

TB Vax ARM Webinar

July Webinar – Transcript

Tuesday, 16 July 2024

Shaun Palmer (TB Vax ARM): Okay. We're at three past the hour, so I think we can begin while others slowly join the meeting. Thank you, everyone, for joining the call this morning, this afternoon, this evening, wherever you may be joining from, I'm Shaun Palmer and this is the latest [TB Vaccine Advocacy Roadmap](#), or TB Vax ARM, webinar.

Shaun Palmer (TB Vax ARM): If it's your first time joining one of our calls, just a quick introduction to the TB Vax ARM. We're a global coalition of TB stakeholders, including TB survivors, civil society organizations, non-profits, and researchers, who are invested in TB vaccine advocacy and research. And together we seek to provide coordinated advocacy efforts that are complementary to ongoing TB vaccine research and development and policy efforts. We hold regular webinars, such as the one today, with partners from around the world, and we're pleased to have you all here today. And just before, I added in the chat a link to the [subscription to our mailing list](#) where you can subscribe, and I'll post that in the chat again for those who have just joined, so you can sign up for our regular updates and be the first to hear about our latest webinars and news.

Shaun Palmer (TB Vax ARM): So, we've convened the meeting today with TB vaccines continuing to be firmly in the global spotlight with quite impressive efforts underway with the [TB Vaccine Accelerator Council](#). The [7th Global Forum on TB vaccines](#) will soon take place in Rio de Janeiro in October, and there was the announcement in June of the inclusion of new TB vaccines in [Gavi's Vaccine Investment Strategy](#).

Shaun Palmer (TB Vax ARM): So, we're joined here today by several speakers who will be sharing updates on these key activities. First, we'll have Mike Frick, TB program co-director at [Treatment Action Group](#) who will share some updates on the Accelerator Council. We'll then be joined by Ignacio Esteban, a manager in the policy team at Gavi. He will speak about the inclusion of new TB vaccines in Gavi's Vaccine Investment Strategy. Peter Ng'ola Owiti, a member of [Gavi's Civil Society Steering Committee](#), among other boards such as Stop TB Partnership and the Working Group on New TB Vaccines, will also join to share some community perspectives on this much welcome announcement. And then finally, Ishan Bhatkoti, Advocacy and Communications Officer at [Stop TB](#), will update us on the [UN High Level Meeting on Antimicrobial Resistance](#).

Shaun Palmer (TB Vax ARM): There'll be an opportunity to ask questions and share your own thoughts after each speaker. We just ask you to please raise your hand via the gesture button at the bottom of Zoom, or just drop your question in the chat and we'll make sure that the speakers give you a response. So, without further ado, I would like to invite Mike Frick to the microphone to share some updates on the Accelerator Council. Mike, over to you.

Mike Frick (TAG): Alright. Thanks, Shaun. Hi, everybody. Hi from New York. Great to see everybody this morning. I'm just going to pull up some slides. I made a quick presentation. Shouldn't take too long. Let me just make sure they're in the right mode. So, I think there's been a lot of interest in this new entity that's called the WHO TB Vaccine Accelerator Council. And as one of the civil society representatives to the council, I thought it would be a good opportunity to update stakeholders and community and civil society about what the Council is, who the members are, what it's been up to so far and where it's going.

Mike Frick (TAG): So, some of this may be known to you already and other pieces of information may be new. But just so that we all have the latest information moving forward on this new global group hosted by WHO. So, to give you a bit of background about what the council is and where it came from, this was an initiative announced by the WHO Director General for the first time in January of 2023 at the World Economic Forum in Davos. There was an event there where he announced the intention of WHO to set up this group.

Mike Frick (TAG): And for a long time, there were a lot of questions. What is this group? Who's going to be on it? What is it going to be tasked to do? And that really started to come into clarity on the sidelines of the second UN High Level Meeting on TB in September of 2023, where the council was established. That was sort of the first time that the group was convened in New York. And then the Council, in a sense, held two, what they call, High Level Meetings. One was virtual, which happened toward the back end of last year, and the second meeting was held recently in May of 2024 on the sidelines of the World Health Assembly.

Mike Frick (TAG): And I think the WHO has [a website](#) where they had provided some good information on the Council and its membership, which I encourage you to check out. And they've been updating this periodically. But the role of the Council and its mission is really to foster high level coordination and alignment between funders, global agencies, governments and what they've termed end users, beneficiaries, people who need new TB vaccines, on the important challenges in TB vaccine development and to take action and provide advice on the actions that are needed to address them. And the vision of the Council is really to boost the TB vaccine pipeline and to facilitate approval, access and use of effective new TB vaccines as a critical step to halt the epidemic. So, the mission is really in the name itself - acceleration. And as you can see from these statements, the Council is not only focused on research or only focused on access and implementation, it's addressing both.

Mike Frick (TAG): So, the idea is to accelerate the pace of research and development to ensure there's a healthy pipeline of vaccine candidates that they progress through clinical trials, that those trials generate the evidence needed for strong WHO policy recommendations and licensure, and that there are mechanisms in place to pick up those vaccines that reach those milestones and make them accessible to people in need.

