



Animal &
Plant Health
Agency

Final summary report on the Approved Tuberculin Tester (ATT) Pilot England.

16 March 2020

Completed by: Sue Quinney - Veterinary Advisor (VA), Contract Management Team, APHA



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The Animal and Plant Health Agency (APHA) is an executive agency of the Department for Environment, Food & Rural Affairs, and also works on behalf of the Scottish Government and Welsh Government.

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Background

On 5 December 2018 following the public consultation held in Summer 2018, APHA commenced a Pilot Study to evaluate the use of Approved Tuberculin Testers (ATTs) (non-veterinary personnel) to carry out skin TB testing of cattle in England in private veterinary practice.

APHA identified the following potential benefits of using ATTs in private practice. To:

- enable Veterinary Delivery Partners (VDPs) in England to increase the breadth of their workforce so that they can handle any future increases in TB testing e.g. the phased introduction in 2020 of default six-monthly surveillance testing, instead of annual testing, for higher risk herds in the High Risk TB Area of England
- provide contingency in the face of the current and worsening shortage of cattle veterinarians in England by supplementing the practice workforce
- enable veterinary surgeons to focus more on specific veterinary tasks that require veterinary judgement or signature.
- provide increased bovine TB testing resilience in the event of an exotic notifiable disease outbreak and also a pool of resource available to help in an outbreak
- enable veterinary businesses to continue to provide a cost-effective TB testing service, whilst maintaining high quality standards, to their commercial and government customers
- provide a cost-effective solution for practices in England who carry out relatively low levels of TB testing (e.g. in the Low Risk Area)

Consultation responses emphasised the need for robust veterinary supervision and quality assurance (QA) for ATTs and the APHA Pilot was set up to ensure that these particular areas were closely trialled and examined.

The objectives of the Pilot were to test the methods and procedures concerned with the use of ATTs by private veterinary businesses including registration, theoretical and practical training, supervision, authorisation, performance and QA. The Pilot has been used to make improvements to those methods and procedures, and the outcomes have been used as evidence to inform a decision whether to introduce the use of ATTs on a larger scale in private veterinary practices.

APHA requested that all five VDPs in England consider the option of using ATTs and identify suitable practices in their respective regions that would be able to support an ATT and accept the risks associated with the Pilot.

To ensure maximum oversight and increase the likelihood that the practices would commit fully to the duration of the Pilot, nine VDP shareholder practices were recruited to take part in the first phase of the Pilot – the Proof of Concept (PoC) phase. Two additional non-VDP shareholder practices (but still sub-contracted to the VDP), identified by the VDPs, were also recruited to take part to test the processes outside of the VDP shareholder practices. The PoC practices are located in the following VDP regions – Devon and Cornwall (5), Wessex (3) North (2) Midlands (1).

Following a review of the PoC completed in May 2019, a decision was made to recruit a limited number of additional practices for the remainder of the Pilot. All VDP sub-contracted practices had been notified in advance of this possibility and were invited to forward expressions of interest to their regional VDP.

Review of the PoC Phase

The following objectives of the PoC, against which various criteria were set, were reviewed in late April and early May 2019 when the pilot had been running for almost five months:

1. the training provision
2. the ability of the ATT to understand and interpret the instructions
3. the authorisation process
4. the Approved Veterinary Supervisor (AVS) role
5. the new administrative and IT processes
6. the ability of the ATT to carry out TB testing under direct supervision
7. the ability of the ATT to record test results and correctly submit tests via their AVS
8. the ability of the ATT to demonstrate competency in carrying out a TB test to the required standard to gain full authorisation (limited)

Phase 2 of the ATT Pilot

The decision to roll out to Phase Two was agreed at a Project Board meeting on 2 May 2019 following confirmation that all the previously agreed criteria had been met for phase one.

Phase Two commenced on 7 May 2019 with the recruitment of eleven additional practices located in the following VDP regions – Devon and Cornwall (4), Wessex (2) North (4) Midlands (1). One of the Wessex located practices has a catchment area that extends into the South East. Three of these practices subsequently withdrew from the Pilot before recruiting an ATT (Midlands/Devon and Cornwall) or before training commenced (North).

The PoC tested the systems and training. Phase Two brought in a greater range of practices and therefore more data to inform the final decision on rollout of ATTs to private practices.

