

SOUND OFF: THREE ACTIVISTS REFLECT ON COMMUNITY VICTORIES AND PRIORITIES IN TB RESEARCH

By Mike Frick and Lindsay McKenna

An interview with Sarah Mulera, Ezio Távora, and Wim Vandeveld

TAG's TB Project co-directors interviewed Sarah Mulera, Ezio Távora Dos Santos Filho, and Wim Vandeveld, three activists from three continents who have led efforts to promote community engagement in TB research. Sarah, Ezio, and Wim's experiences span decades, and their expertise stretches from engaging communities at specific clinical trial sites to working with community advisory boards (CABs) on the national, regional, and global levels. We asked each to reflect on notable victories won by communities as well as unresolved challenges in TB research.

Sarah began community engagement work 10 years ago after losing a relative and friends to TB. Today, she coordinates two CABs in Kenya that are affiliated with the Kenya Medical Research Institute. She has also served as the community representative to the TB Alliance Stakeholders Association.

Ezio started doing AIDS advocacy in the 1980s and CAB work in the 1990s. He coordinates the Brazilian National TB CAB (CCAP) and directs the community engagement program for the STREAM study—one of the largest multidrug-resistant TB treatment trials in history. He is a member of the Global TB Community Advisory Board (Global TB CAB).

Wim Vandeveld became involved with CABs about 18 years ago, first working with the European Community Advisory Board at the European AIDS Treatment Group. He was a founding member and has served as chair of the Global TB CAB, where he remains an active member. He works at GNP+ as the liaison officer for the Unitaids board Communities Delegation.

TAG: What are some of the big victories that TB CABs have won over the past 5–10 years?

Ezio: Progress has been immense since we started, specifically for the establishment of CABs. I started helping the TB Alliance with their first sites in Africa back in 2004 and 2005. We also had a CAB in Rio de Janeiro related to the CREATE consortium. [CREATE was an \$80 million project in Brazil, Zambia, and South Africa that studied the impact of novel TB-HIV interventions.] The work I do now on STREAM is totally related to what I did previously with other TB studies.

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— Ezio Távora Dos Santos Filho

It would be unethical to have a clinical trial in TB nowadays if there is not a community eye supervising, overseeing the process, and making sure there is a feedback [mechanism] to society. We are going towards my ideal scenario, where every study has to have a CAB.

Sarah: To me, the role of CABs has been very significant in gaining community buy-in for research. When I started coordinating CABs in Kenya, there was a lot of resistance to research. Community members thought that they were being used as guinea pigs. As much as researchers tried, the community resisted—until the CAB was formed. When we formed CABs is when we started getting to the grassroots and getting information about why there was resistance to research.

We came to realize that results were not disseminated, so due to this the resistance began. We started making sure that after every clinical trial, we disseminate the results, beginning with very core stakeholders, like the patients themselves. Through CABs involving different stakeholders, we have been able to gain trust. Communities look at research and they see that this is our own thing; it is something that is going to benefit all of us. Everybody is able to give their views, which get absorbed into the research system. By doing this, every stakeholder sees how research is going to benefit us.

Wim: From working with national, regional, and global CABs, I can definitely say that there's been huge progress. When we started, we really had to fight to be heard. That has changed amazingly—I believe NIH [U.S. National Institutes of Health] made CABs mandatory for all of their AIDS clinical trial sites. We also see that in Unitaid, which is a large funder of TB studies: Civil society engagement is now required in every grant. That made a big change in the acceptance of CABs by the research community as an equal partner.

We can measure progress by how we've influenced research through protocol reviews, seeing how our comments are taken on, and how studies are changed for the better. We know we've been effective because even before we start looking at protocols, researchers already have in mind what comments we might give.

TAG: You've spoken about progress not only in terms of the acceptability of research within communities, but also acceptance of community views by researchers themselves. Are there examples where CABs have changed the direction of a study?

Ezio: I think the Global TB CAB has done a good job trying to shape the research agenda. Although sometimes we knock our faces against the wall when we ask for changes that are not implemented.

For the implementation of studies, there is huge progress with the existence of CABs. A good example is the PROVE-IT study in Brazil, where there was a lot of criticism about the way the study was designed by the communities right before the study was approved. [PROVE-IT assessed the rollout of new TB diagnostics in Brazil.] Two years later, the researchers were proceeding with partnerships exactly like the CAB members had suggested at the beginning.

