Despite significant progress in recent decades, tuberculosis continues to be a major cause of mortality in many parts of the world, and in some areas, even in high-income countries including the UK, it is on the rise once more. This resurgence is caused by two major challenges: people living with HIV, which greatly increases the risk of developing active TB disease, and the emergence of multi drug-resistant forms of TB that are extremely difficult to treat.

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In recent years, the TB Centre at the School has become established as a collaborative hub to further develop and co-ordinate this work. Thanks to the leadership of David Moore, and now Helen Fletcher, the Centre is growing to encompass all aspects of research from laboratory science in host and pathogen biology, deciphering the genetic code of drug resistant strains, to implementing new control strategies.

This report highlights some of the projects, partnerships and areas in which the Centre is engaged. There is much to do, and as always the biggest challenge is to persuade governments and funders to work together and act strategically to build effective health systems and services. TB has throughout history been closely linked with poverty, and its control will come through sustained public health and socio-economic interventions that improve people’s quality of life.

I hope you will be inspired by what you read here to support the work of the TB Centre and join us in the common goal to understand, control, and ultimately eliminate this disease.

Baron Peter Piot
Director and
Professor of Global Health
London School of Hygiene & Tropical Medicine

Foreword: working to tackle the intractable challenges of tuberculosis

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About the TB Centre

TB kills more people worldwide than any other disease. In 2014, 9.6 million people contracted TB and 1.5 million died from the disease. However, the number of people with a new diagnosis of TB has fallen by an average of 1.5% per year since 2000, and ending the disease by 2030 is among the health targets of the newly adopted Sustainable Development Goals. This is a daunting task, but if researchers, governments, NGOs, industry and funders respond now, working together we can achieve it.

The TB Centre at the London School of Hygiene & Tropical Medicine brings together more than 120 laboratory scientists, clinicians, epidemiologists, statisticians, public health specialists and policy-makers. Our shared purpose is to reduce the global burden of TB, through high quality research, education and knowledge translation.

Innovation

Through consultancy work, research meetings, seminars and journal clubs, we disseminate our work and generate new ideas. Members of the TB Centre are global leaders in areas including:

- clinical trial design
- epidemiology
- tracing of TB transmission using molecular tools
- host-pathogen interactions
- development and implementation of new diagnostics
- mathematical modelling
- health economics
- health systems research

Collaboration

We work in more than 20 countries with high prevalence of TB across Asia, Africa and Latin America, and our researchers are strongly integrated with local academic institutions, governments and international organisations.

Investing in the future

We are committed to training the next generations of TB researchers, and have an active student community within the TB Centre. Our collective goal is to generate new knowledge, and to transfer the highest quality research into policy and practice, and ultimately real-world impact. We invite you to join us.

Helen Fletcher, Director, TB Centre
Katherine Fielding, Deputy Director, TB Centre

http://tb.lshtm.ac.uk
Twitter: @LSHTM_TB

This publication was collated and edited by Steve Smith, Helen Fletcher, David Moore and Patrick Wilson, November 2015.
Clinical trials: towards effective diagnosis and treatment

Progress towards rapid and reliable diagnosis followed by effective drug treatment is vital in the effort to control tuberculosis. TB Centre investigators have been awarded funding for a number of major clinical trials which aim to effect this progress.

Rapid urine-based screening for TB to reduce AIDS-related mortality in hospitalised patients in Africa

Post-mortem studies show that TB is the cause of between one-third and two-thirds of adult HIV/AIDS-related deaths recorded in health facilities in sub-Saharan Africa. However, around one half of these TB cases are undiagnosed at the time of death, highlighting the urgent need for new diagnostic approaches. Background studies conducted in Cape Town by Stephen Lawn show that a large majority of TB cases can be rapidly diagnosed from a urine sample within the first 24 hours of acute hospital admission, using a combination of two techniques: Determine TB-LAM lateral-flow urine test and Xpert MTB/RIF testing of concentrated urine.

