Department
for Environment
Food & Rural Affairs

Bovine Tuberculosis Evidence Plan

Policy portfolio: Animal Health and Welfare: Disease Control

Policy area within portfolio: Bovine TB

Timeframe covered by Evidence Plan: 2013/14 – 2017/18

Date of Evidence Plan: March 2013

This evidence plan was correct at the time of publication (March 2013). However, Defra is currently undertaking a review of its policy priorities and in some areas the policy, and therefore evidence needs, will continue to develop and may change quite rapidly. If you have any queries about the evidence priorities covered in this plan, please contact StrategicEvidence@defra.gsi.gov.uk.

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1. Policy context

What are the key policy outcomes for the policy programme/area?

Bovine tuberculosis (TB) is a pressing animal health problem. It is predominantly a disease of cattle but can affect a range of species including man. Bovine TB is a statutory disease and is subject to a compulsory control scheme based on tuberculin skin testing, slaughter of animals that test positive ('reactors') and movement restrictions placed on herds/farms where those animals are found, meat inspection and milk pasteurisation. TB control has been hampered by the presence of a significant reservoir of the disease in badgers in parts of England and Wales and the fact that current diagnostic tests are not sufficiently sensitive to detect all infected cattle in a herd.

The incidence rate of bovine TB in cattle in England and Wales has been rising for 25 years and has worsened since the 2001 Foot and Mouth Disease outbreak, but the incidence in Scotland has remained relatively low and stable. The area with a relatively high incidence of bovine TB has spread geographically from isolated pockets in the late 1980s and now covers large areas of the West and South West of England and Wales. Additionally, there has been an increase in the severity of disease in the areas which were traditionally affected by bovine TB. In 2012, there were over 5,100 recorded new incidents of TB and over 38,000 cattle were slaughtered in GB for TB control reasons. The average cost of a TB herd breakdown has been estimated at £30,000 (approximate 2/3rds of which falls to Government and 1/3rd to farmers). This does not include non-monetary costs, for example emotional stress experienced by the farmer. Routine surveillance tests detect the disease early so few animals develop clinical disease and therefore the welfare consequences of disease in cattle are negligible, although there can be indirect welfare consequences as a result of a TB herd breakdown e.g. overstocking due to movement restrictions.

While milk pasteurisation means that transmission of *M. bovis*, the causative agent of bovine TB, to humans is rare, there are a very small number of cases each year associated with the consumption of raw milk. Current surveillance to remove infected cattle at an early stage curtails the course of disease in individual cattle and reduces the risk of transmission from this primarily airborne disease to humans. In 2012 the Food Standards Agency (FSA) commissioned the Advisory Committee on the Microbiological Safety of Food (ACMSF) to review the potential public health risks associated with the consumption of meat, milk and milk-products from *M. bovis* infected cattle, which concluded that the risks to consumers in the UK remained very low and existing control points were adequate despite the increasing prevalence of infection in cattle.

The cost to Government of controlling bovine TB in England, Wales and Scotland was over £100million in 2011/12. These costs are rising year by year so there is a strong case for early effective action to turn this around. The Animal Health and Welfare Board for England (AHWBE) has therefore made the eradication of bTB in England one of its key

outcomes. The farming industry and Government need to work in partnership to achieve eradication of bTB (Officially TB free status) which would provide the following benefits:

Protect and promote the health and welfare of farmed animals;

Meet international (in particular EU) and domestic legal commitments and maintain the UK's reputation for safe and high quality food;

Maintain productive and sustainable beef and dairy sectors by securing opportunities for international trade and minimising environmental impacts;

Reduce the cost of TB to farmers and taxpayers; and

Protect the health of the public and maintain public confidence in the safety of products entering the food chain.

While eradicating bovine TB is the long term goal, additional measures are needed now to stop the disease spreading and to start to reverse the rising trend. The Coalition government in England committed, as part of a package of measures, to develop affordable options for a carefully-managed and science-led policy of badger control in areas with high and persistent level of bovine TB. The consequent policy for badger control, which allows groups of farmers and landowners to apply for licences to cull badgers subject to certain strict criteria, was announced in December 2011. The policy is due to piloted in two areas in summer 2013. Defra are also continuing to fund a four year Badger Vaccine Deployment Project, which has provided a platform for the training of lay vaccinators and assessment of the cost and practicality of using the badger vaccine. Bovine TB is also a high priority for the Welsh Government, which has decided to pursue a badger vaccination policy in line with its new Strategic Framework for Bovine TB Eradication.

