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Quantification of *Mycobacterium bovis* transmission in a badger vaccine field trial

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ABSTRACT

In the UK and Ireland, Bacille Calmette-Guérin (BCG) vaccination of badgers has been suggested as one of a number of strategies to control or even eradicate *Mycobacterium bovis* infection in badgers. In this manuscript, we present the results of a badger field trial conducted in Ireland and discuss how the novel trial design and analytical methods allowed the effects of vaccination on protection against infection and, more importantly, on transmission to be estimated. The trial area was divided into three zones North to South (A, B and C) where vaccination coverages of 0, 50 and 100%, respectively, were applied. Badgers were trapped over a 4 year period. Badgers were assigned to either placebo or vaccine treatment, with treatment allocation occurring randomly in zone B. Blood samples were collected at each capture, and serology was performed in these samples using a chemiluminescent multiplex ELISA system (Enfer test). The analysis aimed to compare new infections occurring in non-infected non-vaccinated badgers to those in non-infected vaccinated ones, while accounting for the zone in which the badger was trapped and the infection pressure to which this individual badger was exposed. In total, 440 records on subsequent trappings of individual non-infected badgers were available for analysis. Over the study period, 55 new infections occurred in non-vaccinated (out of 239 = 23.0%) and 40 in vaccinated (out of 201 = 19.9%) badgers. A Generalized Linear Model (GLM) with a cloglog link function was used for analysis. Statistical analysis showed that susceptibility to natural exposure with *M. bovis* was reduced in vaccinated compared to placebo treated badgers: vaccine efficacy for susceptibility, VE_S, was 59% (95% CI = 6.5%–82%). However, a complete lack of effect from BCG vaccination on the infectivity of vaccinated badgers was observed, i.e. vaccine efficacy for infectiousness (VE_I) was 0%. Further, the basic reproduction ratio as a function of vaccination coverage (p) (i.e. R(p)) was estimated. Given that the prevalence of *M. bovis* infection in badgers in endemic areas in Ireland is approximately 18%, we estimated the reproduction ratio in the unvaccinated population as R(0) = 1.22. Because VE_S was now known, the reproduction ratio for a fully vaccinated population was estimated as R(1) = 0.50. These results imply that with vaccination coverage in badgers exceeding 30%, eradication of *M. bovis* in badgers in Ireland is feasible, provided that the current control measures also remain in place.

1. Introduction

Bovine tuberculosis (bTB, caused by infection with *Mycobacterium bovis*) is a chronic inflammatory disease of bovidae (Bezos et al., 2014). A control/eradication programme for bTB in cattle started in Ireland in 1959 not only to address the economic losses associated with the infection (Caminiti et al., 2016), but also its zoonotic potential (Langer and LoBue, 2014). In the first ten years of the control programme, with a focus on measures to limit cattle to cattle transmission, the incidence of *M. bovis* infection in cattle was reduced from 17% to 0.5% (More and Good, 2006). Subsequently, progress has been slow, despite ongoing application of intense control strategies, which raised concerns about a role for one or more reservoirs of *M. bovis* maintaining transmission. Over the years, this hypothesis has been confirmed, including work highlighting high prevalence of infection in badgers (*Meles meles*) (Corner et al., 2005). Since then substantial research has been conducted to understand transmission of *M. bovis* between cattle and badgers, and of potential strategies capable of reducing this transmission. One such strategy is the use of BCG (Bacille Calmette-Guérin) badger vaccination (More and Good 2006).

