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HIV treatment activism moves into the TB field

HIV activists challenge the TB field to look afresh at models of care

"HIV and TB represent almost diametrical opposites when it comes to public prominence, when we compare diagnostics, treatment and prevention research, when we compare funding and, in fact, when we compare practice..." said Zackie Achmat of South Africa's Treatment Activist Campaign. However, he added, "lessons learned from HIV/AIDS activism ... can assist in eradicating tuberculosis."

Achmat was speaking at the opening ceremony of the 36th World Conference on Lung Health (the World Conference), the annual meeting of the International Union against Tuberculosis and Lung Disease (the Union), held from October 18-22 in Paris. The choice of an activist, renowned primarily for his work in HIV/AIDS, to give the opening address at what is mostly a TB meeting, was in keeping with the theme of this year's World Conference, which gave unprecedented attention to HIV disease and to the potential role that social mobilisation (marshalling community and treatment activist support) could play in combating TB.

Until recently, Achmat said, "the active involvement of communities [in the fight against TB] has been limited or absent." Now, many working in the field of TB are hopeful that the development of grassroots TB treatment activism will help generate increased public awareness, healthcare resources and research funding for TB — just as activists have done in HIV disease.

While treatment advocates share these goals, Achmat surprised many TB specialists attending the World Conference by suggesting that in order to mobilize a grassroots TB community, they may have to re-evaluate DOTS (direct observed therapy), the strategy, promoted by the Union which forms the very foundation for TB control programmes globally. According to Achmat, "DOTS has its roots in paternalistic public health approaches" and is "unacceptable because it limits the autonomy and the dignity of every person [with tuberculosis]. The system itself is problematic and we need to look at it."

Background on tuberculosis and TB coinfection

Tuberculosis affects much more of the global population than HIV. About a third of the world's population, or 2 billion people, are currently infected with the TB bacillus (*mycobacteria tuberculosis* or MTB). Over the course of a year, approximately 8 million people develop active TB.

With the development of combination TB therapy, the disease became curable, and with the widespread and consistent use of treatment, TB transmission became very rare in Western countries. However, as Achmat noted in his address: "the global, social, political and health emergency presented by the HIV and AIDS epidemic has once again propelled tuberculosis into a public health emergency."

At present, an estimated one third of the HIV-positive population worldwide is co-infected with tuberculosis, while 70% of those with active tuberculosis are also HIV-positive. People with HIV who are exposed to MTB are around 30 times more likely to develop active disease than people who are HIV-negative. Antiretroviral therapy (ART) has only a limited effect upon the risk of developing active TB,

since people with HIV may fall ill with TB even with higher CD4 cell counts.

Currently, TB is the leading cause of death among people who are HIV-positive. Across the globe, around 2 million people die of the disease each year.

The Gates Foundation supporting treatment activism

These deaths are senseless, as Dr. Helene Gayle of the Gates Foundation would tell the audience in a plenary session later during the conference, "Nearly every death [from TB] is a needless death. This disease is treatable, and in terms of the actual cost of treatment, treatment is affordable."

Because it hasn't been perceived as a problem for the developed world, TB research has been neglected for decades. The Gates Foundation has been one of the few organisations to respond to the TB crisis, injecting much needed funding towards the development of better diagnostic, prevention and treatment tools. However, much greater investment is needed from governments, other funders and multilateral organizations.

As examples of how TB research and control is being neglected, Dr. Gayle said that of the eight Millennium Development Goals, TB control was mentioned only as a sub-goal "lumped together with other diseases;" that funding for TB only amounts to 15% of the funding from the Global Fund; and "at the very same WHO meeting that TB was declared an African emergency, WHO pledged additional money for malaria, and HIV but not for tuberculosis." Dr. Gayle said.

What can change this trend? "Governments and markets can only be moved by people," said Dr. Gayle "We need much greater advocacy and activism and action from all of us. Now is the time to embrace a bolder notion of what we can do and that means adapting a more aggressive approach to outreach and activism."

And the Gates Foundation has backed Dr. Gayle's words with support for Treatment Action Group's TB/HIV Project and annual workshops for the mobilisation of an international TB/HIV Community. As a result, the participation of activists at TB policy meetings has been steadily increasing. While HIV activists are still learning the many nuances of the TB world —and there were numerous instances of misunderstandings or a clash of disease cultures at the World Conference— for the most part, the TB specialists are trying to lure HIV treatment activists to their cause.

The model of HIV treatment activism for TB

Achmat provided a blueprint for how successful TB treatment advocacy works: starting with a human rights approach to health, and harnessing rigorous science to improve the quality of healthcare — which has only been made possible by the development of scientific and treatment literacy among the activist community.

