Wednesday 11th December 2024

Bovine Tuberculosis

Background:

- Bovine tuberculosis (bTB) is a chronic infectious bacterial disease in animals caused by members of the Mycobacterium complex, primarily by *Mycobacterium bovis*, but occasionally by *Mycobacterium caprae* and *Mycobacterium tuberculosis*[1].
- In the UK, bTB is classified as both a notifiable and zoonotic disease[2] in cattle.
    - In the 1930s, bTB was a significant **public health issue**. In 1934, an estimated 40% of dairy herds were infected with *M.bovis*, resulting in approximately 2,500 human deaths annually, predominantly amongst children, and 50,000 additional cases of the disease[3].
    - The introduction of compulsory test and cull regimes, post-mortem carcass inspection and widespread milk pasteurisation has **significantly reduced the risk of bTB transmission to humans**. Between 2009-2018, the UK reports an average of 25-41 human cases of *M.bovis* infection annually[4].
        - Most cases involve individuals born in the UK before 1960, suggesting reactivation of latent infections acquired when bTB prevalence in cattle was higher and public health measures were less robust[4]. Approximately 20% of human cases occur in individuals born outside the UK, likely due to exposure to infection abroad[4].
- In cattle, bTB primarily manifests as a respiratory disease, causing caseonecrosis pneumonia. It is transmitted through direct nose-to-nose contact and indirectly through contact with bodily fluids such as, urine, faeces and saliva[5].
- The disease develops slowly and clinical signs are rarely observed in the UK due to regular statutory testing.
    - Notably, 92% of cattle naturally infected with *M.bovis* exhibit no clinical signs despite showing severe and disseminated lesions identified at post-mortem inspection (PMI)[6].
- Treatment of bTB in cattle is prohibited by the EU[7] due to long treatment periods, poor efficacy and the risk of development of antimicrobial resistance[8].
- Beyond its zoonotic potential, bTB causes substantial economic and welfare challenges to farmers. In the 2018 Godfray report, they say '*The prevalence of the disease in parts of the country, coupled with the test and slaughter strategy that is the basis of disease control, makes the risk and consequences of infection one of the greatest factors affecting the livelihoods of numerous farmers*.'[9]
    - bTB affects cattle welfare, reduces farm productivity, and imposes significant costs on farmers, the industry and trade[10].
    - The combined financial burden of bTB on taxpayers and the industry is estimated at £150 million annually[11].
    - In England, over 30,000 cattle are slaughtered each year due to bTB, causing severe emotional and financial strain on farmers[12].
- Control measures for bTB in the UK include preventing cattle-to-cattle transmission through test and cull regimes, reducing wildlife-to-cattle transmission via farm biosecurity measures and badger culling,

[1] https://www.woah.org/en/disease/bovine-tuberculosis/
[2] https://www.gov.uk/guidance/bovine-tb
[3] https://acmsf.food.gov.uk/sites/default/files/multimedia/pdfs/committee/acm995mbovis.pdf
[4] https://www.gov.uk/government/publications/mycobacterium-bovis-mbovis-tuberculosis-annual-data/mycobacterium-bovis-notifications-to-national-tuberculosis-surveillance-uk-2000-to-2023
[5] https://www.gov.uk/guidance/bovine-tb
[6] Menin Á, Fleith R, Reck C, Marlow M, Fernandes P, Pilati C, Báfica A. Asymptomatic cattle naturally infected with Mycobacterium bovis present exacerbated tissue pathology and bacterial dissemination. PLoS One. 2013;8(1):e53884. doi: 10.1371/journal.pone.0053884. Epub 2013 Jan 9. PMID: 23326525; PMCID: PMC3541226.
[7] https://www.nadis.org.uk/disease-a-z/cattle/bovine-tb/#:~:text=Treatment,are%20placed%20on%20the%20herd.
[8] https://www.woah.org/fileadmin/Home/eng/Media_Center/docs/pdf/Disease_cards/BOVINE-TB-EN.pdf
[9] https://assets.publishing.service.gov.uk/media/5beed433e5274a2af111f622/tb-review-final-report-corrected.pdf
[10] Tschopp R, Conlan AJK, Gemechu G, et al. Effect of Bovine Tuberculosis on Selected Productivity Parameters and Trading in Dairy Cattle Kept Under Intensive Husbandry in Central Ethiopia. *Front Vet Sci.* 2021;8:698768. Published 2021 Jul 21. doi:10.3389/fvets.2021.698768
[11] https://www.gov.uk/government/publications/a-strategy-for-achieving-bovine-tuberculosis-free-status-for-england-2018-review-government-response/executive-summary#fn:1
[12] https://assets.publishing.service.gov.uk/media/5e60ad0de90e077e3d2678d2/bovine-tb-strategy-review-government-response.pdf

and safeguarding human health through milk pasteurisation and condemnation of bTB meat if found in more than one organ or location on the carcass.

- In England, bTB has been subject to a statutory eradication programmed based of a 2014 government strategy to achieve officially TB free (OTF) status for the whole country by 2038[13].
    - Eradication has been difficult to achieve in the UK due to established reservoirs of disease (predominantly the European badger[14]) and the presence of persistently infected cattle which often remain asymptomatic and are not detected by statutory testing.
- Since 2014, over £1 billion has been spent on bTB control in English cattle herds[15], resulting in the slaughter of over 278,000 cattle and the culling of over 230,000 badgers[16].
    - Despite this huge investment, eradication remains a long way off. Critics argue that this level of expenditure is disproportionate given bTB no longer represents a major public health threat in the UK. However, progress towards eradication is critical for securing OTF status, which underpins the national and international trading of animal products and ensures the long-term sustainability of farmers, the broader agricultural industry, and food security in the UK.

Key Legislation and Policies:

- The legislative background for bTB in the UK reflects a longstanding and evolving effort to manage and control bTB due to its economic and animal welfare implications, as well as public health concerns given its zoonotic potential. Devolved nations have tailored policies to regional needs and bTB incidence, balancing disease control with ethical considerations and public opinion on badger management.
- **Legislation:**
    - The Animal Health Act (1981)[17]
        - This Act grants the Government powers to control and eradicate animal diseases, including bTB. It underpins the UK's broader animal health policies, empowering the government to implement testing, impose movement restrictions and enforce biosecurity measures to limit the spread of diseases like bTB.
        - Under this act, it is an offence to fail to seek written consent from the APHA for the use of certain private bTB tests in cattle.
    - The Cattle Compensation (England) Order 2019[18]
        - Establishes compensation criteria for cattle slaughtered due to bTB infection under the Animal Health Act 1981.
    - The Tuberculosis in Animals (England) Order 2021
        - An order under the Animal Health Act 1981.
            - Replaces The Tuberculosis (England) Order 2014 and The Tuberculosis (Deer and Camelid) (England) Order 2014[19].
        - Consolidates tuberculosis control regimes for domestic ruminants, pigs, camelids and captive deer.
        - This order covers testing regimes, recording requirements, notification protocols, animal movement restrictions protocol and defines low risk areas of England[20].
        - It prohibits the use of bTB tests without specific permission from the Secretory of State and allows the APHA to share TB incidence data of all cattle herds in England.
- **Policies:**
    - Voluntary Eradication Program (1935):

[13] https://assets.publishing.service.gov.uk/media/6390707ae90e071dfff6de10/Bovine_Tuberculosis_in_England_in_2021.pdf
[14] https://www.bva.co.uk/media/3629/bva-policy-position-on-the-control-and-eradication-of-bovine-tb.pdf
[15] https://questions-statements.parliament.uk/written-questions/detail/2022-10-11/HL2483/#:~:text=We%20estimate%20that%20the%20total,the%20last%2010%20financial%20years.
[16] https://deframedia.blog.gov.uk/2024/09/02/government-announces-tb-eradication-strategy-to-end-the-badger-cull/
[17] https://www.legislation.gov.uk/ukpga/1981/22
[18] https://www.legislation.gov.uk/uksi/2019/945
[19] http://apha.defra.gov.uk/documents/ov/Briefing-Note-4021.pdf
[20] https://www.legislation.gov.uk/uksi/2021/1001

- Initially voluntary, the eradication progam became compulsory in 1950, mainly due to the prevalence of *M.bovis* infection in humans[21].
  - The compulsory regime used intra-dermal tuberculin testing and initiated the slaughter of infected cattle as a key control strategy.
  - This test and cull regime was very successful, confining bTB to a few areas in the south-west England.

