

EDCTP Fact Sheet

World TB Day 2010: EDCTP joins the world in accelerating innovation against Tuberculosis

This year's World TB Day theme: "On the move against tuberculosis: Innovate to accelerate action" addresses a critical aspect of the core business and values of EDCTP. The programme aims to reduce poverty in sub-Saharan Africa by accelerating development of clinical interventions against tuberculosis, HIV/AIDS and malaria. EDCTP engages with researchers, policy makers, product developers and like-minded organisations to speed up the development of new or improved prevention and treatment interventions against tuberculosis malaria and HIV/AIDS. Today EDCTP joins the world by expressing its continued commitment in the fight against tuberculosis in line with this year's theme.

The World Health Organization (WHO) estimates that one-third of the world population is infected by the bacterium that causes TB, and that the majority of new cases occur in developing countries, especially in South-East Asia and in sub-Saharan Africa. Although there is evidence that the epidemic in Africa has been slowing in the recent years and appears to have stabilised or begun to fall, the highest number of deaths and the mortality per capita are still seen in the African continent. Additionally, there is a major concern of the role of HIV/AIDS which fuels the TB epidemic in Africa. HIV is the single most important factor contributing to the increase in incidence of TB since 1990. In some areas, control efforts are complicated by the emerging major threat of drug-resistant TB including multidrug-resistant (MDR-TB) and extensively drug-resistant (XDR TB) tuberculosis.

As expressed in previous World TB Days the world will never eliminate TB without new and more effective drugs, diagnostics and vaccines. The world urgently needs simpler and faster drug regimens that treat all forms of TB; rapid and more accurate diagnostic tools that detect TB; and a vaccine or vaccines that will be effective in preventing TB in people of all ages irrespective of immune status. EDCTP underlines the urgency of the above issues and is exploring synergy and complementarities with other partners active in the field of TB prevention and treatment through funding of TB activities within EDCTP scope.

TB Vaccines

Currently the most effective vaccine is BCG (Bacille Calmette-Guérin). The World Health Organisation recommends that to increase coverage all children in TB-endemic countries should receive this vaccine at birth. However, BCG has a few downsides: it neither fully protects children from developing TB nor protects adults already infected with TB; and its protection is not lifelong. Therefore development of more effective vaccines is urgently required.



Lack of sufficient capacity and sites to conduct such trials in sub-Saharan Africa are among the major challenges. EDCTP has since 2007 funded site upgrading and preparation projects for the conduct of TB vaccine trials in eleven African countries namely Ethiopia, Guinea-Bissau, Kenya, Madagascar, Mozambique, Senegal, South Africa, Tanzania, The Gambia, and Uganda.

TB drugs

The current TB drugs require patients to take a large number of tablets per day and to continue taking them for at least 6 months, preferably taken under the Directly Observed Treatment (DOT) strategy. The challenge of large amount of pills coupled with the long therapy duration reduces patient adherence to treatment. In addition, some of the drugs in the current combination interact with anti-retroviral treatment (ART), preventing patients to start both treatments together. Since 2007 EDCTP has funded TB drug related trials in nine African countries including Ethiopia, Gabon, Kenya, Mozambique, South Africa, Tanzania, Uganda, Zambia and Zimbabwe.

TB diagnosis

Current TB diagnosis based on sputum examination is cheap but not very sensitive resulting in some patients with TB being missed by the test. The nature of the test requires a specific number of bacteria to be present before the examiner in a laboratory can see them. Moreover, HIV infection makes the number of bacteria in sputum scanty due to reduced immune response. In 2009 EDCTP committed to spend 8 million Euro to support three consortia studying improvement of TB diagnosis. These projects involve nine African countries namely Ethiopia, Malawi, Namibia, South Africa, Tanzania, The Gambia, Uganda, Zambia and Zimbabwe.

EDCTP funded TB research activities

To date EDCTP has committed € 39.11 Million to fund trials in the following areas:

- Surrogate markers to predict the outcome of anti-tuberculosis therapy (South Africa)
- Rapid evaluation of moxifloxacin in the treatment of sputum smear positive tuberculosis (South Africa, Tanzania and Zambia)
- A controlled clinical trial to evaluate high-dose rifampentine and moxifloxacin in the treatment of pulmonary tuberculosis (Mozambique, South Africa, Zambia and Zimbabwe)
- Determining the optimal doses of antiretroviral and anti-tuberculosis medications when used in combination for the treatment of HIV/TB in co-infected patients (South Africa)
- Optimisation of tuberculosis and HIV co-treatment in Africa looking at pharmacokinetic and pharmacogenetic aspects on drug-drug interactions between rifampicin and efavirenz (Ethiopia and Tanzania)
- Pan-African Consortium for Evaluating Anti-tuberculosis agents (PanACEA) in Gabon, Kenya, South Africa, Tanzania, Uganda and Zambia.

Approximately € 37.06 million have been committed towards site preparedness and capacity building for TB vaccine trials in the following projects:

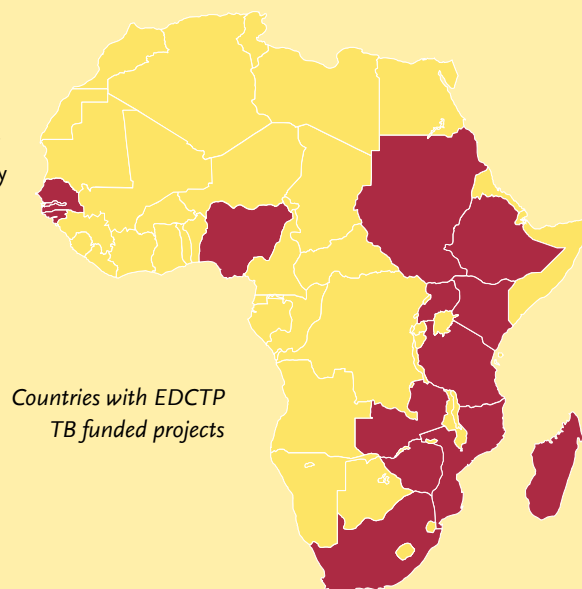
- Prospective epidemiological studies of TB in neonates and adolescents in preparation for future vaccine trials in Karemo Division of Siaya District in Western Kenya
- Toward conducting phase III trials of novel TB vaccines in Ugandan infants and adolescents
- Capacity building for the conduct of ICH-GCP level TB vaccine trials in high risk populations in Ethiopia and East Africa
- Conduct of ICH-GCP level Phase II TB vaccine trials in high risk populations in Ethiopia and Guinea-Bissau
- A multi-centre phase II trial of a new TB vaccine in African infants in Kenya, South Africa and Uganda
- A proof of concept phase IIb trial to evaluate the protective efficacy of a booster MVA85A vaccine administered to healthy HIV-infected adults in Senegal, South Africa and The Gambia.

Future plans in the fight against TB

In 2010 EDCTP will spend more funds on projects conducting phase II and phase III TB vaccine trials in TB/HIV co-infection and TB vaccines. Additionally, EDCTP will continue to fund infrastructure development at African research sites, training of African researchers and supporting research enabling environment of regulatory and ethical procedures. Currently with 20 TB funded projects (including Senior Fellowships), the goal of accelerating the development of new or improved drugs, vaccines and diagnostics against tuberculosis is coming to reality.

More information on TB and World TB Day

- **World TB Day website**
http://www.stoptb.org/events/world_tb_day/2010
- **Stop TB Partnership**
<http://www.stoptb.org>



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