

GENERAL VACCINATION QUERIES

Why vaccinate badgers against bovine TB?

Badgers are a significant source of bovine TB infection in cattle and are involved in the maintenance of the disease, so in order to be able to control or eradicate the disease in cattle, we have to deal with the infection in badgers too. Reducing the level of bovine TB infection in badgers could also reduce the level of infection in cattle.

How could vaccinating badgers reduce bovine TB in cattle?

Vaccinating badgers reduces the severity of the disease in those that become infected after vaccination. A reduction in the prevalence and severity of disease in the badger population will reduce the potential for transmission of TB from badgers to cattle.

Could it make bovine TB worse?

No. Studies have shown that vaccination doesn't exacerbate the disease in already infected badgers. Nor does it increase excretion of bacteria or lead to an increased risk of transmission of bovine TB.

What vaccine is being used?

The only vaccine that is currently available for use against TB in any species, including humans, is Bacille Calmette-Guérin (BCG). The only difference between the human BCG and BadgerBCG, the UK licensed vaccine for badgers, is that the dose given to badgers is higher than that given to humans.

Is the vaccine safe for use in badgers?

Yes. Scientific research has been carried out which demonstrated that BCG was safe for use in badgers. This was necessary in order for the vaccine to be licensed for use by the Veterinary Medicines Directorate.

What effect does vaccination have on badgers?

Research has demonstrated that vaccination reduces the severity and progression of TB in badgers that were experimentally infected with bovine TB after vaccination. BCG vaccination also reduced the amount of bacteria excreted in urine, faeces and other clinical samples. Such effects in the field are likely to translate into a reduced risk of transmission to cattle.

Does it fully protect all badgers that are vaccinated

As with any vaccine, not all vaccinated individuals will be fully protected. However, laboratory studies indicated that in common with other species, BCG vaccination did significantly reduce the overall disease burden. A recent field study of wild badgers showed that of the badgers that tested negative for TB at the outset, vaccination led to a significant reduction in the incidence of positive responses to a blood test that we know is a good indicator of the extent and severity of TB infection.

Do you have to vaccinate every badger?

No. Only a proportion of the susceptible population (that is those that are not already infected with bovine TB) need to benefit from the protective effects of the vaccine in order to reduce the prevalence of infection in the population. This is known as herd immunity and works on the principle that if some of the population are protected from the disease it is less likely that an infected individual will come into contact with a susceptible individual, therefore, the disease is less likely to be passed on. Obviously, the higher the proportion of protected individuals there are in a population, the lower the number of animals that could become infected.

How will badgers be vaccinated?

Currently, the only available vaccine is an injectable one. Badgers are trapped in cages, injected with vaccine then released.

Are there any welfare issues with trapping badgers for vaccination?

Cage trapping of badgers has been undertaken for over 30 years. Research has shown that, when trapping is carried out by properly trained and experienced personnel, the number of badgers injured in cage traps is very low, with the majority of those injured only suffering minor abrasions.

Why can't you use oral vaccine bait?

There is research currently underway in the UK in developing oral vaccine bait for use in badgers, however the possibility of a usable oral badger vaccine is many years away and we can't say for sure when one will be available. There are a number of issues currently being researched, including formulating a bait that is both palatable to badgers and keeps the BCG viable both in the environment and in the acidic conditions of a badgers stomach. A further range of questions around the best way to deploy bait are being researched, including: how many baits, where best to place them, how many days to feed for, what is the best time of year to deploy bait, how to avoid other species eating bait. The answers to these questions and others will determine the most cost-effective way to deploy an oral bait vaccine to badgers.

What is happening with vaccination of wildlife against bovine TB in other countries?

They are currently carrying out research into oral vaccination of badgers in Ireland and injectable and oral vaccination of possums in New Zealand.

Why is it taking so long for vaccines to be widely available when we've been vaccinating humans for years?

Whilst the programme of work has been designed to minimise the time required on delivering licensed vaccines, research by its nature takes time and much of the work has to be carried out sequentially. There are defined steps in obtaining a licence, or Marketing Authorisation, from the Veterinary Medicines Directorate for vaccines, which include studies to demonstrate both vaccine safety and efficacy. New diagnostic tests for badgers had to be developed initially, starting in 1999, to enable badger vaccine research to begin.

