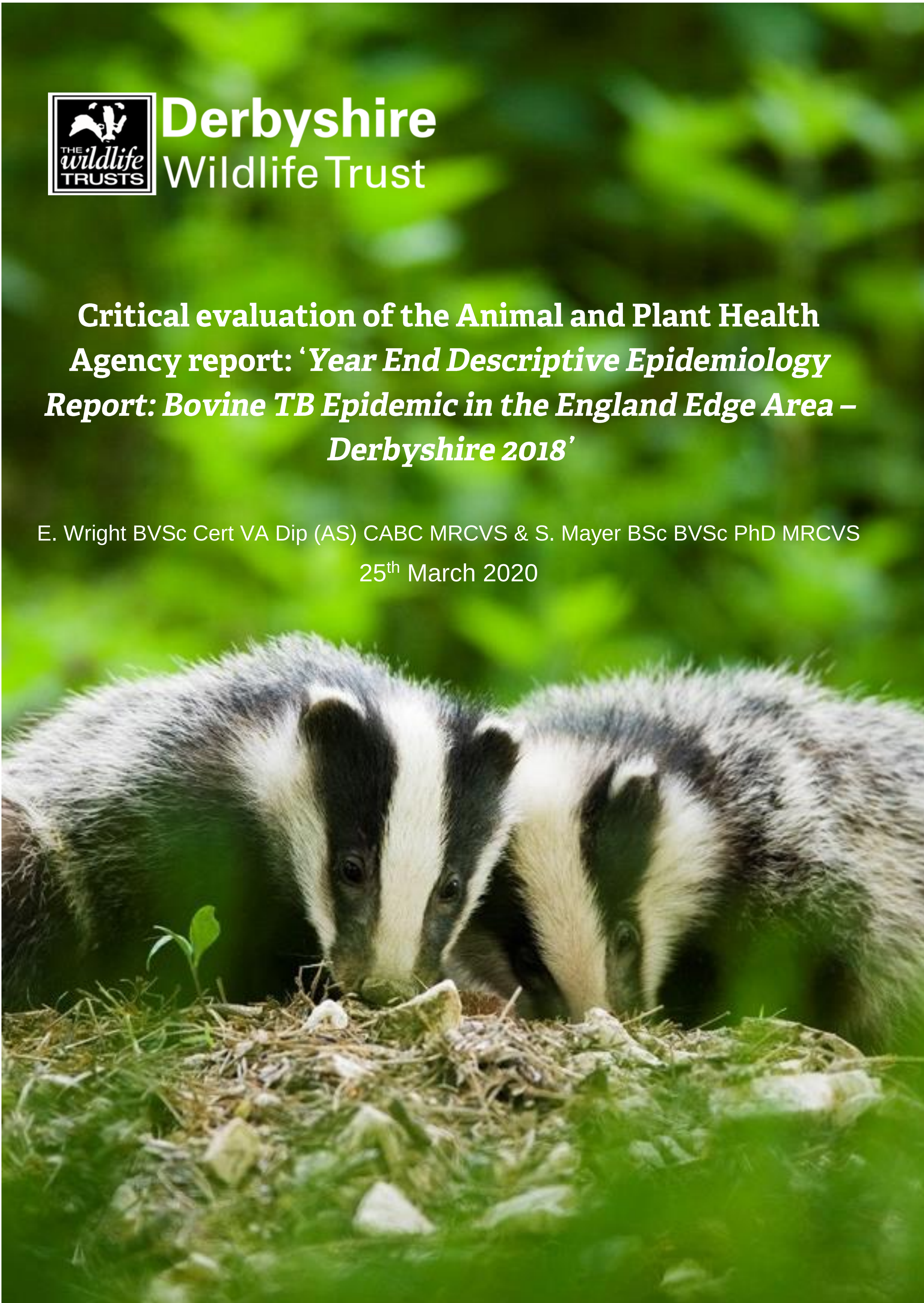

Derbyshire
Wildlife Trust

Critical evaluation of the Animal and Plant Health Agency report: '*Year End Descriptive Epidemiology Report: Bovine TB Epidemic in the England Edge Area – Derbyshire 2018*'

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Preface

Derbyshire Wildlife Trust has been vaccinating badgers against TB since 2014. We wanted to protect wildlife whist supporting farmers who were facing the threat of TB in their cattle. The scale of our vaccination has increased. In 2019 we vaccinated 221 badgers on 120 km^2 in Derbyshire working with 52 landowners and farmers and we continue to expand. Culling badgers in Derbyshire would threaten the very basis of this work.

DWT was very surprised to see that the Animal and Plant Health Agency (APHA) had reported that 77% of new cases of TB in cattle in Derbyshire in 2018 were caused by badgers. The APHA figure implicating badgers in such a large number of bovine TB outbreaks was used to call for a cull of badgers in Derbyshire. However, the figure of 77% is much larger than any estimate in the peer reviewed scientific literature for the role of badgers in bovine TB which ranges from 5-36% of cases. To understand how the APHA had arrived at such a high figure and how reliable it was, we commissioned this evaluation. It wasn't easy for the researchers. The APHA's published report is not detailed and the methodology and data it used were not in the public domain and could only be obtained through Freedom of Information requests by our researchers and others. The APHA also declined to meet the researchers to discuss the report.

Our evaluation indicates that the APHA estimate cannot be relied upon and should not be used for establishing TB control measures. The methodology is inherently subjective, has been subject to bias towards badgers being the cause of outbreaks and neglected cattle-based risks such as persistent infections, shortcomings in testing and cattle movements. The APHA also claimed that TB is endemic in badgers in parts of Derbyshire without any data at all on whether, in fact, badgers are carrying the disease organism.

Farmers struggling with bovine TB will not be helped by reports which blame badgers whilst neglecting other more important factors. Culling badgers on the basis of the APHA report should not be allowed in Derbyshire. The current badger vaccination programme being undertaken by Derbyshire Wildlife Trust, along with its key partner the National Trust, should be allowed to continue and expanded with appropriate Government support. The APHA have used a similar approach in other areas of the country to justify badger culling which may also be similarly misleading and this is extremely concerning.

Tim Birch

Director of Nature's Recovery

Critical evaluation of the Animal and Plant Health Agency report: '*Year End Descriptive Epidemiology Report: Bovine TB Epidemic in the England Edge Area – Derbyshire 2018'*

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/830849/apha-epid-report-edge-area-derbyshire1.pdf

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1. Executive summary

This paper evaluates the Animal and Plant Health Agency (APHA) report, '*Year End Descriptive Epidemiology Report: Bovine TB Epidemic in the England Edge Area – Derbyshire 2018'*, henceforth referred to as the 'APHA report'. In particular, the paper explores evidence around the validity of two specific statements on the APHA report that: "*The most likely infection source for 77% of the new breakdowns in 2018 was wildlife*" and that: "*Enhancement of TB control measures in badgers is needed"*. The main findings are that:-

1. The APHA report fails to provide an adequate explanation of the amount and weight of evidence necessary 'in the field' to categorise and rank risk pathways for TB transmission in relation to wildlife. The risk assessments used within the APHA report involve the investigating officers' judgements and opinions and therefore a degree of subjectivity is inherent in the methodology. As a consequence, it is possible that that assessment is incorrect and the real source of TB infection is not the one deemed 'most likely' by the vet performing the assessment. The subjectivity and uncertainties within these analyses should have been discussed in more detail and the confidence levels quantified, as this has bearing on the outcome of the risk assessments. The final impression presented in the scoring system is one of a mathematically meaningful result which is not possible in the real-world dynamics of TB transmission.

2. The APHA vet assigned to each outbreak assesses the risk of exposure to *M.bovis* infection (*Mycobacterium bovis*, the causative agent of bovine TB) from badgers to cattle based solely on the presence or absence of badger activity in the vicinity of a herd breakdown. The vets have no detailed disease data for the badger population and have to make a large and unsupported assumption that badgers are a source of disease on essentially any farms where they are present. Some of the vets may not have received appropriate training in badger ecology.