On the PROVE-IT study, one thing that I was really proud of was the fact that the CABs had time to revise the protocol and almost completely rewrite the informed consent form. My boss at the time was furious, thinking that I was going to delay his study. On the contrary, the fact that the CABs revised those instruments accelerated approval at the ethics committee and at other committees.

TAG: Ezio, you said that sometimes in trying to influence research, we end up banging our heads against the wall. Why is there a wall in the first place?

Ezio: Many researchers are very close colleagues and are usually keen on community engagement. But when it comes to influencing study design, I think we have a long way to go.

Wim: But we've been quite successful with some studies. We [Global TB CAB] managed to tweak the STREAM protocol because of reaching out to the donor, USAID [the U.S. Agency for International Development]. We also have a watchdog role that has a preemptive influence even before we see the protocol. I'm thinking of the inclusion and exclusion criteria regarding age restrictions, pregnant women.

Sarah: Initially for us in Kenya, it wasn't easy for the CAB to be allowed to review protocols and informed consent forms. But something has changed, because usually we are called on to review both. We have gotten somewhere, but we are still hoping to see improvements. For example, we are usually given protocols to review just after they [researchers]

have already printed them. Our response was that the CAB is supposed to be given the informed consent and the protocol to review before the final draft.

TAG: What role have CABs played in implementing research findings?

Sarah: This was evident when we had to roll out the new pediatric formulations [of first-line TB drugs]. The role of CABs was to reach out to the government and the community to create awareness that this product is good. For pediatric tuberculosis, the old treatment was very difficult—administering the drugs was not very accurate. We went door to door informing community members and handing out materials, passing on the information to the community and the government that a new drug has come. Through this, Kenya was the first country that rolled out the new pediatric formulations.

Wim: I've seen great examples of CABs distributing study results to grassroots communities. I remember some TB vaccine work where community town hall meetings gathered as many participants as possible to explain the trial results. Especially for prevention, it can be hard to explain negative results. That's hugely important.

Ezio: We [CCAP] did a couple of surveys and found that there were about 1,400 studies on TB going on in Brazil. But very little is being implemented and turning into policy. That is exactly why we want to do a better job.

I think the best example of engaging communities in implementing policies would be the CREATE Consortium THRio study in Brazil. [The THRio trial studied TB preventive therapy for people with HIV.] There was community engagement since the beginning, and TB activists helped to spread information on TB prophylaxis for people living with HIV. There was an immense impact at the study sites. Then the study finished, the CAB was dismantled, and that initiative went down the drain. Physicians no longer were doing prophylaxis. Activists were no longer advocating for it.

Wim: To add: we have been relatively successful placing research-literate community members on national and

international guideline panels. It is almost standard now that civil society representatives, whether or not they come from CABs, are members of guideline committees.

TAG: Looking forward, what are one or two issues you think TB CABs will need to address in the next five years?

Sarah: It's very important to sustain CABs, even during the period after research dissemination, when we are waiting to see what is yet to come up in the pipeline. Because we are not yet there. We need more, better products. Community is paramount in the fight to end TB. It's very important to sustain this link.

Wim: First, I think CABs should reach out more to generic manufacturers, which are at some point necessary in the access work. Also more engagement with regulators. Second is measuring the impact of our work. I wouldn't call it cost-effectiveness of CABs, but at least some evaluation of our work and publishing these achievements. And third, we'll have to continue to build the capacity of our CAB members on fields that we haven't looked at much, like diagnostics or regulatory work.

Ezio: We still have to convince the scientific community that CABs are not there to jeopardize the interest of the studies, but actually to help implement and get the best results. The role of CABs is far from being understood yet. I agree with Sarah about the sustainability issue—that's absolutely fundamental. Wim is absolutely right: We have to understand our impact. I am a qualitative methods person, and it's very hard for me to work with my Anglo-Saxon colleagues on this concept of measurement. The simple existence of a CAB has a symbolic power that already makes researchers and institutions think twice about what they are doing. This is very difficult, almost impossible, to measure. This accountability that the CABs bring is crucial, but it's still not understood.

This interview, which was conducted by phone, has been edited for clarity and length.