



Department  
for Environment  
Food & Rural Affairs



Animal &  
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# Badger Vaccination against TB – Information Pack



Forestry Commission  
England



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# What are we going to cover?

## Introduction to badger vaccination

- Why do we vaccinate?
- Why should we vaccinate badgers?
- BCG Vaccination

## The evidence

- Effect of badger vaccination on cattle TB incidence
- Protective effects of badger vaccination

## Planning a badger vaccination project

- How many badgers do you need to vaccinate?
- How to get a licence
- Training
- Example of costs



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# Introduction to badger vaccination

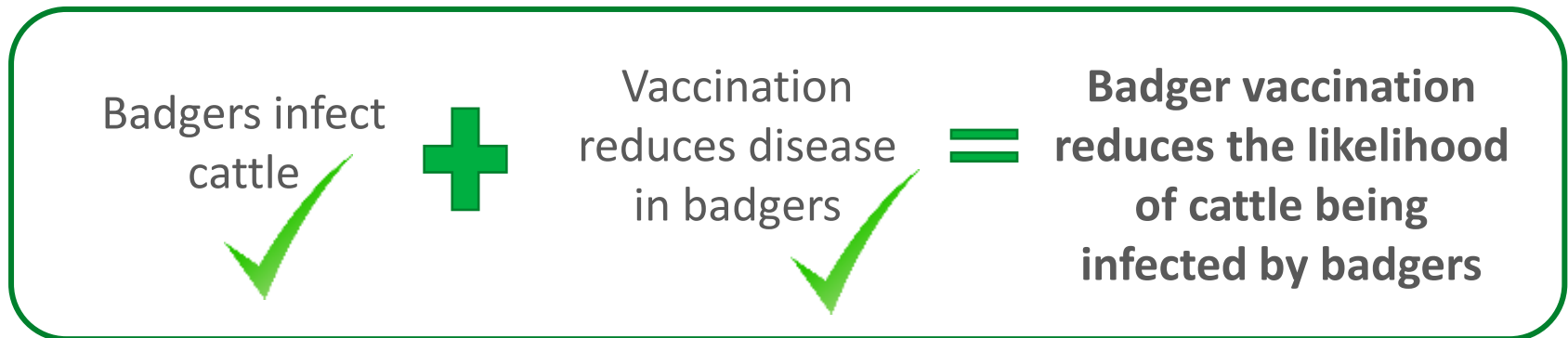
Key points to set the scene

# Why should we vaccinate badgers?

At the present stage in the bTB eradication strategy, we have evidence that:

- **Badgers contribute to TB in cattle**
- **Vaccinating badgers reduces disease in badgers**

Therefore..



Badger vaccination should have a **positive effect** on **TB incidence in cattle**

# Why do we vaccinate?

Vaccines are like fire safety training – you have to practice so you know what to do if a fire happens

A vaccine **teaches your immune system what a disease looks like and how to protect you.**

A Vaccine uses a **dead (inactivated)** or **‘weakened’ (attenuated)** version of the pathogen

Most vaccines are **prophylactic** – given BEFORE infection to build up immunity and prevent infection

Others are **therapeutic** – given AFTER infection has occurred, to boost the immune system against the pathogen.

# BCG Vaccine

The BCG vaccine is a live vaccine which uses a **weakened strain of *Mycobacterium bovis*** (called *Mycobacterium bovis* BCG).

After *M. bovis* was sub-cultured over many years by scientists Calmette and Guerin, they became aware that it had **lost it's ability to cause TB (become non-pathogenic), but was otherwise no different** to the original *M. bovis* strain.

## BCG vaccine:

- **Cannot cause a TB-like infection** in immunocompetent individuals
- **Is a prophylactic vaccine** and so **will not cure an infected animal**



# Is badger vaccination safe?

## ✓ Yes – badger vaccination with BCG is safe

- Two scientific studies have been carried out to investigate the **safety and efficacy** in badgers vaccinated with BCG<sup>1,2</sup>.
- There is no evidence of negative effects on badger health and welfare<sup>1</sup>.
- Badger BCG is a **licensed veterinary product**.
- BCG is not excreted by vaccinated badgers in laboratory or field studies<sup>3</sup>.
- As badger vaccination does not remove badgers from the population, changes to behaviour (known as social perturbation) do not occur<sup>4</sup>.



# BCG vaccination in badgers

Licensed in 2010 in the UK by the Veterinary Medicines Directorate

- For the **active immunisation of badgers to reduce lesions** of tuberculosis caused by *M. bovis*
- For **use in badgers from the age at which they emerge** from the sett
- By intramuscular injection

Based on various experiments by APHA in 2000's



BadgerBCG being reconstituted in the field



# Badger vaccination key points

- Vaccinating susceptible badgers **reduces the risk of infection and disease spread** within the **social group**.
- Vaccination reduces the **severity and progress of disease** in uninfected badgers that are infected after vaccination.
- We do not need to vaccinate every badger:
  - By vaccinating annually, **the number of vaccinated badgers will gradually increase** as infected individuals die off and **cubs are protected indirectly through the herd immunity effect**.
  - **The more badgers are vaccinated, the more infection rates will fall.**





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# The Evidence

Effect of badger vaccination on cattle TB incidence

# Evidence for effects on cattle TB incidence

## Background

- Demonstrating the effects of badger vaccination on cattle TB incidence is challenging because:
  - Multiple factors influence herd TB risk (for example, herd size, herd type, and cattle movements),
  - TB incidence in cattle varies over time,
  - The role of badgers in transmission can vary from farm to farm, and
  - To observe a statistically significant effect we need large sample sizes (e.g., large cattle herds), comparison areas and multivariate analyses to control for other factors which affect cattle incidence



**To date, no field studies have been carried out in the UK to specifically assess badger vaccination's effect on cattle TB incidence.**

# Evidence for effects on cattle TB incidence

## Background

- Two policy initiatives in Great Britain have involved large-scale vaccination of badgers but were not designed as research studies to measure the effect of vaccination on cattle TB incidence:
  - Badger Vaccine Deployment Project (BVDP) in Gloucestershire
  - Intensive Action Area (IAA) in West Wales
- There has been one successful project/research study in Ireland
- The 'non-inferiority' trial in seven areas.

