Review of Science and Epidemiology – Northern Ireland's Bovine Eradication Programme proposals by the Tuberculosis Strategic Partnership Group (TBSPG)

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Context and approach of the TB Strategic Partnership Group

The TB Strategic Partnership Group (TBSPG) was established by the then Minister of Agriculture and Rural Development, Michelle O'Neill MLA, in September 2014 with the inaugural meeting of the TBSPG taking place on 7 November 2014.

The TBSPG operates independently from the Department, although the Chief Veterinary Officer and the Director of Animal Health and Welfare Policy Division are *ex officio* members of the Group. The Chair of the Group, Mr Sean Hogan, is independent, as are the external members of the group consisting of two former Presidents of the Ulster Farmers' Union, Mr John Thompson and Mr Campbell Tweed plus two experts in the scientific and veterinary fields, Dr. Cecil McMurray and Dr George McIlroy.

Specifically, the TBSPG has been tasked to act in the public interest to: develop a long-term strategy to eradicate TB; produce an associated action plan to implement the strategy; provide advice on how the strategy can be delivered and outcomes achieved; and engage with a wide range of stakeholders and gather evidence to support their final recommendations.

Throughout the TBSPG's deliberations, extensive evidence was gathered through a number of mechanisms including receiving direct evidence on the science and epidemiology of the infection, reviewing extensive published information in the peer reviewed scientific literature and through direct contact with various personnel and TB veterinary and scientific experts to clarify and elaborate on issues as they arose. This was especially pertinent in other jurisdictions where similar epidemiological factors exist and disease eradication was positively progressed. This work will be referred to throughout this review and the associated annexes.

The TBSPG met with the ARD Committee in June 2015 and subsequently published their Interim Report. This was followed by a public consultation exercise, which ended in September 2015. Following on from the responses received from this consultation exercise and the extensive evidence gathering carried out to date, the TBSPG have developed a series of draft recommendations within seven distinct thematic areas to directly address the task of eradicating TB from the cattle population in Northern Ireland.

Several separate pieces of work have been commissioned by the TBSPG to analyse the likely financial/economic and behavioral impacts of the draft recommendations developed by them. It was also identified that, in order to properly assess the overall impact of the draft recommendations, an epidemiological/scientific analysis of the likely impact on overall infection trends will also be required. Both Dr McIlroy and Dr McMurray have had extensive experience of TB issues prior to appointment on the TBSPG.

Therefore the TBSPG decided that this piece of work would be undertaken by Drs. McIlroy and McMurray, assisted by independent experts and with the final product being reviewed by an independent academic with a detailed, practical knowledge of TB eradication programmes.

Introduction

The purpose of this report is to review relevant TBSPG Recommendations from a scientific/epidemiological perspective to assure the scientific basis for the Recommendations and their potential impact on infection levels.

We have assessed the recommendations contained in three thematic areas namely;

- 1) Tools and Processes (Annex A)
- 2) Wildlife and Vaccination.(Annex B)
- 3) Farm Practice and Biosecurity. (Annex C)

These are the thematic areas that relate to epidemiological principles and will exert the most direct influence on infection levels. The other thematic areas, for example governance and finance & funding, will be critical parts of the Group's final report and to the success of the eradication programme, but they cannot be individually assessed from a scientific /epidemiological perspective and are therefore beyond the scope of this review. However, they are taken into account in the evaluation of the potential effectiveness of the implementation of the full package of recommendations.

Based on available evidence the review process has enabled:

- I. The assurance of the accuracy and validity of the available scientific evidence base and rationale for each recommendation.
- II. The estimation of the overarching impact of implementation of all the report's recommendations; a "do nothing" option (no government testing or bTB programme; and a "Status Quo" option (maintenance of the current programme to tackle the infection). The TBSPG will not accept selective implementation of its recommendations as that will not lead to eradication of the disease within a meaningful timescale. Therefore, there has been no consideration of partial implementation of the TBSPG recommendations. The TBSPG does, however, acknowledge that there may be an inescapable time lag before all the recommendations can be fully implemented and this has to be taken into account when considering the timing of the discernible impact.

