

ANNEX B

WILDLIFE & VACCINATION

The TBSPG's main objective is to eradicate bTB in the cattle population in Northern Ireland. The primary purpose of the Group's badger intervention strategy is to address the bTB reservoir in badgers to help eradicate bTB in cattle herds and contribute to the health of the badger population.

The cattle population in Northern Ireland will be subjected to enhanced control measures, including the increased use of more sensitive diagnostics to identify infection at an early stage and mitigate the potential spread of bTB to neighbouring cattle and badger populations.

TBSPG recognise that the spread of bTB may be caused in many different ways, one of which may be connected to wildlife, and it is in these situations that wildlife intervention may be required.

Badgers are known to be an infected species with bTB, and conservative estimates suggest that 17% of badgers in Northern Ireland are infected (based on the on-going RTA survey; e.g. see Abernethy et al. 2011) although this figure may be significantly higher when "forensic" approaches are used to increase the sensitivity of post-mortem testing (Murphy et al. 2010; Corner et al. 2012) and in "hot spot" areas based on evidence from a project undertaken in Ireland. TBSPG recently reviewed the functionality of the Northern Ireland RTA survey and made appropriate recommendations. That review is to be found in the Appendix to this section.

There have been significant scientific studies and research published, however the means (i.e. the major route of transmission) of TB transmission between badgers and cattle has not been conclusively established. The data suggest that transmission is bi-directional, with some inter species seeding of infection between hosts (e.g. Byrne et al. 2015a; Biek et al. 2012). Large scale culling projects have demonstrated that reducing badger density can reduce cattle breakdown risk, indicating evidence of badger-to-cattle transmission (Eves 1999; Gallagher and Clifton-Hadley 2000; Griffin et al. 2005; Donnelly et al. 2006). It is recognised that the badger is not regarded as a dead-end host (e.g. Graham et al. 2013) i.e. incapable of infecting other susceptible animals. The relevant scientific evidence indicates that badgers excrete the organism (via respiration, urine and faeces) which enables them to infect other susceptible hosts, including cattle, (e.g. Corner et al. 2012; Gavier-Widen et al. 2001; King et al. 2015), potentially by both direct and indirect contact. .

On the basis that badgers are a known and accepted reservoir of TB (for a review see: Ni Bhuachalla et al. 2014) and play a role in the maintenance of infection, any effective strategy to eradicate TB must have a policy and associated action plan, to address all sources involved in the spread of TB, including badgers.

1. WILDLIFE INTERVENTION – CULLING

1.1 Issue

It is accepted that the badger population is a reservoir for TB in Ireland and the UK (for a review see: Ní Bhuachalla et al. 2014 and Corner et al., 2011). The TBSPG understands that to effectively tackle the complex issue surrounding TB in cattle, it is critically important to address the wildlife dimension to enable eradication of TB.

A part of the approach to wildlife currently employed in England (e.g. Carter et al. 2012), Wales

(<http://gov.wales/topics/environmentcountryside/ahw/disease/bovinetuberculosis/intensive-action-area/?lang=en>) and the Republic of Ireland (e.g. Aznar et al. 2011; O’Keeffe et al. 2016) is the use of the BCG vaccination to confer, over a period of time, a level of protection to badger social groups (this will be addressed further in section 2). Vaccination is, however, ineffective in infected badgers (Chambers et al. 2014) and given the level of badger density in Northern Ireland (Reid et al. 2012), and related bTB infection (Abernethy et al. 2011), TBSPG consider that before a widespread vaccination policy could be effective, it is necessary to employ a removal strategy, to reduce the overall level of infection in the badger population (by reducing the number of infected badgers per unit area). Culling activities in Ireland suggest that repeated culling can lead to reduced prevalence in badger populations in proactive (large-scale, repeated annually, intensive; Corner et al. 2008), targeted (smaller scale, repeated annually, intensive; Byrne et al. 2015a), but not reactive culling (small scale, not repeated annually; Corner et al. 2008). However, similar results were not found during cull trials in England (Woodroffe et al. 2008). During the Randomised Badger Cull Trial (RBCT), badger prevalence increased with time during the intervention – however, since there was a significant decrease in badger density, the density of infected animals per unit area may have decreased also, allowing for the beneficial effect of culling to be recorded overall in cattle during that study (Woodroffe et al. 2008). A simulation model using parameters from the Republic of Ireland has shown that a combination strategy of culling followed by vaccination can be effective in reducing and maintaining reduced infection levels in badgers, under the model conditions and assumptions therein (Abdou et al. 2016). A second model, by Smith et al. (2012) suggests that culling with ring vaccination could yield net benefits in terms of reducing cattle herd breakdowns using parameters derived predominantly from English badger populations.

Badger culling in the Republic of Ireland has led to measurable benefits in terms of a reduction in prevalence of bTB in culled badger populations and local cattle populations during two large scale studies (Eves 1999; Griffin et al. 2005). However, mixed results were reported during a large-scale study in GB (RBCT; Donnelly et al. 2006). A significant reduction in cattle bTB herd risk was recorded within proactive cull areas within the replicated study. However, there was a significant temporary increase in risk to cattle herds surrounding culls areas (~2km around cull zones; Donnelly et al. 2006) which was attributed to the “perturbation effect” hypothesis. This perturbation effect is a hypothesis that proposes that the removal of badgers can alter movement of surviving badgers, called social perturbation, which in turn can increase the transmission of *M. bovis* within badger populations and furthermore spill over into cattle populations (Carter et al. 2012; Donnelly et al. 2006). These effects have not yet been recorded in cattle populations from Ireland surrounding

culled areas (Olea-Popelka et al. 2009; White et al. 2016). These diverging outcomes could be related to a number of factors, including the density of populations found in south-western GB relative to badger populations in Ireland (O'Connor et al. 2012). TBSPG are cognisant that it is critical that research is conducted, as part of the badger intervention programme, to clarify whether the negative trends associated with the perturbation effect hypothesis occurs in Northern Ireland following badger removal. TBSPG has also suggested an intervention which may mitigate such an effect (by having a test, vaccinate or remove programme in a buffer area around the proposed cull zones).

TBSPG acknowledge that any action relating to badgers, particularly their removal (culling), is emotive and controversial (Enticott 2015; O'Hagan et al. 2016). Badgers are a protected species under the Wildlife Order (Northern Ireland) 1985 and also internationally under the Bern Convention. DAERA will need to take account of this in its implementation of any cull policy.

There is the possibility of other wildlife species that may act as wildlife hosts of bTB, in particular deer and there is evidence that deer populations on the island of Ireland have generally increased (Carden et al. 2011). Deer are a known host of *M. bovis* in a number of countries, including in North America (O'Brien et al. 2006) and in Europe (Hardstaff et al. 2014). However, there are currently little data to support the contention that deer act as a reservoir (self-sustaining) of infection into cattle, that they are not a spill-over host (non-self sustaining) or that they come into contact with cattle at national scales (outside of local situations where forest abuts pasture) in Northern Ireland (Delahay et al. 2002; Ward et al. 2009; Putman et al. 2011). And more research would be required to assess the role of deer in the epidemiology of bTB in Northern Ireland, and whether intervention is warranted.

TBSPG has considered the impact of other species, e.g. feral cats and rats, and see no significant epidemiological evidence to indicate that they are a significant factor in the spread of bTB.

1.2 Recommendation

- The TBSPG recommend that DAERA implements a badger control policy to reduce the overall level of infection in the badger population alongside additional measures targeted at cattle herds.
- The TBSPG also recommend that any badger policy is based on a multiplicity of tools which can be used as appropriate, subject to the particular circumstances that pertain. These tools would include:
 - a. the culling of badgers in areas of high incidence, (recurrent and persistent), of bTB in cattle for a minimum of 4 years;
 - b. the vaccination of badgers, in a variety of disease situations, including follow-up vaccination for a minimum of 3 years after a badger removal operation has been completed in a chosen area;
 - c. the vaccination of badgers together with removal of test positive badgers in an area surrounding the removal zone, to mitigate the risks associated with social perturbation (social perturbation being the

increased movement of badgers surviving a cull and the disruption of social groups surrounding a culled area; Tuytens et al. 2000).

Further intervention would be considered by TBEP on the basis of evaluation and available scientific evidence.

- TBSPG also recommend the continued monitoring and evaluation of epidemiological evidence regarding the significance of bTB in deer, and other species.

1.3 Rationale for change

It is widely accepted by the scientific community that badgers play a role in maintaining bovine TB in the UK and Ireland (for a review see: Ní Bhuachalla et al. 2014 and Corner et al., 2011). Reducing the level of disease in the badger population is seen as being a key component in the package of measures to eradicate TB in cattle (e.g. Sheridan et al. 2014).

Vaccination is ineffective in eliminating bTB infection from already infected badgers (Chambers et al. 2014), and so in order to provide the best possible opportunity for vaccination to be effective, the strategic removal of badgers must be undertaken first (this principle has been assessed in a recent model by Abdou et al. 2016). Intensive, proactive, removal of badgers has been shown to reduce disease in contiguous cattle populations, e.g. the English Randomised Badger Cull Trial (RBCT; Donnelly et al. 2006; DEFRA 2007) and the East Offaly (Eves 1999) and Four Area Studies (Griffin et al. 2005) in the Republic of Ireland. Early non-replicated badger removals in England also give some observational support for a reduced risk of cattle herd breakdowns in culled/removal areas (Clifton-Hadley et al. 1995; Krebs et al. 1997; Gallagher and Clifton-Hadley 2000). However, these studies were criticised over lack of replication, lack of an explicit control area and the scale of the undertaking (Krebs et al. 1997).

Significantly, follow-up studies have shown that the initial impact of reduced levels of bTB in contiguous cattle have been maintained for up to five years (or longer) after the removal exercise was concluded after early intervention trials in England (Clifton-Hadley et al. 1995; Krebs et al. 1997; Gallagher and Clifton-Hadley 2000), after the RBCT (Donnelly et al. 2011) and in the Four Area Project (Byrne et al. 2014). In the East Offaly project area, targeted culling after proactive culling maintained declining trends in bTB levels over a 15 year period (Kelly et al. 2008).

In studies following up on the Irish Four Areas Study, Byrne et al (2014) found that the risk of herd breakdowns were lower in former culled areas relative to former control areas 10 years after the cull trial (Byrne et al. 2014). Furthermore, herd breakdowns were associated with higher badger density areas earlier in the study period.

Any intervention needs to be based on sound scientific rationale. It also needs to have a measureable and meaningful impact on bTB levels over a period of time within an intervention area. Therefore, the size of the area and scale of intervention need to correlate to the level of impact on the disease. TBSPG have taken into consideration the wildlife intervention programmes in England, ROI, Wales and New

Zealand, and the scale at which these interventions are taken, in determining their approach. For example, the RBCT cull areas were each approximately 100km² in size (Donnelly et al. 2006), which is currently the size of the licensed cull areas in England (see https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/489845/badger-culling-guidance-ne.pdf). The East Offaly project cull area was 528km² (Eves 1999; Kelly et al. 2008), while the Four Area Project cull areas varied from 188km² to 305km² (Griffin et al. 2005).

TBSPG also acknowledge that they must consider the pragmatic aspects of resources and budget in coming to any recommendation, but particularly in relation to wildlife given the resource intensive nature of any intervention programme.

The approach recommended by TBSPG combines using culling to deal with infection in a targeted area with associated vaccination and removal of test positive badgers in a buffer area to minimise the impact of a potential “perturbation effect” caused by the removal of badgers, and improve the likelihood of the recolonisation of culled areas with healthy vaccinated badgers.

TBSPG has suggested that in the buffer area the DPP test would be used alongside vaccination. The DPP test, along with its predecessor, the Brock Stat Pak Test, is believed to have a higher sensitivity in relation to heavily infected badgers (Chambers et al. 2008). Therefore, in principle, the removal of this category of animal should accelerate the rate at which vaccination is effective in protecting the badger population. Recent modelling exercises suggested that culling with vaccination can result in disease reduction in badger populations using parameters from Republic of Ireland (Abdou et al. 2016) and the UK (Smith et al 2013), once perturbation was not invoked in the UK model (Smith et al. 2013). Other modelling studies from England suggest that culling with ring vaccination can have benefits in terms of reducing bTB cattle herd breakdown risk (Smith et al. 2012). Most remaining badgers resident in the vaccinated area would be protected, and if disease is already present, its spread could be inhibited.

