THE NORTHERN IRELAND
TB ERADICATION PARTNERSHIP ADVICE
on
BOVINE TUBERCULOSIS
in
NORTHERN IRELAND

MAY 2018 – JUNE 2019

June 2019

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This Paper outlines the considered views of the TBEP Members

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EXECUTIVE SUMMARY

The first recommendation of the TB Strategic Partnership Group (TBSPG) Report, launched in December 2016, related to the governance structure that would oversee the next phase in a programme to eradicate bovine tuberculosis in the Northern Ireland Herd.

"*To establish effective governance arrangements to oversee the reduction and eradication of bTB so enabling the farming industry, Government, PVPs, nature conservationists and other key stakeholders to work in partnership, with the principle of shared commitment.* "

The TB Eradication Partnership (TBEP) was established in June 2018 as part of the out-workings of recommendation 1:1 of that report which states: -

Recommendation 1.1: *We recommend that a new governance structure should be put in place, with the establishment of:*

• *an NI level oversight body, the TB Eradication Partnership (TBEP)*

• *a small number of Regional Eradication Partnerships (REPs), and*

• *responsive local Disease Response Teams (DRTs).*

Each level should involve representatives from the farming industry working in partnership with DAERA, PVPs, nature conservationists, bTB scientific experts, and other key stakeholders. They would, operate under the principles of active participation by everyone, have a focus on disease eradication and an ability to influence policy and disease control. At an NI level they would work in partnership with Government in developing strategic direction.

Since the formation of the TBEP, it has met with most of the major stakeholders and a list of those meetings (and proposed future meetings) are within the body of this advice.

The TBEP has given extensive consideration to the major aspects of the bTB programme including finance and funding, compensations levels, wildlife intervention, infection control on farms, the role of the Department (DAERA), farmers and Private Veterinary practices that could and should, be instrumental in delivering a cultural change across all of the influencing factors that currently inhibit a continuous downward trajectory and eventual eradication of the disease.

The TBEP is cognisant that not all of its advice will be universally welcomed and some enactment of it will require, if accepted, Ministerial approval and resource allocation. However, this advisory paper to DAERA outlines the TBEP's considered opinion as to the measures necessary to affect such a change.

Key Messages:

The current bTB programme is unlikely to result in any significant continuous downward trajectory in disease incidence rates across Northern Ireland and the argument for the need for further intervention across a number of areas has been established.

The continuing escalation of the overall financial cost is of significant concern to the TBEP and is deemed unsustainable. The case for cost controls and the sharing of the financial burden has also been established to the satisfaction of TBEP members.

The recognition of the need for compromise and a change in cultural attitudes across all of the stakeholder groupings is also well established in the view of TBEP members.

Evidence gathered by the TBEP indicates that the eradication of bTB will only be achieved if all disease reservoirs, across both bovine and wildlife populations are addressed effectively.

The role of veterinary surgeons, both Private and Departmental, is crucial in the promotion of good infection control practices on farms, and in relation to cattle movements generally, and is well established to the satisfaction of TBEP members.

1. TB ERADICATION PARTNERSHIP / ROLE & REMIT OF TBEP

a. The TB Eradication Partnership (TBEP) is the over-arching tier of three proposed levels within new governance and disease response structures in Northern Ireland, each having specific responsibilities.

   The TBEP:

b. Will fulfil an independent expert advisory role, providing advice to the DAERA Chief Veterinary Officer (CVO) and policy makers within DAERA on strategic and operational issues and will monitor progress of the bTB Eradication Programme. The TBEP will have access to the DAERA Minister / Permanent Secretary on any significant issue and will give evidence to the NI Assembly Agriculture, Environment and Rural Affairs Committee (AERA Committee) as required.

c. Will provide advice and oversight of the bTB Eradication Strategy, along with its implementation. This remit will include participating in and inputting to a formal review of the bTB Eradication Strategy every 5 years.

d. Will provide policy advice and bring forward policy proposals for consideration. It is, however, important to note that ultimate responsibility for decisions in relation to policy remains with DAERA / the DAERA Minister; that the Department retains budgetary responsibility; retains operational delivery of the bTB Programme and that the Department remains the Competent Authority for all matters relating to the EU or whatever is established post Brexit.

e. Will ensure that DAERA is kept informed of any changes which are likely to impact on the strategic direction of a bTB Eradication Strategy and what actions are needed to deal with such changes.

f. Will consider reports and recommendations from Regional Eradication Partnerships.

g. Will present an annual bTB eradication progress report to DAERA / the DAERA Minister.

h. Will develop a communications and promotional strategy and action plan in respect of bTB eradication initiatives.

i. DAERA personnel will provide a Secretariat function for the TBEP. A record will be kept of all meetings. A record of meetings at which DAERA officials are in attendance will be drafted by the TBEP Secretariat. A record of all other TBEP meetings will be drafted by the Chair of the TBEP.

2. PROGRAMME OF WORK / SCHEDULE OF MEETINGS 2018-2019

a. The TBEP has discussed and identified objectives that are considered measurable, challenging and attainable over the 12-month period from establishment of the Partnership on 1st June 2018, but recognise the limitations given the absence of an agriculture Minister.

b. These include:
   - A constructive analysis of the responses to DAERA's consultation on its proposals to eradicate bTB (https://www.daera-ni.gov.uk/consultations/bovine-tuberculosis-eradication-strategy-northern-ireland).
   - Establishment of the Partnership's credibility through meeting with key stakeholders.
   - Consideration of proposals to fill current vacant positions on TBEP (or how to ensure access to those sectors' input / views). There has been limited progress on this, and conversations have been held, but so far, regrettably, these positions remain unfilled. The TBEP recognise the value of other perspectives and remain hopeful that these outstanding positions be taken up.
   - Review of the current bTB programme.
   - Aim to have the majority of the TBSPG recommendations either operational, or in train with recognisable and realistic dates for their inclusion in the bTB programme.

c. Members discussed and agreed to engage closely with the stakeholder leadership, key decision makers and those who could influence the trajectory of the bTB programme.

d. Members agreed that advice given to DAERA could be made publicly available where doing so would not conflict with confidentiality or FoI considerations.

e. These objectives would be achieved through;
   - Stakeholder Meetings with conservation and environmental groups, PVPs and farming interests, DAERA policy officials, food processors and marts.
   - Briefing and discussion of issues for development of considered views to present to DAERA on:
     - Wildlife intervention
     - Finance, compensation, capping, levies
     - DAERA consultation proposals, short/medium/long term actions
     - Governance structures, establishment of REPs and DRTs
     - Research, E&I bids, bTB proposals

f. Development of TBEP communication and information exchange actions with stakeholders, public and DAERA / other government departments through social media e.g. twitter, blog, and the DAERA web site.

