## <u>The Randomised Badger Culling Trial (Proactive & Reactive culling)</u>

1. The Krebs Review[1] on Bovine TB in Cattle and Badgers reported in 1997 and concluded that despite there being *"compelling"* evidence that badgers were involved in transmitting infection to cattle, the development of a control policy was made difficult because the effectiveness of badger culling could not be quantified with the data available. It therefore recommended that a large-scale field trial - the Randomised Badger Culling Trial (RBCT) - be set up to quantify the impact of culling badgers on incidence of TB in cattle, and to determine the effectiveness of strategies to reduce the risk of a TB cattle herd breakdown.

2. The Independent Scientific Group on Cattle TB (ISG), which included several members of the Krebs Review group, was formed in 1998 to plan and subsequently provide independent oversight of the RBCT. It also provided advice on the content and direction of Defra's (then MAFF's) TB research programme. The ISG published their Final Report on 18 June 2007[2].

3. The RBCT represents nearly 10 years of work (1998-2007) and nearly £50 million of taxpayer investment. The results of this robust experimental trial are fully published and peer-reviewed and represent the most substantial and coherent evidence base for the evaluation of badger culling. The trial was conducted in thirty x 100km^2 areas of South west and Central England, each located in a high-risk area for cattle TB. The 30 areas were grouped into 10 sets of three, each called a triplet (see **Figure 1**). Within each triplet, one area was subjected to repeated (approximately annual) culling across all accessible/consent land (**proactive culling**), and in one area the badgers were culled on a single occasion locally on and near farmland where recent outbreaks of TB had occurred in cattle (**reactive culling**). The remaining area received no culling (**survey only**) and acted as an experimental control with which the culling areas could be compared. Participating farmers were aware of the treatment being applied to their area (i.e. they were not blinded).
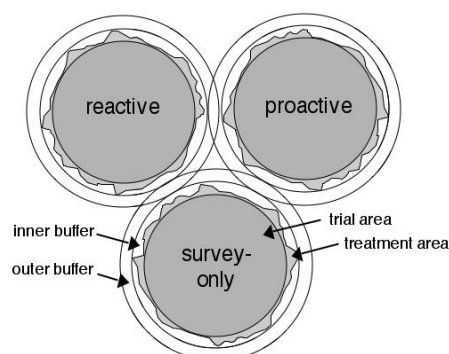
Figure 1. Schematic representation of trial areas in a triplet

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[1] Krebs, J.R., Anderson, R., Clutton-Brock, T., Morrison, I., Young, D., Donnelly, C., Frost, S., & Woodroffe, R. 1997. *Bovine tuberculosis in cattle and badgers.* H.M.S.O., London.
[2] Bourne, J., Donnelly, C.A., Cox, D.R., Gettinby, G., McInerney, J.P., Morrison, W.I., & Woodroffe, R. 2007. *Bovine TB: the scientific evidence* Defra www.defra.gov.uk/animalh/tb/isg/pdf/final_report.pdf, London.

4. The ISG's final report explicitly states that badgers contribute significantly to the disease in cattle. They also confirm that there is a dynamic cycle of infection between cattle and badgers, identifying that in the circumstances where TB in cattle is not being routinely controlled (e.g. during the Foot & Mouth Disease – FMD - outbreak in 2001) there was a rise in TB prevalence in both species. The final report concludes that it is unrealistic to envisage elimination of disease from some of the high TB incidence areas of the country in anything other than the very long term. This was seen as a consequence of failure to remove all infected cattle from some farms because of weaknesses with the testing regime (e.g. poor sensitivity of the tuberculin skin test, and the need for increased pre-movement testing and more extensive use of the gamma-interferon blood test – the latter two were introduced as Defra policies in 2006) and reintroduction of disease by badgers.

5. One of the conclusions the ISG reached at an early stage was that because not all badgers had been caught after the trial had started, it would not be possible to accurately quantify the relative importance of badgers and cattle in transmitting infection (as the trial as envisaged by Krebs was originally intended to do) and so the objective of the trial changed to an assessment of policy options for culling (see ISG first report[3]). However there is evidence from the RBCT that at least 40-50% of cattle herd breakdowns were due to badgers in high incidence areas (the effect seen in the core of proactively culled areas).

Results of the RBCT

6. It is important that when we use a figure from a scientific study to make predictions about what we expect to see in the future we recognise the statistical uncertainty that is associated with that figure. The easiest way to do this is by including a confidence interval (CI, see **Box 1**). The width of the confidence interval is related to the precision of the estimate, it indicates the range in which we can be confident that the true figure lies.

Box 1: The interpretation of p-values and confidence intervals

These are ways of showing whether an effect is statistically significant. The p-value is the probability that you would see an effect of this size or larger if the treatment (in this case culling) had no effect. Usually, a p-value below 0.05 (which is equivalent to 5%) is interpreted as statistically significant and a p-value above 0.05 is not. However, this 5% threshold is a scientific convention and therefore somewhat arbitrary. The lower the p-value, the more confident one can be that the effect is 'real'.