About the authors

Both Dr McIlroy and Dr McMurray have had extensive experience of TB issues prior to appointment on the TBSPSG. Background information on both can be found at below.

DR GEORGE MCILROY MVB, MSc, PhD, MRCVS, FIFST, FloD, FInstLM



Background

Dr George McIlroy has been a Board Member of the Northern Ireland Fishery Harbour Authority since April 2012, where he is Chair of the Stakeholder Committees for Northern Ireland's three fishing ports. He has been a Trustee and Board Member of the National Museums Northern Ireland since December 2013 and is also a Board Member of the Western Health and Social Care Trust since December 2015. He is a former Chief Executive and Accounting Officer of the Agri-Food and Biosciences Institute, a former Chief Scientific Officer/Deputy Secretary and Deputy Chief Veterinary Officer, responsible for Veterinary Policy, in DARD. Previously, he was Head of Epidemiology at the Veterinary Science Laboratory, Stormont.

Dr McIlroy also has ten years experience working on Boards in the private sector, as Group Veterinary/Technical Director of two large international companies in the Agrifood Industry. He volunteers as a member of Board Committees of the Institute of Food Science and Technology and with the charity Tearfund, as a member of the Business Development Group and a long-standing volunteer.

DR CECIL MCMURRAY C.B.E. (FRSC, FIFST, PhD, BSc, BAgr, C Chem)



Background

Dr Cecil McMurray C.B.E has been a Member of the Northern Ireland Food Chain Certification (NIFCC) Committee since February 2003 and a Member of the Agri-Food and Biosciences Institute (AFBI) Board since March 2012. He has been the MD of Sci Tec Consultancy since July 2003, providing consultancy advice locally and internationally, including to the European Commission and World Bank. Until December 2013 he was the Chair of Defra's TB Diagnostic Advisory Group and also a Member of Defra's Bovine TB Scientific Advisory Body. He is a former Chief

Scientific Officer for DARD/DANI, where he also held senior veterinary research positions. He is a former Head of the Food and Agriculture Chemistry Department in the Faculty of Agriculture at Queen's University. He has held research positions at Harvard University and the University of Bristol, and was a Member of the Governing Body of the Rowett Research Institute in Aberdeen. He was also a Member of the Management Board responsible for the establishment and early management of Northern Ireland Co-operation Overseas (NI-CO). He is an Honorary Member of the Northern Ireland Veterinary Association. In 2002 he received a C.B.E. for Public Service.

Methodology taken for this review

As previously outlined, TBSPG has gathered a significant volume of evidence and opinion from a wide range of sources.

This information has been distilled into the recommendations that will be in the TBSPG's final report.

The recommendations are each supported by a description of the issue, rationale for change, evidence, detail, impact and time line.

The recommendations and supporting material are included in this review document. Each recommendation in the three Thematic Areas included in this review has been reviewed from a scientific and epidemiological perspective.

The supporting evidence has been scrutinised to ensure that it is appropriate and as up to date as possible.

The evidence base for this review is all retrospective and based on evidence within the public domain or made accessible confidentially to the TBSPG during its evidence gathering.

No prospective data modelling was undertaken solely for the purposes of this review. The recommendations have been assessed to ensure that they are proportionate, scientifically and epidemiologically justified and represent the best approach, in the public interest, to enable the eradication of the infection.

The impact of the implementation of the recommendations <u>in full</u> has been projected, based on available evidence and data referring to international experience.

'Do nothing' and 'status quo' options have also been assessed for comparative purposes.

As explained in the introduction, partial implementation has not been considered in this review and furthermore, there is little evidence (nationally or internationally) that could help to quantify the relative impact of the different cattle interventions on an individual basis. Furthermore, there is no existing methodology to determine their individual impact and isolate this from that which would be achieved as an integral part of a package of mutually dependent recommendations.

It is clearly not feasible to implement all recommendations from the start so a staged implementation has been taken into account in the review.

