

A bovine tuberculosis policy conundrum in 2023

On the scientific evidence
relating to the Animal
and Plant Health Agency/
DEFRA policy concept for
'Epidemiological' badger culling.

APRIL 2023

An Independent report
by researchers and veterinarians to
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Summary

Since 2013, the government has authorised and licensed dozens of ‘intensive’ four-year badger culls, with subsequent five-year ‘supplementary’ culls, reducing badger numbers by an estimated 70% across much of southwest and central England. Culling has followed the spread of bovine tuberculosis (bTB) further, across the Edge Area (EA) of central England starting in 2017. From 2018, a new approach has been trialled at two locations in the ‘Low Risk Area’ (LRA) of the north and east of England, where bTB outbreaks from imported diseased cattle have formed clusters of new bTB herd breakdowns. Termed ‘epidemiological culling’ (EC), in government documentation, it aims to kill all (100%) of resident badgers in a newly diseased ‘Minimum Infected Area’ and heavily reduce them in an outer area followed by vaccination of surviving badgers in the third year, as in Cumbria. The epidemiology of bTB in the EA and LRA generally differs from that of the High Risk Area (HRA) where disease has been embedded for longer.

As a result, policy appears to be pointed towards a similar approach to that of the Republic of Ireland (RoI) since 2004, which recently includes a badger vaccination component. In RoI badgers have been locally eradicated since 1992, with around 6,000 badgers culled each year, resulting in a total cull of around 120,000 over a period of roughly 20 years. Despite this, bTB in cattle herds persists due to ineffective cattle testing and movement controls. More recently around 6000 badgers have been vaccinated each year in RoI, also with no measurable response. In Wales bTB is gradually reducing at a similar rate to that of England, but without culling badgers, suggesting that such interventions are both ineffective and unnecessary even in heavily bTB diseased areas to prevent the spread of disease in cattle.

The March 2020, government “Next Steps” policy for England (2) proposes to phase-out intensive and supplementary culling by February 2026. The most recent and extensive published study of government data indicates badger culling has brought no measureable benefit to the HRA. Policy indicates that intensive and supplementary culling will be replaced by cattle and badger vaccination, with EC in ‘exceptional circumstances’ only, using criteria and methods developed by the Animal and Plant Health Agency (APHA). Those methods are the subject of this report.

The main technical evidence-base for EC is considered in this report. Specifically;

- The **Risk Pathways' (RP)** approach to determining the source of individual bTB infections;
- The spatial distribution of **bTB Reservoirs** in cattle and in samples of badgers from post-mortem study, and;
- The results from **Whole Genome Sequencing (WGS)** sampling, examining differences between strains and their mutations in defined areas, over time.

Evidence from scrutiny of these three main categories of investigation and the practical findings from the four-year long EC cull reference 'model' in bTB Hotspot 21, in Cumbria, collectively show:

- a) There is no clear evidence that badgers play any significant role in the spread and maintenance of bTB in cattle herds where new bTB clusters are formed.
- b) The scientific evidence from use of EC suggests it is not sufficiently robust to justify veterinary approval for any wider use.
- c) There is a continued, deep seated lack of attention to basic disease prevention measures within APHA, formed around a belief that infection from badgers negates the success of other interventions.

The use of EC is advocated by Defra, APHA and the government stakeholder information provider *TB Hub*. <https://tbhub.co.uk/>. Until the belief in the role of badgers in the spread of bTB is broken, substantial progress with bTB elimination in England will continue to be severely hampered. EC is a serious misdirection of professional epidemiology and an unjustified distraction from the main need to better identify and control disease in cattle herds and the spread caused by frequent cattle movements. An independent review or inquiry is needed because of the nature of the problem and the serious draw it has on public subsidy.



Chapter 1. Introduction and Methods

1.1 Since 2013, government policy has enabled the killing of over 210,000 mostly healthy badgers, by shooting free-roaming badgers at night using rifles ('controlled shooting') or by trapping and shooting them in metal cage traps. "Controlled shooting" is poorly named and causes many badgers not to be killed outright and to escape injured. This has been done despite legal challenge, under Section 10 of *The Protection of Badgers Act 1992* (1), for the purposes of controlling the spread of disease. 'Controlled' shooting now accounts for more than 71% of shot badgers. Policy to-date has seen a total of 72 badger cull areas introduced in the High Risk Area (HRA), the Edge Area (EA) and the Low Risk Area (LRA) of England. As of September 2022, culling took place across 25,042 Sq.km of the HRA, 6,509 Sq.km of the EA and 122 Sq.km of the LRA. Figure 1. shows the current location of the designated risk areas in England and the counties of the current HRA.

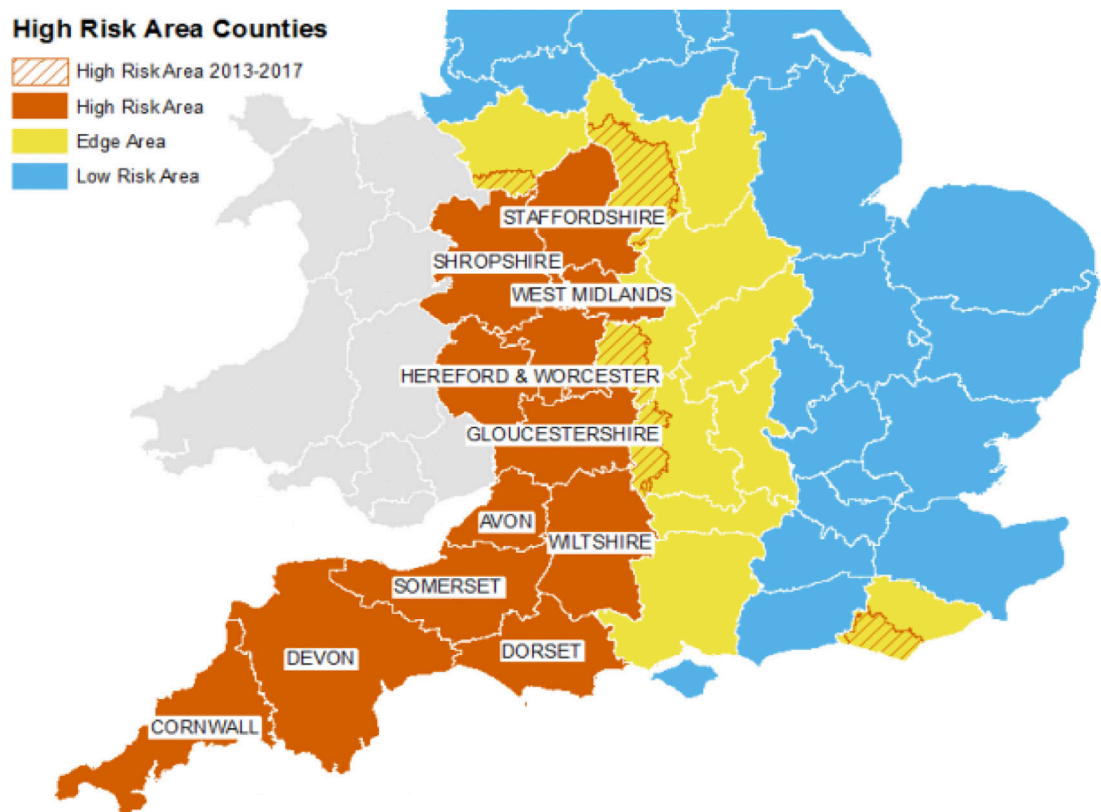


Figure 1. Location of the designated risk areas in England Adapted from APHA, 2021 (Ref 11). Bovine Tuberculosis in England in 2020 Epidemiological analysis of the 2020 data and historical trends, October 2021. Note, the northern part of the Low Risk Area including Cumbria is not shown. Crown copyright

- 1.2 The form of culling now known as ‘Epidemiological culling’ (EC) that could be applied to the whole of England in the future, has been carried out since autumn 2018, south of Penrith in Central East Cumbria (Cull Area 32) in the Low Risk Area (LRA). This is within an area called Hotspot 21 and undertaken on an experimental basis referred to previously as ‘LRA culling’. Events in Cumbria are described as representing the ‘model’ future approach to badger culling in the “Next Steps” March 2020 policy revision (2). LRA culling and EC aims to remove the maximum number (100 %) of badgers from what is called a Minimum Infected Area (MIA), in and around farms where there is a growing cluster of herd incidents and where TB free status has been suspended or withdrawn. Badgers have also been found to be bTB infected in these areas.



Shot badgers awaiting incineration in England in 2022.

- 1.3 Culling in the LRA incorporates aspects of ‘proactive’ and ‘reactive’ culling methods, as carried out in an unblinded field experiment: the *Randomised Badger Culling Trial* (RBCT) 1998-2005 (3). In effect it is proactive culling but with the reactive cull aim of removing all (100%), rather than an estimated 70% or more badgers targeted under the intensive cull licences issued to-date in England. As such, it represents a potential intensification of past proactive badger culling, if it were ever applied nationally.

- 1.4 The Cumbria badger cull area in 2018 was initially 190 Sq.km and was extended to 214 Sq.km in subsequent years and comprises an MIA with a size guesstimated at 87 Sq.km Badger vaccination in the designated outer (surrounding) area, which is expected to have low badger bTB infection, was introduced in the third year, to try to reduce infection rates in badgers recolonising the MIA. Badger vaccination is based on the unsubstantiated assumption that this may have a positive impact on reducing bTB prevalence in cattle. To date, EC has been carried out in two areas: Cumbria Area 32, since 2018 and Lincolnshire Area 54, since 2020.
- 1.5 Area-based 'reactive' type culling, with a similar approach of 100% local badger removal has been undertaken in the RoI since 2004, where bTB nevertheless remains endemic. Following 18 years of interventions including badger culling, the RoI has introduced policy changes. Since 2020, each year around 3,000 badgers have been vaccinated and 3,000 culled. In Wales, where badgers have not been culled at scale, and badger culling has been ruled out as a future prospect (4) there have been small scale badger vaccination projects with some government support. There has been no widespread badger culling in Wales or Northern Ireland to date.

2020 policy changes and uncertainty surrounding badger culling science.

- 1.6 What are reported to be the last of the four-year intensive cull (IC) licences and authorisations were issued in autumn 2022. These are likely to result, with additional SC, in the shooting of a further estimated 66,000 (total IC+SC) or more, largely uninfected badgers between 2022 and 2026. These figures include badgers killed within 871 Sq.km of land added to existing cull areas since 2017; the equivalent of three further cull zones. The 2020 "Next Steps" policy announcing the possibility of wider use of EC, where local APHA assessments decide this is necessary, would replace IC and SC following their conclusion on 31 January 2026. Any such policy change will be subject to public consultation.