Why can't we vaccinate cattle?

Cattle vaccination against TB is currently prohibited under EU legislation. Currently, the only vaccine candidate for use in cattle is BCG which interferes with the mandatory tuberculin skin test. Vaccinated cattle could become positive to the tuberculin skin test and herds could not be declared Officially TB Free (OTF) for trading purposes. Therefore, as part of the UK research programme we are developing and validating a diagnostic test to differentiate between infected and vaccinated animals (a so-called 'DIVA test'). Changes will be required to the EU legislation to allow this test to be used in place of, or alongside, the tuberculin skin test to confer OTF status.

What other EU Member States are likely to be interested in a TB vaccine for use in cattle / changing EU law to use a TB vaccine in cattle?

Interest is limited at the moment - but this may change when a licensed product and a validated DIVA test are available.

What research has gone into vaccines, how much has been invested and what agencies are involved?

Defra has been funding research into TB vaccines for use in cattle and badgers since 1998 and the total investment in vaccine development has reached more than £30 million. Defra has been working alongside the Veterinary Laboratories Agency, which leads the vaccine research on Defra's behalf and The Food and Environment Research Agency (Fera), which has over 30 years experience of trapping and injecting badgers. Defra also maintains close links with international researchers particularly in the Republic of Ireland and New Zealand. Defra and the VLA are also working in close cooperation with researchers working on new vaccines for TB in humans.

BADGER VACCINE DEPLOYMENT PROJECT AND LAY VACCINATORS TRAINING COURSE

What is the Badger Vaccine Deployment Project?

It is a Defra funded project trapping and vaccinating badgers against bovine TB in an area of England badly affected by bovine TB in cattle. Fera is currently offering training; "Cage Trapping and Vaccination of Badgers Course" to help build capacity to vaccinate badgers.

How often should badgers be vaccinated?

It will be necessary to vaccinate badgers on an annual basis in order to ensure that we vaccinate as many naive cubs as possible when they emerge in late spring each year. Most badgers have a lifespan of just 3 to 5 years and the annual population turnover of the UK badger population is estimated to be 30%. Safety studies have shown that there is no detrimental effect on vaccinating badgers annually.

How will you know which badgers have been vaccinated?

Badger social groups will normally be trapped for a maximum of two consecutive nights. Badgers that are caught on the first night are given a temporary mark so that they are not vaccinated again if trapped on the second night. There is no suitable way to permanently mark a badger without having to anaesthetise it first, which would greatly increase the disturbance to the badgers and the costs of a vaccination programme. Research has shown that there will be no detrimental effects if a badger is vaccinated on more than one occasion.

How long will badgers be kept in the trap?

Badgers will be trapped overnight, vaccinated and released near their setts early the following day. They are unlikely to be in the trap for more than 12 hours.

How many traps will be placed per sett?

The aim will be for saturation trapping, which will involve two traps for each badger believed to be occupying each sett.

What if a sick or injured animal is caught in a trap?

Training and Standard Operating Procedures outline steps that need to be taken in the event of a badger being trapped that is seriously injured. Procedures include contacting a local vet.

What if a member of the public finds a trapped badger?

The traps will be clearly labelled so people will be aware of the reason badgers are being trapped and that they will be released unharmed. There will also be a monitoring process and a phone number for people to ring if they have any particular concerns.

If you are trapping badgers, why not test them for bovine TB?

There is currently no reliable diagnostic field test for bovine TB in live badgers, so it is not possible for badgers infected with bTB to be accurately identified in the field.

Why doesn't vaccination cause perturbation?

Perturbation is caused by the disruption of the social structure through the permanent removal of badgers from the social group. This increased ranging behaviour results in greater opportunities for contact with badgers from other social groups, which leads to an increase in the spread of infection. Badgers have been trapped, anaesthetised and sampled routinely at the FERA Woodchester study site for over 30 years and perturbation of the badger population has not been observed. This suggests that, as badgers that are vaccinated are released at the point of capture the next morning, there is no disruption of the existing social structure and therefore perturbation will not occur.

