Interim report on the August 2024 pre-publication response to the July 2024 re-evaluation of evidence and analyses of proactive culling (published in 2006), as a part of the Randomised Badger Culling Trial (RBCT), 1998-2005.

Paul R. Torgerson 1 and Thomas E.S. Langton 2.

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1. Section of Veterinary Epidemiology, Vetsuisse Faculty, University of Zürich, Zürich, Switzerland. 2. Herpetofauna Consultants International, Suffolk, UK.

One-page non-specialist summary

Results of proactive culling of European badger *Meles meles* during *The Randomised Badger Culling Trial,* published in 2006, have been subject to independent statistical re-evaluation. The latest re-evaluation by Torgerson et al. was published July 2024 in *Nature Scientific Reports*, uncovering irregularities in the description of the methodology used and modelling.

Despite the extensive efforts of two of the 2006 paper 'defending authors' in two August 2024 manuscripts, the qualified new models and conclusions are based upon approaches that make analysis inconclusive and do little to 'robustly' defend the original analysis. They serve only to support the view that the conclusions based upon OTF-W incidence of 'confirmed' cattle herd breakdowns are unsafe, and this offers a plausible reason why badger culling policy has not been shown to be effective since its applied use in England from 2013.

The August 2024 analysis does nothing to deal with the modern understanding of tuberculin test (SICCT) that makes the use of 'all reactors' the compelling indicator of recorded new infection and upon which badger culling made no difference to herd incidence rate. Overall, there are concerns that statistical methods are being used to try to fortify conclusions from a small-scale interrupted field trial, at the expense of plain-sight learning from long term cattle-based disease control operations. For these reasons the original 2006 and subsequent August 2024 analyses remain unsafe with uncertainty resting over the validity of analyses used and their interpretation. The August 2024 version includes elements that are contradictory and misleading. The case remains a useful exemplar of the issues that surround the reproducibility crisis in science.

The August 2024 manuscripts do not provide sufficient evidence to contradict the conclusions of the Torgerson et al. July 2024 paper, despite the claims made. This may just seem like a spat between statisticians. But the presumed efficacy of badger culling has resulted in huge public expenditure and the destruction of a large numbers of healthy iconic wildlife species. Therefore, it is vitally important that the evidence base is reliable. The simple fact that different teams of statisticians from prestigious institutes in two different countries are unable to agree on the interpretation of the RBCT, is evidence in itself of a lack of reliability and hence undermines the scientific basis of the use of badger culling as a disease control intervention.

1. Introduction

Results of proactive culling of European badger *Meles meles* during *The Randomised Badger Culling Trial* (RBCT), were published in 2006 [1] [**the 2006 paper] and** have been subject to independent statistical re-evaluation since 2019 [2,3]. The latest re-evaluation [3] published July 2024 [**the July re-evaluation**] uncovered irregularities in the description of the methodology used in the 2006 paper and benefited from hindsight of improved modern understanding of bovine TB (bTB) epidemiology in cattle.

Concerns arise from an immediate response to the July 2024 re-evaluation in two manuscripts concerning proactive culling within and beyond the culling areas by two of the principal 2006 RBCT authors and another [**the defending authors**] [4,5]. These are termed [**the August 2024 manuscript/s**]. With most emphasis on the first of these entitled "An extensive re-evaluation of evidence and analyses of the Randomised Badger Culling Trial (RBCT) I: Within proactive culling areas".

Fresh concerns also surround whether or not the RBCT had a clear pre-planned detailed statistical analytical protocol, and this relates also to model choice, suitability and strength. Further, the understanding of disease control management expressed in the August 2024 manuscripts is questioned. These form the content of this interim report and further elaboration will be published at the earliest opportunity.

The August 2024 manuscripts of the *Royal Society Open Science* journal [4.5] include reference to a previously unseen note from 1998 on statistical aspects of the badger culling trial [6] that may or may not add to the description by the Independent Scientific Group on Cattle TB to a Government Agricultural Select Committee in 2000 [7]. This later document is non-specific regarding accounting for greatly differing number of cattle herds in the 20 study areas. The defending authors make efforts to support their original conclusions regarding substantive bTB control benefit and disbenefit associated with badger removal by lethal control.

