55, 44% of respondents), "direct support for people with TB" (50, 40%), which could include things like peer support and adherence counseling, and "community TB service provision" (46, 37%), encompassing activities like contact tracing, access to diagnosis, and treatment provision. Only 36 groups (29%) selected "policy advocacy (any level)" directed toward entities like national TB programs, ministries of health, or the WHO. Even fewer groups (31, 25%) chose "demand creation for TB services and tools."

Figure 1

Region of Operation

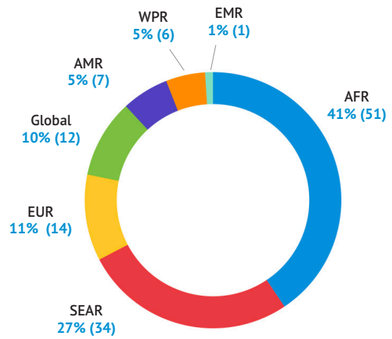


Figure 2

Organizations by Type

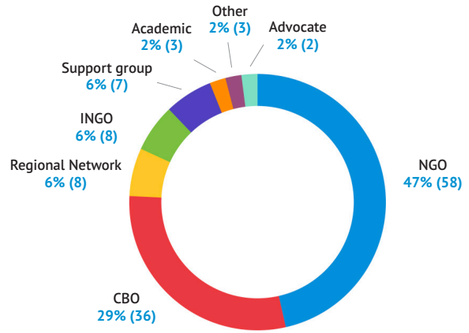


Figure 3

CBO Areas of Work

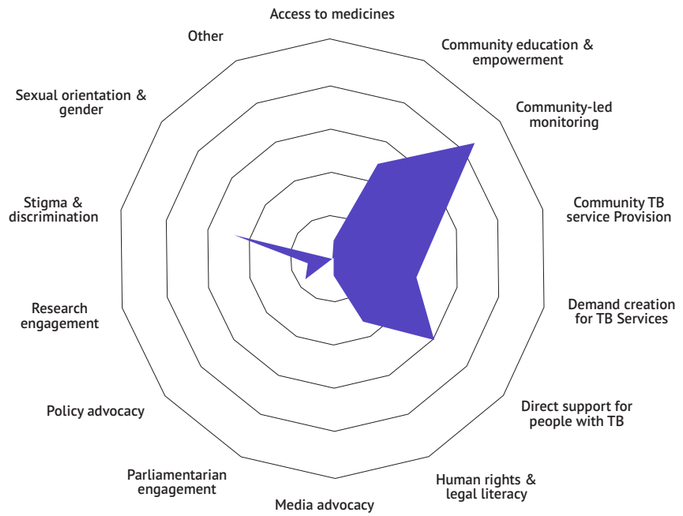
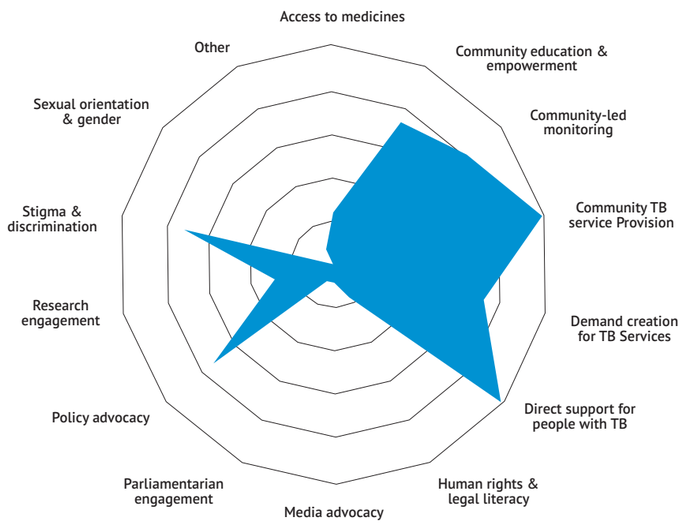


Figure 4

National NGO Areas of Work



For CBOs, the top two focus areas were "community-led monitoring" (21, 58%) and "direct support for people with TB" (15, 42%). The most frequently cited focus areas among national NGOs were "community TB service provision" (25, 43%) and "direct support for people with TB" (25, 43%). Seventy-five percent of INGOs and 63% percent of regional organizations included policy making among their top three focus areas, compared with 31% and 11% of NGOs and CBOs, respectively. Figures 3 and 4 illustrate how the thrust of NGO and CBO activity is weighted toward community-level activities with less emphasis on policy advocacy, parliamentarian cultivation, research engagement, and media work.

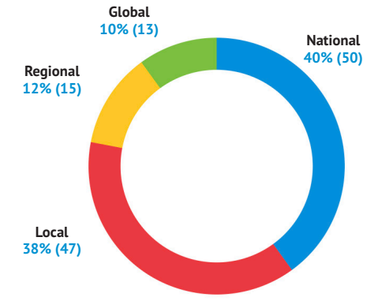
Notably, community-led monitoring (CLM) and direct support for people with TB were priorities across all organization types, including at the global and regional levels. Fifty-five respondents (44%) selected CLM as a focus area, highlighting this as a critical function that CSOs can provide in vaccine introduction. CLM, according to UNAIDS, "is a cyclical process in which people affected by health inequities . . . systematically monitor services, analyze the data they collect, and conduct evidence-driven advocacy to improve service delivery, generate solutions and create an enabling environment for their well-being."[25]

Although only 36 (29%) respondents included policy advocacy among their top three priorities, when asked to identify the types of policy-making or advisory bodies they interact with, nearly all respondents indicated some level of policy engagement. The following policy or advisory bodies were mentioned most often: "Ministry of Health" (81, 65%), "local health departments" (78, 62%), "Stop TB Partnership – national, regional, or global platforms" (76, 61%), and Global Fund Country Coordinating Mechanisms (59, 47%).

When asked to indicate their primary level of work, respondents split evenly between "national" (40%) and "local (referring to community, district, or provincial)" (38%) levels (Figure 5). Twelve percent reported a "regional" focus (i.e., working across countries in the same region) and 10% said their primary level of work was "global."

Figure 5

Primary Level of Work



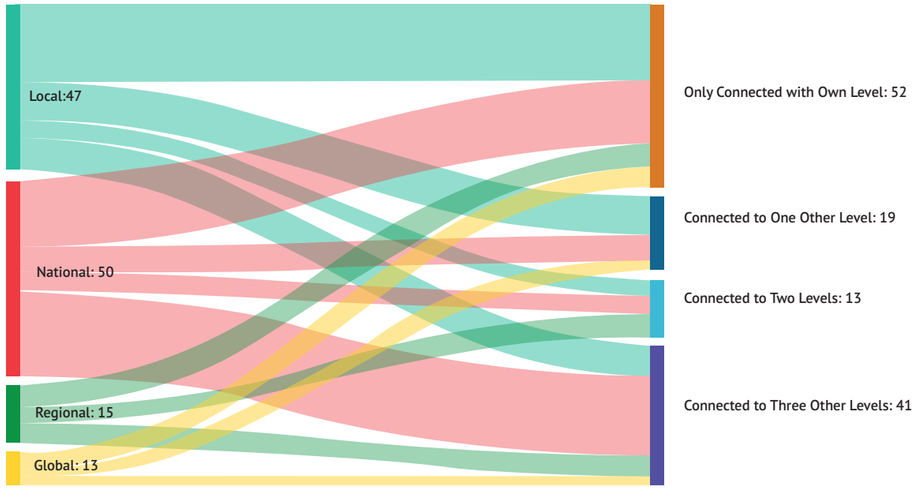
Network Interconnectedness

To assess how respondents were integrated into the larger TB civil society and community ecosystem, we analyzed the degree each organization was networked with organizations working at different levels. Groups were asked to indicate if they worked with organizations at the local, national, regional, and/or global levels.

Findings demonstrated a polarization effect, with near-equal proportions of groups working either only with other organizations at the same level — i.e., local organizations working with local organizations (52, 42% of respondents) — or working across all four

Figure 6

Civil Society Network Connections



levels (41, 33% of respondents). Only 25% of groups surveyed worked with other organizations operating at one (19, 15%) or two (13, 10%) additional levels (Figure 6).

Zooming in, local-based organizations were predominantly (24, 51%) working only with other local groups, with only 19% networked at all four levels. Among global groups, 38% (5) worked only with other globally oriented groups and 46% (6) worked across all levels. Given the important role of civil society at all levels in driving vaccine implementation, demand, and acceptability, there is a clear need for greater networking and collaboration in advance of new TB vaccine rollout. Recommendations drawn from key informant interviews and country policy portraits (presented in other sections of this report) echo this need, stressing the importance of greater integration of groups working at all levels to ensure coordinated advocacy.

National groups demonstrate the potential to serve as network linchpins or bridge organizations connecting groups operating on different levels. The majority (66%) of nationally focused organizations work with groups at one (14%), two (10%) or all (42%) other levels. Resourcing national groups that are well positioned to draw together civil society and community stakeholders across levels may prove an effective means of enhancing collaboration across civil society for enhanced coordination around TB vaccine policy making and advocacy.

TB Prevention Experience

Almost all respondents (110, 88%) had conducted TB prevention-related activities (Figure 7). The top reported TB prevention-related activities were "service provision" (77, 70%), "stigma and discrimination reduction" (69, 63%), "community education, empowerment, and capacitation" (65, 59%), "demand creation for TB prevention" (64, 58%), and "community-led monitoring" (58, 53%).

Among groups with TB prevention experience, 75% reported having done work related to TB prevention treatment (TPT) and another 14% had not but were interested (Figure 8).

Figure 7

Prior TB Prevention Experience

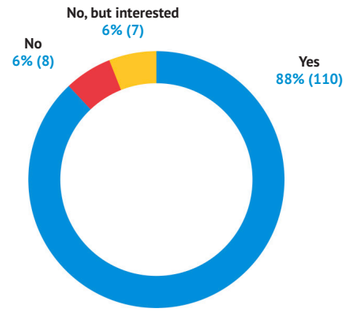
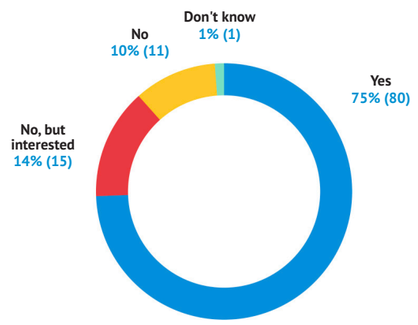


Figure 8

Experience Working on TPT

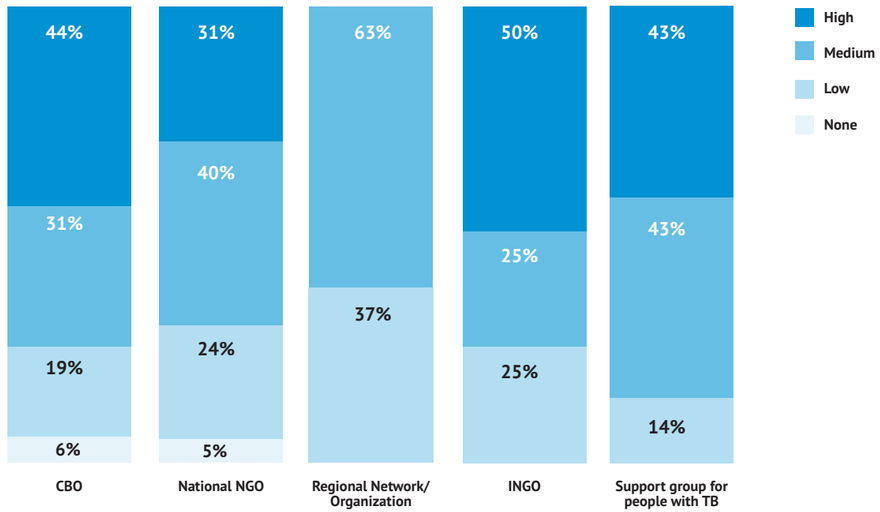


To assess prior CSO experience working on TB prevention, we created a composite score combining responses to three questions: "Does your organization conduct (or has it ever conducted) TB prevention related activities?"; "Has your organization done any work related to TB preventive treatment?"; and "Do you currently engage in activities related to TB vaccine research, readiness, or policy?" Organizations were given a point if they answered "yes" to any of these questions, with possible scores ranging from 0 to 3. We then classed final scores into four categories reflecting different experience levels with prevention work: high, medium, low, and none. Scores are shown in Figure 9.

Across organization types, 50% of INGOs, 44% of CBOs, and 43% of support groups for people with TB had high TB prevention experience scores compared with 31% of national NGOs. Among eight regional networks, 63% scored medium and 37% scored low, with none scoring in the high category. The distribution of scores suggests that there is a solid base of TB prevention experience across organization types, but there is ample room to build on this foundation. TB prevention is a relatively new focal area in global TB elimination efforts, first coming to policy prominence with the advent of the End TB Strategy in 2015 and contemporaneous investments by donors like Unitaid to introduce short-course TPT regimens such as 3HP and 1HP (e.g., the IMPAACT4TB project, which included a funding set-aside for community-based organizations to build demand for 3HP and 1HP and advocate for national policy change).[26] Prior to this, prevention was considered a niche area of work, secondary to TB diagnosis and treatment, with recommendations for TPT limited to PLHIV and child contacts and primarily undertaken in the context of TB/HIV integration.[27]

Figure 9

TB Prevention Experience Scores



Vaccine Experience

Seventy-five organizations (60%) reported no prior engagement in any TB vaccine-related work (Figure 10). Among 42 (34%) organizations indicating some previous engagement on TB vaccines, 20 reported working at the national level and 11 each at the regional and global levels. For those already engaged, the most frequently mentioned areas of work were "advocacy for equitable access" (62%) and "community engagement in TB vaccine research" (51%). Other areas of considerable engagement included "demand creation" and "community engagement for TB vaccine education" (43% for both).

Although existing experience with TB vaccine work is modest, interest in engaging with TB vaccine readiness is high (Figure 11). Eighty-three percent of respondents (104) said they were "very interested" in TB vaccine readiness work and another 14% (17) were "somewhat interested."

Regarding current engagement in any other (non-TB-related) vaccine work, only 32% (40) of respondents reported "yes." Those activities were largely related to "COVID-19" (26, 65%), "Human Papilloma Virus" (18, 45%), "Hepatitis B Virus" (13, 33%), and "malaria" (12, 30%).

Figure 10

Current Engagement on TB Vaccines

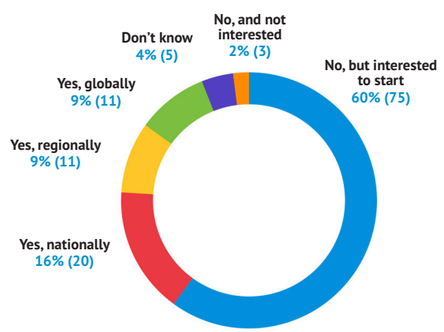
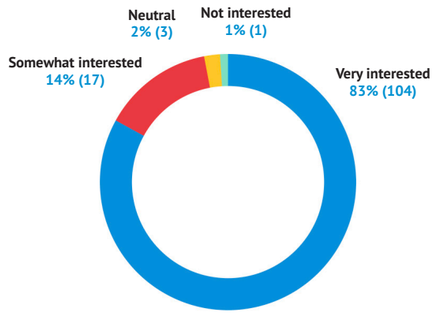


Figure 11

Interest in TB Vaccine Readiness Work



To assess familiarity with vaccine policy making, we created a composite score combining responses to four questions: "Are you familiar with the *WHO Evidence Considerations for Vaccine Policy Development for Tuberculosis Vaccines Intended for Adults and Adolescents (ECVP)?*"; "Are you familiar with the WHO Global Framework for New TB Vaccine Introduction?"; "Rate your understanding of how immunization policy is made in your context"; and "Have you ever engaged with a NITAG, RITAG, or global vaccine advisory body?" For questions assessing familiarity, a score of 0 was assigned to "no familiarity" with a maximum score of 2 for high familiarity. Composite scores could range from 0 to 7; we grouped scores into three categories reflecting different levels of existing knowledge: high (>5), medium (3–5), and low (<3). Scores are shown in Figure 12.

Most respondents had "low" or "medium" vaccine policy familiarity scores (106, 85%). Among CBOs and NGOs, just seven and four, respectively, had "high" familiarity, with about two-thirds of CBOs and almost half of NGOs reporting "low" familiarity. Most regional networks/organizations reported "low" familiarity. The concentration of low and medium scores across organizational types reveals substantial room for learning and highlights technical capacity build-

Figure 12

Vaccine Policy Familiarity Scores

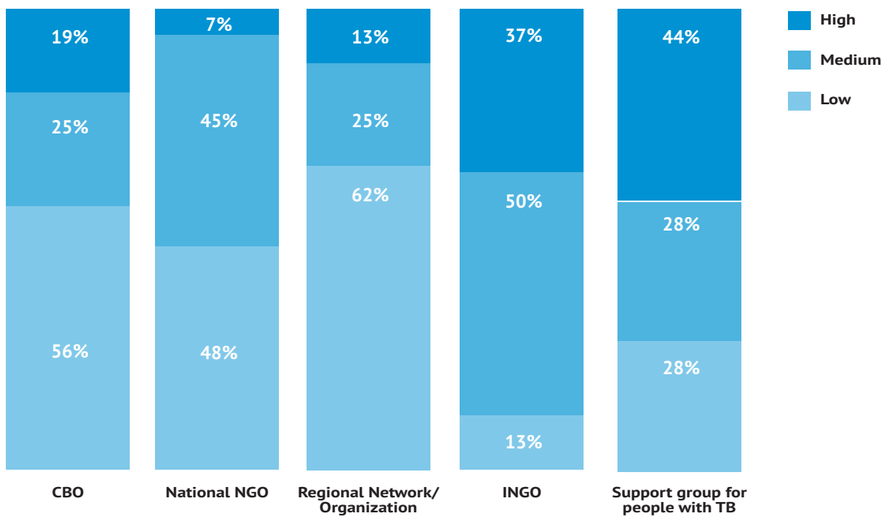
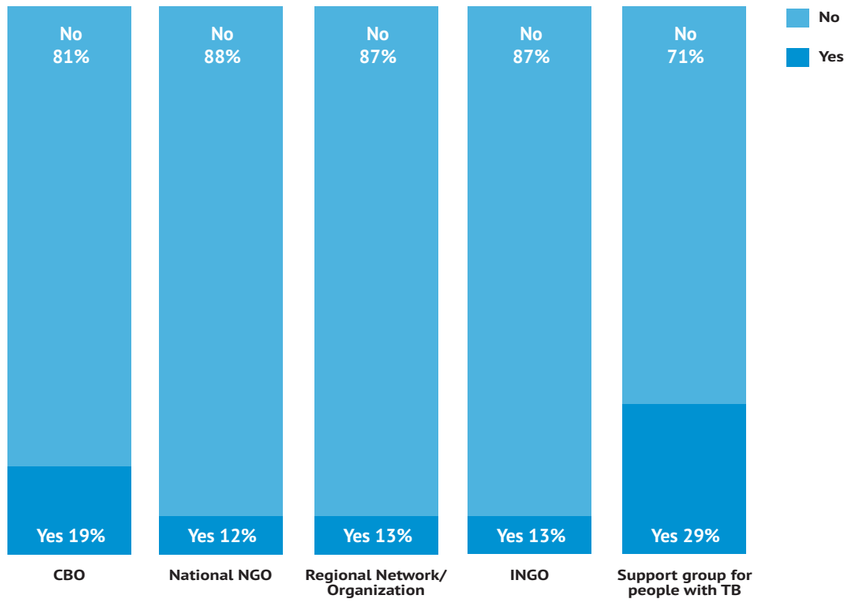


Figure 13

Previous NITAG Engagement



ing on immunization policy making as an important intervention to prepare CSOs to engage in TB vaccine readiness.

One concrete illustration of the relative lack of vaccine policy prowess among TB civil society is the fact that just 17% (21) of survey respondents reported ever having engaged with a national immunization technical advisory group (NITAG), regional immunization technical advisory group (RITAG), or global vaccine advisory body (Figure 13). Whereas all academic/research institutions that completed the survey reported NITAG engagement, only 19% of CBOs and 12% of national NGOs did so. In terms of regional distribution, engagement with NITAGs (or similar vaccine policy-making bodies) was highest in the region of the Americas, where 43% of respondents reported relevant engagement, and lowest in the Southeast Asia region (6% of respondents). Twenty-five percent of global organizations and 20% of organizations in the African region had engaged NITAGs.

The lack of NITAG engagement is perhaps not surprising, given that no new TB vaccines have come before NITAGs for review. This finding dovetails with insights from the key informant interviews and country policy portraits (discussed in section two) that most NITAGs lack formal structures for engaging civil society. It also contrasts with the rich tradition of community engagement in TB policy making in which most national TB programs invite community representatives to participate in guideline groups, technical committees, review panels, and strategic dialogues. This practice has historic roots in the HIV response, reflecting rights-based practice and principles such as "nothing about us without us" and the "greater involvement of people with AIDS." Over time, community engagement in all aspects of TB programming has matured into a well-recognized norm, one based on a model that centers "affected communities" (i.e., those directly impacted by TB) as experts in the TB response.

Involvement of civil society and communities in policy making is also recommended in the WHO End TB Strategy and affirmed in the political declaration of the 2023 United Nations High-Level Meeting on TB.[28] The WHO's *Guidance on Engagement of Communities and Civil Society to End Tuberculosis* states: "Meaningful community and civil society engagement to end TB requires that people affected by TB are equal partners in the TB response, with ministries of health and their NTPs." It goes on to say, "Community engagement for the TB response includes engagement in governance, policy development, decision-making," in addition to implementation and monitoring, and should unfold across all levels.[29]

As new TB vaccines come before NITAGs for review, there will be an expectation among TB CSOs for policy decisions to accommodate and account for community perspectives. This will require adaptation on both sides, but particularly among immunization bodies unaccustomed to inviting civil society into policy-making processes as equal members.

Capacity and Readiness to Engage

Concerning organizational capacity (resources/personnel/expertise) to engage in TB vaccine preparedness, only 20% (24) felt "fully prepared" (Figure 14). Most respondents felt either "somewhat prepared but may need additional support" (51, 44%) or "not currently prepared but interested in building our capacity" (42, 36%).

Respondents highlighted "funding opportunities" (104, 83%) and "technical assistance and training on TB vaccines" (101, 81%) as the top kinds of support needed to strengthen their organization's role in TB vaccine preparedness work. Eighty-two respondents (66%) also selected "networking and partnership opportunities" as an area where additional support would be needed.

In terms of contributing to TB vaccine preparedness, the top three areas in which respondents expressed interest were "capacity building" (57, 46%), "advocacy for equitable access" (48, 38%), and "demand creation" (47, 38%). A high number of respondents also chose "community engagement in TB vaccine research" (46, 37%), and "monitoring and evaluation of TB vaccine rollout" (39, 31%).

Figure 14

Capacity to Engage in TB Vaccine Work

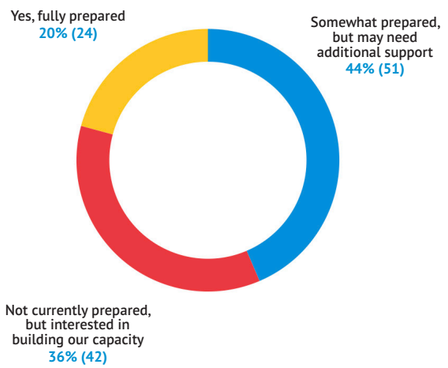
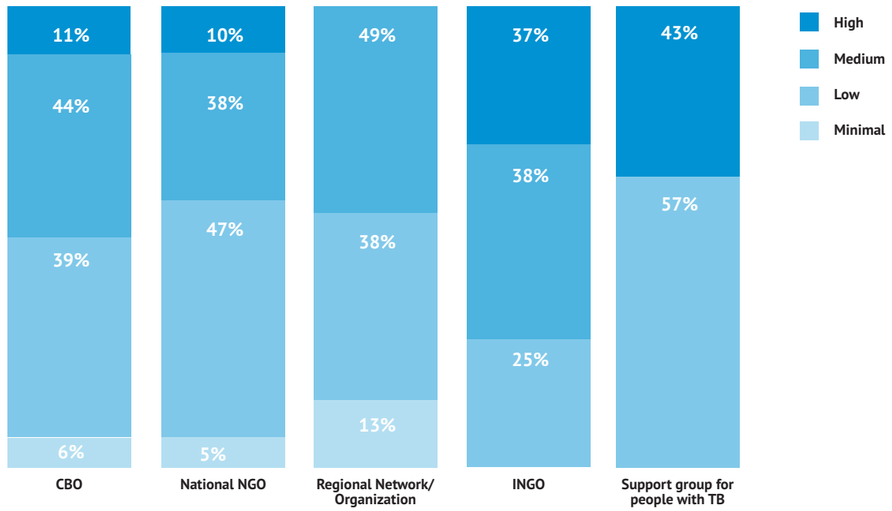


Figure 15

Vaccine Readiness Ranking



To assess organizational readiness to engage in TB vaccine work, we created a composite score combining answers to 12 questions that probed previous experiences (with TB prevention, TPT, and WHO Expanded Program on Immunization [EPI]); familiarity with vaccine policy making; interest in engaging with TB vaccine work; and perceived capacity to engage. For most questions, "yes" answers were assigned a score of 1, with higher weights given to answers indicating prior NITAG engagement and EPI work. The range of possible scores was 0 to 25; we grouped scores into four categories: minimal (<6), low (6–11), medium (12–18), and high (>18). Scores are shown in Figure 15.

Most CBOs ranked low (14, 39%) and medium (16, 44%) in terms of TB vaccine readiness, as did NGOs, where 27 groups (47%) ranked low and 22 (38%) scored medium. In the African region, only 6 of 51 (12%) groups scored high; 22 (39%) had medium scores and 21 (41%) low scores. A similar pattern played out in the Southeast Asian region, where only three (8%) groups scored high compared with 11 (32%) scoring medium and 17 (50%) low. Only in the Americas did most respondents rank high in readiness (although the number of responses from this region was low). We also examined vaccine readiness scores by organizational maturity but did not uncover major differences between organizations with more than five years of experience versus those with two to five years or newer groups with less than two years.

About half (61, 49%) of respondents reported being "somewhat familiar" with the WHO's *Evidence Considerations for Vaccine Policy Development for Tuberculosis Vaccines Intended for Adults and Adolescents* (ECVP). Thirty-three percent were "not familiar" and 18% were "very familiar" with it.

Table 1

Civil Society Contributions to TB Vaccine Preparedness

Rank	Biggest Barriers to TB Vaccine Readiness in Your Context	Areas of TB Vaccine Preparedness Where Community Advocacy Could Make the Largest Difference
1	Limited information about TB vaccine research and the pipeline	Community engagement for TB vaccine education
2	Limited community vaccine literacy	Inclusion of high-risk and marginalized populations in vaccine delivery
3	Insufficient funding for vaccine implementation	Demand creation for vaccine uptake
4	Low political will	Community engagement in TB vaccine research
5	Vaccine hesitancy	Addressing myths and mis-/disinformation about vaccines

Thirteen percent of respondents were very familiar with the WHO's *Global Framework to Prepare for Country Introduction of New TB Vaccines for Adults and Adolescents* (WHO Global Framework) and 47% were "somewhat familiar." Forty percent were "not familiar" with it.

Concerning understanding of how immunization policy is made in respondents' contexts, just 12% (15) of respondents were "very familiar (e.g., have participated in developing immunization policy in your context)," 54% were "somewhat familiar (e.g., have attended lectures, dialogues, or seminars on the topic of immunization policy but have not participated directly)," and 34% were "not familiar."

At the end of the survey, respondents were asked to select the three biggest barriers to TB vaccine readiness in their context and the top three areas of TB vaccine preparedness where community advocacy could make the biggest difference. Table 1 shows the most frequently selected areas.

Open-Ended Survey Responses

Respondents were invited to answer eight open-ended questions on TB vaccine readiness; on current TB prevention and general vaccine experiences and needs; on perceived opportunities; and on the role of donors and vaccine developers in supporting community engagement in this area.

When asked to describe their TB prevention work, respondents largely focused on community engagement and awareness-raising; and organizations consistently highlighted education campaigns, community dialogues, and addressing stigma. Contact tracing and referral systems were also frequently mentioned, with many organizations involved in identifying household contacts of people with TB and linking them to screening and preventive treatment. Many respondents focused on advocacy, both at the community and policy levels, to promote short-course TPT regimens like 3HP and 1HP. Respondents also mentioned capacity-building, such as training community health workers,

health care providers, and community members on TPT delivery and awareness.

In describing vaccine-related work, respondents mostly named COVID-19 vaccine promotion. Also consistently emphasized were demand creation, dispelling myths, and addressing vaccine hesitancy. One nonprofit vaccine developer (IAVI) reported a wide range of TB vaccine work that, in addition to core product development activities, included "advocacy for equitable vaccine access" and "community engagement in TB vaccine education and demand creation for TB vaccine uptake." IAVI also engaged in policy development for TB vaccine introduction and in "supply planning and pricing strategies." No other groups shared examples of TB vaccine work of similar depth and breadth.

Most respondents' activities centered on broader vaccine advocacy and access (including work on malaria, HIV, HPV, HBV, and routine immunizations, especially targeting vulnerable populations) and engaging in community-based mobilization and education, serving as intermediaries between health systems and communities to build vaccine confidence and improve uptake. Some organizations reported engaging in policy and technical support, including working with government partners to strengthen vaccine delivery systems.

