

Interferon gamma release assays for Diagnostic Evaluation of Active tuberculosis (IDEA): test accuracy study and economic evaluation

Yemisi Takwoingi,¹ Hilary Whitworth,^{2,3}
Melanie Rees-Roberts,^{2,4} Amarjit Badhan,^{2,4}
Christopher Partlett,¹ Nathan Green,^{5,6,7,8}
Aime Boakye,^{2,4} Heather Lambie,² Luigi Marongiu,²
Mark Jit,^{8,9} Peter White,^{5,6,7,8} Jonathan J Deeks,¹
Onn Min Kon^{2,4,10} and Ajit Lalvani^{2,4*} on behalf of
the Interferon Gamma Release Assays for Diagnostic
Evaluation of Active Tuberculosis (IDEA) study group[†]

¹Institute of Applied Health Research, University of Birmingham, Birmingham, UK

²Tuberculosis Research Centre, National Heart and Lung Institute, Imperial College London, London, UK

³Department of Clinical Research, London School of Hygiene & Tropical Medicine, London, UK

⁴National Institute for Health Research (NIHR) Health Protection Research Unit in Respiratory Infections, Imperial College London, London, UK

⁵NIHR Health Protection Research Unit in Modelling Methodology, Imperial College London, London, UK

⁶Medical Research Council (MRC) Centre for Outbreak Analysis and Modelling, Imperial College London, London, UK

⁷Department of Infectious Disease Epidemiology, Imperial College London, London, UK

⁸Modelling and Economics Unit, Centre for Infectious Disease Surveillance and Control, Public Health England, London, UK

⁹Department of Infectious Disease Epidemiology, London School of Hygiene & Tropical Medicine, London, UK

¹⁰St Mary's Hospital, Imperial College Healthcare Trust, London, UK

*Corresponding author a.lalvani@imperial.ac.uk

†For a full list of IDEA study collaborators, please see *Acknowledgements*

Declared competing interests of authors: Ajit Lalvani is the named inventor for several patents underpinning T-cell-based diagnosis including interferon gamma, enzyme-linked immunospot assay, ESAT-6, CFP-10, Rv3615c, Rv3873 and Rv3879c. He has royalty entitlements from the University of Oxford spin-out company (Oxford Immunotec plc), in which he has held a minority share of equity and he is a member of the Efficacy and Mechanism Evaluation Board. Jonathan J Deeks is a member of the Health Technology Assessment (HTA) Commissioning Board and the HTA Efficient Study Designs Board. Onn Min Kon is chairperson of the UK Joint Tuberculosis Committee. Peter White has received research funding from Otsuka SA for a retrospective study of multidrug-resistant tuberculosis treatment in several eastern European countries outside the submitted work. He received grants from the Medical Research Council during the conduct of the study.

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Plain English summary

Interferon gamma release assays for diagnosing active tuberculosis

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Plain English summary

Tuberculosis (TB) is one of the world's most important infectious diseases. In 2014, 1.5 million deaths were caused by the disease – about one death every 25 seconds. Traditional diagnosis of TB is based partly on the tuberculin skin test. Blood tests such as QuantiFERON GOLD In-Tube (QFT-GIT; Cellestis, Carnegie, VIC, Australia) and T-SPOT.*TB*[®] (Oxford Immunotec, Abingdon, UK) are now available. However, these two tests are not used as part of current NHS practice because of the lack of evidence about how well the tests perform when diagnosing symptomatic (active) TB in routine clinical practice.

The purpose of our study was to compare the ability of QFT-GIT and T-SPOT.*TB* to differentiate people with active TB from those without active TB in a population suspected of the disease. We also assessed new blood tests that are currently being developed for diagnosis of active TB.

We recruited 1074 patients with suspected TB from 14 NHS hospitals in London, Slough, Oxford, Leicester and Birmingham into our study. We found that T-SPOT.*TB* correctly detected more people with active TB than QFT-GIT; T-SPOT.*TB* would miss about 18 people out of every 100, whereas QFT-GIT would miss about 33 people out of every 100 with active TB.

For this reason, neither test is good enough for routine clinical use because the number of people with active TB who are incorrectly diagnosed as not having active TB is unacceptably high. In addition, neither test is good value for money. However, we did find that some of the newer blood tests performed better than T-SPOT.*TB* and their usefulness should be further investigated.

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