Stop TB Partnership

WORKING GROUP ON NEW TB VACCINES

2024 Annual Meeting

12 November 2024

Bali, Indonesia

7TH GLOBAL FORUM ON TB VACCINES | 8-10 October 2024 Rio de Janeiro, Brazil

Driving innovation from discovery to access

Overview and Key Outcomes: 7th Global Forum on TB Vaccines

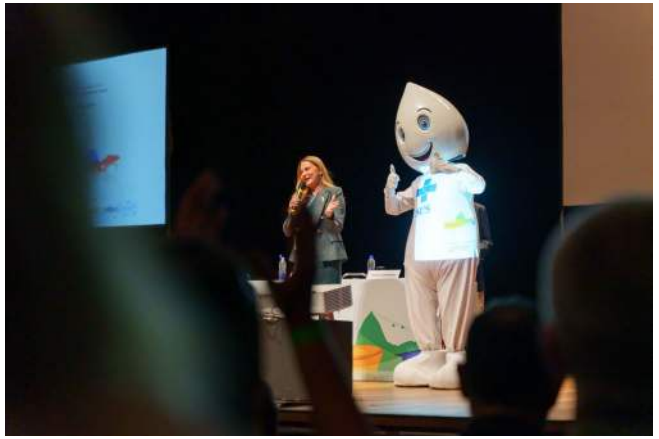
7th Global Forum on TB Vaccines
8 – 10 October 2024
Rio de Janeiro, Brazil

7TH GLOBAL FORUM ON TB VACCINES | 8-10 October 2024 Rio de Janeiro, Brazil
Driving innovation from discovery to access

- First Global Forum convened in the Americas
- Nearly **340 registrations** from **34 countries**
- More than 120 participants identified as **early career researchers**
- Convened under the overarching theme “Driving innovation from discovery to access”, program addressed the full spectrum of research and development and explored strategies to ensure new TB vaccines reach the populations that most need them and to maximize the public health impact
- Program was developed around five thematic tracks, aligned with global frameworks for TB vaccine development and implementation
- 85 speakers across 20 plenary, oral abstract, discussion, and poster viewing sessions

Opening and Closing Sessions

Keynote address by WHO Chief Scientist Jeremy Farrar



Secretary of Health Surveillance and Environmental Health Ethel Maciel and Brazil Vaccine Mascot Zé Gontinha welcome participants

Opening panel discussion with Suvanand Sahu (Stop TB Partnership), Mario Moreira (Fiocruz), Nina Russell (Gates Foundation), Ruben Rizzi (BioNTech, Mark Hatherill (SATVI) and Ethel Maciel (Ministry of Health)

Lucica Ditiu (Stop TB Partnership) and Michel Kazatchkine give remarks during the Closing Session

Diversifying the TB Vaccine Pipeline

David Lewinsohn

Program-at-a-glance

7TH GLOBAL FORUM ON TB VACCINES | 8-10 October 2024 | Rio de Janeiro, Brazil
Driving innovation from discovery to access

Time	Tuesday, 8 October	Wednesday, 9 October	Thursday, 10 October	Friday, 11 October
08:30 – 09:00	Poster Set-up	Arrival | Coffee | Networking	Arrival | Coffee | Networking	**Site Visits**
09:00 – 09:30	Registration | Coffee Poster Viewing	**Plenary 3:** Advancing TB vaccine clinical development: Learning from experience & looking to the future	**Plenary 5:** Innovative approaches to TB vaccine development	
09:30 – 10:00				
10:00 – 10:30	**Opening Session & Keynote Address**			
10:30 – 11:00				
11:00 – 11:30		Coffee/Tea Break	Coffee/Tea Break	
11:30 – 12:00		**Oral Abstract Sessions** • **OA1:** Mechanisms of biomarkers & protection, novel approaches, human challenge, optimizing animal models • **OA2:** Advancing clinical development	**Oral Abstract Sessions** • **OA3:** Improved formulation & delivery platforms, preclinical research • **OA4:** Impact, implementation, policy	
12:00 – 12:30				
12:30 – 13:00	Lunch			
13:00 – 13:30		Lunch	Lunch	
13:30 – 14:00	**Plenary 1:** From discovery to access			
14:00 – 14:30		**Plenary 4**: Country scale-up & implementation of new TB vaccines	**Discussion Sessions (x3)**	
14:30 – 15:00				
15:00 – 15:30	Break | Poster Viewing		Break (15 mins)	
15:30 -16:00		Break | Poster Viewing	**Plenary 6:** Enabling TB vaccine development through funding, political will, open science, & engaged communities	
16:00 – 16:30				
16:30 – 17:00	**Plenary 2:** Global & regional enablers for the introduction of new TB vaccines		**Closing Session**	
17:00 – 17:30		**Poster Discussion Sessions (x3)**		
17:30 – 18:00			Free Evening	
18:00 – onward	**Welcome Reception** (Urca 2008)	Free Evening		

This is a preliminary program and subject to change

@GlobForumTBVax | #7GFTBV | #GlobalForumTBVax

TB Vaccine Pipeline

Vaccine candidates under clinical development

There are 15 vaccine candidates in the pipeline as of September 2024, of which 12 are in active trials. The candidates are placed under the phase which corresponds to the most advanced ongoing or completed trial.

