

Annex

Annex 1 - Report of the incidence of bovine tuberculosis in cattle in 2013-14 in the areas of Somerset and Gloucestershire exposed to the first year of industry-led badger culling

Brunton, L. A.¹, Donnelly, C. A.², Ashton, A.³, Prosser, A.³, Ashfield, A.³, Goodchild, A. V.¹, Upton, P.³, Mitchell, A.³, Parry, J. E.¹ & Downs, S. H.¹

¹ Department of Epidemiological Sciences, Animal and Plant Health Agency, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3NB, UK

² Faculty of Medicine, School of Public Health, Imperial College London, St Mary's campus, Norfolk Place, London, W2 1PG, UK

³ Data Systems Group, Animal and Plant Health Agency, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3NB, UK

In 2013, the licensed culling of badgers in order to control bovine tuberculosis (bTB) was piloted in two areas of England. The aim of this policy was to assess the practicalities and impact of the intervention.

Badgers are a known host species for *Mycobacterium bovis* (the causative agent of bTB) and there has been considerable debate over the use of culling to control the transmission of bTB between this wildlife reservoir and cattle. The results of the Randomised Badger Culling Trial (RBCT) conducted in England between 1998 and 2007 indicated that the incidence of confirmed bTB in cattle could be reduced by 23.2% (95% CI: 12.4% to 32.7%) if culling was performed systematically over large areas and sustained for at least four years (Donnelly et al 2007). Three treatments were investigated in the RBCT – proactive culling which was repeated and widespread, reactive culling which was localised and in response to a confirmed cattle bTB incident, and no culling where badgers were surveyed only. Culling badgers was found to be associated with both positive and negative effects on cattle bTB incidence. Reactive culling was associated with an overall detrimental effect on cattle bTB incidence and was suspended before the end of the trial (Donnelly et al 2003). Proactive culling was associated with a reduction in cattle bTB incidence within the trial area, but an increase in incidence in a 2 km wide buffer around the culled area (Donnelly et al 2006). Detrimental effects were considered to be due to the disruption of badger social structures (perturbation) which could affect the rate of contact between cattle and badgers (Woodroffe et al 2006). This meant that the net effect of proactive culling per year was initially detrimental, but a beneficial effect overall was observed after the third year of culling and subsequent culls (Donnelly et al 2007).

In 2013, culling licences were issued for two areas in England by Natural England under the Protection of Badgers Act 1992 to enable groups of farmers and landowners to reduce badger populations (Defra 2012, 2013). Criteria that licencees were required to meet included: an application area to be at least 150 km², at least 70% of the land to be accessible for culling, cattle herds subject to annual bTB testing and reasonable biosecurity to be in place. In addition, culling should plan to reduce the estimated badger population by 70% and be conducted for a minimum of four years (Defra 2013). The first round of culling took place in west Somerset and west Gloucestershire between August and November 2013. Using a combination of cage trapping and controlled shooting of badgers, 955 badgers were culled in Somerset and 924 were culled in Gloucestershire. The 95% confidence intervals for the estimates of the percentage of the population culled

in each area were 37.0% to 50.9% in Somerset and 43.0 % to 55.7% in Gloucestershire, which meant that for both areas the 70% reduction in the estimated population was not achieved (AHVLA 2014).

The impact of the pilot culls in Gloucestershire on cattle bTB incidence has been discussed in recent correspondence to the Veterinary Record (Blowey et al 2015a & 2015b, Woodroffe 2015). A descriptive analysis of the number of reactors to the skin test from a population of 4,000 cattle overseen by two veterinary practices was said to suggest that a decrease was observed between an 18-month period from early/mid 2013 to mid/late 2014. This survey was small and did not consider data from matched un-culled areas, limitations that have already been highlighted (Woodroffe 2015).

Although industry-led culling is a policy and not a scientific experiment, a methodology has been developed to measure the possible association between the policy and incidence of bTB in cattle in the areas subject to culling and a surrounding buffer. To enable a robust assessment of any effects of the intervention on cattle incidence, comparison areas matched to the intervention areas but where no culling has taken place have been identified. The methodology for selecting comparison areas has been developed and reported under Defra project SE3131⁵. The effects of the first year of the cull on bTB in cattle in the intervention areas and comparison areas are explored here using descriptive statistics.