TBSPG looked for relevant examples of programmes that have shown significant decline in incidence and for which data was available. The programmes in the Republic of Ireland and New Zealand have been closely examined and data used to analyse progress in their programmes.

It should be emphasised, as outlined above, that it has not been possible to separate the cause and effect relationships between the different components of existing eradication programmes as these programmes were and are fully integrated in such a way that quantification of the discrete contribution of the individual components is impossible.

This is just the start of a journey. It is anticipated that the products of this review will provide the starting point for progress to be measured against expectations. It will be an ongoing process to review targets, review progress, identify reasons for variance and adapt the programme accordingly.

Assessment of likely impact of bTB control options

i. Do nothing option.

This option refers to the removal of all compulsory field cattle control measures and would, in theory, return Northern Ireland to the situation prior to the introduction of the compulsory bTB eradication scheme in 1959. Previous to its introduction, a voluntary bTB eradication scheme was in place from 1949 but even with this, an estimated 2000 tonnes of meat was condemned due to bTB and a 10% reduction in milk yields in infected animals was suggested (Robinson, 2015). During the 1940s, there was an average of more than 400 clinical bovine cases detected and the dairy cow animal incidence was estimated at 33% (Robinson, 2015). This was during a period when the total cattle population in Northern Ireland was approximately half of present cattle numbers and much less intensive cattle management systems were in place.

Current meat hygiene inspection processes and the continuation of pasteurisation of milk would continue to effectively protect the vast majority of the human population from any increased zoonotic threat posed by increases in bTB incidence in cattle. However, there would be a potentially serious increased risk to those working in close contact with cattle or those that continue to consume unpasteurised milk. Some measures could be instigated in an attempt to minimise this risk e.g. BCG vaccination, bulk milk or cattle testing on risk farms.

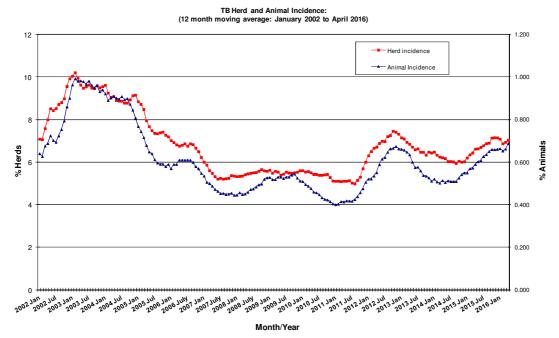
Although the impact on human health may be marginal if live cattle bTB testing was stopped, such a step would threaten export markets. The Northern Ireland cattle industry relies heavily on its trade in meat and milk as well as live cattle movements for its economic viability. Indeed, the threat of Britain prohibiting cattle exports from the island of Ireland was a main driver for the instigation of the compulsory bTB eradication scheme both north and south of the border.

Under the European Directive 64/432 (as amended), each country is required to implement a bTB eradication programme as outlined in this Directive. As the UK is leaving the EU it will most likely have to negotiate trade arrangements and the incidence of bTB and the level of controls applied are very likely to be a factor in negotiations. Similar international bTB control standards are also set out in the OIE (World Organisation for Animal Health) Terrestrial Animal Health Code that permits trade to occur between countries. Failure to meet these standards again would ultimately prevent international trade occurring. This may be obviated to an extent if Britain continued to accept beef and milk from Northern Ireland as they are our main customers. However, such trade would be at the mercy of the supermarkets and their customers which is outside of any legislative control. Moreover, there would be an effect on cross-border trade and would probably tarnish the 'green' imagine currently portrayed of the island of Ireland. It would also affect the 'Fortress Ireland' animal health message that has been relayed by our politicians over recent years. Climatic conditions in Northern Ireland favour grass production over most of the country and it is difficult to see how a proportion of the cattle industry could be replaced with other enterprises in the short to medium term, if there was the expected downturn in cattle trade.

