

BJD - Where to from here?

*Proceedings of the
BJD Review Forum*

*Rydges Airport,
Sydney,*

16th February 2015



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Agenda

Monday 16th February, 2015
 Dreamliner Room
 Rydges Airport, Sydney, NSW

TIME	ITEM	WHO
9:30 am	Welcome and overview of the day	
9:45 am	The review	Duncan Rowland, AHA
	What do we know?	
10:00 am	BJD Trade Implications	Dr M. Schipp, AGDA
10:20 am	Diagnosis of BJD	Dr R. Whittington, UofS
10:40 am	Strain typing: B, C or S	Dr I. Marsh, NSW DPI
11:00 am	Morning tea (30 minutes)	
11:30 am	Economics of BJD control measures	Dr R. Shepherd, Herd Health P/L
11:50 am	Field efficacy of Silirum vaccine	Dr P. Little, Zoetis
12:10 pm	Panel review	Question time
	Where to from here?	
12.30 pm	Facilitated discussion – emerging thoughts on beneficial changes, strengths and weaknesses of the existing policy	Mr B. Trudeau, Facilitator
1:00 pm	Lunch	
1:45 pm	Facilitated discussion – emerging thoughts on beneficial changes, strengths and weaknesses of the existing policy	Mr B. Trudeau, Facilitator
3:45 pm	Wrap -up	

About the Forum

Effective consultation with all interested parties is needed to maximize the value of this review to ensure there is one national approach.

The BJD – Where to from here? Forum is the first step of setting the direction for how BJD is to be dealt with nationally.

The Bovine Johne 's Disease (BJD) Steering Committee has requested that Animal Health Australia (AHA) bring forward a planned review of the National BJD Strategic Plan to as early as possible in 2015. A mid-term review was originally scheduled for the end of the 2015-16 financial year.

As a result of this request AHA is ensuring the review will be undertaken in a manner that allows for all parties (including industry, government and community) to provide input into how Australia is going to manage BJD into the future.

With this in mind, AHA has organised an independent facilitator to bring together the views of all interested parties.

Working with a cross-section of the parties, the facilitator will develop an approach which will be made available for public comment. Responses will be incorporated where appropriate and a further round of consultation will follow. An iterative process like this allows for a wide range of views to be considered and broad consultation to take place.

It is expected that this process will take a number of months, with a view to implementing the resulting revised program by January 2016.

Setting the scene Presentation

Review overview



Australian Animal Health Council Ltd ACN 071 890 956

BJD Review

Where to from here?

February 2015

- **Transparent**
- **Consultative**
- **Iterative**

- **Step 1: Preliminary consultation**
 - Interviews
 - Submissions

- **Step 2: The review forum - TODAY**

- **Step 3: Reference panel & consultation**
 - Mid February (Tomorrow)
 - End March
 - Mid May
 - End June
 - Mid August

- **Step 4: Implementation – 1 Jan 2016**

Consider the:

1. effectiveness of current policies in controlling the disease at the individual farm and national level
2. impact of the disease on individual farm production and access to domestic and international markets
3. potential risks of product contamination and the access to international markets

Identify:

1. the progress of biosecurity, quality assurance and product verification systems that could be applied to the control and management of BJD
2. research developments that can be better utilised in the control of BJD
3. The role of stakeholders in any future industry based program.

What do we know?

Presentations

BJD Trade Implications

Diagnosis of BJD

Strain typing: B, C or S

Economics of control mechanisms

Field efficacy of Silirum vaccine



BJD Review
Market Access
Dr. Mark Schipp (ACVO)
February 2015

National BJD Strategic Plan Review – BJD Trade Implications

Dr Mark Schipp
Australian Chief Veterinary Officer
Department of Agriculture
Australian Government

The Department of Agriculture provides the following information in relation to the trade implications of BJD as they relate to trade in live animals, reproductive materials, meat, animal bi-products and dairy.

Advice in relation to live animals and reproductive materials (embryos and semen) is provided at Attachment A. In brief, many countries have BJD import certification requirements for animals and reproductive material. Extracts of BJD requirements for four major live cattle destinations are provided at Attachment B. Extracts of BJD requirements for reproductive materials to Taiwan and Chile are at Attachment C (noting that these countries have been selected for illustrative purposes only).

In terms of meat market access, a search of available edible meat attestations did not bring up any specific mention of BJD. Exported meat is however required satisfy the requirements under the Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption as being safe for human consumption. The relevant parts of the Standard are at Attachment D.

There are however specific certification requirements in relation to food and animal by-products (including dairy) market access. These included:

-

-
- Milk and dairy products – Customs Union (Russia/Kazakhstan/Belarus)

A certificate which the Customs Union intends to implement in coming years requires that the farm from which dairy products are sourced has been free from paratuberculosis for 6 months. As dairy companies do not have sourcing programs which would allow them to exclude milk from farms with BJD, this requirement is being negotiated with an aim to having it removed.

- Fertiliser containing processed animal protein – South Africa

A statement contained on the current certificate states 'The manure originates from Australian animals that are kept on farms that are not under restrictions for Johne's disease or Anthrax'.

Attachment A: BJD certification requirements for live animals and reproductive materials

Background

Bovine Johne's disease (BJD) is a wasting disease of cattle with significant adverse impacts on livestock production. While most cattle are infected as calves they may not

show any symptoms of BJD for many years, they are still likely to excrete the bacteria before developing clinical signs. The numbers of infected cattle in a herd may start out low, however, the rate of infection can increase significantly if BJD is not controlled. Visibly sick and dying animals can cause animal welfare issues and reduce production.

Consequently many countries legitimately apply control measures both domestically and to imports.

Australia does not currently import cattle, but previous import conditions included BJD requirements.

BJD Controls in overseas countries

BJD occurs in most countries throughout the world. Many of our trading partners have import controls relevant to BJD. A list of countries for which Australia exports cattle to, that have BJD requirements, is attached. The level of control applied to imports varies with the importing country and product. The level of control applied to imports is usually proportional to the importing country's sensitivity to BJD.

Sensitivities to BJD

There is considerable scientific discussion internationally about the possible link between Johne's disease in cattle and Crohn's disease in people. This concern is further heightening trade concerns in some countries.

In general, extensive testing may be required for breeder cattle. For slaughter and feeder cattle, confirmation of herd freedom for a specified time (usually for a number of years) is generally sufficient for most importing countries. While an importing country determines its own import requirements, the Department of Agriculture makes every effort to obtain science based, practical protocols when negotiating with importing countries.

Different strains of BJD

Para tuberculosis or Johne's disease potentially infects a number of species. A number of strains are recognised including the sheep, cattle and bison strain.

Strain types show species preference but this is not absolute. There has been sporadic evidence of disease in cattle caused by Sheep (S) strain. To date there is insufficient evidence to determine if infection with S strain will maintain and spread in cattle under Australian conditions, current national BJD policy doesn't consider S strain as a cause of bovine Johne's disease. The disease has worldwide distribution and there may be strain variation between countries e.g. Indian bison strain.

The different strains could become a trade issue, with different countries raising concerns about different strains. However, to date, this has not occurred.

Trade Issues surrounding BJD testing

Testing for BJD is complex, and can be expensive. A number of concurrent tests are used to test for BJD. This process can take up to 16 weeks, or more if complications arise.

There are limitations to the sensitivity and specificity of testing - this results in it being more aligned to herds than individual animals. Testing should be combined with epidemiological investigations to give more assurances of the herd status of properties or zones.

Blood testing (ELISA) – tests for disease antibodies has the disadvantage of low sensitivity for individual animals. The ELISA can fail to detect infection when it is present. Using ELISA testing of a herd offers moderate sensitivity.

Tests performed on faecal samples are culture (attempting to grow the causative bacteria) and a new molecular technology (HT-J PCR) test that detects the presence of the genetic material (DNA) of the bacteria. Faecal culture and HT-J tests can be run at the same time.

As in faecal culture, the faecal PCR test can only detect the bacteria of an infected animal if it is being shed at the time samples are collected.

The definitive diagnostic test is post slaughter sampling of faeces and tissue for culture and histopathology.

Vaccinated animals can cross react when tested for tuberculosis or paratuberculosis and natural infection will also cause cross reactions. This may impact breeder markets where export testing is required. No market at this stage accepts vaccination as a replacement for serological testing.

If the disease becomes more widespread in the Australian national cattle herd it will become more difficult to provide certification of farm freedom.

Quality and trade

Australia's reputation for export of healthy, quality cattle is important. Exporting BJD infected animals may negatively affect our trade reputation for quality.

Countries that have a requirement for bovine Johne's disease certification



Importing country	Commodity
Argentina	Cattle - semen
Brazil	Cattle - breeder
Brunei	Cattle - slaughter
Canada	Cattle - breeder
Chile	Cattle - breeder
	Cattle - embryos
	Cattle - semen
China	Cattle - breeder
China	Cattle embryos
China	Cattle semen
Colombia	Cattle - semen
Costa Rica	Cattle - semen
Cuba	Cattle - semen
Czech Republic	Cattle - semen
East Timor	Cattle - breeder
Ecuador	Cattle - semen
Indonesia	Cattle - breeder
	Cattle - feeder
Iraq	Cattle - semen
Israel	Cattle - feeder
	Cattle - semen
Japan	Cattle - breeder
	Cattle - feeder
	Cattle - semen
Kazakhstan	Cattle - breeder
Korea	Cattle - embryos
	Cattle - semen
Libya	Cattle - breeder
Malaysia	Cattle - breeder
	Cattle - feeder
	Cattle - slaughter
Mauritius	Cattle - slaughter
Norfolk Island	Cattle - breeder
Oman	Cattle - breeder
	Cattle - breeder
Pakistan	Cattle - embryos
	Cattle - semen
Paraguay	Cattle - semen

Philippines	Cattle - breeder
	Cattle - embryos
	Cattle - feeder
Qatar	Cattle - feeder
	Cattle - semen
Russian Federation	Cattle - breeder
	Cattle - breeder
	Cattle - embryos
	Cattle - feeder
Sabah	Cattle - semen
	Cattle - breeder
	Cattle - slaughter
Sarawak	Cattle - breeder
	Cattle - slaughter
Singapore	Cattle - breeder
Solomon Islands	Cattle - breeder
Sri Lanka	Cattle - breeder
Sudan	Cattle - breeder
Taiwan	Cattle - breeder
	Cattle - embryos
	Cattle - semen
Thailand	Cattle - embryos
	Cattle - semen
Turkey	Cattle - breeder
	Cattle - feeder
	Cattle - slaughter
United Arab Emirates	Cattle - breeder
	Cattle - semen
United States of America	Cattle - breeder
Uruguay	Cattle - embryos
	Cattle - semen
Vanuatu	Cattle - embryos
	Cattle - semen
Vietnam	Cattle - feeder
	Cattle - semen
Zimbabwe	Cattle - semen

Attachment B: Extracts of BJD requirements for three major live cattle destinations

Australian feeder cattle to Israel

Free from Paratuberculosis (Johne's disease) and that no clinical case of the disease has occurred in the herds of origin for at least the last 3 years

Australian feeder cattle to Indonesia

Has been free from clinical evidence of bovine Johne's disease officially reported during the five years prior to shipment.

Australian breeding cattle to China

No clinical cases reported on farm of origin for the past 12 months

Elisa test negative on farm for selection into pre-export isolation

Elisa test negative during pre export isolation

Japanese feeder & breeder (same clause)

Johne's Disease is designated as a reportable disease in Australia.

There has been no clinical, microbiological or serological evidence of Johne's disease and enzootic bovine leucosis on the premises of origin for at least 5 years before the commencement of the examination in item 5.

Attachment C: Extracts of BJD requirements for reproductive materials to Taiwan and Chile

Taiwan bovine embryos

The premises of origin (farm) of the donor cows and bulls to be free from (not been known to occur)-

a) for the previous 1 year ... Paratuberculosis (Johne's disease) ...

The donor bulls and cows shall be tested against the diseases listed below with negative results by the animal quarantine authorities (stating the test methods and dates, sampling dates and test results)-

... Paratuberculosis (Johne's disease) by complement fixation test (CFT) or fecal culture test

Chile bovine semen

1.2.3. RESIDENT ANIMALS

a) The animals shall meet the requirements of 1.2.2 regarding the admission of bulls to the centre.

b) All of the animals residing in the Semen Production Centre shall be subject to permanent health inspection by the Centre Veterinarian and no clinical signs of contagious infectious diseases susceptible to be transmitted through semen shall have been noted during the 6 months prior to the collection of the semen batch destined for Chile.

c) Every 12 months all the animals shall undergo the following diagnostics tests with negative results and/or corresponding treatments and/or vaccinations:

...

Paratuberculosis: ELISA test or complement fixation or faecal cultivation.

Attachment D: Important sections from the Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption

9.19 Before post mortem inspection of a carcass and each of its carcass parts is completed the following are removed or modified only with the approval of the meat safety inspector:

Any defects other than those referred to in clause 9.18 (faecal, urine, milk and other secretions).

Any other indication of a disease or other abnormality or evidence of contamination.

9.20 The following are condemned:

All material that is likely to be affected by contamination or pathological conditions trimmed from the carcass or carcass part.

10.2 Before the post-mortem inspection commences, the meat business gives the meat safety inspector:

(a) details of the inspection of and disposition applied to the animal from which the carcass and its carcass parts are derived.

(b) all information known to the meat business about any disease or other abnormality affecting or suspected of affecting the carcass and its carcass parts and the animal from which the carcass and its carcass parts are derived.

10.13 Carcasses and carcass parts affected or suspected of being affected with a disease or other abnormality that could affect wholesomeness of meat and meat products are not passed for human consumption.

BJD Review – “Where to from here”
Rydges Sydney Airport
16th February 2015

Diagnosis of BJD

Richard Whittington
Faculty of Veterinary Science
The University of Sydney



Topics

1. Stages of BJD and diagnosis
2. Tests and their characteristics
3. Problems in testing for BJD
4. The future – better tests

1. Stages of BJD and diagnosis

- What is BJD?

Infection with *M. paratuberculosis* (*Mptb*)

- Clinical – when there are obvious signs of disease
- Sub-clinical – when there are no obvious signs of disease (but you can measure production losses)

most cases of BJD are sub-clinical

Clinical BJD



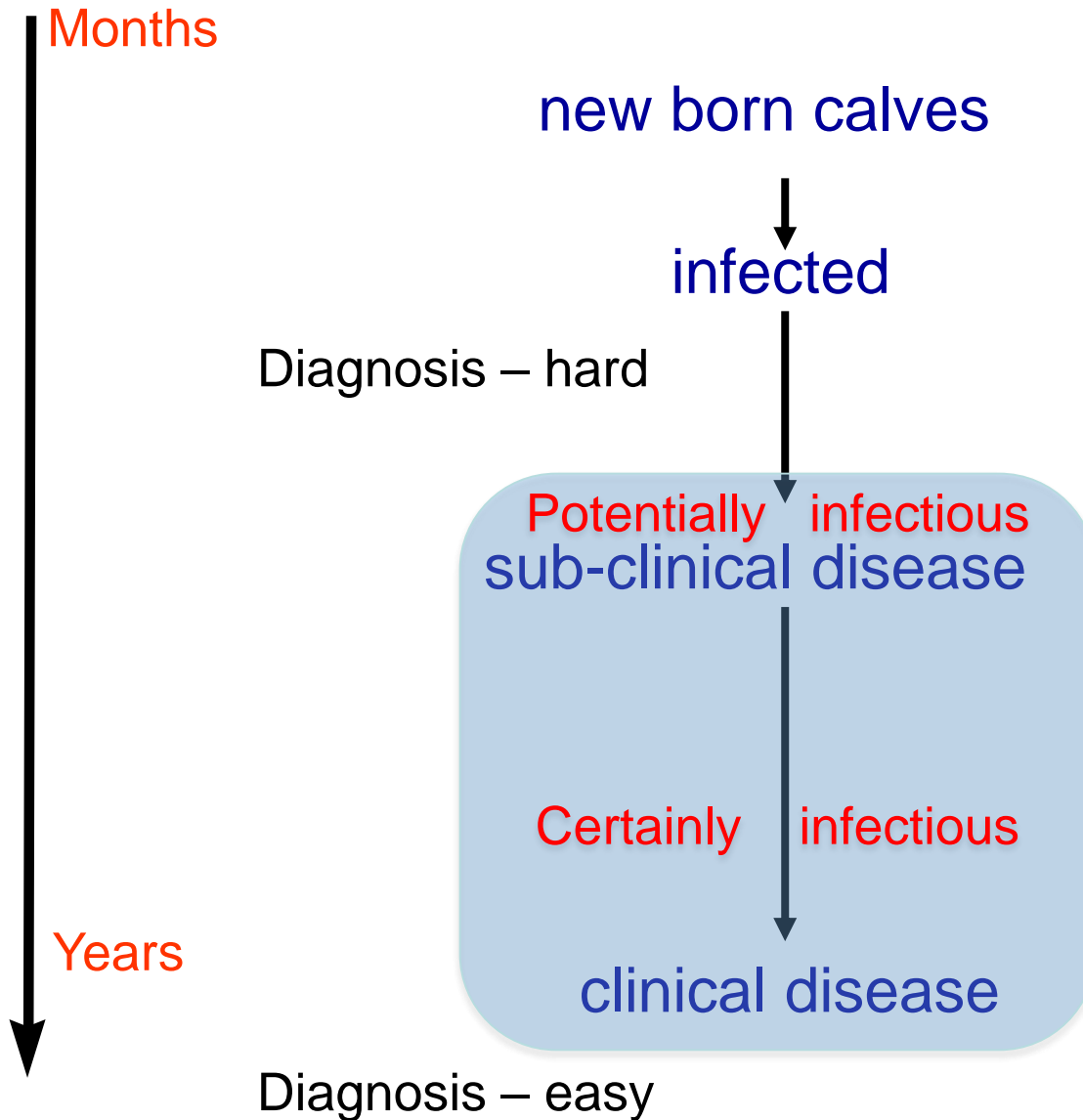
Diagnosis – easy
Most animals test positive

Sub-clinical BJD



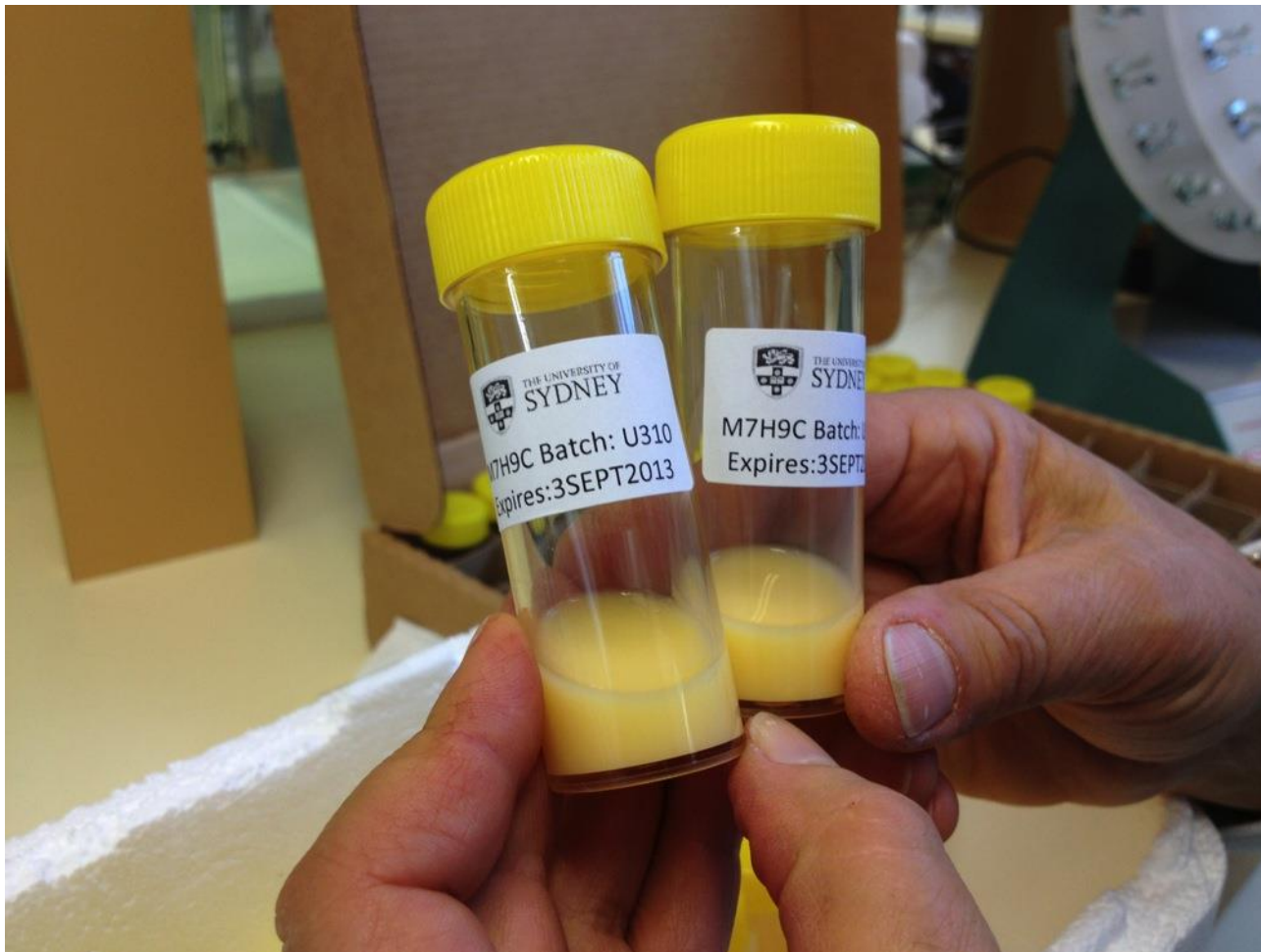
Diagnosis – hard
Many animals test negative

