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Chairman Prof David Macdonald CBE DSc FRSE
 Director, Wildlife Conservation Research Unit, University of Oxford Chair, Science Advisory Committee, Natural England

Prof Rosie Woodroffe

10:15 Comparing the epidemiological effects of badger vaccination and culling
 Prof Rosie Woodroffe, Zoological Society of London



Held at the

Zoological Society of London, Huxley Theatre,
 Regent's Park, London NW1 4RY

3rd October 2013 10.00 am to 17.00 pm

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Meeting Programme

Prof David Macdonald CBE DSc FRSE
 Director, Wildlife Conservation Research Unit,
 University of Oxford Chair, Science Advisory
 Committee, Natural England

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SESSION 1: THE SCIENCE AND DEVELOPMENT OF
 BADGER VACCINATION

10:15 Comparing the epidemiological effects of
 badger vaccination and culling
 Prof Rosie Woodroffe, Zoological Society of
 London

10:35 Badger vaccine development and efficacy
 Dr Mark Chambers, Animal Health & Veterinary
 Laboratories Agency

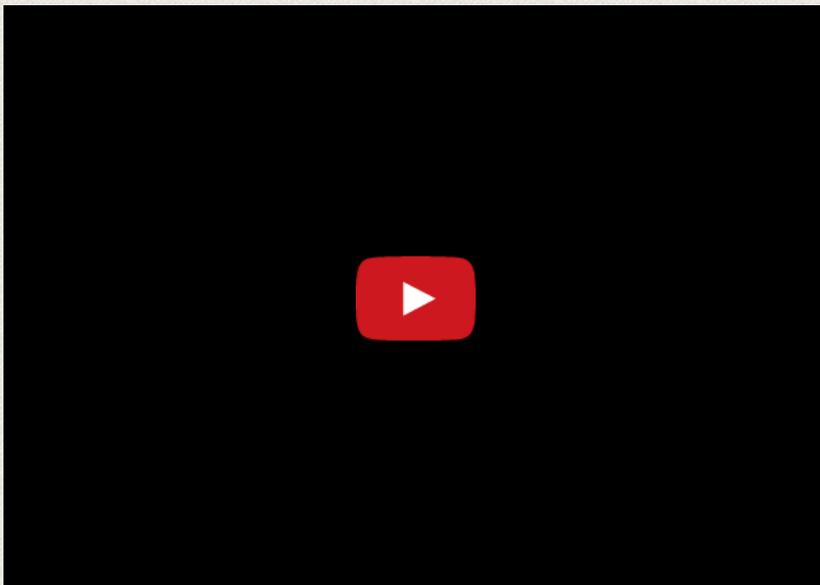


Vaccination and culling have both been used in attempts to control wildlife diseases, but work in fundamentally different ways. Culling is intended to reduce transmission by removing infected animals (which can transmit disease) and by removing susceptible animals (which can become infected). By contrast, vaccination is intended to “remove” susceptible animals by making them immune. Although culling is generally intended to reduce disease transmission, badger culling is associated with increases in the proportion of badgers infected with *Mycobacterium bovis* (the pathogen which causes bovine tuberculosis [TB]). This increase in *M. bovis* transmission reflects changes in badger behaviour caused by culling. Such changes limit the extent to which culling can reduce the density of infected badgers. Unless badger numbers are drastically reduced, badger culling increases the incidence of TB in cattle.

Fewer data are available on the impacts of badger vaccination for TB control. Nevertheless, scientific consensus indicates that this approach would be expected to reduce the proportion of infected badgers, if implemented annually over several years. Vaccination is likely to be less costly than culling because it is unlikely to require much policing. Costs can be reduced still further by involving volunteers in fieldwork.

There is interest in exploring combinations of badger vaccination and culling. Culling would be expected to undermine the benefits of subsequent vaccination by leaving a lower proportion of susceptible animals to be protected by vaccination. Moreover, evidence suggests that perturbation might also compromise attempts at selective culling of infected badgers.

