DAERA scientific opinion on the peer reviewed evidence on badger intervention in relation the control of bovine tuberculosis

This updated scientific opinion reviews the latest evidence on badger intervention strategies to support bovine tuberculosis (bTB) control in Northern Ireland. It builds upon the 2019 Departmental Scientific Opinion (Annex 1) using an updated annotated bibliography of relevant peer reviewed publications covering the period January 2015 to November 2024 (Annex 2). This annotated bibliography incorporated findings from 174 peer reviewed new scientific publications and included relevant peer reviewed papers suggested by stakeholders. The scientific opinion provided below is based on the two aforementioned documents with the purpose of informing policy development by assessing the effectiveness, feasibility and ethical considerations of various wildlife intervention control options. Specifically, these options include proactive culling, vaccination, test and vaccinate or remove (TVR) and a hybrid option that combines these approaches within an undefined area. This scientific opinion will be used along with key drivers to provide an evidence-informed policy for future badger intervention.

The terms of reference for this scientific opinion referred to the 'viability' of the different badger intervention options. For the purposes of this paper, viability was defined as '*the capability of being implemented and is likely to lead to reduced levels of bTB in badgers and cattle in the Northern Ireland context'.*

The broader political, environmental, legal, economic, behavioural or social science aspects that are required in making a final policy decision on an appropriate badger intervention are not considered.

Scientific conclusions of the evidence

For ease of reference, the summary conclusions from the different themes used in the annotated bibliography (Annex 2) are provided below (with slight modifications).

Badger Ecology

Robust badger population data are required to inform modelling of and progression of interventions. In general badgers remain within defined territorial boundaries. This behavioural characteristic may decrease the likelihood of bTB infection by neighbouring social groups or conversely increase infection and spread within a resident group, potentially exacerbated by anthropogenic disturbance. Badgers in Northern Ireland are likely to have a relatively higher numbers of setts in the immediate vicinity of grazing cattle. Biosecurity measures such as fencing off badger setts and latrines may make a significant contribution to reducing the risk of cattle infection by badgers.

The removal of badgers from an area has the potential to encourage ranging behaviour of neighbouring badgers into vacated territories which may increase the chances of spreading bTB.

Modelling exercises estimating badger populations should incorporate data on habitat variables and previous badger management in adjacent areas to ensure that the proposed scale of badger intervention will achieve the desired results rather than potentially exacerbate disease transmission.

Badger welfare & ethics

The papers on badger welfare and ethics help inform on a more holistic policy approach of the bTB/ badger problem, moving beyond traditional assessments of science and economics.

Badger diagnostics

This section outlines the main observations from papers mainly focusing on the diagnosis of *M. bovis* infection in badgers. As well as covering recent research relating to diagnostic tests (DPP test, IFNg test culture, PCR), this section also provides information on the negative welfare impact of capturing and testing badgers.

Transmission dynamics

There is a lack of standardisation/agreed definitions across studies to enable direct comparisons to be made, particularly in relation to indirect/direct contact rates and environmental contamination. This inhibits a fuller understanding of the cattle/badger/*M. bovis* interface. Insights provided through the application of WGS technology show that the relative contribution of the different species to the maintenance of *M. bovis* infection varies between bTB hotspots. However, to enable eradication of bTB in cattle within an area, the infection needs to be controlled in all *M. bovis* reservoir hosts connected to that area.

Proactive Culling

In relation to pro-active culling, it is worthwhile to note the need for meticulous planning in relation to the spatial and temporal extent of the culling, the estimation of the population size, spatial distribution and connectivity of target species. The potential effect of a proactive culling strategy on badger behaviour, such as increased ranging distance, also needs to be taken into account. The majority of previous studies have reported beneficial effects of culling strategies in terms of bTB prevalence in both badger populations and cattle herds. However, it needs to be noted that culling strategies in general were rolled out alongside enhanced cattle-based measures.

Reactive Culling

Trials into reactive, localised culling have shown significant negative effects, not on the land on which culling took place, but on adjoining lands and farms. However, irrespective of the method being used in a trial, thorough preparation, sound methodologies and sufficient resources are paramount.

Test and vaccinate or Remove (TVR)

The TVR project demonstrated that trap side testing of badgers was a practical, real-time decision tool using whole blood DPP testing. The significant year-on-year decrease in badger DPP test positivity needs to be considered along with the design deficiencies of lack of replicate and control areas. However, its legacy of a vaccinated badger population, along with no signs of increased badger perturbation is an advance when moving forward to a vaccination only control measure. The results do suggest that the main driver in the study area was cattle to cattle transmission, highlighting a need for enhanced cattle bTB control measures alongside an area-based badger intervention.

Badger vaccination

The natural science evidence base is consistent with BCG vaccination reducing the susceptibility of badgers to *M. bovis* infection. Various large- and small-scale BCG vaccination studies have been, and continue to be, undertaken in the UK and Ireland. There is a stated desire in the UK and Ireland to pivot from badger culling to badger vaccination, should disease surveillance support such a move. Many of these studies report on vaccination logistics, rather than the field efficacy of BCG vaccination in badgers, and more importantly, the effect of badger BCG vaccination on bTB levels in cattle.

Although highly context-dependent (i.e. much of the landscape had already been subjected to reactive badger culling for several years), the most relevant field trial-based evidence derives from the well-controlled and powered “non-inferiority” trial undertaken in Ireland, which showed that badger BCG vaccination, in context, as carried out in the trial, was not inferior to (i.e. no worse than) targeted badger culling in most, but not all, trial areas. This informed a move to replace reactive badger culling with badger BCG vaccination in a >20,000km^2 area in Ireland.

However, effective vaccination depends on vaccine efficacy and vaccination coverage logistics; both important metrics are currently being estimated for Ireland. Whether badger BCG vaccination, alongside all current and potentially future cattle and wildlife control measures, will be sufficient to control and eradicate bTB in Ireland is the subject of ongoing research.

Whether these findings are currently generalisable to the different context in Northern Ireland is worth considering. For example, Ireland has transitioned from decades of reactive badger culling towards badger BCG vaccination; Northern Ireland has a denser badger population and badger culling has not been policy. Advanced mathematical modelling, with parameters derived from the Northern Ireland context, may be informative.

Modelling

It is difficult to generalise model outputs given they are context dependent and indeed all the models are highly abstracted constructs i.e. not field trials. Some modeling outputs suggest that effective proactive culling is best at reducing bTB levels, but this can lead to a prolonged badger population recovery period or even extinction. Using NI data, one model suggested that TVR would deliver the biggest reduction in cattle bTB level provided there was no increased badger perturbation. If badger perturbation occurred, all intervention outputs were similar (proactive culling, TVR, vaccination). Other models highlight the heterogeneity of cattle and badger infections within an area, which adds to the complexity of making generalized statements. Another model suggested that badger intervention was only fully effective at reducing cattle bTB levels when the areas were close to their eradication threshold. Importantly, modelling indicated that the variation in cattle bTB levels was related to cattle movements, bTB testing frequency and interspecies transmission rates, which may reflect the differences seen between different bTB hotspots (see Transmission dynamics section).

Socio-economics

Three potential "promising approaches" have been highlighted: enhanced participation, collaboration and engagement of stakeholder in decision making, proactive incorporation of scientific evidence and the importance of contextualising as the local context will influence stakeholder acceptance and compliance. Some considered it important to focus on the pathogen, select language carefully when discussing bTB and invest in new innovations, such as vaccines and diagnostic tests.

Miscellaneous

This section discussed findings from various studies conducted in France and also on the novel use of fertility control in badgers. Modelling of fertility control suggested there was little difference in outputs between various intermittent culling regimes, badger vaccination and use of a vaccine combined with fertility control.

Concluding remarks of the annotated bibliography

Peer reviewed published research between 2015 and May 2024 has provided supplemental evidence on the various aspects of badger intervention. On the practical level, all previously identified badger intervention methods (proactive culling, selective culling and vaccination) have been trialled. Of particular note is the switch from culling to vaccination in ROI (although limited culling is retained as an option in hotspot areas) and the proven utility of real time trap side testing of badgers for *M. bovis* infection. Selective culling combined with vaccination was only completed within one area (NI TVR study) hence limiting extrapolation of its results (although a similar approach is currently being piloted in France).