Stages of BJD



2. Tests and their characteristics

Culture detects live bacteria as they grow



HT-J PCR detects DNA of live & dead bacteria

1. Faecal preparation



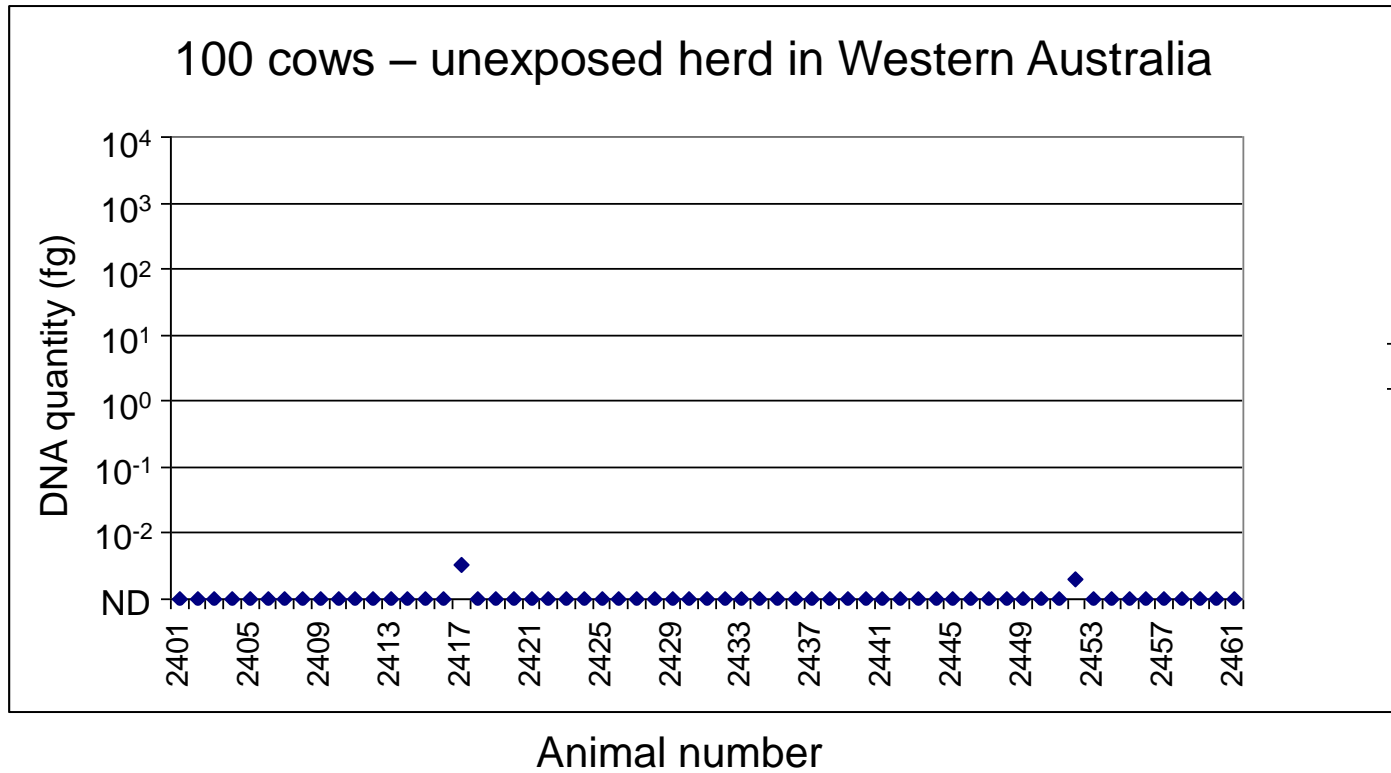
2. DNA extraction



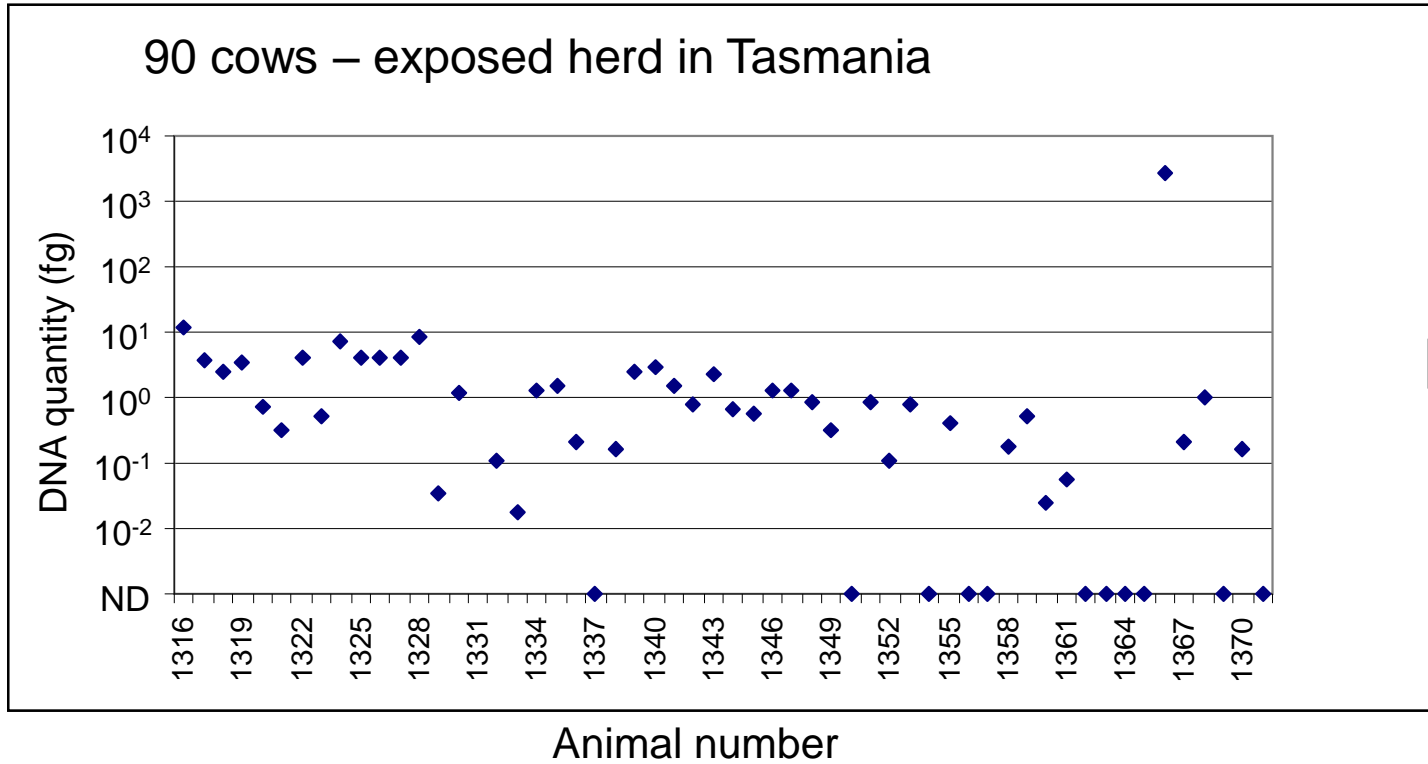
3. Real time quantitative PCR



HT-J



HT-J



Important test characteristic: sensitivity

What % of all infected animals are detected
(based on testing individual animals)

Test	Sensitivity
ELISA blood test	From 7% to 94%
Faecal culture	From 23% to 74%
HT-J	Similar to culture



Example will be shown at 33%
for cows in
mid stage of the disease

ELISA: sensitivity 33%

1 in 3 infected cows in mid stage disease
test positive in this example

Test positive

3 infected cows

Test
negative

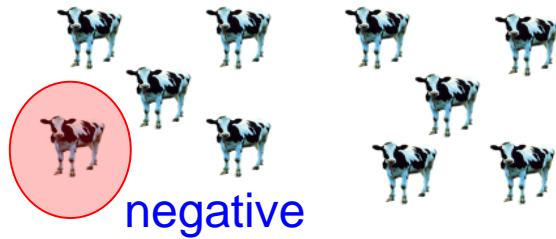


Test
negative

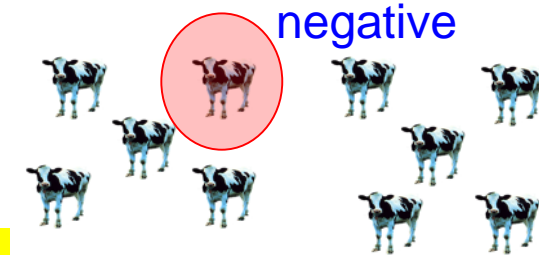
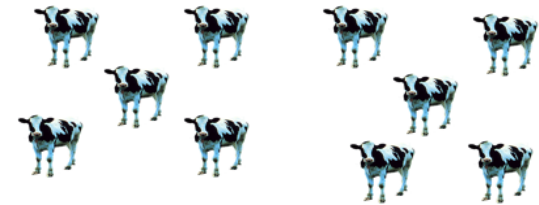
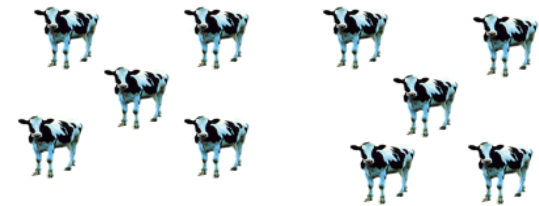
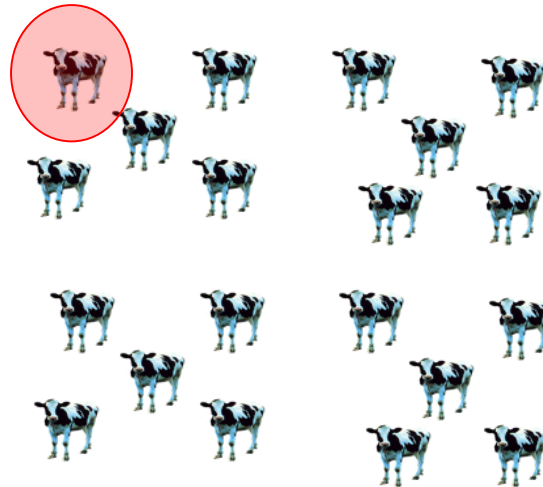
**Herd tests are more reliable
than individual animal tests**

ELISA: sensitivity 33%

100 head breeding herd

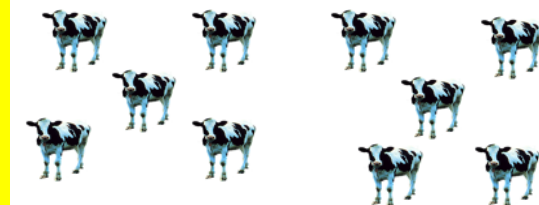


Test positive



To detect BJD in herds:

- large sample sizes
- repeat the testing over months/years



3. Problems in testing for BJD

- Pushing to use tests beyond their scope

Examples

- testing young animals – live export testing
- using HT-J for individual animals

- Compromising on technical matters

Examples

- testing home bred stock too soon – trace forward investigation
- sample size too low
- not randomly sampling in herd testing

More problems

- JD tests are complex and specialised
 - must be supervised by experts in microbiology, immunology and molecular biology. NATA accreditation does not assess competence
- SCAHLS committee abolished December 2014
 - Australian and New Zealand Standard Diagnostic Procedures in limbo
 - New diagnostic test approvals in limbo
 - HT-J Working Group abolished, technical improvements in limbo
- National JD reference lab underfunded, in limbo
 - New batches of commercial test kits must be validated
 - Expert technical advice and a referral service must be available
- Reduced investment from state jurisdictions
 - NSW DPI made its last specialist veterinary microbiologist redundant in 2013
 - QLD closed the animal health lab at Townsville, then sent Johne's disease samples to NSW DPI for testing

Still more problems

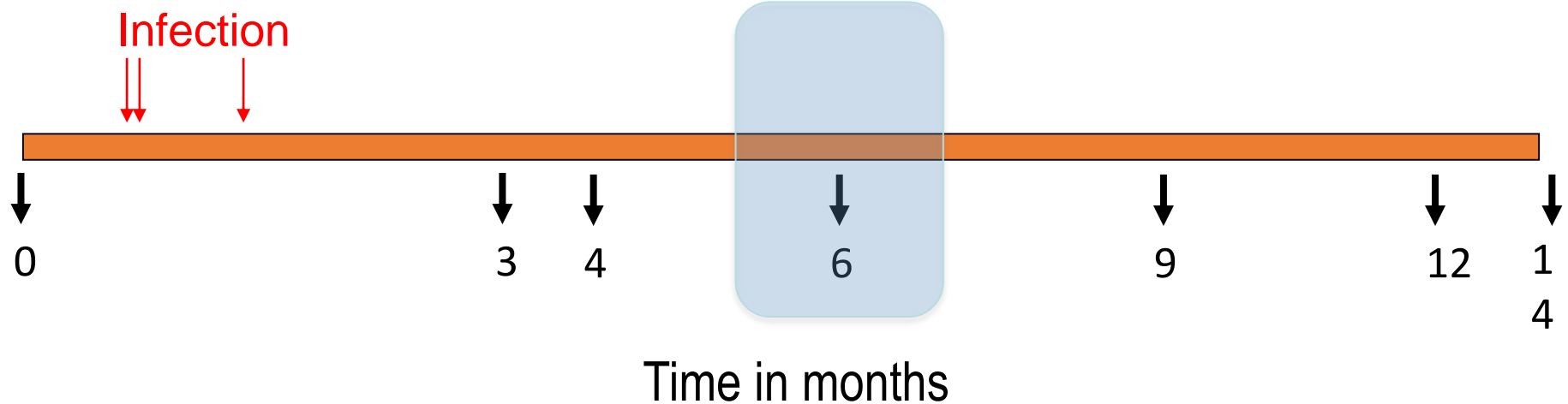
- Inter-laboratory test standardisation is critically important for national and international disease control programs, but is technically demanding and hard to achieve
 - The HT-J working group under SCAHLS was abolished in December 2014
 - Australian National Quality Assurance Program for animal health tests (ANQAP) has had chronic problems implementing a meaningful program for BJD faecal tests
 - University of Sydney participates in
 - ANQAP
 - United States Department of Agriculture BJD proficiency test
 - Japanese National Institute of Animal Health benchmarking for BJD and OJD faecal tests
 - Objective is for us to be able to detect what trading partners are able to detect

4. The future - better tests

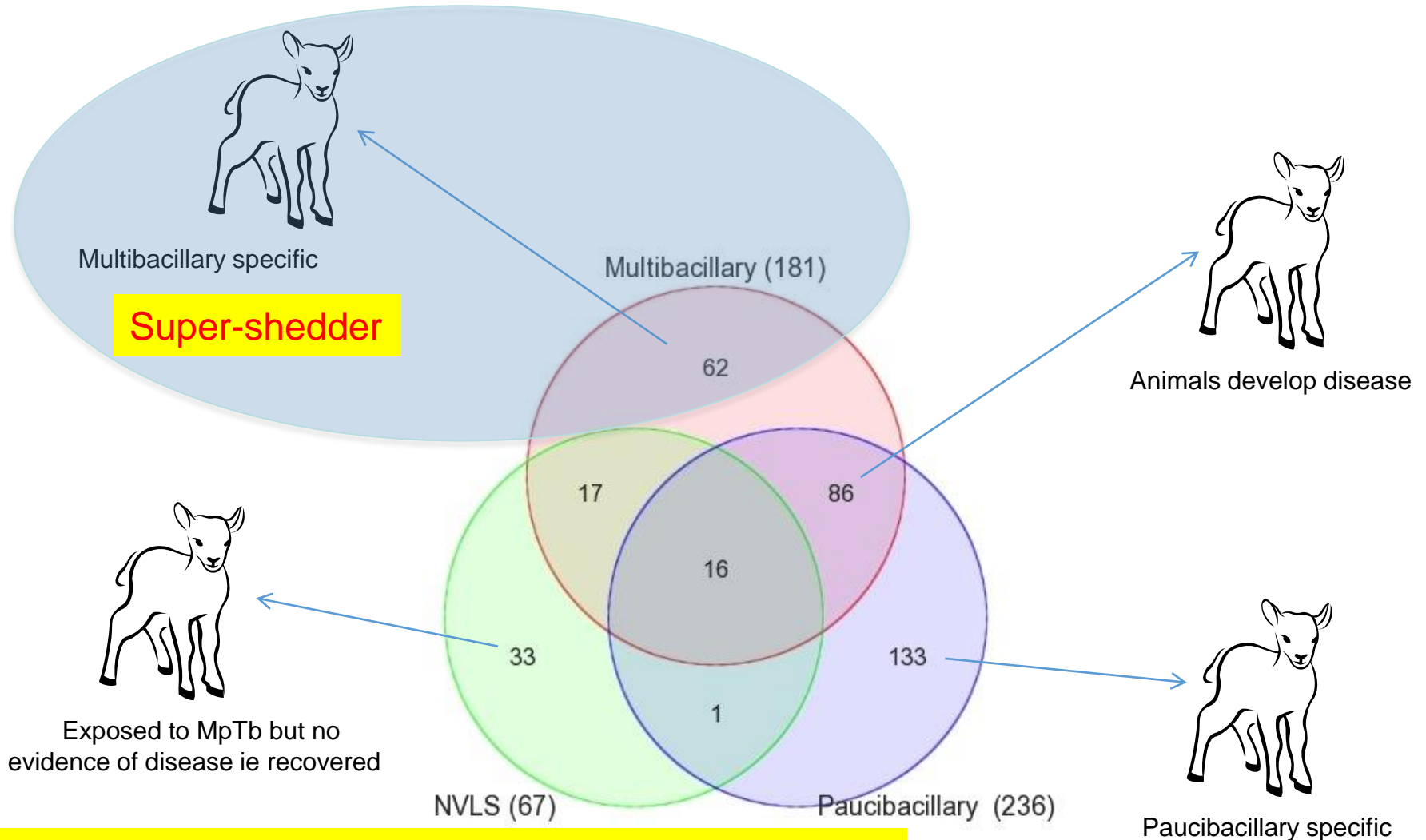
- To be able to test animals before 1 year of age to predict
 - super-shedders
 - resistant animals
 - disseminated infection (meat, milk)
- To enable economical development of improved vaccines that prevent infection



