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Development of a HACCP-based approach to control paratuberculosis in infected Irish dairy herds

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ABSTRACT

Paratuberculosis is a challenging disease to control at farm level, in part due to the poor sensitivity of diagnostic tests and a prolonged incubation period. Simulation studies have highlighted on-farm management to be the most important factor in preventing on-farm spread. A risk assessment (RA) and management plan (MP) approach (collectively, RAMP) has been adopted around the world as the most appropriate method of controlling disease in infected farms. However, there are problems with RAMP that remain to be resolved. The RA relies heavily on farmer recollection and estimation resulting in subjectivity and substantial inter-observer variability. MPs consist of a series of qualitative, farm specific recommendations showing how management can be improved. However, MP assessment is generally conducted informally, and progress is monitored through 'end-point' diagnostic testing of adult animals and repeated risk assessments. Hazard analysis and critical control point (HACCP) has been developed as a proactive alternative to end-point testing. We hypothesise that farm-based HACCP systems may be a useful alternative to RAMP on farms where more intensive monitoring and evaluation of controls for paratuberculosis is required. Therefore, the objective of this methodological study was to develop a HACCP-based system for paratuberculosis control. Critical control points (CCPs) relating to peri-parturient area management, calving, new-born calf management and colostrum management were identified as areas where additional control could be exerted above existing methods. Novel monitoring systems were developed for each CCP, along with targets and corrective actions. This system is intended for use in high prevalence herds, or farms where more robust monitoring of key control points may be beneficial. It is currently being trialled on infected commercial dairy herds in Ireland.

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1. Introduction

Bovine paratuberculosis is a disease characterised by chronic granulomatous enteritis which manifests clinically as a protein-losing enteropathy causing diarrhoea, hypoproteinaemia, emaciation and, eventually death (Sweeney et al., 2012). Adverse effects on animal productivity and losses due to continued spread of infection are key drivers in the attempt to control the disease at farm level. Many major dairy producing countries have introduced control programmes aimed at reducing spread between and within herds (Geraghty et al., 2014). Paratuberculosis is difficult to control on farm because of a prolonged incubation period, poor performance of diagnostic tests and protracted environmental survival (Kennedy and Benedictus, 2001). Simulation studies have highlighted on farm management to be the most important factor in controlling the disease (Kudahl et al., 2007).

Risk assessment and management plans (RAMP) have been widely adopted across many countries with a recognisable control programme (Geraghty et al., 2014) and are generally advocated as an appropriate method for control of paratuberculosis in infected herds (Sweeney et al., 2012). RAMP involves the completion of an initial risk assessment (RA) assigning risk scores to different management procedures and areas. The outcome of the risk assessment is used to inform a management plan (MP) and, in national programmes, may have some bearing on herd categorisation or herd risk score. The approach offers many advantages in being a structured process that gathers a lot of information at the farm level, enhancing the veterinary advisor's understanding of the farming operation (Garry, 2011). A reduction in test positivity associated with the implementation of management practices has been found on a number of small scale investigations on demonstration or study herds using the RAMP approach (Espejo et al., 2012) but

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progress has not been reproduced in larger studies on commercial farms (Sorge et al., 2011).

Nonetheless, there are problems with RAMP that remain to be resolved. Aspects of the RA are subjective, based on observations at the time of a single annual visit or rely heavily on farmer recollection and perception. Importantly, implementation of the management plan is poorly assessed with indirect formal monitoring structures. Therefore, end-point testing of adult animals and comparison of consecutive risk assessments remain the only way of measuring progress with the current system. Whilst the RA adequately captures information on herd level management practices, other more quantitative practices such as the length of time a calf spends with the dam, faecal contamination of milk or colostrum or hygiene in general are not measured or monitored in the current system. Many of the questions in the risk assessment therefore rely on farmer recollection and estimation of performance. Furthermore, scores based on the observations from the veterinarian represent a "point-in-time" assessment which may or may not reflect normality for the farm. This may be particularly important in a seasonal production system. Consequently, there is a degree of subjectivity in the RA evident as substantial inter-observer variability and accounting for 24% of the RAMP score variation (Pieper et al., 2015). Given that the management plan is generally an outcome of the RA, there are implications for how the MP may be affected as a result. The management plan consists of a series of recommendations prioritised according to the perceived greatest risks for transmission (Garry, 2011). Importantly, progress in the current system can therefore only be assessed from end-point diagnostic testing of adult animals or through iterative risk assessments conducted annually (Raizman et al., 2006). This is not ideal given the prolonged incubation period of the disease and because aspects of the RA cannot accurately assess practices on the farm. Compliance with the management plan has been found to be poor (Ridge et al., 2005; Sorge et al., 2010). In some cases farmer reported compliance may not be strongly associated with veterinary RA score assessment of compliance (Sorge et al., 2011) and a common reason for poor compliance among farmers is the perception that they have always done what the veterinarian has advised (Sorge et al., 2010). These findings suggest a possible disconnection between the RA scores, what the farmer perceives to be occurring on the farm and what is actually happening on the farm. Plans consist of a series of qualitative, farm specific recommendations showing how management can be improved. This is comparable to the good farming practice approach to quality control and representing a top–down approach to disease management (Noordhuizen and Welpelo, 1996).