Given the above impacts, it is difficult to see in qualitative terms how the agricultural industry could adapt and survive a reversion to the do nothing option.

ii. Status quo option

The current bTB eradication programme is effective in that it is approved by the European Union (EU) and meets OIE standards allowing trade to continue across the EU and further afield as other countries cannot boycott meat, milk and cattle movements while approved animal health standards are being met. While the current programme meets all the required standards and meets the primary objective of maintaining open trading routes, there is no evidence that bTB eradication is achievable with the current programme and the infection incidence staying fairly level over the last decade (see figure below).



The reason for lack of progress is unclear, despite attempts to establish why including a review conducted by the NI Assembly Agriculture Committee, Anon, 2012).

Although the current bTB eradication programme does allow for free trade and attracts an EU co-funding of £4-5 million annually, the cost of its implementation is substantial (approaching £30 million annually). All of this cost and most of the infection risk is a burden to the tax payer and with ongoing increasing financial pressures and lack of progress towards eradication, it is not acceptable to maintain the *status quo*. Therefore acceptance of a *status quo* would result in an ongoing annual control programme *ad infitinum*, which would not be in the best public interest or value for money for the public purse.

Although there may be an economic argument for this option, it may be a risky option politically in the future given the small proportion of the population that are actually involved in the agricultural industry and considering other financial pressures on the public purse. Variations on this *status quo* model do exist where cost sharing options other than solely from the tax payers' pocket could be considered. However, in the short to medium term, such a fundamental change does not appear to be likely unless there is a total revamping of the bTB eradication programme.

In addition we are aware that our bTB status will be under the spotlight and may have implications for trade with EU countries post BREXIT.

i. Implement TBSPG recommendations in full

Assessment of potential effectiveness of full recommended package of recommendations

TBSPG have made a series of recommendations which, in their view, should lead to significant reductions in bTB incidence in Northern Ireland. These recommendations relate to the following thematic areas: Farm practice and biosecurity, tools and processes, Wildlife and Vaccination, Governance, Culture and Communication, and Finance, funding and compensation. For the purposes of this assessment, we focus on the potential impacts of Farm practice and biosecurity, tools and processes, Wildlife and Vaccination only as they relate to epidemiological principles.

There is limited evidence for the impact of integrated packages to control and eradicate bTB internationally. There are some examples of bTB problems in domestic hosts where wildlife are implicated, for example white tailed deer in Michigan (O'Brien et al. 2006), buffalo, lions and other wildlife species in South Africa (Michel et al. 2006), however there are only a few examples of where integrated programmes are/were successfully implemented to eradicate infection (namely, Australia (Radunz 2006), New Zealand (Livingstone et al. 2015) and the Republic of Ireland (Sheridan et al. 2014).

Australia successfully declared freedom from bTB in 1997, after a coordinated programme starting in 1970 (a 27 year program in total; More et al. 2015). Despite official freedom declared, Australia still maintains sensitive surveillance systems at abattoir and strict risk management of potentially exposed hosts (Radunz 2006; More et al. 2015). There was no wildlife reservoir per se in Australia, however there was a feral population of water buffalo (and cattle) which were bTB infected during the eradication program which had to be managed alongside domestic cattle herds (Radunz 2006; More et al. 2015). The TBSPG were cognisant of the achievements made in Australia, and referred to the reviews of Radunz (2006) and More et al. (2015), however, for this exercise it was decided that New Zealand and the Republic of Ireland were used as international comparators for the impact of an integrated eradication program. The reasons for this were based on: 1. The presence of a wildlife reservoir of infection (the possum in New Zealand (Roberts 1996); the badger in Republic of Ireland (Griffin et al. 2005); 2. Similarities in terms of production and landscape types; 3. Both Republic of Ireland (e.g. Sheridan 2011, McGrath et al. 2014) and NZ (e.g. Livingstone et al. 2015; Hutchings et al. 2013) have long standing ongoing programmes which are showing strong signs of success. 4. Senior members of their teams (Dr. Margaret Good, pers. comm. Republic of Ireland; Dr. Paul Livingstone, pers. comm. NZ) were prepared to share their long-term data sets which permitted analysis of their progress with disease control (see below), which is used here to assess the likely impacts of an integrated eradication program.