While there continues to be disparity of analytical/statistical opinion on the outputs relating to the RBCT, new evidence suggests that the Badger Control Policy (BCP) implemented in areas of England appears to have been effective in decreasing cattle bTB levels. However, the BCP included aspects over and above direct badger intervention and additional bTB cattle control measures have also been contemporaneously introduced within the high-risk area of England. Indeed, for any badger intervention to succeed in the longer term, bTB control measures in cattle also need to be effective in reducing or preventing bTB re-introduction to the area as well as limiting re-infections of the badger population (through badger movement or cattle-badger transmission).

With respect to badger vaccination, injectable vaccine is still the only viable option as there are logistical obstacles relating to oral bait vaccine delivery. This means that badgers do need to be captured to enable vaccination or testing, which does pose a welfare issue. However, actual physical injuries seem to be minor in most of badgers captured by cages or stopped restraints.

Modelling outputs do tend to demonstrate that badger intervention can reduce bTB levels with methods involving a lethal component (proactive or selective culling) providing a faster bTB response than vaccination only. However, there has been an increase in publications on the socio-economic aspects of bTB in relation to stakeholder knowledge, opinions and behaviours related to badger intervention options. They tend to highlight the need to consider ethics and public opinion as well as any scientific evidence base in relation to badger intervention.

Importantly, effective, positive engagement by all stakeholders is required to enable bTB eradication.

Scientific Opinion Conclusions:

1. **Previous opinions validated.**

The opinions, conclusions and control options identified in the original 2019 Department Scientific Opinion document (Annex 1) are given further support and validation from the scientific papers and reports that have been published and documented in the annotated bibliography (Annex 2).

2. **Badger intervention remains necessary**

   Badgers and cattle form a two-host transmission system. Modelling and genomic evidence confirms bidirectional transmission of *Mycobacterium bovis* between them. Wildlife intervention is therefore an essential component of any bTB eradication strategy.

3. **Cattle controls are equally critical**

   Cattle-to-cattle transmission appears to be a primary driver of cattle infections. Without strengthened parallel cattle measures, wildlife interventions alone are unlikely to achieve eradication.

4. **Vaccination is the long-term goal**

   Badger vaccination with BCG reduces susceptibility to infection and can create indirect protection within populations. However, it is slow to act and less effective in areas with high infection prevalence unless preceded by a reduction in infection pressure (e.g. via culling or selective removal). Sustained, high-coverage badger vaccination over many years is likely to be required using a vaccination only approach in areas where the infection is endemic in badgers.

5. **Proactive culling can reduce bTB but is indiscriminate**

   Field trials and modelling show that large-scale, sustained culling can reduce bTB in cattle and badgers. However, most badgers removed are uninfected, and concerns persist over animal welfare, public acceptability, and potential ecological impacts. In Ireland, the hypothesised badger perturbation effect caused by culling appears minimal compared to England but the effect in Northern Ireland is unknown.

6. **TVR shows promise**

   Northern Ireland's 5-year TVR trial within a 100km^2 single area significantly reduced *M. bovis* prevalence in badgers without disrupting their social structure. However, analysis did not demonstrate a potential impact on cattle herd incidence, suggesting that the main driver in the study area was cattle to cattle transmission, highlighting the need for concurrent cattle measures.

7. **Hybrid strategies are conceptually strong**
   Modelling and field data support combining methods such as proactive culling or TVR followed by long-term vaccination. A new flexible approach proposed by the Chief Veterinary Officer (CVO) involves using TVR to assess *M. bovis* infection patterns in year one, followed by area-specific application of culling, vaccination, or continued TVR. While theoretically attractive, this adaptive strategy has not yet been trialled and therefore has no modelling or field data support. As with all interventions, it requires careful design, logistical planning, and stakeholder engagement.
8. **Welfare and ethical concerns are central**
   All badger interventions require live capture or free shooting, raising potential ethical and welfare considerations. When conducted to high standards, cage trapping and restraints cause minimal injury but both methods were categorised as having intermediate welfare scores. Published papers recorded that 16% of badgers caught in restraints exhibited more than minor injuries compared with 3% trapped in cages. Free shooting may carry a higher risk of suffering and is less reliable. Ethical analysis highlights the need for proportionate, justifiable policies that minimise harm and respect both human and animal interests.
9. **Future policy must be multi-faceted**
   There is no one-size-fits-all solution. Effective bTB control in the TB Transformation Programme will require coordinated action across cattle and wildlife, tailored to local areas and conditions. Decision-making should be evidence-based, ethically sound, and flexible enough to integrate new tools and technologies.

Opinion Summary

Based on the peer reviewed scientific evidence, all options (TVR, proactive culling, vaccination) are considered scientifically viable options. Scientific viability should be assessed in parallel with ethical and welfare considerations.

However, using the ‘vaccination only’ option would require many years of implementation and high coverage to achieve the same result as other options that include a lethal component. In this context vaccination is perhaps more suitable for deployment as an exit strategy from intervention with a removal component.

In relation to pro-active culling, there are serious ethical disadvantages to consider given that it will remove a large majority of the healthy badgers from an area. This is particularly pertinent given that other viable options are available. The potential effect of a proactive culling strategy on badger behaviour, such as increased ranging distance, also needs to be taken into account.

TVR provides for a targeted approach removing only those animals found using the DPP test to be infected with bTB. As fewer animals will be removed, it would have a significantly lesser impact on badger numbers and therefore the ecology in the area. It has to be noted though that to date there has not been a comprehensive deployment of TVR on a 100km^2 basis outside of research.

Conceptually hybrid solutions could viably be deployed in NI with the aim of informing future policy, rather than implementation of a defined finished product. This intervention potentially combines all three wildlife intervention strategies in a targeted, adaptive way to address bTB levels in badgers and cattle. It should be noted that this concept has not been deployed before, and detailed, specific, modelling has not yet been carried out to predict likely outcomes.

It is again important to note that badger intervention without appropriate cattle bTB control measures being in place will not result in effective reduction in bTB levels in cattle and therefore it is crucial that both control strategies are used in parallel with each other.

Annex 1: Scientific Opinion on the Available Evidence on Badger Intervention” August 2019.

Scientific Opinion on the Available Evidence on Badger Intervention

Agreed by: Michael Hatch (Deputy Chief Veterinary Officer, VSAHG) & Helen Anderson (Director of Natural Environment Division, NIEA) on 30 August 2019

This reflects the outcome of discussion between NIEA and VSAHG at which an agreed interpretation of the evidence was reached and updates the scientific opinion previously agreed on 12 December 2018.

1. Purpose

This paper provides opinion on the scientific evidence on badger intervention options for Northem Ireland that;

- Is based on current scientific evidence;
- takes into account policies/strategies in other jurisdictions and their reported progress;

It aims to feed this information into considerations by policy makers charged with short-listing the most feasible badger intervention options.

2. Method

This paper builds on the scientific justification provided for the TBSPG report on wildlife intervention recommendation (TBSPG, Annex B) supplemented by the independent peer review of the TBSPG report carried out by Professor Simon More (Centre for Veterinary Epidemiology and Risk Analysis, University College Dublin (CVERAt UCD)); referred to as the scientific peer reviews (SPR) within this paper (TBSPG, 2016; More 2016a,b). It is recommended that the reader refers to the aforementioned papers while considering this document (https://www.daerani.gov.uk/pubiications/tbspq-bovine-tb-eradication-strateqy-ni) along with the additional scientific papers referenced in this report.

This review also draws on subsequent ROI and GB scientific papers published since the TBSPG report as well as other reports and communications from these jurisdictions. This paper also incorporates some of the preliminary evidence arising from the DAERA five year badger research project involving a test, vaccinate or remove (TVR) intervention in which the field work was completed this autumn (2018).

It has been jointly written by VSAHG and NIEA officials for consideration by the DAERA Wildlife Working Group.

3. Caveats

This paper provides an update on the available science; it is stressed that there is a lot of uncertainty still surrounding this topic. The broader political, environmental, legal, economic, behavioural or social science aspects that are required in making a final policy decision on an appropriate badger intervention are not considered.

The paper considers badger intervention over large areas where cattle bTB levels are relatively high, recurrent or persistent, and where badger density is also estimated to be high, as described in the TBSPG report and identified using a methodology developed by DAERA (VEU, 2017). It does not therefore revisit intervention in response to tocalised bovine bTB herd breakdowns (reactive culling).