Platform

- Mycobacterial - Live attenuated
- Mycobacterial - Inactivated
- Viral vector
- Protein/Adjuvant
- RNA

Trial staus

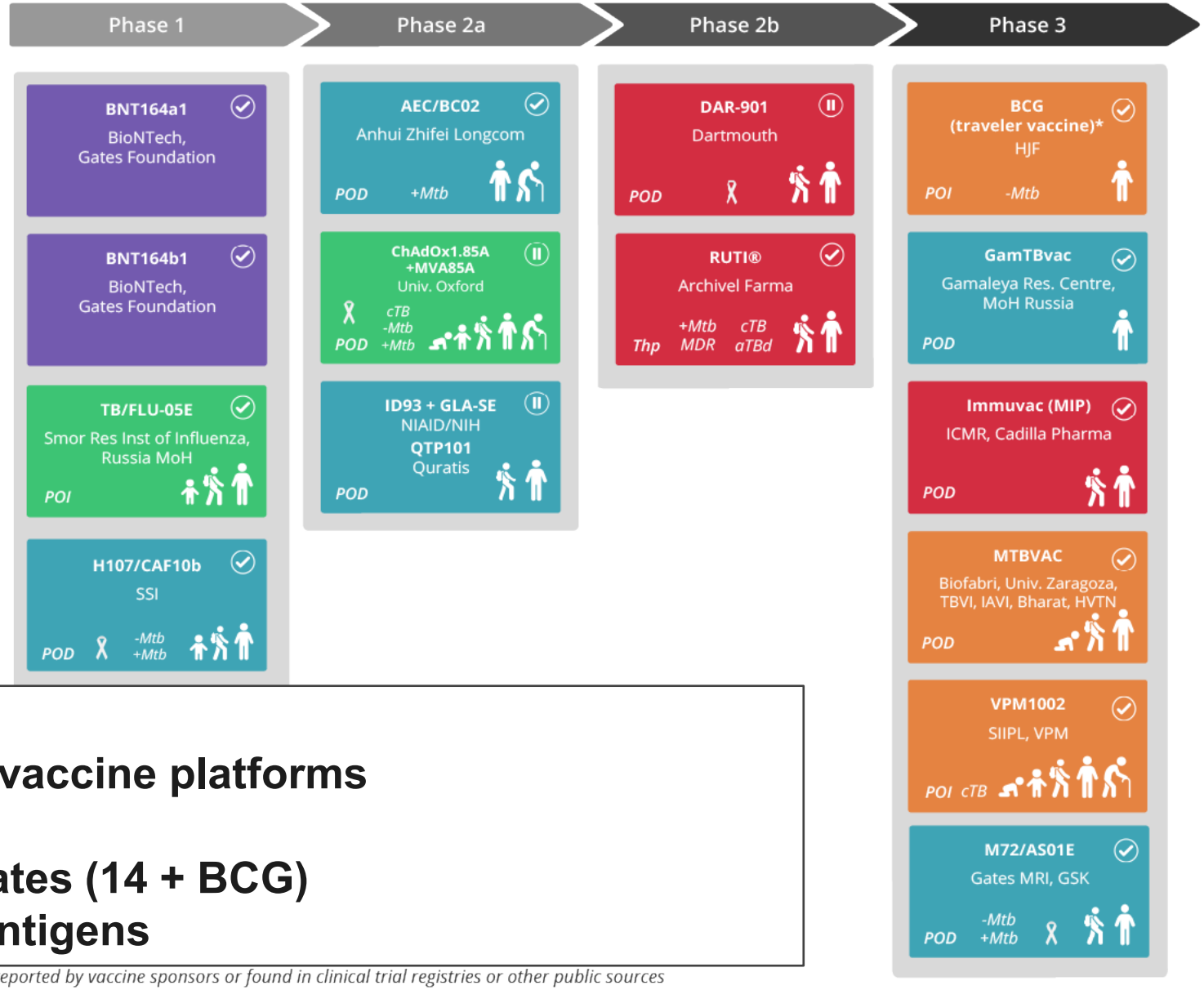
- Active trials
- No active trials

Candidate target population

- Elderly
- Adults
- Adolescents
- Children
- Infants
- People living with HIV
- -Mtb — People without Mtb infection
- +Mtb — People with Mtb infection
- aTBd — People with active TB disease
- MDR — People with MDR-TB
- cTB — People cured of active TB

Primary candidate indication

- *POI* — Prevention of Infection
- *POD* — Prevention of Disease
- *POR* — Prevention of Recurrence
- *Thp* — Therapeutic



Strength:

Diversity of vaccine platforms

Weakness:

Few candidates (14 + BCG)

Few novel antigens

Information reported by vaccine sponsors or found in clinical trial registries or other public sources

Institutions listed are vaccine sponsors and development partners

Additional information, including the full list of clinical trials for each candidate, can be accessed via the QR code or at newtbvaccines.org/tb-vaccine-pipeline/

Last update: 2 September 2024

Stop TB Partnership
WORKING GROUP ON NEW TB VACCINES

Key Topics Addressed

Efforts to develop biomarkers, correlates of protection, and measure of bacterial burden

- Lessons learned from the M72 prevention of disease trial (Nemes) and the H56:IC31 prevention of recurrence trial (Scriba, Mendelsohn)
- Intravenous BCG in nonhuman primates (Darrah, Verreck)
- Aerosol BCG (Li)
- Understanding bacterial burden through the lymph node (Young)

Increase diversity through novel approaches and delivery platforms

- Increasing the diversity of antigens (Ogongo)
- Explore novel delivery platforms for TB vaccines, including self-adjuvanting vaccines (Tran et al) and RNA (Fulton, Kovalchuke)
- Co-infection (Cohen) and humanized mouse model (Trentini) for clearance of infection

Highlights

Optimize animal models to better reflect human disease

- Ultra low-dose (Plumlee, Fulton) and NHP models (Verreck, Darrah) for **prevention of infection**
- Using the mouse co-infection (Plumlee) and humanized mouse as a model for immunotherapy (Trentini) for **clearance of infection**

Human challenge model/Controlled human infection model

- Progress and lessons learned in developing an aerosol BCG human challenge model

Accelerating Clinical Development

Ann Ginsberg

(no slides)

Ensuring Public Heath Impact & Implementation of New TB Vaccines

Richard White

Highlights

Impressive country preparedness

- Preparing the landscape for TB vaccines: South Africa's strategic planning

First data on new (TB) vaccine acceptability

- Generic vaccines in TB HBCs
- TB Vx - HCW/community in Zambia; pregnant women in 4 countries; adolescents in Khayelitsha; adolescents in Mozambique
- Standardised survey questions available

Useful modelling/framework activities

- What to do if vaccine doses are limited? & Fair allocation frameworks?
- TB vaccine impact models being developed *in* LMICs – India at conf (Jessy); S Africa, Indonesia, Brazil coming...