An additional and critical benefit is that vaccinated badgers could migrate into the removal area after a period of culling and be protected from any residual infection in the badger and cattle populations, or the sett environment. The movement of badgers into culled areas is based on the principle of source-sink dynamics, where badgers will move into vacant niche or resource (sink) from a source population. Such dynamics have been suggested to occur after culling in Republic of Ireland (Sleeman et al. 2009; Byrne et al. 2013; Byrne et al. 2016), and during re-establishment phases in Great Britain after removal (Tuytens et al. 2000; Carter et al. 2007). In adopting this vaccination approach, the TBSPG recommendations would also encourage farmer participation, for example, by taking adequate bio-security measures, especially in intervention areas (Sayers et al. 2013; O’Hagan et al. 2016). Increased resistance via vaccination would also help to protect badgers in the buffer area that may come into contact with any remaining potentially infected badgers that may migrate from the cull area.

1.4 Evidence

There are many published papers on badger removal and the role of the badger in the spread of TB. TBSPG acknowledge that there are many opinions expressed on the issue of transmission and infection. It has sought to consider a very broad spectrum of scientific evidence and reach an objective conclusion based on this evidence and its own discussions. It has the objectives of eradicating TB, removing infection from cattle, and removing infection from the badger population using the most effective and practical means to do so. Numerous research papers (see reference list below for pertinent examples) were considered by the Group to arrive at this conclusion (Allen et al. 2011).

Removal of badgers has been shown to reduce disease in contiguous cattle populations e.g. the English RBCT (DEFRA 2007) and the East Offaly (Eves 1999) and Four Area Studies in the Republic of Ireland (Griffin et al. 2005). Studies have shown that the initial impacts on reduced levels of TB in neighbouring cattle have been maintained for up to five years after removal was ended (or longer). These long term effects have been recorded after early intervention trials in England (Clifton-Hadley et al. 1995; Krebs et al. 1997; Gallagher and Clifton-Hadley 2000), after the RBCT (Donnelly et al. 2011) and the Four Area Project (Byrne et al. 2014). It should be pointed out that vaccination in the surrounding area would help to protect badgers that are re-colonizing the areas that have been subject to culling.

During the East Offaly project, intensive sustained culling of badgers coincided with the animal bTB rate (measured in positive animals per 1000 tested (APT)) decline from 3.91 APT in 1988 to 0.46 APT IN 1995 (88% decline, before and after culling; see Eves 1999). In context, the typical APT at the time was 3.8-7.2 in Ireland (Fallon & Hammond 1999). O'Mairtin et al. (1998) found that there were 1.4 odds of breakdown in control areas relative to culled areas. Kelly et al. (2008) found that proactive culling in the east Offaly area reduced risk of cattle herds significantly, while targeted culling maintained lowered risk over a period of 15 years. Raw data from that study suggested that the restriction rate in the inner removal area went from 6.03% (1989) to 1.68% (1995) during the period of proactive culling. The targeted culling that followed kept the restriction rate to 2.6%-4.3% from 1996-2004. A survival model suggested that risk declined significantly over the period of the study in the inner cull area relative to the control area baseline ($p=0.01$).

During the Four Area Project, Griffin et al. (2005) reported a 60–96% decrease in the rate at which herds were becoming the subject of a confirmed restriction in culled areas, relative to control areas. This equated to a 56.6% average reduction in restricted herds in culled areas over the study period (before and after reduction; 1997-2002).

In the RBCT trials, the summary indicated that in the proactive cull area there was on average a reduction of 23% in the incidence of TB in cattle (the final report was made by Bourne et al. (2007). In follow up studies over a 6 year period, there was a reduction in bTB of 28% and over the entire period the reduction was 26% (Godfray et al 2013). Woolhouse and Wood (2015) highlight that after the initial latent period between initial cull and being able to measure benefits there was “roughly halved the incidence of TB in cattle herds in the culling area following 4–7 annual badger culls”.

A re-evaluation of the RBCT data by the UK chief scientist in 2007 stated that; “Removal of badgers should take place alongside the continued application of controls in cattle in the area. Removal of badgers is the best option available at the moment to reduce the reservoir of infection in cattle”, (King 2007).

The House of Commons Select Committee (2008) recognised “that under certain well defined circumstances that it is possible that removal could make a contribution towards the reduction of TB in hot – spot areas”. This was dependent on the extent (geographic scale) and the efficacy (the proportion removed) of the culling operations.

Previous work in England has indicated that proactive removal over large areas may reduce disease levels but is not cost effective (DEFRA 2007). Free shooting of badgers has taken place in specific high incidence areas in England although there is as yet insufficient data to quantify the effect on cattle incidence. TBSPG is not considering recommending the English approach of free shooting though they have taken cognisance of their work and findings.

In March 2012 the Welsh Government embarked on a five year badger vaccination project within one of their Intensive Action Area (IAA) as part of efforts to eradicate bovine TB from cattle in Wales. The decision to vaccinate badgers was made following consideration of the Report of the Bovine TB Science Review Group. A report of the 4th year of operation can be accessed at the link referenced below.¹

In the Republic of Ireland there has been a policy of badger removal for a number of years (official establishment of a wildlife unit occurred in 2002 (Sheridan et al. 2014), with a national program of culling being rolled out in 2004 onwards (O’Keeffe 2006)) around breakdown farms in specific areas with a high incidence of disease, and where other sources of infection have been ruled out (O’Keeffe 2006; Sheridan et al. 2014). Republic of Ireland disease levels have reduced significantly over this time (Abernethy et al. 2013; McGrath et al. 2014; More and Good 2015), but the contribution that badger removal alone has made to this reduction cannot be easily quantified, given that the removal is undertaken alongside enhancement of other TB control measures (Sheridan et al. 2014). What can be noted is that over the last 15 years the incidence of bTB has reduced by almost 50% to less than 4% in 2015 (cf. over 8% in 2000). Badger removal alone is not a long term option in the Republic of Ireland and ultimately they want to move to a programme which includes vaccination (Byrne et al. 2014; Sheridan et al. 2014). Much of their current research is focused on this approach (Eves 1999).

In Northern Ireland, there is no experience of widespread removal or vaccination of badgers; however the DAERA Test Vaccinate or Remove Wildlife Intervention Research Study² does involve the removal of badgers that test positive to a sett side test. This is a 5 year research project and Year 3 has just been completed. Year 1 (2014)³ and Year 2 (2015)⁴ reports are available. The practical experience gained

¹ <http://gov.wales/docs/drah/publications/160404-bovine-tb-iaa-report-4.pdf>

² <https://www.daera-ni.gov.uk/articles/test-and-vaccinate-or-remove-tvr-wildlife-intervention-research>

³ <https://www.daera-ni.gov.uk/publications/tvr-wildlife-intervention-research-project-year-1-report-2014>

⁴ <https://www.daera-ni.gov.uk/publications/tvr-wildlife-intervention-research-project-year-2-report-2015>

from the TVR study to date shows that testing and removal or vaccination of badgers can be delivered in the field. There is, however, as yet, insufficient evidence to draw a conclusion on the overall value of the TVR as an intervention approach in its own right. That said, we agree with the principle of TVR and have seen sufficient evidence to conclude that there would be merit in using a TVR approach, as a means of mitigating any potential adverse perturbation effect around any intervention area.

The TVR study may also provide detailed information on badger behavior in the local situation, which is essential because of the potential differences in badger ecology and behavior here compared with other locations. We consider that any TVR evidence, alongside the results of any other local or international studies, should be used to inform the continual development of the badger intervention strategy.

Thus while there is as yet, insufficient evidence to draw a final conclusion on TVR, it has been clearly demonstrated to be practical and, as explained previously, on first principles, TBSPG see the TVR approach as having a protective role as outlined in the recommendations for initial wildlife intervention.

1.5 Detail

Protocol for Badger culling **Identification of an intervention area**

TBSPG recommends that it (and in time its successor **TBEP; TB Eradication Partnership**) would provide the Department with its assessment on suitable locations for wildlife interventions. Once local disease response groups are established they would inform the TBEP considerations (see the work of TBSPG on governance).

In putting forward its recommendations to the Department, TBSPG, and in time TBEP, would consider criteria which might include factors such as:

- Assessment of bTB incidence in the cattle population in the area
- Other potential causal factors;
- Evidence of badger activity in the area;
- Evidence of bTB in the badger population.

The criteria would be reviewed regularly.

The intervention area would comprise a central core zone surrounded by an outer buffer zone. It is anticipated that the total area(s) identified would be as large as is possible - e.g. more than circa 100 sq. km (for illustrative purposes, a circle with a radius of 6km). The best data available on the impact of culling on cattle herd risk comes from proactive culling studies over large areas (i.e. the RBCT (Donnelly et al. 2006) and the FAP (Griffin et al. 2005)), and therefore rolling out programmes that are as similar as possible would increase the probability of replicating their positive findings. An intervention area of 100km² correlates with the area size selected in England.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/48984

[5/badger-culling-guidance-ne.pdf](#)), and it is the scale at which interventions took place during the RBCT (Donnelly et al. 2006). Intervention sites could be located near natural boundaries e.g. rivers, mountain ranges, coastlines etc., to act as barriers to badger dispersal (Sleeman et al. 2009; Etherington et al. 2014) wherever possible to reduce any possibility of a social perturbation effect (Tuytens et al. 2000) which could lead to disease spread.

An additional benefit of larger areas is that the surrounding buffer zone would be proportionately smaller (relative to the total area) and therefore easier and more cost effective to manage (i.e. the area to perimeter ratio would be smaller, the larger the area). It therefore follows that the central core zone would be proportionally larger which is likely to increase the overall effectiveness of the intervention.

TBSPG recognise that the Department would ultimately make the decision in relation to intervention areas but would be informed by the TBSPG (and in time its successor TBEP) recommendations and as new epidemiological evidence emerges

Intervention areas identified – drawing boundaries

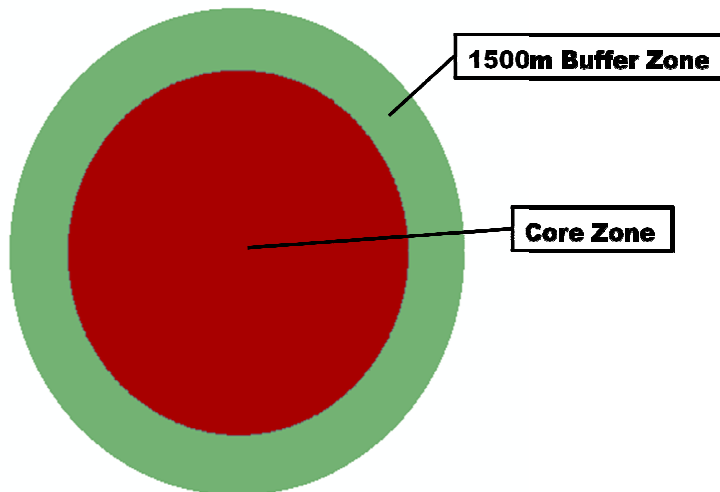
Once an area has been identified and selected for intervention, the area itself should be clearly identified and boundaries mapped (an example of the use of Geographic Information Systems (GIS) for this purpose can be found in Etherington et al. 2014). The lands included in the intervention area would be based on the local disease situation, the topography of the area and wildlife ecology. This would ensure that potential movement of badgers into/out of the area would be taken into account in the configuration of any intervention area, no matter how large or small. Given the proposed size of the initial intervention areas it is inevitable that non infected farms are included, but this is necessary to effectively tackle the disease because of its distribution within the defined area. The proposed approach in the core zone is that **badgers would be culled.**

Boundaries and barriers such as major rivers lakes or mountains which may inhibit or restrict badger movement (Sleeman et al. 2009; Etherington et al. 2014), can be considered when determining an intervention area (Etherington et al. 2014). Where such boundaries and barriers do not exist, a further **buffer zone** of up to circa 1500 metres around the edge of the core zone area would be identified. This is at a similar scale to the mean inter-sett movements records from a large-scale movement study from Republic of Ireland (1.6km; Byrne et al. 2014; Byrne et al. 2016), and is smaller than mean dispersal distances found at higher densities (Cheeseman et al. 1988; MacDonald et al. 2008). A test, vaccinate or remove approach is proposed for the buffer zone.

Intervention

A schematic diagram of the intervention layout is presented in Diagram 1 below.

Diagram 1: Schematic diagram of the intervention badger plan



The first stage in the process would be a survey to locate main badger setts in the proposed intervention area.

