

Executive Summary

The background of the page is a complex, abstract geometric pattern. It consists of numerous overlapping, semi-transparent lines and squares in various shades of red, pink, and orange. The lines are oriented diagonally, creating a grid-like structure that is more fluid and organic than a standard grid. The overall effect is a vibrant, textured background that complements the white text.

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 dispar-

ities 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 rep-

resents 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 Organization¹⁰ 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 pre-

paredness 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.



Endnotes

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