According to Achmat, the fight for access to healthcare is essentially political for a number of reasons: "The working class and poor are more vulnerable to infection and less likely to receive treatment and care. For example, the structural migrant system in South Africa is as much responsible for TB as it is for HIV. Women are culturally and economically subservient to men and therefore more vulnerable to infection. Rich countries fail to assist poor countries in their access to healthcare. Governments everywhere neglect the needs to health, educational employment and social security of poor people. This creates vulnerability to infection, illness and premature death."

“Our vision has to be one of social justice,” said Achmat. But in addition to a belief in the human rights to life and quality healthcare, successful treatment activism is based upon the belief in the inherent potential of individuals, even the most poor or disadvantaged, to learn how to take charge of their own lives and their own healthcare, with the capacity even to become an expert in the most technical aspects of his or her disease.

“For the HIV and AIDS community,” said Achmat, “the most important achievement has been to harness rigorous science to ensure greater individual as well as public health outcomes: Development of antiretroviral drugs, development of new diagnostics, clinical trials for prevention and for treatment, active use and promotion of epidemiology, countering HIV denialism [on scientific grounds], advocating for research and programmatic funding. These are some of the areas that people living with HIV/AIDS and AIDS activists have developed expertise in with the aim, only, of saving lives.”

Achmat tried to assure the audience that treatment activists are “committed to rigorous science that respects the integrity of scientists and the scientific process. This suggests active promotion of scientific literacy... by activists, by scientists, by clinicians within our own community.”

This scientific literacy is the result of “the mutual education of activists in the scientific and clinical community on science and regular structured interaction between activists, community representatives scientists, health professionals and policy makers.”

This usually starts with treatment literacy. “In relation to HIV/AIDS, the epidemic has altered the traditional relationship between health professional and patient in all parts of the world,” Achmat said. “90% of our work as the Treatment Action Campaign is treatment literacy work. What does it mean? It means people taking responsibility and control of their own health, their medication and society – that principal that we are the most important resources to transform the HIV/AIDS epidemic and health care services. [Treatment literacy training] makes it possible for someone from the poorest health district to [converse with experts and government policy makers]. Treatment literacy is central to the development of a cadre of leadership – and that is based on an understanding of patient autonomy.”

And therein lies the treatment activist community’s chief complaint with DOTS. “Central to the implementation of DOTS is that people with TB have to take their treatment under supervision by someone else... Patients are not regarded as independent autonomous people with dignity and the ability to take control of their own health or illness. People with TB are treated as public health cases,” said Achmat.

By not treating people with TB as individuals who can be empowered and educated, the TB world may be missing opportunities to develop them as a resource, to nurture a TB community to help with advocacy, screening and prevention and more patient-centred adherence support programmes.

The TB establishment's response

While Achmat’s comments on DOTS drew scattered applause from the treatment advocates in the crowd, the response from the rest of the audience was muted at best.

In fact, after Achmat’s presentation, one doctor from Nepal rushed up to Union officials and said “please, don’t let them take away DOTS.” And the following day, this reporter spoke others who were discussing the “reckless course” that they feared the HIV activists were suggesting. “We have to confront this – a lot of

people are frightened by this because the activists are powerful and their voices are loud,” said another doctor.

To public health experts working in TB, DOTS represents far more than simply the observation of treatment. DOTS is the brand name for a package of services used by tuberculosis control programmes. In addition to directly observed therapy, DOTS requires the national government’s commitment for sustained anti-TB efforts (including education and training of caregivers and treatment supporters), adequate systems for surveillance and case detection as well as regular and uninterrupted drug supplies.

Of course, the activists are not questioning these other aspects of DOTS, merely the focus on the observation of therapy – and the associated failure to empower and educate people with TB.

But many TB experts believe that direct observed therapy is non-negotiable. They note that transmission of MTB is, after all, via the air and the consequences of poor adherence to TB treatment can spread far beyond the individual. And there are circumstances, such as when patients have failed to take their medicine and developed multidrug resistant TB (MDR-TB), where the public health consequences of poor adherence are such that the decision of whether to take treatment cannot be left up to the individual. Many TB experts believe that the adherence programmes where treatment is not supervised are too lax to be trusted.

It was telling that the Union chose a TB expert to give a presentation on “what does and doesn’t work for adherence to antiretroviral therapy.” Dr. Kenneth Castro, an assistant U.S. Surgeon General and Director of the Division of Tuberculosis Elimination at the Centers for Disease Control, began his talk with a discussion of DOTS.