Overall, badger vaccination may potentially contribute more than culling to eventual TB eradication, because the proportion of infected badgers would be reduced rather than increased. While the consequences of badger vaccination for cattle TB control are still unknown, unfavourable comparisons with culling are frequently based on an incomplete picture of the consequences of culling.



ROSIE'S POWERPOINT ABOVE AND PRESENTATION BELOW

10:55 Development of oral badger vaccines
Dr Eamonn Gormley, School of Veterinary
Medicine, University of Dublin

11:15 Coffee

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11:30 Badger vaccination - impacts and
implementation in the field
Dr Gavin Wilson, Wildlife Programme, Animal
Health & Veterinary Laboratories Agency

11:50 From fridge to field -- using badger
vaccination at the business scale
Dr Gordon McGlone OBE, former CEO of
Gloucestershire Wildlife Trust

SESSION 2: THE SCIENCE AND DEVELOPMENT OF CATTLE VACCINATION

12:10 Development of cattle vaccines
Dr Martin Vordermeier, Animal Health &
Veterinary Laboratories Agency

12:30 The development of a test to
differentiate infected from vaccinated animals
Dr Cath Rees, Associate Professor of
Microbiology, University of Nottingham

12:50 Lunch



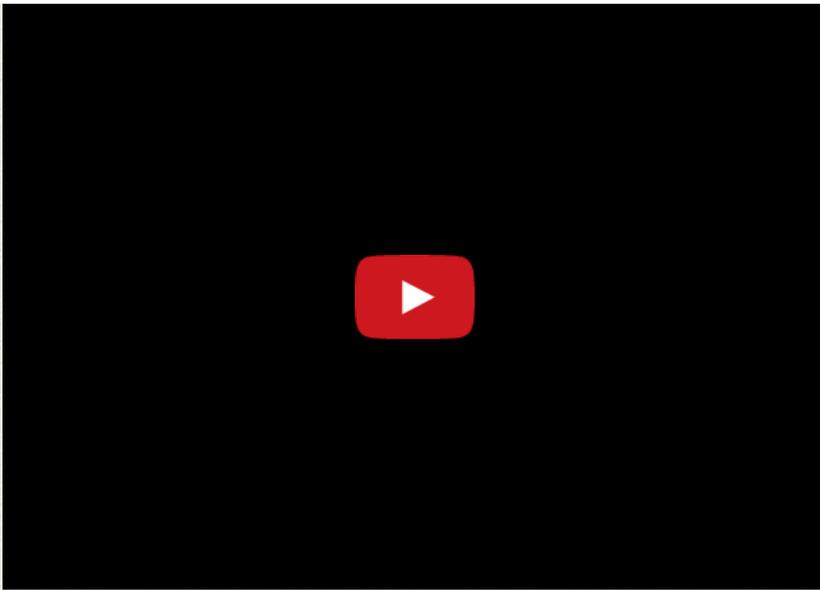
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SESSION 3: BOVINE TB VACCINATION POLICY

14:00 Developing policy for the use of TB
vaccines in badgers and cattle in England
Stephen Cane, Department of Environment,
Food and Rural Affairs

14:30 Developing policy for the use of TB
vaccines in badgers and cattle in Wales
Prof Christianne Glossop, Chief Veterinary
Officer, Welsh Government

15:00 Tea



Dr Mark Chambers

10:35 Badger vaccine development and efficacy
Dr Mark Chambers, Animal Health--Veterinary Laboratories Agency



Increased incidence of bovine TB in the UK caused by infection with *Mycobacterium bovis* is a cause of considerable economic loss to farmers and Government. Eurasian badgers represent the most significant wildlife source of recurrent *M. bovis* infection to cattle in the UK.

In March 2010 a licence was granted to AHVLA for an injectable form of Bacille Calmette-Guérin (BCG) vaccine for use in Eurasian badgers in the UK -- called BadgerBCG. This was the culmination of 10 years of effort and £11 million of government investment. Vaccination of badgers against TB with BCG is now one of the disease control options available. Over 4000 doses of the vaccine have been administered since July 2010.