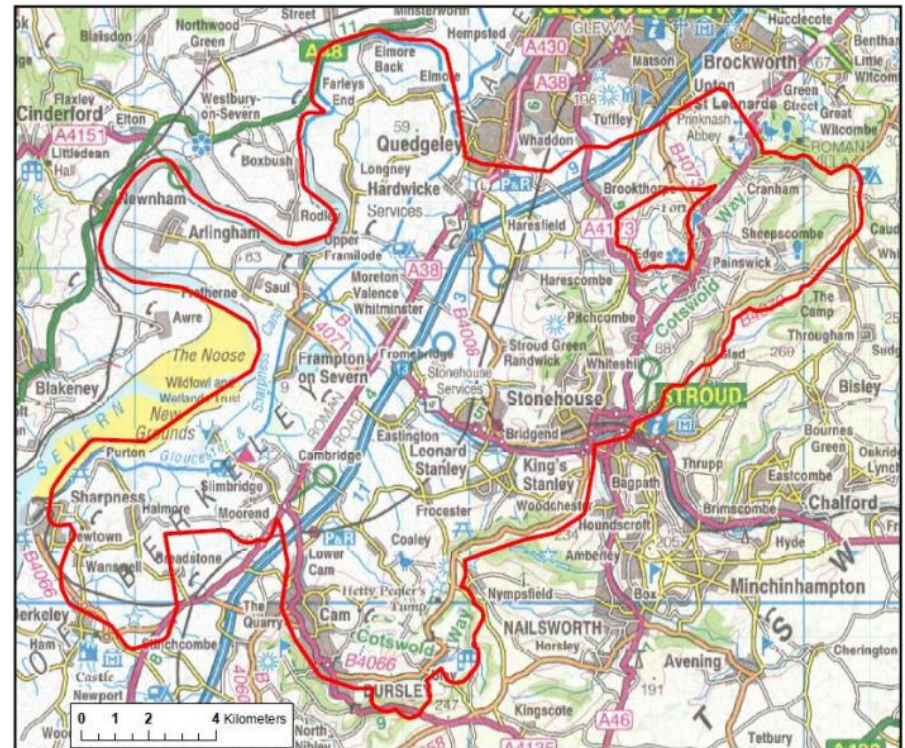
# Effect on cattle TB incidence – GB

## Badger Vaccine Deployment Project (BVDP) (2010 – 2014)

### Aims:

- To develop practical knowledge on the processes involved in large scale vaccination
- Develop capacity to train lay-vaccinators

The BVDP was not designed to trial effect of vaccination on cattle TB incidence



The BVDP was carried out over a 100 km<sup>2</sup> area in Gloucestershire, England

# Effect on cattle TB incidence – GB

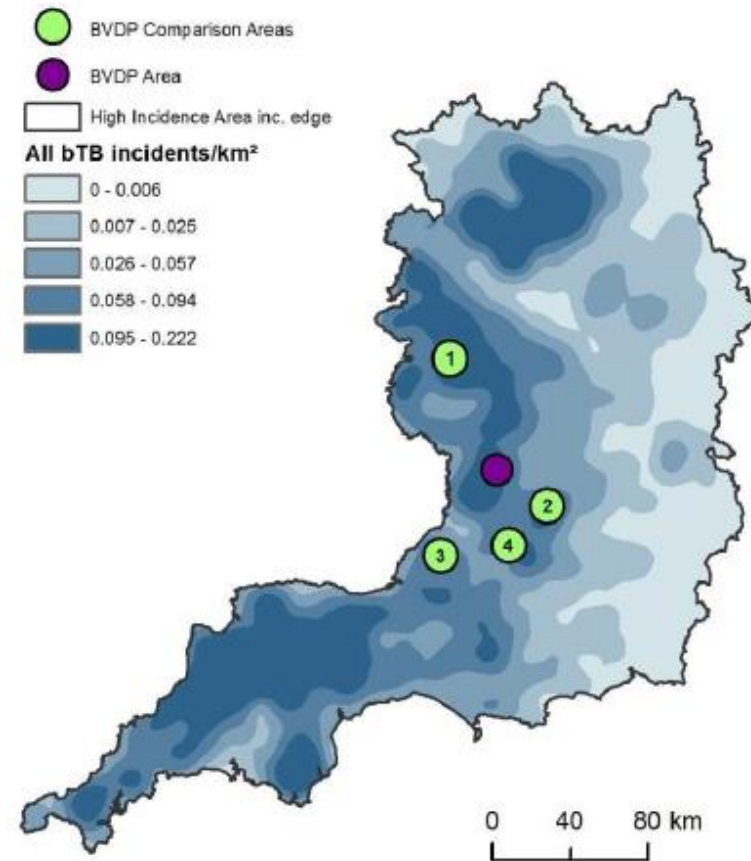
## Badger Vaccine Deployment Project (BVDP) (2010 – 2014)

### Method:

- A simple descriptive analysis looking at cattle TB trends in the BVDP area and four comparison areas.

### Result:

- **Significantly decreasing trend in TB herd incidence in the BVDP area**
- Incidence of lesion or culture-positive TB breakdowns in cattle herds also decreased in three of the four comparison areas, making it difficult to attribute the decrease in cattle TB incidence to badger vaccination only.



# Effect on cattle TB incidence – GB

## Intensive Action Area (IAA) (2010 – 2015)

### Aims:

- Implemented a mixture of cattle control measures alongside badger vaccination including:
  - Biosecurity
  - Increased testing
  - Cattle controls
- The IAA was not designed to trial effect of vaccination on cattle TB incidence



The IAA study was carried out over a 288 km<sup>2</sup> area in North Pembrokeeshire, Wales

# Effect on cattle TB incidence – GB

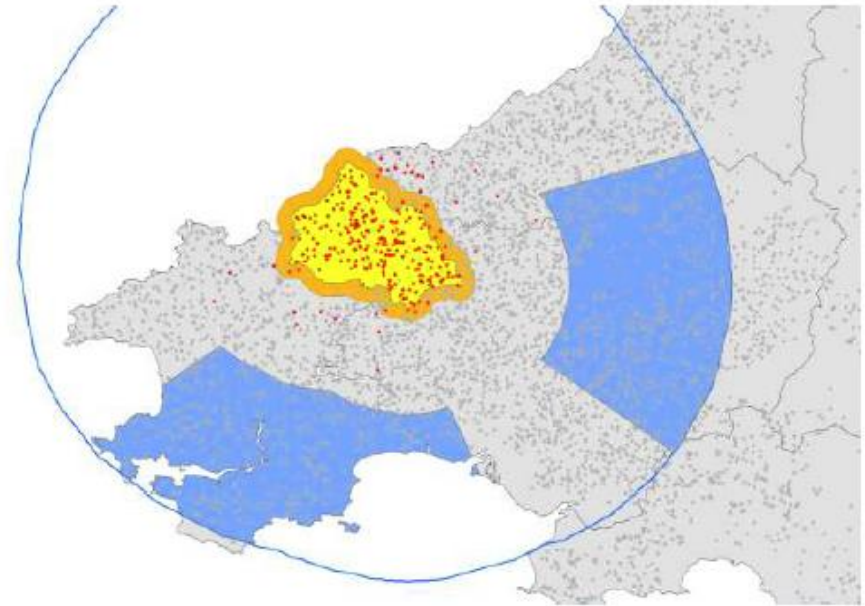
## Intensive Action Area (IAA)

### Method:

- Looked at TB incidence in the IAA and comparison areas

### Result:

- **35% reduction in the number of new incidents per 100 herd years at risk\* following the introduction of all interventions**
- It's not clear what part vaccination played in this reduction because:
  - The mix of control measures made it difficult to compare the IAA and comparison areas, and
  - There was a 23% reduction in the comparison area



**\*New incidents per 100 herd years at risk (100 HYAR):** TB herd incidence rate is calculated as the number of new herd incidents (breakdowns) detected during the reporting period, divided by the total time that herds under surveillance during that period were at risk of infection.