No consideration is given within the paper regarding the impact of any enhanced cattle measures required to minimise cattle-to-badger transmission as it is limited to considerations of the methods relating to badger intervention. However, it is noted that the recent English bTB review placed emphasis on improving farm biosecurity measures; alongside other measures (Godfray et al, 2018).

As there is no published evidence from any long term badger intervention in NI, most of the evidence is based on English and Irish experiences. There cannot be a direct read across from England and Ireland as there are ecological and practical differences that will create a degree of uncertainty around outcomes (e.g. O'Connor et al, 2012).

4. Purpose of a Badger Intervention

M. bovis is transmitted within and between populations of badgers and cattle (Godfray et al, 2013, 2018) and therefore badgers play a role in maintaining bovine tuberculosis (bTB) in cattle. The involvement of badgers is also cited in the underpinning evidence for the TBSPG and the independent review of that evidence (SPR page 40, para 92).

International experience has shown that bTB eradication will only be achieved by simultaneously addressing all factors that meaningfully contribute to the persistence and spread of M. bovis in all animal populations (SPR page 45, para 101 The purpose of a badger intervention is to reduce transmission within the badger population and between badgers and cattle.

Godfray et al (2013, 2018) also concluded that, in designing bTB control programmes for known and potential high bTB incidence areas, benefits will be obtained from implementing effective measures that target the disease in both cattle and wildlife in the same area. The best type or combination of interventions may differ between high and low incidence areas.

More (2016a; SPR page 42, para 96) states that the options to limit transmission from badgers to cattle are reliant on either a) a reduction in the adequacy of contact or b) the proportion of the population susceptible.

a. Options to limit adequacy of contact

So far, these have been restricted to efforts to reduce the number of contacts per unit time through either

i. badger culling ji. improved biosecurity (relevant to badger to cattle transmission)

b. Options to reduce the proportion of population susceptible

i.Badger vaccination ii.Cattle vaccination

The remit of the paper is to consider badger intervention options only and does not examine evidence concerning either biosecurity or cattle vaccination.

5. Options

The intervention options considered over a large area (>100km^2) are:

i. Vaccination ii. Non selective culling (proactive) iii. Selective culling and vaccination (Test Vaccinate or Remove (TVR)) iv. Selective culling and vaccination enhanced by non-selective culling in badger bTB "hotspot" areas (Enhanced TVR (eTVR))

v. Options ii — iv followed by vaccination only.

6. The evidence

i. Vaccination

a. Experimental trials indicate a significant decrease in the number and severity of gross lesions, lower bacterial load in the lungs and fewer sites of infection in naive, BCG vaccinated badgers that were then challenged with large doses of M. bovis. The main protective effect is a reduction in the severity and progression of the disease following M. bovis challenge. On this basis, Prof. More concluded that it was reasonable to expect vaccination to reduce M. bovis prevalence in badgers and in high cattle prevalence areas, over time. However no data are publically available to assess the magnitude and timing of these effects in the cattle population (SPR Page 45, para 104) although model outputs have given some indications. Moreover, vaccination field trials in UK and Ireland have been encouraging although they were in badger populations with relatively low bTB levels (Chambers et al, 2011; Carter et al, 2012; Gormley et al, 2017; Aznar et al, 2018). The use of BadgerBCG, which is licensed for use in the IJK, is associated with a 74% reduction in the bTB seropositive incidence in badgers (Chambers et al, 2011). An individual badger risk reduction of 76% from vaccination was claimed in a field study along with indirect protection of unvaccinated cubs (Carter et al, 2012). However, similar reductions in badger TB prevalence were seen in vaccinated and control groups across the four year study (Carter et al, 2012; Table S5 in supplemental data).

b. There is no evidence of either a beneficial or detrimental effect of BCG vaccination in bTB infected badgers. Therefore vaccination has the potential to provide benefit only to those animals that are not bTB infected (or otherwise sensitised to mycobacteria) at the time of BCG vaccination (SPR page 47, para 111; Aznar et al, 2018).

c. Pseudo-vertical transmission is believed to be an important feature of M. bovis infection in badgers and may be a key factor in maintaining infection within local populations. Logically therefore, the force of infection will be greater in high compared to low prevalence badger populations (SPR page 47, para 112).

d. These issues have raised concerns as to whether badger vaccination alone would be sufficient to limit transmission given the force of infection in the badger population. M. bovis infection in badgers can be very high in Ireland reaching up to 43% in hot spot areas (SPR Page 47, para 113). In the badger bTB detection survey in the Aghadowey area, 6 out of 19 randomly tested badgers were positive to the DPP test (sensitivity 84%; Jinks et al, 2019) and all 6 confirmed with M. bovis (bTB prevalence 32%; 95% confidence interval 15%-54%). Therefore in such areas in NI, the badger bTB prevalence could be as high as the Irish hotspot areas.

e. Infected badgers can harbour M. bovis for several years and are therefore a potential on-going intermittent source of bTB infection.

f. Although the duration of immunity against bTB is unknown, the licensed product for vaccination of badgers against TB (BadgerBCG) recommends annual vaccination for coverage reasons rather than immunological responses (in view of the estimated 30% badger tumover rate and badger movements).

g. A number of modeling studies have generally highlighted the value of long term vaccination in reducing bTB incidence in badger populations (SPR page 46, para 105). Abdou et al (2016) showed the limited impact of vaccination alone on bTB infection in badger populations and the substantial improvement when vaccination was preceded by 5 years of culling (SPR page 48, para 116a). Other modelling results were broadly similar (Smith et al, 2001 , 2016 ; Wilkinson et al, 2004), that is, the impact of badger vaccination atone on cattle bTB prevalence took many more years to achieve without first introducing a proactive lethal element, such as culling (SPR page 48, para 116b). Hardstaff et al (2013) found that vaccination alone could be an effective disease control strategy in higher density badger populations, but only with annual deployment of a vaccine with an efficacy of around 80%. The effectiveness of this strategy was reduced by the presence of external sources of infection (SPR page 48, para 116c).

h. Two major field trials, the Kilkenny study and non-inferiority trial, have recently been completed in Ireland. The purpose of the trials was to provide information needed to move them safely from a cull-only policy to an approach that could incorporate vaccination of badgers in place of culling.

j. The Kilkenny trial (Aznar et alt 2018) found that vaccine efficacy for susceptibility (VEs); reduction in susceptibility to natural exposure with M. bovis in vaccinated compared to placebo treated badgers) was 59% (95% confidence interval = 6.5-82%). A complete lack of effect from BCG vaccination on the infectivity of infected badgers was also observed i.e. the vaccine efficacy for infectiousness was 0%. On the basis that the prevalence of M. bovis in endemic areas in Ireland is approximately 18% modelling of the results from the study (Aznar et ai, 2018) stated that 'with vaccination coverage in badgers exceeding 30%, eradication of M. bovis in badgers in Ireland is feasible, provided that the current control measures also remain in place' (it is unclear if this output assumes no increase in badger density). Discussion with Professor More, a co-author of the paper, indicated that this outcome was predicated on the programme of culling that had reduced badger bTB prevalence to the level quoted.

j. Earlier analysis of the Kilkenny trial (Gormley et al, 2017) showed that among vaccinated badgers that seroconverted (indicative of bTB infection), the mean time to seroconversion was significantly longer compared with unvaccinated badgers. There was also a significant difference in the rate of seroconversion between vaccinated and unvaccinated badgers and in the proportion of animals presenting with M. bovis culture confirmed lesions.

The results demonstrated that serial oral BCG vaccination confers protection to badgers within that area and could be used to reduce incidence rates in bTB infected populations in badgers. The paper also concluded that vaccine efficacy increases with serial coverage (from 36% [95% CI: -62%– 75%] vaccination rounds 1 & 2 to 84% [95% a: 29%97%] in vaccination rounds 3-6).

k. The general consensus in Ireland is that badger culling will be required in areas of high bTB risk prior to mass vaccination, specifically to reduce the prevalence of M. bovis in the emergent badger population (SPR page 48, para 115).

l. There has been widespread vaccine deployment, as a study (O'Keeffe, 2017), in seven large areas previously subject to badger culling, in six Irish counties (2014-2017). The study has been designed as a non-inferiority trial, to determine whether vaccination is not inferior (<1 % difference) to area-wide targeted badger culling in terms of bTB herd incidence. The preliminary outcome of this work has shown that vaccination is not inferior and on that basis Ireland are proceeding to gradually replace culling with vaccination (O'Keeffe, 2017).

m. An intensive action area (IAA) was undertaken in Wales where badger vaccination was deployed over a four year period. Scientific assessment of this project has not been undertaken as badger vaccination was only one of a number of measures employed in this one area (APHA, 2017).

