

## Analysis of the impact of badger culling on bovine tuberculosis in cattle in the high-risk area of England, 2009-2020

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#### Abstract

Background: Since 2013, badger culling has been part of the UK Government's strategy for controlling bovine tuberculosis (bTB) within a high-risk area (HRA) in England. Government surveillance data now enables an examination of bTB herd incidence and prevalence, its headline indicators, within and outside cull areas over the period 2009-2020.

Methods: Analysis compared herd incidence and prevalence data from within and outside badger culling areas. A range of models (GLMs, GLMMs, GAMs and GAMMs) were used to analyse incidence and prevalence in culled and unculled areas using frequentist and Bayesian approaches. Change in incidence across ten county areas within the HRA for the period 2010-2020 was also compared.

Results: Analyses based on Defra published data using a variety of statistical methodologies did not suggest that badger culling affected herd bTB incidence or prevalence over the study period. In 9 of 10 counties, bTB incidence peaked and began to fall before badger culling commenced.

Limitations: There are limitations around the data available on culling location, temporal information and other confounding factors. As such, further analysis of any future datasets that may be released on bTB levels in areas where badger culling has been implemented is warranted.

Conclusion: This examination of government data obtained over a wide area and a long time period failed to identify a meaningful effect of badger culling on bTB in English cattle herds. These findings may have implications for the use of badger culling in current and future bTB control policy.

### **INTRODUCTION**

Bovine tuberculosis (bTB) is a disease with marked economic and social consequences for the cattle farming industry in much of the United Kingdom and elsewhere. Over £100 million of public money is spent per annum<sup>1</sup> on attempts to control the disease in cattle in England. Human cases of bTB in the UK are now very low, with just 36 recorded cases in 2020.<sup>2</sup> Despite gaining legal protection under the Protection of Badgers Act 1992 (PBA), badgers (Meles meles) have been systematically killed in England since 2013 using licences issued by Natural England under Section 10(2)(a) of the PBA, which permit culling in licensed areas outside of the main badger breeding season using specified methods. The majority of cull areas exist within the high-risk area (HRA) for bTB in the west and south

west of England. Culling badgers is ostensibly carried out to reduce transmission of bTB from badgers to cattle.<sup>3</sup> Licensed culling within the HRA aims to reduce the badger population in cull areas by at least 70% over a 4-year intensive cull, with subsequent supplementary culling for up to 5 years to maintain a low badger population. Initially there were three small pilot cull areas. Two commenced culling in 2013 in Gloucestershire (cull area 01) and Somerset (cull area 02), and the third in Dorset in 2015 (cull area 03). Culling was rolled out more widely from 2016, and by 2020 the majority (67%) of the HRA was subject to culling. The HRA is an area defined geographically by county, in which cattle herds are considered to have a greater likelihood of experiencing a bTB breakdown. It includes geographical areas in which there is a relatively high herd prevalence of bTB.<sup>4</sup> The badger culling policy

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currently includes approvals to continue existing culls and to instigate multiple new intensive and supplementary badger culls in 2022 following further expansion of culling in 2021.<sup>5</sup> Natural England reported that, by the end of 2020, badger culling had resulted in the deaths of approximately 140,000 badgers across England, approximately 129,000 of which had been culled within licensed areas in the HRA.<sup>6</sup>

Killing badgers as a method of controlling bTB in cattle in the UK is politically and scientifically controversial. In its report on the randomised badger culling trial (RBCT) in 2007,<sup>7</sup> the Independent Scientific Group on Cattle TB charged with analysing the data concluded that badger culling 'can make no meaningful contribution to cattle TB control in Britain'. This conclusion was based on the study's findings that, although the incidence of confirmed bTB in cattle herds was reduced in areas subjected to proactive culling compared with unculled areas, there were increases in farms surrounding the proactive culling areas, which were hypothesised to reflect a 'perturbation effect' of surviving badgers spreading bTB over a wider area.<sup>8,9</sup>

A more recent analysis compared data from the first three relatively small pilot badger cull areas for the period 2013–2017 with several unculled comparison areas.<sup>10</sup> For the Gloucestershire 01 pilot cull area, the study claimed a reduction in bTB herd incidence of 66% over 4 years relative to unculled comparison areas, and in the Somerset 02 pilot cull area a 37% reduction, which were attributed to badger culling. The authors of this study were unable to isolate potentially confounding influences such as the effects of onfarm veterinary and risk management advice including improved hygiene standards at farms within culled areas, together with 'unknown or unmeasured confounding' and subjective 'misclassification biases'.

However, subsequent scrutiny of the data for these areas between 2013 and 2018 found no convincing downward trend in the prevalence of bTB among cattle herds associated with the culling of badgers.<sup>11</sup> In contrast to the first study of pilot culls, the authors of the second analysis noted that the fall in incidence in Gloucestershire reported until 2017 was reversed by an increase in OTF-W incidents of 130% in the subsequent 12-month period.