g. **SCHEDULE OF MEETINGS – TB ERADICATION PARTNERSHIP**

- Tuesday **22nd May 2018** – Inaugural meeting, Glenree House, Newry
- Tuesday **12th June 2018** – Receive briefing / overview of the current bTB Programme and an analysis of responses to the consultation on the department's response to the TBSPG's published Strategy and recommendations - Room 233 DDH
- Tuesday **17th July 2018** – Receive briefing / update on Finance & funding and Wildlife, Room 229 Dundonald House
- Tuesday **24th July 2018** – Engagement meeting with the UFU, at UFU HQ, 475 Antrim Road, Belfast BT15 3DA
- Thursday **23rd August 2018** – Engagement meeting with Ulster Wildlife, Room 229, DDH
- Tuesday **4th September 2018** – TBEP meeting, Hillsborough
- Thursday **4th October 2018** - Scheduled monthly meeting, Room 935 DDH
- Tuesday **9th October 2018** – Engagement with the NI Badger Group & the USPCA
- Tuesday **9th October 2018** – Engagement with the Association of Veterinary Surgeons Practicing in Northern Ireland
- Tuesday **16th October 2018** – Visit to observe TVR Research project
- Tuesday **30th October 2018** – Study visit to observe badger capture operation in Co. Monaghan
- Wednesday **7th November 2018** – Attend UK TB Liaison Group meeting, observer status / engagement with DAFM officials
- Thursday **8th November 2018** – Scheduled monthly meeting, Room 106a DDH
- Friday **14th December 2018** – Meeting (VC) with Prof. Rosie Woodroffe, Room 106 DDH
- Wednesday **9th January 2019** Scheduled meeting, Morrison Room, AFBI Hillsborough
- Monday **14th January 2019** - scheduled meeting, 11th Floor DDH
- Thursday **31st January 2019** - scheduled meeting, CAFRE Greenmount Campus
- Monday **11th February 2019** – Update on TVR Research Project, Room 233 DDH
- Thursday **21st February 2019** scheduled meeting, Room 229 DDH
- Thursday **14th March 2019** scheduled meeting, Room 229 DDH
- Wednesday **3rd April 2019**. Presentation on bTB/TVR
- Thursday **18th April 2019** scheduled meeting, Room 233 DDH
- Thursday **2nd May 2019** scheduled meeting in Greenmount
- Tuesday **21st May 2019** scheduled meeting, Room 233 DDH

The TBEP also advised that it would like to include a visit to a local DAERA District Veterinary Office and a meeting with AFBI, which are still to be arranged.

h. Other items identified, which TBEP might consider further as part of its work schedule, include:

- Investigate the potential for interferon-gamma (INFγ) testing to be carried out by the private sector and to assess if the current INFγ programme is optimal for Northern Ireland e.g. using the AFBI Omagh Lab for processing samples derived from farms in the west.
- Development of research proposals in respect of wild deer and camelids (e.g. alpacas and llamas) to get specific information on the risks that other species could play in the transmission of bTB to cattle and keeping under review bTB research relevant to the bTB programme.
- Development of actions / awareness raising initiatives to promote an "informed purchasing" approach to bringing stock onto holding
- Work with DAERA Scientific Adviser to facilitate meetings with internationally recognised experts at the (*M.bovis)* Conference 2020 to help inform N.I Agri Food decision makers
- Explore, with DAERA & stakeholders, the establishment of Approved Finishing Herds (AFHs) in N. Ireland.
- Embed bTB education particularly with young farmers, within CAFRE and industry leaders; e.g. business development groups and student education.
- How to enforce the isolation of animals on farms taking into account practical and welfare considerations on-farm.

3. AFFECTING CULTURAL CHANGE

a. At the inaugural meeting of the TBEP on 22 May 2018 the committee recognised the scale of the challenge in helping to shape future policy and in providing direction and challenge to those tasked with understanding and eradicating this disease. The TBEP considered all of the work carried out over many years by scientists, ecologists and others, and more recently by the TBSPG - looking at past efforts to contain and reduce the incidence and proliferation of bTB and determining how the TBEP could harness the efforts of all stakeholders in developing an effective plan to tackle this disease.

b. The TBEP met with many of the significant stakeholders and interest groups with the objective of listening, understanding and appreciating the variety of viewpoints and how they influenced the present opinions of those stakeholders

c. Cultural change has been defined as "modification through innovation, invention, discovery or contact with other societies". The culture of any group can also be a very important strategic lever. The same cultural forces that bring resistance can also be harnessed to drive the changes required but this will only happen when effort is harnessed and aligned to a common goal**.**

If we are willing to genuinely and dispassionately look to the experiences elsewhere, the balance of available scientific evidence, recorded outcomes from here and other jurisdictions and accept that there is no progression in this fight without some degree of compromise, we can move forward to finally eradicate this disease.

d. International examples of successful bTB eradication illustrate the need to have high levels of industry engagement in programme governance, management and cost-sharing. In the Australian example, one commentator noted that the programme *'enjoyed industry "ownership" and involvement at all levels of management,'* (More et al., 2015) and another that *'the involvement of industry in both funding and policy development was an essential factor in achieving the outcome of the campaign'* (Radunz, 2006). In Australia the bTB eradication programme led to the formation of Animal Health Australia which now oversees much of the national animal health programmes there. In New Zealand OSPRI, a non-governmental organisation, manages both the TBfree New Zealand programme and the national animal identification and traceability system. Both of these examples provide models for how a national eradication programme could be developed where there is public/private sharing of both programme ownership and direction as well as programme cost sharing. The TBEP suggest that a key weakness of the NI bTB eradication programme is a lack of programme ownership by the industry, exacerbated by frustrations around the lack of progress over many years. The TBEP suggest that there are international models for how industry could be encouraged and supported to become more engaged in bTB control measures.

e. The TBEP recognise that this is a marathon and not a sprint, but both start on the same line. The TBEP fully recognise that education and ongoing engagement are crucial to drive change. Education on the barriers to effective prevention, on the benefit of controlled movement of high risk livestock, on how the disease is spread, the hidden cost to the industry and how to best protect the farm business, is crucial and must go hand in hand with the successful rollout of any new strategy. Agreed common goals can bring cultures together.

f. The TBEP recognised the need to develop significant cultural change recognising the difficulty in changing established practices and opinions. The TBEP realised that individuals and the industry need to be educated on badger ecology, the need to adopt good biosecurity, infection control measures and encouraged to demonstrate commitment to such.

g. The TBEP recognises that there are deeply held views on how to mitigate wildlife infection risks. It became clear to us that in order to appreciate and embrace a new way of tackling bTB, stakeholders needed to clearly see the link between their own understanding and practices, and where necessary be open-minded in exploring fresh approaches. The common goal of disease eradication must be the unifying objective. Cultural change involving behavioural change will require sustained effort, helped by increasing the opportunities to repeat and reinforce key messages.

The TBEP recognises that bTB testing is seen merely as an accepted part of the landscape albeit a colossal cost and inconvenience. The prevailing culture is one of acceptance.

h. A stated objective of the TBSPG was to **"re-balance the cost of the disease between the public and private sectors, so encouraging a change of culture and attitude and a shared commitment to the control and eradication of bTB and to identify new sustainable arrangements which would allow Government to maximise and better deploy resources".**

Breaking this down there are important themes to highlight from this understanding.

i. Currently the direct costs are not shared and the approach to eradication amongst farmers is not uniform. Sharing of costs is seen as an option to encourage greater involvement and the TBEP supports the need for this but would encourage greater recovery costs from reactors which, for the most part, enter the food chain. The present returns are disappointing in light of the huge pressure to tackle and reduce the annual cost of the programme. There is no intervention on wildlife here - so a reservoir of transmittable disease goes unchecked whilst all cattle are tested repeatedly during their lifetime.

j. PVPs participate in a bTB testing programme but their role could be much greater and productive. There is anecdotal evidence to suggest that the practice of cattle from different herds occupying the same air-space in communal sheds over the winter months needs to be addressed as a significant factor in disease spread. PVPs and DAERA should take every opportunity to educate the farming community about the disease risks presented by such practices. We believe that in addition to ensuring that testing is carried out correctly, a key focus should be on how PVPs can assist their clients to control infection when present and provide bespoke advice on how to prevent infection introduction or re-introduction.

The TBEP recommends that DAERA and the Agri-Food industry consider the applicability of international models which could be adopted to facilitate better industry & PVP engagement with the NI bTB eradication programme.