To obtain the licence, a series of studies were conducted in both captive and wild badgers to demonstrate vaccine safety and efficacy. I shall describe these and present highlights from the programme of work.

The cost of trapping and vaccinating badgers with BadgerBCG has been estimated to be £1700-£4,000 per km². A vaccine that can be delivered orally is a potentially cheaper and more practical way of vaccinating large numbers of badgers in the wild than an injectable vaccine, although this is dependent on the required dose and number of baits that need to be delivered per sett to ensure adequate uptake.

AHVLA has been leading on the oral badger vaccine effort since 2005. Whilst the steps to licensing an oral vaccine are the same as for the injectable vaccine the research and development phase is demanding and there is no guarantee of a successful outcome. I shall give a brief outline of some of the issues to consider in the development and licensing of an oral vaccine and describe progress to date. Much of the work is on-going and specific details are commercial in-confidence.



Session 4: DISCUSSION FORUM
15:15 Panel Discussion
All speakers
16:30 Meeting closes



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Principal topics will include:

How vaccines work at the individual and herd levels.
Recent uses of vaccination for disease control and elimination in wild and domestic animals.

Current status and prospects for cattle vaccination against Bovine TB.
Development of oral badger vaccines.
Practical low cost deployment of injected badger vaccination.

Followed by discussion and debate with a panel drawn from the main speakers and other experts.

Who should attend:

Politicians, policy advisers, farming and food industry representatives, conservationists, vets, and academics involved or interested in the control of Bovine TB in livestock and wildlife.

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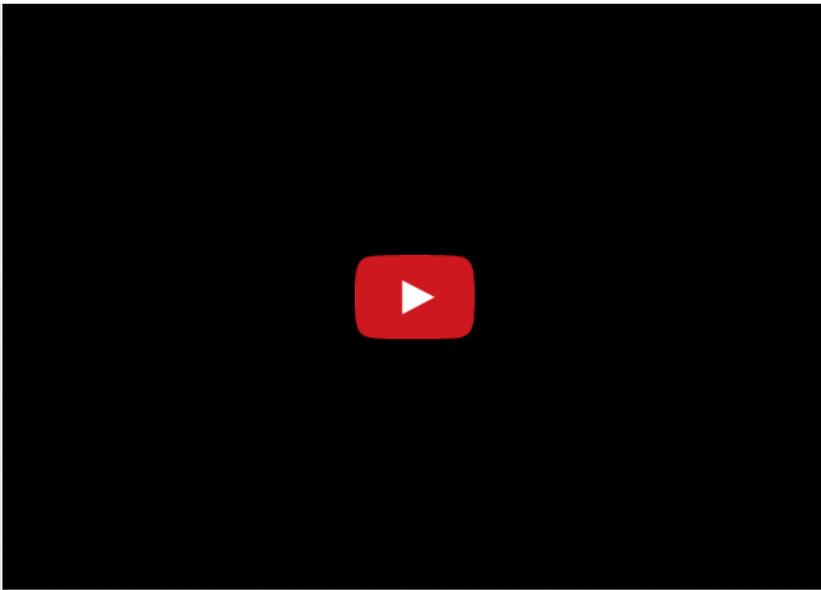
Dr Eamonn Gormley

