

Review of TB testing procedures:

Report for Defra and the Welsh Assembly Government
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Review of TB Testing Procedures

for

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Summary: This study is a review of the way instructions, procedures and interpretive material for TB testing are promulgated, reviewed and complied with by Local Veterinary Inspectors in England and Wales.

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Executive Summary

Background

This report presents the results of an initial and rapid review of the way instructions, procedures and interpretive material for TB testing are promulgated, reviewed and complied with by Local Veterinary Inspectors (LVIs) in England and Wales.

The study findings are based on meetings with a selection of Animal Health Divisional Offices of the State Veterinary Service (SVS) and on a half-day workshop held with a group of experienced LVIs to review the test procedure in detail, identify possible deviations from the Manual of Procedures and to explore the significance and reasons for those deviations.

This study was carried out rapidly and consulted with only a limited number of LVIs and members of the SVS. It represents a “snap shot” of the situation with regard to TB testing in England and Wales in March 2006. The study has not been able to assess the variability of practice between LVIs and around the country and has focussed on high risk TB testing areas. The findings have not been reviewed with other stakeholders or with professional bodies. These factors must be borne in mind when considering the findings from this study.

Conclusion

The study has not identified any factors that would fundamentally undermine the validity of the TB testing process as a disease control measure. However, there are routine deviations from the Manual of Procedures that mean that it may not always be possible for the veterinarian who has carried out a test to declare that the procedures were followed strictly.

Findings

- The study has indicated that deviations from the procedures are common – in some aspects almost universal. This is true for SVS staff as well as for LVIs. This does not mean that the test will not identify animals that have been exposed to TB, but that the procedures have not all been followed strictly.
- All LVIs consulted were committed to the identification and control of TB, and considered that they were conducting the tests effectively so that any infected animals would be identified.
- It was reported that non-compliance with the TB test procedures may result in some inconclusive reactors (IRs) being missed, but that it was most unlikely that it would result in missing a reactor. The significance of this must be considered against the sensitivity of the test.
- TB tests on the whole are conducted in a spirit of cooperation with the farmer. It is important that this spirit of cooperation is not reduced in any attempt to reduce deviations from TB testing procedures.
- There are parts of the procedures that were generally considered to be inappropriate or no longer applicable. These make it difficult to insist that the procedures as a whole are followed strictly. For example, there is a requirement to sterilise the syringe and needles by boiling before use although the test is not conducted in a sterile environment. The view of many in the veterinary profession was that strict adherence to the full procedure was simply not a practical option in the modern farming environment.
- LVIs feel that the present procedures are overly prescriptive and do not allow room for the LVI to make a professional judgement in using the test to make a proper diagnosis.
- Many of the deviations result from either *optimising* or *situational* errors. Optimising errors are due to the pressures of trying to get the job done quickly; this has been exacerbated by the steady increase in herd sizes. There is often a need to get through a lot of animals

within one day. Situation errors arise from the conditions at the farm, which may include the adequacy of the handling facilities, the weather, and the nature of the animals. It was repeatedly pointed out that many of the continental cross breed animals that are now common can be very difficult to handle and pose a serious risk of injury to the LVI conducting the TB test. Faced with fractious animals moving about violently in the crush the LVI will try and minimise his exposure by reducing the number of times he handles the animal.

- A number of the deviations were influenced by the equipment used; these had not changed for a long time, and could be improved with some fresh ideas.
- IT solutions to support LVIs in preparing for and recording the results of TB tests are used by the larger LVI practices, some of whom also use handheld data entry devices, but are not used by many. Such systems are likely to reduce errors and should be more efficient for both the LVI practice and the SVS administration.
- There is a lack of supervision and monitoring of LVI performance by the SVS. Not all divisions carry out supervised tests before they are given a permanent appointment and there is no systematic monitoring of subsequent performance.

Recommendations

- There is an urgent need to carry out a thorough review of the present “Manual of Procedures”. Consideration should be given to the degree to which situational deviations and mistakes can be managed out, and the degree to which optimising deviations are acceptable. It is important not only that that the test is effective, but that LVIs conform with the procedure (once revised) to ensure that the results are defensible. It is recognised that the UK has to conform to the requirements of EU Council Directive 64/432/EEC which is very prescriptive on the test protocol and may limit the options for change.
- SVS procedures for approval and monitoring of LVIs should be reviewed, and consideration given to a process of ongoing monitoring or audit.
- The effectiveness of the present IT solutions should be reviewed, and their use encouraged.
- Consideration should be given to ways of helping manufacturers improve the design of equipment used in TB tests, including skin measurement, combined syringe and marker and cattle crushes.

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1.0 Introduction and Objectives

The aim of this study is to carry out an initial and rapid review of the way instructions, procedures and interpretive material for TB testing are promulgated, reviewed and complied with by Local Veterinary Inspectors in England and Wales.

The key questions to be answered by the review are:

- Are LVIs getting instructions from the SVS?
- Are the instructions fit for purpose?
- How do LVIs know whether or not they are using the latest instructions?
- To what extent are the instructions followed by LVIs?
- What checks are in place to ensure that the instructions are being used and followed correctly?

1.1 Background

In December 2005, the owner of a Dexter bull calf identified as a positive TB reactor during a routine herd test in Devon refused to allow the animal to be taken for slaughter and demanded a retest. The State Veterinary Service (SVS) refused and initiated proceedings to seize the animal. During the preparation of evidence it became clear that the Local Veterinary Inspector (LVI) who had conducted the test had not carried out the test in full accordance with the instructions in the Manual of Procedures for LVIs (Section 1A) issued by the SVS. As a result, the court proceeds were dropped, the SVS agreed to carry out a retest (which resulted in the animal being confirmed as a reactor) and the Minister issued an apology to the owner and agreed that Defra would pay the legal costs.

This episode indicated the fact that some LVIs may not be following all the instructions in the Manual of Procedures and raised questions as to the validity of the results of the TB testing programme. As a result, DNV Consulting were asked to expand the remit of the work they were already doing for Defra and the Welsh Assembly Government on the capacity and readiness of the veterinary profession for the pre-movement testing of cattle for bovine TB to include the instructions and interpretive material and their use by LVIs (Written Ministerial Statement, 2nd March 2006).

1.2 Method

It was required that this initial study be carried out rapidly and this dictated the approach and depth of assessment that was possible. Meetings were held with the Divisional Veterinary Manager (DVM) and/or the lead Veterinary Officer (VO) for TB at 3 Animal Health Divisional Offices (AHDO), Exeter, Carmarthen and Taunton. In addition a half-day workshop was held with a group of experienced LVIs to review the test procedure in detail, identify possible deviations from the Manual of Procedures and to explore the significance and reasons for those deviations. The Agenda and list of attendees at this meeting is given in Appendix I.

1.3 Det Norske Veritas (DNV)

DNV is an independent foundation, established in 1864, with the objective of safeguarding life, property and the environment. DNV is among the world's leading companies in managing risks in areas of safety and the environment for today's industrial and societal settings. Throughout its history DNV has had a rule-setting function and/or determined conformance and compliance

to Rules, Standards and Regulations. Being an independent, autonomous and self-owned foundation, DNV undertakes third party services requiring high technical expertise and the utmost integrity in all respects.

This study has been undertaken by DNV Consulting, the risk management consulting business of DNV.

1.4 Conflicts of Interest

This report has been prepared as an independent assessment. DNV has no links to farming or other interests that could be affected by the requirement for pre-movement testing. Philip Comer, who has overall responsibility for the study within DNV, is a Partner in a hill farm on Exmoor where he and his wife run a beef suckler herd.

1.5 Acknowledgements

This study has been carried out in a short time frame and would not have been possible without the full and positive support from veterinarians, both in the State Veterinary Service and in Private practice. We are very grateful to all those who have contributed to this study.