The establishment of Regional Eradication Partnerships and local Disease Response Teams, as envisaged by the TBSPG, would encourage greater involvement/ownership, by the industry, and should be established when they have a role to play.

4. SCIENTIFIC PERSPECTIVES

a. Herd infection dynamics

Despite substantial and ongoing efforts to control bTB, the annual animal apparent prevalence of the infection within NI herds has remained between 0.6 and 0.9% for the past 20 years (figures 1 & 2). While there has been substantial year to year variation and evidence of cyclical changes to herd and animal incidences (figure 2), it is clear that there is little evidence to support the view that the current programme will achieve substantial reductions in bTB in the cattle population beyond this prevalence range.

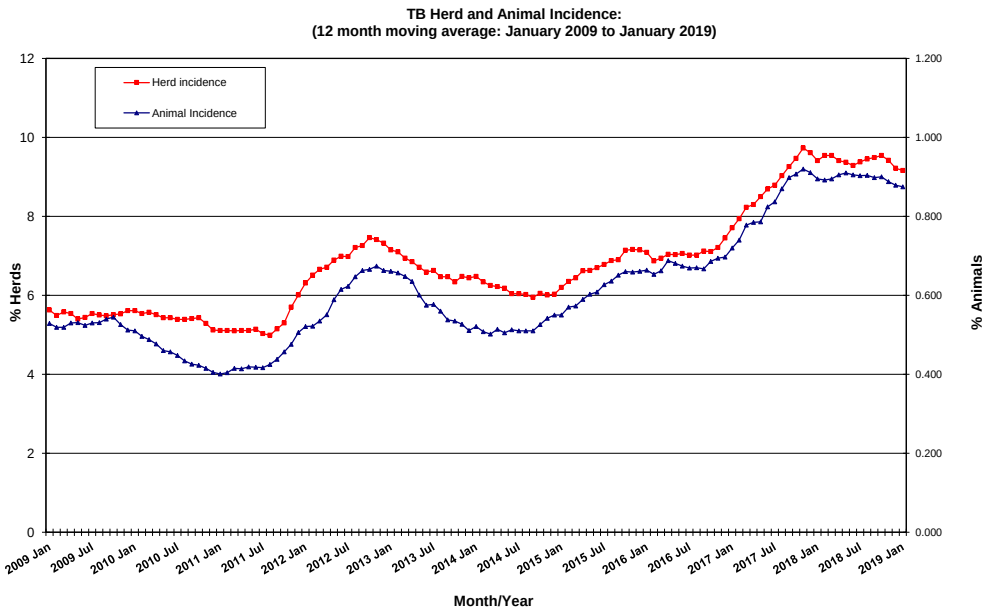

Figure 1. Herd and animal Incidence in NI 2009 – 2019. (Source DAERA VEU)

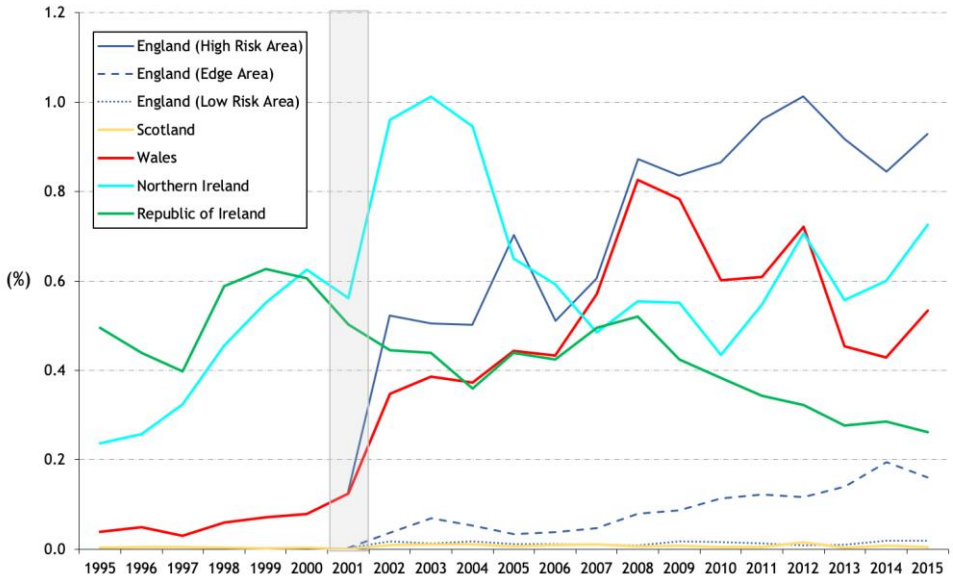

Figure 2. Annual apparent animal prevalence. The risk areas in England are only presented from 2001. The shaded area represents the duration of the foot and mouth epidemic. (More et al., 2018).

While the broad picture is clear there are some observations that can be made concerning the current infection picture within NI. Most notable has been a substantial increase in bTB incidence over the past 4 years. There is no clear explanation for this rise. It is possible that this is merely a reflection of noise or year to year variations. However, there does appear to be a certain cyclicity to the incidence of disease with apparent increases followed by decreases every 2-4 years. While it will be undoubtedly difficult to identify what, if any, causes there may be to these patterns, it would be valuable if some epidemiological analysis could be undertaken

to posit and test possible causes for these changes over time. For example, we note that there was a long-term trend in increasing bTB prevalence from a low point during the 1990s. This rising trend was well before the Foot and Mouth outbreak of 2001 and suggests that while this outbreak may well have increased the incidence of bTB it was not the only explanation. There would appear to have been an upward trend before this incident. Understanding likely causes for the changing dynamics of infection incidence are foundational to providing rational interventions that might mitigate such risks.

The primary areas where bTB is found are in NI, Wales, Southwest England and the Republic of Ireland (RoI) **(Figure 3).** It is noteworthy that the medium-term incidence trends in all these regions has been flat or upward with the only exception being the RoI. Within the RoI the incidence has decreased substantially since 2000. However more recently evidence suggests that this decline has plateaued **(Figure 4).** Despite differences in how the disease in measured, it is clear that there is a substantial difference in infection rates in NI compared to the RoI and therefore it appears reasonable to assume that the difference between the two programmes can, at least in part, be attributed to the differences in the programmes in each jurisdiction. One of the most significant of these differences is in the approach to wildlife intervention which is discussed later.

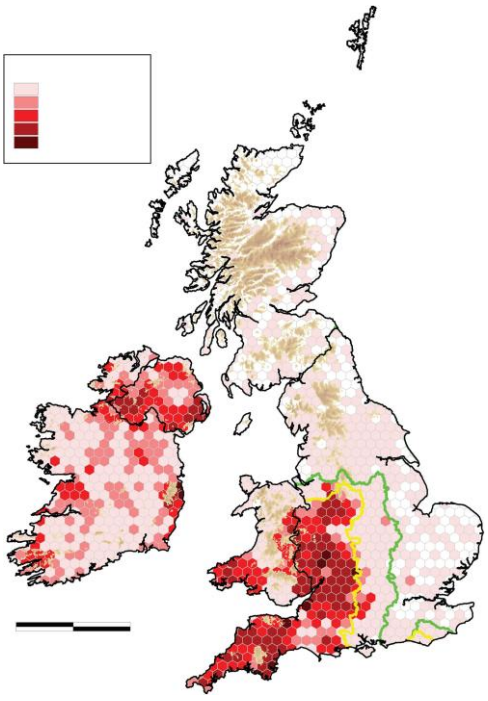

Figure 3. Cumulative apparent animal prevalence, 2012–2015 (*sum of reactors (2012–2015) per hexagon divided by the sum of the mean population per herd (2012–2015) per hexagon.* The yellow and green lines delineate the boundaries between the High-Risk Area and the Edge Area, and between the Edge Area and the Low Risk Area, respectively.

