



Consortium to Respond Effectively to the AIDS TB Epidemic

# DECEMBER 2010

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## CREATE Publishes IPT Supplement in *AIDS*: Focus on Implementation Issues



In a supplement published Nov. 18 in the journal *AIDS*, researchers affiliated with CREATE report that widespread implementation of isoniazid preventive therapy (IPT) is feasible, safe and, in one study, associated with a decreased risk of AIDS-related mortality. The investigators note that toxicity from IPT is minimal when monitored monthly by trained nurses and that high levels of uptake can be achieved with community mobilization.

"This is exciting news for the global fight against TB and HIV," said Richard Chaisson, principal investigator of CREATE. "We have positive signs that IPT provides a safe and effective way to prevent TB in people living with HIV. The final results of the three trials that we are conducting in South Africa, Zambia and Brazil are not yet ready, but partial results from studies conducted by Thibela TB in South Africa and THRio in Brazil suggest that we are on the right path."

## TB & HIV

FIND TB

TREAT TB

PREVENT TB

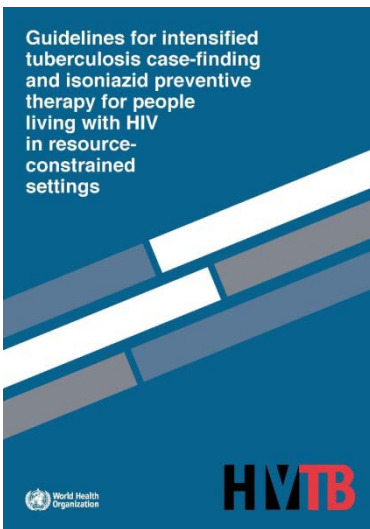


## WHO Launches IPT and ICF Guidelines for

TB and HIV are prevalent among workers in the gold-mining industry in South Africa, and several of the articles published in the *AIDS* supplement present data from a study of community-wide IPT in the mines there. The research intervention was conducted by the Aurum Institute of Johannesburg, in collaboration with the London School of Hygiene and Tropical Medicine, between 2006 and 2010.

One article found that mortality was lower among individuals receiving IPT in combination with antiretroviral therapy for HIV infection. These results support the routine use of IPT in

## People Living with HIV



On December 1st, World AIDS Day, the World Health Organization has launched its guidelines for Isoniazid Preventive Therapy (IPT) and Intensified Case-Finding (ICF) for people living with HIV.

Some of the key recommendations are:

- Adults and adolescents living with HIV should be screened for TB with a clinical algorithm and those who do not report any symptoms of current cough, fever, weight loss or night sweats are unlikely to have active TB and should be offered IPT;
- Adults and adolescents living with HIV and screened with a clinical algorithm for TB, and who report any one of the symptoms of current cough, fever, weight loss or night sweats may have

conjunction with ART. The studies also determined that people who undergo IPT experience few adverse events. Of the 24,221 participants in the clinical trial, only 130 experienced important side effects related to treatment. Serious adverse events, such as liver toxicity, were rare, and the study found that clinical criteria can be used to screen patients for serious toxicity risks and safely monitor patients while they are on IPT.

Another paper established that chest radiography, where available, can be a useful adjunct to symptom screening in ruling out active TB. The identification and exclusion of active TB cases is critical to ensuring the long-term effectiveness of IPT because active TB must be treated with a combination of antibiotics to prevent the development of drug-resistant TB strains.

In one of the supplement studies, conducted among 29 public health clinics in Rio de Janeiro, more than 5,000 HIV-infected patients had tuberculin skin tests placed; of the 94 percent of the tests that were read, 18 percent were positive. Eighty-three percent of those with positive skin tests have completed therapy to date, and fewer than 2 percent have had minor adverse effects. The researchers said that this study demonstrates that IPT can be incorporated successfully into existing public health clinics.

The consortium expects to conclude a series of clinical trials in Brazil, South Africa and Zambia in late 2011, with final results starting to be disseminated as early as Spring 2011.

A link to download the articles from the CREATE Supplement can be found in our website (<http://www.tbhiv-create.org>) or on our [Facebook Group Page](#).