Experimental infection models

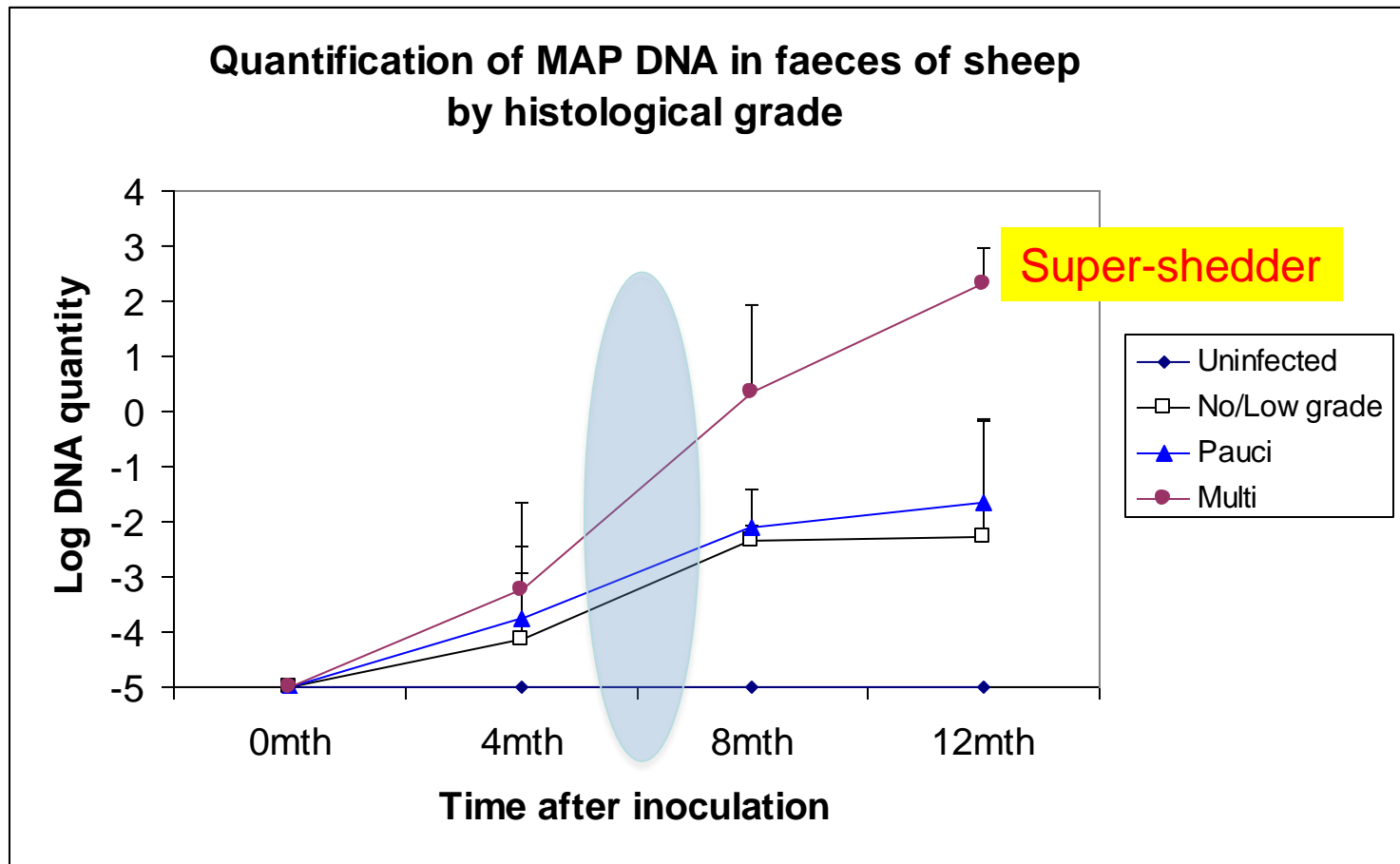


Gene activity identified



This study is the first to identify specific gene panels that are indicative of pathological outcome

Early faecal testing



Example – predicting supershedders at a young age

Diagnosis in young cattle – basic research

- New blood tests

Based on immunology

- Cytokines and antibodies
- Cell proliferation assays

Based on genomics

- Gene expression profiles

- Combined with HT-J faecal test

Objective:

Accurate prediction of infection outcome at 6 months of age



Herd management to reduce transmission of BJD

Acknowledgements



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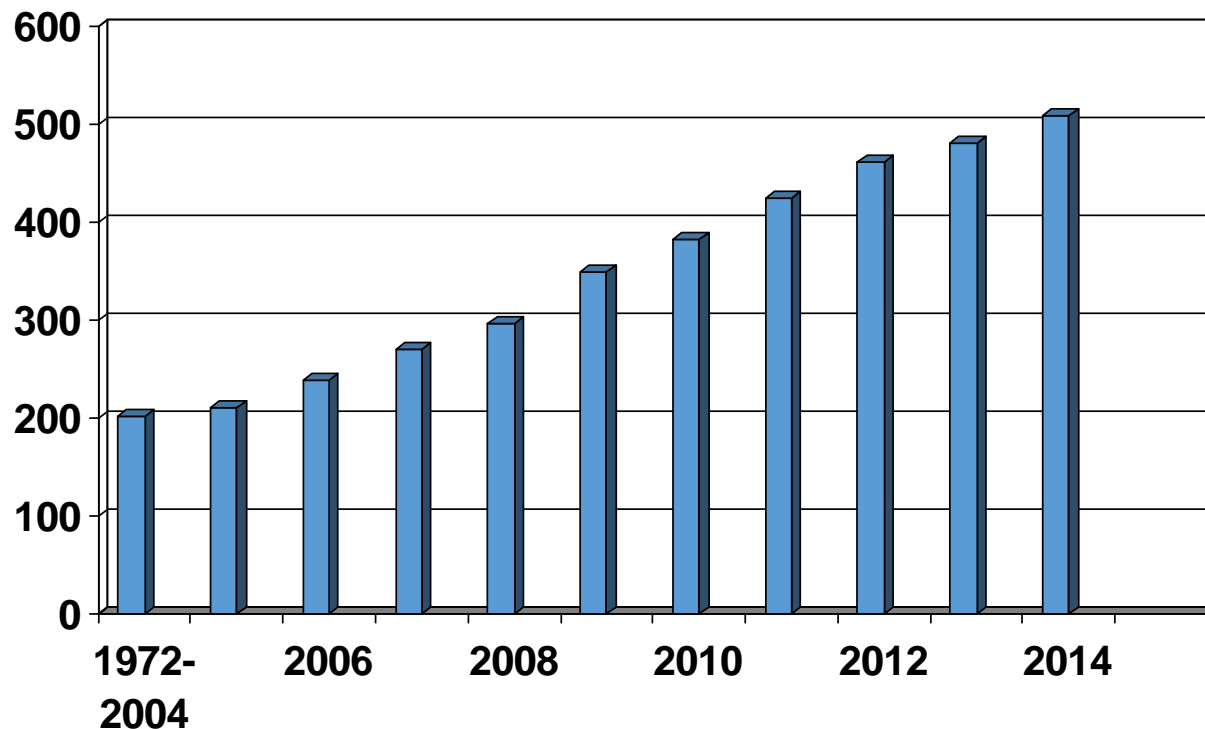
WOOLPRODUCERS
AUSTRALIA



Industry &
Investment



Total scientific papers mentioning Crohn's and paratuberculosis



Patterson DS, Allen WM (1972). [Chronic mycobacterial enteritis in ruminants as a model of Crohn's disease.](#) Proc R Soc Med. 65: 998-1001

Diagnosis of BJD

Professor Richard Whittington
Faculty of Veterinary Science
The University of Sydney
425 Werombi Road, Camden NSW 2570

Introduction

The diagnosis of Johne's disease in cattle (BJD) can be simple and quick, or a serious challenge. How can this be so? To answer this question we need to briefly review the way BJD develops in an animal, how it spreads between animals, the laboratory technology that is available to measure these events and the circumstances in which diagnostic tests are used.

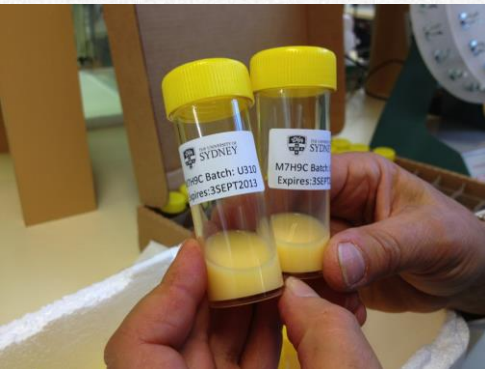
Another important question is whether the diagnosis of JD can be improved? The answer is an emphatic "yes", but it depends on research and development, which will also be reviewed in this short paper.

Current approaches to diagnosis of BJD

i) How JD develops in an animal.

JD is caused by the bacterium *Mycobacterium avium* subsp. *paratuberculosis* (abbreviated here as Mptb). This bacterium multiplies inside cells in the intestinal lining tissues and is shed into faeces. It also lives in cells near the udder, and is shed into milk. Most calves are infected orally either from faeces on the cow's udder, or by swallowing infected milk. Some calves are infected before they are born, because Mptb can pass into the pregnant uterus from the blood or lymphatic system of the cow.

After infection very little seems to happen for several years. Eventually the bacteria multiply and overcome the immune system of the young cow, and then the infection can progressively intensify. Eventually the bacteria cause so much damage to the intestine that diarrhea develops, the cow loses weight and eventually dies.



Only a small proportion of infected cows become visibly sick and die (these are called clinical cases). Some cows are infected for life but do not show any obvious signs (these are called sub-clinical cases). We believe that some cows may recover completely from the infection. Furthermore we believe that some calves are resistant to infection, and never become infected despite ongoing exposure to the bacteria.

Thus at any time in an infected herd of cattle there can be:

- a. Exposed but non-infected cows
- b. Sub-clinically infected cows (most infected cows are in this group)
- c. Pre-clinically and clinically affected cows (a few)
- d. Recovered cows (a few)

Why is this important? The reason is because diagnostic tests work well in some specific categories of cows and poorly in others. This will be explained below.

ii) How JD spreads between animals, farms, regions and countries.

- a. Transmission between animals on an infected farm.

Most of the infectious Mptb bacteria in a farm environment come from relatively few cows – the ones that are approaching the pre-clinical phase of the disease. These few cows shed millions of Mptb in every gram of their faeces. It probably takes only a few hundred to thousand bacteria to cause infection in a calf. Obviously the detection and removal of the highly infectious cows, which are also called super-shedders, should be a priority in any farm disease control program, because the risk of exposure of calves can be reduced dramatically. Good tests are available to detect super-shedders and cows that are about to become clinical cases.

- b. Spread between farms, regions and countries.

This usually occurs by movement of livestock. In this case any animal that is incubating the bacteria can be responsible for spreading the disease. This kind of spread rarely occurs due to pre-clinical or clinical cases, and is most often due to movement of sub-clinical cases. The incubation period can be years, for much of the time infected cows might shed the bacteria in faeces only intermittently, and by the time the disease shows up it may not be obvious how it even arrived on the farm. Consider an infected yearling animal that is purchased from another farm and does not ever show outward signs of BJD – by the time it sheds enough bacteria in its faeces to cause infection in home bred calves, and for those calves to become older cows that show the first signs of the disease, a decade or more may elapse.

This phenomenon explains the mode of spread and delayed discovery of OJD in sheep in Western Australia and in BJD in cattle in far north Queensland.

To stop this kind of spread it is necessary to use a very rigorous testing protocol.

Why is this information important? The answer is because different tests and testing protocols must be applied for different purposes.

iii) Application of tests for diagnosis of BJD. (Each type of test is explained below).

a. Clinical and pre-clinical cases.

Diagnosis is relatively easy using a combination of post mortem examination, microscopic examination of faeces, histopathology, rapid faecal PCR, faecal culture and sometimes ELISA. The diagnosis should be able to be confirmed quickly (1 week) because rapid tests can be used to confirm the differential diagnosis made by the investigating veterinarian.

b. Sub-clinical cases.

Diagnosis may be simple and rapid or it may be very difficult to confirm, depending on how long the infection has been present in individual cows in a herd. If the infection was introduced recently, if few animals are infected, or if the introduced animals cannot be found and tested, confirming infection can be very difficult. This is the greatest dilemma in BJD control.

Depending on the reason for testing, the following approaches can be used to diagnose sub-clinical infection:

- i. Post mortem and histopathology – quick and applicable when the suspect introduced animals can be found. Confirm findings using culture.
- ii. ELISA to rapidly screen the adult herd, followed by faecal tests or post mortem examination to confirm infection in any “reactors”.
- iii. Pooled faecal tests to screen the herd. Applicable when many animals need to be tested. Direct faecal PCR is rapid; faecal culture is slow.

c. When infection is thought to be absent.

The Market Assurance Program is an example of a situation when tests for BJD are used to show that Mptb infection is unlikely to be present. Other examples include clearing sales, stud sales, testing for entry to agricultural shows, testing for entry to AI centres, and live animal export testing. In each of these situations the preferred outcome is usually a negative test result! Options for testing are limited to non-lethal tests such as ELISA and faecal tests.

The tests may be applied at herd or individual animal level. The protocols for testing to show that infection is not present are potentially complicated. Their value is far greater when used at herd level than at individual animal level. The likelihood of obtaining the correct outcome is greatly increased when animals of appropriate age are tested in appropriate numbers using an appropriate test. This is not always done.

The examples given above of test applications are not exhaustive and are included for illustrative purposes only.

iv) Types of tests and accuracy of tests for BJD

The commercially available tests for BJD are listed in Table 1. The tests fall into two broad groups - tests that measure the reaction of the cow to the bacterium (ELISA blood test and pathology) and definitive tests for the bacterium Mptb itself (culture, PCR).

Table 1. Commercially available laboratory tests for BJD

Test	Accuracy¹	Cost²	Speed³
Post mortem examination and histopathology (often confirmed by culture)	High in clinical and pre-clinical cases; low in others	\$200	1 week (but longer to confirm by culture)
ELISA blood test	Moderate in clinical and pre-clinical cases; low in others	\$10	1 week
Faecal culture	High in clinical and pre-clinical cases. Low to moderate in sub-clinical cases	\$100	3 months
Direct faecal PCR (HT-J)	High in clinical and pre-clinical cases. Low to moderate in sub-clinical cases Note: validated as a herd test.	\$100	1 week

1 Accuracy. The potential for the test to detect all infected animals in a herd. More information is given in Table 2.

2 Cost. These are broad estimates and actual prices can vary dramatically between laboratories

3 Speed. Time from collection of samples until results are available assuming no complications

The accuracy of a diagnostic test is measured formally by estimating its sensitivity and specificity. Sensitivity is the proportion of BJD cases detected by the test. Specificity is the proportion of healthy animals that test negative. These parameters are determined by studying individual animals with and without the disease. It is well known that current tests for BJD do not detect a high proportion of the infected animals in a herd (Table 2). However, the tests are capable of detecting clinical and pre-clinical cases relatively well, i.e. they work best in older animals where the infection is more advanced – the higher values for sensitivity shown in Table 2 are for such animals. The wide range of sensitivity shown in Table 2 is due to the spectrum of stages of disease that characterize BJD. Fortunately the tests are quite specific (Table 2); the exception is ELISA when applied to cattle in northern Australia where cross reactions occur.

Table 2. Sensitivity and specificity reported for laboratory tests for BJD based on numerous published studies

Test	Sensitivity %	Specificity %
Faecal culture	23-74	98-100
ELISA	7-94	40-100
HT-J	Matched to culture	Matched to culture

This table was prepared from data in Nielsen, S.S., Toft, N., 2008. Ante mortem diagnosis of paratuberculosis: a review of accuracies of ELISA, interferon-gamma assay and faecal culture techniques. Vet Microbiol 129, 217-235.

Data for HT-J is available in Plain et al, 2014. High-Throughput Direct Fecal PCR Assay for Detection of Mycobacterium avium subsp paratuberculosis in Sheep and Cattle. J Clin Microbiol 52, 745-757.

When used at herd level, the low sensitivity of blood and faecal tests for individual animal diagnosis can be overcome. Internationally agreed guidelines are applied, and these guidelines are implicit in BJD market assurance program protocols. Herd level testing involves testing multiple animals to provide a certain level of confidence (usually 95%) of detecting a certain level of infection (usually 2% or 5%) if present in the herd. Repeated herd testing allows for the long incubation period in BJD, and allows animals to advance in the disease process over time so that they will be detected. Over time, the confidence that the herd is free of infection increases. Unfortunately this also means that a proportion of herds will “fall over” at each subsequent test.

As the tests work best in pre-clinical and clinical cases, and as most pre-clinical and clinical BJD cases are adult animals, usually older age classes, the problems of applying tests to cattle at a young age should be apparent, and these problems are accentuated when individual animals are proposed for testing to rule out infection with Mptb.

When the source herd or population is known to be exposed to Mptb, negative test results from individual young animals would lack any validity.

Problems in BJD diagnosis and testing

The following issues need to be considered in the context of BJD diagnosis:

1. Widening the application of diagnostic tests. There is sometimes a tendency to try to use tests beyond their validation or scope, for example in young animals (e.g. live animal export testing), individual animals (eg HT-J which was approved as a herd test), or too early after potential exposure to Mptb (e.g. trace forward investigation)
2. Over-reliance on tests and under-reliance on herd history and epidemiological investigation
3. Compromise on technical aspects of herd level testing such as reducing sample size, non-random sampling and compromise of other assumptions
4. JD test standardisation requirements. JD tests are complex and specialised. The protocols must be supervised and standardized. Commercial test kits need to be validated. All of this requires substantial multidisciplinary expertise. Such expertise is disappearing in Australia due to government laboratory cutbacks. The committee that used to oversee standards was abolished in December 2014 (SCAHLs). Also abolished was the technical working group that managed conduct of the HT-J test nationally.
5. The national JD reference laboratory is not currently offering a full service and has been chronically under-funded.
6. Inter-laboratory check testing is important for national quality control, but is technically demanding and hard to achieve. There have been chronic problems implementing BJD faecal culture in the national quality assurance program for animal health labs (ANQAP), associated with procurement of authentic samples and underfunding of the national reference laboratory. The HT-J test is not included in ANQAP, and one round of inter-laboratory testing was coordinated by volunteers from the SCAHLs committee (abolished recently). The University of Sydney laboratory participates in a USDA program because of lack of a suitable program in Australia.

Future approaches to diagnosis of BJD

The value of research and development

Research funded by MLA in Australia has led to substantial discovery, improvement and insurance in BJD diagnosis over the last ten years. The current commercially available tests for detection of the bacterium Mptb were developed and validated in Australia:

- i) the new culture medium M7H9C, which underpins BJD diagnosis, was developed because a multinational company withdrew its medium from the global market
- ii) the HT-J rapid faecal PCR test was developed to overcome problematic delays in reporting culture results and is the only fully validated faecal PCR for BJD in the world; HT-J is benchmarked against similar technology that is now used in Japan in a bid to stop Mptb from Japanese cattle from entering the human food chain;
- iii) the IS1311 strain typing test is discussed in this workshop in the companion paper by Ian Marsh
- iv) the approach of pooled faecal culture

These advances are the product of research and development, a background activity that underpins the Australian livestock industries. It is reasonable to assume that research and development will continue to deliver advances. What are the prospects for BJD diagnosis?