- Devolved Policies:
  - England:
    - 25-year bTB Eradication Strategy (2014)
      - Aims to achieve OTF status for England by 2038.
      - Outlines the Governments rationale for action to address bTB and eradication measures, including the controversial badger cull[22].
      - In England, the Government has implemented badger culling policy since 2011, initially starting with pilot studies and then as part of the eradication strategy.
    - Following the Godfray Report (2018), an independent review into bTB 25-year strategy for England, the Government's response (2020) proposed a phased approach to end badger culling with increased emphasis on badger vaccination and biosecurity improvements.
    - Badger Edge Vaccination Scheme[23]:
      - Taking forward a commitment from the bTB eradication strategy this scheme provided funding towards the cost of vaccinating badgers in the Edge Area of England with the BCG vaccine for 4 years from 2019 to 2023.
  - Wales:
    - Objective of eradiating TB from Wales by 2041[24].
    - Wales TB Eradication Delivery Programme 2023-2028[25]
      - The principles of the programme include prevention (promotion of good biosecurity and informed purchasing), rapid diagnostics and frequent testing, movement restrictions to stop spread and test and cull with a post-breakdown testing policy.
  - Scotland[26]:
    - Achieved OTF status in September 2009 under the EU 64/432/EEC due to low and stable incidence of bTB in Scottish cattle herds.
      - Since leaving the EU, Scotland's OTF status is recognised under EU 2021/404. Demonstrating continued freedom from disease is essential for trade between Scotland and the EU.
      - There is a zero-tolerance policy on herds which fail to test by a specified testing date and compensation payments are reduced (as in England).
    - The Scottish Government has therefore established a risk-based approach to surveillance while protecting its status, for example, low risk herds that meet certain criteria are exempt from routine four-yearly surveillance testing. The majority of cattle herds have a default testing interval of 4 years.
  - Northern Ireland[27]:
    - Bovine Tuberculosis Control Scheme (NI) 2024:

[21] https://www.jpccr.eu/pdf-71288-8517?filename=Historical%20aspects%20of.pdf
[22] http://www.bovinetb.info/docs/badger-culling-in-england.pdf
[23] https://www.gov.uk/government/publications/badger-edge-vaccination-scheme-2-bevs-2/scheme-outline
[24] https://www.gov.wales/sites/default/files/publications/2023-03/wales-bovine-tb-eradication-programme-delivery-plan-2023_0.pdf
[25] https://www.gov.wales/sites/default/files/publications/2023-03/wales-bovine-tb-eradication-programme-delivery-plan-2023_0.pdf
[26] https://www.gov.scot/publications/bovine-tb/pages/testing-surveillance/
[27] https://www.daera-ni.gov.uk/articles/bovine-tuberculosis-tb-control-programme

- Aims to prevent and eradicate bTB in Northern Ireland and compensate farmers for loss of animals under tests and cull eradication programme. The strategy involved test and slaughter controls, movement controls and compensation schemes.

The Godfray Report[28]

- In 2018, Sir Charles Godfray and his team published a comprehensive review of England's bTB control strategy. The report stressed the importance of flexible policies to efficiently incorporate new insights from surveillance and research into policy for widespread implementation and proposed region-specific interventions to enhance disease control and eradicate bTB effectively.
- **Recommendations:**
    - Improved governance:
        - Foster industry and farmer ownership of bTB control efforts while retaining high-level policy making in Defra.
        - Centralise disease control operations (combining APHA, Natural England and local authorities) to improve efficiency, avoid duplication, improve co-ordination and cost effectiveness of control measures.
    - Changing surveillance and diagnostics testing protocols:
        - Balance the trade-offs between test specificity (minimising false positives) and sensitivity (identifying more infected cattle).
        - They suggest the use of the more sensitive Single Intradermal Cervical Test (SICT), used in the EU, for high-risk areas (HRAs) and edge areas (EAs) to enable early detection of disease. Positive cases should be re-tested with interferon gamma to reduce the false positives.
            - In low-risk areas (LRAs) '*the numbers of new infections detected would not justify the increased number of false positives*.'
            - In the short term, this would increase the number of herd breakdowns as more infections will be revealed by more sensitive test – it is important to remember this is **not** a failure of policy just the outcome of a more sensitive testing protocol.
        - Combination of tuberculin skin test, interferon-gamma test and IDEXX ELISA in high-risk scenarios, such as persistently infected herds, badger cull areas and edge areas.
            - There would be increased costs associated with this, but the reduced transmission benefits would be substantial.
        - Improving tuberculin quality with defined DIVA antigens to improve standardisation and further improve specificity of the skin test.
            - This will aid the roll out of mass cattle vaccination against bTB.
        - Routine use of whole genome sequencing to help identify disease transmission pathways (currently this is limited to PCR positive animals at PMI).
    - Risk-based animal trade:
        - The report recommended prohibition of the trade of high-risk cattle across the UK.
        - Utilise the Livestock Information Service (LIS) for information on cattle movements in the UK via electronic identification tags. From this data, risk of cattle infection can be determined and made readily available prior to purchase/market so risk of trade in an infected cow is reduced.
            - For cattle, roll-out of this scheme is anticipated for autumn 2025[29].
        - Alter the recording requirements to make it mandatory to record cattle movements within 10 miles from their registered holding, particularly in EAs – LIS will aid in this data collection.

[28] https://assets.publishing.service.gov.uk/media/5beed433e5274a2af111f622/tb-review-final-report-corrected.pdf
[29] https://ahdb.org.uk/LIP