If a disease control intervention is to be considered an effective approach to reducing bTB in cattle, its efficacy needs to be demonstrated at a regional scale.<sup>12</sup> Statistical data for the HRA released by the Department for Environment, Food and Rural Affairs (Defra) up to 10 March 2021<sup>13</sup> enables an examination of bTB herd incidence and prevalence in culled and unculled areas across the HRA for the period 2010–2020, and a county-level analysis (see Methods below). Comparisons of data from culled and unculled areas of the HRA are presented over a period of 11 years and 4 months, from September 2009 to December 2020, during which time over 20,000 cattle herds were tested for bTB each year across the study area of approximately 37,000 km<sup>2</sup>.

#### **METHODS**

These analyses examine annual bTB herd incidence and prevalence at selected timepoints, in cattle herds within the bTB HRA of England. The analyses use different time periods across the study period according to the data used and the type of analysis conducted.

The study uses the incidence rate for herds in which bTB infection has been newly confirmed through post-mortem tests in at least one animal from the herd. Such herds are designated officially tuberculosis free – withdrawn (OTF-W). The incidence rate of OTF-W per 100 herd years at risk (HYAR) is a Defra head-line indicator for bTB breakdowns in cattle. Historically this has also formed a reference statistic for changing levels of bTB in cattle within badger cull areas.<sup>7,14</sup> Defra defines OTF-W incidence rate as the rate of occurrence of OTF-W incidents (confirmed breakdowns), calculated as the number of OTF-W incidents per 100 HYAR.<sup>15</sup>

In terms of prevalence, herds placed under restriction include OTF-W herds but also herds in which bTB is suspected but unconfirmed; such herds are designated officially tuberculosis free – suspended (OTF-S). BTB herd prevalence is defined as the number of disease restricted herds (OTF-S + OTF-W) as a proportion of herds in existence (HIE) (Registered on SAM: Animal and Plant Health Agency data system) at each calendar year-end. Herd prevalence is the second headline indicator used by Defra to monitor bTB herd breakdowns in cattle, including within badger cull areas.<sup>16</sup>

Data used for this analysis are the official figures released by Defra and its agencies. The sources of this data, and the data themselves, are presented in tabular form Annex 1 (Tables A1-A5). While herd breakdown data is made available by county each month, data for the areas being culled in each county is not, since cull area boundaries are not disclosed by government.

The total number of herds that have experienced bTB breakdowns, and the total number of herds, within culled and unculled areas of the HRA, is published by APHA. Thus, while it is not currently possible to compare culled and unculled areas at the county level, it is possible at a regional scale, since the total number of herds within culled and unculled areas of the HRA can be calculated.

In this study, a comparison was made of bTB herd incidence (cull year) and prevalence (calendar end) between the total culled and the total unculled HRA land. Changes in bTB herd incidence in the HRA were also examined at the county level over a 10-year period.

## A comparison between culled and unculled areas of the HRA, 2013–2019

This analysis compared herd incidence and prevalence across the HRA in places where badger culling was taking place, with areas where it was not, using



**FIGURE 1** Percentage of land culled or unculled in the high-risk area of England from 2013 to 2020. *Source*: Defra 2020 Setting the minimum and maximum numbers in badger cull areas. Advice to Natural England. [Previous annual online reports also provide cull area size information]

12-month cull year periods beginning in September 2013 (coinciding with the commencement of culling in pilot areas 01 and 02 in 2013). By the end of the 2019 calendar year, there were 40 badger cull areas across the HRA that had completed between one and seven years of badger culling (2013–2019), comprising up to 4 years of intensive and in some cases up to a further 3 years of supplementary culling.

The ratio of culled to unculled land area within the HRA is different in each year, as new cull areas are licensed (Figure 1). However, the comparisons between culled and unculled areas have been made within and not between years.

The first 30 badger cull areas for which data were available were used for the comparison between the culled and unculled HRA, these being areas where badger culling commenced between 2013 and 2018 inclusive. The relevant badger cull monitoring report<sup>17</sup> provides cattle bTB data for the first 32 cull areas. From these, Area 11 (Cheshire, Edge Area) and Area 32 (Cumbria, low-risk area) were excluded since they fall outside the HRA. To calculate herd incidence and prevalence, figures for each cull year for HIE, OTF-W, and OTF-S were extracted from Defra publications<sup>13,18,19</sup> for the period 2013–2019 inclusive, and for the following areas:

- a. The total HRA.<sup>18</sup> Cull year data (September to August) for HYAR is not published and was estimated using the annual risk for the second calendar year of each cull period. An alternative approach was tested and produced very similar results; see Supplementary Information S1.
- b. The combined culled areas of the HRA. These data are available and calculated for each cull year.<sup>6,18</sup> Data from each individual cull area in each year were summed to obtain the figure for the combined cull areas for each cull year between 2013 and 2019.

c. By subtraction (a–b) the values for HIE, OTF-W incidence and herd prevalence for the unculled areas of the HRA were established.