A 95% confidence interval for a particular figure is the range of values within which one can be 95% confident that the 'true' figure lies. Whether zero is included in the interval is used to judge whether the figure is significantly different from zero. For example, if the figure is an estimation of the size of a beneficial effect, the benefit can be said to be statistically significant if the 95% confidence interval does not include zero. Again, 95% is an arbitrary figure but is accepted by convention as the normal level of confidence to use.

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[3] Bourne, FJ., Donnelly, CA., Cox, DR., Gettinby, G., McInerney, JP., Morrison, WI., Woodroffe, R. *Towards a sustainable policy to control TB in cattle – A scientific initiative.* 1998. First report of the Independent Scientific Group on cattle TB.

Proactive culling

7. The RBCT measured the effects of proactive culling in two regions: an inner core area where culling actually took place ('culling area') and an approximately 2km wide ring just outside the cull area where no culling took place, but effects on bTB incidence in cattle were seen (2km ring). 'Survey-only areas' are areas used for comparison, with efforts made to use areas that were similar in most respects except for the fact that culling did not take place there.

8. In the RBCT, annual proactive culling over 4-7 years (due to the gradual recruitment of study areas and the interruption from the 2001 FMD outbreak) on accessible land in ten 100 km^2 areas was associated with a 23.2% decrease (95%CI: 12.4% decrease to 32.7% decrease) in confirmed TB herd incidence inside culling areas when compared with survey-only areas. However, proactive culling was also associated with a 24.5% increase (95%CI: 0.6% decrease to 56.0% increase) in confirmed TB herd incidence in the 2km ring when compared with survey-only areas[4,5].

9. The ISG hypothesised[6] that the increase in TB incidence observed in the 2km ring was a result of changes in badger behaviour brought about by culling. Badgers typically live in social groups of 4-7 animals, with defined territorial boundaries. Culling disrupts the organisation of these social groups, which causes surviving badgers to range more widely than they would normally and come into contact more often with other animals (including both cattle and other badgers). This is called **perturbation**. This increased ranging is thought to be behind the increase in bovine TB prevalence in badgers in the 2km ring. Therefore, although total badger numbers were significantly reduced by culling in the trial, the probability of bovine TB being transmitted from the remaining infected badgers to cattle increased in the short term, particularly at the edge of a culled area. This is known as the **'perturbation effect'**.

10. Since the end of the RBCT, regular (6 monthly) monitoring has continued in the proactively culled and survey-only areas **(Figure 2)**. For the majority of triplets (date of last cull ranges from May to October 2005) we now have data on cattle TB incidence for five years after culling stopped (described in Jenkins *et al.* 2010 as four years post-trial data, which is taken to start one year after the last cull). From the start of the post-trial period to 2 July 2010, incidence of confirmed TB breakdowns in the proactive culling areas was 34.1% lower (95%CI: 23.0% decrease to 43.6% decrease) than in survey only areas, and in the 2km ring outside proactive trial areas was 5.6% lower (95%CI: 31.0% decrease to 29.1% increase) than outside survey-only areas. **Therefore, the positive impacts on herd breakdowns of culling were maintained over a period of time while the**

[4] Donnelly, C.A., Woodroffe, R., Cox, D.R., Bourne, F.J., Cheeseman, C.L., 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 cattle tuberculosis.* Nature, 439, 843-846.

[5] Donnelly, C.A., Wei, G., Johnston, W.T., Cox, D.R., Woodroffe, R., Bourne, F.J., Cheeseman, C.L., Clifton-Hadley, R.S., Gettinby, G., Gilks, P., Jenkins, H.E., Le Fevre, A.M., McInerney, J.P., & Morrison, W.I. (2007). *Impacts of widespread badger culling on cattle tuberculosis: concluding analyses from a large-scale field trial.* International Journal of Infectious Disease, 11, 300-308.

[6] Woodroffe, R., Donnelly, CA., Woodroffe, R., Cox, DR., Bourne, FJ., Cheeseman, CL., Delahay, RJ, Gettinby, G., McInerney, JP., Morrision, 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.

