PRACTICAL BIOSTATISTICS FOR PHARMACISTS: ENHANCING CLINICAL DECISION-MAKING

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DISCLOSURES

Faculty

Amanda Grady, faculty for this activity, have no relevant financial relationship(s) with ineligible companies to disclose.

Planners

None of the planners for this activity have any relevant financial relationships with ineligible companies to disclose.

PRE-TEST

1. What is true for normally distributed data?
2. When is an assessment of power necessary for interpretation of a study?
3. When can a student *t*-test be conducted?
4. True or False: Risk and odds can be used interchangeably.

OBJECTIVES

Upon completion of this activity, pharmacists should be able to:

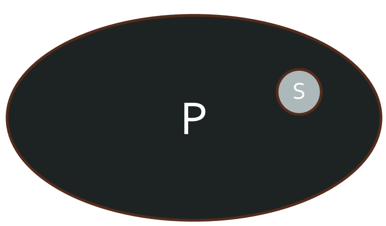
- Differentiate among core concepts of inferential statistics (eg, confidence intervals, type 1 and type 2 error, statistical power, statistical significance)
- Evaluate the appropriate statistical test when given data points

TYPES OF DATA AND VARIABLES

POPULATION VERSUS SAMPLE

Population – large, unobserved collection of N (all possible) patients

Sample – subset of *n* patients selected from the population



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TYPES OF DATA

Discrete — Nominal, Ordinal

Continuous — Interval, Ratio

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DISCRETE DATA

- Nominal ("categorical") variables **Examples: mortality, cardiovascular event**
  - Categorical names assigned (eg, "yes" or "no")
  - Number or code then assigned to make data numeric
  - No arithmetic relationship
- Ordinal variables **Examples: pain scale, Hamilton Depression Rating Scale (HAM-D)**
  - Predefined number of categories with an implied rank
  - Distance between categories is not necessarily equal

CONTINUOUS DATA

- Constant, defined units of measure
- EQUAL distance between increments
- Interval scale **Examples: temperature in °C or °F, dates**
  - Arbitrary "0" assigned
  - Difference between 2 values is meaningful and consistent
- Ratio scale **Examples: heart rate, hemoglobin A1c**
  - Absolute "0" exists

VARIABLES

- Characteristic being observed or measured
- Independent (or predictor) variable
  - Intervention
  - Controlled by the investigator
- Dependent (or response) variable
  - Outcome of interest in the trial (eg, cure rate)
  - Changes observed by the investigator in response to the independent variable

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DESCRIPTIVE & INFERENTIAL STATISTICS

<u>**DESCRIPTIVE**</u> & INFERENTIAL STATISTICS

GENERAL OVERVIEW

Statistics is "the acquisition of knowledge through the process of observation"

- Means of explaining and/or identifying variability within sample data
- Method of collecting, classifying, summarizing, and analyzing
- Quantifies probability and extent the independent variable may be impacting the dependent variable (or outcome)
- Two types of statistics include **Descriptive** AND **Inferential**

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DESCRIPTIVE STATISTICS

- Presents, summarizes, and organizes data in a useful form
- Describes data *without* reaching any conclusion(s)
- Includes measures of central tendency and variability
- Central tendency measures include:
  - Mean
  - Median
  - Mode

Normally-Distributed Data (mmHg)
60, 63, 65, 67, 70
Mean = 65; median = 65

Right-Skewed Data (mmHg)
58, 60, 63, 65, 115
Mean = 72; median = 63

Key point: When data are normally distributed, mean = median = mode.