The RBCT was a very small-scale field trial in terms of its sampling frames of just 10 pairs. However, it required an extremely large financial expenditure (£81 Million at today's values) and was conducted in 'hotspot' areas with rapidly accelerating TB infection [8]. The proactive culling experiment removed an estimated 70% of the badger population, across

accessible land in areas of around 100 sq. km, with ten unculled comparison areas. Three of the ten paired areas were interrupted by a 'Foot and Mouth' disease outbreak, that when taken into account rendered the proactive experiment inconclusive [9], but findings were still analysed to try to investigate potential effects of badger culling on cattle herd disease incidence.

The primary concern in the more recent re-evaluation is that there was an inappropriate approach to the handling of comparative rates of herd incidence, due to simple non-observance of standard approaches to epidemiology in favour of statistically expedient methods that showed the predicted effect.

2. Methods

Scrutiny of the August 2024 manuscripts revealed concerns regarding the defending authors position and are documented in four categories as follows.

a) Issues in model comparisons.
b) Incorrect statements regarding disease control outcomes
c) Failure to recognise the onward effect of the 2006 analytical failure, upon multiple subsequent publications and policy outcomes.
d) The 'perturbation effect hypothesis'

3. Results

3.1 Issues in model comparisons.

3.1.1 Model selection metrics

The defending authors used model performance metrics AICc, BIC and LOOCV to argue that the statistical analysis originally reported in 2006 [1] was robust in comparison to the July 2024 [3] paper. The July 2024 paper, like the August 2024 manuscripts [4,5] used a variety of statistical models to explore the relationship between badger culling and the herd incidence of bTB infection. The July 2024 [3] analysis concluded that the "best" or most optimal model demonstrated that there was insufficient evidence to conclude that badger culling had an association with new cases of bTB in cattle herds during the RBCT.

The defending authors dismissed the use of AICc (a standard metric for statistical performance, especially when there is a small sample size) as being useful only as a "predictive metric" but would rather use the BIC as it gives "better performance for goodness of fit." Leaving aside the point that a predictive model would be better for an experiment used to inform and drive mass-culling policy, the actual difference between the BIC of the Nature model reported in 2006[1] (155.24) is only marginally better than the optimal model reported in July 2024 [3] (155.52). The difference is so small that it can be dismissed as useful for model selection.

The respective values for the AICc models were 154.20 (July 2024 [3] model) and 202.96 (2006 model): a huge difference, suggesting, by the defending authors own arguments, that it has far better predictive powers. Finally, without citing any metrics, the defending authors claim that the optimal model in the July 2024 [3] paper had systemic differences between model predictions and confirmed incidence. This claim is demonstrably unsound, at least in a relative sense by comparing the predictive check of the 2006 model compared with the same predictive check in the July 2024 model. As further evidence, the LOOCV metric, which is an important predictive metric, for the 2006 model is 9.97, somewhat inferior to the 8.81 of the optimal model reported in the July 2024 paper. Also note the defending authors dismissal of AICc because it is a "predictive metric".

3.1.2 Correct adjustments for herds (population) at risk of infection.

The defending authors continue to confuse the offset with overdispersion.

"*Another approach to modelling overdispersed data is the usage of an offset variable which enables modelling the count variable (here confirmed herd breakdowns) as a rate, and the usage of an offset variable means that the corresponding regression coefficient is constrained to be 1.*"

The offset variable ensures the incidence is modelled as a rate by using the population at risk per unit time as the denominator. This is a separate concept to overdispersion which is a method of modelling clumped data.

However, they state:

"Alternatively, assuming an offset variable may be deduced to not be supported by evidence (i.e. the number of events may increase non-proportionally with the population at risk) , one can use an unconstrained regression coefficient and hence, instead of assuming the slope for the variable is exactly 1, the slope parameter is estimated."