Mike Frick (TAG): And the membership of the Council, it's really a ministerial level body at a certain level and composed primarily of government representatives for most countries, that is,

representatives from Ministries of Health. It also includes representatives of multilateral agencies, major funders, development banks and community and civil society. So, on this next slide, I'm just providing you an overview of the membership. The Council at the current moment is co-chaired by the Ministers of Health of Brazil and Indonesia. And then other countries that are represented at the ministerial level include France, Kenya, Vietnam, Pakistan, South Africa, the Philippines, and the United States, which is represented by individuals from the National Institutes of Health. And then you have other partners, including at least three development banks, the European Investment Bank, the World Bank, and the African Development Bank. You have major funders like the Gates Foundation and Wellcome, your multilateral agencies, GAVI, Global Fund, UNITAID, Stop TB Partnership.

Mike Frick (TAG): And then there are seats for civil society. I'm occupying one of the civil society seats. My understanding is that there will be a second seat that will be filled at a certain point in time. I don't have information on who that person is yet. Maybe some of you know more than I do on that front. I believe that that person will be nominated from the Civil Society Task Force at the Global TB Program at WHO.

Mike Frick (TAG): One other thing about the membership to appreciate is shown on the right side of the screen, and this is sort of about the governance of the council. It's been organized into what are called sort of a Ministerial Board and a Principal Group. And basically, as I understand it, the Ministerial Board, that's the government representatives. This is a WHO initiative, so the emphasis is on member states and the actions that governments in WHO member states will take. And then there's a Principal Group which includes the other stakeholders, the multilateral agencies, the development banks, the funders. And so that's how the Council is sort of set up.

Mike Frick (TAG): The next slide provides you a little bit of information on the second meeting that the Council held in May 2024, this was a meeting on the sidelines of the World Health Assembly. It was a short event, 90 minutes to 2 hours long. And the purpose was really to review and endorse a document laying out key goals and milestones for the council's first term of work, which will be 2024 into 2025. And this document was informed and shaped at previous meetings of the Council in September 2023 and November 2023, and really crystallized into three high level objectives which I'm sharing on this slide here. The first is to accelerate the diversification of the TB vaccine portfolio by facilitating translational and clinical research. And under this, there are milestones to develop financing strategies for research by which they've specified this will primarily be financing strategies focused on push funding, things like grants, that sort of thing, and to catalyze new investments across the research continuum.

Mike Frick (TAG): The second high level objective is, I think, where a lot of attention will focus on the immediate future and is probably of most excitement to many here. It's to accelerate the identification of market solutions, to incentivize late-stage development, ensure scalable production, procurement, and equitable and affordable access. And the milestone under the second high level objective is to develop and launch what's called a pull incentive mechanism for vaccine procurement and late-stage development. So, this would be something like an advance market commitment, an

agreement for pre-purchase, some kind of financial platform that could de-risk all the activities that need to take place in manufacturing and supply to have a plan for buying vaccines and making them available once they show safety and efficacy in late-stage clinical trials. And this pull incentive mechanism would obviously be something that's new to the TB vaccine field, something that we don't have yet.

Mike Frick (TAG): And the third high level objective is to accelerate implementation and uptake. And here the milestone is to develop what's called a costed learning agenda, which would be a sort of suite of research and other readiness activities to support vaccine preparedness. So, this will be the three high level goals that the Council is working toward.

Mike Frick (TAG): And you can see in the milestones some of what, concretely, the Council has in mind in order to set up and establish in terms of immediate next steps. The work of the Council itself will be undertaken and coordinated by a Secretariat or a Strategic Coordination Office that will be sitting and working closely with WHO. And to that end, WHO this month published a request for proposals to identify organizations or groups that would like to play the function of the Strategic Coordination Office. So the deadline for responding to that RFP is July 29th, and I put the link to the UN contracting site there where you can read more about it. The hope and aspiration is that the group selected to play this function will be from or have very strong ties to the Global South or high TB burden countries, places where vaccine research is likely to take place.

Mike Frick (TAG): And I think that's something that we in civil society can watch and encourage and push for. As I understand it, the Secretariat Office will then establish strategic and technical working groups, which will work with the Ministerial Board of the Council and the Principal Group to take forward the actual work toward these three high level objectives. And these technical working groups will either be new, where we need to create something that doesn't exist yet, or could potentially make use of existing platforms where they might already exist because the TB vaccine world is pretty organized. We have a lot of groups and bodies such as the TB Vax ARM group on the advocacy side, groups on the scientific side. And so, we're already very well networked and we don't necessarily need to create things from scratch or reinvent the wheel. And so, I think part of the goal of the Secretariat will be to decide where we need to create something new versus where we can work with something that already exists, a structure that's in place already.

Mike Frick (TAG): At the second council meeting, the WHO shared four main work streams, what they called work streams or thematic areas. That will be the focus of some of these groups. And these include vaccine science and research, product development, manufacturing and policy access, strategy and financing. And then the fourth, which I think is really interesting and nicely phrased, country delivery, readiness, advocacy, and trust.

