

Warm Up Quiz

Which of the following is a method of controlling bias?

1. Blinding
2. Randomization
3. Multivariable statistical analysis
4. Standardization of procedures
5. All of the above
6. None of the above

Decisions on dairies/feedlots should be evaluated by?

1. Benchmarking
2. Guessing
3. Evidence Based medicine
4. Randomized commercial field trials

What do you hope to learn by the end of the day today?

1. Nothing
2. How to interpret field trials
3. How to conduct and interpret field trials
4. How to analyze multivariable repeated measures logistic regression and/or Cox proportional hazards models with time dependent covariates

Issues when designing, conducting, and analyzing field trials

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Types of Study Designs: Descriptive

- Case Report
- Case Series
- Survey

These are relatively easy to do, but offer little "proof", and may or may not be related to your world

Types of Study Designs: Analytic

- Observational
 - Cross-sectional
 - Cohort
 - Case-control
- Experimental
 - Laboratory
 - Controlled Trials

Which type of study most regularly appears in JAVMA or CVJ?

1. Descriptive
2. Observational
3. Experimental

<u>Observational</u>	<u>Difficulty?</u>	<u>Strength of Proof?</u>	<u>Real World?</u>
Cross-sectional	moderate	moderate	Moderate
Cohort	high	high	Very high
Case-Control	moderate	moderate	high
<u>Experimental</u>			
Laboratory	moderate	Very high	Low
Controlled Trial	high	Very high	Very High

CAUTION!

- Bad Data is worse than No Data
 - Inference from Bad Data is likely worse than "guessing"

Wrong over and over
versus

Right sometimes, wrong sometimes

- Controlled Field Trials are not for every dairy/feedlot or every veterinarian in every situation...

8 Steps to Conducting Field Trials

1. Objective
 1. FUNDING SOURCE
2. Hypothesis
3. Define Study Population/Design
4. Sample Size
 1. ACTUAL FUNDING
5. Allocation of subjects
6. Data Collection/Measuring the Outcome(s)
7. Analysis of Data
8. Interpretable presentation of findings

1. Objective of the study

- Want to learn more about something...

2. Testable Hypothesis

- Null hypothesis
 - $A = B$
 - One-sided or two?
- Alternative hypothesis
 - $A \neq B$

3. Define Study Population/Design

- To what do you wish to generalize the results?
- What is unit of analysis/experimental unit?

300 cows/pen; 4 pens;
want to evaluate 4 feed ingredients.
What is sample size/treatment group?

- 1
- 4
- 300
- 1200

4. Sample Size

**Sample Size Considerations:
application for disease monitoring
& considerations for field trials**

- The magical 12-15 samples:
 - Metabolic Testing (NEFA/BHBA)
 - Lepto hardjo-bovis testing
- The unfortunate >300 observations...
 - Repro performance trials
 - Antibiotic efficacy

Sample Size Considerations

and a couple of other things...

I need to know...

- Is my repro getting better or worse?
 - Is my treatment protocol working?
 - Is there a difference between treatment groups
- Do I have X disease in my herd?
- What proportion of my cows have Y disease?

Sample: A partial selection of animals from a larger group (herd) from which blood, tissues, etc are collected for testing. A judgment will be made about the larger group based on the findings from the sample.

Statistical Sampling:

- Tells us how lazy and cheap we can be:
 - Not enough time to see all the cows
 - Not enough money to "test" all the cows
- BUT, we're vets and try to make money by being correct at least some of the time...
- So we learn how to sample!

Sampling types:

- Simple Random
 - Unbiased and independent
- Systematic
- Targeted
- Stratified
- Convenience
- Haphazard

5. Sampling / Allocation types:

- Haphazard
- Convenience
- Stratified
- Systematic
- Simple Random
 - Unbiased and independent
 - Every individual has an equal chance of being in the sample

6. Data Collection/Measuring the Outcome(s)

- Case definitions
- Bias
- Blinding
- Choosing the important ones

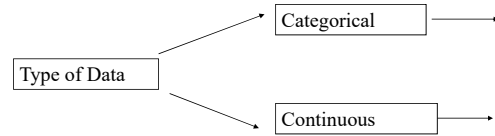
7. Data Analysis

- Summary/Descriptive Data
- Hypothesis Testing
- Decision Making

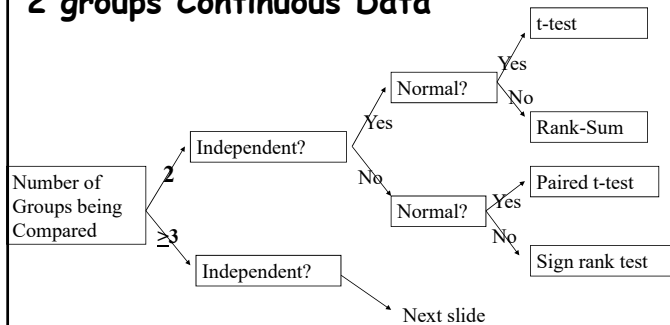
Steps for Data Analysis

1. Check distribution of data
 - Good time to find errors in data entry
2. Decide what analysis method to use
3. Evaluate how well assumptions are met
 - e.g. 2 independent samples, number of subjects
4. Interpret results in light of following:
 - Was method appropriate?
 - Is the result precise (or was sample size adequate)?
 - What are potential sources of bias?
 - Confounding, selection of sample, data recording etc.