Land immediately surrounding cull areas ('buffer areas') were included in the unculled area category. Government epidemiological data indicates a paucity of evidence for perturbation-related increases in bTB in buffer areas since the badger culls began in 2013<sup>20</sup> and the recent study of three cull areas did not find an increase in bTB incidence rates in cattle herds in buffer areas.<sup>10</sup>

#### Statistical methods

A simple method was used to calculate 95% credible intervals for incidence rates and prevalence. Prevalence (PP) was calculated for the end of each year as PP = 100 × RCH/N, where N is the number of herds present at the end of the year, and RCH is restricted cattle herds (OTF-W + OTF-S). It is reasonable to assume that RCH has a binomial distribution. A Bayesian approach was adopted by assuming that  $\theta$  = RCH/N has a beta distribution and choosing an uninformative Jeffrey's prior for  $\theta$ , so that  $\theta$ (prior)~beta(0.5, 0.5). Standard theory shows that this leads to a beta posterior distribution of the form  $\theta$ (post)~beta(RCH+0.5, *N*+ 0.5).<sup>21</sup> This allowed construction of 95% credible intervals for PP in each year (R code<sup>22</sup> in Supplementary Information S2).

Incidence rate (IR) was calculated for each year as IR =  $100 \times CB/HYAR$ , where CB is the number of confirmed breakdowns (OTF-W incidents) in the year and HYAR is the herd years at risk for that year. We adopted an equivalent Bayesian approach for IR as for PP above, by assuming that CB/HYAR has a beta distribution. A similar approach has been used for modelling childhood tuberculosis.<sup>23</sup>

A series of generalised linear models (GLMs), generalised linear mixed models (GLMMs), generalised additive models (GAMs) and generalised additive mixed models (GAMMs) were used to analyse the incidence of new breakdowns in culled and unculled areas and the prevalence of new breakdowns. Poisson regression models were used in this analysis with the dependent variable as the number of confirmed breakdowns, with (log<sub>e</sub>) HYAR as the offset term. The year of observation was used as a random effect. Incidence rate ratios (IRR) were calculated for fixed effects (e.g. the presence or absence of badger culling) and the incidence of OTF-W. An IRR above 1 indicates a positive association of the fixed effect with the dependent variable, while an IRR below 1 indicates a negative association. Observational group of herds (ie culled/unculled in each year) was also treated as a random effect in an alternative analysis. Culled area (yes), or unculled (no), and time since culling began were included as explanatory fixed variables.

In addition, data for incidence in the HRA for the 4 years preceding the commencement of culling were also included. The initial analysis took a frequentist approach using the R packages gamm4 and lme4 (R code<sup>22</sup> in Supplementary Information S2).

As an alternative, bTB herd incidence data were analysed using Bayesian regression with the R package brms<sup>24</sup> using minimally informative priors. In this approach we analysed all possible models, that is, with a linear and nonlinear effect of time, absence of time as a covariate, the association with culling and the presence or absence of year as a random effect. We also explored if herd density (herds per 100 sq km) was associated with incidence of OTF-W. All the model results were compared using Bayes factors (R package bayestestR).<sup>21</sup> All code and data used in analyses reported in this paper are provided in the supplementary material.

## Comparisons between ten counties of the HRA

To illustrate changes in bTB herd incidence over the decade 2010–2020, OTF-W incidence was considered as a percentage of HIE at the beginning of each (calendar year) reporting period. Information on the incidence of OTF-W at the county level was extracted from the completed 10-year statistical data for the period.<sup>15</sup>

#### Change in the incidence rate of OTF-W between 2 'lightly' culled and 2 'heavily' culled HRA counties for the period 2010–2020

A four-county comparison of the annual OTF-W incidence rate over the period 2010–2020 was made using

the two counties where badger culling commenced most recently (Avon in 2019 and Shropshire in 2020) and two of the longer running cull counties (Dorset from 2015 and Devon from 2016). The land area of Dorset and Devon under badger culling by 2019 was estimated to be more than 75% by virtue of the number of badger cull licences issued since 2013 and the size of those licensed areas. The terms 'lightly' and 'heavily' reflect both the duration and land area coverage of culling within the county unit areas over time.

# Change in the incidence rate of OTF-W between sub-regions of the HRA, for the period 2010–2020

The second comparison plotted change in OTF-W incidence per year, over the period 2010–2020 for the following 10 HRA counties: Avon, Cornwall, Devon, Dorset, Gloucestershire, Hereford & Worcestershire, Shropshire, Somerset, Staffordshire and Wiltshire (Figure 2). Herefordshire and Worcestershire's results are combined. Graphs for the West Midlands were not included because it is a small, largely heavily urbanised area with relatively few herds and few OTF-W incidents per year. The 'county unit' areas can be used as a proxy for geographic counties, to enable examination of sub-regional change in bTB herd breakdown, since most of each cull area falls within that named county.