Mike Frick (TAG): The second high level objective, to develop that pull incentive mechanism, as part of that, there was an idea shared at the Council meeting. The idea hasn't yet been confirmed. So don't take this as a statement of intention, but just as an FYI, or something to watch out for. There's an idea to hold a potential conference in 2025 on TB vaccine financing, and at this conference there

would be options presented for what a pull mechanism could look like. The idea would not be, I think, to hold a separate financing conference. Next year is obviously really busy with financing meetings, with Global Fund replenishment, UNITAID replenishment, other big replenishment drives and efforts. And so, this would probably be synched to align with those without competing with them and would be held on the back of a kind of existing meeting on the calendar, G20, G7, one of these things. Perhaps there are also some plans at WHO to do some country level workshops and meetings on vaccine preparedness and readiness.

Mike Frick (TAG): I think that's my last slide. Yeah. So happy to take questions on the Council and its work and things are still coming into shape as you can see. But I think the picture has gotten a lot more clear than it was this time last year, even in September at the High Level Meeting. Back to you Shaun and I'll stop screen share.

Shaun Palmer (TB Vax ARM): Thanks, Mike, for that really comprehensive overview of where the Accelerator Council stands right now and what does finally seem to be some really concrete developments. And hopefully by the end of the year we'll have more clarity on who will be leading that secretariat and what kind of more concrete deliverables can be expected out of those various working groups as well. I see Katy, Katy Wright, has her hand up as well. Katy, do you want to go ahead?

Katy Kidd Wright (GFAN): I do. Sorry, it took me a minute to find my controls. Thanks very much. Hi, everyone. I'm Katie Kidd Wright from the Global Fund Advocates Network. This is my first of these calls, so I'm really glad I was able to join today because Mike, I heard about your role on this particular body, and I've been curious about sort of how it's working. And I just wondered two points. One, would it be helpful to have a bit of external advocacy to, like quicken up the other civil society kind of position and make recommendations around affected communities potentially being seriously considered for that, given, you know, where you are. So, there is a balance of civil society and affected communities. And then so just a question as to whether that would be helpful to have some external facing, you know, some external advocacy to support that because as a standalone CSO rep, sometimes that gets a bit lonely, but also it gets to be a huge burden.

Katy Kidd Wright (GFAN): Right. And then secondly, with the recent start of adoption and rollout around these new malaria vaccines, I wondered whether or not colleagues here where you might have been having conversations with malaria, CSO and community colleagues about both the pre-rollout process, but also how the early rollout is going, to see if there are any lessons learned. This is a conversation that I've wondered whether or not it's happening. I wonder whether or not anybody is better placed to facilitate them than myself, because I don't actually sit within this community very often, but just wanting to know if that's happening and whether that would be useful to see if we could drum up some support and information both for you, Mike, but also whomever the next rep from some of communities is. Thank you.

Mike Frick (TAG): Yeah, great questions. I'm really glad I won't be the only civil society representative. I think on the first question about whether advocacy to speed up the selection

process for that second person would be helpful or not. My sense is that like the intention to have somebody is there, it's not a fight about filling the seat. It's just a matter of process. And I know and I do believe that that seat is meant to be filled by somebody from the CSTF, the Civil Society Task Force at Global TB, and I know that group was reconstituted. There was a call for new members that concluded a month or two ago. It's probably just a matter of time to get them oriented, to have them develop a process to nominate someone or select somebody from that group. So I think in terms of advocacy, maybe not like a push, but like a polite email or letter to the Global TB Program and the CSTF, just to get an update, I think couldn't hurt and would confirm that indeed that's the plan and that my understanding is right.

Mike Frick (TAG): The second question. Yeah, I would... if those conversations are happening with malaria CSO representatives on the experience of rolling out our RTSs and now R21, the new malaria vaccines. I'm not a part of them. But I would love to talk to people in the malaria field from community and civil society and learn about their process, which I understand has been rocky in moments and a bit of a rollercoaster ride. I think that would be super, super valuable. And the more that we can bring TB and malaria together to kind of share some lessons, cautionary tales, things that can be done differently, would be great. And so if you can help facilitate that, or I know there are colleagues here from the Global Fund, CSO Networks, I see on the line, that would be wonderful. Thanks.

Shaun Palmer (TB Vax ARM): Thanks, Katy, for that question. And you know, on the learning from community members and civil society members in the malaria vaccine space, you know, these are similar suggestions that have been raised, I think, regarding COVID vaccine rollout, but also HPV vaccine rollout too. And it's something that those engaged more intimately in their country readiness work that is ongoing by SMART4TB among many other groups, I think can speak better to about how they might be engaged moving forward. But a great point to raise. And Ezio, you have your hand raised as well, and then after this we will move on to the next speaker. Ezio, please go ahead.

Ezio Távara (REDE-TB): Thank you. Finally found where the hand raise was, it was kind of lost in my screen. So many people. Thank you, Shaun. Thank you, Mike, for this great update. And for your work. I would just like to highlight something that I said a couple of weeks ago in Geneva in the UNITAID's meeting. It's that I have the sense that we are a bit, how to say, distant from the major developers and major actors from the Global South, which are BRICS members, which are not very much represented in this in this initiative, like we have to strengthen this participation. I think that there is a lot of development and vaccine progress also in India and BRICS countries. I think that they are a great place, field, to explore and probably strong donors. Possibly with strong donors. So we have to widen this cooperation. I mean, among the members, I think it's a great opportunity to do that. I think this advocacy also has to play a role in this whole process. But I think we can progress a lot. So I think I see that as a great opportunity for us all, so that we could interact more and include some other representatives. Thank you.

