

TB Vax ARM Webinar

#Wins4TBVax Panel Discussion – Transcript

Thursday, 4 April 2024

Shaun Palmer (TB Vax ARM): Good morning, good afternoon, and good evening. Thank you to everyone for joining today's TB Vaccine Advocacy Roadmap (TB Vax ARM) webinar as we explore some of the key advocacy priority priorities for TB vaccine development and delivery. Following the launch of our #Wins4TBVax campaign last month around World TB Day.

Shaun Palmer (TB Vax ARM): We're joined today by a panel of expert speaker who will be sharing insights on the three wins that we've defined. So, thank you to Birgitte Giersing from the WHO, Rupali Limaye, from SMART4TB, Sahu Suvanand, from Stop TB, and Maiko Tonini, from the Ministry of Health, Brazil, for joining us today to share their insights on these topics, and a big thanks to Priyanka Aiyer from GFAN for providing some welcome tech support.

Shaun Palmer (TB Vax ARM): Before we invite the first of the speakers, I'm pleased to share the #Wins4TBVax with everyone on the call today, just to provide some context and background on this campaign. Ahead of World TB Day, the TB Vax ARM outlined three key advocacy wins for the field to achieve by 2026 in order to effectively advance TB vaccine development and ensure their equitable and affordable access this decade. These wins have been developed to guide our advocacy efforts for the coming two years following last year's United High-Level Meeting on TB where world governments endorsed commitments to invest at least US\$5 billion a year in TB research and development, including US\$1.25 billion dollars for new TB vaccines. And this also included a commitment to develop and roll out new TB vaccines this decade, preferably within five years.

Shaun Palmer (TB Vax ARM): This also recognizes that new TB vaccines could be available this decade with some ready for licensure as early as 2028. We have at least 16 candidates in the clinical pipeline, including multiple promising candidates in late stage efficacy trials, and several more in pre-clinical development. And efforts are underway to ensure that new TB vaccines will be equitably and affordably accessible to all who need them.

Shaun Palmer (TB Vax ARM): So, as you can see on the screen, here are the three wins on the left-hand side. You can visit the link that's just on the screen and in the chat or access it via the QR code to read through our wins in detail and endorse them as part of our ongoing campaign throughout this year. I just wanted to quickly touch upon each of the wins to make sure **everyone has a full context of how we developed them and what we hope to achieve through them. The first win is to see measurable increases in national and joint multilateral funding and financing for TB**

vaccine R&D. So, this is in acknowledgement of the need to meet that US\$5 billion annual TB R&D funding target, noting that governments must now increase public investments for TB research to 0.15% of their country's total research expenditure to meet their fair share targets.

Shaun Palmer (TB Vax ARM): So, what would this first win look like? What we'd like to see is that governments and multilaterals make diversified, increased joint investments in TB vaccine development; that governments make significant progress towards meeting fair share targets; that relevant funders at all levels explicitly include TB vaccine R&D in funding calls and strategies; and that the WHO TB Vaccine Accelerator Council will also prioritize and facilitate R&D financing.

Shaun Palmer (TB Vax ARM): **Our second win is to see explicit and transparent commitments and plans from developers and governments to ensure equitable access.** And what would this look like? Well, we'd like to see relevant global agencies include TB vaccines in their vaccine delivery strategies; to see relevant bodies prioritize TB vaccines and articulate implementation strategies relevant to their country context; to see developers make access plans transparent and publicly available and a bench assessment for vaccine access is developed; and finally to see developers and implementing bodies facilitate robust collaboration with and leadership of TB affected communities and civil society.

Shaun Palmer (TB Vax ARM): **The third win is that we will see TB vaccines and TB R&D more broadly integrated into antimicrobial resistance and other relevant global health agendas.** And what would this win look like? We'd like to see key AMR declarations, including at the United Nations High Level Meeting on AMR this year, prioritize TB vaccines; to see global, regional and national bodies explicitly include TB vaccines in AMR and pandemic preparedness strategies; and then, thirdly, to see national governments and multilateral initiatives issue AMR funding calls that support TB vaccine R&D in alignment with the WHO's call for accelerated development of TB vaccines to prevent AMR.

Shaun Palmer (TB Vax ARM): And so, when you visit the #Wins4TBVax page, we also share some of our plans as the TB Vax ARM that we hope to do, or that we plan to do, and also some ideas of what you can do. So, on our side as the TB Vax ARM, we'll continue to develop resources, campaigns, and policy briefs; we'll be liaising with representatives of relevant bodies and institutions, whether that be through open letter writing, consultations, or bilateral meetings; we'll be collaborating with civil society and community members advocating to key global agencies; we'll be supporting the development of a benchmark assessment for vaccine access plans; and we'll be contributing to increased TB vaccine literacy and demand generation efforts.