Summary on Vaccination only (Option i)

Collectively, the scientific evidence summarised above raises concerns as to whether badger vaccination by itself will be sufficient to limit bTB transmission in areas where there is a high level of bTB infection in badgers. The general consensus from Ireland is that badger culling will be required in high badger bTB prevalence areas prior to use of mass vaccination. In areas of relatively low badger bTB prevalence and low badger density, relatively moderate BCG vaccination coverage may be an effective option,

ii. Non selective culling (proactive)

Culling in other jurisdictions of the British Isles

a. There is evidence from England and Ireland to show that culling over a large area (>100km^2) for a number of years will reduce badger density, badger bTB prevalence (in Ireland at least) and cattle herd incidence (TBSPG, Annex B, 1.4).

b. Follow-up studies have shown that the initial impact on cattle herd incidence of proactive culling were maintained for several years after termination of the trials (TBSPG Annex B, 1.3). It should be noted that this effect was also observed in the RBCT proactive cull areas where there was no follow up badger intervention.

c. Culling is currently the principal badger intervention used in England and Ireland. The current policies using proactive culling in England and targeted culling in Ireland started in 2013 and 2004, respectively, the difference between the two approaches is that in England culling takes place over a large, a priori defined, area. In Ireland, the initiation of culling in a new area is triggered by a cattle herd bTB breakdown, and is repeatedly conducted in the

2km radius around those herds. Over time, this repeated culling nature in Ireland has caused these cull areas to merge forming larger contiguous cull areas.

d. An analysis of the first two years of the badger culls in Gloucestershire and Somerset has been published (Brunton et al, 2017). The paper has assessed the association between cattle bTB incidence and badger culling over a 2 year period. It is heavily caveated because of the very short time scale and explicitly warns that "it would be unwise to use these findings to develop generalizable inferences about the effectiveness of the policy at present". After adjustment for confounding factors, a multivariable analysis showed that reductions in bTB herd incidence were associated with culling in both intervention areas when compared to areas with no culling. An increase in incidence was associated with culling in the 2km buffer surrounding the Somerset intervention area but not in Gloucestershire. bTB herd incidence data relating to the TVR project would further caution over-interpretation of these findings as there is large between-year variability observed within and across the TVR area and three control ('hands-off) areas studied.

e. The original 4 year licences for culling in Gloucestershire and Somerset have recently been extended for a further 4 years.

f. In Ireland, during a large scale replicated cull trial known as the four area study (Griffin et al, 2005), badger bTB prevalence declined over time in proactively culled areas (Comer et al, 2008).

g. Also in Ireland, a significant reduction in badger bTB prevalence over time has been observed based upon badgers culled in areas where there has been extensive culling (up to 30% of the agricultural area of the country) as part of the national programme of targeted removal (Byrne et al, 2015 and DAFM, personal communication). The available Irish data (DAFM, unpublished data) show badger bTB prevalence within these intervention areas did decrease between 2008 and 2012 (22.75%, 95%Cl 20.8-24.8 to 9.37%, 95%Cl 8.3-10.6). However, there was increasing badger bTB prevalence year on year from 2012 (9.37%, 95%Cl 8.3-10.6) to 2015 (14.65%, 95%Cl 13.1-16.4). There were changes to the areas culled during that time that may have impacted on the badger bTB prevalence estimates (DAFM, personal communication). No data on badger bTB prevalence in Ireland are available after 2015.

h. Ireland is gradually rolling out a policy of replacing most of their cull areas with vaccination (Houtsma et a}, 2018). They consider that there will be a need for culling in some circumstances, even after full roll out of this approach (DAFM, personal communication).

i. One issue highlighted by the TVR research study (DAERA, 2017) is that initial indications suggest that the starting badger bTB prevalence may have been quite low (12%; 95% 7.1-19.0%; Jinks, API-IA, unpublished data). The methodology developed for selection of the TVR area (VEU, 2013) used the Irish findings that high bTB cattle herd incidence was a proxy for high badger bTB prevalence (Murphy et al, 2011). In the TVR study area, this assumption did not appear to hold. However, other badger and cattle metrics are included in the selection of future potential badger intervention areas in an attempt to mitigate against such a risk (VEU, 2017).

Perturbation and the Perturbation Effect

j. 'Perturbation' is a term given to changes in the territorial behaviour of badgers when badger populations are disturbed. A 'perturbation effect[t] is a hypothesis that posits that the changes in territorial behaviour of badgers, when infection is residing within the population, can lead to an increase in bTB infection transmission. Most of the evidence for the hypothesised perturbation effect, at least evidence relating to increased risk to neighbouring cattle herds around culled areas, comes from the Randomised Badger Culling Trial (RBCT) that took place between 1998 and 2005 (Woodroffe et al, 2006) although this hypothesis has been challenged (More et al, 2007). However, this is indirectly supported by evidence from Woodchester Park and other studies in England (Carter et al, 2007; Rogers et al, 1998; Vicente et al, 2007; Weber et al, 2013).

k. The RBCT found that while bTB outbreaks in cattle declined inside the proactive badger cull areas, an increase was seen in the surrounding 2km area. The reason for this increase is thought to be due to the increased perturbation of the badger social groups surrounding culled areas leading to increased bTB transmission. The scientists proposed that although there was a reduction in badger numbers within the cull area, the remaining badgers roamed over a wider area (Woodroffe et al, 2006). Additionally, mechanisms whereby indirect effects of culling on neighbouring social groups through the inward movement of badgers into the vacant territories ("vacuum effects"; Carter et al, 2007), have also been invoked to explain the patterns of risk. It is thought that these processes may lead to more contact between badgers and cattle and increasing the likelihood of badgers spreading disease to cattle, although this is unproven. The exact mechanism by which TB prevalence increases in perturbed populations has yet to be elucidated

l. The increased infection levels observed in the RBCT in cattle herds adjacent to areas where culling was carried out was short lived. The perturbation effect in the surrounding area was seen to disappear within 18 months after the end of culling (Jenkins, Woodroffe & Donnelly 2010).

m. It is currently not known if there is a threshold of badger removal at which a perturbation effect is not observed. It has been suggested that to reduce the risk of culling induced perturbation effect, a minimum of 70% of the population is required to be removed to mimic the conditions within the RBCT (Donnelly and Woodroffet 2015). However, variation in proportion of the badger population removed during the RBCT have been published during the initial culls (32%-77% removal; Smith and Cheeseman, 2007) and in metrics of relative abundance (Woodroffe et al, 2008). The 95% confidence intervals associated with potential activation of badger perturbation were so wide, even removal of one badger from a social group could not be discounted as potentially causing perturbation (Bielby et al, 2014).

n. In Ireland social perturbation of badgers has been described (i.e. how changes in abundance can alter socio-spatial dynamics of badger populations (O'CorryCrowe et al, 1993; Sleeman and Mulcahy, 2005), however there has been no evidence in support of the perturbation effect (i.e. social perturbation being associated with increasing badger and subsequently cattle bTB risk; SPR page 50, 118b iv).

o. Aspects of badger ecology differs across jurisdictions and the badger population density in England is typically greater than in Ireland and NI (compare Ireland: Feore, 1994; Smal, 1995; Sheridan, 2011; Reid et al, 2012; Byrne et al, 2012; Byrne et al, 2014a; with GB: Thornton 1988; Cresswell et al, 1990; Wilson et al, 1997; Judge et at, 2017). However, modelling outputs would suggest this has little influence on various interventions with respect to badger bTB within intervention areas between SW England and NI (Smith et al, 2016).

p. With proactive culling, it is recommended that hard boundaries are utilised where possible to reduce badger movements in and out of the cull area

(TBSPG, 2016).

q. For the badger culls in England, Defra guidance to Natural England who consider cull licence applications, is that applicants must put in place reasonable measures to mitigate the risk to non-participating farmers and landowners of a potential increase in confirmed new bTB incidents in vulnerable livestock within the culled area and in the 2km ring surrounding it (Defra, 2018). Applicants are asked to design their areas with hard boundaries to mitigate against any possible perturbation effect.

r. The culling policies implemented in Somerset and Gloucestershire have been analysed (Brunton et al, 2017) and concluded that an increase in incidence was associated with culling in the 2km buffer surrounding the Somerset intervention area but not in Gloucestershire (the caveat 'd' above applies).

s. There is some evidence from simulation models that culling can be more effective than vaccination strategies alone and that culling with a 2km ring vaccination is more effective than culling or vaccination alone (TBSPG, Annex B, page 12, 1.6).

