Cattle vaccination 'no magic wand to wipe out bTB'

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Cattle vaccination is no "magic wand" to wipe out bovine tuberculosis, but used in conjunction with existing control measures, it could offer farmers an important tool to help prevent TB infection in their herds, say scientists.

"I don't think it can be a strategy on its own - you have to use all the tools in your toolbox," said Glyn Hewinson, chief scientist at the Animal Health and Veterinary Laboratories Agency (AHVLA).

"But clearly the level of investment that's going into the development of TB vaccines shows the commitment to develop these important tools to control TB in the UK."

DEFRA has budgeted £15.5m for research into developing effective cattle TB vaccines over the next four years. Since 1998, more than £23m has been invested in cattle vaccine and associated research and development.

In the short-term, a modified form of the human tuberculosis vaccine BCG (Mycobacterium bovis Bacille Calmette-Guérin) is the lead cattle vaccine candidate.

EU legislation

An injectable form of BCG has been licensed for use against badgers. However, vaccination of cattle against TB is currently prohibited by EU legislation, mainly because BCG can interfere with the tuberculin skin test, which is recognised as the primary diagnostic test for TB in cattle.

In an attempt to clear the way for a cattle vaccine, the AHVLA has developed a blood test - a DIVA test - which can distinguish between infected and vaccinated animals.

DEFRA is working with the EU to change the current legislation to allow a BCG cattle vaccine and the DIVA test to be used in combination to tackle bovine TB. The aim is to allow both to be used legally in the UK - but the timetable remains uncertain.

Pros and cons of vaccine	
Pros	• The safety data is unprecedented in humans, which gives a level of confidence • The costs of a BCG cattle vaccine are low, especially compared with trapping and vaccinating badgers
Cons	• BCG vaccine does not give 100% protection, which is true of any vaccine. Estimates range from 50-70% DIVA test is currently required to use alongside the BCG vaccine • The DIVA adds costs when used in conjunction with vaccination

In January, the AHVLA submitted an application to the UK's Veterinary Medicines Directorate (VMD) for a marketing authorisation for a licence to use BCG as a cattle vaccine.

Prof Hewinson said: "We cannot share the performance characteristics at this stage as it is still confidential and being evaluated by the VMD.

"It's a complex process. The clock starts ticking when you submit (the dossier), but each time there's a question, the clock stops until we answer that question. We should have the feedback from the VMD within the year.

"But the VMD will only be able to grant a marketing authorisation for BCG once the existing EU prohibition on vaccination of cattle against TB is lifted."

Because field trials are banned in the UK, the AHVLA has been collaborating with countries where vaccination programmes are ongoing, including the USA, Argentina, Ethiopia, Mexico and New Zealand.

In particular, small-scale field trials carried out in Ethiopia over two years, funded by the Wellcome Trust, have revealed a level of efficacy that could be expected from cattle vaccination.

A herd with 100% infected animals was chosen for the field study. Young cows were introduced into the herd, some were vaccinated and some were left unvaccinated.

Comparison

At the end of the experiment, vaccinated animals were compared with controls, and 56% of the vaccinated animals showed no signs of infection compared with the non-vaccinated animals. A similar study in Mexico showed a protective efficacy of approximately 60%.

Commenting on the results, Prof Hewinson said: "Although these are small-scale trials, they are indicative of the sort of protection one might expect, but larger-scale trials will be required to give us greater certainty around the effects of vaccination.

"The results also show that vaccination does not protect all animals, which is why you need a DIVA test so that you are able to remove infected animals from a vaccinated herd."

A follow-up study is now being repeated in Ethiopia through funding from the Gates Foundation and the Department for International Development (DFID).

DEFRA's key policies

Cattle vaccination is a key area of DEFRA's Bovine TB Eradication Programme, alongside:

- Cattle surveillance and control measures to address cattle-to-cattle transmission
- Promoting good biosecurity to address transmission between cattle and between badgers and cattle

Prof Hewinson said researchers had already figured out the optimum BCG dose for cattle to give the best levels of protection.

The duration of immunity with the current vaccine is between one and two years, which would mean annual vaccination would be required at farm level, he added.

- Badger culling to control TB in badgers to reduce transmission from badgers to cattle in TB "hotspots"
- Research and development into an oral badger TB vaccine
- Tackling TB in non-bovine farmed species, including pigs, goats, deer, alpacas, sheep and llamas

A medium-term approach to cattle vaccination is looking at producing vaccines that improve BCG and its performance. This initiative is being linked to global multi-million pound efforts to develop improved TB vaccines for humans.

In the long-term, scientists are trying to develop effective vaccines against TB that do not sensitise cows to the tuberculin skin test and therefore would not require an additional DIVA test.

However, Prof Hewinson said the legal obstacles to cattle vaccination should not be underestimated.

"If we are going to generate data to show how effective the vaccine is, we will need to do field trials at some stage to know how effective the vaccines are in the UK, but that's not possible because it's illegal at the moment," he said.

Unlike the UK, many European countries do not have problems with bovine TB, so there is only a limited amount of work going on at European level on cattle vaccines.

Prof Hewinson said a small but well co-ordinated number of countries was involved in developing TB cattle vaccines around the world.

"You need to carry out experiments under high containment and facilities are limited and expensive," he added.

A DEFRA spokesman said: "Vaccination is one of our goals to help stop the devastating spread of bovine TB. We are investing £15.5m in their development over the next four years, but vaccination is not currently a viable alternative as there remain significant licensing and regulatory barriers before cattle vaccines can be used."

John Royle, NFU chief farm policy adviser, said: "Cattle vaccination is not the perfect solution when you still have the presence of TB in wildlife. You have still got to do something with badgers.

"If you vaccinated cattle you are still going to get TB breakdowns - it would just reduce the size and severity of the breakdown.

"If and when we get cattle vaccination in this country, we will need to consider how it is deployed and which areas we would use it in first. The key for me would be using it on the edge of low-risk areas.

"The cost of BCG is £20 a dose and if we are vaccinating annually, it's a lot of money. Would farmers be happy to pay this much?"