A limited badger capture survey in the intervention area would be undertaken to obtain blood samples for testing. Once the necessary licences and permissions have been obtained, badgers from a statistically determined number of setts. The first badger that is captured at each sett would be tested using the sett side DPP test and if positive would be removed for post mortem examination and additional laboratory tests. Test negative badgers would be released. The sampling would be designed to allow the conclusion that if bTB is confirmed in at least one test positive badger, there is a bTB prevalence of at least 30% in the badger population that has been sampled and therefore the intervention should proceed. If infection is not confirmed, no further intervention should proceed at that time.

It is anticipated that any initial badger capture and testing would be carried out by DAERA staff. It is not envisaged that the location of cull areas would be placed in the public domain.

This intervention programme would be in two stages, firstly in the buffer zone and then in the core zone. Phasing the programme in this way means badgers are vaccinated and protected, as far as possible, from a potential perturbation effect, should it occur.

Badger Capture

There is a choice of two methods of capture available, cages and stopped restraints. Cages have been used effectively by DAERA in the TVR study area with capture efficiency increasing with experience. Stopped restraints are multi-stranded wire trap that restrains badgers around the body (principally the thorax or abdomen; Murphy et al. 2009; Byrne et al. 2015b). They are currently used as part of the bTB scheme in

the Republic of Ireland, in both culling (e.g. Byrne et al. 2013) and vaccination programmes (e.g. Byrne et al. 2012).

Both are considered to be acceptable from a welfare perspective. The RoI has monitored use of stopped restraints closely and shown that they result in the majority of animals sustaining minimal injury (Murphy et al. 2009) and a zero recorded trap attributable death rate (Byrne et al. 2015b). 99% of badgers captured in Republic of Ireland over 2009-2012 had injuries in the category “mild” using the international trapping standards equivalent by Talling and Inglis (2009). There is little directly comparable evidence to compare stopped restraints vs cage traps in terms of injury, however it appears that both methods rarely result in serious injuries (compare Murphy et al. 2009 with Woodroffe et al. 2005). Stopped restraints may result in more superficial injuries than cage traps, however.

Restraints are considered preferable to cage traps for the roll out of national policy in the Republic of Ireland due to their ease of use, logistical considerations and their presumed increased efficacy relative to cage-traps (O'Connor et al. 2012).

TBSPG does not have a preference, as long as the method employed results in maximum capture efficiency. TBSPG recommends that the use of both is explored to establish the most efficient approach.

Buffer Zone

Outside the core zone, up to a further 1500 metres (the buffer zone) badgers would be captured and tested using the pen side DPP test. If they are test positive they would be dispatched by lethal injection as the badgers would already have been anaesthetised. All other badgers would be vaccinated, micro-chipped and released.

Core Zone

In the core zone, badgers would be captured and dispatched by shooting.

This process, in both the buffer and the core zones, would be repeated for a minimum of 4 years. Any badgers captured within the core zone which have been previously captured, vaccinated and released, would not be culled.

A minimum aim is 70% capture (and treatment) in both the core zone and the buffer zone over the intervention period. The benefits of culling badgers during large scale trials were found when large proportions of the resident population were removed; it was estimated that ~70% of badgers were removed during the RBCT during the initial cull of badgers in 7 of the 10 intervention areas (Smith and Cheeseman 2007; Woodroffe et al. 2008; Bourne et al. 2007). The suggested figure of 85% removal efficiency was reported by Sleeman et al. (2009) during the first two years of the FAP. McDonald (2014) presented an overview of the relationship between culling intensity and the beneficial outcome in terms of reducing disease risk. That paper suggested that the greater the intensity of the cull, the greater the likelihood of a positive outcome. Approximately 50% of the badgers are expected to be captured in each trapping season (based on Byrne et al. 2012 extrapolated to specifications of the Republic of Ireland cull programme; Abdou et al. 2016). TBSPG suggest that culling should take place for a minimum of four years, but recognises that this time

period is dependent on successful reduction in density of at least 70%. If culling efficacy is low, this 4 year period may need to be extended, in line with international experience (up to 7 years; see Eves 1999; Bourne et al. 2007; Griffin et al. 2005; Gallagher and Clifton-Hadley 2000). These timelines are based on the results of the Thornbury removal project (6 years; Clifton-Hadley 2000), east Offaly project (7 years of culling; Eves 1999), the four area project (5 years of culling; Griffin et al. 2005) and the RBCT (4 to 7 years (average 5.2 cull years per triplet) of culling depending on triplet; Bourne et al. 2007). Woolhouse and Wood (2015) highlight that after the initial latent period between initial cull and being able to measure benefits during the RBCT, “[culling] roughly halved the incidence of TB in cattle herds in the culling area following 4–7 annual badger culls”.

With an anticipated high removal rate (minimum of 50-70% per annum), it follows therefore that over a (minimum) 4 year period, a high percentage of the badgers would be removed/vaccinated (Smith and Cheeseman 2007; Woodroffe et al. 2008; Byrne et al. 2012). However, reduction in density via culling would be counteracted by fecundity and inward migration. It is anticipated that after 4 years or more of culling the density of infected badgers would have significantly decreased. Inwardly migrating disease-free and vaccinated badgers may be resistant to infection. The buildup of a “healthy” badger population would be predicated on the inward movement of a vaccinated population from the “buffer” zone. Vaccination of badgers in the buffer zone would provide a population of mainly vaccinated, and therefore more bTB resistant (potentially less infectious due to reduced severity of infection (Chambers et al. 2014)), badgers to repopulate the intervention area when the removal strategy is concluded. The increased resistance would also help to protect badgers in the buffer area that may come into contact with potentially infected badgers that may migrate from the cull area.

TBSPG also recommends that vaccination takes place in the core zone after culling has ended, and that this vaccination continues for a minimum of 3 years. The actual length of time for which this vaccination would continue should be reviewed regularly, based on the disease situation at the time, and any additional scientific evidence. It may vary from area to area, depending on disease outcomes and risks. As the population density would be low after culling, it is anticipated that less effort per unit area would be required to achieve high vaccine coverage in this area. The management details for the interventions would be overseen by TBEP.

1.6 Impact

The TBSPG’s recommendation for an effective badger intervention strategy encompasses both a cull area and a buffer zone with vaccination combined with selective removal, and is based on scientific/epidemiological principles.

There is evidence from simulation models that culling can be more effective than vaccination strategies alone (Smith et al. 2012; Abdou et al. 2016). Smith et al. (2012) modelled the effect of culling with a 2km ring vaccination strategy, and found it to be more effective than culling or vaccination alone. The TBSPG’s recommendation is based on the best available evidence however it should be noted, the conditions in Northern Ireland may be different to either Republic of Ireland or Great Britain, and therefore the model outcomes should be taken with

some caution. A simple illustration of the potential outcome of culling compared to a TVR approach is provided in paragraph 3.1 below.

TBSPG recognises the value of modelling as a tool to investigate the likely impacts of differing intervention strategies (e.g. Abdou et al. 2016; Hardstaff et al. 2013; Smith et al. 2012). Often these strategies cannot be tested empirically without great expense, time and effort – therefore, the development of mathematical/simulation models can be a cost-effective process to develop a mechanistic understanding of a disease intervention (Abdou et al. 2016). TBSPG recognize that such tools have been utilized for a number of purposes in bTB research North America (Cosgrove et al. 2012), New Zealand (Barlow et al. 1997), England (Shirley et al. 2003), Republic of Ireland (e.g. Abdou et al. 2016) and elsewhere (Perez et al. 2002).

TBSPG recognise that future ecological and epidemiological research and analysis is critical during the intervention periods. This would allow for the development and updating of Northern Ireland models, for bTB in cattle or badgers, using parameters derived from Northern Irish data.

TBSPG are conscious of the sensitivities of any intervention and effective monitoring would help to provide transparency.

1.7 Timeline

TBSPG envisage that the intervention programme could commence in 2018. They recognise that experience of delivery in the field would help optimise the identification of areas, the protocol to be adopted and ultimately the impact on disease levels. TBSPG is also aware that it is possible that legislative change may be required and that this may extend the timescale for initiation.

TBSPG envisage that the initial interventions would start in 2 or 3 areas and be gradually rolled out year on year. This would allow expertise and experience to be developed and ensure that management processes were robust. Based on the mapping of current high incidence areas in NI, it is estimated that ultimately around 10 areas would be targeted. The number and size of areas should be kept under review by DAERA and the TBEP.

1.8 Monitoring

TBSPG recognise that an important component of a wildlife intervention includes inbuilt mechanisms of monitoring the performance of the interventions. TBSPG are also aware that such monitoring needs to be practical and measurable to ensure the data can be generated readily, and then used to inform the programme of issues and allow managers to adapt their processes for better outcomes (adaptive management; Byrne et al. 2015; Powell and Proulx 2003).

Best practice within wildlife management suggests that mechanisms to monitor trends in injuries, as a proxy of animal welfare, is established (Murphy et al. 2009; Byrne et al. 2015b; Woodroffe et al. 2005; Munro et al. 2014). Methodology should allow for the rapid assessment of a large number of animals in a standardized fashion, which allows for the analysis of data and dissemination to staff engaged in the programme (Byrne et al. 2015a). TBSPG suggests that formalized rapid

assessment (both ante- and post-mortem) of badger trap-related injuries are made and recorded, and that these data are analyzed and reviewed by staff and TBEP over the course of interventions as a monitoring tool and to allow for improvements to be made over time.

TBSPG also recognizes that it is vital that a measure of the levels of bTB is recorded from badger populations where interventions are undertaken, to ensure that trend analysis can be undertaken (e.g. Byrne et al. 2015a). Data on the results of the buffer area should be documented and retained for future analysis, with the understanding of the limitations of the pen-side tests available (Chambers et al. 2008). Culture confirmation is the standard used to establish infection within a population (Drewe et al. 2010; Gormley et al. 2014). Therefore, animals culled as part of the intervention should be assessed for their bTB status at post-mortem using a standardized and comparable practice (Jenkins et al. 2008; Byrne et al. 2015a). Standardised practices, as suggested as part of the newly enhanced RTA survey (see above) could be incorporated into the monitoring protocols for PM examination of badgers from the cull zones. Within the current badger culling regime in the Republic of Ireland, a systematic sample of every third badger culled is examined for visible lesions, with tissue harvesting (including bite wounds if present), for culturing (Byrne et al. 2015a). TBSPG recommends that an appropriate sampling regime be developed, coupled with appropriate post-mortem harvesting of tissues for culture of the *M. bovis* organism.

2. Wildlife Vaccination

2.1 Issue

It is accepted that the badger population is a reservoir for TB (for a review see: Ní Bhuachalla et al. 2014; Corner et al., 2011). The TBSPG understands that to effectively tackle the complex issue surrounding TB in cattle, it is critically important to address the wildlife dimension to enable eradication of TB.

A part of the approach to wildlife currently employed in England, Wales and the Republic of Ireland is the use of the BCG vaccination to confer, over a period of time, a level of protection to badger social groups. Evidence from the literature suggests that BCG vaccination can impart a protective effect in terms of disease progression (Corner et al. 2010; Chambers et al. 2011). Furthermore, there is some field evidence that a “herd immunity” effect may occur where a high proportion of animals are vaccinated (Carter et al. 2012). Modeling studies highlight that vaccination schemes have greatest beneficial effect where coverage is high (e.g. Abdou et al. 2016), with models suggesting that coverage of 40-50% per annum yielding benefits (Wilkinson et al. 2004). These benefits could reduce potential risk of infection to cattle.

Currently, deployment of the vaccine is by capture and injection. This has both an intensive resource and cost implication. Furthermore, there is currently an additional risk of a global shortage of BCG vaccine, which is impacting on the sourcing BCG for badger interventions.

Vaccination is, however, ineffective in infected badgers (Chambers et al. 2014) and given the badger density (Reid et al. 2012), and related bTB infection (Abernethy et al. 2011). TBSPG consider that before a widespread vaccination policy could be effective, it is necessary to employ a removal strategy, to reduce the overall level of infection in the badger population (see above).

Work is on-going to develop an effective method to provide vaccination through bait which would be ingested by badgers (Chambers et al. 2014). Currently this is only at the preliminary design study stage and a lot of work is still to be completed before a viable product has been developed and a manufacturer has been identified. DAERA is engaged in discussions with colleagues in DEFRA to be part of a potential multi-national partnership which is seeking to develop and test an oral bait vaccine. Early discussions have involved England, France and the Republic of Ireland. The use of the oral bait vaccine is viewed by TBSPG as being critical in any future approach to wildlife intervention. The Group would strongly advocate the trial of an oral bait vaccine in Northern Ireland at the earliest opportunity. However, it is likely to be at least 10 years or more before the production of a fully licensed and viable oral bait vaccine product, with Marketing Authorisation, is available.