10:55 Development of oral badger vaccines

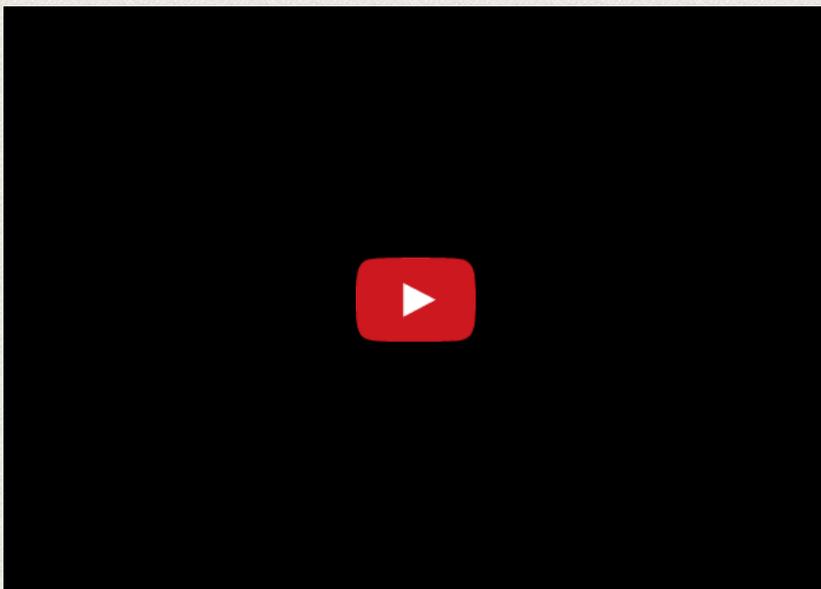
Dr Eamonn Gormley, School of Veterinary Medicine, University of Dublin



The eradication of tuberculosis from cattle herds in Ireland and the UK is compromised because infected wildlife species, such as Eurasian badgers (*Meles meles*), share the same environment and contribute to transmission of infection. The short-term options for dealing with tuberculosis in the wildlife reservoir hosts are limited to segregation of domestic animals from the wildlife or culling of the wildlife host, which remains highly controversial. Vaccination of badgers against *M. bovis*, if successfully employed, could directly facilitate the advancement of bovine tuberculosis eradication. Programmes of research into vaccination of badgers are being undertaken in both countries and vaccine trials in captive badgers have established that the *M. bovis* bacille Calmette-Guérin (BCG) vaccine, when delivered by the oral route, can induce a protective response that limits the distribution and severity of tuberculosis disease following experimental challenge. The results from a field oral vaccine trial in Ireland will provide a framework for the development and implementation of strategies that will address the disease in badger populations, and if successful will remove this major impediment to bovine tuberculosis eradication.



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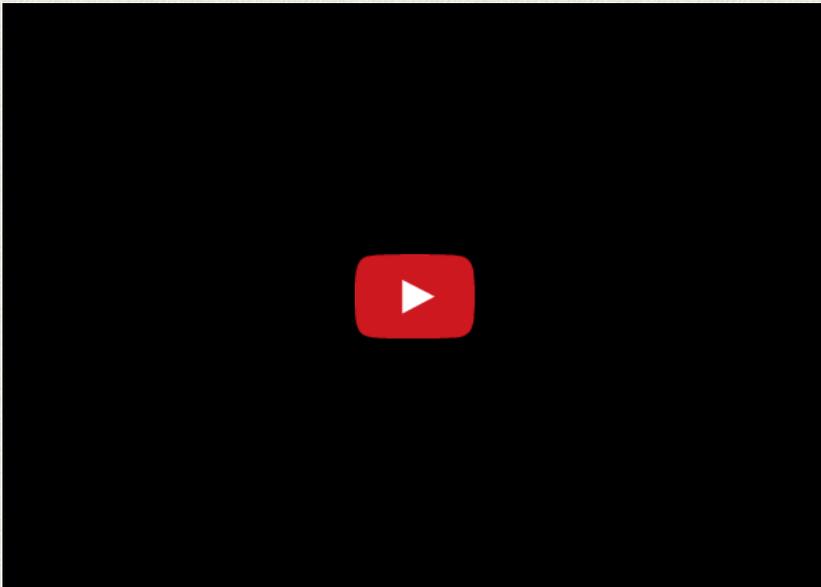
Dr Gavin Wilson

