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CONVENTION ON THE CONSERVATION OF EUROPEAN WILDLIFE
AND NATURAL HABITATS

Standing Committee

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Other complaints

STEADY DECLINE OF THE NATIONAL BADGER (*MELES MELES*) POPULATION IN IRELAND

REPORT BY THE GOVERNMENT

Document prepared by
the Department of Arts, Heritage and the Gaeltacht of Ireland

An Roinn
Ealaíon, Oidhreachta agus Gaeltachta
Department of
Arts, Heritage and the Gaeltacht

COMPLAINT: STEADY DECLINE OF THE NATIONAL BADGER (MELES MELES) POPULATION IN IRELAND

Response by the Irish Authorities to a complaint made by the Irish Wildlife Trust and Mark Stephens to the Council of Europe on a possible breach of the Bern Convention in relation to the culling of badgers in Ireland

1. Introduction

The response has been compiled by the two Government Departments who have responsibility for the badger population in Ireland

- The Department of Agriculture, Food and the Marine (DAFM) who operate the capturing of badgers under the bovine TB eradication programme; and
- The Department of Arts, Heritage and the Gaeltacht (DAHG) who issue licences to DAFM to undertake the capturing programme.

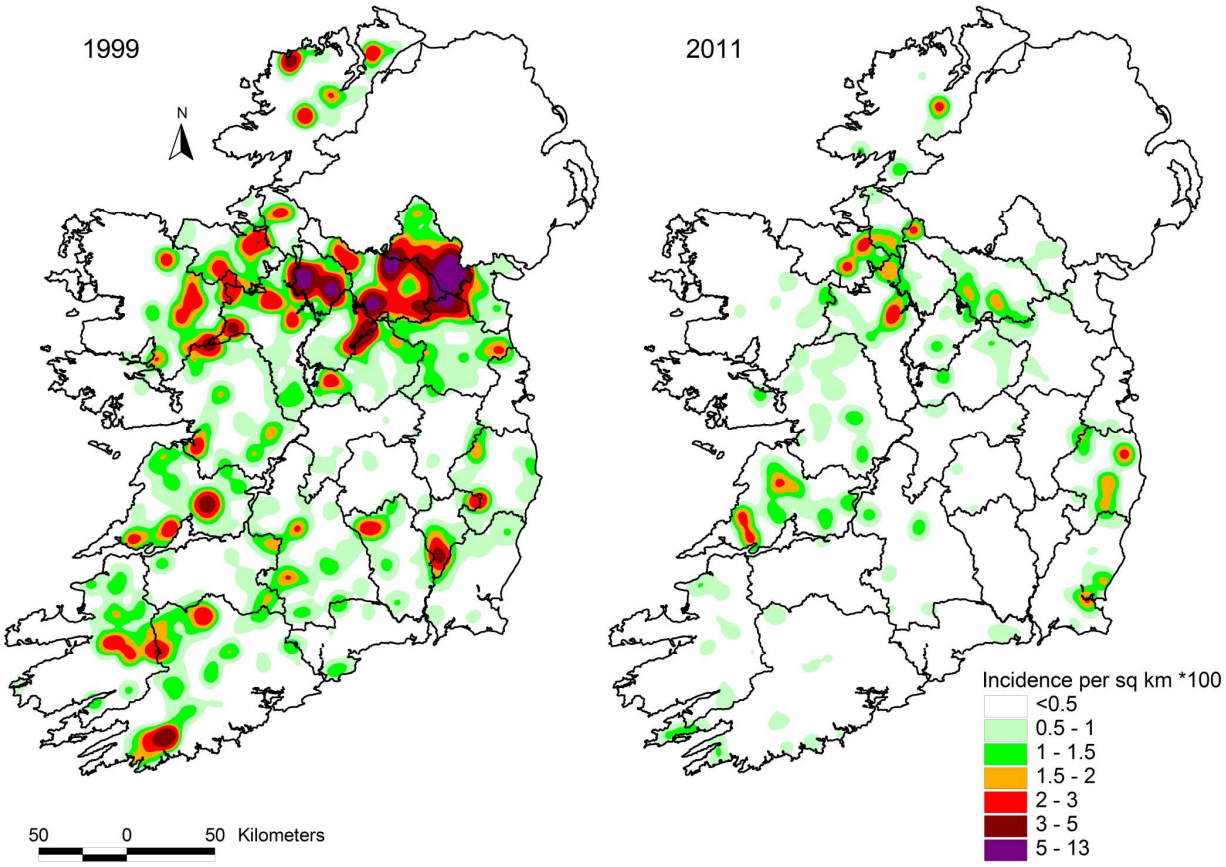
This document responds to the various points raised by the Irish Wildlife Trust and provides published documentation in order to reply in a comprehensive fashion to the complaint.

2. Background to the bovine TB Eradication Programme in Ireland

Ireland commenced a 'test and slaughter' programme to eradicate bovine TB in 1954. At that time bovine TB was the greatest cause of loss from an infectious source and the animal reactor incidence of bovine TB in cattle was 17% (22% in cows and 8% in other cattle). The early years of the programme resulted in rapid progress toward the ultimate goal of eradication, and in 1965 the country was provisionally declared as "attested" or bovine TB free on the assumption that the early trend lines would continue to full eradication.

This improvement did not materialise and between 1965 and 1985, no effective improvement occurred with reactor numbers remaining at 35,000 reactors (plus or minus 5,000) per year. A wildlife component (badgers) was identified in the early 1980s as a significant source of seeding new infections to cattle and a number of scientific trials were carried out which quantified the magnitude of this source of infection and methods to counter it.

In 2003, a national programme of controlling badger populations in areas where serious outbreaks of bovine TB, was identified and deemed part of a cattle-badger interaction locally was put in place by the DAFM. As a result of this programme, the annual animal level incidence of bovine TB in cattle declined to 0.24% by 2010. The number of SICTT (Single Intradermal Cervical Tuberculin Test) reactors fell from 39,847 in 2000 and to 20,211 in 2010, (herd incidences of 7.53% and 4.65% respectively). The following maps give an indication of the decrease in the incidence of TB in Ireland in the period 1999 to 2011.



TB reactors per sq km

Current research is focusing on replacing the long-term culling of badgers with vaccination with BCG.

3. Badgers and the Wildlife Acts

The badger is a species that is protected under the Wildlife Acts. However, it has been identified as an important reservoir of *Mycobacterium bovis*, the bacterium that causes TB in cattle. The Department of Arts Heritage and the Gaeltacht has facilitated the bovine TB eradication programme of DAFM for many years by licensing that Department to remove badgers where local outbreaks have occurred in cattle herds. There has been an agreement in place for a number of years between the two Departments where the cumulative percentage of agricultural land under capture for badgers could not exceed 30%.

Since 2004, DAHG have issued licences annually to DAFM, one for each Divisional Veterinary Office (DVO) allowing the removal of badgers from infected areas. However, there have been periods where licences have been issued for a shorter time period.

Under the licences issued by DAHG, badgers are captured where they are implicated in an outbreak of TB. Capturing is undertaken only in areas where serious outbreaks of TB have been identified in cattle herds and where an epidemiological investigation carried out by DAFM's Veterinary Inspectorate has found that badgers are the likely source of infection. Successive capturing operations focus predominately on the same areas, which results in local reductions in badger numbers. This lower local density of badgers will lead to less animal to animal (badgers or cattle) transmission of TB.

4. Population estimates of badgers in Ireland, Northern Ireland and elsewhere.

The core of the IWT complaint is that the Irish badger population is under threat of becoming extinct due to the bovine TB eradication programme. The evidence quoted in the IWT paper suggest that population estimates of 148,000 (1995), 84,000 (2009) and 60,000 in 2012 are trending such that

badgers will become extinct by 2020. It is the Irish authorities' contention that this argument is flawed and our reasoning is presented in the accompanying commentary.

DAFM have prepared a specific document in response to this aspect of the IWT complaint; *Badger numbers and what constitutes a sustainable population?* (Appendix A). The document explains the background to the estimates of population that have been published previously by Smal and by Sleeman. One could extrapolate from these studies that the national badger population in 2000 was somewhere between 70,000 and 120,000 with a mean value of circa 95,000. The best estimate of the national population in 2012 is somewhere between 50,000 and 85,000, mean circa 70,000 badgers. While a population reduction over this period is still evident, it is clear that this level of decline will not continue. Already the amount of new land being brought under treatment annually is decreasing. As the badger vaccination programme is gradually rolled out, the level of culling will be further reduced.

By definition, local populations have been and are being impacted by DAFMs culling program because, where local breakdowns due to tuberculosis in cattle herds are associated epidemiologically with badgers, local populations are culled and densities are maintained at lowered levels as a matter of policy. Nonetheless, the current population estimates are based on badger densities that are at the higher end of density estimates from other countries on mainland Europe and are not close to levels at which the badger population at county or regional level could be consider to be under threat.

Two further documents are enclosed in relation to the impact of culling. *The ecology of the European Badger (Meles meles) in Ireland: A Review* (Appendix B), *Impact of culling on relative abundance of the European Badger (Meles meles) in Ireland* (Appendix C).

5. Medium Term National Strategy

The Medium Term National Strategy (Appendix D) prepared by DAFM is based on a targeted intervention around serious herd breakdowns (>3 standard reactors) where badgers have been implicated in a breakdown by epidemiology carried out by local DAFM Veterinary Inspectors. This programme is successful, in that episodes of bovine TB in herds are reducing in frequency since the policy began and, in turn, this results in a reducing rate of new land being added to the national cumulative pool of land under capture. This document presents and discusses the output data which is considered as evidence that the programme is successfully delivering its targeted objectives.

The issue of the cumulative growth in areas under capture since 2003, in individual counties, of land within 500m of setts approved for capture as per national policy is addressed in paragraph 7.

The issue of bovine TB levels in local badger populations are addressed in two documents published by *Veterinary Journal* at Appendices E and F.

6. Vaccination of badgers

DAFM has being conducting a research program since 2001 that is exploring elements of possible benefits of vaccinating badgers with BCG. There are currently two elements of research underway. A project is running in Kilkenny in which badgers have been given an oral preparation of BCG vaccine and the protective effects will be measured against a cohort of badgers in the same areas that have received a placebo. The background to this work is detailed in the document prepared by DAFM - *Control of tuberculosis in badgers by vaccination* (Appendix G)

A separate but related project is also running and will be based on results from the badgers orally vaccinated in Kilkenny. The document prepared by DAFM at Appendix H - *Trial Design to Measure the Effect of Oral Vaccination* explains the background and methodologies that will be used in these analyses.

Separately to the trials running in Kilkenny, trials are in planning where intramuscular injection of BCG and release of vaccinated badgers will be compared with continued culling in selected counties nationally, details of which are outlined in the document *Proposal for a series of trials in which intramuscular vaccination of badgers with BCG* etc (Appendix I). Further trials will commence later in 2012 in selected areas in counties Cork, Longford, Monaghan and Tipperary. It is anticipated that trials in a further two counties will commence in 2013.

7. The origin, basis and justification of the 30% limit of the total Agricultural land area on which culling could take place.

Ireland comprises some 70,000Km^2 of land. Of this, roughly 50,000 Km^2 is considered agricultural land and is claimed for Area Aid under the EU Common Agricultural Policy. Of this, the badger capturing programme operates on 15,000 Km^2. Specifically for reasons of conservation no capturing takes place on the remaining 35,000 Km^2 of agricultural land or the remaining 20,000Km^2 of non-agricultural land where badgers also reside. There is a scientific basis behind how 15,000 Km^2 area is calculated.

It is considered that the IWT document misrepresents how the areas are selected, calculated and represented. A document (Appendix J) prepared by the Veterinary Sciences Centre of University College Dublin addresses the IWT claim by setting out the criteria for identifying areas under capture.

8. Comparison between Northern Ireland and this State

The IWC in their complaint make the claim that the incidence of TB in Northern Ireland, where badger culling is not carried out, is similar to TB levels in Ireland. The implications of this claim are that the culling of badgers in Ireland has no impact on the incidence of TB and, accordingly, does not serve any useful purpose. It is the Irish authorities' contention that, as indicated in paragraph 2 above, the incidence of TB in Ireland has fallen significantly over the last ten years, particularly since 2004. Furthermore, the incidence of TB in Northern Ireland is significantly higher than in Ireland.

Published statistics on the incidence of TB in Ireland and Northern Ireland (and in GB also) are not comparable because of the differences in the methodology for defining outbreaks of TB. For example, in Ireland, all breakdowns, irrespective of whether they are confirmed by the laboratory, are regarded as breakdowns and are included in the official statistics. In Northern Ireland, however, incidences of TB detected via slaughter house surveillance are not deemed to be "outbreaks" and are not included in the official statistics unless TB is detected in the herd at a follow-up skin test on-farm. These "incidences" account for about 25% of outbreaks of TB in Ireland. In addition, in Northern Ireland outbreaks of five or less "reactors" are not included in the official statistics unless disease is confirmed.

In view of the difficulty in comparing the trends in the incidence in Ireland, Northern Ireland, England and Wales, the authorities in these various jurisdictions have collaborated in producing a document using standardised definitions and measures. This document titled *Bovine tuberculosis in the United Kingdom and Republic of Ireland" 1995 to 2010* is currently at review stage and will be published by the journal *Veterinary Record* shortly. While the standardised definitions and measures used in the document are not without problems in that they do not entirely resolve the issues described above, they do nevertheless provide a better basis for comparing trends in bovine TB than official statistics and they show clearly diverging trends in these countries.

For example, in the period 1995-2010, the animal incidence of TB increased by 380% in England, by 190% in Wales and by 74% in Northern Ireland. On the other hand, animal incidence in Ireland fell by 32% in the same period. It should be noted that the incidence of TB in Ireland fell by a further 10% in Ireland in 2011 compared to an increase of 15% in Northern Ireland, with the result that animal incidence in Northern Ireland in 2011 was, at 0.48 %, 65% higher than in Ireland (0.29%).

Department of Arts, Heritage and the Gaeltacht, Dublin, Ireland

3 September 2012

Enclosures

Appendix A - Badger numbers and what constitutes a sustainable population?

