

Setting up an on-farm field trial for producers

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Abstract

Animal health and performance research trials are commonly performed to evaluate ways to improve production efficiency and well-being. The objective will be to highlight how to set up research projects in the field. The research objective establishes the groundwork for the rest of the trial. When selecting which animals to use for the study, the main considerations are the population of animals which a person wants to apply the results. Randomization is a critical part of the research process to make sure the treatment groups are similar at the beginning of the study. Develop a protocol which outlines all the procedures performed and data collected during the study. A 1-2 page summary is sufficient to explain all the concepts for a field study. The most important part of conducting the study is to follow the protocol developed. You need to ensure all data collected are accurate. The reason for conducting the research is to apply the results in the field to make a difference. Before applying, consider the production system where the study was performed, and the study population to determine if results will apply in different production systems. Conducting research in the field can provide valuable insight on which practices impact outcomes of interest.

Key words: design, objective, research

Introduction

Animal health and performance research trials are commonly performed to evaluate ways to improve production efficiency and well-being. Management strategies, product evaluation and food safety components related to animal health, performance and economics are a few of the types of trials able to be performed in animal production systems. There are multiple types of research trials including randomized control trials, prospective/retrospective cohort, cross-sectional, observational, challenge, systematic reviews, meta-analyses, simulation models, algorithm and survey.^{2,4} Each one of these types of trials and analyses are able to answer different types of questions if performed appropriately.

These proceedings will focus on the randomized control trials performed in the field. The objective will be to highlight how to setup research projects in the field by defining the research objective, protocol development, conducting the study, data integrity, statistical analysis and applying the results in the field. These will not be all-comprehensive, but provide overview of important topics to consider when setting up and conducting research in the field.

Defining the research objective

Defining the research objective is one of the most critical parts of a research study. The research objective establishes the groundwork for the rest of the trial. The research objective is the primary question the project plans to evaluate and answer, and is important in identifying the necessary steps needed to conduct the research project. While establishing the plan for materials and methods, one needs to constantly refer to the

research objective to make sure each part is necessary to answer the defined objective. It can be easy when putting together a plan to begin to think about additional information which may be acquired while performing the study. If not careful, more time and effort may be placed on obtaining the additional information and distract from the primary objective.

Creating a secondary objective for a research study is acceptable, as long as the secondary objective does not interfere with the primary objective. The primary objective should not be sacrificed in any way, shape or form to accommodate gathering data for the secondary objective. Consider the secondary objective as a tag-on study to an ongoing research project. The primary objective is the reason the study is being performed, but the secondary objective is being added onto the project with the chance of obtaining information without having to use additional animals for research; thus, trying to maximize research efficiency; however, if the secondary objective interferes with the primary objective, then both objectives are not maximally executed and the entire trial may be ruined. Interfering may include anything from processing a subset of animals additional times to entering a pen to make visual observations and disrupting the natural social structure and behavior patterns animals exhibit.

Protocol development

The protocol provides detail of all steps and practices which will be completed as part of the project. The protocol may include information such as what all products will be administered, data collected at time of enrollment and follow-up, how animals will be randomized to treatment group, will observers be blinded to treatment group, and the experimental unit. More details about these procedures are provided in the rest of the proceedings. Development of the protocol is an iterative process as one frequently reviews and determine what is feasible to execute.

Sample size calculations are recommended to determine appropriate number of animals needed to include in research study.³ There are a lot of estimates which go into the sample size calculation which greatly influence the number of animals required; however, knowledge of the important biological and economical outcomes will allow for more accurate sample size calculations. The researcher should have basic knowledge of anticipated outcomes for the standard (or control) practice. To determine the magnitude of difference, one must consider the biological and/or economical difference needed to implement the new protocol evaluated.⁸ While there are many assumptions which go into the sample size calculation, it is still important to perform prior to conducting the study to determine if appropriate number of animals are available. If the sample size calculation estimates 10,000 animals, but was only planning on for 100 animals, then you need to consider if you want to scale up the size of research study, refine the objective, or consider a completely new study.

Protocol needs to be detailed enough for another research to be able to review and conduct the study. It's also important for the other personnel to be able to comprehend the necessary procedures. Generally, a 1-2 page summary is sufficient to explain all the concepts for a field study. Projects which require a more detailed protocol likely require more oversight and time commitment from the researcher.

Study population selection

The study population is the group of animals which is going to be used for the research study. When selecting which animals to use for the study, the main considerations are the population of animals which you want to apply the results and the availability of desired sample population.¹¹ If the desire is to apply the results in the field to low-risk calves for developing bovine respiratory disease, then the study population needs to be low-risk calves.