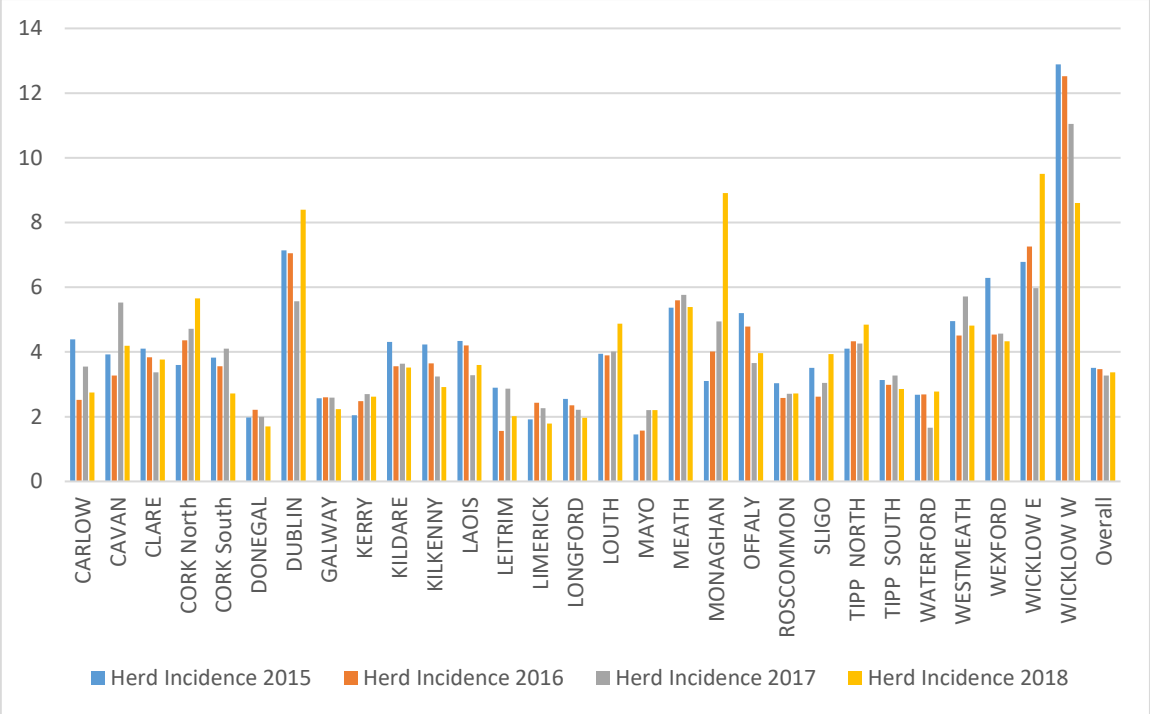

Figure 4. Republic of Ireland TB Herd Prevalence by County. Data accessed 20/03/2019. https://www.agriculture.gov.ie/animalhealthwelfare/diseasecontrol/bovinetb/statistics/tbstats/

An important observation of the NI and RoI data is the heterogeneity of infection prevalence and infection trends across different regions. While infection remains endemic across the island of Ireland, these substantial geographical differences suggest that there are significant area differences which may indicate the need for bespoke approaches depending on the varying reasons that might underpin these differences. Plausible reasons for these differences could include farm type, farm management, wildlife risk, land type and the implementation of current controls, all of which are, at least in principle, amenable to investigation.

An important consideration in measuring the effectiveness of any infection control programme is the probable effect any combination of interventions is likely to have on the Reproductive Ratio (R_o). This is the average number of secondary cases caused by each primary case. An epidemic can only be sustained if this ratio is 1 or greater. The current estimated R_o for the RoI badger-cattle transmission system is between 1.07 and 1.16 (Simon More personal communication). With the addition of vaccination this has been estimated to be 0.93-0.97 (Aznar et al., 2018). As far as we are aware a similar estimate has not been carried out within NI. It would be valuable to estimate this as a baseline figure for NI and as an ongoing means of measuring the effect of interventions and the likely timelines any interventions might take to achieve eradication. An example of how such an approach can be used to inform policy and benchmark progress is illustrated by work carried out for the RoI BVD eradication programme. In this case retention of persistently infected cattle has significant impacts on the likely timeline to eradication. Differing levels of intervention (in this case retention levels of PI animal) were modelled to illustrate the likely impact this would have on the success of the BVD programme.

It would be valuable to develop a similar approach for bTB in NI, to allow 'what if' questions to be modelled, such as, the risk of undisclosed TB in herds, neighbour to neighbour risks and environmental exposure risks including direct and indirect contact with wildlife hosts and interventions that could be adopted to mitigate these risks.

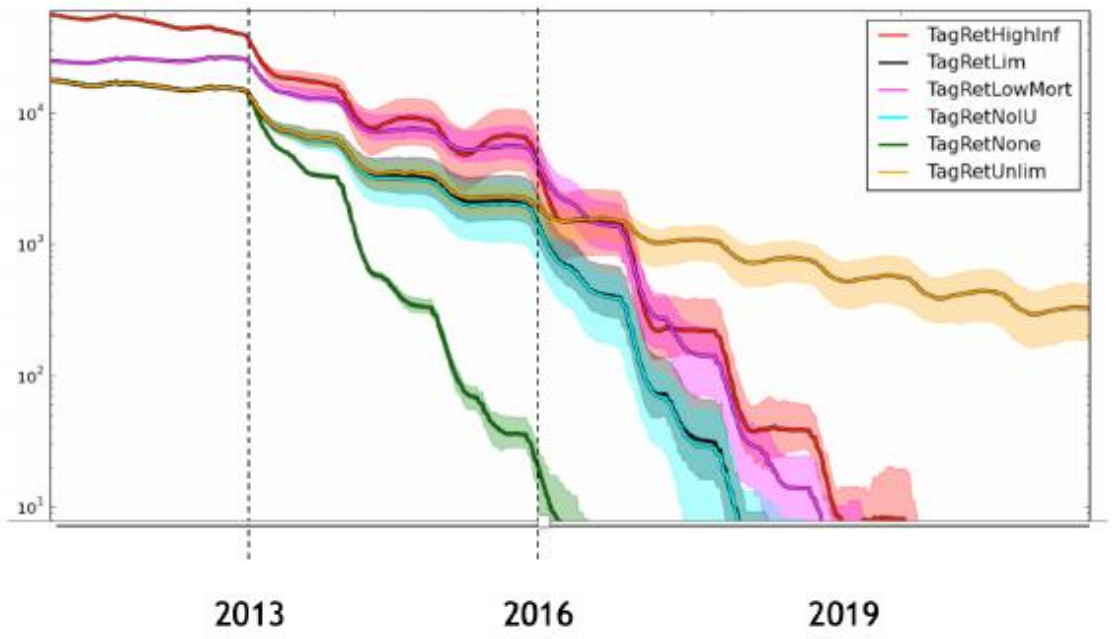

Figure 5. Estimated decline of BVD Persistently Infected cattle in RoI. Green line where all PIs are removed immediately, Purple & Blue lines variations of high levels of retention initially followed by high levels of prompt removal, yellow line retention of PIs at ongoing high levels. (Thulke et al., 2017).

One of the largest challenges to bTB control is the observation that many herds infected with bTB experience persistent infection despite ongoing on-farm cattle controls. The two main drivers for this persistence are;

- infection in the locality associated with neighbouring cattle and wildlife reservoirs
- residual, undisclosed, infection within the herd (More and Good, 2015).