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Preparing the landscape for TB vaccines: South Africa's strategic planning

Ndjeka et al, S Africa MoH

Describe country preparedness

South Africa has prioritised vaccine preparedness as reflected in the NTP Strategic Plan, 2023-28. In collaboration with the national TB Think Tank and NAGI, preparatory work for the introduction of TB vaccines is currently in progress

=> Encouraging

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New tuberculosis vaccines are in late-stage trials, but how confident is the public in high burden countries in vaccines?

Hesketh et al, GAVI/LSHTM

Analysis of existing vax confidence data in TB HBCs

Of the 18 countries included, 14 had an overall 2023 vaccine confidence score of 80% or higher. Four countries had a score over 90%: Vietnam (98.5%), Ethiopia (95.5%), India (91.8%), and Sierra Leone (90.6%).

Cameroon had the lowest score with 63.0% followed by Ukraine (66.2%), Russia (70.5%), and South Africa (75.5%). These four countries make up 5.75% of the total TB burden in our sample and may require future attention to ensure confidence in a new TB vaccine.

Country	Estimated number of incident TB cases in 2022	Combined vaccine confidence score for 2023 (% positive)	Difference in combined vaccine score compared to 2022 (% difference)
India	2,820,000	91.8	-4.8
Indonesia	1,060,000	84.3	*NA*
Philippines	737,000	84.8	+4.1
Pakistan	608,000	83.8	+5.1
Nigeria	479,000	89.1	+6.0
DRC	314,000	83.2	+7.2
South Africa	280,000	75.5	+0.7
Vietnam	172,000	98.5	+0.6
Ethiopia	156,000	95.5	NA
Kenya	128,000	89.3	+3.9
Thailand	111,000	87.2	*NA*
Brazil	105,000	88.5	-3.4
Uganda	94,000	88.9	+3.4
Russia	56,000	70.5	+5.9
Cameroon	44,000	63.0	-11.4
Ukraine	36,000	66.2	*NA*
Sierra Leone	25,000	90.6	*NA*
Liberia	16,000	87.9	*NA*

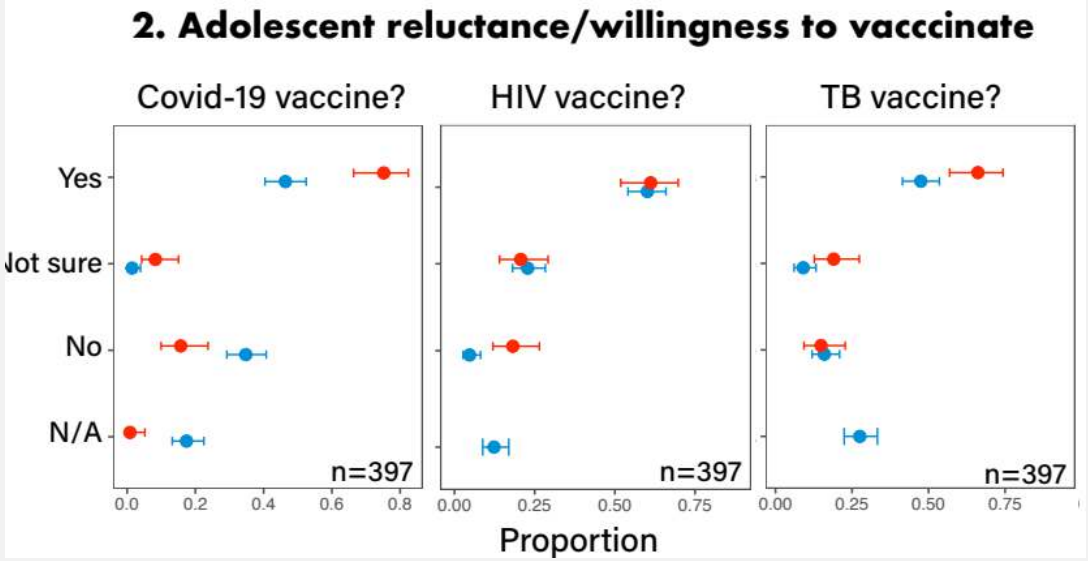
➔ Encouraging, with caveats

Insights into TB vaccine acceptability among adolescents in Khayelitsha through community engagement

Koch et al, UCT

Adolescents (400), Khayelitsha, South Africa

High acceptability, but reasons for not sure/no often due to lack of understanding about TB risk



=> Encouraging, but education necessary

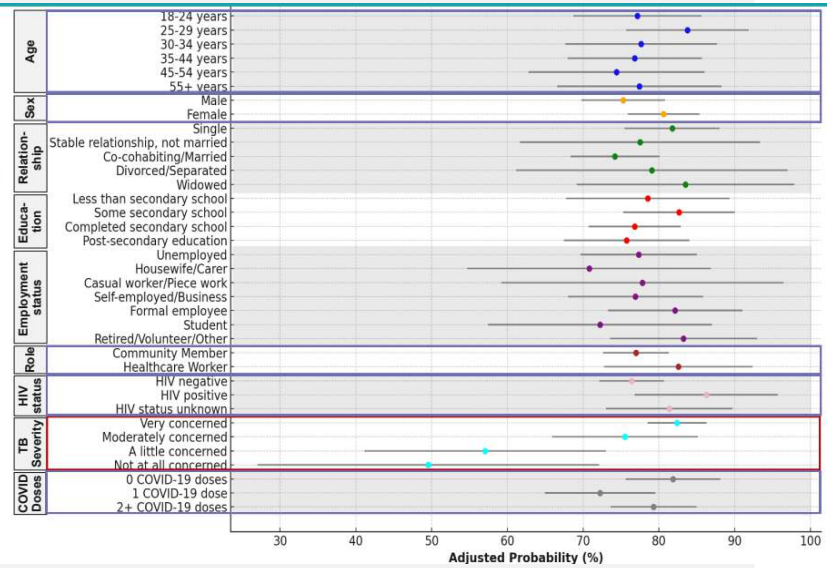
Willingness to receive a future adult tuberculosis vaccine in Lusaka, Zambia: Perspectives from community members and healthcare workers.

