

## Vaccination

(paper supporting the blog TB, Badgers and Cattle in The UK: A Campaign Ripe For A Re-boot, at <http://threeworlds.campaignstrategy.org>)

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### Introduction

The idea of vaccinating against TB goes back over 100 years and versions of the 'BCG' vaccine have been used in humans, cattle and badgers. The 'Bacillus Calmette-Guerin' or BCG is made from a weakened strain of the TB bacterium, has been given to people since 1927 and is the most widely used vaccine in the world.

The NHS says that in people, the vaccine is thought to 'protect up to 80% of people against the most severe forms of TB [including bacterial meningitis] for at least 15 years, perhaps even up to 60 years'. It is less effective against TB infection in the lungs.

Studies have shown that about 50-100% (a median of 76%) of cattle vaccinated with BCG are effectively protected against TB.

There were just over 5,000 cases of TB recorded in people in England in 2017 (mostly among recent immigrants). It's mainly spread from person to person through aerosol droplets and requires prolonged close contact, which is one reason why it is strongly associated with poverty and bad living conditions, and still at a high level in some parts of the world. A few cases of cattle-to-human infection still occur in the UK, although milk pasteurisation and checks on slaughtered meat stopped most of that transmission in the 1950s.

According to the Oxford Vaccine Knowledge Project 'the bacterium used for the [human] vaccine is called *Mycobacterium bovis*, which causes TB in animals such as cows and badgers'. It was first given to school children in 1953 and went out of general use in the UK in 2005 as cases had declined.

The Oxford group explains:

*'The tuberculin skin test ... may be given before you are offered the BCG vaccine. If you develop a hard red lump at the test site, this is a positive result. It means that your immune system already recognises TB, because you have been exposed to the disease in the past. In this case you should not be given the BCG vaccine because you already have some immunity to TB, and the vaccine may cause unpleasant side effects. If you have no reaction to the skin test, this is a negative result, and you can safely have the BCG vaccine'*

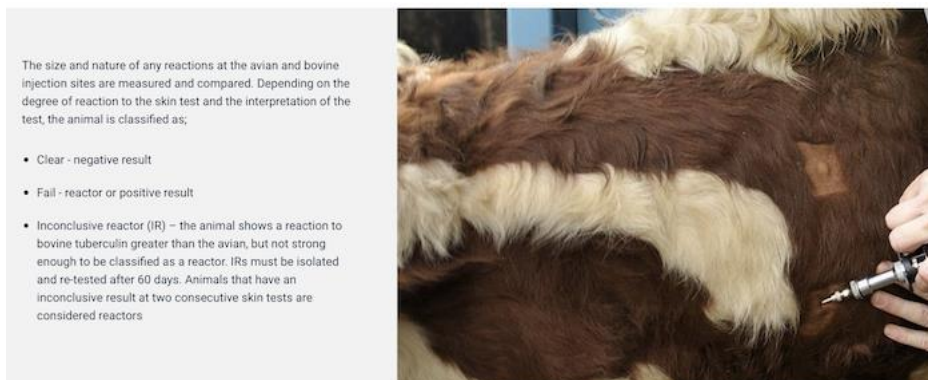
Although with different objectives, this is similar to the standard 'SICCT' test (single intradermal comparative cervical tuberculin test) used in cattle. This looks for signs of an

immune response indicating past or current infection, rather than looking for the bacteria themselves, because TB is slow growing chronic infection and the bacteria are very good at 'hiding' in cells.

Cows are injected with 'tuberculin' (a complicated mix of proteins from lab-grown TB bacteria which have been killed by heating) and if they develop a strong skin reaction they are classed as 'reactors' considered to have TB, and should be removed and slaughtered. If they show no reaction they are assumed to be clear of TB. If it's intermediate then they are classed as "IRs' or Inconclusive Reactors.

Tbhub explains that the test involves giving two types of tuberculin, one from the sort of bacterium that cause TB in cattle and another (avian or bird TB) which the cows may have come across in the environment and reacted to but cannot give them TB. These are injected at two different spots on the neck:

*The skin test is comparative as the animal's immune response to injections of both bovine and avian (bird) tuberculin is measured and compared. By simultaneously injecting two types of tuberculin into the deep layers of the skin of the neck, the test can better distinguish between animals infected with M. bovis and animals previously exposed to or infected with other types of mycobacteria found in the environment which do not cause bovine TB.*



*From TBHub – administering the test*

The size of any swelling (greatest at 48 – 72 hours after injection) is then measured. Cows actually infected with TB are known to show a bigger swelling at that injection site. No reaction gives a 'clear' result or pass, a strong bovine TB reaction gives a 'fail' (Reactor) but if the reaction to the bovine is greater than to the avian tuberculin but not strong enough to be classed as a 'fail', it is designated IR or Inconclusive Reactor. (As the test is relative not binary or yes/no, a lot depends on the thresholds set ('severity') and the way the test is conducted by different people).