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DESCRIPTIVE STATISTICS

- Variability measures include:
  - Range
  - Interquartile range (IQR)
  - Percentile
  - Coefficient of variation (CV)
  - **Standard deviation (SD)**
  - **Standard error of the mean (SEM)**

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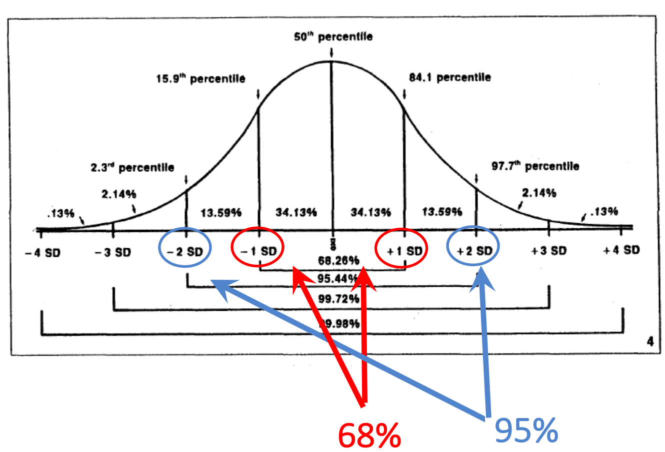
DESCRIPTIVE STATISTICS

- Standard deviation (SD)
  - Quantifies variation of sample data around the mean
  - Mathematically, SD = √ variance
  - Relevant only for normally distributed, continuous data



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DESCRIPTIVE STATISTICS

- Standard error of the mean (SEM)
  - Frequently referred to as "standard error"
  - Quantifies precision of population mean estimate based on sample mean observed
  - Mathematically, SEM = $\frac{\mathrm{SD}}{\sqrt{(n)}}$, SD = standard deviation, n = sample size
  - Decreases as sample size increases, indicating the estimate for the population mean becomes more precise
  - Directly proportional to width of the confidence interval (CI) for the sample mean

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DESCRIPTIVE & INFERENTIAL STATISTICS

DESCRIPTIVE & **INFERENTIAL** STATISTICS

INFERENTIAL STATISTICS

- Tests the validity of inferences or generalizations made about the overall population based on data observed for a representative sample
- Hypothesis testing
  - Null hypothesis (H_0)
    - No difference between groups
  - Alternative hypothesis (H_1)
    - A difference exists between groups
  - Researchers either REJECT or FAIL to REJECT H_0

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UNDERSTANDING STATISTICAL ERRORS

- Type I error (α)
  - Probability of concluding there is a difference when there is not one
  - "False positive rate"
- Type II error (β)
  - Probability of concluding there is no difference when there is a difference
  - "False negative rate"

Key point: α and β are set by researcher *a priori*

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KNOWLEDGE CHECK

Real World Truth

Study Results	H_0 is true (No difference)	H_0 is NOT true (Difference exists)
Accept H_0 (No difference)	✓	Type II error β
Reject H_0 (Difference exists)	Type I error α	✓

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DEMYSTIFYING THE *P*-VALUE

- Definition: probability of obtaining a result at least as extreme as the observed result when there is no difference between groups
  - How incompatible data are with the null hypothesis
- Computed from data analysis
- Size of *P* value is not correlated with importance of result
- *P* value and α are NOT synonymous

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DEMYSTIFYING THE *P*-VALUE

Traditional Mindset	ATOM Mindset
• Base "statistical significance" solely on the P value ○ Reject H_0 when P value < α ○ Convention is to set α at 0.05	• Evaluate statistics in a holistic manner ○ **A**ccept uncertainty ○ Be **T**houghtful ○ Be **O**pen ○ Be **M**odest

Wasserstein, et al. The American Statistician. 2019;73:Sup1:1-19.

STATISTICAL POWER

- Definition: ability to detect a difference between treatment groups if a difference truly exists
- Mathematically, Power = 1 – β
- Convention is to set power at 80% to 90%
  - Willing to accept 10% to 20% chance of missing a true difference between groups
- Insufficient power causes type II error

Key point: critical to consider power if no difference was found; irrelevant to consider if a significant difference was observed.