Methodology

Using routinely collected surveillance data on bTB in cattle, bTB is being assessed in cattle herds located within areas where industry-led culling is conducted (so called “intervention” areas), and compared to bTB in herds in comparison areas matched on key characteristics that affect cattle bTB risk. The incidence of bTB in cattle is also being monitored in 2 km buffer areas surrounding the intervention areas and compared to incidence in similarly defined areas around comparison areas. The reason for including buffer areas was to monitor potentially adverse effects on cattle bTB incidence (observed in the RBCT) thought to be associated with increased movement (perturbation) of infected badgers (Donnelly et al 2006). A protocol for monitoring the effect of culling on bTB in cattle has been developed and has been reviewed by independent auditors. The first culls in the two areas licensed to date (west Somerset and west Gloucestershire), were conducted in autumn 2013 and included a six-week pilot period evaluated by the Independent Expert Panel (2014). A second year of culling took place in both areas during autumn 2014.

Definitions

Baseline date: The date on which the culling is initiated in an intervention area. Cattle bTB incidents prior to this date are not attributable to any effects of culling.

Intervention: Industry-led badger culling (and any future bTB control policies introduced into culling areas that are not similarly introduced into comparison areas).

Intervention area: Area where badger culling has been licensed.

Comparison area: Land of similar size, shape and cattle bTB risk to the intervention area with which it is matched.

⁵

<http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&Completed=2&ProjectID=18287#Description>

Buffer area: Land up to 2 km from the outside edge of an intervention or comparison area in which cattle bTB incidence is monitored but no culling is conducted.

Project population: Cattle herds recorded on the Animal and Plant Health Agency (APHA) TB database SAM as in existence in intervention and comparison areas and adjoining land (buffer areas) on the baseline date. Farm location is based on geo-coordinates recorded on SAM. The location of land parcels associated with each farm is based on information recorded on the Customer and Land Database (CLAD).

Primary outcome: New bTB incidents in cattle herds confirmed by post-mortem evidence of infection with *M. bovis*. These incidents are reported as having their Officially Tuberculosis Free Status Withdrawn (OTF-W) and are incidents with cattle that react to the tuberculin skin test and have macroscopic lesions observed at post-mortem examination or at least one slaughtered animal from which *M. bovis* is isolated from tissues from slaughtered cattle. Bovine TB incidents in cattle herds resulting from the detection of reactors but without post-mortem evidence of infection are reported as having their Officially Tuberculosis Free Status suspended (OTF-S). In this report, OTF-S incidents are included in measures of all bTB incidents, but are not assessed separately as OTF-W incidents are. This is because the RBCT only showed an association between OTF-W incidence and culling (Independent Scientific Group, 2007).

Prevalence: Prevalence is described as the proportion of herds under restriction as a result of a bTB incident at the end of the reporting period. We calculate the proportion of herds at the mid-point of the last month of the reporting period; specifically this is calculated as 16 days prior to the end of the reporting period.

Incidence: Incidence is described as the number of new incidents per 100 unrestricted herds tested in each year. Incidence rate is calculated as the number of incidents per 100 herd-years at risk. The time at risk denominator is the sum of the time herds were at risk of a new bTB infection, calculated from the periods the herds were not under restrictions (Downs et al, 2013). When calculating time at risk we identified some herds with long periods of time at risk due to 'erroneous' periods between tests. These were either due to periods of herd inactivity, incorrect marking of test types or alternatively tests not required as premises are approved finishing units not requiring routine herd testing. To reduce bias caused by inaccurate herd test histories, time period of risk was summarised as the median time at risk of herds in each individual area for each reporting period.

Statistical analysis

The population of herds in each area at the baseline date is described in Annex Table Ax1. Total number of herds across all 10 comparison areas is given along with the median number of herds.

Annex Table Ax1: Number of herds in each area at the baseline date (start of Year 1)

	Area	Number of herds at baseline date
Somerset	Central	154
	Buffer	88
	Comparison	1,863 (median = 173)
	Comparison buffer	1,199 (median = 118)
Gloucestershire	Central	215
	Buffer	121
	Comparison	1,713 (median = 174)
	Comparison buffer	1,008 (median = 104)
Total	Central	369
	Buffer	209
	Comparison	3,576 (median = 173)
	Comparison buffer	2,207 (median = 107)

Statistics describing bTB in cattle in each intervention area, in the 2km-wide buffer area around each intervention area where no culling was conducted, and for the 20 comparison areas (10 per intervention area) were produced. Statistics for comparison areas were performed on data that had been averaged across the 10 comparison areas per intervention area. The time periods investigated were the first 12 months following the baseline date and the periods 0-12 months, 12-24 months, 24-36 months and 0-36 months prior to the baseline data. For conciseness, these periods have been labelled as years (Annex Table Ax2). In addition, the whole three-year period prior to the baseline date was used for investigating historic incidence rate (Annex Table Ax2).