When asked what they saw to be the greatest opportunities for CSOs in TB vaccine preparedness, the most common themes were "community education" and "demand creation." Respondents consistently emphasized their role as trusted intermediaries who can combat misinformation and build vaccine acceptance — a dynamic echoed in the country policy portraits discussed later in this report. As one advocate from Zambia highlighted, "CSOs are trusted actors within communities and are well-positioned to raise awareness, provide accurate information, and address vaccine hesitancy through culturally appropriate and grassroots-driven approaches."

The second major opportunity described was advocacy and policy engagement. Respondents emphasized CSO capacity to influence national health agendas, secure funding, and ensure equitable access. An NGO representative to the TB Social Observatory in Latin America noted a full range of ways CSOs can be involved: "In Bolivia, civil society organizations have a key opportunity in the preparation of the TB vaccine through community monitoring, education and awareness to reduce stigma, and advocacy in the formulation of inclusive policies. In addition, they can strengthen equitable access to vaccination in vulnerable populations, articulate strategic alliances to mobilize resources, and train community promoters to ensure effective implementation."

Capacity building and training were also consistently highlighted as opportunities for CSOs in TB vaccine preparedness. Many respondents emphasized monitoring and accountability, with CSOs positioned to track vaccine rollout, collect community feedback through, for example, the use of social accountability tools (e.g., scorecards), and ensure transparency in decision making.

On how funders and researchers should engage CSOs in TB vaccine readiness, the overwhelming consensus was that early, meaningful, and sustained engagement

was essential for success. Equal ("not top-down") partnership and being involved from the beginning of a process, not as an afterthought, was of paramount importance to respondents. An INGO in Bangladesh noted, "Funders and vaccine developers should see CSOs as co-designers, not just communicators. Genuine, well-resourced, and early engagement with CSOs will help ensure that TB vaccine rollout is equitable and community driven." Rather than simply being tasked with conveying information, CSOs ought to be included in decision-making processes, policy development, and strategic planning — and not invited into a pre-determined strategy.

Capacity building and sustained funding were seen as critical enablers for meaningful and effective CSO engagement in TB vaccine preparedness. Respondents emphasized the importance of direct financial support to CSOs — in particular, long-term/multiyear, flexible funding (rather than short-term project funding). Stable, predictable funding is needed for CSOs to participate more effectively and "strengthen our community education, social monitoring, and equitable access to vaccination activities," according to one respondent from Bolivia. An advocate from Zambia noted that "supporting CSOs to lead community dialogues, address misinformation, and amplify the voices of TB survivors and vulnerable populations can significantly boost public trust and vaccine uptake. Flexible funding mechanisms are crucial to allow CSOs to respond quickly and effectively to changing community dynamics."

CSOs described themselves as trusted intermediaries who can bridge gaps between vaccine developers, policy makers, and communities, particularly for addressing vaccine hesitancy and reaching vulnerable populations. A Zambian respondent shared that "CSOs bring unique insights into community needs, behaviors, and barriers, which are critical for designing people-centered strategies. Funders and developers should involve CSOs in consultations, advisory boards, and technical working groups to co-create communication plans, rollout strategies, and community engagement frameworks that are context-specific and responsive to real-world challenges."

Another universal theme was access to timely, accurate information and technical guidance. Respondents voiced a need for regular updates on vaccine development, simplified training materials, and communication tools. One respondent, from an NGO in Azerbaijan, highlighted the need for coordinating platforms: "A very important factor is the existence of a coordinating center or platform that could bring together the efforts of all stakeholders, including government agencies, donors, vaccine developers and CSOs. This model will help avoid duplication, establish an exchange of experience, and ensure broader and more equal coverage."

The WHO TB Vaccine Accelerator Council provides such a platform for governments, funders, and other stakeholders to unite around the shared goal of facilitating new TB vaccine development and delivery. Civil society is represented on the Accelerator Council's principals group, and the Council has engaged civil society in specific work streams, for example consulting CSOs in its work to propose financing and access solutions for new TB vaccines. The Accelerator Council's plan to establish

a working group on "country readiness, advocacy, and community partnerships" could create a more formalized platform for bringing civil society into conversation with governments, donors, and vaccine developers in a regular way.

Some respondents raised language accessibility and equity as concerns. An advocate from Côte d'Ivoire noted, "The working language should not be in English. It is discriminatory for French and Portuguese speakers." Real-time information sharing, such as "having a database or pipeline report of ongoing or upcoming vaccine studies in respective countries for us to have better linkages and be up to speed on what studies are being carried out," was also identified as a need by a respondent from a TB survivor group in Kenya.

Key Informant Interviews

Key informants brought invaluable insights to complement the survey data. TAG spoke with nine international NGO staff, academics, NITAG members, and advocates working at global, regional, national, and local settings. Interviews centered on questions related to challenges and opportunities for CSO engagement in TB vaccine preparedness and gave plenty of space for additional observations (see online Appendix).

Barriers and Challenges

Resource Constraints

Interviewees elucidated a wide range of challenges facing CSO engagement in TB vaccine preparedness, from systemic to organizational to community level. Resource constraints emerged as the most critical barrier, made worse by halts to foreign aid. Multiple respondents described how funding gaps undermine essential community-level work.

> What are the foundational funding [structures] to make sure that these organizations are always there? Now there will be maybe even a bigger impact on the presence of these organizations, just because of the global funding cuts. *(Vaccine policy specialist, medical humanitarian INGO)*

> We haven't started the community dialogues [on new TB vaccines] because we don't have funding at that level. If civil society and communities don't get funding, then those structures kind of become dysfunctional. *(Gavi CSO Constituency Steering Committee representative, Kenya)*

> Our organization has limited activities and cannot bring services to geographically isolated or displaced areas. We are not supported. We are just doing our volunteer works with our own money. *(CBO leader, Philippines)*

Compounding funding challenges was civil society exclusion from decision-making processes: "Many CSOs don't have a seat at the table where decisions are being made, and so because of that, it's very challenging for them to negotiate for funding as well," according to an NGO director in South Africa.

Knowledge Gaps

At the organizational level, knowledge gaps were consistently mentioned as a fundamental barrier to effective engagement. A critical challenge identified across contexts was the need for technical capacity building and treatment literacy.

> A key challenge is the knowledge gap. The field is rapidly changing, and even those of us who would consider ourselves immunologists, we need to keep reading and attending seminars and attending courses to stay up to date. We do not currently have a very structured training program for civil society in the context of vaccinology. *(Director, NITAG Support Hub, Africa)*

> I must be very candid to say that we require technical knowledge, like on TB vaccine candidates, especially regarding their efficiency and dosage, schedules, and the storage requirements. The organization would benefit from updated training modules, because we don't have much information. *(NGO director, India)*

> TAG has done an excellent job with the [Unitaid funded] ASCENT and IMPAACT4TB projects, around doing capacity buildings for the CSOs to actually have the technical know-how; that's very, very important. Sometimes all this information is missing. *(NGO director, Nigeria)*

Community participation in policy making was also mentioned as a problem due to issues with selection and access.

> Civil society is quite diverse, but we do need to have better education [. . .] of our civil societies. You have a lot of people with good intentions, but not necessarily the knowledge that's needed for what and when to support [a vaccine]. It's quite different to have someone who knows what they're talking about and advocates for that. *(Former Chair, Global NITAG Network)*

> Sometimes there's issues with selecting the right organization for that role [. . .] What is the access of these community groups to the policy making, and what is their visibility within the policy making? *(Vaccine policy specialist, medical humanitarian INGO)*

Coordination Gaps

At the government level, coordination gaps were seen as impeding effective vaccine introduction. A lack of funding was perceived as a serious hamper on country-level coordination and government programs availing of CSO support.

> CSOs can play a key role around leadership and coordination. In Nigeria, [the] National Primary Healthcare Development Agency (NPHDA) is in charge of primary health care centers. When TB vaccines come in, we want to utilize them, right? That will require strong collaboration between the TB Program, located at the Ministry of Health, and the NPHDA [. . .] but we have always seen issues around coordination. For COVID-19, that was the main issue. COVID-19 was with [the] Ministry, and you need health care workers, who are under NPHDA, and you need to work together. So, I feel like even before the vaccines come in, there is a need for established coordination. *(NGO director, Nigeria)*

Many respondents noted opportunities to build on existing structures while addressing critical gaps; for example, a Gavi CSO Constituency Steering Committee representative from Kenya said, "We already have elaborate structures . . . The problem is that, are these structures functioning?" This interviewee went on to describe how the government often relies on civil society to organize working groups or task forces: "The government, for a long time, has been relying on partners to hold these meetings together. So if partners don't come with money, then the meetings don't take place, and we lose contact. If civil society and communities don't get funding, then those structures become dysfunctional."

While several respondents shared successful models of government-CSO collaboration, others revealed the complexity of these relationships. One model was a multisectoral approach through an "accountability framework" that includes regular meetings with relevant ministries, including the Treasury, which allocates funds. Another government-CSO partnership model shared was collaborative monitoring to track progress. This relationship, however, was not always smooth. According to a leader of a South African NGO, "Sometimes civil society is sidelined, and sometimes what ends up happening is, instead of a partnership, civil society often ends up fighting government."

Trust and Hesitancy

At the community level, vaccine hesitancy was described as a major barrier, along with research misconceptions and language and cultural barriers when reaching marginalized communities, such as tribal groups. Interviewees also emphasized the need for culturally and religiously sensitive approaches, without which vaccines were met with resistance.

> The confusions emerged basically from the barrier of language. The language barrier, if we can mitigate [that], then everything would be sorted. *(NGO director, India)*

> Because of the programmatic decision around only targeting nine- to 14 year-olds [for HPV vaccines], communities were asking, 'Why are you targeting only this specific group? Are you trying to reduce our population? Are you trying to stop girls from giving birth in the future?' *(NGO director, Nigeria)*

A number of key informants shared the opinion that pro-vaccine advocates often "get tired and move on," while antivaccine voices "ceaselessly repeat their misinformation and dominate the public sphere." Many respondents emphasized the concept of "immunizing against misinformation" early and proactively, rather than trying to counter it once it has spread.

"There is hesitancy in every new intervention," one CBO respondent from the Philippines explained. She went on to say, "If we could provide the right information so that they could decide on their own to accept or to benefit from the vaccine. We remember that our first President of the Philippines died of TB . . . Because at that time, there is no cure for TB yet, and because of R&D, now our members, TB survivors, are TB free."

TB Vaccine-Specific Challenges

Respondents identified several challenges unique to TB vaccine introduction, including vaccine fatigue. As the Gavi CSO Constituency Steering Committee representative from Kenya noted, "We are living in an era where communities are having vaccine fatigue. As the pathogens increase, the vaccines [are] increasing, and therefore the communities are having fatigues."

This community-level fatigue mirrors what another INGO respondent in Africa described as governments' "conundrum of prioritization" when facing multiple new vaccine options and implementation demands.

Other interviewees revealed economic and perception challenges: "My feeling is that the vaccine is not going to be cheap, and the sense of need of TB vaccines is not well established in the community," said the Global NITAG Network chair.

TB stigma was raised as a fundamental barrier to community programming, one that undermines diagnosis and treatment when culturally sensitive treatment literacy is absent. Stigma is so profound that, as one interviewee from Nigeria explained, even funding and treatment is not enough to encourage service uptake: "Funds are given to people with drug-resistant TB to come to the facility as transportation stipend. [But] we are having patients saying, 'No.' You know, the Nigerian context, with poverty and all that, saying no to the money because they just don't want anything to do with the disease. Can you imagine, if this person does not want to be treated? If money is not going to influence, do you see how bad that is?"

Opportunities and Enablers

Qualitative interviews unearthed CSOs' many unique strengths, which respondents pointed out cannot be replicated by formal health systems. CSOs serve multiple critical functions in vaccine ecosystems. According to a vaccine policy specialist at a medical humanitarian INGO, "I think demand, generation, advocacy, community engagement, are such key parts of what civil society does. We need to make sure that civil society is really seen as an integral part of immunization activities."

Leveraging Trust to Build Demand

Interviewees touched on the critical role of CSOs in both policy development and vaccine implementation, and the need to leverage existing infrastructure rather than build new systems from scratch. Community-based approaches were described as powerful, and the trust factor was universally highlighted — starting with the unique bridging role CSOs play in connecting communities to TB vaccine science. As explained by the NITAG Support Hub director, "Most trial sites will have either a civil society representative or community members representing the communities. That is the link between the scientists and the community." This connection proves essential for building trust and understanding, as he noted: "We've learnt that it's one thing to have the vaccine on the shelf; it's another thing to have that vaccine get to the arms of the people."

Trust was also seen as driving demand for TB services and tools. When an advocate vouches for an intervention, it is more likely to be taken up by the community.

> We can reach the people who are most in need of the information . . . They believe us, because they have experienced how we cared for them. *(CBO leader, Philippines)*

> From experience from TB, we've seen that if you're able to provide adequate information to them to say, okay, yeah, we just don't want you to get infected. You should take this [preventive treatment] — people are

> actually willing to do that, and they trust you. You've developed trusted relationships. *(NGO director, Nigeria)*

> The entire uptake of it really depends largely on the work that civil society organizations will do in pushing for the demand with the communities, ensuring there is proper education from structures that are trusted by communities. *(INGO leader, South Africa)*

Inherent to this potential is the recognition that there is no one-size-fits-all model.

> Not just civil society — engaging the local organizations, trusted organizations, sometimes it's religious leaders that you need to engage, or schools, or whomever is trusted in that community and making sure [. . .] It's never a one-size-fits-all when it comes to this. If we design a program, and I think that's sometimes a bit of barrier that we see on the Gavi side, is that we cannot put the same template on every country, and definitely not [at the] subnational level. *(Global INGO vaccine policy specialist)*

Cultivating CSO-Government Partnerships

One respondent, at an Africa-based INGO, emphasized the importance of "putting government at the center" of private sector integration, social contracting, community work, and donor coordination. She advocated for consolidating and simplifying funding mechanisms while establishing "guardrails" like dedicated funding set-asides for civil society.

A former Global NITAG Network chair noted how the health system could leverage CSO expertise: "It's for the NITAGs to look at this evidence and make a recommendation to the Minister of Health . . . Then the MOH will need partners, and those partners will include civil society."

He went on to describe how legal mandates can both strengthen and constrain civil society inclusion, reflecting on the difficulty of selecting appropriate CSO representatives and how this led, in Guatemala, to the strategy of inviting CSOs based on the specific vaccine under evaluation. The former Global NITAG Network chair elaborated:

> In my mind, [community] should be part of every part of the process, because it's hard for [a NITAG] to get a sense of how the population is actually feeling, how they're going to get the recommendation and vaccine. Also, they are really good allies as you implement, but at the end of the day, it's not easy to have them throughout the whole process.

This interviewee went on to describe how the transition of the country's NITAG from an advisory group constituted under the Ministry of Health to one mandated by law affected its civil society engagement. In this case, lawmakers said they could not legally mandate the inclusion of civil society in the NITAG. But once the law went into effect, the NITAG had the latitude to invite external observers, including from civil society. These participants are not full NITAG members, however, and cannot vote on decisions. In this NITAG coordinator's mind, this is a common problem for NITAGs: "That's an issue not only for us, but I think for most NITAGs, even really developed NITAGs like in the United States. They don't have an official representative [from civil society]. They invite people to participate and share their input, [but] they don't vote."

Cultural Sensitivity and Community Autonomy

Respondents shared innovative approaches to community engagement that prioritize cultural sensitivity and community autonomy. Reflecting on maintaining support for measles vaccination, the director of an NGO that works with tribal populations in India stressed the importance of working with "community influencers" to calibrate information to different levels of community understanding.

> We have used community media, community radio in their own language, in their own dialect, with the local stories as well as songs. And it is not by us — the community media is being led by the tribal women. They are going to the field; they are telling their own stories. If you give them the space, if you delegate your so-called power to them, you can see rather miraculous change at the ground level. *(NGO director, India)*

Interviewees concurred on civil society's essential role in ensuring community-centered policies through the power of peer education and lived experience.

> There are a lot of roles that civil society can play, especially when it comes to community engagement, ACSM (advocacy, communication, and social mobilization) in general. We need to develop policies in the first place. We need to make sure that the policies are patient centered. We also need to make sure that these policies are community centered. *(NGO director, Nigeria)*

Community health care workers were consistently identified as an untapped resource, especially given the implicit trust imbued in them by their communities. Engaging women was seen as a critical access advantage in many cultural contexts. As the Nigerian NGO director noted, "One key thing that we need to sustain is female field officers, female volunteers, because they can enter everywhere, like all the households . . . The cultural context here is that a woman can enter any household, while men are restricted. If you have patients that don't want to come to the hospital, she'll be able to see them with their eyes. If we have people that are most likely contacts, we should be able to also encourage them to come to the households, while the men will only be able to engage with the men outside, and that is limited."

Respondents emphasized CSOs' critical role in strengthening vaccination touchpoints beyond routine childhood immunization, as countries adopt increasingly complex vaccination schedules with limited absorption capacity. Another observation from a South African NGO leader was that adult vaccination programs delivered only at clinics "might miss a big population of adults."

Reaching Marginalized Populations

A respondent from a medical humanitarian INGO emphasized CSOs' crucial role in getting vaccines to the hardest-to-reach populations: "I think the big barrier, from our perspective, is also the equity perspective,

if you look at how vaccination is happening, and I'm afraid that might become more amplified now, with the funding cuts: we go for large numbers, for as little money. But, if you go to the hardest-to-reach communities, the immunization programs don't reach them."

She emphasized CSOs are "where we really need to push," giving an example of disparities in measles vaccine coverage from 2023: "Measles coverage was 17% lower in fragile conflict settings versus stable settings. And that's at the national level. If you zoom in at the subnational level, it's way worse." She also highlighted that "when we look at what CSOs are trying to achieve, it's complementing the government and supplementing the government's activities, and definitely not trying to replace it."

Multiple respondents emphasized CSOs' unique ability to reach marginalized communities that formal health systems often miss:

> We are having almost 40 types of tribal people in West Bengal. There are 705 types of tribal people [across the country] . . . These tribal people are completely different from each other in many respects . . . If we can't rollout in a way that is culturally sensitive, that is gender sensitive, as well as language sensitive, then we need a different setup because they are the last mile of the population. *(NGO director, India)*

Leveraging Community Data

Another respondent from an INGO in Africa noted systemic weaknesses that CSOs often fill: "So many countries don't have strong data systems, and they often rely on NGOs — your JSIs and your VillageReach and others — to really support their information systems [. . .] A lot of innovators and CSOs can play a critical role in ensuring countries have sufficient and strong enough data systems that can really help in decision making, and also to have visibility into what is happening."

In her view, effective government-community coordination depends on platforms that are not disease specific:

> To be able to actually leverage the full power of civil society, that coordination bit is going to be so important. It mustn't be a platform just for TB. It must be a platform that can be leveraged across the board. Because with civil society organizations, that's where you have your community health worker programming, that's where you have people who really know the communities that you're targeting with this TB vaccine. *(INGO leader, Africa)*

Another respondent from a global INGO agreed that central-government-level policy work is a crucial first stop in TB vaccine preparedness work, and providing community data is essential there: "All policy development is being done at the center, and then it's been disseminated at the state level. For the TPT project, we obviously had to engage the national TB program, and they were like, 'Give us all the community interventions, give us data to show that some of these intervention work, because some of these policies are not really driven by data.'"

Table 2

CSO Intervention Opportunities

Vaccine Literacy	Organizations with established community education programs should develop locally appropriate vaccine literacy initiatives that use community media, trusted messengers, and cultural storytelling to "immunize against misinformation" and nurture pro-science vaccine information systems.
Policy Development	Existing relationships with national health systems provide platforms for CSO policy influence, particularly through early engagement with national TB programs. National immunization programs should build relationships with TB CSOs, and NITAGs should create space for CSO participation.
Demand Creation	CSOs should build on demonstrated success in TB prevention activities and community mobilization to lead culturally appropriate demand creation that addresses vaccine hesitancy proactively.
Implementation Planning	CSO networks spanning national, regional, and global levels should coordinate implementation, particularly for reaching hard-to-access populations through existing and trusted community systems.
Equity Promotion	Organizations already serving marginalized populations such as people who use drugs, Indigenous communities, people deprived of liberty, and other key population groups should advocate for equitable access and address implementation barriers that formal health systems overlook.
Implementation Monitoring	CSOs should adapt existing CLM platforms to include TB vaccine indicators, and funders should support advocates to collect data on vaccine uptake and use it as the basis for dialogue with national health systems.

The same respondent went on to note that "policy review takes time — but if from inception we're able to develop policies that are . . . data driven and they work, then we have made significant progress and maybe we are increasing the chances of acceptance and probably achieving the desired objectives." As this reflection shows, civil society can strengthen existing government platforms and processes with community data to support evidence-based policy.

Recommendations for Funders

The evidence is clear that CSOs are not optional partners in TB vaccine introduction, but essential infrastructure. Yet, with 97% of survey respondents expressing interest in vaccine preparedness but just 20% feeling "fully prepared," strategic investments in community engagement infrastructure (capacity, coordination platforms, networking opportunities) are urgent and necessary.

The collective contributions of the diverse TB advocates and implementers who participated in this study offer valuable information to prepare for optimal rollout of adolescent and adult TB vaccines. Their actionable insights, if adequately supported by funders, can help transform the reach and scale of vaccine uptake and help future generations live TB free.

Survey respondents reported three primary barriers: limited information about TB vaccine research, insufficient vaccine literacy, and inadequate funding. These gaps exist alongside demonstrated capacity for community education, advocacy, and direct service provision across diverse contexts and populations.

- Strong Foundation, Significant Gaps: Eighty percent of respondents have more than five years of TB experience and 94% are legally registered, yet just 20% feel "fully prepared" for vaccine preparedness work. Most organizations require additional support or capacity building to effectively engage. While a considerable number report some engagement in TB vaccine-related activities already, only one-fourth consider it a primary focus.
- Universal Interest, Limited Engagement: There is near-universal interest in vaccine preparedness and a solid foundation of experience working on TB prevention, including TB preventive treatment. This presents a significant engagement opportunity, particularly when considering that surveyed organizations already work with some of the highest-priority populations for new TB vaccines, such as PLHIV (77%) and women and girls (58%).
- Knowledge and Policy Engagement Barriers: Only 18% of respondents were "very familiar" with WHO's ECVP, a framework intended to reduce delays in vaccine introduction by facilitating early engagement among stakeholders involved in vaccine development, regulatory approval, and policy making. Only 60% of groups have some familiarity with the WHO's Global Framework, a plan for the rapid introduction and scale-up of TB vaccines. Among the 17% of respondents who had ever engaged with NITAGs or RITAGs, most were academic/research institutions. This policy engagement gap limits CSOs' ability to influence vaccine introduction strategies at critical decision-making moments, despite most organizations already working with ministries of health on TB or other health issues.

Our research shows that there are critical intervention points where strategic investment could spark catalytic change in the vaccine readiness landscape. To take advantage of these opportunities, funders should act on the following recommendations:

1. Transform the Funding Architecture from Fragmented Projects to Sustainable Infrastructure

Current funding models inadequately support the sustained engagement required for vaccine preparedness. With 104 organizations (83%) identifying funding as their top support need, and numerous highly motivated yet systematically underfunded community groups struggling to obtain support, the evidence is clear that piecemeal, project-based funding cannot sustain the comprehensive community engagement required for successful new TB vaccine introduction.

Critical actions for funders:

- Establish dedicated, multiyear funding streams specifically for TB vaccine preparedness activities among CSOs at all levels (global, regional, national, local).
- Establish foundational funding for organizations serving as bridges between vaccine developers and communities. These organizations engage in technical advocacy that connects other segments of civil society to critical information on the pipeline and demystifies global policy-making, regulatory, and procurement processes.
- Implement the Gavi 10% set-aside model for civil society across all TB vaccine funding mechanisms to ensure support for CSOs is mainstreamed in market shaping and delivery investments.
- Create guardrails within funding mechanisms to ensure community engagement resources reach grassroots organizations (and not only larger, well-connected INGOs).
- Develop sustainable financing that extends beyond vaccine introduction to long-term investments in community systems engaged in vaccine delivery, demand creation, community-led monitoring, and vaccine literacy.

Table 3 summarizes several funding models from the TB, immunization, and human rights fields that reflect elements of the above recommendations and can be adapted to support CSO involvement in TB vaccine readiness. These are examples of different CSO funding approaches and are not exhaustive.

2. Build Systematic Capacity Rooted in Cultural Competency and Local Innovation

The second-highest support need identified by organizations (101 respondents, 80%) was technical assistance and training. Organizations need training extending beyond basic vaccine information to broader technical competencies enabling meaningful policy engagement.

Priority interventions for funders:

- Develop structured training programs covering vaccine literacy (e.g., pipeline updates, TB vaccine science, clinical trials), policy analysis, and NITAG engagement skills.
- Create mentorship networks pairing experienced vaccine advocates or policy makers with TB CSOs eager to engage but newer to immunization work.
- Support the development of gender- and culturally sensitive communication strategies that also address religious concerns and community misconceptions.
- Build capacity for evidence-based advocacy that can influence national TB and immunization programs, including CLM.
- Strengthen programs for women community health workers, recognizing their unique access advantages.

Table 3

Different Models, Many Ways to Invest in CSOs

Funding Model	Field	Description	TB Vaccine Application
Challenge Facility for Civil Society	TB	The Challenge Facility for Civil Society (CFCS) is the Stop TB Partnership's flagship program for investing in communities and people affected by TB. Through thematically focused funding calls, CFCS provides grants and technical assistance to support community-led work in TB globally, regionally, nationally, and locally.	Funders underwrite a CFCS funding round dedicated to community interventions for new TB vaccines, administered by the Stop TB Partnership.
Solidaire Network	Human rights/ social justice	Solidaire Network is a community of donor organizations and individual funders that hosts pooled funds that can be mobilized quickly to get critical funding to the frontlines of intersectional social justice movements. Solidaire 1) organizes a movement-aligned base of donors interested in resourcing long-term power-building and 2) accompanies movements as they contest for power by funding experimentation and infrastructure. Solidaire supports diverse organizational structures (e.g., nonprofits, LLCs, collectives).	Funders establish pooled funds to support CSO contributions to new TB vaccine policy making, introduction, delivery, and evaluation. The program would provide easy-to-access funding for project-specific work as well as long-term movement support by funding CSO infrastructure and capacity.
The Mercury Project	Immunization	Hosted by the Social Science Research Council, the Mercury Project brought together teams of social scientists and community practitioners under a common research framework to identify effective interventions to build vaccine demand. Eighteen teams in the United States, Africa, Asia, Latin America, and the Caribbean received funding to evaluate a portfolio of interventions united by a common theory of change.	Funders support a linked initiative of CSO-academic partnerships to undertake evidence-driven, locally relevant, theoretically aligned work to understand and build demand for new TB vaccines in different countries. The program could be administered by an academic partner, preferably in a high-TB-burden country.
IMPAACT4TB Community Partners	TB	Run by TAG, the IMPAACT4TB Community Partners program was a dedicated fund set aside for CSOs within IMPAACT4TB, a Unitaid investment led by Aurum Institute to catalyze global uptake of short-course TPT. Through the Community Partnership program, TAG awarded >$800,000 in competitive small grants to CSOs to undertake locally relevant policy advocacy, demand creation, and treatment literacy. Grant recipients received ongoing technical coaching in the science and delivery of TPT through TAG's "advocacy capacity strengthening" model.	Donors set aside dedicated CSO funding within larger investments supporting TB vaccine market access and demand creation. CSO funding set-asides could be administered by global or regional CSO partners with experience awarding small grants to peer organizations and with the ability to augment grants with technical capacity building.
Equity-First Vaccination Initiative (EVI)	Immunization	Funded by the Rockefeller Foundation, the EVI supported 100 community organizations in five U.S. cities and connected them with national organizations serving as "capacity building, research and learning partners." The goal was to reduce COVID-19 vaccination racial disparities and to orient public health systems toward more equitable outcomes.	Funders establish a flagship program on TB vaccine equity by funding community-based organizations in concert with academic and civil society resource partners under a common goal and program of work.

3. Address Motivations and Stigma through Early and Proactive Community Preparation

Vaccine introduction faces complex challenges including vaccine fatigue, TB stigma, and misinformation, on top of what one respondent described as the "conundrum of prioritization" in the landscape of multiplying vaccine choices facing governments. Organizations report that behavioral change, not just information provision, represents a fundamental challenge. Successful approaches leverage lived experience, community-led narratives, and trusted relationships to address deep-rooted fears and misconceptions. To achieve "vaccine acceptability and uptake, demand creation led by and rooted in trusted community structures" was seen as essential, especially given pervasive TB stigma.

Strategic approaches for funders:

- Launch comprehensive anti-stigma campaigns that go beyond education to address underlying beliefs and social barriers.
- Develop proactive "immunization against misinformation" strategies that build community resilience before vaccine introduction.

- **Support TB survivor-led advocacy and peer education programs** that center lived experience and promote vaccine literacy ambassadors from among TB survivors and members of clinical trial community advisory boards.
- **Create community-centered policies** ensuring that marginalized populations are prioritized in vaccine drives.
- **Establish early preparation mechanisms** that address coordination gaps between TB programs, immunization systems, and community health services.
- **Host regular community forums** to address questions and concerns and destigmatize information seeking around TB.

Addressing systemic barriers and enhancing coordination between governments and civil society were seen as essential. To realize the potentially transformative collaborations between CSOs, governments, donors, vaccine developers, and other stakeholders who are necessary for effective vaccine rollout, ceding and sharing space and power was described as of paramount importance. Space for civil society should come with tangible, sustainable support for CSOs to develop country-specific policy priorities and advocacy strategies. CSOs want involvement, capacity to facilitate coordination across programs and systems, and ways to contribute to planning across all health system levels.