Shaun Palmer (TB Vax ARM): And what can you do as advocates? Well, you can find out what your country is doing to support global health R&D, and if you visit the website, we provide a few extra ideas on how you can do that; you can reach out to decision makers in your country to learn how they are supporting TB vaccine development and ask them to meet your country's fair share targets; and you can amplify, share, and adapt TB vaccine advocacy resources in your local context to raise awareness and work with other organizations. We always welcome any support from advocates in our network to help us with translations and disseminating these resources further. You can subscribe to our mailing list to stay up to date and let us know if you'd like to support us with any specific actions, or if there's anything we can do to help you in your own advocacy efforts. You can email me at the address on screen or via our regular TB Vax ARM communications.

Shaun Palmer (TB Vax ARM): On that note I'm very happy to welcome our first speaker to take the floor. Birgitte Giersing, team lead of vaccine prioritization and platforms at the WHO, who is here today to discuss some of the WHO's access initiatives as well as to provide some insights and updates on the WHO's TB Vaccine Accelerator Council. Birgitte, over to you.

Birgitte Giersing (WHO): Thank you, Shaun. Hello, everybody! It's great to be here. Thanks for including me on this panel to give you an update of some of the work we've been doing over the last few months and couple of years actually. So, you may be aware that WHO has been working with stakeholders in the TB community for some time to develop guidance for developers. Back in 2018 we produced [Preferred Product Characteristics](#) that set goals for vaccines in the pipeline around parameters such as efficacy, number of doses, delivery strategies, and so on. Following that, we commissioned work to assess the [public health and socioeconomic impact of TB vaccines](#) that meet those parameters that we set forth in in those characteristics. We've also participated in the development of the R&D roadmap that was published by the Amsterdam Institute of Global Health and Development.

Birgitte Giersing (WHO): And then, more recently, as the pipeline has matured as Shaun described, now with many candidates coming into late-stage development, we've really expanded our focus to start to prepare for success and to think about what is going to be needed to successfully, rapidly implement and deploy a vaccine when we have one that meets the needs of policy makers. So, most recently, we've [developed guidance on the data and evidence](#) that we think will be helpful to inform policy makers. So, after regulatory approval, really asking what kind of additional data and evidence will be needed for countries to make decisions to introduce a vaccine. And we've also [developed a framework to prepare for country introduction](#), and this was through extensive consultations with stakeholders at the country in the regional level.

Birgitte Giersing (WHO): And then last year we used the framework of activities that we need to be engaging in to prepare for implementation, to undertake a gap analysis to see where there were already existing entities [and] organizations engaged in preparing for implementation. And it's not going to surprise anybody on this call to learn that one of the major gaps that we identified was financing across the value chain. So both for R&D, as well as for procurement and delivery. And that really rose to the top of this analysis as the most important gap that we need to address. And this procurement and delivery gap is particularly concerning, because I know, as you all know, most of the high burden countries are not supported by Gavi financing. We're going to need some kind of alternative additional innovative financing mechanism to ensure some affordable supply and financing and market shaping efforts. And in addition, most of the vaccines in the pipeline and the population that we're really seeking to reach with new vaccines is adults and adolescents. This is a new population where we don't in many cases have established programs or mechanisms to deploy vaccines. And so we really need to also invest in health systems readiness for these new candidates as well as think through issues around vaccine acceptability to actually ensure uptake.

Birgitte Giersing (WHO): So, as you know, last year, the [TB Vaccine Accelerator Council](#) was announced. It was launched by Dr. Tedros at the World Economic Forum. And then in September of last year, the Council members were actually announced, and they were convened at the World Health Assembly. So, the purpose of the TB Vaccine Accelerator is really to foster high level coordination and alignment between funders, global agencies, governments, and end users, and really to address challenges in vaccine development, to accelerate development, and to boost the pipeline and funding within that. So, the Council members are composed of ministers from high burden countries but also from non-TB endemic countries, as well as heads of investment banks and donors. Civil society is represented, and we will soon be adding a TB survivor from the WHO TB Civil Society Task Force and the Stop TB Partnership is also represented on the Council.

Birgitte Giersing (WHO): In the last few weeks, we've been making progress on defining specific focus areas for the accelerator, and we will be reconvening in May. We hope to make some announcements at the end of May around the final objectives and milestones for the Accelerator. But for now, I can confirm that the proposed objectives are heavily focused on devising novel financing strategies, to diversify the pipeline, to push funding, as well as to identify novel market solutions or incentives to ensure investments are made into manufacturing and equitably distributing vaccines that meet the characteristics and the acceptable criteria of policy makers.

Birgitte Giersing (WHO): So, a lot of this work at that financing level is obviously going to be informed by what are the regulatory pathways? What are the policy needs? What are the manufacturers needing? What is the demand and acceptability of these vaccines. So, in parallel, we

are now looking into the feasibility of setting up the strategic Coordination office to pull, integrate, and coordinate all of these work streams across these different aspects.