Annex Table Ax2: Start and end dates for each of the reporting periods used to assess cattle bTB in the Somerset and Gloucestershire intervention areas

Somerset			
Reporting period	Description	Start Date	End Date
3 years prior, total	The entire three years prior to the intervention	26/08/2010	25/08/2013
3 years prior	The year which began three years prior to the intervention	26/08/2010	25/08/2011
2 years prior	The year which began two years prior to the intervention	26/08/2011	25/08/2012
1 year prior	The year prior to the intervention	26/08/2012	25/08/2013
Year 1	First year of the intervention	26/08/2013	25/08/2014
Gloucestershire			
Reporting period	Description	Start Date	End Date
3 years prior, total	The entire three years prior to the intervention	03/09/2010	02/09/2013
3 years prior	The year which began three years prior to the intervention	03/09/2010	02/09/2011
2 years prior	The year which began two years prior to the intervention	03/09/2011	02/09/2012
1 year prior	The year prior to the intervention	03/09/2012	02/09/2013
Year 1	First year of the intervention	03/09/2013	02/09/2014

Differences between areas in the number of reactors and recurrence of disease were investigated. Recurrence of disease is described retrospectively, as the proportion of herds with an OTF-W incident in the reporting period which had an incident in the previous three years. It is also described prospectively, as the number and proportion of herds with a history of bTB in the previous three years which suffered any incident in the reporting period compared with the proportion of herds with no history of bTB which suffered any incident in the reporting period. The numbers of reactors to the single intradermal comparative cervical test (SICCT skin test) or gamma interferon test are described per incident in each area. The number used is the total number of reactors throughout the whole duration of the incident, for incidents that ended in the reporting period regardless of when they started.

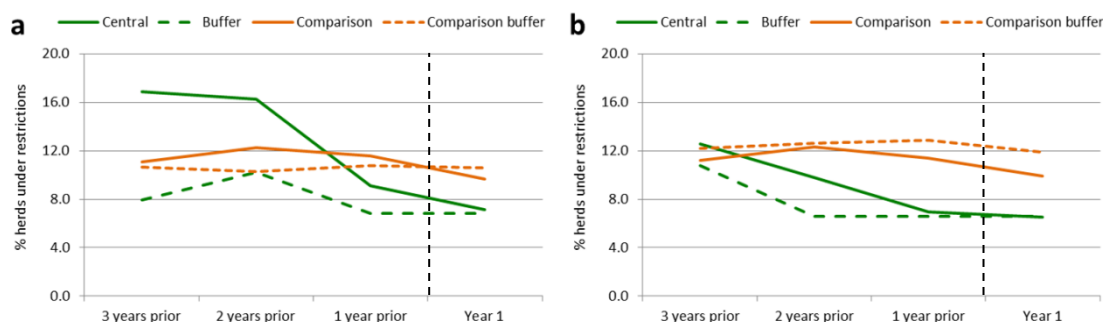
Differences between the incidence rate in intervention and comparison areas were investigated. Crude incidence rate ratios were calculated for both the intervention areas and buffer areas in each reporting period for OTF-W incidents only. In all statistical analyses a probability level of $P < 0.05$ was considered to be statistically significant.