## Testing Issues

Here begin a lot of problems because over time different assumptions have been made about what an 'intermediate' reaction signifies, and policies on what to do with 'IR' cattle have varied. These are just some of the many issues facing scientists trying to retrospectively interpret the effectiveness of TB in cattle controls in the UK.

The IR designation has been controversial because it can leave cattle which go on to become infected and infectious, in the herd. So as a control measure, this can be like throwing a cordon around the problem but with a large and invisible hole in it.

Tuberculin is also a variable product and this can introduce further uncertainty in comparing results of field studies.

The SICCT test is very 'specific' meaning that it throws up hardly any false-positives. This is good from the farmer's point of view as it is unlikely to lead to healthy cattle being killed even though they don't have TB. But overall it has a quite low 'sensitivity'. Officially in the UK it is assumed to be about 80% sensitive but cross-checking with more sensitive and newer tests has shown that this may be as low as 50% (the 80% is an 'average' of 52-100%). In 2013 a [review](#) of the science around bovine TB by Charles Godfray and nine others reported a 'credible' range of herd-level sensitivity for SICCT of 27-74% with a mean of 50%.

In other words, 20% - 50% of all the cattle that actually have TB, may not be detected (false negatives). This has led to a lot of arguments about probable or possible transmission to other cattle and badgers, and about the attribution TB outbreaks in cattle, to badgers (eg on the grounds that a herd was assumed to be TB free). TbHub cites a 'missed' rate of 20-25% cattle on one round of TB testing at standard level of test severity.

### **More Sensitive Testing – 'Enhanced Surveillance'**

More sensitive testing was used in a study described by Dick Sibley in the journal *Cattle Practice* in 2018 ([text here](#)). The research took place from October 2012 – December 2017, at Gatcombe Farm in Devon where there was a long-running TB outbreak. It involved a geographically isolated holding with a beef herd grazed on grass, and an indoor herd of 300 dairy cows which never went outdoors. Examination of badger latrines in the area showed 31% of samples were positive for TB although none of the beef cattle had ever tested positive for TB and badgers were not seen in or around the buildings.

The dairy cows, which had a long history of TB, were tested using the standard SICCT test. In 2015 34 cows (about 10% of those tested) gave a positive reaction to the SICCT test but not pronounced enough to class as 'Reactors' or 'Inconclusive Reactors', using standard assessment rules. When further examined with a more sensitive test (Actiphage), 30 (88%) tested positive. All the cows which had ever showed a positive reaction to bovine TB in the SICCT tests were then followed-up with two more sensitive tests to check for TB in their saliva and faeces, as well as a test for TB antibodies. A series of different tests were used over years and revealed cows which were 'shedding' (infectious TB), and cows with TB which were not shedding.

The battery of more precise 'novel' tests required a special government licence. These were able to detect latent asymptomatic TB infections and repeated detailed testing of saliva and cattle faeces showed that faeces were the likely route of environmental transmission to other cattle and wildlife. Nine separate additional biosecurity measures were employed (for

example ways of dealing with slurry) and starting in 2017, badgers were vaccinated using the BCG vaccine. By 2018 the herd was declared TB free.

Sibley wrote:

*'Overall, 192 cattle were identified as High Risk TB Cows during the control period from October 2015 to June 2018. Of these 161 were tested at least once with Actiphage (the others were culled before Actiphage testing was performed). Of these 129 had at least one positive phage test (80% of all High Risk TB Cows have been positive to Actiphage) suggesting there is a hidden reservoir of infection in cows that are not classed as reactors under the standard interpretation of the SICCT.'*

Sibley noted:

*'this clinical investigation demonstrated the challenges that face large herds with high risks of disease spread [in] attempting attempting to eradicate a disease that can exist in latent form and is difficult to detect using insensitive tests. The system is a potential method to control and eradicate disease in the chronic, persistently infected herds which may be acting as the true reservoir of infection in bTB endemically infected areas such as the South West'.*

And

'The potential for environmental contamination from infected dung, slurry and farm yard manure is significant'. The 'enhanced surveillance' system relied on repeated testing using several different tests, and the farmer involved was an enthusiastic 'investor in health' rather than accepting just 'paying the costs of disease', and also took rigorous steps against another serious cattle infection, Johne's disease.