The change in the HRA boundary in 2018 to achieve a county-based approach meant some former part-HRA areas were incorporated into the 'edge' area. Despite this, recent APHA data have been retrospectively updated to reflect the current HRA boundary, so it is possible to examine change over time consistently within county cull areas and to monitor changes in the incidence of OTF-W. The ratio of culled to unculled area changes as more land is culled, but the incidence of OTF-W in each county, expressed as a percentage of HIE, provides a consistent measure by which to consider change within and between counties over the study period (2010–2020) in a readily accessible format.

### RESULTS

## A comparison between culled and unculled areas of the HRA, 2013–2019

A comparison of OTF-W incidence (herds in existence per 100 years at risk), between culled and unculled areas of the HRA, 2013–2019

The paired differences of OTF-W incidence between culled and unculled areas per 100 years at risk are generally similar with overlapping confidence intervals, with OTF-W incidence levels slightly lower in unculled areas in most years (Figure 3).

**FIGURE 2** Diagram of the 10 counties or county-based administrative areas making up the entire rural high-risk area (excluding West Midlands) referred to in this study, as also used in Defra epidemiological reports and retaining the administrative area of Avon





**FIGURE 3** Incidence rate with confidence intervals of OTF-W per hundred herd years at risk within and outside 30 badger cull areas of the high-risk area of England, during badger cull years (September to August) 2013/14 to 2018/19. Incidence in the 3 years before badger culling is also shown

#### A comparison of bTB prevalence (herds under restriction as a proportion of all registered herds) between culled and unculled areas of the HRA, 2013–2019

The pattern of herd bTB prevalence is similar to that of OTF-W herd incidence 2013–2019 (Figure 4).

Generalised linear models (GLMs), generalised linear mixed models (GLMMs), generalised additive

models (GAMs) and generalised additive mixed models (GAMMs) were used to analyse and compare the incidence and prevalence of new breakdowns in culled and unculled areas.

The statistical models failed to demonstrate any association of culling with either the incidence or the prevalence of herd breakdowns. With the frequentist approach, there was a significant nonlinear association with time with an initial increase in breakdown



**FIGURE 4** Herd prevalence with confidence intervals within and outside 30 badger cull areas in the high-risk area of England at year-end, 2013–2019

**TABLE 1** Comparison of Bayesian regression models with and without 'cull' and 'time' included as a fixed effects for the period of 2013–2018. The higher the Bayes factor, the greater support for the model, compared to the null model with just an intercept and no random effect. Direct comparison of two models can be made by the ratio of the Bayes factor. Comparing model 1 (including culling) to model 2 (without culling) = 1.33e16/4.52e16 = 0.29, the random effects model with culling as a covariate has less support compared to the same model including culling as a covariate

Model No.	Model fixed effects	Model random effects	Bayes factor	AIC	Type of model	Rate ratio (cred, intervals) Bayesian model	Rate ratio (CI) frequentist model
1.	Cull + nonlinear time	Year	1.33e16	123.9	GAMM	1.05 (0.99–1.11)	1.05 (0.99–1.11)
2.	Nonlinear time	Year	4.52e16	124.7	GAMM		
3.	Cull + linear time	Year	4.77e16	124.5	GLMM	1.05 (0.99–1.11)	1.05 (0.99–1.11)
4.	Cull	Year	7.00e16	130.3	GLMM	1.05 (0.99–1.11)	1.04 (0.99-1.10)
5.	Interaction of cull and time	Year	3.69e15	125.6	GLMM	1.22 (0.83–1.81)	1.27 (0.85–1.86)
6	Linear time	Year	1.69e17	124.9	GLMM		
7.	None	Year	2.93e17	130.4	GLMM		
8.	Cull + nonlinear time	None	5.32e16	118.4	GAM	1.05 (0.99–1.11)	1.05 (0.99–1.11)
9.	Nonlinear time	None	1.58e17	119.5	GAM		
10.	Linear time	None	2.74e14	143.5	GLM		
11.	Cull	None	2.89	207.2	GLM	0.93 (0.88-0.98)	0.93 (0.88–0.98)
12.	Linear time + cull	None	2.71e13	142.5	GLM	1.02 (0.97-1.08)	1.02 (0.97-1.08)
13.	None	None	1 (NULL model)	212.8	GLM		

incidence followed by a decline reaching the lowest level in 2019, the final year of observation. Similar results were seen with herd prevalence.

The parameter representing cull was not significant in the most parsimonious random effects model (model 1, Table 1) (p value = 0.094 IRR = 1.05, CI 0.99–1.11). This frequentist result suggests that it is not possible to reject the null hypothesis that badger culling had no effect on the incidence of new herd breakdowns. Moreover, the direction of the effect is opposite that which the culling is intended to achieve. The Bayesian analysis indicated a similar IRR of 1.05 but has a different interpretation. Thus, the IRR has 95% credible limits of 0.99–1.11. The probability distribution of the IRR (Figure 5) indicates that there is a greater probability mass of the IRR above 1 (i.e. badger culling is associated with an increase in herd incidence) than below 1 (i.e. badger culling is associated with a decreased herd incidence).