3. The report fails to acknowledge the considerable volume of evidence pointing to the relatively poor sensitivity (the proportion of truly infected individuals in the screened population that are identified as infected by the test) of the single intradermal comparative cervical test (SICCT) in cattle and the implications for this in attributing pathways of infection. The limitations of the SICCT test mean that a proportion of infected cattle are not disclosed and a failure to adequately consider these factors may have resulted in an underestimation of the potentially important role of residual infection and cattle movements in the risk assessments for 2018.

4. The APHA report claims that there are endemically infected badger populations in Derbyshire, without citing scientific evidence to support the claim. A recent survey of road traffic accident badgers found that *Mycobacterium tuberculosis* complex (including *M. bovis*) was isolated from only 4% of dead badgers from across Derbyshire [1] (Professor Malcolm Bennett, personal communication). This level of infection in Derbyshire badgers does not support the suggestion that the disease is endemic in Derbyshire badgers at a county level. Furthermore, the APHA report claims that Derbyshire has a higher than average population density of badgers, without any supporting scientific reference material. The report compares parts of the county with the epidemiology of the

High Risk Areas (HRA), although low prevalence of *M.bovis* in the badger population combined with data indicating a comparatively lower density of badgers means the epidemiology of TB is not necessarily similar to the HRA and analogies cannot be simply drawn.

5. The partly subjective nature of the methodology and the uncertainties of assigning risk pathways, especially on the unlikely assumptions about TB in badgers, means that the 77% result is likely to be an overestimate. The estimate is also much higher than any modelling study in the published literature further questioning the validity of the result. The Executive Summary of the APHA report states: "*The most likely infection source for 77% of the new breakdowns in 2018 was wildlife*" [2, p. 3] but omits the important caveat written within the detail of the report: "*Therefore the relative proportions of each risk pathway are very approximate, and broad generalisations only can be made from these data"* [2, p. 16] . Excluding the limitations of the analyses from the executive summary contributes to a misdirection in emphasis afforded to the risk assessments.

2. Introduction

The Animal and Plant Health Agency (APHA) report, '*Year End Descriptive Epidemiology Report: Bovine TB Epidemic in the England Edge Area – Derbyshire 2018'* [2], reviews the epidemiology of bovine TB in Derbyshire in 2018. It considers the increasing incidence of TB in cattle (bTB) in south Derbyshire and evaluates the causes of new outbreaks. In particular, the report concludes that: "*The most likely infection source for 77% of the new breakdowns in 2018 was wildlife* (p3)" and that: "*Enhancement of TB control measures in badgers is needed"* (p4). These findings have been used to challenge the Government's decision not to allow a cull of badgers in Derbyshire because of the badger TB vaccination program already running in the county [3] [4]. The estimated proportion of 77% of new breakdowns being caused by badgers is an unprecedented claim. This raises questions about its reliability and whether it has been overestimated and other risk factors neglected as result. If the estimate is unreliable the disease will not be effectively tackled and will perpetuate demands for badger culling. Therefore, this review of the report was commissioned by the Derbyshire Wildlife Trust to examine the APHA's findings in detail.

The APHA report has been examined and reviewed in the light of existing scientific literature and data in the public domain, including other relevant APHA publications, with particular attention being paid to the role of badgers. Areas of uncertainty in the methodology were identified and a freedom of information request (FOI) was submitted to the relevant team at the APHA to obtain clarification and enable a robust analysis. Other applicants' FOI responses were also used to support the evaluation[1]. Repeated requests for meetings with members of the APHA team were denied (which was said to be due to impracticalities and staffing constraints), preventing an open dialogue which would have enabled further questions to be answered and any miscommunication prevented.

The APHA report contains information obtained from raw data held by the APHA SAM RADAR TB reception database (the I.T. system used to manage TB testing) and LIMS (Laboratory Information Management System) and TB Culture system. The data provide useful information regarding the epidemiology within the county which can be used to compare regions and years to support a wider understanding of disease progression.

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[1] The freedom of information submissions and responses are available on request

The initial section of this evaluation examines the methodology and delivery of the risk pathway assessments. Further sections examine areas of contention or ambiguity within the report. It considers the way in which the risks from badgers are evaluated and makes comparison to how residual infection and cattle movements are considered. The issue of sensitivity of the skin test for bTB is reviewed. The APHA report is considered in relation to any possible bias towards badgers as being the main cause of new outbreaks to the neglect of other causes.

3. The risk assessment methodology

Bovine TB in England is subject to a statutory eradication programme and within this strategy England is divided into three risk surveillance areas as determined by the level of disease i.e. 'High Risk Area' (HRA), 'Edge area' and 'Low Risk Area' (LRA) [5] . From January 2018 the whole of Derbyshire has been classified as an 'Edge Area'. Previously, the north and south eastern fringes of the county were defined as 'Edge' and the southwest as 'High Risk'. In 2018, there were 143 new TB breakdowns across the whole county (20 in the 'Edge Area' and 123 in the former HRA), up from 112 in 2017 but lower than the high of 2012 [2]. Within the higher incidence portions of the 'Edge Area', six monthly routine surveillance TB testing replaced annual testing in January 2018 but herds in the rest of the 'Edge Area' remained under annual surveillance testing [2].

When a new breakdown occurs it is classified as an OTF-S (officially bovine tuberculosis free status suspended) incident if all test reactors fail to disclose visible lesions and culture results are negative at post-mortem examination. OTF-W (Officially bovine tuberculosis free status withdrawn) status refers to a herd with a TB incident in which the presence of tuberculosis is confirmed in at least one animal by the isolation and culture of *M. bovis* (*Mycobacterium bovis*, the causative agent of bovine TB), or if classical lesions of tuberculosis are seen at post mortem examination [6]. Whenever possible in OTF-W incidences the cultured M.bovis is genotyped with the aim to identify and classify the organism using a sequence of numbers and letters. This information allows for the comparison of identified genotypes between herds and geographical areas and helps with identifying its source [6]. OTF-W herds in Derbyshire are also subject to mandatory interferon gamma blood testing since Jan 2018 [2] [6].

Once a TB breakdown occurs, it triggers an investigation by an assigned APHA veterinary surgeon described as an 'investigating officer'. The 'Bovine tuberculosis in Great Britain in 2018 Explanatory supplement to the annual reports' [6] describes the stages:

> *An assessment is made early on during the investigation and management of the incident, to help guide and prioritise immediate actions; this is the 'provisional assessment'. It is then repeated when all evidence has been gathered/received including e.g. post- mortem, tracing and culture results; this is the 'final' assessment. The same protocol is used for both provisional and final assessments*. [6, p. 31]

These assessments form the basis of the risk pathway analysis to assign source attribution which is then described and used in the regional reports and to inform policy proposals.

Some of the information gathered to support the investigation is collected during farm visits whilst remote data analysis is also employed. Only limited descriptions of the methodology are given in the Derbyshire report [2] or elsewhere [6] [5]. In order to evaluate the APHA report, multiple freedom of information (FOI) responses provided by the APHA were analysed. The letters and numbers used by the APHA to reference the FOI requests are used here i.e. ATIC ****.

The investigation officer's task is to assess potential **hazards** (source of infection) and **risk pathways** (route by which infection may have entered the herd) associated with each hazard. The APHA veterinary surgeon is required to complete a Disease Report Form (DRF) as part of the investigation.

> *The investigating officer is asked to assess all the evidence available to identify the route by which TB infection entered the holding. As there are usually several plausible possibilities, the protocol asks the investigator to use all available evidence plus veterinary judgement to describe how likely the various possibilities are* [6, p. 31]

The first step is the completion of the Disease report form (DRF) after a farm visit.

a. Disease Report Form

This section explains how the DRF is used to collect data and information. Understanding the form is important since the information from a DRF is used to include or exclude potential risk pathways in the final assessment. A blank copy of the DRF and information regarding the analysis were obtained via a freedom of information request (FOI: ATIC 1920). All possible risk pathways are documented by the officer in the DRF including those that have been excluded e.g. movements on a completely closed farm [6]. However only three can be chosen for the final part of the quantitative risk assessment, with all other pathways excluded from the final analysis.