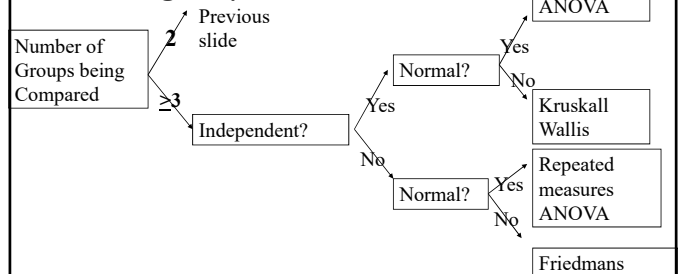
Approach to Data



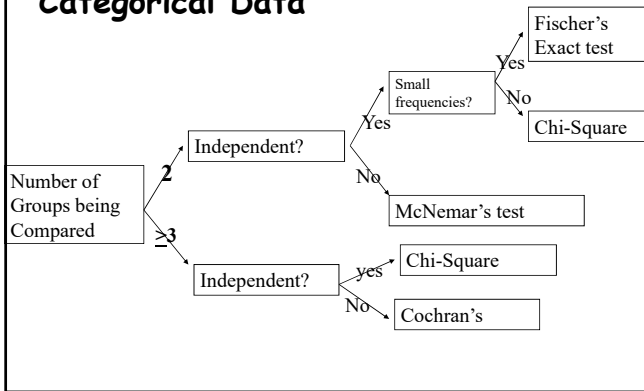
2 groups Continuous Data



≥ 3 groups Continuous Data



Categorical Data



Errors in Hypothesis Testing

Accept Null Hypothesis	Null Hypothesis	True
Accept Null Hypothesis	Alternative Hypothesis	Type II (beta)
Reject Null Hypothesis	Null Hypothesis	Type I (alpha)
Reject Null Hypothesis	Alternative Hypothesis	True

Do you think you can help your clients with a randomized field trial?

1. Yes
2. No
3. Maybe

Do you think you can conduct a randomized field trial?

1. Yes
2. No
3. Maybe

Effect of pre-milking stimulation on milking performance

Effect of forestripping on milking performance

• Introduction:

- Anecdotal consensus that fore-stripping is beneficial
(e.g. Rasmussen et al, NMC, 2000)
- Some peer-reviewed literature disputes this claim
(e.g. Wagner and Ruegg, JDS, 2002)
- Some models show increased parlor throughput with little udder prep
(e.g. Thomas et al, JDS, 1996)

Effect of forestripping on milking performance

Question of Interest:

What is appropriate fore-stripping?

Does it matter at all?



Testable Hypothesis(es)...

- Null hypothesis
 - One-sided or two?
- Alternative hypothesis

Effect of forestripping on milking performance

Materials and Methods

- Dairy in NYS
 - Freestall dairy with 2000 lactating cows
 - Parlor milked 3x
- Cows **randomized** to 1 of 2 treatment groups
 1. Pre-dip only
 2. Pre-dip and 3 strips all 4 quarters

Issues to consider when doing trials...

Materials and Methods

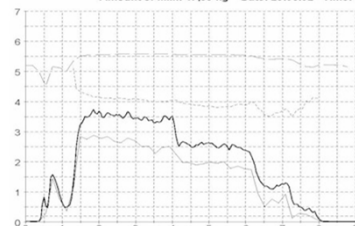
- Allocation of subjects to treatment group...
 - Simple Random
 - Unbiased and independent
 - Systematic
 - Targeted
 - Stratified
 - Convenience
 - Haphazard

Effect of forestripping on milking performance

Outcomes measured via Lactocorder®:

Cow-side continuous mass-flow meter

Flow [kg/min] Herd Number: 00092083 Animal: 311 000000
Amount of Milk: 17.33 kg Date: 25.08.02 Time: 1



Effect of forestripping on milking performance

Materials and Methods

- Milking Procedure:
 1. Start Lactocorder
 2. Pre-dip, Start Stop-Watch
 3. Fore-strip or not according to randomization
 4. After 60 seconds, Wipe all teats
 5. Attach milking unit 90 seconds after pre-dip
 6. Stop Lactocorder when unit is removed via ATO

Effect of forestripping on milking performance

Outcomes measured via Lactocorder®:

1. % Bimodal Milk Flow
2. Total Unit on Time
3. Milk



Sample Size

- Categorical Outcomes
- Continuous Outcomes

Input of DATA:	RESULTS:
Proportion in population 1 (P1): 50	Sample size per treatment group:
Proportion in population 2 (P2): 45	One-Tailed: 135
Level of Confidence (C): 95%	Two-Tailed: 172
Power (P): 80%	

Input of DATA:	RESULTS:
Expected mean in group 1: 5	Difference between means: 0.500
Expected mean in group 2: 5.5	Level of Confidence (C): 95%
Expected Standard Deviation: 1.5	Power (P): 80%

Effect of forestripping on milking performance

Materials and Methods

- Analysis
 - Univariable Analysis
 - Multivariable Analysis

Effect of forestripping on milking performance

Results: summary stats

- Total cow-milkings:
- Cow-milkings/treatment group:
- Parity:
- DIM:

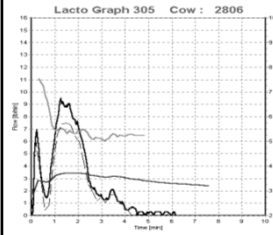
Effect of forestripping on milking performance

Parameter	No forestrip (n=___)	3 strips, 4 quarters (n=___)
% Bimodality		
Unit on time (min)		

Effect of forestripping on milking performance

Results

Bimodal milk flow curves were _____ in _____ group; RR = _____ (CI = _____)



Effect of forestripping on milking performance

Discussion:

- Pre-milking stimulation via forestripping is...

Effect of forestripping on milking performance

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