The three-year Screening for Tuberculosis to Reduce AIDS-Related Mortality in Hospitalized Patients in Africa (STAMP) study, started in 2015, is an individually-randomised controlled trial that will assess the clinical outcomes of standard sputum-based testing with Xpert MTB/RIF plus additional urine-based screening, compared with the standard screening alone. Funded by a UK Medical Research Council, Department for International Development and Wellcome Trust Global Clinical Trials Scheme grant award of £2.1 million.

Principal Investigator: Alison Grant; TB Centre co-investigators: Katherine Fielding, Anna Vassall

The XTEND study: evaluating Xpert MTB/RIF as a first line TB test in South Africa

The XTEND study evaluated the impact of the new diagnostic test Xpert MTB/RIF in the context of its national roll-out in South Africa. It was a cluster-randomised trial, in which study clinics were randomised to early implementation of Xpert MTB/RIF as their first-line TB diagnostic test, while control clinics continued to use smear microscopy, which is the standard test. The study included over 4,600 people giving sputum to be tested for TB.

The results, recently published in Lancet Global Health, showed that mortality at six months was not lower in study clinics using Xpert MTB/RIF than in the control clinics using microscopy, and the number of people starting TB treatment by six months was also not changed. However the proportion of people with a confirmed TB diagnosis was higher in the clinics using Xpert. These results imply that implementation of a new diagnostic test with higher sensitivity may not, in isolation, improve patient outcomes for drug sensitive TB. Improved outcomes may need better linkage to TB and HIV care.

Xpert MTB/RIF versus sputum microscopy as the initial diagnostic test for tuberculosis: a cluster-randomised trial embedded in South African rollout of Xpert MTB/RIF.


The quest for new and improved TB vaccines

The current vaccine against tuberculosis, Bacille Calmette Guérin (BCG) is nearly a century old and does not provide effective protection against TB, especially in high incidence settings where it is most needed. To eventually eliminate TB, we need a new, highly efficacious vaccine. The TB Vaccine Initiative consortium (TBVAC2020) has been granted 24.6 million euros from the European Horizon 2020 programme and other government sources to advance new TB vaccine candidates from discovery to clinical development. Three TB Centre principal investigators, Hazel Dockrell, Gregory Bancroft and Helen Fletcher, are leading on three separate projects as part of a consortium of 40 research institutes, pioneering innovative approaches to vaccine development.

Discovery and development of TB biomarkers of protection

The Biomarkers of Protection work package of TBVAC2020 aims to optimise the measurement of candidate biomarkers and develop methods such as the Mycobacterial Growth Inhibition assay, which indicate the level of immunity a person has against TB. Host immune responses will be correlated with TB disease risk and the effect of helminth worm infections on mycobacterial growth inhibition will be analysed.

TB Centre members: Helen Fletcher, Andrea Zeimer, Hazel Dockrell, Steven Smith, Mateusz Hasso Agopsowicz, Shaheeda Ammar

Preclinical Model Development

People are often affected by conditions that increase their risk of developing TB. These conditions include HIV, obesity and diabetes. New animal models will be developed to better reflect these human conditions that are associated with increased TB disease risk. This will improve our chances of identifying vaccines to protect vulnerable populations.

TB Centre members: Helen Fletcher, Andrea Zeimer
Selected TB Centre activities around the world

Multi-drug resistant TB and interaction with diabetes in Peru
In addition to ongoing diagnostic, epidemiological and genomic studies largely focussed on multidrug resistant TB in Peru, Centre researchers are working with partners at Universidade Peruana Cayetano Heredia (UPCH) in Lima on the EU-funded TANDEM consortium project. The association between TB and diabetes mellitus is being investigated using established laboratory and community-based research platforms here and at partner sites in Indonesia, Peru, Malawi and South Africa. Both the School and UPCH are core partners in the global TB genomics programme known as CRyPTIC, the Comprehensive Resistance Prediction for Tuberculosis International Collaboration.

Clinical trials looking at immunological reactions in leprosy
With help from the School, a two-year clinical trial with individual randomisation led by epidemiologists from the Oswaldo Cruz Foundation in Recife, Brazil and the School started in March 2014. The objective is to estimate the incremental cost-effectiveness of a protocol for screening and diagnosis of TB in HIV patients. The study includes screening by clinical algorithm, followed by diagnosis with gene Xpert MTB/RIF, sputum smear microscopy and chest X-ray.