Herd density did not appear to be a significant factor associated with OTF-W incidence. For example, adding density as a fixed effect covariate in 10

Frequency

0.9

Badger Cull Area

2018



16

Incidence per 100 Herd Years

12

2013

FIGURE 6



IRR

1.1

model 1 gives a p value of 0.76 for the IRR of herd density.

Similar results were seen if the pre-culling bTB herd incidence data from 2009-2012 was included in the analysis (R Code in supplementary information 2).

Analysis of competing models using Bayes factors suggested that the best random effects model was one without co-variates (model 7, Table 1). All the random effects models which included cull (models 1, 3, 4 and 5) had an IRR for cull that was more likely to be above 1 than below.

With the frequentist random effects models, the model with the lowest Akaike information criterion (AIC)<sup>25</sup> included cull and nonlinear time as covariates, with the point estimate of the IRR above 1, but lower confidence intervals below 1 (model 1).

When the random effect was removed, the Bayesian model with the most support was model 9, where cull was not a covariate and time was a nonlinear fixed effect. With the frequentist model, model 8 had the lowest AIC, but again the IRR for cull had a point estimate of above 1. Figure 6 gives the model prediction for the years 2013–2018 (years in which culling was implemented) based on the random effects model 1. This shows that the incidence in the culled areas and unculled areas had parallel projections, consistent with culling having no effect.

Figure 7 illustrates the model prediction for the variation in OTF-W incidence from 2009 to 2018 and illustrates that OTF-W incidences had stopped rising by 2013, before badger culling was implemented.

Alternative models with year as a fixed effect instead of a random effect gave similar results (Table 1). Analysing the alternative models, the GAMM gave the greatest support for a model that did not include culling as a covariate. Furthermore, the model which excluded 'cull' as a fixed effect (model 2) was more likely than one including 'cull' as a fixed effect (model 1). The model with the only fixed effect as 'linear time' (model 6) had more support than any random

effects model which included cull. However, the random effect model with the most support was one with an intercept only, that is, no covariates (model 7). In the models without random effects, the model with the most support was model 10, again without cull as a covariate. The only model where the IRR for cull was significantly less than 1 was the model without random effects and without time as a covariate (model 11). However, this model had the least support in terms of Bayes factors of all the models investigated (compared to the null model) and had the highest AIC in the frequentist approach.

Finally, a model that investigated the change in incidence as the dependent variable was analysed. This had a simple linear model approach, where the change in incidence for the year was the incidence in that year minus the incidence in the previous year. Post hoc analysis demonstrated that the model residuals were consistent with this approach. With this analysis neither culling, herd density nor time were significant covariates. Therefore, there was no evidence that change in incidence was associated with the presence of badger culling.

R Code and data for all models is included in the supplementary materials (S2)

#### A comparison between 10 counties of the HRA, 2010–2020

Change in the incidence rate of OTF-W between 2 heavily culled and 2 lightly culled HRA counties 2010–2020

Figure 8 demonstrates how similar the OTF-W herd incidence pattern has been between the four counties over time, regardless of the degree of badger culling, even though incidence rates differ considerably between counties. The heavily culled counties of Dorset and Devon fared no better than the lightly culled Avon and Shropshire.



FIGURE 7 Model prediction for the variation in OTF-W incidence from 2009 to 2018



**FIGURE 8** Change in the incidence rate of OTF-W expressed as a percentage of herds in existence in heavily badger culled HRA counties (Devon/Dorset), only recently culled counties (Shropshire/Avon) and their comparison with the total HRA, 2010–2020. Arrows denote commencement of badger culling for the first time in that county with one or more cull areas

## Change in the incidence rate of OTF-W between sub-regions of the HRA, 2010–2020

An examination of data from counties divided into two HRA sub-regions (4 central England counties and 6 southwest England counties) revealed strikingly similar patterns in herd bTB incidence over the decade with OTF-W incidence rising, peaking, and then falling.

In the four central England counties (Gloucestershire, Shropshire, Staffordshire, and Hereford & Worcestershire), the peak was between 2011 and 2013 (Figure 9). In Shropshire, peak OTF-W incidence fell from 2013 despite a large rise in incidence in 2017.

In the six southwest counties (Avon, Cornwall, Devon, Dorset, Somerset and Wiltshire) the OTF-W peak occurred in 2015, except in Dorset which peaked a year earlier (Figure 10).

Across the HRA of England, the OTF-W incidence peak was followed by a largely consistent decline in extent and duration between the HRA counties of central and southwest England from the peak to the final year of surveillance data in 2020. These records confirm that, except for Somerset, OTF-W incidence peaked and began to decline in all counties well before badger culling commenced. It is striking that the trend in OTF-W incidence rate in individual counties in southwest England is closely mirrored by the trend in incidence rate in the HRA overall.