early negative effect on confirmed herd breakdowns on surrounding land disappeared relatively quickly. We cannot be sure exactly when this happened, but the first data-point in the post-trial period is calculated from cattle incidence data from 12-18 months after culling stopped and shows no detrimental effect.
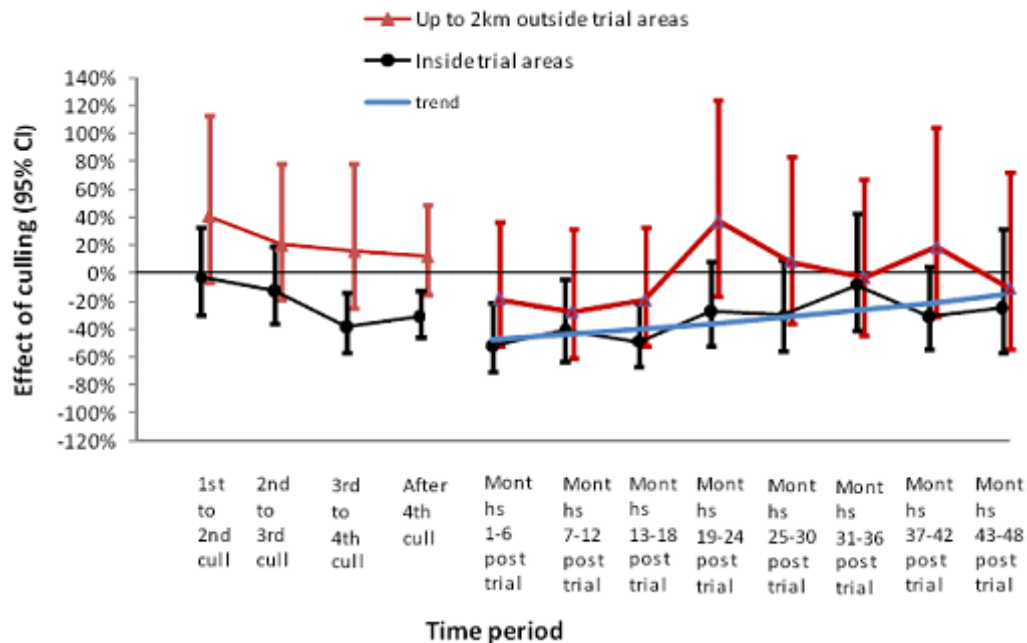
Figure 2. Estimated effects of proactive culling on the incidence of confirmed cattle TB breakdowns inside trial areas and up to 2km outside trial area boundaries. The estimated effects of proactive culling are stratified by time periods defined by the timings of the culls during the trial, and by 6-month periods from 1 year after the last proactive cull (post-trial period)[7].

11. Overall, from the first cull to 5 years after the last cull (i.e. up to July 2010) there was a 28.3% reduction (95%CI: 20.9% decrease to 35.0% decrease) in TB confirmed cattle herd incidence in culling areas when compared with survey-only areas. Confirmed TB herd incidence in the 2km ring was comparable with that in survey-only areas (9% increase in incidence, 95%CI: 15.5% decrease to 40.7% increase)[8,9]. **Table 1** describes the effects of culling on TB cattle herd breakdowns seen both during the culling period, for 5 years after the last cull and from the first cull to 5 years after the last cull.

[7] Figure produced from data in Donnelly, CA., Jenkins, HE & RW Woodroffe. 2010. *Analysis of further data (to 2 July 2010) on the impacts on cattle TB incidence of repeated badger culling.* PLoS ONE comment. http://www.plosone.org/annotation/listThread.action?inReplyTo=info%3Adoi%2F10.1371%2Fannotation%2Fae30 e6f1-2ad2-4b9d-88c1-cbb11a3d4619&root=info%3Adoi%2F10.1371%2Fannotation%2Fae30e6f1-2ad2-4b9d-88c1-cbb11a3d4619 Last accessed 22.07.10. Figure used with the authors permission and subject to the conditions of the Creative Commons Attribution Licence (http://creativecommons.org/licenses/by/3.0/).
[8] Jenkins, HE., Woodroffe, R., Donnelly, CA. 2008. *The effects of annual widespread badger culls on cattle tuberculosis following the cessation of culling.* International Journal of Infectious Disease 12: 457–465.
[9] Jenkins, HE., Woodroffe, R & Donnelly, CA. 2010. *The duration of the effects of repeated widespread badger culling on cattle tuberculosis following the cessation of culling.* PLoS ONE. 5(2): e9090, DOI:10.1371/journal. pone.0009090.

	First cull to one year after the last cull	One year after the last cull to 2 July 2010	First cull to 2 July 2010 (during- and post-trial periods combined)
Inside 100km^2 proactively culled trial areas	-23.2% (-32.7% to -12.4%)	-34.1% (-43.6% to -23.0%)	-28.3% (-35.0% to -20.9%)
Adjoining lands ≤ 2km outside culled trial areas (not culled)	+24.5% (-0.6% to +56.0%)	-5.6% (-31.0% to +29.1%)	+9.0% (-15.5% to +40.7%)

Table 1. *Comparison of estimates of overall effects of proactive badger culling on the incidence of confirmed cattle TB breakdowns on lands inside and up to 2km outside trial areas derived from successive analyses of RBCT data reported in July 2010 (95%CI in brackets).*

12. The ISG report, and more recent papers on post-trial analyses, consider the likely effects of an increase in the size of the culled area. As the cull area increases (assuming it is circular) it also increases in size relative to the 2km-wide unculled ring, so the overall effects of the culls become increasingly dominated by the effects in the culled area rather than the surrounding unculled ring. These estimates assume that effects are consistent throughout affected areas. **Jenkins *et al*. (2010) show that to be 97.5% confident that culling will be beneficial it must be carried out over an area of at least 141km^2** (see **Figure 3**). This figure is derived from data collected up to July 2009. There is no empirical evidence from an experimental study covering an area of this size.