2.0 The Tuberculin Test

There are a number of versions of the tuberculin test used for routine screening of cattle for bovine tuberculosis by different countries, although all are based on the same principle. The tuberculin tests are the internationally accepted standard and the most robust tool currently available for the diagnosis of infection by the bovine TB organism. In the UK the single intradermal comparative cervical tuberculin (SICCT) test has been used since 1947. The technique and interpretation of the tuberculin tests are defined both in national procedures and by international bodies (e.g. OIE, Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, 2004; and in Annex B to EU Council Directive 64/432/EEC). In the UK the test procedure is defined in the "Manual of Procedures for Local Veterinary Inspectors: Section 1A – Tuberculosis-Panel 1A." The present version is dated 03 April 2002.

The test detects a delayed type hypersensitivity reaction to the intradermal injection of tuberculin. The SICCT and other tuberculin tests involve the injection of a small volume of tuberculin into the skin and then examining the injection site about 72 hours later for any sign of inflammation. In the SICCT both bovine and avian tuberculin are injected simultaneously at adjacent sites on the neck of the animal. This allows for better discrimination between animals infected with the bovine TB organism and those exposed to other mycobacterium. A recent review paper (R. de la Rua-Domenech, *et al.*, 2006) provides a good summary of the background and use of the tuberculin tests.

The single intradermal comparative cervical tuberculin (SICCT) test, commonly known as the tuberculin skin test, is a well established screening test for TB in cattle. It is a test approved and recognised by the EU Commission and the international Animal Health Organisation (OIE) as a primary, effective tool for the diagnosis of TB in cattle and other species, by virtue of its overall accuracy, robustness and relative simplicity (as demonstrated in several field evaluations conducted throughout the world). The current standard interpretation of the SICCT test is designed to maximise specificity (and so minimise the probability of false positives) whilst retaining good sensitivity (probability of identifying infected cattle as positives). A correctly performed SICCT test is expected to detect approximately 80% (range from 75% to 95.5%) of all infected cattle at any one test (at standard interpretation). The specificity of the SICCT test as used in the UK is reported as being 99.9% or better. This means that if the test is applied to cattle that are not infected with TB in UK conditions that one out of one thousand would be wrongly identified as a reactor.

The probability that an infected herd is detected by a screening test will be equal to or greater than that for individual animals as the herd-level sensitivity is a function of the animal level sensitivity, the within herd prevalence of infection and the number of cattle tested.

In any test of this type it is important that it is conducted in a methodical and defined way in order to ensure that reliable judgements of the test results are made for each animal. The main steps as defined in the Manual of Procedures are summarised below.

Preparation

1. Syringes, needles etc should be sterilised by boiling before use.
2. Strict attention should be paid to hygienic measures and the needle should be wiped with dry cotton wool between each animal to prevent possible spread of micro-organisms.

Day One

3. Identify animal and enter its official ear tag in testing record/ notebook, together with description of age, sex and breed.
4. Ensure that there are no skin blemishes or other pathological conditions present at the elected sites that might interfere with the skin measurement or test.
5. Clip the hair from an area approximately 2 cm diameter at each injection site to mark the site.
6. Raise a fold of skin at each site, measure the thickness of the fold with the callipers and record the measurement.
7. Inject 0.1ml of appropriate tuberculin so that it is lodged intradermally (upper site for avian tuberculin or left hand side of neck for young animals)
8. Check that a palpable nodule is present within the skin. If such a nodule is not present and it is thought that the tuberculin may have been injected subcutaneously, a further pair of injections should be made using sites on the other side of the neck. The action should be annotated in the testing notebook.
9. Provide the owner/agent with the batch numbers and expiry dates of the tuberculins used and remind him/her that a record of tuberculin use must be made in the farm medicines book. Record the fact that the farmer was advised to make a record of the tuberculin use on the TB52/52A form.

Day Two

The test should be read 72 hours after initial injection of tuberculin.

10. Confirm the identity of each animal
11. Re-measure the fold of skin at each site and record the measurements in the notebook, along with a description of the type of reaction observed.
12. Interpret the results.

Other than in exceptional circumstances, the complete tuberculin test must be carried out by the same LVI to ensure that individual variation does not affect test interpretation. Skin measurements must always be taken, using the same set of callipers, on both test days.

The UK Manual of Procedures has to comply with the requirements of the EU Council Directive 64/432/EEC (Annex B). Paragraph 2.2.5.1 of this directive states:

Technique:

Injection sites shall be clipped and cleansed. A fold of skin within each clipped area shall be taken between the forefinger and thumb and measured with callipers and recorded. The dose of tuberculin shall then be injected by a method that ensures that the tuberculin is delivered intradermally. A short sterile needle, bevel edge outwards, with graduated syringe charged with tuberculin, inserted obliquely into the deeper layers of the skin may be used. A correct injection shall be confirmed by palpating a small pea-like swelling at each site of injection. The skin-fold thickness of each injection site shall be remeasured 72 hours (\pm 4 hours) after injection and recorded.

3.0 Training, Approval and Monitoring of LVIs for TB Testing

The work of LVIs covers a number of different areas, including brucellosis testing, investigating possible cases of anthrax etc. This study has only looked at approval and training of LVIs specifically for TB testing. Whilst there is a common approach in the SVS there will also be variations between the AHDOs which have not been fully investigated as only 3 AHDOs have been interviewed for the study.

3.1 Approval and Training

- A veterinarian is put forward for training and approval as an LVI by the veterinary practice. A veterinarian should have been in the practice for at least 3 months before going for training, but there was flexibility in this depending on when training sessions were being held.
- AHDOs are required to hold at least 2 training sessions for LVIs each year. AHDOs in high risk TB areas will often run more than this (Exeter ran 6 last year) and will put on additional courses to meet demand.
- When the practice applies for a veterinarian to be trained they are asked to sign a declaration to say that the individual is competent in TB testing (Form LVI 1B (Rev.8/94) Application for LVI training).
- In a guidance note sent out by one AHDO (Truro) to LVI practices it is pointed out that *“the practice is required to provide the necessary practical training to enable the candidate to achieve the technical competencies referred to above”*. It also states: *“Regarding TB testing, the candidate should understand the practicalities of carrying out the test, including Health & Safety responsibilities, identification of the animals and be able to undertake the correct procedure for carrying out the test on day 1 and for reading and recording the results on day 2.”* It also reminds the practice that: *“Instructions are contained in Section 1A of the Manual of Procedures for LVIs, with a detailed description of the testing technique and procedures at section 7.”*
- The training sessions are usually one day with a major part of this being dedicated to TB. The TB training will be carried out by an experienced VO and will cover the background to TB, the key steps in the test process, the interpretation of the test results and the documentation that needs to be completed. The training does not cover the practical aspects of administering the test itself; this is done by the vet’s practice and should be under the guidance and supervision of the Practice Principal.
- The VOs carrying out the training noted that there is a spectrum of experience in the veterinarians experience and awareness of the Manual of Procedures at the training sessions.
- Once a vet has attended the training day they are given a “Provisional Appointment” as an LVI on Panel 1A. The provisional LVI is then able to carry out TB tests on their own.
- In some divisions, the provisional LVI will have a supervised test within 6 months of their provisional appointment. If they pass they are then fully approved. In some areas, pressure of resources means that it is often 12 months before the supervised test takes place.
- In other divisions they do not carry out supervised tests, and the provisional LVI is confirmed after 6 months provided no non-conformities have been reported.

3.2 Performance Monitoring

There is no formal process to monitor the performance of an LVI once they have been approved. They are regarded as professionals able to carry out the tasks required in a competent manner.