Appendix B - *The ecology of the European Badger (Meles meles) in Ireland: A Review*

Appendix C - Impact of culling on relative abundance of the European Badger (*Meles meles*) in Ireland

Appendix D - The Medium Term National Strategy

Appendix E – The distribution of *Mycobacterium bovis* infection in naturally infected badgers

Appendix F – The prevalence and distribution of *Mycobacterium infection* in European Badgers (Meles meles) as determined by enhanced post mortem examination and bacteriological culture

Appendix G - Control of tuberculosis in badgers by vaccination

Appendix H - Trial Design to Measure the Effect of Oral Vaccination

Appendix I - Proposal for a series of trials in which intramuscular vaccination of badgers with BCG etc

Appendix J – Calculation of Wildlife Administration Unit Treated Land Areas, Veterinary Sciences Centre of University College Dublin

APPENDIX A - BADGER NUMBERS AND WHAT CONSTITUTES A SUSTAINABLE POPULATION?

J.O'Keeffe and A. Byrne.

Introduction

Over the past 30 years there has been a considerable debate around the important question "What is the badger population in Ireland?" Two formal studies have taken place that generated estimates that representing point in time estimates of the true national badger population. There are considerable difficulties accurately estimating a wildlife population's size at a national scale due a number of uncertainties inherent in such calculations. Sample size will have a major impact on the precision of any estimate. In general, the larger the sample size the greater the precision and trust we can have in a model estimate. Degrees of uncertainty also vary depending on the extent and the intensity of survey methods, and these relate to the size of the areas surveyed and the likelihood that some sett locations are missed. Commonly, uncertainty surrounds how setts are classified (main setts versus outliers), and assumptions being made that all main setts represent single territories and social groups (this is not always the case; Byrne et al. 2012a). In addition there can be significant variation in capture probabilities which may affect estimates of social group sizes. Finally, there is a large degree of uncertainty due to the variation in the population dynamics of a national population, which may be effected by factors such as climate over time (e.g. see Macdonald et al. 2010). Therefore any estimate of the national population must be considered against a backdrop of these uncertainties.

What is the National Badger Population?

In the past 20 years two major studies have attempted to generate estimates of the Irish badger population. Both were done in good faith, and used data that was available at the time, so are both valid but must be viewed as being "of their time" and the best attempts possible given the data then available to the authors.

A Walsh Fellow Post-Graduate study is presently underway that is analysing/evaluating data collected by DAFMs field staff who deliver the operational side of DAFMs Medium Term Wildlife strategy 2002-present. The details of this strategy are explained elsewhere in this dossier (see Chapt4). These studies will result in robust models of the national badger population, but unfortunately, this element of the Fellowship will not be completed until the end of 2012. Papers (A, B and C below) relevant to this topic from this study are included in this chapter.

A Review paper published by *Biology and Environment – Proceedings of the Royal Irish Academy*:

The ecology of the European Badger (*Meles meles*) in Ireland: a review

Andrew W. Byrne, D. Paddy Sleeman, James O'Keeffe and John Davenport

B Paper published in the *European Journal of Wildlife Research*

Impact of culling on relative abundance of the European badger (*Meles meles*) in Ireland

Andrew W. Byrne, James O'Keeffe, D. Paddy Sleeman, John Davenport and S. Wayne Martin

C Draft Paper in preparation

Estimating population size and trappability of the badger (*Meles meles*) through mark-recapture: implications for large-scale bovine tuberculosis vaccination programmes

Andrew W. Byrne, Denise Murphy, James O'Keeffe, John Davenport, D. Paddy Sleeman, Stuart Green, Leigh Corner, Eamonn Gormley and S. Wayne Martin

Paper A (The Ecology Of The European Badger (Meles Meles) In Ireland: A Review) contains the following passage:

"Although progress has been made in estimating the distribution and density of badger populations, national population estimates have varied widely in the Republic of Ireland. Future research should concentrate on filling gaps in our knowledge, including population models and predictive spatial modelling that will contribute to vaccine delivery, management and conservation strategies."

The previous population estimates come for work published by Smal in 1995 (the Badger and Habitat Survey; BHS) and by Sleeman et al. published in 2009. The Smal work estimated 200,000 badgers and the Sleeman paper suggested a lower figure of 84,000.

Why such a difference between two authors?

These studies used data derived from different surveys, and used different methodologies to generate their respective results.

In the case of Smal, in his "The Badger and Habitat Survey of Ireland" he used survey data from 729 individually surveyed 1km^2 grids of land. These 1 Km^2 grids were in turn the most south-westerly in larger 10 Km^2 grids that cover the island of Ireland. The Northern Ireland (NI)1 km^2 grids were also surveyed at that time and those results published by Feore and Montgomery (1999), with further analysis presented in Feore's PhD thesis (1994).

The Smal study used the survey results of this 1% of the ROI land area, on which 1378 setts were found. Of these, main setts:other setts were assigned in a 1:3 ratio, with a mean of 4 setts assigned per social group. A social group size of 5.9 was applied as the multiplier across the estimated 34,000 social groups nationally resulting in a population estimate of 200,500. This method, similarly applied on the NI data yielded an estimate of population there of approximately 50,000 (Feore 1994). It should be noted that only 21% of setts surveyed in NI were considered main setts compared to 25% in ROI. This estimate was re-adjusted for the variation in social group size according to broad landscape types (Feore and Montgomery 1999). The revised figure for Northern Ireland in the mid-1990s was 37,600 (95% CI 29,000-46,300). A revised figure, incorporating variation in social group size according to landscape type, was never undertaken with the dataset generated during the BHS. Byrne et al. (2012A) highlighted this discrepancy and used a 'rule of thumb' guide to adjust the estimate of Smal (1995). However, this adjustment was only meant as a guide and the authors strongly suggest that the adjusted figure should be treated with due caution, especially in the context of the Republic of Ireland having more landscapes with low badger densities than that of Northern Ireland.

Since Smal's survey work was undertaken, a number of other more detailed survey efforts have taken place. Between 1997-2002, the Four Area Project (FAP) was undertaken and this involved a detailed survey of 960 km^2 of countryside (Cork 188km^2 ,Donegal 215km^2 ,Kilkenny 252km^2 ,Monaghan 305km^2). Data from this study was the basis for Sleeman et al's (2009) population estimate. Sleeman took the 960 Km^2 surveyed area, overlaid it with a 0.25 Km^2 grid and divided the badgers captured in those areas amongst grid polygons. Corine land usage data was then estimated per grid, and a national estimate of badger numbers was generated based on a model relating national Corine data with badger numbers. The accuracy of Sleeman et al's estimate is related to how accurately Corine definitions of land use reflect badger densities.. What Sleeman et al. concluded in their discussion was that "**badgers may not be as numerous as the last estimate (Smal 1995; 200,000) had suggested".** Sleeman et al. (2009) model suggested a national population size of 84,000 (95% CI 72,000-95,000), which would result in a mean national density of 1.20 badgers km^{-2} (95% CI 1.03-1.36).

Since 2002, DAFMs staff has surveyed around 12,000 km^2 of the nation's 70,000 Km^2. The majority of this surveyed area constitutes agricultural land* (*land claimed under EU area aid schemes). Currently approximately 50,000km^2 of the Irish landscape is claimed under area aid schemes. The 12,000 Km^2 is substantially larger than the previous areas used by Smal (729 Km^2) and Sleeman et al. (960 Km^2). These surveys have resulted in locating and recording the position of circa 30,000 setts, with badgers being captured at approximately 10,000 of these setts. From this substantial dataset the following can be proposed:

1. A mean estimate of social group size of 5.9 is likely too high across landscapes in Ireland. Capturing data since 2002 would suggests groups of 3-4 are more typical for Irish populations in

agricultural landscapes. However, it should be noted that there is a high degree of variability across social groups within the national population. It should also be noted that group sizes estimated during the FAP was 3.9 badgers per main sett.

2. Estimates of main sett density established during the BHS of 0.55 main setts km^{-2} are probably an overestimate. Main sett densities estimated for three counties in Ireland suggest densities of 0.43-0.49 main setts km^{-2} (Paper B.). Furthermore, unpublished work from the Kilkenny vaccine trial area suggests a main sett density of 0.42 main setts km^{-2}. Conservatively, this may indicate that mean densities should be lowered by 10%. Recalibration would reduce Smal's estimate of main setts from 34,000 to 30,600 nationally. Applying the median of 3 badgers and the higher figure of 4 per social group, would reduce the 200,500 estimate to between (x3) 91,800 and (x4)122,400.

The NI surveys (Feore1994) were repeated by Reid (2008), and that resulted in a revised estimate of 33,500 badgers (95% CI 26,000-41,200) with a mean density of 2.42 badger km^{-2} (95% CI 1.88-2.98). These estimates were not significantly different than the revised estimates from Feore (1994), taking into account variation in group size across landscape types.

Until 2000, one can reasonably assume that there were somewhere between 70,000 and 120,000 (~95,000 mean value) badgers in the Republic of Ireland, with an additional 25% in Northern Ireland.

Estimating the figure appropriate to 2012 requires some assumptions until further on-going studies are completed. The assumptions used in the following section are based on conservative estimates taken from the badger literature for the island of Ireland.

On the 20,000 km^2 of land that is not farmed, there are perhaps 10,000 badgers (this is based on a conservative assumption of an average density of 0.5 badgers per km^2.) On the 35,000 km^2 of land farmed but not captured on, there are perhaps between 35-63,000 badgers (assuming a mean density of between 1.0-1.8 badgers per km^2). On the 15,000 km^2 of lands captured annually there are probably between 5-7.5K badgers (between 0.35-0.50 badgers per km^2 assuming an absolute reduction in density due to culling of 50-81%). These estimates equate to an upper estimate of as many as 80,500 and a lower estimate of 50,000 with a mean of circa 70,000. This conservative estimate suggests a national density of one badger km^{-2} (lower estimate: 0.71 badgers km^{-2}; upper estimate: 1.15 badgers km^{-2}).

Higher estimated densities of 80,500 per 70,000 km^2 equate to a mean of 1.150* badgers per km^2.

(*This average is made up of densities of 0.5 km^{-2} on areas not farmed, 1.8 Km^{-2}on areas farmed but not captured and 0.5 Km^2 on areas farmed where badgers are captured annually.)

Lower estimate densities of 50,000 per 70,000 km^2 equate to 0.714* badgers per Km^2 .

(*This average is made up of densities of 0.5 Km^2 on areas not farmed, 1.0 Km^2on areas farmed but not captured and 0.35 Km^2 on areas farmed where badgers are captured annually.)

The attached papers, which were mentioned earlier (B and C), are based on data derived from the capturing program implemented by DAFM staff in counties Longford, Monaghan and Tipperary (B), and a capture-release study ongoing in county Kilkenny (C).

The data from Kilkenny (see paper referred to in C) suggests that where a capturing effort is attempted, not more than 50% of the badgers likely to be present are actually captured (per capture attempt) and this may even be as low as 30% if the more extremes of what is probable were assumed to be the norm.

The paper containing the analysis of capturing in selected counties (B) gives estimates of the yield of badgers captured over a six-year period following capturing commencing at any given sett approved for capture. The relevance of these analyses to our discussion on population size and the impact of culling is that even after 6 years of removals, badgers remain in those targeted areas and removal rates trend toward a steady state equilibrium that is above zero and is probably primarily driven by inward

migration of badgers from surrounding areas of greater densities. We do not know the rate of immigration into culled areas nor the reproductive response of the remaining population after a cull (it may be likely that fecundity increases due to decreased density, alleviating competition for resources).

What density of badgers is required such that a population is self-sustaining?

The pertinent question "*what is the density of badgers required for a self –sustaining population*?" remains and is not known for Ireland. Useful comparative information is available from studies done elsewhere in continental Europe where the densities of healthy, self-sustaining populations have been studied.

The highest recorded badger densities, either at local or national levels, have been reported from populations within the British Isles (Byrne et al. 2012). Badger populations are being sustained elsewhere at considerably lower densities than those being reported in the British Isles. Most badger populations have grown in recent decades according to the IUCN red list files (Kranz et al. 2008) despite hunting pressure in much of the species range, mortality due to road traffic accidents and persecution. A recent IUCN Regional Red List suggested that the badger population in Ireland was not threatened and were of 'least concern' (Marnell et al. 2009).

Estimated badger densities are presented below for 27 countries outside of Britain and Ireland which have data on badger populations. Badger social group sizes are also significantly smaller than typical group sizes reported in Britain or Ireland. Data on group size are presented below for 11 badger populations from continental Europe. For reference, mean group size estimated across studies from Ireland is 3-4 (range: 1.8-5.9) badgers; for Britain 5-6 (range: 3.3-8.8) badgers (Byrne et al. 2012).

Data on densities of European badger (*Meles meles*) populations outside of the British Isles

We used data derived from recent research or review papers relating to badger densities. Where available we have presented data as a range of recorded values across studies within countries. As populations generally across have changed (mostly increased; Kranz et al. 2008) in abundance in recent decades we avoided referring back to data presented in the review undertaken by Griffith et al. in 1993, except where more recent figures were unable to be sourced. Estimates from Griffiths et al. should be considered as minimum national densities.