        - Risky trading behaviour can be disincentivised by reducing compensation.
        - Extensions of mandatory post movement resting from HRAs to EAs (has been adopted) with the use of the most sensitive test (has not yet been adopted).
    - <u>Wildlife reservoirs – badger culling policy needs to be flexible and evidence-based</u>
        - Reducing the threat of badger to cattle transmission by culling or non-lethal measures (BCG vaccination) will reduce the incidence of disease in cattle. As this is highly controversial the decision to perform a badger cull needs to be made by Government Ministers and informed by scientific evidence (flexible policy).
            - Badger culling exhibits a perturbation effect to adjacent non-culled areas. Therefore, for culling to be effective it needs to cover a large area and utilise natural barriers to restrict badger movement.
            - Evidence from the Randomised Badger Culling Trial suggests the benefits of culling repeated annually for four years persist for some years after the cull has ended. Therefore, periodic culling is a more promising strategy than continuous culling over four years.
        - There is limited evidence that other wildlife species pose a substantial threat to disease transmission to cattle.
    - <u>Biosecurity improvements:</u>
        - Overall, there is low uptake in this control strategy due to motivation and implementation time, labour and costs.
        - To improve uptake, biosecurity requirements should be collated from different accreditation schemes and supermarket requirements.
        - '*Recent evidence that the potential for bovine TB to be dispersed by spreading slurry or manure on the land may have been under-appreciated.*'[28] More research on this possible transmission route and mitigation strategies if appropriate should be explored.
- **Government Response[30]:**
    - The Government stressed that the test-and-cull policy remains the cornerstone of bTB control.
    - Top priorities:
        1. Accelerate work to deploy a cattle vaccine against bTB in the next five years, i.e., by 2024.
        2. Development of improved testing and movement restriction protocol:
            a. More sensitive tests.
            b. DIVA tests.
            c. Greater use of on-farm restrictions of cattle classified as inconclusive reactors.
        3. Prevention of spread form the wildlife reservoir:
            a. Phasing out of the badger cull and moving towards badger vaccination in areas where the four-year intensive cull has been carried out.
            b. EAs remain subject to culling but this decision must be supported by epidemiological evidence.
        4. Incentivises the uptake of on-farm biosecurity.
        5. Establish a bTB partnership between government and industry to encourage shared ownership and decision making towards effective governance at every level for effective disease eradication.

[30] Next steps for the strategy for achieving bovine tuberculosis free status for England, Defra, March 2020
https://assets.publishing.service.gov.uk/media/5e60ad0de90e077e3d2678d2/bovine-tb-strategy-review-government-response.pdf

Bovine TB Incidence in Cattle the UK

- Definitions:
  - **Prevalence** – a snapshot of the number of existing diseased animals within a specific population at a specific time.
    - Useful to understand the overall impact of a disease in a population.
    - Number of infected individuals/total population, often expressed as a percentage or per 1,000 animals.
  - **Incidence** – quantifies the number of new disease outbreaks in a specific population over a defined period.
    - Useful for understanding how rapidly a disease is spread within a community.
    - Number of new cases/population at risk during time period, often expressed as incidence per 1,000 individuals.
- Past incidence:
  - In 1934, before the adoption of milk pasteurisation and compulsory testing of cattle, it is estimated that over 40% of dairy cows in Great Britain (GB) were infected with *M. bovis* and 0.5% suffered from bTB infections of the udder[31].
  - With the voluntary, turned compulsory (1950), test and slaughter policy and improvements to PMI in slaughterhouses, bTB incidence and prevalence reduced significantly in GB from the 1950s to the mid-1980s (Figure 1)[32]. The lowest prevalence levels were recorded in 1979 with 0.49% at the herd level and 0.018% of all tested cattle. Since the 1980s, bTB incidence has increased to a peak in 2008 where 6.4% of herds were culture or lesion positive[27].

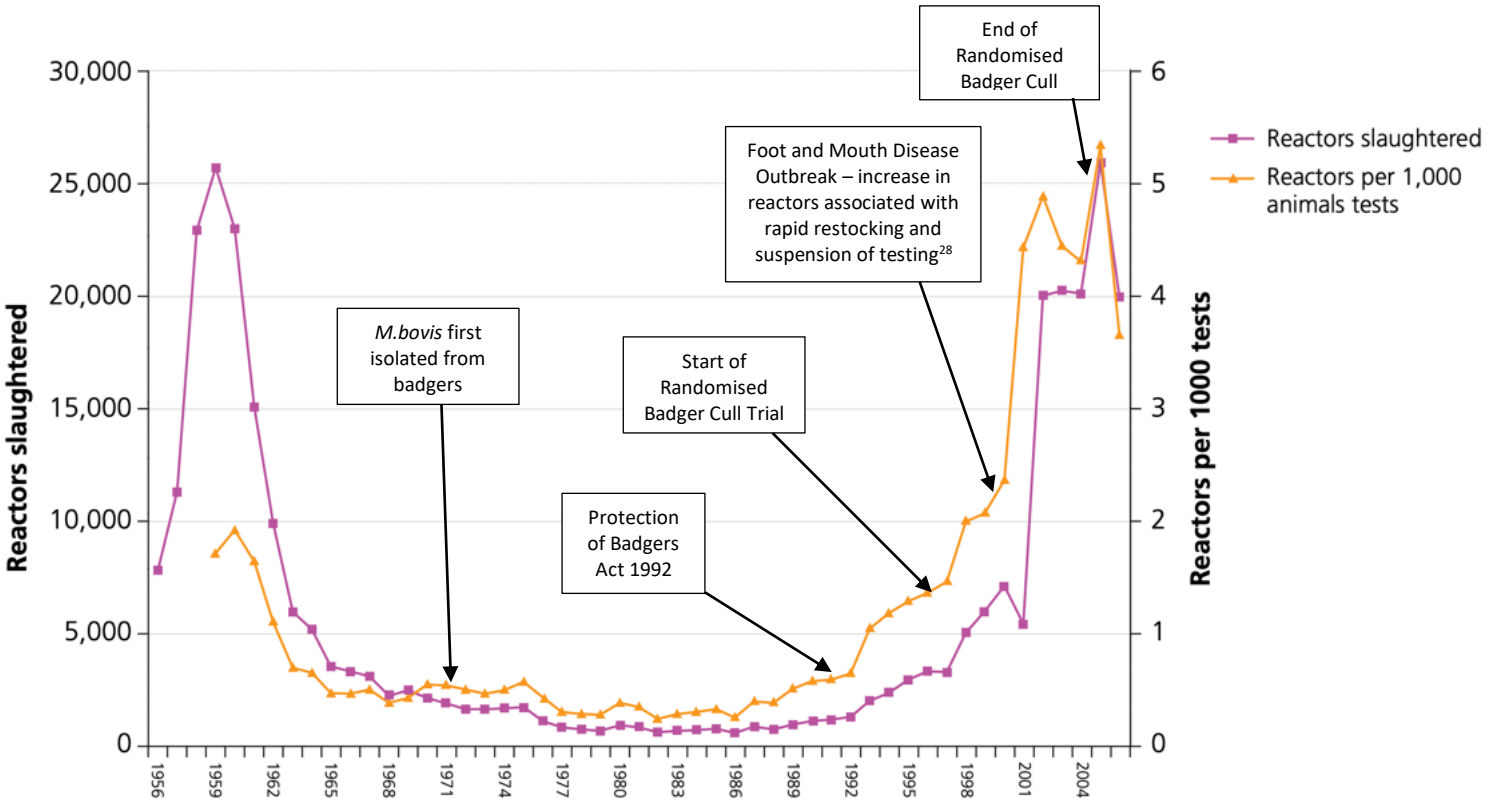

Figure 1: Number and rate of bTB tuberculin test reactors disclosed in GB 1956-2006

  - Since *M.bovis* was first found in badgers in 1971, badgers were culled through to the mid-80's. Some argue that increase in cases coincided with changes in policy which strengthened the

[31] https://acmsf.food.gov.uk/sites/default/files/multimedia/pdfs/committee/acm995mbovis.pdf
[32] Animal Health 2006: Report of the Chief Veterinary Officer

protection of badgers through legislation[33]. However, multifactorial issues are likely responsible for the spike in bTB from the mid 1980s, a few of which are highlighted in Figure 1[34]. Additionally, **bTB incidence was reducing** in the 1960's **before** the implementation of badger culling, highlighted in Figure 1.