Mike Frick (TAG): Totally agree. And I believe that if countries were to express strong interest and wanted to join the Council and get involved, the door would be open. Right. There's not like a cap on political interest or will to join the group. And as you point out...

Ezio Távara (REDE-TB): It's important we highlight that because we have the sensation that we are talking from four different publics. There is only one public, which is people affected by TB, and the other half of the burden is in and among the BRICS countries. So, I mean, how can we talk when the half of the problem is not very well represented? Okay, Brazil is there but the highest burden among three other countries of the BRICS, or four, so I think we have to have a room to explore that and work closer, but thank you, I totally agree, thank you.

Mike Frick (TAG): Thanks, Ezio.

Shaun Palmer (TB Vax ARM): Thanks, Ezio and thanks again Mike. So, I'll now call on Ignacio Esteban from Gavi to share some updates and insights on Gavi's recent decision to include new TB vaccines in the Vaccine Investment Strategy. I see a question in the chat that I think somewhat relates to Ignacio's talk, and will revert back to that question after the presentation. So, Ignacio, over to you.

Ignacio Esteban (Gavi): Great. Thanks, Shaun, and thanks everyone. Hi, from Geneva. We're very happy to be here to present to you about the recent updates around Gavi's role in the TB vaccine world. So, first we would like to start the presentation of today's meeting with this great news that Shaun told you about and you probably heard about already, is that in June, last June, the Gavi Board approved our next five-year strategic period and one of those approvals was support for new vaccines. And within those vaccines we have the approval, in principle, for our new vaccines for TB, for adults and adolescents.

Ignacio Esteban (Gavi): So, what we would like to present to you is how this decision was made, what are the basis for the decision and what it entails, and what our expected next steps are as well. And we're happy to take any questions at the end as well. So, this decision was part of the Vaccine Investment Strategy. This is the evidence-based approach of the Gavi Alliance to try to identify the immunizations investment for our next strategic period, in this case will be for GAVI 6.0 from 2026 to 2030, which is conducted every five years. It takes around two years and is based on a transparent methodology that is publicly available for anyone interested, on our website. So, a white paper, and it's based on an analytical review of evidence on multiple modeling exercises, including price forecasting, health and bank modeling, and the economic impact as well, and is based on multiple consultations, as you will see in the next slide.

Ignacio Esteban (Gavi): And its main objective is to provide strategic decision making, to provide to the board the best available evidence for them to make the best-informed decision of which investments Gavi should include into our portfolio. It also aims to provide predictability to countries, donors, to have long term planning of the vaccines that will become available hopefully one day for our portfolio. It informs our strategy, and it also informs how much money we'll need for the next

strategic period. So, it informs our resource mobilization. And there are different types of investment that can result out of this process.

Ignacio Esteban (Gavi): One is a vaccine program, a traditional routine immunization program, but also global supplies, and also the support for learning agendas as well. So, in terms of this assessment that was conducted in the last two years for tuberculosis vaccines for adults and adolescent, was conducted in close collaboration with multiple technical partners that you can see in the slide. And probably some of you are here on the call today. And it was based on multiple criteria of decision analysis using different workstreams, such as demand forecasting, impact modeling, price forecasting. Another multiple quantitative analysis, such as value for money, procurement cost, and also qualitative analysis, such as what is the epidemic potential of each of the diseases that were compared to. What is the impact on AMR? What is the impact on climate change? What is Gavi's comparative advantage in this vaccine in terms of what could be market shaping opportunities for GAVI and these particular vaccines? And this process was based not only and informed on multiple technical consultations, but also we heard from countries from civil society, we heard from alliance partners, and from manufacturers as well, to try to provide to the board the most informed, best available evidence for them to make the decision on what vaccines to include in the future.

Ignacio Esteban (Gavi): And now, just to provide you a quick overview of what the investment case looks like. And just to tell you all the slides on all our TB vaccine investment case are going to be available on our website very, very soon. But in order to come up with this analysis, including, for example, demand forecasting, health impact modeling, we had to come up, through our consultations, with different vaccination strategies to try to reflect this expected impact.

Ignacio Esteban (Gavi): So, just a quick overview. This is what the primary vaccination strategies we used for our analysis were. Our primary strategy was a routine immunization program with two doses separated by one month vaccination, and at 15-year-old. But we also look at alternative strategies, such as a one dose of 14-year-olds and also one of catch-up campaigns for a narrow target range, adolescents, and a more broad one up to 44 year olds. And on the assumptions that the decisions that this analysis was based on will be publicly available. And you will see that I will help you to take any questions as well.

Ignacio Esteban (Gavi): And just to show you more examples of what the analysis entailed and how the final decisions were made. This is the demand forecasting where we first looked at country interactions based on multiple inputs and countries experiences in country readiness. We looked at how many countries would be expected to introduce this new vaccine in the next ten years. And then we also looked at volumes, how many doses would be expected to be needed in order for this vaccine to be introduced and implemented successfully? And all this information, the volumes, the demand, and the price forecasting, all fed into the financial implications for Gavi and countries as well. That was presented to the board in June in order to make this final decision, the inclusion of TB vaccines within our Vaccine Investment Strategy.