Location	*Population density (km^{-2})*	*Signatories to the Bern Convention (date)**	*Paper referred*
Albania	0.09	Yes (31/10/1995)	Griffiths et al. 1993. *Council of Europe*
Austria	0.36	Yes (19/9/1979)	Griffiths et al. 1993. *Council of Europe*
Belarus	0.09**	No	Sidorovich et al. 2011. *Ann. Zool. Fenn.*
Belgium	0.1-0.74	Yes (8/10/1997)	Venderick 2007. *PhD Université De Liège.*
Bulgaria	0.10-0.90	No (Accession 31/1/1991	Griffiths et al. 1993. *Council of Europe*
Croatia	0.02-0.04	Yes (3/11/1999)	Griffiths et al. 1993. *Council of Europe*
Czech Rep.	0.12-0.98	Yes (8/10/1997)	Johnson et al. 2002. *J. Biogeog.;* Lara-Romero et al. 2011. *Mamm. Rev.*
Denmark	0.50-1.50	Yes (19/9/1979)	Aaris-Sørensen 1995, *Ann. Zool. Fenn.*
Estonia	0.04	No (Accession 3/8/1992)	Griffiths et al. 1993. *Council of Europe*
Finland	0.24	Yes (19/9/1979)	Lara-Romero et al. 2011. *Mamm. Rev.*
France	1.60	Yes (19/9/1979)	Schley et al. 2004. *Mamm. Rev.*

Germany	0.40-0.80	Yes (19/9/1979)	Keuling et al. 2010. *Euro. J. Wildl. Res.*
Hungary	0.30-1.50	No (Accession 16/11/1989)	Griffiths et al. 1993. *Council of Europe*
Italy	0.98-1.00	Yes (19/9/1979)	Johnson et al. 2002. *J. Biogeog.;* Remonti et al. 2006. *Folia Zoo.*
Latvia	0.30	Yes (23/1/1997)	Johnson et al. 2002. *J. Biogeog.*
Luxembourg	0.65-0.91	Yes (19/9/1979)	Schley et al. 2004. *Mamm. Rev.*
Netherlands	0.19	Yes (19/9/1979)	Lara-Romero et al. 2011. *Mamm. Rev.*
Norway	0.50	Yes (19/9/1979)	Lara-Romero et al. 2011. *Mamm. Rev.*
Poland	0.16-0.59	Yes (24/3/1995)	Johnson et al. 2002. *J. Biogeog.;* Lara-Romero et al. 2011. *Mamm. Rev.*
Portugal	0.42	Yes (19/9/1979)	Lara-Romero et al. 2011. *Mamm. Rev.*
Russia (west)	0.46	No	Johnson et al. 2002. *J. Biogeog.;* Lara-Romero et al. 2011. *Mamm. Rev.*
Slovakia	0.20	Yes (28/4/1994)	Griffiths et al. 1993. *Council of Europe*
Slovenia	0.25	Yes (20/10/1998)	Griffiths et al. 1993. *Council of Europe*
Spain	0.28-1.98	Yes (19/9/1979)	Johnson et al. 2002. *J. Biogeog.;* Lara-Romero et al. 2011. *Mamm. Rev.*
Sweden	0.01-0.25^ (North)	Yes (19/9/1979)	Seiler et al. 2003. *PhD Uppsala.*
	2.00-3.00 (South)		
Switzerland	0.50-1.80	Yes (19/9/1979)	Johnson et al. 2002. *J. Biogeog.*
Ukraine	0.50-1.80	Yes (17/8/1998)	Schley et al. 2004. *Mamm. Rev.*
Mean (minimum density, including Griffith et al. 1993)	0.41 (SD 0.45)		
Mean (maximum density, excluding Griffith et al. 1993)	0.90 (SD 0.74)		

* Taken from the following website: http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=104&CM=8&DF=&CL=ENG

** This population is considered threatened.

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Feore, S. and Montgomery, W.I. 1999 Habitat effects on the spatial ecology of the European badger (*Meles meles*). Journal of Zoology 247, 537_49.

Feore, S.M. 1994 The distribution and abundance of the badger *Meles meles* L. Unpublished PhD Thesis, Queens University Belfast.

Macdonald, D. W., Newman, C., Buesching, C. D. and Nouvellet, P. (2010), Are badgers '*Under The Weather*'? Direct and indirect impacts of climate variation on European badger (*Meles meles*) population dynamics. Global Change Biology, 16: 2913–2922

Sleeman, D.P., Davenport, J., More, S.J., Clegg, T.A., Collins, J.D., Martin, S.W., Williams, D.H., Griffin, J.M. and O'Boyle, I. 2009c How many Eurasian badgers *Meles meles* L. are there in the Republic of Ireland? European Journal of Wildlife Research 55, 333_44.

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APPENDIX B - THE ECOLOGY OF THE EUROPEAN BADGER (MELES MELES) IN IRELAND: A REVIEW

By Andrew W. Byrne, D. Paddy Sleeman, James O'Keeffe and John Davenport

ABSTRACT

The badger is an ecologically and economically important species. Detailed knowledge of aspects of the ecology of this animal in Ireland has only emerged through research over recent decades. Here, we review what is known about the species' Irish populations and compare these findings with populations in Britain and Europe. Like populations elsewhere, setts are preferentially constructed on south or southeast facing sloping ground in well-drained soil types. Unlike in Britain, Irish badger main setts are less complex and most commonly found in hedgerows. Badgers utilise many habitat types, but greater badger densities have been associated with landscapes with high proportions of pasture and broadleaf woodlands. Badgers in Ireland tend to have seasonally varied diets, with less dependence on earthworms than some other populations in northwest Europe. Recent research suggests that females exhibit later onset and timing of reproductive events, smaller litter sizes and lower loss of blastocysts than populations studied in Britain. Adult social groups in Ireland tend to be smaller than in Britain, though significantly larger than social groups from continental Europe.

Although progress has been made in estimating the distribution and density of badger populations, national population estimates have varied widely in the Republic of Ireland. Future research should concentrate on filling gaps in our knowledge, including population models and predictive spatial modelling that will contribute to vaccine delivery, management and conservation strategies.

Link

http://www.ria.ie/getmedia/7a138728-0f68-40fb-ac68-0bae68fec1b8/BIOE201202_2.pdf.aspx

APPENDIX C - IMPACT OF CULLING ON RELATIVE ABUNDANCE OF THE EUROPEAN BADGER (*MELES MELES*) IN IRELAND

By Andrew W. Byrne, James O'Keeffe, D. Paddy Sleeman, John Davenport, S. Wayne Martin

ABSTRACT

The European Badger (*Meles meles*) has been implicated in the epidemiology of bovine tuberculosis in cattle populations in the Republic of Ireland. Badger populations have been subject to a culling regime in areas with chronic histories of bTB cattle herd breakdowns. Removal data from 2004 to 2010 were used to model the impact of culling on populations in areas under capture. Additionally, changes in field signs of badger activity were used as an index of abundance to support, or otherwise, the outcomes of the removal models. Significant reductions in standardised badger captures over time were found across three large study areas (total area, 1,355 km^2). Assuming that all inactive setts were vacant, an overall linear trend model suggested that badger captures had decreased by 78 % for setts with 6 years of repeated capturing operations. Given the uncertainty associated with the relationship between sett activity and badger presence, we repeated the linear modelling using two 'what if' scenarios. Assuming that individual badgers were missed on 10 % or 20 % of occasions at inactive setts, the estimated decline over 6 years is lowered to 71 % or 64 %, respectively. The decline profile consisted of a steep initial decrease in captures within the first 2 years, followed by a more gradual decrease thereafter. The number of active openings at setts (burrows) declined significantly in all three areas; but the magnitude of this decline varied significantly amongst study areas (41–82 %). There was a significant increase in the probability of setts becoming dormant with time. The removal programme was more intense (mean, 0.45 badgers culled km^{-2} $year^{-1}$) than previous experimental badger removals in Ireland but some captures may be attributed to immigrant badgers as no attempt was made to limit inward dispersal from areas not under management. Results from this study suggest that significant reductions in badger density occurred in the areas where management had taken place. Since other non-culled badger populations in Northern Ireland and Britain exhibited stable population trends, we attribute the reduction in relative abundance to the culling regime. Further studies of the dynamics of this reduction are required to quantify how it is counteracted by immigration from populations outside of culled areas.

Link:

http://rd.springer.com/article/10.1007/s10344-012-0643-1

APPENDIX D - THE MEDIUM TERM NATIONAL STRATEGY

Medium Term National Strategy 2003-

The Bovine Tuberculosis Eradication (bTB) program operating in Ireland is based around a number of measures that involve both animal and herd level controls. Principle among these is a legal requirement that herds are tested each year using the Single Intradermal Cervical Comparative test (SICCT). Herds trading animals through cattle marts or farm-to-farm sales must have had a test within the previous 365 days, otherwise permissions to trade are suspended. Animals intended for slaughter at export/domestic abattoirs must equally be within a 365 day window of their previous test.

The presence of one or more standard test positive animals (Bovine-Avain Increase 5mm or more) result in a herd loosing it's freedom to trade except for direct slaughter at abattoirs via movement permits. Trading status is returned when a herd passes a minimum of two (2) clear reactor retests carried out a minimum of 60day intervals following removal of last identified reactor animal(s). When a herd's trading status is withdrawn, it is said to be experiencing an "episode" of bTB. On average, episodes last for 190 days, and are unpopular with cattle farmers due to the disruption caused to normal trading patterns.

Table 1 TB Episodes by Episode Severity (Std. reactors / episode) and Year Nationally

	No. of Std. Reactors / Episode						
Year	0	1	2	3	4 - 10	>10	No. Episodes
2002	2,533	2,540	1,049	553	1,105	401	8,181
2003	2,219	2,442	1,000	533	1,001	335	7,530
2004	2,114	2,122	943	452	916	284	6,831
2005	2,066	2,037	877	484	1,018	339	6,821
2006	2,185	1,872	801	409	878	387	6,532
2007	2,441	2,131	924	485	979	391	7,351
2008	2,333	2,056	958	540	972	350	7,209
2009	2,011	1,797	842	384	770	316	6,120
2010	1,929	1,677	753	359	647	254	5,619
2011	1,611	1,584	712	352	629	190	5,078

	Percentages of No. of Episodes						
Year	0	1	2	3	4 - 10	>10	All Episodes
2002	31.0%	31.0%	12.8%	6.8%	13.5%	4.9%	100.0%
2003	29.5%	32.4%	13.3%	7.1%	13.3%	4.4%	100.0%
2004	30.9%	31.1%	13.8%	6.6%	13.4%	4.2%	100.0%
2005	30.3%	29.9%	12.9%	7.1%	14.9%	5.0%	100.0%
2006	33.5%	28.7%	12.3%	6.3%	13.4%	5.9%	100.0%
2007	33.2%	29.0%	12.6%	6.6%	13.3%	5.3%	100.0%
2008	32.4%	28.5%	13.3%	7.5%	13.5%	4.9%	100.0%
2009	32.9%	29.4%	13.8%	6.3%	12.6%	5.2%	100.0%
2010	34.3%	29.8%	13.4%	6.4%	11.5%	4.5%	100.0%
2011	31.7%	31.2%	14.0%	6.9%	12.4%	3.7%	100.0%

In Table1, the frequency of episodes that occurred between 2002-2011 are listed. There has been a steady decline in the numbers of episodes over the period. The wildlife program is considered a significant contributor to this downward trend in bTB episodes.

Qualitatively, not all episodes are equal in importance. Studies have shown that any given herds risk of additional future breakdowns is directly proportional to the numbers of standard reactor animals occurring at their most recent episode. The greater the numbers of standard reactors identified over the course of an episode the shorter the interval, on average, to that herd's next episode.

DAFMs wildlife program targets localities where the more serious bTB episodes are identified, which are where episodes having **3 or more standard reactor animals** have occurred and these are termed "qualifying breakdowns". Qualifying breakdowns are visited by state veterinarians who carry out epidemiological investigations that seek to identify the cause of the TB outbreak. Evidence of a purchased/introduced infected animal is first sought, and if that potential risk is ruled out and if badgers are present in the local environment of the herd, a survey and culling program is put in place.

Table 2Qualifying breakdowns 2002-2011

Year	3	4 – 10	>10	3 or more
2002	553	1,105	401	2,059
2003	533	1,001	335	1,869
2004	452	916	284	1,652
2005	484	1,018	339	1,841
2006	409	878	387	1,674
2007	485	979	391	1,855
2008	540	972	350	1,862
2009	384	770	316	1,470
2010	359	647	254	1,260
2011	352	629	190	1,171

On average, 50% of qualifying breakdowns end up having badgers implicated as being involved in the outbreak and culling programs are established in these localities. As is evident from Table2, the rate at which qualifying herds are being identified has been reducing since the current strategy began in 2003, with fewer "new" culling areas being added to the cumulative area under capture each year.

The methodology used to select and to calculate the area under capture is outlined in detail in Chapter 2. The area under capture expands each year, as new capture areas are added as a consequence of new qualifying breakdowns joining the capturing areas. The growth of the area under capture is outlined in Appendix4.2. At the end of 2005, 8.14% of the country's agricultural land was being captured annually, and this cumulative area of land under capture has risen over the years since 2005 and reached 29.18% at the end of Dec.2011. While each year has seen an increase in the overall hectares that fall within area under capture, the rate of increase in the area under capture is increasing at a declining rate as shown in Table3.

Table 3. Rate of Growth of Lands under Capture 2006-2011.

2006	plus 5.94% (from 8.14% to 14.09%) equating to 42.16% of new land added
2007	plus 4.41% (from 14.09% to 18.50%) equating to 23.84% of new land added
2008	plus 3.57% (from 18.50% to 22.07%) equating to 16.18% of new land added
2009	plus 3.50% (from 22.07% to 25.59%) equating to 13.67% of new land added
2010	plus 2.14% (from 25.59% to 27.71%) equating to 7.72% of new land added
2011	plus 1.47% (from 27.71% to 29.18%) equating to 5.04% of new land added

The next enhancement to the current program is that continued culling will be compared with an alternative strategy whereby badgers will be vaccinated intramuscularly with BCG vaccine and if vaccination of badgers is effective in limiting intra-species infection in badgers and inter-species with cattle, then long-term culling will be replaced by an initial culling program that will be followed by long-term vaccination. These trials are commencing in 2012, and will require to be running for 4 years before any evaluations will be attempted. The current program will therefore continue until 2016. This will involve the area under capture increasing by somewhere in the range of 5-7%, of

which 1.5-2% will be under vaccination, assuming the trends in growth of areas under capture continue as outlined in Table3.

The effect on badgers captured under the program.

The effects the population control program being operated by DAFM on badger numbers nationally is discussed in detail in Chapter3. Date in Table4 are the results of the culturing that is carried out on badgers removed as part of the capturing program running in high risk bTB areas that are represented among those 15,000Km^2 of farmlands where capturing takes place. Tissue samples are harvested from roughly 30% of badgers captured, and represents a random sample of tissue from the freshest cohort of badgers that arrive at the pathology labs for evaluation. The culturing is done on a pooled sample of tissue collected from up to 14 sites, and culturing is attempted using one plate per badger.