- <u>Current incidence:</u>
  - bTB is currently endemic in England and Wales.
  - Scotland has been declared officially bTB free (OTF) since 2009, meaning it has few, sporadic breakdowns.
    - This is defined as '*the percentage of herds confirmed as bTB infected not exceeding 0.2%, or representing 0.1% of bovids[35] per year for six consecutive years*[36].'
  - The most recent Quarterly Overview of bTB statistics from DEFRA, with data collected between July 2023 and June 2024, shows[37]:
    - England:
      - **Herd incidence** was 7.4, an increase of 0.2 from the previous year.
        - This means that for every 1,000 unrestricted herds we expect a breakdown in 74 herds each year.
        - This has decreased by 7% since 2021 but increased in low-risk areas over this period.
      - In June 2024, 4.2% of herds were not TB-free - a very slight **decrease** from the previous year (4.3%).
        - EAs have shown an increase in herd prevalence to 4.8%.
    - Wales:
      - **Herd incidence** has **risen** to 6.9 (0.3 increase from the previous year), and **herd prevalence** has **risen** to 5.6% (increase of 0.3%).
    - Scotland – herd incidence and prevalence remain **very low at 0.5.**
  - In England, 21,943 animals were slaughtered between July 2023 and June 2024, with 11,789 slaughtered in Wales, showing a 14% and 24% increase from the previous year, respectively[29]. Culling cattle has significant corresponding costs to farmers, both financially and emotionally, and the taxpayer through compensation at slaughter[38].
    - In England, the epicentre for bTB is in the southwest, particularly Cornwall, Devon and Dorset. As shown in table 1, there has been little improvement in bTB prevalence in

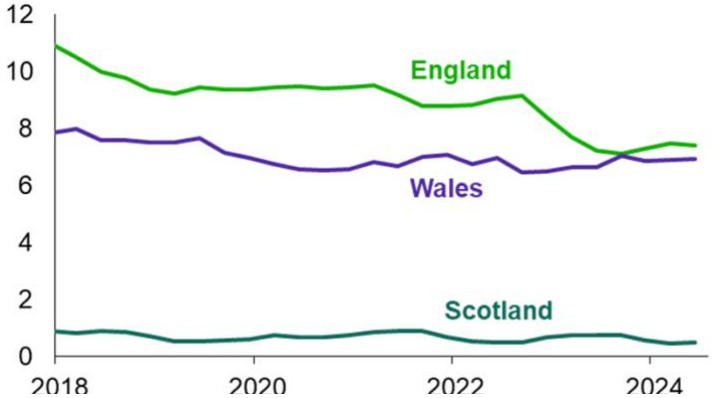

Figure 3: Herd Incidence (new herd breakdowns per 100 herd years at risk of infection) 2018-2024

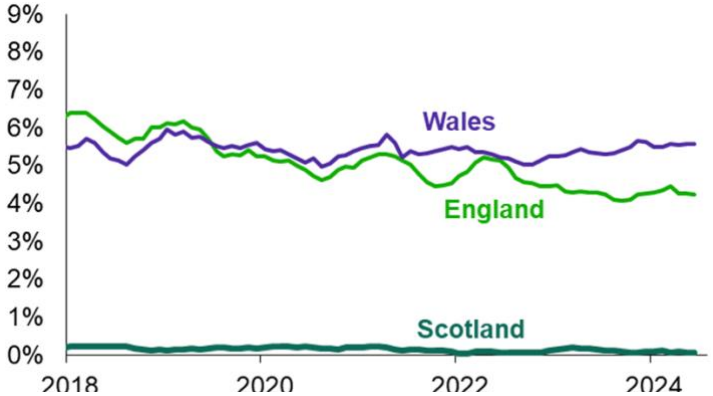

Figure 2: Herd prevalence (restricted herds) as a percentage of all registered herds 2018-2024

[33]Bennett, R. ORCID: https://orcid.org/0000-0003-3226-8370 (2017) The political economy of bovine tuberculosis in Great Britain. Revue Scientifique et Technique, 36 (1). pp. 105-114. ISSN 0253-1933 doi: https://doi.org/10.20506/rst.36.1.2614 Available at https://centaur.reading.ac.uk/65754/
[34] https://assets.publishing.service.gov.uk/media/5e60ad0de90e077e3d2678d2/bovine-tb-strategy-review-government-response.pdf
[35] https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmfile=chapitre_bovine_tuberculosis.htm
[36] Allen AR, Skuce RA, Byrne AW. Bovine Tuberculosis in Britain and Ireland - A Perfect Storm? the Confluence of Potential Ecological and Epidemiological Impediments to Controlling a Chronic Infectious Disease [published correction appears in Front Vet Sci. 2019 Jul 02;6:213. doi: 10.3389/fvets.2019.00213]. *Front*
[37] https://www.gov.uk/government/statistics/incidence-of-tuberculosis-tb-in-cattle-in-great-britain/quarterly-tb-in-cattle-in-great-britain-statistics-notice-june-2024
[38] https://deframedia.blog.gov.uk/2024/09/02/government-announces-tb-eradication-strategy-to-end-the-badger-cull/

the past five years despite significant badger culling over 80% of the land area. Currently over 600 herds are not OTF - representing over 8% of all herds in England[39].

Table 1: bTB prevalence in Cornwall, Devon and Dorset on the 31st December each year from 2019-2023[40]

End of Year	Total Herds	Non-OTF	Percentage of all herds (%)
2019	8696	873	10.04
2020	8690	747	8.60
2021	8217	643	7.83
2022	8020	714	8.90
2023	7929	666	8.40

- When looking at long-term data relating to herd prevalence i.e., number of herds non-OTF, we need to contextualise the trends in terms of the number of herds in a region each year. For example, between 2019 and 2023, there has been an 8.8% reduction in herd number in Cornwall, Devon and Dorset. Despite actual herd non-OTF status reducing, the percentage of herds non-OTF is fairly constant as the herd numbers have reduced but the number of infected animals remains at similar levels.

Current bTB Control Measures

- The Labour Government is currently conducting a 'rapid review' of bTB control in Great Britain. The review aims to address the efficacy and sustainability of existing strategies for managing bTB and the phase out of the badger cull, which remain a significant challenge to the farming industry and public policy.
- Prevention of cattle-cattle transmission:
    1. **Test-and-cull policy**
        - Statutory testing and slaughter of infected animals, with compensation to farmers, has been a cornerstone bTB control policy since the 1950s. The Single Intradermal Comparative Cervical Tuberculin Test (SICCT) is the primary skin test in the UK and testing frequency varies based on regional bTB risk (Figure 4).
        - Testing frequency:
            - Generally, in England[41]:
                - High-risk areas (HRAs) – routine testing every six months.
                - Edge areas (EAs) – routine testing every 6 or 12 months depending on risk.
                - Low-risk areas (LRAs) – routine 4-yearly testing, unless within a 3km radius of a new bTB outbreak[42].
            - In Wales, annual testing is standard, with six-month interval in hers within the Intensive Action Area.
            - In Scotland, testing is every 4 years, with exemptions for certain low-risk herds.
        - All herds which are up to date with testing and have no positive tests are classified as Officially TB Free (**OTF**).
            - If a reactor to the SICCT is found, OTF status is lost and the reactor must be slaughtered, with subsequent repeat testing of the remainder of the herd in 60 days.

[39] https://savemetrust.co.uk/2024/08/20/defraspin/
[40] Data from private meeting with Dick Sibley
[41] bTB Testing Regime Briefing, Fiona Shuttleworth, VPRF, November 2024
[42] https://www.gov.uk/guidance/bovine-tb-testing-intervals

- Movement restrictions are placed on those in the 3km radial zone in an attempt to prevent further spread.
- Moving bovids over 42 days old requires pre-movement testing within 60 days, and post-movement testing dependent on the risk status of where animals are being moved to and from[43].