For the purposes of this assessment, eradication in the context of this paper is the ability to achieve the EU target for freedom "the percentage of bovine herds confirmed as infected with tuberculosis has not exceeded 0.1 % per year of all herds

for six consecutive years and at least 99.9 % of herds have achieved officially tuberculosis-free status each year for six consecutive years, the calculation of this latter percentage to take place on 31 December each calendar year". Current trends in bTB levels in Northern Ireland suggest eradication is not achievable under the current scheme (see 'status quo' option above), and hence why an integrated programme is required.

Time to eradication

It is not possible to use either exemplar country to estimate time to freedom, as official freedom has not been achieved in either country. However, given the data from the Republic of Ireland and New Zealand, statistical projections can be made using as few assumptions as possible. New Zealand is close to official bTB freedom (under the definition used here of 0.1% herd incidence), with herd prevalence of <0.2% being reported in 2011-2012 (Hutchings et al. 2013; Livingstone et al. 2015). Future strategic planning for vector (possum) disease eradication is planned over an additional 15 year time-line (Hutchings et al. 2013). Livingstone et al. (2015) outlines the history and development of the New Zealand integrated program, and highlights that renewed coordinated possum control program was implemented from 1987/1990 onwards, which is reflected in the associated costs shown in figure 1 below. Taken this period as the start of the integrated eradication program, the incidence of bTB showed a general increase followed by a significant decrease. Therefore, the period to reach incidence levels reaching <0.2% took **25-30 years in** New Zealand. Because of the long-tail of this decay curve (exponential time to eradication) it is likely the eradication may take a number of years further of strict controls (Livingstone et al. 2015).

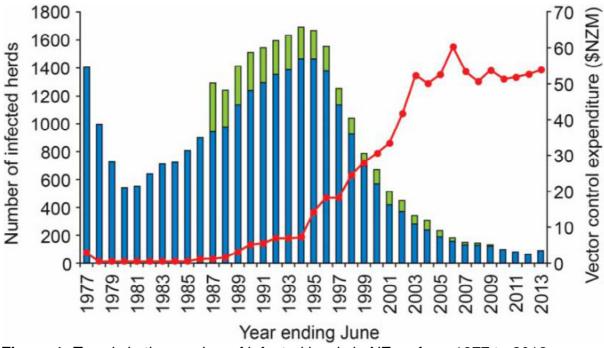


Figure 1: Trends in the number of infected herds in NZ up from 1977 to 2013

Data on the progress of the bTB progress in NZ have been provided (under an Operational Solutions for Primary Industries (OSPRI) confidentiality agreement) and

presented below, with additional analyses (by Dr. Cecil McMurray). The data covers various aspects of the NZ TB Control programme and each parameter is in three parts: a. VFA data refers to data from herds in the vector free area – where there is a low level of infection. b. VRA data refers to the vector restricted area i.e. where the vectors are not yet under control. c. Pooled data covering (VFA plus VRA data) i.e. the totality of the NZ TB control programme. The graphs below relate to the long term NZ bTB datasets; from 1991/92 the methodology changed with the introduction of two distinct areas depending on the presence or absence of disease vectors.

Figure 1 demonstrates that the NZ program since 1977 has had two peaks in infected herd numbers in 1977 (n=1402) and 1995 (n=1463). Considering the integrated programme was established from around 1987-1990 onward, the graph shows that there was an initial increase in reactor herds, during which infection was being detected and cleared from herds and surrounding wildlife. The benefits of the programme were detected in global trends after 1995. At the animal level, the highest detection rate (per 10000 animals tested) was found in 1991, before the decline.