Multiple studies have identified the contribution of residual infection to the persistence of bTB in an area (More et al., 2015). Clearly to address persistent infection requires all of the likely drivers for it to be addressed, namely diagnostic efficiency, wildlife risk and neighbouring herd risks (see discussion later). Currently herds that are subject to persistent infection constitute an ongoing risk to other herds even following statutory herd movement de-restrictions. Recognising this risk, other programmes have adopted risk based trading approaches, most notably Australia (More et al., 2015) and New Zealand (Hutchings et al., 2015).

Currently there is concern that any move towards a risk-based trading system for NI to inform bTB disease risks to animal purchasers is likely to have a disproportionate effect on the NI cattle industry due to the large number of herds that have or have recently had bTB. However, we note that all successful bTB eradication programmes have, at some point in the evolution of their programmes, adopted a risk-based trading approach. Given that, there may be a variety of options that could be applied (ranging from bTB specific measures to more generic measures

of common risks such as herd turnover rates). However, it is the considered opinion of the TBEP that any risk-based trading approach could not be successfully implemented until other measures were in place such as a meaningful wildlife intervention.

The TBEP recommend that DAERA;

- **explore future strategies to support risk-based trading**
- **strengthen epidemiological expertise to provide not only descriptive statistics of bovine TB within N. Ireland but to identify probable determinants of disease pattern changes. This is likely to include the further development of expertise in data handling and modelling.**

b. Cattle diagnostics

The diagnosis of tuberculosis, whether it be human or bovine, is challenging. There is currently no test which fulfils all the criteria necessary to identify all infected animals. The four key measures for any diagnostic test are its sensitivity, specificity, positive predictive value and negative predictive value (see below).

Of these the most useful are the predictive values as these give an indication of how reliable any test result is likely to be. Predictive values are determined by test sensitivity, specificity but also disease prevalence. Overwhelmingly the most important characteristic for any test where the disease prevalence is at the current levels estimated for bTB in cattle in NI is test specificity.

The current animal disease prevalence is estimated to be approximately 0.9%. If it is assumed that the sensitivity of the test is 60%, increasing the specificity of the test from 99.5% to 99.8% changes the positive predictive value of the test from 55% to 75% (figures 6 & 7). In other words, on average, at the lower specificity only 55% of positive test results reflect truly infected animals (45% are not infected) whereas at a specificity of 99.8%, 75% of test positive animals are on average actually infected. This illustrates the need to ensure that any test applied to the entire or a large proportion of the population of cattle in NI must have a very high specificity. Tests with lower specificities may have a role to play but care will need to be exercised in their application as they will undoubtedly lead to significant numbers of false positive test results. This is most important for widespread cattle testing but will be less of an issue where smaller numbers of animals are tested, e.g. at herd or cohort level or for wildlife testing. It is noteworthy that for those herds in NI with chronic infection, specificity estimates for severe interpretation for the SICCT are lower than generally accepted (Lahuerta-Marin et al., 2018). The reasons for this are uncertain but it does appear that herds with chronic or persistent bTB infection are, in general, epidemiologically different from herds with sporadic bTB. This could be due a range of reasons including undisclosed herd infection, ongoing re-infection from local sources including wildlife reservoirs and local factors leading to false positive results. It does highlight the likely need for bespoke interventions depending on the local disease picture.

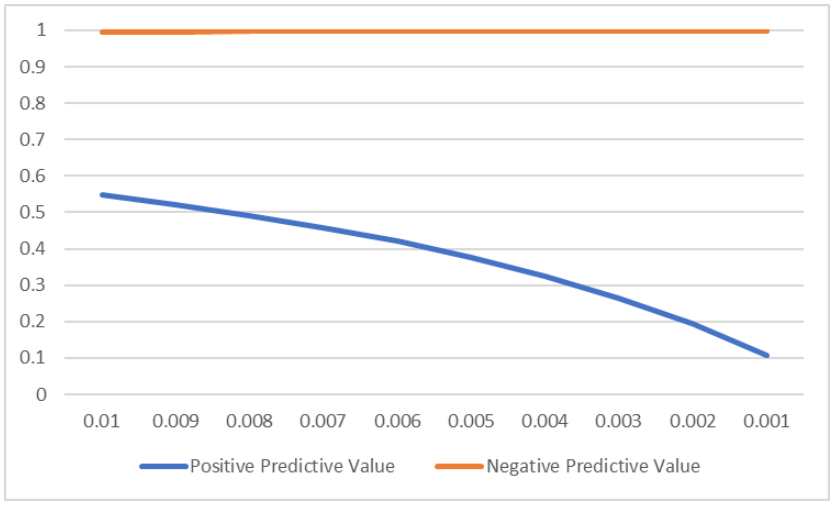

Figure 6. Positive and Negative Predictive Values for a test with 99.5% Specificity and 60% Sensitivity a population of animals with disease prevalence's between 0.1-1%.

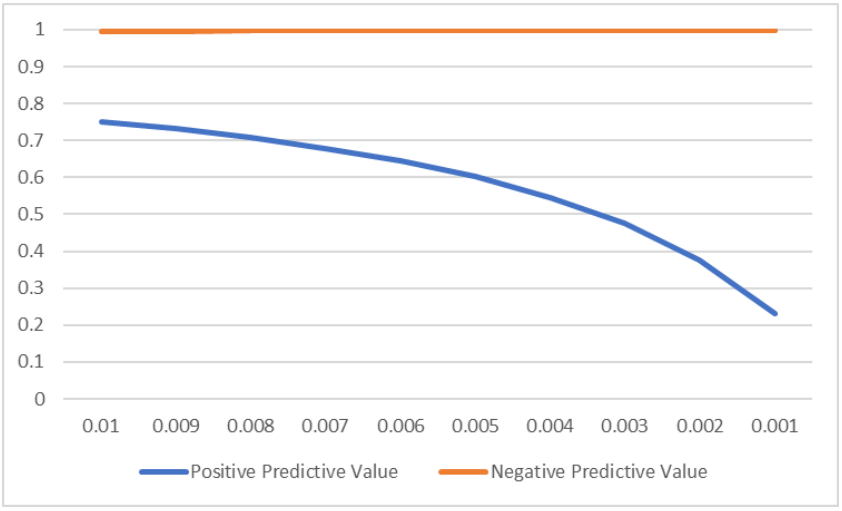

Figure 7. Positive and Negative Predictive Values for a test with 99.8% Specificity and 60% Sensitivity a population of animals with disease prevalence's between 0.1-1%.

While the specificity of the SICCT is widely recognised as very high, its sensitivity is estimated as being relatively poor. If the sensitivity of the test could be increased this would significantly improve test performance and the Positive Predictive Value of the test. Increasing the sensitivity of the test from 60% to 80% would be expected to increase the predictive value of the test overall by about 5% (figure 8).