Summary on Proactive culling (Option ii)

Two separate culling trials demonstrate a significant benefit in multi-annual proactive culling with respect to the reduction in cattle herd bTB incidence (Donnelly et al, 2006; Griffin et al, 2005) with extended benefits indicated for several years after cessation of the culling (Byrne et al, 2014b; Donnelly et al, 2011; Jenkins et al, 2010).

This robust evidence is tempered with the potential for a perturbation effect peripheral to the proactive culling area, although this was not observed in the Irish situation. Use of geographical boundaries could limit any potential perturbation effect or use of a buffer vaccination area as proposed by TBSPG.

iii. Test and Vaccinate or Remove (TVR)

a. TVR has been demonstrated to be feasible and, on first principles of infectious disease control, could have a protective role through selective culling to remove bTB infected badgers, hence decreasing the infection load, and by vaccination to enhance immunity against bTB in the remaining badger population.

b. The DAERA TVR research study was not designed to provide evidence of a statistically significant effect of the TVR approach on badger or cattle bTB levels (DAERA, 2017). It could, however, provide very useful ecological and logistical information that can contribute to planning and costings. No other field trials using a TVR approach have been carried out. Modelling results are equivocal on the timescale as to whether TVR would take a longer timescale than proactive culling to reach similar badger TB prevalence levels within each model (Abdou et al, 2016; Smith et al, 2016).

c. There is currently limited information about the effectiveness of TVR in badgers. Modelling would suggest that TVR would be effective in reducing bTB levels in badgers and cattle if there was no perturbation effect (Smith el al, 2013, 2016). Preliminary field results would conclude that there appears to be no apparent negative impact of such an intervention approach in terms of increasing prevalence within the badger population or badger perturbation
(O'Hagan et al, 2019, DAERNAPHA, unpublished data).

d. TVR could strengthen the ability of vaccination to limit transmission through the selective removal of infected (and potentially infectious) badgers, thereby reducing infection prevalence in the residual population during the vaccination period. Several factors could reduce the effectiveness of this strategy including test sensitivity and a perturbation effect (SPR additional comments page 3 para 7).

e. Early indications from the TVR study are that perturbation is not an issue using this type of intervention (O'Hagan et alt 2019; 16.5% of captured badgers were removed during the first year of TVR intervention and no increased ranging behaviour was observed; with an estimated capture rates of approximately 55%). However, the TVR project occurred in one 100km^2 area with no replicates and the only control was the before and after design. Therefore this TVR study was not of a sufficient scale or design to demonstrate any statistically significant impact on bTB levels in badgers or cattle.

f. Wales recently adopted a targeted test and remove (as no BCG vaccine was available during 2016/17) approach in the area around chronic bTB cattle herds but there has been no evaluation of its effect on the breakdown herds.

g. Modelling of TVR in the absence of a perturbation effect resulted in dramatic declines in the number of infected badgers and hence confirmed bTB herd breakdowns in the management area, with some small benefit in the ring immediately beyond (Smith et al, 2013). In the presence of a perturbation effect (at a level as seen in the RBCT), TVR simulations showed an initial rise in the number of infected badgers (and bTB herd breakdowns) in both the treatment area and the immediately surrounding ring. However, bi-annual treatment in the first year substantially reduced the negative effects of badger perturbation in the model and led to a noticeable reduction in the number of bTB herd breakdowns over a ten-year period (compared to the same effort distributed on an annual basis). The modelling results suggest that the number of infected badgers in the treatment area should decline by about 60% in Northem Ireland over a five-year period of treatment (30% if a perturbation effect occurs in a manner similar to that seen during the RBCT), if a variable control strategy is adopted. In the absence of a perturbation effect, this may equate to a 30% reduction in the incidence of bTB in cattle in the core area over the five-year period. With a perturbation effect simulated, the reduction would be too small to be detected in cattle over this time period.

h. Further modelling by this group (Smith et at, 2016) compared different intervention strategies (vaccination, proactive culling, TVR) for both SW England and Nt. As usual, there were large levels of uncertainty surrounding the model outputs but, TVR without a perturbation effect gave slightly better results than non-selective culling with respect to the mean number of infected badgers and the mean cattle herd breakdown rate. This effect was negated if a perturbation effect was included.

i. Modelling would also indicate that significantly less badgers (up to 83% less) would be removed during a five-year TVR approach compared to proactive culling (Smith et al, 2016).

j. This TVR modelling was carried out using the test characteristics for the Brock-TB StatPak test. The replacement to this test, the Dual Path Platform (DPP) VetTB test, demonstrated a higher sensitivity (80% using Band 1 only cf. 50%) and therefore would detect more truly bTB infected badgers (Jinks et al, 2019) and this may indicate that use of the DPP test would be more effective than the modelling suggests (specificity values are similar for both tests, circa 93%). Moreover, a proportion of the truly negative badgers will be protected through vaccination.

Summary on TVR (Option iii)

From infectious disease control principles and modelling outputs, WR could have a positive impact on both badger and cattle bTB levels but the imperfect nature of the DPP test and of BCG vaccine efficacy may suggest that it may take a longer time period to achieve an equivalent end point as proactive culling (although modelling results are equivocal on this point). Selective culling will remove significantly less badgers and this may lessen social perturbation (cf. proactive culling) and hence the risk of any perturbation effect. However, to date, no field trials have been undertaken to formulate evidence to support or refute a TVR approach.

iv. Enhanced TVR

a. Even in heavily infected badger populations (30-40% bTB prevalence; Murphy et alt 201 Oh the majority of badgers that are removed during a proactive cull will not have bTB.

b, Visual inspection of the TVR project would suggest that there is heterogeneity of badger bTB infection across the $100km^2$ study area. This would again indicate that there may be a significant proportion of a potential badger intervention area where badgers would be culled that may not be infected with bTB (Menzies, personal communication). Heterogeneity of badger bTB infection across social groups over time is also observed within the
Woodchester Park study area in England (Carter et al, 2012).

c. At a county level within Ireland, badger apparent prevalence varied from <3.5% culture positive (e.g. Co. Monaghan) to >17% (e.g. County Clare) based on animals culled from 2007-2012 (Byrne et al, 2015).

d. Modelling results from the Kilkenny study (Aznar et al, 2018) stated that 'with vaccination coverage in badgers exceeding 30%, eradication of M. bovis in badgers in Ireland is feasible, provided that the current control measures also remain in place' (see vaccination section). This was on the basis that the true badger prevalence of M. bovis in endemic areas in Ireland was approximately 18%.

e. It raises the possibility of the potential option of more targeted proactive or reactive culling in sub-areas within a larger intervention area; ie, enhanced TVR. While this is a conceptually available option, there is currently no evidence that this approach would work.