Given limited civic space in many countries, it is incumbent upon funders to advocate for explicit inclusion of CSO representatives in advisory and decision-making spaces, promoting policies that protect civic space, enable CSO participation in health policy processes, and support the development of national community engagement strategies for vaccine introduction.

Conclusion

A promising TB vaccine pipeline with multiple candidates in late-stage efficacy trials demands urgent action to prepare for the success of these new tools. The path from vaccine development to community uptake runs directly through community and civil society organizations that are, by their own assessment, underresourced, undertrained, and underengaged in preparedness activities, but ideally positioned and galvanized to take a leading role in rollout.

TAG's landscape assessment of 125 TB CSOs across 42 countries reveals a rich constellation of organizations and advocates, most of whom express deep interest in taking up TB vaccine readiness work. A few can start immediately, building on existing activity; most, however, expressed a significant need for political space, improved coordination mechanisms, and adequate resourcing and tailored capacitation to meet the moment.

This global ecosystem of organizations and networks, with its deep community connections and advocacy experience, embodies a commitment to ending the TB pandemic. Yet, systematic CSO engagement remains severely constrained. TAG's scoping study points to the need for immediate, sustained, and strategic partnerships among CSOs, vaccine developers, policy makers, and funders who recognize that ending TB requires not just effective vaccines, but effective community engagement to ensure those vaccines reach the people who need them most. Strategic investment in CSO capacity, coordination platforms, and enabling environments will empower civil society to tap into its potential and effectively contribute to vaccine introduction and scale-up towards a world free of TB.

Country Policy Portraits: Civil Society Engagement in Vaccine Policy Across National Archetypes

Country Policy Portraits

This section presents country policy portraits illustrating how vaccine policy is made in seven countries, with particular attention to the presence or absence of community and civil society involvement. The seven countries profiled represent different archetypes of high-TB-burden countries that would be benefit from new TB vaccines: Bangladesh, Kazakhstan, Kenya, Malawi, Mongolia, South Africa, and Vietnam. The seven countries were chosen to represent a mix of settings with respect to Gavi and Global Fund eligibility, World Bank country income level, TB epidemiology, and history of state–civil society relations.

Each archetype serves as a guide for how vaccine policy making may operate in similar contexts. Understanding what is shared or different across national archetypes provides insight into how CSO engagement in vaccine decision making can be strengthened in a range of settings. No archetype optimally involves communities and civil society in all aspects of vaccine policy making. But all countries have experiences that can inspire productive arrangements if adopted in other places.

Each portrait was developed by a local TB advocate associated with one of TAG's three regional CAB partners: AFROCAB, APCASO, and ECAT. Authors worked from a common template to collect information on nine domains (see Box). TAG then worked with authors to condense each portrait into a four-page illustration. Each portrait ends with the author proposing 1) an easy win that would strengthen the role of communities and civil society in immunization work and 2) a high-impact change that would offer the greatest improvement in CSO inclusion.

Country Policy Portrait Domains

- Vaccine decision making
- Data for decision making
- Vaccine implementation
- Existing vaccines and recommendations
- Vaccine planning, preparedness, and sustainability
- Financing vaccines
- Strengthening community engagement and impact
- Vaccine information landscape
- Vaccine hesitancy and mis-/disinformation

Across the seven countries, suggestions for easy wins and high-impact changes point toward a clear common recommendation: normalize, formalize, and institutionalize civil society participation in vaccine decision making. This same recommendation was also echoed strongly in the survey findings and key informant interviews in section one of this report.

Although there is not a single process to determine vaccine policy across these countries, in most of the archetypes examined here, decision-making spaces lack formal CSO representation. For example, CSOs are almost entirely excluded from NITAGs. In one country, Bangladesh, CSOs currently make up three of 15 NITAG representatives but come from either large NGOs (ICDDR,B) or global civil society structures (the chair of the Gavi CSO constituency). In most places, CSO engagement is left to informal or ad hoc forums — stakeholder consultations, public comment periods, or external advocacy by influential groups. Even in contexts where CSOs exert some influence, they are often relegated to the margins, or prescribed roles in vaccine implementation and rollout well after concrete policies are formulated.

The easy wins and high-impact changes suggested by portrait authors include creating dedicated forums for engaging CSOs on vaccine-related issues, designating NITAG seats for CSO representatives, establishing national CABs to guide vaccine introduction, and integrating community and civil society voices into other relevant health policy-making spaces. Some authors pointed to a need to establish legal frameworks to guide public involvement in vaccine decision making, implementation, and evaluation. Such frameworks could be leveraged to establish specific roles for CSOs within the vaccine ecosystem, which in turn might help foster trust by establishing clear standards for public participation, transparency, and accountability.

Table 4

Capacity Strengthening Needs of CSOs to Engage with National Immunization Programs

Areas	Needed Capacities and Skills
Vaccine policy and immunization planning	Training on National Immunization Program structure, NITAG functions, and vaccine decision making
Funding and governance	Understanding of national budgeting processes and skills in resource mobilization
Vaccine safety	Understanding of adverse event reporting systems, and skills for community education
Equity and rights-based access to vaccines	Skills to advocate for marginalized populations (e.g., homeless, people who use drugs, migrants, persons deprived of liberty, LGBTQ+)
Risk communication and misinformation	Systems to track and respond to mis-/disinformation, and platforms for community dialogue
Community-led monitoring	Training in data collection, and systems for feedback and continual monitoring

In line with one of the key recommendations coming out of the landscape assessment in section one, CSOs need to be strengthened and equipped with the necessary knowledge and skills to engage meaningfully with national immunization programs. Investments by governments and funders in training, information-sharing, and education for CSOs and communities could serve a dual purpose of demonstrating a political commitment to strengthening civic engagement in vaccine work while ensuring that CSOs can effectively shape policy recommendations. It is insufficient to bring CSOs to decision-making tables without providing the knowledge and tools so they can participate fully as equal members. In Table 4, the author of the Mongolia policy portrait matched areas of engagement to capacitation needs; although developed for Mongolia, the listed needs speak to all the countries profiled.

The process of creating a country policy portrait is itself an exercise in building understanding of how vaccine policy and planning occur in a specific context. Advocates in other countries can use the same template used here, available on TAG's website, to learn about their NITAG, national immunization program, and other aspects of vaccine policy making.

Abbreviations Used in the Country Policy Portraits

ASEAN: Association of Southeast Asian Nations

EPI: Essential Program on Immunization (sometimes Expanded Program on Immunization)

MOH: Ministry of Health (or Ministry of Healthcare)

MOHFW: Ministry of Health and Family Welfare (Bangladesh)

NDOH: National Department of Health (South Africa)

NIP: National Immunization Program

NITAG: National Immunization Technical Advisory Group

NRA: National Regulatory Authority

NTP: National TB Program

NVIP: National Vaccines and Immunization Program (Kenya)

SRA: Stringent Regulatory Authority

WHO: World Health Organization

USAID: United States Agency for International Development

U.S. FDA: United States Food and Drug Administration

Source notes:

NITAG maturity rankings are taken from the Global NITAG Network map and based on the 6 criteria in the WHO-UNICEF Joint Reporting form: https://www.nitag-resource.org/network/map

NRA maturity rankings are taken from the WHO list of NRAs operating at maturity level 3 (ML3) and maturity level 4 (ML4): https://www.who.int/publications/m/item/list-of-nras-operating-at-ml3-and-ml4

COUNTRY POLICY PORTRAITS

Kazakhstan
Population: 20.6 million
World Bank Income: MIC
WHO Status: High MDR-TB
WHO Region: Europe

(N/A)

Kenya
Population: 56.4 million
World Bank Income: LMIC
WHO Status: High TB & TB/HIV
WHO Region: Africa

Accelerated Transition

Mongolia
Population: 3.54 million
World Bank Income: UMIC
WHO Status: High TB & MDR-TB
WHO Region: Western Pacific

(2015)

Vietnam
Population: 101.1 million
World Bank Income: LMIC
WHO Status: High TB & MDR-TB
WHO Region: SE Asia

(2020)

Malawi
Population: 21.1 million
World Bank Income: LIC
WHO Status: High TB/HIV
WHO Region: Africa

Initial Self-Financing

South Africa
Population: 64.0 million
World Bank Income: UMIC
WHO Status: High TB, TB/HIV, MDR-TB
WHO Region: Africa

(N/A)

Bangladesh
Population: 173.6 million
World Bank Income: LMIC
WHO Status: High TB & MDR-TB
WHO Region: SE Asia

Accelerated Transition

Key

Gavi Eligible (*status)*

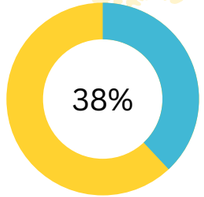
Gavi Ineligible *(year of ineligibility)*

Global Fund Eligible (TB)

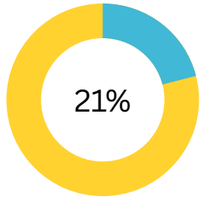
BANGLADESH

Population: 170 million
World Bank Income: LMIC
WHO Status: High TB & MDR-TB
WHO Region: SE Asia

Funding & Financing



Funding for TB Programs
In 2023, 38% of TB funding in Bangladesh came from domestic resources (blue).



Funding for Vaccine Programs
Bangladesh's immunization program is still largely donor dependent, with 21% (blue) coming from domestic resources.

Bangladesh is reliant on external funding for both the TB and immunization programs. The Global Fund is the largest donor to the TB Program, historically supplemented by USAID support for diagnostics, treatment, and health system strengthening.

Gavi is the primary supporter of Bangladesh's immunization program, supporting and guiding vaccine implementation from policy review to procurement. Currently in Gavi's accelerated transition phase, Bangladesh has increased self-financing of its immunization program. Domestic investments are primarily for co-financing vaccine purchase, infrastructure, operational costs, and staffing.

Decision Making	*Political Visibility*	*Information Environment*
NITAG Est. 2019 13 members	**TB Vaccines in National Health Strategy** No, formal strategy does not exist. Vaccines included in program strategies	**CSOs Spreading Antivaccine Information?** No
NITAG Representation Diverse expertise, mandate requires CSO members and has 3 CSO representatives	**TB Vaccines in National TB Strategy** Yes, including novel TB vaccines	**Faith Leaders Spreading Antivaccine Information?** No, not extensively
NITAG Transparency Meetings and minutes are not shared with the public	**TB Vaccines in National Immunization Strategy** Yes, BCG	**Political Leaders Spreading Antivaccine Information?** No
Primary Decision Makers The MOHFW holds the primary responsibility for deciding to introduce new vaccines. NITAG recommendation of a vaccine is required for MOHFW approval and implementation. The NITAG mandate requires inclusion of CSO representatives, but current community and civil society representatives come from larger NGOs.	**Political Will to End TB** Bangladesh recently increased domestic funding for TB and introduced the National Strategic Plan to End TB 2024–2030. The framework emphasizes TB prevention and intersectoral collaboration to reduce TB risk factors (e.g., undernutrition). The plan also recognizes the need for future TB vaccines and other new tools to accelerate progress.	**Strategy to Address Mis-/Disinformation** No single, formal strategy for combating vaccine mis-/disinformation exists. However, Bangladesh has developed a comprehensive multi-year communication strategy to promote vaccination and acceptance across multiple platforms tailored to each community.

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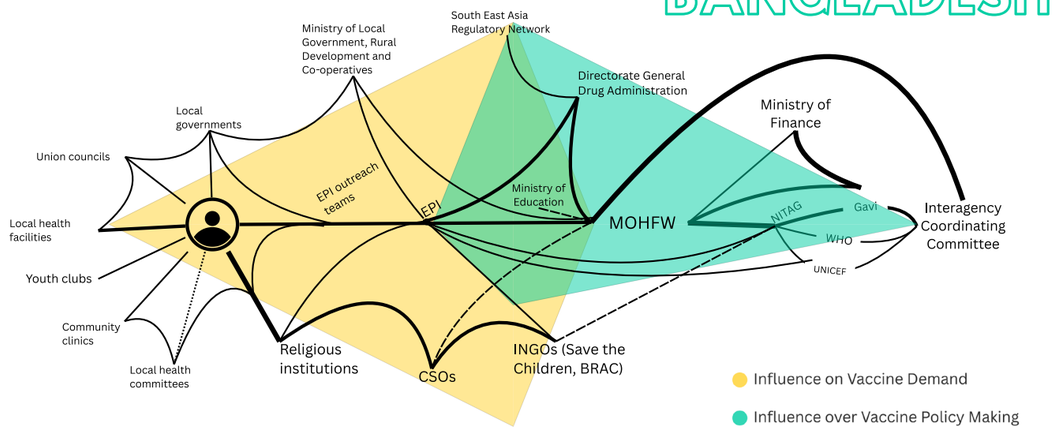
BANGLADESH



Web of Vaccine Influence

This web depicts the interlocking relationships between different stakeholders across the vaccine policy landscape and the relative strength of influence of each grouping. At the center is the recipient of vaccination. Stakeholders nearer to the person icon operate closer to individual beneficiaries of vaccination, but actors at the edge still exert a large influence.

What happens in one part of the web is felt in other parts, even if seemingly far away. Some strands in the web are stronger than others (here, the influence of the NITAG and MOHFW). Bangladesh's web reveals the top-heavy approach to vaccine decision making, in which decision making is primarily influenced by multilaterals, the NITAG, and the MOHFW, with few formal channels for CSO input, though CSOs play a larger role in vaccine demand and acceptance.

Data for Decision Making

Bangladesh is unique in that NITAG recommendation is mandatory for vaccine introduction (and not merely advisory). The NITAG consults with external stakeholders, including government ministries, international partners (e.g., Gavi, WHO), and academic experts to review trial data and programmatic factors for introduction of the vaccine. After NITAG endorsement, a proposal is submitted to the Inter-Agency Coordinating Committee made up of the MOHFW, Gavi, WHO, UNICEF, and other partners) to review and make the final policy. The Directorate General of Drug Administration (DGDA) under the MOHFW is Bangladesh's regulatory authority responsible for vaccines and medicines. The DGDA also collaborates with the NITAG to review new vaccines before recommendations are issued. The DGDA has regulatory reliance with several organizations, including the WHO and the South-East Asia Regulatory Network platform that facilitates collaboration and reliance among NRAs in the region.

NITAG Maturity	★★★★★★
NRA Maturity	Below ML3
Local Trial Data Requirement	✓*
Local Manufacture	✗

*Required, but may be waived if WHO-PQ or stringent regulatory authorities have approved

Procurement

Bangladesh law requires that procurement of all medicines and vaccines follows a standardized process, beginning with a needs assessment to establish required volumes for purchase. This is followed by a review and funding allocation process overseen by the MOHFW in collaboration with international partners and donors like Gavi and UNICEF. For vaccines without external funding support, Bangladesh covers the entire cost of procurement. Following funding allocation, a tendering process begins with suppliers invited to submit bids, which are evaluated through a preestablished, competitive, and transparent process.

Bangladesh often collaborates with UNICEF to procure vaccines, leveraging UNICEF's procurement mechanisms to ensure the most cost-effective procurement prices.

Implementation

Bangladesh has developed a standard implementation protocol to introduce new vaccines into the country. The protocol begins by collecting locally relevant data to address any unanswered questions about vaccine safety and efficacy. During this period, the MOHFW in partnership with Gavi will assess the costs of introducing the vaccine and identify funding gaps as well as develop a public communication strategy, a surveillance plan, and training programs for service providers.

Working with the MOHFW, the Ministry of Local Government, Rural Development and Co-operatives develops a vaccine rollout plan with local government bodies (e.g., city councils, municipalities, union councils). Local health committees work with EPI and local outreach teams and local governments to develop an action plan to address vaccine access and equity at the grassroots level.

Before the final implementation plan can be initiated, the NITAG, DGDA, and MOHFW review and approve the plan before the MOHFW issues a formal endorsement of the vaccine and rollout.

Vaccine Hesitancy and Misinformation

Bangladesh has experienced some vaccine hesitancy and misinformation on a vaccine-by-vaccine basis. Often, vaccine hesitancy and misinformation have been rooted in concerns about religious acceptability (e.g., concerns about vaccines and fasting) or reproductive health. The HPV vaccine, for example, was associated with rumors about vaccine-caused infertility or promiscuity. To combat misinformation within these communities, religious leaders worked closely with EPI to reassure communities and issue religious rulings affirming vaccine safety and permissibility within the religious practice.

Consumer Cost and Transparency

Bangladesh primarily purchases vaccines through UNICEF, which promotes pricing transparency and reduces the need for civil society oversight into vaccine pricing at the local level. However, CSOs are represented in EPI committees, which provides them with a forum to raise concerns from the community level about pricing, if access barriers arise.

BANGLADESH

Civil Society as the Foundation of Community Awareness and Trust in Vaccines

Because of Bangladesh's top-down vaccine decision-making structure, CSOs are largely kept out of policy-making spaces outside of ad hoc consultations and engagement in specific EPI committees. This dynamic has given CSOs and community little room to influence policy as it is being developed. Despite their absence from decision-making spaces, civil society and community groups have claimed a integral role in vaccine implementation at the local level.

Information Sharing

Civil society plays a crucial role in information dissemination and addressing vaccine hesitancy. Groups will use miking, which involves broadcasting announcements via loudspeakers mounted on rickshaws, vans, or positioned at local gatherings. Miking can quickly and cheaply disseminate information about vaccines, vaccination schedules, and eligibility in the local dialect, making information easy to understand and to share in real time. Civil society groups also coordinate directly with media outlets and schools to promote accurate information, combat myths, and encourage vaccine buy-in. During COVID-19 vaccine rollout, civil society groups leveraged all available tactics to promote vaccine uptake.

Community Mobilization

Beyond sharing information, civil society groups also play a significant role in community engagement, mobilization, and service delivery. CSOs tap into their deep ties in the communities they serve to coordinate community events, vaccine discussions, and ultimately mobilization to vaccination. Groups also provide logistical support to ensure vaccination sites are accessible, identify high-risk groups for outreach, conduct outreach to high-risk and rural populations, and mobilize local caregivers to expand the health care workforce for vaccination campaigns.

Monitoring

Throughout implementation and rollout, CSOs will leverage the same grassroots networks they rely on to spread vaccine awareness and mobilize communities to conduct community-level monitoring on accessibility and monitoring for any emerging concerns.

While decision making regularly excludes civil society and community engagement, vaccine implementation and acceptance rely heavily on their relationships with communities across the country.

BANGLADESH

Spotlight:

Since its inception in 2000, Gavi has supported Bangladesh in funding and implementing vaccines to ensure widespread coverage. Gavi's investment has been critical for boosting vaccination rates in Bangladesh over the past quarter-century. Despite the clear benefits of this support, there have been some unanticipated impacts. Gavi's large role in financing and supporting vaccination in Bangladesh has contributed to top-down, centralized decision making for vaccine policy that vests ample power in multilaterals.

In Bangladesh, while the MOHFW is the formal decision maker, an Interagency Coordinating Committee (ICC) made up of representatives from Gavi, WHO, UNICEF, and INGOs and chaired by the MOHFW makes the final policy recommendation. The ICC's high proportion of multilateral representatives shifts decision making away from impacted communities and closer to global experts who are less attuned to the diversity of needs across Bangladesh. This top-heavy dynamic is echoed during the vaccine budgeting phase, as all budget planning must follow Gavi's structure and approval process to advance vaccine introduction.

The involvement of Gavi, WHO, and UNICEF during the review, planning, and implementation phases means they carry outsized influence over Bangladesh policy, often in the absence of representatives from Bangladesh civil society and affected communities. This has far-reaching implications as Bangladesh approaches Gavi graduation. As Gavi has long provided critical funding and technical input, government institutions have had limited opportunities to independently develop policy and technical experience. Strengthening local capacity and leadership is now a priority as Bangladesh prepares to transition from donor support. Similarly, while the ICC has some larger INGO representatives, civil society at large has not been well capacitated and integrated into the policy-making process. This leaves civil society without the adequate tools or access necessary to push back on Gavi, UNICEF, and WHO directives and tailor Bangladesh's vaccine policy to local contexts.

"CSOs should actively participate in policy discussions at earlier stages to ensure policies are more inclusive and widely accepted."

Strengthening the Role of Civil Society in Bangladesh's National Immunization Program

An **easy win** that would strengthen the role of civil society in vaccine programming:

- CSOs participate in the EPI decision-making committees.
- CSOs enhance their technical knowledge, networks, and engagement with influential leaders to improve expertise sharing and coordination. CSOs work closely with local communities to empower communities toward local stewardship of vaccine policy.

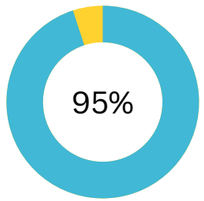
A **high-impact change** that would offer the greatest improvement in civil society inclusion:

- Forming a national-level group representing diverse segments of society and CSOs to ensure broad public participation in vaccine policy making.
- Recognizing and formalizing the role of CSOs in vaccine policy making and implementation, with a memorandum of understanding with the MOHFW and NITAG guaranteeing civil society engagement in policy making and delineating responsibility to advocate for vaccines.

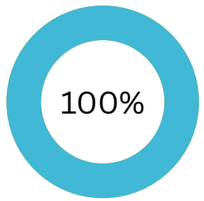
KAZAKHSTAN

Population: 20.3 million
World Bank Income: UMIC
WHO Status: High MDR-TB
WHO Region: Europe

Funding & Financing



Funding for TB Programs
In 2023, 95% of TB funding in Kazakhstan came from domestic resources (blue).



Funding for Vaccine Programs
Kazakhstan's vaccination program is self-funded.

Kazakhstan is not eligible to receive support from Gavi and funds its immunization program with domestic resources raised from republican (national) and local budgets. The republican budget funds HPV and COVID-19 vaccines, while local budgets cover other routine vaccines included in the national immunization schedule.

Domestic resources fund 100% of vaccine procurement, managed by SK-Pharmacia, a limited liability partnership that reports to the MOH.

Kazakhstan's TB program is mostly domestically funded, but the country continues to receive support from the Global Fund and other international partners.

Decision Making	*Political Visibility*	*Information Environment*
NITAG Est. 2012 17 members	**TB Vaccines in National Health Strategy** No	**CSOs Spreading Antivaccine Information?** No, not in widespread manner
NITAG Representation Diverse expertise, but no civil society	**TB Vaccines in National TB Strategy** No	**Faith Leaders Spreading Antivaccine Information?** No, not extensively
NITAG Transparency Some meetings are public, but minutes are not published	**TB Vaccines in National Immunization Strategy** No	**Political Leaders Spreading Antivaccine Information?** No
Primary Decision Makers The MOH is responsible for approving the list of vaccines included in the national immunization calendar. The NITAG plays an advisory role to the MOH, meeting twice a year. Civil society and community groups are not represented on the NITAG but may be invited as outside, nonvoting observers on occasion.	**Political Will to End TB** Civil society has prepared a draft TB Multisectoral Accountability Framework (MAF) and shared it with the government. The MAF includes access to TPT but does not discuss TB vaccines. Kazakhstan has a national roadmap for addressing TB (2023–2025); including vaccines in the next roadmap is one opportunity to increase political visibility.	**Strategy to Address Mis-/Disinformation** No standalone strategy for combating vaccine mis/disinformation though activities to increase acceptance of specific vaccines is undertaken. A 2021 UNICEF survey found that health care professionals are the main source of information on immunization.

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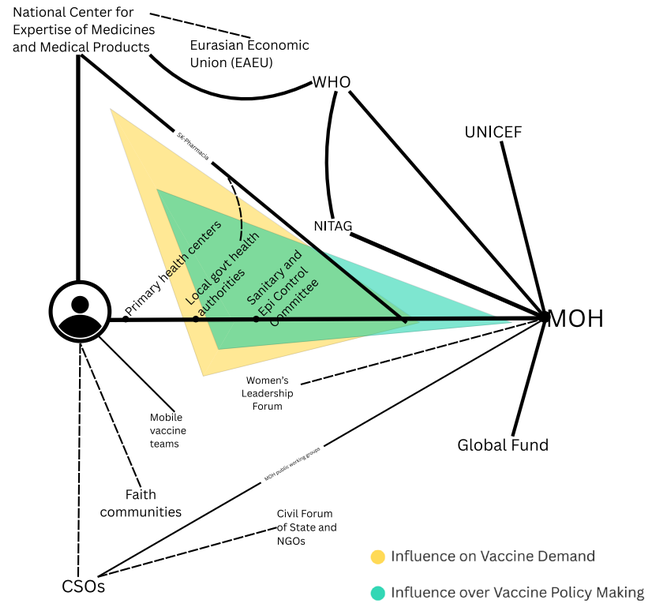
KAZAKHSTAN



Web of Vaccine Influence

This web depicts the interlocking relationships between different stakeholders across the vaccine policy landscape and the relative strength of influence of each grouping. At the center is the recipient of vaccination. Stakeholders near the center operate closer to individual beneficiaries of vaccination, but actors at the edge may still exert a large influence.

What happens in one part of the web is felt in other parts, even if seemingly far away. Some strands in the web are stronger than others (here, the influence of the MOH). Other strands may be broken or nonexistent (notice the lack of connection between the NITAG and CSOs). The web shows that CSOs currently play a limited role in immunization programs in Kazakhstan.

Data for Decision Making

The National Technical Advisory Group of Experts on Population Immunization acts as Kazakhstan's NITAG and plays an advisory role to the MOH. The National Center for Expertise of Medicines and Medical Products is Kazakhstan's regulatory body; it operates below WHO maturity level 3. Kazakhstan does not require local clinical trial data to register a vaccine for use; however, local data can facilitate the approval process and enhance regulatory confidence, especially for products not yet approved by stringent regulatory authorities in other countries (e.g., EMA, U.S. FDA). There is no mandate for domestic manufacture, but medicines produced in Kazakhstan may have a competitive advantage in public tenders.

NITAG Maturity ★★★★★★
NRA Maturity Below ML3
Local Trial Data Requirement ✗
Local Manufacture ✓*
* Not required but preference through tendering process

Procurement

SK-Pharmacia, a limited liability partnership founded in 2009 that reports to the MOH, is responsible for vaccine procurement and distribution. Article 245 of the national health code defines the role of a single distributor, establishing SK-Pharmacia as the sole legal entity with responsibility for organizing public procurement of pharmaceutical products within the package of state-guaranteed medical services. SK-Pharmacia procures vaccines through tenders or direct negotiations with suppliers. Vaccines endorsed and prequalified by the WHO are typically procured from foreign manufacturers and imported.

Kazakhstan is a member of the Eurasian Economic Union (EAEU), together with Armenia, Belarus, Kyrgyzstan, and Russia. In 2025, the EAEU approved the draft "Concept for the Development of a Common Market for Medicines." The aim is to cultivate a functional common market for medicines, including through the cooperation in registration procedures and pharmaceutical production.

Implementation

Routine vaccination is carried out by a network of primary health care providers throughout the country. Most vaccines are administered in clinics; however, mobile vaccination teams can be organized to respond to urgent situations or extend access to areas without nearby health centers.

The private sector plays a limited role in vaccine delivery. Private medical centers can import and offer any vaccine as long as it is registered with Kazakhstan's national regulatory agency.

Vaccine Hesitancy and Misinformation

Overall, Kazakhstan has not faced major public scandals or controversies related to vaccines, but misinformation is an emerging concern and was a factor during COVID-19. A UNICEF report (2022) found that half of COVID-19 vaccine misinformation in the Kazakhstani social media ecosystem was spread by no more than two dozen accounts. Misinformation circulating in Kazakhstan is influenced by antivaccine movements in Russia and the United States. Accounts spreading misinformation invoke emotionally charged, right-wing rhetoric and emphasize themes of internal/external divisions.

There is no widespread opposition to vaccines among faith-based organizations, though the Church of Scientology (not officially registered as a religious association in Kazakhstan) has been involved in spreading antivaccine sentiment. While vaccine acceptance remains high, one of the main reasons for refusal to vaccinate is parents' religious beliefs. To address this, the MOH has plans to strengthen its cooperation with religious organizations such as the Spiritual Administration of Muslims in Kazakhstan.

Consumer Cost and Transparency

All tender-related information from SK-Pharmacia is made available through government web platforms. However, SK-Pharmacia has at times published incomplete or inaccurate tender data and has been implicated in several corruption scandals, raising concerns about transparency and fairness in procurement processes. While civil society does not have an official role in monitoring vaccine pricing, some civil society groups regularly monitor the prices of other health commodities such as medicines for HIV, TB, and hepatitis C virus. Civil society also engages with SK-Pharmacia on medicines pricing and transparency.

KAZAKHSTAN

Dividing Responsibilities for Immunization Nationally and Locally

Kazakhstan's immunization program is built around an intentional division of responsibilities between national and local governments.

The MOH has overall oversight of immunization planning, product registration, vaccine procurement (via SK-Pharmacia), and financing.

Local health authorities assess the annual demand for vaccines in each region, develop vaccination plans, set targets for vaccination coverage, sign contracts with SK-Pharmacia for procurement, and manage funds for immunization provided by the national government. According to MOH Order No. 150 (2023): "Planning, organization, and carrying out of preventive vaccinations to the population are carried out by local public health authorities of regions, cities of republican significance (Almaty, Shymkent), and the capital (Astana)." There are 20 administrative units, including 17 regional governments and three cities.