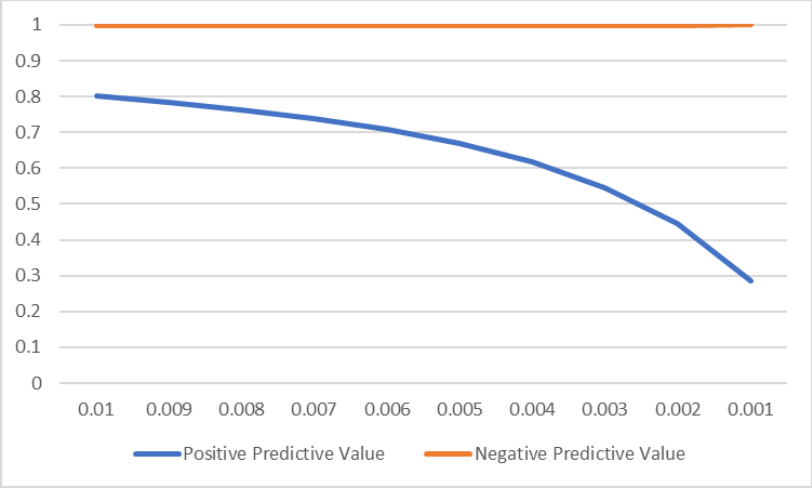

Figure 8. Positive and Negative Predictive Values for a test with 99.8% Specificity and 80% Sensitivity a population of animals with disease prevalence's between 0.1-1%.

This raises the question of what the likely reasons for the poor sensitivity of the test are. There are a large number of possible reasons some of which are included in the sidebar. For each there are numerous potential interactions between each category as well as a long list of subcategories. For example, factors that affect host immune responses may include age and sex of animals, other infections, animal nutrition and stage of production cycle (e.g. negative energy balance during peak lactation). Many of these are either speculative or have limited evidence. However, many of them are untested. The TBEP suggests that DAERA should consider commissioning a review of potential test confounders to include a knowledge gap analysis. The potency and analytical specificity of commercially available tuberculins must currently be determined against the International Standard (IS) of bovine and avian PPD using bioassays in *M. bovis* infected and *M. avium* sensitised guinea pigs (GP). GP bioassays on commercially available PPDs suggest a substantial disparity in the quality of available avian and bovine PPDs (D. Bakker personal communication).

There is considerable evidence of an interaction between Johne's Disease and bovine TB (Byrne et al., 2018). Chronically infected herds with bTB have a significantly increased risk of also having evidence of Johne's Disease with this association being strongest in herds with higher apparent prevalence levels of Johne's Disease. While there are a range of possible explanations and mechanisms for this interaction, the most plausible explanation for this interaction is

Some possible TB Test Confounders

- Bacterial subversion of immune responses (e.g. anergic responses)
- Host genetic response variability
- Bacterial strain differences
- Host immune response competency
- Co-infection (e.g. Johne's Disease, Avian TB, Liver Fluke)
- Applicability of currently used testing reagents (tuberculin's).
- Poor testing techniques
- Test site interference

probably through interference of the SICCT. If this is correct it would be expected that infection with, or possibly exposure to, MAP the causal agent for Johne's Disease would elicit responses to avian tuberculin. In animals that are infected with bTB this could mask any measurable bovine responses, the nett effect being to reduce test sensitivity. The TBEP believes that the evidence is now sufficient to indicate that DAERA should support or facilitate the control of Johne's Disease within NI (aside from any other benefits that might accrue from Johne's Disease control).

The interferon-gamma test has been frequently demonstrated to have a superior sensitivity but an inferior specificity compared to the SICCT use (Lahuerta-Marin et al., 2016). Therefore, its application is valuable to the TB eradication programme in identifying additional TB infected animals. However, its relative poorer specificity which inevitably reduces its positive predictive value precludes its very widescale use. Its primary value will be in those herds which are likely to have undisclosed residual infection. However, it is also clear that animals that test positive to the interferon gamma test, at least in those herds eligible to be tested within NI, have an overall substantially increased risk of having bTB (Lahuerta-Marin et al., 2015). Currently these animals are not required to be slaughtered and are free to be traded. As a minimum it would seem prudent that any animal that tests positive to the interferon gamma test is precluded from movement to another farm.

Further it is well recognised that under the current testing regime animals with any inconclusive test result have a much greater likelihood of being bTB infected, and so the TBEP considers that the movement of these animals poses a substantial risk to other herds.

The characteristics of the interferon gamma test are influenced by the time it takes from blood collection to processing in the lab and by the 'cut-off' used to classify an animal as positive. Historically samples taken within NI have had to be processed on the same day as collection. This has necessitated the need to have samples taken sufficiently early to allow them to be delivered to AFBI, Stormont. Consideration should be given to assessing if this need for same day testing is necessary (as other jurisdictions allow next day testing) and whether a change in testing protocols would significantly adversely affect test characteristics. Also, it would be valuable to review whether the currently applied cut-offs are optimal. If the cut-offs were raised this would inevitably improve test specificity while also reducing test sensitivity. A reduction in test sensitivity might be acceptable if it would allow more widespread application of the test (depending upon the degree it would have on reducing sensitivity). It may be helpful for DAERA to commission a 'Receiver Operating Curve' (ROC) analysis or equivalent to help determine the optimal testing protocols for field use. If it found that same day testing is required, consideration might be given to using the AFBI-Omagh lab for blood processing to allow easier access to testing from the west of the province.

The TBEP is aware of the development of several novel diagnostic tests that could become useful, in due course, to further support the identification of infected animals. However, essential pre-requisites of any new test will be that its characteristics and costs are acceptable to allow its application. One such potential test, which the TBEP is aware of, is a novel serological test which we understand is currently undergoing extensive international validation trials. If this, or another test, was demonstrated to have adequate test characteristics, the TBEP would wish to explore with DAERA how it might be applied within the bTB eradication programme. For example, one application could be through pre-movement testing. Such an application could be very valuable to further mitigate the risk of disease transmission in traded animals, akin to that which was applied during the Brucellosis eradication programme.

The TBEP Recommends:

- **That DAERA should restrict movement of IC animal to other herds, except to slaughter.**
- **That DAERA should review known or possible TB test confounders. e.g. Johne's Disease**
- **That DAERA review the current lab protocols for interferon gamma testing to ensure they are optimised for field use within NI.**

c. TB & Scientific Research

The area of TB research in general, and bTB research in particular, is an ever-growing area of work locally, nationally and internationally. It is crucial that new understanding as it develops, that might be of value to the NI bTB Eradication programme, is identified, understood and, where appropriate, taken account of by both government and industry. The TBEP recommends that there is active surveillance of the bTB literature as it is added to and that a digest of these findings, understandable to a non-specialist audience, are communicated to key decision makers within DAERA as well as to industry leaders. The TBEP therefore recommends that DAERA;

- **Consider supporting some of the key stakeholder groups in NI to meet and engage with scientists at the *M. bovis* conference in Galway in 2020.**
- **Undertake or commission a regular (quarterly of biannually) updated digest in plain English of research publications on bTB including simple summaries of key findings to be circulated to decision makers within the TB Eradication Programme and the local Agri-Food industry.**

5. FUNDING & FINANCE

In NI the annual cost of bTB control is now approaching £40 million. This is not sustainable. In addition to this on-going cost to the public purse, the disease has a significant financial impact on the wider agricultural community. Farms incur significant costs of time and labour, loss of market opportunities and less efficient use of farm resources which have a substantial effect on farm profitability and the sustainability of the wider cattle industry. The TBEP considered three ways to address this on-going cost:

a. **A bTB strategy which realistically delivers a significant reduction of bTB levels on farm.**
This is the most straightforward way to rapidly reduce compensation costs, testing costs and on-farm costs. The TBEP met with a wide variety of stakeholders and reviewed approaches in England, Wales and the RoI and considered the results of their different policies. These jurisdictions have addressed the reservoir of bTB infection in wildlife in different ways over varying periods of time, with varying degrees of success. The TBEP recognise that this is a highly controversial issue with widely differing views, and it is difficult to find a common approach across all stakeholders. Ultimately the role of the TBEP is to advise DAERA on the eradication of bTB using the best information available, and as such the approach in the RoI has the best track record of cost-effective bTB reduction in the cattle population over time. The TBEP notes that the TVR study in NI has some interesting, although very preliminary, results which may in time suggest an alternative method of control. However, at this stage, the TBEP is of the opinion that this option is likely to be more costly. Currently there is no clear evidence for its effectiveness in controlling bTB in cattle.