### Violet Chihota Study Coordinator for Thibela TB

My name is Violet Chihota, and I started working at the Aurum Institute as a study coordinator for Thibela TB in December of 2005. It has been fulfilling working on a study that is making a difference in the communities we work in.

My main responsibilities include setting up and running projects which are



active TB and should be evaluated for TB and other diseases;

- Adults and adolescents living with HIV who have an unknown or positive TST status and are unlikely to have active TB should receive at least six months of IPT as part of a comprehensive package of HIV care. IPT should be given to such individuals irrespective of the degree of immunosuppression, and also to those on ART, those who have previously been treated for TB and pregnant women;

- Adults and adolescents living with HIV who have an unknown or positive TST status and who are unlikely to have active TB should receive at least 36 months of IPT. IPT should be given to such individuals irrespective of the degree of immunosuppression, and also to those on ART, those who have previously been treated for TB and pregnant women. TST is not a requirement for initiating IPT in people living with HIV;

- People living with HIV who have a positive TST benefit more from IPT; TST can be used where feasible to identify such individuals.

A copy of the guidelines can be downloaded [here](#), or through our [Facebook Page](#).

key to making Thibela TB work; firstly collecting data on TB cases which are the basis for the primary outcome of the study. For this study it is very important that we document all TB episodes occurring in each cluster. Secondly, in each Thibela TB cluster, screening those suspected of having TB as part of the study investigating strategies for improving the detection of TB; and thirdly, running a TB prevalence survey in each cluster at the end of the follow up for the Thibela TB study.

For the laboratory based studies it is equally important to enroll all eligible participants, collect a sputum specimen and ensure that laboratory results are received within reasonable time and used to manage patients. To achieve this, I interact with many different people including the teams on the ground (Thibela TB teams, hospital and primary health care staff), the laboratory staff, data management, investigators, ethics committees, stakeholders and funders.

The major challenges I face every day are to ensure that we meet study targets on time and collect quality data in the many different clusters that we work in, and we overcome those challenges by working closely with all those involved in the studies, especially the participants, to ensure they have an understanding of the study and its objectives.

I hope the Thibela study achieves all of its goals, which include a reduction in TB incidence in the communities that have received IPT, hopefully improving control of the disease; the opportunity for more people to be screened for TB in the mining communities and that through this we have strengthening health care services; a better understanding of TB and HIV/AIDS within the communities in which we were working, which is provided through the health education that the study teams have been giving as part of the Thibela TB study. This will empower the communities in the fight against TB;

Lastly, I hope to see an uptake of the lessons that have been learnt/we are still to learning in Thibela TB in South Africa and worldwide and that they will be commonplace strategies for the fight against TB.

### Articles Published Recently

[Twelve-monthly versus six-monthly radiological screening for active case-finding of tuberculosis: a randomised controlled trial.](#)

Churchyard GJ, Fielding K, Roux S, Corbett EL, Chaisson RE, De Cock KM, Hayes RJ, Grant AD.

## CREATE Annual Meeting Highlights

CREATE's Annual Meeting took place in Cape Town, South Africa, from November 1-5, bringing together the studies' scientists, representatives of the South African government, the Bill and Melinda Gates Foundation, the World Health Organization, and other authorities in HIV-related TB to discuss the latest advances in the 3 CREATE studies and to showcase how new guidelines for IPT and ICF are being implemented especially in South Africa.

Karen Jennings, from the Cape Town Municipality, discussed the challenges in integrating TB and HIV services in the city, but also reported progress and support of the government in doing so; Susan Dorman, of the Johns Hopkins University shared exciting findings on the Xpert diagnostic tool for TB cultures and drug resistance testing; Brian Williams from SACEMA highlighted the importance of early management of HIV and its impact on TB; and the CREATE principal investigators and researchers reported on the studies early results and policy and advocacy activities.

For the next CREATE Annual Meeting final

[The implementation of isoniazid preventive therapy in HIV clinics: the experience from the TB/HIV in Rio \(THRio\) study.](#)  
Durovni B, Cavalcante SC, Saraceni V, Vellozo V, Israel G, King BS, Cohn S, Efron A, Pacheco AG, Moulton LH, Chaisson RE, Golub JE.