TBSPG also note the work being undertaken within the Kilkenny vaccine efficacy trial (Aznar et al. 2011) and the non-inferiority vaccine trial (O’Keeffe et al. 2016) being undertaken in the Republic of Ireland, and suggests continued review of recommendations as results of these studies become available (2017 onwards).

2.2 Recommendation

- The Group recommends that a badger vaccination strategy along with badger removal is implemented in support of an effective disease control strategy. The Group recommends that the injectable vaccine is used as part of the intervention approach, until an oral vaccine is available.
- It is recommended that, when available, the oral badger vaccine should be deployed via an effective bait method on a more widespread basis provided it is cost effective. This widespread vaccination of badgers, deployed in suitable areas at increased risk of TB transmission, would be an integral part of a successful and sustainable, long term curtailment of TB infection in badgers.

2.3 Rationale for change

The Group’s objective for an on-going and strategic vaccination programme (running concurrent with a strategic removal programme, as evidenced in RoI (see Sheridan et al. 2011 & 2014 for a discussion of the Republic of Ireland’s integrated approach)) would see the level of bTB in infected badger populations being reduced in a sustainable manner and thus reduce the risk of transmission to the cattle population. Vaccination may also mean the need for a removal programme is reduced, or may allow for mitigation of potential social perturbation effects. The use of oral bait vaccine is seen as a key part of the long term strategy for TB eradication.

2.4 Evidence

Vaccines are widely used to reduce the spread of a disease in a population by stimulating the body's immune response, although it is recognised that vaccination is probably ineffective in individuals already infected with disease (Chambers et al. 2014). Vaccination has been successfully used in eradication programmes for viral diseases (e.g. rabies in North America and Europe (Cross et al. 2007)), but the efficacy of vaccination in bacterial diseases, such as bTB, is more problematic. However, the BCG vaccine has been successfully used in humans since the 1920s and is prepared from a live, weakened (attenuated) strain of the TB bacteria (Waters et al. 2012).

An injectable BCG-based TB badger vaccine (BadgerBCG) has been licensed since 2010 (Brown et al. 2013). The principle of vaccination is to raise the immunity against bTB within the badger population which, over time, would reduce the severity of infection and reduce opportunities for badger to badger, or badger to cattle transmission. Research into the efficacy of the BCG-based vaccine against tuberculosis has been recently carried out in captive badgers in the south of Ireland and has established as proof of principle that vaccination, when delivered by a variety of routes (including intra-dermal and oral), can protect badgers against bTB (e.g. Chambers et al. 2011; Lesellier et al. 2006; Corner et al. 2010). Data generated from the English Badger Vaccination Deployment Project⁵ and the Badger Vaccination Project⁶ in Wales and projects carried out in the south of Ireland (Aznar et al. 2011) may help evaluate the long-term cost/benefit of badger vaccination under field conditions.

Governments in both regions (England and the Republic of Ireland) recognise the potential benefits of vaccination, in conjunction with strategic badger removal, as part of an overall integrated control and eradication strategy in high risk areas (Sheridan et al. 2014; Boyd 2015). However, it must be recognised that there is a high cost relating to implementation of such programmes and the extended duration of time that vaccination requires (Wilkinson et al. 2004; Chambers et al. 2014). It is noted that the Westminster EFRA Select Committee has commented on the initial use of vaccination in previously infected badger populations, saying that, "*badger vaccination must form part of any strategy to eradicate bovine TB, though badger vaccines cannot cure diseased badgers. These diseased animals would continue to infect cattle herds.*" Hence the opinion of the TBSPG, that there is a need for a removal strategy along with vaccination.

2.5 Detail

The Group would encourage the use of the badger vaccine as part of a strategic control programme. Given the current indicators of the level of infection in the badger population and that vaccine is not effective in infected animals, we consider that vaccination alone would not achieve the desired effect within a reasonable timescale. There may be occasional situations where it could be used on its own in very specific circumstances at the recommendation of local Disease Response Teams. The

⁵ English Badger Vaccination Deployment Project: <https://www.gov.uk/government/publications/badger-vaccine-deployment-project-lesson-learned-report>

⁶ Welsh Badger vaccination in the Intensive Action Area:

<http://gov.wales/topics/environmentcountryside/ahw/disease/bovinetuberculosis/intensive-action-area/badger-vaccination-iaa/?lang=en>

overall role it can play must be kept under active review as technologies develop and infection levels in badgers fall.

2.6 Impact

The Group believes that in the long term a strategy of wildlife vaccination would significantly improve the disease situation in both wildlife and cattle. This is based on international experience based on integrated bTB control programmes in wildlife and cattle undertaken in the Republic of Ireland (Sheridan et al. 2014) and New Zealand (Livingstone et al. 2015).

3. Justification for Recommending an inclusive Badger Intervention Programme which combines a Badger Removal Strategy and a concurrent Ring Vaccination Strategy.

The TBSP Group's recommendation for an effective badger intervention strategy encompasses both a core (removal) area and a buffer (based on TVR principles) area. The following demonstrates the scientific/epidemiological principles, on which the strategy was determined.

3.1 Core (Cull) Area

The primary objective of the removal of all badgers caught in this area is to reduce the level of TB in a wildlife reservoir. The scientific/epidemiological rationale for the total removal of captured badgers versus a TVR based intervention strategy in these areas is quantified below. This rationale should be kept under review, and any TVR evidence, alongside the results of any other local or international studies, used to inform the continual development of the badger intervention strategy. The following is a hypothetical exercise which is designed to illustrate the potential approximate differences in disease levels attained in a control zone (badger culling) and a 'ring' buffer zone (Test Vaccinate or Remove).

If 100 badgers reside in the main setts identified in the established control area, then approximately 70 can be expected to be captured over the duration of an effective intervention campaign. If these are all culled then 30 are left. If the prevalence of TB in the badger population is approximately a third (33%) then 10 infected badgers would remain (assuming: 1. No bias in captures in terms of disease status; 2. The prevalence within the badger population remains the same, i.e. no perturbation effect; 3. There is no immigration (demographically closed population)).

If a vaccination intervention strategy, based on the TVR principles, is implemented then the 70 captured badgers would be subjected to the "sett side" test (eg DPP) which has a declared sensitivity of circa 50%. When the prevalence of the disease is similarly 1/3rd (33%) of the badger population, then approximately 23 of the 70 badgers would be infected and when subjected to the "sett side" test, 50% would be considered positive and culled. The rest of the original 23 infected badgers (approx 12), would be vaccinated and released. Accepting that 10 of the 30 badgers which were **not** captured would be infected, then a total of approx. 22 (10 + 12) infected badgers would remain in the core area. Vaccination is considered to be ineffective in

animals already infected, and therefore all of the 22 badgers, out of the original total of 100, would continue to provide a reservoir of TB to associated cattle herds. Notably, this would have been immediately reduced to 10 infected badgers when a removal intervention strategy is implemented in a comparable core area. It should be noted, that we assume no herd-immunity effect with the principals set out above.

In summary, removal in a core area with a 33% (1/3rd) prevalence of infection can rapidly reduce the number of diseased badgers to a lower level, than a TVR based vaccination strategy. These figures should be used with caution, and only as a basic framework from which we could theoretically expect outcomes, given a simple closed system. Modelling exercises in both Republic of Ireland and England have investigated the use of vaccination and culling approaches to control bTB in badgers (Abdou et al. 2016; Smith et al. 2001; Smith et al. 2002; Smith et al. 2012). Most models indicate that widespread, proactive, intensive culling has the greatest impact on disease levels in badgers, with generally larger impacts than vaccination alone (e.g. Abdou et al. 2016). Abdou et al. (2016) showed that a culling regime followed by vaccination, reduced bTB risk significantly with vaccination maintaining a low level of bTB prevalence while the badger population recovered. Smith et al. (2012) showed that a ring vaccination can work to reduce risk of cattle herd breakdowns, while mitigating modelled perturbation effects. These models concur with the epidemiological principles set out by TBSPG.

3.2 Buffer (based on TVR principles) Area

The primary objective of a ring vaccinated area around the core (cull) area is to provide a buffer zone of more resistant badgers and thus mitigate the potential for increased spread of disease caused by the potential perturbation effect, if it occurs here (Tuytens et al. 2001; for a modeling example, see Smith et al. 2012). In addition, the ring vaccination area would provide a population of vaccinated and therefore more resistant badgers to repopulate the control area when the culling strategy is ultimately concluded (source-sink dynamic; Byrne et al. 2013). This is necessary as a low but protracted level of infection will persist in the control area due to the presence of a small number of infected badgers (not removed during the course of the badger culling campaign) and/or the prolonged survival of viable TB micro-organisms in the environment (King et al. 2015). It is anticipated that a culling strategy in an identified core area will be required for a minimum period of 4 years to be effective and measurable. Examples from large scale cull trials (like the RBCT (Bourne et al. 2008), FAP (Griffin et al. 2005), East Offaly Project (Eves 1999) have shown that it takes a number of years (a lag phase) before the effects of the intervention accrue and before an effect can be measured (More et al. 2007). This is due to a number of biological phenomena (see More et al. 2007). Furthermore, because the possible level of badger trappability (Tuytens et al. 1999; Byrne et al. 2012; Smith and Cheeseman 2007), it may take multiple trapping events to significantly reduce badger density (Byrne et al. 2013).

The four year timeframe will enable the reduction in the level of infection in the ring vaccination area, when a TVR based strategy is employed, by the removal of approximately 50% of the infected badgers which are captured over this period and the presence of a vaccinated population which is more resistant to infection. Notably, with time, the number of animals already infected prior to the delivery of the vaccine

will decline, either due to the disease, age or natural attrition, and the number of new animals becoming infected will be substantively reduced as a consequence of the on-going vaccination strategy (potential herd immunity effects; Carter et al. 2012). It is anticipated that this combined effect will progressively reduce the level of infection in the overall badger population in the buffer area.

In summary, a ring vaccination area (based on TVR principles) will provide a buffer zone of more resistant badgers to mitigate the possible adverse effects of social perturbation from the removal area, should it occur. The ring vaccination area will also provide a vital population of more resistant badgers, with a reduced level of infection, to facilitate the inevitable medium to long-term repopulation of the core (cull) areas.

The combined epidemiological/scientific approaches, advocated in the Group's recommendation for an effective badger intervention strategy, combined with the other recommended measures, if implemented in both the core (cull) areas and buffer (based on TVR principles) areas, is likely to address the bTB reservoir in badgers to help eradicate bTB in cattle herds and contribute to the health of the badger population.

In addition, this integrated approach of both a control (cull) area and a buffer (based on TVR principles) area would be more acceptable to a greater, diverse range of key stakeholders.

4. Northern Ireland's Badger Road Traffic Accident (RTA) Survey

1. The current RTA survey has been in place since 1998. Currently it is the only mechanism by which it is possible to obtain an estimate of the level of TB infection in the Northern Ireland badger population notwithstanding the more detailed studies being carried out under the auspices of the localised TVR study.
2. Similar studies have recently started in Wales and will soon start in England (collaboration between University of Nottingham, University of Liverpool and University of Surrey: <http://www.nottingham.ac.uk/vet/survey-for-tb-in-road-killed-badgers.aspx>) focusing on the Edge TB control area. In addition, a limited study has been carried out in Cheshire which was organised by the University of Liverpool (see Appendix 1 for further details). It is of note that the Great Britain studies are known as Badger Found Dead studies.
3. In the Republic of Ireland, information on the background trends in bTB prevalence in badgers is assessed by sampling of culled badgers (Byrne et al. 2015b). Every third badger culled (badger culling in the Republic of Ireland occurs in a targeted fashion in response to a herd breakdown where badgers have been identified as a possible risk) is subjected to PM and *M. bovis* culture (Byrne et al. 2015).
4. Two surveys of the distribution and abundance of the badger population have been carried out on the Northern Ireland (Reid et al. 2008). The last study which was funded by DARD produced *inter alia* extensive maps of badger sett distribution, a habitat suitability map and an estimate of badger numbers.
5. The survey estimated that there were 0.56 social groups per 1 km² (95% CI 0.43-0.69) giving an estimated total abundance of 7,500 badger social groups (95% CI 5,900–9,300; Reid et al. 2012). The estimated total abundance of badgers in Northern Ireland during 2007/08 was 33,500 badgers (95% CI 26,000-41,200).