The DRF contains questions to direct the officers' investigations and guidance material is available to support their decision making. Data collected includes history of individual TB reactors, the TB history of the farm and surrounding area, movement histories, herd type and husbandry, location of contiguous farms, post-mortem results and culture / genotyping for OTF-W herds.

Some of the variables are determined remotely from government datasets, e.g. Cattle Tracing System (CTS). Landownership data are used to assess contiguous neighbours [6], and access to farmers' records are needed for non-reported movements [6].

Information regarding farm management practices and husbandry can only be obtained via farm visits or contact with the farmers. Wildlife attribution is assessed by examining the proximity of wildlife habitats and activity with respect to the farmyards, pastures and access to food resources (FOI: ATIC 1905). For example, location of badger setts, evidence of badger runs, badger latrines and wildlife sightings (live and dead) at pasture and near buildings. Assessment of the biosecurity measures to mitigate wildlife-to-cattle contact is also undertaken. The TB infection status of wildlife on the farm is not investigated (FOI: ATIC 1905) and analysis of the environment for contamination (or other means of wildlife surveillance) is not performed. Reporting of detailed information on slurry and manure production and handling is not required.

Disease report forms are not completed for breakdown farms which do not receive a veterinary investigation visit (FOI: ATIC 1920).

The next step is assigning the risk pathways

b. Hazard and risk pathway assessment

The list of possible hazards and risk pathways is not in the published literature but was obtained via FOI requests (ATIC 1905, 1871). These hazards (bold) and risk pathways (italics) are:- **fomites** (*contaminated vehicles; purchased feed or bedding; shared equipment or machinery; contaminated slurry or manure*), **infected badgers** (*exposure at grazing where feed at grazing is accessible or inaccessible to badgers; exposure at housing where feed stores are accessible or inaccessible to badgers*), **infected cattle** (*cattle movements; residual infection in the herd; contiguous*), **infected domestic animals, other wild animals** and **non-specific reaction** (*Mycobacterium other than M. bovis or false positive*) and **unknowns**.

The vet is required to choose up to three of the most plausible risk pathways for inclusion in the final quantitative risk assessment and to rank these according to relative risk. In order to decide which risk pathways to select and the final probability value (rank) for each, the investigating officer is given the following guidance:

Definite – evidence-based

Most likely – (most biologically plausible of several options) evidence-based

Likely – (more than just possible) evidence-based

Possible – (biologically plausible)

There is no explanation in the Disease Report Form (DRF) or in the APHA report of the weight of evidence needed to make these judgements. For example, whether there is a standard list of potential evidence from which the officer has to select a minimum number to justify allocation.

Scaling factors based on a rank order centroid approach (ROC) (FOI: ATIC 1920) [7] are then used for each probability value assigned by the investigating officer.

Definite = 8

Most Likely = 4

Likely = 2

Possible = 1

The proportion each hazard/risk pathway contributes towards a single TB incident is then calculated by inputting the weighted scores into a mathematical formula (algorithm). This approach to risk assessment is semi-quantitative and the mathematical algorithm is based on ‘rank order centroid’ (ROC) [7]. Although semi-quantitative analyses can be consistent and systematic, there is also subjectivity inherent in the method [8]. The subjectivity within this analysis should have been explained and explored in more detail since it has bearing on the selection of risk pathways and later the emphasis given to them.

When devising risk assessments, expertise from epidemiologists, ecologists and diagnostic scientists is required [8]. It is not clear from the available information what expertise was sought in the analysis design.

Rank order centroid is a standard method to quantify a ranked order and is used to apply weighting to the level of certainty assigned to each of the three risk pathways. ROC is used because decision-makers can usually rank items much more comfortably than give weight to them [7]. The APHA risk assessments use ROC in a novel way and previous similar applications could not be found in open published literature. The APHA approach does not always rank the hazards (they could all be ‘likely’, for example) and it does not explain the rationale for the scaling factors used.

The APHA’s report also does not detail the sensitivity analysis (if any) that was performed on the methodology. Sensitivity analysis determines which uncertainties have the largest impact on assessment performance measures, helps to decide which factors to include and aids understanding the robustness of the model and the significance of the uncertainties [8].

In response to a FOI request (ATIC 1871), the APHA provided the excel workbook that shows the calculations to produce weighted scores as to the determination of the source of infection in new herd breakdowns in Derbyshire in 2018. The workbook shows calculations for 120 herds of the 143 new herd breakdowns in total [2]. Disease report forms are not completed for farms which do not receive a veterinary investigation (FOI: ATIC 1920) and a risk assessment analysis and weighting would not be performed in these cases. It is not clear whether 23 farms did not have a farm visit or that their details have not yet been included in the workbook provided.

The workbook has been analysed and the findings described below.

In 38 cases (3 cattle risk pathways and 35 badger risk pathways) only one risk pathway was chosen for the final assessment. The investigating officer must have decided there was sufficient evidence to positively exclude all other risk pathways except the one. However, this seems highly unrealistic, especially in relation to wildlife attribution. Whether these judgements were questioned at the auditing stage is not known (see section 4).

The most important point to emphasise is that the final calculation is a numerical representation based on the investigating officers’ judgement and opinions and is not fact but subject to considerable uncertainty and unknowns.

c. Key uncertainties in the risk assessment

Any assumptions made during the design of a risk assessment should be stated along with the reliability of the data [8]. The APHA report highlights some of the uncertainties of the methodology but shortcomings and assumptions are not emphasised alongside the headline descriptive analysis and the limitations are only briefly acknowledged. No confidence intervals are provided for the calculated proportions. The impression thereby given, is that the ‘algorithms’ used will yield mathematically meaningful results in relation to the real-world dynamics of TB. But any consideration of uncertainty (as a lack of confidence in assignment of likelihood categories) will affect the conclusions that are drawn.

The following uncertainties discussed below appear in APHA documents:

Lack of genotyping and gaps in the epidemiological evidence

Genotyping in OTF-S herds is not possible since isolation of *M.bovis* is not achievable (by definition, as no organism has been cultured). The lack of genotyping increases the difficulty in attributing source of infection as the report acknowledges.

> ***….****this methodology also included those incidents where certainty about risk pathways was lower because of gaps in the epidemiological evidence. The effect of uncertainty has been increased by the inclusion of OTFS herds, where by definition, no genotype was*

> *determined.* ***Therefore the relative proportions of each risk pathway are very approximate, and broad generalisations only can be made from these data*** [2, p. 16] *[emphasis added]*

Uncertainties relating to the genotype of an outbreak will have effects on the reliability of the collated data. Tracing the source of the disease without genotyping in OTF-S herds is clearly more problematic because it immediately reduces the evidence base and could lead to errors in ranking attributions, especially if there is bias. Of the 120 farms analysed in the workbook provided, 50 were OTF-S herds and 70 were OTF-W herds. A small percentage of OTF-W breakdowns may not have had a spoligotype (genotyping) identified either (FOI: ATIC 1951). The uncertainty is greater in all the herds where genotyping did not take place.

The proportion of risk pathways where there were 'gaps in epidemiological evidence' is not stated in the APHA report.