The following objectives were added to the objectives set for the PoC (see above):

1. the performance of the ATT in terms of TB testing outcomes e.g. numbers of reactors, IRs or reactions found compared to that expected (see below)
2. the maintenance of the required levels of veterinary supervision
3. the ATT performance on farm – outcomes of on farm audits
4. farmer acceptance and perception of ATTs

Two authorised ATTs left early in the Pilot and were replaced by the practice during Phase Two - one on maternity leave and the other for personal reasons not disclosed.

Four practices have withdrawn from the Pilot – one due to a change in ownership of the practice, one due to the termination of the ATT's employment and two due to the ATTs no longer wishing to continue in the role. None of these ATTs had completed the training.

A total of seventeen ATTs have gained full authorisation to test without direct supervision. Fifteen of these remain in the Pilot. One ATT is yet to be fully authorised.

Main Pilot Issues

Proof of Concept Phase

Two main issues arose during the PoC:

1. A Sam IT test submission workaround had to be used as the required functionality in Sam to permit ATTs to correctly complete tests and for AVS sign off did not exist. This was necessarily cumbersome and resource intensive for the practices and APHA. Errors could easily be made and in a few cases test results were incorrectly submitted without the correct declarations from the AVS or ATT.
2. Nomination of the AVS and their acceptance of the role on the ATT training record. The way the training database was set up permitted ATTs to gain conditional authorisation prior to having a confirmed AVS and this led to the need to chase the ATTs/practices. There was potential for non-compliance with the requirement to have an AVS in place prior to any testing taking place by an ATT.

With the small numbers of ATTs in the PoC phase, these issues were promptly identified and addressed. However more robust solutions were required to prevent similar risks and issues occurring in future especially as it would be impossible to manage with a greater numbers of ATTs. Solutions to both of these issues were identified and implemented promptly.

See Phase two issues point 4 for a subsequent failure of the Sam solution implemented in the PoC phase.

Phase Two

1. **Injury.** One ATT was injured whilst measuring skin reactions on day 2 of a test resulting in loss of a fingertip. The ATT was still in training with the AVS present. The ATT was experienced with cattle and the practice report that after investigation of the incident, that this was not an ATT specific injury and it could have happened to any TB tester. There were no unacceptable risks identified.
2. **Farmer challenge of an IR result.** An IR result was challenged by a farmer who knew that the ATT was recently authorised to test alone. The ATT responded appropriately and the AVS attended to resolve the situation.
3. **AVS non-compliance with the eligibility criteria for the role.** One AVS had not had the required audit prior to accepting and carrying out the role. This was a misunderstanding of the requirements which have now been made more explicit in the declaration required when the AVS accepts the role.

4. **Test result submission error.** Submission of ten test charts without veterinary sign off by one ATT only. This identified a significant fault with Sam as it should not be possible for anyone but an OV to sign off a test chart. It highlighted a much wider issue in that administrative staff could have also submitted tests using the same process. A fix has been implemented to ensure that this cannot happen again in future. However it does raise an issue with the individual ATT and AVS, both of whom had clear instructions of the requirement for veterinary sign off of tests. The AVS should have identified the issue when no tests were received from the ATT for sign off. Instead it was identified by APHA. It was lack of understanding in the practice and not deliberate. These tests have since had AVS sign off to ensure their validity.
5. **ATT carrying out ineligible test types.** For the Pilot, ATT testing is restricted to Government funded statutory tests carried out in England only. One ATT carried out a number of private tests – pre and post movement - which were picked up by APHA. This was unintentional and ceased as soon as it was raised. There was no risk to the test validity as this was a commercial restriction introduced for the pilot only restriction was for the Pilot purely for commercial reasons and all tests were carried out in the presence of the AVS.
6. **Expired authorisation** - two ATTs continued to test when their authorisation was temporarily expired as a result of failure to upload the six month on farm assessment report onto their training record. In one case this was a misunderstanding as the assessment had been submitted to APHA. The other was because the assessment went overdue by two weeks and the ATT needed to test in order to complete the assessment. This process will be amended to address this situation for the future.