- In the year leading up to June 2024:
  - 9,712,762 bTB tests were conducted across GB[30].
  - 33,926 animals being slaughtered[30] as reactors, inconclusive reactors or direct contacts.
  - The estimate cost of this policy is £150 million annually[8], shared between the UK farming industry and taxpayers.
- **Concerns** with the test-and-cull policy:
  - The SICCT statutory test has a relatively low sensitivity, estimated as 81% by Defra, but many field studies suggest actual sensitivity may range between 36-60%, with severe interpretation being slightly higher, at 65-77%[44]. This means as many as **half of all infected animals may remain undetected** and are a potential source of infections in herds.
    - **Severe interp**retation increases false positives (decreases specificity) as a trade-off for increased sensitivity and is currently used in **breakdown he**rds[45].
    - When the SICCT is used in combination with the gamma-interferon test it improves sensitivity, as cattle can be detected at earlier stages of infection, but there is still a clear need for an improved primary screening test[20].
  - Currently, extended testing (including gamma-interferon) is **only permitted** in herds classified as **persistently infected** or in animals with **visible lesions (VL)** at PMI.
    - This is restrictive as very **few animals develop visible lesions** even if they are reactors. This is because the statuary testing aims to identify these animals before long-term infection develops (associated with VLs).
  - Furthermore, once a herd is classified as OTF, **veterinarians are unable to perform any bTB testing, including the SICCT, outside of the routine surveillance testing intervals**. Therefore, if the statutory tests have left undetected animals in the herd - they will not be detected and removed/managed out until the next statutory test is due, giving ample time for the infection to continue spreading amongst the herd.
  - There are **only two APHA verified tests** currently in the UK – the SICCT and gamma interferon. Alternative tests, **IDEXX ELISA, Actiphage** and **Enferplex**, **require prior permission from the APHA** for their usage. Increasing the accessibility and availability of alternative testing to improve detection of infected animals missed by statutory tests may help improve bTB control.

2. **Cattle vaccination**
   - Defra has invested £50 million in the development of a vaccine and the associated Differentiating Infected from Vaccinated Animals (DIVA) test detecting bTB proteins not present in the vaccine. In the UK, Phase 3 field trials are underway for a cattle **BCG**

[43] https://www.gov.uk/government/publications/bovine-tb-pre-movement-and-post-movement-testing-in-great-britain/guidance-bovine-tb-pre-movement-and-post-movement-testing
[44] A. Lahuerta-Marin, M.G. Milne, J. McNair, R.A. Skuce, S.H. McBride, F.D. Menzies, S.J.W. McDowell, A.W. Byrne, I.G. Handel, B.M. de C. Bronsvoort, Bayesian latent class estimation of sensitivity and specificity parameters of diagnostic tests for bovine tuberculosis in chronically infected herds in Northern Ireland, The Veterinary Journal,Volume 238,2018,Pages 15-21,ISSN 1090-0233,https://doi.org/10.1016/j.tvjl.2018.04.019.
[45] https://tbhub.co.uk/tb-policy/england/use-of-severe-interpretation-for-trace-tb-tests/

vaccine and **DIVA test combination** (DST-F), with the intention to make this deployable in the coming years, a promising future development for cattle protection against bTB[46].

- However:
  - The efficacy of vaccination is variable[47], as some vaccinated cattle may still acquire and transmit the disease, despite a **reduction in severity** of bTB and **transmission probability** to unvaccinated individuals[48,49].
  - Vaccination interferes with current bTB statutory tests which possibly complicates international trade. Defra have sought early engagement with trading partners such as the World Organisation for Animal Heath (WOAH) and the EU to minimise the impact on future trade post vaccine roll-out.
    - The WOAH terrestrial code standards **do not** require any additional controls for **international trade in fresh meat and meat-by-products** as these are considered safe commodities[50]. However, there are implications for the import milk and milk products, of animals for breeding or rearing purposes – practices still permitted under the Animal Welfare (Livestock Exports) Act 2024[51] – and the import of bovid semen and embryos[52].
    - Similarly, the export health certificate required for animal by-product exports to the EU **does not** contain specific bTB surveillance requirements nor does it prevent the export of meat from BCG-vaccinated cattle **at this moment in time.**
  - Therefore, DIVA development is crucial for vaccine roll-out in the UK, with early trials proving promising[53].

- <u>Prevention of wildlife to cattle transmission:</u>

1. **<u>Badger Culling:</u>**
   - This highly controversial policy was introduced in England in 2013, following the Randomised Badger Cull Trial (RBCT) (1998-2007) which suggested a 29% decrease in bTB incidence in areas where culling was implemented[54]. Data was collected by the APHA to show incidence and prevalence of bTB in badger control areas[55]. Multivariable analyses conducted using the data showed there was a significant reduction in incidence in areas subject to badger control[56,57].
   - However, there are numerous concerns with the basis of the study:
     - <u>Statistical concerns</u> - Recent studies identified flaws in the RBCT's statistical modelling, with overestimated culling benefits. When corrected using more

[46] https://www.gov.uk/government/news/field-trials-for-bovine-tb-cattle-vaccine-and-skin-test-move-to-next-phase--2#:~:text=Field%20trials%20for%20a%20cattle,cattle%20against%20this%20endemic%20disease.
[47] https://www.woah.org/fileadmin/Home/eng/Media_Center/docs/pdf/Disease_cards/BOVINE-TB-EN.pdf
[48] https://www.cam.ac.uk/research/news/tb-vaccine-may-enable-elimination-of-the-disease-in-cattle-by-reducing-its-spread
[49] Fromsa A, Willgert K, Srinivasan S, Mekonnen G, Bedada W, Gumi B, Lakew M, Tadesse B, Bayissa B, Sirak A, Girma Abdela M, Gebre S, Chibssa T, Veerasami M, Vordermeier HM, Bakker D, Berg S, Ameni G, Juleff N, de Jong MCM, Wood J, Conlan A, Kapur V. BCG vaccination reduces bovine tuberculosis transmission, improving prospects for elimination. Science. 2024 Mar 29;383(6690):eadl3962. doi: 10.1126/science.adl3962. Epub 2024 Mar 29. PMID: 38547287.
[50] https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmfile=chapitre_bovine_tuberculosis.htm
[51] https://www.legislation.gov.uk/ukpga/2024/11/contents
[52] https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmfile=chapitre_bovine_tuberculosis.htm
[53] Thomas Holder, Michael Coad, Grace Allan, Phillip J. Hogarth, H. Martin Vordermeier, Gareth J. Jones, Vaccination of calves with Bacillus Calmette-Guerin Danish strain 1331 results in a duration of immunity of at least 52 weeks,Vaccine,Volume 41, Issue 48,2023,Pages 7290-7296,ISSN 0264-410X,https://doi.org/10.1016/j.vaccine.2023.10.060.
[54] The Duration of the Effects of Repeated Widespread Badger Culling on Cattle Tuberculosis Following the Cessation of Culling Jenkins HE, Woodroffe R, Donnelly CA (2010) The Duration of the Effects of Repeated Widespread Badger Culling on Cattle Tuberculosis Following the Cessation of Culling. PLOS ONE 5(2): e9090. https://doi.org/10.1371/journal.pone.0009090
[55] https://assets.publishing.service.gov.uk/media/635b9683d3bf7f20e28883ee/monitoring-report-2013-2021.pdf
[56] Birch, C.P.D., Bakrania, M., Prosser, A. *et al.* Difference in differences analysis evaluates the effects of the badger control policy on bovine tuberculosis in England. *Sci Rep* **14**, 4849 (2024). https://doi.org/10.1038/s41598-024-54062-4
[57] Downs SH, Prosser A, Ashton A, Ashfield S, Brunton LA, Brouwer A, Upton P, Robertson A, Donnelly CA, Parry JE. Assessing effects from four years of industry-led badger culling in England on the incidence of bovine tuberculosis in cattle, 2013-2017. Sci Rep. 2019 Oct 11;9(1):14666. doi: 10.1038/s41598-019-49957-6. PMID: 31604960; PMCID: PMC6789095.

appropriate statistical analysis, the results were not reproducible[58]. Further large-scale analyses have failed to find significant effects of badger culls in high-risk bTB areas[59].