b. **Better recovery of reactor compensations values from the market.**
At present DAERA recovers a limited amount of on-farm compensation costs. A greater return could significantly reduce the cost of bTB control. The TBEP suggests that DAERA investigate the RoI model, review the structure of their tendering process and adapt accordingly.

c. **Address the issue of compensation levels paid to farmers.**
The TBEP fully recognise the financial challenges that bTB outbreaks create within any farm business. bTB restricted farms face significant on-going costs in time, labour and feedstuffs. The TBEP also recognise the fact that compensation does not cover for loss of future earnings and the increased costs at farm level during the periods of restriction. However, given the significant cost to the public purse and the need to encourage cultural change within the farming industry the TBEP considers that it is realistic to examine compensation levels. The TBEP is also aware that a small number of farmers do engage in fraudulent activity to take advantage of the present compensation regime. The TBEP strongly encourage DAERA to explore all legal avenues, both criminal and civil, to identify and prosecute all those involved. Further, DAERA should review the legal penalties and ensure that they properly reflect the impact that the actions of a small minority have on bTB prevalence and the on-going public expense. Penalties should be sufficient to act as a suitable deterrent to any potential financial gain from engaging in fraud.

d. **The TBEP initially advise that a cap on individual animal compensation is applied at the level of £5000.**

This figure should be reduced over time as reactor rates decrease and commercial insurance becomes more widely available. Furthermore, the TBEP recognises that it is important to ensure that farmers utilise all available measures to minimise the risks of bTB on their own farms. These include grazing management, farm fencing, purchasing decisions, on-farm hygiene and minimising contact with wildlife sources.

e. **The TBEP is of the opinion that a small percentage reduction to compensation payments would encourage greater emphasis on infection control.**

The TBEP recommends that a 10% reduction to compensation is payable on the first five animals in any 12-month period after the reactors are identified. As the majority of bTB outbreaks result in four or fewer reactors being removed such a measure would encourage widespread involvement by the farming community and would generate worthwhile savings to the public purse but crucially does not irreversibly damage the small number of businesses which are severely affected and lose large numbers of reactors. Given the impact and sensitivity of compensation changes the TBEP advise that these are not introduced until there is a significant change in approach to wildlife intervention in NI.

6. WILDLIFE INTERVENTION

a. It is arguably the case that one of the most controversial issues in relation to any discussion considering the eradication of bovine tuberculosis is how to approach the disease reservoir in the wildlife population, specifically the badger population, through a structured intervention programme.

Whilst the TBEP accept that some of the measures implemented by DAERA recently have had a positive impact on disease incidence rate reductions, the TBEP is of the view that the current programme is unlikely to result in any significant continuous downward trajectory towards eradication in the absence of an intervention policy.

b. The TBEP consider that there is definitive evidence that badgers act as a wildlife reservoir for bTB in cattle in GB, NI and the RoI (Donnelly and Nouvellet, 2013)(White et al., 2013)(Biek et al., 2012). While it remains controversial as to the degree to which bTB is acquired from badgers, estimates suggest that in England, while the proportion of bTB directly acquired from badgers was small (approx.6%), the overall effect was that approximately 50% of bTB in cattle was consequential from initial badger to cattle transmission (Donnelly and Nouvellet, 2013).

c. Estimates for the prevalence of bTB in badgers in NI have been made based upon road traffic accident post-mortem analyses. These show that the confirmed level of bTB in badgers was approximately 15% (Courcier et al., 2018). Given that the methods used for this analysis, of necessity, will have underestimated the actual disease prevalence, the true disease prevalence is likely to be much higher. A similar apparent prevalence has been found in

badgers tested as part of the TVR project. This suggests that the RTA badgers survey reflects the infection levels in the wider badger population. The infection prevalence in badgers within NI is at least 15 times greater than that in cattle. Given that there are currently no controls on bTB in badgers this figure appears to be quite stable over time and therefore could be useful as a baseline measure for any future interventions to reduce bTB in badgers and therefore the risk of further transmission between badgers and between badgers and cattle.

d. Due to the risk of bTB spread from badgers there is consensus on the need to include controls to address the risk of cattle acquiring bTB from badgers (Aznar et al., 2018). There is a significant body of literature which has attempted to assess the various potential interventions that could be applied to control badger-cattle-badger transmission networks. Included in this literature are apparent contradictions on what might be the optimal approach (Allen et al., 2018). It is not the purpose of this paper to review this literature. However, some broad observations can be made. At least some of the variations in proposed and actual interventions can be attributed to variations in the landscape density and ecology of badgers (Guerrero et al., 2018). In South West England badger density appears to be much higher than in Ireland. It is likely that badger ecology in N. Ireland will be more akin to that found in the Republic of Ireland. Also in Ireland significant variations in badger ecology across differing landscapes suggest that a simple single approach may not be universally applicable (Guerrero et al., 2018).

e. Experience in the RoI indicates that culling has been a significant factor in reducing the prevalence of TB in badgers (Martin et al., 2015) and in cattle (Byrne et al., 2014). Despite this, concerns have been raised around the risk of perturbation following the Randomised Badger Culling Trial in England (Donnelly et al., 2007). These observations were subsequently challenged (More et al., 2007). In follow-up analysis it was shown that any measurable perturbation effect quickly waned with a modest overall reduction in bTB in cattle in areas adjoining cull zones after culling had finished (Jenkins et al.,). These authors speculated that the effects of culling which were more modest in this trial compared to the four area trial in Ireland (Griffin et al., 2005) may have been due to the likelihood that in the RoI;

    - land occupier compliance was higher;
    - the use of stop restraints, rather than cage traps, may have allowed a higher proportion of badgers to be captured; and
    - the culling areas were selected to have geographical barriers such as coastline and rivers which would impede badger re-colonisation.

This is further supported by a recent publication using a spatial metapopulation model which provides plausible explanations for the observations that some badger cull interventions have led to measurable perturbation effects while others have not (Prentice et al., 2019). The outputs from this model indicate that culling can be effective at reducing disease incidence and perturbation can be avoided provided there is sufficient animal population reduction sustained over an adequate time period. The authors suggest that there are 'Goldilocks's zones' of intervention where animal reductions are sufficiently high and sustained to allow disease control but avoid the elimination of the species from the area.

f. An alternative to proactive culling is to utilise the Test/Vaccinate/Remove (TVR) model that has been researched in NI. There remains relatively little available information to allow the TBEP to assess this. This research study was not designed to investigate the effectiveness of TVR intervention on bTB in cattle and, as such, the TBEP is unable to recommend this approach as a method for the eradication of bTB at this time.

g. The TBEP puts forward a number of observations/recommendations on this approach:
    - **That the outputs from this research project are published in peer reviewed journals as soon as possible so that the outputs can be assessed internationally by experts in the relevant fields.**
    - **The effectiveness of TVR is largely dependent on the efficiency of badger capture and the accuracy of badger field tests. Therefore, it is essential that an assessment is made of the capture success rate of using cages and of the sensitivity and specificity of the badger side test.**
    - **That ecological outputs from the research study are published which would include the stability of badger eco-systems following modest numbers of badgers removed to provide an assessment of whether there is likely to be any perturbation effect of applying TVR.**

h. It is the view of the TBEP that the best model for how to progress a wildlife intervention, for which information is available, is that which has been applied in the RoI. This assumes that badger ecology and cattle/badger infection interactions are most likely to be similar across the island of Ireland.