HIV-related TB in Malawi: clinical trials on diagnosis, treatment and outcomes
Malawi-Liverpool-Wellcome Trust and College of Medicine in Blantyre host a number of TB Centre investigators and projects including a major randomised controlled trials of diagnostic interventions, funded by the UK Medical Research Council, Department for International Development and Wellcome Trust Global Clinical Trials Scheme, as well as the US National Institutes of Health and in-house. The site also undertakes comprehensive extended monitoring and evaluation of all registering TB patients in Blantyre City. A recently developed online system known as “ePAL” – the electronic Participant Locator and Wellcome Trust Global Clinical Trials Scheme, and Wellcome Trust Global Council, Department for International Development and Wellcome Trust Global Clinical Trials Scheme, as well as the US National Institutes of Health and in-house.

HIV-related TB co-infection in Brazil
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Treatment trials for drug-sensitive and drug-resistant TB in Indonesia
A recently completed trial in adults with drug-sensitive pulmonary TB in Jakarta and AYMM in Africa showed that a four-month experimental treatment with the drug gatifloxacin was not as effective as the standard treatment with ethambutol for six months. These results were published in the New England Journal of Medicine in 2014, and we are now working with Medecins Sans Frontieres on a new trial using bedaquiline and pretomanid.

Africa Centre TB programme
KwaZulu-Natal is one of few African regions with high TB incidence, and the highest prevalence of multidrug-resistant TB in South Africa. Here, the Africa Centre, in which the School is a key collaborator, is developing a multidisciplinary research programme in order to understand TB transmission, and develop interventions to interrupt it. Initial projects include a TB treatment cohort including multidrug resistant TB, using epidemiological, geospatial and molecular data to understand TB transmission networks; and a study to estimate the incidence of TB infection among adolescents.

The immunology of TB in adults and infants
We have several projects around the immunology of TB in both adults and infants, funded by the UK Medical Research Council, The Welcome Trust and the European Union. In adults, we have a particular interest in the B cell immune response to T cells and in clinical trials of new TB vaccines. In infants, we have two projects looking at whether the latent TB infection that occurs in African mothers affects their children’s response to BCG following birth, and whether randomised controlled trials of delayed BCG, to determine whether BCG non-specifically stimulates the infant innate immune system to protect against unrelated infections.

Contacts: Stephen Cooper, Sarah Pentling and Alison Kirkham

Leprosy projects in India
Patients with leprosy and neuropsychiatric pain show a poor quality of life and psychological wellbeing, in a project looking at nerve damage characteristics and somatosensory profiles of leprosy patients in low-income resource settings. School researchers have identified a novel profile of sensory loss to thermal and mechanical stimuli, combining both peripheral and central deficits. They have also shown that adding azathioprine to leprosy immune-suppresser does not improve patient outcomes, an important negative result.

Contacts: Reena Harsh and Diana Lookwood

Research Programme on control
In a five year collaboration between the School, Saw Swee Hock School of Public Health, University of Singapore, the Cambodia National Institute of Public Health and TB Programme, and Phnom Penh University of Health Sciences, researchers are conducting a series of linked projects in qualitative methods, epidemiology, genomics, transmission, data modelling and health economics. The overarching goal is to define a variety of options to reform Cambodia’s TB Programme and interventions, and to assess their likely impact and costs over the next 15 years.

Contacts: Richard Coyle and Mikhail Khan

Improving adherence to treatment for drug-susceptible TB
Mobile text messaging and medication monitors have the potential to improve adherence to TB treatment and reduce the need for directly observed treatment. Researchers from the School and the National Center for Tuberculosis Control and Prevention in China conducted a cluster-randomised trial in four provinces in China, to assess the effectiveness of these interventions.

Patients either received text message reminders, an electronic medication monitor, both, or no reminders for their six month treatment period. Patients receiving no reminders missed 30% of their medication doses and patients receiving text messages missed 27%. Patients with an electronic medication monitor both opened and closed their medication boxes if not opened at the agreed time – only missed 17% of doses, and those who received both text messages and medication monitors missed just 14%, clearly demonstrating improved adherence.