- Godfray Report (2019) – The report acknowledged evidence of badger-to-cattle transmission[60], but emphasised the perturbation effect found from the RBCT – disrupting badger social structures through culling can increase bTB spread to areas adjacent to cull zones. It recommended shifting towards non-lethal badger control measures.

- Comparative research suggests cattle-to-cattle transmission drives bTB infection more significantly than badger-to-cattle transmission. For example,
  - A study in Woodchester Park found that within species transmission (cow-cow) occurs at around twice as much as interspecies transmission (badger to cow), despite the high density of badgers in the region[61]. Though these findings are less generalisable to areas with higher cattle movement.
  - Analysis in Northern Ireland similarly show cattle-to-cattle transmission is likely driving the local epidemic, with cattle-to-badger transmission occurring at a higher rate than badger-to-cattle transmission[62].
- Even where cull methods are reported as effective, this is often **without comparison** of other non-lethal badger control methods (e.g., badger vaccination and fertility control), and improved farm biosecurity.

2. Badger Vaccination:

- Badgers are vaccinated using the human Bacillus Calmette-Guerin (BCG) vaccine, licensed for use in 2010[63]. Vaccination requires a licence under the Protection of Badgers Act 1992 for the capture and marking of badgers.
  - The vaccine does not prevent acquisition of *M.bovis* by badgers, but rather reduces the severity and infectivity of bTB within the badger population with the aim of reducing the transmission to cattle[64].
    - A 2011 study found only dosages 10x higher than in the human BCG vaccine, was there a signification reduction in the faecal excretion of *M.bovis* by badgers[65].
  - Requires good wildlife penetration to be effective, and it is currently unknown the exact prevalence of bTB in badger populations in the UK, with general consensus at around 1-9% of the population[66].
- Current Vaccination Initiatives:
  - The Badger Edge Vaccination Scheme[67] (BEVS) provided funding towards the costs of vaccinating badgers in the EAs in England. It has been run in two phases, concluded in 2023.
  - Vaccinating East Sussex Badgers[68] is a five-year project covering 250km^2, launched in 2021.

[58] Torgerson, P.R., Hartnack, S., Rasmussen, P. *et al.* Absence of effects of widespread badger culling on tuberculosis in cattle. *Sci Rep* **14**, 16326 (2024). https://doi.org/10.1038/s41598-024-67160-0
[59] Langton TES, Jones MW, McGill I. Analysis of the impact of badger culling on bovine tuberculosis in cattle in the high-risk area of England, 2009–2020. *Vet Rec*. 2022;e1384. https://doi.org/10.1002/vetr.1384
[60] https://assets.publishing.service.gov.uk/media/5beed433e5274a2af111f622/tb-review-final-report-corrected.pdf
[61] Joseph Crispell, Clare H Benton, Daniel Balaz, Nicola De Maio, Assel Ahkmetova, Adrian Allen, Roman Biek, Eleanor L Presho, James Dale, Glyn Hewinson, Samantha J Lycett, Javier Nunez-Garcia, Robin A Skuce, Hannah Trewby, Daniel J Wilson, Ruth N Zadoks, Richard J Delahay, Rowland Raymond Kao (2019) Combining genomics and epidemiology to analyse bi-directional transmission of Mycobacterium bovis in a multi-host system eLife 8:e45833 https://doi.org/
[62] https://www.microbiologyresearch.org/content/journal/mgen/10.1099/mgen.0.001023
[63] https://tbhub.co.uk/wp-content/uploads/2024/09/Badger-vaccination-process-guide_19.09.24_TB_hub.pdf
[64] https://tbhub.co.uk/wp-content/uploads/2022/06/AR-factsheet-badger-vaccination-01.06.22.pdf
[65] Lesellier S, Palmer S, Gowtage-Sequiera S, Ashford R, Dalley D, Davé D, Weyer U, Salguero FJ, Nunez A, Crawshaw T, Corner LA, Hewinson RG, Chambers MA. Protection of Eurasian badgers (Meles meles) from tuberculosis after intra-muscular vaccination with different doses of BCG. Vaccine. 2011 May 12;29(21):3782-90. doi: 10.1016/j.vaccine.2011.03.028. Epub 2011 Apr 7. PMID: 21440035.
[66] https://www.badgertrust.org.uk/post/why-badger-vaccination-won-t-save-the-badger
[67] https://www.gov.uk/government/publications/badger-edge-vaccination-scheme-2-bevs-2/scheme-outline
[68] https://www.vesba.org.uk

- Cost of Vaccination:
  - The BEVS in Nottinghamshire which vaccinated 275 badgers cost Defra £30,000/year[69]. A 2013 estimate places vaccinations costs at £2,250/km^2/year requiring at least four years of sustained effort[70].
- Concerns:
  - The cost-effectiveness of badger vaccination programmes remains uncertain and effective vaccination requires sufficient wildlife penetration, but data on badger numbers and prevalence of bTB in their population is limited. It is reassuring to note that the current Government are attempting to conduct the first badger census in over a decade which will help fill this data gap.
  - Some experts express concerns that if the basic reproduction number (R_0) of bTB in badgers is below 1, then any mitigation measures in badger is useless as the disease could decline naturally without intervention.

Recommendations for Future Policy

- The UK continues to have some of the highest levels of bTB among developed nations[15], with growing evidence pointing to persistent infection in cattle as a primary driver of disease spread. Concerns with current policy highlights the need for a revised, multifaceted, innovative, evidence-based approach to bTB control.
- New policy should aim to minimise cost, reduce disruption to farmers, address the underlying reservoirs of infection, ensure practical implementation and balance public health, animal health and welfare, and economic viability. A reassessment of current effectiveness and long-term viability of the keystone 'test-and-cull' policy is essential to prioritise animal health and welfare and farmer wellbeing.
- In order to meet WOAH requirements of OFT status for the UK, the disease must remain notifiable and herds subject to surveillance testing for at least two years before PMI and other antemortem testing can be carried out[71].
- Key areas of focus include:
  1. Funding realignment
  2. Improvements in diagnostics and disease surveillance
  3. Exploration of vaccination strategies for cattle and badgers
  4. Balanced wildlife management
  5. Enhancing biosecurity measures
  6. Risk-based cattle trading
  7. Research areas
- **Funding Realignment:**
  - The current funding model for bTB control, centred on compensation from compulsory culling of reactors, places an unsustainable financial burden on both taxpayers and the farming industry, which currently exceeds £150 million annually. A shift in funding priorities is needed to support more effective and economically viable bTB control measures.
  - Re-evaluate Compensation Policies:
    - Current Inefficiencies:
      - Compensation for culled cattle is disproportionate, particularly as the majority (50-80%[72]) of animals testing positive for bTB using the SICCT show no visible lesions (NVLs) at PMI in Great Britain. Given bTB positive carcases with NVL and VL which are localised to one organ or location on the carcass