13. The estimates of overall effects of proactive badger culling on the incidence of confirmed cattle TB breakdowns on land inside and up to 2km outside trial areas were translated by the ISG into estimates of absolute numbers of herd breakdowns prevented and caused by proactive culling. **This crucially depends on a number of starting assumptions including the initial confirmed cattle herd TB incidence per annum, the density of cattle herds in any area and the size of the area culled.**
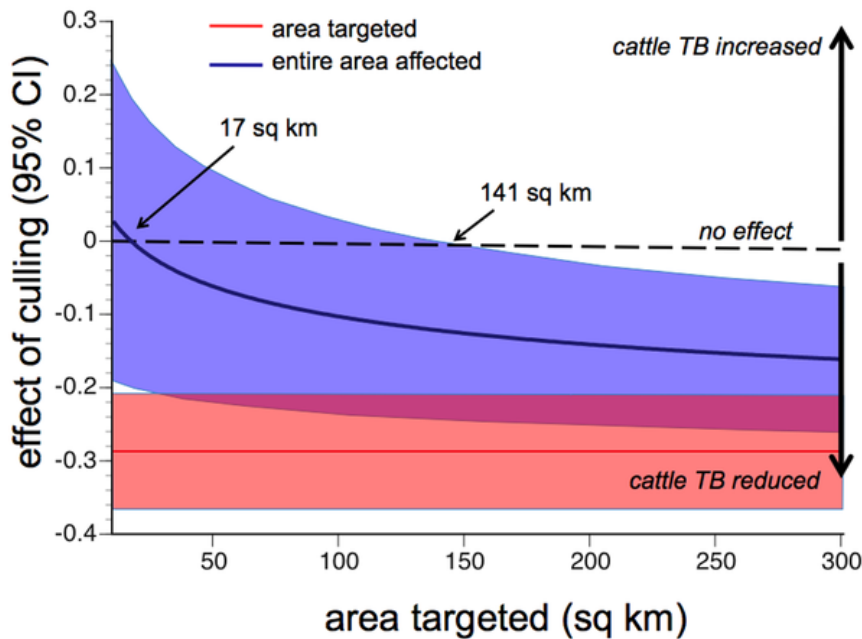
Figure 3. Extrapolation of overall effects to culling areas of different sizes. The blue area shows the 95% confidence interval for the overall impact (combining the impact inside the targeted area with that seen $2km^2$ outside) of different sized circular culling areas. The red area shows the impact inside the targeted area only. The estimated overall effect is of increased incidence for areas smaller than $17km^2$, moving to a decreased incidence when areas larger than $17km^2$ are targeted. The effect of decreased overall incidence is statistically significant for areas larger than $141km$[9].

14. Jenkins *et al* (2010)[9] estimated the overall number of breakdowns that would be prevented both during, and after, a 5-year proactive cull - as carried out in the RBCT. Based on annual culling over an idealised circular culling area of $150km^2$, with an average of 1.25 herds per km^2 and a background incidence rate of 0.08 confirmed breakdowns/herd/annum, five years' proactive culling would be expected to prevent 17.4 out of 75 breakdowns inside the culled area (a 23.2% reduction), while prompting 12.1 additional breakdowns on adjoining land (a 24.5% increase), giving an overall total of 5.3 breakdowns prevented. In the 2.5 years following culling, 15.8 breakdowns inside the culled area would be prevented (a 42.0% reduction), and 1.5 prevented on adjoining land (a 6.0% reduction), giving overall total of 17.3 breakdowns prevented. Hence, the total impact of culling such an idealised area would be to prevent 22.6 out of 187 breakdowns over 7.5 years.

15. The cost saving per breakdown prevented was then compared to the annual cost of conducting a cull to look at the overall cost effectiveness of a culling strategy. This constitutes a saving of £610,200 at £27,000/breakdown. For comparison, the cost of conducting five annual culls over a 150 km^2 area, 75% of which was accessible for culling, is estimated as £2.14 million for cage-trapping (as undertaken in the RBCT) at £3,800/km^2/year, or £1.35 million for snaring or gassing at roughly £2,400/km^2/year. The predicted annual cost of a farmer-led culling operation is estimated to be around £562,500 at £1,000/km^2/year.

16. Overall, the numbers of breakdowns prevented during and after culling were found not to be sufficient to offset the financial costs of conducting the culls (as

done in the RBCT by Government operatives).   Both the ISG and former-members of the ISG who co-authored later papers that presented post-trial analyses (ex-ISG vice-Chair Prof. Christl Donnelly and Prof. Rosie Woodroffe) concluded that, *"These results combined with evaluation of alternative culling methods, suggest that badger culling is unlikely to contribute effectively to the control of cattle TB in Britain"*[2, 8, 9].

17. These findings were found to be broadly consistent with those of a recent analysis by Wilkinson *et al* (2010) which assessed the potential financial outcomes of badger culling by combining a transmission model and data on costs and benefits, where cage-trapping of 70% badgers produced a net economic loss in all simulations, with these losses being greater than those associated with the other culling options considered (shooting, free-ranging badgers, snaring and gassing). The authors concluded, *"Model results strongly indicate that although, if perturbation were restricted, extensive badger culling could reduce rates in cattle, overall an economic loss would be more likely than a benefit."*[10]

18. However, recently published modelling work by Donnelly & Hone (2010)[11] using the RBCT data indicated that only 3.4% of herds would be expected to have a breakdown in a year where there was no disease transmission from infected badgers and concluded, "TB in cattle herds could be substantially reduced, possibly even eliminated, in the absence of transmission from badgers to cattle."

