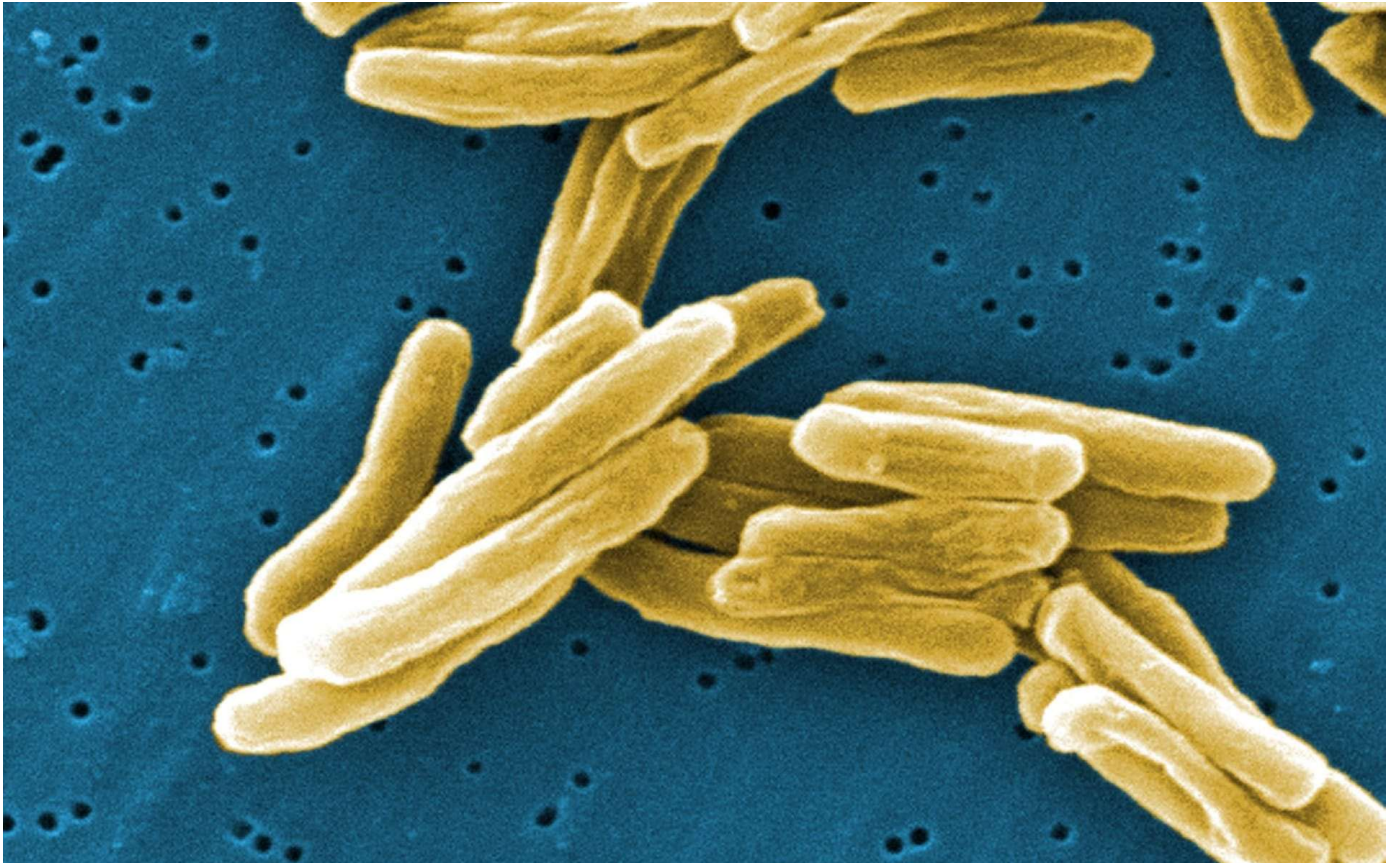


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Oxford University scientists gave babies trial TB vaccine 'that did not work on monkeys'



The Tuberculosis bacteria CREDIT: PA

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Oxford University is embroiled in an ethics row after scientists were accused of questionable conduct over a controversial trial of a new vaccine (<https://www.telegraph.co.uk/health>) on African babies.

Professor Peter Beverley, a former senior academic at the university, complained that scientists planned to test a new tuberculosis vaccine on more than a thousand infants without sharing data suggesting that monkeys given the immunisation had appeared to “die rapidly”.

“Certainly here in this experiment there was no evidence whatsoever that this is an effective booster vaccine,” Prof Beverley said.