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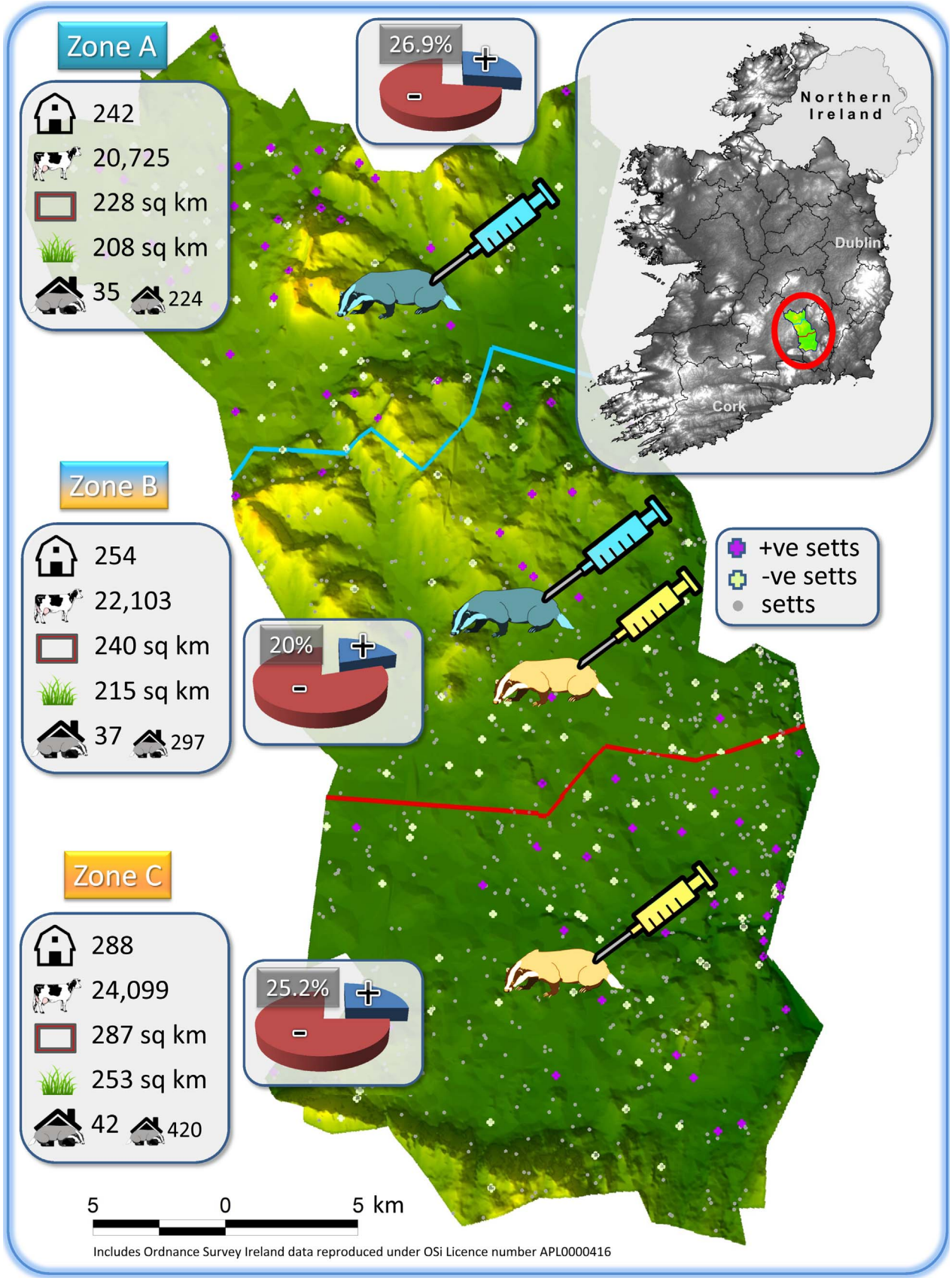

Fig. 1. Topographic map of the Irish badger vaccine field trial showing: number of farms and bovines, zone area and area of farmed grassland (sq km), and number of main and secondary badger setts per zone. From north to south, zones A, B and C indicate vaccine (blue badger) and/or placebo (yellow badger) allocation. Estimated *M. bovis* prevalence in badgers at the end of the first year is shown per zone (pie charts). Badger setts are represented as: all surveyed setts (grey dots), setts with at least one positive badger trapped in the first year (purple cross), setts with at least one negative badger trapped in the first year (light green cross). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)