Using the results the RBCT to estimate the effects of culling under different circumstances

19. Given the different effects inside and outside the culled area it is desirable to have a figure describing the overall effect. By extrapolating from the results of the RBCT, it is possible to estimate the **average net effect of culling on confirmed cattle TB herd breakdowns** for a range of scenarios (i.e. by varying the size of the culled area, cattle herd density and annual herd incidence in both the culling area and adjacent ring). This is done by working out the number of breakdowns saved and gained over a nine year period (with five annual culls), as described in paragraphs 13 and 14.

20. As an illustrative example, using the most up-to-date figures from the RBCT post-trial analyses (i.e. the average effect of culling on confirmed herd breakdowns up to 2 July 2010, see **Table 1**)[12] and assuming an initial cattle TB incidence of 0.15 confirmed new incidents (CNIs) per km^2 within the 150km^2 area and 0.10 CNIs per km^2 in the neighbouring area, which is consistent with the Veterinary Laboratories Agencies recent estimates of incidence in the worst affected TB

[10] Wilkinson, D., Bennett, R., McFarlane, I., Rushton, S., Shirley, M & Smith, GC. (2009). *Cost-benefit analysis model of badger (*Meles meles*) culling to reduce cattle herd tuberculosis breakdowns, with particular reference to badger perturbation*, Journal of Wildlife Diseases 45: 1062-1088.

[11] Donnelly, CA & Hone, J. (2010). *Is there an association between levels of bovine tuberculosis in cattle herds and badgers?* Statistical Communications in Infectious Diseases 2 (1).
http://www.bepress.com/scid/vol2/iss1/art3/

[12] Donnelly, CA., Jenkins, HE & RW Woodroffe. 2010. *Analysis of further data (to 2 July 2010) on the impacts on cattle TB incidence of repeated badger culling.* PLoS ONE comment.
http://www.plosone.org/annotation/listThread.action?inReplyTo=info%3Adoi%2F10.1371%2Fannotation%2Fae3
0e6f1-2ad2-4b9d-88c1-cbb11a3d4619&root=info%3Adoi%2F10.1371%2Fannotation%2Fae30e6f1-2ad2-4b9d-
88c1-cbb11a3d4619 Last accessed 22.07.10.

areas, the effects of culling can be estimated in a 150km^2 circle plus 99km^2 area within the 2km ring boundary. Five years' proactive culling would be expected to prevent 26.1 out of 112.5 breakdowns inside the culled area (a 23.2% reduction), while prompting 12.2 additional breakdowns on adjoining land (a 24.5% increase), giving an overall total of 13.9 breakdowns prevented. In the years following culling, 30.7 breakdowns inside the culled area would be prevented (a 34.1% reduction), and 2.2 prevented on adjoining land (a 5.6% reduction) giving an overall total of 32.9 breakdowns prevented. Hence the total impact of culling such an idealised area would be to prevent 46.8 out of 292 breakdowns over 9 years and **the net benefit of culling is a 16.0% reduction (95%CI: 7.9% decrease to 24.2% decrease) in TB cattle herd incidence over the entire 249km^2 area (150km^2 culled area and 99km^2 adjacent 2km ring)**. This estimate may change slightly as we continue to collect and analyse more data from RBCT areas and will vary according to what starting assumptions are made about the size of the culled area, initial herd incidence per annum and the density of cattle herds.

21. A range of possible scenarios is considered in **Table 2** below. The overall size of the effect depends on the balance between the effects in the culled area and those in the adjacent 2km ring. In turn, each of these effects depend on the size of the area and background levels of TB, which may not be the same in the culled area and in the adjacent 2km ring.

22. It must be noted that these figures are derived from the effect observed in the RBCT and depend upon a number of assumptions. For example, it is assumed that the size of the average effect of culling over 100km^2 areas in the RBCT will scale to areas of a different size and that different herd densities and annual incidence are affected by culling in the same way, and that these effects are consistent across the entire culled area or adjacent ring. There is no empirical evidence from an experimental study investigating the effect of culling over these various scenarios.

Size of area	TB Confirmed New Incidents (CNIs) in the culled area per km per year/ *TB CNIs in 2km ring per km per year*[13]		
	0.10/*0.10**	0.15/*0.10***	0.085/*0.046*†
150 km^2 (*surrounding area is 99 km^2*)	-12.4% (-21.8% to -3.1%)	-16.0% (-24.2% to -7.9%)	-17.7% (-25.4% to -10.0%)
300 km^2 (*surrounding area is 135.4 km^2*)	-15.9% (-24.1% to -7.7%)	-19.0% (-26.4% to -11.6%)	-20.4% (-27.5% to -13.2%)

Table 2: The <u>estimated average net effect</u> of proactive badger culling on the incidence of confirmed cattle TB breakdowns culling over a range of scenarios. Figures in italics correspond to the 2km ring.

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[13] * As used in the example reported in Jenkins *et al.* (2010)
**VLA most recent estimates of incidence in the worst affected areas in England
†Average initial incidence observed in the RBCT

23. Using the method described above, the Welsh Assembly Government estimated an overall net benefit of culling over a six year period (five annual culls plus one year post-cull) over a 125km^2 circle with 91km^2 area within the 2km boundary as 9% (using figures and assumptions from Jenkins *et al.* 2008). Again, it should be noted that these are theoretical calculations based on an idealised circular culling area and are dependent on a range of factors including herd density and TB cattle herd incidence.