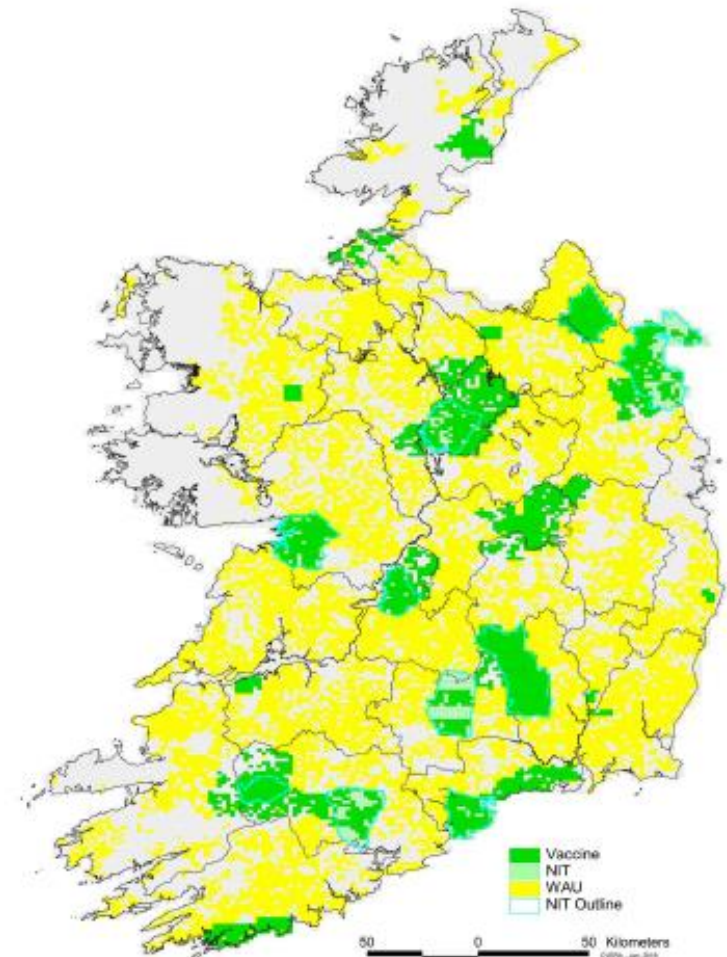
# Effect on cattle TB incidence – Ireland

## Non-inferiority trial (2011 – 2017)

### Aims:

- A large scale trial undertaken in seven counties in Ireland to investigate the impacts of badger vaccination on cattle TB.
- The trial was designed to evaluate if vaccination of badgers was as good as continuing with culling.
- The badger population in the trial area had been reduced through culling to 0.5 badgers per km<sup>2</sup> before vaccination. **So, the findings are only applicable to post-cull areas in GB.**

Map showing National Quartile Distribution per County 1<sup>st</sup>. Jan, 2019.



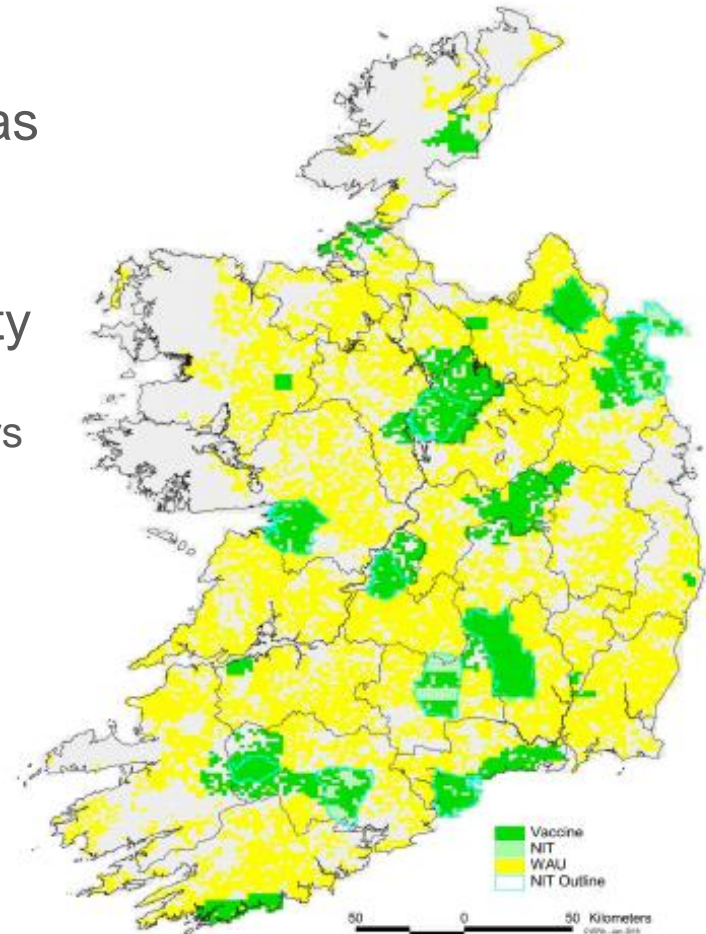
# Effect on cattle TB incidence – Ireland

## Non-inferiority trial (2011 – 2017)

### Result:

- Vaccination was found to be as effective as long-term continuous culling in lowering cattle TB incidence in four counties
- Vaccination was ‘ambivalent’ in one county
  - Differences in cattle incidence between the vaccine area and cull area were observed years before vaccination began, so vaccination is unlikely to be the cause of the differences
- Vaccination was ‘inferior’ in two counties
  - Further investigation found that in one of the counties, 87% of vaccine-area cattle were purchased from a high risk cattle mart (compared to 3% of the comparison cull-area herds)

Map showing National Quartile Distribution per County 1<sup>st</sup> Jan, 2019.



# Effect on cattle TB incidence – Ireland

## Non-inferiority trial

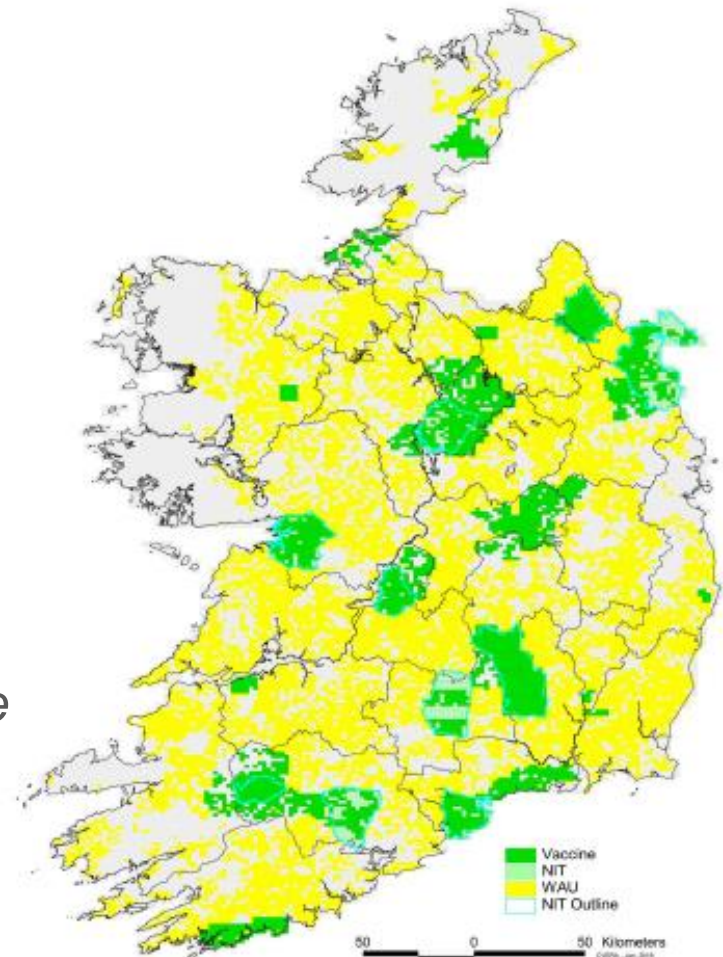
### Outcomes:

The preliminary results from this trial contributed to the evidence base for Ireland’s decision to gradually replace all badger culling with BCG vaccination to achieve their goal of officially TB-free country status by 2030.