Table4 Numbers of Badgers cultured and their outcomes 2008-2011

Year	Number of Badger's sampled/tested	Number culture positive
2008	1,754	399 (23%)
2009	1,129	159 (15%)
2010	2279	305 (13.38%)
2011	1978	228 (11.5%)

This culturing protocol is not the most sensitive that could be delivered, but is deemed sufficient given the resource and cost constraints currently applying. In relative terms, the levels of bTB in badgers has fallen from 23% in 2008 to 11.5% in 2011. It has been established that badgers in areas experiencing serious outbreaks of bTB in cattle when removed have bTB confirmed in between 40-50% of cases. It has also been established that local populations of badgers in areas that have remained free of bTB for the previous five (5) years, despite having cattle present have bTB levels of 15%. The declining rate of bTB in the culture results outlined in Table4 reflect the consequences of removing the more heavily infected residents of "high risk areas", and their replacement by inward migration of neighbouring badgers that likely are representative of less heavily bTB infected populations akin to those populations with 15% prevalence.

This observed decline in the prevalence of bTB in badgers culled in "high bTB risk" areas can expected to have the following outcomes:

- Fewer infected badgers in these areas leading to fewer newly infected badgers and cattle from a local badger source.
- Fewer new outbreaks of bTB in herds locally due to a badger source.

The effects of the program on bTB levels overall in cattle.

Data presented previously at Table 1 outlines the declining rate at which new herd breakdowns are being detected. Additional data is presented in Table 5 which confirms these outcomes. The data in Table 5 outlines the results of tests that are carried out on cattle slaughtered at export plants annually. Under EU regulations, all carcasses must be examined and passed fit for human consumption. Among the evaluations carried out by Public Health personnel at meat plants, carcasses are examined for evidence of bTB and any tissues suspected of containing TB-like lesions (evidence of TB) are sent for laboratory confirmation. Since 2007, the rate of lesions confirmed at slaughter has fallen from 20.7 to 13.3 per 10.000 (0.207% to 0.133%), which is an improvement of 30%. This is evidence of a

Table5.

Year	Routine animals slaughtered (non-reactor)	Suspect Lesion submissions from routine animals slaughtered (non-reactor)	Submission Rate total lesions per 10,000 routine animals slaughtered	Lesions with TB confirmed	TB confirmed per 10,000 routine animals slaughtered	Suspect lesion due to other than TB	Suspect lesions other than TB per 10000 routine animals slaughtered
2007	1,744,717	6,234	35.7	3,613	20.7	2,621	15.0
2008	1,638,803	4,821	29.4	3,198	19.5	1,623	9.9
2009	1,584,435	5,652	35.7	2,947	18.6	2,705	**17.1**
2010	1,697,755	5,330	31.4	2,859	16.8	2,471	14.6
2011	1,624,728	4,553	28.0	2,161	13.3	2,392	14.7

reduced risk of intra-species infection with bTB in cattle, and is a further component leading to the lower rates of herd breakdowns due to bTB that have been described in Table1.

The data in Tables4 and 5 explains the respective the micro level components that are taking place in the national badger and cattle populations that are leading to the macro trends in incidence of bTB described in Chapter1 and in Table1 of the current chapter.

APPENDIX E – THE DISTRIBUTION OF *MYCOBACTERIUM BOVIS* INFECTION IN NATURALLY INFECTED BADGERS

By Corner LA, O'Meara D, Costello E, Lesellier S, Gormley E.

Source

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Abstract

Populations of Eurasian badgers (Meles meles) with tuberculosis (Mycobacterium bovis infection) are a significant reservoir of infection for cattle in Ireland and the United Kingdom. In this study the distribution of infection, histological lesions and gross lesions was determined in a sample of 132 culled badgers from naturally-infected wild populations. Badgers were culled when an epidemiological investigation following a tuberculosis breakdown in a cattle herd implicated badgers as the probable source of infection. The definition of tuberculosis infection was based on the isolation of M. bovis from tissues or clinical samples. An accurate diagnosis of infection was achieved by culturing a wide range of lymph nodes (LN) and organ tissues (mean 32.1) and clinical samples (faeces and urine) from each badger. Infection was detected in 57/132 badgers (43.2%). Histological lesions consistent with tuberculosis were seen in 39/57 (68.4%) culture-positive and 7/75 (9.3%) culture-negative animals. Gross lesions were seen in only 30/57 (52.6%) infected badgers, leaving a high proportion (47.4%) of infected animals with latent infection (no grossly visible lesions). The most frequently infected tissues were the lungs and axillary LN, followed by the deep cervical LN, parotid LN and tracheobronchial LN. The data support the hypotheses that in badgers there are only two significant routes of infection, namely, the lower respiratory tract and bite wounds, and that badgers are very susceptible to infection but resistant to the development and progression of the disease. At all levels of disease severity, infection was found in widely dispersed anatomical locations suggesting that there is early dissemination of infection in the period preceding the development of active immunity.

Link

http://www.ncbi.nlm.nih.gov/pubmed/22542391

APPENDIX F – THE PREVALENCE AND DISTRIBUTION OF *MYCOBACTERIUM INFECTION* IN EUROPEAN BADGERS (MELES MELES) AS DETERMINED BY ENHANCED POST MORTEM EXAMINATION AND BACTERIOLOGICAL CULTURE

By Murphy D, Gormley E, Costello E, O'Meara D, Corner LA.

Source

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Abstract

The accurate diagnosis of Mycobacterium bovis infection in badgers is key to understanding the epidemiology of tuberculosis in this species and has significant implications for devising strategies to limit spread of the disease. In this study, badgers (n=215) in the Republic of Ireland were examined at post mortem and tissues were collected from a range of anatomical locations and pooled into groups for bacterial culture of M. bovis. By assessing confirmed gross visible lesions (VL) alone, infection was detected in 12.1% of badgers. However, by including the results of all culture positive pooled samples, the overall infection prevalence increased significantly to 36.3%. Two-thirds (66.7%) of infected animals had no visible lesions (NVL). While the thoracic cavity (lungs and pulmonary lymph nodes) was found to be the most common site of infection, in a proportion of animals infection was absent from the lungs and draining lymph nodes and was confined to the lymph nodes of the carcase or the head. This may indicate an early extrapulmonary dissemination of infection or alternatively, in the case of the head lymph nodes, a secondary pathogenic pathway involving the lymphoid tissues of the upper respiratory tract (URT).

Link:

http://www.ncbi.nlm.nih.gov/pubmed/19545882

APPENDIX G - CONTROL OF TUBERCULOSIS IN BADGERS BY VACCINATION

Vaccination as a control strategy

Since tuberculous badgers were first identified over 30 years ago, badger culling has been undertaken in Ireland in an attempt to limit transmission to cattle. Both selective and non-selective culling strategies have been used; the primary goal of culling is to decrease the size of the badger population in order to reduce the risk of transmission to cattle. When sustained over large areas, non-selective removal of badgers leads to a significant reduction in the incidence of tuberculosis in associated cattle populations (Donnelly et al., 2006; Donnelly et al., 2007; Griffin et al., 2005). The aim of selective culling is to remove the most heavily infected animals or social groups in the population in response to severe breakdowns in cattle and this strategy has been shown to decrease the risk of TB transmission to cattle (Olea-Popelka et al., 2009).

However, recognizing that the badger is a protected species under national and international law, an alternative strategy to culling currently being explored is the development of a tuberculosis vaccine for badgers (Gormley and Collins, 2000). Vaccination is a pragmatic approach to combating the disease in wildlife as it provides a non-destructive method of controlling disease: vaccination may also prove effective for controlling tuberculosis in cattle. The aim of vaccination is to reduce the prevalence of infection in the badger population or to change the expression of the disease and lower the risk of transmission. Therefore, successful vaccination can be defined as either prevention of infection or decreased severity of disease with a resultant decrease in excretion and a lower risk of transmission. An injectable BCG vaccine has been granted a license for use in the UK and a field trial of this vaccine demonstrated that the vaccine reduced the number of *M. bovis* sero-positive badgers by 74%, compared with non-vaccinated badgers (Chambers et al., 2011).

Current badger vaccine research in Ireland

A 15-year work program was established by DAMF in 1998 to develop and adapt the BCG vaccine to protect badgers against tuberculosis and provide scientific support for the incorporation of vaccination into the Irish national tuberculosis control and eradication program. The program has been designed to follow a logical sequence of studies using captive badgers in a purpose built facility, complemented by studies of badgers in their natural environment. In studies with captive badgers we have found that the BCG vaccine (the vaccine used to control Tb in humans) can generate protection against tuberculosis when delivered by a number of routes including the oral route. However, whereas captive badger studies are the most cost effective way of examining various aspects of the immune response and the induction of a protective response by vaccination, such studies cannot show that BCG vaccine will be protective in free-ranging badgers or provide a estimate of vaccine efficacy. This can only be determined in a field trial. Any field trial will, by necessity, use an oral delivery system as that is likely to be the method of choice for any broad scale application of vaccine.

Co Kilkenny vaccine field trial

A 3-year long oral vaccine field trial in badgers is currently underway and nearing completion in Co Kilkenny with the aim of demonstrating that the protection observed in captive badger studies also occurs in wild badgers under conditions of natural *M. bovis* transmission, and to measure vaccine efficacy (Corner et al., 2009). In the Field Trial, badgers are being vaccinated with the BCG-Danish vaccine encapsulated in a semi-solid matrix that has been prepared specifically for this purpose by a collaborating laboratory in New Zealand. The trial is also providing a practical base for understanding the logistics of oral delivery to wild badger populations. In choosing a site to conduct the study, the Kilkenny area designated for the trial fulfilled the required criteria for the vaccine study area. The prevalence of tuberculosis in the badger population in the area was predicted to be ~30% (established through historical records obtained from badger culling data within or adjacent to the chosen field site). All the setts have been identified and the area has been surveyed to establish that the required population (300 badgers initial population) is present.

The trial area has been divided into three zones (matched initially by number of main setts, herd size and terrain) each with a different level of vaccine coverage. In Zone 1, 100% of captured badgers have received vaccine. In Zone 2 there has been 50:50 sequential coverage with vaccine or placebo when the

captured badgers were being processed. In Zone 3, 100% of captured animals have received placebo. The overall vaccine coverage is 50% in the trial area. In the trial badgers have been "hand vaccinated", that is, each animal individually orally dosed with the vaccine. This has ensured that there is an accurate record of which badgers are vaccinated, when they were vaccinated and ensure that there is no environmental contamination with live BCG. Vaccine and placebo control samples are 'double-blind' coded and field staff are unaware of the vaccine status of individual animals.

Throughout the trial, estimates of changing incidence have been made from the measurements of individual immune responses. At the end of the study the area will be depopulated and all badgers examined for tuberculosis by culture. The vaccine efficacy will be estimated from a comparison of the number of infected badgers in the vaccinated group with the non-vaccinated control group (Aznar et al., 2011). It is anticipated that the preliminary results from the field trial will be available in early 2013.

Vaccination of badger populations in Ireland

With badger vaccine field trials underway, attention is now focusing on the types of vaccination strategies that might be implemented in a vaccine program. There are a number of development options available. Considering the cost and long lead time of research, and the ongoing cost of the disease to the cattle industry in Ireland, a tempting option might be to take the encouraging results of captive badger studies and simply deploy the vaccine over large areas in the hope that it is effective. However, such ill-conceived use of the vaccine could lead to erroneous conclusions, the most likely being the false conclusion that the vaccine is ineffective.

The key goal of population vaccination is to reach and maintain the threshold for herd immunity i.e., as the immune proportion of the population increases through vaccination, a positive effect is conferred on the non-vaccinated portion, resulting in a decrease in the overall disease risk. Achieving herd immunity will directly impact on the transmission risk to vaccinated individuals within the population but will also have an indirect effect on the non-vaccinated susceptible proportion of the targeted population by decreasing infection pressure. The vaccine will only be protective against new infections and will have no therapeutic effect in badgers already infected. Some vaccinates may develop disease due to overwhelming challenge and the frequency of this will decline as the overall prevalence declines. The generation and maintenance of herd immunity will occur through the accumulation of protected individuals above a threshold level. When this threshold is reached and maintained, the disease will eventually disappear from the population. The accumulation of immune individuals will be achieved by continued revaccination of the population and the increased survival of vaccinated over non-vaccinated badgers, and the slow decline in the number of tuberculous badgers through diseased induced mortality and deaths due to other causes.

Strategic options for vaccine delivery

No single vaccination strategy will be suitable to control infection in all populations of badgers and a number of different options will need to be considered to optimize the chances of vaccine success. For example, the objectives for vaccination in high prevalence areas will be to reduce prevalence of disease and this differs somewhat from low prevalence areas where the objective will be to prevent infection of the population or its elimination.

Which badgers to vaccinate?

Many infected badgers live long lives and infected sows may reproduce successfully (Cheeseman et al., 1989; Gallagher and Clifton-Hadley, 2000). The risk of infection within the badger population appears to be equal for all age groups with no specific age associated risk (Murphy et al., 2010). Therefore, as badgers age they accumulate a risk of becoming infected. Therefore, in the context of vaccination it will be necessary to target all age classes of susceptible animals.

Where to vaccinate?

The time required for vaccination to exert an impact on a population of badgers where infection exists will be fastest where the incidence and prevalence of disease is low. In these areas the transmission rates will be relatively low and herd immunity can be generated in a shorter time period compared with high prevalence areas. In these latter areas where the transmission rates are high, it will

be imperative to maintain vaccination of a higher proportion of the susceptible population to generate herd immunity.

When and for how long to vaccinate?

The two key components that influence the optimal timing of vaccination are the duration of immunity afforded by BCG and the rationale underpinning a schedule for vaccination. The BCG vaccine has been delivered to humans throughout the world for at least 80 years and studies suggest that protection is maintained for at least 15 years (Weir et al., 2008). However, in wild animal populations the schedule of vaccination is likely to have a greater impact on population immunity than the duration of BCG protection. Badger cubs are born in early spring, and it would be desirable to vaccinate them as young as possible. A schedule of at least annual revaccination of the population may be necessary if disease eradication is the desired endpoint. An annual schedule of vaccine delivery will also facilitate vaccination of immigrants from non-vaccinated populations and animals that may have been missed in previous rounds of vaccination.