Forecast

The following discussion is based on outcomes from current basic research on BJD and OJD at the University of Sydney, funded by MLA. A quantum leap is required in understanding how and why BJD develops in some cattle but not others in an infected herd. It is now apparent that the final outcome for an individual cow, which may not be obvious until the cow is 4 to 6 years old (or older), is determined early in life by a number of internal and external factors including: the genetic makeup of the cow, the dose of Mptb that it was exposed to, possibly the strain of Mptb and importantly, the behavior of the immune system in the first year. We have preliminary evidence that tests conducted within the first year of life are predictive of final disease outcome. We are currently exploring this in both sheep and calves. The findings are also highly relevant to understanding how JD vaccines work, and for developing better vaccines.

A test called the interferon gamma assay has been applied in research trials, but has not been applied in routine diagnosis due to lack of validation. We have shown that it is a good indicator of exposure to Mptb rather than infection with Mptb. In other words, we can tell whether a herd has been exposed to Mptb, but not necessarily whether individual cows have become infected. This test is an example of a cytokine assay, and it measures facets of the immune response. There are literally dozens of cytokines that play a role in BJD, few of which have ever been studied. We are currently developing and exploring combination cytokine assays to untangle the complex immune response in the first year of life, to develop immune predictors for BJD.

Due to technical advances in genetics there is now a capacity to evaluate the genotype of individual cattle at the level of the DNA sequence of specific genes, and to understand the role this plays in progression of the disease, and so in diagnosis.

It seems highly likely that a panel of tests can be developed to:

- i) reveal the presence of Mptb in herds directly or show evidence of exposure of cattle to the organism
- ii) identify cattle at greatest risk of becoming super-shedders, before they do so.
- iii) Identify individuals that will or will not respond favorably to vaccination

These developments would allow a range of new disease control practices to be developed and evaluated.

BJD forum Monday 16 February 2015, Rydges International Airport Hotel, Sydney.

**Strain typing. B, S or C or not B, S or C?
That is the question.**

Ian Marsh^{a*} and Richard Whittington^b

^aElizabeth Macarthur Agricultural Institute, NSW Department of Primary Industries, Menangle, Australia.

^bFaculty of Veterinary Science, University of Sydney, Australia

What is a strain?

Two common uses of the term strain

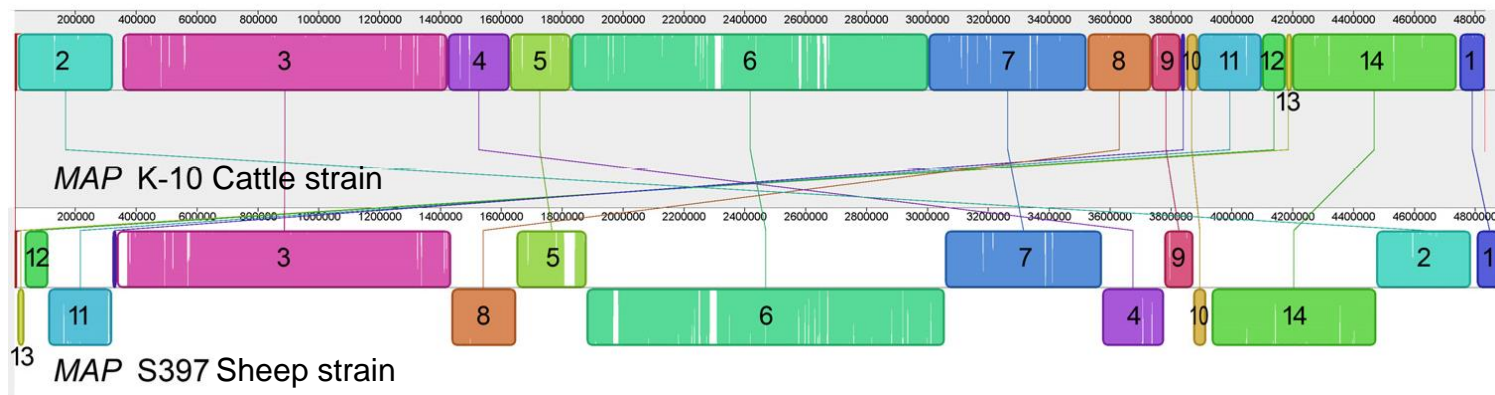
- (1) Taxonomically, a bacterial strain is a population of bacteria that descend from a single organism or pure culture
- (2) Epidemiologically, a strain refers to a phenotypic (biochemistry, physical appearance or virulence) or genotypic (DNA-based) difference that can be used reliably to differentiate bacteria

For the purposes of this presentation I will be applying the following definition:

A genotypic (DNA-based) difference that can be used reliably to differentiate bacteria

Strain typing - WGS

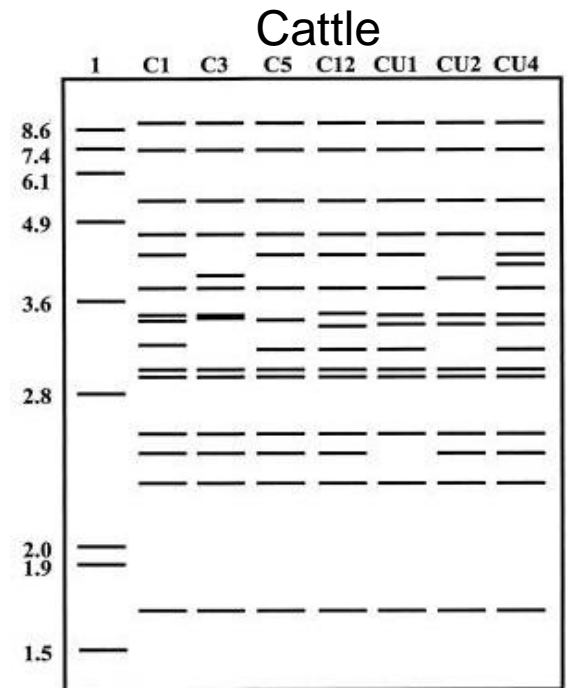
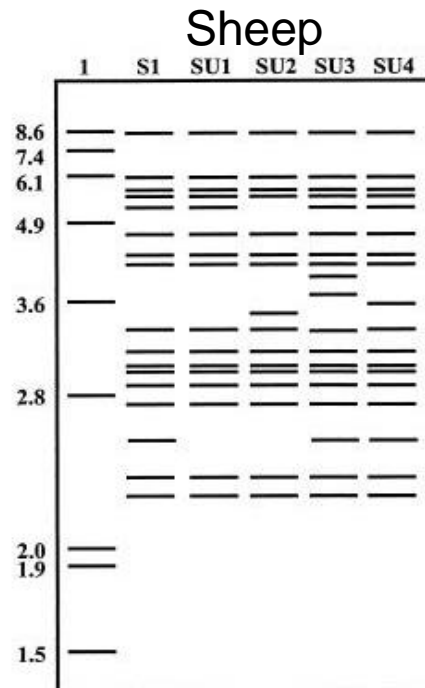
- Whole genome sequencing (WGS)
- Very complicated, expensive but very informative
- Unrealistic for routine epidemiology at present
- Not done for American B strain biotype, to the best of my knowledge
- Has been done on the Indian B strain Biotype, 99.91% homology to MAP4, a human isolate from the USA (Singh et al, Genome 2013, 1:1)
- Recently used to characterise *M.ptb* isolated from breast milk of a Crohn's disease patient. Highly similar to C strain (Bannantine et al. Genome Announc 2014 2:e01252-13)



(Bannantine et al. BMC Genomics 2012, 13:89)

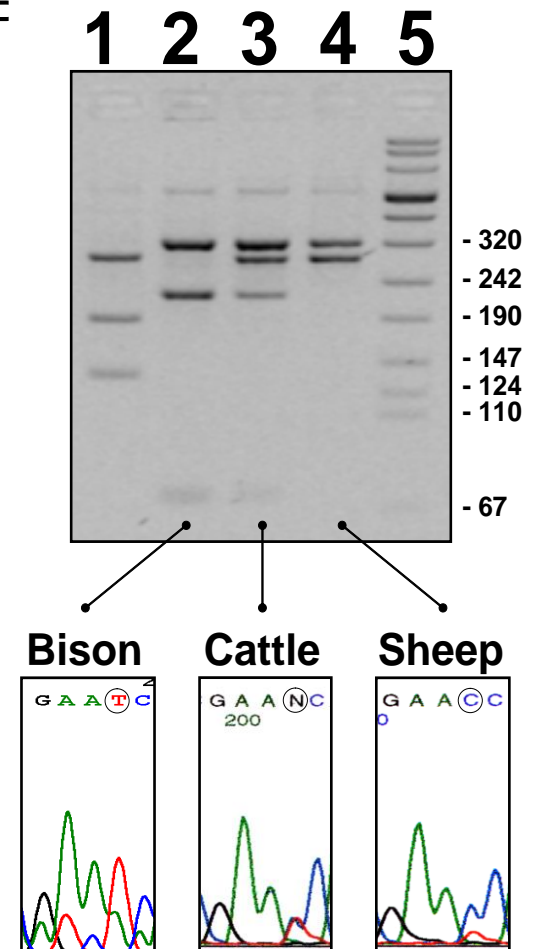
Strain typing - RFLP

- Restriction Fragment Length Polymorphism (RFLP) (Whittington et al., *Journal of Clinical Microbiology* 2000; 38:9)
- Less complicated, less informative compared with WGS
- More complicated, more informative than IS1311 strain typing
- Standard test used internationally for epidemiology for the last 25 years
- Time consuming, expensive
- Suited to epidemiology



Strain typing – IS 1311

- IS 1311 strain typing (Marsh et al, 1999 Molecular and Cellular Probes.13)
- Less complicated, less informative compared with RFLF
- Standard test used for strain identity for 16 years
- Quick, inexpensive
- NOT suited to epidemiology
- Only strain typing test required to date to support national Johne's disease programmes



Strain typing – Others

- Pulsed Field Gel Electrophoresis (PFGE)
- Variable Number Tandem Repeat (VNTR)
- Amplified Fragment Length Polymorphism (AFLP)
- Short Sequence Repeat (SSR)
- Others

- Varying degrees of:
 - complication
 - information
 - speed
 - expense
 - application to epidemiology

Validation

- Typing techniques must be validated prior to use in an epidemiological investigation according to a critical performance criteria
 - **typeability** (the ability to interpret results),
 - **reproducibility** (how easily the test can reproduce the same result when run in different laboratories)
 - **stability** (reproducibility over time)
 - **discriminatory power** (the ability to discriminate between closely related strains, that is, the number of strains identified compared to the number of strains that exist)
- The right typing technique must be chosen to address the question

Fit for purpose

Lessons

- Manufacturer test, colour test and tyre test tell nothing more than that:
 - Manufacturer
 - Colour, at the time of the test
 - Tyres, at the time of the test

- They DO NOT tell us anything else about the car, that is:
 - Petrol or diesel
 - Automatic or manual
 - Registered or unregistered

These require further tests

Lessons

- Primary Test – Highly stable over time
 - Car example – Manufacturer
 - The make of a car is never going to change
 - GOOD long term test
- Secondary test – Stable over time some potential for change
 - Car example – Colour
 - Owner or subsequent owners might repaint car
 - GOOD long to medium term test
- Tertiary test
 - Car example – Tyre Brand
 - Owner or subsequent owners **highly likely** to change tyre brands
 - GOOD short term test
- The right typing technique must be chosen to address the question

Fit for purpose

Expectations

- Primary test, very stable over time
 - IS1311, B, S and C will always be B, S and C
 - Car manufacture, manufacturer will never change
- Secondary test, reasonably stable over time
 - RFLP, S and C will always be S and C, sub-strains may differ slightly but always correlate back to IS1311 strain type
 - Why? IS1311 and RFLP were co validated against each other
 - Car colour, most will never change BUT the odd one will
- Tertiary test, expect a lot of change over time
 - Other typing tests, may not correlate back to primary or secondary test
 - Tyre brand, change almost inevitable
- WGS – equivalent to pulling the entire car apart and laying it out on a big factory floor part by part

What we don't know

- No strain typing technique to date, produces results that are directly linked to the mechanisms that explain
 - host specificity
 - pathogenicity
- At present, these are just markers that correlate with host specificity or some other genotypic or phenotypic characteristic

What we do know

- Via the numerous projects undertaken by the Australian Johne's Disease research group, the data on RFLP and IS1311 strain typing is valid. These have been referenced many many times in internationally referred journal articles and are still considered to be the definitive studies
- Should there be the need to correlate strain type and the mechanisms of host specificity and/or pathogenicity, there will need to be more research

NSW DPI's latest contribution

- Ian Roth and Rory Authur approved a \$50K investment in the latest in strain typing capability
- Bio Molecular Systems (BMS) Qseq
- Allows for strain typing close to the sensitivity of HT-J
- IS1311 Strain typing in one day
- Currently being validated against other IS1311 tests
- Results are based on sequence data
- Would be nice to get some funding to complete validation



Conclusion

- B, S or C or not B, S or C? That is the question. They are! B, S and C
- Strain typing does not tell us about the disease-causing potential of a particular *M.ptb* isolate in different species. This has been a research question for some years
- In Australia, the strain typing tests have been meticulously validated to stand the test of time and are still considered the international standards for strain typing for B, S or C

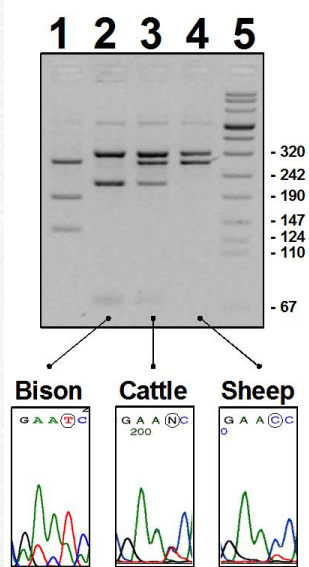
Acknowledgements

- Johne's disease research team headed by Richard Whittington
- Meat and Livestock Australia
- Animal Health Australia
- Sheepmeat Council of Australia
- Cattle Council of Australia
- WoolProducers Australia



Strain typing. B, S or C or not B, S or C? That is the question.

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What is a bacterial strain?

The term bacterial strain now exists in two broad contexts: bacterial taxonomy and bacterial epidemiology and the definition differs accordingly. Taxonomically, a bacterial strain is a population of bacteria that descend from a single organism or pure culture. The epidemiological definition of strain refers to a phenotypic (biochemistry, physical appearance or virulence) or genotypic (DNA-based) difference that can be used reliably to differentiate bacteria. Traditional bacteriology has focused on phenotypic differences, while modern molecular bacteriology focuses on genotypic differences. It is very useful for disease control purposes when molecular differences are matched to a property of the bacterium such as its host preference or virulence, and it is in this context that strain typing of *Mycobacterium avium* subsp. paratuberculosis (M.ptb) can be important. For the purpose of this paper a strain of M.ptb will be considered a genotypically distinct variant that has some correlation with a host preference.

Sheep vs Cattle strains of (M.ptb)

Johne's disease was first diagnosed in Australian cattle in 1925⁴. Johne's disease has since been reported in goats in 1977³, sheep in 1980⁶ and alpaca in 1993⁷.

Johne's disease presents differently in cattle and sheep with respect to clinical, pathological and epidemiological features⁹. Early observations on the epidemiology of the disease⁸ and culturability of the organism from different hosts² suggested the existence of two strains of M.ptb. Then, DNA-based studies, looking at M.ptb isolates from a range of hosts using restriction fragment length polymorphism (RFLP) on genomic DNA, confirmed the existence of two distinct groups of M.ptb¹.

These are now commonly referred to as C (from cattle) and S (from sheep) strains. While specific but minor differences were observed in the genomes of the two strains, no inferences could be made on how these explained the resulting host specificity¹. Comparisons of the whole genome from C and S strains have demonstrated a high degree of similarity in terms of genes that are present but have demonstrated substantial genomic rearrangement.

In Australia and New Zealand, most cases of BJD are caused by C strains and most cases of OJD are caused by S strains. However, host specificity of the S and C strains appears to be incomplete. C strains are promiscuous and can cause disease in most species, while S strains tend to be associated mainly with sheep. Goats and deer seem to be susceptible to both strains. However, where there has been opportunity over a long time for infected sheep, cattle and other species to mix (such as in Europe), the pattern of host preference of S and C strains is harder to observe.

Genotypic differences between the S and C strains have been well characterised and linked to host specificity using standardised IS900 and IS1311 (genes present in both S and C genomes) restriction fragment length polymorphism (RFLP) typing. The RFLP technique became the definitive tool for strain typing in the 1980s and early 1990s. Capable of differentiating between the two strains and even sub-strains within each strain, RFLP is time consuming and expensive. RFLP typing was replaced by a simpler test that could differentiate between the S and C strains directly using the IS1311 gene⁵. The new test, developed in an MLA-funded project, is based on IS1311, and has become the international standard for primary strain typing of M.ptb. It has been extensively used and referenced in research and diagnostic studies all over the world.

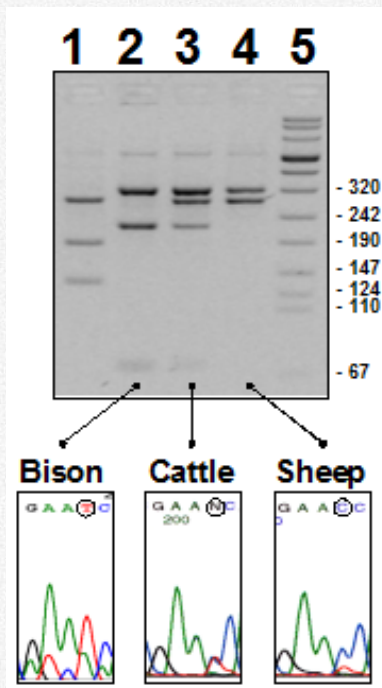
Both the RFLP and IS1311 tests have been used to type human isolates of M.ptb, and to date all appear to be C strain.

The Bison strain

During the late 1990s Dr Robert Whitlock of the University of Pennsylvania approached Dr Richard Whittington regarding the presence M.ptb in a herd of Bison (Bison Bison) in Montana USA. DNA was obtained from the M.ptb isolated from the Bison and subjected to the new IS1311 test. The results indicated a new genetic variant which was designated the Bison strain¹⁰. The IS1311 test has been used internationally to screen for the Bison strain, which has now been found frequently in both the United States and India. Up until the discovery of the Bison strain in cattle in Queensland in 2012-2013, this strain had not been reported in Australia. Following the discovery of this strain during this investigation, Queensland researchers undertook an epidemiological investigation of M.ptb in Queensland using alternate molecular strain typing techniques to trace the movement of the disease within this state¹¹.

IS1311, the test, the results and the implications

If you look closely at the figure to the right you will see the results of the IS1311 test for *Mycobacterium avium* subsp. *avium* (lane 1) and the Bison, Sheep and Cattle strains of *M.ptb* (lanes 2, 3 and 4, respectively). Lane 5 is for size reference only. Each strain is clearly distinguished by a unique DNA profile (fingerprint) and all three can be readily differentiated from *Mycobacterium avium* subsp. *avium*. Below the results are the DNA sequences from each strain that give rise to this outcome. The circled letters indicate the genetic variant in each strain responsible for the unique profile. Currently, the IS1311 test is the only strain typing test required to support national Johne's disease programmes. Differentiation between S and C strains may be required to support the decision on action to be taken. Whilst the genetic differences in the IS1311 gene have been validated as a marker for host specificity no evidence exists to suggest this is the actual cause of host specificity or pathogenicity.



Advanced molecular strain typing to identify the origin of outbreaks

The ability to identify subtypes within the S and C strains may make it possible to look at the spread of disease within populations and geographic regions. As knowledge of the *M.ptb* genome increased in the early 2000s new strain typing techniques started to emerge. This coincided with a growing interest in modern molecular epidemiology. Sabat et al, 2013 have prepared a review of molecular typing techniques for those wishing to read more¹². For now, what is clear is that each typing technique must be validated prior to its use in an epidemiological investigation.