The Minister of Agriculture, Food and the Marine, Michael Creed announced that...

*“Vaccination of badgers is now part of the TB eradication programme; this will eventually **replace a majority of the current culling program**”*

Map showing National Quartile Distribution per County 1<sup>st</sup>.Jan, 2019.



# Modelling studies

## Background

- The effects of badger vaccination have been assessed in modelling studies
- Modelling studies simulate the effects of different disease control measures to predict outcomes in badger and cattle populations
- Models make necessary assumptions when predicting outcomes, for example:
  - Badger and cattle population sizes
  - Rate of disease transmission
  - Level of disease

**A model is only as good as the assumptions and data that it is based on. It is difficult for models to accurately predict long term consequences but they are very good at comparing relative effects of options, thus, output is not a prediction of numbers, but a prediction of best choice of method.**

# Effect on cattle – Modelling

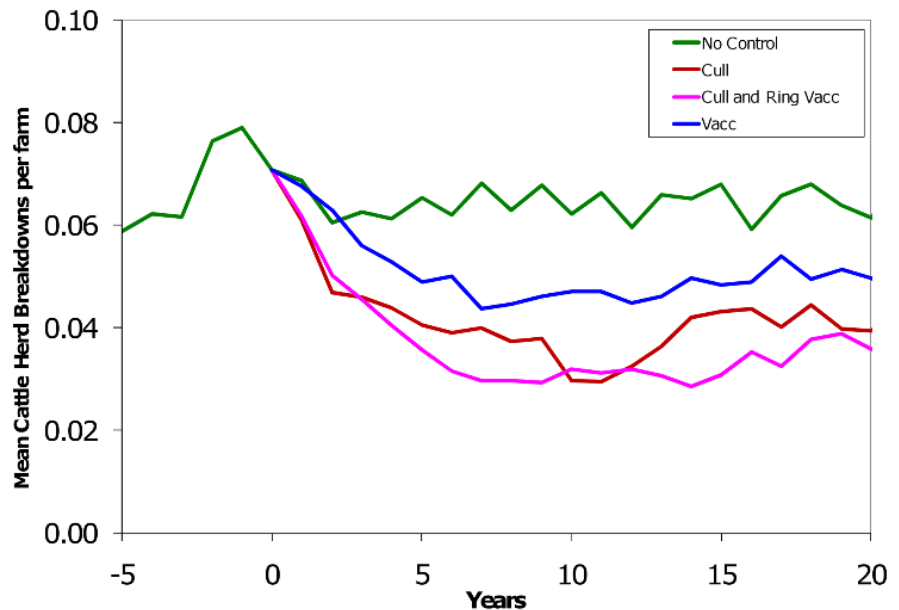
## Aim:

Modelling of interventions that could be implemented in the badger population to reduce cattle TB incidence in previously non-culled areas.

## Results:

**Culling reduced the herd breakdown rate by 18% compared to 11% reduction by badger vaccination. Results were assessed over a 10-year period: five years of treatment followed by five years of no treatment.**

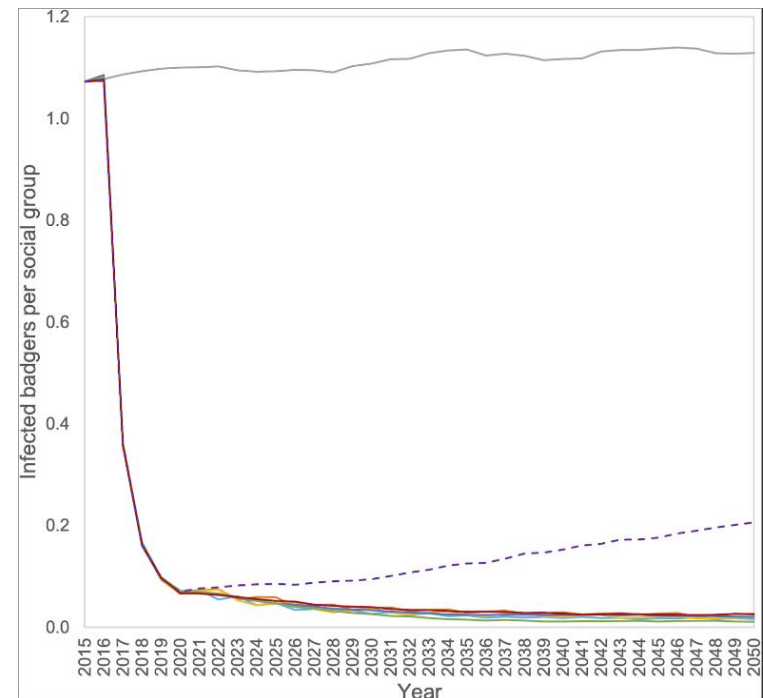
(a) The core



# Effect on badgers – Modelling

**Aim:** Modelling of badger control options that could be implemented in the badger population in a post-cull area (from 2021 in the figure) to reduce cattle TB incidence.

**Results: Vaccination reduced the number of infected badgers per social group and was comparable with continued culling, indicating that vaccination could be used as an exit strategy from culling to maintain reductions in cattle incidence.**



Mean number of infected badgers per social group; no badger control (grey), and intensive cull followed by no control (purple dashed), annual supplementary culling (dark blue), biannual culling (light blue), culling every third year (orange), culling for two out of four years (yellow), vaccination (green) and vaccination with fertility control (red).

# Recap – key points

## Effect of badger vaccination on cattle TB incidence

- In the BVDP, there was a **significantly decreasing trend**, but also in three comparison areas.
- In the IAA, **35% reduction in the rate of new TB breakdowns** (per 100 HYAR) – but not clear on the role of vaccination and comparison area also saw a reduction.
- In Ireland, **vaccination can be as effective as long-term continuous culling in lowering cattle TB incidence**, once badger population densities are first reduced by culling.
- Modelling shows **vaccination reduces the incidence rate of herd breakdowns by 11%** compared to an 18% reduction by culling in previously un-culled areas.
- In post-cull areas, modelling indicates that **vaccination reduces the number of infected badgers per social group**, giving comparable benefits to culling.



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# The evidence

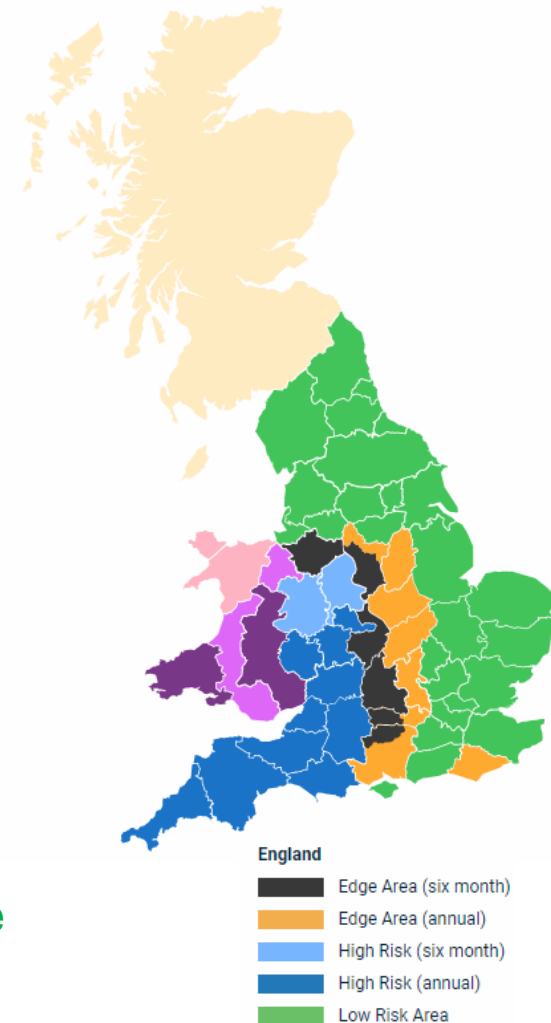
Protective effects of vaccinating badgers



# Lab-based Studies

- Badgers were trapped in **Low Risk Areas** of England.
- They were then **confirmed TB-free** by repeat testing with interferon-gamma (IFN- $\gamma$ ) and culture of clinical samples - **three consecutive negative results** in three months.
- Seventeen weeks **after vaccination with BCG, all badgers (vaccinated and controls) were infected** with *M. bovis*.
- Twelve weeks after experimental infection\*, badgers were euthanised and **post mortem examination** carried out.