- 1.7 Badger culling is described by the present Chief Veterinary Officer Christine Middlemiss as controversial (5). The objective establishment of any scientific link between badger removal and the rate of bTB cattle herd incidence is lacking, with government continuing to rely on the RBCT (3,6) despite its paucity of replicates and subjective selection of reactor data, and modelling methodology. Additionally, there was significant disruption of that research by the 'Foot and Mouth Disease' epidemic in 2001. Six stages of uncertainty in relation to the evidence-base for badger culling are summarized at Annex 1.
- 1.8 Ensuing bTB policies have been anchored to the findings of the RBCT and increasingly policy is based upon the views from members of some within the farming and veterinary communities that culling wildlife vectors must play an integral role in bTB control. This relates to the out-dated thinking from the 1990s that badgers are responsible for a majority of cattle herd bTB incidents and the solution depends upon removing them, to enable cattle measures to work. This is something that real world evidence consistently fails to bear out, with such evidence pointing towards other problems. Such as inadequate cattle testing and movement control restrictions and undetected residual infection in cows that test negative for bTB by the standard SICCT test. The sensitivity of the SICCT test over the last decade has become more fully understood to be considerably limited for a range of reasons.

Current policy science

- 1.9 As indicated above, the current policy intentions that have been presented are that IC and SC will be concluded by 2026 and that, subject to research findings, the results of field testing and licensing requirements, cattle and badger vaccination may be introduced. EC will also take place in what are described as 'exceptional' circumstances.
- 1.10 This report considers the approaches taken by APHA and within government contracted research science, to develop an evidence base to support the continuance of badger culling in England.

There are three main categories:

- Procedures determining the origin of bTB infection, termed: **'Risk Pathways' (RP)**
- Spatial studies using molecular techniques to identify bTB strains/spoligotypes in clusters or 'reservoirs', and related studies, termed: **Reservoir Studies (RS)**
- Use of the molecular techniques on bacteria collected from cattle and badgers and examination of spatial and temporal variation, termed: **Whole Genome Sequencing (WGS)**

Risk Pathways methodology aims to identify the likely source of a bTB incident, defined as *hazards* and the pathway(s) by which disease entered the herd. The source and pathways are determined by an APHA appointed 'investigating vet' and recorded on a Disease Report Form (DRF).

Reservoir Studies have been carried out by sampling 'roadkilled' badgers and cattle *postmortem results*, in situations where wildlife was claimed to act as a vector or maintenance bTB reservoir, with the potential to transmit *M.bovis*, (*Mycobacterium bovis*) the bacteria causing bovine tuberculosis, within their own population and spread and perpetuate local bTB incidents in cattle herds. The prevalence of the disease in badgers is difficult to determine due to uncertain culture sensitivity.



The failure of the SICCT test to remove sufficient infected cows has been at the root of the current bTB epidemic.

Whole Genome Sequencing enables examination of entire or nearly entire genetic sequences of bTB bacteria, taken from cattle and badger lesions at *post-mortem* and subsequently cultured. WGS has been introduced to try to examine the potential direction of disease transfer/transmission. Shared DNA sequences within a particular strain or genotype and subtle mutations can be examined to try to elucidate *M.bovis* associations between and within species. Modelling studies using the frequency of shared mutations between species try to estimate direction of transmission. WGS investigations have increased during the last four years across most of the UK, primarily to trace infection derived from cattle movements in the beef and dairy single host species system. Directionality in a multi-host system (including other livestock species and wildlife) is far more difficult to determine, and the results of WGS analyses must be interpreted with great caution.



Chapter 2. Risk Pathways (RP)

- 2.1 BTB incidents (both OTF-W and OTF-S) are investigated to assess the hazard (source of infection) and risk pathway. A 'provisional assessment' is made early during the management of an incident, to help guide and prioritise immediate actions. A 'final assessment' is then undertaken when all evidence has been gathered, including, e.g. *post mortem*, back-tracing and culture results. The same protocol is used for both provisional and final assessments. In the HRA, one third of new incidents are randomly selected for investigation. The aim is to investigate all new incidents in the EA and LRA but in the EA this is not always possible.
- 2.2 Prior to 2017 the badger control policy used outcomes from the RBCT and subsequent analysis as the primary scientific reference. Animal and Plant Agency (APHA) Epidemiology reports for 2017 (7) and 2018 (8) rely on the outcomes of Risk Pathway (RP) analysis whereby bTB incidents are attributed by 'weighted contribution' to different sources of infection. Weighted scores of bTB incidents attributed to infection from badgers have ranged from around 23% in Hampshire to around 81% in Cornwall (8).
- 2.3 Data collected and documented on a Disease Report Form (DRF) includes the history of individual bTB reactors; bTB history on the farm and surrounding area; herd and husbandry types; cattle movement histories; location of contiguous farms and their infection status; post-mortem results and culture / genotyping for withdrawn (OTF-W) herds. Some of the variables are determined remotely from government datasets. The bTB infection status of badgers, and potential environmental bTB contamination such as slurry and manure movements are not investigated.

2.4 The investigating vet is required to choose up to three of the most plausible hazards for inclusion in a final risk assessment, ranked by perceived risk.

- Definite – evidence-based
- Most likely – (most biologically plausible of several options): evidence-based
- Likely – (more than just possible): evidence-based
- Possible – (biologically plausible)

There is no explanation in the DRF or in the APHA report of the weight of evidence needed to make these judgements. The determination becomes in most cases largely subjective, with unknown origin being split largely between 'badger' and 'unknown' source.

2.5 The DRF attempts to identify hazards that 'possibly', 'likely' or 'definitely' contribute to the source of infection. Such is the design of the DRF, that a disease source ascribed as 'wildlife' can far outweigh that ascribed to cattle. The investigating vet assesses the evidence available to try to identify the route by which bTB infection entered the holding and uses veterinary judgement to make this decision. The source(s) of infection for each incident is weighted by the degree of certainty ascribed by the vet. Much if not all the evidence relating to badgers as the source of infection is anecdotal and is therefore subject to unconscious or other bias. Evidence relating to infected badgers is usually completely lacking, beyond their known presence in the area, whereas evidence relating to cattle is more likely to be robust, having been derived from genotyping, cattle movement records and cattle testing.

2.6 In 2020 two veterinarians prepared a report (the 'DWT report', (9)), addressing and criticizing an APHA claim that 77% of bTB herd incidents in Derbyshire in 2018 were most likely caused by direct infection from badgers.

2.7 The RP methodology is heavily caveated and the executive summary of the APHA Epidemiology report for Derbyshire is suitably cautious:

"As a result, the relative proportions of each risk pathway is very approximate and only broad generalisations should be made from these data. "

The subjective approach and presentation by APHA appear to lead to bias and inconsistency, lacking basic veterinary and epidemiological standards, yet this approach still persists.

- 2.8 In 2020 APHA indicated its intention to produce a peer-reviewed paper on the newly adopted RP methodology (10). If this new approach is adopted, it could pave the way to even more routine attribution of bTB herd incidents to wildlife at a local level. It will further train and encourage vets to use an imprecise system resting on epidemiologically speculative and unreliable evidence, which by distracting from true cause, could represent a threat to bTB control.
- 2.9 In response to the concerns raised in the 2020 DWT report, APHA made a small concession, by introducing 'buffering' to give more emphasis on uncertainty. However, this made very little overall difference, attribution to badgers was reduced by 5-10%, but still averaged over 50% in the HRA (11). It should be noted that the only government reference science estimates direct badger to cattle infection rates of between 0.0 and 5.7% of OTF-W incidence, according to the data selected (12).
- 2.10 In Northern Ireland a different DRF has been used to that in Great Britain. However, it is equally likely to foster bias and misdiagnosis.





Chapter 3. Bovine tuberculosis reservoir and related studies

- 3.1 A government appointed policy review of bTB control in England by the 'Godfray Group' in 2018 stated that ***"There is no scientific consensus about whether the disease is self-sustaining in badgers."***, and hence the uncertainty in its role, other than as a spillover host for bTB in cattle in the English countryside (13). Substantial evidence now exists, via county analyses, that proactive badger culling is not necessary to initiate bTB decline (14).
- 3.2 By way of further enquiry, spatial investigation of badger and cattle infections have been undertaken in England and Wales. The most comprehensive, published in 2021, ranged over the Edge Area counties of Cheshire, Derbyshire, Nottinghamshire, Leicestershire, Warwickshire, and Northamptonshire (15).
- 3.3 This major study examined 610 badger carcasses found dead on roads over the period 2016–2017. The prevalence of a range of TB bacterial strains allowed a greater degree of precision in identification of similar *Mycobacterium* pathogens involved. The prevalence of what are termed bTB-like organisms or *Mycobacterium tuberculosis* complex (MTC), detected *post-mortem* in badgers was 8.3%. The county-level prevalence of a wide range of MTC ranged from around 4.0 - 15.0 %. The spatial distribution of MTC spoligotypes recovered from badgers and cattle varied significantly. Only in one area, with elevated levels of cattle infection in Cheshire (Figure 2.), did the strain in cattle overlap notably with that in badgers. The study concluded that cattle to cattle infection is the more likely cause of disease proliferation in the other five areas and quite possibly in all of them. This suggests that Edge Area infection is arriving via cattle movement and being proliferated locally by cattle, not wildlife.

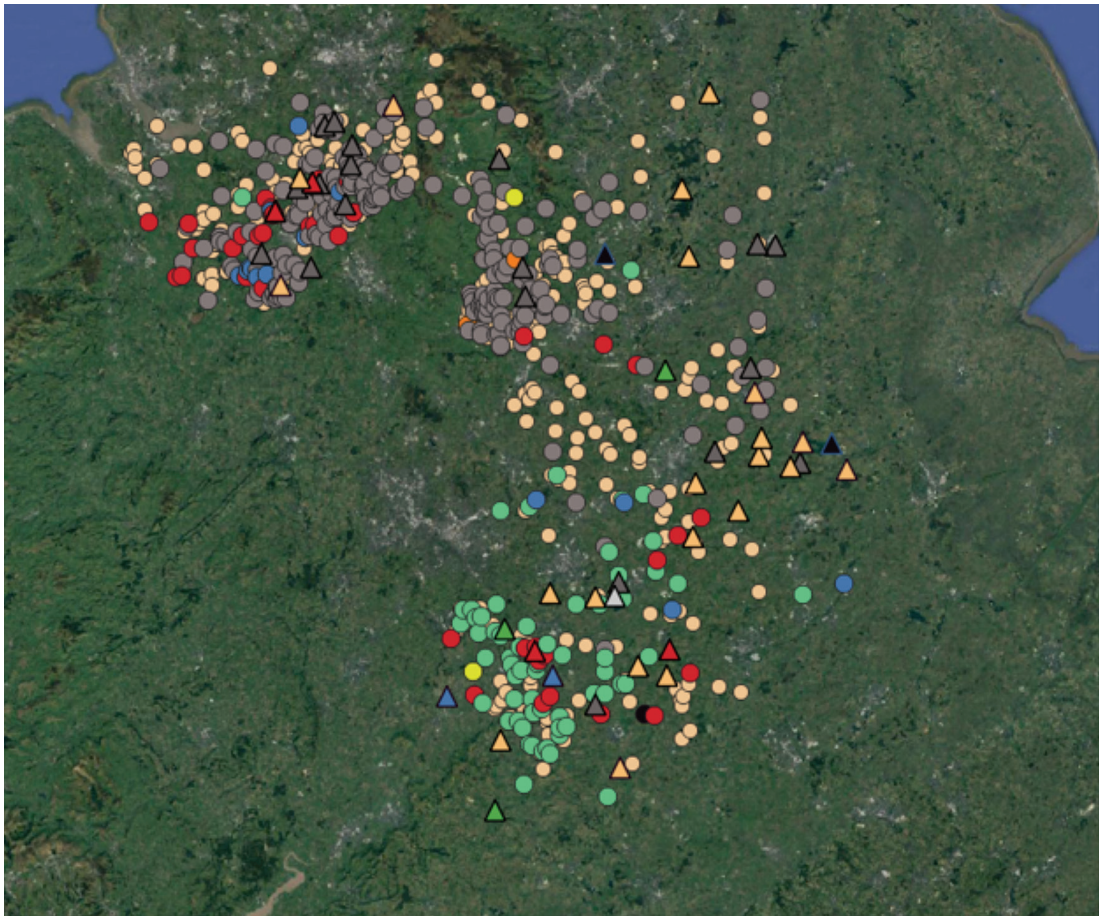


Figure 2. Adapted from Swift et al. 2021, Figure 3. Overall distribution of spoligotypes of MTC isolate locations from the northern English EDGE Area cattle (circles) and from badgers (triangles), Colours indicate spoligotypes/genotypes; Grey = SB0129 / 25, Red = SB0263 /17, Green = SB272 / 10, Blue = SB140 / 9, Black = SB1016 /130, Tan = either not characterised or rare and in badgers probably *M.microti*.