These issues are not dissimilar to those encountered in systems such as food production. In that context, hazard analysis and critical control point (HACCP) offers potential to address some of the shortcomings of conventional quality management. HACCP is a risk-based system developed as a proactive alternative to end-point testing, to help ensure safety of food (Ropkins and Beck, 2000). HACCP has since been adapted to all stages of the food chain (Ropkins and Beck, 2000) with the key principles being retained, but can also be adapted and applied to scenarios where a more efficient and proactive form of control and management is desired.

Since 2006, HACCP-based programmes are required in the EU at all stages of the food chain with the exception of primary production (European Commission, 2004a,b,c). This legislation also advises "Member States to encourage operators at the level of primary production to apply such (HACCP) principles as far as possible" (European Commission 2004a, p3). We hypothesise that a HACCP-based approach to paratuberculosis may address some of the weaknesses of the RAMP approach. HACCP incorporates risk assessment with structured risk management and a formal, documented monitoring system (Noordhuizen and Frankena, 1999). A focus on measurable outcomes and formal monitoring structures with measureable critical limits (European Commission, 1997), facilitates accurate identification and quantification of the magnitude of risks (Gardner, 1997). Furthermore short term target setting that is more amenable to external audit is possible. In this methodological paper, we describe the development of a HACCP-based programme for the control of paratuberculosis. The approach is designed for use in Irish dairy herds where a greater level of control is desired such as high prevalence herds, but is of wider applicability. A secondary objective was to present the evidence supporting the selection of critical control points along with targets and critical limits.

Table 1
Steps taken in the development of a HACCP-based programme for on farm use as adapted by Noordhuizen (2008).

Step 1	Assemble a multidisciplinary, facility-based Farm Quality Control Team
Step 2	Describe the final product
Step 3	Identify the intended use of the product
Step 4	Develop a flow diagram which describes the production process. Work from the whole farm level to the detailing of separate steps up to the detailing within the steps
Step 5	Verify the correctness of the flow diagram with the team members and the farm workers
Step 6	Prepare a list of steps in the production process at which targeted risks occur. Identify the hazards and prioritise them; identify the risks; conduct risk weighing
Step 7	Identify the critical control points (CCP) in the production process required to eliminate or reduce the hazards and risks.
Step 8	Establish critical limits and standards, or specific targets for triggering the implementation of corrective and preventative measures associated with each CCP identified in step 7.
Step 9	Establish an on-farm monitoring programme and its requirements regarding each CCP. Use the results of monitoring to adjust the procedures and maintain control of the production process. Use monitoring also for herd performance assessment.
Step 10	Determine corrective measures, to take when monitoring results indicate that a value falls outside its target or tolerance level and hence control is lost.
Step 11	Establish effective record-keeping procedures that document the HACCP-like programme has been implemented, is operational and effective
Step 12	Establish procedures to verify that the HACCP-like programme is working correctly (*e.g.* internal reviews yearly; external verification and audits; periodic revalidation of the programme)

2. Material and methods

Building upon the veterinary risk assessment and management plan that forms the basis of the Animal Health Ireland national programme, a novel HACCP-based approach was used to create a paratuberculosis control programme that could be applied as a management tool on infected Irish dairy farms.

HACCP principles, developed by the Codex Alimentarius Commission (European Commission, 1997) have been adapted for use at farm level (Cullor, 1995) and summarised (Noordhuizen, 2008). These principles (Table 1) were applied in a systematic manner to the hazard *Mycobacterium avium* subsp. *paratuberculosis* ensuring that all relevant activities on a typical Irish dairy farm were addressed.

The central concept of HACCP is the identification of critical control points (CCP) and associated monitoring, corrective action and verification procedures. A CCP is defined as a point, step or procedure at which control can be applied and a hazard can be prevented, eliminated, or reduced to an acceptable level (Codex Alimentarius Commission, 2003)

Some authors have advocated the use of the term Points of Particular Attention (PoPA) rather than CCPs, when using HACCP principles on farm in acknowledgement of potential difficulties

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