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In This Issue

[IUATLD Conference Recap](#)

[Video Corner](#)

[Thibela TB - The Path Towards Results](#)

[Celine Gounder - Director for Delivery, CREATE](#)

[Articles Published Recently](#)

Thibela TB - The Path Towards Results



After nearly 5 years, the Thibela TB intervention stage of the project is drawing to a close. Starting in early 2005 with the Tau Tona mine shaft near Carletonville, the Thibela project has worked its way across 15 clusters to end with the Bambanani Mine near Welkom, in the Free State Province. (Bambanani study volunteers with project manager Flora Popane in the photo above).

The last official study participant will take his last dose of Isoniazid (INH) in the intervention at Bambanani on the 28th of February 2010. "This is a major milestone for Thibela TB", said Dr. Dave Clark, Aurum's Deputy CEO. "The team has enrolled over 30,000 participants into the program to take preventive INH, a significant achievement in the fight against TB in our country."

What has been quite remarkable at the final intervention cluster is the astounding number of volunteers for Thibela TB - over 95% of the workforce at Bambanani - evidence of a community mobilization phenomenon unheard of in clinical trials before. "I am so proud of my team in achieving this together with the people of Bambanani", said Flora Popane,

TB & HIV

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Study Gives Hope to Tuberculosis-Stricken Countries

A study released by the U.S. Centers for Disease Control and Prevention (CDC) found that 36 months of continuous isoniazid preventive therapy (IPT) reduced the risk of developing active tuberculosis (TB) disease by 92% in HIV-infected individuals who test positive for latent TB infection, when compared to the standard 6 month regimen.

CDC conducted the randomized, controlled study in Botswana at the request of the Ministry of Health. To better understand the efficacy of continuous TB preventive therapy, researchers compared the results of 6 months of IPT to 36 months of therapy. Six months of IPT is currently prescribed to persons with HIV infection to prevent latent TB infection from progression to active TB disease.

CDC began the \$12 million study in 2004 and will continue to follow study participants through 2011. This is the first TB clinical trial in Botswana, and was designed to examine how IPT and anti-retroviral therapy (ART), which is used to treat patients with HIV/AIDS, contribute to TB prevention.

For more information about CDC's BOTUSA - A United States-Botswana Partnership visit:

<http://www.cdc.gov/botusa/TB-HIVResearch.htm>

Regional Project Manager for the Free State. Towards the end of this last cluster, >75% of volunteers were retained on the study, further evidence of a job well done.

Elsewhere in the study, the switch to the measurement periods of the protocol have gone well, with two shafts completing the final culture prevalence survey and several others underway or in final stage planning for primary and secondary end point measurement.

Another key component of the main part of the study has been the Electronic Data Capture system. This system has been steadily gathering enormous amounts of data from all the participants at the various sites. The main study database will also capture its last live details on the 28th February. Trisha Crawford, Thibela's Senior Data Manager, and her team have set the very ambitious task of getting to database lock by the end of March 2010 and right now, they are on track to achieving this goal. A locked database is key for investigators to begin the challenging, but pivotal task, of analyzing the data goldmine that has come from all the work so far.

"We are finally at the beginning of the end in this audacious study. I too am very proud of all this remarkable team has achieved across the various regions. We are also grateful to the thousands of mineworkers who have risen up to fight TB. We now have to finish what we have so painstakingly put together over the last few years. But I know I can count on my team to see this through to the final analysis", adds Gavin Churchyard, Thibela TB principal investigator. The study is set to publish final results early in 2012, but hopefully much interim information on lessons learned and other research questions will come from the data in the next two years.

Celine Gounder, M.D. Director for Delivery - CREATE



I'm Celine Gounder, an infectious diseases specialist and epidemiologist at Johns Hopkins, and the Director for Delivery for CREATE. Prior to coming to Johns Hopkins for a post-doctoral fellowship in Infectious Diseases, I completed a residency in Internal Medicine at the Massachusetts General Hospital in Boston, medical school at the University of Washington in Seattle, and a Master of Science in Epidemiology at Johns Hopkins.

I worked for Ralph Nader and Gordon Douglas in the late 1990s on issues around global and U. S. TB policy and funding, during which time I also met and

**IUATLD Conference
Recap - Cancun
December 2009**

As part of the International Union Against Tuberculosis and Lung Disease conference in Cancun, Mexico, last December, CREATE researchers reported on several aspects of the three studies in Zambia, South Africa and Brazil.