- The two maps below (taken from Reid et al. 2012) show the mean social group density across Northern Ireland and also the habitat suitability for sett location.
6. More recently DAERA also commissioned AFBI to carry out two localised sett surveys for two 100 km² areas; one of which became the current TVR study area.
 7. Further research and information on badger population dynamics and other aspects of the ecology of badgers in the TVR area is recommended and should be published in due course.

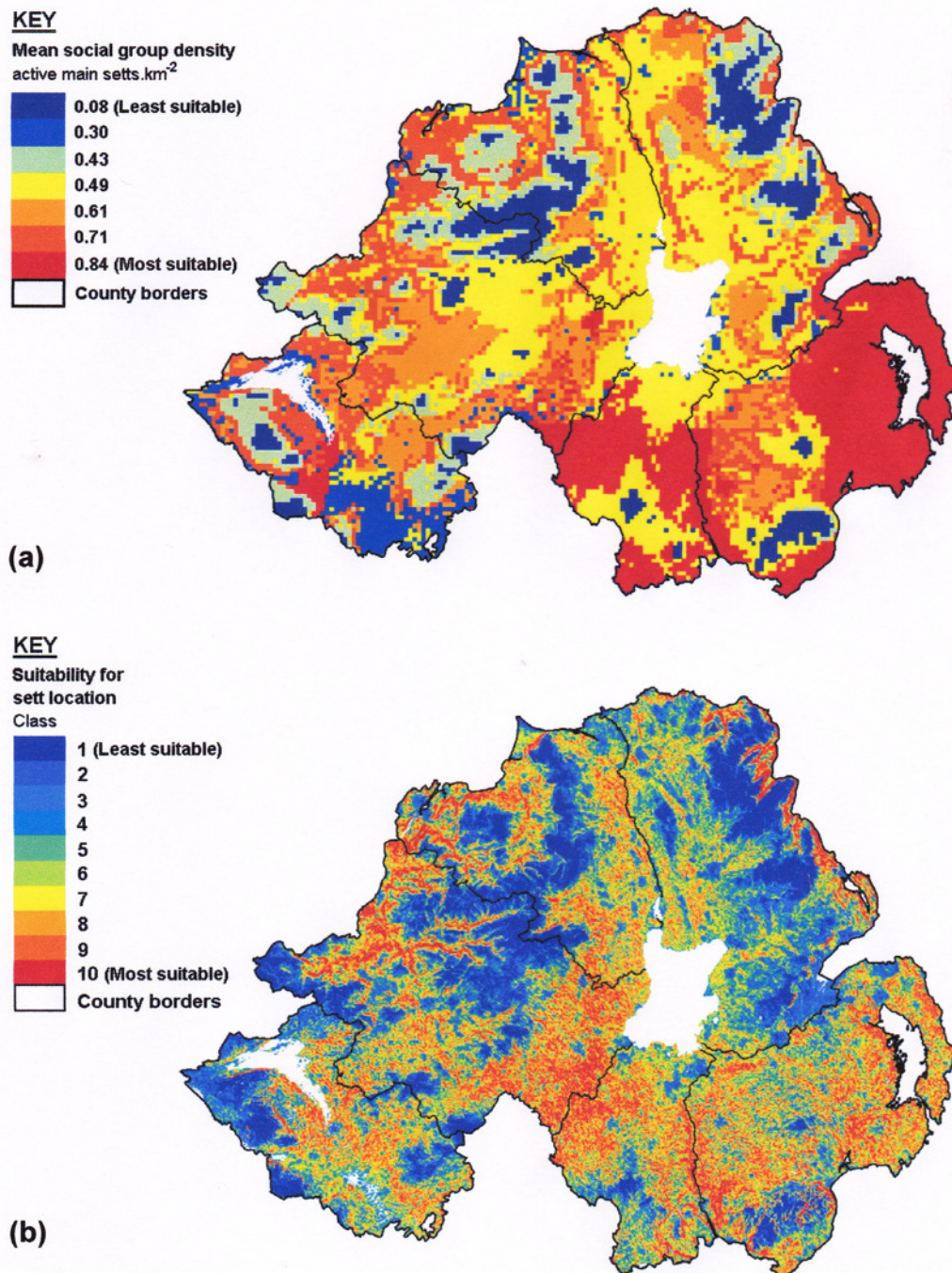


Fig. 1: a. Spatial model of mean badger social group density across Northern Ireland on the land class group scale (from the multiplicative model) compared

to b. Landscape favourability (suitability) for badger presence on a 25m scale (from the bio-geographical model).

4. The location of badgers found dead on the roads have been mapped as shown in figure 2 below. Note the green circles in the figure below indicate the location of badgers which were negative for TB. It is apparent that the acquisition of dead badgers is not uniformly distributed across Northern Ireland. This geographic patterning suggests the dataset is spatially biased, and hence not necessarily representative of the badger population more generally (sample bias).

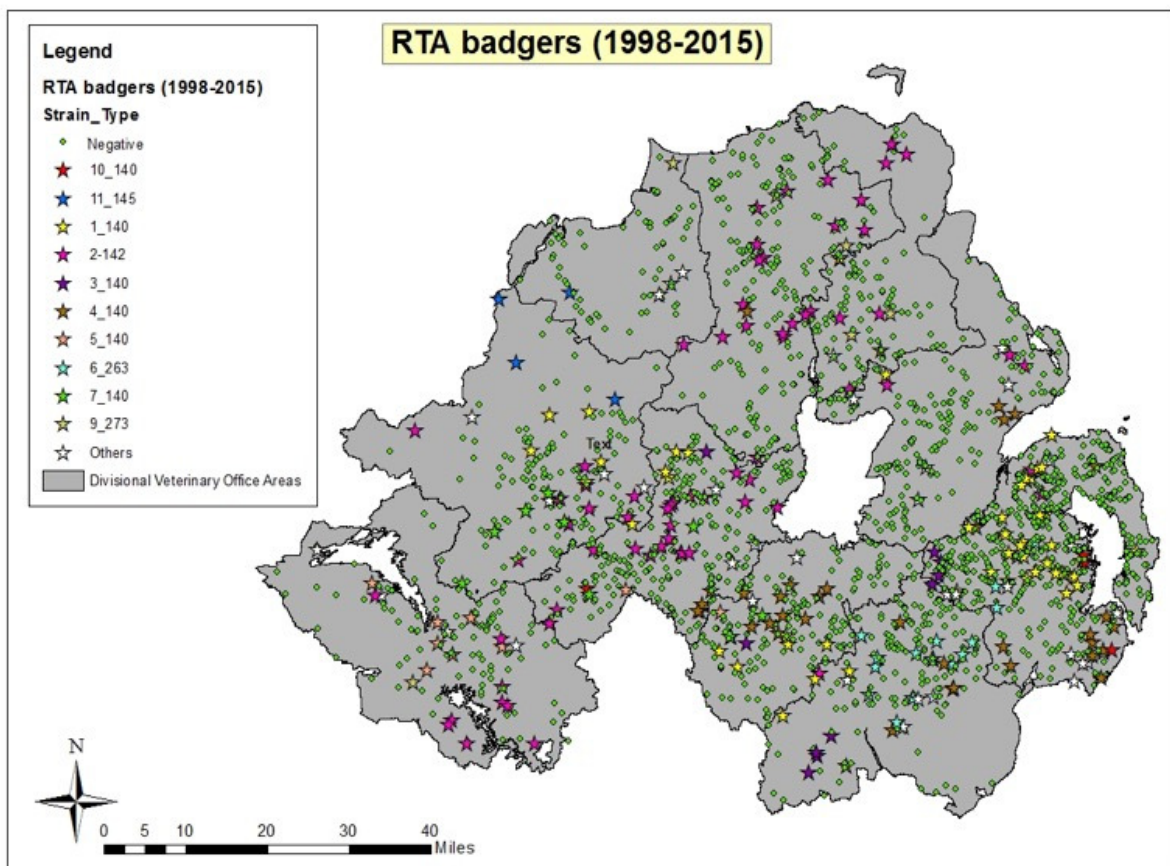


Figure 2: Location of badgers found dead in Northern Ireland (1998-2015). Green points relate to badgers where *M. bovis* could not be isolated. Strain types have also been mapped (star shaped markers).

5. Part of the spatial bias is partially related to the location of collection centres for badger carcasses. This issue is being addressed by locating another collection centre in Coleraine.

6. Over recent years DAERA have analysed the results of the RTA and these results are summarised in the following diagram (Courcier et al. 2011) and table 1.

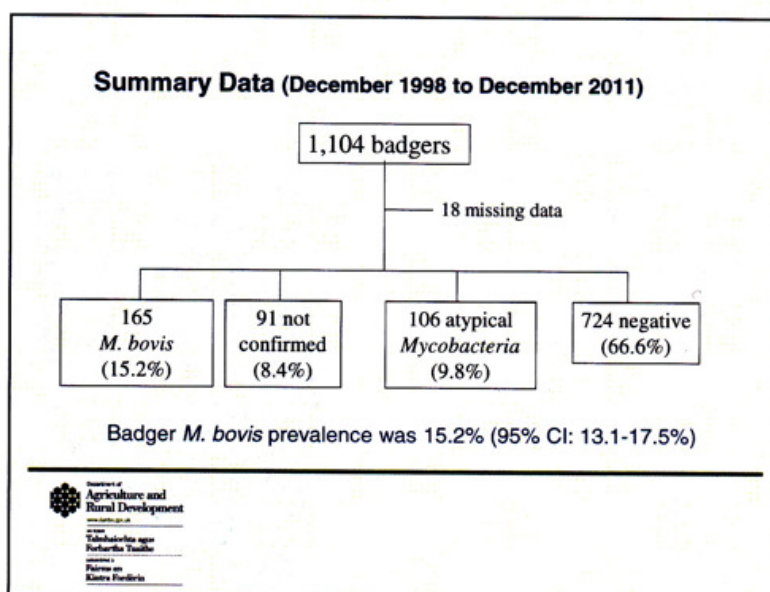


Table 1: Descriptive statistics of RTA in Northern Ireland from 1998-2014.

Year	Number of RTA badgers subjected to post mortem examination	Number positive RTA badgers	% positive (95% CI*) RTA badgers	Number negative RTA badgers	% negative (95% CI*) RTA badgers
1998	3	1	33.3% (5.6-79.8%)	2	66.7% (20.2-94.4%)
1999	135	23	17.0% (11.6-24.3%)	112	83.0% (75.7-88.4%)
2000	78	22	28.2% (19.4-39.1%)	56	71.8% (60.9-80.6%)
2001	20	5	25.0% (10.8-47.3%)	15	75.0% (52.8-89.2%)
2002	61	30	49.2% (37.1-61.4%)	31	50.8% (38.6-62.9%)
2003	70	24	34.3% (24.2-46.0%)	46	65.7% (54.0-75.8%)
2004	56	15	26.8% (16.9-39.7%)	41	73.2% (60.3-83.1%)
2005	61	18	29.5% (19.5-42.0%)	43	70.5% (58.1-80.5%)
2006	100	12	12.0% (6.9-20.0%)	88	88.0% (80.0-93.2%)
2007	68	10	14.7% (8.0-25.2%)	58	85.3% (74.8-92.0%)
2008	102	13	12.7% (7.5-20.7%)	89	87.3% (79.3-92.5%)
2009	104	8	7.7% (3.7-14.7%)	96	92.3% (85.4-96.3%)
2010	98	13	13.3% (7.8-21.5%)	85	86.7% (78.5-92.2%)
2011	144	17	11.8% (7.4-18.2%)	127	88.2% (81.8-92.6%)
2012	232	36	15.5% (11.4-20.8%)	196	84.5% (79.2-88.6%)
2013	219	38	17.4% (12.9-23.0%)	181	82.7% (77.1- 87.1%)
2014	277	41	14.8% (11.1-19.5%)	236	85.2% (80.5-88.9%)

1998-2014	1828	326	17.8% (16.2-19.7%)	1502	82.2% (80.3-83.9%)
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* 95% Confidence Interval (calculated using the modified Wald Method): DARD M O'Hagan VEU July 2015

- The survey depends on the public notifying DAERA of dead badgers, once notified DAERA provides a collection facility and the animal is transported to the Veterinary Science Laboratory (AFBI) at Stormont for post mortem examination, necropsy of a defined set of tissues which are then subject to culture for *Mycobacterium bovis*. Note, that the current scheme does not undertake extensive "forensic" type post-mortem.
- Corner et al (2012) has carried out detailed post mortems on Irish badgers and identified the sites of infection. The following two diagrams summarise these findings. Figure 3 below shows the sites from which *M. bovis* can be isolated, while figure 4 shows the location of the most frequent isolation sites. This study demonstrates that while *M. bovis* can be isolated from multiple sites it is much more frequently isolated from a limited range of lymph nodes.