This validation must include critical performance criteria such as typeability (the ability to interpret results), reproducibility (how easily the test can reproduce the same result when run in different laboratories), stability (reproducibility over time) and discriminatory power (the ability to discriminate between closely related strains, that is, the number of strains identified compared to the number of strains that exist). Importantly, a strain typing technique must be re-validated for every new application it is used for. Ultimately, failure to validate tests thoroughly may give a false or distorted sense of reality when they are applied.

What do strain typing results actually mean?

If two disease outbreaks are due to different strains of M.ptb the outbreaks are not connected. If two outbreaks are due to the same strain of M.ptb they might be connected, eg through trade in livestock, straying livestock or transfer of infection across a common property boundary fence. When MLA sponsored a large strain typing study in 1999 it was shown that BJD in dairy cattle was separate from BJD in beef cattle, and that OJD was distinct from BJD – in other words Johne’s disease in these different livestock sectors were quite distinct. This was very useful epidemiological information.

The extent to which a strain typing method can separate closely related strains influences the extent to which it can be used in tracing investigations to identify the true source of infection. This issue is relevant in the context of human isolates of M.ptb – where do they really come from?

Strain typing does not tell us about the disease-causing potential of a particular M.ptb isolate in different species. This has been a research question for some years.

Conclusion

Strain typing in the epidemiological sense, refers to the use of genotypic variations within and between strains that can be used to reliably differentiate them. These genotypic variations must be validated as fit for purpose as was done with IS900 RFLP and IS1311 PCR-REA tests. A cautious approach to interpretation of strain typing results is required for disease tracing and in public health investigations.

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Economics of BJD in the cattle industry

Non-regulatory economic impacts of BJD in commercial dairy
& beef herds

Richard Shephard BVSc MVS PhD

Why this analysis is needed

- BJD is confusing – with many regulatory impacts – that dominate thinking about ‘why control?’
- Many farms are of ‘unknown’ or ‘suspect’ status
- We need to understand the ‘real’ cost of disease in a commercial cattle herds
- Quantifying cost will assist farmers to decide if control is worthwhile to them

BJD pared back: is it a production disease of importance?

Assumptions

- Commercial herd – no trading of bloodstock
- Any human food safety aspects ignored
- Unimpaired ability to obtain agistment
- No impact on land value
- No BJD control – disease stabilised in herd

Actual physical impact of BJD to a typical producer

How BJD affects profit (under assumptions)

- Subclinical infection
 - A small proportion of a herd is infected
 - Probably minimal impact in most shedders
- Clinical disease
 - Only a proportion of infected animals become clinical
 - Premature loss of animals from the herd
 - Loss of weight
 - Reduced production

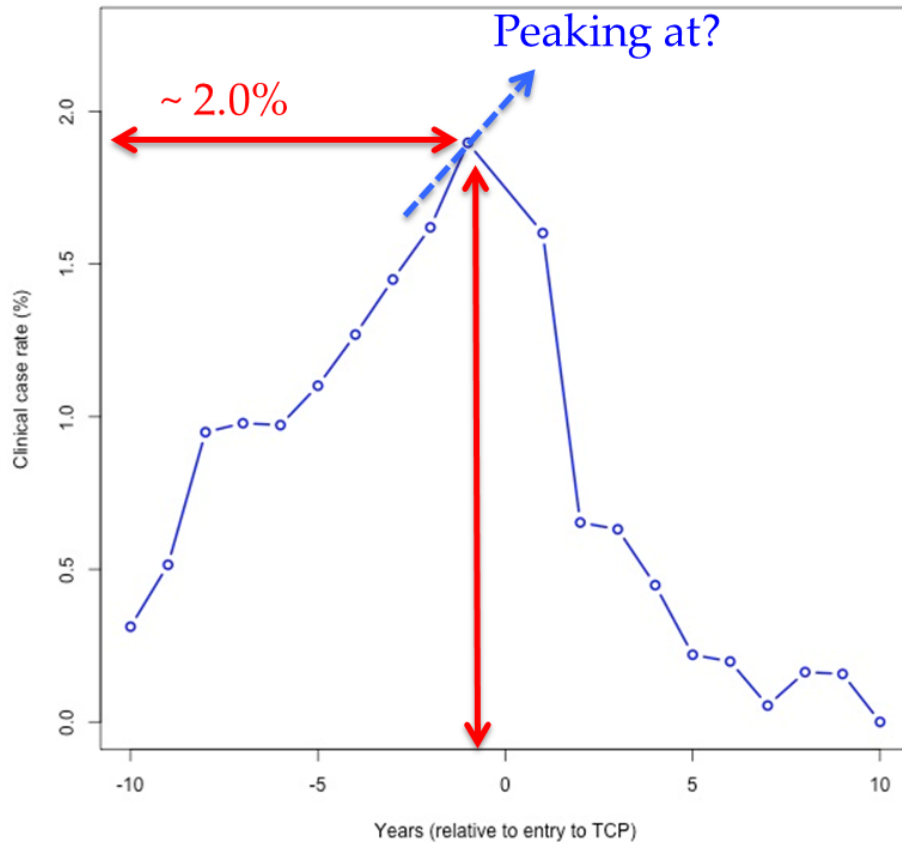
The economics of BJD is all about clinical cases

Dairy



Clinical case rates

Clinical case rate in TCP herds (pre- and post-entry)



- Only a few animals are infected and only a few of these become clinical
- Around 1.8% of cows became clinical in the year before entering the Victorian test-and-control program
- Modelling suggests incidence could peak at 2.6% per annum

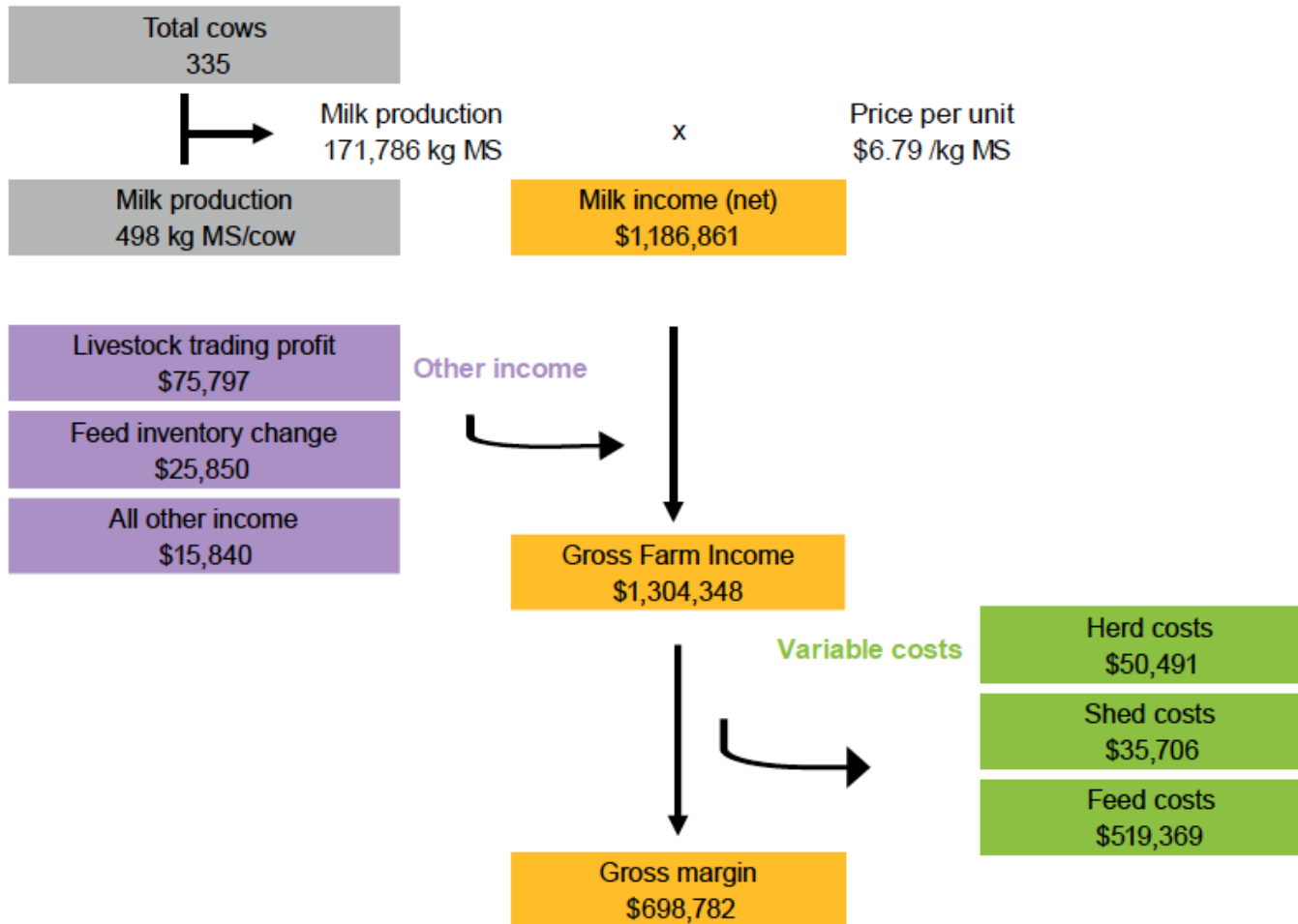
Age at break-down

- Average age of clinical cases was 5.9 years from Victorian TCP program
- Most cows are in their third lactation when culled
- The herd loses 1+ years of productive and profitable life on average for each clinical case lost

Losses

- Current losses
 - 14% reduced milk income in year of culling
 - No slaughter value
- Future losses
 - 1+ lactations
 - 1+ calves
 - Final cull value (if healthy)
- Most dairy herds struggle for replacements so early loss of a productive cow cannot easily be covered

Typical earnings



Source: Dairy Farm Monitor Project Victoria 2013/14 Annual Report

Cow annual performance

Source	Level	Parameter	Value	
DFMP	Cow	Milk production (kg solids)	513	
		Milk income (\$)	3,543	
		Livestock income (\$)	226	
		Other income (\$)	124	
		Feed costs (\$)	1,550	
		Herd & dairy costs (\$)	257	
		Gross margin (\$)	2,086	
		Production	Milk prices (\$/kg milk solids)	6.91
			Feed costs (\$/kg milk solids)	3.02
ADHIS	Age cohort	Milk production (l)	Relative prodn (cf 2YO)	
	2YO	6,067	100%	
	3YO	6,720	111%	
	4+YO	7,135	118%	

Age structure – cow-age model

Age	Conditional survival	Cumulative survival	% milking herd	Annual litres	Annual milk solids (kg)
1	0.980	0.980		-	-
2	0.980	0.960		-	-
3	0.805	0.773	24%	6,050	443
4	0.861	0.666	19%	6,655	488
5	0.809	0.539	17%	7,260	532
6	0.792	0.427	13%	7,865	577
7	0.670	0.286	11%	7,865	577
8	0.650	0.186	7%	7,260	532
9	0.535	0.099	5%	7,260	532
10	0.521	0.052	2%	6,655	488
11	0.402	0.021	1%	6,655	488
12	0.000	0.000	1%	6,050	443
Total	-	-	Lifetime	69,575	5100

Good match between ADHIS & MISTRO herd & cow production statistics

Comparison of model with DFMP

Parameter	Actual	Modelled	Error (%)
Milk production (kg milk solids)	171,149	171,786	-0.37%
Milk income (\$)	1,182,643	1,186,861	-0.36%
Livestock income (\$)	74,705	75,797	-1.46%
Other income (\$)	41,690	41,690	0.00%
Total income (\$)	1,299,037	1,304,348	-0.41%
Herd & shed costs (\$)	87,100	86,197	1.04%
Feed costs (\$)	513,448	519,369	-1.15%
Total costs (\$)	600,548	605,566	-0.84%
Gross margin (\$)	698,489	698,782	-0.04%

The cow-age model accurately estimates performance

Cow age – income and costs

Age	Feed costs (\$)	Herd costs (\$)	Total costs (\$)	Milk income (\$)	Livestock income (\$)	Total income (\$)	Gross margin (profit; \$)	Cum. profit (\$)	NPV future profit (\$)
1	100	300	400	-	-	-	-400	-400	6,108
2	123	368	490	-	42	44	-446	-846	6,860
3	1,278	192	1,470	2,943	175	3,137	1,667	821	5,535
4	1,131	155	1,286	2,606	128	2,745	1,459	2,280	4,353
5	1,063	133	1,196	2,448	121	2,581	1,385	3,666	3,186
6	931	108	1,039	2,145	100	2,257	1,218	4,883	2,127
7	738	85	823	1,699	95	1,808	985	5,869	1,248
8	456	57	513	1,051	65	1,126	613	6,481	698
9	297	37	334	683	49	741	407	6,888	326
10	145	20	165	335	27	366	201	7,089	141
11	76	10	86	175	16	193	107	7,197	41
12	28	4	32	64	9	75	43	7,239	-
Total	6,365	1,469	7,834	14,148	827	15,073	7,239	-	-

Loss of a 5-year-old means a loss of \$3,186 in profit

Clinical case losses

- Each clinical cow has current lactation losses of at least \$217 and future (lost) lactation losses of \$3,186
- Total losses per clinical case = \$3,403

Annual incidence	Avg. no clinicals	Total annual loss	Loss per milking cow	Cost to buy replacements (\$1,500 ea)
1.8%	4.7	\$15,994	\$61.46	\$7,000+
2.6%	6.8	\$23,140	\$88.32	\$10,000+

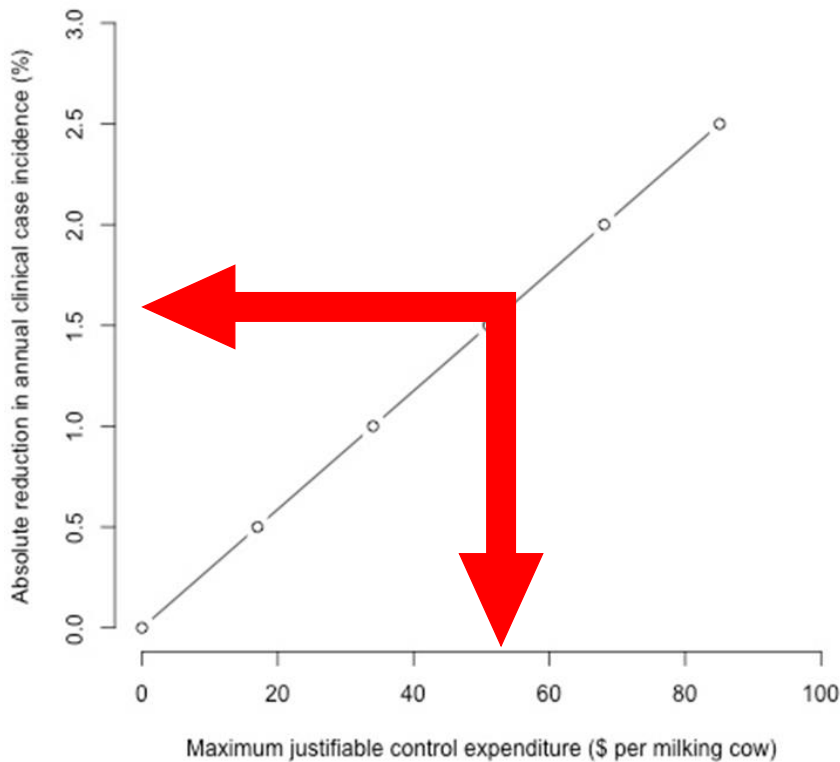
- Alternatively, buy pregnant cows to replace lost clinicals
 - Often variable supply, price, quality, disease status...

Herd-level losses

	BJD clinical prevalence					
Herd size	0.50%	1.00%	1.50%	2.00%	2.50%	3.00%
200	\$3,403	\$6,806	\$10,208	\$13,611	\$17,014	\$20,417
300	\$5,104	\$10,208	\$15,313	\$20,417	\$25,521	\$30,625
400	\$6,806	\$13,611	\$20,417	\$27,223	\$34,028	\$40,834
500	\$8,507	\$17,014	\$25,521	\$34,028	\$42,535	\$51,042
600	\$10,208	\$20,417	\$30,625	\$40,834	\$51,042	\$61,251
700	\$11,910	\$23,820	\$35,730	\$47,640	\$59,549	\$71,459
800	\$13,611	\$27,223	\$40,834	\$54,445	\$68,057	\$81,668
900	\$15,313	\$30,625	\$45,938	\$61,251	\$76,564	\$91,876
1000	\$17,014	\$34,028	\$51,042	\$68,057	\$85,071	\$102,085
Average annual cost (\$/cow/yr)	\$17.01	\$34.03	\$51.04	\$68.06	\$85.07	\$102.08

These are minimum estimates of lost annual profit due to BJD

Justifiable expenditure on control



- Cost versus effectiveness has to be considered
- Need to practically eliminate clinical cases
 - For most farms this would be an absolute reduction of \sim 1.5% per annum
- Can spend up to \$50 per cow per year

Dairy conclusions

- BJD losses in commercial dairy herds are between \$15,000 – \$23,000 for an average sized herd (262 cows)
- Losses are related to clinical cases
- The clinical case rate can take 20 years until it peaks in newly infected herds (or in herds leaving control programs)
- Losses justify control spends of up to \$50 cow/year...
- ...**but** the control has to effectively eliminate clinical disease

Beef



Beef data

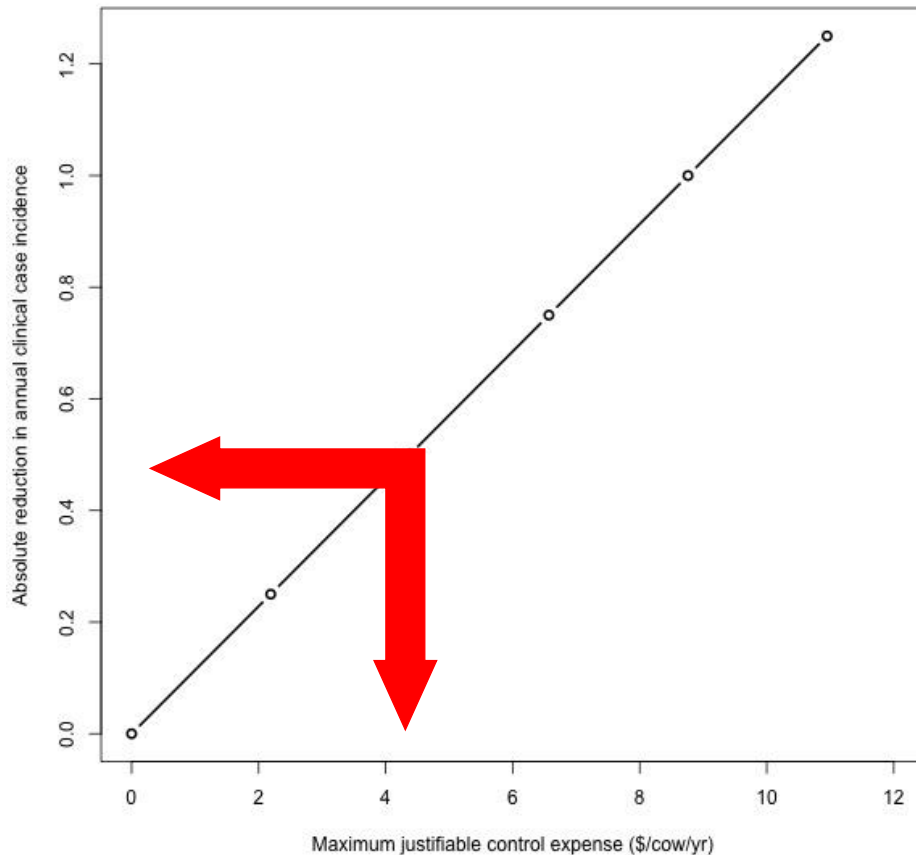
- Webb Ware et al 10-year NPV projection of 200-cow infected beef herd
- \$87,664 increased loss between herd with 'baseline' infected (<1% clinicals) and herd with 5% annual cow mortality and no impact on sale prices
- This estimates the NPV at \$876 per clinical case

Herd-level losses

	BJD clinical prevalence					
<u>Herd size</u>	<u>0.25%</u>	<u>0.50%</u>	<u>0.75%</u>	<u>1.00%</u>	<u>1.50%</u>	<u>2.00%</u>
200	438	876	1,314	1,752	2,628	3,504
300	657	1,314	1,971	2,628	3,942	5,256
400	876	1,752	2,628	3,504	5,256	7,008
500	1,095	2,190	3,285	4,380	6,570	8,760
600	1,314	2,628	3,942	5,256	7,884	10,512
700	1,533	3,066	4,599	6,132	9,198	12,264
800	1,752	3,504	5,256	7,008	10,512	14,016
900	1,971	3,942	5,913	7,884	11,826	15,768
1000	2,190	4,380	6,570	8,760	13,140	17,520
Average annual cost (\$/cow/yr)	2.19	4.38	6.57	8.76	13.14	17.52

Again, these are non-regulatory estimates of lost annual profit due to BJD

Justifiable expenditure on control



Cost versus effectiveness has to be considered

Need to practically eliminate clinical cases

- For most farms this would be an absolute reduction of $\sim 0.5-1.0\%$ per annum

Can spend **up to** \$8 per cow per year (1.0%)

- <\$4 per cow for most (<0.5%)

Beef conclusions

- Non-regulatory BJD losses in commercial beef herds are small. Most infected herds would lose < \$1,000 per year
- Maximum prevalence of BJD in beef herds is unknown – but likely to be lower than for dairy herds.
- Losses can only justify control spends of a maximum of \$8/cow/year ... and only in herds with 1%+ clinicals
- Again control has to effectively eliminate clinical disease
- Gaps in knowledge – steady-state prevalence? Effectiveness of various controls?