Ignacio Esteban (Gavi): And this is to show you part of the analysis that we conducted for health impact modeling. Health impact was based on the model from the London School and the Boston University, where we looked at how many deaths would be expected to be averted if a new TB vaccine is introduced in Gavi countries. So, we're looking at a total of 230K total deaths averted in the next ten years. And we also looked at disability adjusted life years averted. And all of this information allows us to compare different investments within the Vaccine Investment Strategy 2024, but also against our current portfolio to try to make the best decision.

Ignacio Esteban (Gavi): So, this is a slide where we compare them. In orange, you can see the different candidates that were included in the Vaccine Investment 2024, but we also compare deaths averted per 100K to our more recent investment decisions, such as the Vaccine Investment 2018 where you see rabies and the Hep B. And in green at the top down you can see our existing portfolio. This was to provide to the board how this potential new investment was ranked to each other. And the next slide summarizes the same information for disability adjusted life years as well.

Ignacio Esteban (Gavi): So, coming back to where we started, we are very happy to share with you that the board has now approved the inclusion of TB vaccine, a new TB vaccine for adults. One of the lessons I wanted to give you a little more detail about was what the decision actually entailed. So, there were three main decisions made at the June board, and the first one was to approve, in principle, support for our TB vaccine program, contingent on the availability of a licensed product for adults. One of the lessons outcomes of our regulatory and technical review process and meeting the financial assumptions used as a basis for a TB investment case.

Ignacio Esteban (Gavi): So, to go into details of this, this is an *in-principle* decision. This is a strategic decision to give Gavi the mandate because as you all know, the TB vaccine for adults and adolescents is still not available. And also to clarify that any kind of investment is contingent on the availability of this licensed product, but also that it needs to have a [WHO prequalification](#) and [SAGE recommendation](#). Once there is further clarity on all this policy on regulatory pathways and also on the clinical pipeline of the vaccines, we will have to go back to the board to present the final investment case. And that would allow us to start with program design as well.

Ignacio Esteban (Gavi): The second key point of this board meeting in June was that it was acknowledged that Gavi needs to continue exploring together with partners and WHO on the Accelerator Council, the design of timely market shaping interventions aimed at assuring that TB vaccine supply matches anticipated demand with a minimal lag. And the third key decision point was to approve Vaccine Investment Learning Agendas. The Learning Agenda for Tuberculosis is included. This is our research process to try to fulfill key evidence gaps that will inform our program to implementation. So, with that, I'll handover now to Nidhee. They are from the policy team as well, and will quickly talk you over our potential next steps on all of the information that I presented. Thank you.

Nidhee Jadeja (Gavi): Thanks, Nacho, and hi, everybody. Just to briefly walk you through the "what next" question, as Nacho explained, the process up until now really involved extensive stakeholder

consultations and analysis to help us develop and refine the investment case that we presented to the board. And we have an *in-principle* decision that really, really reflected their recognition of the work that needs to start to take place now at a global level to ensure that that we have success once the vaccines are entering the market.

Nidhee Jadeja (Gavi): And as Nacho said, we will be having to come back to the board once a PQ [prequalification] is in sight for these novel vaccines. And so, a lot of the work now is about getting an understanding of being able to fill in the gaps and refine our understanding of what a vaccine program could look like and what will be the ask, essentially, of the Gavi board once we come back with a refined investment case and ironing out the further programmatic details. We really do rely on WHO PQ and SAGE recommendations, and they will really inform and guide what the program will look like.

Nidhee Jadeja (Gavi): And so, in terms of timelines and if the expected product development timelines are met, we're anticipating WHO PQ and SAGE to hopefully occur around 2028 or during the mid-to-late 6.0 period, in Gavi speak. So, it's really all hands-on deck now. And we're very much coordinating with WHO. We're part of the Accelerator Council that Mike talked to us about. We're working with partners as this global momentum is really increasing to prepare for these vaccines. And our market shaping colleagues are working closely with the manufacturers to prepare these vaccines for market entry.

Nidhee Jadeja (Gavi): As was alluded to, a key part of understanding and filling in the gaps for the final board decision will be addressing the learning agenda. What that means is key data and evidence gaps and also understanding what the advocacy needs will be ahead of these program launches. And it's very much a joint coordinated effort across stakeholders. We are already starting to pick up, as Katy had alluded to, early learning lessons from the malaria experience, but also our other vaccine programs like HPV, where we had to introduce into an, albeit earlier, adolescent time point. But nonetheless, there are some, some good learning lessons to capture that. And we really look forward to working with you as civil society partners as part of those overall reflections to help us improve and inform the future TB vaccine program planning.

Nidhee Jadeja (Gavi): I think it's important to also state that from Gavi's perspective, we really do view these vaccines as a complementary tool in the suite of existing TB prevention and control interventions. And part of a planning for the program and addressing prioritized learning agenda questions will be about understanding the best ways that a vaccine can fit and integrate into existing TB control programs... can fit into the existing country immunization and TB control programs. And so, we really will be working with all partners to get a better sense of how we can best optimize the use of the vaccines alongside our other interventions. So, we really look forward to working with you all towards a successful rollout and hearing your ideas and feedback. So, thank you very much.