There is no single solution to tackling bovine TB – we need to use every tool in the toolbox. Measures aimed at tackling transmission of the disease between cattle will continue to be central to the bovine TB control strategy and need a comprehensive and balanced package of measures to tackle bovine TB. This strategy will include measures to find and control the disease in cattle, measures to control the disease in badgers and focused research and development to continue to increase our understanding of the disease and develop new tools which could be deployed in the field.

Policy Objectives – Prevent spread of bTB to new areas; continue to eliminate TB quickly when it occurs in a low risk and incidence area; and bear down on bTB in high risk areas.

Intended Outcomes – Avoidance of agricultural production losses; delivery of reduced costs to the tax payer for TB surveillance, compensation and control; delivery of social and economic benefits to farmers, farming families and rural communities and economies by reducing the impact on farm businesses and ensuring freedom to trade; avoidance of human health impacts and associated costs; increased appreciation and investment in farm husbandry and bio-security measures by the industry; and improvements to the

credibility of the bTB surveillance and control programme in England and Wales leading to improved partnership with industry and the EU.

2. + 3. Current and near-term evidence objectives and Future evidence needs

What are the current and near-term objectives for evidence and how do they align to policy outcomes?

The objectives of the bTB research programme in the short and long term are as follows

Evidence objective	Current and near-term evidence objectives	Future evidence needs
Vaccination	High- The licensing of Bacillus Calmette-Guerin (BCG) vaccine for use in cattle (the Marketing Authorisation for which is currently being scrutinized by the Veterinary Medicines Directorate (VMD)) and the validation of an associated test to differentiate infected from vaccinated animals (DIVA)). Use of cattle vaccination will also require acceptance by the EU. While those negotiations are outside the scope of evidence, further research and development will be required to support the case for acceptance of this control measure e.g. data from its use under UK field conditions. High - The development and licensing of an efficacious oral vaccine for badgers that is inexpensive to deploy (relative to the already licensed and available injectable vaccine), and development of strategies for using this in the field.	Medium - A vaccine which does not cause cattle to react to the tuberculin skin test, also called a non-sensitising vaccine. Medium – Evidence on the effect of badger vaccination on cattle TB incidence.

Diagnostics	High - In order to control bTB more sensitive and specific cattle tests are required, particularly a DIVA test that can distinguish between an infected and vaccinated animal to accompany the BCG-based cattle vaccine, as described above, validation of which may require additional data from the field. Medium - An improved method for detecting *M. bovis* in samples taken at slaughter from reactor animals (animals that have tested positive to the skin-test). High - There is also a need to improve the sensitivity and reliability of available surveillance tools to detect infected cattle, such as monitoring and improvement of slaughterhouse surveillance, moving away from tuberculin based skin and interferon-gamma tests, and improving post-mortem culture techniques.	High - An alternative to the skin test that is cheaper and/or better and acceptable to other countries for trading purposes, e.g. use of DIVA antigens. Medium - Sensitive and practical badger diagnostics to allow us to assess the geographical scale of the wildlife reservoir and make informed judgements in applying control methods. This includes both non-invasive tests to identify infected badgers, e.g. work to develop more sensitive diagnostics and development of non-invasive blood sampling devices, and tests to identify setts/areas where infected badgers are resident, e.g. further development of Polymerase Chain Reaction (PCR) tests to detect *M. bovis* in environmental samples.
Epidemiology	High - There is a continuing need to improve our understanding of the epidemiology of the disease and the interaction within and between cattle and badgers. This includes the development and use of mathematical models, to inform the development, application, assessment and review/evaluation of TB policy control tools. High - Field epidemiology also needs to be strengthened to improve incorporation of local information into the national picture of the epidemic. Medium - Work is also required to identify other methods of monitoring and controlling the epidemic, e.g. improved genetic analysis/spoligotyping of isolates and understanding the genetics of resistance in cattle. Work is also underway to develop risk	High - How can we best measure and evaluate the effect of the many different interventions on bTB. Medium - Determining the relative rates of transmission from cattle to badgers and badgers to cattle, and how does this vary across the country.

