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CREATE 

CREATE Trials Achieve Key Milestones

As CREATE completes its fourth year of work, a number of major milestones have been reached in the three community-randomized trials. Below are some of these milestones:

Thibela - 19,000th participant enrolled



The Thibela study is comparing the efficacy of community-wide isoniazid preventive therapy (IPT) with the standard of care in reducing TB incidence among gold miners in South Africa.

The study has progressed substantially in the past year, and recently celebrated the enrollment of its 19,000th participant. More than 17,000 workers have now started IPT, and more than 12,000 are enrolled in a baseline TB prevalence study. This large and ambitious trial has conducted more than 80,000 clinic visits, and required 570,000 staff hours. More than 4 million isoniazid tablets have been packed, labeled and dispensed.

Thibela was awarded the **GCPj Award** for "**Most Innovative Patient Recruitment Strategy**" and was nominated for "**Clinical Trial which Best Promoted Access to Treatment**" earlier this year.

Zamstar - 4,000th household receives intervention

UNGASS Meeting



CREATE representatives attended the HIV-TB Global Leaders' Forum at the 2008 UNGASS (UN General Assembly Special Session).

Several opinion leaders from around the world participated including former U.S. President Bill Clinton. Among the topics in discussion:

- The need for bold leadership to cut the number of tuberculosis-related HIV/AIDS deaths;
- The emergence of drug resistant strains of tuberculosis as a global security issue;
- The need for new tools to address HIV/tuberculosis co-infection.

Community Involvement TB Research Symposium

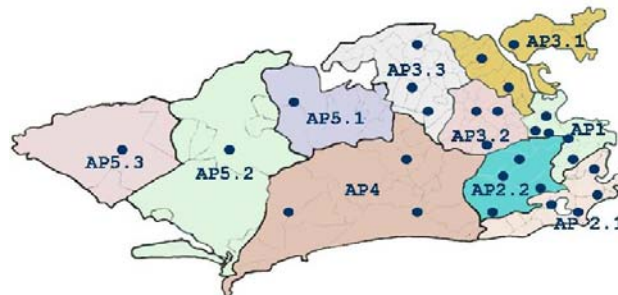
The Zamstar trial is testing the impact of enhanced TB case finding in the community and household contact evaluations on TB prevalence in 24 communities in South Africa and Zambia.



The study recently enrolled its 4,000th household, and rates of HIV testing amongst contacts exceeds 50%. Additionally, more than 8,500 individuals with symptoms of TB have had sputum evaluations through the enhanced case finding intervention. To accomplish such broad impact, the study team has conducted more than 300 community-based drama performances and delivered more than 60,000 educational materials to residents of participating areas every year since the beginning of the study.

"Household counselling saved our lives"- says a member of one of the Zambian communities. Randomized communities participate in intensified case finding and/or household-level TB/HIV activities.

THRio - 29 clinics receive intervention for 17,000 patients



(Photo: Map of the City of Rio de Janeiro with the 29 public health HIV clinics participating in the THRio study)

The THRio study is determining if implementation of a policy of widespread use of isoniazid preventive therapy (IPT) in HIV-infected patients with access to antiretroviral therapy (ART) reduces the incidence of active TB in the HIV clinic population.

After 2.5 years of a novel 'stepped-wedge' design intervention, all clinics are now receiving the full intervention, which also includes TB case finding to rule out



CREATE is sponsoring a symposium in Paris, France, on October 16, 2008 to discuss community engagement in TB Research in conjunction with the **International Union Against Tuberculosis and Lung Disease**.

Participants will discuss responsibility to communities, ethical considerations in community trials, and anticipated needs for community involvement in future trials.

For more information: contact: adeluca1@jhmi.edu.

From FIND - Rapid Diagnosis for MDR-TB

A new test to diagnose MDR-TB is being developed by FIND (Foundation for Innovative New Diagnostics).

According to FIND, the new test could diagnose MDR-TB and XDR-TB in as early as two days, instead of the 2-3 months it takes today, especially in limited-resources settings.

A press release with details about the new test is available [here](#).

active TB before starting IPT.

Approximately 17,000 HIV+ patients are included in the study, the majority of whom are receiving ART free of charge through Brazil's model HIV/AIDS program. Uptake of TB screening and IPT has been excellent, with more than 70% of the patient population ultimately receiving the intervention.

Featuring Flora Masabata Popane - Thibela TB



I worked for 11 years as a Professional Nurse, then as a Unit Manager before joining Thibela. After completing my studies in Masters Degree, I started with the Thibela TB project in Carletonville as a Team Leader and moved to Welkom to take up the position of the Project Manager.

My favorite part of working with the Thibela study is the knowledge that what we are doing might help in the control of TB in our country. With our efforts, we might be able to prove that community wide TB prevention is a significant part of TB control. We might also be able to give answers about TB resistance in the mines. We are not only giving Isoniazid Preventive Therapy within the mines, but we are also strengthening the existing Mine Health Services by assisting with the identification of TB suspects within the mines where we work.

Maintaining high daily recruitment numbers at a site is a challenge. We always start with very high daily recruitment, but the numbers gradually drop. The staff puts on an extra effort, sometimes working earlier or later to accommodate miners working different shifts to access the

**Integrating Research
and Advocacy -
Strategies for TB/HIV
Advocates**

CREATE Policy and Advocacy Core and the Global Alliance for TB Drug Development are hosting a meeting of Zambian HIV/TB advocates on September 22, 2008 in Lusaka, Zambia.

This will be an opportunity to inform Zambian TB/HIV advocates on progress with the ZAMSTAR Study, as well as hone skills for research advocacy. The Global Alliance for TB Drug Development will present on clinical trials development in Zambia.

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study centre. We have staff meetings daily to reassess if we are accessing all the miners with our recruitment activities. We use different communication tools, play Thibela DVDs and songs, and recorded messages to talk about adherence. We also use the established Participant Advisory Groups and Thibela Advisory Groups to address some challenges.

My hopes are that at the end of the study, Thibela would have made a significant difference in the control of TB within the mining communities where we work. I hope that our efforts will benefit our country and maybe the world at large. It is very sad how we see our people dying of TB every day and how we continue to have new challenges in terms of dealing with TB as a disease in the world. I will feel very proud if the contributions that I made with my team helped to change the picture of TB for the better. If that happened, then it will mean victory for us as Thibela and as individuals. Perhaps we can sing a new Thibela song then, a song of victory and hope.

Articles Published Recently

Saraceni V, King BS, Cavalcante SC, Golub JE, Lauria LM, Moulton LH, Chaisson RE, Durovni B. [Tuberculosis as primary cause of death among AIDS cases in Rio de Janeiro, Brazil](#)

Meintjes G, Lawn SD, Scano F, Maartens G, French MA, Wordria W, Elliott JH, Murdoch D, Wilkinson RJ, Seyler C, John L, van der Loeff MS, Reiss P, Lynen L, Janoff EN, Gilks C, Colebunders R; for the International Network for the Study of HIV-associated IRIS. [Tuberculosis-associated immune reconstitution inflammatory syndrome: case definitions for use in resource-limited settings](#)