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Quality control in the national bovine tuberculosis eradication programme in Ireland

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Summary
The Irish bovine tuberculosis (BTB) eradication programme operates under national legislation and fulfils the requirements of the European Union Trade Directive 64/432. The programme includes annual single intradermal comparative tuberculin test (SICTT) screening of all herds, prompt removal of test reactors and further consequential retesting of herds. Continuous evaluation of all relevant activities is essential to deliver an effective national programme and to reassure all stakeholders that the highest possible standards are attained. Quality control (QC) is a recognised process in the delivery of quality products or services. This paper presents a review of QC in the BTB eradication programme in Ireland, with particular emphasis on field surveillance and the assessment of private veterinary practitioner performance. A broad range of programme elements subjected to QC are described, including personnel, training, equipment, tuberculins and laboratories.

Keywords
Bovine tuberculosis – Field surveillance – Ireland – *Mycobacterium bovis* – Performance – Quality control.

Introduction

Quality control (QC) is a managerial process by which the actual and desired performance of goods or services is compared (30). The objectives of QC are to produce a product or service that meets the end-user requirements and is deliverable on time and at an economically viable cost (1). Quality control in veterinary laboratories is well documented (36). Some information is available about QC in Veterinary Services (5), principally concerning the development of tools to externally audit QC processes within Veterinary Services. As yet, however, little has been written about QC in national animal disease control programmes.

This paper presents a review of QC in the national bovine tuberculosis (BTB) eradication programme in Ireland, with particular emphasis on field surveillance.

The Irish bovine tuberculosis eradication programme

The Irish BTB eradication programme, established in 1954, and operated on test-and-cull principles, uses two main methods to detect BTB: the single intradermal comparative tuberculin test (SICTT) for live animals on farm, and abattoir surveillance of all carcasses. Initial progress towards eradication was rapid, and by the mid-1960s animal incidence was 0.4% (19). Subsequently, however, progress has stalled and disease levels have remained largely unchanged. It is accepted that BTB is endemic in the Irish badger population and that further significant progress in eradication will not be possible until a solution is found to negate the impact of the wildlife disease reservoir (25). Difficulties encountered in the Irish BTB eradication programme have been critically assessed and reviewed (34).

The Department of Agriculture, Food and the Marine (DAFM; previously the Department of Agriculture, Fisheries and Food) implements, manages and monitors programme delivery. An Animal Health Computer System (AHCS) plays a key role in programme management. Research support to the programme ensures that there is now a clear understanding of disease dynamics, and of the relative contribution of various control measures. The programme, as implemented under Irish legislation (28), meets the requirements of the European Union (EU) Trade Directive 64/432/EEC (9).

Annual surveillance in all herds is conducted by private veterinary practitioners (PVPs) and government Veterinary Inspectors (VIs), using the SICTT (14, 32, 38). Cattle that test positive (reactors) are rapidly removed and slaughtered, movement restrictions are imposed, and other cattle in the herd are retested. Restricted herds are prohibited from trade (cattle can only be removed for slaughter) until all animals test negative twice at two-month intervals (9).

Abattoir surveillance of attested cattle (that is, animals from herds considered free of infection) is also an important additional method of detecting infected herds, accounting for approximately 30% of herd restrictions annually.

An overview of quality control in the national programme

In Ireland, there are 116,815 holdings and a total of 6.3 million bovine animals (16). Under the Irish BTB eradication programme, all herds are subject to annual testing. Detection of positive animals results in restrictions on the movement of cattle from the herd: only reactor animals and animals going directly to slaughter can be removed (farmers receive compensation at market value for reactor animals). Once premises have been cleaned and disinfected, movement restrictions are lifted and animals can be moved from the herd, but only after a minimum of two clear tests, the second of which must be carried out at a minimum of four months from the date of removal of the last positive animal (9). In 2010, 8.3 million individual animal tests were carried out and a total of 20,211 reactor animals were removed. Between 2000 and 2010, the herd incidence fell from 8.2% to 4.7%, and the number of positive animals removed dropped from 45,000 to 20,211. Quality control in the Irish programme incorporates:

– inputs, including personnel, training, standard operating procedures, equipment, test reagents and the computerised recording system

– performance, which covers post-mortem surveillance, laboratory and diagnostic procedures, applied research and the performance of the SICTT in the field

– outputs, such as the test results, programme delivery and the computer data for analysis.

Personnel

Veterinary practitioners

Veterinary practitioners registered with the Veterinary Council of Ireland (VCI; www.vci.ie) are authorised by the Minister for Agriculture, Food and the Marine under the Diseases of Animals Act 1966. Approval to test on behalf of the Minister is based on satisfactory attendance at formal training, display of competence at a supervised test(s), compliance with annual testing instructions and signature of a contract with DAFM. Approximately 2,700 veterinary practitioners are registered with the VCI: 2,300 PVPs and 348 VIs who work exclusively for the State Veterinary Service. Most of those employed by the State are permanent VIs (330); the other 18 work on a full-time, temporary basis ('whole-time temporary VIs' [WTVIs]). Approximately 1,100 PVPs nominated by their private clients conduct SICTTs under the BTB eradication programme while engaged in farm animal practice. Veterinary inspectors and WTVIs also carry out SICTTs, although normally only in high-risk and breakdown herds. Of 9 million animal SICTTs conducted in 2009, 94.8% were conducted by PVPs, 5% by WTVIs and 0.2% by VIs.