Kerkhoff et al, UCSF

Aim - To reach adult community members and HCWs in high TB burden settings, it is crucial to understand both preliminary willingness to receive a TB vaccine and communication preferences to design strategies to optimize demand and acceptance.

Zambia community (400) and HCWs (100) from low covid vx uptake communities

- **High predicted TB vaccine intention across most subgroups and no major differences.**
  - HCWs (83%) and CMs (77%), age, sex, or HIV status
- **No association with number of COVID-19 vaccine doses.**
- **Intention strongly associated with perceived TB threat.**
  - Both TB risk perception and concern about TB severity



➔ Encouraging, but education necessary

Acceptability of a novel TB vaccine or BCG booster among adults, caretakers of adolescents and adolescents in Manhiça District, southern Mozambique

Garcia-Basteiro, Manhica Health Research Center (CISM), Mozambique

Aim - Document intention to receive a new TB vaccine or BCG booster dose among adults, adolescents (aged 9-17) and their caretakers, in Manhiça, southern Mozambique.

Overall, intention to receive a new TB vaccine or a BCG booster among adults and adolescents is high in southern Mozambique

Table. Intention to vaccinate by group and gender for new TB vaccine or a BCG booster dose

	Adult			Adolescent			Caretaker		
Characteristic	Male N = 59[†]	Female N = 92[†]	Overall N = 151[†]	Male N = 14[†]	Female N = 27[†]	Overall N = 41[†]	Male N = 5[†]	Female N = 44[†]	Overall N = 49[†]
Would Receive New TB Vaccine									
Yes	44 (75%)	68 (74%)	112 (74%)	11 (79%)	25 (93%)	36 (88%)	5 (100%)	31 (70%)	36 (73%)
No	11 (19%)	4 (4.3%)	15 (9.9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (9.1%)	4 (8.2%)
Maybe	4 (6.8%)	20 (22%)	24 (16%)	3 (21%)	2 (7.4%)	5 (12%)	0 (0%)	9 (20%)	9 (18%)
Would Receive BCG Booster									
Yes	54 (92%)	71 (77%)	125 (83%)	11 (79%)	26 (96%)	37 (90%)	5 (100%)	39 (89%)	44 (90%)
No	2 (3.4%)	8 (8.7%)	10 (6.6%)	0 (0%)	1 (3.7%)	1 (2.4%)	0 (0%)	2 (4.5%)	2 (4.1%)
Maybe	3 (5.1%)	13 (14%)	16 (11%)	3 (21%)	0 (0%)	3 (7.3%)	0 (0%)	3 (6.8%)	3 (6.1%)

[†] n (%)

=> Encouraging

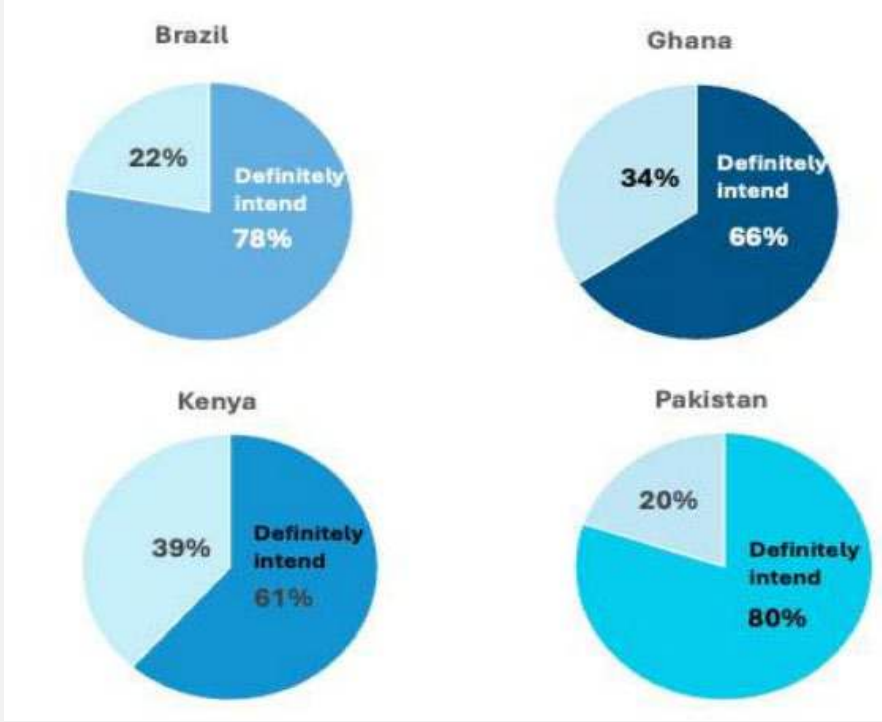
Willingness to receive a future TB vaccine among pregnant women living in Brazil, Ghana, Kenya, and Pakistan

Limaye et al, JHU

Our study assessed the willingness of pregnant women across four countries - Brazil, Ghana, Kenya, and Pakistan to receive a future TB vaccine.