24. These estimates are based on the <u>average effects</u> observed in the RBCT (i.e. those listed in Table 1). The RBCT provides evidence on what factors must be taken into account when designing a proactive culling strategy to maximise its chance of having a beneficial effect. What is seen in reality will depend on this range of factors that have an influence on how effective the culling strategy is and how well the perturbation effect is controlled for, including:

   ▪ cattle herd size;
   ▪ density of badgers;
   ▪ badger TB prevalence;
   ▪ culling efficacy (number of badgers caught/time caught in);
   ▪ land access;
   ▪ coordination of the culling effort; and
   ▪ barriers to badger movement.

   This is discussed further in paragraphs 33-39 below.

   Reviewing the RBCT results and the ISG's conclusions

25. The large number of biases inherent in any field trial makes interpretation of the results generated from them difficult. The ISG's final conclusion (on top of the difficulties of the reactive cull result – see below) has been subject to much debate and, at the request of both the then Defra Secretary of State and Chief Scientific Advisers Professors Howard Dalton and Robert Watson respectively, three groups were asked to review findings from the RBCT:

   a. the Godfray Review[14], set up in 2003 to review the progress in the RBCT subsequent to the delays due to FMD in 2001-02. During the review the reactive cull part of the RBCT was stopped because of the adverse effect on herd breakdowns seen;

   b. a small group of experts chaired by Sir David King[15] (at that time the government Chief Scientific Adviser) immediately following publication of the ISG Final Report in 2007; and

   c. the bTB Science Advisory Body chaired by Prof. Quintin McKellar, Principal of the Royal Veterinary College, were asked to advise on the scientific conclusions presented in the Jenkins et al (2010) paper shortly after its

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[14] Godfray, CJ., Curnow, RN., Dye, C., Pfeiffer, D., Sutherland, WJ., Woolhouse, MEJ. 2004. *Independent Scientific Review of the Randomised Badger Culling Trial and Associated Epidemiological Research*. HMSO.
[15] King, D., Roper, T.J., Young, D., Woolhouse, M.E.J., Collins, D.A., & Wood, P. (2007). *Tuberculosis in cattle and badgers: a report by the Chief Scientific Adviser, Sir David King* http://www.dius.gov.uk/publications/experts%20advice%20on%20badgers%20and%20cattle%20TB.pdf, London.

publication in March 2010. This review was led by the Epidemiology & Wildlife Risks Programme Advisory Group (a sub-group of TB Science Advisory Body, chaired by Prof. Dirk Pfeiffer, an eminent veterinary epidemiologist based at the Royal Veterinary College)[16].

a. The Godfray Review

26. Professor Charles Godfray and his expert panel were asked to review the progress of the RBCT and associated epidemiological research, to advise on the prospects for the projects achieving their objectives and the time-scales involved, and to comment on how the results inform Defra policy-making. At the time a number of factors, including delays in training skilled staff and the Foot and Mouth Disease epidemic of 2001 had delayed the RBCT, which was running about two years behind schedule, and during the review the reactive treatment of the RBCT was suspended after it appeared to be leading to an increased risk of TB in cattle.

27. Godfray advised that continuation of the <u>proactive treatment</u> of the RBCT would achieve the statistical target of distinguishing whether or not proactive culling can reduce the incidence of herd breakdowns by 20%, with 90% confidence, sometime between late 2004 and early 2008 and that the ISG should be fully supported in their continuing work with the trial. The panel expressed the difficulty of generalising the result from one culling method to others that might be implemented as a national policy option. Godfray recommended that pending more detailed analysis of the data, the results from the <u>reactive treatment</u> should neither be viewed as evidence for the perturbation hypothesis nor as evidence for or against the role of badgers in bovine TB transmission. Similarly, the results at the time the treatment was halted should not be interpreted as evidence against (or, of course, for) a reactive culling policy. The report recommended that Defra bovine TB policy be developed on the assumption that badgers are a significant wildlife reservoir for the disease, but also acknowledged that the RBCT may not settle once and for all the question of badger involvement in bovine TB transmission.

b. Sir David King's review

28. Sir David King's group only considered, *"scientific issues relating to the role that badger culling could play in controlling and reducing levels of cattle TB in England,"* and did not include an assessment of the cost-effectiveness of introducing such a policy. The group included five independent experts from various fields of biology, including ecology, immunology, epidemiology, microbiology and veterinary medicine, who had extensive experience of the issues surrounding the epidemiology and control of bovine TB.

29. The King report endorsed the ISG's conclusion that badgers are a clear source of infection for cattle, but it did <u>not</u> endorse the conclusion that the removal of badgers cannot meaningfully contribute to the control of cattle TB in England.

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[16] Pfeiffer (2010). *Review of Jenkins et al. (2010) The duration of the effects of repeated widespread badger culling on cattle tuberculosis following the cessation of culling. PLoS ONE (5)2: e9090.*

The King report concluded that **removal of badgers from areas of the country where there is high and persistent incidence of TB in cattle was the best option available to reduce the reservoir of infection in badgers and that this should take place alongside the continued application of cattle controls**. Like many other review groups, including those led by Krebs and Godfray, it also concluded that in the longer term, alternative or additional means of controlling TB in badgers, such as vaccination, may become available and that research into these should continue.