This issue was discussed extensively in the July 2024 [3] paper. Nevertheless, the defending authors have simply ignored the fact that the slope does not increase at all in the 2006 model, clearly not even “increasing non-proportionally with the population at risk”. Thus the 2006 model preferred by the defending authors is both biologically and epidemiological implausible and therefore the model must be mis-specified, even if claimed statistical checks say otherwise. This exemplifies the tension between plain statistical approach and the experience of the epidemiologist.

3.1.3 Overfitting

The defending authors have all but completely overlooked the main overfitting issue. This is almost certainly why, generally, the 2006 model has poorer metrics (e.g. AICc, LOOCV) then the optimal model proposed in the July 2024 paper. The 2006 model has 13 free parameters with only 20 data points; while that proposed in the July 2024 paper has 3 free parameters, with generally better fitting metrics. There has been much debate in the statistical literature with regard to the number of predictors compared to the number of data points. This has been referred to as the 1 in 10 rule, although it has been argued that 1 predictor for every five data points may suffice. Although most research on this issue has been directed at binomial regression models, it should be noted that a binomial model and Poisson model are asymptotically equivalent. As the 2006 models has 13 predictors for 20 data points it satisfies the $p<n$ rule (p is the number of predictors and n the number of data points) so avoids saturation (although not by much), so there are clear issues of the potential for overfitting.

In that respect, model checks of the 2006 model show there are issues of collinearity, which are absent from the 2024 model.

3.1.4 Quasipoisson model

The defending authors make an issue of the quasipoisson model, especially in respect that model comparisons cannot be made due to no likelihood structure. But then use of a generalized Poisson model in the July 2024 paper [3], deals with this issue.

3.1.5 Modern interpretation of SICCT test reactors

The defending authors have avoided mention of a key issue of the inclusion or not of unconfirmed breakdowns in the analysis. Unconfirmed breakdowns are when one or more cattle in the herd test positive for the SICCT test but cannot be confirmed by finding lesions and/or a positive culture of *Mycobacterium bovis*. Recent work has shown that the specificity of the SICCT was close to 100% at standard interpretation during the RBCT [10]. Hence RBCT cattle which were SICCT positive, but had no visible lesions, at *post mortem* were likely at the earlier stages of infection: and hence, in hindsight would be essential in the analysis of an experiment that was designed to monitor any effect of an intervention on infection in cattle. There was no evidence of an effect of badger culling on total number of herd breakdowns (confirmed and unconfirmed together) either in the 2006 analysis or in the more extensive analysis in the July 2024 publication.

3.2 Incorrect statements regarding disease control outcomes.

3.2.1 Comparison of Wales with England

The defending authors maintain:

"In Wales, widespread badger culling no longer takes place and the Bovine TB Eradication Programme has outlined the government's ambition to prohibit badger culling and instead promote a badger vaccination policy. There has been a general long-term trend in Wales of declining herd incidents over the past decade and 94.6% of herds were estimated to be TB-free as of Q3 2023, yet recent trends include 1.7% and 6.4% increases to the reported number of animals slaughtered and new herd incidents between October 2021 to September 2022 and October 2022 to September 2023."

However, these remarks about badger culling Wales are incorrect, as badger culling has always been prohibited in Wales other than for very small experiments. Wales has seen eight farms subject to a mini-study of Test-Vaccinate-Remove from 2017 to 2023 [11] at a cost of around £1.6 Million, where around 16 badgers per year were euthanised. During 2020 it was revealed that some vaccinated badgers were destroyed in error as a result of a conflict between the cross reactivity of BCG Sofia vaccine and the DPP test and the work abandoned.