Shaun Palmer (TB Vax ARM): Thank you, Nacho and Nidhee for that presentation and providing some more insights on how the decision-making process worked and what it might entail for TB vaccines moving forward. We'll have some time for questions from the audience in just a moment. I

first of all just wanted to hand over to Peter Owiti, who's on Gavi's Civil Society Steering Committee, to share some perspectives from the community network. Peter, over to you.

Peter Ng'ola Owiti (Gavi CSO Steering Committee): Yeah, and thank you, everyone. And we're happy to be here. As has been said, my name is Peter. I am based in Kenya and I'm one of the CSOs in the Steering Committee in GAVI. And I [inaudible]... already covered what was in the strategy and in the board meetings. And we as civil society has been mentioning in a few statements that the world is very expectant of the TB vaccine because we haven't had new vaccines for 100 years. And so we are expecting that we get the vaccine as early as 2027 so that we can prevent this infectious disease. And therefore, in that excitement as communities, we don't want to go through the problems that we had with COVID vaccines, that we must be prepared so that we have from port to arm. That immediately the vaccines have been approved, then they are able to be accessed by everybody.

Peter Ng'ola Owiti (Gavi CSO Steering Committee): And that brings in the issue of price, that we know Gavi is going into replenishment, and we know we are heading to a year of replenishment. But in 2024, up to 2026, there's a lot of replenishments going to take place... Global Fund. And also do we have that issue of climate? And so it is that the money is not just enough, and we know that vaccines will be more expensive before any market shaping takes place. So, we are cognisant that after ARVs were discovered, it took a long time to come to Africa or to the people who needed it most because of their pricing. And that means that those people who need tuberculosis vaccines must be able to push their countries to be ready to procure or ready to make arrangements early enough so that those vaccines reach as fast as possible to the communities and the people who need it most.

Peter Ng'ola Owiti (Gavi CSO Steering Committee): That, again, means establishing the health system. We know vaccines have to be stored in cold places, so the cold chain has to be prepared as well in advance. We know there are some funds that have been provided by COVID platforms. The countermeasures, the medical countermeasure platforms, and the qualities have been developed. But there is need also to expand it to areas particularly difficult to access. And there was something else about the eligibility. We know Gavi has been pushing for eligibility based on the GNI, but at 2700 we were thinking it can be lowered a little bit also so that as many countries are eligible to access the vaccines. The issue of involving communities at an early stage and right from the planning. We who were in the COVID vaccine knows that health systems strengthening, and community engagement always is an afterthought.

Peter Ng'ola Owiti (Gavi CSO Steering Committee): And therefore, if we have learned our lessons that we engage the communities. And I am glad we are always finding our spaces as in global health initiatives better than it was before. But that's something that we can build up so that the communities are part of the planning so that we don't have to ask many questions, we don't have to have a hesitancy and push backs when the vaccines come in. We are learning from malaria vaccine, that the malaria vaccine has been there, but that malaria endemic areas are quite wide. But why the

slow uptake of the vaccine? Of course, one vaccine is more expensive, and countries say they can't afford it. They feel they would save costs by just treating malaria without taking the vaccine.

Peter Ng'ola Owiti (Gavi CSO Steering Committee): Now, the other issue is the number of doses that the children have to undertake, and those bring a lot of complications. And that is lessons that in advance we have to prepare for, are for the adolescents and young people who are going to take the TB vaccine, that we have to make sure that these vaccines are able to reach that kind of population. And lastly, I want to talk about the authorization. We know that in endemic areas, the Global South, sometimes the authorization of the vaccines takes much longer. And so, we were talking in the Lusaka Agenda that the authorization should be regional, so that the AMA authorizes first for the African region instead of each country authorizing. And then we have the slow... like we are doing with malaria, where Ivory Coast has already gone ahead, and some countries are still behind. That's an area that we need to look for.

Peter Ng'ola Owiti (Gavi CSO Steering Committee): And lastly, I want to talk about the demand creation. And this is where I feel looking at 78 people attending this meeting, quite a number of us are communities and we want to spread out the platform and we become part of the demand creation early enough so that when the vaccines eventually arrive, we want the smoothest uptake and use case in this particular vaccine because of the time it has taken to get the vaccine. Thank you very much.

Shaun Palmer (TB Vax ARM): Thank you, Peter, for sharing those many important reflections and perspectives. And I'm sure Nidhee and Ignacio will be taking that back to their team as they continue in this work. We have a couple of minutes for questions before I hand over to Ishan for some updates on the High-Level Meeting on Antimicrobial Resistance. So, I invite anyone on the call to please share your question in the chat or to raise your hand and you can ask away.

Shaun Palmer (TB Vax ARM): I had one quick question in the meantime, just while people reflect on their own, relating to how Gavi intends to support adolescent and adult vaccination given them being, you know, the key demographic. And one of Ignacio's slides showed modeling for, was it 14, 15-year-olds, and then a larger age bracket, and then it was up to 43 years old? I was just wondering if you could clarify a little how Gavi's future strategy may work to ensure that the broader age range of adolescents and adults are captured, given the demographic most impacted.