Results

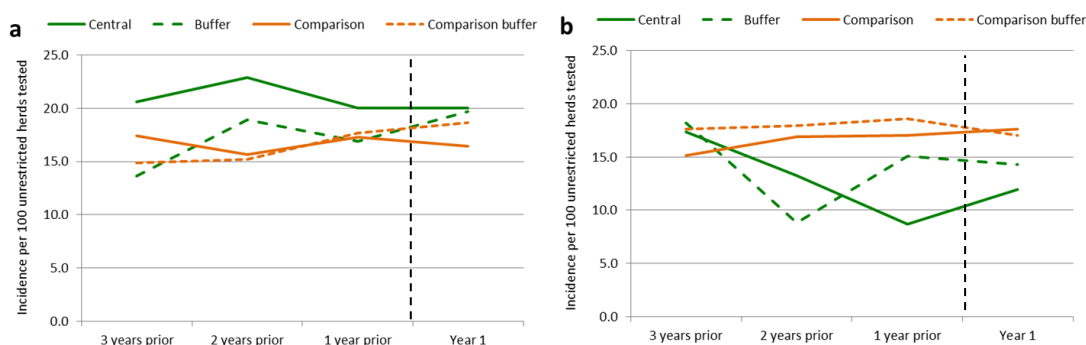
Prevalence and incidence

The prevalence of herds under restriction for OTF-W incidents only, per area and reporting period, is presented in Annex Figure Ax1. Prevalence appears to have declined since 2010 across all areas, and this includes a decline between 2012-13 (1 year prior) and the first year of follow-up. This decline was most apparent in the Somerset areas.

The number of new incidents per 100 unrestricted herds tested is presented in Annex Figure Ax2. No obvious trend in incidence over time was apparent for any of the areas.



Annex Figure Ax1: Temporal changes in the number of herds under restrictions (OTF-W incidents only) at the end of the reporting period per 100 herds, in Somerset (a) and Gloucestershire (b) intervention areas and their respective buffer areas, and comparison areas and buffer areas. The horizontal axis represents the mid point of the last month of the reporting period.



Annex Figure Ax2: Temporal changes in OTF-W incidence per 100 unrestricted herds tested in Somerset (a) and Gloucestershire (b) intervention areas and their respective buffer areas, and comparison areas and their respective buffer areas

Reactors

Very little difference was observed in the median number of reactors per area, prior to, or in the first year following the cull. The interquartile ranges for the number of reactors were overlapping between central, comparison and buffer areas in both the Somerset and Gloucestershire areas (Annex Table Ax3).

Annex Table Ax3: Total number and median number (with interquartile range) of reactors per incident (for all incidents and for OTF-W incidents only)

ALL INCIDENTS												
Reporting period	Central			Buffer			Comparison			Comparison buffer		
	No. of reactors	Mean	Median (IQR)	No. of reactors	Mean	Median (IQR)	No. of reactors	Mean	Median (IQR)	No. of reactors	Mean	Median (IQR)
Somerset												
3 years prior,	105	5.8	4 (1,7)	71	7.1	2 (1,14)	909	4.8	2 (1,5)	748	5.8	2 (1,5)
2 years prior	279	7.5	3 (1,6)	62	4.8	1 (1,6)	1589	6.0	2 (1,5)	1332	7.4	2 (1,6)
1 year prior	246	5.5	3 (2,7)	103	6.1	2 (1,3)	2354	7.2	2 (1,7)	1378	6.8	2 (1,5.5)
Year 1	208	5.8	3 (1,6)	81	4.8	3 (1,7)	2164	6.6	2 (1,5)	1592	7.6	2 (1,6)
Gloucester												
3 years prior	252	7.6	2 (1,7)	88	5.9	2 (1,6)	1201	7.0	2 (1,7)	694	6.9	2 (1,7.5)
2 years prior	196	5.4	2 (1,4)	189	9.5	3 (1,10.5)	1526	5.7	2 (1,5)	1631	9.6	2 (1,5)
1 year prior	91	4.0	3 (1,7)	47	2.5	1 (0,2)	2287	7.6	2 (1,8)	1162	6.2	2 (1,6)
Year 1	161	5.8	2 (1,4)	65	3.0	1 (1,3)	1917	6.0	2 (1,5)	1255	7.1	2 (1,5)
OTF-W INCIDENTS												
Reporting period	Central			Buffer			Comparison			Comparison buffer		
	No. of reactors	Mean	Median (IQR)	No. of reactors	Mean	Median (IQR)	No. of reactors	Mean	Median (IQR)	No. of reactors	Mean	Median (IQR)
Somerset												
3 years prior	98	6.5	4 (1,7)	69	8.6	6 (1,15.5)	822	5.6	2 (1,7)	706	7.4	3 (1,6)
2 years prior	271	9.0	4 (2,9)	60	5.5	2 (1,6)	1492	7.3	2 (1,8)	1292	8.5	3 (1,8)
1 year prior	233	6.3	3 (2,9)	99	7.6	2 (1,16)	2304	8.4	3 (1,9)	1321	8.1	3 (1,8)
Year 1	199	6.2	3 (1,6.5)	80	5.0	3 (1,5.7.5)	2094	7.6	2 (1,7)	1530	8.9	3 (1,8)
Gloucester												
3 years prior	227	9.9	4 (2,14)	83	7.5	3 (1,6)	1142	8.1	3 (1,9)	631	7.6	3 (1,8)
2 years prior	185	6.9	2 (1,7)	183	10.8	4 (1,14)	1440	7.1	3 (1,7)	1586	11.7	3 (1,7)
1 year prior	85	4.3	3 (1,7)	45	2.8	1 (0.5,3)	2197	9.0	3 (1,9)	1115	7.5	2 (1,8)
Year 1	151	7.2	3 (2,5)	58	3.6	1 (1,5)	1863	6.9	2 (1,6)	1218	8.5	2 (1,6)