\*To note that badgers were artificially infected with an amount of *M. bovis* much higher than that expected to be found in the field. Therefore results observed need to take this into account.



# Lab-based Studies

**Key finding - Vaccinated badgers had fewer TB lesions in their organs than unvaccinated individuals (controls)**

*Chambers et al (2010) Bacillus Calmette-Guerin (BCG) vaccination reduces the severity and progression of tuberculosis in badgers*

**Key finding - A higher dose of BCG\* provides better protection and reduces excretion of *M. bovis* in vaccinated badgers**

\*The high dose is 10x the human BCG dose and is what is administered to each badger in the field

*Lesellier et al (2011) Protection of Eurasian badgers (*Meles meles*) from tuberculosis after intra-muscular vaccination with different doses of BCG*

# Field-based Studies

Carried out in a 55 km<sup>2</sup> area in Gloucestershire, chosen due to its **high badger density**.

**Badger social groups** were identified by bait marking, then randomly assigned to either be **vaccinated or controls**.

Active setts were trapped at least **twice a year**, across a **four year period**.

Badgers were microchipped and tattooed so they could be identified at repeated trap events.

Samples were taken at each trap event including urine, faeces, blood and wound samples (if present).



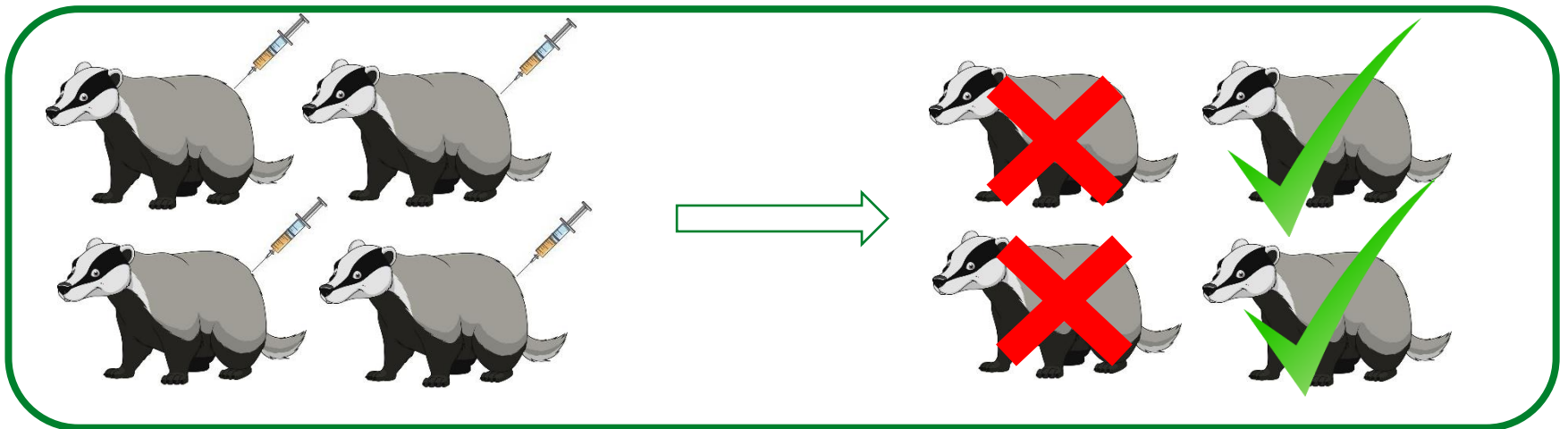
Vaccination = grey  
Control = white

# Field-based Studies

## Key finding - Vaccination **reduces disease in badgers**

*What the research says - Injection with BCG reduced the risk of vaccinated animals testing positive for *M. bovis* by:*

- *At least 54% when using the 'triple test' (Gamma + Stat-Pak + culture)*
- *At least 76% when using the 'double test' (Stat-Pak + culture)*