Although only broad generalisations can be made from the data, the report repeatedly refers back to the findings as if they are factual. For example:

> *As shown in Figure 13, approximately 77% of all new herd incidents in Derbyshire in 2018 were attributed to infected badgers…* [2, p. 16]

Uncertainty in attributing pathway of infection

The APHA acknowledges the difficulty in assigning risk pathways and highlights the imprecision of the decisions:

> Although ***it will often not be possible on a particular farm to say for certain how the cattle got infected,*** *consideration of how* **this may have** *happened in light of the husbandry practised, biosecurity measures in place, and other findings in the investigation will make some pathways* **more likely** *than others* [6, p. 32]*[emphasis added]*

The demanding nature of the assessments are similarly recognised in the 'Bovine tuberculosis in England in 2018' report:

> *Assessing how a herd became infected with TB is very challenging, as TB is a chronic insidious infection in which clinical signs are usually only apparent when the disease is advanced….. Therefore, the evidence to retrospectively establish which route brought the infection into a herd can be difficult to reconstruct*. [5, p. 35]

With no access to the individual DRFs, analysis of each officer's judgements cannot be made. One significant assumption is that potential contact (direct or indirect) between badgers and cattle (or cattle-to-cattle) leads to disease (see below) and yet very little consideration is given to this assumption in the document and is only mentioned briefly in a supplementary report, where it states:

> *All these are potential risk pathways which may or not materialise depending on whether there is a level of exposure to the hazard (e.g. an infected cow or badger; infected material in the environment, etc.) and the degree of it on a particular farm* [6, p. 8]

The design of the assessment and especially how the ranking system is interpreted by the investigating officer will have a marked effect on the level of uncertainty and outcome of the assessment [8]. The probability values given to the officer to assign risk pathways are vague and ambiguous. This may lead to variability in interpretation and a lack of repeatability between officers [9] [10]. A FAO/WHO report on “Risk Characterization of Microbiological Hazards in Foods. Microbiological Risk Assessment Series (MRA) 17 (2009)” notes that:

> *..a number of studies have shown that even professionals well-versed in probability ideas who regularly make decision based on risk assessments have no consistent interpretations of probability phrases (‘likely’, ‘almost certain’, etc.), which could lead to inconsistency and lack of transparency*….. [9, p. 38]

Further analysis of the risk pathway assessments is described in sections 5-7

Loss of data related to cattle movements on fragmented farms

There has been a recent increase in the extent to which individual farms are fragmented into non-contiguous holdings [11]. A temporary land association (TLA) associates a permanent CPH with land or a building that’s within 10 miles of that CPH’s main livestock handling area. It is not necessary to report or record livestock movements between fragmented land and the rest of the CPH. Access to farmers’ records are needed for these non-reported movements [6].

Typically, a Geographic Information System (GIS) is used to integrate map data (i.e. boundaries, land class) with use and disease status associated with the fragmented land and its contiguous land. The supplementary report highlights a problem in attempting to determine the extent of farm fragmentation using GIS [6]. This may affect the accuracy of some of the risk pathway assessments since vital data on fragmented herds may be lost leading to a significant gap in the epidemiological evidence and increasing uncertainty.

The risk posed from large fragmented herds is recognised in a recent Welsh Government publication:

> *While a herd is under TB restrictions, it is possible for farmers to move cattle to other sites included in their holding, or another holding under their control. This potentially presents a significant risk of disease spread as it enables continual movement between separate units with potentially different levels of risk and subsequent mixing of sub-populations of cattle, each with its own level of risk assessment associated with it. This is likely to perpetuate the problems of disease circulation within the herd* [12, p. 30]

d. Risk Assessment Quality Control

Given the challenges involved in assigning risk and reconstructing retrospectively the source of a TB breakdown, training of staff and auditing the final assessments is vital. The process of quality control ensures confidence in the findings.

A national DRF training initiative for all APHA field vets took place in 2017 (FOI: ATIC 1920). This was peer reviewed and covered ‘source attribution’ (i.e. the possible sources of bTB infection in a herd breakdown). The expectation is that each potential hazard was given the same level of consideration during the training and that bias was avoided. The officers receive risk pathway assessment training and guidance is provided in the form of training materials based on the relevant information and data sources to create the evidence base (FOI: ATIC 1920).

Specific training in badger ecology is made available in the form of a symposium which includes classroom, field and on-farm training (FOI: ATIC 1920). This training includes badger ecology, behaviour, badger and deer TB and badger TB epidemiology. The symposium includes training techniques for performing badger surveys and surveillance. Only approximately 54% (as of Jan 2020) of APHA field vets in England and Wales have received training in badger ecology (FOI: ATIC 1920). Without further information, the proportion of Derbyshire APHA team members who have attended the badger ecology training is not known nor is it known how the course is validated and the attendees assessed.

It seems that not all the farms with new outbreaks were visited by APHA vets. The excel workbook provided by the APHA (FOI: ATIC 1871) shows the calculations for 120 new herd breakdowns in Derbyshire in 2018 when the total was 143.

> *"For the Edge Area, as many assessments as possible are completed with the finite resources available, and the level is close to 100%. In situations where not all incidents can receive an assessment, new incidents are randomly selected for assessment in order to maintain a representative overview of the area Bovine tuberculosis in England in 2018"* [5, p. 35].

Analysis of the data is only possible for 84% of the farms and the proportion of farms visited is not clear. Disease report forms are not completed for farms which do not receive a veterinary investigation and visit (FOI: ATIC 1920). The remaining 23 herds have either not been assessed or are not included in the workbook provided by the APHA.

A proportion of the risk assessments go through an auditing process in which good evidence and reasoning is checked by the auditor (FOI: ATIC 1871, 1920). If the evidence is unclear, a discussion between the investigating officer and an auditor is held, to challenge the decisions made by the former and to check for bias, allowing corrections to be made as necessary. In 2018, approximately 50% of DRFs were audited in Derbyshire and this included a sample from each vet completing the risk assessments in the county. The more experienced vets who submitted good quality work had fewer DRF's reviewed (FOI: ATIC 1871).

Conclusion

Questions remain over the quality of the risk assessment methodology, especially relating to the allocation of wildlife attribution and the uncertainties associated with it. It is important to stress that the calculation is a numerical representation based on the investigating officers' judgement and opinions. Almost half of those undertaking the risk assessment may not have had training in badger ecology and a proportion (probably around 15%) of the farms newly infected with TB did not have visits from APHA vets. Only about 50% of the assessments were audited.

4. Badgers and risk pathway assignment

The investigating officer has to make a judgement on which (up to 3) risk pathways to choose and the ranking of those risk pathways. Some of the methods of data capture (DRF) and uncertainties in the data have been discussed above. Whilst badgers are included in the risk assessment, it is not clear what weight and quality of evidence is needed to support the allocation of risk associated with exposure to badgers. As discussed previously, the officer looks for location of setts, evidence of badger runs, latrines and digging. Observational evidence of sightings of badgers (live and dead) at pasture and near buildings observed by farmers and APHA staff is also used. The APHA does not routinely employ CCTV monitoring (ATIC 1951) and there is no indication that camera traps are deployed. Other data capture techniques such as hair traps (to assess badger numbers) [13] and submission of badger faeces for PCR testing are not routinely used (ATIC 1951). The evidence is therefore observational, subjective and vulnerable to bias and assumptions.

The exact nature of transmission pathways between cattle and badgers is not known but possible routes could include direct contact i.e. close or nose-to-nose (i.e. aerosol spread) or indirect contact via inhalation and /or ingestion [14]. Indirect contact involves environmental contamination via faeces, urine, discharging wounds or saliva. Transmission could potentially occur at pasture or in farm yards and buildings with possible contamination of food and water resources. Observational field studies have shown relatively infrequent direct contact between badgers and cattle, variable degrees of indirect contact [14] [15] [16] [17]and heterogeneity in the likelihood of badgers making farm yard visits [18]. In one of the observational studies, 40% of the farms had badger activity but the frequency of visits was highly variable and difficult to predict, with only 11% of farms having visits on more than 50% of nights. A small number of farms had badgers visiting frequently whereas many had low levels of activity [18]. The density of badger setts within 500m of the farm and the number of cattle sheds were positively associated with the presence of badgers in farmyards, whilst the presence of an occupied dwelling reduced the chance [18]. In this study, the number of cattle housed on a farm was negatively associated with the presence of badgers. This is in stark contrast to the reported risk of TB infection increasing proportionally with the size of a herd [2] [19] [20] . Using simple univariate analyses, the same study found no evidence that badger visits were associated with the current TB status of the farm [18].