From time to time, the SVS will receive reports of an LVIs performance that indicates that test procedures are not being followed properly. This may come from a farmer when the SVS carries out the follow up test when a reactor or IR has been identified, or when an incorrect animal has been identified as a reactor or IR. In these cases the following actions would be taken:

- Phone call to the vet to understand the problem and advice given on corrective actions.
- If serious, or poor response from vet, a letter would be sent setting out the problem and requiring the vet to follow instructions. This letter would be placed on the LVI's file.
- In some divisions, and when warranted, the vet would be interviewed by the DVM or senior VO.
- If the deviations are considered to be very serious, or are repeated, then the LVI could be suspended for a time from the LVI register.
- Busy AHDOs will send out a number of warning letters (a dozen or so per year in Carmarthen and Exeter). Suspensions are less common but do occur from time to time (3 last year in Exeter).

Each LVI practice will have a nominated VO as their liaison officer. It is normal practice for the VO to visit each of the practices he or she is responsible for once a year. This is primarily a liaison meeting, but is to some degree a review of the practice's equipment and procedures. The visit would normally include:

- Auditing the anthrax investigation equipment and procedures;
- Check that the practice has current chapters for the Manual of Procedures, and that they are up to date;
- Check on medicines;
- Review performance on carrying out TB tests and submitting TB test charts or be provided with additional training;
- Raise any issues that have come up.

3.3 Review of TB Test Charts

The test chart (form TB52 and TB52A) is sent to the AHDO by the LVI following each test carried out. Each chart is checked and reviewed by the SVS staff. All short interval tests and any tests showing IRs or reactors will be checked by the duty vet. Clear tests will usually be checked only by the administration staff, although a proportion will be reviewed by a VO.

The chart will be checked to ensure that all the animals that should have been tested according to the test code have been tested and check that the details on the TB52 form are correct. Two IT applications, VeBus and TBMaster, prepopulate some of the fields on the form (e.g., setting the number of animals not tested to zero) and this is not always set correctly by the LVI practice.

The individual readings will be reviewed and the interpretation checked. This is made much easier when the forms are completed on VeBus or TBMaster.

4.0 Deviations from Test Procedures

4.1 Method

The expected deviations from test procedures were reviewed during a half-day workshop with a group of experienced LVIs. The purpose of the workshop was to review the way in which TB tests are carried out in practice, to identify deviations from the “Manual of Procedures for LVIs - Section 1A” and to explore the significance and reasons for those deviations.

A structured approach was taken to identify, describe and prioritise the importance of deviations from test procedures. For each step in the testing procedure, possible deviations were brainstormed, described and possible causes for the deviation examined. Each of the deviations were then prioritised by considering how often it might occur (likelihood) and the significance of the affect (consequence). In addition, possible improvements or actions for consideration were put forward by the team.

It should be emphasised that the deviations identified and the prioritisation associated with them are the outcome of a single, relatively short workshop involving a limited number of LVIs. Whilst all those present were experienced and most had been practising as LVIs for many years, the outcomes represent the opinions of those involved and have not been verified or reviewed by a wider audience.

A generic classification of the types of rule breaking, developed to help understand health and safety failures in the oil industry (See Figure 1), has been used to classify the types of deviation identified by the team.

Figure 1 - Types of Procedure Violations

Type of Violation	Description	Possible causes	Possible Solutions
Unintentional <i>Understanding</i>	<i>People do not know how to apply the procedures</i> Problems with Understanding may arise from the use of difficult language in procedures, many cross-references and a general failure to consider the level of users when designing and writing the procedures.	<ul style="list-style-type: none"> Poor writing Complexity Failure to understand users 	<ul style="list-style-type: none"> Rewrite (use native languages and improve logic) Reduce cross-references Assess understanding in staff and designers
Unintentional <i>Awareness</i>	<i>People act as if there is no procedure</i> If procedures are not available on site, or people are not sufficiently familiar with the procedures, people will operate as if the rules or procedures do not exist.	<ul style="list-style-type: none"> Poor Training Lack of availability on site 	<ul style="list-style-type: none"> Test active knowledge of rules and procedures Make easily accessible
Routine	<i>Rules are broken, because they are felt to be irrelevant or because people no longer appreciate the dangers</i> Violations often become routine when the effort of rule following is felt to be greater than the apparent benefits. Jobs may be perceived as having little risk, when done by a skilled person, or the procedures may be felt to be unnecessary, even by a well-intentioned and motivated workforce. Unless control is exercised, a culture that tolerates violations is created.	<ul style="list-style-type: none"> Unnecessary rules Poor attitudes to compliance Weak supervision 	<ul style="list-style-type: none"> Scrap rules Improve attitudes Force compliance
Situational	<i>It is impossible to get the job done by following procedures strictly</i> Some violations occur when there is a gap between what the rules or procedures require and what is available or possible. Lack of local resources or failure to understand real working conditions may increase pressure to violate in order to get the job done and achieve targets.	<ul style="list-style-type: none"> Lack of resources Failure to understand working conditions 	<ul style="list-style-type: none"> Provide resources as required Apply Variance Procedures Make realistic procedures with those involved
Optimising	<i>It is sometimes possible to get the job done faster, more conveniently or have a thrill by not adhering to the rules</i> Incentives, such as a bonus for meeting targets or achieving personal goals, may encourage optimising violations. It should be noted that such violations can serve as the basis for improvements in productivity and safety if brought out into the open, communicated, discussed and approved.	<ul style="list-style-type: none"> Personal convenience Opportunities 	<ul style="list-style-type: none"> Make rules easier to follow Introduce rewritten rules
Exceptional	<i>People have to solve problems for the first time and fail to follow good practice</i> In new, difficult or dangerous situations there may not be any procedural guidance or experience. This kind of violation may be more frequent in jobs that require a great deal of novel problem solving. It is competence, rather than procedures, that will help to reduce the occurrence of rare, yet dangerous violations.	<ul style="list-style-type: none"> Unexpected situations – no obvious rules Pressure for progress No definition of 'exceptional' 	<ul style="list-style-type: none"> Train for the unexpected Develop situation awareness skills Develop guidance

Source: Shell, Managing Rule Breaking: The Toolkit. April 2002

The likelihood and consequence of each deviation was rated on a one to four scale. Consequences were assessed purely in terms of the result to the TB testing process and the objective of controlling bovine TB in the UK, and did not consider the potential for the deviations to be challenged or negative publicity for TB testing.

The likelihood and consequence classification were subsequently combined to give an overall prioritisation using a simple qualitative 4 by 4 risk matrix. The combinations of likelihood and consequence on the risk matrix were then grouped into a set of four risk levels:

1. Green – Low risk (tolerable)
2. Yellow – Medium risk: action should be taken to reduce the risk if practicable
3. High – High risk: This outcome is probably not acceptable and action should be taken to reduce the risk
4. Critical – Critical risk: This risk would not be acceptable

As this is a novel application for such a risk matrix the definition and groupings of the risk levels will need to be reviewed. At the present these levels reflect the view of the project team.

Figure 2 – Risk Matrix

L i k e l i h o o d	A - Frequent	2	3	4	4
	B - Occasional	1	2	3	4
	C - Rarely	1	1	2	3
	D - Improbable	1	1	1	2
		1 Low	2 Moderate	3 Major	4 Severe
		Consequence			

4.2 Workshop Results

A full record of the workshop with the list of deviations brainstormed is given in Appendix 2. For each of the deviations identified the possible causes and expected consequences are recorded. The consequence and likelihood ratings agreed by the team are given with the resulting risk rating. Finally any possible actions or changes considered by the team are recorded.