Birgitte Giersing (WHO): In particular, we've been working with Gavi as they are in the midst of their Vaccine Investment Strategy, and you may be aware that in their analysis, so far,

TB vaccines for adults and adolescents rank highest in terms of potential health impact, value for money, and economic impact. The decision on whether or not to include TB vaccines in their Investment Strategy will be made in June of this year. But we are in the meantime in discussion with Gavi and others about setting up a working group as part of the Strategic Coordination Office related to mechanisms for shaping, financing, and access mechanisms. So, there's a lot going on, a very exciting time. We hope to have some more concrete information in the next two-to-three months to share with you. But a very exciting time, and I look forward to continued dialogue on this. Thanks, over to you, Shaun.

Shaun Palmer (TB Vax ARM): Thanks a lot, Gitte, for those updates. And wonderful to hear that actions under the Accelerator Council are moving along, and I'm sure I speak for all of us in saying that I look forward to hearing more on that in the months to come. It's indeed a very exciting time for TB vaccine development and delivery with so many unique efforts ongoing. And in many cases, TB vaccine is really a beta test for vaccine delivery for adults and adolescents. And there's a lot for us to learn from existing efforts to apply to TB vaccines. But TB vaccine delivery is going to teach us so much in the years to come.

Shaun Palmer (TB Vax ARM): So, we'll have time for Q&A at the end of the speakers' interventions, but some what building on Gitte's intervention just now I'm pleased to invite Rupali, associate professor at Johns Hopkins Bloomberg School of Public Health, and the lead of SMART4TB's TB vaccines efforts. Rupali is going to be sharing some of her insights from SMART4TB's work on ongoing country preparedness efforts. So, Rupali, please take the mic.

Rupali Limaye (SMART4TB): Thank you, Shaun. And thanks for the opportunity to be here. As Shaun mentioned, I'm here representing the SMART4TB consortium, which is a consortium of a number of different organizations, including Johns Hopkins, UCSF, as well as TAG. So, thank you for the opportunity to present some of our work.

Rupali Limaye (SMART4TB): So, I want to start, and it was so great to hear Gitte's update as well with regards to a number of developments especially related to the Council, with specifically related to advocacy at a very high level to ensure there's R&D along the whole continuum. When we're thinking about tuberculosis vaccines, I like to start this out as someone that works in vaccine acceptance, that vaccines don't save lives with vaccination does. And as we are thinking about the

ways in which we are, hopefully fingers crossed, going to have a number of TB vaccine candidates, it's important for us to think about what are the levers we need to think and really persuade people on to accept a TB vaccine?

Rupali Limaye (SMART4TB): COVID really changed the landscape related to vaccination and vaccines, and while there was a number of positive things that came out of the COVID pandemic, including new technologies, for example, as well as the use of innovation and utilization, I would say, of innovative delivery platforms, it also came with a number of challenges. In general, it really impacted trust in science, and more specifically trust in vaccines. And so, this is really changed. The landscape, with regards to how individuals in the public view vaccines, view vaccination, and view science and technology, broadly speaking.

Rupali Limaye (SMART4TB): And so, pre-covid, one thing that was really, I think, quite telling for us is that typically with regards to vaccine acceptance, there were really four main reasons why people may have concerns about taking a specific vaccine. Whether this is a paediatric vaccine, an adult vaccine, or an adolescent vaccine.

Rupali Limaye (SMART4TB): The first really had to do with vaccine ingredients. People had concerns about specific types of ingredients. We heard this during COVID, where individuals we know in many, many countries, we're worried about the mRNA products and what that might mean with regards to effects on one's body.

Rupali Limaye (SMART4TB): The second really had to do with the vaccine schedule. If you compare the vaccine schedule, particularly the paediatric schedule. From now until 10 years ago, we have a huge number of vaccines that we're asking parents to vaccinate their children with. And this has caused a lot of concern because parents are concerned. Does my child, need this many vaccines and this many doses?

Rupali Limaye (SMART4TB): The third really focused on risk perception. So, individuals that might be aware of a vaccine preventable disease might not actually know anything about it. We hear this a lot. Still, when we talk about measles and rubella, people will say I've never even seen rubella in my life, and even if I've seen rubella, I don't necessarily think it's severe enough to warrant an action, i.e., getting a vaccine.

Rupali Limaye (SMART4TB): And then the fourth driver pre-COVID really focused us on this idea of a link between vaccines and severe adverse events. This continues to persist across all swathes of society. In low- and middle-income countries, as well as high-income countries, related to the fact that vaccines may cause longer, not just acute effects, but longer effects that can really change development. For example, COVID then shifted this a bit more.

Rupali Limaye (SMART4TB): So, we still see these drivers when we think about vaccine confidence. But additional drivers were then added during COVID, unfortunately, and those really had to do with misinformation. So, this is misinformation not only transmitted through social media networks and platforms, but also transmitted, interpersonally related specifically to vaccines. The second had to do with polarization. Our world, unfortunately, has become increasingly polarized and more extreme in our views, not only related to science, but related specifically to vaccines. And the third, really focused on untrustworthiness, is what I like to call it. So, these racial and colonial underpinnings, with regards to science and really distrust in healthcare systems, has really impacted our ability to really reach the public with life saving products, including vaccines.