30. The ISG published a response[17] to the report and subsequently met with Sir David King to discuss his concerns. Whilst the groups did not resolve their disagreement over the potential future role of culling to control bovine TB in England, they did agree on a number of conditions that a culling strategy must meet in order to maximise its chance of having a beneficial effect on incidence of TB cattle herd breakdowns (paragraphs 33-39 below). The main conclusions of the two reports differ because the ISG concluded that it was not practically or economically feasible to carry out culling on the scale necessary to gain beneficial effects, whereas Sir David King's group did not include the costs of culling in their considerations.

c.   bTB SAB – sub-group review

31. Prof. Pfeiffer's review was restricted to the Jenkins et al. (2010) paper that presented the most recent RBCT data on the duration of effects of repeated badger culling on cattle TB after culling stopped in the trial areas. He concluded that as the analysis was based exclusively on RBCT data, any conclusions are only informed by one particular, spatially and temporally limited culling operation. **Therefore, extrapolation of the results to other circumstances, or the viability of culling as part of a strategy involving other measures (e.g. vaccination) is highly speculative and it is not possible to infer from these data the potential use of culling in combination with, or followed by, other possible interventions such as badger or cattle vaccination.** However, information from this and other studies could be used in dynamic models to predict the impact of different methods of TB control.

32. On the economic analyses presented in the paper, Pfeiffer's group emphasised that the authors focused on the cost effectiveness of culling as carried out in the RBCT (i.e. one particular, spatially and temporally limited culling operation carried out and paid for by Government) and ignored the uncertainty associated with estimates of the effect of culling on confirmed TB breakdowns in cattle, as well as of the various cost/benefit values, which had to be based on assumptions. Furthermore, they highlighted that the ISG's conclusion that culling is not cost effective is based solely on a consideration of immediate costs and benefits – no account being taken of potential long-term costs and benefits.

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[17] Bourne, J., Donnelly, C.A., Cox, D.R., Gettinby, G., McInerney, J.P., Morrison, W.I., & Woodroffe, R. (2007). *Response to "Tuberculosis in Cattle & Badgers: A report by the Chief Scientific Advisor."* *http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/isg/documents/isg-responsetosirdking.pdf*

Results from the RBCT that can inform a culling strategy

33. Despite the debate around the validity of the ISG's conclusion relating to the cost effectiveness of culling, evidence from the RBCT can be used to help identify factors that must be taken into account when designing a proactive culling strategy to maximise its chance of having a beneficial effect.

34. **Culling in areas where there is a high and persistence level of bovine TB in cattle**. Areas of England (SW and Midlands) and Wales that show high incidence of TB in cattle also have high numbers of badgers, and TB is considered to be endemic here with clustering of the same strains of *M. bovis* being found in both species[18]. In the RBCT it was estimated that 40-50% of cattle TB could be attributed to a badger source (paragraph 5 above).

35. **Four consecutive annual removal operations appear to be the minimum needed to give overall beneficial results on a local scale.** The ISG showed in the RBCT that the benefits of culling did not start to outweigh the disbenefits until the fourth annual cull had taken place. Although it had been intended that one removal programme should take place each year in each proactive trial area annually for 5 years, in practice, most of the areas had five removal operations (range 4 to 7) over 5 or 6 years (range 4 to 8 years). Furthermore, the trial was interrupted by the outbreak of Foot and Mouth Disease in 2001 and analysis was complicated further by the subsequent disruptions to TB testing. **The beneficial effect on incidence of confirmed TB herd breakdowns appeared to increase with repeated removals** (11.2% increase with each removal during the life of trial), suggesting the biologically plausible conclusion that continuing to remove badgers beyond four years may increase the benefits further. Whilst on-going annual culls might well have further benefits in terms of reduced incidence of TB breakdowns within culled areas, there would be further costs associated with the additional culls.

36. **Culling should be delivered in a co-ordinated manner and done as completely and efficiently as possible**. The only data in terms of **participation rate** for culling and land coverage are from the RBCT. Across the 10 proactive treatment areas, 70% of the land inside proactive treatment areas was directly accessible for culling (range 50-87%). **Culling efficacy** (i.e. the proportion of the badger population removed) in each of the proactive removal trial areas during the RBCT was around 70% (measured indirectly from field signs[19] and by modelling carried out by FERA[20]). Any future culling would need to remove at least this many badgers to achieve the reductions seen in herd incidence during the RBCT. The relationship between culling efficacy and disease incidence is not thought to be linear and the effect of removing more or fewer badgers is not known.

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[18] Smith, NH., Dale, J., Inwald, J., Palmer, S., Gordon, SV., Hewinson, G., Maynard Smith, J., 2003. *The population structure of Mycobacterium bovis in Great Britain: Clonal expansion.* PNAS. 100:15271-15275.