He cited the Public Health Tuberculosis Guidelines Panel’s consensus statement from 1998 that evaluated 27 different TB studies looking at the outcome of therapy using “enhanced” DOTS, modified DOTS (DOTS on a less frequent basis) or unsupervised therapy – and noted that best outcomes were always seen in the studies with enhanced DOTS (Chaulk and Kazandjian). “These by and large consisted of case management with supportive measures, incentives and enablers and as you move away from case management and focus almost exclusively on the ingestion of therapy you lose some [effectiveness], and you keep losing more as you steer towards non-supervised therapy. So for us in the TB community in the US especially – it’s been fairly clear that the way to go is to have a patient-centred approach to provision of DOTS.”

Then Dr. Castro proceeded straight into a discussion of DOTS for ART (DOT-ART or DART) and spent most of his talk focused on it – despite the fact that DOT-ART is not at all the norm in antiretroviral care. However, it has been evaluated in a few studies and here, too, Dr. Castro noted that an enhanced approach with “flexibility and partnership between the participants and the programme are absolutely critical” to the success of DOT-ART in people with HIV.”

In a way, Dr. Castro seemed to be positioning himself as sort of a “compassionate conservative” on DOTS. Though to be fair, one reason for the focus on DOT-ART could have been to help the audience, mostly from the TB world, visualise how to integrate ART into existing tuberculosis control programmes. A number of studies suggest that the easiest way to make ART available through TB clinics might be to administer it through their existing drug delivery mechanisms, which is usually DOTS or “enhanced” DOTS. He cited at least one pilot study in South Africa that had done this successfully (Jack) and the Union has several similar pilot studies ongoing in different resource-limited settings.

Encouraging TB and HIV programmes to be flexible and patient-centred is a step in the right direction – and may be as

much of a concession as the TB world is willing to make – but it didn't go far enough for the HIV treatment advocates in the audience, a number of whom spoke out in the discussion session after Dr. Castro's talk.

Said Chris Green of the Spiritua Foundation in Indonesia, "there are ways to do this without DOTS and get very high rates of adherence. In the developing world, we have seen better than 95% adherence without going to these extremes... Providing information to the patient is the crucial element."

Tracy Swann of the Treatment Action Group noted that: "Even using the term DOTS or "enhanced" DOTS reflects a limited paradigm and we really need to look at the bigger picture."

For example, DOTS programmes that require patients to travel the clinic to be observed taking their medications, usually cost money and take commuting time away from work. Both factors have been demonstrated to be a barrier to adherence.

Swann pointed out that the cost of transportation to clinic might actually cancel out any benefit offered by DOTS – and that such programmes were insensitive to the patient and setting. "I hope that we are moving towards a paradigm that will be more culturally specific, location specific, and resource specific," she said.

Dr. Castro agreed that factors such as education are an important component of patient support and had been part of the background standard of care in many of the studies that he cited. And to Swann, he responded that problems such as transport costs could be easily addressed by enhanced DOTS, for example in New York, "by giving the patient a subway token."

But while that might work in New York, providing the equivalent of a subway token in sub-Saharan Africa (the cost of transportation and the cost of lost work time) to and from the clinic (for daily lifelong therapy) are unlikely to be within the means of most TB control programmes. In fact, Dr. Castro had noted that most national tuberculosis programmes are already stretched thin and quoted a paper by Dr. Gerald Friedland and colleagues "To accomplish integration of tuberculosis and HIV/AIDS care and use of HAART in the tuberculosis DOT programs... tuberculosis programs will require the addition of new resources and personnel, as well as training to accommodate the necessary increased program responsibilities." Until more resources are devoted to national TB programmes, it's hard to imagine many of them being able to reimburse patient travel and missed work costs.

Community-based adherence support

An alternative would be to rely more on the local community. Dr. Castro was enthusiastic about the prospects for greater participation of the community, noting the positive results from groups working in Haiti, and Malawi, which strongly rely on community based adherence support, *accompagnateurs* (see below) or a support partner such as a friend or family member.

Earlier at the TB meeting, Dr. Fernet Léandre described the experience of Zanmi Lasante (Partners in Health), which uses an enhanced DOTS-like approach to provide comprehensive HIV care, free-of-charge to patients in rural Haiti. Zanmi Lasante is Haiti's largest health-centred NGO, with over 1000 healthcare workers, providing care to 8000 HIV-positive patients, 1880 of whom are now receiving DOT-ART. Initially, patients with HIV infection were assigned community health workers who would visit daily to deliver HIV medications, however, many outreach workers began to visit patients more often than once a day and gradually became "*accompagnateurs*" who also provided essential moral and social support to the patients, even accompanying people with HIV on their

clinic visits. *Accompagnateurs* are now trained to recognise common treatment-related side effects and the signs of HIV-related illnesses, and to report any new medical or socio-economic developments to clinic staff. It's a great success with a drop-out rate of less than 2%.