Time frame for vaccination to control tuberculosis in badgers

If eradication of the disease in the targeted population is the objective of the program, uniform vaccination of the entire population, or a significant proportion of it, will need to continue until the last infected badger is removed from the population. The vaccine effect will be seen as a gradual decrease in the number of diseased animals in that population. There will be infected individuals that have a very long lifespan, living with tuberculosis for many years. It is these animals that will determine the length of time that vaccination must continue. Continued vaccination of badgers over large geographic areas for 15-20 years would be a conservative estimate for the time required to reduce the incidence of tuberculosis in badgers to the extent that eradication was a realistic end-point. However, a combination of strategies that includes a targeted culling component of badgers in response to cattle breakdowns, predicated on the knowledge that infected cattle are sentinels for high Tb prevalence in associated badger populations (Murphy et al., 2011), could significantly shorten this time frame.*The impact of badger vaccination on cattle*

The effects of badger vaccination will be detectable first in the badger population; however, it will take many years of repeated vaccination before the disease declines in the badgers. It is unclear at present what constitutes the best measure for determining a positive effect of badger vaccination on tuberculosis in cattle. A decline in herd breakdown incidence might provide an initial useful measure. In Ireland, during the 5-year period of badger removal in the Four Area Project (FAP), the odds and hazard ratios of a confirmed restriction in the removal areas were significantly lower than in matched reference areas (Griffin et al., 2005). To achieve the same reduction level with vaccination, the areas would need to be at least the same size as those in the FAP. However, because the decline in the disease prevalence in badgers will be slow, even with repeated vaccination, the corresponding decline in herd breakdowns will also be gradual. In other words, it may take many additional years to observe the same reduction in herd breakdown incidence resulting from vaccination when compared with culling. Given our knowledge of disease transmission rates in badgers and vaccine efficacy, it is likely that a minimum period of 5 years of continued vaccination of badgers over large geographic areas would be required to significantly impact on the prevalence of Tb infected cattle in those areas.

Conclusions

In spite of the recent advances made in developing a vaccine for use in badgers, considerable challenges remain prior to full implementation of a vaccination programme, whether it is based on oral or parenteral delivery. Not least is the development of efficient vaccine baiting systems to achieve high vaccine coverage in targeted populations. The environmental impact and effects of the vaccine on non-target species also will need to be determined. In making decisions on the appropriate strategies to employ and the method of vaccine delivery, the desired outcome needs to be carefully considered. If the aim of the vaccination is to eradicate the disease from badgers then it will only be necessary to vaccinate for a finite period of time, until the last infected animal is removed from the population. If the primary aim of the vaccination is to lower the herd prevalence in cattle, without achieving eradication in badgers, then vaccination will need to be continued indefinitely. In addition, the vaccination program will need to be carried out against the background of exhaustive investigation of

tuberculosis in cattle, animal husbandry methods, and herd management–related factors that may affect cattle-to-cattle and badger-to-cattle transmission. Nevertheless, by removing the influence of the reservoir host, an effective badger vaccination program could help improve the efficiency of the tuberculin testing programme for controlling cattle-to-cattle spread and would also address a major impediment to the eradication of bovine tuberculosis in Ireland.

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APPENDIX H - TRIAL DESIGN TO MEASURE THE EFFECT OF ORAL VACCINATION

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Abstract

The principal wildlife reservoir *Mycobacterium bovis* in Ireland is European badger. Studies in the Republic of Ireland (RoI) have shown that badgers culled in association with cattle herd breakdowns (focal culling) have a higher prevalence of infection than the badger population at large. This observation is used as the justification for the medium term national strategy of focal badger culling. A vaccination strategy for the control of Tb in badgers is a preferred option. The BCG vaccine has been shown to induce protection in captive badgers. Although you can test vaccines in a control environment with precise information on infection pressure, it would be controversial to assume that similar effects of the vaccination would be seen in the wild where other environmental and or ecological factors could affect the results. For this reason a vaccine field trial to assess the impact of vaccination on the incidence of tuberculosis in a wild badger population has been designed as part of a ten year project to control and eradicate tuberculosis in cattle in Ireland.

The selected study area for the vaccine trial (approximately 755 square kilometers) was divided into three zones each of which has similar characteristics in terms of size,number of main badger setts, cattle herds, cattle and land classification type. Three different vaccination levels (100%, 50% and 0%) will be randomly allocated to the three zones in a way that a gradient of vaccination coverage North to South is achieved. Therefore the medium zone (Zone B) will be vaccinated at a 50% coverage but Zone A and C will be randomly allocated with 100% or 0% vaccination coverage. Vaccination within Zone B will also be done randomly. Badgers will be captured, vaccinated with a lipid-formulated oral BCG vaccine or a placebo depending on the allocated treatment and then released. Each time badgers are captured during a round of trapping they will be examined and a blood sample collected. Humoral assays will be conducted on serum. Four years later at the end of the study, the area will be depopulated and all captured badgers will be subjected to detailed post mortem examination, histology and bacterial culture.

The objective of this paper is to describe the trial design, epidemiological methods that helped to mount the vaccine trial and the subsequent data analysis. The analysis will enable evaluation of the effect of vaccination on disease transmission under field conditions. It will also aim to quantify the magnitude of the observed effect and to improve our knowledge on the biological effects of the vaccination on susceptibility and infectiousness of the badgers in the trial.

Introduction

Ireland initiated an eradication program for bovine tuberculosis (bTB) as early as 1950 (More and Good, 2006). The adopted test-slaughter policy achieved reduction in cattle tuberculosis prevalence by 97%, going from 17% to 0.5% prevalence in the initial ten years (Watchorn, 1965). Subsequently to that initial drop, tuberculosis prevalence in Ireland has remained the same despite the introduction of other measures aimed at reducing cattle to cattle transmission (Griffin and Dolan, 1995).

It was in the 1970's in England that badgers were first suspected to be a reservoir for Mycobacterium bovis (Krebs, 1997). The first infected badger was discovered in Ireland in 1974 (Noonan et al., 1975). Since then numerous papers have been published in Ireland and England that confirm badgers as the main M bovis reservoir in these countries (Barrow and Gallagher, 1981; Cheeseman et al., 1981; Fagan, 1993; Gallagher et al., 1998). A recent study carried out in Ireland detected a prevalence of 36.3% in badgers trapped as part of DAFF culling operations; the prevalence observed here was much higher than in previous studies where less comprehensive bacteriological culture examination had been used (Murphy et al., 2009).

The precise role of badgers in the maintenance of bTB is not completely clear. Different epidemiological studies in Ireland have linked badger removal with a subsequent reduction in bTB incidence (Eves, 1999; Griffin et al., 2005; More and Good, 2006). However, in a field study carried out in Britain, the reduction in cattle TB incidence in culled areas was only modest and an increase in TB incidence was observed in non culled neighboring areas (Woodroffe et al., 2007). Furthermore, Pope et al., (2007) concluded that the increased prevalence observed in neighboring areas was associated to medium and long-distance badger dispersal and emphasized the importance of taking into account the potential negative effects associated to badger dispersal when using culling as a disease control strategy. Although there are discrepancies between different studies about the efficiency of badger culling in the control of cattle TB, they all provide compelling evidence that badgers play an important role in the maintenance of bTB. Therefore, addressing infection in badgers is considered vital when trying to control bovine tuberculosis in the aforementioned countries. The fact that badger culling is not a viable long-term strategy for TB control has led different governments to look for alternatives to control bovine tuberculosis.

In 2001 a 10 year work program was designed in Ireland to study the possibility of using Bacillus Calmette-Guerin (BCG) vaccine in badgers to help in the control and eradication of bTB in cattle. The program consisted of a sequence of studies carried out initially in a purpose built facility and subsequently in the field, that would provide scientific support for the use of the vaccine as a TB control strategy in badgers(Corner et al., 2007; Lesellier et al., 2009). Although you can test vaccines in a control environment with precise information on infection pressure, it would be controversial to assume that similar effects of the vaccination program would be seen in the wild where other environmental and or ecological factors could affect the results. For this reason a vaccine field trial to assess the impact of vaccination on the incidence of tuberculosis in a wild badger population has been designed as part of the ten year project.

The objective of this paper is to describe the trial design, epidemiological methods that helped to mount the vaccine trial and the subsequent data analysis. The analysis will enable evaluation of the effect of vaccination on disease transmission under field conditions. It will also aim to quantify the magnitude of the observed effect and to improve our knowledge on the biological effects of the vaccination on susceptibility and infectiousness of badgers in the trial.

Theoretical basis: a review

Initial considerations to design a vaccine trial

Specifying clear question(s) of interest is essential when designing a trial to evaluate the effects of vaccination. Different vaccination programs have different aims; the question of interest could vary from how good vaccination is at protecting the individual against infection to what reduction in infectiousness can be achieved by vaccination among others. The effect of interest is going to determine the study unit, parameters of effect as well as the level of information required (Halloran et al., 1997). The main question of interest in our study was to determine how efficient badger vaccination is at reducing M bovis transmission.

Vaccines that are successful at reducing disease transmission in a population will have a beneficial effect in vaccinated as well as in unvaccinated individuals and these effects can be quite different. The effects of a vaccination program in the unvaccinated individuals are normally referred to as "indirect effects" while the term "total effect" is used to refer to the direct (due to individual protection) and indirect effects (due to population-level-effects) observed in the vaccinated group (Halloran et al., 1999). To gain a better understanding of the way BCG vaccine works, we defined two

more secondary questions of interest in our study: how much of the vaccine effect in vaccinated badgers was due to protection of the vaccinated individual (Vaccine Efficacy for Susceptibility, VE_S) and how much was the total effect of the vaccination program (Vaccine Efficacy for Infectiousness, VE_I).

Parameters of effect

The transmission parameter between vaccinated and unvaccinated badgers in its four different forms: transmission from a vaccinated to a vaccinated badger (β_{VV}), from a vaccinated to an unvaccinated badger (β_{VU}) and from an unvaccinated to a vaccinated (β_{UV}) and an unvaccinated badger (β_{UU}) were defined as the basic parameters of interest. These four parameters will allow us to assess the three previously defined questions of interest by calculating the Basic Reproduction Number (R_0), VE_S and VE_I.

The average number of secondary cases caused by one typically infected individual in a fully susceptible population (Diekmann and Heesterbeek 2000) is called the Basic Reproduction Number (R_0). R_0 is determined by the transmission rates between vaccinated and unvaccinated badgers and the time infected badgers remain infectious. Transmission rates are a combination of the infectiousness of the donor and the susceptibility of the recipient individuals; since vaccination with BCG has the potential to affect both, R_0 will be an important parameter for understanding the impact of badger vaccination in disease transmission and population dynamics of M Bovis. The vaccine badger trial was designed to estimate R_0 as a function of the fraction of the vaccination coverage for a given VE_S and VE_I.

Vaccine efficacy/effectiveness has been traditionally defined as 1 minus some measure of relative risk (RR) of the vaccinated group compared to the non vaccinated group (Halloran et al., 1999). In the past, the main objective of vaccine studies was to measure individual protection against infection or disease (vaccine efficacy for susceptibility, VE_S). Although not that much appreciated in the past but equally important is the ability of a vaccine to reduce the duration or severity of the infectiousness of vaccinates who become infected or Vaccine Efficacy for Infectiousness (VE_I) (Longini et al., 1998). The latter effect has been recently observed when vaccinating badgers using BCG vaccine by the subcutaneous or mucosal routes (Corner et al., 2008). In the experiment, M. bovis was recovered from both vaccinated and non vaccinated badgers after being challenged with the mycobacterium. A reduction of the size, number and distribution of the gross and histological lesions in vaccinated badgers compared to non vaccinated badgers was demonstrated. Vaccination was not seen to confer individual protection against infection in the mentioned study, but this has to be cautiously interpreted as vaccine protection could be dependent on the infection dose and is not known what the infectious dose is in natural infections. Estimation of VE_S and VE_I will give us a deep understanding of the biological ways BCG vaccine works in a wild badger population.

Information required and selection of trial design

Information on which badgers are infected and when they become infected is necessary to estimate the four β parameters. The vaccination status of the badgers and disease incidence data would also be required.

Indirect effects in unvaccinated individuals are not desirable and should be minimized when the question of interest is to assess the ability of a vaccine to protect the individual; that is why indirect effects tend to be associated with negative effects. Although, when the main effect of interest is to assess the use of vaccination in reducing disease transmission in a population, both indirect and direct effects are of interest. Longini et al., 1998 demonstrated that when individual contact information is not available, VE_S and VE_I can be estimated if a trial is conducted in at least two populations vaccinated at different coverage levels. The badger vaccine trial was designed to achieve a North-South gradient in vaccination coverage. Because transmission rates for individual badgers depend on the badger surroundings a model was built to correct for differences between the three vaccination zones.

Epidemiological contribution to the design of the vaccine trial

Study site

Prior deciding on study site for the badger vaccine trial, different epidemiological and logistic factors were considered:

- Because of the actual badger culling pollicy in Ireland, it was important to assure that the area selected for the vaccine trial had been protected from proactive culling for some time before the commencement of the trial. Proactive badger culling in that area would have had a negative effect not just in the total number of individuals captured but also in the initial prevalence.
- Knowledge of the area in terms of setts location was considered an advantage.
- Support from the local farming community as well as from from both the Divisional Veterinary Offices (DVO) and the Reference Veterinary Laboratories (RVL) was vital.

The area finally selected for the vaccine trial was located in County Kilkenny. The size of the area is approximately 755 square kilometers. This area had been part of one of the reference areas in the Four Area Project (FAP) (Griffin et al., 2005) and it will have been protected from proactive culling for at least two years by the time the vaccine trial starts. A prevalence of infection of 30% was expected based on historical data referring to neighbouring areas (removal area in the FAP). Some of the badgers setts in the study site had been also previously identified. Local farmers had been part of a previous study and they were known to be cooperative. The same applied to DVO's and the Reference Veterinary Laboratory.

Study design

Based on the objectives mentioned previously the area selected was divided into three zones with similar characteristics in terms of size, number of main badger setts, cattle herds, cattle and land classification (Figure 2). The aim was to achieve similar infection pressure from cattle and badgers in the three zones. Natural boundaries such as rivers or cities were used when possible as part of the perimeter of the study area or as a separation between the three zones.