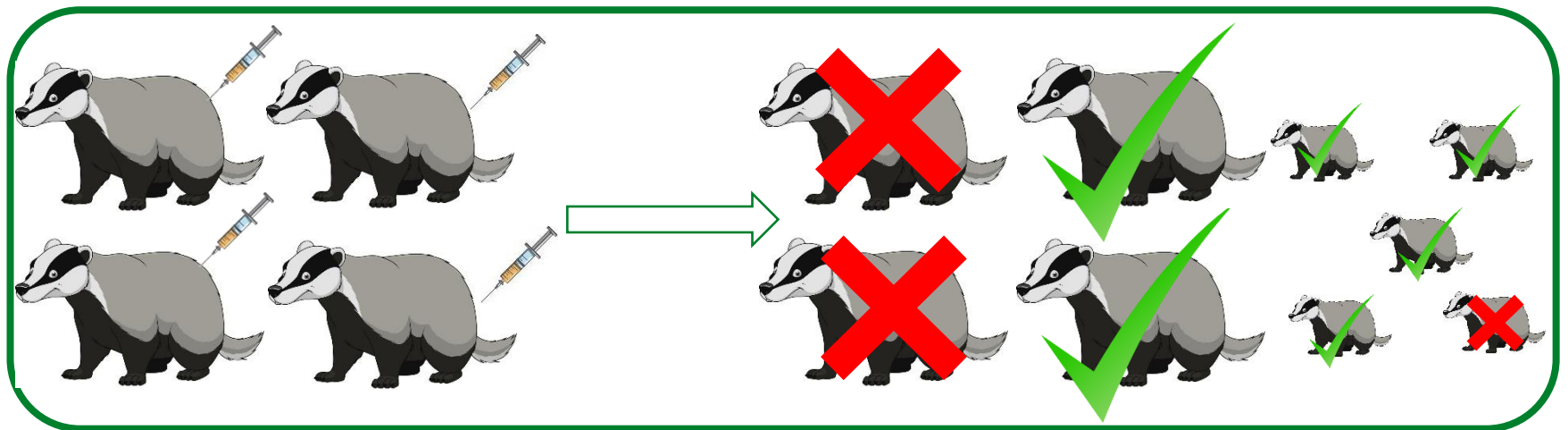


# Field-based Studies

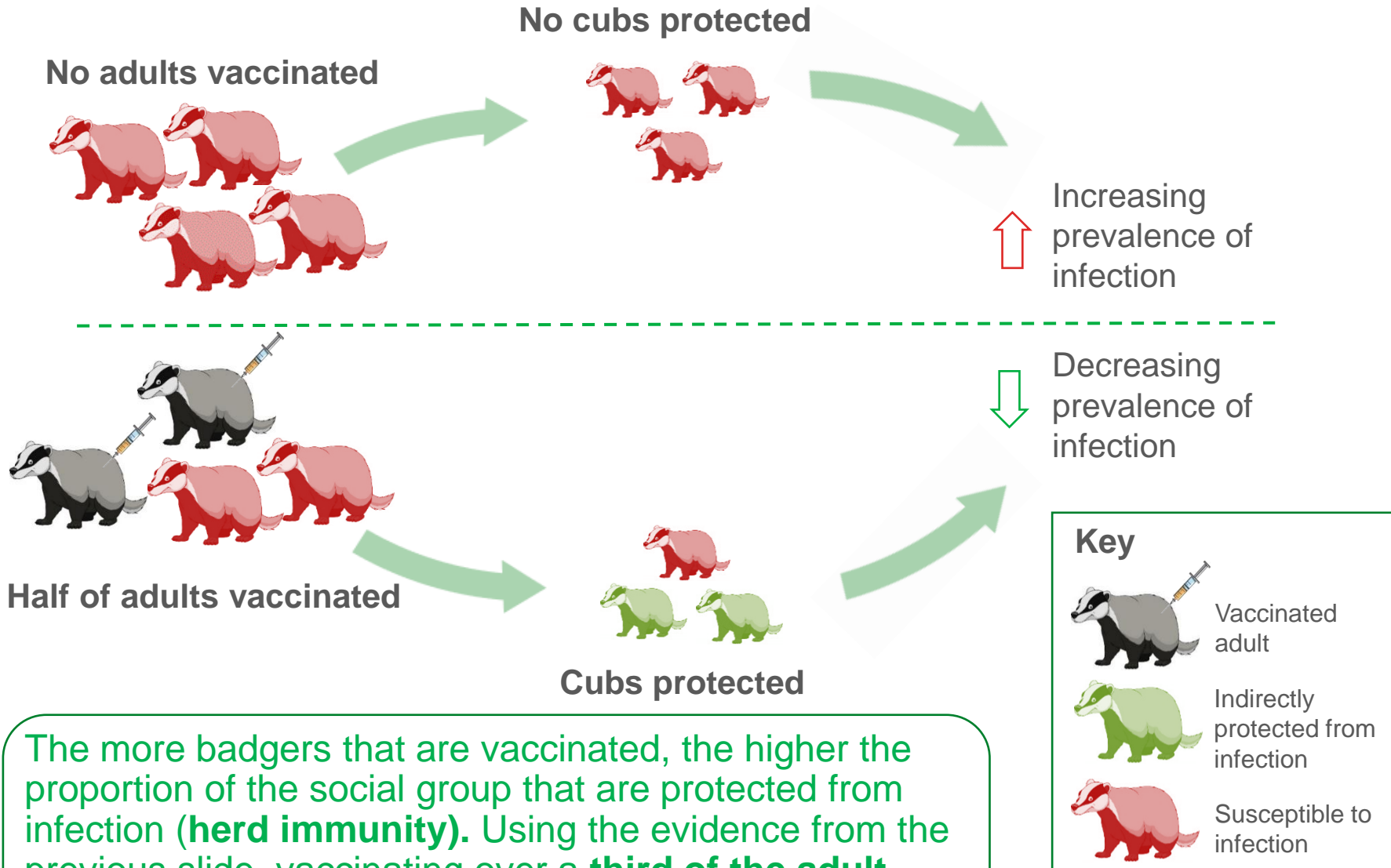
## Key finding - The vaccine provides a **herd immunity effect** at a social group level

*What the research says - indirect protection to unvaccinated cubs increased with the proportion of vaccinated adults in the social group, up to a maximum of 92% reduction in positive testing cubs.*

*Carter et al (2012) BCG vaccination reduced risk of tuberculosis infection in vaccinated badgers and unvaccinated cubs*



# Herd Immunity Effect

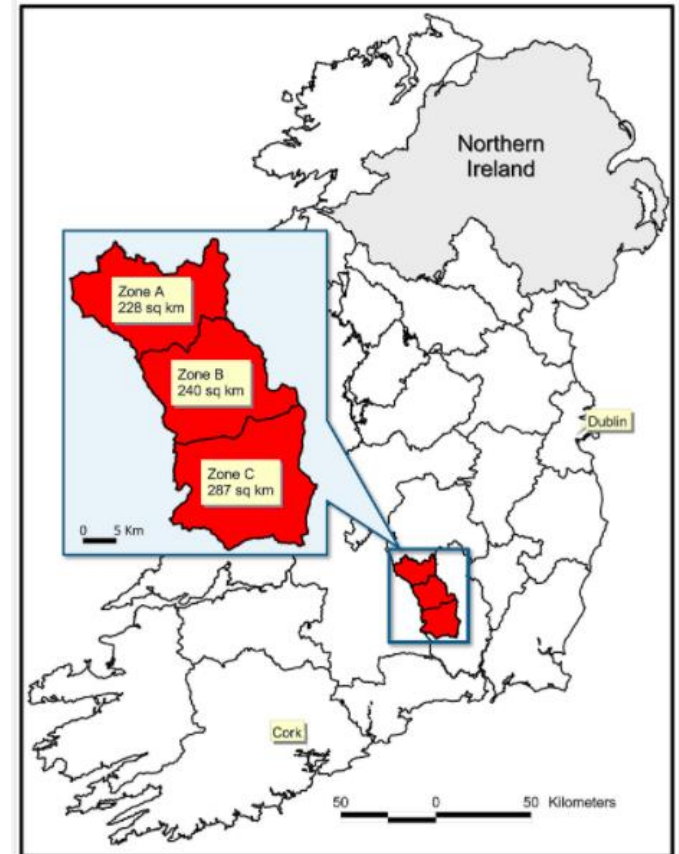


The more badgers that are vaccinated, the higher the proportion of the social group that are protected from infection (**herd immunity**). Using the evidence from the previous slide, vaccinating over a **third of the adult badger social group can protect up to 92% of unvaccinated cubs.**

# Efficacy of vaccinating badgers

## Oral BCG Vaccine field study - County Kilkenny, Ireland

- Three year oral BCG vaccine field study that aimed to determine if the oral BCG vaccine had any **protective effect in badgers exposed to natural TB infection**.
- The study area was divided into three zones:
  - Zone A: Treated orally with placebo
  - Zone B: Randomly assigned 50%: 50% treatment with BCG or placebo
  - Zone C: Treated orally with BCG
- At the end of the study, post-mortem analysis was carried out on treated badgers from each zone and on non-treated new badgers that were captured for the first time on the final year's sweep.



Map locations of the vaccine trial sites in County Kilkenny, Ireland.

# Efficacy of vaccinating badgers

## Oral BCG Vaccine field study - County Kilkenny, Ireland

### Key finding – Manual oral vaccination of anaesthetised badgers using BCG protects against disease in badgers

- A significantly lower number of animals with culture-confirmed gross lesions among the vaccinated badgers (9%) compared with non-vaccinated badgers (26%).

Gormley et al. (2017). Oral vaccination of free-living badgers (*Meles meles*) with Bacille Calmette Guerin (BCG) vaccine confers protection against Tuberculosis.