11:30 Badger vaccination - impacts and implementation in the field

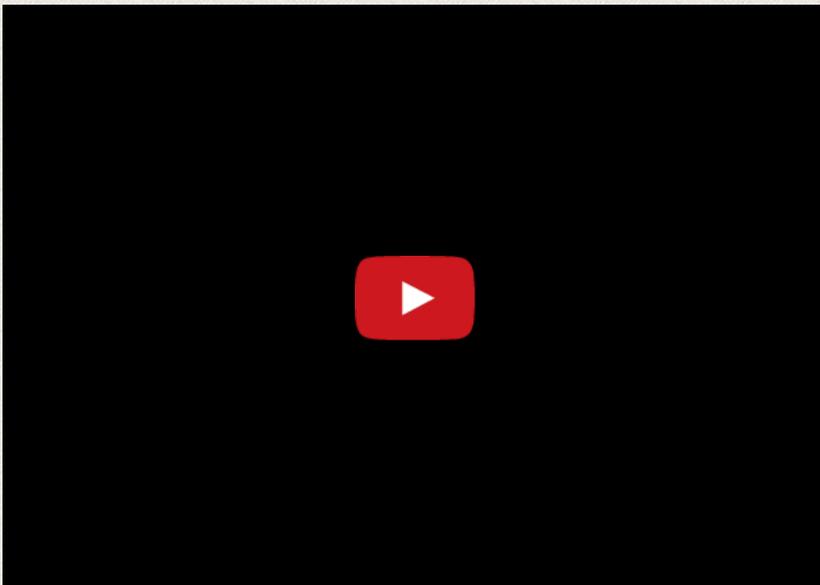
Dr Gavin Wilson, Wildlife Programme, Animal Health--Veterinary Laboratories Agency



BadgerBCG, an injectable vaccine against bovine tuberculosis, was licenced in March 2010 after being shown to be safe and efficacious in badgers. Soon after, the Veterinary Surgery (Vaccination of Badgers against Tuberculosis) Order 2010 came into effect allowing trained lay persons to vaccinate badgers by injection, under the direction of a veterinary surgeon. In June 2010, the Badger Vaccine Deployment Project (BVDP) was launched, aiming to vaccinate badgers in the endemic TB area, build farmer confidence in vaccination, and learn lessons about vaccine deployment. The BVDP area includes over 100 farm premises, covering approximately 100km² of Gloucestershire farmland. A key component of the BVDP is a bespoke course to train lay vaccinators, approved by the Secretary of State and developed in consultation with the Royal College of Veterinary Surgeons. This four day course covers the essentials of legal responsibilities, cage trapping badgers, and storage and handling of BadgerBCG. Under the Certificate of Competence Scheme, all lay vaccinators submit detailed records to AHVLA showing location and numbers of badgers vaccinated. Hence, we maintain a growing record of all vaccinations carried out in England and Wales. Up to the end of 2012, a total of 4029 vaccine doses had been delivered in England and Wales. In 2012 alone, 998 were vaccinated in the BVDP, 1424 in the Welsh Intensive Action Area, and a further 278 vaccinations were delivered by a range of other organisations. To date, 167 people have attended the training course. Although BadgerBCG has a proven protective effect in badgers, a key knowledge gap is an understanding of the effect that badger vaccination may have on reducing the incidence of disease in cattle. We are discussing with Defra and academic collaborators the possible use of the growing badger vaccination database to help address this issue.