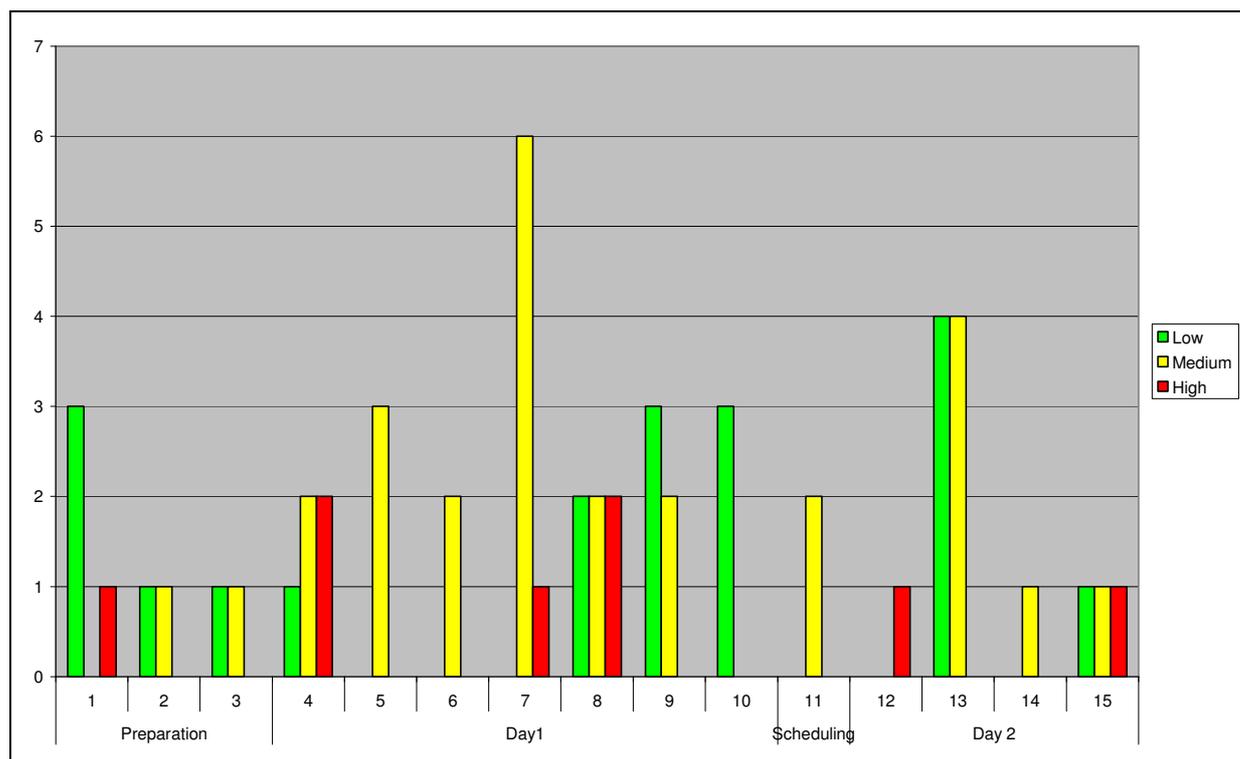
No critical (i.e. level 4) deviations were identified. The deviations that were prioritised as medium or high risk are listed below in Table1, categorised by the type of deviation. The numbers given in bracket for each deviation refer to the row in the workshop record in Appendix 2. This analysis shows a range of reasons for the deviations, but that most fall into one of three categories:

- Optimising: where the deviation occurs mainly as a result of a desire or pressure to get the work done faster;
- Situational: where it is felt that it is difficult to follow the procedures due to the conditions or safety concerns;

Mistakes: where the deviation is not intentional and as a result of a mistake or error on the part of the LVI.

It is also interesting to see how the deviations identified by the team are distributed over the various steps that make up a TB test. This is shown in Figure 3 and shows a significant grouping of deviations on Day 1, around the critical steps of measuring the skin thickness and injecting tuberculin (steps 7 & 8), and then again on Day 2 for step 13, re-measuring the skin to identify any reaction.

Figure 3: Number of deviations by Level of Priority and TB test steps



Eight of the deviations were ranked as having a High risk rating. These have each been considered in more detail in Table 2. Of these eight, one (1.2) is not the responsibility of the LVI, and two (4.1 & 4.2) are related to the potential mis-identification of animals. The significance of both of these is probably overstated as there would be the opportunity to recheck the animal's identity on day 2 if a reaction was observed.

The last of the eight high risk deviations concerns transcription errors. Again, the significance may be somewhat overstated as it is likely that these would be identified as the farmer would know which animals were identified as positive or IR on the test day.

This leaves four significant deviations that concern the measurement of skin thickness, the injection of the tuberculin and identification of the animals; all central to the performance of the test. Of these four two were classed as *Optimising* errors, i.e. due to a desire to get the task completed quickly, one was *Situational* (due to the conditions in which the test may be carried out) and one was classed as a *Mistake*, though the error could well be forced due to both situational and optimising factors.

Table 1 - Significant Deviations from Procedure

Reason for deviations from procedures	Medium-level priorities	High-level priorities (Intolerable)
Mistakes	<ul style="list-style-type: none"> • Measurement recorded incorrectly (7.7) • Bovine and avian injections mixed up (8.2) • Wrong tuberculin loaded into syringe - bovine and avian vials mixed up (8.6) • Any second injection (needed because first was ineffective) not annotated in the testing book (9.5) • Transcription errors (using VeBus) (15.1) 	<ul style="list-style-type: none"> • Injection made below skin (8.1) • Transcription errors (manual) (15.2)
Unintentional (<i>Understanding</i>)	<ul style="list-style-type: none"> • Failure to interpret difference correctly on farm (14.1) 	-
Unintentional (<i>Awareness</i>)	<ul style="list-style-type: none"> • Farmer (rather than the LVI) reads the ear tags, without cross checking (4.4) 	-
Routine	<ul style="list-style-type: none"> • Syringes, needles are not sterilised by boiling before use (2.1) • Cotton wool not used to clean needle between each animal (3.1) 	<ul style="list-style-type: none"> • Animals identified using only last three digits of tag number (4.1)
Situational	<ul style="list-style-type: none"> • Skin TB not recorded (5.3) • Farmer records information, and makes mistakes (4.5) • Hair not clipped (unsafe to do so) (6.1) • Hair not clipped sufficiently to comply with procedure (6.2) • Measurement not taken near 2 cm clip (7.4) • Measurement with calliper taken poorly (7.6) • Second visit less than 72 hours after injection (more than 6hrs before) (11.1) • Second visit is more than 72 hours after injection (more than 6 hrs after) (11.2) • Inaccurate measurement (13.7) 	<ul style="list-style-type: none"> • Not injecting where clipped (8.5)

Table 1 - Significant Deviations from Procedure

Reason for deviations from procedures	Medium-level priorities	High-level priorities (Intolerable)
Optimising	<ul style="list-style-type: none"> • Only visual check made for blemishes or other pathological conditions (especially for thick coated animals) at the time of injection (5.1) • No record made of condition in the surrounding area (to the elected sites) (5.2) • Skin measured at only one injection site (7.2) • Fingers used instead of callipers (7.3) • Check for palpable nodule made only by palming (no palpation) (9.3) • Measurements not made when there is no swelling (13.1) • Missing of any additional injection on other side of the neck (13.3) • Swelling type of reaction is not determined (13.6) 	<ul style="list-style-type: none"> • Ear tags missing and cattle not marked and recorded (4.2) • Skin not measured - for some or all animals (7.1) • Identify not confirmed if no reaction (12.1)
Exceptional	-	<ul style="list-style-type: none"> • Farmer does not want TB test carried out (1.2)
<p>Note: Figures in brackets refer to deviations in the workshop record in Appendix 2.</p>		

A common theme from these deviations was the equipment being used. This has not changed significantly for a long time. Several LVIs felt that there were opportunities to improve the way the test was conducted and reduce the risks to LVIs by having a fresh look at the equipment used. Ideas put forward for consideration included:

- A better measuring device
- Design of syringe and needles to reduce risk of sub-cutaneous injections
- Redesign of syringe to incorporate a device to mark injection site.