Rupali Limaye (SMART4TB): And so, for us, what's really important that we are trying to work on through SMART4TB is really to think about vaccine preparedness and the way that we have thought about this is really in 2 different ways. So, one is the demand side, right? How exactly do we better understand what are some of the drivers as to why people will or will not accept a tuberculosis vaccine or other vaccine products. The candidates in the pipeline are currently focused on adolescents and adults. It will be really important to think about what are the lessons from COVID, but what are also the lessons from HPV and the sort of the barriers that had to really be overcome with regards to HPV acceptance.

Rupali Limaye (SMART4TB): In addition to that, we also need to think about how health systems are really ready to deploy such a vaccine. COVID really tested the world's ability to deliver an adult vaccine at scale. We had never seen anything like that before. So, I am hopeful that we'll be able to use some of those innovative strategies to reach adults, to reach adolescents, and even to reach kiddos.

Rupali Limaye (SMART4TB): During COVID, in the TB space and so for SMART4TB, our goal is to really think about both of these factors. The demand side factors as well as the health system readiness factors, so that fingers crossed, when a tuberculosis vaccine is available, is pre-qualified, we do have Gavi support for all of the things that we need in line for people to be able to access this vaccine. Countries are ready and the public is ready, more importantly. So, we're trying to think about this holistically, not only about the beneficiaries that could get the vaccine, but those that influence them. So, healthcare workers, policy makers, religious leaders, community leaders, etc.

Rupali Limaye (SMART4TB): So, we're really excited that we'll start this year with this research in two countries – in Kenya as well as South Africa. And we will hopefully add two countries to our portfolio every year, moving forward, where we will really do a deep dive into this demand work as well as health system readiness work. So, thank you so much, Shaun, for allowing us the opportunity to present a little bit about what we're planning to do, and I'll hand it back over to you.

Shaun Palmer (TB Vax ARM): Thank you, Rupali, for sharing your insights on this work and for the updates on SMART4TB's efforts in particular. And I can only echo what I've heard you say before back in the Union Conference in Paris, that “vaccines don't save lives, vaccination does”. And you know, it's really clearly critical that we are engaging in this country preparedness and implementation research alongside late-stage development to avoid those costly delays when the vaccines are available, and learning from previous efforts that we've seen in COVID, and also with HPV. And you know, it's great to see all of this impressive work that is going on in the TB vaccine space.

Shaun Palmer (TB Vax ARM): But, as we know, TB is also well positioned in many other cross-cutting health domains, including notably in the AMR space. Yet, TB vaccines remain excluded from AMR funding and research instruments. With the High-Level Meeting on AMR taking place in September this year, we face a strategic opportunity to globally prioritize TB vaccines in this agenda as part of our broader efforts to firmly place TB itself in the global AMR agenda. So, I'm pleased to now invite Suvanand Sahu, deputy executive director of Stop TB, who has joined us today to share some insights on how we can advocate for TB vaccines in the context of this upcoming High-Level Meeting. Over to you, Sahu.

Suvanand Sahu (Stop TB): Thank you. Thank you, Shaun. And Good morning, good afternoon, or good evening, depending on from where you are connecting. This is something, as Shaun said, very timely, because the antimicrobial resistance UN High-Level Meeting is coming up in September this year. I thought, it will be good if I can share a few slides with you to talk about something that we often don't talk, and this is about vaccines, TB vaccines, when we are talking about AMR. I think all of you are quite convinced that TB is a major part of AMR. It is a major issue, and it has to be part of the AMR agenda. We often cite drug-resistant TB numbers. The latest numbers, as you may have seen, the global burden of disease of 1.27 million annual deaths directly attributable to AMR. And we also know from the World TB Report that 160,000 deaths are due to drug-resistant TB, so a big proportion of antimicrobial deaths are due to TB. So that case has been made, and we have to emphasize that point that AMR has to be considering TB as a center point of whatever is being discussed there.

Suvanand Sahu (Stop TB): We also know that TB is airborne, and we saw from the COVID-19 pandemic how airborne diseases can spread and create havoc if you don't control and don't put an end to drug-resistant TB. This can be a global health security risk. But the good news is that TB, as well as drug-resistant TB can be diagnosed, treated, and also prevented. Now before I come to the vaccine, let me just remind us that vaccine is not the only thing that we talk about in terms of progress. And in TB, there are several tools there, starting from diagnosis with rapid molecular test,

and new tests are coming like X-ray. And we saw the possibilities with AI there. Genomic sequencing as well. On the treatment side, we have seen great progress being made with new medicines. New treatment, shortened treatment, simpler treatment on the prevention side – a lot can be done. But probably we have not the full potential of what is possible.