    While there is substantial evidence that the wildlife intervention within the RoI has had a significant impact on bTB in cattle, it is clear that, on its own, it is not likely to be sustainable in the medium to long term nor likely to be sufficient on its own to eliminate the risk of transmission between badger and cattle. Evidence from the RoI indicates an overall direction of travel which will ultimately replace badger culling with vaccination. Vaccination has now been demonstrated, under field conditions in the RoI, to confer sufficient protection to allow its use (Gormley et al., 2017). The success of vaccination is predicated on a sufficient proportion of the badger population being free from disease and therefore responsive to vaccination (Aznar et al., 2018). This recent publication indicates that where there is a sufficient reduction of bTB in badgers in the RoI, vaccination becomes a feasible approach to reducing the Reproducibility Ratio of bTB within badgers and between badgers and cattle to below 1. While this is not likely to be applicable within NI at present due to the high badger infection prevalence, any intervention should have as an ultimate goal the replacement of badger culling with vaccination.

i. Deer are noted as being a possible wildlife reservoir of bTB in the RoI. Measures of bTB in wild deer are sparse with evidence suggesting a low carriage rate (Simon More personal communication). Nonetheless, the potential of deer acting as a wildlife reservoir is real. For example they pose a significant challenge to bTB controls in North America where white tailed deer are recognised as a wildlife reservoir of infection in cattle (Palmer et al., 2014). However, the likelihood of transmission between deer and cattle in North America is likely to be greatly increased due to practices to support deer hunting such as wild deer feeding and so findings

in N. America may not be directly applicable to NI. However, given the lack of knowledge it is possible that deer might be a source of infection in certain areas within NI. Therefore, it would be prudent to undertake surveillance to assess what risk wild deer might pose to the NI cattle population to inform how any risk might be mitigated.

j. Taken together and acknowledging the undoubted uncertainties regarding wildlife interventions the TBEP recommends that DAERA;

- **Progress a wildlife intervention strategy based on the experiences of the RoI as we believe that this is the most appropriate model for NI given the broadly similar badger ecology and the evidence that this approach has made a significant contribution to controlling bovine TB within the RoI.**
- **Publish, including in peer reviewed journals, the outcomes from the TVR research project to inform future decisions on wildlife interventions.**
- **In developing a wildlife strategy, ensure that it is sufficiently flexible to take account of emerging evidences to refine and improve the intervention. This includes undertaking sufficient surveillance within and around intervention areas to measure key outcomes of success and identify at an early stage any negative effects intervention might be causing, to allow the rapid instigation of corrective measures, should this be necessary.**

7. THE ROLE OF PRIVATE VETERINARY PRACTITIONERS in THE bTB PROGRAMME

a. Following meetings with PVP representatives, the TBEP acknowledged their frustration and disappointment due to their limited involvement in the bTB eradication scheme whereby their role is confined to carrying out the tests. The TBEP is of the opinion, subject to further training, that PVPs are in a unique position to advise their clients on overall infection control and disease prevention, and they have an important role to play in disease investigation. In his 2018 report, Sir Charles Godfray notes;

"An important part of farmers taking more ownership of the disease is ensuring that they receive the best advice (for example on safe trading practices, on-farm controls and biosecurity) from trusted sources. Existing information available on the web (TB Hub) is very good, though obviously farmers must be motivated to find and make use of it. We believe the role of private veterinarians in providing advice is particularly important and should be supported, taking into account the true costs of its provision for veterinary businesses".

Many veterinary practices are now offering tailor made herd health schemes for their clients, with many veterinary surgeons undergoing specialist training to offer advice so that clients can comply with the requirements of schemes such as CHeCS, Red Tractor and Milksure. They are already involved in the BVD eradication scheme and are advising clients on Johne's Disease and IBR eradication.

The TBEP is of the opinion that a next logical step would be to increase their involvement in a new bTB eradication strategy.

PVPs advise us that increasingly they are experiencing difficulties recruiting staff. The TBEP recognises the issue of availability of large animal vets.

b. From our discussions with representatives of PVPs, the TBEP concludes that the existing relationship between themselves and DAERA could be much improved with the following simple changes:
    - providing better communication channels e.g. the TBEP understands that information regarding the final interpretation of results is rarely conveyed to PVPs;
    - opening up discussions to relieve bottlenecks to ensure smooth and efficient working practices e.g. short notice rearrangement of bTB tests; and
    - acknowledgement of their concerns regarding certain aspects of the management of the scheme e.g. application of certain KPIs and some appeals procedures.

    Both PVPs and DAERA representatives have spoken, at different times, of a "them and us" mentality which is at variance with the need for the paradigm shift in attitude from all stakeholders which was recommended in the TBSPG report. There is a perception among PVPs that DAERA staff are not subject to the same contractual obligations e.g., KPIs and Service Credits, as they are. The TBEP is of the opinion that there should be greater transparency with regard to the productivity and KPI achievement of DAERA staff in order to benchmark comparable standards. This could contribute to cultivating a much-improved relationship.

c. With regard to DNA tagging of reactor animals, whilst not mandatory at the moment, PVPs advise that they foresee difficulties when it becomes a requirement. During a pilot scheme run by two veterinary practices several years ago, it was found that the extra time taken to carry out the DNA tagging, and associated documentation adversely affected the ability to maintain an efficient schedule of work leading to problems with timekeeping and maintaining KPIs. The equipment available was not suitable for taking a sample from a mature animal, which could pose Health and Safety concerns.
    - **The TBEP recommends that these matters are addressed prior to the implementation of DNA tagging.**

8. COMMUNICATIONS

a. The TBEP is cognisant that many of these decisions will be Ministerial, but we feel that more progress could have been made on this aspect of the recommendations since the launch of the TBSPG report in 2016 and the TBEP recommends that DAERA address this as a matter of urgency.

    The TBEP notes that the English and Welsh authorities have dedicated websites, TB Hub and Cymorth TB, to advise and inform herd owners on best practice regarding prevention and control of bTB within their herds.

    In Wales, specially trained PVPs, subcontracted to the Delivery Partners, are visiting infected farms to give support and advice on minimising the impact and helping the herd owners to understand the risks associated with the disease.

In England, the TB Advisory Service has trained PVPs who can carry out farm visits and offer advice specific to that particular farm. Their TB Hub has details of help lines, practical guidance, up to date information on movement controls, epidemiology, compensation and much more. Some of these details are available on the DAERA website but are more difficult to access.

In the ROI funding is provided via the Knowledge Transfer Scheme in order to allow PVPs to provide free advice to herd owners on control and prevention of a number of diseases including bTB.

- **The TBEP recommends that Northern Ireland should also have a separate dedicated website which should be more user friendly and provide a positive step in the education of herd owners. One mechanism that could be considered is the NICS MyNI.life platform.**

b. The TBEP believes that the Biosecurity Questionnaire currently in place is not conducive, in its current form, to achieving the aim for which it was originally intended and needs to be changed. Feedback from PVPs would indicate that most herd owners do not answer objectively and often ask the PVP what they should say. The TBEP's view is that it doesn't stimulate discussion on biosecurity (infection control) and is seen by many as a box-ticking exercise.

- **The TBEP recommends that a more holistic approach be taken to "infection control", similar in style as is done in GB and the ROI, to advise on the management and avoidance of situations which have the potential to lead to the introduction of any infectious disease including bTB. A "risk assessment audit" would be of great benefit to all herd health plans which are increasingly being carried out by PVPs for their clients.**

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