Is there any point in vaccinating badgers on land if a farmer's neighbours aren't doing the same?

Yes. It is not necessary to trap and vaccinate every badger to provide protection. Whilst it would be advantageous to vaccinate as many badgers as possible in a group and in groups in close proximity to one another, as long as the majority of animals are vaccinated from the social groups that access your farm, it is difficult to maintain a chain of infection when large numbers of a population are immune. The stable social structure of badger groups, with limited mixing of individuals between groups, lends itself to the generation of this 'herd immunity' through vaccination.

Could a farmer specify the months for trapping and vaccination on his land in order to avoid the shooting season for example?

Yes, the arrangements for access to your land will be made with Fera and they will discuss with you a mutually convenient time.

Wouldn't it be easier to wait for an oral vaccine to become available and use this in a deployment project?

Defra aims to use every tool available in tackling bovine TB. The possibility of a usable oral badger vaccine is many years away. We can't say for sure when one will be available. As a licensed injectable BCG vaccine is already available Defra wants to maximise its use by deploying it now. Use of the injectable vaccine will help to evaluate the logistics of deploying a vaccine to badgers as well as building confidence in the use of vaccines which will aid the future use of an oral vaccine once this becomes available.

What if an oral badger vaccine was available before the end of the deployment project?

Because of its flexible nature, there is the possibility that the project could be adapted to take into account the availability of an oral badger vaccine.

How is the vaccine obtained?

BadgerBCG is a Prescription only Medicine - Veterinarian (PoM-V). This means that the vaccine can only be prescribed by a vet.

Who can cage trap badgers to inject the vaccine?

A licence to trap badgers has to be issued by Natural England (or the appropriate licensing authority in Wales or Scotland) before badgers can be caged trapped and vaccinated. Lay vaccinators that have passed the Cage Trapping and Vaccination of Badgers Course offered by Fera and been issued with a certificate of competence can apply for a licence.

Who are you targeting this training at; and how many do you expect to attend the course?

The licensed injectable BadgerBCG vaccine is now available and we have always believed that there would be a commercial market out there for lay vaccinators. So we hope that some will see this as a business opportunity. Some landowners may also be interested in having the capacity to vaccinate the badgers on their land themselves and wildlife group members may also want to undertake the training. The scale and nature of the demand will become clearer in time and Fera expects to have some 50 places available each year on its trapping and vaccination course.

Where can details of the training course be found?

Please email badgervaccine@ahvla.gsi.gov.uk for further details or visit <http://www.defra.gov.uk/ahvla-en/science/bovine-tb/bvdp/>

Will you be collecting roadkill?

No. Previous Road Traffic Accident (RTA) surveys have only been able to confirm the presence of disease in the areas that they have been carried out in and have not given accurate data on incidence of disease. For example, the RTA survey carried out as part of the RBCT, which ran from November 2000 to December 2004, derived estimates for the 7 counties in which it was carried out (average prevalence of 15%), but it was not possible to estimate prevalence accurately at smaller spatial scales because of the small numbers of animals collected.

Despite the considerable effort to locate and collect carcasses only a single badger was collected each year from most parishes (around 60% of the total) and the overwhelming majority of parishes (97%) yielded 5 or fewer badgers each year - illustrating the limited ability of a survey of this kind to provide precise estimates of prevalence in small areas. Furthermore there would be a risk of biased results as the project is not being carried out as a randomised study.

SCIENTIFIC / TECHNICAL Q&A

Is the vaccine safe for badgers?

BCG is one of the most widely used vaccines in the world, with an unparalleled safety record. Despite the very large number of humans as well as laboratory mice and guinea pigs that have been vaccinated with BCG over any decades, there have been very few reports of adverse reactions. As part of the preparation for submission for authorisation to use the product, an experimental safety study performed to Good Laboratory Practice (GLP) accreditation was completed successfully at VLA in 2005 and published in the journal *Veterinary Immunology & Immunopathology* in 2006 and data from a four year field trial completed in 2010, were submitted as part of the licence application. Reports can be found on the Defra website: <http://www.defra.gov.uk/animal-diseases/a-z/bovine-tb/publications/>

Will vaccinating badgers prevent bovine TB in cattle?