From the research described above, it is evident that detailed examination of a farm is needed to establish the likelihood of the presence or absence of badgers in the vicinity of a premises. A ‘badger assessment tool’ has recently been designed to try to help farmers make these predictions based on farm characteristics [18]. Importantly, however, these farm characteristics and the DRFs do not provide any information on the level of infection or the level of infectiousness of individual badgers [18]. This is a crucial point in understanding the validity of the risk assessments and how the results should be viewed and used in the wider context of TB control. The APHA vets only assess the risk of possible contact (direct or indirect) between badgers and cattle. The risk of transmission between them can only be assumed since potential exposure to a badger (which may or may not be infected and may or may not be shedding) does not necessarily lead to infection [21]. For an individual cow to become infected via contact with a badger all the following assumptions need to be fulfilled [20] [14]:

a) A badger is infected with *M. bovis* (The vet does not determine the TB infection status of individual badgers on or around the farm as part of the risk pathway assessment (FOI: ATIC 1905). This would be possible if resources were made available. For example, a veterinary investigation of a persistent outbreak of bovine tuberculosis on a Devon farm incorporated badger faecal analysis using the RD4 qPCR method [22] to look for the presence of *M. bovis* [23])
b) A badger is excreting *M. bovis* at the time of exposure
c) A badger is excreting at a dose liable to lead to infection
d) The cow receives a sufficient dose in a suitable form by an appropriate route. The dose received will depend on the type and length of contact with the badger and is affected by a multitude of variables e.g. the time of year, the behaviour of the badger and the hierarchical status of the cow [20]. Direct transmission of *M. bovis* from badgers to cattle via expired air or bodily contact is considered a low risk [15]. Indirect contact might be more important in terms of disease transmission at pasture [14].
e) The cow is susceptible to infection [20]. Host susceptibility may be affected by many factors e.g. genetics [24], diseases (particularly those that cause immunosuppression) and the reproductive status of the cow [24].

There seems to be very little available evidence to allow the investigating officer to decide the likely contact patterns between cattle and badgers whilst the infection status of badgers within the vicinity of a farm is unknown. The probability values 'Definite', 'Most likely' and 'Likely' are intended to be evidence based, however any such evidence is circumstantial. Given the lack of robust evidence, the credibility of assigning a risk pathway associated with badgers to any other probability value other than "Possible" (is described as biologically plausible) is low.

It also seems likely that a lack of any cattle evidence is used to support a default source attribution to badgers:

> *Figure 7 shows the incidents most probably associated with a wildlife source, from information gathered during farm visits. Looking at farm activity and lack of cattle movements reveal a clustering of incidents to the west and south of Derbyshire…,* [2, p. 11]

Lack of evidence of any other risk pathway is not a plausible reason for assigning attribution in another.

Of the 120 herds analysed in the APHA workbook, the hazard associated with badgers was the sole allocation in 35 (almost 30%) of them i.e. the investigating officer decided there was sufficient evidence to positively exclude all other risk pathways except one. The certainty "Definite" is used once in the 120 breakdowns in Derbyshire and this was a risk pathway attributed to badgers. Where the hazard of both 'badgers' and 'cattle' were assigned to a herd (53 herds), in 70% of these cases the risk pathways associated with badgers were ranked higher than those associated with cattle. In fact, risk pathways associated with badgers account for 148 of a total of 234 of the final risk pathways allocated. Risk pathways associated with cattle occur only 73 out of the 234 allocations. These proportions seem unlikely given the uncertainties and assumptions made about wildlife attribution.

Risk pathways associated with badgers were frequently ranked in the 'most likely' and 'likely' category where *evidence* is necessary although as discussed above, no ranking above 'possible' seems supportable.

Conclusion The Disease Report Forms should be updated to include more emphasis on cattle transmission pathways, slurry/manure production and less bias towards wildlife. The DRF and risk assessment analyses identify badgers as a likely source of infection based largely on whether they are present or not. There are no detailed disease data for the badger population and very large and unsupported assumptions are made that all badgers are infected and could be a source of disease. Therefore, the proportion of herds where badgers were allocated as the most likely source of infection is likely to have been greatly overestimated.

5. TB Surveillance Testing – shortcomings of the skin test and neglect of cattle risk pathways

The single intradermal comparative cervical tuberculin (SICCT) test forms the basis of identification of TB in cattle in the UK. Various studies have been conducted to ascertain the sensitivity (the proportion of truly infected individuals in the screened population that are identified as infected by the test) and specificity of the SICCT test. The resultant sensitivity determined varies between studies, study design and whether standard or severe interpretation is used [25] [26] [27] [28]. A recent study in chronically infected herds in Northern Ireland [28] estimated a sensitivity of 40.5–57.7% at standard interpretation and 49.0–60.6% at severe interpretation. A slightly older study estimated an overall sensitivity of 81% at standard interpretation and 85% at severe interpretation [29]. In a recent Bayesian meta-analysis, the SICCT test at standard interpretation was estimated to have a median sensitivity of 50% by one model and 64% using a second model [25] . The authors comment that *"these estimates can only be described as low or moderate, which is of concern given the widespread use of the SICCT test and its official status as a standalone test"* [25, p. 101]. Based on this latter analysis up to 50% of positive animals could be missed at standard interpretation.

However, in their report the APHA claims that *"… the TB skin test used alone could miss a* ***small*** *proportion of truly infected animals"* p 20 [emphasis added] which is a potentially misleading and inaccurate statement.

The limitations of the SICCT test are likely to have a profound effect on the epidemiology of TB in the UK. For instance, since the sensitivity at standard interpretation is poor, infection will remain undetected in a proportion of herds where there is a single or low number of infected animals (the median number of reactors removed per incident UK wide has remained at two [6]) which may pose a risk to the rest of the herd [30] [20].

A comparison of two within-herd transmission models [31], estimated that 50% (33%–67%) in one model and 24% (11%–42%) in the second model of recurrent breakdowns could be attributed to infection missed by tuberculin testing. The models suggest that many infected cattle are missed during the testing process and these cattle are then triggering further breakdowns [31]. In both these models the rate of cattle-to-cattle transmission within a herd was estimated to increase, non-linearly, with herd size [31]. This correlates with the findings of the reported risk of TB infection increasing proportionally with the size of a herd.

When severe interpretation (automatically applied upon confirmation of TB in a herd) is used in a herd there is an improvement in sensitivity although infected animals are still likely to be missed. When the IFN-γ assay is applied in parallel with the SICTT test then the sensitivity improves further (parallel testing involves administering two or more tests. If any of the tests are positive, the cow is considered to be a reactor). In one study which examined the IFN-γ test, the combined sensitivity of SICTT and IFN-γ was either 96.4% or 98.6% (depending on IFN-γ test parameters) relative to lesion detection as the gold standard diagnostic test [32].

Since January 2018, parallel testing in OTF-W herds in Derbyshire has been introduced, thus increasing the sensitivity of the TB testing regime. In previous years when only the SICCT test was used for surveillance, it is likely that more infected animals were remaining undetected and that this fraction were likely contributing to recurrent breakdowns [33]. Forty five per cent of the reactors in Derbyshire were disclosed by interferon gamma (IFN-g) blood test in 2018 [2].

Neglect of residual infection as a driver of risk

Despite the evidence described above, residual infection as a risk pathway seems to have been neglected in the APHA report. The APHA report states "*of the breakdowns which were new in 2018, almost 40% had history of infection in the previous 3 years"* [2, p. 20].

Conclusions for the country as a whole show that:

*In the Edge Area and LRA, the odds of having a new TB incident in 2018 was approximately two and a half times higher in herds with a history of TB compared to herds with no TB history (Edge OR 2.6 95% CI 2.2-3.1; LRA OR 2.4 95% CI 1.1-4.9), while in the HRA it was approximately twice as high (OR 1.9 95% CI 1.8-2.1)…….Recurrence may have a number of causes, likely relating to location, biosecurity, **residual undetected cattle infection**, and/or buying or other management practices.* [5, pp. 30,31] [emphasis added]

Analysing the APHA's Derbyshire workbook, there are only 20 out of 120 herds where residual infection was ranked as a risk pathway i.e. only 16% of all herds in the workbook (5.3% based on the weighted value [2]). Of these herds, residual infection was ranked as "most likely" in only 3 herds and "possible" or "likely" in the remaining herds. There are 19 herds where both residual infection and exposure to badgers were given as risk pathways. Of these 19, the risk pathway associated with badgers was given a higher risk probability value in 16 cases. Given almost 40% of new breakdowns had a history of infection in the previous 3 years, it is hard to understand how so few risk pathways were assigned to residual infection. It appears that an assumption was made in many of these herds that reinfection of cattle has occurred via badgers as a result of repeated exposure (whether direct or by environmental contamination). However, there are many possible sources of exposure to *M. bovis* at pasture or housing from undetected residual infection. *M. bovis* can be transmitted from naturally infected cows to other cattle via pasture [20] or in cattle sheds and farm buildings. A recent study investigating transmission rates between cattle and badgers found that transmission within each species (cattle to cattle, or badger to badger) occurred more often than transmission between species (i.e. badger to cattle, or cattle to badger) [34].