#### DISCUSSION

The present study provides an analysis of real-world changes to herd OTF-W incidence and prevalence over the longer term, and over much wider areas, than the

**FIGURE 9** Change in the incidence rate of OTF-W expressed as a percentage of herds in existence in counties in the central England HRA. Arrows denote commencement of badger culling for the first time in that county with one or more cull areas. Incidents of OTF-W peak 2011–2013

**FIGURE 10** Change in the incidence rate of OTF-W expressed as a percentage of herds in existence in HRA counties in southwest England. Arrows denote commencement of badger culling for the first time in that county with one or more cull areas. Incidents of OTF-W peak in 2014/15



Analyses are based on data from over 200,000 herd measurements in a period of 11 years and 4 months. The analyses do not provide any evidence for the efficacy of badger culling as a bTB control intervention.

In the four 'county unit' OTF-W incidence comparison (Figure 8), heavily culled counties had similar disease reduction patterns as lightly culled counties, with peaks at or before 2015 and reductions thereafter. This suggests that factors other than badger culling are influencing bTB herd incidence in cattle. There have been similar modest improvements in OTF-W incidence across both culled and unculled areas of the HRA since 2015 (Figures 8–10).

To examine the hypothesis that badger culling is responsible for these falls in OTF-W incidence across the HRA, it is also necessary to review the timeline of cattle-based measures introduced since 2010, and to consider their contribution. The main cattle-based bTB control measures introduced between 2010 and 2020 are summarised in Table 2.

The main cattle test used to monitor bTB in cattle, the SICCT (single intradermal comparative cervical tuberculin) skin test, has a mean individual animal test sensitivity of 49% (95% CI: 27-74%) when used at standard interpretation.<sup>28–31</sup> It follows that there are tens of thousands of infected cattle across the HRA which are missed by SICCT and remain within herds as a 'hidden reservoir'.<sup>32</sup> Any control measure which reduces the number of cattle in this hidden reservoir is highly likely to have disease control benefits.

A move to annual SICCT testing in the HRA was initiated in 2010 and complete by 2013. This would have detected a proportion of the hidden reservoir in many herds at an earlier stage and is consistent with the temporary increase in OTF-W incidence seen in Figures 8–10 in the first half of the decade. With the wider application of severe interpretation of the SICCT test, with short interval testing for all herd breakdowns from 2016, the rolling mean number of SICCT test reactors per breakdown in the HRA rose from around six reactors to close to 10 reactors,<sup>33</sup> thus removing a greater proportion of the hidden reservoir from each breakdown herd.

The use of interferon-gamma testing (IFN $\gamma$ ) as a supplement to SICCT testing was initially focused in pilot badger cull areas, beginning in 2013 in south Gloucestershire and Somerset<sup>34</sup> with a much higher percentage of bTB-infected animals detected in many breakdown herds where IFN $\gamma$  was used.<sup>35</sup> It is noteworthy that despite ongoing removal from cull areas of these additional infected cattle detected by IFN $\gamma$  which, despite the low level of false positive diagnoses,<sup>36,37</sup> would be expected to reduce both recrudescence within herds and onward transmission to new herds, our study still shows no concomitant





<b>TABLE 2</b> Changes to bTB testing and cattle control measures in the high-risk area, 2010–2020 <sup>3,27</sup>				
Year	Bovine TB cattle control measures introduced to the HRA 2010–2020			
2010	Phasing in of annual SICCT testing began within the HRA, with testing every two years in adjoining areas.			
2011–2012	Introduction of an extensive suite of cattle movement restrictions. Compensation payments were reduced for overdue bTB tests.			
2013	Herd testing intervals were determined on a county basis and annual testing of herds was extended to all the counties a the edge of the HRA.			
2014	Mandatory IFN-γ tests were used in persistent outbreaks where herds had been under restriction for more than 18 months. The de-restricting of parts of some TB-restricted (non-OTF) holdings to allow cattle movements was ended. Pre-movement testing rules were changed to prevent exemptions that allowed cattle movements between holdings that are part of the same sole occupancy authority (SOA) and to and from common land.			
2016	Introduction of a compulsory requirement for two consecutive clear short interval SICCT tests at severe interpretation, for all bTB breakdown herds before regaining OTF status.			
2017	In the HRA: Introduction of mandatory IFN-y parallel testing of OTF-W breakdown herds in the HRA where repeated skin testing of the herd has failed to resolve a TB breakdown. Used where transmission from cattle is considered most likely and where two years of badger culling had been completed. Tighter controls on cattle movements were introduced, with severe interpretation extended to cattle traced from breakdown herds. Use of severe interpretation of the SICCT test to increase test sensitivity in cattle traced from lesion/culture positive breakdown herds.			
2018	Increase in use of IFNy testing.			

fall in the incidence or prevalence of bTB in cull areas when compared to unculled areas. By 2017, IFN $\gamma$  was introduced more widely within the HRA,<sup>36,37</sup> with increased use in 2018 in many counties.<sup>38</sup> By removing a greater proportion of the hidden bTB reservoir, this would be expected to contribute significantly to declining OTF-W incidence and prevalence across the HRA.