Ignacio Esteban (Gavi): Thanks Shaun. And that I think that's a very important question. When Gavi started, we started vaccinating infants. Through the years, our scope and mandate has increased, vaccinating even adults and older adults through COVAX. As Nidhee mentioned, we're now getting to where we also vaccinate adolescent since we started with the HPV program. We're also have now very recently launched the tetanus and diphtheria booster programs of adolescent time points as well. As Nidhee was mentioning, this will be based on the current age range of the clinical trials. This will be older adolescent.

Ignacio Esteban (Gavi): And through Gavi, eligible countries can apply for health system strengthening support in order to have a more robust strength on the delivery platform. Through

the 6.0 strategy discussions, there is a health system strengthening policy that is being updated and is going to be presented to the board as well, where all the decisions on how the health system and how can Gavi together with partner support, this will be discussed in line of all the new vaccine investments made as well. But agreed that making vaccine available will not be enough on its own and we have to start thinking about how we all can start those kind of incentives and investments we can make to have more robust and strengthened health system to deliver this vaccine smoothly, as Peter well said. Thanks.

Shaun Palmer (TB Vax ARM): Thank you, Ignacio, and Nidhee, sorry...

Nidhee Jadeja (Gavi): Yes, I'll just add to provide some context on the investment case that's developed based on the consultations and the analysis, is it's the intelligence we receive where we model and present. The most likely scenario is based on the lead candidate and the information that we receive. But ultimately what the program looks like will follow the WHO SAGE recommendations. And so, what we present to the board are... a most likely scenario. But in the process between now and the final investment case that's presented, we will be tracking and working with partners to see how product development is happening. What is the reality on the ground? What are we... which product are we going to be ending up with? Where is some of the refining needed? How do we need to think about priority groups? What is the most likely vaccine rollout scenario over various time points? So, it's all those questions that need to be ironed out. So, what's presented as a likely scenario, but it's not cast... it's not written in stone about what the final sort of program rollout will look like.

Shaun Palmer (TB Vax ARM): And thank you Nidhee for that clarification of what, you know, is clearly a fluid and dynamic process, but reflective of where we are in the development pipeline. And Ezio and Mike, you both have your hands raised. So, I'll go to Ezio first and Mike, and then we'll hand over to the Ishan.

Ezio Távara (REDE-TB): Thank you. Thank you, Shaun. Peter has covered many of the points that I would like to have seen raised. But... And lately, some of the questions, that have been my questions, have been answered. But since this is a discussion on the advocacy roadmap, I think what we should address is like what is the role of Gavi, in terms of order products, how Gavi also be supporting the implementation of vaccines rollout in general terms, how it's committed with that.

Ezio Távara (REDE-TB): Another... I would like to also raise an aspect which is going to be very important. On the day before the Global Forum in Rio, we are going to have obviously a community meeting and some of us will be meeting, but we are also having an important workshop on a people deprived of liberty. I mean, people in prison. So, how we address the vaccine and the ethical aspects and inclusion of these people in trials and access to this people which are extremely vulnerable and that should be always on the on our radar. So, I think we will have a bunch to discuss on that. Thank you so much.

Shaun Palmer (TB Vax ARM): Thank you, Ezio. And then, Mike, if you want to ask your question and then Nidhee and Ignacio can respond to yours and Ezio's statement together. Yeah.

Mike Frick (TAG): It's maybe a bigger question than the time we have and I'm new to GAVI, so it's probably one that you get a lot. But Ignacio, I noticed on one of your slides you had modelled TB with Gavi eligible countries and then the impact for Gavi eligible plus middle income. And I was just, since we know as TB advocates on the line that so much of the TB burden is in upper middle-income countries, if you could comment just on Gavi's positioning with the middle-income country strategy overall for TB specifically?

Ignacio Esteban (Gavi): Thanks, of course. And thanks, Mike, for asking this because it's obviously a very important question because the TB burden is not only in Gavi eligible countries, but it's even higher in some high burden countries that are not included with our eligibility status. The reason why we include it in our analysis is to support the board decisions on how we could support countries that are eligible at this stage within Gavi. Since 2020, we have this approach called the [MICs approach](#), so the 5.1 strategy, that is kind of a tool to address equity and sustainability transfer to immunization programs for middle-income countries. And the main objective is to prevent backsliding in vaccine coverage in those former Gavi eligible countries. But also, to drive the sustainable introduction of key vaccines. So, for some middle-income countries that are [inaudible] eligibility status there and all this information is available on our website where we explain what the MICs approach is.

Ignacio Esteban (Gavi): But we provide technical assistance. We provide a flexible funding to cover a one-off cost. We provide catalytic finance, and we also provide support for some specific vaccines. As of today, we provide PCV, rotavirus and HPV, and the reason why we also model middle income countries for TB, because we definitely think this will be important to address not only for Gavi but all our multilateral agencies. So, there is a new MICs strategy approach, a new catalytic phase where these discussions are happening to go with the operationalization of the 6.0 strategy. So, in the next year, there will be also a decision on how we could address this and on whether a tuberculosis vaccine, if ever deployed, could also be supportive for MICs as well. Thank you.

Shaun Palmer (TB Vax ARM): Thanks again Ignacio and Nidhee for this really useful update. And as the TB vaccine, we'll be continuing to engage with Gavi and sharing updates as they emerge, you know, in what will be the coming, what, four or five, six years, I imagine. We have a couple of minutes left and I just wanted to hand the floor over to Ishan, who's going to share some quick updates on the United Nations High Level Meeting on Antimicrobial Resistance.