The mischaracterisation of the situation in Wales also fails to mention the extremely similar trends in herd incidence in England and Wales over time, which provides convincing evidence that similar levels of disease control can be achieved without badger culling. This strongly corroborates findings that culling in England has been ineffective [12]. The reference to an increase in Wales since 2021, is well recorded localised infection, with Whole Genome Sequencing demonstrating cattle movements to the *Low TB Area* from a higher risk TB area during 2017. Similarly, the increase in incidents in *Intermediate TB Area North* is driven by movements across county and country borders of west Shropshire, southwest Cheshire and Wales. *High TB Area West* has a considerable number of large dairy herds. There is a high number of recurrent breakdowns which suggests either a high reinfection rate or infection which persists in the herd after it is declared Officially TB-Free [13].

Figures to March 2024 show good progress in Wales, despite an increase of 20% in the High West, but a decrease of **-53%** in Wales-Low, **-33%** in Intermediate North and **-29%** in Intermediate mid. (Defra 2024). While progress is held back by the new infection from England it is wrong to infer Wales is a country where Bovine TB control is less effective than in England [14].

Deputy first Minister of Wales: Huw Iranca-Davis in a statement in May 2024 [15] indicated:

"But just to be clear, from 2012, which is the year before badger control policy in England, to 2023, on the latest published data, the herd incidence in England decreased from 9.8 to 7.3; it was a 26 per cent decrease. In Wales, over the same period, herd incidence decreased from 10 to 6.8. It's a 31.3 per cent decrease. I simply put that on record—those are Department for Environment, Food and Rural Affairs figures, by the way—to say that

we are doing things differently in Wales, in line with our programme for government, but we're also succeeding in many ways."

3.2.2 Use of confidential DEFRA reports.

In the Introduction (para 1.2) to the August manuscript by the defending authors it is stated with respect to post-RBCT observations that *"The estimated beneficial effects of culling within inner trial areas persisted to the last six months period analysed (over 78 months)."* However, this is simply an unpublished previously confidential report to DEFRA with a graph of the period from 2005 (6 years after 2005) i.e. to-2011, with results showing large confidence intervals and a trend of gradual increase of bTB levels from the proposed relatively lowered state of infection.

3.2.3 Current culling outcomes are unable to indicate causation

While this is correct in some senses in relation to cull-control comparisons and this is recognised in such publications, the comment overlooks what could be done by the Animal and Plant Health agency with the very detailed and sophisticated data that they hold. Analyses such as random effects models and proximity studies could interrogate the broader data set for trends and patterns over time. If this has been done, it is not mentioned or discussed. APHA's reluctance to unlink personal data from scientific data is apparently behind their position not to share such data and this remains a strong unhelpful impediment to progress. Reference in the August 2024 manuscript to a paper [16] where 56% decline in incidence is attributed to badger culling, is a good example of mis-cited epidemiology and the causation is merely an opinion and premise that rests on assumptions from the 2006 paper, that the effect is contributed to by badger culling, rather than the improved cattle testing and movement control efforts. This behaviour is a cause of huge confusion, brings epidemiology into disrepute and is central to prevention of effective disease control.

3.3 How the 2006 analysis influences multiple subsequent publications and policy outcomes

It is not generally realised that the RBCT was such a slight trial in terms of sample size, with a limited capacity to deliver meaningful results. The trial saw a period of bTB disease increase that is not overtly obvious in the ISG 2007 overview report [8]. Herd (OTF-W) incidence doubled from around 20% to around 40% of herds infected over the study period in every single cull and control area, that was selected as a localised disease hotspot for study. Table 1 gives the face value results from the RBCT experiment showing this, with data simply calculated from ISG Table 5.4 (page 94).

It is sometimes reported that in a comparison of the proactive cull and control pairs that bTB went up in four areas and down in six areas after simple adjustments, however the raw data implies plainly that disease was increasing at a gradual rate across all areas. What this means is that any modelled decreases are a putative slowing of increase not actual decreases, this being something that gets lost in the story behind the statistical complexities.