(note: Defra has previously asked the Commission if they can recommend a more effective measuring device which they could field test.)

Another area related to equipment is the use of IT solutions, both for organising the test and reporting to the SVS and for recording on site using hand held devices. These systems can increase efficiency and reduce errors.

A number of the deviations identified by the team highlighted aspects of the procedures that were generally considered to be inappropriate and were routinely not followed. An obvious example is the requirement to sterilise the equipment by boiling. This was not done by any of the LVIs we spoke to, was considered unnecessary and would probably damage the equipment. Another example is the requirement to wipe the needle with dry cotton wool between each animal. When parts of the instructions are generally considered to be wrong and are not followed by the majority of practitioners, then it undermines the rest. It is difficult to insist that the instructions are followed if parts of them are no longer appropriate.

A more contentious example of this is the common practice of “reading” the test manually; by the LVI feeling each animal and identifying any that had any reaction. It was universally accepted by all those consulted (including senior VOs) that a veterinarian could consistently identify a measurable reaction in this way and that measuring every animal again on the 2nd day would have no benefit. All LVIs also reported that they would measure carefully, often multiple times, any animal they identified as having any reaction.

These examples show that there is an urgent need to thoroughly review the present set of instructions.

Table 2: Evaluation of High Risk Deviations

Deviation	Discussion
Farmer does not want TB test carried out (1.2)	<p>If a farmer has no need to move cattle off his holding he may decide to delay a TB test for some time and accept a restriction. It was thought that this could be reasonably common (classed as B-occasional).</p> <p>The consequence was rated as High as this could mean a delay in detecting any infected animals on the holding with the possibility of infecting other animals in the herd.</p> <p>Comment: Not known how often this occurs. Not LVI responsibility.</p>
Animals identified using only last three digits of tag number (4.1)	<p>This is standard practice, as most of the time the last three digits will identify the animal. However, there will occasionally be duplicates and if care is not taken this may not be spotted on a manual record (typically the person recording will be checking against a printed list). Normally such an error would be spotted when the animal with the duplicate tag appears, but there is the possibility of a mistake.</p> <p>The consequence of this event is not regarded as being serious (Consequence rating 2, moderate), as if a reaction occurs the animal's identity would be thoroughly checked at that time.</p> <p>The overall risk rating comes out as High (level 3) as this is regarded as a routine practice (Likelihood rating A, frequent), which probably overstates the significance.</p> <p>Actions: need to emphasise need to cross check animal identity to ensure the ear tag recorded is correct. This failure would be minimised by use of hand held data entry tools, as these will highlight any duplicates.</p>
Ear tags missing and cattle not marked and recorded (4.2)	<p>It is quite common for ear tags to be missing as these do fall out from time to time; the deviation here is for the LVI not to make some mark in order to identify the animal on the 2nd day. The consequence remains low as for the previous deviation and the likelihood is probably overstated. i.e. ears tags missing is common, but it would be normal good practice for the LVI to make some mark (e.g. one LVI cut roman numerals on rump with scissors) so overall deviation likelihood is probably B or C, making risk rating 2 or possibly 1.</p>
Skin not measured - for some or all animals (7.1)	<p>It was reported that some LVIs did not measure at all on day 1, relying on more detailed measurements adjacent to any reaction on day 2 if a reaction was observed. It is not known how common this practice is and so it was rated as Occasional (B). This may well overestimate the likelihood as most members of the team felt this to be sub-standard practice and needs further validation to see how common this practice is.</p> <p>It was felt that this kind of practice (and use of fingers rather than</p>

	<p>callipers(7.3) and measuring at only one place(7.2)) occurred due to pressure on time where large numbers of cattle were being tested and due to health and safety concerns with certain types of stock which were difficult to handle.</p> <p>Actions: Importance of measuring needs to be re-emphasised to discourage this practice. Also consideration could be given to encouraging the design of a better measuring device.</p>
<p>Injection made below skin (8.1)</p>	<p>If the tuberculin is injected sub-cutaneously rather than intradermally as intended the efficacy of the test will be reduced and some infected animals could be missed. The consequence of this deviation may therefore serious.</p> <p>If this does occur it could be due to poor training and/or lack of experience with the equipment. Incorrect matching of needle size and collar can result in too much needle being exposed, increasing the likelihood of a sub-cutaneous injection.</p> <p>Action: Ensure this aspect is properly covered in training. Standardise needle sizes to make this mistake less likely.</p>
<p>Not injecting where clipped (8.5)</p>	<p>Not injecting at the clip mark could result in incorrect measurements on day 2, although this would probably not be the case for a full reaction. It was felt that the consequence of this was therefore Major (level 3) and that it could occur reasonably frequently (Occasional).</p> <p>The main cause would be fractious animals moving about significantly in the crush.</p> <p>Action: The issues with clipping with scissors (and hazards associated with this) and not injecting at the mark could be avoided if a mark could be made at the same time as the tuberculin is injected. Consider supporting a design project to develop new equipment.</p>
<p>Identify not confirmed if no reaction (12.1)</p>	<p>It was reported that it was common practice, by SVS VO staff as well as LVIs, to fully identify only those animals with a reaction on day 2, provided that there was confidence and trust in the farmer. LVIs felt that it would be very unusual for a farmer to try and not present animals to hide reactions. LVIs reported that if they had doubts about the farmer they would check identities.</p> <p>It would take significantly longer to have to restrain each animal sufficiently to read each ear tag and cross check against the previous record.</p> <p>Whilst the consequence of this practice was considered to be only Moderate (level 2), it was regarded as being Frequent, resulting in a risk rating of High. This probably overstates the significance attached to this practice by the team.</p> <p>However, it was noted that the table valuation system now in use to</p>

	<p>value animals slaughtered under TB restrictions may affect the farmer's attitude. With the table valuation system there will be situations where the value of the animal to the farmer, as a healthy animal, will be very different from that in the table, for example with prime breeding stock.</p> <p>Action: Consider changing procedures so that animals that are clearly not IR or reactors need not be identified and measured. Such an approach would be based on trust with farmers. Review impact of table of valuations on farmer's attitude and support for TB testing and control.</p>
<p>Transcription errors (manual) (15.2)</p>	<p>It is normal for the test record made on farm during the test to be transcribed by practice ancillary staff, onto the TB52A form or using an IT solution (VeBus or TBMaster). Transcription errors may not be easy to spot, resulting in misidentification of an infected animal. However, it is likely that the farmer would know which of his animals were identified as reactors or IRs and the mistake be picked up.</p> <p>Action: Transcription errors will be more likely with manual systems, so the likelihood of this would be reduced by encouraging wider use of the IT systems available.</p>

5.0 Findings and Recommendations

This study has been carried out rapidly and has consulted with only a limited number of LVIs and members of the SVS. It represents a “snap shot” of the situation with regard to TB testing in England and Wales in March 2006. The study has not been able to assess the variability of practice between LVIs and around the country; it has focussed on high risk TB testing areas. The findings have not been reviewed with other stakeholders or with professional bodies. These factors must be borne in mind when considering the findings from this study.