[Why have trials of isoniazid preventive therapy among people with HIV infection not demonstrated an effect on mortality? Did close examination of the trees obscure our view of the wood?](#)  
Grant AD, Fielding KL, Charalambous S, Chaisson RE, Churchyard GJ.

[Isoniazid preventive therapy for HIV-infected people: evidence to support implementation.](#)  
Eldred LJ, Churchyard G, Durovni B, Godfrey-Faussett P, Grant AD, Getahun H, Chaisson RE.

['Team up against TB': promoting involvement in Thibela TB, a trial of community-wide tuberculosis preventive therapy.](#)  
Grant AD, Coetzee L, Fielding KL, Lewis JJ, Ntshela S, Luttig MM, Mngadi KT, Muller D, Popane F, Mdluli J, Mngadi N, Sefuthi C, Clark DA, Churchyard G.

[Implementation of isoniazid preventive therapy for people living with HIV worldwide: barriers and solutions.](#)  
Getahun H, Granich R, Sculier D, Gunneberg C, Blanc L, Nunn P, Raviglione M.

[Estimating the Extent of Underreporting of Mortality among HIV-Infected Individuals in Rio de Janeiro, Brazil.](#)  
Pacheco AG, Saraceni V, Tuboi SH, Lauria LM, Moulton LH, Faulhaber JX, King B, Golub JE, Durovni B, Cavalcante S, Harrison LH, Chaisson RE, Schechter M.

[Quantitative analysis of a urine-based assay for detection of lipoarabinomannan in patients with tuberculosis.](#)  
Shah M, Martinson NA, Chaisson RE, Martin DJ, Variava E, Dorman SE.

[Evaluation of the Capilia TB assay for culture confirmation of Mycobacterium tuberculosis infections in Zambia and South Africa.](#)  
Muyoyeta M, de Haas PE, Mueller DH, van Helden PD, Mwenge L, Schaap A, Kruger C, van Pittius NC, Lawrence K, Beyers N, Godfrey-Faussett P, Ayles H.

[Adverse events with isoniazid preventive therapy: experience from a large trial.](#)  
Grant AD, Mngadi KT, van Halsema CL, Luttig MM, Fielding KL, Churchyard GJ.

[Symptom and chest radiographic screening for infectious](#)

results of the studies are expected and the future of the Consortium will be discussed with researchers and sponsors.

For more photos of the meeting, visit our [Facebook Page](#).



THRIO study researchers.

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[CREATE website](#)**

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need to update your  
email information?**

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[tuberculosis prior to starting isoniazid preventive therapy: yield and proportion missed at screening.](#)

Churchyard GJ, Fielding KL, Lewis JJ, Chihota VN, Hanifa Y, Grant AD.

[Comparison of two active case-finding strategies for community-based diagnosis of symptomatic smear-positive tuberculosis and control of infectious tuberculosis in Harare, Zimbabwe \(DETECTB\): a cluster-randomised trial.](#)

Corbett EL, Bandason T, Duong T, Dauya E, Makamure B, Churchyard GJ, Williams BG, Munyati SS, Butterworth AE, Mason PR, Mungofa S, Hayes RJ.

[Children's role in enhanced case finding in Zambia.](#)

Bond V, Chilikwela L, Simwinga M, Reade Z, Ayles H, Godfrey-Faussett P, Hunleth J.

Some abstracts may be missing. Contact [create@jhmi.edu](mailto:create@jhmi.edu) for publication requests.

## WHO/CREATE Symposium at CROI

Every year the TB/HIV Working Group of the STOP TB Partnership, the World Health Organization (WHO) and CREATE hold a pre-conference symposium at the Conference on Retroviruses and Opportunistic Infections (CROI). This year, the symposium will take place on Sunday, February 27, 2011, from 11:30 a.m. to 1:30 p.m. in Boston, Massachusetts.

The venue for the meeting will be announced in January. The main objective of this meeting is to promote high level scientific interchange of ideas and research priorities about TB and HIV. This year the meeting will focus on the use of Xpert MTB/RIF to diagnose drug susceptible and drug resistant TB among people living with HIV.

For more information, please e-mail [create@jhmi.edu](mailto:create@jhmi.edu).

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