As with all TB control measures vaccination adds another tool we can use. Vaccinating badgers is a risk reduction measure. It reduces the risk of badgers catching TB, resulting in fewer infected badgers. This in turn may reduce the risk of transmission from badgers to cattle.

How long will it take to see a positive effect on the levels of bovine TB in cattle?

Mathematical modelling work carried out by researchers at both the Food and Environment Research Agency (Fera, formerly the Central Science Laboratory) and Veterinary Laboratories Agency (VLA) showed that a number of factors will influence the how long it will take for a reduction in disease levels in badgers to translate into an impact on cattle disease. These include vaccine efficacy, the proportion of badgers vaccinated, what contribution badgers make to the disease in cattle and how effective cattle controls are at preventing cattle to cattle spread.

The vaccine is unlikely to benefit already infected badgers, in which case these animals will need to die off naturally for the disease risk to cattle from badgers to be reduced. Most badgers have a lifespan of just 3 to 5 years and the annual population turnover of the UK badger population is estimated to be 30%, therefore we expect that it will take 5 years to vaccinate a sufficient number of naive badgers to achieve herd immunity and reduce TB incidence within a badger population. We do not know how long it will take for this to translate in to a reduction in cattle herd breakdowns.

Will vaccinated badgers excrete BCG, which could subsequently sensitise cattle to the skin test?

In the BCG Good Laboratory Practice safety studies badgers were given at least 10 times the licensed dose there was no evidence BCG was shed and there was no evidence that BCG was shed from vaccinated badgers in the 4 year field trial, therefore the use of the vaccine in badgers would not be expected to compromise the tuberculin skin test in cattle.

Will trapping badgers cause them stress and make them more susceptible to infection or exacerbate disease in already infected badgers?

While there may be effects in other species, there is no scientific evidence to show that stress affects immune function in badgers in such a way as to adversely affect their response to vaccination or increase disease. Furthermore, badgers captured following a period of pre-baiting frequently do not avoid recapture and will repeatedly enter traps for a food reward, suggesting the badgers are not particularly stressed by cage trapping procedures when carried out correctly under established Standard Operating Procedures. Badgers are trapped overnight and released early the following morning after vaccination.

What if badgers are trapped and injected multiple times in short succession

They won't be. Vaccinated badgers will be given a temporary mark (e.g. with livestock spray marker) to minimise any risk of the same badgers being vaccinated more than once in any annual trapping sessions at a given location. In the event that this did happen however, there is no evidence that repeat administration of BCG to badgers causes any adverse effects or results in excretion of the vaccine.

How will you know if the vaccine works?

BCG has been shown to protective effect in captive badgers and we are not including measurement of vaccine efficacy as part of the project because this would require a large randomised scientific trial.

How long does the vaccine take to give badger immunity?

Under experimental conditions badgers were shown to give an immune response to BCG between 3-4 weeks after vaccination. The immune response is that measured by the gamma-interferon test, i.e. is a measure of cell mediated immunity and not a direct correlate of protection.

If cattle became infected with bovine TB after use of vaccine in badgers on the farm could you identify the strain of *M. bovis* (BCG) used in the vaccine and differentiate that from the local strain? [i.e. is there a way to see if the vaccine posed a risk to cattle / looking for reassurance about increased shedding]

There is no evidence to suggest that badgers will shed the BCG after administration of injectable vaccine for it to present a risk to cattle.

Can BCG protect badgers against all the different strains of *M. bovis*?

There is no evidence to suggest otherwise. BCG in man protects against many different strains of human TB worldwide.

Why are you using BCG when we're no longer using it in humans?

BCG is still being used in humans in GB, however, following advice from the Joint Committee on Vaccination and Immunisation (JCVI) in July 2005 the UK's universal BCG vaccination programme delivered through schools was replaced with an improved programme of targeted vaccination for those individuals who are at greater risk. These recommendations reflected the changing patterns of TB infection and better protect children and others who are at higher risk.

Has the vaccine been / will it be trialled in camelids?

There are no plans to trial the vaccine in camelids.