Below are some of the abstracts and poster sessions presented:

**PS-94760-05
Tuberculosis in patients receiving HAART in a South African study cohort**

**PS-94203-05
Missed opportunities for early TB diagnosis by an active case finding campaign in a slum, Rio de Janeiro**

**PS-94501-06
Evaluation of the role of community health workers in the provision of DOTS in urban Brazil**

**PS-94202-07
Active tuberculosis case finding in 11 impoverished communities in Rio de Janeiro, Brazil**

**PS-94821-07
Use of containerized laboratories in the ZAMSTAR TB Prevalence Survey in Zambia**

To read the abstracts, visit the [IUATLD Cancun Abstract Book](#).

began to collaborate with Richard (Dick) Chaisson. I have been working with Dick for more than a decade now, studying TB diagnostics and screening programs to reduce the burden of TB among HIV-infected persons, first in Rio de Janeiro and later in Soweto.

In the past year, I integrated active case-finding (ACF) for TB with prevention of mother-to-child transmission (PMTCT) of HIV services delivered at the antenatal clinics in Soweto, which serve ~30,000 pregnant women per year, a third of whom are HIV-infected. Initial findings will be presented at the Conference on Retroviruses and Opportunistic Infections (CROI) in February.

While in South Africa, I also worked closely with Gavin Churchyard on studies in Tembisa of intensified case-finding (ICF) incorporating the urine LAM, and provider-initiated TB screening in primary health clinics. I provided technical support to the South African RMC in preparing and writing South Africa's Round 9 GFATM application, and was also invited to provide feedback on the South African DOH's new isoniazid preventive therapy (IPT) guidelines.

As Director for Delivery, I am now developing collaborations for scale-up of ICF/ACF and IPT beyond CREATE, including in Ethiopia, Malawi, Nigeria, Rwanda, Botswana, Tanzania, Swaziland and possibly also Latin America. I am pursuing these collaborations through PEPFAR, CDC GAP, national MOHs, the Elizabeth Glaser Pediatric AIDS Foundation, PAHO and various local implementers.

Articles Published Recently

[Recurrent Tuberculosis: Relapse, Reinfection, and HIV](#)

Chaisson RE, Churchyard GJ.
J Infect Dis. 2010 Feb 1.

[Community-randomized trial of enhanced DOTS for tuberculosis control in Rio de Janeiro, Brazil](#)

Cavalcante SC, Durovni B, Barnes GL, Souza FB, Silva RF, Barroso PF, Mohan CI, Miller A, Golub JE, Chaisson RE.
Int J Tuberc Lung Dis. 2010 Feb 14.

[Incidence of tuberculosis and HIV and progression of silicosis and lung function impairment among former Basotho gold miners](#)

Park HH, Girdler-Brown BV, Churchyard GJ, White NW, Ehrlich RI.
Am J Ind Med. 2009 Dec; 52(12):901-8.

[HIV infection does not affect active case finding of tuberculosis in South African gold miners](#)

Lewis JJ, Charalambous S, Day JH, Fielding KL, Grant AD, Hayes RJ, Corbett EL, Churchyard GJ.

Video Corner

Here you can see videos produced by CREATE and other institutions focused on creating awareness to the need of better tools to curb the increasing TB epidemic.

[Union World Conference 2009: Nuestra Casa by Damien Schumann](#) - An exhibit to highlight the living conditions of TB patients in the border between Mexico and the U.S.A.

[Thibela TB - South Africa Tuberculosis Prevention](#)

[THRio - Tuberculosis Prevention in Rio de Janeiro](#)

Am J Respir Crit Care Med. 2009 Dec 15;180(12):1271-8

[Screening and preventive therapy for tuberculosis](#)
Marais BJ, Ayles H, Graham SM, Godfrey-Faussett P.
Clin Chest Med. 2009 Dec;30(4):827-46, x

[The fourth I: scaling up implementation of collaborative TB-HIV activities to protect vulnerable mothers and infants](#)
Gie RP, Beyers N.
Int J Tuberc Lung Dis. 2009 Dec;13(12):1443.

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