In contrast to the variable likelihood of contact between cattle and badger faeces, the potential for cattle-to-cattle contact with faeces is inevitable and the volumes and weight of cattle faeces compared to badger faeces is orders of magnitude higher. The nature of cattle faeces mean aerosolization is more likely and inhalation is a more effective mechanism for the spread of *M. bovis.*

At Gatcombe Farm in Devon (where there was a persistent outbreak of bovine tuberculosis) a rd4 qPCR investigation of cattle faeces detected *M. bovis* in a number of samples and confirmed the risk posed by this route [23]. *M.* bovis is known to survive in faeces for several months [35] and spreading of manure all year round is a risk factor [19].

Storing slurry is another known risk factor for bTB herd breakdown [19] along with using contractors to spread slurry. Few farmers stated that contractors washed or disinfected their equipment after use [36]. This lack of biosecurity could potentially allow contaminated slurry from one farm to infect another. Unless contaminated slurry is handled, stored and spread carefully, it has the potential to contaminate pasture, soil and silage [37]. Additionally, aerosols can carry *M. bovis* during spreading [37].

The Disease Report Forms (DRFs) do not direct the officer to investigate slurry and manure storage and management**.** In contrast, the DRFs do ask the officer to question the potential for cattle to be exposed to badger excreta.

To summarise, attributing such a low proportion of the 40% recurrent breakdowns to residual infection is not supported by the evidence available on the risk of infection remaining in a herd, especially since parallel testing to improve the sensitivity of the testing regimes has only recently been introduced. Bourne and colleagues [30] concluded that:

> *Infection has been shown to result in development of overt disease in some animals but most infected animals either develop limited pathology or have no visible evidence of disease. Some of the latter animals are not diagnosed by the tuberculin skin test. They are potential disease transmitters and therefore pose a threat to disease security of the herd. Collectively, the results of these studies demonstrate that cattle-to-cattle transmission of infection plays an important role in maintenance of infection with M. bovis in the cattle population and confirm the dynamic and infectious nature of the disease*. [30, p. 139]

Neglect of cattle movements as a driver of risk

The APHA Bovine TB in England report refers to cattle movements as a risk pathway but it seems to be given little emphasis in the final assessment in Derbyshire.

> *In the Edge Area the epidemic continued to propagate, driven mainly by the introduction of cattle with undetected infection, but also by the development of local areas of endemic bovine TB that in some cases may be driven by infection in the local badger population* [5, p. 4]

Purchasing and introducing infected cattle into a herd, even in an area endemic with bTB can introduce the possibility of further exposure and reinfection [19]. Since the single intradermal comparative cervical test (SICCT) test alone is used for pre and post movement testing, then given its poor sensitivity, a proportion of those cattle movements will involve infected cattle. Given the very large number of movements this could be a potentially important source of new infections [11]. The number of cattle movements that took place in Derbyshire during 2018 is not recorded in the report, although 381,424 cattle were moved into the whole of the ‘Edge Area’ of which 84,554 were movements from the HRA and 209,724 from other parts of the edge area.

Attempts are made to recover *M. bovis* from OTF-W incidents and to perform molecular typing to identify its genotype. *M. bovis* in cattle has distinct regional genotypes or 'spoligotypes', which may be associated with specific geographical areas ('homeranges') [5]. In OTF-W breakdowns where the *M. bovis* is genotyped, this information can be used to infer movement. For example, if a genotype typically found in Devon e.g. 11:a is found in Derbyshire cattle, this can be used as evidence that cattle movement has been spreading the disease. However, as stated by the report, the 'local' genotype in Derbyshire (25:a) has a very wide geographic distribution, which may make it difficult to identify cattle movements.

> *There is also the possibility that, given that three quarters of the genotype detected are 25:a and this has an extremely large geographical distribution, some cases where the disease spread is classified as local could actually have been brought by cattle moved within the home range of this genotype therefore obscuring the effects of cattle movements in the development of the epidemic* [2, p. 16]

For example, cattle could be moved over considerable distances into a herd, resulting in a TB breakdown, but because the genotype is 25:a (i.e. the 'local' genotype in Derbyshire) there is no obvious genetic evidence for movements as being the source of infection. If genotype 25:a is found in a breakdown it is possible that the investigating officer may wrongly conclude that another risk pathway e.g. exposure to badgers (i.e. not cattle movement) is a more plausible explanation for what appears to be local spread.

There is also the potential for infection to spread if OTF (Officially bovine tuberculosis free) status is regained after passing the required tests and infected but undetected cattle are moved onto the farm or between holdings within the same farm.

> *when a herd regains OTF status, cattle purchases may be made which may also increase risk of bringing tb into the herd or there may be cattle movement between holdings under the same ownership within large enterprises* [2, p. 20]

Given the extent of cattle movements, the possible loss of data in fragmented herds and the poor sensitivity of SICCT used in pre-movement testing, it is hard to understand how, in a large proportion of the incidents, risk pathways attributed to cattle movement were ranked lower than those associated with badgers. In the APHA workbook there are only 32 incidents where cattle movements are assigned as a risk pathway. Of 27 incidents where cattle movement is assigned as a risk pathway alongside that of badgers, on 18 occasions the risk pathway attributed to badger source is ranked higher than that for cattle movement i.e. 66% of these incidents.

This deflects attention from possibly more important risk pathways. For example, the report highlights the fact that markets are still used by Derbyshire farms in the nearby HRA (Leek) which poses a risk of disease dissemination [2]. However, local authority supervision of these market gatherings has been reduced in recent years and breaches in the licensing controls are not known [2]. This is worrying as buying from markets is a risk factor for herd breakdowns [19].

> *Although a few larger dairy herds source their replacements from TB-free areas of the UK or Europe, the use of markets in the nearby HRA appears to still pose a risk of disease dissemination to Derbyshire. There is some incipient recognition and awareness of the need for informed purchasing of cattle but this is a message that still needs to be embraced by the wider farming community.* [2, p. 23]

Inconclusive reactors

Inconclusive reactors (IR) can be indicators of undiagnosed infection. In one study, IR-only herds had 2.7 times the risk of a subsequent incident compared to negative testing herds in the first year and that retesting alone may be insufficient to reduce this risk [38]. Other studies have highlighted the likely presence of undetected infection in chronically infected herds and the potential risk this poses to the ongoing transmission of infection [39]. In the Edge Area, thirty eight percent of Inconclusive Reactor-only test herds went on to have an incident within the following 15 months [5].

Conclusion

Given the amassed scientific evidence that indicates a high risk from residual infection, it is inconsistent that the results of the DRFs and risk assessment analysis for Derbyshire suggests there is likely to be little risk. Latent or undiagnosed infection in some cattle poses a risk to other cattle in the herd and can underestimate levels of infection and lead to new infections [21] [23] [38]. Excluding 'residual infection' as a risk pathway in so many of the total breakdowns that were recurrent undermines confidence in the risk assessment process. If residual infection is being significantly underestimated, then this must mean that other sources (such as wildlife) are being significantly overestimated. Residual infection must be considered as a substantial driver of the epizootic in Derbyshire.

The influence of local cattle movements and the limitations of the pre and post movement SICCT test would suggest that cattle movements are likely to be responsible for a significant proportion of the herd breakdowns.

The APHA in their Derbyshire report have shown a worrying disregard for the considerable volume of evidence pointing to the poor sensitivity of the SICCT test and the implications for this in attributing pathways of infection. In these incidences where herd breakdowns occur residual infection or missed reactors are likely to pose a much higher risk rather than potential exposure to badgers.

6. Bias towards risks from badgers

a. Comparison to the HRA

The prevalence of bTB in the original 'Edge Area' has decreased slightly from 2017. The increase in prevalence across the county is driven by an increase in the former HRA portion of Derbyshire.