[69] https://www.bbc.co.uk/news/uk-england-nottinghamshire-65017116
[70] https://webarchive.nationalarchives.gov.uk/ukgwa/20130402173326/http:/archive.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/documents/bovine-tb-impact-assessment.pdf
[71] https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmfile=chapitre_bovine_tuberculosis.htm
[72] Nuñez-Garcia J, Downs SH, Parry JE, Abernethy DA, Broughan JM, Cameron AR, Cook AJ, de la Rua-Domenech R, Goodchild AV, Gunn J, More SJ, Rhodes S, Rolfe S, Sharp M, Upton PA, Vordermeier HM, Watson E, Welsh M, Whelan AO, Woolliams JA, Clifton-Hadley RS, Greiner M. Meta-analyses of the sensitivity and specificity of ante-mortem and post-mortem diagnostic tests for bovine tuberculosis in the UK and Ireland. Prev Vet Med. 2018 May 1;153:94-107. doi: 10.1016/j.prevetmed.2017.02.017. Epub 2017 Mar 6. PMID: 28347519.

are permitted to enter the human food chain this raises questions about the necessity and scale of current compensation.

- Proposed Change:
  - Compensate the condemned carcasses (approximately 33% of all VL cattle in June 2023-June 2024[73]) and redirect the remaining compensation funds (of bTB positive animals with NVL or localised lesions) toward funding enhanced testing, veterinary intervention and specific bTB management plans for breakdown herds. The funding should be conditional on implementing recommended interventions and meeting specified disease control targets to encourage proactive engagements with multifaceted bTB control measures.
  - This approach depends on changing the management of reactor cattle in herds (see below) and prioritises maintaining herd viability and farmer welfare while maintaining rigorous disease control standards.

- **Modern approaches to bTB diagnostics:**
  - Currently, insufficient infected cattle are disclosed by statutory testing leading to an undetected reservoir of infection in cattle herds, increasing cattle-to-cattle transmission and resulting in significant environmental contamination with *M.bovis.*
  - **Objective:** Improve testing protocols to enhance sensitivity, detect hidden infections, and reduce transmission risks.
    - Improved sensitivity of statutory testing:
      - Adopt the EU's statutory skin test - Single Intradermal Cervical Test (**SICT**) - as recommended by the Godfray Report (2019), which offers higher sensitivity[25] compared to the SICCT, in HRAs and EAs of England to enable early detection of infection.
    - Increased used of non-statutory tests:
      - Allow greater flexibility in using non-validated bTB tests, such as IDEXX ELISA, Enferplex and Actiphage, as **enhanced testing** to identify cattle missed by statutory tests. These tests will be particularly useful in:
        - Breakdown herds
        - Herds which have just regained OTF status.
      - Currently, the use of these tests requires prior permission from the APHA, despite Enferplex and IDEXX ELISA being WOAH validated.
        - Enferplex use is limited to private use on long-term bTB restricted herds, funded by farmers with **no compensation** for reactors[74].
      - The combined use of IDEXX and Actiphage tests were trialed successfully at Gatcombe Farm in Devon[75], which regained OTF status through enhanced diagnostics, strict biosecurity and badger vaccination.
    - Flexible testing protocols:
      - Freedom for farmers and veterinarians **to test outside of statutory schedules,** including pre- and post-movement testing of all cattle, using statutory or enhanced tests, **regardless of OTF status**. This will be particularly useful in identification of persistently or latently infected animals which remain undetected by statutory tests in high-risk herds.
    - Managing the outcomes of positive tests:
      - Replace blanket policies of compulsory slaughter and compensation with herd-specific strategies aimed at maintaining herd viability while managing bTB infection risks to the rest of the herd. Key components include:

[73] FOI data supplied by the FSA January 2024
[74] https://www.fwi.co.uk/livestock/health-welfare/livestock-diseases/bovine-tb/farmers-and-vets-report-positive-results-in-new-tb-test-trial
[75] https://www.proquest.com/openview/757746528bbe3f77680ae9a29e421d7a/1?cbl=2041027&pq-origsite=gscholar

- **Strict Isolation and Removal**: Infected cattle should be isolated, with their removal managed based on economic and disease control considerations. For example, dairy herds may naturally phase out infected animals through annual herd replacement cycles.
- **Minimize Disruption**: This would reduce cost to industry and taxpayers and enable industry to take back aspects of disease management and control without destroying farmers livelihoods[76]

- Case Studies:
  - **Gatcombe Farm, Devon:** Combine IDEXX ELISA and Actiphage diagnostics with strict biosecurity, and badger vaccination in the surrounding areas to regain OTF status. In 2020, the herd lost its OTF status following cessation of the testing programme[77]. This suggests merit to a **multimodal approach** to testing to prioritise prevention of a herd-level breakdown by targeting individual shedders that are currently escaping detection.
  - Another small-holding in Devon, with 20 breeding females, attempted total biosecurity, with 7km mesh fence built around entire perimeter, 60cm below ground, 1.8m above, and simultaneous badger culling - but since 2021 there have been 37 bTB reactors[78]. This again points to the need for **measures beyond** the current **biosecurity** and testing practices, to tackle hidden infectious cattle and alternative transmission routes.
- Predicted Outcomes:
  - Short-term impact:
    - Enhanced testing will initially increase bTB incidence as previously undetected infections are identified.
    - The increased use of enhanced tests will come as a direct cost to the industry.
  - Long-term benefit:
    - By identifying hidden reservoirs of infection, sustained cattle to cattle transmission will reduce limiting repeat breakdown herds and there will be an improvement in overall bTB control outcomes.

- **Cattle Vaccination:**
  - Vaccination of cattle against bTB offers a promising avenue for reducing disease transmission and prevalence, but several challenges must be addressed before widespread implementation.
    - Efficacy and Infectivity:
      - Evidence suggests vaccination with Bacillus Calmette-Guérin (BCG) may reduce infectivity of *M. bovis* in vaccinated cattle. However, further research is needed to confirm its impact on transmission rates and overall disease control.
    - DIVA Test Requirement:
      - A **DIVA test** is **essential** for widespread vaccine deployment. Without it, vaccination interferes with the **SICCT** complicating:
        - Disease surveillance and monitoring - hindering accurate detection and management of outbreaks.
        - Trade in live cattle and animal by-products, particularly with the EU, where stringent requirements exist for bTB-free certification of cattle and dairy exports.
  - Current Developments:

[76] Watt, N.J. and Cutler, K. (2024), 'It is impossible to meet our officially bTB-free targets with the current testing policy'. Veterinary Record, 194: 359-359. https://doi.org/10.1002/vetr.4241
[77] https://www.proquest.com/openview/e526a47b42a76e36d96ed240cc8217a5/1?pq-origsite=gscholar&cbl=2041027
[78] Sibley, D. (2024), Open debate required on TB testing and transmission. Veterinary Record, 194: 440-440. https://doi.org/10.1002/vetr.4364

- **Phase 3 field trials** are underway for a combination BCG vaccine and DIVA test (**DST-F**), with the aim of making this deployable in the coming years. This represents a significant step forward in protecting cattle from bTB while maintaining effective surveillance systems[79].
- The **Godfray Report (2019)[25]** recommended establishing a **single bovine TB authority** to coordinate vaccine rollout and manage accreditation schemes for farms adhering to high biosecurity standards. Such a body could streamline vaccine implementation and improve disease management.