~400 per country

We surveyed 1597 women total. When asked about their intentions to receive a future TB vaccine, the majority of women in each country indicated that they would "definitely intend to receive a TB vaccine": 77.9% in Brazil, 65.6% in Ghana, 61.5% in Kenya, and 80.2% in Pakistan



=> Encouraging

- Now standardised survey questions available, to improve comparability
- Contact rebecca.clark@lsthm.ac.uk

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Useful modelling/framework activities

- **What to do if vaccine doses are limited? & Fair allocation frameworks?**
- **TB vaccine impact models being developed *in* LMICs – India at conf (Jessy); S Africa, Indonesia, Brazil coming…**

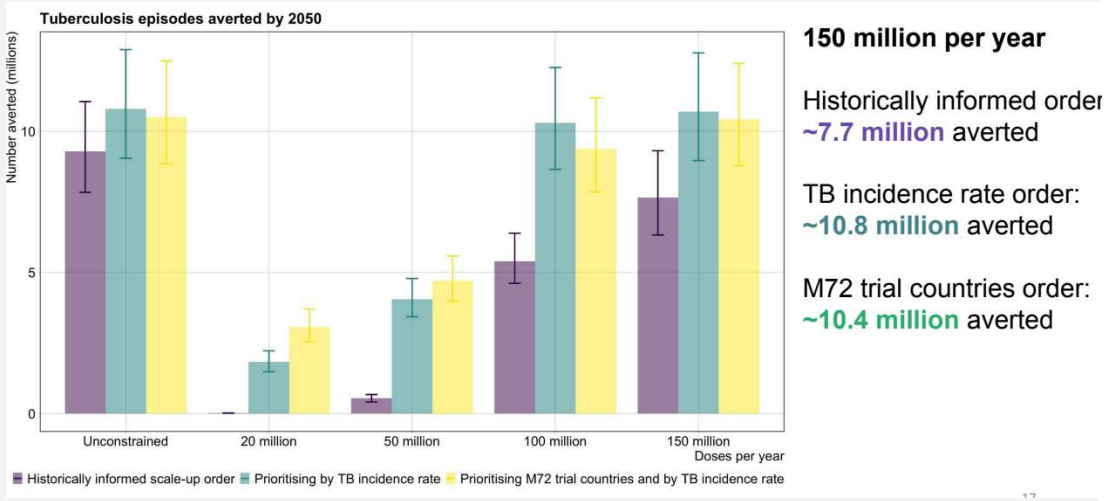
‘Facing up to reality— What to do if M72/AS01E doses are limited?’

Clark et al, LSHTM

Aim - used modelling to investigate the difference in impact from varying the number of vaccine doses available and varying the country-specific order of vaccine introduction.

Country introduction order:

- Historically Informed
- TB incidence rate/ M72 trial countries first



=> Makes a big difference, especially at low dose availability

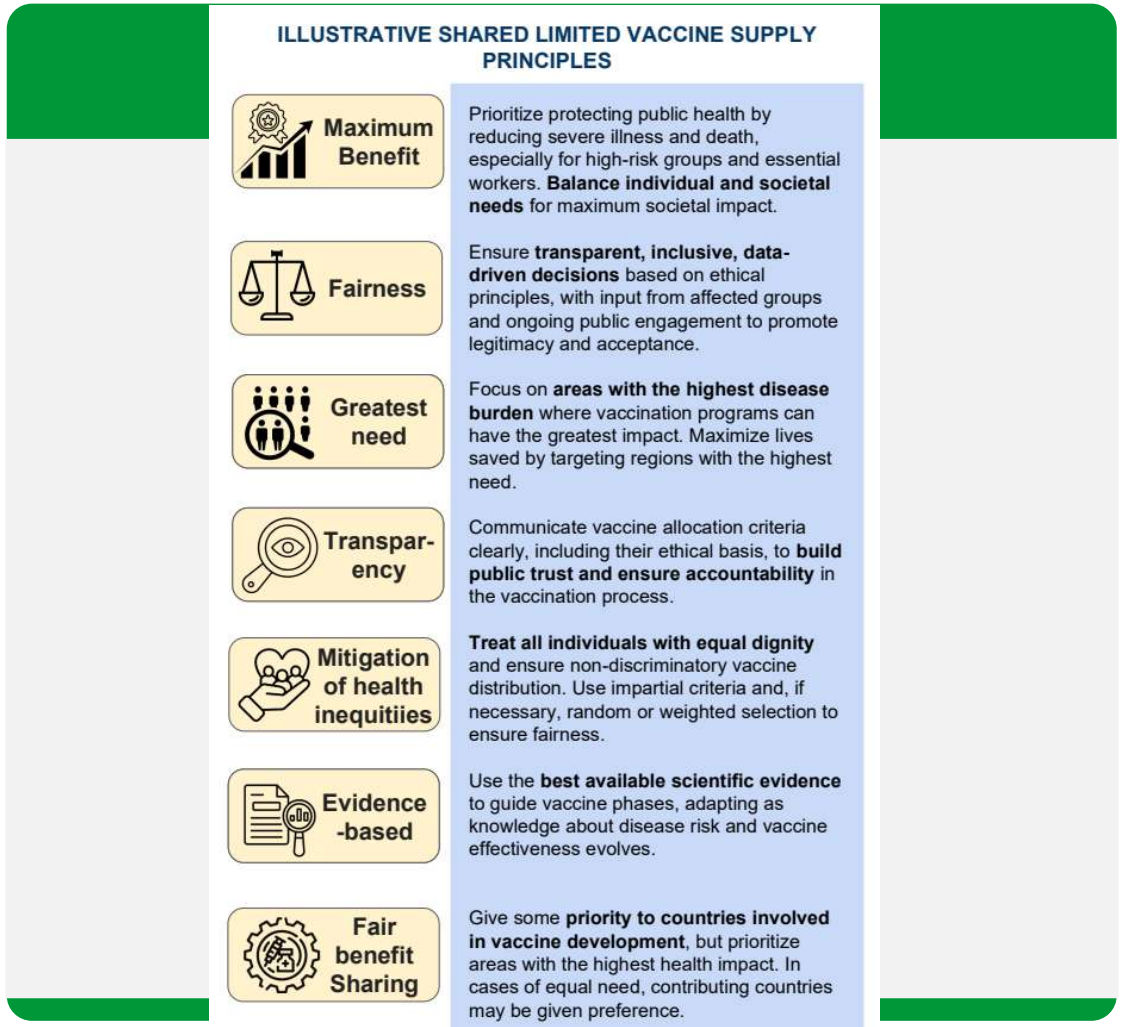
Navigating the unknown: Ensuring equitable TB vaccine access to maximize health impact