General

1. **Reaction requirements** - some practices reported difficulty in meeting the requirement to identify thirty oedematous skin reactions within a reasonable timescale. This type of reaction is less commonly encountered than circumscribed reactions. To assist with this, ATTs can move to another practice where oedematous reactions are commonly seen under the supervision of another AVS or deputy. The numbers of reactions required was not reduced during the pilot, but ATTs no longer have to see a minimum amount in their own tests – they can observe them in tests carried out by another tester. APHA has considered detailed feedback from the AVSs at the end of the pilot and whilst the number of reactions required will remain the same, the minimum number of each of circumscribed and oedematous has been reduced from 30 of each to 20 of each for the future.

Summary

The participating practices have been fully engaged with the Pilot, providing ongoing feedback throughout. Where issues have arisen, individual practices have worked with APHA to address them in a positive manner.

The majority of the criteria set for the Pilot have been met. For the few that were not met, there are reasonable explanations which means that the validity of the Pilot was not compromised.

All recorded risks have been mitigated or can be mitigated before further rollout. All issues have been resolved and action taken to reduce future risk of recurrence. Many of the issues raised during the Pilot are not ATT specific but have highlighted issues common to any TB tester, particularly recent veterinary graduates e.g. injury, challenge of a test result, test chart audit non-compliances.

Positive feedback was received from ATTs on the quality of the training and veterinary supervision. All agreed that the training adequately prepared them for being a fully authorised ATT. Training assessor feedback indicates that ATTs are attaining a level of competency during training at least as good as, and often exceeding, that of newly qualified OVs. This includes the ability to communicate with farmers, handle cattle and execution of the TB test itself.

ATT performance, as measured in the Pilot, was at least as good as that demonstrated by the current main TB testing personnel – OVs. The majority of the fully authorised ATTs are reporting at least as many IRs, reactors and skin reactions as expected. As an average ATTs recorded 55% more skin reactions than OVs ($p \leq 0.01$). The differences were not statistically significant in terms of number of reactors but were in terms of reactions disclosed. APHA used this data to target a single outlier ATT for audit. The audit was compliant and the lower than expected reactor/IR rates of this ATT may have been due to other factors. Similar reports have identified OVs who appear to be performing outside the expected levels in terms of reactors/IRs identified and reactions recorded. These data are a valuable new tool that will improve QA of delivery for all TB testers. APHA will use these data to target outlier OVs and ATTs for audit.

The VDP auditing has provided the required QA with APHA confirming a high standard of auditing by the VDP. Three of seventeen ATT audits had non-compliances – all minor, two of which related to application of the actual test. These were all corrected at the audit and test validity was not compromised. Follow up audits have been carried out for two of these and they were fully compliant. The third was only carried out in January 2020 and a follow up audit will be carried out in due course. Assessments by the AVSs have provided additional assurance.

The results of monitoring and various surveys indicates that the level of ATT supervision during training was very high and has been maintained subsequently as required. Test chart audits have identified only four tests for two ATTs where test chart sign off has been completed by an OV other than an AVS or deputy. This confirms a high level of AVS oversight and awareness. The case where the ATT submitted test results without any veterinary sign off does raise concern over the level of supervision and awareness of responsibility in that particular case. However this should not have been possible and will not be possible now that the required SAM IT fix has been implemented. In the case of a challenged IR result, the AVS attended as required to resolve the situation.

Feedback is strongly in favour of the use of ATTs in private practice. The vast majority of farmers surveyed during the pilot were very accepting of the ATT role. ATTs were praised by farmers for their high quality TB testing, professionalism and cattle handling skills. The overall higher than expected response rate to the survey suggests that farmers do have a keen interest in the future of this role and that the ATT visit to their farm made enough impact to encourage them to respond. This is also reflected in the number of written comments left in the free text box at the end of the survey – they were given the option to skip this question but 40% of respondents chose to add comments.

One practice withdrew from the Pilot before recruiting an ATT as their existing veterinary staff would not support an ATT as they considered the role a threat to their future employment as TB testers.

It is not unreasonable that some issues occurred during the Pilot. The process was completely new to the participating practices. All of the issues were promptly identified and addressed. Where possible, actions have been taken to prevent or reduce the risk of recurrence. Monitoring of areas where issues have arisen can be incorporated as part of the roll out of ATTs, and future instructions will highlight the areas where issues have arisen to minimise the risk of recurrence.

Recommendations

These recommendations are based on the information and data available at the end of the Pilot, 1 February 2020, and some additional information that has since been received.