3.4 The study was also extended to a group of five other counties: Oxfordshire, Hampshire, East Sussex, Buckinghamshire, and Berkshire, across which a total of 372 badger carcasses were collected for analysis. MTC in badgers was absent from samples from counties other than Oxfordshire, where it was identified in 3.8% of carcasses (16). There is therefore no clear link from this reservoir study to suggest that badgers have caused or maintained the spreading bTB epidemic in the Edge Area over the last decade or more.

- 3.5 An initial study in Wales in 2012 of around 450 badger carcasses suggested that cattle movements play the dominant role in the spatial distribution of *M.bovis* (17). In an '*all Wales Badgers Found Dead*' study (2014-2016) (18), of 1,863 badger carcasses found the prevalence of bTB in badgers since 2005–2006 to be in decline: from 13.3% to 7.3%. Direction of any cross-species transmission could not be determined.
- 3.6 Finally, the 2021 Welsh Government Consultation Document (19), addressing the question '*What is driving the disease?*' found that the bTB strains present across Wales were closely related to those in bTB endemic areas in the incident cluster on the border of Wales and England. Molecular epidemiology pointed to the source being local movement of cattle into the cluster in Wales near the English border from adjacent endemic bTB areas of Shropshire and Cheshire. It found that residual and undisclosed infection (infected cattle not readily identified via SICCT tests) was a major factor. The bTB incidence recurrence rate was found to be relatively high. Both reintroduction of the disease through cattle movements from the adjacent EA/HRA as well as residual infection have led to new incidents with identical or very similar bTB strains to those from previous incidents. Further, genetic sequencing suggests disease transmission is via cattle across country and county borders with joint home ranges of the bTB genotype, incorporating parts of west Shropshire and southwest Cheshire. Wildlife surveillance evidence showed that there was no recognised significant reservoir of the disease in the badger population over the previous decade.

More models that tried to show that wildlife plays a significant role

- 3.7 Despite conflicting historical evidence, models have been published using the hypothesis that wildlife has an important role in maintaining bTB in cattle herds (20). This study presents a stochastic simulation model in an effort to simulate *M.bovis* transmission among cattle, transfer by cattle movements and transmission from 'environmental reservoirs'.

- 3.8 The study claimed that: *“The fitted model explained over 99% of the variation among numbers of breakdowns in four defined regions and surveillance streams in 2010.”* Such claims immediately arouse concern from a statistical perspective. Even with a perfect model with all the valid predictors as causality, there is randomness that will reduce the explanatory power of the model below 100%. The likelihood is that the model is almost certainly over-fitted. It is telling that the authors do not explain how such a good model was derived.
- 3.9 While there is some reference to over-fitting and the use of 2016 data to check the model, having stated that 2016 data was like 2010 data, the authors provided no indication that standard checks, such as cross-validation, had been carried out. A model may explain the data perfectly, given sufficient parameters, but its predictive powers will be highly limited. While the R^2 looks strong (0.9930), there can be serious problems with an overfitted model. Regression coefficients may represent ‘noise’ rather than genuine relationships in the population. Additionally, an overfitted regression model is tailor-made to fit the random quirks of one sample but may be less likely to fit the random quirks of another sample. Thus, overfitting a regression model reduces its value to generalize outside the original dataset. There is a strong impression that policy-based evidence is being generated here, instead of objective science of genuine epidemiological value.

The Defra 2020 ‘Next Steps’ strategy for achieving bTB-free status for England

- 3.10 In March 2020 George Eustice, the then Secretary of State for Environment, Food and Rural Affairs, introduced a “Next Steps policy” for achieving bovine tuberculosis free status for England (2) which included the following statement:

“I am updating the House on today’s publication of the government’s response to Professor Sir Charles Godfray’s independent review of our 25-year strategy to eradicate bovine TB (bTB) in England by 2038. While the government must retain the ability to introduce new cull zones where the disease is rife, our aim will be to allow future badger culls only where the epidemiological evidence points to a significant reservoir of the disease in badgers”

However, the term 'significant reservoir' of the disease in badgers remains undefined.

3.11 APHA funded studies (21) have sought to try to define what is called '**a local *M.bovis* reservoir potentially shared by cattle and badgers.**' The aim of the study was to develop criteria using currently available data, for '**defining areas with *M.bovis* reservoirs associated with badgers within the Edge Areas of England**'. Performance was estimated by using Latent Class Analysis (LCA) using data from badger tuberculosis surveys. However, there was insufficient bTB data, and/or WGS data from badgers to develop a definition for a 'reservoir'. Instead, a definition for an *M.bovis* reservoir was developed using cattle TB surveillance data.

3.12 Spatial units of (25 Sq.km) in the Edge Area were defined as having a bTB reservoir if they had;

- (i) at least one bTB incident in at least three of the previous 7 years,
- (ii) at least one bTB incident in a cattle herd confirmed by *post-mortem* tests as due to local *M.bovis* infection and not attributable to cattle movements in the previous 2 years, or;
- (iii) more 'confirmed' bTB incidents than 'un-confirmed' in the previous 2 years.

3.13 Approximately 20% of the Edge Area was classified as having a local *M.bovis* reservoir using the cattle-based definition. With an assumed bTB prevalence in Edge Area badgers of 15% (11), sensitivity for the local *M.bovis* reservoir definition varied from 25.7% to 64.8%. Specificity was 91.9 %. The mean sensitivity of LCA badger data model, assuming an infection prevalence of 7.5% in badgers, was calculated at only 14%, making it unsuitable.

3.14 Over 90% of the local bTB reservoir was in stable endemic bTB areas, identified through previous work. Its spatial distribution was largely consistent with local veterinary knowledge. Uncertainty in the reservoir's spatial distribution was explored through its recalculation, in spatial units shifted in different directions.

- 3.15 The spatial distribution of *M.bovis* isolates from cattle were examined for genetic relatedness using WGS. However, the badger data could not be similarly analysed, as WGS of badger isolates were not routinely conducted by APHA prior to 2017 and virtually all the badger data were from earlier studies. While the study is sparse on data relating to wildlife, that relating to cattle is extensive.
- 3.16 The authors recommended that the definition should be re evaluated as further data on badger infection with *M.bovis* becomes available. The evidence to support a wildlife reservoir is highly dependent on DRF and RP input data, but the authors fail to mention the risk of bias in these sources of information.
- 3.17 The current study selects spatial units (hexagons) of 25 Sq.km plus a buffer of 25 Sq.km. The buffer was added around the local reservoir border to indicate the range of possible bTB spread from the reservoir. Brunton et al. 2015 (22), uses 6.25 Sq.km. hexagonal cells as base resolution. The larger units have the effect of hiding areas where there is potentially no infection, with the effect of promoting culling over a wider area.
- 3.18 The conclusion of the study states:

“This work increases the information available for locally focused TB controls. A novel approach was taken to define the areas on the basis of cattle TB surveillance data because of the scarcity of direct evidence for the presence or absence of TB in badgers. This approach has been rarely used with TB and may have useful applications for other geographical regions.”

Northern Ireland

- 3.19 In Northern Ireland DAERA has been monitoring TB prevalence in roadkill badgers (badgers found dead) since 1998 (23). The estimated mean annual prevalence of bTB in badgers was c.16% over the period 2016-2020 (24). To date the direction of interspecies transmission has not been determined.

3.20 Overall, in NI, studies show that *M.bovis* has evolved and continues to evolve into many strain types with slight genetic differences. When *M.bovis* is isolated (i.e. there is a positive culture result), DAERA sends the isolate for strain typing and has done so since 2009. *M.bovis* strain types were isolated during 2020 with the “top 10” accounting for about 85% of samples. Strain types change over time due to:

- Newly imported strains coming into NI from GB or RoI
- Re-occurrence of older strains that have been seen previously.
- New ‘daughter’ strains being generated by mutations of existing strains

3.21 Figure 3. shows strains in 2014-2015 to be geographically localized across NI. The ‘out of range’ strains found away from their cluster are highly likely to represent the infected cattle movements from a centre of disease, reinforcing the problem of frequent disease spread by the NI cattle trading and movements system as the key maintenance driver for the epidemic.