Limaye et al, JHU

A scoping literature review is underway to identify key principles and strategies from vaccine introduction strategies

Key considerations include prioritizing based on need, maximizing health impact, ensuring equity, access, and affordability

The goal is to create a transparent, evidence-based framework that informs national and global policy under conditions of limited supply, while market shaping and communication efforts work toward meeting global demand



TB vaccine impact models being developed *in* LMICs – India at conf (Jessy); S Africa, Indonesia, Brazil coming…

Jessy Joseph et al, IAVI (India)

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Driving innovation from discovery to access

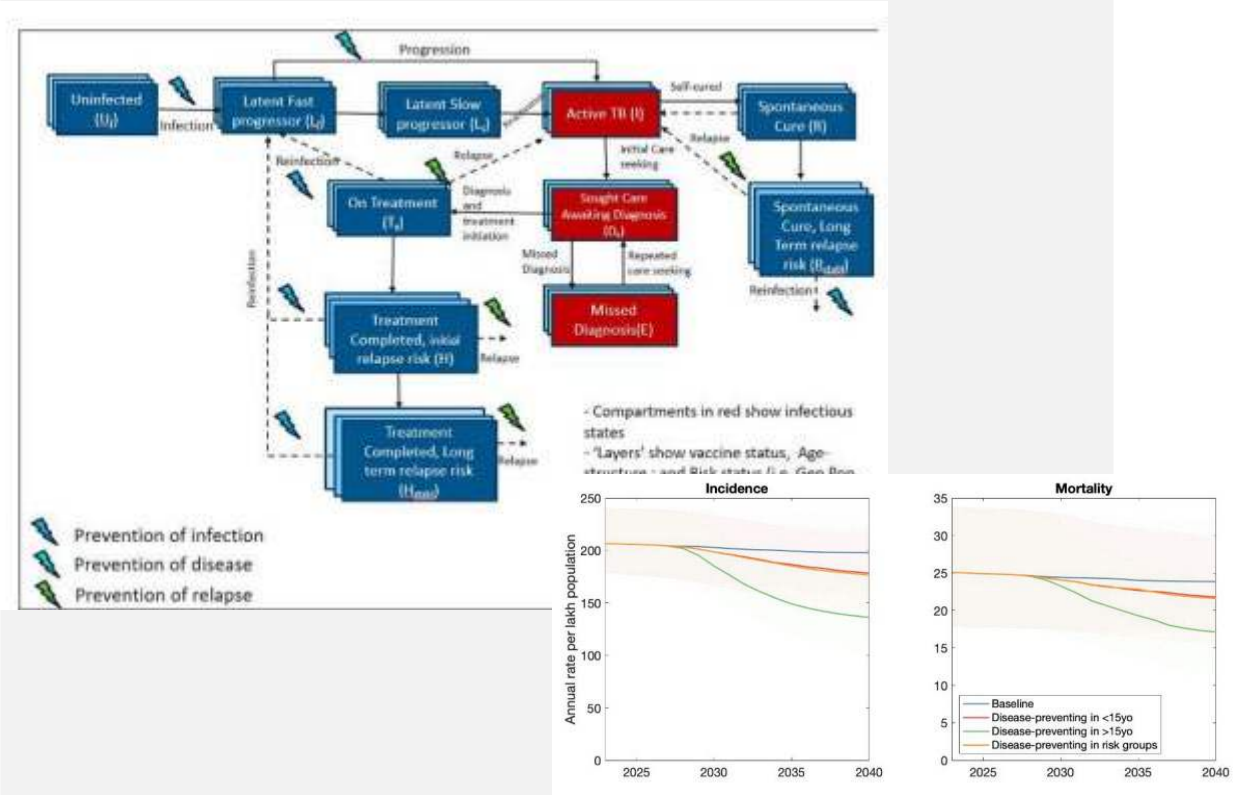
Advancing evidence-informed in-country decision-making for new TB vaccine introduction: A responsive and integrated vaccine modelling approach from India

Aim - used modelling to investigate the difference in impact from varying the number of vaccine doses available and varying the country-specific order of vaccine introduction.

By

- Historically Informed
- TB incidence rate/ M72 trial countries first

=> Make a big difference, especially at low dose availability



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Enabling Factors, Community Engagement & Advocacy

Shaun Palmer

Meet the committee

This was the first Forum with a dedicated Community Engagement Committee.

The committee members led the development of the Community Declaration and spoke in plenaries across the program.

Keyuri Arvind Bhanushali
Survivors Against TB,
India

Peter Ngo'la Owiti
GAVI CSO Steering Committee,
Kenya

Paulina Siniatkina
TBpeople,
Netherlands

Ani Herna Sari
Rekat Peduli,
Indonesia

Patrick P. Agbassi
Global TB CAB| Envopharm,
Côte d'Ivoire

Ezio Távora
Rede-TB,
Brazil

Rosa Herrera
Global TB CAB | Universidad Autónoma de Durango, Campus Mexicali,
Mexico

Jackie Cuen
We Are TB/Somos TB,
USA

Shaun Palmer
IAVI | TB Vax ARM,
Netherlands

Vanessa Mwebaza Muwanga
WGNV,
South Africa

Community Declaration

What is it?