Suvanand Sahu (Stop TB): We learned from COVID how airborne infection, prevention and control can play an important role. We haven't done that enough in TB, although there have been some attempts at that. There is also TB preventive treatment. We do that well for contacts of TB patients, but often forget that contacts of drug-resistant TB will require a special regimen. There are some guidelines about it, but often not well used, and more research is needed into it. We know that nutrition can be an important factor in preventing TB, the [RATIONS trial](#) has demonstrated it. And then let me come to vaccines. Vaccines are not yet there. Besides BCG, that we know. But once the vaccines are there it could have a big impact because it can prevent TB, but it can also prevent drug-resistant TB.

Suvanand Sahu (Stop TB): Now let me make a few things. So, a few points about vaccines. I think the point I wanted to make is vaccines can eliminate drug-susceptible TB as well as prevent drug-resistant TB. We have to think about it. That you know, research into new drugs is essential. They are needed. But we have also seen how over the past several decades and also the new drugs that once you start using antibiotics, you are bound to develop some resistance. The TB bug is very smart and develops resistance to antibiotics. For example, bedaquiline and delamanid. There is documentation in scientific papers about the levels of drug resistance to these drugs. Also pretomanid, there is some evidence of resistance development not in humans, but in animal models. So, whenever we have antibiotics being used, there will be some kind of resistance developing. So, the point I'm making is the only way to end, and for good eliminate drug-resistance is to prevent infections from developing and vaccines play an important role in that.

Suvanand Sahu (Stop TB): This is not just me saying it. There is a document from WHO, which probably in the TB space we don't discuss and haven't in my recollection, we haven't discussed this a lot. There is a document which says that vaccines have an important role in antimicrobial resistance and the role is very clearly defined in this document, if you look at the Global Action Plan on Antimicrobial Resistance amongst the tools that are included, there are not just the diagnostics medicines, but also vaccines. Vaccines can block the transmission, can reduce the levels of infectious disease, and thereby can reduce the use of antimicrobials, and once the use of antimicrobials decreases, naturally, the antimicrobial resistance will decrease. This is something that in the TB community we haven't talked enough, we haven't made any advocacy efforts to link the R&D happening in TB vaccines. And the ultimate rollout of TB vaccines that we plan to do that will have a

big impact on drug-resistant TB. And also because drug-resistant TB is such a big part of AMR, it is an important AMR tool that we have today.

Suvanand Sahu (Stop TB): So, the point I wanted to make with this short presentation is that we will do a lot of advocacy from Stop TB Partnership for antimicrobial resistance at the UN High-Level Meeting happening in September this year. In the run up to that there will be civil society hearing, the Multi-Stakeholder Hearing, and also negotiations on the political declaration. There will be several points during those events that we should be able to reach out to the stakeholders, to the co-facilitators, to the missions in New York, with some important messages. We will do it for TB and drug-resistant TB, but I think we should not forget that new TB vaccines should be an important part of that, because only through vaccines, we can put an end to drug-resistant TB, so vaccines, effective new TB vaccines can end and eliminate drug-resistant TB. Vaccines can prevent drug-resistant TB. Vaccines can reduce the need for antibiotic use, and therefore the research and development and the rollout of TB vaccines should be part of the AMR Agenda.

Suvanand Sahu (Stop TB): I also wanted to put it in context that I'm not saying that diagnostics and drugs are not important. But we have to realize that vaccines have a specific role, that it reduces the need for antibiotics. And as long as we don't depend on vaccines and prevention of infection, we just depend on diagnostics and drugs. Even if they are new drugs, they will at some point develop resistance. So,

I think we, all of us, should advocate for new TB vaccines, both for the R&D and the rollout to be part of the AMR agenda. There will be questions asked about why vaccines are not yet there. We don't know their efficacy, and that's fine, but I think we need to believe that our pipeline of TB vaccines will deliver. And as Shaun was saying, by 2028, that's the plan. The Stop TB Board had a big discussion on this, so 2028 there should be a vaccine, and the vaccine should play a important role in preventing TB, and therefore contributing in the antimicrobial resistance agenda. Thank you.

Shaun Palmer (TB Vax ARM): Thank you very much, Sahu, for your insightful presentation. And I think it's clear that just as we mustn't talk about combating AMR without talking about ending TB, we can't talk about ending TB without talking about the need for vaccines, which will play a really important role in preventing drug-resistant TB. And we look forward to engaging with Stop TB in support of our collective advocacy efforts ahead of the AMR HLM. And last year, as the TB Vax ARM, we developed a [policy brief on TB vaccines and AMR](#). We'll be sharing this in the follow up email. But I'll also just drop it in the chat for anyone who's interested, which is just there now.