- “Further analysis of the data estimated that **vaccinated animals had 59% reduction in susceptibility to infection**”
- Extrapolating the results to a wide scale suggested that disease **eradication in the Irish badger-cattle system was feasible if vaccinating at least 30% of the badger population, provided cattle control measures continued to be implemented.**”

Aznar et al. (2018) Qualification of *Mycobacterium bovis* transmission in a badger vaccine field trial.



# Efficacy of vaccinating badgers

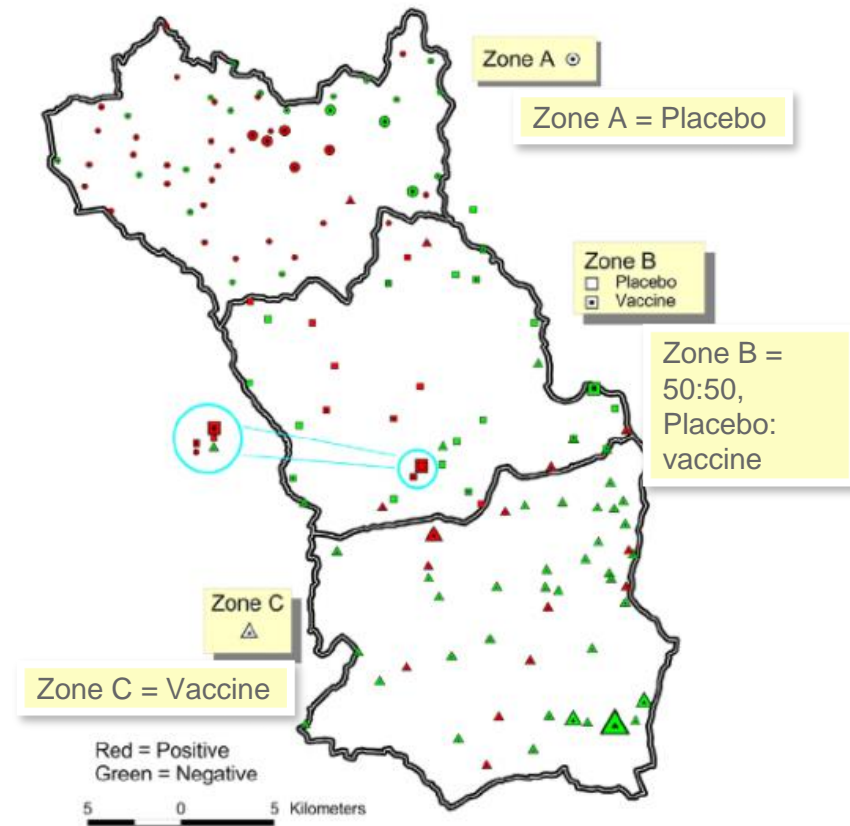
## Oral BCG Vaccine field study - County Kilkenny, Ireland

**Key finding - Manual oral vaccination of anaesthetised badgers using BCG resulted in an indirect protective effect in untreated badgers**

In Zone C (vaccinated) there was:

- **Reduced TB prevalence in vaccinated badgers, and**
- **No evidence of infection found (PME) in any of the 83 badgers that had never been vaccinated in the area.**

These results are consistent with an **indirect protective effect** in the **unvaccinated badgers**, suggesting a level of **population immunity**.

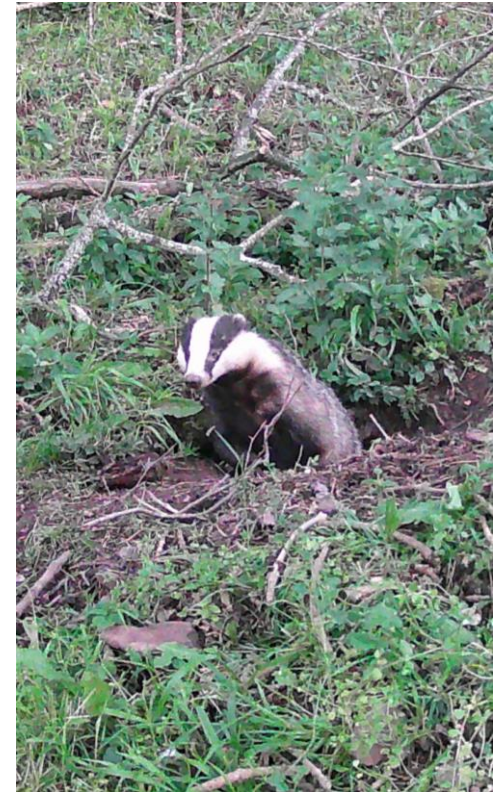


The distribution of enrolled badgers and *M. bovis* status at the location of capture within their zone of enrolment. Green = TB negative, red = confirmed TB positive. Zone B had additional captures of badgers that were recruited in and migrated from Zones A and C. Circled symbol shows cluster of infected badgers from three zones.

# Recap – key points

## The protective effects of vaccinating badgers

- Vaccinated badgers have **fewer lesions of TB** than unvaccinated individuals
- Vaccination **reduces shedding** of *M. bovis*
- Vaccination **reduces disease** at a social group level
- The vaccine provides a **herd immunity effect** at a social group level
- Manual oral vaccination of anaesthetised badgers using BCG also **protects against disease** in badgers and **resulted in an indirect protective effect in untreated badgers**



## Recap – key points

The evidence available supports the principle that badger vaccination deployed on a large scale can help to eliminate *M. bovis* from the badger-cattle system

Badgers infect  
cattle



Vaccination  
reduces disease  
in badgers



**Badger vaccination  
reduces the likelihood  
of cattle being  
infected by badgers**

**Badger vaccination should have a positive effect  
on TB incidence in cattle**



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# Planning a badger vaccination project

# How many badgers should we vaccinate?

- It is very unlikely that every badger in a social group would be able to be vaccinated.
  - some may be trap-shy or be dependant cubs which remain underground.
- By vaccinating annually, the number of immunised badgers will increase relative to the number of infected badgers which would naturally die off. Those unvaccinated badgers that remain susceptible will be protected through the **herd immunity effect**.
- **The goal is to vaccinate as many badgers as possible to achieve herd immunity effects.**

## Reminder:

The **more badgers that are vaccinated**, the **higher the proportion of badgers** in the population that will be protected from infection. So, increasing the number of vaccinated badgers will reduce the number of susceptible individuals. **The more vaccinated, the better!**

# Where are we vaccinating badgers?

## APHA-led badger vaccination

- In 2022, we are undertaking APHA led badger vaccination in several areas where the intensive badger cull has ended.
- By delivering vaccination in post cull areas, we will better understand **the practicalities of vaccinating a reduced badger population and the effect on the disease spread to cattle herds.**
- APHA have carried vaccination in TB hotspot in Cumbria since 2020 and have developed expertise in vaccinating reduced badger populations.



Badger footprint

# Where are we vaccinating badgers?

## Farmer and privately-led badger vaccination

- We have also funded a farmer-led badger vaccination project in East Sussex, to help the farming community deliver vaccination over a 250 kmsq area.
  - More information is available at <https://www.vesba.org.uk/>
- We have also helped fund privately-led vaccination projects in the Edge Area of England through the Badger Edge Vaccination Scheme (BEVS 2).
  - This scheme is now in its final year and aims to create locally protected badger populations, which can act as a barrier between areas where TB is present in cattle and areas without TB.