Summary on enhanced TVR (Option iv)

eTVR should work based on first principles but it is further complicated by the issue of a theoretical perturbation effect. There is a much larger degree of scientific uncertainty associated with such an approach. Also, there are no trials or modelling outputs to support eTVR and the ability to identify mini-areas where you would proactively cull is also a major issue.

v. Options ii-iv followed by vaccination

a. For bTB eradication, the national bTB programme may need to consider the inclusion of a long-term strategy of badger vaccination throughout NI, conducted over an extended period with a high level of vaccine coverage (SPR page 6, para 17).

b. Modelling results from the Kilkenny study (Aznar et al, 2018) stated that 'with vaccination coverage in badgers exceeding 30%, eradication of M. bovis in badgers in Ireland is feasible, provided that the current control measures also remain in place' (see vaccination section).

c. On the basis of the unpublished results of the Kilkenny and non-inferiority trials, Ireland is now using vaccination as a tool to limit the transmission of M. bovis between badgers, and from badgers to cattle in areas where there has been badger culling.

d. Ireland intend to replace continued culling with vaccination, although they will continue to cull when necessary (Houtsma et al, 2018).

e. There is a paucity of evidence to indicate as to when an intervention would switch to vaccination. With efficacious serial annual proactive culling, a high percentage of badgers would be removed after a four-year period (Smith and Cheeseman, 2007). However, there is little evidential basis to conclude that this is long enough to switch to a vaccination programme to effectively control bTB in a badger population.

f. In Ireland, where they are gradually switching to badger vaccination from badger culling, their culling programme has been carried out in these areas for at least ten years with the inferiority trial indicated it is prudent to switch from culling to vaccination after this length of time (O'Keeffe, 2017; Houtsma et al, 2018).

g. It is likely that vaccination will be required for many years, if eradication is to be achieved (SPR additional comments page 5, para 16; Abdou et al, 2016; Comer et al, 2009; Delahay et al, 2003; Robinson et al, 2012; Wilkinson et al, 2004).

h, There is no direct evidence on the effectiveness of vaccination following TVR or eTVR interventions. However, one would expect a smoother transition from TVR/eTVR to vaccination as this approach would have a relatively minor impact on reduction of the badger population size and the majority of the remaining badger population will already have been vaccinated (cf. proactive culling where the badger population is much reduced and none of the remaining badgers have been vaccinated).

Summary on Options ii-iv followed by vaccination

It appears that a longer-term badger vaccination strategy would have general scientific support although the unpublished Irish inferiority trial presents as the only potential field evidence that it would be effective, at least in the short term. Modelling outputs also support follow up badger vaccination. Parameters cannot be accurately set through which a switch between interventions to vaccination can be dictated. Circumstantial evidence would suggest that the intervention switch timescale may be between 4-10 years.

Summary points of the scientific evidence

<u>Vaccination</u>

1. BCG vaccination can protect naive badgers from progression to advanced M.

bovis infection.

2. BCG vaccination can reduce bTB spread between badgers.
3. BCG vaccination could with time lead to eradication of M. bovis in badgers.
4. its efficacy in high bTB prevalence populations is uncertain and there are concerns around whether it would be sufficient to reduce spread of infection.

Proactive culling

5. Multi-annual proactive culling over large areas is the only intervention with published field evidence that it leads to a reduction in cattle bTB incidence.
6. There is a relatively strong evidence base for proactive culling based on two independent controlled field trials, so this provides less uncertainty about the outcome from this approach regarding achieving a reduction in cattle herd incidence.
7. Large scale proactive badger culling is currently taking place in England but there is insufficient evidence to allow a judgement on its effect on bTB levels in cattle and any perturbation effect.
8. The majority of badgers removed through such an approach would not have TB infection.

Perturbation effect

9. Social perturbation (i.e. disruption of badger social structure) has been reported from Britain and Ireland.
10. The perturbation effect hypothesis (social disruption leading to increase TB levels in badgers and consequently spilling over to cattle populations) has been reported in England but not in Ireland.
11. There is a lack of evidence from Ireland of the hypothesised perturbation effect. Although a different intervention approach (reactive culling) was used in Ireland compared to proactive culling in England, it ultimately resulted in a similar scenario with reactive culling areas coalescing.

TVR

12. Modelling exercises have suggested that TVR should work but this is complicated by the issue of a hypothesised perturbation effect. There is a larger degree of uncertainty associated with such an approach, including the risk of releasing false negative badgers although the naive badger population would be provided with some protection through BCG vaccination.

13. Preliminary analysis of data from the TVR project in NI indicated no evidence of badger perturbation (note the qualifications previously mentioned regarding this project).
14. The more focused cull effort selectively removes test positive badgers that are far more likely to have bTB infection than test negative badgers.

eTVR

15. eTVR should work on first principles but lacks modelling outputs and the caveats in (1244) and (1342) also apply.
16. Identification of the sub-areas for proactive culling is an issue.

TBSPG approach

17. The TBSPG approach takes account of the above information and is supported by independent expert advice. It incorporates a cull over a large area with a protective TVR ring to mitigate against any perturbation effect.
18. 0n the basis of 1 og above there is an argument for not having the TVR buffer ring (or vaccination ring) around a cull area. This would enable the intervention area to be used to its maximum effect. Indeed, England does not insist on a protective vaccination ring for their industry-led cull areas. Hard boundaries, as described in the TBSPG report, would still be used where possible as a matter of best practice (as illustrated in the proposed area selection approach; VEU, 2017).

Follow-up vaccination

19, Targeted culling has taken place in Ireland for more than 10 years.
20. In some culling areas, on the basis of the outcome of their non-inferiority trial results, Ireland are replacing culling with vaccination. This is in part due to the recognition that long-term culling was not ecologically desirable.
21. The longer-term outcome from use of culling followed by vaccination remains unknown.

Discussion of the scientific evidence

There was agreement that badger intervention was necessary and that its purpose was to break the cycle of spread of infection between badgers and cattle. Both species need to be targeted, therefore cattle measures are required to reduce the risk of continued spread of infection to the badger population. The tong term strategic aim is to use vaccination to protect badgers and reduce intra- and interspecies spread. It is most likely that badger vaccination will be required as an integral part of the TB programme for many years. In discussion, it was agreed in principle that application of biosecurity measures should also be encouraged to reduce spread between the species.

The current scientific evidence base would suggest that moving immediately to vaccination only is not an effective option as its efficacy in high bTB prevalence badger populations is unlikely to be sufficient to reduce the spread of infection. It is generally agreed that a reduction of the infection load within a badger population is required to enable vaccination to then be utilised in the control of bTB.

To date, most of the published evidence is linked to the effect of repeated proactive culling on cattle disease levels over a range of timescales. Indeed, the two controlled trials both show positive impacts of proactive culling within intervention areas. Use of proactive culling is indiscriminate and therefore a high proportion of the badgers removed are not infected (up to 83% more badgers removed than with a TVR approach over five years). It will create disturbance of the local badger population within and immediately outside of the intervention area. The evidence for proactive culling causing a perturbation effect is mixed. However, badger ecology in NI would be considered to be more aligned to that within Ireland (as the island can arguably be considered as one epidemiological unit) where no significant perturbation effect was observed. Moreover, there is evidence to suggest that the benefits of a proactive badger cull have been maintained for a number of years post-intervention within cull zones within both Ireland and GB. Increased herd risk in the periphery of the RBCT, associated with the perturbation effect hypothesis, was also found to be transitory.

From first principles of infectious disease control and modelling outputs, TVR has the potential to remove infected badgers and build a protected population with significantly less disruption to the existing population. In his assessment of the TVR approach in his Scientific Review, Professor More stated that there were a number of factors that could reduce its effectiveness, including test sensitivity and the perturbation effect. However, the sensitivity of the DPP test has subsequently been calculated to be 80% (higher than the 50% used in the published models) and the early indications from the TVR study are that there is no evidence of badger perturbation. No field trials aimed at assessing the impact of a TVR approach on cattle bTB herd incidence have been carried out, which adds uncertainty to the outcomes from such an approach (cf. proactive culling).

For potential cull interventions, there is a shortage of evidence of the metrics that could be used to determine when culling can stop and be replaced by vaccination. For proactive culling, this probably lies between 4-10 years based on indirect field observations but is less defined for a TVR approach.

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References

Abdou, tvl., Frankenat K., O'Keeffe, J. and Byrne, A.W. (2016). Effect of culling and vaccination on bovine tuberculosis infection in a European badger (Meles meles) population by spatial simulation modeling. Preventive Veterinary Medicine, 125, 1930.

APHA (2017). Differences between Bovine TB indicators in the Intensive Action Area and the comparison area (1 May 2010 to 30 April 2016). Report for the Welsh Govemment. Pp. 53. https://aov.wales/differences-between-bovine-tb-indicatorsintensive-action-area-and-comparison-area-l -may-2010-30

Aznar, 1., Frankenat K., More S.J., O'Keefe, J., McGrath, G.. and de Jong, M.C. (2018). Quantification of Mycobacterium bovis in a badger field trial. Preventative Veterinary Medicine, 149, 29-37.