Shaun Palmer (TB Vax ARM): Which brings us to our final speaker. Last, but not least, of the day. Maiko Tonini, Research and Project Management Advisor for HIV, TB, Viral Hepatitis, and STI's at the

Ministry of Health in Brazil. And Maiko has joined us to speak about Brazil's engagement in support of TB vaccine development and delivery, including as host country of the 7th Global Forum on TB Vaccines that will take place in Rio de Janeiro in October. Following Maiko's intervention, there will be time for a Q&A from the audience. So, if you have any questions, please feel free to drop them in the chat, or you can ask them after Maiko's presentation. So, Maiko, over to you.

Maiko Tonini (MoH/BRA): Thank you, Shaun. Thank you for this invitation to speak here today. It's always a pleasure to talk about the role we envision for Brazil as an advocate, an international advocate, for TB vaccines. And not only for that, for TB elimination as a public health problem and for equal access to health. So, it's easy for me to speak after everyone already did a great job explaining why we need TB vaccines, and this should be so obvious to everyone right now. And it is obvious to us here in Brazil. And this is why I hope today to talk a little bit more about what we have been doing on the international stage to push this agenda forward and also talking a little bit about our homework. What we are doing locally to ensure that people have access to proper healthcare, including TB vaccines available right now, and the ones that will be available in the future.

Maiko Tonini (MoH/BRA): So, Brazil is stepping up from very successful presidencies of the G20 group from Indonesia and India, and both countries have presented tuberculosis as a priority problem to be solved. And right now, we are also enforcing tuberculosis as a major concern internationally for the G20 group. Brazil's presidency of the G20 is focused around three foundational axes in healthcare. And these axes are to keep working towards the third sustainable development goal, the development goal that talks about health and wellbeing. And that's something that all countries should be working towards, also strengthening national healthcare systems for greater inclusivity, resilience, and quality, and finally, promoting health, equity, or health equality.

Maiko Tonini (MoH/BRA): These are all very aspirational objectives, and these are directives rather than aims. But the very first priority and the very first aim of the G20 presidency of Brazil regarding health care is the establishment of a regional production and innovation alliance among all G20 countries, and this initiative aims to foster innovation and production of vaccines, medicines, and diagnostics for diseases that affect mainly the impoverished populations and the most vulnerable populations among us. This alliance should convene governments international organizations, financial institutions, research bodies, and the private sector to create an ecosystem that promotes research development and equitable access to new health solutions.

Maiko Tonini (MoH/BRA): And only last Tuesday, I was at a meeting preparing for the National Conference of Science and Technology, which will take place next year, and we'll set the National agenda for Science and Technology for the next 10 years. Our Minister of Health, Nísia Trindade

Lima, spoke at this conference and she enforced that the COVID-19 pandemic exposed several vulnerabilities related to immunization and access to vaccines. And she also stated that an alliance among the G20 countries for the global production of vaccines is fundamental and will be a priority of the Brazilian G20 Presidency. What Brazil wants with this alliance is to decentralize the development and the global production of vaccines to face current and future health challenges, such as endemics, epidemics, and future pandemics. And in this process, ensuring equality of access to these new technologies, so that the global South will not be left behind again when new technologies become available.

Maiko Tonini (MoH/BRA): In this initiative, it complements and reaffirms the role of Brazil as co-chair of the WHO TB Vaccine Accelerator Council which aims to facilitate the development and the deployment of new and effective vaccines. So, we are aligning our local policies to our international advocacy on the international stage. Also, the Brazilian Government is committed to strengthening the local capabilities to produce health care related goods and reduce our dependency on the international markets, especially for vaccines. Our goal in Brazil is to fulfill 70% of the unified healthcare system needs for vaccines, drugs, and medical equipment by 2033 from national and regional manufacturers.

Maiko Tonini (MoH/BRA): To this end, Brazil is planning a robust investment program to develop the national Industrial Healthcare complex which was launched last year. And we'll have investments reaching 8 billion dollars until 2026. These investments include national development and production of vaccines and high-cost drugs, especially those that are aimed for socially determined diseases, such as tuberculosis. In this regard, Brazil has partnered with the World Health Organization to establish an mRNA vaccine hub at our state-of-the-art research institution, Fiocruz.

Maiko Tonini (MoH/BRA): So, the Ministry of Health is leveraging this partnership with WHO and the mRNA vaccine hub to fund the initial stages, to develop and test a new mRNA TB vaccine and diversify the current pipeline for TB vaccines. At the same time, we must never forget that TB is a disease with strong social determinants. This has necessarily to be tackled from different angles. It's not a single a problem with a single route. And this is why Brazil has launched the Brazil Saudável program, healthy Brazil program. It started last year, but was signed by President Lula this year, and it aims to bring together 14 different ministries acknowledging that tuberculosis has several different causes, and will not be tackled only by the Ministry of Health. It needs the Ministry of Science and Technology. It needs social inclusion. So, this is why we are bringing all these different expertises and these different political agendas around this common goal of tackling socially determined diseases. And this is all spearheaded by tuberculosis, by means of this Brazil Saudável program.