Using a standardized planning form, local clinics draw up monthly, facility-level vaccine distribution plans based on the number of people registered to a particular location. Forms are submitted to district health offices and then transferred to regional health offices for consolidation into a single regional plan. Though standardized, this process preserves significant leeway for the application of professional judgement by individual planning officials ("adjusters").

Based on these plans, local governments allocate funding for vaccination from central MOH budget transfers. Regional authorities also sign direct contracts with SK-Pharmacia for procurement of vaccines. Local budgets cover costs associated with most vaccines included in the national vaccine calendar, but HPV and COVID-19 vaccines fall within the republican (national) budget.

Pharmacovigilance occurs through a centralized system managed by the National Center for Expertise of Medicines and Medical Devices. All health care professionals are required by law to report adverse events, including those related to vaccines.

Civil society does not have a visible role in vaccine planning, procurement, or implementation.

KAZAKHSTAN

Spotlight:

Civil society in Kazakhstan as a whole has played a passive role in vaccine policy development and introduction. The government has at times engaged large associations in specific vaccine campaigns (e.g., the Women Leaders Forum and HPV vaccination), and medical groups have disseminated information on vaccines among health care workers (e.g., Medsupportkz, a volunteer movement created during the COVID-19 pandemic to support health care professionals with access to information). But there is no formal process by which the government engages with civil society on vaccine decision making, planning, or implementation.

In a sign that the government is interested in deepening its engagement with civil society, the "Comprehensive Plan for Improvement of the National Immunization System of the Population of the Republic of Kazakhstan, 2023–2025" proposes the following opportunities for civil society participation:

- Educating students, teachers, and parents on the importance of vaccination.
- Assisting with vaccination efforts for migrants, refugees, and other temporary residents of Kazakhstan.
- Developing communication plans for introducing vaccines against new types of infectious disease.
- Developing and distributing informational and educational materials on the importance of vaccination.
- Encouraging parents and other stakeholders to report adverse events after immunization.
- Involving opinion leaders at the national and regional levels to popularize immunization.

Civic space in Kazakhstan is actively developing, and the capacity of civil society actors in the health space is growing. Since 2003, the government of Kazakhstan has held a regular Civil Forum, which provides a platform for dialogue between the state and NGOs on a variety of issues, including health. The government has also created an Open Regulations Portal to allow for public discussion of draft legal acts. In the health sector, the MOH and SK-Pharmacia both have public working groups to host interactions between health agencies and civil society representatives.

Strengthening the Role of Civil Society in Kazakhstan's National Immunization Program

An **easy win** that would strengthen the role of civil society in vaccine programming:

- One area where civil society can be empowered to participate in vaccine policy development is joint planning for comprehensive immunization programs, including advocacy, information, dissemination, and awareness raising to prevent misinformation.
- Addressing access gaps — affordability, availability, and equity issues — in new vaccine introduction is another area where civil society can contribute.

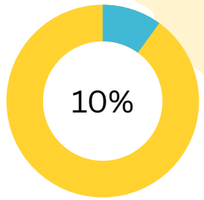
A **high-impact change** that would offer the greatest improvement in civil society inclusion:

- Identifying and publicly exposing channels for disseminating misinformation about vaccination and the motives of actors involved in spreading misinformation.

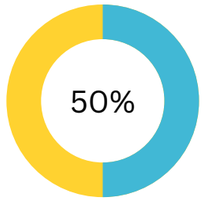
KENYA

Population: 55 million
World Bank Income: LMIC
WHO Status: High TB & TB/HIV
WHO Region: Africa

Funding & Financing



Funding for TB Programs
In 2023, 10% of TB funding in Kenya came from domestic resources (blue).



Funding for Vaccine Programs
In 2023, Kenya's vaccination program was 50% (blue) self-funded.

Kenya is reliant on external support for new vaccine introductions, participating in Gavi's tiered financing model since 2008 and increasing its share of contributions to the immunization program from 10% to 50% since 2017. The WHO and, previously, USAID have contributed to closing the remaining financing gaps in the immunization program.

The Global Fund is the largest single contributor to Kenya's TB program. Domestic funding makes up a small proportion of the NTP's budget, increasing gradually under the Global Fund's co-financing requirement and Kenya's commitments to meeting the 2023 UN HLM on TB targets. Kenya has more recently started emphasizing domestic resource mobilization to reduce reliance on external lenders and promote health system sustainability.

Decision Making	*Political Visibility*	*Information Environment*
NITAG Est. 2015 9 members	**TB Vaccines in National Health Strategy** Yes	**CSOs Spreading Antivaccine Information?** Yes
NITAG Representation Diverse expertise, but no civil society	**TB Vaccines in National TB Strategy** Yes	**Faith Leaders Spreading Antivaccine Information?** Yes
NITAG Transparency Meetings and minutes are not shared with the public	**TB Vaccines in National Immunization Strategy** Yes, BCG	**Political Leaders Spreading Antivaccine Information?** Yes, on occasion
Primary Decision Makers The National Vaccines and Immunization Programme (NVIP), under the MOH, holds the primary responsibility for reviewing and approving vaccines, with KENITAG, Kenya's NITAG, providing expert advice. There is no formal process for engaging civil society and community in any decision-making organization beyond stakeholder consultations.	**Political Will to End TB** Kenya launched the 2024 National Plan for TB, Leprosy, and Lung Health in response to the 2023 UN HLM on TB. The plan includes frameworks to coordinate all sectors around the social determinants of TB and integrates vaccine planning. Kenya has aligned with global TB targets, including increased domestic financing, and has strengthened regional and cross-border TB programming.	**Strategy to Address Mis/Disinformation** Kenya has implemented a National Communications Strategy to promote vaccines through proactive, coordinated campaigns. The communication strategy is comprehensive, multichannel, and multisectoral, and it leverages mass media, digital platforms, and community engagement for maximum impact.

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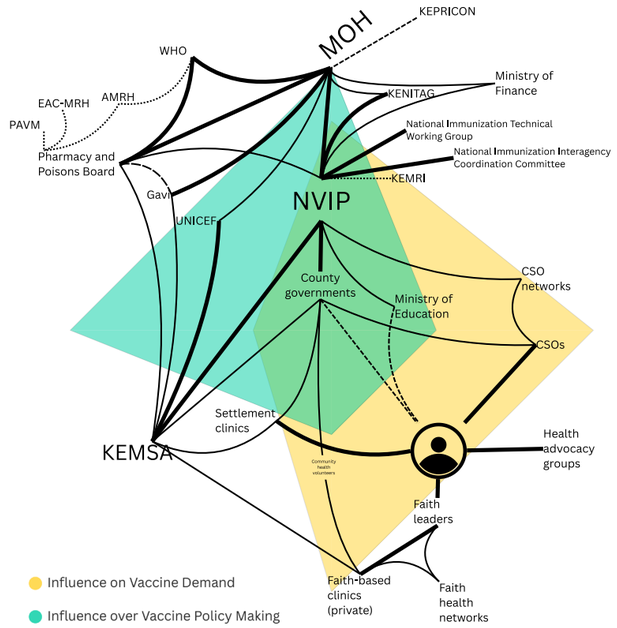
KENYA



Web of Vaccine Influence

This web depicts the interlocking relationships between different stakeholders across the vaccine policy landscape and the relative strength of influence of each grouping. At the center is the recipient of vaccination. Stakeholders near the center operate closer to individual beneficiaries of vaccination, but actors at the edge may still exert a large influence.

What happens in one part of the web is felt in other parts, even if seemingly far away. Some strands connect to disparate parts of the web (notice how KEMSA, the NVIP, and the MOH are axes around which the entire network operates). Other strands may be nonexistent (notice the lack of connection between the KENITAG and civil society, faith, or community groups). The web shows that CSOs currently play a limited role in immunization policy in Kenya, but have strong influence during implementation.

Data for Decision Making

NITAG Maturity	★★★★★★
NRA Maturity	Below ML3
Local Trial Data Requirement	✗*
Local Manufacture	✗†

*Not required except in cases of high disease burden; †Not required, but incentivized

Following a request from the MOH, KENITAG initiates review of novel vaccines or vaccine policy changes. Technical working groups are developed for each policy, drawing representatives from KENITAG and the research community with specialized expertise relevant to each review. The Pharmacy and Poisons Board (PPB) works closely with KENITAG during vaccine review and is responsible for regulating vaccines and other medicines. PPB has established regulatory reliance with several partners and is a signatory to the African Medicines Agency treaty, which aims to establish a continental regulatory authority. Kenya strongly prefers localclinical trial data, but it is not mandatory for approval unless the vaccine targets a disease with high prevalence in Kenya (e.g., malaria vaccine). Manufacturing policy encourages domestic manufacture of vaccines, with government policy pushing toward Kenya's first locally produced vaccine by 2027, but stops short of requiring it at this time. Pharmaceutical production receives tax exemptions to promote local manufacturing efforts and strategic partnerships with domestic manufacturers to boost local fill-and-finish capacity.

Procurement

The NVIP, in collaboration with the National Treasury, Gavi, and county health departments, develops a budget and procurement plan. The MOH reviews the plan for alignment with national health priorities. The Kenya Medical Supplies Authority (KEMSA) works closely with the MOH, Gavi, and UNICEF to manage the procurement process, with UNICEF acting as the procurement agent for all Gavi-funded vaccines and KEMSA initiating a tender process for all other vaccines. Following procurement, KEMSA takes over responsibility for vaccine warehousing and distribution to local facilities and county governments.

Implementation

Vaccine implementation proceeds through close collaboration with federal and county governments. The NVIP oversees the planning, coordination, training, monitoring, and timelines of vaccine delivery across the country. County health departments create micro-plans for health facility capacitation trainings, local delivery protocols, and community outreach. During the implementation phase, civil society works with county governments and communities to identify and document any challenges to vaccine access.

Vaccines are administered through a mix of public health infrastructure and targeted outreach efforts coordinated by the NVIP: public health clinics, faith-based and private clinics, mass immunization campaigns, settlement clinics, and school immunization. For remote areas, health care workers are sent to rural settlements to ensure broad vaccine coverage.

Vaccine Hesitancy and Misinformation

Religious, political, and community leaders all have shared vaccine misinformation, creating mistrust in the health system. When those amplifying misinformation are high-trust figures, vaccine hesitancy is amplified, requiring intensive counter-campaigns.

Civil society plays a large role in combating vaccine hesitancy (see: Spotlight), engaging pro-vaccine religious and cultural leaders to organize door-to-door outreach campaigns to encourage vaccination. Given the high degree of trust religious figures enjoy in Kenyan society, a pro-vaccine religious leader can be an effective counterweight to misinformation campaigns.

Consumer Cost and Transparency

Under the Division of Vaccines and Immunization Comprehensive Multi-Year Plan, routine immunizations are provided free of charge, primarily to cover vaccination for those under five. However, additional vaccines for high-risk groups (e.g., tetanus for pregnancy, HPV for young girls) have been included in the program for older individuals. Vaccines considered "voluntary" or associated with travel will often carry out-of-pocket expenses.

While KEMSA provides some mechanisms to support pricing transparency through the Public Procurement Oversight portal for routine vaccines, vaccine prices in the private sector are not regulated or systematically monitored. As a result, there is limited civil society engagement in price monitoring, and the private sector can set prices absent accountability.

KENYA

All in This Together: Collaboration to Communicate the Value of Vaccines

Kenya has developed a National Communication Strategy for promoting vaccines and other pro-health messages through government-led campaigns. Campaigns are guided by integrated health promotion plans that are embedded within the National Immunization Policy, aligning all campaigns with the overall objectives of the government's immunization policy. The communication strategy emphasizes evidence-based messaging and leverages target audience segmentation, diverse media channels, and trusted messengers to reach all of society.

In the case of the HPV vaccine:

- The president personally led the HPV vaccine introduction campaign to reinforce trust and vaccine safety.
- CSOs worked with media to promote the voices of technical experts, clergy, and policy makers to discuss positive impact of the vaccine.
- Influential faith leaders publicly endorsed the vaccine.

While Kenya has begun targeting vaccine misinformation through the communication strategy, the country has not yet developed a single consolidated national strategy for misinformation. In addition to the immunization communication campaigns, Kenya trains community health workers to address vaccine myths and educate communities during face-to-face dialogue and local radio journalists on best practices to verify vaccine information in local dialects. Collectively, these efforts have improved accuracy during radio call-in shows and reduced the amplification of rumors. To support these efforts, the MOH conducts social media monitoring to measure public sentiment online. This allows the MOH to identify antivaccine rumors as they emerge and proactively respond with messages addressing misconceptions before they spread widely.

In the case of COVID-19 vaccination:

- Kenya developed a digital campaign targeting the urban youth population on popular social media platforms, with social influencers spreading pro-vaccine messaging.
- A partnership with Meta allowed Kenya to test messaging and optimize the vaccine campaign across demographic groups.

Beyond government-led efforts, the health communication strategy also places high importance on partnerships with civil society networks to design and implement inclusive outreach and demand generation campaigns tailored to each community. The government's Health Promotion Unit works in tandem with civil society groups to engage communities through mass media and share informational resources.

KENYA

Spotlight:

Kenya's civil society network plays a supportive and corrective role in addressing vaccine-related controversies in partnership with the MOH, thereby driving vaccine acceptance. From its position between government and the communities it serves, civil society acts as a translator of pro-public health information, ensuring broad understanding of the benefits of vaccines. The importance of civil society in promoting vaccine acceptance is particularly evident during times of fear, controversy, or misinformation, when communities turn to trusted CSOs to understand conflicting reports and manage concerns. Some examples include:

Tetanus
In 2014, when religious groups raised concerns about the tetanus vaccine and advocated for independent safety testing, civil society and community advocates defended the integrity of the immunization program. When independent testing verified the safety findings of the government tests, civil society restarted the tetanus vaccination campaign with a greater focus on community engagement and transparency to combat government mistrust and support community acceptance.

OPV
Similar mistrust arose in 2015, associated with the oral polio vaccine (OPV). Civil society worked closely with the MOH and other stakeholders to dispel myths about OPV, support clear communications of OPV risks, and eventually lead community campaigns to advocate for the switch to OPV2 when it became available.

COVID-19
To preemptively combat fears about the COVID-19 vaccine, civil society organized community forums, engaged local media to share evidence-based pro-vaccine messaging, and worked closely with community leaders and influencers to combat vaccine hesitancy before it began.

Kenyan civil society efforts have been foundational to advancing vaccine uptake, especially among communities with low trust in government health systems. A future TB vaccine will similarly rely on the efforts of civil society to build trust and understanding in the communities civil society serves.

> ***"Overall, civil society in Kenya has remained a central player in vaccine acceptance, acting as a bridge between government and community — especially during times of fear, controversy, or misinformation."***

Strengthening the Role of Civil Society in Kenya's National Immunization Program

An **easy win** that would strengthen the role of civil society in vaccine programming:

- Formally include civil society representatives in KENITAG to ensure community voices and lived experiences directly inform vaccine policy decisions, promote transparency, and enhance public trust and uptake.

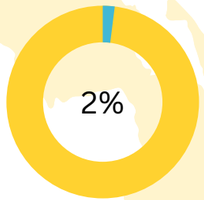
A **high-impact change** that would offer the greatest improvement in civil society inclusion:

- Institutionalize a national Civil Society Immunization Forum with a formal mandate to advise the MOH on vaccine priorities, rollout strategies, demand creation, and equity monitoring. Such a platform would enable sustained, structured engagement of communities across all stages of vaccine policy making, ensuring policies are people centered and contextually relevant.

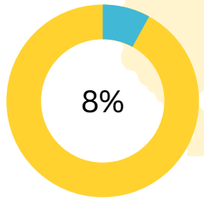
MALAWI

Population: 21.1 million
World Bank Income: LIC
WHO Status: High TB/HIV
WHO Region: Africa

Funding & Financing



Funding for TB Programs
In 2023, 98% of TB program funding in Malawi came from international sources (yellow).



Funding for Vaccine Programs
Malawi's immunization program is heavily reliant on international funding, with the bulk (92%, yellow) coming from Gavi and bilateral donors.

Malawi is heavily reliant on international sources to fund both TB and immunization services. Gavi, Health Services Joint Fund (Norway, Germany, and the United Kingdom), GSK, and UNICEF support the immunization program, while the Global Fund (and previously USAID) funds the TB program.

The Government of Malawi's immunization contributions support operational costs required to ensure continuous delivery, as well as a $0.20 per vaccine dose contribution to procurement, in line with Gavi policies.

As the destruction of USAID reshapes the global health funding landscape, Malawi is exploring sustainable and innovative financing models to bolster domestic support for both programs looking forward.

Decision Making	*Political Visibility*	*Information Environment*
NITAG Est. 2015 10 members	**TB Vaccines in National Health Strategy** Yes, BCG	**CSOs Spreading Antivaccine Information?** No, not in widespread manner
NITAG Representation Diverse expertise, but no civil society	**TB Vaccines in National TB Strategy** Yes, BCG	**Faith Leaders Spreading Antivaccine Information?** No, not extensively
NITAG Transparency MAITAG meetings and notes are not open to the public, but some are webcast	**TB Vaccines in National Immunization Strategy** Yes, BCG	**Political Leaders spreading anti-vaccine information?** No
Primary Decision Makers The MOH is responsible for reviewing, approving, and implementing vaccines. MAITAG, Malawi's NITAG, reviews evidence and issues advisory recommendations for the MOH's consideration and collaborates closely with the EPI. CSOs are not represented in MAITAG or offered opportunities to engage with MAITAG directly. CSOs do engage in MOH-led consultations.	**Political Will to End TB** TB enjoys high political visibility in Malawi. The First Lady is a strong advocate for TB awareness and stigma reduction, and the country has pledged to end TB by 2030. In addition to participating in TB vaccine trials, Malawi developed a comprehensive 5-year National Strategic Plan to guide strategy to address TB through cross-sectoral partnerships and support for investment in TB diagnostics and treatment.	**Strategy to Address Mis-/Disinformation** Malawi does not have a comprehensive national strategy for combating mis-/disinformation, but it does have initiatives to address mis-/disinformation and promote vaccine uptake, including the Health Education Service, which provides information and refutes misconceptions through education and collaboration with community leaders and influencers.

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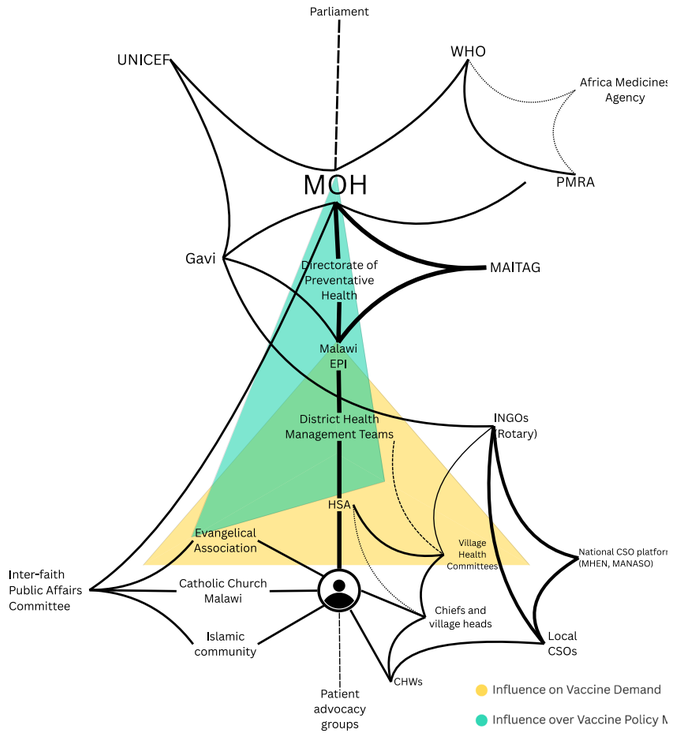
MALAWI



Web of Vaccine Influence

This web depicts the interlocking relationships between different stakeholders across the vaccine policy landscape and the relative strength of influence of each grouping. At the center is the recipient of vaccination. Stakeholders near the center operate closer to individual beneficiaries of vaccination, but actors at the edge may still exert a large influence.

In Malawi's web we see the influence of faith leadership, which directly interfaces with the MOH and UNICEF while retaining its close position and strong influence over community vaccine demand. Power over vaccine policy making is concentrated within the MOH, with coordination between national, regional, and local authorities. Community and faith leaders drive vaccine implementation and demand in close coordination.

Data for Decision Making

The MOH is the centralized coordinator of all immunization decision making. The Malawi Immunization Technical Advisory Group (MAITAG) provides the MOH advisory guidance on vaccine introduction, strategy, and implementation and the Pharmacy and Medicines Regulatory Authority (PMRA) is responsible for ensuring the quality, safety, and efficacy of vaccines.

To assess vaccine introduction and safety, Malawi requires clinical trial data from local populations. However, that requirement may be waived for vaccines approved by stringent regulatory authorities (e.g., U.S. FDA). Generally, Malawi leverages regulatory reliance partnerships to ease approval processes and is part of the African Medicines Regulatory Harmonization Initiative to harmonize regulation across the continent.

NITAG Maturity	★★★★★★
NRA Maturity	Below ML3
Local Trial Data Requirement	✓*
Local Manufacture	✗

*Required, but may be waived if stringent regulatory authorities have approved

Procurement

The MOH, in collaboration with the WHO and UNICEF, is responsible for planning for and procuring vaccines. The MOH develops a vaccine introduction plan including vaccine demand forecasting and budget estimates for vaccine procurement, distribution, storage, and delivery, as well as training, social mobilization, and monitoring and evaluation. UNICEF serves as the primary procurement agency, with Malawi national procurement procedures aligning with UNICEF policies. The government coordinates with international donors (e.g., Gavi, the Global Fund) to mobilize funding and allocates domestic funding for vaccine procurement within the national budget.

Implementation

When introducing new vaccines, Malawi first runs a pilot introduction in select areas to assess feasibility and effectiveness, followed by the gradual scale-up of vaccinations countrywide. During implementation, the MOH works closely with district management teams, civil society, community-based organizations, and village health committees to promote vaccines in their communities.

Malawi leverages both Health Surveillance Assistants, coordinated and paid by the local government, and Community Health Volunteers, volunteers from local organizations, to administer vaccines. Vaccine access varies based on each community, with vaccines administered in clinics, hospitals, mobile sites, schools, churches, palaces, or even outdoors in remote areas.

Vaccine Hesitancy and Misinformation

Malawi has experienced some controversies surrounding vaccines, leading to hesitancy. Vaccine hesitancy is driven primarily by traditional healers, community members, and some political leaders and religious groups that have shared disinformation about the components or safety of vaccines (e.g., vaccines make girls barren, are associated with Satan, etc.). Malawi leverages an "all of the above" approach to countering misinformation: partnering with education services, engaging religious organization and political leaders to convey accurate information, leveraging social media and community outreach campaigns, and training traditional healers on vaccine safety and effectiveness.

Consumer Cost and Transparency

Vaccines in Malawi are free of charge, yet many Malawians incur costs due to the need to travel to vaccination sites. CSOs advocate for affordable and accessible health care, including vaccination services, and easier access to routine health care services.

At the national level, the Malawi National Pricing Committee is made up of expert members tasked with setting and monitoring medicine and vaccine prices for affordability and accessibility. The committee uses several tools, including Malawi's Medicine Price Monitoring System, the WHO's Global Vaccine Market Report, the WHO's Vaccine Price Transparency Initiative, and PAHO's Vaccine Procurement Price Database to monitor vaccine pricing in Malawi and globally. This pricing transparency helps inform budgets for vaccination programs.

MALAWI

Malawi's National-Local Approach to Vaccine Implementation

The vaccination program in Malawi has two centers of gravity — the national government, which makes vaccine policy decisions for the country, and the community-level organizations that implement the policy on the ground. These poles work in tandem to adapt vaccine policy to each community's context, opting for a diffusion of decision making. Local leaders and stakeholders work closely with district health management teams to integrate local vaccine implementation plans within national vaccination and prevention strategies.

Local vaccine implementation follows a partnership approach between local and national government coordination. During implementation, government-coordinated Health Surveillance Agents (HSAs) and civil society–coordinated Community Health Volunteers (CHVs) worked together to administer vaccines and promote vaccination in partnership with local leaders and stakeholders. HSAs are responsible for managing community, family, and environmental health initiatives, prevention and control of communicable diseases, and case management, in addition to immunization programs. Each HSA goes through a six-week training program to provide regular health care to 1,000 people in their community. HSAs work in tandem with CHVs to leverage their relationships and trust from the community to disseminate vaccine information and ensure widespread vaccine reach in each community.

CHVs also assist community organizations to monitor vaccine coverage and equity, helping to expose gaps. CHVs and CSOs provide health counseling and vaccine follow-up. One CSO network, Malawi Health Equity Network, worked with local mothers' groups to identify and contact immunization holdouts and ensure their children were vaccinated. CHVs are also empowered to administer some vaccines. During COVID-19 vaccination campaigns, CHVs went to marketplaces and door to door to administer COVID-19, cholera, and malaria vaccines, boosting vaccine coverage.

HSAs and CHVs play a significant role in adapting government vaccination policy to the community and facility level. They build trust within the community, leveraging ongoing relationships with patients and community leaders to promote health education, address misinformation, and mobilize communities in vaccination campaigns. Malawi's relatively high vaccine support is the result of the emphasis placed on community trust, strong relationships between community members and their health care providers, and vaccine policies responsive to local contexts and social networks.

MALAWI

Spotlight:

Religious leaders and faith groups have significant influence over vaccine policy making and demand creation in Malawi. Faith groups leverage their platforms and community trust to endorse vaccines (e.g., through public statements, messaging in sermons, etc.) to influence uptake among their congregations. Faith-based organizations also develop and support community health initiatives including community clinics, hospitals, and outreach programs to support vaccine promotion. Some examples include:

- The Catholic Church in Malawi publicly endorsed HPV vaccination campaigns and encouraged congregants to get vaccinated.
- The Evangelical Association of Malawi partnered with the government to promote vaccination and to disseminate vaccine information during COVID-19.

Interfaith coalitions have formed to work together to support vaccine uptake and acceptability within the broader community, with unifying messages of vaccines as pro-life and pro-health. One of these coalitions, the Public Affairs Committee, works directly with the government to advise on political and economic issues — including vaccines. These partnerships between faith institutions and government allow for regular sharing of expertise, information, and community perspectives between key decision makers, influencing vaccine decision making, strategy, and approaches to overcoming misinformation and vaccine hesitancy.

While some faith-based communities stand in opposition to vaccines, Malawi's faith groups are largely supportive of vaccines and have been instrumental to driving demand and coordinating government and civil society action around vaccines.

"By engaging faith-based communities and religious leaders, vaccine policy makers and implementers can leverage the trust, influence, and reach of these groups to promote vaccine acceptance and uptake and overall public health."

Strengthening the Role of Civil Society in Malawi's National Immunization Program

An **easy win** that would strengthen the role of civil society in vaccine programming:

- Restructure the Malawi EPI's existing technical health committees to include a committee made up of representatives from CSOs, community groups, and faith-based organizations. This committee would serve as a formal mechanism providing feedback on vaccine policies. Further, the group could be empowered to bolster community engagement and participation in decision making and transparency and accountability in vaccine policy making and implementation.

A **high-impact change** offering the greatest improvement in civil society and community inclusion:

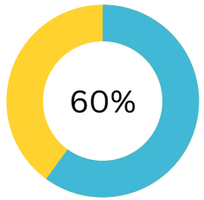
- Formalize and institutionalize community-led vaccine decision making. This can be accomplished by a) establishing Community Vaccine Advisory Boards at the local, district, and national levels; b) capacitating and resourcing the boards to ensure they have the necessary skills and knowledge; and c) enabling community-led and informed vaccine introduction and implementation decision making through these boards, positioning them as equal stakeholders in the vaccine policy-making process.

These changes would empower communities to take ownership of vaccine decision making, improve vaccine uptake by increasing trust and confidence in the program, and enhance accountability and transparency.

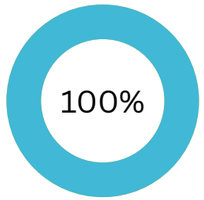
MONGOLIA

Population: 3.5 million
World Bank Income: UMIC
WHO Status: High TB & MDR-TB
WHO Region: Western Pacific

Funding & Financing



Funding for TB Programs
In 2023, 60% of TB funding in Mongolia came from domestic resources (blue).



Funding for Vaccine Programs
Mongolia's vaccination program is self-funded.

Mongolia transitioned from Gavi eligibility in 2015. The government is the main funder of the NIP, though external support (mainly via UNICEF) supports capacity building, emergency preparedness, and sustaining immunization coverage. The World Bank provided emergency financing during COVID-19.

Domestic resources fund a majority of Mongolia's TB program, reaching a peak of 81% in 2019 prior to the pandemic and holding at ~60% in years since. Under the Debt2Health initiative, Mongolia redirected 29 million euros of national debt held by Germany toward Global Fund–led health system strengthening with a focus on TB and HIV.