An examination of the timescale of changes in the incidence of OTF-W in 10 HRA counties over the decade 2010–2020 demonstrates that the epidemic had peaked in all 10 counties and was declining from the end of 2015. The rate of decline of OTF-W incidence is similar between individual counties and closely mirrors the pattern seen across the HRA. It is not clear why incidence peaked around 3 years earlier in central English counties than in the southwest. However, what is apparent is that the decline in OTF-W incidence was underway before badger culling commenced.

In 6 of the 10 HRA counties, the decline from peak OTF-W incidence commenced 2 years before badger culling started, and in 9 of the 10 areas, the peak in OTF-W incidence occurred before the introduction of badger culling in that county. By the start of 2018, OTF-W incidence had fallen by up to a third in most counties, but only 22% of the HRA (8500 of 37,000 sq km) had been subject to badger culling, and much of that area for only 1 or 2 years. While intensive badger culling had been implemented in 47 areas covering approximately 67% of the HRA by 2020, the proportion of the HRA that had undergone a full 4-year cull by the end of 2020 was still less than 25% of the geographic area. This strongly suggests that measures other than badger culling are responsible for the decreases in OTF-W incidence over the wider HRA during the study period.

Taken together with the findings that badger culling has had no discernible impact on herd OTF-W incidence and prevalence across the HRA, the cattle-based measures described above are the most likely explanation for the changes over time, demonstrating slow efficacy of cattle measures as they are increasingly tightened.

Given the relatively low sensitivity of the SICCT test at individual animal level, even at severe interpretation, it is highly likely that infected but undetected cattle routinely remain in herds following restoration of OTF status. Because the same insensitive SICCT test is used for both pre-and post-movement testing, this hidden disease reservoir will likely result not only in recrudescence of bTB within herds, but also spread to new herds and new geographical areas. It follows that this undetected within-herd prevalence acts to perpetuate the bTB epidemic, including in areas beyond the HRA to which cattle are transported.

During the same period as this study (2009–2020), Wales achieved similar reductions in herd bTB incidence as England,<sup>39</sup> through the introduction of improved bTB testing and other cattle measures,<sup>40</sup> and without widespread badger culling. This suggests that bTB in cattle can indeed be controlled through cattle measures alone, as was predicted by the Independent Scientific Group in 2007.<sup>7</sup>

#### Study approaches and limitations

Areas subject to badger culling in England since 2013 have not been selected randomly, and culling area boundaries remain undisclosed. Both factors limit the extent to which estimates of the effect of culling on bTB can be made. For example, if badger cull area boundaries were available, analysis would be possible for each of the 30 HRA cull areas and unculled comparison areas. Wider geospatial data, and controlling for a range of confounding factors such as percentage of persistent herds and ratio of beef to dairy herds, could also be applied.

Regular monitoring of the effect of culling is imperative when there is uncertainty over efficacy. However, to date the only published study comparing bTB incidence and prevalence in culled to unculled areas is limited to three small cull areas over a limited period and acknowledges both the difficulty in predicting effects using modelling, and that badger culling policy needs to be evaluated alongside other TB controls.<sup>10</sup> The present study approaches these challenges by considering much larger datasets covering the whole of the HRA over a longer period and alongside cattle interventions.

The move away from multiple small comparison areas might invite criticism regarding a lack of control over potentially confounding variables. However, the much greater dataset included in this analysis should address anomalies that result from small samples. The approach would be expected to identify real differences between herd bTB incidence and prevalence between culled and unculled areas, should they exist. If badger to cattle transmission has previously prevented effective disease control, a substantial reduction in herd incidence in culled areas should have been evident within the first 12–24 months of operation.<sup>26</sup>

The statistical modelling investigated, as far as the available data would allow, the independent association of incidence and prevalence of OTF-W. It compared the area where badger culling was undertaken, with the area where it was not. In all analyses, models that included the covariate of time gave a better statistical description of the data than models without. Only when time was not included as a covariate was there an association of decrease in incidence or prevalence in cull areas compared to unculled area and then only in the model without random effects. This is to be expected, if there were a general decline in incidence since 2013 when culling was initiated, no covariates other than culling were included in the analysis, and the cull area was expanded during the culling period. If culling were associated with a decrease in OTF-W incidence or prevalence, then the decrease would be expected to be greater in the cull areas compared to the unculled areas over time. This was not seen in any of the statistical models and is illustrated in Figure 6. While caution is required, it is difficult to conclude, given the data, that badger culling was associated with the general decline in the incidence of OTF-W. A more likely explanation is the decline is due to other factors occurring concomitantly in both culled and unculled areas.

Results show descriptive representations of headline indicators of bTB and with the application of a range of models. They therefore represent a properly applied series of tests for the data, against which past and future analyses may be referenced.

