

Tailgate vaccinology

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Abstract

Vaccination is an important tool to improve herd health as part of an overall biosecurity program. The large number of vaccines available, differences in vaccine efficacy, and diversity of management schemes and production goals can complicate the designing of a vaccination program and emphasizes the need to tailor such programs to the needs of individual clients. There is no single best approach to fashioning bovine vaccine protocols; therefore, it is imperative that the veterinarian understand the differences in vaccine labeling and formulation, and mesh this knowledge with the goals and management scheme of the client in the selection and timing of vaccinations. This presentation will review factors necessary to consider in the formation of vaccination programs, and discuss the application of these factors to both dairy and beef operations.

Résumé

La vaccination est un outil important pour améliorer la santé du troupeau dans le cadre d'un programme global de biosécurité. Le grand nombre de vaccins disponibles, les différences au niveau de leur efficacité et la diversité des systèmes de gestion et des objectifs de production compliquent la planification d'un programme de vaccination et met en lumière le besoin d'adapter de tels programmes aux besoins de chaque client. Il n'y a pas une simple bonne approche pour développer un programme de vaccination chez les bovins. Il est donc impératif que le vétérinaire comprenne les différences d'étiquetage et de formulation des vaccins et incorpore cette connaissance avec les objectifs et le système de gestion du client pour le choix et le calendrier des vaccinations. Cette présentation fait le survol des facteurs qu'il faut considérer dans l'établissement d'un programme de vaccination et discute de l'application de ces facteurs dans l'élevage des bovins laitiers et de boucherie.

Introduction

Vaccination programs for cattle are designed to protect or minimize disease caused by various infectious

organisms. The veterinarian serves an important role in assisting the producer in the design and implementation of a vaccination program that is both cost-effective and effectual in the improvement or maintenance of herd health. Vaccines differ in their immunogenicity, clinical effectiveness, cost, and duration of induced immunity. Likewise, the infection pressure of any given agent on a group of cattle will depend on multiple factors including, but not limited to, the herd management system, housing, age, previous exposure, season, geographic location, and closed/open status of the herd. Consequently, vaccination programs will differ from farm-to-farm to account for these factors in accordance with the production goals of the producer.

Vaccine Label Claims

Licensing and labeling claims for veterinary vaccines are regulated by the USDA APHIS's Center for Veterinary Biologics. The Center is charged with enforcement of the Virus Serum Toxin Act to ensure that available veterinary biologics are pure, safe, potent, and effective. Historically, vaccines have been granted a license under 1 of 5 label claims, depending on the level of protection afforded by the vaccine. The 5 levels of protection, in order of greatest to least protection, are: 1) prevention of infection; 2) prevention of disease; 3) aid in disease prevention; 4) aid in disease control; and 5) other claims. The prevention of infection claim can only be made when vaccines are able to prevent all colonization and/or replication of the target organism in vaccinated and challenged animals. In order to obtain a prevention of disease claim, the vaccine must be shown to be highly effective in preventing clinical disease in challenged vaccinates. Specifically, the entire 95% confidence interval estimate of efficacy must equal or exceed 80%. The third label claim is allowed when disease in challenged vaccinates is prevented by a clinically significant amount, but at a rate that precludes a claim of disease prevention. Vaccines that alleviate disease severity, reduce disease duration or delay disease onset can be labeled as an aid in disease control. Finally, vaccines with demonstrated beneficial effects apart from direct disease control, such as reduced shedding, may make

such claims on the label.

A change to a simpler labeling format is currently under consideration. On April 21, 2014, APHIS published a proposed rule¹ to replace the current 5-tiered label claim system with a single, uniform label format. The comment period on the proposed change is scheduled to close June 20, 2014, with a final ruling expected to follow at some later date. Under the proposed rule, any of the previous label statements would be replaced with the statement “This product has been shown to be effective for the vaccination of healthy animals ___ weeks of age or older against ____”. A summary of efficacy and safety data provided by the licensee to APHIS would be publicly available on the APHIS Center for Veterinary Biologics website; statements referring the user to the web site could be included in marketing and promotional materials. However, the change is not intended to affect currently licensed products as they would not need to be re-licensed under the current proposal.