A second study is now underway, using a more robust medication monitor and examining clinical outcomes. These studies are funded by the Bill & Melinda Gates Foundation.

Contacts: Kathrina Fakhri and James Lewis

Note: The lines and points on the map indicate in which areas these projects are based. They are not meant to be geographically accurate.

Malawi Epidemiology and Intervention Research
In the Karonga Prevention Study, now part of the Malawi Epidemiology and Intervention Research Unit, is using traditional epidemiology and whole genome sequencing on long term population-based data to find out how and where TB transmission occurs, whether transmission is from or to others, and how TB interacts with HIV.

Contacts: Judith Quist and Mia Creagan

Health systems and policy research
Members of the TB Centre have collaborated on two important studies in South Asia, and are engaging in further Research with policy makers.

In Pakistan we collaborated with the National TB Programme on an important cohort study which showed that treatment outcomes were similar for multi-drug resistant TB patients treated using locally procured drugs and international quality assured drugs. We also conducted a multi-country analysis of patient sector engagement in TB management across South Asia.

Contact: Minah Khan

Intertlinked Projects in Myanmar and Yunnan Province, China
In Myanmar, TB Centre researchers are undertaking a case control study to determine risk factors associated with multidrug resistant TB. In Yunnan, qualitative research is addressing questions of access and stigma amongst patients with TB and the role of gender in seeking health services. We are also analysing the costs and cost-effectiveness of community-based multidrug resistance TB treatment programmes. These projects are funded by UNAIDS and we are working in collaboration with FH300, Myanmar National TB Programme and Yunnan Centre for Disease Control.

Contacts: Richard Coyle and Mikhail Khan

Pathway and the involvement of governments and nongovernmental organisations in the TB programmes in Zambia
Zambart is a major research collaboration between the School and the University of Zambia. Current Zambart studies include a TB vaccine trial with Aeras and Glaxosmithkline, diagnostics studies of Quantifee plus, a TB and meningitis study, and a study of the relationship between TB, HIV and diabetes, as well as HTN071/PopART which looks at TB in the context of universal test and treat for HIV.

Contacts: Helen Ayres

Image 1 of 2

Cambodia

Pakistan

Uzbekistan

India

Malawi

Zambia

Uganda

Ethiopia

Zimbabwe

South Africa

Swaziland

Botswana

Kenya

Guinea

Benin

Cameroon

Burkina Faso

Morocco

Kenya

Senegal

Ukraine

Pakistan

Image 2 of 2

Biennial Report 2015

5
Towards better control of HIV-related TB

The Consortium to Respond Effectively to the AIDS/TB Epidemic (CREATE) is an international research consortium funded by the Bill & Melinda Gates Foundation to assess the impact of novel strategies for controlling HIV-related TB. It has funded three large cluster-randomised trials including the ZAMSTAR and Thibela TB studies, in which TB Centre researchers have leading roles.

Thibela TB: mass screening and treatment in mining communities

The Thibela TB study was conducted in South African goldmines where notification rates of people with TB in 2008 were 3,000 per 100,000 miners, despite a control programme in the mines following international guidelines, and regular radiological screening. Since conventional control methods were not working in this setting, we investigated a radical method to control TB. Thibela TB, which is “Prevent TB” in Sesotho, took the approach of screening the whole workforce for TB, treating those diagnosed and providing preventive therapy (nine months of anti-TB drug isoniazid) for those eligible. This intervention was compared with the current standard of care, and we assessed the overall impact on TB incidence and prevalence.

The Thibela TB study has generated 23 publications including contributions to a supplement in AIDS in 2010, and we continue to analyse data. Safety data and our experiences of implementing isoniazid preventive therapy has contributed to the roll-out of preventive therapy for people living with HIV. Our main findings, published in the New England Journal of Medicine in 2014, disappointingly showed the intervention did not improve TB control at the population-level in these gold mines. A large scale mathematical modelling exercise helped to explain our results and suggested that a much more intensive “combination prevention” approach will be needed to improve TB control in the mines.