The Veterinary Council of Ireland

The VCI is the statutory body established under the Veterinary Practice Act 2005 (30) to regulate and manage the practice of veterinary medicine in the State in the public interest. Its role is to safeguard the health and welfare of animals committed to veterinary care through the regulation of the educational, ethical and clinical standards of the veterinary profession, thereby protecting the interests of those dependent on animals and assuring public health.

Practitioner training

A formal compulsory SICTT training course is provided by DAFM for new applicants and for PVPs deemed in need of retraining. Courses are held quarterly and cater for approximately 80 new applicants and 20 retrainees during each year. The course consists of an introduction to the BTB programme, certification issues, bacteriology and SICTT technique training (including video recordings of field tests, practical training in equipment maintenance, injection technique and test reading). Approval of a PVP for testing is granted after satisfactory attendance at a training course and demonstration of testing competence at tests supervised by a VI.

National handbook

Official policy and standard operating procedures for the categorisation of herds, test prioritisation, risk assessment, management of diseased herds, epidemiological investigations, PVP supervision, etc. are set out in the *Handbook for the Veterinary Management of Herds Under Restriction due to Tuberculosis* (22). The manual is revised every three years to ensure continued improvement of QC within the programme.

Field surveillance

Equipment

The SICTT is conducted using a set of equipment that includes McLintock syringes, calipers, tuberculin and a handheld computer used for recording test details (32). McLintock pre-set syringes are manufactured by Bar Knight McLintock Limited, Scotland. These are precision instruments, designed for accuracy of dose and speed of use. The McLintock syringe is pre-set for up to 20 doses, each of 0.1 ml, which are delivered by intradermal injection using short Record- or Schimmel-type needles. They are of rugged construction, are in use worldwide, and are chosen by most agencies conducting eradication schemes.

Equipment is subject to QC by DAFM. Syringes must be serviced annually by one of three approved service companies that have personnel trained to undertake specialist tasks, such as replacement or repair of critical parts. DAFM personnel inspect each service company, including their service laboratories, equipment, procedures and records, annually. Each syringe is identified by a code engraved on the main block to facilitate individual purchase certification and subsequent servicing records. To maintain testing approval, each PVP must submit purchase or service certificates for at least two syringes annually. Records are maintained on the AHCS (Fig. 1).

Tuberculin

Tuberculin is supplied to DAFM under a contract which details the precise supply requirements relating to tuberculin specification, packaging, shelf life, supply and potency.

a) Specification. The preparation, potency and labelling of each batch of bottled tuberculin must conform to Directive 2001/82/EC (12) and Directive 91/412/EEC (10). Under Irish legislation, the only tuberculin that may be used on cattle is that supplied by DAFM. The tuberculin used in the Irish programme has a full marketing authorisation issued by the Irish Medicines Board. It is manufactured in compliance with the principles and guidelines of good manufacturing practices as per Article 51 of Directive 2001/82/EC (12) and as specified in Commission Directive 91/412/EEC (10). The manufacturer is required to have conducted assays on guinea pigs sensitised with living *Mycobacterium bovis*. Storage must be at 4°C but, in accordance with the marketing authorisation, must be stable at ambient temperatures of between +2°C and +37°C for 14 days. Distribution to PVPs is therefore possible without cold-chain maintenance, which allows PVPs to keep the tuberculin intended for immediate use at ambient temperatures. The potency of the field-issued bovine tuberculin should not be less than 30,000 International Units (IU) per ml (+/– 30%, between 2,100 and 3,900 IU/dose for a 0.1 ml dose) when tested in guinea pigs sensitised by living *M. bovis*, strain AN5. When tested in Irish cattle, the potency should be at least 30,000 IU/ml. This potency requirement exceeds the minimum specified in Directive 64/432/EEC (20,000 IU/ml) and thus ensures that the sensitivity of the SICTT as performed in Ireland is maximised.

b) Packaging. The packaging requirements are designed to minimise wastage and reduce the possibility of inadvertent use of the incorrect tuberculin:

– avian tuberculin: with permitted red colourant in 2.2 ml vials with aluminium sealing caps, pink/red in colour and labelled pink

– bovine tuberculin: 2.2 ml vials with aluminium sealing caps, blue/silver in colour and labelled in blue

– tuberculin is supplied in kit form comprising paired vials of avian and bovine tuberculin; the tuberculin supplied should have a potency of 3,000 (± 30%)] IU (bovine) and 2,500 (± 20%) IU (avian) per dose, and the pairs must not exceed a maximum potency difference of 500 IU.

