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An investigation of the efficacy of a polyvalent mastitis vaccine using different vaccination regimens under field conditions in the United Kingdom

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ABSTRACT

Vaccination can play a useful role in mastitis control programs, although there is a relative dearth of large, well-controlled field efficacy studies. This paper presents the findings on the use of a commercially available vaccine (Startvac, Hipra UK Ltd., Nottingham, UK) on commercial units under UK field conditions. In total, 3,130 cows were recruited from 7 farms and were randomly allocated, within farm, to 1 of 3 groups. The first group received the vaccine following the label regimen, the second group was vaccinated every 90 d following an initial vaccination course, and the third group was left unvaccinated to act as controls. Vaccine efficacy was assessed in the first 120 d of lactation. Data were available for analysis from 1,696 lactations in 1,549 cows. In total, 779 cases of clinical mastitis occurred in the 3 study groups, and we detected no significant difference in the incidence or prevalence of clinical or subclinical mastitis between any of the 3 groups. Mastitis vaccination following the label regimen was associated with a significant reduction in the severity of clinical cases. Cows in this group were at significantly decreased odds of developing clinical mastitis presenting with more than just milk changes [odds ratio: 0.58; 95% confidence interval (CI): 0.35–0.98]. Similarly, each additional vaccination resulted in a cow being at decreased odds of developing clinical mastitis presenting with more than just milk changes (odds ratio: 0.87; 95% CI: 0.77–0.98). Although no cows were culled because of severe mastitis in either of the vaccinated groups, we detected no significant difference in the mastitis-related culling rate between groups. Analysis of milk production data demonstrated that, on average, cows on the label regimen produced a higher volume of milk (231 L; 95% CI: 104.1–357.4) and more milk solids (12.36 kg; 95% CI: 3.12–21.60) than unvaccinated cows in the first 120 d of lactation. Conservative analysis suggested that a return on investment of 2.57:1 could be expected under UK conditions based on increased milk yield alone.
Key words: vaccination, mastitis, milk production, coliform, *Escherichia coli*

INTRODUCTION

Clinical and subclinical mastitis remain a major cause of financial loss to the dairy industry and a significant challenge to the dairy producer, with a large number of herds still experiencing unacceptable levels of disease (Bradley et al., 2007b). Several treatments and control measures are available to the practitioner but these are often apparently insufficient to control the disease on farm (Green et al., 2007).

Effective mastitis vaccination has long been the "holy grail" of mastitis control. However, despite development of several vaccines in the 1980s, based on the J5 *Escherichia coli* mutant, such vaccines to date, although demonstrating an ability to reduce the severity of clinical signs and duration of infection, have failed to demonstrate a reduction in the rate of IMI (Hogan et al., 1992; Wilson et al., 2007a). Investigation of the use of J5 coliform vaccines has also demonstrated a positive effect on production in that vaccinated cows have been shown to recover milk yield after a clinical case more quickly than unvaccinated cows (Wilson et al., 2007b, 2008, 2009).

Although mastitis vaccines have been available in many jurisdictions, this has not been the case in the European Union until relatively recently. However, a polyvalent mastitis vaccine directed against both enterobacterial and staphylococcal species has been approved for use in the European Union (Startvac; Hipra UK Ltd., Nottingham, UK). Registration studies demonstrated a reduction in IMI with coliform and *Staphylococcus* spp. and a decrease in severity of clinical signs of disease when using the product (http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Scientific_Discussion/veterinary/000130/WC500068576.pdf). However, these registration studies were based primarily in southern Europe and were con-

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ducted under very different climatic and management conditions to those seen in northern Europe and the United Kingdom.

A significant constraint to the use of mastitis vaccines has been the relatively onerous vaccination regimens (Wilson and González, 2003) that are necessary to achieve the desired level of efficacy. These often necessitate vaccination both before and after calving (González et al., 1989). This has led to the development of more practical, farmer-friendly approaches to vaccination when J5 core antigen vaccines have been deployed in the field, such as a rolling schedule of vaccination of all cows in the herd on a quarterly basis. Other attempts at improving efficacy have also been made by increasing the number of vaccinations (Erskine et al., 2007) and by vaccinating earlier in the lactation cycle (Gurjar et al., 2013), in part to reduce the effect of IMI acquired during the dry period (Bradley and Green, 2000).

The aim of the study outlined here was to investigate the efficacy of a multivalent mastitis vaccine (Startvac; Hipra UK Ltd.) in the control of bovine mastitis under UK field conditions using both the label regimen and a schedule of quarterly vaccination.

MATERIALS AND METHODS

Herd Selection

Seven commercial dairy herds, in the southwestern United Kingdom, were selected to participate in the study based on location, likelihood of compliance with the study protocol, suitable herd records, a suitably maintained milking machine, and enrollment in regular DHI testing. No strict criteria were applied pertaining to bulk milk SCC or clinical mastitis incidence. Each herd was visited by a veterinarian to provide suitable training to ensure study compliance.

Cow Selection

All cows and heifers approaching their first calving were eligible for recruitment to the study, contingent on being in good health, having 4 functional quarters, teats free of significant teat lesions, and an estimated calving date to allow vaccination at predicted times before calving.

Vaccine Selection

The vaccine selected for use in this study (Startvac; Hipra UK Ltd.) was a polyvalent product containing inactivated *Escherichia coli* J5 and inactivated *Staphylococcus aureus* (CP8) strain SP 140, expressing slime-associated antigenic complex (SAAC), utilizing a liquid paraffin adjuvant and containing benzyl alcohol as an excipient.

Study Protocol

Enrollment. Farms were initially visited and all lactating and nonlactating adult cows present on the farm were recruited to the study. Herd personnel were trained to maximize compliance with the study protocol. Training encompassed the identification, scoring, and aseptic sampling of clinical mastitis and the use of the California Mastitis Test. Thereafter, each site was visited weekly to allow recruitment of heifers and purchased cows joining the herd as well as the collation of farm records, sample collection, reinforcement of training, and the administration of vaccinations as outlined below.

Treatment Allocation and Administration. At the initial visit to each site, all eligible cows were randomly allocated to 1 of the 3 study groups; namely, unvaccinated, label, and rolling regimen groups. Thereafter, cows joining the herd were also randomly allocated to 1 of the 3 study groups. Heifers were recruited if service dates had been accurately recorded. Once enrolled, cows remained in the same treatment group for subsequent lactations. All vaccinations were administered by study personnel.

Cows in the unvaccinated group acted as negative controls and did not receive any vaccinations. Cows recruited to the label and rolling groups were vaccinated (by deep intramuscular injection) according to the schedule outlined below. The study was conducted under field conditions and, therefore, vaccinations were carried out weekly, with all vaccinations due in the next 7 d being undertaken at each visit (i.e., cows due to be vaccinated 45 d before calving may have been vaccinated between 52 and 45 d before calving).

Rolling Vaccination Regimen. Cows recruited to the rolling group were vaccinated on the day of recruitment (d 0), 28 d later (d 28), 62 d thereafter (d 90), and then every 90 d until the end of the study. New cows entering the herd were vaccinated at the earliest opportunity and followed the same regimen, although they received their vaccinations at a different time from the majority of cows that entered this regimen.

Label Vaccination Regimen. Cows recruited to the label group were not vaccinated on enrollment but were monitored and subsequently vaccinated according to the licensed regimen at 45 d before the estimated date of calving (based on herd records), 35 d later (10 d before the estimated date of calving, although this could actually be postcalving if cows calved early), and 52 d postcalving. Label regimen cows were not vac-