Frequently, studies are done in populations with higher incidence of disease to provide more observations for statistical analysis. Low frequency of events, such as bovine respiratory disease, require a much larger sample size to evaluate.⁶ If positive results are observed in a different study population than desired, there is a need to repeat the study with the desired study population. Additional research takes time and money while decisions need to be made in the field. Extrapolation of the results to different populations is commonly done, and requires knowledge of the biological and production system.

Randomization/blocking

Randomization is a critical part of the research process to make sure the treatment groups are similar at the beginning of the study. Randomization is used to prevent selection bias.¹⁰ The act of randomization does not need to be a complicated process. An effective method is to draw a treatment group out of a hat, and assign the first animal able to the first treatment group. The next animal in the chute would be assigned to the next treatment group drawn out of the hat. The sequence would then continue until animal animals are assigned for that group. For the next group of animals to enroll into the study, re-draw the treatment groups out of the hat. Using random numbers to assign animals to a treatment group is also an appropriate method; however, generally requires more complicated enrollment procedure. An important process is to ensure the animals receive the treatment group as expected.

Blocking is a procedure which arranges the experimental unit in groups which are similar to another. Deciding what to block for is determined based on knowledge of biological systems and number of experimental units. Arrival weight has been shown to have significant association with feedlot health outcomes.^{1,7} If doing a smaller study to evaluate health outcomes, you may want to consider using blocking to make sure treatment groups are similar to begin the study; however, the researcher will need to know each individual animal's body weight to block. It may require processing the animals twice to gather the information. If performing larger studies, there isn't as much need to block as the randomization process should allocate animals appropriately; however, there are not firm guidelines when blocking is and is not needed. Knowledge of the amount of variation in the study population and potential impact on outcome of interest is needed.

Table 1 shows an example of blocking animals by body weight to treatment group. These data are from a study which evaluated splitting the distal scrotum during band castration on health and performance outcomes.⁵ Each calf had individual weights collected. Animals were sorted smallest to largest based on body weight collected in a spreadsheet and assigned into blocks. The two lightest weight animals were assigned to one block, the next two lightest calves assigned to next block, and so on. Random numbers were then created, and the smallest random number within each block was assigned to the treatment group in which the scrotum was split during the banding processing. The largest random number within each block was assigned to the group in which the scrotum was left intact during the banding process. Determining which order the treatment groups were assigned to the smallest or largest random number was done by drawing the treatments out of a hat, and the first treatment group drawn assigned to the smallest random number.

Conducting the study

After the protocol is fully developed is the exciting part of conducting the study. The most important part of conducting the study is to follow the protocol developed. A lot of time and thought process was put into the protocol to appropriately evaluate. Any deviations from the protocol need to be documented. You need to ensure all data collected are accurate. If the data are not valid, there is nothing on the statistical analysis side which can correct for the non-valid data.

Statistical analysis

The statistical analysis part is a function to evaluate if the difference observed was due to chance or was real. Knowledge of the study design and protocol is needed for appropriate statistical analyses.⁸⁻¹⁰ There are multiple programs available for statistical analysis (e.g. Excel, R, JMP, SAS, STATA, MatLAB and WinBUGS). Appropriate statistical analysis is also dependent on the type of outcome variable (quantitative or qualitative). Quantitative outcomes are numerical values assigned to outcomes which can be continuous or whole numbers. Qualitative outcomes are subjective scoring systems. Different statistical models are used for different types of outcome variables. Consultation with a statistician is recommended on how to appropriately use some of these programs. Please contact the statistician prior to conducting the study, so they are able to provide any input on development of the protocol.

Application of results in the field

The reason for conducting the research is to apply the results in the field to make a difference. Before applying, consider the production system where the study was performed and study the population to determine if results will apply in different production systems. You need to consider if the research study needs to be repeated in a different production setting or study population before applying outcomes to other systems. When evaluating data and results from different sources, evaluate the data to determine if you arrive at the same conclusions as reported.

Table 1: Example of blocking randomization cattle by body weight to treatment group from distal splitting of scrotum banding study.⁵

Tag	Weight	Block	Random number	Treatment group
2451246	674	1	0.488518538	Intact
2341246	758	1	0.272963243	Split
2591246	846	2	0.426491300	Split
2381246	860	2	0.824348519	Intact
2431246	864	3	0.741665259	Intact
2571246	864	3	0.025331838	Split
2401246	872	4	0.547756080	Intact
2291246	884	4	0.411813412	Split

Conclusions

Conducting research in the field can provide valuable insight on which practices impact outcomes of interest. You need to take the time to develop, review and refine the protocol prior to conducting the study. Knowledge of the capabilities of the crew and biological systems are necessary for appropriate execution.

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