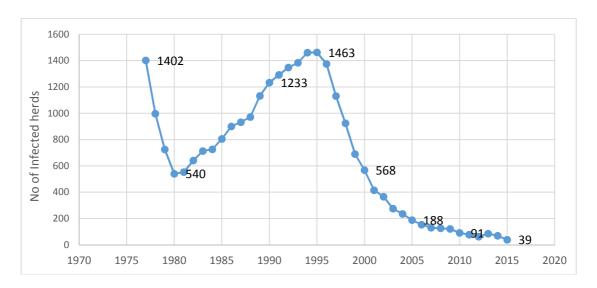


Figure 2: Long-term trend in the number of bTB infected herds in NZ (1977-2015).

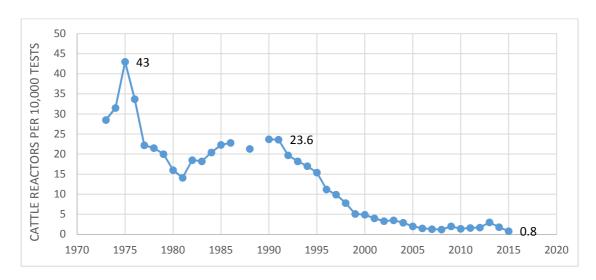


Figure 3: Long-term trend in the number of cattle reactors per 10,000 tests in NZ (1973-2015).

In the analysis presented in figure 4, it is clear that linear regression analysis is of limited value when using the raw data, and more importantly, is best analysed following logarithmic conversion i.e. an exponential decay reflecting the current advanced state of disease control in New Zealand.

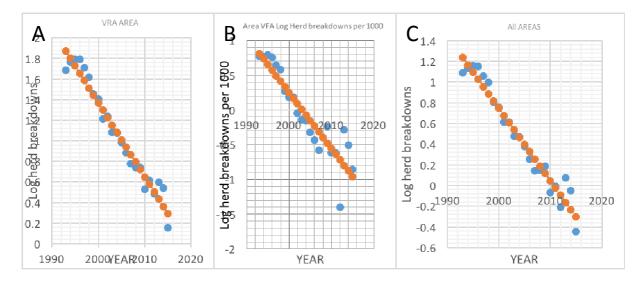


Figure 4: Data on the herd breakdowns in New Zealand over time, where the number of breakdowns has been log-transformed to meet the assumption of a linear regression. The following graphs display the data in two colours – blue dots are the raw data while red dots are the fitted data derived from the linear regression analysis. A. VRA area only. B. VFA area only. C. All areas.

Table 1: Associated linear regression outputs from models presented in figure 4.

DATA	R	SLOPE	SE	INTERCEPT	SE
	Squared				
ALL	0.955	-0.070	0.003	140.766	6.655
VFA	0.841	-0.081	0.008	161.489	15.316
VRA	0.962	-0.072	0.003	145.259	6.242

The log-transformed linear regression parameters for combination of the two control areas (VFA & VRA) combined is presented in figure 5 below. This chart indicates a log decay in the number of infected herds over time, with the following linear equation: log(No. of infected herds) = -0.07434*(YEAR) + 151.423. Assuming this log-linear exponential decay, NZ should approach freedom from disease towards 2030. This indicates a total period of sustained controlled of approximately **40 years**.

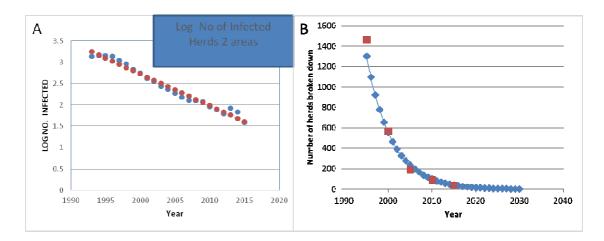


Figure 5: Data on the herd breakdowns in New Zealand over time, where the number of breakdowns have been log-transformed to meet the assumption of a linear regression (A) and the back-transformed data to project estimated number of herd breakdowns up to 2030 (B).

Figure 6 shows the trends in detected animal infection levels in Republic of Ireland since 1965. Significant progress has been recorded in recent years, coinciding with the most recent policy developments including national roll-out of a wildlife intervention (see Sheridan 2011 and Sheridan et al. 2014 for overview of policy developments in Republic of Ireland). The national wildlife intervention strategy was put into effect from 2002 onwards (Sheridan et al. 2014).