He claimed the information was not given to regulators when an application to do the trial was initially submitted.

In the monkey study, five out of six of the animals infected with TB who were given the experimental vaccine had become “very unwell” and had to be put down.

An information sheet given to families in South Africa participating in the trial said the vaccine had been tested on animals and humans and was “safe and effective” in animals.

Professor Jimmy Volmink, Dean of the Faculty of Medicine and Health Sciences at Stellenbosch University, told The Telegraph the information sheet did not appear to reflect the evidence from the monkey study, which was “not right”.

He said people affected by tuberculosis were often poor and “not very highly educated”, making it particularly important that they were given “clear, understandable information.”

Tuberculosis | The facts

What is tuberculosis?

Tuberculosis is a bacterial infection caused by *Mycobacterium tuberculosis*, it mainly affects the lungs - although it can reach other organs too. Symptoms include a persistent cough, night sweating, fever, fatigue and weight loss. Overall, a relatively small proportion (5-15 per cent) of the estimated 1.7 billion people infected with *M. tuberculosis* will develop the disease during their lifetime, although recent research questions this.

How do you catch it?

TB is passed through the air and can be caught from being exposed to an infected person coughing and sneezing. It is a disease of poverty and mainly affects those in poorer countries or with low immune systems. The probability of developing TB is much higher among people with HIV, diabetes and those who smoke, drink and are malnourished.

How is it treated?

The standard treatment for the least complicated form of the disease is a six-month regimen of four drugs. Treatment for multi-drug resistant TB (MDR-TB) is longer - new guidelines recommend a nine to 12-month course of treatment. However, not all countries have implemented this and treatment can take up to 20 months, including a series of daily painful injections.

What is the incidence of TB around the world?

According to the latest data from the WHO there were 6.3 million new cases of TB in 2016 - out of a total of 10.4 million cases. Of these, around 490,000 were drug-resistant cases, half of which were in India, China and the Russian Federation.

Source: WHO Global Tuberculosis Report 2017



Tuberculosis is caused by bacteria, which is passed on through coughing and sneezing CREDIT: DAVID JONES/PA

Almost 1,500 babies in South Africa received the new jab and parents were paid in the region of £10 for taking part.

The South African regulator which approved the trial admitted to this newspaper that the information sheet given to parents “could be construed as misleading”, raising questions about whether families were sufficiently informed.

[The scientists at Oxford](https://www.telegraph.co.uk/university-of-oxford/) (https://www.telegraph.co.uk/university-of-oxford/) who carried out the trial maintain that the jab was safe for children and that their experiment was approved by several regulators in advance.

They said they followed the infants’ development for two years after the immunisation was given – a time period approved by the regulators.

The monkey study that concerned Prof Beverley began in November 2006 and the application to test the vaccine in the Western Cape was submitted 18 months later.

Around this time, Prof Beverley said he heard that the animals in a study had to be euthanized “rather rapidly”.

All the monkeys were infected with TB, but one group was given the widely used BCG jab, a second was given no immunisation and a third was given BCG plus new vaccine.

The baby trial began in July 2009 and almost half of the 2,800 infants taking part were given the new jab.

In 2013, the outcome of the trial on the infants was announced and concluded that the new vaccine offered no increased protection.

Professor Beverley, a principal research fellow at the University of Oxford until 2010, complained formally to the university.

An inquiry was launched and concluded that although there had been no wrongdoing, it “would have been good practice for the potentially adverse reaction observed in the monkey experiment to be reported to the authorities in a more timely fashion.”

Professor Helen McShane, one of the lead scientists who developed the new vaccine, has said that the purpose of the monkey study was to “test the aerosol delivery” to the animals, not to “yield safety information”.

She said it was a “failed experiment” because “there was no difference “ between the groups.

Prof McShane told the Telegraph that there was no delay in providing data from the monkey experiment to regulators.

She said she did not think that families in South Africa were exploited and that regulators had signed off the information sheet that was given to parents.

She added that the monkey trial contained a “limited” number of animals and Professor Beverley was “disgruntled”.

South African Medicines Control Council, which was one of the regulators who approved the trial, said that a “large body of data” – apart from the monkey experiment and which included previous human trials – was considered as part of the approval process.

They also said that the monkey experiment was “not a trial of the vaccine in monkeys” and that “there was no suggestion that the vaccine was unsafe in the monkeys or that it had caused disease or death”

However, when asked about the information sheet that was given to parents, the regulator said, “In retrospect the information on efficacy achieved in the animal studies could be construed as misleading”, although the “evidence of safety in the previous human studies was fairly reported”.

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