APHA ATT Project Board recommends that:

The use of ATTs in private veterinary practice is rolled out more widely across veterinary practices in England subject to certain conditions. Those conditions are required to provide reassurance that the standards of QA and supervision of ATTs is maintained through ongoing monitoring and management by APHA.

Such conditions will be regularly reviewed and subject to amendment as necessary. A list of ATT Requirements (<http://apha.defra.gov.uk/documents/ov/TR539.pdf>) and AVS requirements (<http://apha.defra.gov.uk/documents/ov/TR540.pdf>) are available.

The following are key areas that will provide additional QA and supervisory assurance:

1. The number of ATTs under the supervision of any single AVS to be capped at only one ATT in training at any time, and no more than two ATTs at any given time. At any time an AVS could therefore have:
 - One ATT in training plus one authorised ATT or
 - Two authorised ATTs

The AVS would also be able to act as a deputy for other ATTs simultaneously.

2. An AVS will continue to have a clearly defined role with strict eligibility criteria and responsibilities for which they must certify prior to accepting the AVS role. The eligibility will include the need to have had a fully compliant APHA, VDP or training provider audit (not including a training course practical assessment) in the two years prior to accepting the role.
3. A list of AVSs and deputies will be held for monitoring and audit purposes. Performance of these supervisors will be monitored and audits targeted where required. AVS & deputies will need to inform APHA of any change of circumstances.
4. An ATT will not be granted conditional authorisation unless the AVS and deputy/ies have been confirmed.
5. Maintenance of a high standard of ATT training to be delivered through the contracted training provider. This will include provision of a revalidation course that will be required as follows:
 - Two years from the initial date of authorisation of the ATT
 - Thereafter every four yearsThe training material will be reviewed and enhanced to highlight any real or potential issues identified in the Pilot e.g;
 - The importance of accurately measuring and recording the skin thickness at both the avian and bovine injection sites on day 1 of the test. Training will demonstrate the possible implications on test outcome of not doing so.
 - The importance of measuring skin thickness with two hands.
6. Granting of a six month period of conditional authorisation following successful completion of the theory training. The ATT must test under the direct supervision of an AVS or deputy during this time and until the practical assessment is successfully completed and full authorisation granted. This is a legislative requirement.
7. The AVS will complete an on farm assessment of the ATT testing at least 20 animals at TT1 and TT2 between four and six months after full authorisation is granted. The results will be held on the ATT training record and available for APHA review. Failure to complete the assessment will result in suspension or expiry of the ATT authorisation.
8. A full on farm audit must be carried out for all ATTs by the VDP, APHA or the training provider in the first twelve months following full authorisation. Failure to complete an audit will result in suspension or expiry of the authorisation.
9. Following the initial on farm audit the ATT must have an APHA, VDP or training provider audit at least once every two years. The ATT will have to provide evidence that at least thirty cattle have been tested in every two year interval.
10. APHA will continue to report on the performance of ATTs (and OVs) in terms of numbers of reactors, IRs and reactions identified against that expected. This will enable audits to be targeted to those not performing as expected.

11. APHA will continue to monitor ATT test charts at an appropriate level.
12. APHA will maintain a specific ATT Roll-Out Review Group at least for the first two years post rollout to monitor the role.
13. APHA will ensure that robust processes are in place to ensure that only tests carried out by an OV can be used for export certification purposes.

APHA also recommends that:

- ATTs are not limited to practices carrying out testing for the VDP only, as the standard of QA will be consistent for all TB testers regardless of where they work.
- ATTs are not restricted in the test types that they carry out with the exception of tests that are required for export purposes which they must not perform.
- ATTs do not need to be directly employed by the practice for which they are carrying out the testing. Practices can use subcontracted or 'locum' ATTs to carry out testing.

Decision

The decision has been made to roll out ATTs more widely in England as per the recommendations above and subject to all the conditions being strictly adhered to.

Following the Pilot there are several new processes that need to be implemented before ATTs can be used more widely. In order to ensure a smooth transition for all and that APHA can continue to closely monitor ATTs, it is essential that all these processes are implemented and fully tested prior to the rollout. It is anticipated that this will be by the end of the year. It is therefore expected that ATTs will be able to start enrolling on the training from late in 2020.