Decision Making	*Political Visibility*	*Information Environment*
NITAG Est. 2011 24 members	**TB Vaccines in National Health Strategy** No	**CSOs Spreading Antivaccine Information?** No, not in widespread manner
NITAG Representation Diverse expertise, but no civil society	**TB Vaccines in National TB Strategy** No	**Faith Leaders Spreading Antivaccine Information?** No
NITAG Transparency Regulations stipulate meetings and minutes should be public	**TB Vaccines in National Immunization Strategy** No	**Political Leaders Spreading Antivaccine Information?** No
Primary Decision Makers The Dept. of Public Health Policy and Coordination of MOH develops immunization policy implemented by the NIP of the National Center for Communicable Diseases (NCCD). The NITAG advises the MOH. Civil society and community groups are not represented on the NITAG but may occasionally participate as nonvoting observers.	**Political Will to End TB** A TB Multisectoral Accountability Framework (MAF) was formally integrated into the national TB strategy in 2024. TB prevention is a key focus, but TB vaccines are not discussed. Mongolia finalized a new national TB strategic plan for 2025–2028 in September 2025. Civil society is organized under the Mongolian Anti-TB Coalition, and the TB Parliamentary Lobby Group was recently relaunched.	**Strategy to Address Mis-/Disinformation** No standalone strategy for combating vaccine mis-/disinformation exists, though activities to increase acceptance of specific vaccines are undertaken.

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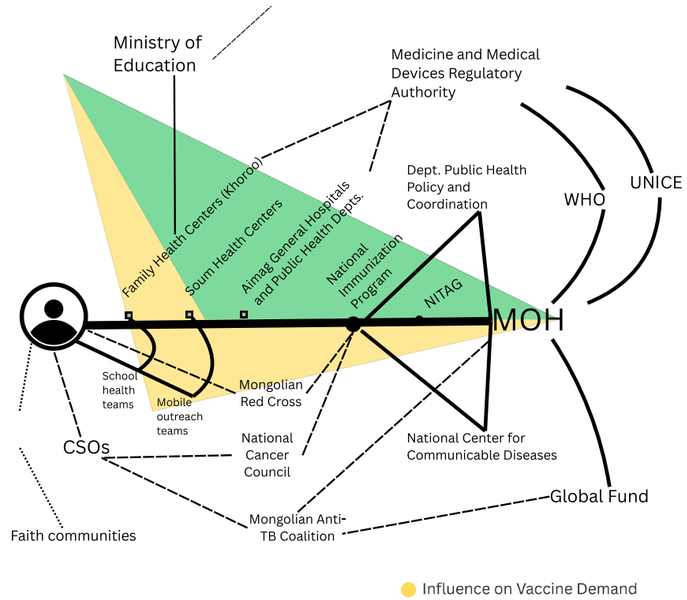
MONGOLIA



Web of Vaccine Influence

This web depicts the interlocking relationships between different stakeholders across the vaccine policy landscape and the relative strength of influence of each grouping. At the center is the recipient of vaccination. Stakeholders near the center operate closer to individual beneficiaries of vaccination, but actors at the edge may still exert a large influence.

What happens in one part of the web is felt in other parts, even if seemingly far away. Some strands in the web are stronger than others (here, the influence of the MOH). Other strands may be broken or nonexistent (notice the lack of direct influence on vaccine uptake exerted by faith communities).

Data for Decision Making

The NITAG is an independent body that advises the MOH on new vaccine introductions, schedules, quality and safety, and delivery. The Medicines and Medical Devices Regulatory Authority (MMRA), established in 2020, is Mongolia's regulatory body; it operates below WHO maturity level 3. The Law on Medicines and Medical Devices (2024) does not require local clinical trials for vaccine approval. Mongolia's regulatory framework permits reliance on international evaluations, and WHO SAGE endorsement and prequalification are usually required. Domestic manufacturing is not a requirement for procurement.

NITAG Maturity ★★★★★★
NRA Maturity < ML3
Local Trial Data Requirement ✗
Local Manufacture ✗

Procurement

The MOH is responsible for procuring vaccines via a standard procedure as follows:

- Provinces submit vaccine supply requests to the NIP/NCCD at the MOH.
- The NCCD compiles requests for review by the Vaccine and Bio-preparation Planning & Coordination Committee.
- The NCCD submits its final proposal to the MOH, which forwards a budget request to the Ministry of Finance to present for approval by Parliament.
- After parliamentary approval, the MOH assumes direct budgetary control and establishes a procurement committee to organize tenders for locally produced vaccines and submits requests to UNICEF for vaccines procured internationally.

CSOs play a limited but emerging role in the national immunization landscape. Their involvement is often informal, not institutionalized, and not reflected in policy documents such as NIP strategies or ministerial orders. […] The Multisectoral Accountability Framework for TB emphasizes the roles of communities and people affected by TB, reflecting a rights-based, whole-of-society approach to TB.

Vaccine Hesitancy and Misinformation

Overall, Mongolia has not had to confront an organized antivaccine movement. There are no formal CSO networks promoting vaccine misinformation, but informal rumor spreading via social media is a challenge. In one instance, an individual associated with the Mongolian Women's Coalition shared misinformation about the HPV vaccine.

The participation of religious leaders in vaccination is relatively limited, as over 80% of the population identifies as Buddhist. There is little evidence of faith-based organizations promoting vaccination in Mongolia; at the same time, the lack of religious opposition has contributed to the smooth implementation of vaccination programs. In a 2022 survey, 78% of respondents agreed that vaccines align with their religious views.

Public Trust and Local Data: Learning from the HPV Vaccine (Re)Introduction

In 2012, Mongolia introduced the HPV vaccine through a pilot program. The program encountered significant resistance, driven by misinformation and lack of locally available data on vaccine safety and efficacy. Widespread concerns included fears that the vaccine could cause infertility, as well as doubts about its necessity. The lack of proactive community engagement and public education contributed to hesitancy; the controversy quickly escalated when national and online media amplified opposition, polarizing public opinion. As a result, the HPV pilot was suspended in less than a year.

In response, the National Cancer Council of Mongolia undertook studies to generate local evidence on the HPV vaccine's safety and effectiveness. The findings were instrumental in rebuilding public trust. Using these data, the National Cancer Council of Mongolia, an NGO, advocated for the inclusion of the HPV vaccine in national immunization policies. In 2023, the MOH approved an updated national immunization schedule, reintroducing the HPV vaccine as a mandatory single-dose regimen for 11-year-old girls and boys.

Health care providers were trained to communicate the benefits and safety of the vaccine, but the reintroduction was not accompanied by a broad public education campaign or community demand generation activities. Consequently, HPV vaccination coverage remains low (<30%).

MONGOLIA

Delivering Vaccines to a Dispersed, Mobile Population across a Vast Geography

Mongolia has 614 designated immunization units that provide routine immunization services across a country known for its vast open spaces and for being the least densely populated country on earth.

These immunization units are part of a well-structured health system organized across *aimag* (provincial), *soum* (subprovincial), and *khoroo* (district and subdistrict) levels.

At the provincial level, aimag general hospitals and public health departments serve as regional hubs for cold-chain storage and vaccine distribution. In addition to providing vaccine services, they are responsible for supervising soum health centers and family health centers, which provide routine childhood and maternal immunization (tetanus toxoid and influenza) at the khoroo levels. Family health centers coordinate school-based vaccination for HPV and tetanus/diphtheria vaccines in collaboration with the Ministry of Education.

In rural areas, mobile immunization teams are deployed from aimag and soum centers. Mobile outreach services provide vaccines for hard-to-reach (remote) populations and nomadic communities and also deploy during extreme weather events and to carry out supplementary immunization activities such as measles vaccination campaigns.

In all settings, vaccines are typically administered by trained vaccinator nurses.

Outside of routine and mobile immunization services, individuals can obtain certain vaccines — HPV, COVID-19, influenza — for a fee at the NCCD's voluntary immunization unit.

The MMRA collects information on vaccine-related adverse events. Health care workers are required to report any suspected adverse reactions to the MMRA, which analyzes the data and forwards the information to the Human Medicines Council for further evaluation and action. The Human Medicines Council is an expert advisory body under the MOH that reviews adverse event data and provides recommendations on regulatory actions, including potential updates to vaccine safety guidelines.

MONGOLIA

Spotlight:

Mongolia does not have a national strategy for achieving vaccine equity. However, Mongolia's legal framework emphasizes nondiscrimination, universal health coverage, and inclusive immunization, thereby supporting equality even in the absence of a dedicated vaccine equity strategy.

At the most foundational level, the Constitution guarantees every citizen the right to health and access to medical care. The Law on Immunization mandates that all Mongolian citizens, as well as foreign nationals and stateless persons, be included in immunization programs. It further supports equitable access by granting individuals the right to choose between public, private, or mixed-ownership health facilities for vaccination and obliges employers to ensure employees receive necessary immunizations — promoting personal choice within a system designed to be fair and inclusive. Other health sector laws and policy documents emphasize principles of nondiscrimination, equity, and human rights.

However, these principles are not fully realized in practice. While gender equality is referenced in legal frameworks, most policies are gender neutral, recognizing men and women without addressing the specific needs and vulnerabilities of different genders.

Stigma and discrimination stemming from TB remain prevalent. The 2022–2023 National TB Stigma and Discrimination Assessment found that nearly half of people with TB reported experiencing stigma. Health facilities were the most frequently reported setting where stigma occurred. In 2024, the Mongolian Anti-TB Coalition completed a Community, Rights, and Gender Assessment that identified priority populations for TB services, including people living in poverty, people who use drugs, PLHIV, and prisoners. Focus group discussions revealed that these groups face significant barriers in accessing health care, largely due to stigma and discrimination.

CSOs have a role to play at each point in the vaccine policy-to-implementation cycle. See Table 4 for ideas from Mongolian communities on where CSOs should be engaged and related capacity-strengthening needs.

Strengthening the Role of Civil Society in Mongolia's National Immunization Program

An **easy win** that would strengthen the role of civil society in vaccine programming:

- Creating one or two observer seats for civil society representatives in Mongolia's NITAG, particularly those working with vulnerable or underserved populations, would bring community perspectives into early-stage policy discussions, improve transparency and trust in vaccine decision making, and establish a formal mechanism to ensure sustained civil society engagement. This change would only require a minor revision to the NITAG's operating procedures.

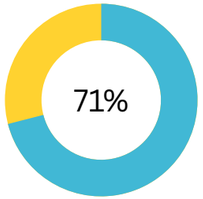
A **high-impact change** that would offer the greatest improvement in civil society inclusion:

- Establishing a Community Immunization Advisory Board (CIAB) linked to the national immunization program would help shape rights-based, equitable vaccine responses and serve as a bridge between decision makers and communities, ensuring policies reflect real lives. The CIAB would be particularly useful for demand generation during new vaccine introductions.

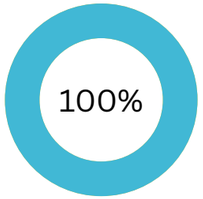
SOUTH AFRICA

Population: 64.0 million
World Bank Income: UMIC
WHO Status: High TB, MDR-TB, TB/HIV
WHO Region: Africa

Funding & Financing



Funding for TB Programs
In 2024, 71% of TB funding in South Africa came from domestic resources (blue).



Funding for Vaccine Programs
South Africa self-funds its vaccination program.

South Africa is not eligible to receive Gavi support. The government provides the primary financial and operational backbones of the National Expanded Programme on Immunization (SA-EPI). UNICEF and the Solidarity Fund supported COVID-19 vaccination efforts.

Domestic resources fund a majority of South Africa's TB program. The Global Fund is the largest external donor, making up around 21% of program funding in 2024. South Africa historically received significant TB support from USAID and PEPFAR, though these funding channels have shrunk or disappeared in the wake of U.S. funding cuts.

Decision Making	*Political Visibility*	*Information Environment*
NITAG Est. 1994 14 members	**TB Vaccines in National Health Strategy** Yes	**CSOs Spreading Antivaccine Information?** No, not in widespread manner
NITAG Representation Diverse expertise, but no civil society	**TB Vaccines in National TB Strategy** Yes	**Faith Leaders Spreading Antivaccine Information?** Some, but not in organized manner
NITAG Transparency Meetings and minutes are not open or posted publicly	**TB Vaccines in National Immunization Strategy** Yes, BCG	**Political Leaders Spreading Antivaccine Information?** Some politicians, appointees, and parties have shared misinformation
Primary Decision Makers The NDOH leads vaccine policy with advice and guidance provided by the NITAG: National Advisory Group on Immunization (NAGI). The NAGI includes space for "community health representative" among its members, but community health is not defined, and CSOs are not currently represented.	**Political Will to End TB** South Africa has demonstrated substantial political will to end TB, with a national strategic plan and multisectoral accountability framework, each of which address new TB vaccines. South Africa leads the world in TB vaccine research and clinical trials. South Africa sits on the WHO TB Vaccine Accelerator Council and co-chairs the Council's working group on financing and access.	**Strategy to Address Mis-/Disinformation** Vaccine misinformation management has revolved around COVID-19. The government developed a training toolkit, fact checking platform, and hotline for reporting misinformation. The strategy was led by the Government Communications and Information System (GCIS) and involved both online and traditional media.

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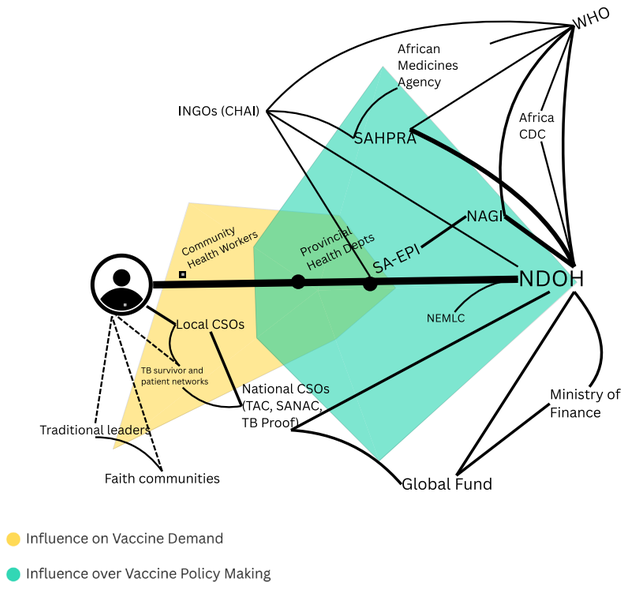
SOUTH AFRICA



Web of Vaccine Influence

This web depicts the interlocking relationships between different stakeholders across the vaccine policy landscape and the relative strength of influence of each grouping. At the center is the recipient of vaccination. Stakeholders near the center operate closer to individual beneficiaries of vaccination, but actors at the edge may still exert a large influence.

What happens in one part of the web is felt in other parts, even if seemingly far away. Some strands in the web are stronger than others (here, the influence of the NDOH). Other strands may be broken or nonexistent (notice the lack of connection between NAGI and CSOs). The web also shows the important constellation of regional and global relationships between South African institutions and organizations like the WHO and African Medicines Agency.

Data for Decision Making

NAGI makes recommendations to the NDOH regarding the inclusion of new vaccines in the SA-EPI. NAGI's advice is necessary but not binding; the NDOH may not fully implement NAGI recommendations when facing resource limitations or policy disagreements. The South African Health Product Regulatory Authority (SAHPRA) is responsible for approving and regulating vaccines and operates at WHO maturity level 3 (vaccines). SAHPRA participates in a number of regulatory reliance schemes, including with other SRAs and regionally through ZAZIBONA (a collaborative medicines registration initiative in Southern Africa).

NITAG Maturity ★★★★★★
NRA Maturity ML3
Local Trial Data Requirement ✗*
Local Manufacture ✗†
*Local data is preferred, but not required for approval †Not required, but incentivized

Procurement

Vaccine procurement occurs through a competitive tender process managed by the NDOH. Local manufacturing is not a requirement for answering a tender, though South Africa's procurement and industrial policies support preferential treatment of locally manufactured vaccines, and a partnership with local producers like BioVac or Aspen can increase the likelihood of success. To compete in the tendering process, a company must work with a local supplier or designate a local agent. The government is placing increasing emphasis on domestic vaccine manufacturing, though most vaccines bought by the NDOH continue to be sourced from external suppliers (see next page).

"Civil society should own the role of building community trust in vaccines by highlighting prevention gaps, setting targets for key groups, representing community values in program planning, monitoring implementation, and refining best practices. This will help the NDOH understand the causes of certain challenges, like why some people are not getting vaccinated. There is a gap between what the department knows and what civil society knows."

Introduction and Implementation

New vaccine introduction in South Africa follows a multistep process involving the interplay of numerous government bodies operating across different levels of administration.

- **Step 1: Initial assessment and recommendation from NAGI.** NAGI's mandate is to advise and guide the NDOH on the decision to introduce new vaccines. NAGI considers disease burden, cost-effectiveness, implementation feasibility, and other evidence when forming recommendations.
- **Step 2: NDOH deliberation and provincial involvement.** Senior NDOH officials deliberate on NAGI's recommendation and consult provincial health departments.
- **Step 3: Funding and implementation.** Once a NAGI recommendation is accepted, the NDOH makes a funding request to the Ministry of Finance. When funding is secured, new vaccines are implemented by the NDOH with support from provincial governments through the SA-EPI.

Other government departments play important roles. SAHPRA reviews and approves vaccines. The National Essential Medicines List Committee reviews data on cost and cost-effectiveness and makes recommendations to the Pricing Evaluation Committee, which makes final decisions on tender outcomes. Within the NDOH, the National Institute for Communicable Diseases and its Center for Vaccines and Immunology conducts public health surveillance and provides laboratory and epidemiological support to the NDOH.

Vaccines are usually offered at primary health care facilities but may be offered in other settings in the context of specific campaigns through mobile vaccination clinics, school programs, or immunization drives. In rural areas, community health care workers play a big role in bridging access to services or points of care.

COVID-19 as a Civil Society Entry Point

The COVID-19 pandemic placed a large demand on government capacity, resulting in the government relying more on CSOs than in previous vaccine drives. CSOs emerged as a reliable partner in identifying and reaching hard-to-reach areas and in connecting key and vulnerable populations (such as PLHIV or people living with other chronic conditions) to vaccines, since there were hesitancy issues among some of these groups. CSOs engaged in door-to-door campaigns, organized community dialogues, worked with media, and monitored problems in vaccine distribution.

SOUTH AFRICA

Investing in Local Manufacturing for Vaccine Sovereignty

Grave inequities in vaccine access during the COVID-19 pandemic laid bare the stark reality that Africa currently produces less than 1% of the vaccines it consumes. To reduce reliance on external suppliers, governments across the continent have prioritized local manufacturing as a central health and development priority and key pillar of pandemic preparedness and response.

In South Africa, this has meant nurturing a nascent but capable vaccine manufacturing sector led by players like BioVac and Aspen Pharmacare.

Established in 2003 as a public-private partnership with the South African government, BioVac engages in different types of partnership activities with external suppliers, including packaging and labeling, fill and finish, and local formulation (e.g., PCV13 vaccine via technology transfer from Pfizer). BioVac has also embarked on research and development of its own vaccines, including for group B streptococcus and oral cholera. BioVac is also part of the mRNA Technology Transfer Hub, a consortium established together with Afrigen, the Medicines Patent Pool, and the WHO to democratize mRNA vaccine capacity across low- and-middle income countries.

Although a clear policy priority, the development of a local vaccine manufacturing industry in South Africa faces a number of serious hurdles. These were illustrated in 2023 when BioVac lost a tender to supply pneumococcal conjugate vaccine to the NDOH that was awarded instead to an external supplier (Serum Institute of India). The incident brought to light the challenge of building competitive, sustainable domestic vaccine manufacturing — a lesson that holds relevance as governments prepare to procure and introduce new TB vaccines.

SOUTH AFRICA

Spotlight:

South Africa has a rich tradition of civil society leadership in health, exemplified by activism targeting the country's response to HIV, which paved the way for global access to affordable antiretroviral treatment, and TB, where the country catalyzed the research and policy enabling access to shorter, safer treatments for drug-resistant TB. In the realm of vaccines, South African civil society played a prominent role in holding the government and pharmaceutical companies accountable for ensuring equitable access to vaccines during the COVID-19 pandemic.

Although civil society voice is prominent in health policy, there are numerous ways to better integrate CSOs into South Africa's national immunization program. Under the status quo, vaccination campaigns are planned by the NDOH and other relevant government departments. CSOs are then expected to help implement campaigns without being part of the planning — a dynamic that should change through purposeful, early involvement of community representatives along the following lines:

- Civil society should collaborate with the NDOH and the Government Communication and Information System to plan vaccine communication campaigns, including by co-designing key messages in local languages and disseminating these through local media.
- The NDOH and provincial departments of health should establish vaccine stakeholder forums to monitor vaccine uptake and any emergent community concerns about vaccine safety.
- Provincial health departments should include TB community leaders and champions in clinic committees to help monitor vaccine implementation, represent community values in outreach strategies, and document best practices.
- The government should fully resource community structures that provide a platform for facilitating vaccine implementation, including local health committees, ward committees, and community health worker initiatives.

"TB stigma is a big issue. Communities do not want to see celebrities tell them to get vaccinated. They want to see real-life experiences shared by people that they encounter in their own communities and neighborhoods."

Strengthening the Role of Civil Society in South Africa's National Immunization Program

An **easy win** that would strengthen the role of civil society in vaccine programming:

- Representation of CSOs at all levels of decision making, including during initial policy development through community representation in NAGI. A community representative should always be involved in the development of new policies — for example, a TB survivor or member of the South African National AIDS Council (SANAC).
- When South Africa decides to introduce a new TB vaccine, the NDOH should appoint a TB survivor as a spokesperson for the vaccine alongside the government on national television and media.

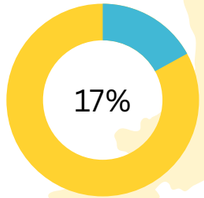
A **high-impact change** that would offer the greatest improvement in civil society inclusion:

- As a long-term vision, the Government of South Africa and CSOs should put together a comprehensive plan for building community leadership and capacity on vaccine introduction. CSOs need to be trained on key data sources of vaccine decision making and the logistics of vaccine implementation to help bridge the gap between what the NDOH knows and what the community knows.

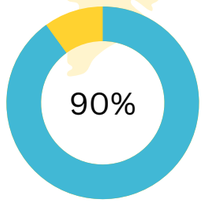
VIETNAM

Population: 101.1 million
World Bank Income: LMIC
WHO Status: High TB & MDR-TB
WHO Region: SE Asia

Funding & Financing



Funding for TB Programs
Vietnam is reliant (83%, yellow) on international funding.



Funding for Vaccine Programs
Vietnam's vaccination program is 90% (blue) self-funded

Since transitioning from Gavi support in 2022, Vietnam has depended on domestic resources for vaccine funding. For new or more expensive vaccines (e.g., rotavirus and polio), Vietnam still receives international support. In recent years, Vietnam has rapidly scaled up its domestic vaccine manufacturing and regulatory capacity, allowing domestic manufacture of key required vaccines (e.g., BCG), reducing costs to the vaccine program.

Vietnam's TB program remains reliant on external funders, including Stop TB Partnership and the Global Fund.

Decision Making	*Political Visibility*	*Information Environment*
NITAG Est. 2017 16 members	**TB Vaccines in National Health Strategy** Yes, BCG	**CSOs Spreading Antivaccine Information?** No, not in organized manner
NITAG Representation Diverse expertise but no CSOs	**TB Vaccines in National TB Strategy** Yes, BCG	**Faith Leaders Spreading Antivaccine Information?** No
NITAG Transparency Membership and minutes not public	**TB Vaccines in National Immunization Strategy** Yes, BCG	**Political Leaders Spreading Antivaccine Information?** No
Primary Decision Makers The MOH is responsible for all vaccine decisions, informed by subgroups including NITAG, Drug Administration of Vietnam and General Department of Preventive Medicine. *CSOs are largely excluded from vaccine decision making, with informal forums available to provide input.*	**Political Will to End TB** Following the 2023 UN HLM on TB, the Prime Minister issued a series of declarations aimed at ending TB and strengthening TB prevention and control — including the intent to develop new TB vaccines. The orders directed ministries to review the National TB Strategy and effectively develop and implement a modernized TB strategy with whole-society participation. The fruits of those efforts are currently developing.	**Strategy to Address Mis-/Disinformation** Vietnam has formal strategies for vaccine acceptability and combating misinformation. The MOH is responsible for developing a core immunization acceptability plan, with communications flowing through media, health care workers, social media, mass organizations, and commune health centers. Commune health centers share information via village loudspeaker and direct outreach.

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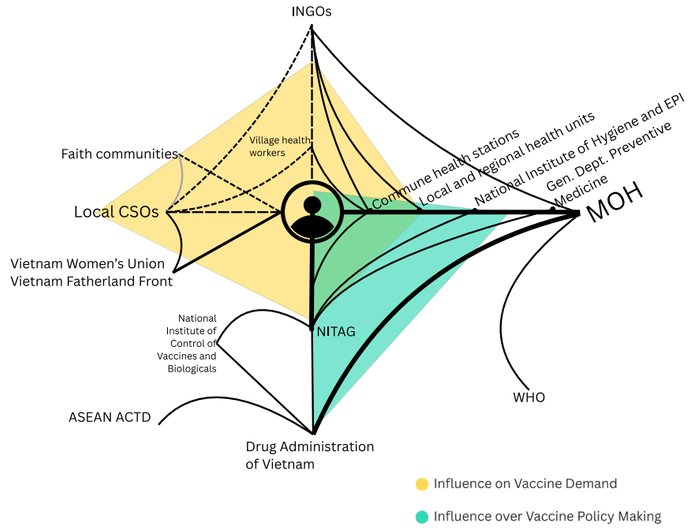

Web of Vaccine Influence

This web depicts the interlocking relationships between different stakeholders across the vaccine policy landscape and the relative strength of influence of each grouping. At the center is the recipient of vaccination. Stakeholders near the center operate closer to individual beneficiaries of vaccination, but actors at the edge may still exert a large influence.

What happens in one part of the web is felt in other parts, even if seemingly far away. Some strands in the web are stronger than others (here, the influence of the MOH). Other strands may be broken or nonexistent (notice how the MOH does not work directly with local CSOs, who exert modest influence on vaccine information and community acceptance).

Data for Decision Making

Data on Asian racial factors are considered necessary by the NITAG to ensure safety in the population, and failure to include clinical data on Asian participants severely limits NITAG recommendation. Data for Vietnam–specific populations are required only for vaccines that are not entirely produced on the production lines under the jurisdiction of stringent regulatory authorities (e.g., U.S. FDA, EMA). Vietnam's NRA maturity is the result of continuous investment and commitment to quality and safety in close cooperation with WHO and regulatory partnerships with ASEAN & WHO-PQ.

NITAG Maturity ★★★★★★
NRA Maturity ML3
Local Trial Data Requirement ✓
Local Manufacture ✓ *
*Preference through tendering process

Procurement

The MOH is the central authority tasked with procuring vaccines. Procurement involves two MOH departments — the Department of Financial Planning, which manages budget development and approval, and the General Department of Preventative Medicine, which oversees vaccine forecast assessments in partnerships with local and regional health departments. Purchase of vaccines largely flows through a national bidding process, with direct procurement or UNICEF contracts used for specific vaccines. Domestically produced vaccines are prioritized in bidding through preferential policies, administrative procedures, and financial support.

"The Ministry of Health is the lead agency making the final decision, but this decision is based on close coordination and a system workflow among specialized departments, technical control units, and advisory and ethics committees. This interaction ensures that vaccines are comprehensively evaluated from research and clinical trials stages through to licensing and introduction into use, as well as being closely monitored thereafter."

Implementation

The General Department of Preventative Medicine (GDPM) carries primary responsibility for directing the implementation of vaccine activities. Working closely with the National Institute of Hygiene and Epidemiology, local clinics, and commune health centers, the GDPM develops specialized vaccine rollout plans built off a standard vaccination framework. Implementation begins with the identification of target groups for vaccination, which informs procurement estimates. Following vaccination, the GDPM coordinates centralized reporting of adverse events and coordinates with the WHO and government agencies tasked with safety monitoring — including the National Institute for Control of Vaccines and Biologicals.

Vaccination Campaigns

Vaccination campaigns are primarily run through commune health stations. Beyond administering vaccines, commune health stations also share vaccine campaign information via local loudspeakers and keep registries of individuals not yet vaccinated — following up with them directly to ensure coverage. Routine vaccination programs mainly target children and pregnant persons, with nonpregnant adults vaccinated on an ad hoc basis via mobile vaccine units, hospitals, temporary sites (e.g., schools), within their neighborhoods, or in their workplace. For hard-to-reach communities (i.e., remote villages), Vietnam deploys mobile vaccination units directly to villages.

Consumer Cost and Transparency

Vietnam's health system ensures that all recommended vaccines are provided free of charge to all persons who qualify. This includes all vaccines included on the EPI list. However, for any vaccines outside of this list, the entire cost is borne by the patient out of pocket. Newer vaccines or vaccines that fall outside of broad public campaigns are those most likely to carry fees to patients. The pricing of these vaccines is centrally managed by the MOH; however, detailed pricing information is not made available to the public and enforcement of out-of-pocket pricing is lacking, with minimal opportunity for individuals to compare costs across facilities. Within this dynamic, CSOs have a limited role in price monitoring in both the public and private sectors, leaving little pricing accountability or transparency for vaccines procured outside of the national vaccine program.

VIETNAM

Vietnamese CSO Engagement in Vaccination: A Case Study of the Rotavirus Vaccine (2023)

During the last vaccine introduction in Vietnam, CSOs and INGOs were engaged to varying degrees across the decision and implementation process.

Decision Making:
Local CSOs were largely excluded from the vaccine decision-making process due to lack of formal venues for community engagement. INGOs, however, supported clinical trials and surveillance in partnership with the Government of Vietnam.

Policy Creation:
Larger INGOs (i.e., PATH) collaborated directly with the MOH as part of expert working groups to review current vaccination policies.

Advocacy:
Community-driven socio-political mass organizations played a large role in advocacy in support of rotavirus vaccine introduction. State-aligned mass organizations like the Vietnam Women's Union and Vietnam Fatherland Front were critical to messaging around preventative measures that undergirded support in vaccines as a tool for prevention. Their efforts underscore the untapped potential for mass organization engagement in vaccine rollout and acceptance.