Sibley noted that 'persistently infected' herds are 'relatively small in number (although they tend to be large herds)', quoting 'only 67 herds of a total of over 4700 cattle herds in Devon (<1.5%)' in June 2018.

Sibley's work at Gatcombe Farm showed it is possible to eliminate TB, at least temporarily, through better testing combined with herd sanitation measures, and shows that a reservoir of TB infection can persist in a cattle herds, undetected by SICCT testing. The beef herd, which was much more exposed to potential transmission of TB from badgers, showed no TB, although that might have been because beef cattle were slaughtered at a younger age than dairy cows.

Another recent study (2019) of a long-infected area (Woodchester Park, Gloucestershire) showed through detailed statistical analysis of the genetics of TB in both badgers and cattle, that past transmission is most frequent within species (from cattle to cattle or badger to badger) but between species, transmission although at much lower level had been up to ten times more frequent from badgers to cattle than vice-versa. In many places, both cattle and badgers are probably infected with TB which is invisible to the standard testing regime used in England.

## Why There's No BCG Cattle Vaccination

A completely different problem has prevented the BCG vaccination being used to control TB in cattle in the UK. This is because the SICCT test cannot distinguish between a cow which has or had TB, and one that has been vaccinated: both will show an immune reaction to the 'tuberculin'. ([A 2014 review by M A Chambers](#) and others cites a rate of 80% of uninfected but vaccinated cattle testing positive to SICCT six months after vaccination).

As a result, it is feared that BCG vaccination of UK cattle could lead to infected cattle or meat being exported, such as to the rest of the EU. (Sibley noted that one of the additional tests he used (Idexx Elisa, an antibody test) is already approved for use in the EU).

The 2014 review of cattle vaccination explains:

*'vaccination of cattle is currently prohibited under EU legislation because of the incomplete protection offered by BCG [vaccination] together with the sensitisation of vaccinated animals to the tuberculin skin test (the primary test prescribed under EU legislation for defining the TB status of cattle and cattle herds)' ...*

(Another expert told me: 'It's actually related to more international trade rules via the OIE (World Animal Health Organization or Office International des Epizooties). The EU elected to go for cattle trade in products under its rules which don't allow vaccination unless it involves a differentiating test which it approves).

The UK began pressing the EU to allow BCG vaccination along with a new 'DIVA' test (a Differentiating Infected from Vaccinated Animals test) in 2012, and negotiations followed. This DIVA test is already used to check for TB infection in humans, and the subsequent research has been to develop a skin test version for cattle. The Chambers review cites a sensitivity of over 90% for trial DIVA reagents and a specificity of 98.7%.

In 2018 the Godfray Review noted that 'Since 1998, Government has invested about £40 million into the development of a cattle vaccine for bovine TB and DIVA tests' (a significant but rather small amount compared to the estimated costs of TB in cattle – a [NFU website](#) puts the cost to taxpayers in England at £500m over 10 years, ie £50m a year).

In July 2020 the UK government announced a DIVA test 'scientific breakthrough'. A DEFRA press release began 'World-leading bovine tuberculosis (bTB) TB cattle vaccination trials are set to get underway in England and Wales as a result of a major breakthrough by government scientists'. There would be four years of trials, 'following 20 years of ground-breaking research into bovine TB vaccines and diagnostic tests'. Environment Secretary George Eustice said:

*This scientific breakthrough is a major step forwards in our battle to see the disease eradicated from this country. As wider preventative measures like cattle vaccines are introduced, we will accelerate other elements of our strategy and start to phase out badger culling in England, as no one wants to continue the cull of a protected species indefinitely*

It noted that the government's response to the Godfray Review had 'set out plans to phase out intensive culling in the next few years'. What exactly the government meant by 'intensive' and 'few' is not clear. So at present there is no cattle vaccine in use in England and livestock farming interests have expressed concern about its possible impact on meat or livestock exports. Meanwhile up to 60,000 badgers are currently being killed to try and reduce TB.