Maiko Tonini (MoH/BRA): In 2024, Brazilian states and municipalities with the highest burden of TB received an additional 20 million dollars exclusively to fund local actions and local initiatives to prevent, control, and for the surveillance of tuberculosis. Also, one of the main goals of Brazil Saudável, Healthy Brazil, is to foster science, technology, and innovation towards the elimination of TB and other socially determined diseases. Also, I would like to highlight here that Brazil has a very successful and resilient immunization program, and this program was always capable of reaching even the most remote communities in this vast country, including indigenous communities, original peoples which live in very hard to reach places and also impoverished urban communities.

Maiko Tonini (MoH/BRA): This is to highlight that we are capable to be early implementers of new TB vaccines. And I'd like to bring an example here, a current example of the implementation of the dengue fever vaccines which is underway in this country. We are the very first country, or one of the very first countries, to make this vaccine widely available and free of charge. The limitation here is not the capacity of the system to provide the vaccine, but the capacity of vaccine manufacturing. And we are ready to be early implementers of TB vaccines as soon as they become available.

Maiko Tonini (MoH/BRA): Last, but not least, I know I've run out of time, but I would like to share my screen now and talk a little bit about the [7th Global Forum on TB Vaccines](#), which will be in Brazil, and we are very proud to host this year. This is the very first time that the Global Forum on TB Vaccines will be convened in the Americas, and we are happy that this will be in Rio de Janeiro from 8-10 October 2024. The theme of this Global Forum will be *driving innovation from discovery to access*, and this aligns perfectly with Brazil's vision for tuberculosis vaccines. We think that innovation and new technologies should be linked to access. New technologies are virtually useless if they are not accessible by everyone, to all those who need them. We hope to see you all in Rio de Janeiro in October, in our beautiful Cidade Das Artes, the venue for this Global Forum. You see that this is a beautiful modernist building, which is a characteristic of many cities in Brazil. The call for abstract will start soon as well as the registration, and you can get more information about this at the [website of the TB Vaccines Forum](#), which you can access by this QR code in the corner of the screen.

Maiko Tonini (MoH/BRA): So, thank you very much, everyone, and it was a pleasure to speak.

Shaun Palmer (TB Vax ARM): Thank you very much, Maiko. It's really wonderful to hear about the many different ways that Brazil is engaged in prioritizing global health R&D, nationally and globally, and particularly with the holistic focus Brazil is taking on TB and TB vaccines, not least in the run up to the 7th Global Forum in October. I think we've seen in recent years the critical importance of high-level political championship in ensuring TB vaccines are a global health priority, and Brazil is certainly helping lead that way alongside countries such as Indonesia, India, and South Africa.

Shaun Palmer (TB Vax ARM): So, we have about 10 minutes left, and I'd like to open the floor to a round of Q&A from participants on the call. If you have any questions, please feel free to drop them in the chat, or raise your hand or unmute yourself and ask away. Peter, please go ahead.

Peter Owiti: Yeah, thank you very much. And thank you for this good webinar. My first question goes to Rupali. You said very well that vaccines don't save lives, vaccination does. And there was a number of communities and civil societies that underwent training with a number of nine modules actually. And they were now to move out and prepare the communities for the upcoming vaccine based on the on the lesson from COVID. And so, we want to prepare the communities from port to arm. At the same time these communities were capacity built, but they are not able to move out of the communities and prepare them for the upcoming vaccines. How are we going to make sure that vaccination saves lives based on that. Thank you.

Rupali Limaye (SMART4TB): Thank you so much for that for that question, Peter, and I think that your take on really thinking about the role of civil society, and I think other local organizations, has been so critical. I mean, I would say, Peter, one thing that we have definitely learned is because there has been such an increase in distrust towards the healthcare system, the importance and need to identify other messengers, just as you're mentioning. So, thinking about CSOs, thinking about other local organizations, such as faith-based leaders, for example, and other community leaders. And I think to your point, Peter, I think that any sort of vaccine preparedness plan has to think about how do we engage these? What do I call them? Non-traditional, non-healthcare worker type of messengers. For the mobilization piece, I think we've seen a lot with regards to where COVID vaccine uptake was successes really was because of a diverse range of messengers and stakeholders that really helped prepare the community, and my hope is that that will be the same process that's used for tuberculosis, and to not forget the lessons that we had during COVID. And so, I'm hopeful that many of these countries, in their preparedness plans will consider and will think about how do we engage with these specific types of different stakeholders that aren't necessarily those that are involved in the healthcare system, but that are from the communities that we're really trying to reach out to? So, I'm not sure if anyone else has comments on this as well, but I think what your point is, is really well taken, and again, I hope that we don't forget those lessons from COVID.

Shaun Palmer (TB Vax ARM): Thank you Rupali for that answer and Peter for your question. If anyone has anything they'd like to add, please do go ahead.

Suvanand Sahu (Stop TB): Can I, Shaun? Can I say something on the on this.

Shaun Palmer (TB Vax ARM): Absolutely. Yeah.