Modified-Live vs Inactivated Vaccines

Viral and bacterial vaccines may be live or inactivated. Modified-live (MLV) vaccines contain an agent that has been altered to eliminate or minimize its capacity to cause disease while still allowing the agent to infect and multiply in the animal. Inactivated vaccines contain killed microorganisms. In deciding which type of vaccine to use, the veterinarian must take into account the advantages and disadvantages of each vaccine type and the goals of the herd health program to maximize the efficiency and efficacy of the vaccination program. The advantages of 1 type are often the disadvantage of the other. In general, inactivated vaccines are safer with little to no risk of the organism reverting to virulent form and causing disease or spreading from animal to animal. They are more stable in storage, and do not require on-farm mixing which decreases the risk of external contamination. However, they are more likely to result in anaphylactic reactions or cause post-vaccinal lumps, which is of particular concern in show animals and those to be sold as breeding stock. Immunity induced by MLV vaccines generally has a wider spectrum of protection, a more rapid onset, and a longer duration than that induced by inactivated vaccines. Although booster doses of MLV vaccines may be required, 1 initial dose may be sufficient to provide clinical protection for some agents. Thus, the choice of which type of vaccine to use, or a combination of both, will depend on several factors that will vary from farm to farm.

Designing Vaccination Protocols

A well-designed vaccination program is one that maximizes herd health through the prevention of in-

fectious disease in a cost-effective manner. As management styles, production goals, labor availability, and herd immunity status varies between herds, there is no single “best” vaccination program that will work on all farms. Rather, the veterinarian must understand the management and goals of a particular unit and craft a program that is effective, yet also results in a high level of compliance. A program that is not implemented because the producer finds it too complex or too labor intensive will fail to yield the desired benefits and result in frustration for both the producer and the veterinarian. Therefore, it is important to tailor the vaccination protocol to each individual farm rather than design a single program that is then pushed on all clients, regardless of management style.

Evidently, when designing a vaccination program, 1 of the first issues to consider will be which agents need to be included in the program. Perusal of the list of USDA approved vaccines and bacterins yields products for nearly 50 separate agents affecting bovine health, exclusive of autogenous vaccines. Adding to the confusion, several vaccines offer combined protection against several agents. Ultimately, the decision of which vaccines to include in the vaccine protocol will depend on local prevalence of any given disease, herd management style, use of the animals, exposure to other livestock and/or wildlife, and production goals of the unit. With this in mind, most bovine vaccine protocols center on protection against the major viral respiratory pathogens (i.e., bovine respiratory syncytial virus, bovine parainfluenza 3 virus, bovine herpesvirus 1, bovine viral diarrhoea virus), and to a lesser extent, the major bacterial respiratory pathogens (e.g., *Mannheimia haemolytica*). Other antigens may be included in the protocol as determined by the veterinarian and producer. Vaccination protocols should not take the place of a robust biosecurity program; conversely, vaccination should be but a small part of a farm’s biosecurity plan.

Timing of vaccination is another critical component of the vaccination program design. In general, vaccination can be event- or calendar-driven. Examples of event-driven vaccination include vaccination of dairy cows at dry-off or beef heifers 1 month prior to breeding. Calendar-driven vaccination is more commonly practiced in dairy operations and involves vaccinating all eligible animals on a given date (e.g., vaccination of the entire herd with a leptospira bacterin twice a year). Calendar-driven vaccination may result in a higher proportion of the herd being vaccinated; however, some vaccinated animals may not be in the ideal immune state to optimally respond to the vaccine. Timing of the vaccination protocol should be decided in conjunction with the producer as incompatibilities in vaccine timing, labor availability, and management style is a dominant factor in failure of the vaccination program.

Conclusion

In summary, vaccination protocols are an important part of the herd health program. In order to achieve the greatest level of protection in a cost-efficient manner, protocols must be tailored to each individual farm or production unit. Vaccines vary in their level of protection and formulation, and the best vaccine for a particular situation will depend on multiple factors. Factors to consider when designing a vaccine program include the type of farm, management style, local disease pres-

ures, and production goals of the client. Vaccination, as part of a strong biosecurity program, will enhance herd health and profit the client by preventing clinical and subclinical losses.

Reference

1. Viruses, serums, toxins and analogous products: single label claim for veterinary biological products; Notice of proposed rulemaking. *Federal Register* 2014;79:22048-22051.