Recurrence

Recurrence is described as the first bTB incident disclosed during the reporting period where the herd was previously under restriction for bTB at any time in the previous three years (36 months). In Annex Table Ax4, this is presented as the proportion of herds with an OTF-W incident in the reporting period which had an incident in the previous three years.

Annex Table Ax4: Proportion of herds with an OTF-W incident in the reporting period which had any bTB incident, or and OTF-W incident in the preceding 36 months

OTF-W in reporting period	Percentage with any previous incident				Percentage with previous OTF-W incident			
	Central	Buffer	Comparison	Comparison buffer	Central	Buffer	Comparison	Comparison buffer
Somerset								
3 years prior	73%	44%	57%	55%	58%	44%	49%	46%
2 years prior	68%	50%	57%	57%	68%	43%	48%	50%
1 year prior	80%	27%	52%	59%	68%	18%	46%	54%
Year 1	62%	71%	62%	60%	50%	71%	54%	54%
Gloucester								
3 years prior	54%	53%	56%	59%	46%	47%	47%	50%
2 years prior	67%	50%	63%	58%	48%	50%	55%	50%
1 year prior	73%	33%	67%	57%	67%	27%	60%	49%
Year 1	53%	60%	56%	65%	32%	47%	50%	60%

In Annex Table Ax5 recurrence is presented prospectively, as the number and proportion of herds with a history of bTB in the previous three years which suffered an incident in the reporting period compared with the proportion of herds with no history of bTB which suffered an incident in the reporting period.

Across areas and reporting periods, the proportion of incidents in the reporting period was generally greater among herds that had a history of any bTB in the preceding three years compared with herds which had no history (Annex Table Ax5). In the Somerset intervention area, herds with a history of bTB were at a higher risk of having an incident in the three years prior to the cull, but this difference was not significant in Year 1 (RR = 1.3, 95% CI = 0.7-2.5). Across all areas, the overall changes to relative risk over time were small, with considerable overlap observed in the 95% confidence intervals, so any changes should be interpreted cautiously.

Annex Table Ax5: Number and proportion of herds with any new bTB incident in the reporting period, in herds with and without a history of any bTB incident in the preceding 36 months