The mixed model approach, with the year of observation as a random effect, controls for unobserved heterogeneity within each year. Such heterogeneity could be caused by other unknown effects that could have contributed to a change in the incidence of herd breakdowns. The frequentist analysis suggests that the null hypothesis that culling has no association with the incidence of herd breakdowns cannot be rejected. This does not prove that there is no association, but given the data and the statistical model, there is insuffi-

cient evidence to indicate that culling has lowered bTB incidence or prevalence. It could be argued that data from more herds over a wider area, if available, might change that conclusion, but it is worth noting that the parameter 'cull', while not significant had an IRR above 1, and the data set was large, so it seems unlikely that additional data would alter this conclusion. The Bayesian analysis also supports this conclusion. The IRR is virtually identical, as might be expected with such a large data set and minimally informative priors. However, Bayesian posterior credible intervals have a different interpretation. Thus, it seems that an IRR greater than 1 is more likely than one less than 1 given the model and data. Furthermore, by considering all the other possible models (Table 1), the model with a nonlinear effect of time gives the best support and is better than a model that includes the presence or absence of 'cull' as an explanatory variable. Therefore, taking this evidence together, the best interpretation is that badger culling has no association with change in herd incidence or prevalence. The interaction model (model 5, Table 1) had less support than models including time and cull or just time. This observation makes a delayed response in the OTF-W incidence or prevalence to culling unlikely.

Only if the parameter 'time' is removed from the analysis, can the parameter 'cull' become significant. However, this would ignore other effects that might have occurred over the period from other interventions introduced previously or in parallel. In effect, the unculled areas acted as controls and the model best supported by the data had similar trajectories in OTF-W incidence in both culled and unculled areas.

Further, if culling contributed to the observed reduction in herd breakdowns over time, then the decrease in herd breakdowns seen in culled areas would be greater than the decrease seen in the unculled areas. This was not seen in the data, with some years having a greater decrease in culled areas, and other years a greater decrease in the unculled areas. Although the Bayesian analysis of the random effects model gives slightly better support for a model where the sole explanatory variable is 'cull' (model 4) rather than the sole explanatory variable being time (model 2), the IRR for cull in model 4 is greater than 1. Finally, when change in incidence is analysed as the dependent variable, again there was no association with culled or unculled area. The decline from 2013 in the incidence of new bTB herd breakdowns is better explained by another factor or factors that affected both culled and unculled areas.

It should be noted that herd density and disease burden may vary between culled and unculled areas of the HRA. Herd density (herds per 100 sq km) and OTF-W variation were additionally analysed as a covariate in all models and did not show any association with incidence or prevalence of bTB herd breakdowns.

To justify a serious intervention involving the killing of large numbers of a protected species, the evidence for disease control benefits needs to be extremely strong. This study provides no evidence to support badger culling as an effective approach to reducing herd OTF-W incidence or prevalence. Trend analyses suggest that reductions in the herd OTF-W incidence and prevalence correlate with the timeline of introduction of cattle-based disease control measures, and these apparent associations warrant further investigation.

#### **CONCLUSIONS**

Changes in herd OTF-W incidence and prevalence within and outside badger cull areas for the period 2013–2019, based on publicly available Defra data, are consistent with a prediction<sup>7</sup> that 'badger culling can make no meaningful contribution to the control of bTB in cattle'. The decline in OTF-W incidence within HRA counties between 2010 and 2020 could be the result of cattle-based disease control measures.

Badger culling is likely not responsible for initiating the levelling off and downward trend in OTF-W incidence in the HRA counties, because levels of badger culling were small-scale and localised before OTF-W incidence peaked and decrease began, in or before 2015. These findings may have implications for current and future bTB control policy, and any future datasets released on bTB levels in areas where badger culling has been implemented warrant further analysis.

#### AUTHOR CONTRIBUTIONS

Tom Langton conceived the study and its analysis. All authors contributed to the manuscript, to data generation and model development.

#### DATA AVAILABILITY STATEMENT

Data used for this analysis are the official figures released by Defra and its agencies. The sources of this data, and the data themselves, are presented in tabular form in Annex 1.

#### ETHICS STATEMENT

This study consists of a statistical analysis of existing published data. No ethical approval was required.

#### FUNDING INFORMATION

No funding was received for this study.

#### CONFLICT OF INTEREST

Tom Langton is a conservation ecologist with involvement in High Court judicial review of decisions surrounding badger culling policy in England. Mark Jones is a veterinarian who works as Head of Policy for the Born Free Foundation, a wildlife charity which aims to have a positive impact on animals in the wild and protect their ecosystems in perpetuity, for their own intrinsic value and for the critical roles they play within the natural world. Born Free has consistently opposed the Government's policy of badger culling on the grounds that it is ineffective, inhumane and unnecessary. Iain McGill is a veterinarian and Director of the Prion Group. The Prion Group provides veterinary services and funds and publishes independent research. The Prion Group has consistently opposed the Government's policy of badger culling on the

grounds that it is ineffective, inhumane, unscientific, and unnecessary.

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#### SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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