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STATISTICAL POWER

- Key factors influencing study power include:
  - **Sample size**: number of patients
  - **α**: threshold for type I error set by investigator
  - **β**: threshold for type II error set by investigator
  - **Effect size**: magnitude of anticipated difference between groups
  - **Standard error**: variability in population being studied
- Sample size calculated *a priori* to aim for adequate power

$$\uparrow \text{Sample size} = \frac{(Z_\alpha + Z_\beta)\ x\ \text{Standard Dev} \uparrow}{\text{Effect Size} \downarrow}$$

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CONFIDENCE INTERVAL (CI)

- Definition: range of values that contains the true but unmeasured estimate for the population
- Estimates effect size and variability around the observed estimate of effect
- General convention is to calculate a 95% CI
- If the experiment were repeated 100 times, 95% of the time the calculated 95% CI would include the true estimate of effect for the larger population

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CI = confidence interval
SEM = standard error of the mean
HR = hazard ratio

CONFIDENCE INTERVAL

- Mathematically,

$$\mu = X \pm 1.96 * SEM$$

where μ is the population parameter estimate, X is the observed point estimate for the sample, 1.96 is the confidence coefficient (based on α chosen *a priori*), and SEM is the standard error of the mean.

- Commonly used for normally distributed continuous data, but can also be calculated for HR, medians, odds ratios (OR), regression slopes, relative risks (RR)
- Does the CI indicate statistical significance? **YES!**

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CONFIDENCE INTERVAL

- Scenario 1 (ratio world) **Hazard ratios, odds ratio, relative risk**
  - A result is statistically significant if the CI does NOT contain 1 for "ratio" outcomes
  - Examples?
- Scenario 2 (non-ratio world) **Blood pressure, A1c, headache free days**
  - A result is statistically significant if the CI does NOT contain 0 for "interval" outcomes
  - Examples?

CONFIDENCE INTERVAL, POWER, AND SAMPLE SIZE

- Remember, width of the CI is directly dependent on SEM
- *And* SEM = $\frac{\text{SD}}{\sqrt{(n)}}$
- The width of the CI as sample size (power) **increases**
- The width of the CI as sample size (power) **decreases**

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CONFIDENCE INTERVAL, POWER, AND SAMPLE SIZE

- Remember, width of the CI is directly dependent on SEM
- *And* SEM = $\frac{\text{SD}}{\sqrt{(n)}}$
- The width of the CI **decreases** as sample size (power) **increases**
- The width of the CI **increases** as sample size (power) **decreases**

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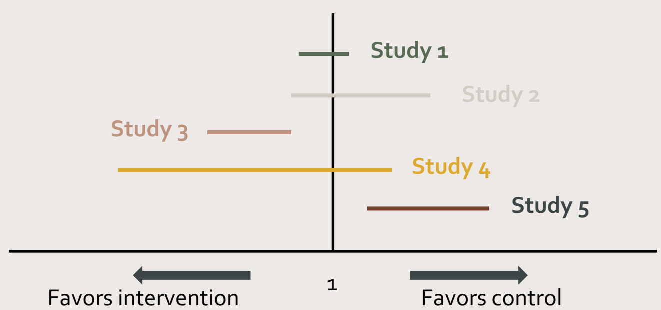
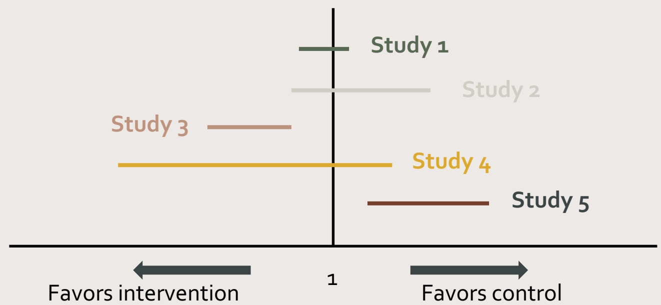
KNOWLEDGE CHECK



Assuming the outcomes were *rate ratios*, which study (or studies) demonstrate a statistically significant difference between the intervention and control groups?

Which study likely had the least number of patients enrolled? Why?

KNOWLEDGE CHECK



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Studies 3 & 5

Which study likely had the least number of patients enrolled? Why?

Study 4

STATISTICAL TESTS

CRITICAL CONSIDERATIONS

Always **important to assess and answer the following to determine an appropriate statistical tests**

- Normal or non-normal distribution?
- Paired or independent samples?
- Study design parallel, pre-post, or crossover?
- Necessary to control for 1 or ≥ 2 independent variables or "confounders?
- Time-to-event analysis?