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Dr Gordon McGlone OBE

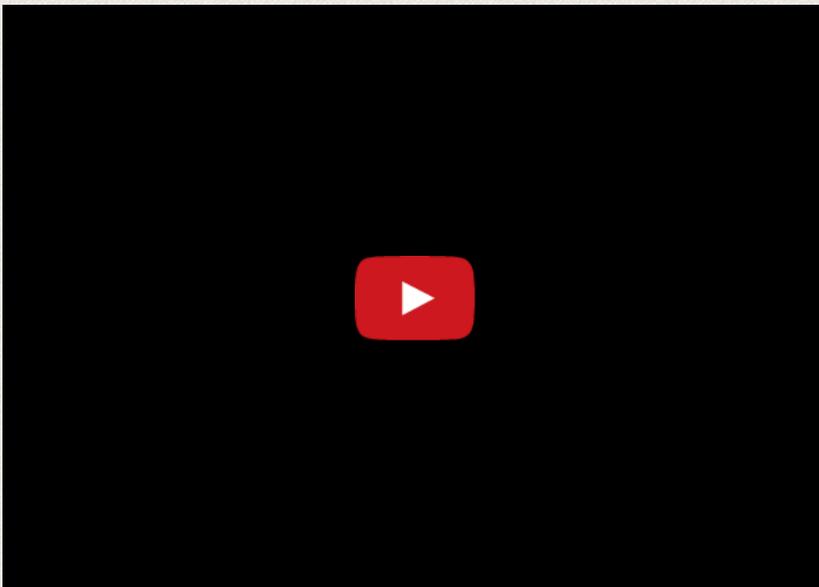
11:50 From fridge to field -- using badger vaccination at the business scale Dr Gordon McGlone OBE, former CEO of Gloucestershire Wildlife Trust



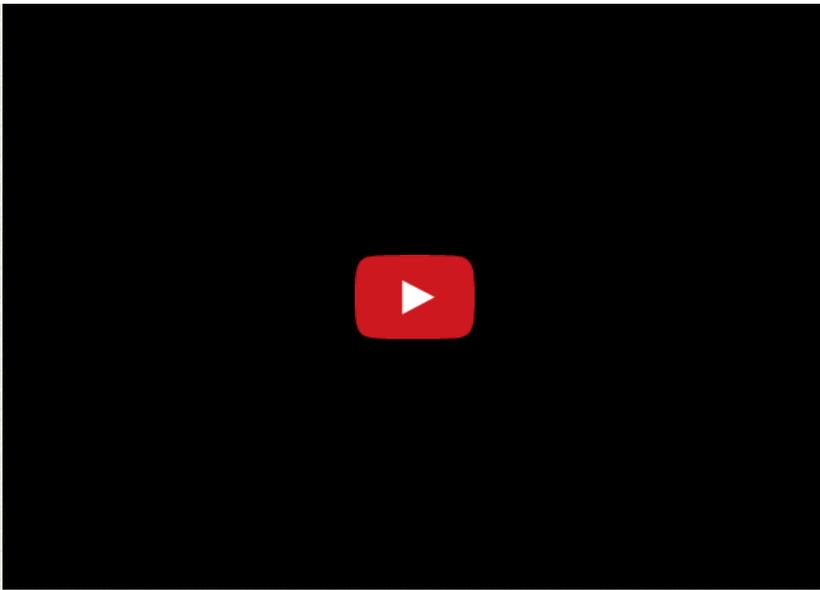
BadgerBCG is available as a veterinary product. It can be used by lay badger vaccinators licensed by Natural England working under the aegis of organisations with a Certificate of Competence.

A summary of the practical experience of field deployment of badger vaccination for the period 2011 to 2013 in England has been compiled for a number of SMEs, including not for profit organisations and a specialist commercial company. Estimated and actual costs have been considered and a typical figure for badger vaccination within land management presented.

Conventional audit cycle headings of Commitment, Planning, Doing and Reviewing have been used for compiling a number of recommendations for improvements to and increased uptake of badger vaccination in England at the business scale.