(I'm told that The breakthrough was rather the vaccine organism which was genetically engineered to give a strain which did not react to the SICCT test, so the press release was not quite correct).

### **Badger Vaccination With BCG**

Not surprisingly, badger vaccination against TB using BCG, does work in reducing disease in badgers. [A paper](#) published in the Proceedings of the Royal Society in 2010, stated:

*In a clinical field study, BCG vaccination of free-living badgers reduced the incidence of positive serological test results by 73.8 per cent. In common with other species, BCG did not appear to prevent infection of badgers subjected to experimental challenge, but did significantly reduce the overall disease burden. BCG vaccination of badgers could comprise an important component of a comprehensive programme of measures to control bovine TB in cattle.*

This is similar to the effect of BCG in people and cattle. The study referred to resulted from the only one of the six English vaccination trials started under the Labour government in 2009, to be continued under the Conservative-Liberal Democrat coalition government of 2010. This was based at Woodchester Park in Gloucestershire. The government [stated in 2010](#):

*'A key finding of the field study, conducted over four years in a naturally infected population of more than 800 wild badgers in Gloucestershire, was that vaccination resulted in a 74 per cent reduction in the proportion of wild badgers testing positive to the antibody blood test for TB in badgers'.*

A Royal Society 2010 [paper](#) observed:

*from a disease-management perspective, the key question will be to determine whether vaccination has an impact on the spread of M. bovis to cattle. What is clear is that while vaccination of badgers is unlikely to be the sole solution to this disease problem, the advent of the first licensed BCG vaccine for use in wildlife could provide a new and important component of a comprehensive programme of bovine TB control for cattle in the UK and Ireland.*

A 2014 [overview article](#) in *Veterinary Record* noted that another study had found:

*'non-vaccinated cubs captured in vaccinated social groups were significantly less likely to test positive to TB when more members of their group had been previously vaccinated.*

*When more than a third of the social group had been previously vaccinated, the risk of non-vaccinated cubs testing positive ... was reduced by 79 per cent. The most plausible explanation ... is that vaccination had reduced the rate of transmission more effectively in social groups where a higher proportion of animals had been vaccinated during the four-year study'.*

Despite encouraging findings such as these, aside from the short time period where a Labour government made badger vaccination a priority, much less official effort has gone into vaccinating badgers in England than into culling badgers. One reason may be practical. Its obviously harder to lay hands on a badger, a wild, nocturnal and often subterranean animal, than on a cow (there has also been much discussion of the merits and difficulties of oral bait vaccines to avoid the necessity of injection). Another might be psychological. Once frustrated farmers and their political representatives had it mind to eliminate badgers as 'the problem', maybe the idea of vaccination felt too much like 'doing something for badgers' rather than 'doing something for farmers'?

At any event, inoculating badgers against TB was proposed by a government vet immediately after badgers were found to have TB back in 1973. During the Wellcome Trust review of the history of bovine TB in 2014, Michael Clark produced a page from his diary to show the response of MAFF vet Dr Archie McDiarmid who he met at a MAFF laboratory shortly after the discovery:

*'What about this news, Archie, that TB has got from cattle into the wildlife population with the badgers. What's the answer to it?' And he said, 'Inoculation.' In my diary I used the word 'inoculation', but he may have said 'vaccination' ... There was the sudden realization among vets, zoologists, and naturalists like myself that this was likely to be a major problem now with badgers'.*

Rather than vaccinating badgers, MAFF at first allowed farmers and landowners to shoot them and then took over culling itself, and gassed badgers, before switching to culling by shooting which has been the default policy in England ever since.

There has been no official trial of badger vaccination in England to see how effective it could be in cutting TB in cattle. A trial of the practicalities of vaccination, which ended in 2015, was funded by Defra. Licences and limited government funds have also been given to NGOs to vaccinate badgers, since 2011.

Two other contributors at the 2014 Wellcome event who discussed badger vaccination were Dr Gordon McGlone, former CEO of the Gloucestershire Wildlife Trust, and Fiona Stuart, former Senior Research Officer at the Central Veterinary Laboratory, Weybridge, where she worked from 1979– 1990.