The APHA report infers that the epidemiology of the disease in the former HRA area of Derbyshire involves a high density of cattle, a high density of badgers and significant disease in both which is considered to be similar to the case in the HRA elsewhere in the country. For example, the report says

> *The high percentage of new herd incidents attributed to badgers in Derbyshire could be due to the fact that most of the incidents occur within the previous HRA of the county where the epidemiology of the disease resembles that of the endemic (HRA) areas of the country.* [2, p. 16]

and that

> *…many of the incidents in 2018 were attributed to infected badgers, which is consistent with observations in other endemic areas of the country. Since the great majority of breakdowns in Derbyshire have occurred in the previous HRA, it is to be expected that the determination of disease risk pathways resembles that of the HRA rather than that expected in other counties in the Edge.* [2, p. 18]

However, limitations in the SICCT are considered to result in approximately 21% of TB herd breakdowns in the HRA retaining at least one infected animal after their restrictions have been lifted [40]. Nationally, over 50% of new TB incidents in the HRA had another TB incident in the previous three years [5]**.** This confirms the importance of recurrent infection as a driver of the epidemic in the HRA.

In the Derbyshire report, the APHA neglect those data which point to residual infection being a more important factor in the HRA and instead point to badgers.

b. Endemicity in the badger population in Derbyshire

The APHA makes the claim that TB is endemic in badger populations in Derbyshire, especially in the west of the county [2, p. 11]. However, there is no scientific reference material provided to support this statement and instead observational epidemiological data (contained with the report) were used (FOI: ATIC 1920) to make the claim.

In contradiction to this key conclusion of the report, page 3, section 5 of the report says:

> *There were no laboratory confirmed isolations of M. bovis in species other than cattle in Derbyshire in 2018. Submission rates are extremely low in other domestic species.* ***There is no systematic surveillance that would reveal such infection in badgers*** *and other wildlife, however, a Defra-funded survey of found dead badgers was conducted in 2016-2017 to look for the presence of M. bovis in badgers in Edge Area counties. The survey results have not yet been published. [emphasis added]*

And that:

> *APHA laboratories have* ***not confirmed any isolations of M. bovis in wild animals such as badgers*** *or wild deer carcases in this area in 2017 and 2018. (P18)* [emphasis added]

The level of *M. bovis* infection in badgers varies widely depending on the area researched. During the Random Badger Culling Trial (2002-2005) patterns of *M. bovis* infection were investigated through the Road Traffic Accident (RTA) Survey in seven counties (Cornwall, Devon, Dorset, Gloucestershire, Herefordshire, Shropshire, Worcestershire) with varying percentages between 3-29% depending on county and year with an overall prevalence of 15% [30]. The independent scientific group also reported that in proactive cull regions, 16.6% of badgers were tuberculous [30]. In a recent roadkill study conducted in the Cheshire area, overall prevalence of *M. bovis* isolated in badgers was 21% which was similar to the prevalence estimates of ‘high-risk’ counties for cattle infection [41].

A recent Defra-funded survey of RTA badgers is awaiting publication and provides contemporary data on levels of TB in badgers in the county. This study found that *Mycobacterium tuberculosis* complex (including *M. bovis* and closely related bacteria) was isolated from only 4 out of 100 (4%)

dead badgers from across Derbyshire [1] (Professor Malcolm Bennett, personal communication). The level of infection in badgers is much lower than that recorded in previous studies in the high risk area, and does not support the suggestion that the disease is endemic in Derbyshire badgers at a county level.

In the Defra-funded survey of RTA badgers the four *Mycobacterium tuberculosis* positive badgers in Derbyshire were scattered over the county, but mainly co-located with cattle breakdowns. However, no badgers were submitted from the south west area of Derbyshire and so there is no information about TB in badgers in this region. In the rest of the county, including the western side where there is expansion of cattle TB, road-kill badgers were obtained for study and yet the total number positive over the whole county is only four [1]. It may be that infection is endemic in certain localised areas, including where the four infected badgers were found, or other potential parts of the county where few badgers were analysed (in the above study). However, APHA identifies badgers as the most likely source of infection in the vast majority of TB breakdowns located across the county of Derbyshire. This is not consistent with the low/localised infection in badgers reported by this latest study and suggests that the role of badgers is likely being vastly overestimated by the APHA.

c. Badger population density

The APHA report makes the claim that Derbyshire has a high density of badgers (p18) and that this will increase the likelihood of their being an important risk factor in TB outbreaks in cattle.

The evidence used by the APHA to determine the density of badgers seems to have been limited to evidence of road kills and from the observational data collected for the DRFs including the number of setts, signs of activity in yards and on pasture and surrounding areas. This observational evidence includes year on year increasing frequency of badger sightings (live and dead) by farmers and APHA staff (FOI: ATIC 1920). No scientific data or reference material are provided to support this and thus the evidence is anecdotal, circumstantial and vulnerable to bias.

Direct estimation of badger numbers is extremely challenging. Badger social group size is variable depending on geographic location and time [13]. A change in the main sett density is not inevitably followed by a proportional change in badger abundance and sett characteristics are a poor predictor of badger numbers [42] [13]. Social group size also varies with the type of landscape or land class of the area [13]. Over the decades, studies estimating badger population numbers have been conducted. Recent studies [42] [13] examined the density and abundance of badger social groups in England. Using the data from these studies it is possible to reconstruct estimates for Derbyshire. Derbyshire landscape is mainly either land class 5 or 6 and using data from the study gives the estimated badger population as 2.51 badgers km^{-2} (class 5) and 1.26 badgers km^{-2} (class 6). South Derbyshire has pockets of land which would be described as Land class 2 with an estimated density of 2.58 badger km^{-2}. All of these are lower than the UK overall density of 3.29 badgers km^{-2}, and much lower than the density for land classes 1 (5.65 badgers km^{-2}) and 4 (5.98 badgers km^{-2}) which cover much of the HRA

Therefore, rather than being high, as claimed by the APHA, the density of badgers in Derbyshire is likely to be relatively lower than other areas in England where TB prevalence in cattle is high.

d. Circumstantial evidence, badgers and TB outbreaks

'*Circumstantial evidence*' is used to implicate badgers in new TB outbreaks. The APHA assign badgers as the source of a spike in breakdowns in 2015 because of sett disturbance associated with railway workings.

> *The source of a significant number of cases in the 2015 spike has been attributed to badgers, and this is thought to be directly linked to major works undertaken on the main Sheffield to Manchester railway line during 2014 and 2015. Circumstantial evidence suggests that there may have been perturbation of the badger population located near to the line, which may have changed the usual pattern of contact between badgers and cattle in the locality* [2, p. 7].

No evidence is provided in the report to substantiate the claim and support the badger perturbation hypothesis. The APHA do not hold maps and dates of railway work and the statement above is based on observational data obtained by APHA vets at the disease investigation visits (FOI: ATIC 1942). It would be interesting to know if the auditing process raised questions about this assessment.

Circumstantial evidence is cited again on page 14 where an increase in new TB outbreaks in August 2018 is hypothesised to be due to increased cattle-badger interactions. Pasture for grazing was poor due to the very dry summer which, it is suggested may have led to increased supplementary feeding of livestock and thus an increased interaction between badgers and cattle. No evidence is given to support this hypothesis.

7. Discrepancies in the data

On page 22 of the document it states a total of **1230** reactor cattle were slaughtered of which **557** were interferon gamma reactors (IFN-γ assay) and **673** were Single Intradermal Comparative Cervical Tuberculin (SICCT) skin test reactors. However, the numbers tabulated on page 29 of the same document (Appendix 3: Summary of the Derbyshire headline cattle TB statistics) are listed as **1,389** IFN-gamma blood test reactors and **842** SICCT reactors i.e. total of **2231**. The numbers displayed in the table (rather than in the descriptive analysis) are identical to those displayed in Appendix 3: Summary of the Cheshire headline cattle TB statistics in the Year End Descriptive Epidemiology Report: Cheshire Year-end report for: 2018 [43].