Findings

- The study has indicated that deviations from the procedures are common – in some aspects almost universal. This is true for SVS staff as well as for LVIs. This does not mean that the test will not identify animals that have been exposed to TB, but that the procedures have not all been followed strictly.
- All LVIs consulted were committed to the identification and control of TB, and considered that they were conducting the tests effectively so that any infected animals would be identified.
- It was reported that non-compliance with the TB test procedures may result in some inconclusive reactors (IRs) being missed, but that it was most unlikely that it would result in missing a reactor. The significance of this must be considered against the sensitivity of the test.
- TB tests on the whole are conducted in a spirit of cooperation with the farmer. It is important that this spirit of cooperation is not reduced in any attempt to reduce deviations from TB testing procedures.
- There are parts of the procedures that were generally considered to be inappropriate or no longer applicable. These make it difficult to insist that the procedures as a whole are followed strictly. For example, there is a requirement to sterilise the syringe and needles by boiling before use although the test is not conducted in a sterile environment. The view of many in the veterinary profession was that strict adherence to the full procedure was simply not a practical option in the modern farming environment.
- LVIs feel that the present procedures are overly prescriptive and do not allow room for the LVI to make a professional judgement in using the test to make a proper diagnosis.
- Many of the deviations result from either *optimising* or *situational* errors. Optimising errors are due to the pressures of trying to get the job done quickly; this has been exacerbated by the steady increase in herd sizes. There is often a need to get through a lot of animals within one day. Situation errors arise from the conditions at the farm, which may include the adequacy of the handling facilities, the weather, and the nature of the animals. It was repeatedly pointed out that many of the continental cross breed animals that are now common can be very difficult to handle and pose a serious risk of injury to the LVI conducting the TB test. Faced with fractious animals moving about violently in the crush the LVI will try and minimise his exposure by reducing the number of times he handles the animal.
- A number of the deviations were influenced by the equipment used; these had not changed for a long time, and could be improved with some fresh ideas.
- IT solutions to support LVIs in preparing for and recording the results of TB tests are used by the larger LVI practices, some of whom also use handheld data entry devices, but are not used by many. Such systems are likely to reduce errors and should be more efficient for both the LVI practice and the SVS administration.

- There is a lack of supervision and monitoring of LVI performance by the SVS. Not all divisions carry out supervised tests before they are given a permanent appointment and there is no systematic monitoring of subsequent performance.

Recommendations

- There is an urgent need to carry out a thorough review of the present “Manual of Procedures”. Consideration should be given to the degree to which situational deviations and mistakes can be managed out, and the degree to which optimising deviations are acceptable. It is important not only that the test is effective, but that LVIs conform with the procedure (once revised) to ensure that the results are defensible. It is recognised that the UK has to conform to the requirements of EU Council Directive 64/432/EEC which is very prescriptive on the test protocol and may limit the options for change.
- SVS procedures for approval and monitoring of LVIs should be reviewed, and consideration given to a process of ongoing monitoring or audit.
- The effectiveness of the present IT solutions should be reviewed, and their use encouraged.
- Consideration should be given to ways of helping manufacturers improve the design of equipment used in TB tests, including skin measurement, combined syringe and marker and cattle crushes.

6.0 References

OIE (2004) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, Chapter 2.3.3. Available at www.oie.int accessed 16-03-06.

de la Rúa-Domenech, R., *et al.*, (2006) Ante mortem diagnosis of tuberculosis in cattle : A review of the tuberculin tests, γ -interferon assay and other ancillary diagnostic techniques. Research in Veterinary Science, in press.

SVS (2002) Manual of Procedures for Local Veterinary Inspectors: Section 1A – Tuberculosis-Panel 1A. Date of Issue 03 April 2002.

Shell, Managing Rule Breaking: The Toolkit. April 2002

Appendix 1 – Agenda and list of Attendees for Review of TB Testing Procedure Workshop

Date and time: 15th March 2006 4.00 pm **Location:** Kingfisher Veterinary Practice,
2 Mountfields Road, Taunton

Objective of Meeting: The objective of the overall study for Defra is to carry out an initial and rapid assessment of the way instructions, procedures and interpretive material for TB testing are promulgated, reviewed and used by Local Veterinary Inspectors. It should answer the following questions:

- Are LVIs getting instructions from the SVS and are they fit for purpose?
- How do LVIs know whether or not they are using the latest instructions?
- To what extent are the instructions followed by LVIs?
- What checks are in place to ensure that the instructions are being used and followed correctly?

The purpose of this meeting is to review the way in which TB tests are carried out in practice, to identify deviations from the “Manual of Procedures for LVIs - Section 1A” and to explore the significance and reasons for those deviations.

Agenda

1. Introductions
2. Purpose of the meeting
3. Training, approval and review of LVIs by the SVS
4. Step by step review of the TB test
 - Instructions
 - Deviations
 - Significance
 - Reasons
5. Any other issues (about TB testing)
6. Conclusions

Delegates

- Andrew Cobner
Penbode Veterinary Group
- Jeremy Darke
Kingfisher Veterinary Practice
- Tom Gliddon
White Lodge Veterinary Practice
- Peter Jiman
Laurels Veterinary Group
- Ian McAllister
McAllister & Davies Veterinary Surgeons
- Nick Roper
Charter Veterinary Hospital Group

Appendix 2 – Risk Log for TB Test Procedure

Process steps	Deviations from procedures	Causes	Consequence description	Consequence rating 1 = Low 2 = Moderate 3 = Major 4 = Severe	Frequency rating A = Frequent B = Occasional C = Rarely D = Improbable	Risk Ranking 1 = Low 2 = Medium 3 = High 4 = Critical	Possible actions/ changes
Preparation							
1. Identify group of animals to be tested	1. SVS identifies wrong test type on worksheet	SVS data incorrect for 1-2 yearly parishes; Large amount of temp staff; experienced staff spend a large percentage of time training; parish system fails to identify contiguous farms; complexities around the parish system; Contiguous farms and parishes hard to split; Unclear whether SVS or LVI are doing follow-up tests.	Delay to test. Not all animals tested	2	C	1	

Process steps	Deviations from procedures	Causes	Consequence description	Consequence rating 1 = Low 2 = Moderate 3 = Major 4 = Severe	Frequency rating A = Frequent B = Occasional C = Rarely D = Improbable	Risk Ranking 1 = Low 2 = Medium 3 = High 4 = Critical	Possible actions/ changes
	2. Farmer does not want TB test carried out.	No need to move cattle.	Farm becomes restricted and remains so until test is completed - which will not be a problem to farmers not wanting to move cattle. However, could result in amplification of bTB within herd if present.	3	B	3	
	3. Incorrect data in CTS/VeBus (animal records incorrect).	Large amount of temp staff; experienced staff spend a large percentage of time training.	Wrong animals tested; 60 day period ignored.	2	C	1	

Process steps	Deviations from procedures	Causes	Consequence description	Consequence rating 1 = Low 2 = Moderate 3 = Major 4 = Severe	Frequency rating A = Frequent B = Occasional C = Rarely D = Improbable	Risk Ranking 1 = Low 2 = Medium 3 = High 4 = Critical	Possible actions/ changes
	4. Wrong type or frequency of tests (i.e. not clear if test should be with standard or severe interpretation).	The type and frequency of tests required is not understood; No record (date details) of previous tests so it is unclear if the test is within 60 days of the last test. With PRMT, tested cattle may not have been sold and still on farm of origin, or sold and on destination farm, when new TB test required (e.g. contiguous test).	Two separate tests conducted within 60 days of each other, such that second test is ineffective.	2	C	1	
2. Syringes, needles etc should be sterilised by boiling before use.	2.1 Syringes, needles are not sterilised by boiling before use.	LVI belief that sterilisation is not required.	No animal health issue. Seals last longer.	1	A	2	The test is not conducted in sterile conditions - the syringe/needle does not need to be sterilised. Needles are designed for multi-use. The requirement to use a sterilised equipment should be removed.