Overall conclusions

- Moderate losses in commercial dairy herds
- Minor losses in commercial beef herds
- Non-regulatory losses occur due to loss of clinical cases
- Expenditure on controls should focus on eliminating clinical cases
- Maximum justifiable expenditure on control is different between beef (<\$8/cow/yr) and dairy (<\$50/cow/yr)

Non-regulatory economic impacts of bovine Johne's disease in endemically infected Australian dairy herds

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Abstract

Objective: To determine the non-regulatory economic impact of bovine Johne's disease (BJD) infection in Victorian dairy herds that do not sell stud animals.

Design: Benefit-cost analysis of an average Victorian dairy herd decomposed into age cohorts applying current industry age structures, production and financial performances.

Results: Loss of a typical five-year-old cow due to clinical BJD is associated with the loss of future profit of \$3,186 being the current value of future income less future costs. Losses due to subclinical disease of \$217 in the year of culling was estimated resulting in a total loss of profit of \$3,403 for a prematurely culled five-year-old dairy cow due to clinical Johne's disease. No losses in infected cows in the year before culling are assumed. The average clinical incidence for infected dairy herds before entry into the Victorian Bovine Johne's test-and-control (TCP) program was 1.8% and the average Victorian dairy herd milked 262 cows in 2013/14 indicating that annual losses of 4.7 clinical cases typically occur. This is associated with a reduction in profit of \$16,000 per annum (\$61.25 per milking cow per year). Modelling suggests that uncontrolled BJD would stabilise at a prevalence resulting in clinical losses of up to 2.6% per annum. This is the loss of 6.8 clinical cases each year from the average herd resulting in an annualised loss of \$23,180 (\$88.49 per milking cow per year).

Conclusion Endemic BJD results in moderate losses in typical infected dairy herds. Effective control – as measured by the almost total eradication of clinical cases – supports expenditure of up to \$50.00 per cow per year.

Introduction

An economic analysis of impact of Bovine Johne's disease (BJD) in beef cattle herds in Australia was reported in 2012¹. No economic analysis of the cost of disease in endemically infected dairy herds has been reported in the past twenty years. This information is an important consideration for farmers in deciding the best way to manage BJD in their dairy herd.

Bovine Johne's disease (BJD) in Australia is almost always due to infection with the cattle-adapted strain of *M. paratuberculosis* subsp. *avium* (MAP)². Approximately 1,150 cattle herds are classified as infected with BJD in Australia³. However there is a large number of dairy herds of suspect or unknown disease status and the actual prevalence of infected dairy herds may exceed 50% in the more intensive southern regions⁴. Infection occurs rarely in beef herds with disease being most prevalent in dairy herds. The highest herd prevalence is in the major dairying states of Victoria and Tasmania but BJD is also common in the dairy herds of New South Wales and South Australia. Infection occurs rarely or is absent elsewhere³. A recent trace forward of purchases from a bison-strain infected Queensland beef stud has identified a number of infected or suspect beef herds throughout the northern Australian beef industry where property disease eradication plans are currently being implemented.

Johne's disease is a complex disease to manage as spread can occur by faecal-oral, milk and in-utero routes^{5,6}. Disease has a generally long incubation period and the organism can survive for extended periods in the environment⁷. Diagnostic tests are of a low sensitivity at most stages of the disease and within-herd prevalence is generally low⁶. Practically, this means that herd managers do not often know precisely how or when infection entered a herd, or the key transmission events that occurred or continue to operate. Testing all animals and culling reactors can reduce the number of clinical cases (generally older animals) but is unlikely to identify many of the latently-infected and subclinically-infected animals. These may continue to contaminate the herd environment through infectious faeces, or transmit the disease vertically to their offspring. Vaccines offer incomplete immunity and cannot be administered to newborn calves and therefore may not eliminate disease from affected herds.

The National BJD Strategic Plan 2012-20 was implemented to assist the beef and dairy industries reduce the spread and impact of BJD in Australia³. The plan is underpinned by the National Johne's Disease Control Program, the overarching agreement between governments and industries for the management of Johne's disease in susceptible species in Australia. The goals of the plan are to: minimise the contamination of farms and farm products; protect non-infected herds while minimising disruption to trade; and help reduce the social, economic and trade impact of BJD at herd, regional and national levels.

Animal Health Australia (AHA) manages this plan on behalf of the Australian livestock industries, government and the veterinary profession, and the respective states and territories administer and tailor delivery for their dairy and beef sectors. The uneven distribution of the disease across the nation and between the beef and dairy sectors has resulted in adoption of a zoning approach. The complexity of a combined zone-, sector- and state-based BJD control program has imposed significant and varying compliance restrictions and costs onto cattle producers, such that the impact of program regulations and the costs of compliance dominate producer thinking and attitudes towards BJD.

Bovine Johne's disease produces a direct economic impact on an infected herd that can be estimated in isolation from the impacts of regulatory programs. Infection can remain subclinical for the productive life of many animals although a proportion of infected animals will go on to develop clinical disease before they are removed from a herd for other reasons (all infected animals become clinical if they live long enough). Progression of the disease is associated with declining production, poorer reproduction, increased clinical symptoms, greater mortality and weight loss. A 2009 USA study found that faecal culture positive (FCP) animals that completed a lactation provided 14% lower milk income and were three times more likely to be culled than culture-negative herd mates on completion of the lactation. Culled FCP cows also returned \$441 less than non-FCP herd mates due to differences in carcass condemnation rates, bodyweights and age between the two groups⁸. Other studies have found an association between BJD and the average live weight of cull cows and also the cow mortality rate. A 10% increase in the proportion of cows testing positive to a BJD blood test was associated with a 33.4 kg reduction in the mean weight of cull animals. Herds with one or more positive BJD blood tests from a random sample of cows had 3.0% higher cow mortality than herds in which all tested cows from a random sample returned a negative test result⁹.

Direct losses arising from reduced milk income or cull values do not fully capture the total losses arising from disease. The future profit from an animal that is prematurely lost from a herd should also be considered. Premature culling changes the current and expected future income and expenditure streams. Lost future milk income may be partially offset by an earlier (but reduced) cull income combined with savings from future health and feed costs. Many dairy farms do not carry surplus replacements such that the premature loss of a middle-aged cow from the herd as a result of culling due to BJD will result in the net loss of future profit in the years following her removal. If she is replaced – often by the retention of an older cow for longer – losses equate to the difference between the future profit of the culled animal and the actual profit from the less effective replacement.

Purchase of replacement animals has an inherent risk of disease introduction and many farmers opt not to buy in cattle. The expected lifetime profit of an animal can be estimated from the age-specific annual survival rates, the predicted age-specific milk production and income, and the final cull value of the animal less the age-specific rearing, health and feed costs. An estimate of the non-regulatory economic impact of BJD in an infected dairy herd can assist farmers and their advisers to identify suitable long-term management approaches for BJD that remains relevant if and as BJD policy and regulations change and especially if total deregulation of BJD management should occur.

In 1994 the (then) Victorian Department of Agriculture estimated the economic impact of BJD at farm level for infected Victorian dairy and beef farms using a whole-farm computer model¹⁰. The model simulated the herd structure of dairy and beef herds in Victoria and a partial-budget economic model was run across a 15-year horizon to allow the effects of changes to herd size and structure arising from premature loss of animals and reduced production to be accrued. Commercial losses due to BJD were assumed to arise from early removal of clinical animals and any production losses in subclinical animals prior to becoming clinical and being removed. A fixed ratio between subclinical and clinical animals was applied with the subclinical period set to last for two years with 6% and 17% reduced milk production for the years immediately preceding clinical disease. Latently-infected animals were assumed to experience no loss. Importantly, regulatory-based losses such as those arising from livestock movement restrictions were included. The model estimated the enterprise losses arising from a single clinical case of BJD to be \$1,803 for an average Victorian dairy herd in 1994¹⁰. A 2012 economic analysis of the financial effects of BJD in beef cattle herds in Australia found that control of BJD was not cost-effective for most infected herds¹. Annual mortality rate had to exceed 1.0% per annum and a 10% discount on price received for cattle sales was necessary to justify a destocking-based eradication program.

The current study applies a similar methodology to the 1994 Victorian Department of Agriculture study, but excludes regulatory impacts and applies current herd and cow production, survival and price data to estimate the long-term cost of BJD for a typical Victorian dairy herd infected with BJD in 2014. The majority of detected infected beef herds between 1991 and 2006 were found to have had only 1 clinical case¹¹.

Materials and Methods

The net present value (NPV) of foregone future income and costs for cows prematurely lost from an infected herd as a result of infection with BJD was calculated by determining the income and cost streams of age cohorts within a typical Victorian dairy herd.

The income and cost streams were derived from the physical and financial performance figures for an average Victorian dairy farm in the 2013/14 financial year obtained from the Dairy Farm Monitor Project (DFMP)¹². This project collates standardised physical and financial data of 75 Victorian dairy farms from across Victoria each year to allow long-term farm performance benchmarking and monitoring. Individual cow age-cohort production and composition figures were obtained from the Australian Dairy Herd Improvement Scheme¹³. Cow age cohort lactation survival probabilities were obtained by querying the HiCo herd recording database (MISTRO™). Cow age-cohort survival probabilities were calculated for farms located in the Macalister Irrigation District of Gippsland, Victoria. The average rate of clinical BJD cases per year in the milking herd and the average age of removal of clinical cases from infected herds were obtained from analysis of the Victorian BJD test-and-control program (TCP)¹⁴. An stochastic individual-cow computer simulation model of BJD within a Victorian dairy herd was used to predict the long-term and steady-state prevalence of infection and clinical case rate in uncontrolled herds¹⁵.

A Microsoft Excel™¹⁶ spreadsheet was constructed to calculate herd age-cohort annual production, survival, income, costs and average profit. Herd-level and age-cohort level physical and financial data were validated against published industry averages. The NPV of future income and costs streams were calculated for each age cohort. This represents the discounted loss of future profit arising from premature loss of an animal of that age. The expected number and age of premature losses due to clinical BJD was used to estimate the total foregone future income from a typical Victorian dairy herd.

A cost-benefit analysis was undertaken to determine the disease loss-expenditure frontier. This is the intersection of the control expenditures and reduction in losses due to disease reduction (zero net return)¹⁷. Quantifying the disease loss-expenditure will assist farmers and advisers with BJD control decisions.

Results

Collated physical, financial and survival averages for the average Victorian dairy herd are presented in Table 1. A total of 574 herd-recording Macalister Irrigation District dairy farms provided data for the calculation of age cohort survival probabilities. Annual rearing costs for replacement calves and yearlings of \$400 and \$500, respectively, were used. A bull calf was valued at \$35 at one week of age, a heifer calf at \$500 and a cull cow at \$400 with 75% of removed adult animals being sold for meat. A 5.0% annual discount rate was used to adjust future income and costs in calculating the NPV of future production.

The age-cohort survival and production estimates for a typical Victorian dairy herd, produced by the model, are presented in Table 2. The predicted average cow production from age-cohort survival and production was 6,970 litres and 510 kg of milk solids. This is a very close fit to the average cow production from the DFMP (512 kg milk solids)¹² and also to the average production of herd recorded cows in 2013/14 (6,881 litres and 501 kg milk solids)¹³. The estimated age-specific income, cost profit and NPV of future profit is presented in Table 3. Age-specific survival, production, income and costs were extrapolated to predict the herd performance of a 335-cow dairy herd in Victoria, as this was the average herd size of the 75 Victorian dairy farms participating in the DFMP. The actual and age-cohort predicted herd production, income and costs and the level of agreement between actual and age-cohort predicted parameters for a 335-cow Victorian dairy herd are presented in Table 4. All individual predicted parameter estimates were within 1.5% of actual values and the overall gross margin estimation error was less than 0.1%.

Analysis of the Victorian TCP data indicated that the average incidence of clinical cases on infected farms in the year immediately preceding entry into the TCP was approximately 1.8%¹⁴. The incidence of clinical cases was increasing in these herds in each year before enrolment in the program. This suggested that, if disease was left unmanaged, the incidence of clinical disease may go on to exceed 2.0% per annum. The BJD sub-model of the computer simulation model (whose herd reproductive and survival sub-model was validated against recent industry reproductive performance data¹⁸) was validated by comparing ELISA test reactor rate and clinical case rates and average ages to the Victorian TCP data. This model was then used to estimate the long-term prevalence of disease and incidence of clinical cases in an uncontrolled herd¹⁵. The model predicted a long-term prevalence of infection of 8.8% and clinical incidence of 2.6%. The average age of a clinical case at removal was 5.9 years in TCP herds. The model predicted an average age between five and six years of age for clinical disease breakdown. Both the TCP analysis and the simulation model indicate that the typical clinical BJD cow is culled in her fifth year and before the start of the fourth lactation on average.

The removal of a clinical cow during its fifth year of life (i.e. during its third lactation) results in losses due to early termination of the current lactation, lost cull value and also lost future profit from missed future lactations. The NPV of future income and cost for a culled non-BJD-infected five-year-old cow is \$3,186 (Table 3) and the NPV for a culled clinical BJD five-year-old cow is at least \$3,403 (Table 5). This assumes the clinical case completes the lactation before culling. The additional loss is due to the 14% reduction in milk income and feed costs for the lactation in the year of culling (resulting in a reduction of the current lactation gross margin of \$217).

Estimated herd losses arising from the premature removal of clinical cases for Victorian dairy herds of varying size and BJD clinical disease incidences is presented in Table 5. The average Victorian dairy herd in 2013/14 milked 262 cows¹⁹. An average-sized infected herd with a BJD clinical case rate of 1.8% (the pre-enrolment clinical incidence rate for Victorian TCP herds¹⁴) would experience a reduction in annual gross margin of \$16,048 (\$61.25 per milking cow) compared to a disease-free herd, arising from the loss of 4 to 5 clinical cases each year. If the clinical incidence was 2.6% (equivalent to the long-term clinical incidence in infected herds undertaking no control as predicted by simulation modelling¹⁵) the loss would increase to \$23,180 (\$88.47 per milking cow) per annum arising from the loss of six to seven clinical cases each year. The average farm in the 2013/14 Victorian Dairy farm Monitor Project milked 335 cows and returned a gross margin of \$698,489¹². If this herd was infected with BJD and had a clinical incidence rate of 1.8% then a reduction in gross margin of \$20,519 is expected due to culling an average of six clinical cows each year. This loss would increase to \$29,639 at a clinical incidence rate of 2.6% arising from loss of eight to nine clinical cases per year.

The break-even line for expenditure on control versus reduction in incidence of clinical disease is presented in Figure 1. An absolute reduction in the rate of clinical cases per year of 1.5% would be expected following highly effective BJD control in most infected Victorian dairy herds. This level of reduction would justify expenditure on BJD control of up to \$50 per milking cow per year. Conversely, expenditure of \$50 per cow per year should produce an almost complete cessation of clinical cases for this cost to be justifiable.

Discussion

Bovine Johne's disease is an extremely well-adapted pathogen. Infection does not result in dramatic change to herd composition – not all animals in a herd become infected – and not all infected animals survive long enough within a commercial herd to develop clinical disease. Herd survival (and therefore pathogen survival) is not threatened. Infection of individuals within a herd occurs at an incidence sufficient to sustain the disease, and the level of bacterial production and environmental contamination by shedders is copious. This results in persistence of the organism within the environment and thus the herd. Eradication has proved almost impossible in most parts of Australia. Physical and financial losses due to the presence of BJD for most infected cattle herds are moderate and disease-induced losses alone are unlikely to threaten to the financial viability of most commercial producers. However a tangible loss of profit in the range of \$16,000 to \$23,000 each year arising from the premature removal of clinical cases can be expected for the average infected Victorian dairy herd undertaking no effective control of BJD.

The estimated NPV for an average five-year-old clinical case of \$3,403 closely matches the inflation-adjusted 1994 NPV estimate from a previous study¹⁰. The 1994 study estimated the NPV of a clinical case at \$1,803 which after adjusting for inflation equates to \$3,307 in 2014¹⁵. The 1994 study included regulatory impacts whereas these were excluded in the current study. The close fit between age-cohort based income and cost streams with herd-level and cow-level physical and financial data observed in the current study suggests that the 1994 study underestimated the total losses due to BJD.

The total cost of BJD to herds is greater than the estimates from this study because of the significant regulation of disease and the financial impacts of the regulations. However, there are many Victorian dairy farms of unknown or suspect BJD status and these herds are not impacted significantly by current regulations. For these farmers the cost-benefit and effectiveness of control are major considerations in decision making about the control of BJD within their herd. Control of BJD in these herds is warranted if the incidence of clinical disease can be effectively eliminated (i.e. at least an absolute reduction in losses of 1.5%) and the cost of this effective control is less than \$50.00 per milking cow per year.