GORDON'S POWERPOINT ABOVE AND PRESENTATION BELOW



Dr Martin Vordermeier

12:10 Development of cattle vaccines

Dr Martin Vordermeier, Animal Health--Veterinary Laboratories Agency



Co--authors: Adam Whelan, Bernardo Villarreal--Ramos, Gareth Jones, R. Glyn Hewinson

Cattle vaccination against bovine TB (bTB) is a disease control tool that could reduce the prevalence, incidence and spread of bTB in the cattle population. Bacille Calmette Guérin (BCG), the human TB vaccine, is the only vaccine that could become available in the medium term for use in cattle. However, it is not licensed for this application, and its functional characterization in respect to its protective efficacy and safety in this target species are required to support licensure. As BCG will compromise the specificity of conventional tuberculin based ante--mortem diagnostic tests, there is also a need for the parallel development of associated diagnostic tests that distinguish infected from vaccinated animals (so--called DIVA). Consequently, research in GB has been directed towards these goals, namely the characterization of BCG in respect to efficacy and safety and the development of immunological DIVA. I will summarize data generated towards these two objectives and also highlight issues that need to be resolved before BCG can be trialed in the field, which is one of the conditions sine qua non towards eventual licensure. However, our development efforts are not restricted to testing BCG as we are also developing measures that improve BCG efficacy, such as so--called heterologous--prime boost approaches that comprise of BCG combined with subunit vaccines. We are also exploring the possibility that vaccines can be developed that will not compromise tuberculin specificity, which would allow the continuation with tuberculin--based diagnosis alongside vaccination. An overarching goal is the definition of host biomarkers that predict vaccine efficacy, whose application would significantly accelerate vaccine development. These objectives are not being developed in isolation as we are fully embedded in a wide network of national and international collaborators of researchers working not only on

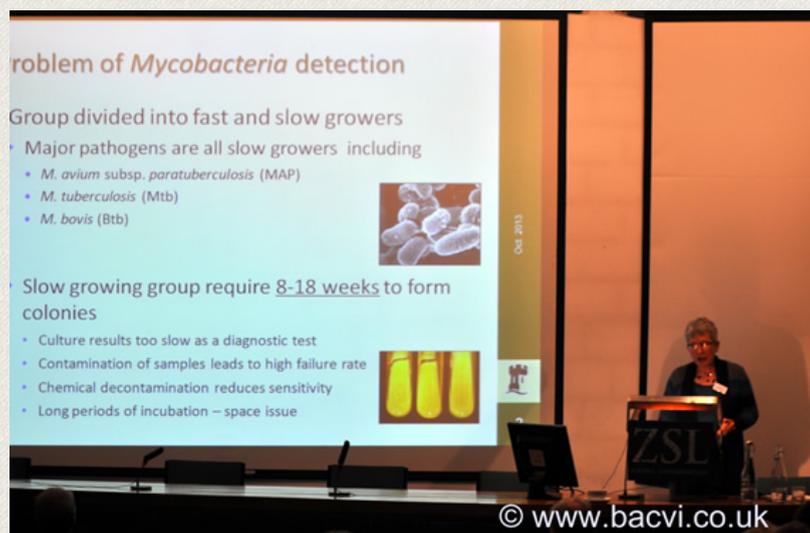
cattle vaccines but also with those engaged in the human TB vaccine development effort.

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Dr Cath Rees

12:30 The development of a test to differentiate infected from vaccinated animals Dr Cath Rees, Associate Professor of Microbiology, University of Nottingham



A rapid method for the detection of human tuberculosis was developed by the University of Nottingham in the 1990's and was commercialised as the FASTPlaqueTB test. We have recently been developing new applications for this bacteriophage--technology, initially focussing on rapid detection of Mycobacterium paratuberculosis (MAP) -- the causative agent of Johne's disease in cattle. Using the original technology combined with PCR we have

demonstrated the sensitive detection of MAP in blood samples from infected cattle within 48 h. Interestingly we have been able to detect MAP in the blood of cattle in the very early stages of infection, before any signs of clinical disease are evident, and also in animals that give negative antibody--based test results. We have also shown that the same phage--based methodology developed for detection of MAP is able to detect bovine TB. There are many reports in the literature that TB can be isolated from the blood of TB--infected cattle, but this cannot be used as a practical diagnostic method due to the long periods of incubation required, the need to work under high levels of biosecurity, and the low sensitivity of culture-- based methods. We are now beginning to investigate whether the phage--based technology can be used to detect live bovine TB cells in blood samples to form the basis of a DIVA test that can Distinguish between Infected and Vaccinated Animals. To allow high through--put analysis of large numbers of samples we have also developed a new assay format that allows detection and identification of Mycobacterial pathogens within 5 h.