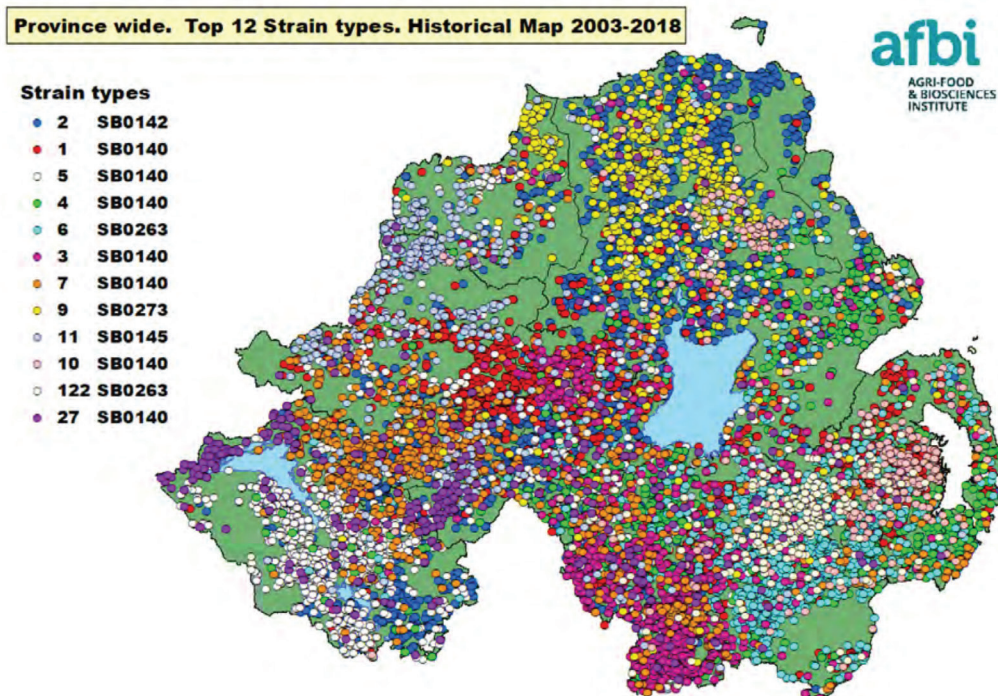


Figure 3. Northern Ireland. Distribution of the most prevalent bTB strain types found in bTB confirmed cases in 2018. 102 *M.bovis* strain types were isolated during 2018 with the top 10 accounting for 84% of the isolates. Source DAERA <https://www.daera-ni.gov.uk/sites/default/files/publications/daera/bovine-tuberculosis-tb-annual-report-2018-final-V2.PDF>

- 3.22 NI studies have examined risk factors for herd OTFW incidents. For historical reasons, farm businesses in Northern Ireland have ‘fragmented’ land usage: one farm may own or rent land in many locations in addition to, or instead of a home-farm holding. Such a system is called ‘conacre’ and results in an extraordinarily frequent level of cattle movements, maximizing livestock contact and hence disease risk exposure. In total around 1.5 million individual cow movements occur per annum.
- 3.23 As a result, farms with highly ‘fragmented’ grazing systems are almost twice as likely to have a bTB positive neighbouring farm. After controlling for herd size, herd type, spatial and temporal factors, it has been found that fragmented grazing increasingly exposed herds to infection originating from the adjoining farm (25).
- 3.24 Studies have also found that the cattle movement network that allows multiple movements between land and marketplaces confounds government movement restriction controls, creating the ideal environment for disease proliferation (26). It is unacceptable that recommendations based upon low quality evidence and cause-arguing claim badger culling as an essential aspect of bTB control strategy. One more recent and blatant example of the overstatement of badger involvement in Bovine TB in cattle is a 2022 paper by the TB Scientific Working Group in Ireland (27).

Conclusions from spatial studies

- 3.25 Overall, many £ millions have been expended on studies to investigate the spatial relationships between domesticated and wild animals, including examining cattle and badgers at *post-mortem*.
- 3.26 The assumption that badgers transmit bTB to new cattle herds once cattle bring bTB into an area is not supported by recent research. Most studies conclude or imply that cattle movements are the main or sole driver of distribution and spread of bovine tuberculosis into new areas.

- 3.27 Other livestock, including sheep, and wild animals such as deer, badger and red fox cannot be entirely ruled out as occasional *M.bovis* vectors. Many mammals are susceptible to and may readily catch bTB from infected pasture or infected prey items. Incidents of infection from these animals remains unknown while the rationale for the epidemic being largely initiated and maintained through cattle movements remains credible and forms the logical baseline.
- 3.28 Findings over the last decade or more have significance in relation to attempts to try to reduce herd bTB incidence and prevalence using a different intervention: badger vaccination. If the general inference from reservoir and other studies is correct, then badger vaccination, while potentially protective of badgers, can have little or no useful purpose in disease control in cattle. In the RoI studies have shown little difference in bTB control in areas where badger populations have been subjected to either culling or culling followed by vaccination. Results are consistent with culling achieving no different association with bTB levels than vaccination. The results from RoI support the conclusion that this is because neither has any significant effect on BTB herd breakdowns.
- 3.29 The inability to show any simple and clear-cut evidence that the culling or vaccination of badgers has any clear efficacy in relation to disease control in cattle over the last 20 years, further suggests a gross misconception regarding the role of badgers in the epidemiology of the national bTB epidemics in cattle in Great Britain and Ireland. Further and of substantial importance, the Welsh Government has achieved significantly declining bTB herd incidence without expenditure on highly speculative badger culling.



Chapter 4. Whole Genome Sequencing

Estimating movement of pathogens using genetic tracing and identification

- 4.1 Identifying small genetic mutations of pathogens as they pass between hosts has potential for epidemiological investigation. However, its capacity to deliver conclusive findings in the exact route of transfer of pathogens between hosts is constrained by accuracy in controlling and sampling multi-host situations in varied commercial settings over space and time.
- 4.2 In relation to bTB, Whole Genome Sequencing (WGS) has been developed and used primarily to determine a source of infection in cattle herds from cattle movements. However, there has been no in-depth approach to investigating transmission between badgers and cattle, despite opportunities to do so. Two main studies, one relating to the more recent outbreak in Cumbria and the other using material collected and stored in Gloucestershire going back two decades, have both reached similar conclusions.
- 4.3 Study of the historic material collected from infected cattle and badgers during the RBCT (28) illustrated the importance of long-distance transmission of bTB from regular cattle sales and movements. Most of the RBCT trial areas contained hotspots that had recently flared up with a single transmission cluster that had been established shortly before sampling. Additionally, the recurrence of herd OTF-W incidents by infection within the same transmission clusters and superspreader events, appear to be driven by cattle, not badgers.

- 4.4 Data indicates that transmission clusters in different parts of the west of England, identified twenty or more years ago and still evident today, were established by long-distance seeding events involving cattle movement, and not by recrudescence from long-established wildlife reservoirs. This answers one of the original questions as to how bTB spread out from relatively small enclaves in the west from the 1970s, increasing from the mid-1990s and particularly due to the post-2001 restocking of untested cows following the Foot and Mouth disease outbreak. Both long and short distance cattle movements are shown to be the historic mechanism of spread of infection.
- 4.5 WGS studies generally report some evidence that a particular strain has been found in a sampled badger and a sampled cow but the frequency (and route) at which this happened was not possible to determine accurately. OTF-W incident clusters are maintained primarily by within-species transmission. DAERA data from Northern Ireland between 1999 and 2011 shows that bTB prevalence in badger populations reduces once bTB in surrounding cattle herds diminishes and this is consistent with badgers being a dead-end spillover host.
- 4.6 With the application of Bayesian phylogenetic and machine-learning approaches to bacterial genome data (29), and by comparing samples from badgers at Woodchester research station in Gloucestershire with those taken from a wide surrounding area, the frequency of infection events can be considered. BTB infection events were said to occur more frequently from badgers to cattle than *vice versa*, but only if the data used were representative, which was uncertain. Badger to cattle transmission was considerably less frequent in comparison to cattle to cattle transmission.

Genomic studies in Northern Ireland

- 4.7 A recent study in Northern Ireland (30) genome sequenced 619 *M.bovis* isolates from badgers and cattle across a 100 Sq.km bTB 'hotspot'. Eight lineages of *M.bovis* were circulating in the study area, seven of which were considered non-endemic, imported by cattle trading and movements. The single endemic lineage exhibited low genetic diversity with an estimated strain emergence some 40-50 years ago, followed by expansion in the 1990s and again in 2011 and 2012.
- 4.8 In this study, isolates from both cattle and badgers were indicative of the sharing of closely related strains, with some evidence for direct or indirect transmission in both directions, not surprisingly, given the time frame. Such findings are consistent with ongoing interspecies transmission but suggest that badger intra-species transmission may not be a major driver of bTB persistence in cattle in the study area.
- 4.9 A study in Cumbria examined epidemiological and evolutionary characteristics of an outbreak of bTB (31). An outbreak affecting both cattle and badgers in Hotspot 21 in Cumbria involving *M.bovis* strain 17:z had a known origin in Northern Ireland (see Chapter 5). There was no previous record of either persistent infection in cattle, or of any infection in wildlife. This study also used mathematical modelling: Bayesian evolutionary analyses and machine learning.
- 4.10 Comparison with *M.bovis* whole-genome sequences from Northern Ireland confirmed this to be from a single introduction and evolutionary analysis supported its arrival directly into the local cattle population in 2010: six years prior to its first discovery in badgers in 2016. Once introduced, the evidence supports *M.bovis* epidemiological dynamics passing through two phases, the first dominated by cattle-to-cattle transmission, before it then became established in the local badger population. The study tried to estimate rates of cross-species transmission, but findings were limited by the uncertainties associated with the methodology.

- 4.11 The Cumbrian study is perhaps the only study with a high degree of reliability, and with simplicity as its strong point. With other studies there remains a degree of speculation inherent in the spatial and temporal considerations and the route of transmission is conjecture rather than being objectively demonstrated. WGS is a powerful tool but has limitations that have sometimes been presented either without clear qualification, or with a degree of confidence that is not scientifically justified, as has been highlighted by reviewers, where peer review comments are 'open access'.
- 4.12 The APHA epidemiology surveillance report for 2021 (32) contains the Agency's first attempt to explain and make use of WGS. There is concern that the APHA epidemiological reports such as that for Cumbria state that the sharing of *M.bovis* clades between cattle and wildlife implies bi-directional transmission within and between both species. The detail and groupings indicate that it is wholly feasible that direction of transmission can occur in just one direction, and this should have been readily detectable.
- 4.13 Twenty two clades were reported in Cumbria badgers, of which only 3 were shared between cattle and badgers. The subgroup numbers are not stated, nor are the closeness of those numbers shared between badger and cattle isolates. The three shared Cumbria clades are described in the report as A D G. The ability to characterise the subgroups helps to identify the degree of inter-relatedness of subgroups A D G in both cattle and badgers, and whether cattle and badgers share identical subgroups. The clades assigned to isolates are designed to be hierarchal, with subgroups sequentially numbered, so it might be expected that the degree of similarity of the subgroup gives a good indication of directionality.
- 4.14 As with Risk Pathways where badgers are assigned to breakdowns in a speculative way, without better discipline there is scope for confirmation bias and misuse of attribution using Whole Genome Sequencing, misleading practitioners, policy makers, farmers and the public.



Chapter 5. Low Risk Area badger culling and vaccination in Cumbria 2018-2022

Background

5.1 The English Low Risk Area (LRA) has had a generally low and stable incidence of bTB infected herds, from repeated long-distance importation of diseased cattle stock from the HRA and EA. Cumbria has around 45,000 cattle in 3,000 herds in beef and dairy production. Farms range from small family holdings to large commercial units. Most herds are managed in a traditional way, with cattle housed between November and March, and grazed outdoors April to October. Grazing on the many areas of common land across the county is frequent and hinders disease control. Common land grazing can be a condition for farm subsidy payments and herds may meet and mix when grazing together, representing an ideal opportunity for pathogen exchange. The location of Hotspot 21 in Cumbria is shown as the larger of two hatched areas in Figure 4. (From a publicly available APHA report).