	based surveillance methodologies to optimise the deployment of resources to monitor the epidemic.	
Wildlife reservoir	High - A better understanding of the wildlife reservoir and identifying what the key routes of transmission between badgers and cattle are and how they can be reduced through improved biosecurity. Medium - Understanding changes in badger numbers in recent years and estimating the effect of low level perturbation on disease transmission.	Medium - Development of non-lethal forms of badger control e.g. immunocontraceptives. High - Development of humane and effective alternative culling methods.
Economics and social science	High - Understanding farmer attitudes to bTB vaccination, barriers and incentives for uptake. Medium - Understanding attitudes to risk-based trading.	High – cross-cutting social science to understand barriers and motivators to bTB controls High - Determining the socio-economic cost of a bTB breakdown. Medium - Improving our estimates of the costs and benefits of different bTB control strategies.

Secondary analysis has and continues to be used in bTB as an alternative to generating new data. This has taken several forms, from research projects focusing carrying our meta-analyses of the bTB diagnostics literature (research project SE3238) to several projects that have been commissioned to analyse different aspects of the Randomised Badger Culling Trial (RBCT) database (research projects SE3239, SE3240, SE3241 and SE3242). In addition several different analyses carried out on the bTB cattle surveillance database under the surveillance contract are secondary analysis.

4. Meeting evidence needs

What approach(es) will be taken to meeting evidence needs?

The approach to meeting R&D evidence needs is guided by standard Defra procedures. Prioritisation and specification of research is determined through discussion with policy colleagues (including Scottish Government & Welsh Government), the independent TB Eradication Advisory Group for England (TBEAG), veterinary advisors, disease experts, the Animal and Plant Health Evidence and Analysis (APHEA) team and livestock industry sector groups as well as being informed by the Veterinary Surveillance Team Risk Management Cycle. More recently, the Animal Health and Welfare Board for England (AHWBE) has also been involved in high level discussions over evidence needs.

Within the bTB programme, evidence priorities are identified through a number of channels, including:

- Ministerial and public interest and concerns over specific bTB issues

- The AHWBE and its sub-group TBEAG are influential in setting the priorities for policy needs that require evidence to be gathered.

- The bTB Science Advisory Body (SAB); this is an advisory group advising Defra both on the scope of its bTB research programme and on the progress of individual projects. The SAB consists of three sub-groups, the Vaccine Programme Advisory Group (VPAG) the Diagnostic Programme Advisory Group (DPAG) and the Epidemiology and Wildlife Risks Programme Advisory Group (EWRPAG).

- Emerging surveillance results from the field are also used to inform future evidence activities.

- Information is also gathered on emerging national and international bTB issues using intelligence gleaned from EU and international contacts, industry stakeholders, NGOs, bTB research scientists and other experts

During the year priorities are identified through the channels outlined above and then meetings are held with members of TB policy, representatives of the devolved administrations (DAs) and evidence specialists. At these meetings evidence gaps are ranked based on short term and long term policy need, scientific likelihood of success, whether they will significantly augment our existing evidence base or help maintain essential scientific capability and the estimated cost of any proposed new research. Where appropriate, policy and science leads may convene to undertake a multi-criteria analysis that allows comparison of research across the programme.

Once identified and prioritised, research needs are procured either through open competition or direct commissioning, with open competition as the default position. All applications are peer reviewed externally complemented by internal expert review regardless of procurement route. Internal expert review engages appropriate policy colleagues, DAs, veterinary experts, scientists and, where appropriate, social researchers

to ensure that all proposed research is challenged for policy relevance in line with government strategic objectives.

R&D projects are monitored by annual reports, site visits and by advisory groups for larger projects that require a greater Defra and/or stakeholder steer. In addition final reports are peer reviewed where appropriate and revised if necessary prior to publication on the Defra web-site. Researchers are also strongly encouraged to publish their results in peer reviewed journals. The goal is to fund high quality scientific research that informs policy decisions. We also work with other funders such as the BBSRC to highlight research topics of mutual interest where joint funding would be appropriate.