c) Shelf life. Tuberculin must have a shelf life of not less than 12 months from the date of delivery to DAFM.

d) Supply. Tuberculins are currently supplied by tender on a five-year contract with Prionics, Lelystad BV. Recently, a

Syringe certificates

Number	Syringe ID	Certification Date	Number	Syringe ID	Certification Date
1	C**/*1	27/08/2008	2	CV**/*2	27/08/2008

Fig. 1
Record of syringe service in the Animal Health Computer System

full marketing authorisation for this tuberculin has been obtained in Ireland and a number of other European countries.

e) Potency. DAFM routinely conducts between two and three potency assays on bovine tuberculin each year in cattle naturally infected with *M. bovis*. The trials are conducted in DAFM's Central Veterinary Research Laboratory (CVRL) on tuberculins chosen at random from the supply to be used in the field.

Animal Health Computer System

The AHCS was introduced in 2004, to update, enhance and replace the system that had been in operation since 1986. The new system is linked to other DAFM databases, such as the national Animal Identification and Movement System (AIMS), thus facilitating rapid and accurate online electronic communication between all those involved in the programme, including PVP offices, abattoirs, laboratories and DAFM. Private veterinary practitioners and their staff view client herds, apply for test approval, input an advance itinerary, download current herd profiles, and record and report test details electronically. Approximately 98% of all PVP testing is currently reported electronically. The remaining 2% of PVPs use paper-based reporting which is transcribed to the AHCS by DAFM personnel. The PVPs that continue to use paper are usually older practitioners who have not adapted to modern technological advances and for whom paper-based reporting is easier.

Post-mortem surveillance

Surveillance at routine slaughter

Abattoir surveillance plays an important role in the early detection of BTB-infected herds and of animals not reactive to the SICTT. Routine ante- and post-mortem inspections of all bovines slaughtered in Irish abattoirs are carried out by PVPs employed on a part-time temporary basis as Temporary Veterinary Inspectors (TVIs). Prior to approval for part-time meat inspection duties, PVPs must attend two weeks of training at an approved abattoir. This training involves:

– instruction by DAFM on all aspects of ante- and post-mortem inspection, in accordance with EU Regulation 854/2004 (13)

– observation of correct post-mortem technique

– practice of each technique, including visual inspection, palpation and incision of organs and lymph nodes.

Official approval is granted following satisfactory completion of training.

Performance of TVIs is monitored on an ongoing basis by the VI in charge of each abattoir.

During 2009, 1.6 million cattle (approximately 25% of the total cattle population [16]) were examined at routine slaughter and lesions were found on 5,652 animals. Of these, 2,689 were diagnosed as tuberculous lesions on the basis of histopathological examination and 258 following culture. These diagnoses accounted for 1,879 (32%) of 5,860 herd restrictions during 2009. However, as is normal, follow-up tests failed to disclose any further SICTT-positive animals in 80% of these herds (35). Abattoir surveillance can be used to monitor the BTB status of national herds (8). Visible lesion detection rate (VLR) in recently tested animals is used as one SICTT quality indicator. However, VLR cannot be used directly as an indicator of SICTT reliability. Tuberculin test-negative animals are found at slaughter, with evidence of encapsulated lesions confirmed as caused by *M. bovis*. Where there is no active ongoing infection in the herd of origin, the infection appears to relate to exposure some time, even perhaps years, previously (37). In cases where there is ongoing infection in the herd of origin, it may well have been as a result of recrudescence of tuberculosis in a previously infected animal. In herds with ongoing problems with BTB infection, desensitisation following successive short-interval skin tests may be a contributing factor (32). There are many factors that result in false-negative reactions to the tuberculin test, including immune response variation, tuberculin failure, post-partum immunosuppression, variation in test application and inconsistent interpretation by the tester, difficulties with animal restraint techniques and test facilities, and concealment of reactors by herd owners (14, 32). Standardisation of procedures in Ireland is seen as an essential component of the eradication programme and is achieved by training, supervision and analysis of records of performance of PVPs.

Differences in VLR may also be due to differences in line speed, inspection facilities, examination technique and ability (3).

A study of the efficiency of abattoir surveillance and VLRs in attested Irish cattle during 2003 and 2004 showed substantial differences among Irish abattoirs, as measured by both submission and confirmation rates (18). Improvements in abattoir surveillance efficiency would improve BTB disease control and help to ensure that measures to safeguard food safety are enforced. The VLR increase in attested cattle in 2004 and 2005 is probably a consequence of increased vigilance, following the findings of Frankena *et al.* (18).