Badgers will be captured, vaccinated with a vaccine or a placebo depending on the allocated treatment and then released. Live M. bovis BCG strain Danish will be used. It will be prepared in a lipid formulation for oral delivery. The vaccine will contain 10^8 colony forming units/ml. A lipid only placebo with identical visual characteristics, texture and viscosity to the vaccine, and in identical syringes, will also be used. Vaccine and placebo control samples will be coded at the laboratory where they are processed and neither field staff nor data analist will be aware of the vaccine status of individual animals.

The study will employ a cature-tag-release regime with both cages and stopped wire restraints being used. Badgers in the trial will be "hand vaccinated", that is, each animal will be individually orally dosed with the vaccine. Each badger will be permanently identified with a tattoo and passive transponder (microchip) when first captured. Each time badgers are captured during a round of trapping they will be examined and a blood sample collected. Humoral immune responses will be used to determine the badger's infection status and to detect a change in infection status, that is, to detect both pre-existing infection in badgers as they are recruited to the study and new infections on recapture. Humoral assays will be conducted on serum. Information on the badgers' sex, estimated age (cub, juvenile, and yearling, adult and old adult), body weight, presence of injuries and the GPS location of the cage trap or restraint will be recorded every time badgers are trapped. All data collected in the field will be recorded onto handheld computers. The trial will last four years and there will be two sweeps of the entire area each year. At the end of the study the whole area will be depopulated. A detailed post mortem examination will be conducted on all dead badgers, involving an examination for gross pathology and the collection of samples for histopathology and bacteriology. The severity of infection will also be assessed from the number, distribution and the severity of gross lesions, the number and distribution of histological lesions, and the number and distribution of culture positive tissues and the bacterial load in those tissues.

Where herd breakdowns occur in the trial area prior to, or during the trial, the criteria set out for application for licences to cull badgers in the vicinity of breakdowns will be similar to that that used for the FAP, except that only 3 standard reactors will be required. If culling is required for control of tuberculosis in cattle herds, the culling will be carried out by the dedicated field staff of the project when they next trap in the designated area.

Analysis of the vaccine trial data

General description

The data generated from the vaccine trial will be of the form of a Bernoulli experiment. Badgers' infectious status will be recorded, allocating 1 or 0 depending on whether the badger is infected or not respectively. Infection in this case will be defined by serology results. Records on individual badgers will be taken every time they are trapped (not necessarily at each trapping exercise) such as location of the badgers at the time of the trapping (Zone A, B or C) and vaccination status. Other demographic data will be also recorded.

Some new variables will be calculated from the original data and the final dataset will consist of records containing data observed between each subsequent trapping of each individual badger. Some of the variables will be;

- Time interval or length of time between the two catches (Δt)
- Disease status of the badger at the beginning and at the end of the time interval
- Vaccination status of the badger
- Zone where the animal was observed at the beginning and end of the time interval (A, B or C)
- Prevalence of infection in the area where the badger has been observed during the time interval (PrevA, PrevB, PrevC)
- Fraction of infected badgers that are vaccinated in the zone where the badger has been observed during the time interval (Fv_A, Fv_B, Fv_C)

The rate at which vaccinated/non vaccinated badgers acquire infection from vaccinated and not vaccinated badgers can be estimated based on the observed probability of becoming infected for each of these individuals (β_{VV}, β_{VU}, β_{UV}, β_{UU}). For example, β_{UV} will be the rate at which a vaccinated badger acquires infection from a non vaccinated badger.

The estimated β parameters will be used to calculate VE_S, VE_I and R_0 as a function of the vaccination coverage.

Estimation of the β parameters

If we ignore at this stage the vaccination state of the animals a stochastic susceptible-infectious (SI) model can be used to describe the transmission of M Bovis in the trial by which infectious contacts can occur if infectious and susceptible individuals are present. The number of infectious contacts encounter by a randomly chosen individual in a period of time Δt follows then a Poisson distribution with parameter: $(\beta I/N)\,\Delta t$.

Where:

β= Infection parameter

Δt= Time interval

I= Number of infectious individuals

N= Total number of individuals

I/N=prevalence of infected badgers

From the above it can be derived that the probability of a susceptible animal escaping infection in a period of time Δt is $e^{-\beta I\,\Delta t\,/N}$, and therefore the probability of at least one event occurring in that time will be defined as:

$$1- e^{- \beta I \Delta t /N}$$

The observed infectious status of an individual badger at the end of the time interval between two catches (C) can be modeled using a binomial distribution where S is the number of susceptible badgers at the beginning of the time interval (0 or 1 depending on whether the badger is already infected or not respectively) and the probability of this badger to become infected during that time interval is defined by $1- e^{- \beta I \Delta t /N}$

$$C= S (1- e^{- \beta I \Delta t /N})$$

Based on serology we will be able to determine the infectious status of the individual badgers (C), and by using a Generalized Linear Model (GLM) with a complementary-log-log link function, a binomial error function and offset log(I/N*Δt) the infection parameter β can be calculated.

Because of the introduction of the vaccination process there is going to be some heterogeneity in terms of infectivity and susceptibility of the badgers. What has been explained above still applies when using vaccination but in this case four different infection parameters rather than one can be estimated from the observed data: β_{VV}, β_{VU}, β_{UV} and $\beta_{UU.}$ The sub-indexes V and U stand for vaccinated and non vaccinated respectively. The first sub index will refer to the vaccination state of the badger from which infection is coming from and the second sub index to the vaccination state of the susceptible animal that has been in contact with the first. Therefore β_{UV} will be the infection parameter that will describe the rate at which a vaccinated badger will acquire infection from a non vaccinated badger.

Lets assume that a badger that was originally trapped in Zone A at time t is trapped again in Zone A at time t+1 and that this badger had been vaccinated at time t. Vaccination coverage in Zone A will aim to be 100% although not all badgers are going to be trapped in each trapping exercise. This hypothetical badger will then have infection pressure coming from vaccinated and non-vaccinated infected badgers. The number of infectious contacts encounter by this randomly selected badger in that period of time will be defined by:

$$(\beta_{VV} I_V/N + \beta_{UV} I_U/N) \Delta t$$

If we assume that there is a multiplicative effect seeing as the fraction of infected vaccinated badgers increases, and after doing some algebraic manipulations:

$$Exp [\beta_{VV} F_{VA} + \beta_{UV} (1-F_{VA})] PrevA \Delta t$$

or:

$$Exp [\beta_{UV} + (\beta_{VV} -\beta_{UV}) F_{VA}] PrevA \Delta t$$

where F_{VA} is the fraction of infected badgers that are vaccinated in Zone A and PrevA is the prevalence of infection in Zone A.

If we make $\beta_{UV} = K_0$ and $(\beta_{VV} -\beta_{UV}) = K_1$ then we can write:

$$C_V = S (1- e^{-Exp [K_0+K_1 F_{VA}] PrevA \Delta t})$$

As we know the observed infectious status of that specific badger (C_V) at the end of the time interval (Δt), we can fit a GLM with Log (PrevA Δt) as an offset and calculate K_0 and K_1. We can subsequently calculate β_{UV} and β_{VV} as:

$\beta_{UV} = Exp[K_0]$

$\beta_{VV} = Exp[K_0+K_1]$

If we apply the same logic to model the observed infectious status of an unvaccinated badger (C_U) that was trapped in zone A at time t and at time t+1, we could estimate β_{UU} and β_{VU} as:

$$C_U = S (1- e^{-Exp [k_0+k_1 F_{VA}] PrevA \Delta t})$$

Being $\beta_{UU} = Exp[k_0]$ and $\beta_{VU} = Exp[k_0 + k_1]$

These calculations will apply to all three zones but in zone C there will be no vaccinated badgers so F_{VC} will be zero and that zone does not contribute to the estimation of k_1 and thus that area does not give information for β_{VU}.

Vaccine Efficacy for susceptibility can be calculated then as:

$$\mathbf{VE_S = 1- \beta_{UV} / \beta_{UU}}$$

We can also calculate Vaccine Efficacy for infectiousness as:

$$\mathbf{VE_i = 1- \beta_{VU} / \beta_{UU}}$$

Finally we estimate $R_0(f)$ where f is the fraction of vaccinated as:

$$\mathbf{R_0(f)=f\ \beta_{VV}\ T+ (1-f)\ \beta_{UU}T}$$

where T is the duration of the ´infectious" period of a typical infected individual.

If $\beta_{UU}T < 1$ no vaccination is needed and when $\beta_{VV}T > 1$ vaccination does not help. Otherwise the vaccination fraction necessary in order to achieve $R_0(f) < 1$ can be calculated.

Discussion

Vaccine feasibility studies are design to help to prepare for vaccine trials by using a wide range of epidemiological methodologies. Their aim is to answer questions that could vary from identifying the most cost-effective way to select high risk individuals, to estimate the incidence of infection in the recruited volunteers amongst other questions. Although feasibility studies are quite common in human vaccine field trials, it is not that easy to find them in the clinical trial literature (Suligoi et al., 2004). When it comes to the veterinary field the literature is virtually non existent. With this in mind, the aim of this paper was to discuss the theory applied when designing the badger vaccine trial as well as the epidemiological methodology and statistical analysis that will help to interpret the results obtained. The independent review of the paper will also assure that possible caveats on the design and/or analysis will be dealt with prior to the start of the vaccination program.

Defining specific questions of interest in the early stages of the vaccine trial was considered crucial. Estimation of the Basic Reproduction Number (R_0) calculated as a function of the vaccination coverage will give us invaluable information on the impact of vaccination in disease transmission and dynamics of M Bovis in badgers. Although the vaccine trial will not be able to answer whether bovine TB can be addressed by using vaccination in badgers, a mathematical model of bTB transmission that describes the disease in cattle and badgers in the Republic of Ireland is currently under development and the parameters obtained in the vaccine trial will be used to assess different control and eradication options in cattle.

The importance of considering the potential indirect effects associated with the vaccination program in badgers has been highlighted in the paper; furthermore it has been shown how to estimate VE_S and VE_I by using different vaccination coverage in the study area. The area was divided into three zones A, B and C, such that differences in infection pressure in the three zones at the beginning of the trial were minimized. Although, there is an inherent assumption that the contact patterns between badgers will be similar in the three zones. We believe that this is a reasonable assumption as the size of the total area is sufficiently small and the landscape and distribution of setts is very similar in the three zones. Further changes on infection pressure in the three zones will occur as the vaccine starts working and so a model was designed as part of the analysis to correct for these changes.

When possible, natural boundaries were used to define the perimeter of the study area as well as the separations between the three zones. Some of the rivers used as part of the boundaries will provide an effective barrier in keeping badgers in or out of the study area, although it is also possible that some other boundaries such as roads could be trespassed. We believe the number of trespassers will be minimal based on badger's range and distance of outside setts from the actual area boundaries. For simplicity reasons the analysis shown in the paper only accounts for badgers that are trapped in the same zone as they were trapped previously, nonetheless the final model can be modified to accommodate other scenarios where badgers move from one zone to another.

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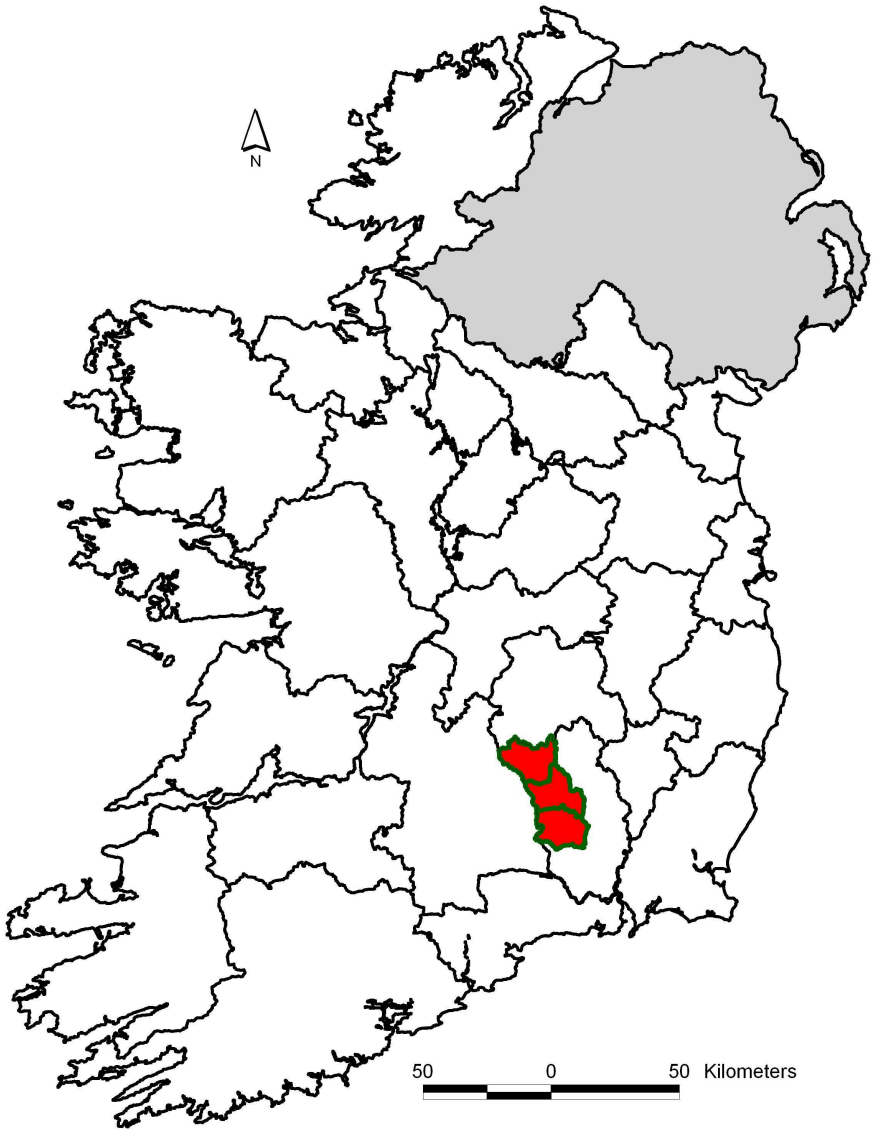