STATISTICAL TESTS

Parametric tests

Continuous, normally distributed data

Nonparametric tests

Not normally distributed data

Most commonly categorical and ordinal data

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ANCOVA = analysis of variance
ANCOVA = analysis of covariance

PARAMETRIC TEST EXAMPLES

Test	# of groups	Groups related?	Confounders?
Student *t*-test	2	Independent	None
Paired student *t*-test	2	Paired	None
One-way ANOVA	≥ 3	Independent	None
Two-way ANOVA	≥ 3	Independent	1 confounder
Repeated Measures ANOVA	≥ 3	Related	None
ANCOVA	≥ 2	Independent	≥ 1 confounder

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NONPARAMETRIC TEST EXAMPLES

Test	# of groups	Groups related?	Type of data	Confounders?
Kruskal-Wallis test	≥ 3	Independent	Ordinal	None
Friedman test	≥ 3	Crossover	Ordinal	None
Chi square (χ2) test	≥ 2	Independent	Categorical/nominal	None
Fisher's Exact test	≥ 3	Independent	Categorical/nominal	None
Mantel-Haenszel	2	Independent	Categorical/nominal	1 confounder
Logistic regression	≥ 2	Independent	Categorical/nominal	≥ 2 confounder
McNemar's test	2	Paired/matched	Categorical/nominal	None
Cochran's Q test	≥ 3	Related	Categorical/nominal	None

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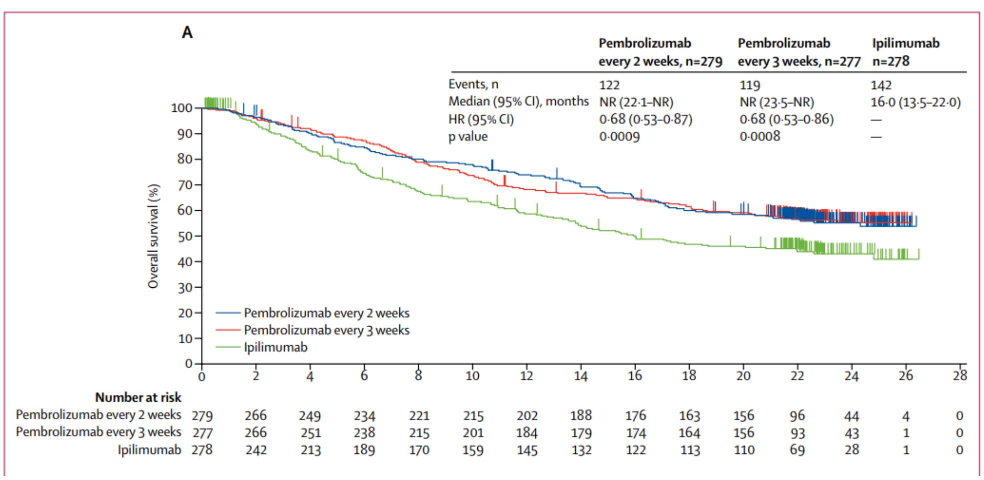
TIME-TO-EVENT ANALYSES

KAPLAN-MEIER ANALYSES



Schachter J, et al. Lancet. 2017 Oct 21;390(10105):1853-1862.

STATISTICAL TESTS IN CONJUNCTION WITH SURVIVAL CURVES

- Objective way to determine if there is a statistically significant difference in survival curves between study groups
- **Log-rank test**
  - Alternatively called the Mantel-Cox method
  - Equal weight of death at any time point during trial
- **Gehan-Breslow-Wilcoxon method**
  - Alternatively called Wilcoxon's test
  - More weight given to death earlier in the trial

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STATISTICAL TESTS IN CONJUNCTION WITH SURVIVAL CURVES

- **Cox's proportional hazards regression model**
  - Assumes the proportion (or ratio) of hazard between patient groups is constant over time
  - Identifies differences between survival curves while simultaneously adjusting for the impact independent covariates may have on time-to-event
  - Independent covariates are fit in model and given different weights to generate an overall HR
  - Conditional probability an event will occur given survival up to that point in time