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Pages

Layouts

Typography

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Extras

Stephen Cane

14:00 Developing policy for the use of TB vaccines in badgers and cattle in England
Stephen Cane, Department of Environment, Food and Rural Affairs



Few people would dispute that achieving freedom from bovine TB in England should be high on any Government's agenda. There is far less agreement, however, on the means by which it should be achieved - or, more precisely, whether it is right to use some of the available tools at all. So decisions for Ministers on what interventions to deploy - or not deploy -- are always tough and often controversial.

Happily, vaccination is a tool that just about all organisations agree should be in the toolbox. The questions with which Governments grapple then tend to be about how much of a finite resource should be devoted to vaccination - resource for delivery of available vaccines and resource for developing new and better vaccines - which in turn informs things like who does it, what is done and how.

In England, the Coalition Government's ambition to develop an oral vaccine for badgers and bring a cattle vaccine to the market is evidenced by its investment in R&D. Despite the fact it is possible that research will never yield an efficacious oral badger vaccine, high priority is being given to further efficacy studies. On cattle vaccination, despite the big regulatory hurdles - necessary hurdles given that any veterinary medicine needs to be safe to animals, those who administer them and those who consume their products - work towards field trials likely to cost tens of millions of pounds is moving with pace. It is necessary process, rather than money, that will continue to be the major constraint to progress towards both

of these highly prized goals.

There is more of a debate to be had on the ways in which the Government can be the catalyst for increased use of the injectable badger vaccine. There is no sizeable army of public sector vaccinators that could be turned loose in those parts of the countryside where the Government would like to see more and quicker progress. The capacity of others with whom the Government might share responsibility for vaccination is similarly constrained. The uptake of the badger vaccination fund this year is evidence of that. So it is important to look more closely at ways in which capacity can be built and the good intentions of many turned into practical action.



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Prof Christianne Glossop

14:30 Developing policy for the use of TB vaccines in badgers and cattle in Wales Prof Christianne Glossop, Chief Veterinary Officer, Welsh Government



TB eradication is a priority for Welsh Government, farmers and veterinary profession. Launched in 2007, our TB Eradication Programme is based on four basic principles of infectious disease control namely:

- Keeping infection out (biosecurity)
- Rapid early identification of infection Limiting the spread of infection
- Elimination of all sources of infection

Over the past 5 years, the focus has been on the development and delivery of policy at the national level e.g. annual testing of all herds of cattle, zero tolerance to non-compliance, and increased awareness of biosecurity. It is clear however, that the disease

picture across Wales is not uniform, and that alongside these national measures we need also to take a more localised approach. To achieve this we have now appointed a dedicated TB epidemiologist to work with the Animal Health Veterinary Laboratories Agency case vets and also private practitioners to start acting in a more focussed way to deal with the unique characteristics of the TB epidemic of each area. The challenge is to identify the most appropriate tools for the differing disease scenarios - to achieve a more targeted approach as we drive towards eradication.

The overall strategy is underpinned by the recognition that all interested parties need to work honestly and in co-operation with each other - hence our programme structure which includes Regional Eradication Boards and significant engagement at a local level. It also recognises that we must keep abreast of new developments across all disease control disciplines if we are to achieve our ambitious and long-term objective of a TB-Free Wales. As a long-term objective, we aim to make best use of new technologies as they become available e.g. in the fields of disease prevention, diagnostics and genetics. Vaccination is a tool that has yet to be exploited to the full. This presentation will consider the Welsh approach to exploring the potential benefits and limitations of vaccination in badgers, and in cattle, as we strive towards freedom from TB.



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