Process steps	Deviations from procedures	Causes	Consequence description	Consequence rating 1 = Low 2 = Moderate 3 = Major 4 = Severe	Frequency rating A = Frequent B = Occasional C = Rarely D = Improbable	Risk Ranking 1 = Low 2 = Medium 3 = High 4 = Critical	Possible actions/ changes
	2.2 Wiped needles reused until broken or dropped, rather than using a sterilised (or new) needle every time.	Run out of replacements, spare syringe not taken to site, bent needles straightened by LVI. Same needles used on more than one test if doing several small tests in one day.	Possible risk of infection. However, within the group there was no experience of infections despite the large number of TB tests carried out.	1	B	1	
3. Strict attention should be paid to hygienic measures and the needle should be wiped with dry cotton wool between each animal to prevent possible spread of micro-organisms.	3.1 Cotton wool not used to clean needle after each injection.	Dry cotton wool not held to be effective by LVIs; LVI clean when there is need.	If blood is present on needle, and not removed, could result in the possible transmission of infection (EBL).	1	A	2	Change the test to state that wiping with cotton wool is only required when blood is present; wiping every time is excessive and should not be required.
	3.2 Contaminated cotton wool used to clean needle.	Cotton wool stored in holder where dirt collects.	Possible infection of cattle.	1	C	1	

Process steps	Deviations from procedures	Causes	Consequence description	Consequence rating 1 = Low 2 = Moderate 3 = Major 4 = Severe	Frequency rating A = Frequent B = Occasional C = Rarely D = Improbable	Risk Ranking 1 = Low 2 = Medium 3 = High 4 = Critical	Possible actions/ changes
Day One							
4. Identify animal and enter its official ear tag in testing record/ notebook, together with description of age, sex and breed.	4.1 Animals identified using only last three digits of tag number.	The last three digits are used for speed	Errors-wrong animal identified. However, if IRs or Reactors are found animal identity will be properly checked on day 2.	2	A	3	Ensure the LVIs know the importance of cross checking to ensure that the ear tag is correct. Promote the use of hand-held data entry device.
	4.2 Ear tags missing, and cattle not marked and recorded.	Farmer does not check all ear tags are present (5/100 are generally missing); poor practice by LVI.	Cannot identify correct animal on day 2. Possible test error. However, if IRs or Reactors are found animal identity will be properly checked on day 2.	2	A	3	Animal should be marked, e.g. scissor marks on rump (roman numerals)
	4.3 Mistakes with writing records.	Sloppy working by LVI.	Possible test error if reaction - no skin measurement available.	2	C	1	
	4.4 Farmer (rather than the LVI) reads the ear tags, without cross checking.	Reliance on farmers	Incorrect animal records - Possible test error if reaction - no skin measurement available.	3	C	2	

Process steps	Deviations from procedures	Causes	Consequence description	Consequence rating 1 = Low 2 = Moderate 3 = Major 4 = Severe	Frequency rating A = Frequent B = Occasional C = Rarely D = Improbable	Risk Ranking 1 = Low 2 = Medium 3 = High 4 = Critical	Possible actions/ changes
	4.5 Farmer records information, and makes mistakes.	Reliance on farmers	Only if not picked up on day 2.	3	C	2	
5. Ensure that there are no skin blemishes or other pathological conditions present at the elected sites that might interfere with the skin measurement or test.	5.1 Only visual check made for blemishes or other pathological conditions (especially for thick coated animals).	Poor practice by LVI.	Skin blemishes or other pathological conditions might be missed that might interfere with the skin measurement or test.	3	C	2	
	5.2 No record made of condition in the surrounding area (to the elected sites).	Poor practice by LVI.	Interpretation is made in the absence of knowledge about skin blemishes or other pathological conditions. Possible test error	3	C	2	
	5.3 Skin TB not recorded	Poor practice by LVI.	Interpretation is made in the absence of knowledge about skin blemishes or other pathological conditions. Possible test error	3	C	2	

Process steps	Deviations from procedures	Causes	Consequence description	Consequence rating 1 = Low 2 = Moderate 3 = Major 4 = Severe	Frequency rating A = Frequent B = Occasional C = Rarely D = Improbable	Risk Ranking 1 = Low 2 = Medium 3 = High 4 = Critical	Possible actions/ changes
6. Clip the hair from an area approximately 2 cm diameter at each injection site to mark the site.	6.1 Hair not clipped.	Routine Violation; Unsafe for LVI to clip, for example there could be the risk of damaging hands when working with fractious cattle; self-locking yokes not designed for TB testing.	No marker available for 2nd day; possible error in skin measurement.	2	B	2	Liaise with manufacturers of cattle crushes and yokes to make improve design for TB testing. Communicate the importance of clipping. Consider use of clippers rather than scissors. Emphasise need to mark, rather than to remove hair (e.g., question need to specify 2 cm diameter). Set up project with design department to design equipment that can inject and mark at same time.
	6.2 Hair not clipped sufficiently to comply with procedure.	In middle of summer the coat is too thin and may have bald patches so not possible to clip.	Not necessary to clip, injection site will be visible.	1	A	2	Change procedure to allow discretion on need to clip where the injection site is clearly visible.

Process steps	Deviations from procedures	Causes	Consequence description	Consequence rating 1 = Low 2 = Moderate 3 = Major 4 = Severe	Frequency rating A = Frequent B = Occasional C = Rarely D = Improbable	Risk Ranking 1 = Low 2 = Medium 3 = High 4 = Critical	Possible actions/ changes
7. Raise a fold of skin at each site, measure the thickness of the fold with the callipers and record the measurement.	7.1 Skin not measured - for some or all animals.	LVI wanting to work quickly; not practical: measuring dangerous because animal is fractious.	Lack of comparison measurement, could miss IRs	3	B	3	Need to redesign measuring device
	7.2 Skin measured at only one injection site.	LVI wanting to work quickly; not practical: measuring dangerous because animal is fractious.	Lack of comparison measurement at one site, could miss IRs	2	B	2	
	7.3 Fingers used instead of callipers.	Calliper design is poor for this purpose; over confidence in LVI ability to measure by hand	Inaccurate measurement, resulting in incorrect test result.	2	B	2	Some calliper designs considered better than others for this task. Review design of callipers.
	7.4 Measurement not taken near 2 cm clip.	Animal moving around.	Inaccurate measurement, resulting in incorrect test result.	2	B	2	
	7.5 LVI ignores folds, for example as in young bulls, such that inconsistent site is found.	Need to work quickly.	Inaccurate measurement, resulting in incorrect test result.	3	C	2	
	7.6 Measurement with calliper taken poorly.	Cold and/or bad weather makes holding and measuring difficult.	Inaccurate measurement, resulting in incorrect test result.	2	B	2	

Process steps	Deviations from procedures	Causes	Consequence description	Consequence rating 1 = Low 2 = Moderate 3 = Major 4 = Severe	Frequency rating A = Frequent B = Occasional C = Rarely D = Improbable	Risk Ranking 1 = Low 2 = Medium 3 = High 4 = Critical	Possible actions/ changes
	7.7 Measurement recorded incorrectly.		Record incorrect, such that a IR or reactor might be more or less likely.	3	C	2	
8. Inject 0.1ml of appropriate tuberculin so that it is lodged intradermally (upper site for avian tuberculin or left hand side of neck for young animals)	8.1 Injection made below skin.	Mistake; poor injecting technique (such as injecting straight forward rather than at an angle); wrong sizes of needle and collar on syringe so that too much needle exposed.	Test is only effective if the tuberculin is injected into the skin. Under the skin would result in reduced reaction even if the animal was exposed to TB.	4	C	3	Training of LVIs in use of equipment; standardisation of needle sizes.
	8.2 Bovine and avian injections mixed up.	Syringe put back into the wrong holster; sequencing error by LVI.	Test result will be inverted. LVI normally novice when this is done.	3	C	2	
	8.3 Too much tuberculin injected.	Error: Lack of understanding by LVI- more not necessarily better.	Unknown.	1	D	1	