Shaun Palmer (TB Vax ARM): Apologies for the short time, but we appreciate your updates, nonetheless. Over to you.

Ishan Bhatkoti (Stop TB): Thanks, Shaun. I'm a bit mindful of the time. So, from last week on, the formal negotiations on the AMR have begun. The first round of negotiations was on Thursday and Friday and before that we had received a revised draft of the AMR Declaration. And I must say that it's almost looking like a TB declaration of sorts. We had about seven mentions of tuberculosis in the whole draft and besides that, we have some of the good numbers. There's a strong mention about the vaccines and there's a very strong support for the independent scientific Panel on AMR... with

the UK actually supporting to pledge... to fund it. Apart from that, Saudi Arabia is also in favour of an Independent Scientific Panel.

Ishan Bhatkoti (Stop TB): And the dedicated, eight references, actually on paragraph 211, 14, 20, 37, 60 and 61. UHC [Universal Health Coverage] is also mentioned over there in a very broad way, but paragraph 60 of the revised draft talks of TB and it has extended and expanded mentions of the language that was supported and suggested by Stop TB Partnership and the key TB drafts. Mostly the TB high burden countries and G77 are working strongly to ensure that TB remains within the AMR declaration and the language is pretty strong.

Ishan Bhatkoti (Stop TB): The next round... So, I'm still in touch with the missions to get an update of what transpired in the rounds that they had, their formal rounds of negotiations they had last week. So probably by next update we will be having something to talk about. And then we'll decide on what the strategy should be and how do we engage with the missions again in New York to try and figure out who the troublemakers and where the support systems within the UN are. Yeah, that's a very, very brief update on the AMR Declaration.

Shaun Palmer (TB Vax ARM): Thank you Ishan, it's much appreciated in what I know is a very short time. And we'll share links out to all the latest information in our follow-up email. If anyone does have any other questions, please do share them in the chat and we'll share them with the relevant speaker and include them in the follow up email later this week.

Shaun Palmer (TB Vax ARM): So, we have about two minutes. We have time for maybe one more question. Does anyone have any questions for Ishan specifically on the HLM on AMR process? Yes, Lucile, please go.

Lucile Hermant (Global Health Strategies): Yes. Hello, can you hear me correctly?

Shaun Palmer (TB Vax ARM): Yes, we can.

Lucile Hermant (Global Health Strategies): And I thank you so much Ishan for your very detailed and brief updates. Maybe one very general question and maybe a bit too casual, but to be quick, are there some states, countries, stakeholders opposed to TB language in the in upcoming AMR Declaration?

Ishan Bhatkoti (Stop TB): Yes, there are the usual suspects, if I would say, do expect some sort of resistance from the draft that we saw the last... There was some resistance from Russia on a minor word. But I think that's being resolved. And it has been resolved actually, because the revised draft that we received had no mentions of the things that Russia was opposing. It was more on in terms of the language on whether we use families or we use the term household. So that would make a lot of difference. Besides, apart from that, I mean, if the negotiations go absolutely fine by August, the draft should be then placed in silent procedure. So, the negotiations are in a very critical phase at this point.

Shaun Palmer (TB Vax ARM): Thank you for that response and thank you to all of the speakers today for joining us and sharing the insights on these really critical topics. We'll be following up with a follow up email later this week, which will include a link to the recording, a transcript, and an answer to any of the questions left in the chat that we have not been able to answer on the call today.

Shaun Palmer (TB Vax ARM): I know this ended up being quite a busy call and had more content than we anticipated. But we appreciate everyone's time and attention for the webinar. In any case, if you have any questions in the meantime, please feel free to email me. Just respond to any of the emails you received from me about this event, and I'll be sure to get back in touch. And yeah, again, just thank you everyone for your time and support for the TB Vax ARM today.

Offline Q&A

We have been seeing some bottlenecks in implementing TPT in the private sector. Are there any strategies/ reflection on how to bring private sector on board for demand generation/ execution of strategy/ consultation?

The role of the private sector in service delivery varies across Gavi countries, and the degree of Gavi's engagement with the private sector is country specific. We would be keen to gain insights from the experience of non-vaccine TB intervention rollout to overcome bottlenecks for both TB vaccines and non-vaccine interventions, working with relevant partners and stakeholders.

Does the Gavi modeling assume parallel outcome scenarios for coverage of existing interventions? For example, high levels of testing and treatment, nutrition levels, etc.?

The modelling approach incorporates various inputs and assumptions, including disease burden, country-specific vaccine adoption patterns, political will, and financing among others, with specific adjustments made for each vaccine. As mentioned in the webinar, the modelling at this stage represents the best indicative scenario based on extensive consultations and current lead candidates, but is not definitive. The real work now involves refining our understanding of how these vaccine programmes will function at the country level and identifying necessary considerations. One of the key learning agenda priorities as endorsed by the Board is to generate evidence and data to better understand how new TB vaccines can be integrated into existing TB healthcare and general primary healthcare services, and determine the most cost-effective strategies for combining vaccine and non-vaccine interventions.