Table 1. Number of herds and bTB herd (OTF-W incidence) in the three years prior to and during the (average) four year* badger cull periods inside the cull and control treatment areas. **Data from ISG Table 5.4 (page 94)**

	Cull area county/ies	No. herds **Cull** Areas	**Cull** B'downs Prior	%	**Cull** B'downs	%	No. herds **Control** Areas	**Control** B'downs Prior	%	**Control** B'downs	%
A	Gloucs/Herefordshire	**71**	33	**46**	40	**56**	**86**	33	**38**	67	**78**
B	Cornwall/Devon	**152**	40	**26**	98	**64**	**132**	27	**20**	70	**53**
C	East Cornwall	**105**	15	**14**	34	**32**	**174**	27	**16**	99	**57**
D	Hereford	**97**	28	**29**	39	**40**	**106**	30	**28**	49	**46**
E	North Wiltshire	**116**	25	**22**	42	**36**	**97**	28	**29**	67	**69**
F	West Cornwall	**138**	12	**9**	16	**12**	**191**	34	**18**	64	**34**
G	Derbyshire/Staffs	**245**	26	**11**	83	**34**	**131**	15	**11**	54	**41**
H	Devon/Somerset	**63**	23	**37**	36	**57**	**130**	22	**17**	42	**32**
I	Gloucestershire	**100**	30	**30**	38	**38**	**98**	19	**19**	31	**32**
J	Devon	**114**	25	**22**	46	**40**	**123**	18	**15**	40	**33**
	TOTALS	**1,201**	**257**	**21%**	**472**	**39%**	**1,268**	**253**	**20%**	**583**	**46%**
	PER YEAR AVERAGE			**7%**		**10%**			**7%**		**11%**

Note: culling was for average around 4 years but varied considerably.

There is also an issue as to what the effect of interventions might be once bTB disease levels are falling as opposed to climbing as they were 1998-2005. Studies of recent bTB interventions show a response to the introduction of annual SICCT over 2-5 years [12] before the roll out of badger culling. As annual testing was introduced in or before the year prior to the RBCT commencing and has a delayed and variable response, (as much as with stock brought in during the experiment [12]), it is not surprising to see a slowing of growth during the RBCT experiment years. This is one simple explanation for the driver of any of the detected effects attributed to badger removal.

There are very many post-2006 studies and reports which rely on an assumption that the coefficient value (i.e. -0.207) in the RBCT results for the proactive culling parameter in the log linear Poisson model is a true reflection of the expected effect size for reduction in incidence in response to culling. Re-examination of data from the 2006 paper, suggests otherwise and hence undermines the badger culling policy in England and Ireland. Other recent papers cited in the August 2024 manuscripts suffer the same statistical issue as the 2006 paper, that is the misuse of the exposure variable. In both these papers the authors report their results as incidence rate ratios (IRR), when in fact they report incidence ratios (IR), that is they did not correctly control for exposure by using an offset. Other issues prevail.

3.4 Perturbation effect hypothesis

In the July 2024 paper and August 2024 manuscripts analyses, no single model fit outperforms across all information criteria and predictive accuracy metrics.
In the August 2024 (manuscript II) the position is:

"Nevertheless, the best-fitting GLM (model 8) in terms of several information criteria [such as corrected Akaike information criterion (AICc) which measures predictive capabilities] and several leave-one-out predictive accuracy metrics (which approximate model generalizability) is a model which does not account for any effect of culling on confirmed herd breakdowns in neighbouring areas. However, despite the representative fit of the model without any modelled culling effect, other model fits (such as the original Poisson GLM of in generalized Poisson form) attain superior values for other information criteria

such as Bayesian information criterion (BIC) (which is a measure of goodness of fit unlike Akaike information criterion and AICc which measures predictive accuracy).”

The model proposed by the July 2024 paper is of greater use for generalisation. Although the BIC for model 7 is marginally better in the August 2024 manuscript 2 compared with model 8 in the July 2024 paper (143.8 vs 145.8), it is not as noteworthy as the huge difference in AICc between the models. The model now adopted as evidence for the perturbation effect (based on a single metric) was one proposed in the July 2024 paper (rather than the one in the original 2006 RBCT paper) in order to compare competing models.