All R&D is inherently risky and a balance needs to be struck across the research portfolio between short-term projects to address immediate needs and longer term projects that may answer strategic evidence needs and lay the foundations for short urgent pieces of work to address specific policy requirements. A balance is also maintained between low risk projects, with more limited projected outcomes and more ambitious projects which carry a higher risk of failure, but are consequently more informative and useful if successful. Using independent advice and internal expertise, decisions are taken on how crucial a particular project is and the consequences of a failure to address the issue in question. To mitigate these risks regular monitoring of projects is carried out.

Extensive and regular meetings are held between contractors, the Evidence Team in AHVLA, Defra policy colleagues, DAs and industry stakeholders, to ensure that project results are transmitted and interpreted effectively for use in a policy context. This close relationship also allows feedback of changing policy priorities to the researchers during a project (which can allow for projects to be adjusted if necessary).

Defra engages in a range of international fora for the purposes of information exchange and research coordination and participation in, for example, the European Research Area Network (ERA-Net) and the EU framework programme, has levered significant funds from EU organisations. This has resulted in a total expenditure of approximately €45M of which Defra contributed approximately €5M. This kind of coordinated approach facilitates international collaboration, thereby increasing the availability of expertise from other national research groups and maximising the benefits to individual participants.

5. Evaluating value for money and impact

What approach(es) will be taken to maximise and evaluate value for money and impact from evidence?

The most concrete anticipated deliverables from the bTB evidence program over the next 5-10 years are: a licensed cattle vaccine and validated DIVA test and a licensed oral badger BCG vaccine. However, due to the large number of uncertainties associated with the licensing process and legality of use of the cattle vaccine and scientific challenges faced with the development of the oral badger vaccine, we cannot say with any certainty if and when these products will become available. In particular, the development of the cattle vaccine and DIVA test is contingent on the effectiveness of the BCG vaccine in trials and on negotiations with the EU regarding what evidence is required to validate a DIVA test and allow vaccination of cattle.

R&D will be procured according to the Evidence Handbook and is subject to internal expert input and external peer review that provides an independent scientific challenge.

An effective multi- and inter-disciplinary approach to fulfilling evidence needs is ensured through use of relevant expertise, advisory bodies and collaboration with other funding bodies, both in GB and externally. There is also increasing engagement internally with teams such as Animal and Plant Health Evidence and Analysis (APHEA) team, which offer expertise in economic analysis and social science advice. This alongside external peer review ensures robust and high quality evidence.

Value for money (VFM) will be ensured through peer review of all project proposals (VFM is a specific question we ask peer reviewers to consider) and close monitoring of projects to ensure they do not drift off course. Also that those carrying out research can, when feasible, adjust projects mid-stream in the light of new findings and/or policy priorities.

Value for money is also ensured where possible through co-funding with the animal health industry or other UK research funders (e.g. BBSRC) and more recently with other European Member States and such strong links with other funders enable leverage of funds where possible.

Project specific dissemination strategies are developed at the start of every project to ensure effective communication including how the evidence generated from the work will be used by policy, how stakeholders will be involved and how knowledge will be retained and promoted. Each project is also evaluated once completed with regard to its delivery, timeliness and policy impact, either through internal or external review.

Policy objectives are regularly tested through discussions with internal and external stakeholders (through expert groups). European and international institutions, other Government Departments and Devolved Administrations are also used to inform policy development and implementation.

The evaluation of evidence in Defra is an important and ongoing activity at project level and contributes toward ensuring that good quality, robust evidence is used to underpin

departmental policy[1]. Evaluating the impact of evidence on policy development is complex and often only possible over the long term. Evaluation will necessarily be linked to Defra's Evidence Investment Strategy, which provides a strategic overview of how evidence fits with Defra needs. Programme level evaluation to assess the impact of evidence on policy will be explored (depending on available resource) following publication of the new Evidence Investment Strategy. It will be important that evidence currently being explored will have time to make an impact and for any new direction emerging from the new Evidence Investment Strategy to be tested and incorporated.

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[1] http://archive.defra.gov.uk/corporate/docs/policy/evidence-policy-report.pdf