Stuart: *'We did quite a few years of work on TB vaccination of badgers with BCG in the 1980s, and that again sort of fizzled out at the end of the 1980s, largely due to BSE and lack of funding'.*

*... Going back to the badger vaccination, I think the reason that Defra have not followed up more [with] the Wildlife Trusts is because it was backed as 'a good idea' and Defra licensed the badger vaccine, but **there was no intention of a scientific trial** to be set up because it would have to be on the scale of the RBCT to demonstrate an effect. [my emphasis]*

This is an interesting statement because repeated trials have been funded to investigate (or demonstrate) the effectiveness of badger *culling*. Critics argue that these have not shown it is effective in reducing TB in cattle. Badger vaccination however seems to have been sidelined in England, without even attempting a proper trial of its potential.

Stuart continued:

*We all know that that's just on the absolute borderline of being able to demonstrate an effect. As we said, you could argue it both ways. Vaccination is probably going to be even more difficult to show an effect from the modelling that we had done.*

Dr Gordon McGlone was first CEO of what is now the Gloucestershire Wildlife Trust (GWT) and a member of a (now discontinued) Minister's Advisory Panel on badgers. In 2014 he said:

*the Badger Trust has done some badger vaccination itself. The Wildlife Trusts have got a programme running across a number of counties and are building expertise but it's very small beer in terms of hectares; these are small, still tentative first step. It's not a systematic programme but there is no strategy behind it and I have been puzzled that there has been no interest within Defra to actually steer or influence how badger vaccination, which is taking place, could be done in a more strategic way.*

NGO badger vaccination is still relatively small scale. GWT began the first project in 2011. One of the biggest is that of the Derbyshire Wildlife Trust (DWT) which began in 2014. DWT vaccinated '221 badgers on 120 km<sup>2</sup> in Derbyshire working with 52 landowners and farmers' in 2019. In contrast the current national badger cull targets 60,000 animals. Controversially the 2019 cull included areas near to DWT vaccination projects, leading to a government u-turn and subsequent legal action against the decision by the NFU (which failed in 2020).

The 2018 Godfray Review noted that 'There is currently no systematic surveillance of bovine TB in wildlife' (ie including badgers) and there had been no large scale trial of vaccination in England It stated:

*Moving from lethal to non-lethal control of the disease in badgers is highly desirable. Though research into other options should continue, we believe that the injectable BCG vaccine is the only viable option currently available. At the moment there is limited information about the relative effectiveness of vaccination and culling on incidence of the disease in cattle, though the results from small-scale vaccine projects in England and large-scale deployment of vaccination in the RoI [Republic of Ireland] will help address this.*



Godfray also noted that ‘Culling is not possible in some areas where major landowners (for example the National Trust) have policies not to permit it’ and suggested ‘one possibility would be for badger vaccination to be conducted within cull areas on farms or areas where culling is not accepted’.

## **Irish Studies**

Two Irish studies suggest that badger vaccination can be at least as effective as culling, and combined with other measures, could help eliminate TB in cattle.

Inma Aznar and co-workers conducted a major Irish study of badgers, TB and cattle from September 2009 – July 2013, to test the effect of vaccinating badgers against TB with the BCG vaccine. It was published in Preventive Veterinary Medicine in 2018.

Dividing a large area into three zones and using repeated trapping and tagging, with no vaccination in one zone, 100% in another zone, and no vaccination in the third, they calculated that vaccination reduced ‘susceptibility’ to contracting TB by 59%. Based on the known national Irish incidence of TB in badgers of 18% which implies a R rate of 1.22 in the natural population, they estimated that vaccinating over 30% of the badger population across Ireland could produce a R rate of 0.5, meaning that the disease could be progressively eradicated, so long as other preventive measures remained in place.

In 2020 a team of researchers from Canada, Ireland and the US reported on a five-year study to see if vaccinating badgers performed any better or worse in terms of reducing the incidence of TB in Irish cattle herds, than the conventional practice in the Republic, of responsive targeted badger culling. They found that vaccination was as effective as culling:

*‘Overall, our study results indicated that vaccination was not inferior to targeted badger-culling in four counties and badger vaccination was deemed to produce ambivalent results in one (County Cork North) of the seven study sites in the ROI.*

*A post-study investigation, in County Galway, where vaccination was deemed inferior to target culling, revealed that widespread purchases of cattle from a nearby cattle mart, by herd owners in the vaccination-area, was associated with the increased herd and vaccination-area risk of BTB. No single “biasing hypothesis” was evident for the apparent vaccine inferiority in the second study site (County Monaghan) where vaccination was deemed inferior to targeted culling; hence no further investigations were conducted’.*