Information Sharing and Media Engagement:
Mass organizations, alongside village health workers, led grassroots communications programs in support of vaccine uptake — supporting official MOH and UNICEF messaging and promoting dissemination throughout Vietnam.

Vaccine Rollout:
Health workers of local ethnic communities were critical to overcoming language barriers, building trust among communities, and navigating cultural nuances to generate community buy-in and acceptance in even the most remote communities.

Budgeting:
CSOs were not engaged in the budget or forecasting process for rotavirus vaccines. However, the Vietnam Fatherland Front had previously established a COVID-19 Vaccine Fund that called for financial contributions from community members to support vaccine procurement and participatory budgeting processes — again highlighting the interest and potential of CSOs and community groups to engage.

Overall, INGOs and state-aligned mass organizations have a defined role in vaccine policy making and rollout in Vietnam. However, grassroots groups and smaller, more independent CSOs have not yet been able to claim a role in the process, creating a dynamic in which groups with substantial resources or state approval have the strongest influence over decision making.

Spotlight:

Vietnam is one of the most recent Gavi graduates, moving to fully self-sufficient financing as of 2022. The most recent data show the success of the graduation, with Vietnam funding 90% of its vaccination program with the remaining 10% coming from external funding to support newer vaccines (i.e., Gavi support for rotavirus vaccines), which are currently priced quite high, or as support from existing multilateral programs targeting childhood vaccination (i.e., UNICEF funding injectable polio vaccines).

The success of Vietnam's transition — in which the country went from 60% self-funded in 2020 to 90% in 2023 — is the result of long-term planning between Gavi, Vietnam's NIP, and the MOH paired with longer-term Gavi investments in underlying health system strengthening and infrastructure. These investments allowed Vietnam to expand its domestic manufacturing of vaccines included in the Essential Program on Immunization, keeping costs down following the accelerated transition phase. Since Vietnam transitioned, Gavi has continued to provide ongoing technical assistance, especially for newly introduced vaccines, as well as targeted support for high-cost vaccines to ensure access as Vietnam continues to bolster its domestic investments.

"Strong planning enabled Vietnam to sustain its immunization program after Gavi support ended."

Vaccine Scandals and Hesitancy

Recent vaccine scandals in Vietnam have focused on corrupt behavior of government officials accepting bribes for enhanced access to COVID-19 tools or services. The Vietnamese government swiftly prosecuted the offenders, resulting in minimal disruption to COVID-19 vaccines. This dynamic reflects the relative absence of vaccine hesitancy across Vietnam, with very little organized effort to promote antivaccine mis-/disinformation. Vietnam enjoys cultural factors, such as high social respect for health care workers and trust in the medical community at large, that undercut the impact of vaccine misinformation and generate broad vaccine acceptance.

Strengthening the Role of Civil Society in Vietnam's National Immunization Program

An **easy win** that would strengthen the role of civil society in vaccine programming:

- Civil society is largely excluded from vaccine decision making, with no government-level requirement for open or regular engagement with CSOs in vaccine-related decisions. The development and implementation of regulations that ensure representation of CSOs and communities in committees, advisory boards, and other decision-making forums across clinical trials, licensing, and vaccine deployment would create opportunities for CSOs to shape vaccine policy.

A **high-impact change** that would offer the greatest improvement in civil society inclusion:

- Expansion and formalization of community-led monitoring. CSOs need an official mechanism and resources to independently monitor the implementation of vaccine programs, evaluating their effectiveness and identifying areas for improvement.

TB Vaccine Access in "4D": A Roadmap Charting Civil Society Actions for Equitable Access

TB Vaccine Access in "4D"

Introduction

At the 2023 United Nations High-Level Meeting on TB, member states committed to develop and deliver at least one new TB vaccine by 2028.[30] This roadmap seeks to accelerate introduction of, and maximize global access to, new TB vaccines under development by articulating the interventions civil society can make to secure equitable access.

The roadmap eschews a single definition of access in favor of a principles-based approach that acknowledges access to new TB vaccines as a fundamental entitlement rooted in states' obligations to fulfill the human right to enjoy the benefits and applications of scientific progress (right to science) and the right to enjoy the highest attainable standard of health (right to health). These rights offer a framework for considering access along four lines: availability, accessibility (including affordability), acceptability, and quality — underscored by human rights principles of nondiscrimination, participation, and transparency.

Here, equity is defined as the absence of unfair, avoidable, or remediable differences among and within countries and between groups of people or communities, in line with WHO Pandemic Accord definitions and endorsed by leading ethicists, social scientists, and affected community representatives in the TB response.[31] Equitable access is not the result of a single intervention, but rather the outcome of interlocking actions by multiple stakeholders. Sometimes these stakeholders will work in concert; occasionally, at odds. This roadmap focuses on the role of an overlooked but indispensable player in immunization policy — civil society — in securing equitable access to new TB vaccines.

Structure of the Roadmap

The TB vaccine pipeline contains at least 17 vaccine candidates being evaluated at different stages of clinical development and representing different underlying vaccine platforms (Figure 15): [32]

- **Subunit vaccines (protein/adjuvant).**
  Examples: M72/AS01E, GamTBvac
- **Live attenuated vaccines.**
  Examples: MTBVAC, VPM1002
- Inactivated whole-cell vaccines derived from *Mycobacterium tuberculosis* or closely related mycobacteria.
  Examples: Immuvac (MIP), DAR 901

- **mRNA vaccines.** Examples: BNT164a1 and BNT164b1
- Viral vector vaccines. Examples: ChAdOx1.85A+MVA85A, Ad5-105K

This roadmap focuses on the three highlighted vaccine types that are at the center of preparatory activities undertaken by the Finance and Access Working Group of the WHO TB Vaccine Accelerator Council.[33] These vaccines are collectively referred to as "new TB vaccines" in the text.

These vaccines were chosen to ensure the roadmap considers a variety of access-related factors that are influenced by specific vaccine types, for example clinical trial design, durability of protection, side effects, manufacturing process, storage and transportation, and intellectual property rights. While some candidate vaccines are being studied among infants or tested under other paradigms (prevention of infection, prevention of recurrent TB disease), the discussion here assumes vaccines will be used to prevent TB disease among adolescents and adults, as this is the primary indication for TB vaccine development.

The roadmap outlines a series of recommended actions for CSOs and other stakeholders such as funders, vaccine developers, and manufacturers to take between 2025 and 2030. The earliest normative and regulatory approvals of new TB vaccines are anticipated to occur around 2028, followed by early introduction and initial implementation leading to policy expansion and broader rollout beginning around 2030.

Recommended actions are organized into four areas: Development, Delivery, Demand, and Data. Collectively, these areas offer a "4D" view of interventions to secure equitable access to new TB vaccines.

- Development refers to research and clinical trials of the vaccines.
- Delivery refers to a set of actions required to provide access to vaccines.
- Demand stands for vaccine awareness, preparedness, and uptake among key stakeholders, target groups, and the general population, including people's intent and willingness to receive the vaccine given its characteristics.
- Data refers to collecting information about vaccine implementation to inform follow-up actions and policy expansion, including adverse event reporting, marketing approval status, inclusion in NIPs, and supply disruptions. Data collection cuts across the other three areas.

For each piece of the 4D perspective, the roadmap recommends actions that CSOs and other stakeholder groups should undertake in the ideal scenario. It is not only up to civil society, but also to funders, vaccine developers and manufacturers, multilateral agencies, and

TB Vaccine Access in "4D"

Figure 15

The TB Vaccine Pipeline (as of April 2025)

governments to turn these ideal scenarios into realities. The recommended actions are intended to inform how stakeholders involved in vaccine research, policy making, and delivery should work with civil society to achieve equitable access to new TB vaccines.

Recommendations are based on an analysis of publicly available information about the TB vaccine pipeline, 22 semistructured interviews with experts representing various sectors and regions, and consultations with national and regional civil society organizations, community advisory boards, and communities of people affected by TB. The online Appendix contains a list of stakeholders interviewed and the key documents used to develop the roadmap.

Across the board, interviewees stressed that CSO involvement in vaccine development, as well vaccine delivery, demand creation, and data collection, is essential as communities, being the intended direct beneficiaries of vaccination, should be regarded as co-owners of this whole process.

Development Action Plan

The new TB vaccines covered by this roadmap are in different stages of clinical research (see Figure 15).[34] Based on the indicated completion dates of ongoing and future trials, the timeframe for the development stage has been estimated as 2025–2028 for the most advanced candidate, M72/AS01E. For the other two candidates covered by this roadmap — MTBVAC and BNT164 — development will likely extend to 2030 and beyond.

Action 1

Vaccine developers proactively involve CSOs in the creation of comprehensive research plans to guide clinical trials and other development activities.

The three vaccines covered by the roadmap are positioned differently when it comes to the scope and progress of their clinical trials — from ongoing phase IIa trials (BNT164) to full enrollment in a phase III trial (M72/AS01E). The outcomes of each study will shape further phase II/III trials, as well as post-marketing and phase IV studies if the vaccines show adequate safety and efficacy.

Several key areas in the comprehensive research plan (CRP) require CSO input, including:

- Preferred product characteristics
- Inclusion of key target groups in trials
- Wider geographical coverage of clinical trials
- Innovative trial designs, including head-to-head comparisons of different candidates and studying TB vaccines with TB preventive treatment

The core mechanism by which CSOs can communicate with vaccine developers and other stakeholders is regular community advisory board (CAB) meetings at global, regional, national, and site levels. Other communication platforms include scientific and political events related to TB and events in other fields (e.g., HIV meetings). Wider community representation at these events is necessary to support more comprehensive communication between CSOs and vaccine developers.

Ideal scenario:

Vaccine developers regularly engage with CSOs through CABs and other existing platforms to ensure there are public, and evolving CRPs for vaccine candidates that are open to feedback from the community, as co-owners of the development process.

CSOs ensure CRPs account for TB vaccine preferred product characteristics as defined by the WHO.

The WHO has defined key TB vaccine product attributes in its *Preferred Product Characteristics for New TB Vaccines* guidance document.[35] Key characteristics include:

- 50% or greater efficacy in preventing confirmed pulmonary TB
- Over 10 years of protection after primary immunization
- Minimal number of doses and boosters
- Favorable safety and reactogenicity profile
- Careful investigations for live platform vaccine candidates

CSOs directly involved in discussions with vaccine developers about the CRP can provide feedback regarding preferred product characteristics based on community needs and perceptions. For instance, interviewees indicated preferences for efficacy in preventing confirmed pulmonary TB over 70% (higher than the 50% minimum efficacy threshold specified by the WHO) and single-shot vaccines. CSOs will play a key role in conversations about product characteristic tradeoffs and acceptable risk/benefit concerning vaccine candidates and their evaluation in particular populations.

CSOs advocate for inclusion of key populations in CRPs and clinical trials.

The key populations identified include PLHIV, people living with and without *Mycobacterium tuberculosis* infection, and people cured of TB (i.e., TB survivors). Interviewees identified additional groups including pregnant women, people with diabetes, people using drugs, people in penitentiary institutions, military servants, migrants, and medical and outreach personnel working in the field of TB.

Ongoing trials of new TB vaccines have not consistently included these key populations. CSOs should advocate for inclusion of the identified groups in future clinical trials when discussing TB vaccine development plans with developers. Existing

community-led campaigns can serve as a basis for this work, such as the community consensus on the earlier inclusion of pregnant women and persons in TB research or the advocacy to include people using drugs in trials in the field of HIV.[36,37] CABs should reach out to CSOs representing the respective groups to raise their awareness about TB vaccine trials and collect feedback on specific community needs. Representatives of specific groups can be invited to CAB meetings and involved in developing position papers addressing the inclusion of these groups in clinical trials.

Vaccine developers and funders commit to wider geographical coverage of clinical trials and development activities within the CRP.

Current phase II–III trials are primarily taking place in the African region and in the Southeast Asia region. So far, there are no active trials in Latin America, Eastern Europe and Central Asia, or Middle East and North Africa, even in countries with a high burden of TB.

As shown in the country policy portraits, some countries prefer or require clinical data from their country or from a country in the same region or with similar health systems, epidemiological conditions, or population characteristics. Vaccine developers should discuss the possibility of including additional countries in future trials with regional CABs and networks of people affected by TB, with CSOs positioned to mediate between vaccine developers and national research institutions.

Interviewees noted that it is important for vaccine developers to have information about the local epidemiology, including hot-spot communities, the local clinical trial infrastructure, and the licensure and procurement requirements before designing phase II–III trials. It can be challenging to involve additional countries after planning begins due to budget or logistics considerations.

Vaccine developers stressed the need for clinical trial site capacitation and building community awareness in countries that have less experience in conducting clinical trials. National and global CSOs can contribute to bridging this gap. Snapshot reviews of clinical trial sites developed by CSOs, such as a 2021 report by EATG, "Clinical Trial Sites in Eastern Europe and Central Asia HIV, Viral Hepatitis, Tuberculosis Brief Landscape Review," can be developed by regional CABs with a focus on sites for TB vaccine research.[38]

CSOs engage vaccine developers on the use of innovative trial designs within CRP discussions.

Community representatives should be consulted on the use of innovative trial designs in CRP discussions. Some interviewees recommended that research plans include a comparison of TB vaccines with TPT and look at the efficacy of a strategy combining vaccination with TPT. To date, no clinical trial has been designed to compare a TB vaccine to TPT. Instead, most studies have opted to restrict TPT to PLHIV and require that this group complete TPT prior to randomization.[39] For trials comparing TPT and TB vaccines, experts noted that it might be difficult to demonstrate vaccine efficacy in high-risk groups taking TPT. None of the developers interviewed cited plans for direct TB vaccine and TPT comparisons in the context of clinical trials before licensure.

Clinical trials in which different TB vaccine candidates, especially of the same type, are compared against each other are of interest to some experts. However, this approach may risk early loss of candidates that may demonstrate sufficient safety and efficacy to reach the market at later stages. According to some vaccine developers, it may be better to conduct such trials in post-marketing research. Additionally, some experts are discussing the possibility of including trial endpoints that measure vaccine efficacy against asymptomatic TB.

CSOs have the capacity to provide insights regarding these and other innovative trial designs through CABs and raise awareness about the trials among communities near research sites.

Development Action Plan

Action 2

Vaccine developers commit to meaningfully engaging communities and TB survivors in TB vaccine development as co-owners of the CRP.

Communities of people affected by TB should be considered co-owners of the TB vaccine development process rather than external stakeholders, as they represent either participants of clinical trials or direct beneficiaries of new TB vaccines. Routine CSO engagement should be an integral part of TB vaccine development. This engagement takes the form of implementing general and trial-specific community engagement plans, which should include:

- Trial protocol review by CABs before studies are launched
- Establishment and capacitation of CABs at trial sites
- Collaborations with local communities to ensure efficient trial enrollment
- Community participation in data and safety monitoring boards
- Regular communication between vaccine developers and global, regional, national, and local CABs about the clinical trial progress

Ideal scenario:

Developers work proactively with CSOs to create general and trial-specific community engagement plans as an integral part of CRPs, providing opportunities for communities to engage at each clinical trial stage. CSOs build their capacity in the field of clinical trials.

Vaccine developers involve affected communities and TB survivors in clinical trial protocol development, study implementation, and results dissemination.

TB vaccine developers should adopt a combined, multilevel approach to community engagement based on a central community engagement plan and a budget for activities at the site level. Community engagement plans should include early and regular communication between vaccine developers and the Global TB CAB, regional CABs, and national CABs regarding trial design, progress, and plans for further trials.

Development Action Plan

> “Active engagement with the community at each trial site is essential — fostering consensus around the necessity of clinical trials and boosting the visibility of ongoing studies within the country. Such involvement ensures that the community not only understands the importance of participation but also becomes an advocate for the clinical research being conducted.”

CABs should regularly reach out to TB vaccine developers to foster relationships and dialogue.

Sharing trial protocols and community engagement plans with CSOs, trial site CABs, and regional and global CABs for feedback before the design is finalized stands out as an area for improvement. This is a long-standing practice in HIV drug development, resulting in more comprehensive, patient-centered research and paving the way for better access to treatment.[40,41]

CSOs build their capacity and the capacity of affected communities and TB survivors to engage in TB vaccine research.

Enrollment in the phase III M72/AS01E trial was completed 11 months earlier than expected, which was largely attributed to community engagement at the trial sites and the role of CABs in sharing information with communities.[42] This underscores the critical role of communities in research. To support and strengthen this role, investment in CSO capacity building at all levels is required, particularly at the trial site level. Key areas include general understanding of what participation in clinical trials implies and knowledge of clinical trial design. Examples of community capacity-building projects include TB training curriculums (e.g., CABLab), webinars, and the development and dissemination of community-friendly materials.

Development Action Plan

Action 3

CSOs communicate results of TB vaccine clinical trials widely at the global, regional, and national levels.

One of the key roles of CSOs is communicating information about research progress to a larger multi-stakeholder audience to pave the way for new TB vaccines. In many settings, CSOs are well positioned to disseminate the latest data among politicians, government officials, national TB programs (NTPs) and NIPs, health care professionals, and local communities.

Ideal scenario:

Information regarding the progress of TB vaccine research is disseminated to a broad and diverse range of stakeholders at all levels through CSO communication initiatives.

CSOs hold vaccine developers accountable for transparently communicating research results to clinical trial participants, CAB members, affected community representatives, and other stakeholders.

Vaccine developers must proactively and transparently share results from clinical trials with community representatives, starting with the trial participants. In a positive example of results sharing, investigators of former TB vaccine candidate H56:IC31 shared topline results, key messages, and preliminary analyses of safety and efficacy outcomes with participants and site-level CABs first, and then with researchers, funders, global policy makers, and representatives of affected communities, before formally presenting at a scientific conference (CROI) in March 2024. In contrast, other sponsors have waited months after studies have ended to publicly share results, creating uncertainty about the success or failure of vaccine candidates (e.g., VPM1002). CABs and vaccine developers should define best practices for proactive communication, and CSOs should hold developers accountable for upholding these practices.

CSOs ensure the latest publicly available clinical data reach the largest audience of stakeholders.

Clinical data on TB vaccine development should be widely presented at global, regional, and international conferences and other TB-related events. All lung disease, immunization, and HIV-related conferences should have designated tracks for TB vaccine research. CSOs should advocate for specific sessions on TB vaccines in conference agendas.

CSOs should cooperate with the media to spread up-to-date and accurate information about TB vaccine research to the general public and disseminate relevant information to key stakeholders at the national level, including local communities, health care providers, NTPs, government officials, and policy makers.

Development Action Plan

Action 4

CSOs advocate for sustained and increased funding for TB vaccine research.

The annual $5 billion funding target for TB research was endorsed by countries at the United Nations High-Level Meeting on TB in September 2023. Yet total spending on TB research reached only $1.2 billion in 2023, a quarter of the target. Recent upheavals in U.S. policy will likely undermine TB vaccine research funding, especially given the U.S. National Institutes of Health's position as the largest funder of TB research. The full extent of disruptions to TB research funding will only become clear in time.

CSOs play a pivotal role in advocating for increased and sustained funding for TB research through public campaigns, targeted advocacy with donors and national governments, and TB research spending monitoring.

Ideal scenario:

New donors invest in TB vaccine development, including governments of middle-income countries, and total spending on TB vaccine research reaches the annual funding target of $5 billion by 2028.

CSOs monitor TB vaccine research spending to create an evidence base for advocacy.

TAG regularly monitors global spending for TB vaccine research through an annual global survey of TB research funders, the results of which are published in the *Tuberculosis Research Funding Trends* report series.[43] These data form an essential evidence base for advocating for increased and diversified funding for TB vaccines research. CSOs operating at the national level should adopt this practice by monitoring TB R&D expenditures by their governments.

CSOs advocate for sustained and increased funding for TB vaccine research provided by governments and other funders.

TAG, the Stop TB Partnership, and other advocates have called for governments to commit their fair share to TB research by allocating 0.15% of their total research spending to TB. According to TAG's *Tuberculosis Research Funding Trends* report, in 2023, only two countries met this target: South Africa and India. CSOs should scale up campaigns to persuade their governments to allocate more funding for TB research, especially in view of U.S. funding cuts. As TB vaccine R&D is heavily dependent on philanthropic support, domestic funding is critical to ensure funding sustainability.

During the United Nations High-Level Meeting on Tuberculosis in September 2023, member states adopted a new political declaration and agreed to convene a third United Nations High-Level Meeting in 2028 to review progress. CSOs should commence preparations for advocacy activities

Development Action Plan

in advance of this meeting, beginning as early as 2026.

Members of CSOs who are formally integrated into the advisory or decision-making bodies of donor organizations are encouraged to advocate for funding allocations for TB vaccine research.

CSOs explore and propose new financing models for TB vaccine research to governments and funders.

In the 2024 *Tuberculosis Research Funding Trends* report, TAG highlighted the need to diversify the TB research funding landscape to reduce dependency on traditional "mega-funders," such as the U.S. National Institutes of Health and large philanthropic organizations that comprise a majority share of TB vaccine R&D funding (Gates, Wellcome, Open Philanthropy). Economic realities, such as high sovereign debt burdens, limit the ability of high-TB-burden nations to invest broadly in TB vaccines and underscore the need for new funding models in addition to new funding sources.

Some interviewed experts raised the idea of a TB vaccine research fund, which could serve as a platform for accumulating investments from different donors interested in investing in TB vaccine research. A joint fund could also support trials with head-to-head comparisons of different candidates that developers have been reluctant to initiate. This fund could be created and administrated under the United Nations system, for example, the WHO or Unitaid.

CSOs should shape conversations with governments and other funders about the feasibility of establishing innovative funding models for TB vaccine research and advocate for the implementation of impactful financing solutions for TB vaccine development and delivery.

Funders support CSO advocacy for and engagement in TB vaccine research.

CSOs involved in TB efforts worldwide are calling for increased investment in community-led advocacy — such as the petition for a Fully Funded Challenge Facility for Civil Society.[44] It is essential that these appeals are addressed and supported, and engagement in TB research should be specifically highlighted in funding opportunities for civil society, including through dedicated tracks. CSO-led TB vaccine research activities can include:

- Policy dialogue with vaccine developers, the WHO, and funders through CABs to provide feedback on TB vaccine research
- Mapping and analysis of the TB vaccine clinical trial landscape or trials sites across regions
- Mapping of national regulatory frameworks in the field of vaccine development
- Engagement with developers to address challenges in TB vaccine research, particularly those related to the needs of key and vulnerable populations
- CSO capacity building around TB vaccine research

Delivery Action Plan

The initial preparatory measures for TB vaccine implementation start with comprehensive multi-stakeholder consultations to systematically analyze factors critical to ensuring access. These include anticipated demand, manufacturing volumes, pricing strategies, potential intellectual property (IP) barriers, and licensing and technology transfer. Preparations also encompass consideration of normative and regulatory pathways to facilitate country-level availability. Budget advocacy begins at the same time to secure adequate funding from both donors and governments to procure sufficient vaccine quantities and raise the resources needed to deliver them.

Action 5

CSOs contribute to the development and implementation of comprehensive product-agnostic and product-specific access policies for new TB vaccines.

Interviewees emphasized the importance of having multiple vaccines and suppliers available in the market to balance both purchasing and supply power. They also highlighted the need for geographically diverse manufacturing to ensure a resilient supply chain.

Several product-agnostic roadmaps for new TB vaccines have been developed by the WHO and other stakeholders including the *Global Framework*. The Finance and Access Working Group of the WHO TB Vaccine Accelerator Council presented a report — *Catalyzing Solutions for Equitable Global Access and Sustainable Financing for Novel Tuberculosis Vaccines for Adults and Adolescents* — at South Africa's G20 Summit in November 2025.[45] The report proposes strategic partnerships, financing and procurement mechanisms, and market access solutions, with a particular focus on speeding up vaccine access for high-TB-burden countries.

Delivery Action Plan

As clinical research progresses and new data emerge, access policies will need to evolve. Product-specific policies should be developed by vaccine producers and external stakeholders, including CSOs. Vaccine developers and manufacturers should proactively make access policies public, transparent, and open to feedback from CSOs. Policies should offer clear access solutions for all country archetypes, including Gavi-eligible and self-procuring countries, with a focus on national regulatory approval timelines, manufacturing capacity, affordable pricing, licensing strategies, and IP management.

Some interviewees suggested moving away from the tiered-pricing approach in which Gavi-ineligible countries pay significantly more than Gavi-eligible countries, especially considering that several high-TB-burden countries (e.g., Brazil, Indonesia, India, and the Philippines) do not meet the Gavi eligibility criteria. One solution would be a flat-pricing model covering all low- and middle-income countries (LMICs) and high-TB-burden countries regardless of country income level.

CSOs have played an instrumental role in the development and implementation of access strategies across disease areas. This contribution is acknowledged by all principal public health stakeholders, including governments, UN agencies, pharmaceutical companies, and academic institutions.[46] CSOs have contributed to the development of TB vaccine access policies through their participation in the TB Vaccine Accelerator Council and its working groups. Their efforts have included the preparation of independent analytical papers and engagement with vaccine developers. These activities should expand, utilizing a broader array of tools and ensuring significantly wider representation from diverse affected communities.

Ideal scenario:

Vaccine developers and funders publish comprehensive, transparent, and public access policies for new TB vaccines — both product agnostic and product specific — with input from CSOs, offering solutions to maximize access to new TB vaccines in all countries.

CSOs develop recommendations for TB vaccine access policies, informed by input from a diverse range of key community groups.

The role of civil society in influencing access policies should encompass the following domains:

- Time-bound access solutions for all countries
- Cost of goods and price estimates informed by independent research with a push toward adoption of flat-rate prices close to production costs for as many countries as possible
- Demand estimates for different countries, including key groups and the general population
- IP, licensing, and technology transfer policies with a focus on identifying and mitigating potential barriers
- Procurement and supply solutions designed to maximize and expedite access to populations most in need
- Access considerations for key groups (e.g., PLHIV, people living with diabetes, people using drugs, migrants, prisoners)

Policy recommendations may be presented as policy briefs or research reports, including peer-reviewed studies, and may serve as resources for further advocacy initiatives. As vaccine candidates near market, it will be essential for civil society to develop tailored access strategies that consider the unique characteristics of each candidate.

CSOs share community access recommendations with decision makers by engaging in multi-stakeholder consultations on TB vaccine access policies at all levels.

Several multi-stakeholder mechanisms are available for CSOs to influence TB vaccine access policies across all levels: TB Vaccine Accelerator Council working groups, Gavi CSO Constituency, Communities Delegations to the Global Fund and Unitaid Boards.

To elevate the issue of TB vaccine access to the highest political forums, civil society should leverage major global and regional events, such as the UN High-Level Meetings, G7 and G20 summits, BRICS forums, and other regional political platforms.

CSOs may further advance the cause of equitable access to TB vaccines by actively engaging key stakeholders through CABs, targeting vaccine manufacturers and distributors, donor agencies, UN agencies, and government representatives at political, technical, and scientific forums.

Community consultations concerning access policies should solicit input from all key groups of people who need new TB vaccines. Engaging key populations ensures that policies are equitable, responsive, and reflective of the needs of those most affected.

Delivery Action Plan

> “If a TB vaccine is introduced, it is crucial that civil society advocates for abandoning tiered pricing in favor of a flat-rate model aligned with production costs. This equitable approach can be realized through guaranteed purchase volumes, ensuring fair access for all.”

Action 6

WHO and other normative bodies consult CSOs on policy formation and product review.

Global policy recommendations for new TB vaccines will be set by the Strategic Advisory Group of Experts on Immunization (SAGE) at the WHO. SAGE is responsible for advising WHO on global policy and strategies related to immunization. Their advice informs everything from vaccine research and development, immunization delivery, and vaccine prioritization for the WHO prequalification process.

Financing by Gavi and procurement by UNICEF and the Pan American Health Organization Revolving Fund are dependent on SAGE policy recommendation and WHO prequalification. Countries that procure vaccines with Gavi support must purchase WHO prequalified products or vaccines for which compliance is assured by fully functional national regulatory authorities (NRAs).47

SAGE meetings in March 2023 and September 2025 have featured conversations about new TB vaccines, research plans, and considerations for a potential introduction.[48,49] At the group's September 2025 meeting, members discussed candidates in late-stage clinical development and issues related to the availability of vaccine efficacy data in persons with and without *Mycobacterium tuberculosis* infection and the potential incorporation of asymptomatic TB into clinical trial endpoints. WHO has also established a Technical Advisory Group on Evidence for Clinical and Policy Considerations for New Tuberculosis Vaccines, whose objectives include providing independent advice to WHO and SAGE related to scientific, clinical, regulatory, and policy dimensions of new TB vaccine candidates.[50]

The WHO Vaccines Prequalification Priority List for 2024–2026 includes BCG as a medium-priority vaccine for prequalification. Other TB vaccines fall under the category of "Potential candidate vaccines to be considered during the biennium if development is completed and address public health needs." Manufacturers are encouraged to apply for prequalification of vaccines if they meet key criteria.[51] In many jurisdictions, WHO prequalification is a criterion for accelerated and/or simplified regulatory approval procedures (as shown in the country policy portraits).

Delivery Action Plan

Ideal scenario:

New TB vaccines are designated as high-priority products for WHO prequalification, and the WHO involves CSOs in policy-making and technical advisory processes.

The WHO strengthens engagement with CSOs in SAGE policy development.