[19] Woodroffe. R., Gilks, P., Johnston, WT., Le Fevre, AM., Cox, DR., Donnelly, CA., Bourne, FJ., Cheeseman, CL., Gettinby, G., McInerney, JP., Morrison, WI. 2008. *Effects of culling on badger abundance: implications for tuberculosis control.* Journal of Zoology. 274:28-37.

[20] Smith GC, Cheeseman CL. *Efficacy of trapping during the initial proactive culls in the randomised badger culling trial.* 2007. Veterinary Record. 160:723-726.

37. An additional suggestion made by the ISG is that culling should be **simultaneous** across the culling area. While the final report does not provide firm data to support this point, on the four[21] occasions when RBCT proactive culls were conducted sequentially in smaller sectors, the increase in prevalence of TB in badgers induced by culling was significantly greater.

38. **Culling should be carried out over a minimum size area of 150km^2.** The predicted effects of culling over areas larger than those undertaken in the RBCT can be calculated to assess whether culling would be beneficial over larger areas. This has been re-estimated each time more data on the duration of effects of proactive culling on TB cattle herd breakdowns have become available. The most recent estimate using combined during- and post-trial data suggest that the size of area that would need to be culled to give a 95% confidence of an overall beneficial effect over the culled and 2km ring is based on current timescales of analysis at 141km^2 (see **Figure 3**). This extrapolation is based on clearly specified assumptions, such as annual herd incidence rate and average herd density, which must be borne in mind when interpreting the results, as local conditions will vary. As emphasised in paragraph 12, this figure is derived from existing data collected from the RBCT and there is no empirical evidence from an experimental study covering this size of area.

39. **Steps should be taken to help mitigate the detrimental effects of culling observed in the area surrounding the culled area.** Despite its lack of statistical significance over the entire during- and post-cull period, Pfeiffer's group felt strongly that perturbation as an ecological phenomenon does exist in badgers within England if numbers are reduced by culling, leading to increased risk of transmitting TB as shown by the shape of the disease trend in badgers over time. Perturbation should therefore be taken into account when considering the potential effectiveness of any culling operation. This supports the recommendation made by Sir David King that, where possible, **geographical boundaries** (motorways, conurbations, coast, substantial rivers) or land without cattle should surround the cull area to minimise the disease risk from perturbation (NB: physical boundaries vary in their ability to deter/prevent badgers from crossing them), although RBCT areas were in part selected using this as a criterion and it is recognised that it is hard to quantify the additional merits of such an approach. The use of **vaccination** should also be considered to help mitigate against any detrimental effects caused by culling.

Reactive culling

40. Reactive, localised culling was stopped by Ministers in November 2003 as early interim results from the reactively culled areas showed an increase of 18.9% in new confirmed TB cattle herd incidents when compared with survey-only areas[22]. This led the ISG to conclude that it is highly unlikely that reactive culling, as

[21] Woodroffe, RW., Donnelly, CA., Jenkins, HE., Johnston, WT., Cox, DR., Bourne, FJ., Cheeseman, CL., Delahay, RJ., Clifton-Hadley, RS., Gettinby, G., Gilks, P., Hewinson, RG., McInerney, JP & Morrison, WI. (2006). Culling and cattle controls influence tuberculosis risk for badgers. *Proceedings of the National Academy of Sciences (USA)* **103**, 14713-14717.

[22] Donnelly, C.A., Woodroffe, R., Cox, D.R., Bourne, J., Gettinby, G., Le Fevre, A.M., McInerney, J.P., & Morrison, W.I. (2003) *Impact of localized badger culling on TB incidence in British cattle.* Nature, 426, 834-837.

carried out in the RBCT, could contribute other than negatively to future TB control strategies. The ISG hypothesised that the increase in disease was caused by perturbation of the badger population - culling disturbed territorial behaviour (increased ranging) thereby (presumably) increasing contact rates between badgers and between badgers and cattle. Subsequent studies on this effect at the edges of the proactively culled areas supported this hypothesis but the scientific evidence on perturbation in the context of reactive culling is limited.

41. As highlighted by others[14,15,23] including Sir David King, it could be argued that as the reactive badger culling trials were stopped before robust results could be obtained, it is not possible to comment with any confidence on whether or not reactive removal can make a contribution to controlling TB in cattle. Other groups have voiced concerns about the biological plausibility of the ISG's interpretation of the results (i.e. the short time between culling operations and the observed results, e.g. More et al., 2007[23]) and do not consider that the evidence in the ISG report should be used to either support or rule out a reactive removal strategy. However, the perturbation effect hypothesis is supported by the results of the proactive component of the trial.

42. Some success is reported using reactive culling strategies in the Republic of Ireland (RoI), but there are significant differences with the situation in GB including culling methods (use of stop restraints-a similar but more humane form of capture than locking snares), badger densities (which are much lower in the RoI), badger ecology (in the RoI, badgers tend to live in small groups of 1-2 animals (Eamonn Gormley, personal communication) in hedgerows, rather than larger territorial social groups as in GB) and farming practices (cattle herds in the RoI tend to be smaller).

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[23] More, SJ., Clegg, TA., McGrath, G., Collins, JD., Corner, LAL & Gormley, E. (2007). *Does reactive badger culling lead to an increase in tuberculosis in cattle?* The Veterinary Record 161:208-209.