Area	Reporting period	TB incident in the preceding 36 months		No TB incident in the preceding 36 months		Relative risk ²	95% CI for relative risk	
		No. of herds	Number with incident in reporting period ¹ (%)	No. of herds	Number with incident in reporting period ¹ (%)			
Somerset								
Central	3 years prior	64	24 (37.5)	77	8 (10.4)	3.6	1.7	7.5
	2 years prior	59	23 (39)	78	16 (20.5)	1.9	1.1	3.3
	1 year prior	70	22 (31.4)	70	6 (8.6)	3.7	1.6	8.5
	Year 1	70	16 (22.9)	74	13 (17.6)	1.3	0.7	2.5
Buffer	3 years prior	21	5 (23.8)	62	7 (11.3)	2.1	0.7	5.9
	2 years prior	26	8 (30.8)	60	7 (11.7)	2.6	1.1	6.5
	1 year prior	26	5 (19.2)	58	9 (15.5)	1.2	0.5	3.3
	Year 1	30	10 (33.3)	54	5 (9.3)	3.6	1.4	9.6
Comparison	3 years prior	594	188 (31.6)	1,164	124 (10.7)	3.0	2.4	3.6
	2 years prior	566	149 (26.3)	1,141	123 (10.8)	2.4	2.0	3.0
	1 year prior	588	161 (27.4)	1,123	134 (11.9)	2.3	1.9	2.8
	Year 1	642	164 (25.5)	1,089	116 (10.7)	2.4	1.9	3.0
Comparison buffer	3 years prior	359	93 (25.9)	747	75 (10)	2.6	2.0	3.4
	2 years prior	355	98 (27.6)	744	75 (10.1)	2.7	2.1	3.6
	1 year prior	380	110 (28.9)	729	79 (10.8)	2.7	2.1	3.5
	Year 1	394	114 (28.9)	723	88 (12.2)	2.4	1.9	3.1
Gloucestershire								
Central	3 years prior	73	20 (27.4)	124	17 (13.7)	2.0	1.1	3.6
	2 years prior	78	19 (24.4)	119	9 (7.6)	3.2	1.5	6.8
	1 year prior	77	12 (15.6)	127	5 (3.9)	4.0	1.5	10.8
	Year 1	66	14 (21.2)	137	14 (10.2)	2.1	1.1	4.1
Buffer	3 years prior	39	11 (28.2)	71	8 (11.3)	2.5	1.1	5.7
	2 years prior	37	6 (16.2)	73	6 (8.2)	2.0	0.7	5.7
	1 year prior	35	6 (17.1)	79	15 (19)	0.9	0.4	2.1
	Year 1	45	12 (26.7)	71	7 (9.9)	2.7	1.2	6.4
Comparison	3 years prior	528	142 (26.9)	1,058	106 (10)	2.7	2.1	3.4
	2 years prior	523	179 (34.2)	1,048	102 (9.7)	3.5	2.8	4.4
	1 year prior	532	171 (32.1)	1,027	93 (9.1)	3.5	2.8	4.5
	Year 1	552	160 (29)	1,035	124 (12)	2.4	2.0	3.0
Comparison buffer	3 years prior	319	92 (28.8)	626	65 (10.4)	2.8	2.1	3.7
	2 years prior	300	98 (32.7)	619	81 (13.1)	2.5	1.9	3.2
	1 year prior	313	93 (29.7)	596	72 (12.1)	2.5	1.9	3.2
	Year 1	347	97 (28)	565	56 (9.9)	2.8	2.1	3.8

¹ Herds under restriction for four or more months of the reporting period due to an incident that started before the reporting period were excluded from the analyses.

² Relative risk that herds under movement restrictions in the preceding 36 months had a new bTB incident in the reporting period when compared with herds that had no history of movement restrictions. The relative risk is the proportion of herds with a history of bTB that had a new incident, divided by the proportion of herds with no history of bTB that had a new incident.

Incidence rate per 100 herd years at risk

Incident rate was calculated across both Somerset and Gloucestershire intervention areas. A comparison of OTF-W incidence rate per 100 herd years at risk between intervention and control areas is presented in Annex Table Ax6. Incidence rates were calculated for Year 1, for one year prior to the cull (2012-13), and for the cumulative three year period prior to the cull (i.e. 36 months). There were no significant differences in incidence rate between central and comparison areas, or buffer and comparison areas, across the time series.

Annex Table Ax6: OTF-W incidence rates per 100 herd years at risk and incidence rate ratios (IRR) for central and buffer areas versus comparison areas

Reporting period	Central	Comparison	IRR	P value	Buffer	Comparison buffer	IRR	P value
3 years prior, total	16.1	17.4	0.925	0.364	14.1	17.2	0.815	0.079
1 year prior	13.0	17.0	0.763	0.085	15.0	17.4	0.860	0.445
Year 1	13.2	16.3	0.809	0.165	14.8	17.7	0.839	0.370

Note: the level of significance is $p < 0.05$. P values higher than this are considered not significant.

Discussion

The design of the current badger culling policy in England derives from findings from the RBCT (Independent Scientific Group, 2007). Two areas were licensed in 2013 and industry-led culling will continue for at least four consecutive years in these areas. Unlike the RBCT, the pilot culls in Somerset and Gloucestershire have been industry led, subject to licence criteria, have included controlled shooting of badgers rather than cage trapping and shooting only, and were without simultaneous selection of comparison areas. A standardised method for selecting areas closely matched to the culling areas in terms of factors that affect cattle bTB risk has been developed and a range of measures of cattle bTB incidence in the intervention areas have been assessed. The descriptive analysis showed that there is no statistically significant association between the intervention and cattle bTB incidence in the first year of follow-up. It has been estimated that in order to be likely to observe significant differences in the incidence of OTF-W herd incidents, matched intervention and comparison areas will need to be observed for at least three years after culling begins, and that this increases to four years if only two intervention areas are licenced (Donnelly et al 2015). As such, it is not surprising that no significant differences have been observed in the first year of follow-up.