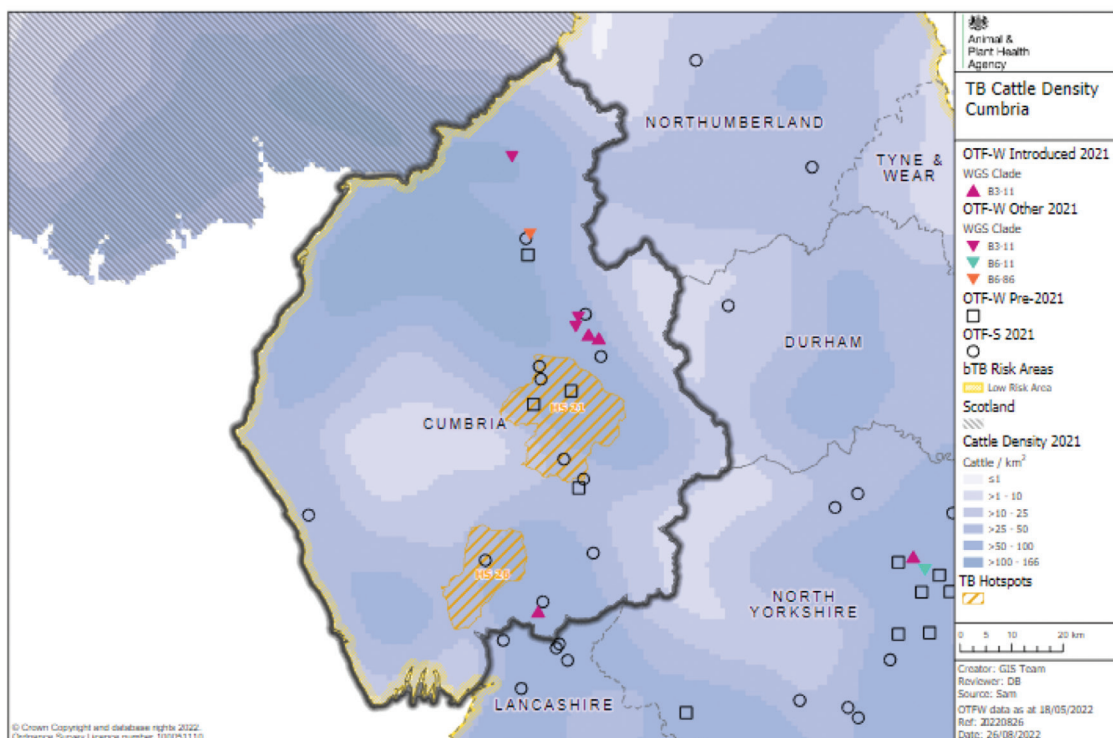


Figure 4. Location of Hotspot 21 (central orange hatched area), approx. 300 Sq.km, that contains badger cull Area 32 in Cumbria within a county of the bTB Low Risk Area for England. Crown copyright.

- 5.2 There are also a considerable number of cattle exchanges between Cumbrian herds and from other parts of the LRA every year. There are several livestock markets, with significant traffic in and out of the county, also involving transfer to and from Scotland and Northern Ireland (33). Movements from the HRA and EA of England, and from Ireland and Wales also occur, many via market auctions. Trading of cattle between farms is commonplace, the entire system being highly open to pathogen transfer between countries and locally. Cumbrian markets and farms are a hub for trade and dispersal of cattle between Great Britain and Ireland.
- 5.3 Purchasers are not necessarily aware of the origin of livestock until point of sale, but only since April 2016 has there been a requirement for a clear post-movement bTB (SICCT) testing. Owners of herds that buy cattle for final 'finishing' (growing-on for slaughter) are less cautious about the sources of their purchased cattle, and many of these cattle will be slaughtered prior to completion of a post-movement test (33).
- 5.4 Since 2013, the failure to control the spread of bTB in England's EA and LRA brought about speculation that this might be the result of a series of events involving badgers, starting with long-distance movement of infected cattle, and followed by a period of several years of infection of badgers, with badgers then spreading disease locally. However, while cattle to cattle infection from cattle movements has been verified, the role of badgers in local spread lacks evidence. The possibility alone gave rise to APHA's development of a 'just in case' approach that seemed to grow from 'guess' to 'accepted pathway' but without adequate and necessary epidemiological evidence. Hence badger cull area no. 32 (BCA 32), was created in 2018, in an area south of Penrith, and its (secret) boundaries within hotspot 21 (Figure 5.), with badger culling commencing in September 2018.

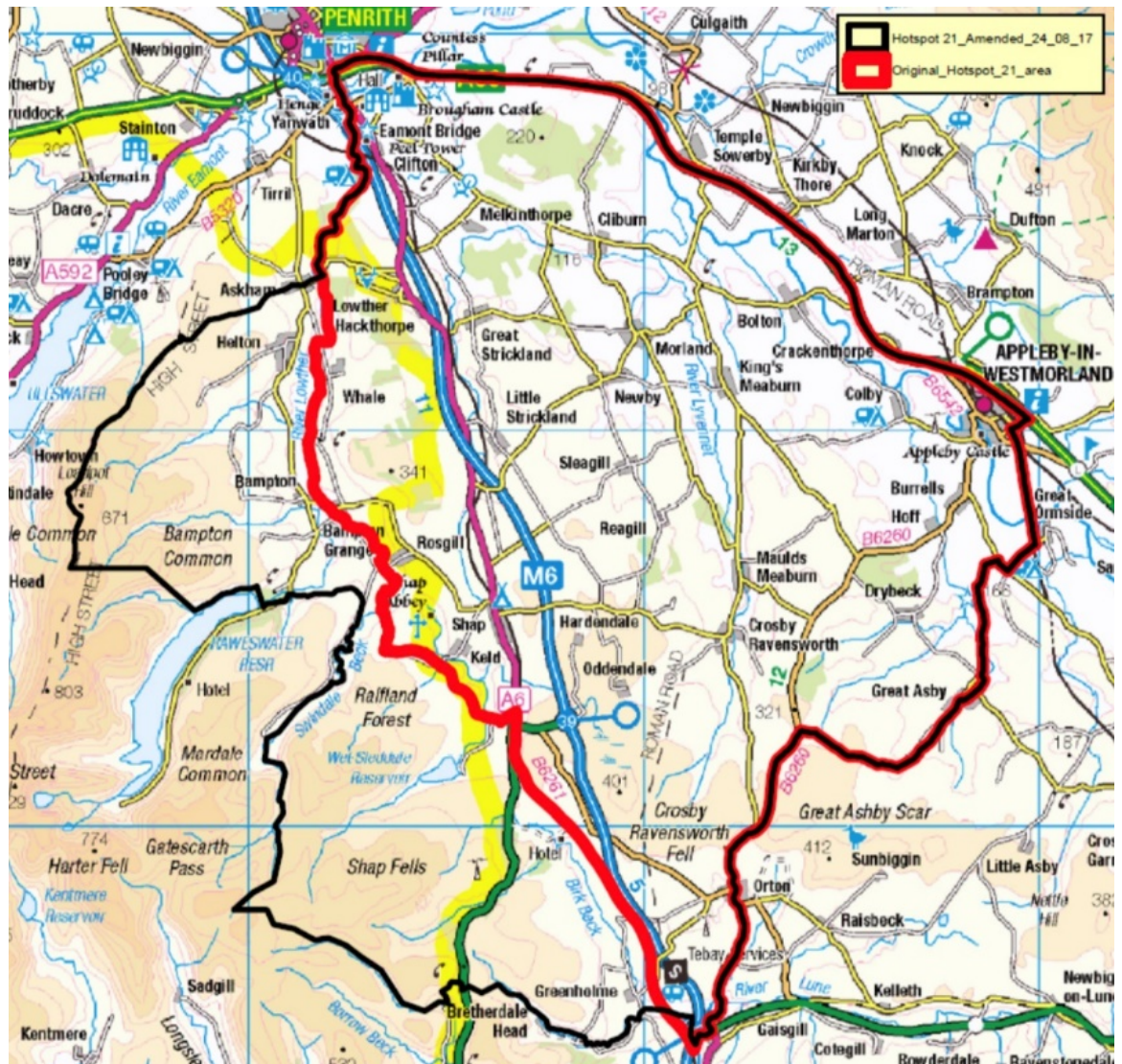


Figure 5. Boundary of Hotspot 21 south of Penrith, Cumbria (Red line) with its amended (enlarged area) from August 2017 (Black line). Source: APHA Epi-reports. Squares in fine blue lines are on a 10 km. grid.

Purpose of the badger cull Area 32 (BCA 32) experiment 2018-to date

5.5 It is likely that badger culling in Cull Area 32 was developed from around 2016 as a 'pilot' for future culling outside the HRA. The government review in 2018 (13) remarked:

“As part of this reassignment of responsibilities farmers could conceivably be allowed to apply for individual licences to control badgers on their premises (subject to appropriate welfare standards).....Because decisions to cull badgers would be made by farmers with a detailed knowledge of the local cattle population and its risks, the control would be more targeted and cheaper.”

As inadequate testing has been unable to stop infected cattle being constantly traded into the EA, this was seen as a way of addressing isolated clusters of incidents. But it was also a reversion to the ‘scorched earth’ approach of the past, adopted elsewhere in Europe as a means of tackling emerging bTB outbreaks. However, in other countries (apart from Ireland) the constant transferring of stock around the countryside is less of a feature in livestock management.

- 5.6 A potential badger culling approach for England after 2025 is described in the 2020 “Next Steps” policy, with BCA 32 being described as a ‘model’ for its application, which is why this chapter examines APHA’s approach and outcomes after badger culling.

The following actions and activities were used to justify badger removal in Cumbria Badger cull area 32 within Hotspot 21.

- Disease Report Form (DRF) and Risk Pathways
- Wildlife Reservoir studies
- WGS/Genotyping
- Modelling

- 5.7 Modelling has been conducted to try to predict the potential endemicity of bTB in the badger population. In initial considerations badger culling was predicted to be the intervention most likely to result in the removal of infection from the badger population (34).

Bovine TB hotspot (HS21) south of Penrith

- 5.8 A cluster of bTB cattle herd incidents emerged in eastern Cumbria from November 2014. Potential Hotspot 21 was declared and cattle, other species of non-bovine farmed animals and wildlife were subject to enhanced bTB surveillance from September 2016.
- 5.9 The index case from November 2014 of *Mycobacterium bovis* was identified as genotype (strain) 17:z. This had not previously been identified in cattle herds in England. Investigations concluded that 17:z was most likely to have been introduced by cattle imported from Northern Ireland. APHA accompanied its decision with the following claim (35).

“The novel genotype identified in the cattle and badgers in this area and the WGS analysis provided evidence that local spread of TB was likely to be occurring within and between both species.”