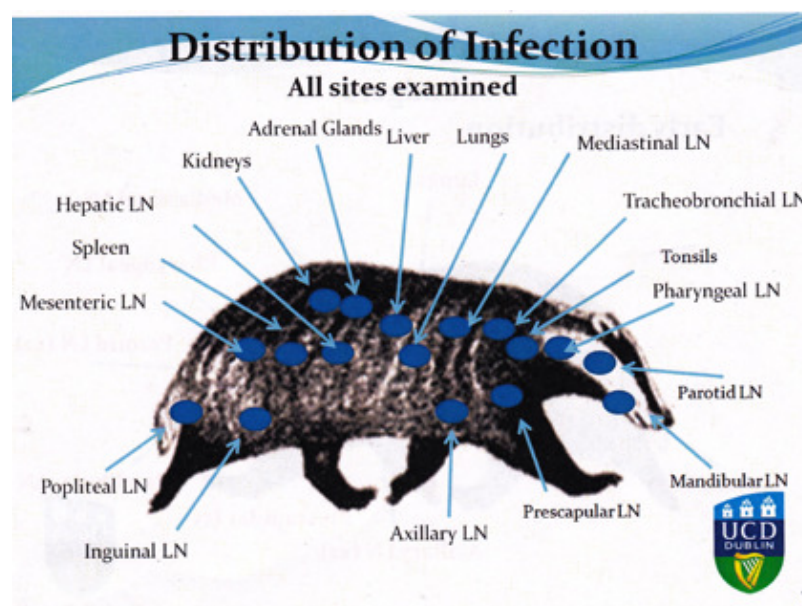


Figure 3: The location of sites (organs/tissues) within badgers from which *M. bovis* has been isolated.

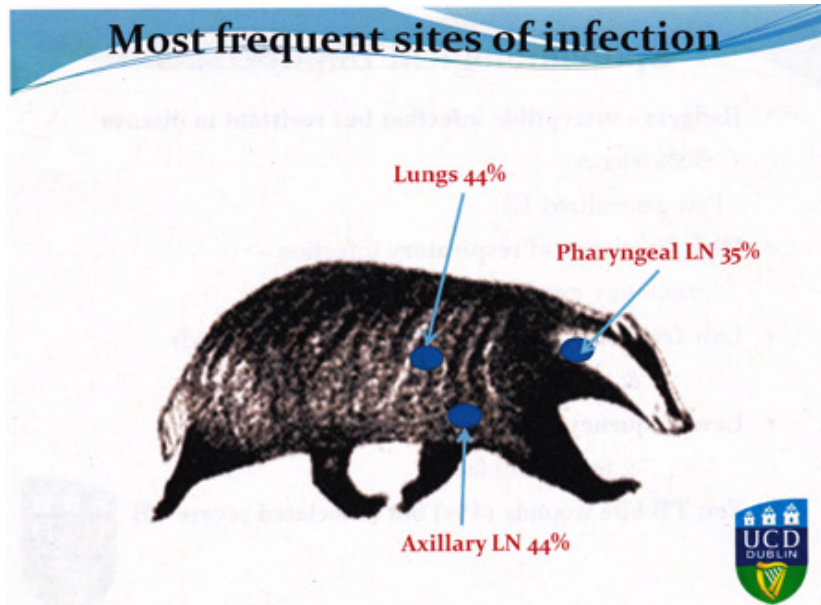


Figure 4: The location of sites (organs/tissues) within badgers from which *M. bovis* has been isolated most frequently.

9. Gallagher and Clifton-Hadley (2000) provided summary data from badger populations from GB. The data from the findings on autopsies of 147 badgers are presented in figure 5.
10. Gallagher and Clifton-Hadley (2000) also summarised their data on lymph node lesions from their own study and in relation to previous studies in GB and the Republic of Ireland. These data are presented in Table 2 below.

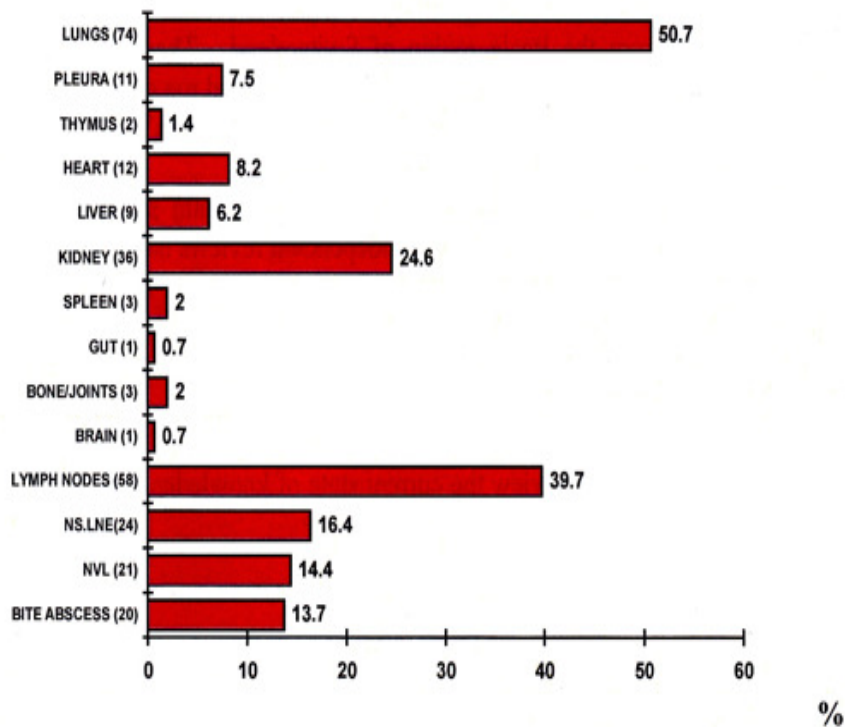


Figure 5: A summary of % lesions found in 146 badgers infected with *M. bovis* (taken from Gallagher and Clifton-Hadley 2000).

Table 2. Distribution of lesions from post-mortem examinations of badgers in Great Britain and the Republic of Ireland from four different studies.

Site of lesion *	Fagan	Gallagher	O'Boyle '97	O'Boyle '98
Submandibular	2	5		
Parotid	2	0	} 75	} 112
Retropharyngeal	4	21		
Prescapular	3	8	26	59
Axillary	0	5	0	0
Sternal	0	2	0	0
Bronchial	8	23	} 72	} 136
Mediastinal	3	12		
Hepatic	0	2	6	13
Gastric	0	1	0	0
Mesenteric	1	2	3	6
Renal	0	1	0	9
Rectal	0	0	0	0
Prefemoral	0	2	0	0
Iliac	0	6	0	0
Popliteal	8	0	26	60
Total carcasses with lesions of TB examined	28	101	194	341

* Lesions were frequently found at more than one site

Table 3. Records of the number of tissues examined; the number for which *M. bovis* was isolated bacteriologically and the % of each tissue which recorded as positive from badgers found dead in Northern Ireland.

SOURCE	TOTAL	No Positive	% Positive
FAECES	2030	42	2.1
KIDNEY	2133	91	4.3
LYMPH POOL	2125	197	9.3
MESENTERIC LN	2057	127	6.2
PRECRURAL & POPLITEAL LN	1829	164	9.0
URINE	420	11	2.6

Table 4. Examines the distribution of tissues which were culture positive and especially identifies those which were uniquely positive as *M. bovis* can be found in multiple tissues in some badgers

SOURCE	NUMBER CONFIRMED CULTURE POSITIVE	NUMBER POSITIVE	% POSITIVE	NUMBER UNIQUELY POSITIVE	% UNIQUELY POSITIVE	% UNIQUE
FAECES	322	42	6.6	9	3.0	4.66
KIDNEY	322	91	28.3	6	2	
LYMPH POOL	322	197	61.2	63	19.6	46.89
MESENTERIC LN	322	127	39.4	25	7.7	
PRECRURAL & POPLITEAL LN	322	164	50.9	63	19.6	

Note the % unique in the right hand column refers to the % unique isolates when the Faeces and Kidney isolates are combined. Similarly, data from the Lymph Node (LN) sites are combined

11. AFBI has reviewed the data on the location of infection in the badger found dead survey, with the results presented in table 3 and table 4.
12. Interpretations of the data presented in these tables suggest that there is little benefit in analysing faeces or kidneys because 95% of infections will be identified from the other tissues sampled. One sample not covered in this analysis is material recovered from wounds (bite marks) etc. TBSPG believe such tissue should be sampled if there is evidence of tubercular lesions.
13. While post mortems are essential to obtain material for bacteriological analysis, it is TBSPGs opinion that there appears to be little point in carrying out histology as it appears to be a poor mechanism for identifying *M. bovis* positive tissue.
14. TBSPG suggests that a follow up study is undertaken by AFBI to estimate the cost savings if the above process refinement was undertaken.
15. TBSPG believe an important use of isolated *M. bovis* from badger RTA material is molecular typing the organism and using this information as an epidemiological tool in understanding the dynamics of the disease.
16. Two methods have been used to date to genotype *M. bovis* from badger material: spoligotyping and VNTR typing. A future potential area is Whole Genome Sequencing (WGS) – see separate paper on WGS. TBSPG recognises the potential insights WGS can make, but also understands the limitations of such technology in the bTB system due to the slow evolutionary rate of *M. bovis* organism.
17. TBSPG highlight the important consideration of the number of badgers collected from the RTA, the distribution of effort to gain a representative sample and the application of research and analysis to help in guiding the appropriate development of the scheme to strengthen the scientific basis for the badger found dead survey going forward.
18. Such research and planning of future surveys should include developing standardised operating procedures (SOPs) to ensure uniform reporting over time, establishing an appropriate sample size and effort.

19. It is TBSPGs opinion that the current survey would be considerably improved if the number of badgers acquired per annum were increased.
20. VEU has estimated that it would require the collection of a minimum of 300 badgers per year to provide reasonable baseline estimate, especially given the between year variability observed in disease levels within the historic dataset.
21. TBSPG recommends that the numbers should be significantly increased, potentially to nearer 500 (if logistically/practically possible; see below for further discussion). In the future when the badger removal programme is introduced (as recommended as part of the integrated programme by TBSPG) more accurate data on the incidence of TB in badgers across Northern Ireland would emerge. However, these data would only pertain to populations where interventions occur. RTA surveys allow for inferences to be made about populations outside of intervention areas.
22. TBSPG believe that the dynamics of the disease in the badger population is as important as the dynamics in the cattle population. TBSPG note that because of the excellent data in the Republic of Ireland, it is possible to say categorically that disease levels are falling in the badger population alongside the fall occurring in the cattle population. Therefore because of the increasing significance of the RTA data TBSPG recommend that the acquisition rate should be increased to approx. 500 badgers per annum.
23. As part of this evaluation TBSPG invited Dr Byrne (AFBI) to carry out basic power calculations on the numbers of badgers required to provide estimates of the numbers of badgers required to detect change in disease status over time. As a result he provided an internal paper "Power Study guidelines for RTA badger surveillance: the power to detect true change". The paper is filed separately. However, figure 6 and table 5 taken from this internal paper is directly appropriate to this discussion.