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Table 1:
Industry-sourced physical,
financial and survival
parameter averages for a
Victorian dairy herd in
2013/14

Source	Level	Parameter	Value
DFMP	Farm	Cows (milking)	335
		Milk production (kg solids)	171,786
		Milk income (\$)	1,186,861
		Livestock income (\$)	75,797
		Other income (\$)	41,690
		Feed costs (\$)	519,369
		Herd & dairy costs (\$)	86,197
	Cow	Milk production (kg solids)	513
		Milk income (\$)	3,543
		Livestock income (\$)	226
		Other income (\$)	124
		Feed costs (\$)	1,550
		Herd & dairy costs (\$)	257
	Production	Milk price (\$/kg milk solids)	6.91
		Feed costs (\$/kg milk solids)	3.02
ADHIS	Age cohort	Milk production (l)	Relative productivity (%)
	2YO	6,067	100
	3YO	6,720	111

4+YO	7,135	118
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	<i>Milk composition</i>	<i>Percentage</i>
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All ages	Fat (%)	4.00
	Protein (%)	3.33
	Solids (%)	7.33

	<i>Conditional survival</i>	<i>Age cohort</i>
--	-----------------------------	-------------------

<i>MISTRO</i>	<i>Age cohort</i>	<i>probability</i>	<i>(% of milking herd)</i>
	2YO	0.805	23.9
	3YO	0.861	19.2
	4YO	0.809	16.6
	5YO	0.792	13.4
	6YO	0.670	10.6
	7YO	0.650	7.1
	8YO	0.535	4.6
	9YO	0.521	2.5
	10YO	0.402	1.3
	11YO	0.546	0.5

Table 2:
 Modelled age-cohort
 survival and production for
 cows in an average Victorian
 dairy herd in 2013/14

Age	Cohort		Annual litres	Annual milk solids (kg)
	conditional survival	Cumulative survival		
1	0.980	0.980	-	-
2	0.980	0.960	-	-
3	0.805	0.773	6,050	443
4	0.861	0.666	6,655	488
5	0.809	0.539	7,260	532
6	0.792	0.427	7,865	577
7	0.670	0.286	7,865	577
8	0.650	0.186	7,260	532
9	0.535	0.099	7,260	532
10	0.521	0.052	6,655	488
11	0.402	0.021	6,655	488
12	0.000	0.000	6,050	443
Total	-	-	69,575	5100

Table 3:
 Modelled age-cohort cost,
 income, profit (gross margin)
 and net present value of
 future profit of a non-BJD-
 infected cow if removed at
 the end of the year in an
 average Victorian dairy herd
 in 2013/14

Age	Feed costs (\$)	Herd costs (\$)	Total			Gross		Cumulative profit (\$)	NPV future profit (\$)
			variable costs (\$)	Milk income (\$)	Livestock income (\$)	Total income (\$)	margin (profit; \$)		
1	100	300	400	-	-	-	-400	-400	6,108
2	123	368	490	-	42	44	-446	-846	6,860
3	1,278	192	1,470	2,943	175	3,137	1,667	821	5,535
4	1,131	155	1,286	2,606	128	2,745	1,459	2,280	4,353
5	1,063	133	1,196	2,448	121	2,581	1,385	3,666	3,186
6	931	108	1,039	2,145	100	2,257	1,218	4,883	2,127
7	738	85	823	1,699	95	1,808	985	5,869	1,248
8	456	57	513	1,051	65	1,126	613	6,481	698
9	297	37	334	683	49	741	407	6,888	326
10	145	20	165	335	27	366	201	7,089	141
11	76	10	86	175	16	193	107	7,197	41
12	28	4	32	64	9	75	43	7,239	-
Total	6,365	1,469	7,834	14,148	827	15,073	7,239	-	-

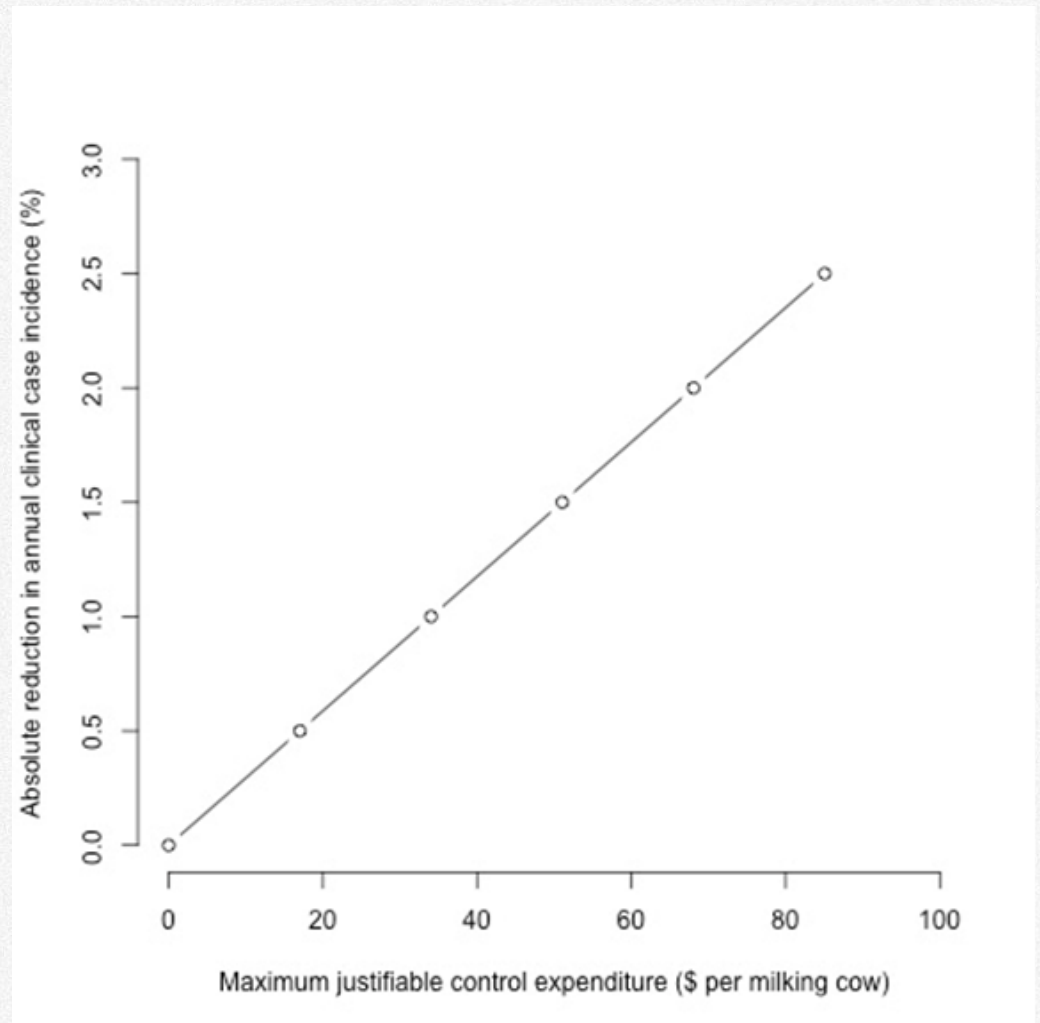
Table 4:
Actual and age-cohort
modelled herd production,
income, cost and profit
estimates for an average
Victorian dairy herd in
2013/14

Parameter	Actual (DFMP)	Modelled	Error (%)
Milk production (kg milk solids)	171,149	171,786	-0.37
Milk income (\$)	1,182,643	1,186,861	-0.36
Livestock income (\$)	74,705	75,797	-1.46
Other income (\$)	41,690	41,690	0.00
Total income (\$)	1,299,037	1,304,348	-0.41
Herd & shed costs (\$)	87,100	86,197	1.04
Feed costs (\$)	513,448	519,369	-1.15
Total costs (\$)	600,548	605,566	-0.84
Gross margin (\$)	698,489	698,782	-0.04

Table 5:
 Net present value (\$) of
 estimated herd losses and
 average loss per milking cow
 due to BJD in Victorian dairy
 herds of various size and
 clinical BJD incidences

Herd size	BJD clinical prevalence				
	0.50%	1.00%	1.50%	2.00%	2.50%
200	3,403	6,806	10,208	13,611	17,014
300	5,104	10,208	15,313	20,417	25,521
400	6,806	13,611	20,417	27,223	34,028
500	8,507	17,014	25,521	34,028	42,535
600	10,208	20,417	30,625	40,834	51,042
700	11,910	23,820	35,730	47,640	59,549
800	13,611	27,223	40,834	54,445	68,057
900	15,313	30,625	45,938	61,251	76,564
1000	17,014	34,028	51,042	68,057	85,071
Avg. cost per milking cow	17.01	34.03	51.04	68.06	85.07

Figure 1:
Maximum justifiable control
expenditure (\$/milking
cow/year) by absolute
reduction in clinical
incidence rate in milking
cows due to controls for
varying levels of reduction





Field Efficacy of Silirum[®] Vaccine in Two Australian Dairy Herds

Peter Little¹, Jack Winterbottom², Mirta Aranda¹, Andrew Hodge¹, Sally Oswin³

1. Veterinary Medicine Research and Development, Zoetis, Parkville, Victoria, Australia

2. Victorian Department of Economic Development, Jobs, Transport and Resources, Maffra, Victoria, Australia

3. Zoetis Australia, Sydney, NSW, Australia

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Maffra Veterinary Centre

- Dr Jakob Malmo

- Dr Gerry Davis

CZ Veterinaria, Spain

Herd Owners and Managers



Where to from here?

Facilitated Discussion: emerging thoughts on beneficial changes, strengths and weaknesses of the existing policy

About the Forum

Facilitated by Mr Benoit Trudeau (Trudeau and Associates), the afternoon session gave participants the opportunity to discuss issues that were foremost in their minds regarding BJD, the classification of the disease, its treatment, the risk-response equation to the disease and the interpretation/application of the rules governing disease management and control.

It is important to acknowledge the participation and positive engagement of those who contributed to a discussion that was not without its sensitivities, some of them associated with harrowing personal experiences.

To those who spoke up in such circumstances, our particular thanks. Otherwise – and while points of view diverged widely at times between contributors – the exchanges were notable for their expression of a shared desire to lay the groundwork for a fresh strategy enriched by experience, fit for contemporary circumstances and reflective of the evolution in both science and management approaches that has occurred in the years since inception.

Nonetheless, readers of this document are asked to respect the spirit in which the discussions took place on the day. Specifically, that the workshop was a private forum, convened for parties with a direct interest in the manner in which BJD has been managed in the past and will be managed in the future; that the deliberations were intentionally structured to create an open, non-partisan and non-judgemental space for the airing of views; and that the exchanges that took place were to be respectful and civil at all times, however strong the opinions or difficult the topics. The outcomes of the discussions are presented below.



TRUDEAU & ASSOCIATES
ADVISERS TO MANAGEMENT

Animal Health Australia

**Review of
the National Bovine Johne's disease ('BJD') Strategy:**

**Record of Proceedings:
Open Workshop of 16 February 2015**

Workshop Participants in confidence

Foreword and Introduction

About this Document: What it is...

1 This document records the substance of the discussions that took place on Monday 16 February 2015 when more than a hundred persons gathered in a workshop environment in Sydney to reflect on the strengths and weaknesses of the present National BJD Management Strategy (the 'strategy') and on the various ways in which it could be improved. It constitutes, in that regard, the record of the proceedings of that workshop.

About this Document: What it is not...

2 This document does not constitute (or purport to represent) a draft of a revised BJD management strategy: that task belongs to another document that will move through a series of iterative steps towards its final form, as part of a process described at the workshop and reflected in the agreement entered into by Trudeau & Associates with Animal Health Australia, the latter as the secretariat function of the review task.

3 As stated at Item 1, the pages that follow record the substance of the views and comments aired in the course of workshop deliberations for consideration during the strategy review process.

About the Workshop

4 The agenda of the workshop appears at Appendix A as a matter of record and reference.

5 It is important to acknowledge the participation and positive engagement of those who contributed to a discussion that was not without its sensitivities, some of them associated with harrowing personal experiences. To those who spoke up in such circumstances, our particular thanks. Otherwise – and while points of view diverged widely at times between contributors – the exchanges were notable for their expression of a shared desire to lay the groundwork for a fresh strategy enriched by experience, fit for contemporary circumstances and reflective of the evolution in both science and management approaches that has occurred in the years since inception.

About Confidentiality and the Spirit of the Workshop

6 A gathering of more than one hundred persons, two of whom were accredited media representatives, can hardly claim to place its deliberations under the seal of confidentiality.

7 Nonetheless, readers of this document are asked to respect the spirit in which the discussions took place on the day. Specifically, that the workshop was a private forum, convened for parties with a direct interest in the manner in which BJD has been managed in the past and will be managed in the future; that the deliberations were intentionally structured to create an open, non-partisan and non-judgemental space for the airing of views; and that the exchanges that took place were to be respectful and civil at all times, however strong the opinions or difficult the topics.

8 That same spirit should continue to prevail throughout the strategy review and development process. The views expressed herein should therefore be treated, I suggest, in accordance with it.

About Workshop Presentations

9 Five presentations opened the workshop and preceded the facilitated discussion. The subject of the presentations and the names of the presenters are recorded in the Agenda (Appendix A). Copies of four of the five presentations have been made available through Animal Health Australia. One of the presentations (on advances in vaccines) was withheld from distribution as the material it contains is deemed proprietary and commercially sensitive.

BENOIT TRUDEAU
Managing Director,
Trudeau & Associates

A Strategy in need of Repair: Noted Inconsistencies in present BJD Management Arrangements and some of their Consequences

A Strategy in need of Significant Repair

9 The title of the section is chosen advisedly: in its present form, the current national BJD strategy is ailing. It is in need of repair: the comments of attendees at the 16 February workshop made that abundantly clear. That there should be an agreed and concerted approach to the management of BJD is not in question. The rationale that underpins that approach, however, along with the spirit that animates it as well as the mechanisms and measures that enable it, are in need of review and recasting.

Four Key Inconsistencies

10 Concerns surrounding consistency were a recurrent theme of the 16 February discussions, with charges of its opposite (i.e. inconsistency) frequently levelled at the strategy in its present form. The notes below reflect the more significant of the charges under four type headings:

- Classification of the disease
- Treatment of the disease
- The risk-response equation to the disease
- Interpretation/application of the rules governing disease management and control.

11 **Classification** – Bovine Johne’s Disease is a listed, notifiable disease under OIE¹ protocols². The chief argument here is that the classification of BJD as a listed, notifiable disease is only partly consistent with the methodology used in determining whether or not a disease should be put on the list. Critics point to the disease failing a number of criteria that govern placement on the list (e.g. proven cause, non-ubiquitousness, significance of impact, reliable testing – among others).

12 **Treatment relative to other notifiable diseases** – While there are many notifiable diseases, BJD attracts markedly more attention than is afforded other diseases that fall under the notification requirement. Worryingly for many, the ‘elevated status’ of BJD in some jurisdictions – a situation that has prevailed for some years, lacks a compelling justification³.

13 **Management of the risk-response equation** – Certain provisions of the BJD management strategy, as interpreted and applied in certain jurisdictions, can have draconian consequences for those whom it catches in its net. Often with roots in perceptions of perceived far-reaching risks to trade (this being the most often-cited concern), the ‘firepower’ the strategy unleashes on those occasions where it is activated has a long-lasting and profoundly consequential effect on affected parties. More generally, the approach to the management of BJD seems ‘overweight’ when considered against the low-level production losses that the disease can cause – losses that are typically well within normal herd management parameters.

14 **Interpretation and application of the rules governing disease management and control** – As the agreed national reference for the disease control programs, the SDR&Gs (‘Standard Definitions, Rules and Guidelines’⁴) are the touchstone of the BJD management strategy. While they have that overarching role, the SDR&Gs are interpreted by jurisdictions and applied with varying levels of stringency from State to State, owing to a range of factors.

1 - Organisation internationale des épizooties (‘OIE’), being the intergovernmental organisation responsible for improving animal health worldwide

2 - While there is a suggested need for the OIE information on BJD to be brought up-to-date, the task is readily recognised as a difficult, complex and long-term undertaking.

3 - In the eyes of some, the discrepancy in treatment amounted to an ‘unhealthy fixation’.

4 - Originally drafted in 1997 and now in their eighth edition

15 Some jurisdictions appear more focused on the spirit of the SDR&Gs (with a consequent measure of leeway in the degree of the severity of the response applied to controlling/managing BJD), while others will tend to a stricter, 'black letter' interpretation of the same rules. Whatever the reasons behind the differences in interpretation, it is clear that the variations in interpretation have a material effect on the measures used to control and manage the disease where it is found to exist, and thus on the livelihood of producers⁵. Put succinctly, the same set of 'rules' can translate to significantly different practices between jurisdictions, to the evident and firmly-voiced frustration of the affected parties.

Some Important Consequences

16 Many of those attending the workshop acknowledged that the present strategy, as it is interpreted and applied, requires urgent review. When aspects of the national BJD strategy found support during workshop discussions, they tended to do so in respect of the intent of the measures rather than for the manner of their application, which too often came in for heavy criticism as ill-considered, ineffectual and counter-productive⁶.

17 In the light of the comments made, it is fair to affirm the following:

- It is recognised that the National BJD Management Strategy, as it is applied, is fostering behaviours contrary to the interests of participants in the production chain by driving the disease (and information about it) underground⁷. The consequences of the phenomenon are significant: obfuscation, dissimulation and perversion of the system; compromised disease surveillance programs; corruption of the integrity of information and knowledge about the disease; compromise of the quality assurance system; discouragement of participation in surveillance and disease monitoring and management programs; and a general increase in disease-related risks⁸.

5 - Use of the term 'livelihood' understates the long-lasting and profound financial, social and personal consequences a quarantine order will have on those whose properties are so treated – effects compounded further by trace-back and trace-forward provisions.

6 - In this last respect, the stigmatising and effectively punitive consequences of quarantining measures were the object of much concern and hardly-concealed frustration.

-
- There is strong support for a thorough review and recasting of the present strategy in favour of a better-considered, better-framed, better-targeted, simpler and more consistent BJD management regime than the present one – one based less on regulatory intervention than it would be on producer-driven management of BJD situations, within a wider, biosecurity-inspired and trade-reconciled perspective.

7 - Often referred to nowadays as the Streisand Effect but first coined in the late XVIIIth century, whereby a set of measures may ‘...encourage the ideas it opposes through the very violence of its prohibitions’.

8 - In short, a well-intentioned policy can, through the manner of its application, bring into play the law of unintended consequences whereby ‘...an intervention in a complex system tends to create unanticipated and often undesirable outcomes [as a reflection] of the hubristic belief that humans can fully control the world around them’.

Managing BJD in a Multi-Variable, Multi-Dimensional Model: Key Considerations

Differing Commercial Interests and Drivers

18 Any discussion of BJD management fundamentals must recognise different types of producer interests: for example, those whose production is destined, in the main, for overseas markets, those whose production targets the local market and those who trade in both; there are also those who trade in younger animals against those whose business is concerned with older ones. The issue of BJD management and control will vary significantly in importance between these producer and interest categories. Yet the application of the current national BJD strategy does not recognise these material differences. It is universal in scope.

International Trade Requirements and their Influence on the BJD Strategy

19 While specific requirements may vary from country to country when it comes to beef (i.e. meat, offal or by-products, as well as dairy and live animal imports), Australia's trading partners seek assurances from the Australian government concerning the health of its exports – specifically, assurances that the exported products originate from herds considered that display no clinical signs of certain diseases, BJD among them as a notifiable disease⁹. The ability to provide the necessary assurances, it is argued, opens the door to trade, while the inability to do so may preclude it¹⁰.

9 - There has been concern surrounding a possible tie between BJD in cattle and Crohn's disease in humans for many years. However, none of the many scientific papers published on the subject have conclusively demonstrated a connection between the two. Yet the concern continues to surface from time to time, perpetuating a climate of uncertainty about an issue that should otherwise have been put to rest some time ago.

Reliance on the States and the Underlying Tie to Economic Considerations

20 In order to provide the required assurances, the Australian Government relies on the States to affirm (or confirm) that the animals or herds involved in export deals have shown no clinical signs of notifiable diseases for the stipulated time period. For those States or Territories with substantial interests in overseas export markets, the perceived necessity to satisfy trade requirements is a material concern. In that perspective, the ability to declare (often large) tracts of land and geographic areas as free from the disease (or 'protected' from it) takes on economic significance. Yet, as stated earlier, for those who have no such interests (or only limited interests in these markets) the affirmation is of less (if any) importance or consequence – as is the matter itself, given the low-level financial impact of clinical cases of the disease on herd economics.

Certification, Testing and Questions of Reliability

21 Where certification is a matter of importance, the ability to certify is a function of testing. What the testing demonstrates (conclusively or otherwise) is itself subject to a number of factors – among them the use of available tests in the recommended manner, the testing methodology applied, the scope and frequency of the testing, the analytical capability available and the rigour of interpretation that is brought to bear on the test results.

22 By virtue of its aetiology, BJD presents particular testing challenges – at least in its subclinical form. Sub-clinical tests are available but they have to be used appropriately to be meaningful. Some, like strain typing, are reliable. Others are less so, with substantial error margins (false positives) possible in a disease that has extended latent periods.

10 - The degree to which an inability to satisfy a trading partner, through certification, that a product comes from a BJD-free zone seems will preclude trade seems to be something of a moot point. Judging by some of the examples adduced in the discussion, an inability to satisfy a BJD-free requirement may not per se prove a 'deal-killer'. Some of Australia's competitors do not meet that requirement, yet their trade appears unaffected: hence the challenge to the 'BJD-free' argument as an essential condition of overseas trade.