Bielby, Jit Donnelly, C.A., Pope, L.C., Burke, T. and Woodroffe, R. (2014). Badger responses to small-scale culling may compromise targeted control of bovine tuberculosis. Proceedings of the National Academy of Sciences, 111 t 9193—9198.

Brunton, L.A., Donnelly, CA., O'Connor, H., Prosser, A., Ashfield, S.i Ashton, A., Uptont P., Mitchell, X, Goodchild, A.V., Parry, J.E. and Downs, S.H. (2017).
Assessing the effects of the first 2 years of industry-led badger culling in England on the incidence of bovine tuberculosis in cattle in 2013-2015. Ecology and Evolution, 4, 7213-7230. https://doi.org/10.1002/ece3.3254

Byrne, A.W., Acevedo, P. , Green, S. and O'Keeffe, J. (2014a). Estimating badger social-group abundance in the Republic of Ireland using cross-validated species distribution modelling. Ecological indicatorst 43, 94-102.

Byme, A.W., Kenny, K., Fogarty, U., O'Keeffe, J.J., More, S.J., McGrath, G., Teeling, M., Martin, S.W. and Dohoo, I.R. (2015). Spatial and temporal analyses of metrics of tuberculosis infection in badgers (Meles meles) from the Republic of Ireland: Trends in apparent prevalence. Preventive Veterinary Medicine, 122, 345-354.

Byrne, A.W.t O'Keeffe, J., Green, S.t Sleeman, D.P., Corner, L.A., Gormley, E., Murphy, D., Martin, S.W. and Davenport, J. (2012). Population estimation and trappability of the European badger (Meles meles): implications for tuberculosis management. Plos One, 7(12), p.e50807

Byrne, A.W., White, P.W.t McGrath, G., O'Keeffe, J. and Martin, S.W. (2014b). Risk of tuberculosis cattle herd breakdowns in Ireland: effects of badger culling effort, density and historic large-scale interventions. Veterinary Research, 45, 109-119.

Carter, S.P., Chambers, M.A., Rushton, S.P., Shirley, M.D.F., Schuchert, P., Pietravalle, S., Murray, A., Rogers, F.t Gettinby, G., Smith, G.C., Delahay, R.J., Hewinson, R.G. and McDonald, R.A. (2012). BCG vaccination reduces risk of tuberculosis infection in vaccinated badgers and unvaccinated badger cubs. PLoS one, 7t e49833.

Carter, S.P.t Delahay, R.J., Smith, G.C., Macdonald, D.W., Riordan, P., Etherington, T.R., Pimley, E.R., Walker, N.J. and Cheeseman, C.L. (2007). Culling-induced social perturbation in Eurasian badgers Meles meles and the management of TB in cattle: an analysis of a critical problem in applied ecology. Proceedings of the Royal Society of London B: Biological Sciences, 274, 2769-2777.

Chambers, M.A., Rogers, F. t Delahay, R.J., Lesellier, S., Ashford, R., Dailey, D., Gowtage, S., Davé, De, Palmer, S., Brewer, J., Crawshaw, T., Clifton-Hadley, R., Carter, S., Cheeseman, C., Hanks, C., Murray, A., Palphramandt K., Pietravallet S., Smith, G.C., Tomlinson, A., Walker, N.J., Wilson, G.J.t Comer, L.A.L., Rushton, S.P., Shirley, M.D.F.t Gettinby, G., McDonald, R.A. and Hewinson, R.G. (2011 Bacillus Calmette Guérin vaccination reduces the severity and progression of tuberculosis in badgers. Proceedings of the Royal Society B: Biological Sciences, 278, 1913-1920.

Corner, L.A.L., Clegg, T.A., More, S.J., Williams, D.H., O'Boyle, 1., Costello, E., Sleeman, D.P. and Griffin, J.M. (2008). The effect of varying levels of population control on the prevalence of tuberculosis in badgers in Ireland. Research in Veterinary Science, 85, 238-249.

Corner, L.A.L., Murphy, D., Costello, E. and Gormley, E. (2009). Tuberculosis in European Badgers (Meles meles) and the control of infection with bacille CalmetteGuérin vaccination. Journal of Wildlife Diseases, 45, 1042-1047.

Cresswell P., Harris, S. and Jefferies, D. J. (1990). The history, distribution, status and habitat requirements of the badger in Britaim Nature Conservancy Council, Peterborough, UK.

Donnelly, C.A., Bento, A.l., Goodchildt A.V. and Downs, S.H. (2015).

Exploration of the power of routine surveillance data to assess the impacts of industry-led badger culling on bovine tuberculosis incidence in cattle herds. Veterinary Record, 177, 417-421.

DAERA (2017). Test and vaccinate or remove (TVR) wildlife intervention research project - year 4 report. https://www.daera-ni.gov.uk/publications/tvr-wildlifeintervention-research-project-year-4-report-2017 .

Defra (2018), Guidance to Natural England: Licences to kill or take badgers for the purpose of preventing the spread of bovine TB under section 10(20(a) of the Protection of Badgers Act 1992. May 2018. Pp. 19. https://assets.publishinq.service.qov.uk/qovernment/uploads/system/uploads/attachment data/file/710537/tb-licensinq-quidance-ne.pdf

Donnelly, C.A. and Woodroffe, R. (2015). Bovine tuberculosis: Badger-cutl targets unlikely to reduce TB. Nature, 526, 640.

Donnelly, C.A., Jenkins, H.E. and Woodroffe, R. (2011). Analysis of further data (to 28 August 2011) on the impacts on cattle TB incidence of repeated badger culling. PLoS One, 5: e9090. Addendum to: Jenkins, H.E., Woodroffe, R. and Donnelly, C.A. (2010). The duration of the effects of repeated widespread badger culling on cattle tuberculosis following the cessation of culling. PLoS Onet 5(2), e9090. doi:10.1371 [journal.pone.0009090

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

Feore, S.M. (1994). The Distribution and Abundance of the Badger Meles meles L. in Northem Ireland. PhD Thesis, Queen's University Belfast. 285 pp.

Godfray, H.C.J., Donnelly, C.A., Hewinson, R.G., Winter, M. and Wood, J.L. (2018). Bovine TB strategy review: Report to Rt Hon Michael Gove MP, Secretary of State, Defra. October, 2018. Pp. 138.

Godfray, H.C.J., Donnelly, C.A., Kao, R.R., Macdonald, D.W., McDonald, RA., Petrokofsky, G., Wood, J.L., Woodroffe, R., Young, D.B. and McLean, A.R (2013). A restatement of the natural science evidence base relevant to the control of bovine tuberculosis in Great Britain. Proceedings of the Royal Society B: Biological Sciences, 280t 1634.

Gormley, E., N" Bhuachallai D., O'Keeffe, J., Murphy, De, Aldwell, F.E., Fitzsimons, T., Stanley, P., Tratalos, J.A., McGrath, G.i Fogarty, N., Kenny, K., More, S.J., Messam, L.L. and Comer, L.A.L. (2017). Oral vaccination of free-living badgers (Meles meles) with Bacille Calmette Guérin (BCG) vaccine confers protection against tuberculosis. Pi-os one, 12, e0168851.

Griffin, J.M., Williams, D.H.t Kelly, G.E., Clegg, T.A., O'Boyle, 1., Collins, J.D. and More, S.J. (2005). The impact of badger removal on the control of tuberculosis in cattle herds in Ireland. Preventive Veterinary Medicine, 67t 237-266.

Hardstaff, J.L., Bulling, M.T., Marion, G.t Hutchings, M.R. and White, P.C.L. (2013). Modetling the impact of vaccination on tuberculosis in badgers. Epidemiology and Infection, 141, 1417-1427.

Houtsma, E., Clegg, T. A., Good, M. and More, S. J. (2018). Further improvement in the control of bovine tuberculosis recurrence in Ireland. Veterinary Record, 183, 622628.

Jenkins, H.E., Morrison, W.l., Cox, D.R., Donnelly, C.A., Johnston, W.T., Boume, F.J., Clifton-Hadley, R.S., Gettinby, G., McInerney, J.P., Watkins, G.H. and Woodroffe, R. (2008). The prevalence, distribution and severity of detectable pathological lesions in badgers naturally infected with Mycobacterium bovis. Epidemiology and Infection, 136, 1350-1361.