Surveillance at reactor slaughter

Lesion detection in reactor cattle becomes more difficult as disease prevalence falls. With short-interval SICTTs and a

short time interval between infection and detection, lesions are more likely to be discrete, fewer in number and less pronounced. The VLR in SICTT reactor cattle at commercial slaughter, where the examination conducted is for fitness for human consumption, is influenced by the efficiency of the examination conducted at the abattoir in question, and routinely may be as low as 47% of the actual lesion rate (4). The non-visible lesion (NVL) designation of SICTT reactor cattle with an apparent absence of gross lesions of BTB is not necessarily an indication that such animals are not infected. *Mycobacterium bovis* was recovered from tissues taken from 19%–28% of these animals (21). There are a variety of reasons why some reactors have no visible lesions and their significance depends on the intrinsic operating characteristics of the screening test, stage of the BTB eradication campaign, thoroughness of examination of reactors at slaughter, time since infection, lesion size and location, BTB prevalence and number of reactors found in the screened herd (4, 24, 36, 37).

The laboratory

The CVRL, the national BTB reference laboratory, is used to QC monitor the BTB eradication programme by means of confirmation of field and abattoir disclosures using histology and culture.

Submissions

– lymph node lesions from routine abattoir surveillance (approximately 5,000 per year)
– selected qualifying reactors from herds with a single reactor (approximately 900 per year) (21)
– reactors from herds subject to an epidemiological investigation (approximately 800 per year).

Diagnostic methods

Approximately 85% of diagnoses are based on histopathological examination, which has the advantages of being rapid and having a high correlation with culture. Samples for culture are decontaminated with 5% oxalic acid, inoculated into a Mycobacteria Growth Indicator Tube and onto Stonebrink's medium, Lowenstein-Jensen medium and blood agar, and incubated for seven weeks. The laboratory and the abattoirs are linked to AHCS, and the progression of any given sample can be monitored while awaiting results.

Checks on the proficiency of culture-testing procedures are organised by the Animal Health and Veterinary Laboratories Agency in Weybridge (United Kingdom). Validation of histopathological diagnosis (through retrospective culture of samples on which a diagnosis was based on histopathological examination alone) routinely confirms that 94%–95% of positive samples (tuberculous lesions) yield *M. bovis* on culture, and 100% of negative samples (actinobacillosis, parasitic granulomas, neoplasia, etc.) are negative on culture.

Blood-based analyses are used as ancillary diagnostic tools, particularly in heavily infected and chronically restricted herds. The anamnestic enzyme-linked immunosorbent assay (ELISA) is used for detection of animals that are anergic to the SICTT; these animals commonly have high infectivity and generalised disease (7). The comparative anamnestic ELISA, using bovine and avian purified protein derivative tuberculin as antigens, is carried out at the CVRL. The conjugate is affinity-purified rabbit anti-bovine immunoglobulin G coupled to horseradish peroxidase by the gluteraldehyde method, used at a dilution of 1:14,000. The substrate used is ortho-phenylenediamine (OPD).

The interferon-γ assay (Bovigam) (26) is applied in infected herds in conjunction with the SICTT to achieve earlier detection of infected animals and therefore improve the efficiency of management of diseased herds. Its sensitivity is higher than the SICTT in infected herds, while its specificity is somewhat lower, thus facilitating removal of high-risk animals that may not have been detected by the SICTT. As the interferon-γ assay enables earlier detection of infected animals, it allows a shortening of the duration of restriction and a reduction in the risk of residual infection in herds.

Microbial genotyping

Genotyping has been used to establish a national map of *M. bovis* strains and, when used in investigating BTB outbreaks, to establish the spatial and temporal distribution of *M. bovis* strains in cattle, badgers and deer. Variable number tandem repeat (VNTR) typing of *M. bovis* isolates is a typing method based on polymerase chain reaction. It is faster to perform than restriction fragment length polymorphism (RFLP) analysis, easy to interpret and reproducible between laboratories. DAFM intends to use a combination of VNTR and spoligotyping (6) in future investigations. An international authoritative database of *M. bovis* spoligotypes is kept at Weybridge, the *Mycobacterium bovis* Spoligotype Database (www.mbovis.org).

Applied research

An extensive programme of applied BTB research funded directly from DAFM is undertaken, including:

– data analysis, epidemiology and support, conducted by the Centre for Veterinary Epidemiology and Risk Analysis at University College Dublin (UCD)

– vaccine development and evaluation, conducted by the Badger Vaccine Project at UCD

– diagnostics, conducted by the TB Diagnostics and Immunology Research Centre at UCD and the CVRL.

The research output from these groups is subject to international peer review, with summary information presented biennially (for example, 33).

Herd owners

Herd owners, of which there are almost 117,000 in Ireland, are required to have all animals identified in accordance with EU legislation (11) and registered on AIMS. A profile of the animals in each herd is downloaded by the testing PVP, who reports the test details together with the animals recorded on the test. Discrepancies between the herd profile and the animals tested are queried by the PVP and followed up by DAFM. Testing facilities are checked prior to approval and registration of new herd numbers and for all herds which undergo inspection by DAFM. The farmer is obliged to provide such assistance or to carry out such instructions as may be necessary to ensure that the test can be performed accurately (28).