Data from the trial have already been instrumental in shaping World Health Organization guidelines, both for screening for active TB among people living with HIV and for community TB screening.

The ZAMSTAR trial: community TB testing and counselling

The Zambia and South Africa tuberculosis and AIDS reduction study (ZAMSTAR) was a cluster-randomised trial of two interventions to reduce the burden of TB at community-level. One was improved community-wide TB testing and the other a household-level intervention to provide TB and HIV counselling to facilitate prompt diagnosis and treatment. The trial was conducted in 24 communities in Zambia and the Western Cape province of South Africa, in partnership with the Zambia AIDS Related TB (ZAMBAT) Project and the Desmond Tutu TB Centre at Stellenbosch.

Around a million people were involved in the trial at a cost of less than one U.S. dollar per person per year. The study’s main finding, published in the Lancet, showed that the household intervention may have reduced prevalence of TB in adults, and that children in the communities that received household counselling were half as likely to become infected with TB.

“In these communities, TB and HIV affect the entire household, so you need to involve not only the TB patient but his or her entire family. If adults are not diagnosed and treated, they can infect children”

Helen Ayles, ZAMSTAR Principal Investigator

TB Modelling and Analysis Consortium

The TB Modelling and Analysis Consortium (TB MAC) is a global community of TB modellers who provide quantitative support for TB policy decisions and implementation. By promoting collaboration and funding research projects, TB MAC has since its inception in 2012 been of great influence in policy debates, and developing the global field of TB modelling.

On the global policy level, TB MAC has updated the World Health Organization methods used to estimate the amount of HIV-related TB globally, and provided input on technical discussions that resulted in the decision by the Global Fund to Fight AIDS, TB and Malaria not to reduce the proportion of funds it allocates to TB. In recent years, TB MAC has also supported the development of tools to integrate modelling into country-level policy discussions. These have been used in collaborations with UNAIDS, the World Health Organization, and the governments of Vietnam, Ghana, South Africa.

In response to the post-2015 End TB Strategy, TB MAC has led the first multi-model TB comparison exercise to assess the feasibility of the new targets of 50% reduction in TB incidence and 75% reduction in TB mortality by 2025 for China, India and South Africa. This work coordinated the efforts of 11 modelling groups, a team of economists and representatives from the country National TB Programmes and advocacy communities. Results from this work have informed policy discussions, in particular in South Africa, where the work has influenced budgets and operational research priorities. The modelling is being used in South Africa in their first ever combined TB and HIV Investment Case.

The consortium is open to anyone who is interested in quantitative methods to improve TB policy and practice. It is funded by a grant to the School from the Bill & Melinda Gates Foundation.

TB centre members: Richard White, Rein Houben, Christina Albertersen, Anna Vassall


Diabetes associated with increased risk of TB in the United Kingdom

Researchers at the TB Centre have used UK electronic routine health records to study the association between diabetes and TB. The project used data taken from general practice consultations and records for up to six million patients over more than 20 years and produced a cohort of more than a quarter of a million patients with diabetes, who were compared with a control group and followed up for incident TB disease. Despite the UK having a very effective primary health care system that incentivises high quality care for chronic diseases such as diabetes, the increased risk of TB was still evident. The study showed that those accessing the least amount of diabetes care were at the greatest risk for TB. The findings have implications for UK national policy proposing to provide high risk groups access to TB screening and treatment in primary care settings.

TB Centre members: Louise Pealing, David Moore


TB and diabetes mellitus in TANDEM

Diabetes increases the risk of TB and seems to impair response to TB treatment. The TANDEM Consortium, funded by the European Union, is investigating the links between TB and type 2 diabetes. Through field work in Peru, South Africa, Romania and Indonesia, TANDEM will determine the most cost-effective approaches to screening for diabetes in TB patients and for TB in diabetes patients. Together with partners in the Netherlands, Germany and New Zealand, molecular interactions between M. tuberculosis infection and diabetes are being elucidated using, fat cells, macrophages, global gene expression analysis and genetic analysis. The TANDEM consortium is funded by a four year European Union grant award of 5.9 million euros.