Jenkins, H.E., Woodroffe, R. and Donnelly, C.A. (2010). The duration of the effects of repeated widespread badger culling on cattle tuberculosis following the cessation of culling. PLoS one, 5, e9090.

Jinks, R.C., Lesellier, S., Smith, F.t Menziest F.D., Ashford, R., Waring, Let Dave, D. , Anderson, P., Stringer, L.A., Pascual-Linaza, L.A., Corbett, D., Thompson, S. and Arnold, M.E. (2019). Evaluating sensitivity and specificity of the DPP TB assay in badgers using Bayesian methods. In preparation.

Judge, J.t Wilson, G.J., Macarthur, R. t McDonald, R.A. and Delahay, R.J. (2017). Abundance of badgers (Meles meles) in England and Wales. Nature: Scientific Reports, 7, 276. DOI:10.1038/s41598-017-00378-3

More, S.J. (2016a). The Bovine Tuberculosis Eradication Programme in Northem Ireland Proposals from the Tuberculosis Strategic Partnership Group (TBSPG) Scientific peer review: Final report. 13 September 2016. Pp. 71. https://www.daerani.gov.uk/sites/default/files/publications/daera/peer-review-of-scientific-appraisal-bysimon-more-ucd.PDF

More, S.J. (2016b). The Bovine Tuberculosis Eradication Programme in Northern Ireland Proposals from the Tuberculosis Strategic Partnership Group (TBSPG) Scientific peer review: Additional comments. 9 November 2016. Pp. 6. https:l/www.daera-ni.qov.uk/sites/default/files/publications/daera/peer-review-ofscientific-appraisal-by-simon-more-additional-comments.PDF

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

Murphy, D. , Gormleyt E.t Collins, D.M., McGrath, G., Sovsic, E., Costello, E. and Corner, L.A.L. (2011). Tuberculosis in cattle herds are sentinels for Mycobacterium bovis infection in European badgers (Meles meles): the Irish Greenfield Study. Veterinary Microbiology, 151, 120-125.

Murphy, n , Gormley, E., Costello, E., O'Meara, D. and Comer, LA.L. (2010). The prevalence and distribution of Mycobacterium bovis infection in European badgers (Meles meles) as determined by enhanced post mortem examination and bacteriological culture. Research in Veterinary Science, 88, 1-5.

O'Connor, C.M.t Haydon, D.T. and Kao, R.R. (2012). An ecological and comparative perspective on the control of bovine tuberculosis in Great Britain and the Republic of Ireland. Preventive Veterinary Medicine, 104, 185-197.

O'Corry-Crowe, G., Eves, J. and Hayden, T.J. (1993). Sett distribution, territory size and population density of badgers (Meles meles L.) in East Offaly. The badger, 35, 56.

O'Keeffe, J. (2017). Replacing badger culling with vaccination in Ireland. Presentation at a one day bovine tuberculosis symposium held at Imperial College, London by the Save Me Trust (28 March 2017).

O'Hagan, M.J.H., Gordon, A.W., McCormick,C.M., Collins, S.F., Trimble, N.A., McGeown, CF., McHugh, G.E., McBride, K.R. and Menzies, F.D. (2019). The effect on ranging behaviour after selective removal of bovine tuberculosis test positive badgers (Meles meles) using a test and vaccinate or remove intervention in Northem Ireland. (In preparation).

Reid, N.t Etherington, T.R., Wilson, G.J., Montgomery, W.l. and McDonald, R,A, (2012). Monitoring and population estimation of the European badger Meles meles in Northem Ireland. Wildlife Biology, 18t 46-57.

Robinson, P.A., Comer, L.A.L., Courcier, E.A., McNairt J.t Artois, M., Menzies, F.D and Abemethy, D.A. (2012). BCG vaccination against tuberculosis in European badgers (Meles meles): A review. Comparative Immunology, Microbiology and Infectious Diseases, 35, 277-287. doi:10.1016/j.cimid.2012.01.009

Rogers, L.M., Delahay, R., Cheeseman, C.L., Langton, S.t Smith, G.C. and CliftonHadley, R.S. (1998). Movement of badgers (Meles meles) in a high— density population: individual, population and disease effects. Proceedings of the Royal Society of London B: Biological Sciences, 265, 269-1276.

Sheridan, M. (2011 Progress in tuberculosis eradication in Ireland. Veterinary Microbiology, 151, 160-169.

Sleemant D.P. and Mulcahy, M.F. (2005). Loss of territoriality in a local badger Meles meles population at Kilmurry, Co Cork, Ireland. Irish Naturalists' Journal, 341 11-19.

Smal, C. (1995). The badger and habitat survey of Ireland. In: Research Project Report Prepared for the National Parks and Wildlife Service and the Department of Agriculture, Food and Forestry, Govemment Publications Service, Dublin, 323 pp.

Smith, G.C., Budgey, R. and Delahay, R.J. (2013). A simulation model to support a study of test and vaccinate or remove (TVR) in Northem Ireland. AHVLA National Wildlife Management Centre report commissioned by DARD. Pp. 81.
https://www.daera-ni.qov.uldsites/default/files/publications/dard/fera-tvr-modellinqreport.pdf

Smith, G.C. and Cheeseman, CL. (2007). Efficacy of trapping during the initial proactive culls in the randomised badger culling trial. Veterinary Record, 160, 723726.

Smith, G.C., Cheeseman, C.L., Clifton-Hadley, R.S. and Wilkinson, D. (2001). A model of bovine tuberculosis in the badger, Meles meles: an evaluation of control strategies. Journal of Applied Ecology, 38, 509-519.

Smith, G.C., Delahay, R.J., McDonald, R.A. and Budgey, R. (2016). Model of selective and non-selective management of badgers (Meles meles) to control bovine tuberculosis in badgers and cattle. PLoS One, 11 (Nov), e0167206.doi:10.1371/journal.pone.0167206.

TBSPG (2016). Bovine tuberculosis eradication strategy for Northern Ireland. Annex B. https://www.daera-ni.qov.uWsites/default/files/publications/daera/annex-b-toscientific-appraisal-wildlife-and-vaccination-science-and-epidemioloqy-proposals-bytbspq.pdf . December 2016. Pp 50.

Thornton, P.S. (1988). Density and distribution of Badgers in south-west England—a predictive model. Mammal Review, 18, 11-23.

VEIJ (2013). Scientific rational and recommendations regarding the selection of provisional areas for implementation of the badger test and vaccinate or removal (TVR) project proposal. February 2013. Pp. 14.

VEIJ (2017). A proposed methodology for the identification and description of potential badger intervention areas. July 2017. Pp. 14.

Vicente, J., Delahay, R.J., Walker, N.J. and Cheeseman, C.L. (2007). Social organization and movement influence the incidence of bovine tuberculosis in an undisturbed high-density badger Meles meles population. Journal of Animal Ecology, 76, 348-360.

Weber, N. , Carter, S.P, Dall, S.D.X., Delahay, R.J., McDonald, J.L., Bearhop, S. and McDonald, R.A. (2013). Badger social networks correlate with tuberculosis infection. Current Biology, 23, R915-R916.

Wilkinson, D., Smith, G.C., Delahay, R.J. and Cheeseman, C.L. (2004). A model of bovine tuberculosis in the badger, Meles meles: an evaluation of different vaccination strategies. Journal of Applied Ecology, 41 , 492-501.

Wilsont G., Harris, S. and McLaren, G. (1997). Changes in the British badger population, 1988 to 1997. People's Trust for Endangered Species.

Woodroffet R., Donnelly, C.A., Jenkins, I-I.E., Johnston, W.T„ Cox, D.R., Boume, F.J„ Cheeseman, C.L., Delahay, R.J., Clifton-Hadley, R.S., Gettinby, G , Gilks, P.,Hewinson, R.G., McInerney, J.P. and Morrison, Wili (2006). Culling and cattle controls influence tuberculosis risk for badgers. Proceedings of the National Academy of Sciences of the United States ofAmerica, 103, 14713-14717.

Woodroffe, R., Gilks, P.t Johnston, W.T., Le Fevre, A.M., Cox, DR., Donnelly, C.A., Bourne, F.J., Cheeseman, C.L., Gettinby, G.t McInemey, J.P. and Morrison, W]. (2008). Effects of culling on badger abundance: impiications for tuberculosis control. Journal of Zoology, 274, 28-37.