- 5.10 Within HS21, from the Nov 2014 index case until 17 February 2022, there were 46 bTB herd incidents across 37 holdings, 24 OTF-Suspended OTF-S and 22 OTF-Withdrawn OTF-W (36). Despite extensive and frequent cattle herd SICCT testing across the area, Whole Genome Sequencing (WGS) of *M.bovis* samples showed that the 17:z ‘strain’ was not detected in cattle cases after 2014 until the year 2017, when several isolates were detected in spatially proximate cattle herds, largely within the Minimum Infected Area (MIA) which forms the central badger cull area. APHA then suggested that the lack of detection of new infections over the 2014-2017 period and close grouping of infections indicated new infections were due to badger to cattle transmission (37). This overlooked the spread from residual reservoirs of latent disease in herds that were declared bTB free, as evidenced by their subsequent recurrent breakdowns.

5.11 From September 2017, extensive '*enhanced disease control measures*' in cattle herds were implemented across HS21 to increase detection and to aid removal of infected cattle at an early stage. These included: six monthly whole-herd SICCT testing of all cattle herds, with consequential pre-movement testing; movement restrictions (OTF status suspended) in herds with inconclusive reactors only, pending the 60-day re-test; mandatory interferon-gamma blood testing of all the OTFW herds and discretionary blood testing of OTFS breakdown herds; severe interpretation of skin tests for both OTF-S and OTF-W incident herds; and samples from all cattle with visible lesions of TB at postmortem submitted for culture and genotyping. There was also ad hoc surveillance of camelids (SICCT test and serology) and goat herds (SICCT test) (37).

5.12 One of the measured outcomes in Badger Cull Area 32 (BCA 32) was the use of *IFN gamma* (gamma interferon) identifying larger numbers of individual reactors once SICCT testing had peaked (Table1.).

	No. SICCT reactors	No. IFN gamma reactors
2015	5	2
2016	35	28
2017	13	20
2018	9	52
2019	10	20
2020	4	1
Total	76	123

Table 1. Difference between recorded individual cattle reactors by test method in BCA 32, Cumbria, 2015-2020, showing peak disclosure using IFN gamma in 2018 (38).

5.13 The reduction in herd incidents in 2018 before and during badger culling should also reflect the use of back-tracing, radial testing and IFN gamma to locate reactors with incidents peaking and falling before badger culling began (Figure 6).

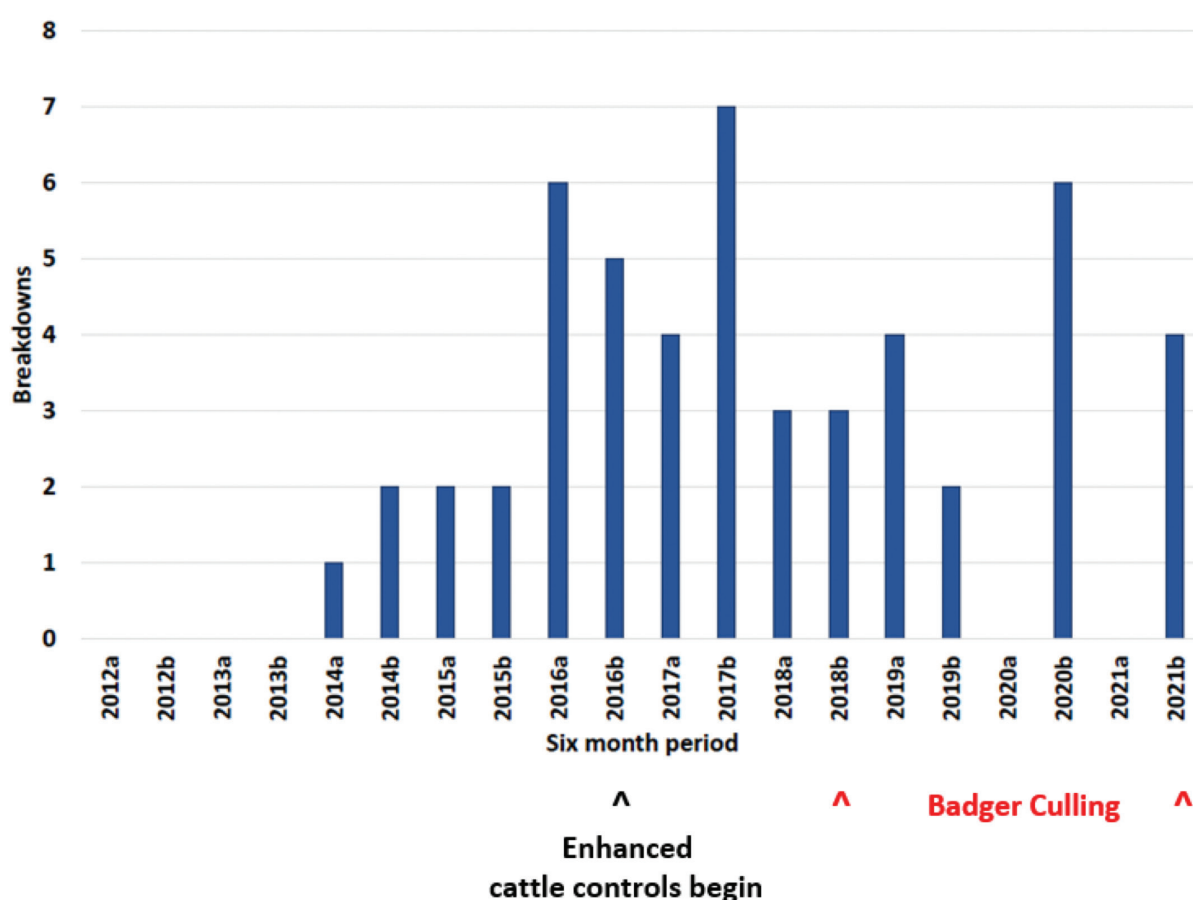


Figure 6. Six-monthly (a: Jan-June, b: July-Dec) change in total incidents (OTF-S + OTF-W) in Cumbria BCA 32 from Herds in Existence. Showing commencement of enhanced cattle measures started in September 2016 and badger culling in September 2018. Data source APHA monitoring report to-2020 and ibTB-Mapping records.

Badger Culling in HS21/BCA32

5.14 The original aim of LRA culling included removal and/or vaccination of badgers from an allocated MIA, based on 'epidemiological and ecological' advice, and from the surrounding area, as a precaution (39). The stated aim was to lower the badger population of the MIA sufficiently to reduce the risk of infection of cattle from badgers 'whether through direct or indirect contact', and ideally to substantially reduce or even eliminate it. Justification was based on what was described as a low level of disease in the LRA generally and the objective of achieving Officially TB-Free status, through taking 'a precautionary approach, with direct and robust intervention involving both cattle and wildlife controls.'

- 5.15 In September 2016, APHA initiated checks for *M.bovis* in 'found dead' badgers and wild deer in HS21. Three of 52 (6%) road killed badgers were found to be infected with the 17:z strain. The three infections were in the same area where 17:z had been previously isolated in local cattle herds, suggesting that over the two-year period, badgers had been infected from cattle.
- 5.16 To facilitate APHA's aim to eliminate bovine TB in both badgers and cattle, badger sett surveying was carried out in the second half of 2017 with some additional areas surveyed in early 2018. These were used to estimate both the density of setts in HS21 and badger social group territory size (40).
- 5.17 The badger control intervention areas include the MIA, based on the location of infected cattle and badgers, the associated farms and contiguous incidents area, with a radius from the estimated average badger social group territory, based on main sett distribution. The boundary of the MIA was amended after 2018 and 2019 operations (36) to encompass the locations of all known infected badgers and cattle incidents where a wildlife source had been suggested using the Risk Pathway Analysis (see Chapter 3). An outer area, also based on estimated average badger social group territory size, surrounding the minimum infected area, was established to address the possibility that infection may have already spread into the wider badger population.
- 5.18 In 2019 the total intervention area was increased by around 11% from 190 to 214 Sq.km. (39). Cage-trapped and controlled shot badger carcasses were subject to *postmortem with culture*, to detect *M.bovis*, with whole genome sequencing of isolates detected. From 2018, the first year of culling, the 17:z genotype was identified in 11% of the 602 badgers culled (MIA 21% Outer area 1.7%), suggesting an increased prevalence had rapidly developed in the badger population.



A young badger of unknown disease status is shot through the head in a cage trap in Cumbria in 2018.

5.19 Data for culling and vaccination between 2018 and 2021 are available (see Table 2 Annex 2). A total of 1,115 badgers were killed and 211 vaccinated by the end of 2021. It is not clear how many badgers vaccinated in 2020 and 2021, were also shot in those years. There is no published data on the percentage of badgers vaccinated or the number of badgers that received more than one dose of vaccine. There was no sign of *M.bovis* in the 236 badgers shot in the outer area in 2019 and only 6 of 322 (c.2%) badgers in that area were found to be *M.bovis* positive in 2018. On the advice of the DEFRA Chief Veterinary Officer, two years of culling with no disclosed infection in the badger population was needed before a move away from culling could be considered (36).

Further considerations

- 5.20 BTB strain 17:z was found following a herd OTF-W incident in 2014 but not again until 2017 despite checks on SICCT test reactor cattle since 2014. The assumption was made by APHA that the strain had been transmitted into the badger population and been spread by them to bring about more distant incidents in 2017. The 2017 incidents were clustered along the Eden valley although one case is 6 km away (See Annex 2, Figure 7) and it is quite possible that the 17:z strain arrived via cattle movements both before and after the index case in 2014 as the exact importation of an infected animal and true index case from NI was not located (31).
- 5.21 Rossi et al. 2021 stated that: ***“While we found little evidence for substantial badger-to- cattle transmission, previous analyses (Crispell et al., 2019) showed that under suitable conditions badgers can be important contributors to cattle disease.”*** This is an example of how epidemiological appraisal can be distorted with speculation; the tentative findings of a paper heavily caveated by peer-review remarks, becomes robust supporting evidence, fitting the policy but lacking strength. As Cumbria was only on 4-year SICCT testing prior to 2014, 17:z could easily have been introduced by cattle some years earlier. Other recent study, in France, estimated badger-to-cattle transmission to be common but was unable to show badger as a possible intermediary in farm-to-farm transmission (41).
- 5.22 It remains unclear whether the badly needed, overdue and revised disease report form (see Godfray 2018) has been developed and put to use. It seems likely that in Cumbria, RP analysis has been as misleading as it was in Derbyshire (9) and elsewhere. Reservoir mapping is not yet in use but is not sensitive enough to provide reliable information on the role of badgers in bTB spread or proliferation. Whole Genome Sequencing has been of no value in identifying the putative role that APHA repeatedly claims badgers have played in bTB incidents in Cumbria since 2014.