In 2018 the Irish government started to roll-out a widespread badger vaccination campaign. The study authors wrote:

*‘Our work supports that decision, but it is clear that identifying and controlling the other critical elements in the causal network of cattle-herd BTB- breakdowns will be needed to help ensure the success of the future BTB- Eradication-Program in the ROI’.*

## **Badgers in Wales**

Culling in Wales was stopped by the Welsh government and badger vaccination was started in 2012 in an 'Intensive Action Area', in West Wales. This involved vaccination of over a thousand badgers in an area of around 250km<sup>2</sup> in both 2012 and 2013 . It was interrupted in 2017 due to a shortage of vaccine and restarted in 2018-19. The Welsh system includes "badger trap, test and removal" policy – a selective badger cull that involves removing badgers that test positive for TB in targeted areas'. It is opposed by the NFU of Wales which wants culling re-instated.

The Wildlife Trusts report that 'badger vaccination is working' in Wales.

*'The Wildlife Trust of South and West Wales (WTSWW) has now completed two years of a five year vaccination programme at its Castle Woods nature reserve near Llandeilo. This vaccination project has been supported by the Welsh Government's Badger Vaccination Grant.*

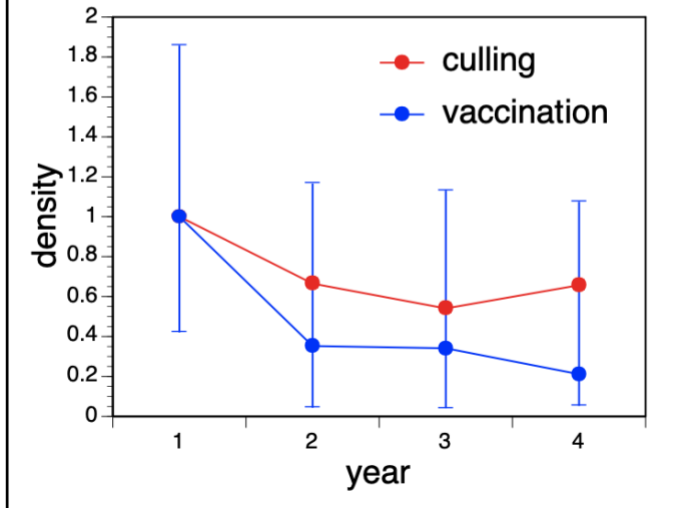
*In 2014, trapping in June resulted in the vaccination of 34 individuals, including 29 cubs. In 2015, trapping in July resulted in the vaccination of 27 individuals, including 23 cubs. WTSWW has estimated that the cost of this work is about £19 per head of cattle protected, per year, based on the area of land used by the vaccinated badgers and basing the cattle stocking density across that area on the average for England and Wales'.*

The Welsh Government currently offers a grant of up to £50,000 a year to farmers, landowners and other private organisations towards half the costs of vaccinating badgers for four years.

There is some suggestion that Welsh badger vaccination has reduced the prevalence of the disease, achieving a similar result to proactive sustained culling in the RBCT. In 2018 a paper the Zoological Society of London (ZSL) stated:

*in a large, contiguous, vaccination area in Wales, prevalence in a sample of road-killed badgers declined from 19% to 4% over four years of vaccination (Figure 4.1) . This ... must be interpreted with great caution as it is derived from a very small sample size (as indicated by the large error bars ...); nevertheless it might represent a reduction in the density of infected badgers at least as great as the average observed in the RBCT proactive culling areas (red line in Figure 4.1). Importantly, this reduction in the density of infected badgers need entail no reduction in the overall badger density; hence vaccination causes no change in badger behaviour and thus avoids the harmful effects associated with culling.*

**Figure 4.1** – Density of infected badgers (relative to the start) over 4 years of RBCT proactive culling and Wales vaccination. Figures for vaccination are calculated from the proportion of road-killed badgers testing positive, assuming constant population size; error bars show exact binomial 95% confidence intervals and are wide due to small sample size. Figures for culling show the simple numbers killed in RBCT proactive culls so have no error bars.



From: [Eradicating TB from cattle and badgers – a review of evidence](#) *Zoological Society of London – September 2018*

The Society asserted:

*‘Badger vaccination can potentially reduce TB risks to cattle at least as fast as widespread culling, but firm evidence is limited. Better evidence could be obtained through a large-scale trial, which we estimate could cost less than the government invests in a single average cull zone’*