Structural Equation Modeling in the Assessment of a Vaccine Quality

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This paper presents a structural equation model for the validation of a system for quality assessment of a vaccine against Infectious Bovine Rhinotracheitis. The difficulty in finding cattle herds free of the herpesvirus B0HV-1 raises the need to develop harmonized and standardized tests in laboratory animals to define the consistency from batch to batch of vaccine potency, in a fast and less expensive way to ensure the presence of reliable products on the market. In this regard, it is of interest to verify the consistency of the serological response of laboratory animals with the protection from disease and infection in cattle. This system involves latent variables and complex relationships between variables. Using simulations based on real experiments the structural equation modeling proved to be a useful technique to validate a model that used serological measurements in laboratory animals as an alternative to the classical challenge tests in cattle to evaluate the effectiveness of the vaccines. This methodology allowed exploring the relationship between variables by components to detect the source of lack of fit. It was found that the relationship between the latent variables *Protection to Infection* and *Laboratory Quality* presented a good fit, showing a high correlation between these concepts. Considering the high reliability of the serological variables measured by ELISA for both animal species, it can be inferred that the measurement of these laboratory variables may be useful in predicting vaccine protection. The effect of the latent variable Protection to Infection on *Protection to Disease* was weak but significant. The structural component of the model showed a good fit, thus validating the initial theory of the relationships between latent variables. The possibility of extending the structural equation modeling for vaccine evaluation involving other viruses that affect cattle is suggested.

Key words: latent variable model, measurement model, vaccine potency, Infectious Bovine Rhinotracheitis.