Quality control of field surveillance

Field inspections

Private veterinary practitioners are subjected to unannounced supervisory field inspections by a VI from the local District Veterinary Office. Until 2010, inspections were conducted once annually, but more frequently when anomalies had been identified. During each inspection, the VI reports on the field inspection protocol, which includes equipment, procedures and technique (details in Box 1). A copy of the supervision report is given to each PVP at the time of inspection, with irregularities noted. During 2010, a total of 534 PVPs were subjected to unannounced field inspections. A total of 29 were deemed not fully satisfactory and 16 were deemed to have failed to reach the required standard. Individual performance of each PVP is measured against peers and disease detection rates. Compliance with contractual conditions such as punctual submission of test reports is tabulated. Field inspections for 2010 and 2011 were allocated on a risk basis, with 93 PVPs targeted in 2011 for a second inspection based on disease-detection performance reports. A further 54 PVPs were subjected to follow-up action based on reports of non-compliance with administrative contractual conditions.

Unsatisfactory reports are followed up with disciplinary measures, as appropriate, laid out in a procedures policy document (17). Disciplinary measures are proportionate to the seriousness of the deficiencies found and range from verbal or written warning to re-inspection, retraining, suspension, referral to VCI or even prosecution.

Individual test approval is granted to a PVP by a VI prior to commencement following submission and approval of an advanced itinerary, thereby facilitating unannounced field test inspection. Failure to submit or adhere to a submitted itinerary invalidates the test approval and is considered a serious breach of procedure. Such failures are documented and itemised in a special report (the ER13A report, see below) and are followed up by way of warning or sanction.

Monitoring performance

A specialist AHCS report (ER13A) has been developed to monitor the performance of PVPs in delivery of the BTB programme. This report captures all data relevant to each PVP and concentrates on key deliverables that affect the quality of both administrative and field performance (Table I).

The ER13A report (see Appendix) summarises the performance of a PVP (both with respect to administration and disease detection) for the period under review. It details the number of discrepancies and also itemises each for the period of the report. Quarterly and annual reports are sent to each PVP. Anomalies are highlighted and followed up by an interview and disciplinary action where appropriate.

Box 1
Field inspection protocol

Field inspection
Unannounced inspection based on advanced itinerary. At least one annually and more frequent in cases where anomalies have been detected

Equipment and procedures
- Disinfection
- Syringes
- Tuberculin
- Recording using approved software
- Data recorded using appropriate PVP code and date of test
- Interrogation of previous herd-testing data
- Use of current herd profile

Testing technique
- Animal identification
- Siting of injections
- Preparation of injection sites
- Measurement of sites/reactions, initial and 72 h
- Confirmation of pea-like swelling post injection
- Identification of reactors

Table I
Measures of administrative and field performance of private veterinary practitioners (PVPs) under the Irish bovine tuberculosis eradication programme

Measures of administrative performance		
Parameter	**Measure of testing**	**Explanation**
1. Advance itinerary submission	Number of tests non-compliant with advanced itinerary	Planned date earlier or later than actual date
2. Test report submissions (a) Clear tests	Number of test reports submitted late	> 7 days post completion
3. Test report submissions (b) Positive tests	Number of test reports submitted late	> 3 days post completion
4. Private test approvals	Number of tests without valid approval	Illegal test
5. AHCS 1 forms*	Number of AHCS 1 forms submitted	An AHCS 1 form allows amendments to be made to details of a test that has previously been certified

Measures of disease-detection performance		
Parameter	**Measure of testing**	**Explanation**
1. Reactor detection rate	Reactor APT	Number of animals positive per thousand animal tests
2. Inconclusive reactor detection rate	Inconclusive APT	Number of animals inconclusive per thousand animal tests
3. Back-traced reactors	Number of BTB reactors detected back-traced to this PVP	Animals disclosed as reactors during the review period whose most recent preceding test was a negative test by this PVP during previous six months
4. BTB confirmed lesions in attested cattle at abattoir	Number of confirmed BTB lesions detected in animals recently tested by this PVP	Animals with confirmed BTB lesions in the review period that were tested by this PVP in preceding six months with a negative or inconclusive result

* An AHCS (Animal Health Computer System) 1 form is a form used by a PVP to make amendments, e.g. animal omissions or identification errors, to details of a previously certified test. A large number of AHCS1 forms indicates careless attention to detail while carrying out tests
APT: animals positive per thousand
BTB: bovine tuberculosis

The PVPs are ranked alongside their peers, both at national and local level, according to these performance indicators, using a numerical risk-based weighting for each value measured on the report (Table II). The lowest performers may be subjected to disciplinary or corrective measures and the bottom 10% are selected for special investigation as high risk and are subjected to additional practice and field inspections with disciplinary measures, as above.

Discussion

Bovine tuberculosis control in Ireland costs approximately €80 million annually: €50 million from government and €30 million from producers (15). Quality control measures are in place to ensure that the key objectives are achieved with the best possible return for the money invested. The eradication of BTB in Ireland has been constrained (25) by an endemically infected wildlife population protected under both national legislation (29) and the Berne Convention on the Conservation of European Wildlife and Natural Habitats (Bern, 19.IX.1979). Various strategies are being developed and employed to negate this constraint. The Irish programme relies on identification of infected herds and removal of infected cattle. The SICTT applied by PVPs is the principal means of identifying infection and, when carried out under field conditions, is a subjective test with considerable scope for variation in application. The AHCS has improved administrative efficiency and has facilitated advanced QC measures, particularly regarding PVP performance in the programme.