Process steps	Deviations from procedures	Causes	Consequence description	Consequence rating 1 = Low 2 = Moderate 3 = Major 4 = Severe	Frequency rating A = Frequent B = Occasional C = Rarely D = Improbable	Risk Ranking 1 = Low 2 = Medium 3 = High 4 = Critical	Possible actions/ changes
	8.4 Too little tuberculin injected.	Syringe leaking; syringe poorly maintained; syringe empty; Air in syringe.	The test will work with relatively small volume of tuberculin - the exact impact on the test is not known.	1	C	1	Advised LVIs to carry spare syringes
	8.5 Not injecting where clipped.	Animal moving around.	Injection site not found on 2nd day.	3	B	3	Redesign equipment so that it can mark and inject simultaneously
	8.6 Wrong tuberculin loaded into syringe - bovine and avian vials mixed up.	Mistake.	Test gives false result.	3	C Unlikely as the bovine and avian tuberculins are different colours. However colours cannot be seen once syringe is loaded, except by squirting some out.	2	
9. Check that a palpable nodule is present on the skin.	9.1 Check for palpable nodule made not made	LVI attempting to speed up test	Any injection errors not noticed.	2	C	1	

Process steps	Deviations from procedures	Causes	Consequence description	Consequence rating 1 = Low 2 = Moderate 3 = Major 4 = Severe	Frequency rating A = Frequent B = Occasional C = Rarely D = Improbable	Risk Ranking 1 = Low 2 = Medium 3 = High 4 = Critical	Possible actions/ changes
If such a nodule is not present and it is thought that the tuberculin may not have been injected subcutaneously, a further pair of injections should be made using sites on the other side of the neck and this action should be annotated in the testing book.	9.2 Check for palpable nodule made only if LVI thinks there has been an injection error	LVI experienced and can tell from action and feel of syringe if injection is not made correctly	Possible failure to miss injection error	1	B	1	
	9.3 Check for palpable nodule made only by palming (no palpation).	LVI attempting to speed up test	Possible failure to miss injection error	2	B	2	
	9.4 Visual check made for animals for which this is not suitable.	Unsafe - hands need to be kept for some time on animal to find nodule.	Possible failure to miss injection error	2	C	1	
	9.5 Any second injection (needed because first was ineffective) not annotated in the testing book.	LVI forgets; poor practice by LVI	Second injection missed. First injection used, which might not work effectively.	3	C	2	
10. Provide the owner/agent with the batch numbers and expiry dates of the tuberculin used and remind him/her that a record of tuberculin use must be made in	10.1 LVI does not provide information to owner/agent.	LVI forgets	Information missing from farm medicine record. Batch numbers recorded on Defra form (TB52) so traceable if needed.	1	B	1	

Process steps	Deviations from procedures	Causes	Consequence description	Consequence rating 1 = Low 2 = Moderate 3 = Major 4 = Severe	Frequency rating A = Frequent B = Occasional C = Rarely D = Improbable	Risk Ranking 1 = Low 2 = Medium 3 = High 4 = Critical	Possible actions/ changes
the farm medicines book. You should record the fact that the farmer was advised to make a record of the tuberculin use on the TB52 form.	10.2 No record of farmer being advised.	LVI forgets	Another test could be made without reference to test made.	1	B	1	
	10.3 Batch number of box and bottles is different for Dutch injection.	LVI unaware of the different batch numbering	Owner/agent is given the wrong batch number	1	B	1	
Day Two							
11. Scheduling of second visit	11.1 Second visit is less than 72 hours after injection (<i>more than 6hrs before</i>).	Poor planning; fitting in with farmers needs.	Reactions not developed fully.	2	B	2	On big herds animal groups should be presented in same order.
	11.2 Second visit is more than 72 hours after injection (<i>more than 6 hrs after</i>).	Previous test over-runs; emergency; poor planning.	Reactions starting to reduce.	2	B	2	

Process steps	Deviations from procedures	Causes	Consequence description	Consequence rating 1 = Low 2 = Moderate 3 = Major 4 = Severe	Frequency rating A = Frequent B = Occasional C = Rarely D = Improbable	Risk Ranking 1 = Low 2 = Medium 3 = High 4 = Critical	Possible actions/ changes
12. Confirm the identity of each animal	12.1 Identify not confirmed if no reaction.	LVI trust in farmers; pressure of time; farmer hides reactors.	Fraud or mistakes not spotted by LVI. Not all animals tested are presented on 2nd Day.	2	A	3	Consider changing procedures so that animals that are clearly not IR or reactors need not be identified and measured. Such an approach would be based on trust with farmers.
13. Remeasure the fold of skin at each site and record the measurements in the notebook, along with a description of the type of reaction observed	13.1 Measurements not made when there is no swelling.	LVI saving time. No need - LVI can tell by feel if there is any reaction that need to be measured	Small swellings, which might give inconclusive results, might be overlooked.	1	A	2	
	13.2 Measurement not made consistently.	Different LVI conducts test; different callipers used.	Incorrect test result	2	C	1	
	13.3 Missing of any additional injection on other side of the neck.	Any second injection not annotated in the testing book; the second injection site is on the other side of the neck, and therefore not visible when looking at the first injection site.	Test result not observed; could miss positive result.	3	C	2	Change procedure to recommend the second injection is made on the same side of the neck.

Process steps	Deviations from procedures	Causes	Consequence description	Consequence rating 1 = Low 2 = Moderate 3 = Major 4 = Severe	Frequency rating A = Frequent B = Occasional C = Rarely D = Improbable	Risk Ranking 1 = Low 2 = Medium 3 = High 4 = Critical	Possible actions/ changes
	13.4 Injury, such as wasp sting, causes a swelling near injection site and mistaken for test reaction.	Failure to clip	False positive.	3	D	1	
	13.5 Farm tampers with injection site between LVI visits.	Desire for compensation payments (was more common when compensation payments were higher).	False positive.	3	D	1	Less likely now with Table of valuations.
	13.6 Swelling type of reaction is not determined.	LVI working too quickly. Use of handheld recording device	Interpretation affected. If reaction is an oedema then likely that animal is a reactor or IR.	3	C	2	Oedema should be recorded whenever present.
	13.7 Inaccurate measurement.	Callipers not accurate to within 1mm; Too quick working.	Test ineffective	3	C	2	Research the ability of vets to measure in practice to 1mm. Modify the test procedure if necessary, but care needed not to compromise sensitivity and specificity of test.
	13.8 Incorrect assumption made that all significant lumps are oedema.	Poor training of LVI	More animals classed as Irs	2	C	1	Better training.

Process steps	Deviations from procedures	Causes	Consequence description	Consequence rating 1 = Low 2 = Moderate 3 = Major 4 = Severe	Frequency rating A = Frequent B = Occasional C = Rarely D = Improbable	Risk Ranking 1 = Low 2 = Medium 3 = High 4 = Critical	Possible actions/ changes
14. Interpret the results.	14.1 Failure to interpret difference correctly on farm	Failure to use the table; inexperience.	Farm not shut down, although it is likely that any error would be spotted later, or during review by SVS (especially if VeBus is used)	2	B	2	
15. Send results to SVS	15.1 Transcription errors (using VeBus or TB master)	Paperwork is dirty from farm; need for manual data transfer; chart not checked by LVI	Test results corrupted	3	C	2	Encourage the wider use of VeBus or TB Master. Use of handheld recording device will reduce errors.
	15.2 Transcription errors (manual)	Paperwork is dirty from farm; need for manual data transfer; chart not checked by LVI	Test results corrupted	3	B	3	Encourage the wider use of VeBus or TB Master.
	15.3 Errors on TB52 form, indicating that all cattle have been tested when this is not the case.	VeBus prepopulates '0s' for animals not tested as standard; Form is often completed by support staff who may not understand that it is important to state whether the whole or part of herd was tested.	SVS records are incorrect - false history may be created for not tested cattle.	2	C	1	

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