- 5.23 The implications from exterminating a protected species across areas in the LRA on the prevailing APHA 'just in case' basis, as opposed to upon credible epidemiological assessment, are extremely serious. These decisions carry considerable cost, resource, animal welfare and potential ecosystem impact implications. The data for Cumbria HS21 show that bTB herd incidents began falling in HS21/BCA 32 before badger culling started, due to a combination of basic measures: disease back-tracing, radial testing and use of gamma interferon testing.
- 5.24 The entire badger population and any inward migrants have effectively been eliminated over around 90 Sq.km of the MIA, and depleted beyond that, with some vaccination over a 200 Sq.km area. Herd incidents with persistent infections remain unresolved, with 8 herds breaking down in up to 7 years since 2014. This demonstrates that existing bTB tests for cattle are not adequate to prevent disease retention within a proportion of herds. Herds released from movement controls (often with trading suspended for just a few months) can then infect other herds before being restricted again (see Annex 2, Table 3), having passed infected stock to a new farm.
- 5.25 Of further concern is that in Cumbria, the number of herds involved are relatively small, yet 1,115 badgers have been killed. While it is no surprise that killing nearly all the badgers at considerable cost has removed detectable bTB in badgers, at least for now, the inability to remove it from herds means that farms will re-infect the repopulating badgers and other wildlife, leading to a cycle of futile wildlife killing, as has taken place in the Republic of Ireland for many years.
- 5.26 There is no direct scientific evidence that badgers infect cattle in open field conditions and the proposed pathways by which this could regularly happen are not plausible. Removing badgers has not been shown to be effective in controlling bTB in cattle in Cumbria BCA 32; the 'model' has failed to demonstrate any disease control benefit. The reasons for this are readily understood - ineffective testing and movement controls and the reluctance of APHA to accept and to deal effectively with the resulting problems associated with latent disease in cattle.

- 5.27 The results of badger culling in BCA 32 provide no indication of any impact upon bTB herd incidence and are consistent with the role of badgers being minimal or non-existent in the maintenance and spread of bTB in cattle in HS21/BCA 32. Nevertheless, APHA appears to plan similar culls based on badger infection confirmation; checks that started in Oxfordshire in 2022, and based on misunderstood or misinterpreted evidence, risking spiralling misuse of disease control resources. This process needs to be stopped before it goes any further. Incorrect statements about badgers being a maintenance host or considered widely to be such (42,43) need to be corrected to show the true scientific consensus that this remains uncertain.
- 5.28 Looking beyond Cumbria, the year-end APHA bTB epidemiology report for 2020 for Oxfordshire, (44) is a good example of how badgers are being unscientifically attributed to causing disease in cattle, with extensive reference to 'wildlife', yet still states: ***'A lack of data for M.bovis infection in wildlife in Oxfordshire in 2020 continues to add uncertainty to any conclusions for wildlife being the source of TB incidents in cattle.'*** These assessments are made largely by a process of elimination of other source pathways, but also from analysis of geographical clusters and WGS information. Thus, any positioning to cull badgers in Oxfordshire is not warranted and the expansion of badger culling into this area is illogical and unwarranted, based on pure supposition and effective denial of a hidden residual reservoir of latent infection, in the herd and across farm holdings.
- 5.29 One of the problems of Cumbria-style EC is that after heavy culling and some vaccination, if cattle or cattle pastures re-infect uninfected recolonising badgers, culling can continue for an unlimited period, effectively providing a mechanism for badger culling if badgers contract bovine TB from cattle, as they will continue to do until it is addressed at source.



Chapter 6. Conclusions

- 6.1 The RBCT experiment was designed at a time when farming representatives claimed that badgers were responsible for all or at least 90% of cattle herd breakdowns. It described opposing benefits and disbenefits for bTB control and from this government estimated benefits might be obtained under certain strictures of control. BTB control policy evaluations later suggested that badger to cattle transfer was responsible for up to around 6% of new infections with 94% being from cattle to cattle transfer, of which 50% cattle to cattle transmissions perhaps originated from badger to cattle transfer (13) but with no explanation of how this might occur.
- 6.2 Irrespective of discussions over the background science or the efficacy of badger culling (44,45), APHA appear to have reverted to the 1980's 'old thinking' that badgers are responsible for the majority of bTB herd breakdowns, which defies the available evidence and is an anathema to any correct application of modern disease epidemiology. This report shows how the proposed APHA 'epidemiological culling' lacks a coherent basis in scientific evidence.
- 6.3 The APHA (and by extension the Government's) interpretation of the available evidence in relation to bTB epidemiology is confused and flawed. This review finds that there has been a compounding accumulation of assumption and error over the last decade. Much if this seems to be the result of extrapolation from a core belief system that badgers are significant to the maintenance and spread of bTB when it is first established in an area, something that scientific research does not support.
- 6.4 The belief appears to rest on a presumption that wherever there is epidemiological uncertainty, badgers must be the cause of disease. It is a risky departure from the normal epidemiological process that treats unknowns as open questions that require further investigation. The consequent actions come at a high cost in terms of finance, time and animal and farmer welfare, because the intervention is not just unsuccessful and distracting, but a self-perpetuating failure.

- 6.5 Far from being the policy 'model' for any future intervention, this report shows that the *Risk Pathways* procedures are unsafe. The evidence from reservoir studies implies, at most, a minimal involvement of badgers in bTB spread and maintenance. The results of Whole Genome Sequencing are far less clear-cut than advocates have suggested. Taken together with findings from Cumbria in the case of Badger Cull Area 32 and Hotspot 21 since 2018, culling is shown to have been an ineffective and misguided approach to tackling the bTB in cattle. Continued inadequate testing and unsatisfactory cattle movement controls remain the driving force in maintaining and spreading the epidemic, yet APHA continues to focus on disease control measures that wrongly assume badger control forms an essential component.
- 6.6 A thorough rethink is required to redress a decade of misinformation and poor epidemiological analysis within APHA and related veterinary bodies. This must challenge a culture that simply assumes major badger involvement in the bTB epidemic and act to re-inform the sector. If badger culling is simply being used as a placebo to enable tighter cattle measures to be accepted by the industry, it must also now be ended. Until effective test, trace and lockdowns are enforced upon cattle, the bTB epidemic cannot be resolved and will continue to be a massive burden to all involved and draw on public finance. While this may represent a major problem for the industry for some years it must now be recognized as essential to bring the epidemic under control.
- 6.7 The failure to develop a coherent national approach to bTB control using more advanced and sensitive tests, quarantine and innovative approaches has enabled bTB to proliferate in the English Edge Area and beyond. Despite some steady reduction of incidence in the High-Risk Area where bTB is most embedded, the crisis needs new strong and coherent leadership. As the national crisis deepens it is demonstrably clear that the management of bTB, as practiced over the last decade, needs substantial and immediate reform.



7. Glossary

Breakdown	Term historically linked to OTF-W declarations relating to cattle herds having a bovine TB infection officially identified.
Free shooting	A method of killing badgers where badgers are shot with rifles at night at distance. It is opposed by the British Veterinary Association on animal welfare grounds.
Gamma interferon	Also called interferon-gamma test (or 'gamma' test), it is a supplementary blood test used alongside the tuberculin skin test to increase detecting TB-infected animals in cattle herds affected by TB breakdowns. However, is less sensitive than the actiphage test that detects live bacteria.
BTB Hotspot	A newly formed cluster of bTB breakdowns following introduction of bovine TB into an area when undetected disease is traded or exchanged by the cattle industry.
Incident	Designation of herds declared OTF-S or OTF-W [note: total incidents = OTF-S + OTF-W, the terms OTF-S Incident and OTF-W incident may also be used].
Incidence	Rate of OTF-W designations over time in an area.
OTF-S	Officially TB Free Status Suspended.
OTF-W	Officially TB Free Status Withdrawn.
Risk Pathways	A way in which a source of bovine TB is categorised in a largely anecdotal way.
SICCT Test	The Single Intradermal Comparative Cervical Tuberculin (SICCT) test or 'tuberculin skin test'. This skin test has been used as an indicator of infection by the bacterium that causes TB in cattle - <i>Mycobacterium bovis</i> (M.bovis). It has an average sensitivity in individual infected cows of around 50% and a herd sensitivity at around 80%.
Spillover host (dead end)	When disease is passed on to a different animal species in the community and does not transmit back significantly to the original host, or to another species.
Maintenance host	A host population or community/ complex in which the pathogen persists in absence of transmission from other hosts.
Whole Genome sequencing	Whole genome sequencing (WGS), also 'full genome sequencing' is the identification of an organism's genome by sequencing an organism's chromosomal DNA and mitochondrial DNA and that can be used to investigate associations of host organisms and vectors given adequate samples from the relevant populations.



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9. Annexes

ANNEX 1. Bovine TB and badger science: the six stages of uncertainty.

- **Stage 1: Misleading assumptions on calf infectiousness and exposure risk.**
The Krebs's Group; 1997 report suggested that newly bTB infected calves and young cattle were infrequently infective. This view does not factor in the shortness and unpredictability of infectiousness at any one time in a calf's first year, or beyond when sold to another farm. A calf might pass bTB on before or after leaving its birth farm and during short and sometimes transitory bursts of infectiousness. Infection brought on due to the stress of market trading, mixing with other stock, arrival or other forms of stress by the ever-growing livestock industry. Anergic cows, those pregnant, under certain medication or carrying other disease, or too young or too old are often not detected by the SICCT test. The hazard of passing of bTB from mother to calf in the womb, and through the mixing and feeding of pooled unpasteurized infected milk to new calves, has been overlooked in experimental design and analyses leading to incorrect findings and assumptions.
- **Stage 2: Inappropriate selection of analytical model.**
Tests of the model used suggest that it overfits the data, resulting in it having a poor predictive value. Alternative and more suitable models find that badger culling had no effect on OTF-W incidents.
- **Stage 3: 50/50 call on results taken forward.**
The 2007 RBCT Report decided not to use all cattle skin test Reactor results following SICCT testing in their main study conclusions, but just those from cows with Visible Lesions (VL) at slaughter and positive culture. The lack of significance of the All-Reactors results, in terms of badger culling reducing herd incidence, was then put to one side, and the VL sub-set that offered a significant discovery was pushed forwards. This was even though inconclusive reactors (a now redundant term) were assumed also to have been bTB infected.
- **Stage 4: 50/50 call, on result to take forward.**
The RBCT conclusion of involvement of badgers in bTB spread is based upon modelling Visible Lesion-only data in particular ways. A sensitivity test, adjusting for actual rather than average cull duration shows that even using the VL/culture positive-only data, the effect is as likely to be insignificant as significant. Further scientific questions arise because of the non-blinded nature of the RBCT- a field trial; any results of such an approach must be handled with extreme caution. Uncertainty is an acceptable result of experimentation, even if it does not resolve the question asked.
- **Stage 5: Hypothesis as likely to be right as wrong.**
In 2007 the strength of the RBCT hypothesis of badgers spreading bTB during culling inside and beyond the periphery of cull areas was criticised by Sir David King the Government Chief Scientific Adviser and his study group. They concluded that the perturbation effect hypothesis of badgers spreading bTB was not strong enough for statistical significance and it was simply a theory with some evidence in need of further validation.
- **Stage 6: Incorrect assumption in key model and selective use of results.**
Modelling used to justify the start of badger culling in 2013 included two key papers (Donnelly and Hone 2010 and Donnelly and Nouvellet 2013). The first used a model for brushtail possums and cattle in New Zealand. This assumed that infection of badgers from cattle was negligible, something now known to be wrong. The 2nd paper, with the first paper factored-in, tried to account for disruption of the RBCT from the 2001 Foot and Mouth Disease (FMD) crisis, mid-study. There were two outcomes. In short, one analysis estimated that badgers might be directly responsible for around 5.7 % of bTB herd incidence. The other one, this time factoring in the potential FMD distortion gave no certainty of an effect (between 0 & 100). Yet the 5.7% and not the 0-100% conclusion was used by government. An additional assumption was that from the modelled 5.7% transmission, there is an unexplained a 50% onward transmission of infection, causing new incidents. This was the tenuous final justification for badger culling to start in 2013.