Key performance indicators in the ER13A report enable comparison of PVP performance over time and between peers. The key measures of performance are critical control points which were chosen because they are objective and readily measurable. Constant experience-based development of both the ER13A and ranking system will lead to further improvements. What has been learned from the composite report is that the vast majority of PVPs are performing to high standards and that those who perform to an unacceptable standard are aware of the report contents and the consequences of adverse reports. It may be possible to introduce performance-based rewards or sanctions based on the performance indicators in the reports as an incentive to attain higher standards. It is legitimately expected that the report will directly result in raising the standards of delivery of the BTB programme

Table II
Extract from the national private veterinary practitioner (PVP) performance ranking in 2008
The table presents examples of risk-based ranking based on disease-detection performance indicators such as BTB confirmed lesions in abattoir and back-traced reactor detection (both of which relate to animals recently tested by the PVP), amendments to test details subsequent to test report submission and certification by PVP (the Animal Health Computer System certificate 1 or AHCS 1 form). The three examples illustrate unsatisfactory, satisfactory and competent levels of performance (poor performers receive a high score in the 'National rank' column)

PVP code	BTB confirmed lesions	Reactors back-traced	Reactor animals per thousand tests	AHCS 1*	Total animal tests	National rank
P*****A	6	25	0	12	8,584	2
P*****B	2	2	3.96	3	15,646	440
P*****C	0	0	3.42	0	10,811	912

*An AHCS 1 form is a form used to make amendments, e.g. animal omissions or identification errors, to details of a previously certified test. A large number of AHCS1 forms indicates careless attention to detail while carrying out tests

and will have a major impact on quality assurance for the public and for the industry.

There has been extensive research in support of programme QC, including publications relating to tuberculin production and evaluation (20, 21, 23), field-based surveillance (2, 27), and slaughterhouse surveillance (3, 4, 18). This paper describes recent advances in the QC of all aspects of the Irish programme. All elements of the Irish programme are subject to constant review and DAFM endeavours to implement identified enhancements to QC within the programme. Computerised reporting has facilitated further QC refinements in an effort to raise standards of delivery so as to ensure value for money for all stakeholders. While much attention has been given to the standard of SICTT by PVPs, little has been documented in the published literature on the subject of QC in disease eradication programmes. It is now possible to give considerable attention to the standard of SICTT application on an objective basis using computerised reports. It is hoped that similar applications may be used in other programmes and schemes both nationally and internationally.

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Contrôle de la qualité du programme national d'éradication de la tuberculose bovine en Irlande

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Résumé
Le programme irlandais d'éradication de la tuberculose bovine s'inscrit dans la législation nationale tout en respectant les dispositions de la Directive 64/432 de l'Union européenne relative aux échanges intracommunautaires de bovins et de porcins. Le programme prévoit le dépistage de tous les troupeaux au moyen du test comparatif intradermique à la tuberculine (TCIT) et l'élimination immédiate des animaux ayant réagi à la tuberculine, suivie d'un nouveau dépistage des troupeaux. Il est nécessaire d'évaluer en permanence l'ensemble des activités

pertinentes de manière à ce que le programme national soit efficace et donne à toutes les parties prenantes l'assurance que les normes appliquées sont du meilleur niveau possible. Le contrôle de la qualité est un processus reconnu dans le domaine de la prestation de produits ou de services de qualité. Les auteurs présentent une étude sur le contrôle de la qualité du programme d'éradication de la tuberculose bovine en Irlande, en mettant particulièrement l'accent sur la surveillance de terrain (et spécifiquement l'évaluation des performances des vétérinaires praticiens privés). Les auteurs passent en revue les diverses composantes du programme faisant l'objet du contrôle de la qualité, parmi lesquelles figurent le personnel, la formation, les équipements, les tuberculines et les laboratoires.

Mots-clés
Contrôle de la qualité – Irlande – *Mycobacterium bovis* – Performances – Surveillance de terrain – Tuberculose bovine.

Control de calidad del programa nacional irlandés de erradicación de la tuberculosis bovina

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Resumen
El programa irlandés de erradicación de la tuberculosis bovina (TB) opera bajo la legislación nacional y se ajusta a los requisitos establecidos en la Directiva 64/432 de la Unión Europea relativa al comercio de bovinos y porcinos. El programa comprende una criba anual de todos los rebaños mediante una sola prueba comparativa de la tuberculina por inyección intradérmica, así como la pronta eliminación de los ejemplares positivos y la subsiguiente realización de un análisis completo del rebaño. Para ejecutar eficazmente un programa nacional y garantizar a todos los interlocutores que se aplican los más rigurosos criterios de calidad es indispensable una evaluación continua de todas las actividades ligadas al programa. El control de calidad es un reconocido proceso para ofrecer productos o servicios de calidad. Los autores exponen el control de calidad del programa de erradicación de la TB en Irlanda, haciendo especial hincapié en la vigilancia sobre el terreno (y más concretamente, en la evaluación de la eficacia de los veterinarios clínicos privados). Para ello describen diversos elementos del programa sujetos a control de calidad, como el personal, la formación, el material, las tuberculinas o los laboratorios.