Formal CSO participation in SAGE is currently minimal. The WHO can invite observers to SAGE meetings, including members of civil society.[52] CSOs are encouraged to engage with SAGE and provide feedback to inform TB vaccine policy and updates to the vaccine prequalification priority list. In turn, SAGE should place more focus on collecting feedback from CSOs by establishing a channel for communication with civil society.

This collaboration should enable CSOs to increase the visibility of SAGE recommendations across the globe, including in self-procuring countries, which may not always look first to SAGE recommendations for vaccine introduction.

CSOs maintain proactive engagement with vaccine manufacturers to ensure the prioritization of expedited WHO prequalification.

Plans regarding WHO prequalification should be systematically included in agendas for all CAB meetings and written correspondence with potential vaccine manufacturers. CSOs should share timely information on WHO prequalification status with all relevant stakeholders, including national governments. This is particularly important in countries where expedited approval processes based on WHO prequalification are applicable.

Action 7

CSOs advocate for timely national approval of TB vaccines by governments and broad regulatory filings by vaccine developers and manufacturers.

Securing national regulatory approval is essential to ensure sustainable access to novel TB vaccines, and, in many jurisdictions, approval is a prerequisite for vaccine inclusion in the NIP. Several pathways can be utilized to more efficiently obtain marketing authorizations for new TB vaccines:

- Simplified and accelerated national approval procedures for WHO-prequalified products or products approved by stringent regulatory authorities (SRAs), including via the WHO Collaborative Registration Procedure.
- The EU-M4all mechanism, used by the European Medicines Agency (EMA), assesses innovative or generic medicines and vaccines that address unmet medical needs or are of major public health interest, for use outside the European Union.[53] The EMA PRIME Scheme is another mechanism used by the EMA to enhance support for the development of health products that target an unmet medical need.[54]
- Regional approval procedures to facilitate national approval in smaller markets (e.g., medicines and vaccines approval under the rules of the Eurasian Economic Union; see the Kazakhstan country policy portrait).
- Some countries may require local clinical trials as a prerequisite for approval, which can delay marketing authorization if licensure trials are not geographically inclusive.

Ideal scenario:

Developers and manufacturers have a public and proactive regulatory approval plan for all countries, considering opportunities for accelerated and simplified procedures, collaborative registration initiatives, and extra requirements for national approval, such as local clinical trials. Developers and manufacturers follow this plan and are open to feedback from CSOs about issues related to the vaccine approval process.

CSOs analyze approval requirements for TB vaccines and monitor the vaccine approval landscape.

Mapping national approval frameworks for medicines and diagnostics related to HIV, HCV, TB, and other diseases has long constituted an area of expertise for civil society. CSOs at the regional and national levels should analyze procedures for country approval of new TB vaccines, with a focus on the following parameters:

- Applicability of regional collaborative approval mechanisms
- Timelines and fees for approvals
- Key documents needed for the dossier
- Availability of fast-track approval and prerequisites
- Requirements for local clinical data to obtain national approval
- Opportunities for supplying vaccines without national approval (e.g., import waivers for vaccines procured through Gavi, Global Fund, or UNICEF)

Once developers file new TB vaccines for WHO prequalification and/or SRA approval, CSOs should commence monitoring the national approval status of these vaccines. This information should be utilized in communications with vaccine manufacturers and other stakeholders to facilitate the approval process and create accountability for timely registration.

Vaccine developers and manufacturers work with CSOs to support national approval of TB vaccines.

Regional and national CSOs and CABs possess substantial experience in offering consultative support to pharmaceutical companies regarding procedures for medicines approval. Their expertise includes identifying potential obstacles, recommending optimal regulatory pathways, and facilitating communication between regulatory agencies and pharmaceutical companies. For instance, engaging with pharmaceutical companies and other treatment access stakeholders to discuss national approval procedures is a key priority for the Eurasian Community for Access to Treatment (ECAT). It is recommended that CABs at all levels incorporate national approval into meeting agendas with vaccine manufacturers and other stakeholders.

Delivery Action Plan

Action 8

Governments strengthen relationships with CSOs to facilitate the integration of new TB vaccines into national health programs.

New TB vaccines may be integrated into national health systems at various levels, from demonstration projects targeting key populations in specific regions to full integration in NIPs. The process requires the involvement of diverse stakeholders, including ministries of health; national TB, HIV, immunization, and harm reduction programs; ministries of education; penitentiary services; NITAGs; and CSOs.

Unlike infant and childhood vaccines, rolling out TB vaccines for adults and adolescents will require new platforms and infrastructure — likely leading to higher costs and increased logistical complexity. However, for certain cohorts — such as PLHIV or people with diabetes — implementation may be possible through integration with existing primary care systems.

There must be a coordination mechanism that brings together all relevant services based on the target groups, and CSOs should play a central role within this mechanism.

Ideal scenario:

By 2030, assuming new TB vaccines demonstrate adequate efficacy and safety, countries will have incorporated the vaccines into NIPs and will have initiated demonstration projects with civil society involvement, including CSO participation in NITAG processes.

NITAGs invite CSOs to participate in vaccine review and policy making.

NITAGs play an indispensable role in decisions to include vaccines in NIPs. However, as the country policy portraits in section two illustrate, most NITAGs do not formally incorporate civil society representatives as voting members, and not all hold public meetings or share minutes afterward. NITAGs appear to have largely underestimated the contributions CSOs can make to vaccine policy making.

Delivery Action Plan

Strengthening connections between CSOs and NITAGs is a key priority. CSOs are strategically positioned to conduct proactive analyses of national requirements for the integration of new TB vaccines into national immunization plans. Additionally, CSOs can facilitate dialogues among national stakeholders, vaccine manufacturers, donors, and technical partners about vaccine introduction.

Governments invite CSOs to participate in multi-stakeholder consultations regarding the integration of TB vaccines in national health care systems.

Government agencies, including NITAGs, NIPs, and NTPs, should invite CSOs to participate in TB vaccine policy making, both directly and through multi-stakeholder platforms. In this context, UN agencies such as the WHO and donor organizations, including the Global Fund and Gavi, should serve as mediators to facilitate these collaborations. Community groups are also encouraged to participate in country-level TB vaccine preparedness workshops organized by the WHO TB Vaccine Accelerator Council, like those organized in Indonesia and South Africa.[55,56]

Governments involve CSOs in new TB vaccine introduction and implementation at the national level.

Demonstration projects may constitute a crucial preliminary phase in the introduction of a new vaccine prior to full inclusion in the NIP. Some countries may opt to introduce new vaccines in limited settings due to constrained funding, supply limitations, or the need to prioritize specific target groups. CSOs should play an integral role in this process by identifying priority populations and geographic areas, facilitating enrollment and retention, and advocating for the transition from demonstration projects to national programs. Governments should invite CSOs to inform the design and direction of TB vaccine implementation and support community-based organizations in vaccine delivery.

NTPs also have an important role to play. Vaccination may be less of a priority for NTPs due to limited budgets, lack of experience dealing with vaccines, and existing programmatic priorities. It will be important for NTPs to proactively determine where vaccines should be positioned within existing prevention strategies, particularly TPT programs. CSOs can assist NTPs by providing consultative support and acting as a bridge between health care programs and communities (see also Demand).

Delivery Action Plan

Delivery Action Plan

Action 9

CSOs intervene to promote sustainable manufacturing, procurement, and supply of new TB vaccines.

CSOs are universally recognized as key stakeholders in ensuring adequate, equitable, and sustainable access to treatment, from manufacturing to delivery. They employ a variety of tools, including direct negotiations, multi-stakeholder dialogue meetings, advocacy and awareness-raising campaigns, and targeted access interventions such as challenging IP barriers.

The product-agnostic and product-specific policies mentioned previously should provide the foundation for CSO-led activities related to manufacturing, procurement, and supply, underpinned by a clear vision for access.

Ideal scenario:

CSOs independently and collaboratively intervene to expedite and maximize access to new TB vaccines through enhanced manufacturing, procurement, and supply.

Vaccine developers identify commercial partners prior to launching phase III trials, and CSOs hold developers accountable for early access planning.

To pave the way for vaccine rollout, it is essential that the identification of and engagement with commercial partners remains a permanent fixture on the agenda whenever CSOs interact with TB vaccine developers and funders. For candidates in later development stages, this should commence before 2028, and for earlier-stage candidates, between 2028 and 2029.

The M72/AS01E vaccine is furthest along in clinical trials, with its phase III trial fully enrolled. But as of early December 2025, the developers had not yet announced a commercial partner and marketing authorization holder. There are three commercial partners for MTBVAC, including Biofabri (Spain), Bharat Biotech (India), and FAP (Fundação Ataulpho de Paiva, Brazil), responsible for different geographic areas. Negotiations with potential partners for BNT164 are expected once the phase II trials have demonstrated sufficient efficacy and safety for advancing the vaccine candidate to phase III.

It is advisable that CSOs, particularly those operating on the global stage and with deep expertise in access work, prioritize this issue when engaging with vaccine developers.

CSOs research and uncover potential challenges to sustainable manufacturing, procurement, and supply of new TB vaccines.

CSOs are uniquely positioned to conduct independent research on TB vaccine access, reinforcing broader efforts to enhance treatment availability in the fight against TB. Moreover, they can actively support studies spearheaded by partners such as the TB Vaccine Accelerator Council, Gavi, the Working Group on TB Vaccines, and others.

> "There is a perception within the TB community that patents are not a concern. However, patents will undoubtedly become an issue [for] new TB vaccines. Numerous patents and applications exist, including in countries with manufacturing capacity, and companies are fighting with each other [over] IP rights. The landscape for vaccine IP is considerably more complex than for drugs, and substantial capacity building is needed to involve communities in IP-related work to ensure equitable access to new TB vaccines."

The following areas of research related to access can be pursued by CSOs:

Manufacturing:

Factors pertaining to manufacturing include requirements based on vaccine types and individual vaccine characteristics (mRNA, live attenuated, whole cell, etc.), including the need for specific ingredients (such as AS01 adjuvant for M72/AS01E), timelines for scaling up manufacturing, and potential manufacturing sites. Interviewees expressed particular concern regarding the availability of AS01, citing factors such as limited manufacturing capacity — especially since it is used in other vaccines and a key component relies on sourcing from the natural world — and potential challenges related to intellectual property.

mRNA vaccines have been characterized as easier to produce compared to traditional vaccines, because the manufacturing process involves routine biochemistry, whereas traditional vaccines rely on biology and cell-based components.[57] An analysis from MSF shows that there are many companies across Africa, Asia, and Latin America capable of producing mRNA vaccines.[58] Research by CSOs could also explore opportunities for leveraging mechanisms such as the WHO mRNA Technology Transfer Hub[59] and Gavi's African Vaccine Manufacturing Accelerator (AVMA)[60] to support sustainable growth of Africa's manufacturing base.[61]

Pricing:

As demonstrated by the WHO list of vaccine prices and the PAHO price list, most widely used vaccines rarely exceed US$1 per dose, due to the immense economies of scale in their production.[62,63]

CSOs have actively contributed to research on prices for TB treatments and diagnostics. Examples include "Estimated generic prices for novel treatments for drug-resistant tuberculosis"[64] and calculations behind advocacy by the Time for $5 campaign to lower the prices for GeneXpert tests.[65] Estimated prices can be compared to actual market prices for new TB vaccines in routine price monitoring and analysis, with substantial discrepancies flagged for advocacy. CSOs possess extensive expertise in price monitoring for medicines, diagnostics, and vaccines and have uncovered notable price disparities between countries. To ensure the affordability of new TB vaccines, it is essential that CSOs and independent experts are empowered with adequate resources to undertake price monitoring and analysis. CSOs should be at the forefront of initiatives to lower the cost of TB vaccines through evidence-based advocacy campaigns.

IP and licensing:

Comprehensive analyses of IP and licensing landscapes are crucial, as these factors shape both the availability and affordability of TB vaccines. The Make Medicines Affordable campaign has prepared a landscape of patents covering M72/AS01E and MTBVAC.[66] Similar patent landscapes should be produced for mRNA-based TB vaccines and other promising candidates. Conducting freedom-to-operate analyses for new TB vaccines is essential to minimize IP risks for any company willing to manufacture these vaccines. CSOs can collaborate with external stakeholders on open-source databases for TB vaccine patents, similar to VaxPal.

Procurement and supply mechanisms:

Countries can generally be classified into two groups: those eligible for Gavi support and those that procure vaccines independently (self-procuring). Gavi-eligible countries benefit from international procurement mechanisms (e.g., UNICEF) and Gavi support in managing vaccine supply chains.[67,68,69] Including new TB vaccines in the respective procurement catalogues once they are approved is a required step towards securing access to these vaccines.

For self-procuring countries, CSOs should proactively conduct research into national procurement requirements. Within established methodologies for analyzing procurement for pharmaceuticals and diagnostics, the following factors may be considered:

- Provisions enabling procurement of unregistered drugs/vaccines
- The need for a drug/vaccine to be included on special lists if procured using government funding (e.g., Essential Medicines List)
- Preferences for local manufacturers

- Centralized (state-level) vs decentralized (provincial-level) procurement and designated agencies responsible for procurement
- Tender timelines, number of bidders, and calculations for initial tender prices
- Requirements for calculating the volume to be procured
- Transparency of the procurement process

Analyses could also assess distributor capacities to deliver new TB vaccines considering transportation and storage requirements to ensure supply sustainability country wide.

Market shaping:

CSOs should track countries where new TB vaccines have been approved and incorporated into national health care systems. This tracking should assess current volumes and pricing, map out the suppliers and distributors involved, and determine whether actual or potential supply shortages exist. Previous research conducted by the WHO on the BCG vaccine highlighted risk factors such as the limited number of suppliers, outdated manufacturing processes, and the scarcity of registered products in certain countries.[70] A notable recent example of where market monopolies have led to supply shortages of life-saving vaccines is cholera.[71] These findings underscore the importance of evaluating similar risks for new TB vaccines — especially the M72/AS01E vaccine with known adjuvant supply monopoly concerns.

CSOs intervene to improve access to TB vaccines across manufacturing, procurement, and supply chains.

Civil society possesses an array of tools to confront access barriers and advance practical solutions for improved vaccine availability. These strategies include opposing unjustified patents, guided by patent landscape analyses. Another would be campaigning for government use and compulsory licensing to enable domestic manufacturing, for example, by invoking local working requirements (national patent law rules that patents should be "worked" domestically to be enforceable). In the campaign to increase access to bedaquiline, CSOs collaborated with a diverse range of stakeholders in advocacy and patent opposition activities.[72] These coordinated actions led to the revocation of some patents and led the company to announce it would not enforce its secondary patents on bedaquiline.[73] As a result, access to generic versions of the medication has expanded globally, leading to lower prices and improved availability.

Civil society can further facilitate price-volume negotiations between purchasers and vaccine suppliers and advocate for multicountry pooled procurement to expand market size and enhance bargaining power. Additionally, encouraging governments to leverage international procurement agencies to pool demand and secure the lowest global prices represents another approach to ensuring equitable access.

Action 10

CSOs advocate for sustainable funding for the introduction and rollout of new TB vaccines.

The allocation of adequate funding constitutes an essential prerequisite for the introduction and deployment of new TB vaccines. This encompasses not only the financial resources necessary for vaccine procurement but also for vaccine distribution. The two principal stakeholder groups involved in this are governments and donor organizations, with Gavi and the Global Fund playing particularly prominent roles.

Interviewees pointed to several potential challenges to sustainable funding. First, the crisis resulting from retrenchment in U.S. foreign aid policy may constrain donor funding for new TB vaccine rollout. Second, the introduction of new TB vaccines entails upfront expenditures by NTPs and NIPs, as these vaccines will supplement, not replace, existing TB prevention strategies. A November 2025 report from the WHO TB Vaccine Accelerator Council Finance and Access working group modeled a "high demand scenario" that assumes a need for one billion TB vaccine regimens globally between 2030 and 2040 (up to 120 million regimens annually in the first five years after introduction) and estimated global procurement costs between US$5 billion to US$8 billion.[74] Future cost savings from diverted treatment and other averted health care systems costs will take time to accrue.[75]

Moreover, there will be additional costs associated with establishing vaccination infrastructure for adults and adolescents. Some countries may be reluctant to assume additional financial burdens unless clear cost-efficiency benefits are demonstrated.

CSOs are well positioned to advocate for funding to procure vaccines, hold governments and donors accountable by tracking expenditure levels, and identify opportunities for optimizing spending without compromising access.

Ideal scenario:

CSOs are resourced to advocate for sustainable financing of new TB vaccines. Building upon their established influence and capabilities, CSOs act as both advocates and watchdogs, ensuring transparency, equity, and efficiency of expenditure throughout the vaccine rollout process.

CSOs assess potential and actual levels of spending on new TB vaccines.

CSOs operating at the national level are encouraged to track TB vaccine expenditures by their governments. Building off ongoing monitoring of global TB research expenditures by TAG (see Development), analogous reports can be regularly produced as new TB vaccines become available. Monitoring efforts will be vital for informing advocacy for increased, diversified, and innovative financing for TB vaccines. Combined with vaccine demand estimates, these reports can also set targets for TB vaccine spending at both global and country levels.

TB vaccine resource tracking may be incorporated into broader research concerning vaccine manufacturing, procurement, and supply.

CSOs push donors and governments to allocate sufficient funding for new TB vaccines.

CSOs should serve as liaisons between affected communities, governments, and donors using existing consultative forums and advocacy campaigns. The agenda for these consultations will include key items: estimated demand based on vaccine characteristics and epidemiology, currently available products with prices and manufacturing capacity, currently available level of donor and government spending by country and financial gaps to be filled, opportunities for procurement optimization and price reductions, and cost-efficiency analyses and investment cases for new TB vaccines.

Examples of stakeholder engagement to bolster funding for new TB vaccines include hosting parliamentary hearings prior to national budget discussions and leveraging global advocacy campaigns to send messages to governments and donors about the need to invest in vaccine readiness and immunization infrastructure.

Funders, governments, and multilateral agencies invest in community-led TB vaccine access interventions.

CSO interventions will be key to ensuring adequate and sustainable access to TB vaccines. However, there is a lack of dedicated resources for CSO activities.

In 2021, Gavi determined that 10% of the total country funding envelope should be reserved for CSOs. However, interviewees noted that it can be challenging to guarantee that a portion of this 10% CSO set aside supports advocacy activities, as governments may be reluctant to fund initiatives that scrutinize their own performance.

A commitment from donors to sustainably allocate funding to CSO-led access activities for new TB vaccines is critical. CSOs can contribute by engaging with key constituencies on the Stop TB Partnership, Gavi, and Global Fund boards. CSOs should also advocate for the inclusion of CSO-led access interventions in Gavi and Global Fund country proposals. When considering funding for access initiatives from the commercial sector, it is essential to address and mitigate potential conflicts of interest.

Demand Action Plan

Demand for the new TB vaccines will be driven by several factors: the target population being adults and adolescents, key groups prioritized for vaccination, the extent to which new TB vaccines are integrated into existing prevention strategies, the availability of financing as international aid budgets shrink, crowded immunization schedules, and the geographical distribution of the TB disease burden (i.e., large disease burden in middle-income countries that are not Gavi eligible).

A report by the WHO TB Vaccine Accelerator Council Finance and Access Working Group projects that the initial launch of TB vaccines under a "high demand scenario" will require a minimum of 50 million full vaccine regimens, peaking around 120 million regimens within the first five years of availability and settling around 90 million annually in the subsequent five years. This scenario balances ambition with feasibility though other scenarios are modeled.[76]

Two primary vaccine deployment strategies are under consideration: mass campaigns targeting the general population aged 15–45, and risk-based approaches prioritizing specific high-risk groups. National prioritization will vary according to epidemiology, financial constraints, sociocultural context, and vaccine supply, which in turn influences procurement volumes. The report assesses that under a "high supply scenario," reflecting optimistic licensure and manufacturing outcomes, the annual number of regimens produced will start around 20 million in 2030, scaling to 60 million mid-decade, before increasing to 160 million regimens by 2040. This means that global demand for TB vaccines will outpace supply in the critical early years of introductions in the absence of corrective intervention.

Demand Action Plan

Action 11

CSOs participate in multi-stakeholder consultations to estimate and build upfront demand for new TB vaccines.

The WHO Global Framework identifies CSOs as key stakeholders in demand forecasting, communication, implementation, and delivery. CSO involvement is essential in defining, advocating for, and mobilizing demand among vulnerable groups, many of whom may be more effectively reached by CSOs than by government entities. CSOs at all levels can contribute to demand planning by participating in multi-stakeholder exercises to produce demand estimates globally, regionally, and nationally. Utilizing information from community-led research and monitoring, CSOs are also positioned to influence decision making around priority populations, to advocate for price-volume negotiations with funders and vaccine manufacturers, to evaluate the extent to which modeled estimates of demand materialize (or not), and to propose solutions for overcoming barriers to converting potential demand into "shots into arms" — especially in the face of constricted vaccine supply.

Ideal scenario:

Sustained collaboration among CSOs, funders, UN agencies, governments, disease programs, and manufacturers results in market-shaping interventions that ensure adequate availability and affordability of the first new TB vaccines to reach market.

CSOs participate in national consultations to estimate the number of people eligible for new TB vaccines.

Preliminary demand estimates should be prepared for each vaccine candidate approaching approval, complementing global demand projections and based on the latest clinical data, starting between 2025 and 2027 for current late-stage candidates (M72/AS01E, MTBVAC). Demand estimates may be derived from official government sources or from independent expert assessments and informed by CLM

initiatives. CSOs have engaged in similar efforts to advance novel all-oral treatment regimens for drug-resistant TB and short-course TPT, providing a valuable foundation for generating demand for new TB vaccines.

There should be dedicated meetings at the global, regional, and national levels to coordinate demand creation activities among stakeholders and between countries, vaccine purchasers, vaccine developers and manufacturers, funders, and CSOs.

CSOs influence demand-based negotiations with manufacturers and advocate for fair price-volume agreements.

The demand estimates put forward by the WHO TB Vaccine Accelerator Council Finance and Access Working Group will serve as the foundation for negotiating access conditions with TB vaccine manufacturers. These negotiations are expected to culminate in price-volume agreements between vaccine producers, funding organizations, procurement agencies, technical partners such as UN agencies, and governments.

During these negotiations, CSOs should advance principles of equitable access and establish clear conditions and red lines regarding key elements of the agreements. This includes advocating for transparency in areas such as the cost of goods and services, pricing structures, and regulatory approval timelines. Furthermore, CSOs should call for technology transfer to facilitate regional and local vaccine production and support the implementation of fair pricing policies.

In addition, CSOs have a crucial role in raising awareness about the estimated need for, and the importance of access to, new TB vaccines — particularly among priority populations. They should monitor and influence negotiations with vaccine manufacturers to ensure that the greatest possible number of countries benefit from the resulting agreements and that the proposed prices closely align with the lowest estimated costs for large-scale procurement based on objective, transparent criteria such as COGs+ tied to volumes sold (see Delivery).

Action 12

CSOs organize vaccine preparedness and demand promotion interventions for new TB vaccines in communities.

Within the broader remit of vaccine preparedness, demand creation is fundamental to achieving access. Stakeholders responsible for introducing new vaccines and executing immunization programs should invest in these activities. Many of these initiatives can be supported or directly implemented by CSOs.

UNICEF's Demand for Health Services: *A Human-Centred Field Guide for Investigating and Responding to Challenges* emphasizes the importance of involving end users and communities in designing health services to ensure that solutions are effective and contextually relevant.[77] The recommended approach supports a bottom-up methodology rooted in community engagement and encourages local definition and development of problems and solutions. Tuberculosis-specific resources should be created to design demand promotion strategies for new TB vaccines.

The Rockefeller Foundation's *Infrastructures of Trust: The Case for Investing in Vaccine Demand* advocates for shifting away from traditional vaccine hesitancy frameworks, asserting that such models misattribute and reduce the responsibility for vaccination to individual motivations and access.[78] The report calls for broadening the conceptual framework and investing substantially in vaccine demand, a perspective that recognizes the influence of institutional and structural determinants of vaccine uptake, alongside individual drivers. The report frames vaccine demand as a society-wide challenge that necessitates significant investment in human resources and programs. It also requires policy and regulatory adjustments, as well as a sustained commitment to building trust, enhancing health equity, and fulfilling the information needs of diverse communities.

Ideal scenario:

Product-agnostic and product-specific interventions to build demand for new TB vaccines are developed and implemented on a rolling basis with the involvement of CSOs at all levels. These frameworks look beyond vaccine hesitancy models to consider institutional and structural drivers of vaccine demand.

Multilateral agencies (WHO, Gavi, Global Fund) and other stakeholders, including CSOs, develop product-agnostic and product-specific guidance for demand creation interventions.

The WHO Global Framework provides a foundation for the development of further guidance aimed at generating demand

for new TB vaccines as they move toward approval. CSOs can play a critical role in guidance development by offering feedback within their subject-matter expertise, tailoring global guidance to local contexts, disseminating guidance among key national stakeholders, and ensuring translation into national policies. Furthermore, CSOs should collaborate with funders, vaccine developers, UN agencies, and government programs to formulate comprehensive frameworks for capacity building and demand generation related to new TB vaccines. These frameworks should draw upon existing tools and resources developed for other vaccines, including the WHO's 2021 demand planning tools for COVID-19 vaccines[79] and UNICEF's 2024 guide on demand promotion for HPV vaccination.[80]

As TB vaccine candidates receive approval, CSOs should work with relevant stakeholders to develop dynamic, product-specific guidance documents. These should provide detailed information on the key features of the approved vaccines, summarize SAGE recommendations, indicate national approvals and WHO prequalification status, and include data on suppliers, pricing, and requirements for transportation and storage.

CSOs implement local demand promotion and vaccine preparedness interventions.

CSOs are expected to play a pivotal role in demand promotion and capacity building at the national level, serving as facilitators in dialogues between international partners and national stakeholders.

A key intervention to promote vaccine preparedness and demand generation includes convening multi-stakeholder meetings with government officials to generate political commitment for new TB vaccine introduction. Training programs for health care providers and community groups are essential to optimize the effectiveness of immunization initiatives, and targeted information campaigns can ensure that crucial messages about new vaccines reach priority audiences. More specific interventions may include advocacy for the establishment of national vaccine preparedness programs within ministries of health or the provision of technical support to NTPs for integrating adult and adolescent TB vaccination into existing service delivery systems. Strengthening the connections between communities and health policy makers from NITAGs, NTPs, and NIPs will further contribute to demand generation and effective implementation.

A careful analysis of previous access campaigns in the TB field is essential to identify best practices and areas for improvement. Experiences from advocacy campaigns to promote access to shorter TB treatments (1/4/6x24),[81] or increase TB funding (TB33% Campaign),[82] must be analyzed to understand what can be immediately adopted versus what must be adapted for new TB vaccines to ensure more effective introduction.

CSOs organize campaigns to communicate information about new TB vaccines.

One of the principal challenges confronting the introduction of new TB vaccines is vaccine hesitancy. Hesitancy encompasses both a general mistrust of vaccines and specific concerns regarding new TB vaccines, particularly as most individuals will already have received the BCG vaccine. Accordingly, considerable effort is required to communicate the necessity of additional TB vaccination and to address more generalized public concerns about new vaccines to promote vaccine uptake among intended beneficiaries. As discourse around vaccines can become politically charged, it is imperative that data supporting vaccine introduction are robust and evidence based.

CSOs can play a significant role by contributing to vaccine preparedness and demand creation frameworks established by key stakeholders or by developing their own frameworks. Collaboration between TB-affected communities and target groups is essential to ensure that the needs of all key populations are adequately reflected.

Recent campaigns that sought to maximize access to novel TB prevention and treatment regimens can serve as valuable references. Learning from past campaigns, future campaigns should include tailored subcomponents for distinct stakeholder groups and operate on an ongoing basis. Sustained and continuous engagement is critical for long-term success, as time-limited campaigns are likely to be less effective against persistent vaccine denialism. Ultimately, the goal is to foster enduring public support for vaccines.

Campaigns related to new TB vaccines should, at a minimum, convey the following information:

- Essential data on vaccine safety, efficacy, and mechanism of action
- Clear information on vaccine administration procedures
- Populations that will benefit from vaccination
- Rationale for focusing vaccination on adults and adolescents
- Discussion of how new vaccines differ from and complement existing TB prevention interventions, such as TPT and BCG vaccination
- Factsheets debunking common myths about vaccines, including those specific to certain vaccine technologies (e.g., live attenuated [MTBVAC] or mRNA [BNT164] vaccines)

Campaigns should be adaptable to different key audiences. Engaging diverse audiences will require collaboration with trusted messengers. For example, CAB representatives who have witnessed TB vaccine trials firsthand and are invested in the science can serve as early ambassadors, effectively communicating the benefits of vaccination to their communities. Cross-sectoral coordination between government agencies will be paramount, including between those responsible for health, social welfare, education, culture, defense, and criminal justice.

International immunization initiatives, such as World Immunization Week and the Zero-Dose Campaign, can be adapted to support TB vaccination efforts. World Tuberculosis Day also presents a strategic opportunity to amplify awareness and promote the importance of TB vaccination.

Demand Action Plan

Demand Action Plan

Action 13

Funders and governments invest in community-led vaccine preparedness and demand promotion interventions.

One of the key messages from interviewees concerned the need for additional financial resources for CSOs, so that they can play a leading role in national vaccine preparedness and demand promotion, bridging the gap between global guidance and national implementation.

Community-led vaccine preparedness and demand promotion interventions should be included as a priority area for both government-led and donor-led funding initiatives to support new TB vaccine introduction. CSOs should proactively develop and propose community-led demand creation interventions adapted to the national context and needs of specific communities and key groups.