This raises questions about how much confidence can be placed in data cited in the report and also the quality of the process used for review. There may be other errors which are not as easy to identify.

8. Conclusions

The aim of this document was to critically evaluate the Derbyshire epidemiology report, particularly the claim made that 77% of TB breakdowns are caused by badgers. The APHA report relies on a risk assessment which depends upon accurate hazard identification and risk pathway analysis, but in all of these areas there is a neglect of uncertainties and unknowns coupled with an unsupported bias towards badgers and neglect of cattle-based risk factors. These include the use of 'circumstantial evidence' regarding a spike in TB incidents in 2015, the suggestion of endemicity of TB in the badger population and the prominence given to the numerical risk assessments which give a spurious sense of precision.

There are questions to be raised about the methodology behind the risk assessments. There is lack of clarity as to the evidence used to support on-site analysis as regards wildlife, there is ambiguity and subjectivity in the assignment of probability values, and it is concerning that not all officers are trained in all aspects of the task (i.e. badger ecology). There seems to be misconceptions about the likelihood of contact between badgers and cattle leading to disease transfer. Although uncertainty about the assessments is raised within the report, this uncertainty and the key limitations of the methodology are not acknowledged in many areas, or in reference to key statements made. These limitations should have been stated clearly within the executive summary i.e. that the source attribution proportions are numerical representation of veterinary judgement and carry considerable margins of error.

The DRF identify badgers as a likely source of infection based largely on whether they are present or absent. There are no detailed disease data for the badger population and a very large and unsupported assumption is made that essentially all badgers are infected and could be a source of disease. But crucially the latest data on TB in Derbyshire suggest that levels of infection in badgers are very low [1].

In addition, other important risk pathways are seemingly neglected because of a failure to recognise limitations in cattle testing. There is scientific evidence that the SICCT test fails to detect infected cattle resulting in a risk of residual infection remaining in herds or of diseased cattle moving between herds. Both of these sources of infection are likely to have been underestimated in the risk assessment analysis. While contact between badger faeces and cattle is explicitly considered, there is more restricted emphasis on, and consideration of, the potential for contamination by infected cattle faeces and cattle to cattle transmission

There are multiple lines of evidence which implicate badgers in the transmission of *M. bovis* to cattle. For example, spatial associations between infection in cattle and badgers [44] [30] [45] which suggests transmission between them [30]. There is evidence of similarity between the spoligotypes of associated cattle and badgers clustered in particular geographical areas [44] [41] and recent genetic evidence of transmission between badgers and cattle in the high risk area [34]. However, the key question is how much do badgers contribute to TB in cattle? Several studies have attempted to estimate this, although the estimates vary considerably depending on the models or methodology used. For example, in one model based on a high-cattle-TB-incidence area it was estimated that 5.7% (Confidence interval: 0.9-25%) of the transmission to cattle herds was badger-to-cattle with the remainder of the average overall contribution from badgers being amplification due to cattle-to-cattle transmission [46]. In another more recent study, environmental reservoirs were estimated to be the source of 36% of individual cattle infections in unrestricted herds, and that cattle-to-cattle transmission was the source of the remaining 64% of infected cattle [47]. Environmental reservoirs could include other sources of environmental transmission between cattle such as slurry and manure, or fomites, as well as badgers [47].

The examples given are estimations based on modelling studies and the models attempt to explain data already available and predict future patterns. The proportion of source attribution to badgers varies between these studies depending on the modelling criteria but the studies show a much larger proportion attributed to cattle-to-cattle transmission than to environmental reservoirs. In none of these studies does the proportion of contribution by badgers reach anywhere near the value of 77%.

The increase in herd breakdowns and total cattle reactors in 2018 can be partially explained by the incorporation of the former HRA part of Derbyshire into this year's statistics. The replacement of annual testing by six-monthly herd surveillance testing in this area will have led to earlier disclosure of disease and an increase in breakdowns during this period. The mandatory addition of interferon gamma testing led to the detection of 45% of TB reactor cattle which would have been missed by SICCT. This increased the number of cattle slaughtered as compared to 2017 when this test was less used. These two points are important factors in explaining the increases described.

The numerous limitations of the DRF data, along with the inconsistencies with the published science, mean that little confidence can be placed in the APHA report conclusions that badgers are responsible for 77% of new TB breakdowns in Derbyshire. It seems likely that this is a significant overestimate of the contribution of badgers to the disease. Yet, within several of the APHA documents, statements are made which lend credence to these results:

> ***Risk pathways for bovine TB infection.*** *The most likely infection source for 77% of the new breakdowns in 2018 was wildlife. This is also the most likely source of infection in beef suckler and dairy herds*. [2, p. 3]
>
> *At county level, the most common source of infection attributed within the HRA or Edge Area was badgers, in Cornwall (80.7%) and Derbyshire (77.4%)* [5, p. 36]

The Executive Summary of the APHA report omits the important caveat "*Therefore the relative proportions of each risk pathway are very approximate, and broad generalisations only can be made from these data"* [2, p. 16]. It is crucial that the reader understands this and its omission from the executive summary contributes to a misdirection in emphasis given to the risk assessments and gives the reader the mistaken belief that the results of the assessments are robust, which means it is easy to come to false conclusions.

Derbyshire farmers should be concerned that they are being presented with potentially misleading information, as if it is factual and without stating the many caveats and limitations. It is disappointing that the report perpetuates a long-standing misconception about role of badgers in bovine TB. The DRFs need updating to further consider the transmission pathways associated with cattle and fomites, and to reduce the bias toward badgers. Information gained from completing updated DRFs could guide bespoke on-farm mitigation techniques (including wildlife access prevention techniques as a simple precautionary measure) but should not be used by stakeholders to inform wider policy.

9. References

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10.Glossary of terms (from Bovine TB in GB in 2018: Explanatory supplement)

APHA	Animal and Plant Health Agency
Contiguous herd	A holding that has a common boundary with the TB incident holding of interest, but includes herds separated only by a short distance
Gamma interferon test (IFN-γ or gIFN or IFNgamma)	Laboratory-based blood test approved as an ancillary diagnostic tool that measures the amount IFN-γ released in whole blood cultures stimulated with tuberculin
Genotype	A unique DNA type of *M. bovis*, defined by a combination of spoligotype (expressed as a number) and VNTR type (expressed as a letter)
Homerange	The geographical area in which a particular genotype of *M. bovis* is typically recovered from infected cattle herds. A 5 km square is considered as part of a certain homerange if there have been three different incidents of that genotype, on at least 2 holdings, within a 5 year window.
Inconclusive reactor	Inconclusive reactors (IRs) are cattle that have a response to the TB skin test that is not strong enough to classify them as reactors

New TB incident	A herd newly found to be infected with TB. Defined as a herd previously OTF in which at least one test reactor, IR taken as a reactor, or a culture-positive slaughterhouse case has been found
OTF	Officially bovine tuberculosis free status
OTF-S	Officially bovine tuberculosis free status suspended. OTF-S is the status of a herd with a TB incident where there is a suspicion of infection being present. A TB incident that did not meet the conditions for an OTF-W incident is classified as an OTF-S incident
OTF-W	Officially bovine tuberculosis free status withdrawn. A TB incident in which additional evidence of M. bovis infection has been identified in at least one slaughtered bovine animal
Persistent herd	A TB incident herd that has been under restrictions for at least 550 days
Reactor	An animal showing a positive reaction result to a single intradermal tuberculin comparative cervical (SICCT) test (a.k.a. the skin test), or to a gamma interferon (IFN-γ) assay consistent with it being infected with M. bovis
Recurrent herd incident	A herd that had a TB incident disclosed in the reporting year that had also been under movement restrictions for a different bTB incident in the previous 36 months
SAM database	APHA's IT system, which records details of herds, TB tests, TB incidents and the details and results of any tested and slaughtered cattle
Sensitivity	The proportion of truly infected individuals in the screened population that are identified as infected (positive) by the test
Severe interpretation	The positive cut-off criterion used to interpret the results of a skin test in TB incident herds in order to achieve a greater sensitivity
SICCT	Single intradermal comparative cervical test
Standard interpretation	The positive cut-off criterion normally used to interpret the results of a skin test

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