- **Non-lethal control in wildlife reservoir:**
  - In August 2024, the Government announced plans to **end the badger cull** by the end of this Parliament in 2029[80]. This policy shift represents an opportunity to transition to evidence-based, non-lethal strategies for managing the wildlife reservoir of bTB and aligns with growing public and scientific support for humane alternatives to culling.
  - Badger population survey and monitoring:
    - The first comprehensive badger population survey in over a decade will provide critical data on population size, bTB prevalence, and the effectiveness of future vaccination programmes.
    - Gathering this crucial evidence addresses concerns about the lack of reliable data underpinning previous culling strategies, which involved significant expenditure with limited understanding of the impact on bTB transmission to cattle.
  - Badger Vaccination:
    - The Badger Vaccinator Field Force and associated vaccination study aims to monitor the effects of vaccination on bTB prevalence in the badger population and assess its efficacy in reducing disease transmission in cattle.
    - A four-year vaccination programme in Cornwall achieved a **74% vaccination rate**, with **0% of badgers testing positive** for bTB[81]. A similar project in East Sussex has benefited from simplified licensing through an online Defra system and subsidies to reduce vaccine costs[82].
  - Badger Fertility Control:
    - Badger population control by deployment of oral contraceptives could **reduce badger density,** limiting their contact with cattle and transmission of bTB. This approach also helps improve degraded habitats caused by badger overpopulation.
    - Challenges to this approach:
      - Badger reproduction is influenced by complex oestrus cycles and delayed implantation, limiting the window for effective contraception between **June and August**[83].
      - Injectable contraceptives targeting gonadotropin-releasing hormone (GnRH) must be repeated every two years to maintain levels of infertility enough to reduce badger population size[84], making this approach labour intensive and costly.
    - Research and development of oral contraceptives could enable cheap, large-scale fertility control, and similar technology has been used to control populations of pigeons in Italy, Belgium and the USA[85]. Badger fertility control should be explored as

[79] https://www.gov.uk/government/news/field-trials-for-bovine-tb-cattle-vaccine-and-skin-test-move-to-next-phase--2#:~:text=Field%20trials%20for%20a%20cattle,cattle%20against%20this%20endemic%20disease.
[80] https://deframedia.blog.gov.uk/2024/09/02/government-announces-tb-eradication-strategy-to-end-the-badger-cull/
[81] Woodroffe, R., Astley, K., Barnecut, R., Brotherton, P. N. M., Donnelly, C. A., Grub, H. M. J., Ham, C., Howe, C., Jones, C., Marriott, C., Miles, V., Rowcliffe, M., Shelley, T., & Truscott, K. (2024). Farmer-led badger vaccination in Cornwall: Epidemiological patterns and social perspectives. *People and Nature*, 6, 1960–1973. https://doi.org/10.1002/pan3.10691
[82] https://tbhub.co.uk/tb-in-wildlife/tb-in-badgers/vaccination-of-badgers-against-tb/
[83] Cowan, D., Smith, G.C., Gomm, M. *et al.* Evaluation of a single-shot gonadotropin-releasing hormone (GnRH) immunocontraceptive vaccine in captive badgers. *Eur J Wildl Res* **65**, 59 (2019). https://doi.org/10.1007/s10344-019-1296-0
[84] Cowan, D., Smith, G.C., Gomm, M. *et al.* Evaluation of a single-shot gonadotropin-releasing hormone (GnRH) immunocontraceptive vaccine in captive badgers. *Eur J Wildl Res* **65**, 59 (2019). https://doi.org/10.1007/s10344-019-1296-0
[85] Massei G. Fertility Control for Wildlife: A European Perspective. *Animals (Basel)*. 2023;13(3):428. Published 2023 Jan 27. doi:10.3390/ani13030428

a complementary tool alongside vaccination to manage badger populations sustainably.

- **Enhancing Biosecurity:**
  - Effective biosecurity measures are essential to prevent the introduction and spread of bovine tuberculosis (bTB) within herds. Key strategies include:
    - **Wildlife Exclusion -** install badger-proof fencing to prevent access to cattle housing, feed stores and water sources.
    - **Reduce High-Risk Cattle Introductions -** avoid purchasing high-risk or introducing potentially infected stock by enhanced assessment of origin herds bTB history and use of LIS.
    - **Minimize Neighbouring Unit Contact -** prevent direct or indirect contact with neighbouring herds through secure boundaries and buffer zones.
    - **Reduce Environmental Contamination -** address contamination risks in drinking water, grazing areas, feed, and slurry management to limit exposure to *M.bovis*.
    - **Human and Equipment Risks -** Implement hygiene measures to reduce risks from visitors, staff, equipment through fomites, ensuring proper sanitation and disinfection protocols.
- **Disincentivising Risky Trading Behaviour:**
  - Cattle movement is a critical factor in bTB transmission and reducing risky trading practices can help prevent farmers buying in infected cattle into clean herds. While some argue that most movements involve direct-to-slaughter or fattening units, risky infectious disease transmission practices, such as allowing cattle at shows for less than 24 hours without testing, need stricter regulation.
  - **Prevent "Clear-Out" Sales**
    - Farmers sometimes sell high-risk stock after regaining Officially TB Free (OTF) status despite knowing their herd is not truly disease-free. Systems like **iTB** could improve purchaser awareness by sharing herd disease history, reducing the spread of infection.
  - **Undetected Reservoirs in Cattle**
    - Cattle with latent infections often remain undetected by statutory tests and can perpetuate infection cycles when traded to new herds. Enhanced testing protocols and stricter trade regulations for pre- and post- movement tests can help address this issue.
  - **Reduced compensation** of bTB positive animals if high-risk animal trading has occurred to disincentive the practice.
- **Research Areas:**
  - Ongoing and future research is vital to understanding and addressing the gaps in bTB control. Fundamentally, improvements in data sharing between the APHA, veterinarians and academics can create unified and informed evidence-based approached to bTB management.
  - **Latency and recrudescence of disease in cattle** – is this a component of the pathology of *M.bovis* in cattle as is it for other mycobacterial infections, for example Johne's disease?
  - Assessment of *M.bovis* transmission pathways:
    - **Faeco-oral transmission** – limited and flawed studies brush this off as an insignificant transmission pathway[86], however non-peer revied evidence suggests it might be crucial in the maintenance of bTB on repeat breakdown farms. Further research is needed to corroborate this claim.
    - **Vertical transmission** - examine mother-to-calf transmission through colostrum and management practices to determine its role in disease persistence.

[86] Palmer S, Williams GA, Brady C, Ryan E, Malczewska K, Bull TJ, Hogarth PJ, Sawyer J. Assessment of the frequency of Mycobacterium bovis shedding in the faeces of naturally and experimentally TB infected cattle. J Appl Microbiol. 2022 Sep;133(3):1832-1842. doi: 10.1111/jam.15677. Epub 2022 Jul 8. PMID: 35729710; PMCID: PMC9544641.

- **Testing Regimes -** assess the efficacy of advanced diagnostics such as faecal PCR, Enferplex, IDEXX ELISA, Actiphage and gamma-interferon testing**.** Case studies, such as Gatcombe Farm, demonstrate the importance of multimodal testing approaches.
- **Badger R_0 -** Investigate the basic reproduction number (R_0) of *M. bovis* in badgers to determine whether they significantly contribute to transmission dynamics or if resources should focus on cattle as the primary reservoir as a more economically viable control method.

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