The defending authors model (whether the original, 2006 model 1 in table 1a, in the August 2024 manuscript 2 on neighbouring areas) or the improved genpois model (model 7 in table 1b in the neighbouring areas manuscript) both have the same problem, in that the parameter for exposure (baseline herds, or herd years at risk) is not significantly different from zero.
The best model which provides no evidence for perturbation has:

1) a better AICc
2) the lowest LOOCV values, and hence is more generalizable which is exactly what you want when you wish to predict an outcome.
3) No evidence of departures from plots of residuals.
4) Gives (more) sensible values of the parameter for exposure (i.e. significantly above 0 [0.612]...a bit lower than if there was an offset (==1), but for model comparison it deals with the potential non-linear increase that is mentioned in the first August 2024 manuscript, as was done in the July 2024 paper.But because the defending authors model is weakly supported by BIC (the goodness of fit), it has been given precedence over all the other issues and one of the models from the July 2024 analysis has been chosen. There is also some bizarre phraseology. It is said in relation to the best-fitting July 2024 GLM (model 8) [bold emphasis added]:

*“....and several leave-one-out predictive accuracy metrics (which **approximate model generalizability**) is a model which does not account for any effect of culling on confirmed herd breakdowns in neighbouring areas. However, ... other model fits (such as the original Poisson GLM in generalized Poisson form) attain superior values for other information criteria such as Bayesian information criterion (BIC)...”.*

It is surprising that this was not picked up in review. And more subtly: the defending authors analysis says of the July 2024 model [bold emphasis added]:

*"the lowest LOOCV MAE (6.86) among the frequentist model fits for the period from the initial cull until 4 September 2005 is attained for model 8, **a model which does not account for any effect of culling in neighbouring areas** and does not make assumptions about offset specification."*

The highlighted text implies that the model is of no use because the effect of culling is not accounted for. This implication is incorrect, as culling as a covariate was checked, but because there was no significant association it was removed from the model to (double) check that it was not influential. This is confirmed as the AICc further decreases when the covariate for culling is removed.

4. Discussion

Despite the extensive efforts of the defending authors in their August 2024 manuscripts, the qualified new models and conclusions, based upon approaches that make analysis inconclusive, do little to ‘robustly’ defend the analysis in the 2006 paper. They serve only to support the view that the conclusions based upon OTF-W incidence of ‘confirmed’ cattle herd breakdowns are unsafe, and offer a plausible reason why badger culling policy since 2013 in England has been ineffective.

The August 2024 analysis does nothing to deal with the modern understanding and interpretation of the tuberculin test (SICCT), that makes the use of ‘all reactors’ the compelling indicator of recorded new infection and upon which badger culling made no difference to herd incidence rate during the RBCT. Overall, there are concerns that statistical

methods in the August 2024 manuscripts are being used to try to fortify conclusions from a small-scale interrupted field trial, at the expense of plain-sight learning from both the RBCT and long-term cattle-based disease control operations.

For these reasons the original 2006 and subsequent August 2024 manuscripts remain unreliable, with uncertainty resting over the validity of all analyses. The August 2024 manuscripts include elements that are contradictory and misleading. The case remains a useful exemplar of the issues that surround the reproducibility crisis in science.

The August 2024 analyses do not adequately address the material in the July 2024 supplementary information and a collaboration between the two sets of authors is advisable for this most important issue.

5. Conclusions

The new August 2024 papers, when analysed forensically, do not provide sufficient evidence to contradict the conclusions of the Torgerson et al. 2024 paper, despite the claims made. This may just seem like a spat between statisticians. But the presumed efficacy of badger culling has resulted in huge public expenditure and the destruction of a large numbers of healthy iconic wildlife species, that as a result, is reported to be close to local extinction in some areas. Therefore, it is vitally important that the evidence base is reliable The simple fact that different teams of statisticians from prestigious institutes in two different countries are unable to agree on the interpretation of the RBCT, is evidence in itself of a lack of reliability and hence undermines the scientific basis of the use of badger culling as a disease control intervention.

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