Palabras clave
Control de calidad – Eficacia – Irlanda – *Mycobacterium bovis* – Tuberculosis bovina – Vigilancia sobre el terreno.

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Appendix

An example of the ER13A private veterinary practitioner (PVP) performance report

The report includes several sections. Detail of instances of non-compliance under each section are itemised.

Review of administration/performance of PVP for TB Scheme **ER13A**
(For "PVP", read PVP or TVI throughout this document)

Review Period: from 01/01/2010 to 11/09/2010 **Review date: 12/09/2010**

PVP Name	Joe Anybody
Address	Anywhere
	Any town
	Co. Kildare
PVP Code	P0****X
Practice	Anywhere Veterinary PRP Practice

Section 1 – Equipment, acknowledgement of annual instructions, summary of compliance with advance itinerary submission requirements

SUMMARY

Section 1 - Submissions

Syringe certificates

Syringe ID 1: 45678	Certification date: 01/02/2010	Expiry date: 31/01/2011
Syringe ID 1: 12345	Certification date: 01/02/2010	Expiry date: 31/01/2011

Acknowledgement of ER4 instructions: **Date of receipt: 01/01/2010**

Review of advance itineraries for period:

a) Number of tests planned by PVP for period:	**47**
i) Number of tests at (a) carried out by PVP on correct dates:	32
ii) Number of tests at (a) carried out by PVP on incorrect dates:	6
iii) Number of tests at (a) carried out by a different PVP:	3
iv) Number of tests at (a) not complete at review date:	6
v) Total: (i) to (iv):	47
b) Other tests carried out by PVP during the review period with advance itinerary irregularities: **i.e. (a) no advance itinerary relating to the period or (b) the advance itinerary relates to a different PVP**	**3**

DETAIL

Review of administration/performance of PVP for TB Scheme - detail

PVP Name:	**Joe Anybody**	**PVP code:**	**P0****X**
Review Period:	**01/01/2010 to 11/09/2010**		
Review date:	**12/09/2010**		

Section 1(a) (ii) Tests planned for the period carried out on incorrect dates

Herd no.	Keeper name	Test ID	Planned injection date	Test completion date	Date profile downloaded
I****266	Keeper 1	33****54	04/01/2010	10/01/2010	13/03/2010
Further records are omitted from this figure					

Section 1(a) (iii) Tests planned for the period carried out by a different PVP

Herd no.	Keeper name	Test ID	Planned injection date	Test completion date	Date profile downloaded	Testing vet
I****741	Keeper 20	33****66	04/01/2010	07/01/2010	13/03/2010	P0****9
Further records are omitted from this figure						

Section 1(a) (iv) Tests planned for the period but not carried out

Herd no.	Keeper name	Test ID	Planned injection date
I****367	Keeper 23	33****45	01/01/2010
Further records are omitted from this figure			

Section 1(b) Unplanned tests carried out during the period (Excludes test type 6)

Herd no.	Keeper name	Test ID	Planned injection date	Test completion date	Date profile downloaded	Planned vet
I****344	Keeper 39	33****08	20/12/2009	07/01/2010	13/03/2010	P0****9
Further records are omitted from this figure						

Section 2 - Private tests (requested and paid for by the animal keeper – ordinarily for animals being bought/sold – and for which prior official approval must be obtained)

SUMMARY

Section 2 - Private test requests & submissions

a)	**Number of private tests carried out without valid approval:**	
	i) No approval for test date:	0
	ii) Approved for different PVP:	0
b)	**Number of private tests approved but no test report submitted for approved dates:**	**6**
c)	**Number of private tests completed in review period:**	**2**
	i) Number of clear tests at (c) that were submitted late:	0
	ii) Number of reactor/inconclusive tests at (c) that were submitted late:	0
d)	**Number of private tests overdue signoff at review date:**	**3**
	(i.e. results entered on AHCS but test not certified)	

DETAIL

Section 2(a) Private tests carried out without valid approval

Section 2(a) (i) Private tests with no approval for test date

Herd no.	Keeper name	Test ID	Test completion date	No. animals tested

Section 2(a) (ii) Private tests approved for a different PVP

Herd no.	Keeper name	Approved PVP	Test ID	Test completion date	Date requested for	No. animals tested

Section 2(b) Private tests approved but no test report submitted for approved dates

Herd no.	Keeper name	Date requested for
I****060	Keeper 42	30/03/2010
Further records are omitted from this figure		

Section 2(c) Private tests submitted late

Note: In the case of off-line PVPs the certified date is the date of receipt of documents in the DVO