Figure 1. Study site selected for the vaccine trial showed in red colour

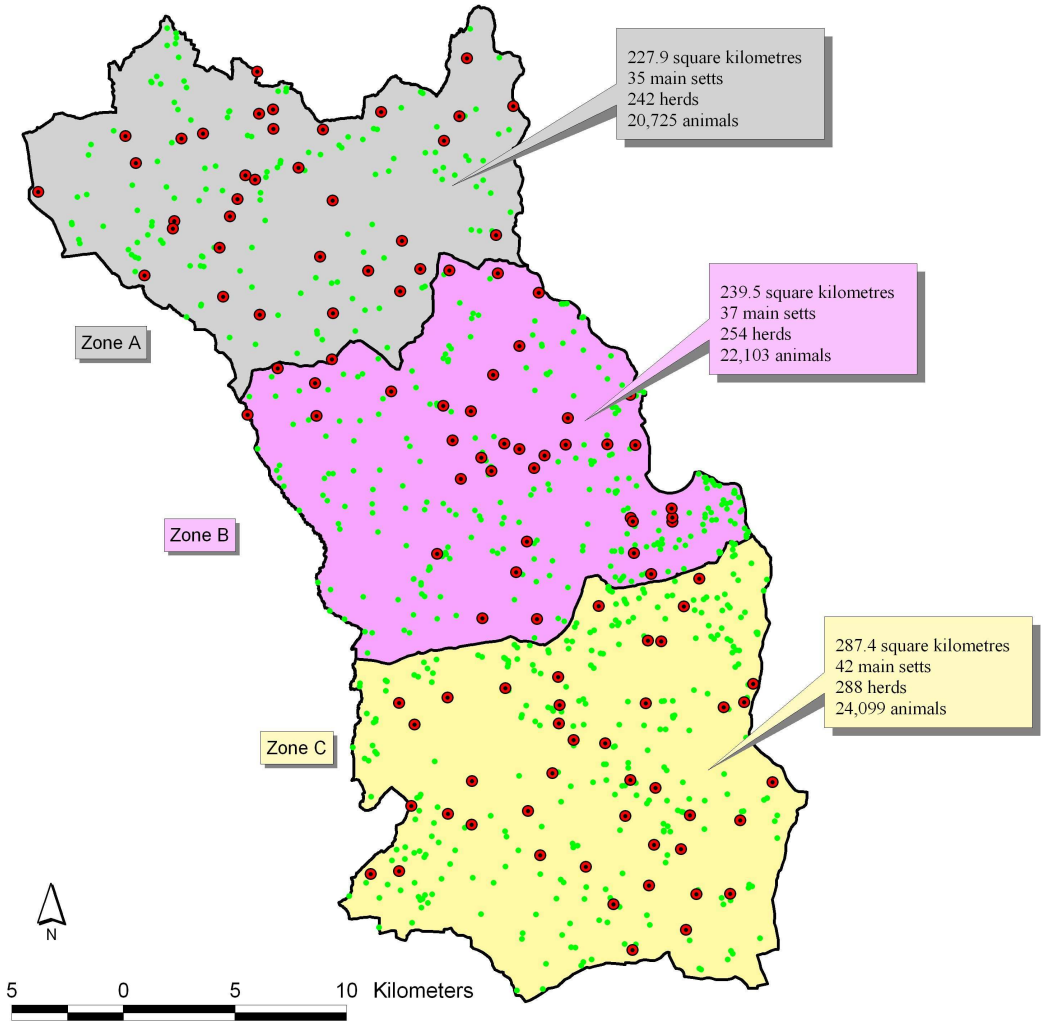

Figure 2. Map showing study area divided into three zones A, B and C (grey, pink and yellow respectively) where vaccination coverage will be of 100, 50 and 0%. Main badger setts are represented with red dots and green dots represent other sett types

APPENDIX I - PROPOSAL FOR A SERIES OF TRIALS IN WHICH INTRAMUSCULAR VACCINATION OF BADGERS WITH BCG ETC

Proposal for a series of field trials in which I/M vaccination of badgers with BCG in controlled populations will be compared with the current interim Wildlife strategy which is based on targeted reactive culling of badgers adjacent to herds identified with serious outbreaks of BTB that are likely due to sharing an environment with TB infected badgers and the subsequent maintanance culling used to keep badgers number low. This will provide for a direct comparison between a maintenance cull policy and maintenance vaccination policy and also allow for an operational assessment of direct capture and vaccinate procedures

Introduction.

Badgers are perhaps the ideal host species for M. bovis because their primitive immune system reacts in more benign way to becoming colonised than what occurs in bovines or humans. The ultimate eradication of TB in the Irish cattle population will remain a technical impossibility until either

(A) badger densities nationally are reduced below a threshold (probably in the range 0.4-0.8 badgers per sq. km) that is sufficiently low to prevent the maintenance of the disease in the badger population while concurrently the test and slaughter programme addresses the disease in the cattle population.

or

(B) vaccination of badgers with BCG reduces and ultimately eradicates the disease in badgers, and it's subsequent transfer to cattle, to a level that will allow the test and slaughter program in cattle to succeed.

Comparing I/M BCG vaccination with continued culling will require the following hypothesis to be tested in a series of field trials.

that vaccinating badgers with I/M BCG in place of ongoing maintenance culling in areas where culling has initially been applied for a minimum of 3 continuous years, results in levels of TB in adjacent cattle herds that are as low or lower than what is being achieved by DAFFs current Wildlife policy of reactively culling badgers in areas where BTB is suspected of being perpetuated by a locally infected badger population.

The trials will require to be undertaken on study sites where each treatment is applied over an area not less than 150 sq. Km. Sites must be selected so that from the perspective of badger culling, a similar regime has been in place for at least the previous 3 years.

A minimum of 6-paired sites (treatment/control) will be required for statistically significant result at the 95% level. If the difference between treatments turns out to be marginal, up to 12-paired sites may be required to achieve the required level of significance. If vaccination proves a sufficiently superior treatment to continued culling such that it could replace culling, one would expect to see clear evidence emerging in 3-5 years of commencement of the comparison.

The outcome variable of the trials will be the incidence of BTB in cattle herds compared between both sites. Local arrangements must be in place to ensure that BTB breakdown herds are managed and SICTT tests are interpreted uniformly between sites and areas where the trials are ongoing.

Criteria for site selection

For a site to be considered, a well established badger culling maintenance programme must be operating continuously for at least 3 years, and the programme must have lowered local densities in the areas under capture such that each new trapping effort results in the capture of inward migrants.

The most suitable sites that currently fill these criteria are (in order) Longford, Tipperary and Monaghan. The other three sites will be identified at a later time

Resources required for a generic site

Farm Relief Staff.

Commonly, DVO areas use either 2 or 3 FRS staff. Where there are 3, the trial will convert one FRS person to a vaccinate/release strategy, and leave the remaining 2 FRS staff on capture and remove. The FRS person on vaccination/release will still operate under the terms of the present DAFM/FRS contract, but would not work the Sat/Sun specified under the 12-day Work Block arrangements. The present contract specified 56 hours working hours over 12 days, whereas the FRS person delivering vaccine will be required to deliver the same 56 hours over 10 days. Were the trial to run at a DVO with 2 FRS staff, one will be converted to vaccination/release.

Veterinary resources

A vet will be required to be in attendance each of the mornings, Tuesday through Friday for on average 2 hours (10.00 – 12.00) for the purpose of administering anaesthetic and vaccine etc

Technical resources

The vaccinating FRS staff person will require supervision/support that will be different to that provided to FRS staff currently delivering the capturing program. At present, most DVOs supervise the FRS staff on a 2FRS:1TAO ratio with some running a 3:1 ratio.

The supervision/support provided to the "capturing/culling FRS" staff person by the TAO involves Day1 assistance laying restraints and Day 12 assistance lifting restraints. Random inspections may be scheduled during the interval between Days 1-12, at the discretion of the SVI/VI/DS.

The "vaccinating/release" FRS person will require TAO/SAO assistance Mon-Friday, for some part of every day. There will be no weekend duties. This will probably equate to roughly 50% of a TAO or SAO staff members time. Data capture will be via portable IT units, and these will be operated by DAFF staff, so the DAFF resource will be scheduled to work with the FRS person on each of the mornings, Tues to Friday.

Usables

Prior to vaccination, badgers will be captured, anaesthetised and tagged with an electronic tag/implant and tattooed.

Electronic tags cost circa €7 each and a **reader** is circa €200. The expected usage for Co. Monaghan is 60-80 badgers in year 1 and 30-40 additional new badgers to the population each subsequent year.

Vaccine circa €10 per badger vaccinated.

Hardware for paperless data recording circa and scanning electronic tags €6,000 per site.

Software for project will cost circa €4000 per site.

Anaesthetic, blood tubes, swabs gloves etc circa €10 per badger.

Analytical resources to evaluate the outcome of the trials. Data storage and management will be undertaken by Paul White, VI, Monaghan/CVERA. Operations manager will be James O'Keeffe and Scientific manager/study design will be Dr. Wayne Martin. These resources will be redirected and roughly cost neutral.

Estimated additional Total costs

The estimated additional costs of carrying out a vaccination/release program over and above a capture/culling program are:

FRS resources:	The vaccination release program will not involve any additional FRS costs.
DAFM Technical resources	0.5 of a SAO/TAOs time will be required, but this resource may be available from within staff numbers currently available within DAFF.
Field VI	0.3 of a VIs time will be required to anaesthetise, vaccinate and take samples from target badgers. This resource may be available from within existing DAFM resources.DAFM T/S An average TAO/SAO costs €6-8K per annum and the extra fieldwork that will accompany vaccination may add 25% to this cost. Pro rata additional costs will be incurred by the attending VI also. Thus the additional T&S cost per site will be in the order of € 5,000 per annum.
Hard/Software	Estimated to be in the region of €10K per site
Analytical costs	Messer's Martin, O'Keeffe and White are involved in ongoing analysis, so their involvement will not incur additional costs.
Badgers	Vaccination and release will result in some costs, previously outlined, as badgers will be tagged electronically, tattooed, vaccinated and samples. These costs totally will come to circa €30 per badger (Vaccine10+Tag7+Anaesthetic/sampling10) Savings will accrue in that captured badgers will be released and not culled, saving costs of transport to IEC, Kill, Co. Kildare and the costs of processes there. Currently, transport of badgers including processing costs at Kill run to €40 per badger. Overall the badger costs will be neutral or even possibly a small saving.

Total additional costs per site, will be in the region of €20K (€10K hardware/software, €5K additional T/S for DAFM staff and €5K sundries).

In Conclusion.

The first study site will be Co. Longford, where the operating protocols will be worked and thoroughly field-tested. When all the procedures have been satisfactorily worked out, the study will be expanded to include other sites (Monaghan and Tipperary initially, elsewhere thereafter).

An outcome to this research can be reasonably expected within 5 years of commencing the work. The outcome will be either the hypothesis is accepted or rejected.

The critical operational challenge will be to ensure that the programme management and test interpretation is completely uniform between herds in vaccine/release areas and herds in capture/removal areas. This will require that systems are in place that

- ensure testing standards are uniform
- ensure management of restricted herds is uniform
- ensure similar criteria are applied to deeming non-standard readings reactor

This can only be guaranteed by imposing a layer of management, beginning with a nominated VI(s) whose primary focus and specific remit is to ensure the necessary standardisation is in place, and is being implemented on a herd by herd basis and that protocols are in place that will result a transparent, accountable and effectively managed process. This will require the redeployment of VI resources within offices servicing the trial.

APPENDIX J – CALCULATION OF WILDLIFE ADMINISTRATION UNIT TREATED LAND AREAS, VETERINARY SCIENCES CENTRE OF UNIVERSITY COLLEGE DUBLIN

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Summary

The Centre for Veterinary Epidemiology and Risk Analysis (CVERA), University College Dublin (UCD), calculates the area of land under Wildlife Administration Unit (WAU) capture on a twice yearly basis. A Geographical Information System (GIS) is used to calculate the area under capture. All badger setts assigned for capture are buffered to a circular distance of 500 metres. Calculated areas are cumulative from the start of the program in 2004.

Introduction

The Centre for Veterinary Epidemiology and Risk Analysis (CVERA), University College Dublin (UCD), monitor applications for badger removals through the Department of Agriculture, Food and the Marine's (DAFM) tuberculosis eradication program. Agreements between the Department of the Environment, Community and Local Government's National Parks and Wildlife Service (NPWS) and DAFM state that an annual County-based badger removal licence be granted once certain operational guidelines are adhered to. Two of these guidelines are monitored by CVERA. These are:

- ensure that capturing at setts can only occur at distances of no more than 2 kilometres from the boundary of the eligible breakdown herd. In the case of setts classified as 'main setts', this distance is reduced to 1.5km, and
- calculate the cumulative area of land that is under capture every 6 months.

Methodology

Using data gathered during previous projects, a method of assigning an accurate and robust representation of area of under capture was formulated. Existing data recorded for the Four Area Project (Griffin *et al.*, 2005) and the East Offaly Project (Martin *et al.*, 1997 and Ó Máirtín *et al.*, 1998) contained the location and sett classification for approximately 6,500 setts (Figure 1). The locations of these study areas represent varying habitat types.

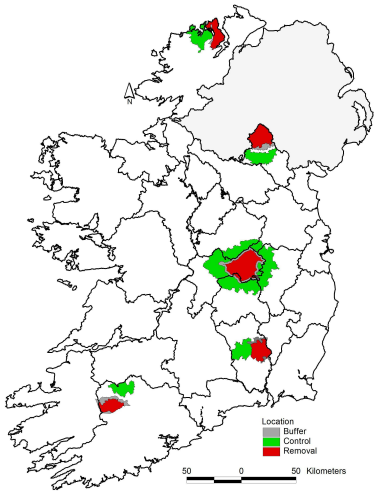

Figure 1. East Offaly and Four Area Badger Removal area locations.