Ideal scenario:

Funders include vaccine preparedness and demand promotion activities in calls for proposals and support community-led interventions across the globe; governments work with CSOs on vaccine preparedness and demand promotion interventions.

Funders establish programs supporting community-led vaccine preparedness and demand promotion activities.

Donors should establish flexible funding programs to support a variety of community-led vaccine preparedness and demand promotion interventions, as well as directly fund CSO-led interventions related to TB vaccination. Funders should consult CSOs in the development of grant programs to tailor opportunities for local context and needs. The first section of this report contains detailed recommendations on how to resource CSOs with examples of different funding models.

CSOs develop and propose projects to build demand for new TB vaccines.

Community-led vaccine preparedness and demand promotion projects can include:

- Research to estimate demand for TB vaccines in key populations
- Communication campaigns/information materials for key populations
- Outreach to refer member of key groups to TB vaccination programs
- Capacity-building trainings for community-based organizations
- Trainings for health care workers
- Budget advocacy

Data Action Plan

Monitoring and evaluation are integral to vaccine access. Data generation has been identified as a fourth, cross-cutting domain that, with *Development, Delivery,* and *Demand*, comprises a 4D view of access.

This section of the roadmap centers community-led monitoring interventions to identify gaps in TB vaccine development, delivery, and demand creation. Data gathered through CLM can guide policies touching all dimensions of TB vaccine access. These efforts supplement monitoring and evaluation by governments, companies, funders, UN agencies, and other stakeholders.

Evidence shows that CLM improves the effectiveness, quality, and accessibility of health programs and empowers affected communities by enabling them to demand high-quality services.[83] According to the Stop TB Partnership, CLM helps identify systemic gaps and trigger action at the local, national, and global levels.[84] The Gavi evidence brief "Community-based monitoring: Evidence on pro-equity interventions to improve immunization coverage for zero-dose children and missed communities," underscores community[-led] monitoring as a key tool enabling communities to document their health care experiences and inequities faced by populations in vulnerable settings — medication shortages, inaccessible services, and substandard care — and collaborate with health systems to promote reform.[85] A report from the Asia-Pacific Exchange on the Role of CLM in TB Programming emphasized that CLM is a powerful model for sustainably improving access to and quality of TB services.[86]

Action 14

CSOs monitor and address TB vaccine availability, accessibility, affordability, and acceptability.

CSOs possess significant expertise in employing CLM to track and report issues related to treatment access, including medication stock-outs due to inadequate or disrupted supply chains. A recent report by ITPC Global highlighted ten success stories from African community-based organizations in which they deployed an adapted CLM tool with 25 indicators.[87] The work led to substantial improvements in pre-exposure prophylaxis (PrEP) uptake among young women, enrollment in differentiated service delivery models, voluntary medical male circumcision, and a marked drop in TB medicine stock-outs between 2022 and 2023, among other areas.

There are several digital tools with a proven track record for effective monitoring, such as OneImpact, I-Monitor, Pereboi websites, and platforms such as CLM-Asia and Ritshidze. Some tools, such as the CLM-Asia platform, contain a dedicated section on specific vaccines (here, hepatitis B). These questions address issues such as administration of the birth dose, completion of the three-dose schedule, and vaccination costs.[88] The Pereboi websites are a forum for service users to report stock-outs or other challenges around treatment access. These websites have been highly effective rapid response tools during crises, such as the COVID-19 pandemic and armed conflicts. During crises, PLHIV without access to antiretroviral therapy were able to obtain consultations, referral support, and medicines from emergency donations.

These digital tools facilitate prompt communication with community members at the grassroots level and enable the collection and analysis of data while preserving the anonymity of information providers. With appropriate adaptation, these platforms can easily be expanded to monitor access to TB vaccines. CLM interventions should be implemented at both the national and regional levels, with technical support from global CSOs as appropriate.

Ideal scenario:

There is a sustainable CLM system related to new TB vaccine rollout with a mechanism for providing feedback and discussing optimization with relevant stakeholders. CLM interventions are implemented at global, regional, and national levels with technical support from global CSOs as appropriate.

> "The community plays a key role in collecting vaccine demand data in individual countries and regions, with a focus on actual needs, rather than needs dictated by available funding. This data is essential for further advocacy in vaccine approval, inclusion in treatment protocols, immunization programs, procurement planning, overcoming price and patent barriers."

CSOs use CLM tools to track ongoing issues related to TB vaccine access.

CLM tools can be employed to monitor key parameters related to the development, delivery, and demand for new TB vaccines. CLM models and indicators can be tailored to the specific characteristics of each vaccine type and project goal. Potential initiatives may include surveys to understand reasons for vaccine refusal, identify zero-dose priority populations, estimate drop-off rates between doses for multidose vaccines, and uncover unique barriers to vaccination for certain key groups and approaches to mitigate them.

The following list presents areas of focus for CLM accompanied by illustrative examples:

- Vaccine Trial Status: TAG publishes regularly updated Pipeline Reports that provide essential information on the progress of TB vaccine research in clear and accessible language.[89]
- WHO Prequalification Status: The WHO maintains a list of prequalified vaccines,[90] forming a comprehensive database that CSOs can use to cross-reference national approval data against products with WHO prequalification status.
- Country Filing and Approval Status: The Eurasian Community for Access to Treatment routinely monitors the approval status of medicines and diagnostics for HIV, HCV, and TB in countries across Eastern Europe and Central Asia and disseminates this information to relevant stakeholders.
- Vaccine Procurement, Focusing on Volumes and Price: The International Treatment Preparedness Coalition (ITPC) monitors procurement activities for drugs treating HIV, HCV, and TB globally. These data are used to inform decision makers about potential challenges and to propose solutions for improving access. Examples include comparative analysis of drug prices

across Latin American countries conducted by RedLam and procurement monitoring in Eastern Europe and Central Asia facilitated by ITPC EECA.

- Shortages and Stock-Outs: Community Treatment Observatories, implemented by ITPC in Africa, and Pereboi websites in Eastern Europe and Central Asia have proven effective in mitigating stock-outs and ensuring consistent supply of essential medicines and vaccines.[91]
- Barriers to Accessing Health Care Institutions: Data from CLM initiatives, such as CLM-Asia and Ritshidze in South Africa,[92] have helped facility managers and health care providers enhance service quality and address barriers to care.

CSOs report CLM results to governments and key stakeholders responsible for shaping TB vaccine policies and practices.

CSOs should use data generated through CLM to promote the delivery of quality services and to adapt existing programs, policies, and strategies. This can only occur if CLM results are shared with and recognized by government partners. Ongoing policy dialogue constitutes a fundamental element of community-led monitoring and research.

CSOs employ a range of advocacy tools to disseminate CLM findings to stakeholders, including stakeholder correspondence, campaigns, and participation in multistakeholder forums. To maximize impact, it is essential that advocacy is a core element of all CLM projects.

> "CLM indicators should be aligned with TB vaccine product characteristics and developed by community organizations through collaborative consultations with beneficiaries [. . .] There should be a set of agreed-upon indicators to enable comparison of results from various CLM projects across the globe."

Action 15

CSOs contribute to vaccine pharmacovigilance systems maintained by governments and industry.

Gathering data about adverse events (AEs) associated with vaccine administration is more effective when beneficiaries and health care workers are aware, motivated, and supported to use pharmacovigilance instruments. CSOs can provide information about real-life experiences of vaccine use to government authorities and manufacturers based on community monitoring and feedback.

CSOs are in a unique position to identify side effects and AEs of demand-limiting concern, i.e., concerns at the front of mind for people hesitant to get vaccinated. AEs tracked by routine pharmacovigilance may not always be the same as those side effects that dissuade people from getting vaccinated or become publicly salient drivers of vaccine hesitancy. Similarly, AEs that matter in implementation may differ from those that stand out as significant in clinical trials.

Ideal scenario:

CSOs strengthen pharmacovigilance of new TB vaccines by ensuring that information about AEs is gathered from vaccine beneficiaries and health care providers and communicated to the relevant authorities and vaccine manufacturers.

CSOs raise awareness among vaccinated people and health care workers about how AEs can be reported.

Both governments and pharmaceutical companies use pharmacovigilance systems to assess vaccine safety after approval and introduction. There are typically public websites where health care workers and patients can leave feedback using standardized pharmacovigilance forms. CSOs should include information about these resources and provide training in how to use them though their capacity-building activities and information materials for communities and health care workers.

CSOs communicate community issues related to pharmacovigilance results to governments and industry.

Data related to pharmacovigilance gathered through CSO activities should be promptly communicated to government authorities and pharmaceutical companies using existing communication platforms and inform communication strategies of new TB vaccines. CSOs should seek to identify any AEs that appear to soften demand for TB vaccines, contribute to hesitancy, or become the focus of mis-/disinformation.

Action 16

Funders and vaccine developers involve CSOs in defining a post-marketing research and implementation agenda.

Phase IV post-marketing studies are crucial for generating additional safety and effectiveness data, particularly for special populations and for evaluating potential expansion of product indications. As in the Development stage, CSOs should play a meaningful role in shaping these studies and disseminating results. Drawing on core expertise, CSOs are well positioned to submit proposals for research projects focused on expanding policy indications for new TB vaccines, addressing community needs, and ensuring that priority groups who may not be covered by initial policy recommendations — such as children and pregnant women — are appropriately considered.

CSOs provide feedback to vaccine developers and funders about the design of and priorities for phase IV trials.

This can be done using the same mechanisms as described in the Development section, through the involvement of CABs at all levels in advance of the trial design finalization.

Funders and vaccine developers communicate study results to community groups and other interested stakeholders.

This can be done using the existing communication and capacity building infrastructure, through briefing webinars, trainings, and information materials (see Development).

Ideal scenario:

Funders and vaccine developers involve CSOs as key stakeholders in designing a post-marketing research agenda for new TB vaccines, from study development to results dissemination.

Action 17

Funders invest in CLM interventions for TB vaccines.

CLM interventions linked to TB vaccine access should be a priority for funding programs supporting the introduction of new TB vaccines. CSOs are encouraged to develop and propose CLM interventions that are tailored to their national contexts and address the specific needs of key populations. Donors should fund this work as an integral component of delivery and demand creation. Maintaining a focus on monitoring and advocating for equitable access to TB vaccines for priority populations in settings where they are criminalized or highly stigmatized is of particular importance.

There are several areas in CLM that will require investments from stakeholders to optimize access to new TB vaccines, especially for key groups:

- Development of community-led monitoring and research methodology for new TB vaccines
- Adaptation of existing CLM and research tools for new TB vaccines
- Monitoring vaccine access for specific key groups that can be better reached by community organizations: adolescents, people using drugs, migrants, prisoners, PLHIV, etc.
- Expanding existing monitoring tools to other countries/regions (adaptation to national context, translation into local languages)

Monitoring and advocacy projects are less likely to receive government support, as they often expose systemic vulnerabilities and propose reforms that are typically met with some resistance from health care systems in their initial phases. Donors are strongly recommended to designate CLM as a specific funding track in calls for proposals for CSO support. This track should exist alongside those for service delivery, awareness raising, and demand promotion, ensuring comprehensive support for equitable access to TB vaccines.

Donors and governments should establish flexible funding programs to support a variety of CLM interventions. CSOs should be involved in the development of grant programs to ensure funding schemes are well suited to produce locally meaningful results. To achieve sustainability and regularity — key to effective monitoring systems — multiyear grants are preferable.

Ideal scenario:

Funders incorporate CLM as a priority area for funding calls and support such initiatives worldwide. Governments support CLM related to tuberculosis vaccination by incorporating community data and insights into immunization program planning and review. CSOs develop and submit CLM proposals concerning TB vaccine access at all levels.

Endnotes

1. World Health Organization. An investment case for new tuberculosis vaccines. Geneva: WHO; 2022. https://www.who.int/publications/i/item/9789240064690.
2. Friedhoff S, Winner D, Dodson K, et al. Infrastructures of trust: The case for investing in vaccine demand. New York: The Rockefeller Foundation; 2022. https://buildingvaccinedemand.org/wp-content/uploads/2022/09/2022-vaccine-demand.pdf.
3. World Health Organization [Press Release]. Global childhood vaccination coverage holds steady, yet over 14 million infants remain unvaccinated – WHO, UNICEF. 15 July 2025. https://www.who.int/news/item/15-07-2025-global-childhood-vaccination-coverage-holds-steady-yet-over-14-million-infants-remain-unvaccinated-who-unicef.
4. Moore S, Hill E, Dyson L, Tildesley M, Keeling M. Retrospectively modeling the effects of increased global vaccine sharing on the COVID-19 pandemic. Nat Med. 2022;28(11): 2416–2423. doi: 10.1038/s41591-022-02064-y.
5. Gozzi N, Chinazzi M, Dean N, et al. Estimating the impact of COVID-19 vaccine inequities: a modeling study. Nat Comm. 2023. 14(1):3272. doi: 10.1038/s41467-023-39098-2.
6. World Health Organization. Framework for the allocation of limited malaria vaccine supply. Geneva: World Health Organization; 2022. https://www.who.int/publications/m/item/framework-for-allocation-of-limited-malaria-vaccine-supply.
7. Biss E. On immunity: an inoculation. Minneapolis, MN: Graywolf Press; 2014.
8. Friedhoff, S., et al. Infrastructures of trust.
9. Ibid.
10. World Health Organization. Global framework to prepare for country introduction of new TB vaccines for adults and adolescents. Geneva: WHO; 2024. https://www.who.int/publications/i/item/9789240086593.
11. Jadeja N, Omumbo J, Adelekan I, et al. Climate and health strategies must take vaccination into account. Nat Microbiol. 2023;8(12):2215–2216. doi:10.1038/s41564-023-01537-1
12. World Health Organization. Research and development for tuberculosis. https://www.who.int/observatories/global-observatory-on-health-research-and-development/analyses-and-syntheses/tuberculosis/analysis-of-tb-r-d-pipeline.
13. Krugman A. The state of global health funding: August 2025. Think Global Health. 2025 July 31. https://www.thinkglobalhealth.org/article/state-global-health-funding-august-2025.
14. World Health Organization [Press Release]. WHO calls for urgent action to address worldwide disruptions in tuberculosis services putting millions of lives at risk. 2025 March 20. https://www.who.int/news/item/20-03-2025-who-calls-for-urgent-action-to-address-worldwide-disruptions-in-tuberculosis-services-putting-millions-of-lives-at-risk.
15. Davison C. USAID funding cuts jeopardize breakthrough drugs and research. Devex. 2025 March 12. https://www.devex.com/news/usaid-funding-cuts-jeopardize-breakthrough-drugs-and-research-109615.
16. Stop TB Partnership. Impact of funding freeze on TB response in high TB burden countries. 2025 March 2. https://www.stoptb.org/news/impact-funding-freeze-tb-response-high-tb-burden-countries.
17. World Health Organization [Press Release]. WHO calls for urgent action.
18. Zumla A, Sahu S, Yeboah-Manu, et al. Breaking dependency: strengthening the global tuberculosis response in the face of USAID cuts. Lancet. 2025;405(10483):958–961. doi: 10.1016/S0140-6736(25)00335-6.
19. World Health Organization [Press Release]. WHO calls for urgent action.

20. Heinzel M, Koenig-Archibugi M. Harmful side effects: how government restrictions against transnational civil society affect global health. Br J Polit Sci. 2023;53(4):1293–1310. doi: 10.1017/S0007123422000564.
21. CIVICUS. 2025 state of civil society report. Johannesburg: CIVICUS; 2025. https://publications.civicus.org/publications/2025-state-of-civil-society-report/.
22. United Nations Office of the High Commissioner for Human Rights. Human rights: a path for solutions. 2024 February 26. https://www.ohchr.org/en/documents/outcome-documents/human-rights-path-solutions.
23. Berkley S. Unraveling the arc of vaccine progress. Science. 2025;389(6763):eaea7053. doi: 10.1126/science.aea7053.
24. World Health Organization. Global tuberculosis report, 2022. Geneva: World Health Organization; 2022. https://www.who.int/teams/global-programme-on-tuberculosis-and-lung-health/tb-reports/global-tuberculosis-report-2022/featured-topics/civil-society-engagement.
25. UNAIDS. Community-led monitoring in action. Geneva: UNAIDS; 2023. https://www.unaids.org/en/resources/documents/2023/community-led-monitoring-in-action.
26. IMPAACT4TB. Civil society engagement on TB prevention. https://impaact4tb.org/civil-society-engagement/.
27. Mabote-Eyde L, Frick M. Are we there yet? TB preventive treatment beyond TB/HIV integration. Tagline. 2023;30(1):4–7. https://www.treatmentactiongroup.org/resources/tagline/tagline-october-2023/are-we-there-yet-tb-preventive-treatment-beyond-tb-hiv-integration/.
28. United Nations General Assembly. Political declaration of the high-level meeting against tuberculosis (A/RES/78/5). 2023 October 5. https://digitallibrary.un.org/record/4025280?ln=en&v=pdf.
29. World Health Organization. Guidance on engagement of communities and civil society to end tuberculosis. Geneva: World Health Organization; 2023. https://www.who.int/publications/i/item/9789240080294.
30. Palmer S. TB vaccines: achievable not aspirational. IAVI. 2025 December 5. https://www.iavi.org/iavi-report/tb-vaccines-achievable-not-aspirational/.
31. Engel N, Apolosi I, Bhargava A, et al. Building social equity and person-centred innovation into the end TB response. Int J Tuberc Lung Dis. 2024;28(11):517–520. doi: 10/5588/ijtld.24.0338.
32. Frick M. Tuberculosis vaccines pipeline report. New York: Treatment Action Group; 2025. https://www.treatmentactiongroup.org/resources/pipeline-report/2024-pipeline-report/.
33. WHO TB Vaccine Accelerator Council Finance and Access Working Group. Finance and access landscape and evidence to date: public summary for consultation. 2025 September 22. https://www.who.int/publications/i/item/9789240116900.
34. Based on the data published at clinicaltrials.gov. Accessed 2025 April 3.
35. World Health Organization. WHO preferred product characteristics for new tuberculosis vaccines. Geneva: World Health Organization; 2018. https://www.who.int/publications/i/item/WHO-IVB-18.06.
36. Treatment Action Group. Washington, D.C. community consensus on the earlier inclusion of pregnant women and persons in TB research. New York: Treatment Action Group; 2024. https://www.treatmentactiongroup.org/publication/washington-dc-community-consensus-on-earlier-inclusion-of-pregnant-women-and-persons-in-tb-research/.
37. See, for instance, the minutes of the meeting between Eastern European and Central Asian Community Advisory Board and ViiV Healthcare in 2019, p.19. https://eeca-cat.info/wp-content/uploads/2019/04/Protokol-GSK-16.10.2019.-Final.pdf.
38. European AIDS Treatment Group. Clinical trial sites in Eastern Europe and Central Asia HIV, viral hepatitis, tuberculosis: brief landscape review. Belgium: EATG; 2021. https://www.eatg.org/wp-content/uploads/2021/06/eatg-eeca-clinical-trial-sites-march-2021.pdf.

39. Rangaka M, Frick M, Churchyard G, et al. Clinical trials of tuberculosis vaccines in the era of increased access to preventive antibiotic treatment. Lancet Respir Med. 2023;11(4):380–390. doi: 10.1016/S2213-2600(23)00084-X.

40. Refer, for instance, to the work by European Community Advisory Board: https://www.eatg.org/projects/ecab/.

41. Berczky T. The impatient patient: a discussion of patient involvement in novel forms of knowledge production—a case study of the European Community Advisory Board on HIV/AIDS. 2013. https://www.eatg.org/wp-content/uploads/2021/04/the-impatient-patient-a-discussion-of-patient-involvement-ecab-case-study.pdf.

42. Joseph A. Major tuberculosis vaccine trial completes enrollment faster than expected. STAT. 2025 April 28. https://www.statnews.com/2025/04/28/major-tuberculosis-vaccine-trial-completes-enrollment-faster-than-expected/.

43. Treatment Action Group. Tuberculosis research funding trends 2005–2023. New York: Treatment Action Group; 2024. https://www.treatmentactiongroup.org/resources/tbrd-report/tbrd-report-2024/.

44. TBpeople Ukraine. A fully funded challenge facility for civil society. 2025 August 30. https://tbpeopleukraine.com/en/petytsiya/.

45. World Health Organization. Catalyzing solutions for equitable global access.

46. UNAIDS [Press Release]. Investing in community-led action will be critical to ending the AIDS epidemic. 2016 April 6. https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2016/april/20160406_CS_HLM.

47. Gavi. Gavi Alliance policy for self-procurement of vaccines and injection safety devices. 2016 June 23. https://www.gavi.org/sites/default/files/about/governance/corporate-policies/08b_Policy-for-Self-Procurement-of-Vaccines.pdf.

48. World Health Organization. Strategic Advisory Group of Experts on Immunization (SAGE) – March 2023. 2023 March 20–23. https://www.who.int/news-room/events/detail/2023/03/20/default-calendar/sage_meeting_march_2023.

49. World Health Organization. Strategic Advisory Group of Experts on Immunization (SAGE) – September 2025. 2025 September 22–25. https://www.who.int/news-room/events/detail/2025/09/22/default-calendar/strategic-advisory-group-of-experts-on-immunization-september-2025.

50. World Health Organization. Evidence considerations for vaccine policy development for tuberculosis vaccines intended for adults and adolescents. Geneva: World Health Organization; 2024. https://www.who.int/publications/i/item/9789240093980.

51. The vaccine is: included in the prequalification priority list; meets the mandatory characteristics for programmatic suitability; has received marketing authorization from the national regulatory authority of reference for prequalification, and for which the NRA responsible for its regulatory oversight is a of maturity level 3 or higher for vaccine-producing countries.

52. World Health Organization. Strategic Advisory Group of Experts on Immunization (SAGE). https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/meetings.

53. European Medicines Agency. Medicines for use outside of the EU — EU-M4all. July 2020. https://www.ema.europa.eu/en/documents/leaflet/infographic-medicines-use-outside-eu-eu-m4all_en.pdf.

54. European Medicines Agency. PRIME: priority medicines. 2025 November 21. https://www.ema.europa.eu/en/human-regulatory-overview/research-development/prime-priority-medicines.

55. World Health Organization [Press Release]. Indonesia takes leadership role in tackling TB with development of new vaccine candidates. 2024 November 13. https://www.who.int/indonesia/news/detail/13-11-2024-indonesia-takes-leadership-role-in-tackling-tb-with-development-of-new-vaccine-candidates.

56. Aurum Institute. TB vaccine preparedness workshop: meeting the experts shaping South Africa's TB vaccine future. 2025 July 22. https://www.auruminstitute.org/component/content/article/15-blog/1064-tb-vaccine-preparedness-workshop-meet-the-experts-shaping-south-africa-s-tb-vaccine-future.

57. Prabhala A, Alsalhani A. Developing countries can make the mRNA vaccines they need. Nat Hum Behav. 2022;6(2):167. doi: 10.1038/s41562-022-01304-y.

58. MSF Access Campaign. Pharmaceutical firms across Asia, Africa and Latin America with potential to manufacture mRNA vaccines. 2021 December 16. https://msfaccess.org/pharmaceutical-firms-across-asia-africa-and-latin-america-potential-manufacture-mrna-vaccines.

59. World Health Organization. The mRNA vaccine technology transfer programme. https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub.

60. Gavi. African Vaccine Manufacturing Accelerator (AVMA). 2025 May 22. https://www.gavi.org/programmes-impact/types-support/regional-manufacturing-strategy/avma.

61. Herder M, Benavides X. 'Our project, your problem?' A case study of the WHO's mRNA technology transfer programme in South Africa. PLOS Glob Public Health. 2024;4(9):e0003173. doi: 10.1371/journal.pgph.0003173.

62. World Health Organization. Market information for access to vaccines. https://www.who.int/teams/immunization-vaccines-and-biologicals/vaccine-access/mi4a/mi4a-vaccine-purchase-data

63. PAHO. Revolving fund vaccine prices 2025. 2025 February 28. https://www.paho.org/en/documents/revolving-fund-vaccine-prices-2025

64. Gotham D, Fortunak J, Pozniak A, et al. Estimated generic prices for novel treatments for drug-resistant tuberculosis. J Antimicrob Chemother. 2017;72(4):1243–1252. doi: 10.1093/jac/dkw522.

65. MSF Access Campaign. Factsheet: "Time for $5" campaign. 2023 September 12. https://msfaccess.org/factsheet-time-5-campaign

66. Pignataro MF, Scopel CT, Maria Lorena Bacigalupo ML, Frick M, Sergiy Kondratyuk S, and Chaves GC. TB vaccine development: monitoring international patent filings to anticipate access challenges. Frontiers in Public Health [under review].

67. Gavi. Immunisation supply chain. https://www.gavi.org/types-support/health-system-and-immunisation-strengthening/immunisation-supply.

68. PAHO. Vaccine prices 2024. https://www.paho.org/en/documents/vaccine-prices-2024.

69. UNICEF. Vaccines product menu. https://www.unicef.org/supply/documents/vaccines-product-menu.

70. World Health Organization. Global market study: BCG vaccine. Geneva: World Health Organization; 2019. https://cdn.who.int/media/docs/default-source/immunization/mi4a/who_bcg_vaccine_global_market_update_may2019.pdf.

71. Burki T. The great cholera vaccine shortage. Lancet. 2024;403(10430):891–892. doi:10.1016/S0140-6726(24)00467-7.

72. Make Medicines Affordable. World TB Day 2021: end patents, end TB. 2024 March 21. https://makemedicinesaffordable.org/world-tb-day-2021-end-patents-end-tb/.

73. Johnson & Johnson. Johnson & Johnson confirms intent not to enforce patents for SIRTURO® (bedaquiline) for the treatment of multidrug-resistant tuberculosis in 134 low- and middle-income countries. 2023 September 29. https://www.jnj.com/media-center/press-releases/johnson-johnson-confirms-intent-not-to-enforce-patents-for-sirturo-bedaquiline-for-the-treatment-of-multidrug-resistant-tuberculosis-in-134-low-and-middle-income-countries

74. World Health Organization. Catalyzing solutions for equitable global access.

75. World Health Organization. An investment case for new tuberculosis vaccines. Geneva: World Health Organization; 2022. https://www.who.int/publications/i/item/9789240064690.

76. World Health Organization. Catalyzing solutions for equitable global access and sustainable financing for novel tuberculosis vaccines for adults and adolescents. Geneva: World Health Organization TB Vaccine Accelerator Council; November 2025. https://www.who.int/publications/i/item/9789240116900.

77. https://www.unicef.org/innovation/reports/demand-health-services

78. UNICEF. Demand for health services: a human-centred field guide for investigating and responding to challenges. New York: UNICEF; 2018. https://buildingvaccinedemand.org/wp-content/uploads/2022/09/2022-vaccine-demand.pdf.

79. World Health Organization. Acceptance and demand for COVID-19 vaccines: interim guidance. Geneva: World Health Organization; 2021. https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccination-demand_planning-tool-2021.1.

80. UNICEF. HPV vaccination: a guide for planning and designing demand promotion interventions. New York: UNICEF; 2024. https://knowledge.unicef.org/health/resource/hpv-vaccination-guide-planning-and-designing-demand-promotion-interventions.

81. Treatment Action Group. Getting better faster: delivering on the promise of new TB treatments — A report from the 1/4/6x24 Campaign. New York: Treatment Action Group; 2024. https://www.treatmentactiongroup.org/publication/getting-better-faster-delivering-on-the-promise-of-new-tb-treatments-a-report-from-the-1-4-6x24-campaign/.

82. TBpeople Global. Our statement to the Global Fund. 2024 October 24. https://tbpeople.org/index.php/2024/12/03/our-statement-to-the-the-global-fund/.

83. UNAIDS. Community-led monitoring in action: emerging evidence and good practice. Geneva: UNAIDS; 2023. https://www.unaids.org/sites/default/files/media_asset/JC3085E_community-led-monitoring-in-action_en.pdf.

84. Stop TB Partnership. Community-led monitoring. https://www.stoptb.org/what-we-do/supporting-communities-overcome-access-barriers/community-led-monitoring.

85. Gavi. Community-based monitoring: evidence on pro-quity interventions to improve immunization coverage for zero-dose children and missed communities. Geneva: Gavi; 2023. https://zdlh.gavi.org/sites/default/files/2023-09/2._evidence_brief_community-based_monitoring.pdf.

86. Global Fund. An Asia-Pacific exchange on the role of community-led monitoring in TB programming. 20 October 2023. https://www.theglobalfund.org/en/community-responses-and-systems/.

87. ITPC. Insight, influence, & impact: 10 big change stories from the citizen science community-led monitoring project in 2023. Johannesburg: ITPC; 2024. https://itpcglobal.org/wp-content/uploads/2024/06/ITPC-Insight-Influence-Impact-Report.pdf.

88. Amfar Treat Asia. Community-led monitoring in Asia. https://data.clm-asia.org/.

89. Frick M. Tuberculosis vaccines pipeline report. New York: Treatment Action Group; 2025. https://www.treatmentactiongroup.org/resources/pipeline-report/2024-pipeline-report/.

90. World Health Organization. List of prequalified vaccines. https://extranet.who.int/prequal/vaccines/list-prequalified-vaccines.

91. Oberth G. Community monitoring grant alleviates stock-outs and improves data quality. Aidspan. 2019 June 25. https://aidspan.org/Blog/view/12179/regional_community_treatment_observatory_catalyzes_global_fund_investments_in_west_africa.

92. Ritshidze. Community-led monitoring data dashboard. https://data.ritshidze.org.za/

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