- An opportunity to **amplify our collective voice**
- **Share our demands** to attendees of the 7th Global Forum and **to leaders and decision makers** about the urgent need to invest in TB vaccine development and introduction

Community Declaration of the
7th Global Forum on TB Vaccines

Distinguished leader,

On behalf of representatives of the global TB community, including the 7th Global Forum Community Engagement Committee and the undersigned, we hereby share the demands of TB affected communities for the development and implementation of new TB vaccines.

It is an injustice that over 3,500 people die from TB every single day. Most of these lives are lost in communities already vulnerable to exploitation due to deep inequalities. TB is a stigmatized disease that shatters families and ruins lives. It is unacceptable that we still rely on the century-old Bacillus Calmette-Guérin (BCG) vaccine, which is largely ineffective in adolescents and adults, among whom 90% of TB disease occurs. **The fact that we still do not have effective TB vaccines is a clear sign that affected communities are not a real priority. It is time to change the story.**

Ending TB is about ensuring everyone gets a fair shot at a healthy life. To achieve this by 2030, we need multiple new vaccines that work for everyone, are available, accessible, and acceptable to all no matter where they live, and are affordable, especially to high burden countries. **We must urgently fast-track TB vaccine research, particularly crucial late-stage trials, while at the same time preparing for their quick and equitable distribution.**

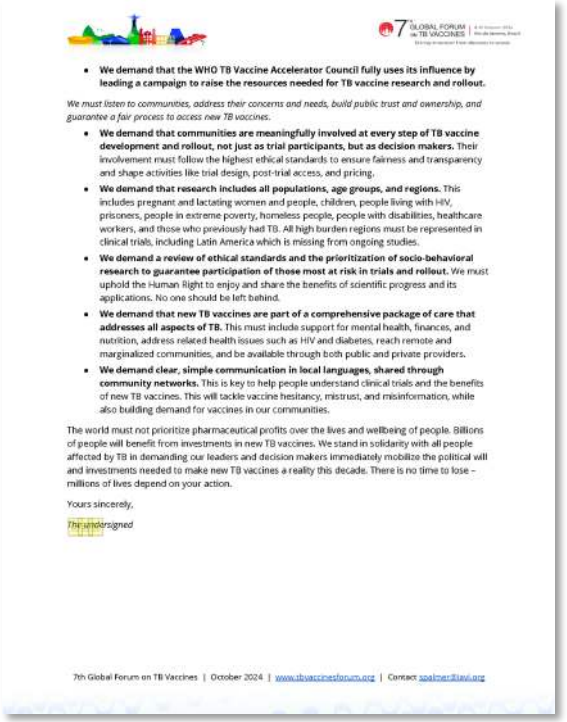
New TB vaccines will save millions of lives and protect the wellbeing and prosperity of billions. TB vaccines can also help control drug-resistant TB and build stronger health and research systems. Investing in TB vaccines now will boost economic growth and improve public health, while leaving the world better prepared to respond to future airborne pandemics.

It is a shame that funding for TB vaccine research has never passed $145 million a year. Our leaders need to act fast to keep their promises made at the 2023 United Nations (UN) High-Level Meeting on TB to **develop and deliver at least one new TB vaccine by 2028.** To reach this goal, UN Member States committed to **invest $5 billion annually in TB research by 2027, with $1.25 billion for vaccines.** Annual funding must therefore increase by almost 10-fold.

We need to overcome chronic underfunding and speed up development and access.

- **We demand joint, increased, and sustained funding of TB vaccine research and rollout, with coordinated paths for their accelerated approval and implementation.** All countries should contribute their fair share, including high burden countries.
- **We demand that vaccines developed with public funds are universally and equitably accessible, and affordable to all countries.** This means attaching access requirements to public funding, supporting the necessary technology transfer, and removing unfair intellectual property barriers.
- **We demand an independent monitoring and evaluation mechanism to ensure accountability of all commitments and investments in TB research.**
- **We demand strengthened research, manufacturing, and delivery capacity in high burden regions to ensure their leadership** in TB vaccine research and implementation.

7th Global Forum on TB Vaccines | October 2024 | www.tbvaccinesforum.org | Contact spalmer@lavi.org



- **We demand that the WHO TB Vaccine Accelerator Council fully uses its influence by leading a campaign to raise the resources needed for TB vaccine research and rollout.**

We must listen to communities, address their concerns and needs, build public trust and ownership, and guarantee a fair process to access new TB vaccines.

- **We demand that communities are meaningfully involved at every step of TB vaccine development and rollout, not just as trial participants, but as decision makers.** Their involvement must follow the highest ethical standards to ensure fairness and transparency and shape activities like trial design, post-trial access, and pricing.
- **We demand that research includes all populations, age groups, and regions.** This includes pregnant and lactating women and people, children, people living with HIV, prisoners, people in extreme poverty, homeless people, people with disabilities, healthcare workers, and those who previously had TB. All high burden regions must be represented in clinical trials, including Latin America which is missing from ongoing studies.
- **We demand a review of ethical standards and the prioritization of socio-behavioral research to guarantee participation of those most at risk in trials and rollout.** We must uphold the Human Right to enjoy and share the benefits of scientific progress and its applications. No one should be left behind.
- **We demand that new TB vaccines are part of a comprehensive package of care that addresses all aspects of TB.** This must include support for mental health, finances, and nutrition, address related health issues such as HIV and diabetes, reach remote and marginalized communities, and be available through both public and private providers.
- **We demand clear, simple communication in local languages, shared through community networks.** This is key to help people understand clinical trials and the benefits of new TB vaccines. This will tackle vaccine hesitancy, mistrust, and misinformation, while also building demand for vaccines in our communities.