The impact of the intervention in the pilot areas (including their buffer areas) will continue to be monitored. Changes in bTB control policy, over the duration of the project, particularly where its application is not equally distributed between intervention and comparison areas will impact the quality of comparisons. In 2013, biosecurity advice was provided to farmers in and around the Somerset and Gloucestershire intervention areas which was not provided to farmers in and around comparison areas. Since then the Government has announced a commitment to provide a comprehensive farm-level risk management programme throughout the cull areas for the next three years (Paterson, 2014). Because the risk management programme may have a beneficial effect in reducing transmission of infection, the independent effects from the badger culls in Somerset and Gloucestershire intervention areas cannot be accurately evaluated. In other words, any

positive or negative effects on cattle bTB incidents detected in future years will be attributable to a combination of policies and not to badger culling alone.

In the first round of culling in the Somerset and Gloucestershire intervention areas in 2013, the target of reducing the pre-cull population by at least 70% was not achieved (Independent Expert Panel, 2014). This means culling conducted in 2013 is unlikely to have been as effective as that conducted in the RBCT and may have had an adverse effect on cattle bTB if it led to greater badger movement and transmission of infection. Initial analysis of the data for the first year of the intervention has not demonstrated any significant association between culling on cattle bTB incidence in the first year, either in the central or buffer areas of the intervention areas. However, as only two intervention areas have been licensed to date, and only a single years' worth of follow-up data is available for analysis here, it is so far unwise to draw any firm conclusions about the impact of the badger culls on cattle bTB incidence. Additionally, this analysis does not include an exploration of other factors related to bTB incidence which may influence the association between the intervention and bTB incidence. A more robust multivariable analysis which explores the effect of other bTB risk factors will be considered once more data is available. It is also likely that there will be a time lag between any effect due to badger removal leading to decreased transmission of infection and any observable reduction in bTB incidence in cattle (More et al 2007).

The descriptive analysis showed different distributions of bTB incidents in the two intervention areas, with incidence being generally lower in the Gloucestershire intervention area than in the comparison areas, but higher in the Somerset intervention area than in the comparison areas. These differences, however, can be observed across all time periods, and so cannot be attributed to the effect of culling.

The results of the RBCT indicated that an increase in cattle bTB incidence could be expected in the buffer areas due to perturbation of the badger population (Donnelly et al 2006; Woodroffe et al 2006). This has not been observed in this analysis, as no effect of intervention on the number of OTF-W incidents in the buffer areas was detected. As highlighted previously though, it is likely that there is currently insufficient power in the study to detect any effect (Donnelly et al 2015).

A reduction in number of reactors in 2014 compared with 2013 was described by Blowey et al (2015a & 2015b). Although slightly different time periods were examined (Blowey et al considered the whole of 2014 which will have included the second round of culling, not the 12 months following the initial culls as considered here), no evidence for a decrease in the number of reactors was observed in this analysis. Almost no difference was observed in the median number of reactors per incident in the intervention areas when comparing across time periods. Some small changes in the interquartile ranges might indicate that some outlier numbers have been removed. This could be indicative of individual herds, which have had a large number of reactors historically, becoming clear of bTB. At a herd population level though, no difference was observed.

Culling licences have been limited to the high risk areas for cattle bTB in England, which are subject to annual testing (Defra 2014). The selection of ten comparison areas per intervention area was a balance between the need for geographic proximity and similarity in other pre-cull factors and the need for adequate comparison data. Comparison areas are likely to be lost if and when licences are issued for new culling areas, as explained in the Introduction.

Although a trial randomising culling to different areas would be the most rigorous design for the evaluation of the effect of the current badger culling policy, this type of design is not possible when the areas where culling is conducted are selected by stakeholders. The long-term value of information from monitoring industry-led culling will depend on the conduct of the cull, the number of areas eventually licensed and the extent to which other bTB control policies remain stable. The results presented here provide some preliminary information as to the impact of the first year of the badger culls in Somerset and Gloucestershire. Continued delivery of the intervention in these areas, and further roll out of the intervention to other areas will enable better assessments to be made of the impact of culling on bTB incidence in cattle.

Acknowledgements

This work was funded by Defra research project SE3131. The contributions of Dr Jennifer Broughan, Joanna Lawes, Adam Brouwer, Heather O'Connor, Dr Anthony Goodchild and Prof. Glyn Hewinson (APHA) are gratefully acknowledged.