Below we assess the progress made since 1999/2000. There is a clear linear progression since 2000 across multiple indicators (figure 7), with a strong correlation between indicators (Regression coefficients > 0.80 in four of the indictors analysed). The number of reactors fell below the long-term minimum of 23,000 reactors in 2010 (20,211 reactors culled) and has dropped to its historic low of approximately 15,000 in 2015. As the disease control programme appears to be showing such steady progress, if the linear progression is maintained it would be expected that infection would reach the critical threshold of disease control by 2030 which is **30 years** from initiation of the consistently downward progression. Table 2 contains the outcome

from the linear regressions tracking progress across multiple indictors. It should be noted that it is unlikely that disease eradication will follow a linear reduction, as demonstrated in NZ, instead a long-tailed distribution is expected. Given this, the projections should be interpreted with caution, considered best case scenario.

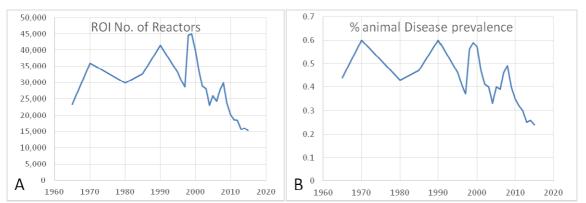


Figure 6: Data on the number of reactors in Republic of Ireland over time from 1965-2015(A) and the animal level disease prevalence (B).

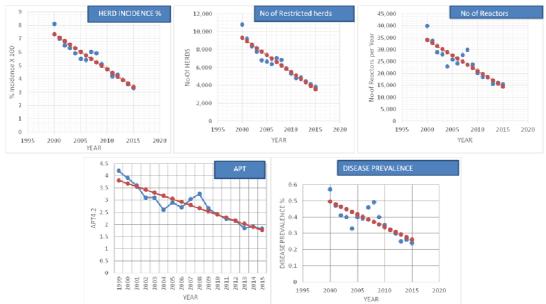


Figure 7: Indicators of disease control progress in Republic of Ireland from 1999/2000 to 2015, including herd incidence, the number of restricted herds, number of reactor animals, the animals testing positive per 1000 (APT), and infection prevalence. Data source: M. Good.

Table 2: Linear regression results for four indicators of disease control progression in Ireland. The projections from the models represent the years with which clearance could be achieved assuming a continued linear decline in prevalence.

CHARACTERISTIC INDICATOR	R²	SLOPE	SE	I'CEPT	SE	Predicted freedom year (assuming linear decline)
Herd Incidence %	0.92	-0.26	0.02	534.98	42.09	2027 - 2028
No. NEW RESTRICTED HERDS	0.91	-385.74	32.89	780807.30	66023.00	2024 - 2025
Number of	0.80	-1304.10	172.24	2642206.00	345763.00	2026 - 2027
REACTORS	0.04	0.00	0.00	04.67	0.07	0001 0000
% INFECTION PREVALENCE	0.64	-0.02	0.00	31.67	6.27	2031 - 2032

It should be noted that it is likely for eradication program to take long periods, as an example it took **40 years** in Sweden to achieve eradication and that was without the complication a wildlife reservoir (Cousins 2001).

Given the experiences of other countries with integrated programs, or who have achieved bTB freedom, we expect the integrated package suggested by TBSPG to approach official freedom in the time-scale of **25-40 years**. Given that a series of interventions are aimed at early detection and removal of infected animals, a lag phase is expected whereby reactor numbers may increase (see figure 1 & 2) at a temporal scale of **4-5 years** (given data from NZ). However, we expect the epidemiological benefits of this will accrue thereafter.

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Evidence base for intervention suites

Annexes A, B and C outline the recommendations being made by TBSPG, and their associated the issues, the evidence and the impact of each proposal.

Annex A is related to Tools and processes thematic area.

Annex B is related to Wildlife and vaccination thematic area

Annex C is related to the Farm practice and biosecurity thematic area.