TB Centre members: Hazel Dockrell, Jackie Clift, Clare Eckold, David Moore, Ulla Griffiths, Yoko Laurence


Taught courses and research degrees relating to TB

Distance learning TB module

The TB module is part of the School’s Infectious Diseases MSc distance learning course. It is multidisciplinary, with biology, pathology and immunology balanced with considerations of broader social and ethical issues. The study material is delivered in digital format, with interactive exercises, figures and animations, and a team of SS tutors supports learning via virtual learning environment discussion forums. Our student body is highly diverse, with approximately 120 students registered each year from around 40 countries worldwide. For full details, visit www.lshtm.ac.uk or contact module organiser jackie.clift@lshtm.ac.uk.

Current PhD students working on TB-related projects

Student Project title
Mateusz Hasso Agopsowicz Epigenetics and immune responses to BCG vaccine
Shaheda Anwar Impact of helminth infection on antymycobacterial Immune responses in UK migrants
Katherine Horton Understanding and assessing the potential impact and cost-effectiveness of targeting men in systematic screening for tuberculosis
Sean M. Cavany Optimising contact tracing for tuberculosis in England
Sophie Rhodes Developing a mathematical modelling framework to predict the best dose in humans for TB vaccines using animal data
Rebecca Harris Informing clinical development of novel TB vaccines through mathematical modelling and development of novel epidemiological tools
Natascha Meunier Characterising bovine tuberculosis in and around the Queen Elizabeth National Park, Uganda
Clare Eckold Host blood gene expression changes through tuberculosis treatment: effect of HIV or type 2 diabetes co-morbidity
Sarah Lou Bailey Understanding the threat of diabetes mellitus to tuberculosis control in sub-Saharan Africa: the impact of HIV and diabetes control
Noemia Teixera-Filha The treatment of HIV/AIDS in Brazil: economic evaluation of strategies for screening and diagnosis of tuberculosis in people living with HIV/AIDS and the use of antiretroviral therapies as a way to reduce morbidity and mortality of tuberculosis in this population
Yoko Laurence Economic evaluation of screening and treatment strategies for concurrent TB and DM in Indonesia, Peru and Romania
Lisa Stockdale Measuring the impact of vaccination on TB drug efficacy
Satina A. Prabowo Investigation of therapeutic vaccination strategy for tuberculosis in an ex/svo mycobacterial growth inhibition assay
Charlotte Sarfas Influence of age on the Y-cell immune response in BCG vaccinated Rhesus macaques
Ivonics Freire Incidence risk of progression to tuberculosis in migrants with fibrotic lesions suggestive of post-TB scarring
Patrick Nguipdop-Djomo Re-emergence of tuberculosis in Western high-income low incidence countries: Levels of BCG vaccines derived protection, and the role of social deprivation
Jordis Nery Silva Effect of a cash transfer programme on tuberculosis incidence, and treatment success in Brazil
William Rudgard Estimate the potential mitigation effect of social protection on TB catastrophic costs
Peter Washa Khan Investigating Mycobacterium tuberculosis transmission in rural Malawi
Ankur Gupta-Wright Hospitalised patients with HIV-associated TB diagnosed by rapid urine-based diagnostic assays: an investigation of factors associated with mortality
Yasmeen Hanifa A study of the frequency and underlying causes for “TB symptoms” in patients attending for HIV care in South Africa
Aaron Karat Prevalence of TB and other treatable diseases at autopsy in South Africa
Patrice Akusa Mawa The impact of maternal infection with Mycobacterium tuberculosis on the infant response to BCG immunisation
Sarah Prentice Does neonatal BCG vaccination provide protection against heterologous pathogens by stimulating the innate immune system?
Amera Khan Determining the feasibility and acceptability of implementing a latent TB infection testing and treatment program at overseas panel sites for US bound immigrants
Jody Pether Tuberculosis host and pathogen genomics
Sedona Sweeny Improving methods to evaluate the poverty impact of disease
Debora Pedrazzoli Impact of socioeconomic determinants on TB control
Mark Lalli Modelling the dynamics and impact of targeted interventions for high-risk groups for National Strategic Plans against tuberculosis: development and application of a modelling tool for in-country decision making

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