Suvanand Sahu (Stop TB): Yeah, I think in TPT, we have experience when we do a prevention activity, people are healthy. They're not sick with TB. When people are sick, they come to the health system for diagnosis and treatment. Then things work out fine. But when people are healthy and give example of TB Preventive Treatment to their contacts, we see a lot of hesitancy, not only on the contacts or the community, but also with the providers of care, who do not want to prescribe TPT. And this may be the case also for vaccines. Most of the vaccine candidate pipeline is similar, or even less efficacious than TPT, so I think it'll be good to look at what is going wrong in TPT and how we can address the TPT hesitancy. That will take us a long way towards being prepared for addressing vaccine hesitancy.

Shaun Palmer (TB Vax ARM): Thank you, Sahu. Just in an interest of time, I'll move along to the next question askers. Lew, would you like to go ahead? And then, after Lew we'll move to Evelyn.

Lewis Schragger (IAVI): Yeah, yeah, thanks very much, thank you, Shaun, for putting on this really interesting symposium this morning. I have a question for Dr. Sahu. I just wanna echo number one, the comments you made about the importance of TB vaccines and preventing drug-resistant TB. I think it is a message that is not widely accepted or appreciated. One of the things that we see from the TB vaccine development side is that there are grants that are available for development of interventions to prevent AMR, but they're not applied to TB vaccine development. And I'm wondering if you have a strategy, if you're thinking of a strategy to try to break some of those boundaries down and get a wider acceptance for the need to support TB vaccine development within the funds that are being put out to prevent the spread of drug resistance.

Suvanand Sahu (Stop TB): Should I go ahead, Shaun, and respond?

Shaun Palmer (TB Vax ARM): Yes, no, please do.

Suvanand Sahu (Stop TB): So, well, thank you, Lewis. I think that's important information as well as a question. I was not fully aware about it. But I think advocacy will need to be done with the funding sources for AMR to include TB vaccine research into it. I think this is something that we will also take up as Stop TB Partnership, but we will also need some guidance from our new tools Working Groups and the researchers in vaccine R&D, which are the potential donors that we should target our advocacy messages on. Maybe you are talking about some countries also like the UK that has championed AMR. Yes, I think that's a good opportunity for advocacy. But I think before that we have to be all aligned in the TB community, that we have to say that TB vaccines are important tools to end the drug-resistant TB epidemic. And therefore, it should play an important role in antimicrobial resistant. Yes, I agree. And this is an advocacy challenge for us. Thank you.

Lewis Schrager (IAVI): Yeah, thanks very much. I look forward to further discussions about that.

Shaun Palmer (TB Vax ARM): Yeah, and a similar challenge that we, as a the TB Vax ARM, have been exploring as well. Which funders are most strategic to target and which funding mechanisms may be most amenable to supporting TB vaccine development, if not TB research more broadly.

Shaun Palmer (TB Vax ARM): So, we have a few minutes left. Evelyn, I'd like to give you a chance for you to ask your question, and then maybe we'll have time for one more.

Evaline Kibuchi (Stop TB Partnership Kenya): Yeah, thank you very much. Mine is very brief. I hope you can hear me. Yeah, I followed Maiko's presentation and he talked about towards TB elimination, and I know in the End TB Strategy we talk about ending TB. So, I just want to be sure whether we now with advocacy around vaccines, that we are talking about elimination and not ending TB. Are we now shifting the language. I just want to be sure about that. Thank you.

Maiko Tonini (MoH/BRA): Thank you for your question. It's a great opportunity to clarify this for Brazilian public policy. When we say elimination, what we mean is bringing the incidence of new cases under 10 cases per each 100,000 people in the country. That's what we would call elimination as a public health problem and also decreasing mortality related to this disease to less than 10 cases per year. So, by this I mean 200 cases per year in this country. So, for Brazilian public policy purposes, this is our goal to be achieved until 2030. And this is what we refer to as elimination of TB. This is our main goal for the TB in Brazil today.

Shaun Palmer (TB Vax ARM): Thank you, Maiko. I think an important clarification for people to think of as we think of how we define eradication, whether at the global level or national levels.

Shaun Palmer (TB Vax ARM): We're pretty much at time, so I don't think we have time for another question. But I just wanted to thank everyone for joining the call today, and especially to our speakers for joining and sharing your own insights on these really critical topics around TB vaccine development and delivery. Thanks again to Priyanka for your very much welcome tech support. And I see a one or two extra questions in the chat. We'll do our best to respond to them, either in the follow up email or future calls... We'll be sending a follow up email early next week. We'll do our best to answer remaining questions in the follow up or in our next calls. If you haven't yet joined the [TB Vax ARM mailing list](#), we encourage you to do that at the link that was just posted in the chat, so you can stay up to date with future advocacy efforts and activities. If you would like a recording of the webinar, if you could just send me an email and then I can send that to you specifically, and I hope to see you all at future TB Vax ARM webinars. Thanks again!