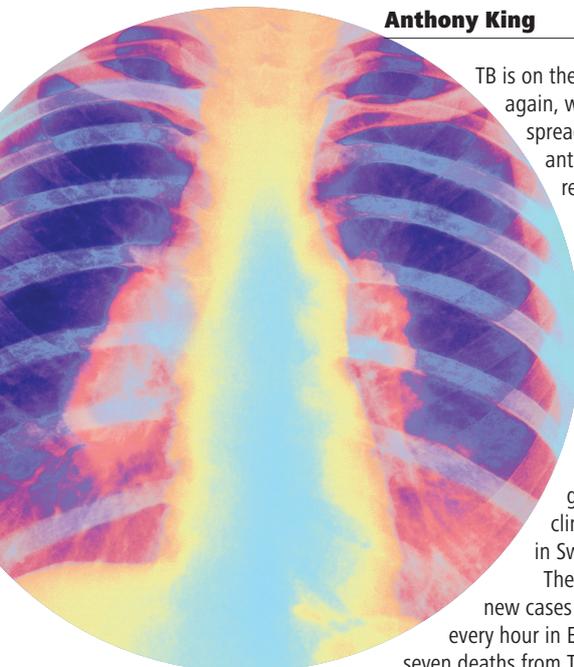


**Clinical trials**

# New TB vaccine set for testing

**Anthony King**



Barts Hospital/Getty

TB is on the march again, with the spread of antibiotic resistant TB a modern concern. Now, a new vaccine to combat this old disease has been given the green light for clinical testing in Switzerland. There are 49 new cases reported every hour in Europe and seven deaths from TB every hour in the European region, according to the World Health Organization. 'We have a vaccine that works in children, but there are still one and a half million people dying every year, says microbiologist

Carlos Martin of the University of Zaragoza in Spain and one of the developers of the new vaccine, MTBVAC.

MTBVAC is owned by the University of Zaragoza which partnered with Spanish biotech Biofabri in its clinical development; both are in the non-profit European Tuberculosis Vaccine Initiative. This is the first vaccine based on *Mycobacterium tuberculosis*, the bacterium that causes TB.

'This will be the first live attenuated vaccine in clinical trials,' Martin says, adding that the vaccine could be in the clinic in about five years if all goes to plan. It relies on weakened TB bacteria due to the removal of two virulence genes.

The vaccine has already undergone preclinical testing. Recruitment of 36 healthy participants for the Swiss trials is scheduled to start immediately. The trial will test MTBVAC for safety, ability to cause adverse reactions and how well it elicits an immune response compared to the present BCG vaccine.

The current BCG vaccine has not had any major impact on the TB epidemic, particularly in adults. It is hoped the new

vaccine will offer life-long protection against all forms of BCG. 'If MTBVAC successfully runs through all phases of clinical evaluation and is shown to be more effective, we could replace BCG,' Martin says.

'Given the nature of the disease, to fully eliminate TB an effective vaccine is essential,' commented Martin Sprenger, director of the European Centre for Disease Prevention and Control.

Immunisation would initially protect individuals but 'unimmunised people would benefit indirectly as the risk of being exposed to an infected person with active disease would decrease,' he added.

Philippe Glaziou, an epidemiologist at the WHO, said about one-third of the 7bn world population is estimated to be infected with TB.

'In Eastern Europe, and particularly in countries of the former Soviet Union, TB is often of the multi-drug resistant type. This is very difficult to treat as the bacilli causing the disease are resistant to the most effective drugs... An effective vaccine could have an enormous public health impact in Europe and the rest of the world,' said Glaziou.

**Drug development**

# Not-so rare diseases affect one in 17

**Maria Burke**

One in 17 people will be affected by a rare medical condition during their lifetime, but such conditions are too often neglected by the NHS, according to a new report by the 2020Health policy think-tank.

The study criticises health professionals who focus on treating a handful of major illnesses rather than the 'increasing number of rarer diseases'. As a result, it says, thousands of people suffer for years with misdiagnosis and inadequate treatment, wasting NHS funds.

The EU defines rare or 'orphan' conditions as those that affect fewer than five in 10,000 of the population. Although today there



are 5000 rare diseases, about five new conditions are described in the medical literature every week, says the report, and this number is likely to mushroom thanks to advances in genomic sequencing. Around 80%

of rare conditions have a genetic component. Presently, the UK offers screening for only five childhood diseases at birth, compared with over 30 in the US and 20 in many European countries.

Interestingly, the pharmaceutical industry appears to have recognised the revenue potential for drugs to treat these diseases. Orphan drug development has experienced a period of 'tremendous growth' which is set to continue, Thomson Reuters reported in August. Its estimates put the market at just over \$50bn at the end of 2011.

It confirmed that developing orphan drugs is economically attractive, despite the smaller patient pool. Within the past few years, many mainstream pharmaceutical companies have established R&D units focused on rare diseases, joining small biotech companies in the search for new orphan drugs.