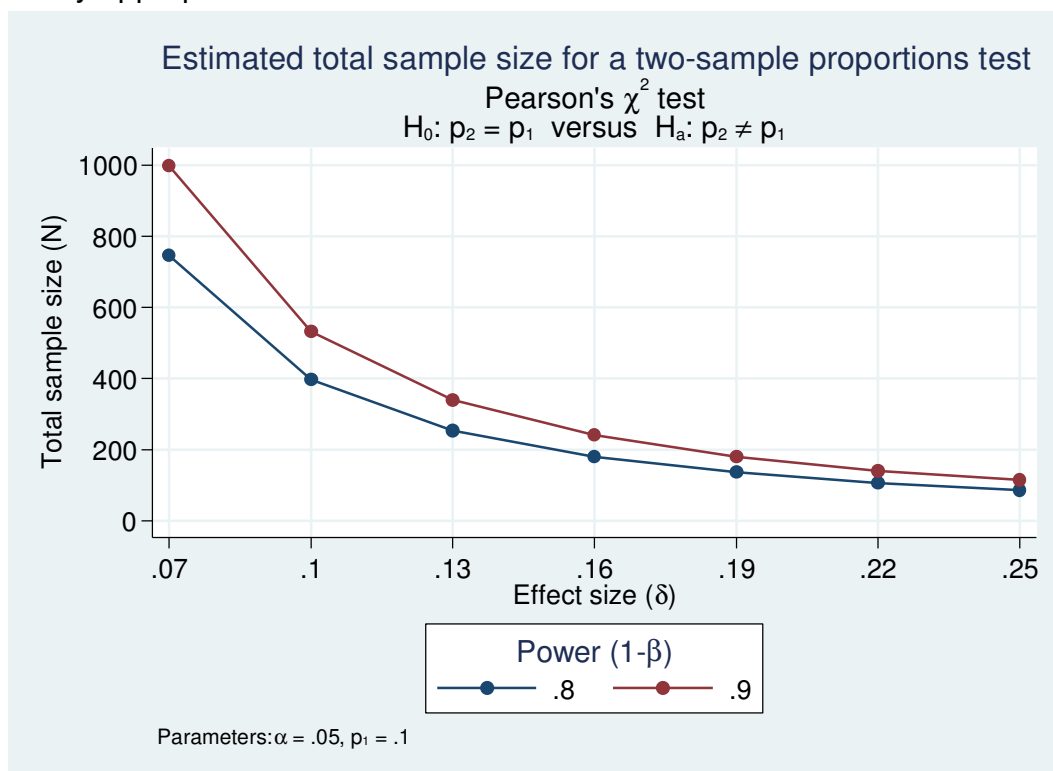


Figure 6: The relationship between total sample size and the change in prevalence across years (delta/effect size). Large sample sizes are required when the change in

prevalence is small (e.g. 7%); smaller sample sizes when large changes in prevalence occurs. Note, that total sample size includes samples from both years. Effect size range: 7% to 25%

24. Figure 6 demonstrates that to obtain the ability to detect quite a large change in disease status (called δ) at a national level (7%), at least 500 badgers are required per annum to achieve a statistical power of 90%. With a statistical power of 80%, the required sample drops to 400 badgers.
25. Table 5 gives an estimate of the badger population size per county, and the expected number of animals to be sampled given a representative sample (i.e. proportional to the estimate badger population size) of the badger population from each county. Currently Co. Down is over-represented in the RTA sampling, while Co. Fermanagh is under-represented.
26. If inter-annual change is compared on a county basis, then sample sizes would need to be significantly larger. TBSPG suggest that 500 is the minimum required to inform on the impact of the disease control programme on the disease status of the badger population outside of intervention areas. The county information (final column of table 5) provides a baseline for the RTA collection programme to enable a statistical analysis with reasonable power on an ongoing basis at a national level.
27. TBSPG also recognises that increasing the sample size and appropriately expending survey effort helps to address to issue of external validity – whereby results from the sampled population can be extrapolated to the broader population. TBSPG recognises that minimising bias is an important goal of the future RTA surveys, including where possible, minimising collection bias, reporting bias, as well as geographic and temporal bias. TBSPG recognise that the latter issue is difficult to resolve, because of the seasonal nature of RTAs on roadways.
28. TBSPG suggests that all BFD data is formally reported (published) and analysed from ecological and epidemiological perspectives, and that these data are considered along with ongoing data collection from within intervention areas and TVR.

Table 5. The relative proportions of samples coming from, and the relative proportion of badger population residing in, each county of Northern Ireland. The expected number of samples from each county if sampling 280, 380 or 480 animals per annum. (Byrne, A. Personal communication)

County	Sample prop. (based on historic data)	Badger pop. per county (based on Reid et al. 2008)	Badger prop. (% of total in each county)	Expected Samples (based on historic prop n=280)	Expected Samples (based on historic prop n=380)	Expected Samples (based on historic prop n=480)	Expected Samples (based on badger pop n=280)	Expected Samples (based on badger pop n=380)	Expected Samples (based on badger pop n=480)
Antrim	16%	5800	17%	44	59	75	48	65	82
Armagh	9%	4500	13%	25	34	43	37	50	64
Derry	12%	4000	12%	35	47	59	33	45	56
Down	43%	9400	28%	121	164	207	77	105	133
Fermanagh	3%	3800	11%	8	11	14	31	42	54
Tyrone	17%	6500	19%	47	64	81	54	73	92
Total	100%	34000	100%	280	380	480	280	380	480

29. DAERA/AFBI has carried out spoligotype and VNTR strain typing of culture *M. bovis* from RTA badgers. The distribution of the spoligotypes has been mapped and is shown in the map in Figure 2 of this report.
30. These data has been spatially analysed by Dr Hannah Trewby as part of her PhD thesis (Univ. of Glasgow), which as yet has not been formally published. TBSPG notes that this analysis (some of which is presented in Fig. 7) could provide the basis of assigning home ranges to the spoligotypes/VNTR strain types.
31. TBSPG also notes that these studies also showed a close association between VNTR types in contiguous cattle and badger populations. Such information is vitally important in tracing disease which is integral to the control programme.
32. This aspect has also been demonstrated by Goodchild et. al. (2012) in relation to the distribution of TB VNTR types in cattle and badgers in Wales. TBSPG therefore, strongly recommends that typing of *M. bovis* isolates from the RTA should continue.

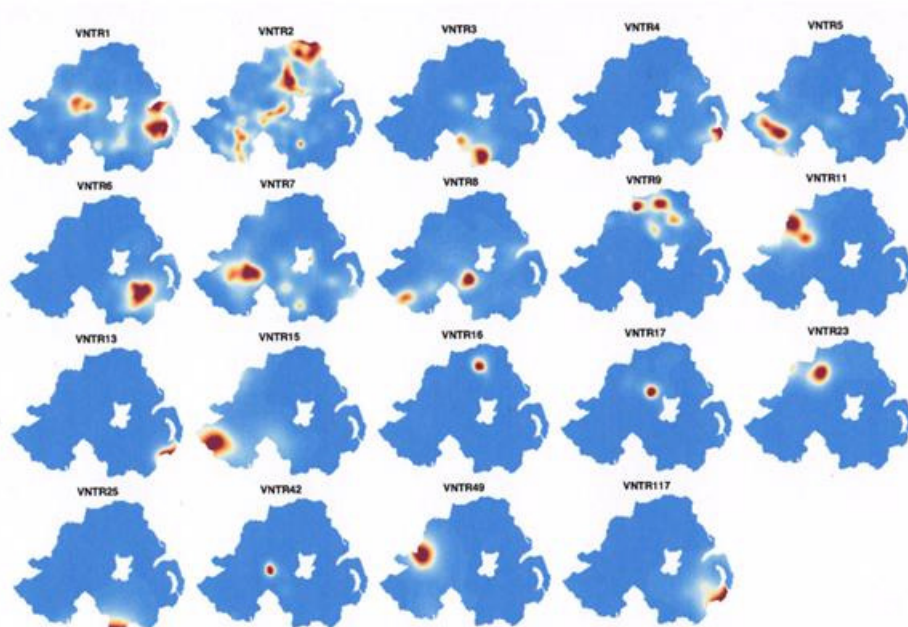


Fig. 7: Spatial probability of occurrence for the nineteen most prevalent Northern Ireland VNTR types 2003- 2010 (from cattle). (with permission Dr Trewby The genetic and spatial epidemiology of bovine tuberculosis in the UK from molecular typing to bacterial whole genome sequencing - PhD Thesis University of Glasgow)

33. The collection of badgers is currently not uniform (see Maps above showing the distribution acquired RTA badgers). TBSPG understand that the DAERA Veterinary Service have already recognised this weakness and steps have been taken to improve the collection service in the NW of the province. TBSPG welcomes this improvement.
34. The name of the RTA needs to be considered. Currently the GB studies go under the banner of Badger Found Dead (BFD) survey. This is in effect is much

more appropriate because a badger obtained from any known location provides useful information of the distribution and *M. bovis* type. TBSPG therefore recommend that the RTA be renamed as the BFD Survey

35. As public and especially farmers have an important role in notifying DAERA of dead badgers attention needs to be given to publicising the scheme more extensively. This activity could be considered an opportunity for citizen science engagement.
36. Conclusions on RTA/BFD survey going forward -
 - a. The RTA/BFD in Northern Ireland should continue in a modified format. Continuity of data is important, however sample sizes have to increase to enhance the power and usefulness of the study on an ongoing basis, appropriate geographic sampling effort needs to be enforced.
 - b. The survey provides independent data on the state of *M. bovis* in N. Ireland badger population which is not available elsewhere (outside of forthcoming interventions).
 - c. There is a case for expanding the survey in order to determine their TB status (to approx. 500 per annum - see table 5 and figure 6). The current approach gives a weak estimate changes in prevalence in both time (inter-annual change) and space (changes between counties). The use of such data would increase in importance as the badger removal programme gets underway. Table 5 also provides a baseline for collecting BFD material on a county basis. However, research is required to ensure that the sampling strategy is well thought out with the potential for modelling to ensure an understanding of the biases that may be present in such datasets.
 - d. Every effort should be made to ensure complete coverage of Northern Ireland (i.e. a representative sample at a minimum spatial scale of county).
 - e. It is recommended that PM material results in the analysis of lymph nodes as per Tables 3 and 4. TBSPG suggest there is little value in examining faeces or kidneys on account of the infrequent unique isolation of *M. bovis*.
 - f. The molecular data (Spoligotype and VNTR) data provides valuable epidemiological data on identifying source areas for disease transmission and the interrelationship survey between *M. bovis* in the badger and cattle populations. A feature TBSPG expects to be enhanced with the introduction of Whole Genome Sequencing
 - g. Consider changing the name of the survey to the Badger Found Dead study

Position in other jurisdictions

a. England

DEFRA have recently tendered for a survey for the EDGE AREA in England. The precise requirement was for:

A study of RTA and other found - dead badgers to assess the prevalence and geographic distribution of tuberculosis in the Edge area of England during the financial year 2016-2017.

The specifics of the survey are on file, but include location information, Post Mortem and Bacteriological examination

A small one-year study has been carried out in the Cheshire area of England under the auspices of the Veterinary School at the Univ. of Liverpool. This study has been given some publicity (Bennett, 2014) but as yet no formal publication seems to have emerged. Recent reports suggest the surveys will be undertaken in collaboration between Universities of Liverpool, Nottingham and Surrey.

b. Wales

The current Badger Found Dead (BFD) survey in Wales started 2012 and is expected to continue for 5 years. This study is focused on the vaccination study area (288 Km²). Two reports⁷ have been produced viz. in 2013 and 2014.

c. Republic of Ireland

Extensive studies on the pathology of TB in Badgers has been carried out over the years which has resulted in multiple publications (see the work of L. Corner and D. Murphy).

Large scale monitoring of badger bTB levels is undertaken as part of the badger culling activity/policy. There one third of all badgers are cultured for *M. bovis* which results in approximately 2000 badgers necropsied and cultured per annum.

Byrne et al. (2015a) recently published an epidemiological investigation of these data. In summary, the paper suggested “our results are consistent with different groups within badger populations having differential exposures and therefore infection risk (for example, parous vs. non-parous females). Furthermore, bTB clusters within the badger population, with greater risk to badgers in setts that are closest to other infected setts. The effective scale of the association of bTB risk between badger and cattle populations may be relatively large in Ireland. Our data indicate that the overall trend in prevalence of *M. bovis* infection in badgers has decreased in Ireland ($P < 0.001$) while controlling for significant confounders over the study period, and follows a longer temporal trend from 2007 to 2013, where unadjusted apparent prevalence declined from 26% to 11% during 2007 to mid-2011, followed by a stable trend between 9 and 11% thereafter (n=10,267)”.

⁷ AHVLA REPORTS of the examination for *M. bovis* in badgers found dead within the Welsh government Intensive Action area (IAA) - reports of project OGO 145 (years 1 and 2) – two separate reports

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Addendum

Minimum number of years for the intervention

TBSPG sought to base their minimum period of culling on data from previous interventions where there was some evidence that the intervention reduced the risk to cattle herds. These studies were: The Thornbury gassing intervention, England (Gallagher and Clifton-Hadley 2000); The East Offaly culling project, Ireland (Eves 1999); the Four Area Project, Ireland (Griffin et al. 2005); Randomised Badger Control Trial (Bourne et al. 2007).

Table A1: The key badger intervention studies undertaken in the UK and Ireland, and their study duration.

Intervention study	Key reference	Removal period
Thornbury	Gallagher and Clifton-Hadley 2000	6 years
East Offaly	Eves 1999	7 years
Four Area Project	Griffin et al. 2005	5 years
RBCT	Bourne et al. 2007	4 to 7 years (average 5.2 cull years)

Table A1 collates the time periods for badger interventions across the four trials. All of these interventions extended over periods greater than 4 years, and therefore this was considered the minimum period for a removal intervention.