The world must not prioritize pharmaceutical profits over the lives and wellbeing of people. Billions of people will benefit from investments in new TB vaccines. We stand in solidarity with all people affected by TB in demanding our leaders and decision makers immediately mobilize the political will and investments needed to make new TB vaccines a reality this decade. There is no time to lose – millions of lives depend on your action.

Yours sincerely,

The undersigned

7th Global Forum on TB Vaccines | October 2024 | www.tbvaccinesforum.org | Contact spalmer@lavi.org

Community Declaration

The process

- **Initial feedback from the global TB community from multilingual webinar** in August
- **First draft prepared by the Committee**, based on the webinar feedback
- **Online consultation survey** to collect feedback on the first draft
- **Final version prepared** based on the survey feedback
- **Open for public sign on** 17 Sep – 10 Oct
- **Presented** during the Declaration **in the Opening Ceremony**

Available in English, French, Hindi, Indonesia, Portuguese, Russian, and Spanish

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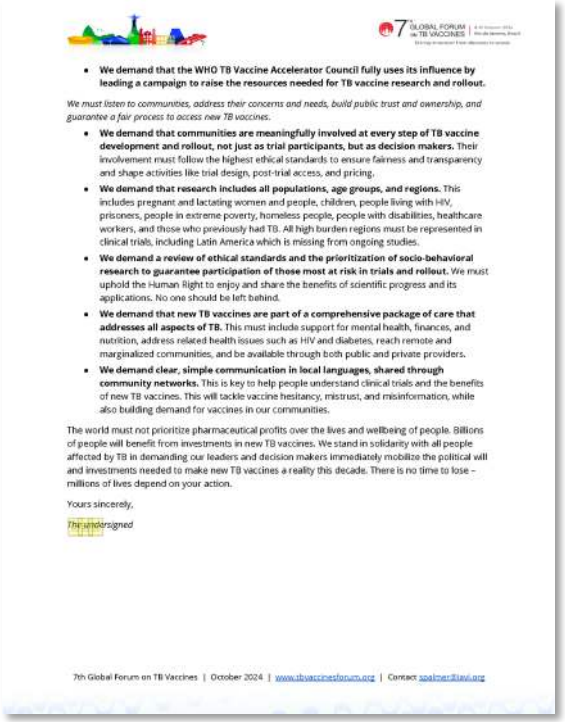

- **We demand that the WHO TB Vaccine Accelerator Council fully uses its influence by leading a campaign to raise the resources needed for TB vaccine research and rollout.**

We must listen to communities, address their concerns and needs, build public trust and ownership, and guarantee a fair process to access new TB vaccines.

- **We demand that communities are meaningfully involved at every step of TB vaccine development and rollout, not just as trial participants, but as decision makers.** Their involvement must follow the highest ethical standards to ensure fairness and transparency and shape activities like trial design, post-trial access, and pricing.
- **We demand that research includes all populations, age groups, and regions.** This includes pregnant and lactating women and people, children, people living with HIV, prisoners, people in extreme poverty, homeless people, people with disabilities, healthcare workers, and those who previously had TB. All high burden regions must be represented in clinical trials, including Latin America which is missing from ongoing studies.
- **We demand a review of ethical standards and the prioritization of socio-behavioral research to guarantee participation of those most at risk in trials and rollout.** We must uphold the Human Right to enjoy and share the benefits of scientific progress and its applications. No one should be left behind.
- **We demand that new TB vaccines are part of a comprehensive package of care that addresses all aspects of TB.** This must include support for mental health, finances, and nutrition, address related health issues such as HIV and diabetes, reach remote and marginalized communities, and be available through both public and private providers.
- **We demand clear, simple communication in local languages, shared through community networks.** This is key to help people understand clinical trials and the benefits of new TB vaccines. This will tackle vaccine hesitancy, mistrust, and misinformation, while also building demand for vaccines in our communities.

The world must not prioritize pharmaceutical profits over the lives and wellbeing of people. Billions of people will benefit from investments in new TB vaccines. We stand in solidarity with all people affected by TB in demanding our leaders and decision makers immediately mobilize the political will and investments needed to make new TB vaccines a reality this decade. There is no time to lose – millions of lives depend on your action.

Yours sincerely,

The undersigned

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7TH GLOBAL FORUM ON TB VACCINES | 8-10 October 2024 Rio de Janeiro, Brazil

Driving innovation from discovery to access

Thank you to the **1,410** individuals and organizations from **81** countries who signed the Community Declaration!

Read the declaration,
share our demands.

bit.ly/7GFTBV
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#7GFTBV | #GlobalForumTBVax

Stop TB Partnership Working Group on New TB Vaccines | iavi | TBVI | SUS | Ministério da Saúde | Governo Federal Brasil União e Reconstrução | REDE-TB

Active participation, meaningful visibility

Paulina Siniatkina presenting the community declaration during the Opening Ceremony (Tue, 8 Oct 2024)

TB IS OVER (if you want it) – art installation by Paulina Siniatkina outside of the Grande Sala, Cidade das Artes

Active participation, meaningful visibility

Committee members spoke at each of the plenary sessions

Ezio Távora, Plenary 1: From discovery to access and Plenary 5: Innovative approaches to TV vaccine R&D

Peter Ngo'la Owiti, Plenary 2: Global & regional enablers for the introduction of new TB vaccines

Keyuri Bhanushali, Plenary 3: Advancing TB vaccine clinical development

Patrick Agbassi, Plenary 4: Country scale-up & implementation of new TB vaccines

Jackie Cuen & Shaun Palmer, Plenary 6: Enabling TB vaccine development through funding political will, open science, & engaged communities