# Training and getting a licence to vaccinate badgers

## New class licence (CL48/CL49)

- As badgers are a protected species, a licence is required to capture them for vaccination using a cage trap and to apply a temporary mark (to show they have been vaccinated).
- In May 2022, Defra introduced a new and simplified licence for vaccinating badgers in England.
- Under the new licences CL48/CL49, those suitably **trained to undertake badger vaccination** can register online as an **authorised person**.
  - This means applicants no longer need to apply for an individual licence, provide extensive information in support of their application or wait 30 days for a decision.
  - The online registration form and further information is available on: [gov.uk](https://www.gov.uk)



# Training and getting a licence to vaccinate badgers

## Training to vaccinate badgers

- There are 3 training modules that providing teaching on how to trap and vaccinate badgers:
  - Module 1: Supporting skills for badger vaccination (not needed to obtain a licence)
  - Module 2: Cage trapping for badger vaccination
  - Module 3: Badger vaccination
- A list of approved training providers is available on [GOV.UK](https://www.gov.uk).
- Once you have the right training certificate, you [can register as an authorised person](#) under the licences CL48/CL49 to:
  - Set cage traps if module 2 has been completed (or other Natural-England-approved badger trapping training ); and/or
  - Vaccinate and mark badgers, if module 3 has been completed.
- If you're unable to register, you may still be able to apply to Natural England for an individual licence on [GOV.UK](https://www.gov.uk).

# Training and getting a licence to vaccinate badgers

## Train the trainer

- Defra launched a 'Train the Trainer' course to enable those with at least one year of practical badger trapping and vaccination experience to qualify to provide training to new vaccinators.
- Once approved, trainers will be able to deliver Module 1, 2, and 3.
- For more information on training, see the guidance here: [Bovine TB: Badger vaccination training - GOV.UK \(www.gov.uk\)](http://www.gov.uk/government/guidance/bovine-tb-badger-vaccination-training)



# Training and getting a licence to vaccinate badgers

## Veterinary Surgeons actively participating on a licence

- A qualified vet can vaccinate badgers captured under the class licence CL48 without needing to register as an authorised person as long as someone else who is registered under that licence is present during the vaccination.
- Vets cannot mark a badger once vaccinated, unless they have been taught how to do this by someone else who is already trained and permitted to do so.
- Once Natural England has verified the above training, the vet can register under CL48/CL49 as an authorised person to 'vaccinate and mark'.

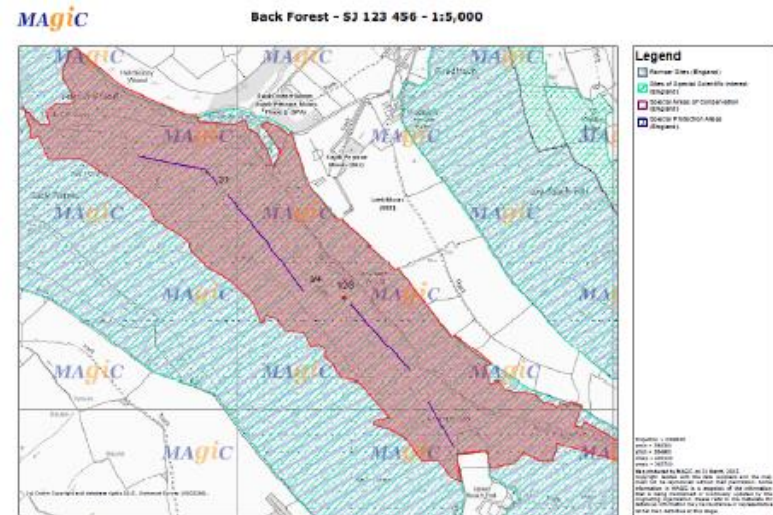
# Engaging with local vets

- There are two roles that need to be covered by a veterinary surgeon
  - **Prescribing vet** – supply BCG vaccine
  - **Directing vet** – available on-call for emergencies e.g. euthanasia due to welfare issues
- Both roles can be covered by the same person
- If not, it is recommended that they are from the same practice/ group or familiar to each other to ensure vet cover at all times
- **Attending Vet** - In the event that Directing Vets are unable to make a site visit themselves, they can delegate this responsibility to a nominated veterinary surgeon



# Establishing the area to vaccinate

- You should aim to cover several neighbouring badger social groups and whole farm areas if possible.
  - The larger the area the better the disease control benefits
- You should get it agreed in writing from the landowner that you can access their land to set cage traps and get a map that clearly shows the boundaries of the area where they have given you access.
- Consider the following factors when identifying land;
  - this should include largely contiguous land with no gaps
  - as much land as possible should be accessible to avoid leaving pockets of unvaccinated badgers
  - consider including land with natural barriers to limit the movement of badgers, e.g large rivers or motorways



Please note: The area depicted in this map was selected at random and bears no relation to any current vaccination licence. Furthermore, neither the boundary nor the sett, latrine or run information has any basis in reality.

# Example costs

Expense		Cost Estimate
<b>Training</b>		
<b>Module 1</b>	Field Surveying	£205
<b>Module 2</b>	Cage trapping for vaccination	£205
<b>Module 3</b>	Badger Vaccination	£1,143
<b>Vaccination</b>		
<b>BCG Vaccine</b>	Per dose	£30 (exc. VAT)
<b>Equipment</b>		
<b>Portable Vaccine Fridge</b>	Per fridge	£600
<b>Cage Trap</b>	Per trap	£45-80
<b>Peanuts</b>	20kg bag	£30
<b>Consumables</b>	e.g. FFP3 Masks, disinfectant, syringes etc	£1,000 plus
<b>Wildlife Camera</b>		£40 plus
<b>Management and Labour</b>		
<b>Travel and Subsistence</b>	Mileage, food etc.	Varies
<b>Vehicle Hire</b>		Varies
<b>Direct Labour</b>	Manager, consultants, contractors for vaccinating or trapping	Varies
<b>Overheads</b>	Upkeep of storage facilities etc,	Varies

**NB. These costs are only approximate and may change dependent on demand.**

# Want more information?

## Useful links

- TB Hub; <https://tbhub.co.uk/tb-in-wildlife/tb-in-badgers/tb-in-badgers-vaccination/>
- Licences to cage-trap and mark badgers for bovine TB vaccination: [Licences to cage-trap and mark badgers for bovine TB vaccination - GOV.UK \(www.gov.uk\)](https://www.gov.uk/guidance/licences-to-cage-trap-and-mark-badgers-for-bovine-tb-vaccination)
- Planning a badger vaccination project; [https://tbhub.co.uk/wp-content/uploads/2020/09/Planning-a-badger-vaccination-project-21.09.20\\_TB\\_hub.pdf](https://tbhub.co.uk/wp-content/uploads/2020/09/Planning-a-badger-vaccination-project-21.09.20_TB_hub.pdf)
- The badger vaccination process; [https://tbhub.co.uk/wp-content/uploads/2020/09/Badger-vaccination-process-guide\\_05.08.20\\_TB\\_hub.pdf](https://tbhub.co.uk/wp-content/uploads/2020/09/Badger-vaccination-process-guide_05.08.20_TB_hub.pdf)

## Useful Contacts

- bTB Engage: [bTBengage@defra.gov.uk](mailto:bTBengage@defra.gov.uk)
- APHA training: [badgervaccine@apha.gov.uk](mailto:badgervaccine@apha.gov.uk) or 020 802 62372
- Defra Badger vaccination: [badger.vaccination@defra.gov.uk](mailto:badger.vaccination@defra.gov.uk)
- Natural England licencing: [bTBVaccination@naturalengland.org.uk](mailto:bTBVaccination@naturalengland.org.uk)