Furthermore, the 4 year timeline was in keeping with other large-scale trials involving badger vaccination on-going in Britain (Carter et al. 2012) and Ireland (Aznar et al. 2011)

Additionally, the TBSPG considered the recorded impact of the culling intervention during the studies. There was a strong decline in the incidence of herd breakdowns in culled areas over the first four years of the Thornbury and East Offaly intervention areas (see Gallagher and Clifton-Hadley 2000 and Eves 1999). During the Four Area trial in Ireland, the greatest difference between removal and control areas was recorded during the fourth and fifth years of the trial (Griffin et al. 2005).

In terms of the attributed decrease in cull areas over time in the RBCT, table A2 below gives the estimated effect of the culling on incidence (Jenkins et al. 2008). The mean benefit of culling was 3.6% after the first to second cull (non-significant (NS)), this increases to 12.9% during the next year (NS) and by the end of the 4th year the benefit was 39.6% (-59.3% to -10.3%; significant). It should be noted that a significant difference between the cull and control areas was not recorded until the 3rd to 4th cull.

Table A2: From Jenkins et al. (2008), the estimated effect of culling on the incidence of Officially TB Free Withdrawn during the study period.

	Estimate (and 95% CI)
1st to 2nd cull	-3.6% (-33.1% to 38.9%)
2nd to 3rd cull	-12.9% (-38.8% to 24.2%)
3rd to 4th cull	-39.6% (-59.3% to -10.3%)
After 4th cull to end of during-trial period	-31.8% (-48.5% to -9.7%)

Other evidence bases consulted, included evaluating the approach being undertaken in England with recent “free shooting” badger trials. Donnelly et al. (2015) was tasked with undertaking a power study, based on data from the RBCT, to assess the ability of these recent English free-shooting trials to generate a significant result in terms of finding a significant decrease in cattle herd incidence. That study suggested that culling in 3 areas, where herd incidence was set at 0.15 per annum, over a four year period, would yield a power of 88% to detect a significant effect using an equal number of control areas (Donnelly et al. 2015). These analyses added confidence that a minimum four year period of culling would be appropriate for interventions in Northern Ireland.

TBSPG were cognisant that any beneficial impacts of badger culling would be predicated on the actual reduction in density achieved, and that this fact would significantly impact on minimum culling period. In other words, the efficiency of culling is as important as the culling period, with the key being to achieve as low a badger density as possible. McDonald (2014) presented an overview of the relationship between culling intensity and the beneficial outcome in terms of reducing disease risk. That paper suggested that the greater the intensity of the cull (in terms of its ability to reduce absolute density), the greater the likelihood of a positive outcome (in terms of reducing risk to cattle herds).

During the first year of the RBCT, Smith and Cheeseman (2007) found large variation in the estimated trapping efficacy across intervention areas. For seven triplets (intervention areas), badger population removal was estimated at 64 % to 77 %, and 32 % to 39 % in the other three study areas. Woodroffe et al. (2008) used data on the density of active setts, latrines, and road kill badgers to assess the effect of culling on the relative abundance (i.e. metrics of abundance) over the years of the Randomised Badger Cull Trial (RBCT). **It took 4 years of culling using cage traps (i.e. the fourth survey of field signs) to achieve large reductions in badger field signs** (e.g. 73% reduction in the density of badger latrines, a 69% reduction in the density of active burrows and a 73% reduction in the density of road-killed badgers). Similarly, during removal programmes in Ireland (East Offaly and Four Area Project), the removal of badgers were always less than 100% efficient. For example, during a small part of the East Offaly cull area where badgers were studied, trappability for a single capture session was estimated to be between 51%-54% (O’Corry-Crowe et al. 1993). By the second year of culling in the area (1990), O’Corry-Crowe et al. (1993) estimated a total removal of 75% of the starting population. Overall, Sleeman et al. (2009) suggested that the removal programme in the Four Area Project was at least 85% efficient over the first two year period of the study, with two culls being undertaken per year.

Given what was achieved in terms of badger removal using capture and cull elsewhere, TBSPG believed that repeated culling was necessary to reduce, and maintain, low badger densities over the intervention period, in order to maximize potential benefits to reducing risk to cattle herds.

Vaccination strategy post-cull - justification

The TBSPG recommends a post-cull vaccination programme be undertaken within the core (cull) zone after the removal programme has achieved significant population reduction (over a minimum of four years). This vaccination strategy is based on first principles, as there have not been any interventions of this type trialled previously. Despite this, there are published outcomes from models where removal programmes have been followed by vaccination schemes (Ramsey and Efford 2010; Abdou et al. 2016). Furthermore, there is an ongoing non-inferiority trial being undertaken in the Republic of Ireland to assess whether there are negative effects of vaccination of badgers after culling, relative to ongoing culling alone (O’Keeffe et al. pers com; More and Good 2015). Effectively, this trial is assessing whether vaccination can maintain reduced risk in lower density badger populations after culling. The use of vaccination after culling is considered a major goal of the “exit strategy” for targeted culling in the Republic of Ireland (Sheridan et al. 2014), as culling alone is not considered a long term sustainable option (Byrne et al. 2014).

The principles the TBSPG based this decision upon are:

1. The reduced badger population will have less bTB in terms of prevalence (Corner et al. 2008) and the number of infected badgers per unit area (Woodroffe et al. 2006);
2. BCG vaccine would have a greater probability of success in a low prevalence population, than an high prevalence population, as BCG does not have an effect on animals already infected (Chambers et al. 2014) and has limited ability to prevent infection in naive hosts (but can reduce active shedding; Chambers et al. 2011).
3. That the badger population would increase in abundance after culling (Tuytens et al. 2000), and this population could become less susceptible to infection by having the growing population immunised (a vaccinated population), with the anticipation that “herd immunity” effects would occur with offspring and the generational turnover of the population (Carter et al. 2012).

Abdou et al. (2016) modelled the impact of culling badgers for 5 years, followed by a vaccination program for up to 15 years thereafter using agent based simulation modelling based on available parameters for an Irish badger population. Culling successfully reduced the prevalence of bTB within the badger population over the five year period, while vaccination (modelled as deployed bait) was able to maintain the lowered prevalence up to 15 years with repeat vaccination. This latter effect was impressive, as during the period the simulated badger population significantly increased in abundance.

Ramsey and Efford (2010) investigated the effects of culling and vaccination of possums using BCG in New Zealand. This work found that repeated culling, or the use the culling along with BCG and fertility control, were the best cost-effective approaches to disease control. However, an initial cull followed by vaccination using

BCG was one of the most cost-effective alternate models of control tested in that system (Ramsey and Efford 2010).

In other wildlife disease situations, Smith and Wilkinson (2003) showed that for rabies in wild foxes, culling followed by vaccination could reduce the period of the epidemic using a simulation model.

TBSPG also considered it prudent that the population had increased resistance to re-exposure to *Mycobacterium bovis* as new susceptible cubs were born (enter into the population) in the growing badger population after culling (Carter et al. 2012).

The vaccination duration undertaken by DAERA will be discussed in the next section. TBSPG is cognisant that vaccination programmes have been rolled out in England, with vaccine administered by lay vaccinators, led by volunteers from farmers and environmental groups (Chambers et al. 2014; Enticott et al. 2014).

Vaccination post-cull duration

There are no direct empirical data to inform exactly the period over which vaccination should occur post-cull, as no such trials have been undertaken. However, there are data on vaccination trials in uncultured populations, modelling exercises and badger population dynamics data that can be used to inform the debate as to how best to proceed in terms of the minimum duration of the proposed post-cull management of badger populations.

Vaccination period post-cull – evidence consulted

Other vaccination program periods:

1. The Kilkenny vaccine trial – This trial was undertaken for **4 years**, with two trapping sweeps per year, in an uncultured badger population (for at least 2 years prior to commencement of the study) in the **Republic of Ireland**. Key reference: Aznar et al. 2011
2. The BCG vaccine safety study in badgers – This safety study was undertaken over a **4 year** period, with 6 capture-treatment attempts over the study period in rural **Gloucestershire, England**. This study suggested that vaccination reduced the risk of individuals testing positive to a suite of bTB tests (Carter et al. 2012); and reported potential reduced risk to unvaccinated cubs in social groups where adults had been vaccinated.
3. The BCG non-inferiority intervention – This one-sided test of vaccination (intra-muscular) of badgers versus continued culling in the **Republic of Ireland**, is designed to assess **4 years** of intervention (Byrne et al. 2014).
4. The Welsh Intensive Action Area – This intervention includes both badger vaccination with cattle measures, and was designed to be implemented over a

5 year period in **Wales** (Welsh government). However, the fifth year of this project has been suspended due to a lack of available vaccine (Bovine TB Eradication Programme IAA Vaccination Project – Year 4 Report).

Badger population coverage – modelling studies

Wilkinson et al. (2004) suggested that **40-50% of healthy badgers need to be vaccinated annually** in a population, if bTB eradication is to be achieved. However, eradication took many years to be achieved. Abdou et al. (2016) modelled before and after scenarios whereby vaccination followed culling. Within that model, **vaccination could maintain low levels of infection prevalence** within the badger population for long periods of time **post-cull** where repeated vaccination programs were implemented.

In order to achieve high coverage levels (i.e. the % vaccinated), **repeated efforts would be required because trappability is below 100% in most cases** (Tuytens et al. 1999; Byrne et al. 2012). After 5 repeated vaccination events, Byrne et al. (2012) reported that approximately 80% of the adult badger population studied were captured and treated. Therefore, given the available literature, it is recommended that multiple years of treatment (vaccination) would be required to achieve sufficient levels of vaccine coverage.

Badger population turnover and repopulation

The following papers sets out the population dynamics of wild badger populations (Anderson and Trewella 1985; Wilkinson et al. 2000). Given these data, it is assumed that **badger populations can turnover at a rate of approximately every 3-5 years** in an undisturbed population (Tuytens et al. 2000; Anderson and Trewella 1985). The model by Anderson and Trewella 1985 suggested that, given the reported R_{max} (the maximum reproductive capacity) for badgers, it would take **5 years recovery time after a cull**. Assuming a logistical growth model, the minimum recovery time of a population can be estimated as $1/R_{max}$. The R_{max} for badgers have been estimated to be 0.3 and 0.46 in two studies (Macdonald et al. 2009; Bright 1993) respectively, which would indicate for the badger the minimum recovery time would be between 2.2-3.3 years.

Empirical data from culled populations suggest that badgers can repopulate areas relatively quickly. For example, Tuytens et al. (2000) described how a medium density badger population (4-8 badgers per km^2) which was culled **and 30% of animals removed, repopulated over a period of three years**.

However, where **near complete removal of badgers** have occurred, the recolonisation period was between **9-10 years** (Cheeseman et al. 1993).

However, this population was of very high density at ~ 20 badger km^{-2} .

Within the proposed cull areas, according with the recommendations of TBSPG, **immigrating badgers could be made up of animals from the vaccinated buffer area**. Tuytens et al. (2000) described how most badgers repopulating

culled social groups, came from surrounding uncultured populations. These vaccinated animals repopulating the cull zone could increase the effectiveness of any post-cull vaccination programme.

Recommendations given the limited available evidence

Given the information presented above, the following could be suggested as a minimum approach:

- **A minimum of three years** of intensive vaccination post-cull would be implemented, however, given local conditions and ongoing analysis of data, **this period could be extended** (at the behest of TBEP and informed by scientific analysis of ongoing data collection)
- Given that: 1. the population would be small post-culling and 2. Immigrating badgers may have already been vaccinated; **a minimum of one vaccination treatment** could be implemented **per year** which may allow for reasonable coverage (similar approaches have been used during the Non-inferiority trial being undertaken in ROI). This annual vaccination recommendation has been suggested also by Delahay et al. (2003). However, given that the population could grow relatively quickly (recolonisation taking somewhere between 3-10 years (see above)), increasing the frequency of vaccination within the areas may need to be increased to two vaccination sweeps per year (following experimental trials like the Kilkenny vaccine trial) to ensure that coverage was kept high and that newly susceptible individuals entering the population (births and immigrants) can be inoculated as soon as possible.
- Because of the significant effects of local conditions on recolonisation (see discussions by Roper 2010; Cheeseman et al. 1993; Tuytens et al. 2000), there should be considerable scope for **local adaptive management** practices to be implemented – as recommended by TBSPG.

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