The patient-centred aspect of the *accompagnateur* approach is similar to the type of care provided by many home-based and palliative care programmes, which stress a continuum of care approach with spiritual and social support for the patient. It would make sense for national TB programmes (especially those with already stretched resources) to partner with community based organisations and NGOs already offering such patient-centred services. Many such HIV-related services exist where supervision of the actual dosing of medication may not be required, but where a reliable "support partner" makes certain that a person takes their medication. Dr. Castro, himself cited the example of the *Medecins sans Frontieres* (MSF) ART project in Khayelitsha (see [aidsmap links](#)).

A similar *Medecins sans Frontieres* project is underway in Thyolo district in Malawi. According to a poster presented at the conference, the project has 465 community volunteers, 1362 trained family caregivers and 9 community nurses who provided care and support to 5106 HIV-positive individuals, of whom 2006 (39%) have WHO stage III or IV disease (Zachariah). 2714 TB patients, of whom 1627 (60%) are HIV-positive, also receive care and support through the project.

The poster demonstrated that community involvement definitely improved treatment outcomes in patients who had started ART.

Outcomes in Patients on ART in Thyolo, Malawi

Outcome	Patients Living in Areas with Community Support (n= 895)	Patients without Community Support (n= 639)	P value
Total n = 1634			
Living and on ART	96%	76%	P<0.001
Deaths	3.5%	15.5%	P<0.001
Defaulted	0.1%	5.2%	P<0.001
Stopped ART	0.8%	3.3%	P<0.001

These results are at least as good, if not better than those reported with DOTS in most other studies – with the advantage of a strengthened community and more treatment literate patients.

Dr. Gayle stressed the importance of such community-based projects for TB: "We need to look at creative ways to expand DOTS in ways that meet the needs of people." She gave an example from rural Ethiopia in which communities formed TB clubs. "People would monitor each other and then take the bus once a month together for check ups. The treatment rates in those communities grew from 45% to 95% and in the process people and communities felt empowered. So let's remember that DOTS in and of itself is not the goal, getting people on treatment is. Dogged adherence to a particular strategy should not get in the way of our overall goal."

Whats in a name? How about Determined (Dedicated) Ongoing Treatment Support?

Community empowerment and individual patient empowerment are not exactly the same thing – but it isn't clear which would better translate to increased TB treatment advocacy or social mobilization that Achmat and Dr. Gayle are seeking.

Even TAG's executive director, Mark Harrington, in an interview with MSF, questions whether individuals with TB are likely to be empowered to become treatment activists. "People that are affected by [TB] are often very marginalised and vulnerable populations and it's not going to be easy for them to mobilise around one set of problems in their lives and that set being TB. And because TB is curable, it's not like something that changes your identity forever. People haven't traditionally had an identity as a TB survivor and then turned that into political advocacy. And disease is intrinsically isolating, as opposed to something that brings people together"

However, when asked if anything could be done to empower a global TB community he added "I think some of the key elements would be a much greater effort by people in the TB world to put the concerns of people with TB at the heart of their program, as opposed to having them be the last to be consulted (for the complete interview, see

<http://www.accessmed-msf.org/prod/publications.asp?scntid=41120051756434&contenttype=PARA&>).

And one place to start, advocate Green said, is with the DOTS name. But even if programmes called enhanced DOTS are gradually transformed into community-based adherence support programmes, with treatment literacy training and without literal supervision of dosing, TB experts would remain wedded to DOTS as a brand name.

According to Green, language is important, and in and of itself can send a message that can empower or disempower a person. Directly observed therapy as a concept actually denies the person with HIV the ability to take charge of their health care. It provides no incentive for them to grow beyond in order to empower people with tuberculosis and help foster a grassroots movement of TB advocates. Green concedes that it may be wise to keep the DOTS brand name, but said that at the very least, its meaning could be changed "Before the meeting, we sat around trying to figure out something else it could for which DOTS could be an acronym."

Of course, even if there is a shift to community/partner based adherence support for TB, in order to control the spread of disease, treatment for newly diagnosed smear-positive TB cases would still need to be directly observed initially — at least, until patients and the support partners they identify can undergo adequate adherence training. This would mean more effort and resources put up front into education and training during the first couple of weeks on treatment,

but after that point, reliance on friends or family members as partners/accompagnateurs to provide adherence support may actually reduce the burden on national tuberculosis programmes, while providing the patient with more freedom, and, potentially, decreasing TB stigma within the community.

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about HATIP

A regular electronic newsletter for health care workers and community-based organisations on HIV treatment in resource-limited settings.

The newsletter is edited by Theo Smart (Cape Town) and Keith Alcorn, NAM's Senior Editor (London).

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