Given the variation in landscape type and the number of setts available in this dataset, it was considered that calculating a mean distance between all main setts in each area would give a value indicative of what we would expect to find nationally. This validated observed distance between main setts would then form the basis for calculating areas under removal.

To calculate the mean distances, all setts within the removal and buffers areas of the study sites were subjected to a Nearest Neighbour analysis (figure 2).

The Average Nearest Neighbor ratio is given as:

$$ANN = \frac{\bar{D}_O}{\bar{D}_E} \quad (1)$$

where $\bar{D}_O$ is the observed mean distance between each feature and their nearest neighbor:

$$\bar{D}_O = \frac{\sum_{i=1}^{n} d_i}{n} \quad (2)$$

and $\bar{D}_E$ is the expected mean distance for the features given a random pattern:

$$\bar{D}_E = \frac{0.5}{\sqrt{n/A}} \quad (3)$$

In the previous equations, d_i equals the distance between feature i and its nearest feature, n corresponds to the total number of features and A is the total study area.

The z_{ANN}-score for the statistic is calculated as:

$$z_{ANN} = \frac{\bar{D}_O - \bar{D}_E}{SE} \quad (4)$$

where:

$$SE = \frac{0.26136}{\sqrt{n^2/A}} \quad (5)$$

Figure 2. Nearest neighbour ratio formula.

The nearest neighbourhood analysis (ArcGIS 10.0, ©ESRI, Redlands, California) calculates the observed mean distance between points. It also generates a ratio between this observed distance and the expected distance (assuming random point patterns) to give a score indicating if the point pattern is clustered, random or dispersed. When the study boundaries are used to refine the analysis it becomes evident that badger main setts are dispersed as far apart from one another as is possible based on geographical constraints. This is what we would expect to see in a territorial animal. The variation in nearest neighbour distances between the different areas is substantial and represents the carrying capacity of the land on badger population and distribution (results in Appendix II).

Generating a circle with a radius of half the distance of the average nearest neighbourhood value of main setts gives us an approximation of the territorial area of a social group. By averaging the nearest neighbourhood distances of main setts from all Four Area Project and East Offaly Project setts,

we achieve a crude estimate of the expected nearest neighbourhood distance nationally (917 metres). Halving this distance therefore gives us a justifiable radius to use as an estimate for calculating land treated for each sett assigned to a WAU capture block. Additional measures are used to ensure that this is a conservative means of calculating area;

- All setts assigned to an approved capture block are assumed to be under capture regardless of that block's capture status, that is, even if a sett has had no removals or restraints placed, it is still included in calculating area treated. As of January 2012, of 29,884 setts assigned for capture (and included in calculating area under capture) 11,986 setts (40%) had no badger captured.
- All setts are buffered to 500 metres regardless of sett classification. This ensures that misclassification of setts does not affect calculations of area treated.

In calculating overall treated areas overlap circles are merged to avoid over-counting of captured land. The treated area figures are cumulative from commencement of WAU activities in 2004. Once a sett is classified as 'assigned', the area 500 metres around that sett will always be considered to be under capture whether or not capturing has taken place.

From an ecological viewpoint, a circle is not an ideal representation of a badger territory. A preferential technique would be to buffer setts as a hexagon, thus creating a division of land more consistent with what is found in nature. If this hexagon were to completely contain a circle of 500 metres radius, the area would be approximately10% greater than the circle. If the hexagon were generated with a 500 metre radius, the area would approximately 18% less than the circle.

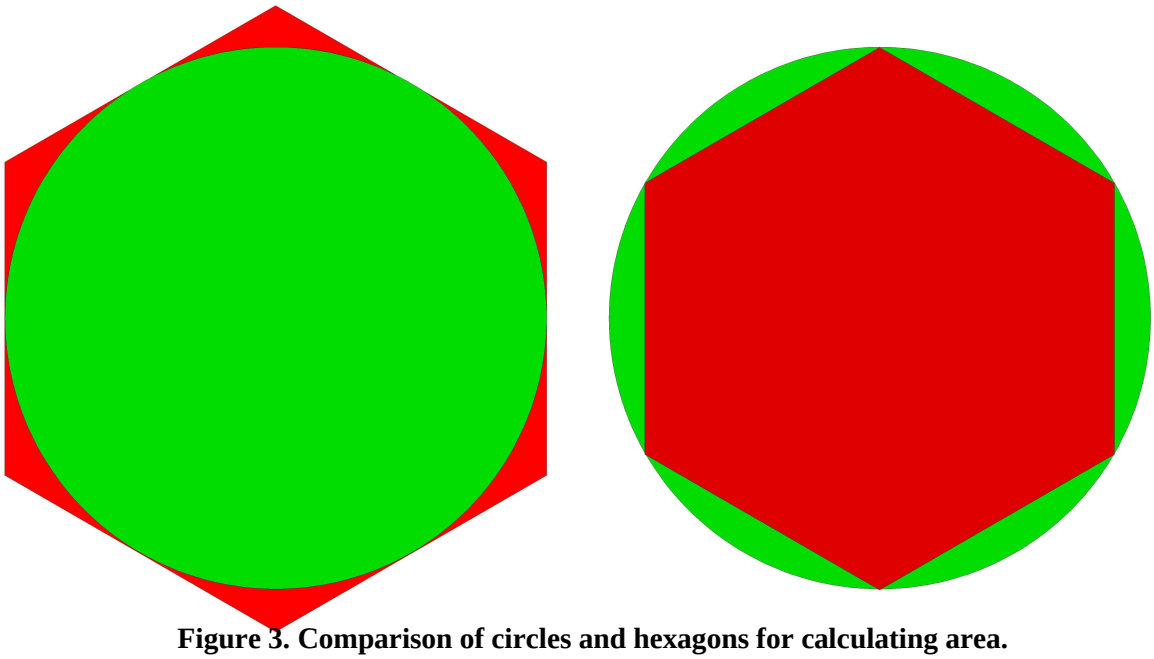

Figure 3. Comparison of circles and hexagons for calculating area.

As this method of calculation is impractical at a national level, it is considered the circular buffering method is a simple and robust way of providing a reliable estimate of land influenced by badger removal.

References

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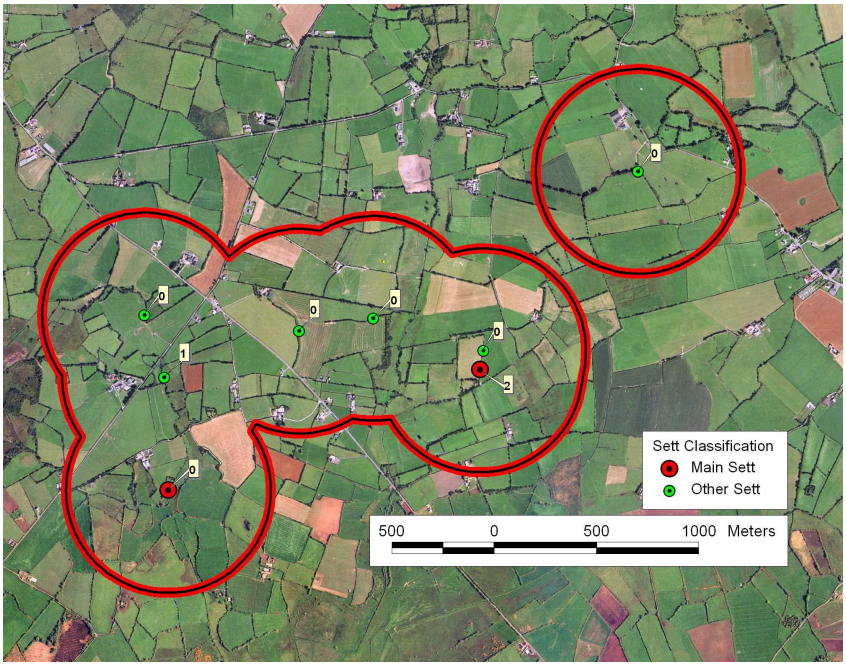
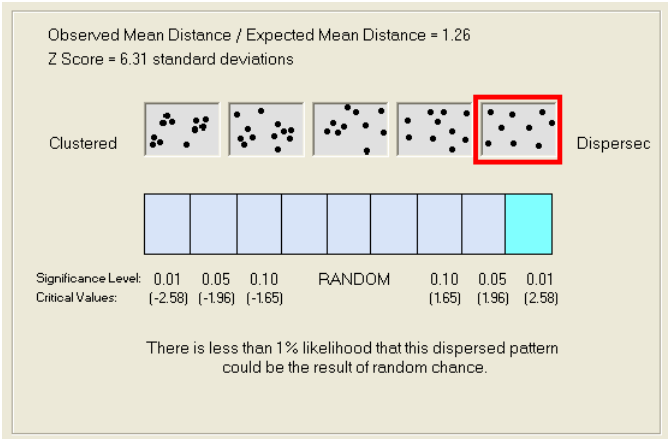
Appendix I



An example of the area associated a capture block in County Laois (3,973,967 square metres). The callout numbers are the number of badgers caught to-date at each sett within the block. The red/black buffer (500m) represents the area that is under capture.

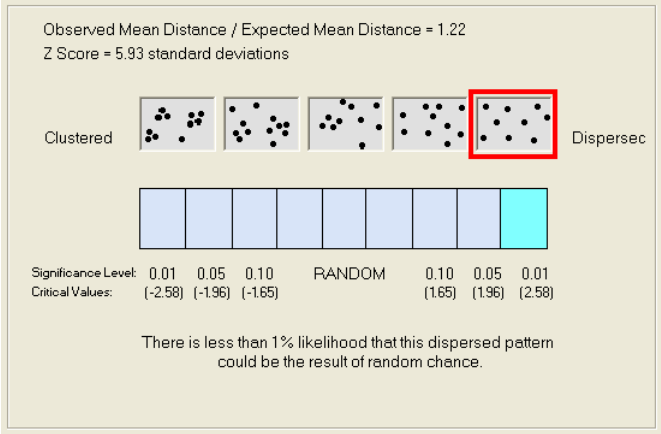
Appendix II

Co. Kilkenny Nearest Neighbourhood Analysis.



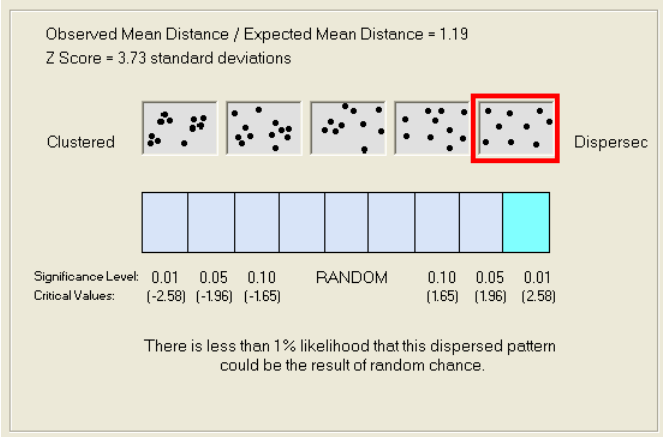
Corrected by area:
Nearest Neighbor Observed Mean Distance = 875.037527
Expected Mean Distance = 694.852325
Nearest Neighbor Ratio = 1.259314
Z Score = 6.314151 Standard Deviations

Co. Cork Nearest Neighbourhood Analysis.



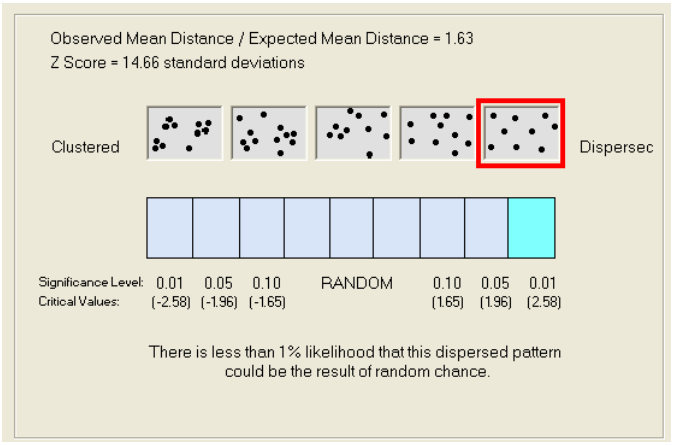
Corrected by area:
Nearest Neighbor Observed Mean Distance = 749.157505
Expected Mean Distance = 615.357219
Nearest Neighbor Ratio = 1.217435
Z Score = 5.926641 Standard Deviations

Co. Donegal Nearest Neighbourhood Analysis.



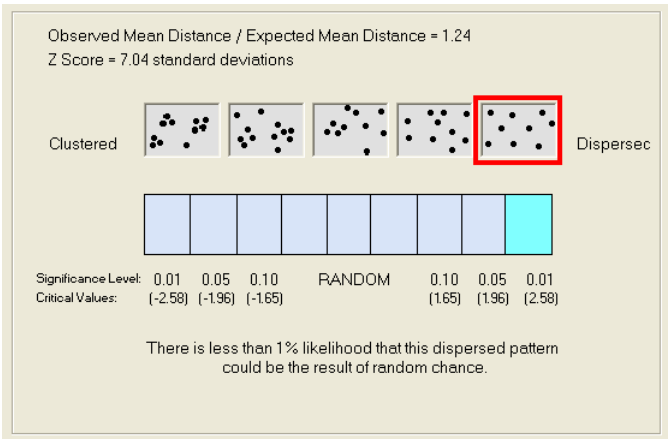
Corrected by area:
Nearest Neighbor Observed Mean Distance = 863.919325
Expected Mean Distance = 727.000782
Nearest Neighbor Ratio = 1.188333
Z Score = 3.726921 Standard Deviations

Co. Monaghan Nearest Neighbourhood Analysis.



Corrected by area:
Nearest Neighbor Observed Mean Distance = 1002.810870
Expected Mean Distance = 616.075066
Nearest Neighbor Ratio = 1.627741
Z Score = 14.659014 Standard Deviations

Co. Offaly Nearest Neighbourhood Analysis.



Corrected by area:
Nearest Neighbor Observed Mean Distance = 1093.290001
Expected Mean Distance = 882.337042
Nearest Neighbor Ratio = 1.239084
Z Score = 7.041354 Standard Deviations