Adapted from: <https://thebadgercrowd.org/scientists-disease-and-communicating-uncertainty>

ANNEX 2.

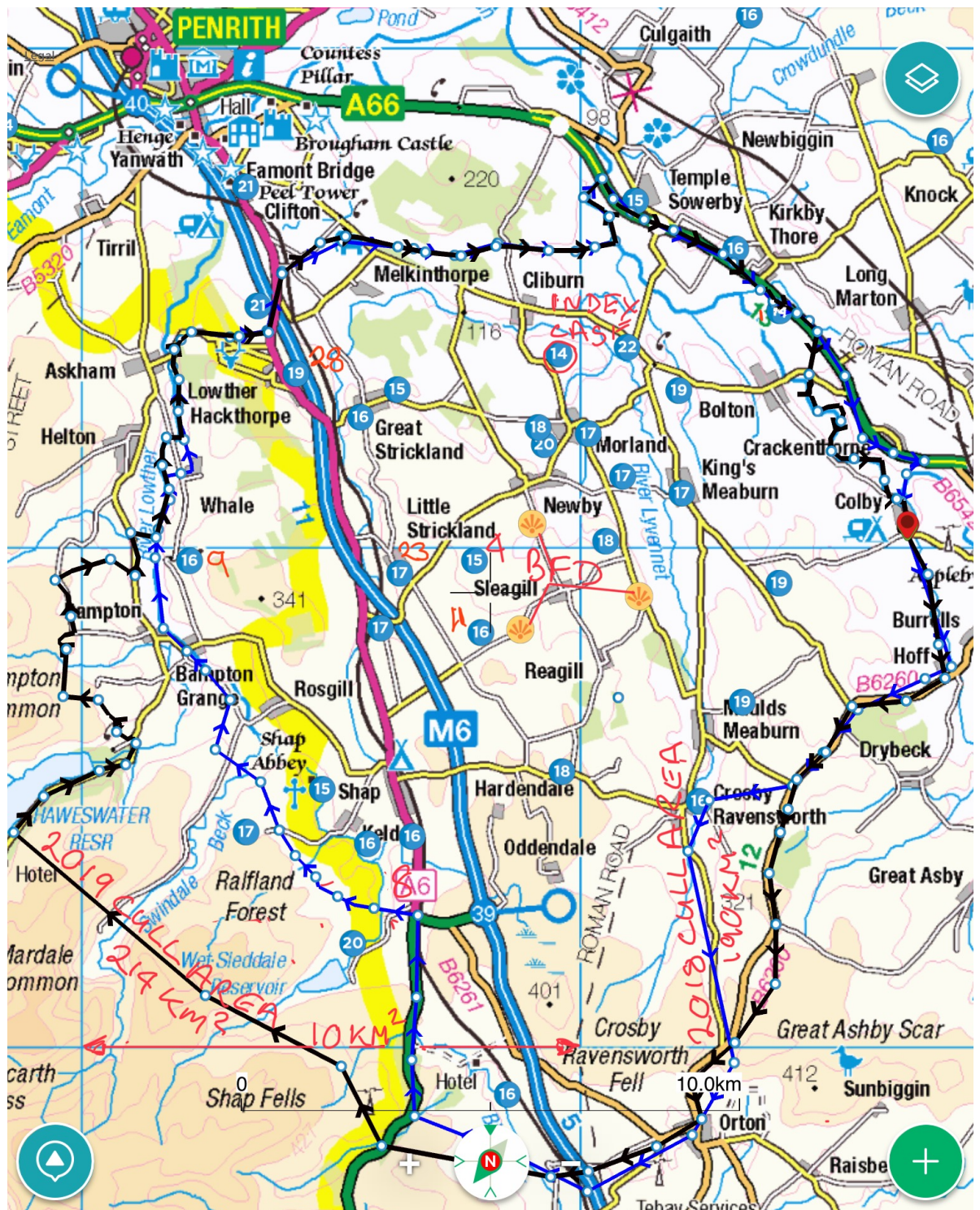
Additional evidence on the lack of efficacy of badger culling in cull area 32/
Hotspot 21, in Cumbria, 2018-2021. see Chapter 5.

	2018	2019	2020	2021	Totals
<u>Badger Cull Area 32 (sq.km)</u>	190	214	214	214	
<u>Badgers culled (no.)</u>					
Cull Area 32	602	317	134	62	1,115
Minimum Intervention Area (MIA)	169	22	134	62	387
Outer Cull Area (OCA)	322	236	0	0	558
Land that straddles MIA & OCA	111	59			170
Number of badgers vaccinated	0	0	100	111	211
Vaccination area Km. sq.	0	0	103	140	
% of land accessible	0	0	64% (67 km.sq.)	65% (91 km.sq.)	
<u>Prevalence of 17:z in <i>postmortem</i> samples (%)</u>					
Cull Area 32	11.1%	1.0%	0%	0%	
Minimum Intervention Area (MIA)	21%	14.3%	0%	0%	
Outer Cull Area	1.7%	0%	0%	0%	

Annex 2, Table 2. Data from the four years of culling and badger vaccination in BCA 32 from 2018 sources are APHA annual reports.

Farm with chronic infection/s	2014	2015	2016	2017	2018	2019	2020	2021	2022
Bridge End Farm	OTF-S				25a		OTF-S		
Dedra Bank Farm		OTF-S	17z type & 25a		OTF-S	OTF-S	OTF-S		
High Knipe			17z	17z			25a		
Longlands Farm			17z	OTF-W Undeter mined					
Little Strickland				17z		OTF-S			
Townend Farm						OTF-S			Awaiting Epi
Roundwaite Farm							OTF-W Undeter mined		Awaiting Epi
Stony Gill (just outside HS21)			17z				OTF-W Not 17z	OTF-S	
Chronic herds n=	1	1	4	4	4	3	5	5	5

Annex 2, Table 3. Chronic bTB farms south of Penrith. Shading shows year or part year herd is under measures (OTF-S/ OTF-W) 2014-2022 for chronic herds (other than Stony Gill) in Badger Cull Areas 32. *M.bovis*, 17z-type = mutated strain. Note at Dedra bank bTB strain 25a was also detected.



Annex 2, Figure 7. Estimated location of Cull Area 32. Showing in blue (with white number indicating year), all bTB incidents (2014-2021), with the index case and the six chronic farm incidents (red - handwritten) ongoing, to give a rapid view on incident distribution, past and present.

Annex 3. Why the APHA view on wildlife and bovine TB overseas, is misguided.

Defra/APHA's current view is as follows*:

*Unlike the human TB bacterium (*Mycobacterium tuberculosis*), *M. bovis* can infect and give rise to lesions and clinical signs of TB in a very wide range of mammals. There are many examples of 'external' reservoirs (maintenance hosts) of *M. bovis* in wild animals posing a persistent risk of infection for cattle herds, such as brushtail possums in New Zealand, white-tailed deer in Michigan, USA, Cape buffalo in South Africa, and wild boar in parts of the Iberian Peninsula. Specifically in the UK, there has long been broad scientific consensus that badgers are implicated in the spread of TB to cattle [1],[2]. More recently, Professor Sir Charles Godfray's independent review of the science published in 2018[3], which brought together leading UK experts, concluded that TB spreads within and between populations of badgers and cattle and that spread from badgers to cattle is an important cause of herd breakdowns in high-incidence areas.*

- **Brushtail possums in New Zealand.**

Culling of over 100,000 possums had little effect on bTB herd breakdowns. It was only when farmers were required to pay for and take strict biosecurity and movement controls of cattle, that the number of cases of bTB began dropping in both cattle and deer. Cattle bTB herd prevalence dropped from 3.87% to 0.35% over a decade or so. There was no evidence that possums had played a significant role.

- **White-tailed deer in Michigan, USA.**

This is a reference to bTB transmission between high density farmed deer and cattle, not a wild situation. Evidence is that infected soil/pasture residues after deer grazing are implicated and this has relevance for disease management in the UK and RoI is with respect to common/conacre grazing and cattle to cattle infection and where deer ranching is taking place.

- **Cape buffalo in South Africa.**

Buffalo is a bovine and so it makes sense that an infected population of buffalo, whether native or introduced around the world might untreated potentially maintain the disease. This holds no relevance to infections held in possums and badgers that are non-bovines and will have different bTB aetiology. Extrapolating from different species in different continents is of limited value.

- **Wild boar in parts of the Iberian Peninsula.**

There are multi-host systems involving wildlife with, e.g., cattle, goats and sheep in Europe. Foxes are now shown to carry bTB in non-visible lesions. Such complex scenarios with more wild mammals differ to the more depleted landscapes of England and comparison is not always relevant although a role for sheep when grazed with cattle is worth investigating.

- **Conclusion.**

Defra's claims of relevant evidence at the start of the policy is as lacking today as in 2011. Proof of disease maintenance by wildlife is circumstantial and not robust. While infected wildlife may catch and then spread disease, the evidence from other countries adds nothing of substance to understanding of bTB in cattle and wildlife in Britain and Ireland. It sets a context where the unique features of each species and habitat involved invokes different analysis according to the behaviour and physiology of wildlife and the distribution and management approaches to the type of farming, stock density and housing in each situation.

* SM-Defra-BTBengage (FFG) reply to questions from 31 August 2022 "Questions regarding Bovine TB policy"

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Dr. Brian Jones is an Immunologist who has published extensively on immune regulation of human diseases, including HIV/AIDS and SARS and who has specialised in diagnostic test development and patterns of stress induced immune dysregulation contributing to infectious diseases. He has most recently become concerned about anergy and diagnostic test false negatives in stressed, intensively farmed cattle.

Mark Jones is a qualified, professional veterinarian with Masters qualifications in both aquatic and wild animal health. He is currently employed by the international charity Born Free, specializing in animal welfare and wildlife protection. He has published analyses of the efficacy of badger culling for bovine TB control in England using government data, and alongside other non-government professionals publicly questions the ethics and efficacy of current wildlife intervention policies.

Tom Langton is a Chartered Biologist and nature conservation consultant, whose work has included aspects of wildlife disease epidemiology for over 30 years, including three publications on bovine tuberculosis and badger culling, since 2019. He has also campaigned to improve public awareness of shortfalls in badger culling science, policy and law since 2017.

Mike Rendle has monitored bovine tuberculosis and badger science across the five countries of the British Isles over the last decades. He is founder of and a policy advisor to the Northern Ireland Badger Group. He has contributed to a range of scientific publications and reports over this period.

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