23 In such circumstances, determining and affirming that an area or zone is 'free' of the disease becomes problematic (however genuine in intent such an affirmation is). Where BJD is concerned, statements made in the absolute are open to challenge, limited as they must be by matters of testing methodology, herd sizes and the land areas involved¹¹. It is not a matter of semantics to see a difference between an affirmation that an area is 'free' of a disease and one that states that that the testing carried out in a given area has found no evidence of the disease. The first statement is an absolute while the second is a qualified one, the veracity of which is dependent upon the quality and attributes of the testing. One must also bear in mind that Johne's disease presents in a variety of strains – e.g. cattle, sheep, goats and camelids, a factor that increases the risk of potential cross-contamination.

The Critical Role of Research and Development

24 The discussion (and at least one of the four presentations) underscored the critical importance of the scientific capability that underpins efforts to understand and manage diseases like BJD. Research and development activities are essential contributors to such activities. Unfortunately, funding for them is under continuous threat and has already suffered substantial reductions.

25 Furthermore, in an environment in which State-based research and testing laboratories operate independently from each other, the question of result standardisation between jurisdictions adds another complexity to the problem of national data integrity surrounding BJD. In a strained economic environment (and without prejudice to autonomous State capabilities), the establishment of a suitably-staffed and equipped central testing laboratory, capable of producing reconciled and reliable standardised results is highly desirable.

11 - One must also bear in mind that Johne's disease presents in a variety of strains – e.g. cattle, sheep, goats and camelids, a factor that increases the risk of potential cross-contamination

Matters of Philosophy:

Zones, Control vs Management and Related Issues

26 Jurisdictional preoccupations aside, BJD is comparatively widespread in south-eastern Australia. Beyond that, its full absence from other parts of the country is well-nigh impossible to verify in absolute terms. That aside, it is fair to say that the presence of BJD is far from uniform. Mapping of BJD occurrence shows areas of low prevalence and areas of high prevalence. The differences play on the level of attention and importance attached to BJD management (and eventually to the measures used to do so as well as the diligence with which action is taken).

27 The desire to protect low-prevalence zones from becoming high-prevalence ones is understandable. The dilemma faced by those who deal with the disease and its geographic inroads concerns the approach that is best taken to the task of managing (or, for some, 'controlling' the disease): many voices at the workshop challenged vigorously the effectiveness of a State-driven, zone-focused, regulatory approach¹², preferring to it instead a property-focused and producer-managed approach, (within a regulatory envelope that defines the choices open to a producer whose herd may be (or is) BJD-affected). At the heart of the discussion lies an unwelcome reality: a widespread disease like BJD is no respecter of State boundaries and jurisdictions, best human efforts to guard the threshold and bar the door notwithstanding.

Matching the Solution to the Problem

28 The answer to a problem must match the nature of that problem. In the eyes of many however, present BJD management arrangements fail to do that, offering instead a mixed and confusing response that seeks to shoehorn and reconcile political, jurisdictional, economic, trade and commercial considerations into what is, in essence, a science-based, epidemiology-driven solution.

29 Clarity must also be had surrounding the notion of 'control', its ultimate aim and achievability. There is a strong body of opinion that the nature of BJD makes the disease one that is to be managed rather than one to be eradicated. In that perspective, talk of eradication on a broad scale is a fiction and certainly not a concept that should form part of a recast BJD management strategy.

12 - Akin to the 'cordon sanitaire' of old

Towards a Better BJD Strategy: Foundation Notions and Principles

30 Notes in this section describe those attributes workshop participants see as important features of any refreshed or recast BJD management strategy. Each of the attributes is set out individually.

31 It is important to note that the listed attributes, framed as principles, do not represent the sum of the attributes a new BJD management policy should incorporate. In other words, the list reproduced here is not exhaustive; rather, it is indicative of some of the more significant, 'front-of-mind' features the participants identified through the day's discussions. Other principles will no doubt come to the fore as the reflection surrounding the new strategy develops.

32 **The Appropriateness Principle** – The principle of appropriateness warrants that any new policy must be conceived with due regard for the long time-frames associated with the disease and its progression (e.g. a minimum six- to seven-year cycle). It also speaks to the necessity of having an approach to BJD that does not produce human, business, operational and financial consequences that are potentially graver, longer-lasting and more costly than the disease it intends to mitigate.

33 The Comprehensiveness Principle – The comprehensiveness principle requires that the recast BJD strategy take account of the many consequences associated with the imposition of quarantine as a disease containment tool. Specifically, the strategy should demonstrate an appreciation of the different and far-reaching implications of a quarantine order: financial consequences, certainly, but also operational and logistical¹³ ones, as well as potentially destructive social and personal ones. Ignoring the comprehensiveness principle opens the door to the manifestation of unintended consequences.

34 The Assistance Principle – The assistance principle aims to counter the stigmatising and effectively punitive aspects that result from the imposition of a quarantine order under the present strategy (even though that is clearly not the intent of the strategy)¹⁴. As its name suggests, the assistance principle foresees the need for the recast strategy to incorporate a well-resourced 'toolkit'¹⁵ that will assist producers (and effectively 'rewards' them) to actively manage their way out of a challenging situation, with as few ill-effects as possible¹⁶. At the very least, the recast strategy must be one that 'does no material and lasting harm' to those who come under its sway.

35 The Affordability Principle – The affordability principle speaks to the need for any recast strategy to be adequately funded on the basis of a reliable cost-benefit analysis¹⁷. The funding in question takes in notions of financial assistance, compensation (if and when circumstances support such a concept) and, most critically, operational resourcing (for activities such as information and education, surveillance, monitoring, testing, research and development as well as producer support). An unfunded strategy will be still-born; a poorly-funded one will see its effectiveness materially compromised.

13 - Some of the logistical issues referred to include the progressive overcrowding of grazing areas as cattle numbers increase while off-property relocation cannot take place, the consequent animal management issues and increased feed costs that follow, among other matters. The problem posed by the presence of vast arid areas, the little feed available in such areas and the associated need for the cattle to move (or moved) represents is only one of many variations on the same theme.

36 **The Fairness Principle** – The fairness principle is a close relative of the affordability principles. Its focus is compensation. Where compensation is envisaged, the aspiration is that such compensation will be adequate, i.e. that it will reflect the fair value of the losses incurred by the producer as a result of a regulator-imposed order, typically in the name of a higher good (such as the protection of trade for an area or region). As with the affordability principle, determination of the fairness of compensation would rest on a comprehensive cost analysis.

37 **The Consistency Principle** – The consistency principle is straightforward: it desires the introduction of as much uniformity as is humanly possible across jurisdictions. The uniformity here has a number of dimensions: legislative and regulatory certainly (though this will not be without its problems in a federation) but, just as importantly, consistency in the administrative constructs, directions, instruments and measures used in the management and control of BJD, including the interpretation of such constructs, directions, instruments and measures¹⁸.

38 **The Prevention Principle** – While management and control activities will be required of necessity when BJD manifests in a verifiable form, there is a strong view that prevention is a fundamental part of any solution. Broadly speaking, the prevention principle is concerned with the on-going provision of education and information to interested parties, ideally as an integral component of on-farm biosecurity programs.

14 - Note was also taken of the toll that the imposition of a quarantine order and the management of its consequences takes on departmental staff who are called upon to deal directly with the parties involved.

15 - A 'tool-kit' that would include, by way of illustration, vaccination and further testing – among many other instruments

16 - Frequent references were made during workshop conversations to the importance of having a clear, well-articulated array of 'pathways forward', i.e. the positive steps by which an affected producer could make his or her way back to a normal mode of operation as quickly and effectively as possible.

17 - Such an analysis would do well to proceed from the same basis as the comprehensiveness principle enunciated earlier in this section.

39 **The Producer-as-Manager Principle** – The present strategy places the onus and the primary responsibility for the management and ‘control’ of BJD situations largely in the hands of regulatory bodies, with the producer whose property is affected relegated in the main to a reactive role. The future strategy should shift the disease management responsibility (and the associated management choices) to the producer, effectively returning to him or her the ability to consider well-defined (regulation-backed, as appropriate) options¹⁹ (i.e. the ‘ways forward’ referred to earlier) and choose between them, should BJD manifest in the herd.

18 - Consistency in notifiability and in the application of the SDR&Gs were two frequently-referenced aspects of the question

19 - A system driven by producer-led disease management initiative in no way implies the absence of regulation. The significant difference is that of producer choice as to the avenues open to him or her within the applicable and largely trade-directed regulations.

Board 2

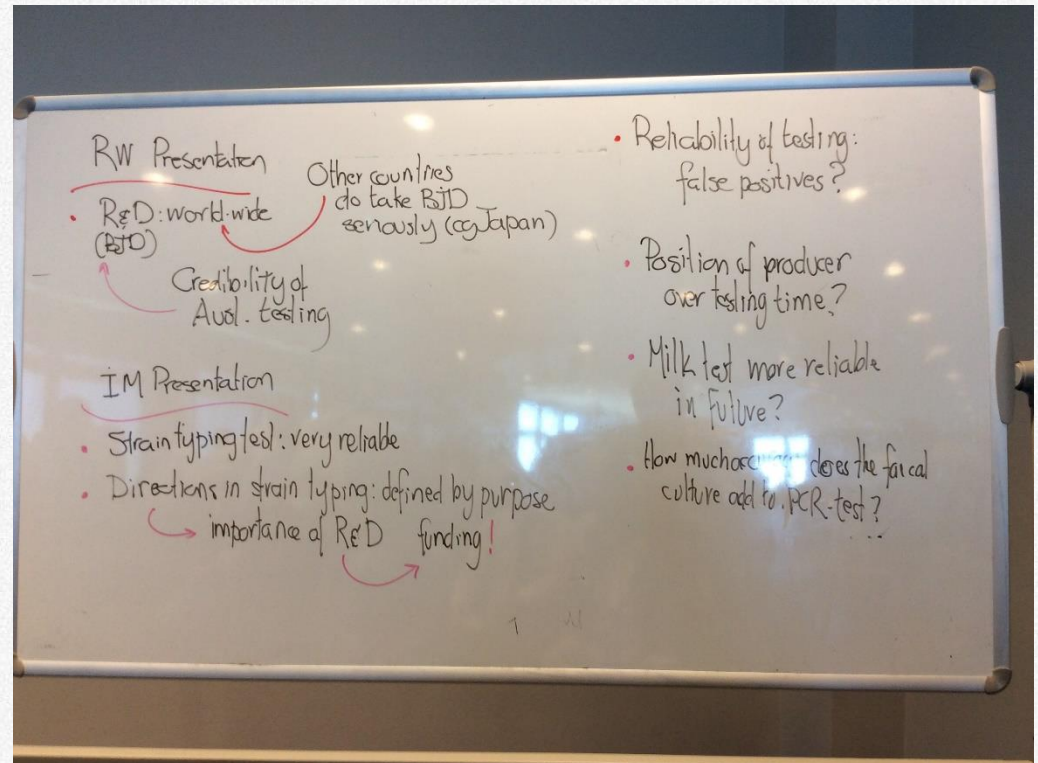
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PASSWORD: Great Event

- Trade restrictions: beef, offal or by-products or live animals
- Commonwealth relies on States to be certified as BJD free
- Surveillance = Market Ass. Programme
- Different interpretations of same rule
- Absence of evidence

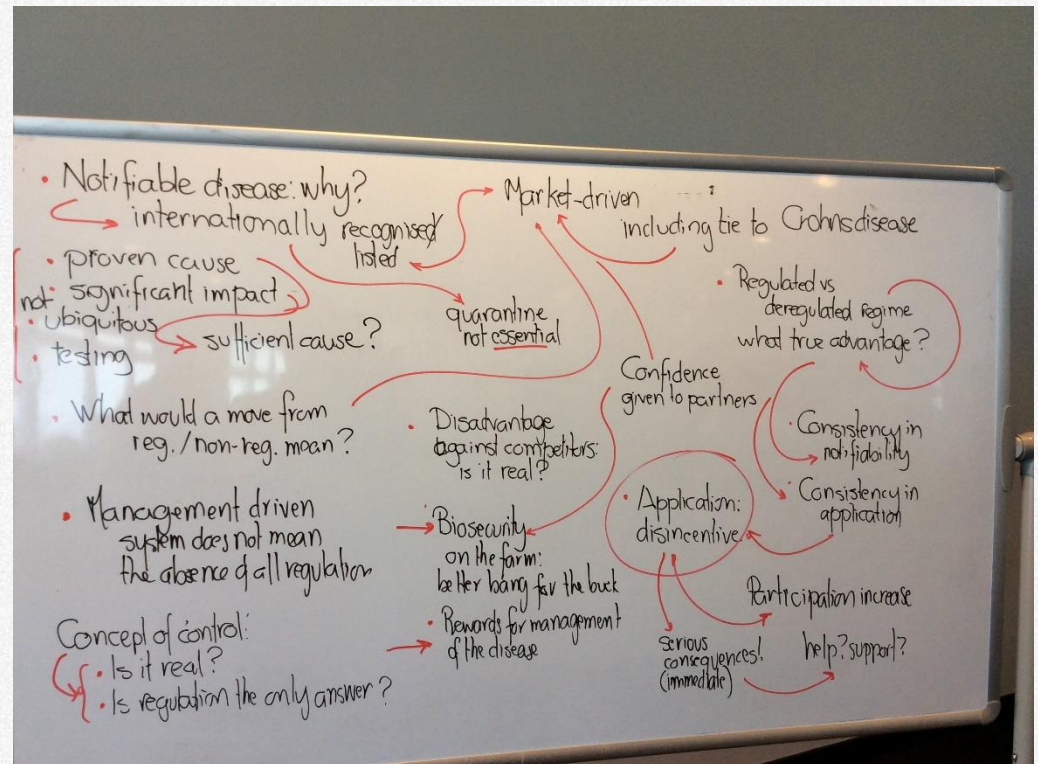
BJD Program necessity?

- national & international markets
- BJD or wider? ← List of other disease
- Credibility of certification ← Increasing inclination to audit world wide
- List of participating countries
- risk level & consequences
- Certification: property freedom alone

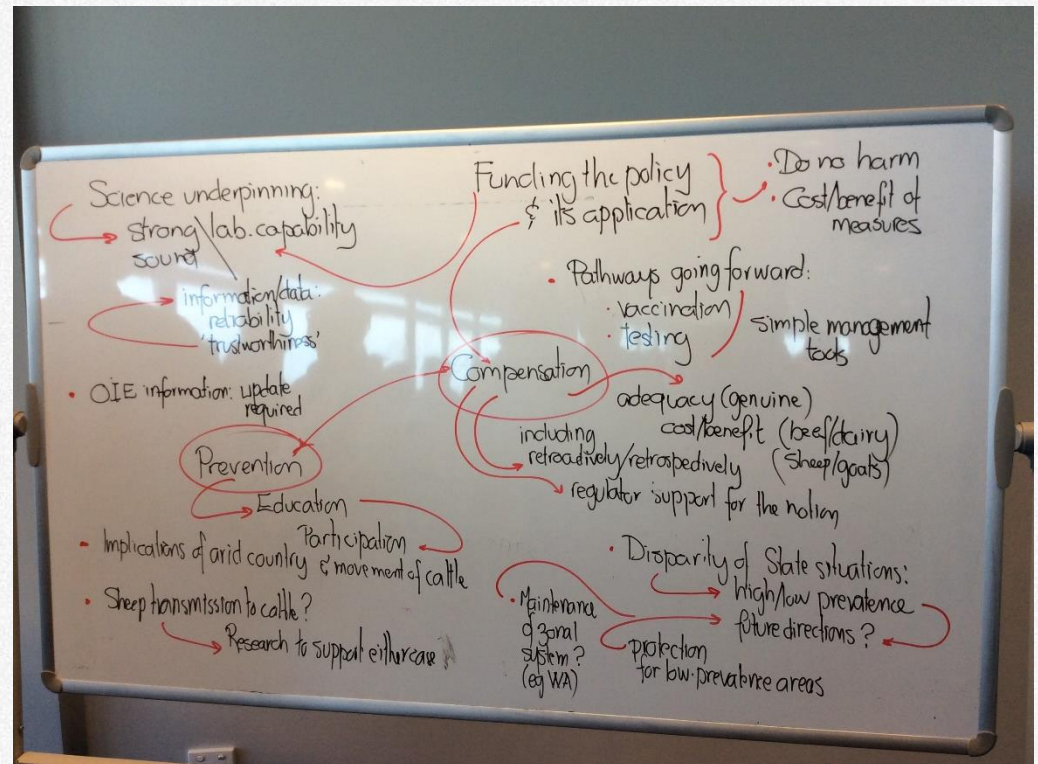
Board 3



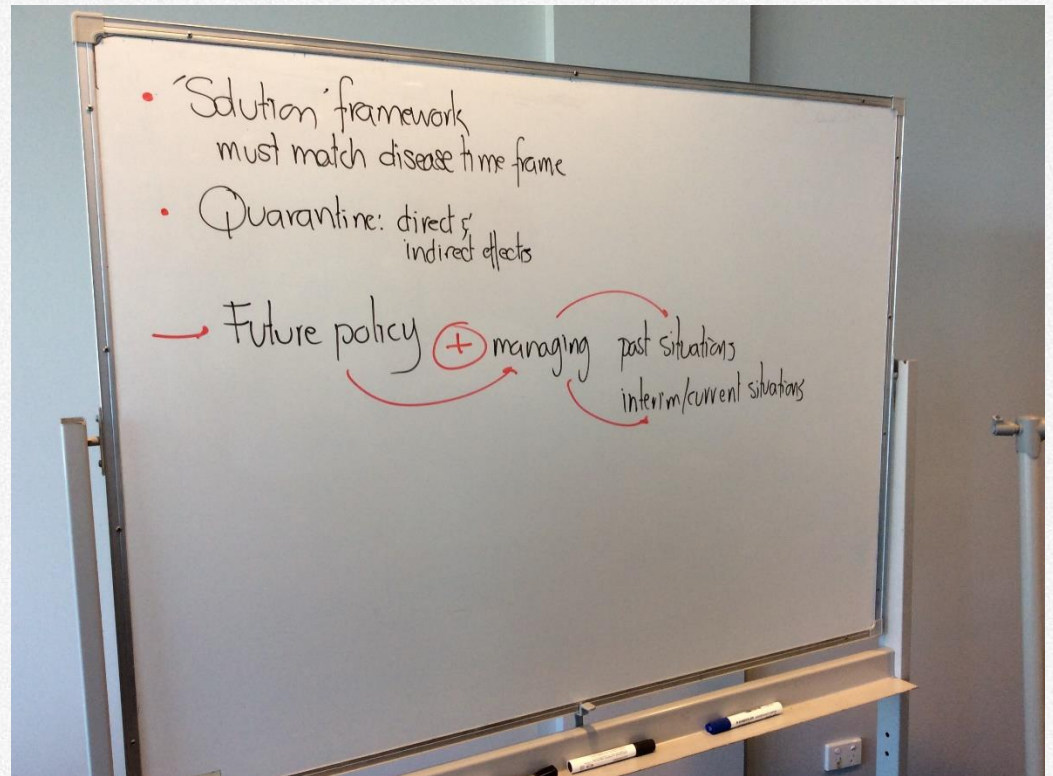
Board 4



Board 5



Board 6



Additional Info

National BJD Strategic Plan 2012-20

<http://www.animalhealthaustralia.com.au/programs/johnes-disease/bjd-home-page/australias-national-bjd-strategic-plan-2012-2020/what-is-the-national-bjd-strategic-plan/>

National BJD Strategic Plan Review

<http://www.animalhealthaustralia.com.au/programs/johnes-disease/bjd-home-page/national-bjd-strategic-plan-review/>

BJD Standard Definitions, Rules and Guidelines

http://www.animalhealthaustralia.com.au/wp-content/uploads/2012/06/BJD_SDRGs_8thED_May2012.pdf

Contact information

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