Section 2(c) (i) Clear tests

Herd no.	Keeper name	Test ID	Test completion date	Certified date	Interval

Section 2(c) (ii) Reactor/inconclusive tests

Herd no.	Keeper name	Test ID	Test completion date	Certified date	Interval

Section 2(d) Private tests overdue sign off at review date

(i.e. results entered on AHCS but test not certified)

Herd no.	Keeper name	Test ID	Test completion date
I****694	Keeper 47	33****25	02/10/2009
Further records are omitted from this figure			

Section 3 – Test report submission (other than private tests) – (3 days for tests with reactors, otherwise 7 days as mandated under legislation)

SUMMARY

Section 3 - Test report submission (other that private test)

a)	**Number of private tests completed in review period:**	**19**
	i) Number of clear tests at A that were submitted late:	5
	ii) Number of reactors/inconclusive tests at A that were submitted late:	0
b)	**Number of tests overdue signoff at review date:** (i.e. results entered on AHCS but test not certified) [Note: Where tests were done in parts, each part is counted separately in (A) and (B) above]	**8**
c)	**Number of tests conducted in parts where the test was not fully completed within 14 days of Commencement of 1st part:**	**2**

DETAIL

Section 3(a) Tests submitted late (other than private tests)

Note: In the case of off-line PVPs the certified date is the date of receipt of documents in the DVO

Section 3(a) (i) Clear tests

Herd no.	Keeper name	Test ID	Test completion date	Certified date	Interval
I****066	Keeper 02	33****25	07/01/2010	27/01/2010	20
Further records are omitted from this figure					

Section 3(a) (ii) Reactor/inconclusive tests

Herd no.	Keeper name	Test ID	Test completion date	Certified date	Interval

Section 3(b) Tests overdue sign off at review date

(i.e. results entered on AHCS but test not certified)

Herd no.	Keeper name	Test ID	Test completion date	Date of associated BR test
I****163	Keeper 49	33****41	13/03/2009	13/03/2009
Further records are omitted from this figure				

Section 3(c) Part tests not completed within 14 days of commencement of 1st part

Herd no.	Keeper name	Part no.	Test ID	Test completion dates		Interval between commencement of first part and completion of final part
I****536	Keeper 52	1st part	33****66	Commenced	07/01/2010	20
		Final part	33****43	Completed	27/01/2010	
Further records are omitted from this figure						

Section 4 – Certification amendments following submission of AHCS 1 forms

SUMMARY

Section 4 - Number of AHCS 1 submissions

(i.e. AHCS 1 forms submitted during the review period)

- Change in test readings 5
- Extra animals added to test 2
- Wrong herd number recorded 2
- Wrong tag number recorded 1
- Wrong test date recorded 2

DETAIL

Section 4(a) AHCS 1 submissions: tests amended during review period

Herd no.	Keeper name	Test ID	Test completion date	Date test amended	Reason for change
I****016	Keeper 55	33****12	02/08/2009	02/08/2010	Change in test readings
I****379	Keeper 32	33****09	07/01/2010	20/08/2010	Wrong herd number recorded
I****247	Keeper 65	33****60	07/01/2010	20/08/2010	Wrong tag number recorded
Further records are omitted from this figure					

Section 5 – Disease detection performance, including reactor detection rate for the review period, TB confirmed lesions at abattoir and back-traced reactors as detected in animals tested within the previous six months by the private veterinary practitioner

SUMMARY

Section 5 - Performance

a)	**Number of animals tested (all DVOs):**		**2400**
b)	**PVP reactor APT:**		**1.8**
c)	**Resident DVO reactor APT:**	**Kildare DVO**	**2.2**
d)	**PVP inconclusive APT:**		**0**
e)	**Resident DVO inconclusive APT**	**Kildare DVO**	**0.1**
f)	**Number of factory lesions in animals tested by PVP** (i.e. animals with positive lesions in the review period that were tested by PVP in preceding six months with a negative or inconclusive result)		**2**
g)	**Number of reactors detected backtraced to PVP:** (i.e. animals disclosed as reactors during the review period whose most recent preceding test was a negative test by PVP in another herd, in previous six months)		**2**

DETAIL

Section 5(f) Number of factory lesions disclosed in animals tested by PVP

(i.e. animals with positive lesions in the review period that were tested by PVP in preceding six months with a negative or inconclusive result)

Animal tag number	Date lesion disclosed	Date tested by PVP	Herd no.	Keeper name	Test ID	Increase	
						A	B
IE**********22	15/01/2010	07/01/2010	I****325	Keeper 68	33****78	0	0
Further records are omitted from this figure							

Section 5(g) Number of reactors detected backtraced to PVP

(i.e. animals disclosed as reactors during the review period whose most recent preceding test was a negative test by PVP in another herd, in the previous six months)

Animal tag number	Date disclosed as reactor	Date tested by PVP	Herd no.	Keeper name	Test ID	Increase	
						A	B
IE**********55	23/01/2010	01/10/2009	I****926	Keeper 57	33****67	0	0
Further records are omitted from this figure							