References

- AHVLA (2014) The efficacy of badger population reduction by controlled shooting and cage trapping, and the change in badger activity following culling from 27/08/2013 to 28/11/2013. Report to Defra 6th February 2014.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300385/ahvla-extension-efficacy.pdf Accessed July 13, 2015.
- Blowey R., Gray C., Griffiths J., Rowe J. (2015a) Bovine TB in the pilot badger cull zone in Gloucestershire. *Veterinary Record* 176: 260.
- Blowey R., Gray C., Griffiths J., Rowe J. (2015b) Bovine TB in the pilot badger cull zone in Gloucestershire. *Veterinary Record* 176: 527-528.
- Defra (2012) Pilot areas confirmed. Press release 19 January 2012
<https://www.gov.uk/government/news/pilot-areas-confirmed>. Accessed May 2, 2014.
- Defra (2013) Guidance to Natural England Licences to kill or take badgers for the purpose of preventing the spread of bovine TB under section 10(2)(a) of the Protection of Badgers Act 1992
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/69464/pb13692-bovinetb-guidance-ne.pdf. Accessed May 2, 2014.
- Defra (2014) Defra response. Pilot badger culls in Somerset and Gloucestershire: Report by the Independent Expert Panel.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300424/pb14158-defra-response-independent-expert-panel.pdf. Accessed April 8, 2014.
- Donnelly CA, Woodroffe R, Cox DR, Bourne J, Gettinby G, Le Fevre AM, McInerney JP, Morrison WI. (2003) Impact of localized badger culling on tuberculosis incidence in British cattle. *Nature* 2003 Dec 18; 426(6968):834-7. Epub 2003 Nov 23.

Donnelly C.A., Woodroffe R., Cox D.R., Bourne F.J., Cheeseman C.L., Clifton-Hadley R.S., Wei G., Gettinby G., Gilks P., Jenkins H., Johnston W.T., Le Fevre A.M., McInerney J.P., Morrison W.I. (2006) Positive and negative effects of widespread badger culling on tuberculosis in cattle. *Nature* 439:843-846.

Donnelly CA, Wei G, Johnston WT, Cox DR, Woodroffe R, Bourne FJ, Cheeseman CL, Clifton-Hadley RS, Gettinby G, Gilks P, Jenkins HE, Le Fevre AM, McInerney JP, Morrison WI (2007) Impacts of widespread badger culling on cattle tuberculosis: concluding analyses from a large-scale field trial. *Int J Infect Dis.* 11(4):300-8.

Donnelly C. A., Bento A. I., Goodchild A. V., Downs S. H. (2015) Exploration of the power or routine surveillance data to assess the impacts of industry-led badger culling on bovine tuberculosis incidence in cattle herds. *Veterinary Record* (In Press).

Downs, S. H., Clifton-Hadley, R. S., Upton, P. U., Milne, I., Ely, E., Gopal, R., Goodchild, A. V., Sayers, A. R. (2013) Tuberculin manufacturing source and breakdown incidence rate of bovine tuberculosis in British cattle, 2005-2009. *Veterinary Record* 172(4): 98.

Independent Expert Panel (2014) Pilot badger culls in Somerset and Gloucestershire. Report by the Independent Expert Panel.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300382/independent-expert-panel-report.pdf. Accessed July 22, 2015.

Independent Scientific Group (2007). Bovine TB: The Scientific Evidence – Final Report of the Independent Scientific Group on Cattle TB. Defra Publications, London HMSO.
http://webarchive.nationalarchives.gov.uk/20090330154646/www.defra.gov.uk/animalh/tb/isg/pdf/final_report.pdf. Accessed July 22, 2015.

More, S. J., Clegg, T. A., McGrath, G., Collins, J. D., Corner, L. A. L., Gormley, E. (2007) Does reactive badger culling lead to an increase in tuberculosis in cattle? *Veterinary Record* 161(6):208-209.

Paterson O. 2014 House of Commons, Statement on strategy for eradication of bovine TB: Hansard: 3 April 2014: Column 1034.

Woodroffe R., Donnelly CA, Cox DR, Bourne FJ, Cheeseman CL, Delahay, RJ, Gettinby, G, McInerney JP and Morrison WI (2006) Effects of culling on badger *Meles meles* spatial organization: implications for the control of bovine tuberculosis. *Journal of Applied Ecology.* 43: 1-10.

Woodroffe R. (2015) Bovine TB in the pilot badger cull zone in Gloucestershire. *Veterinary Record.* 176: 258.