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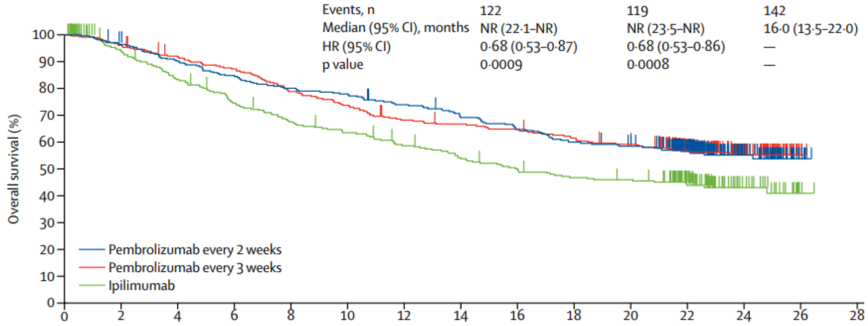
KAPLAN-MEIER ANALYSES

A

	Pembrolizumab every 2 weeks, n=279	Pembrolizumab every 3 weeks, n=277	Ipilimumab n=278
Events, n	122	119	142
Median (95% CI), months	NR (22·1–NR)	NR (23·5–NR)	16·0 (13·5–22·0)
HR (95% CI)	0·68 (0·53–0·87)	0·68 (0·53–0·86)	—
p value	0·0009	0·0008	—



Number at risk

Pembrolizumab every 2 weeks	279	266	249	234	221	215	202	188	176	163	156	96	44	4	0
Pembrolizumab every 3 weeks	277	266	251	238	215	201	184	179	174	164	156	93	43	1	0
Ipilimumab	278	242	213	189	170	159	145	132	122	113	110	69	28	1	0

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ESTIMATES OF EFFECT

COMMONLY REPORTED "RATIO" ESTIMATES OF EFFECT

Estimate of effect	Definition
Relative Risk or Risk Ratio (RR)	Comparison of **absolute risk** in exposed/unexposed group
Odds Ratio (OR)	Comparison of **odds** of an event occurring in exposed/unexposed group
Hazard Ratio (HR)	Comparison of **hazard rate** in exposed/unexposed group

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RISK VERSUS ODDS

Image from: https://www.kickstarter.com/projects/padbury/atelier-playing-cards

... of drawing a heart from a 52-card deck?

$$\text{Risk} = \frac{\text{probability of an event occurring}}{\text{probability of } \textbf{ALL} \text{ possible events}} = \frac{13}{52} = 0.25$$

$$\text{Odds} = \frac{\text{probability of an event occurring}}{\text{probability of an event } \textbf{NOT} \text{ occurring}} = \frac{13}{39} = 0.33$$

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2 X 2 CONTINGENCY TABLE BASICS

Primary Outcome

Treatment Group

	Yes	No	Total
Exposed	A	B	A + B
Unexposed	C	D	C + D

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RELATIVE RISK AND ODDS RATIO

RR	OR	Interpretation
0.75	0.75	25% reduction in risk/odds
1	1	No difference in risk/odds
1.5	1.5	50% increase in the risk/odds
3	3	3-fold (200%) increase in the risk/odds

POST-TEST

1. What is true for normally distributed data?

- The data are nominal (ie, categorical)
- The data have an equivalent mean, median, and mode
- The data are nominal
- The data have a standard deviation within normal limits

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POST-TEST

2. When is an assessment of power necessary for interpretation of a study?

- Suspicion of type 1 error in the study
- No difference was found between the intervention and control group
- A difference was found between the intervention and control group
- Study did not provide confidence intervals, only a statistically significant *P*-value

POST-TEST

3. When can a Student *t*-test be conducted?

- 2 paired groups, ordinal data
- 3 independent groups, nominal data
- 3 paired groups, continuous data
- 2 independent groups, continuous data

POST-TEST

4. True or False: Risk and odds can be used interchangeably.

- True
- False

REFERENCES

Kansas Pharmacists Association // 2025 Annual Meeting & Trade Show August 22-24 // Lawrence, KS

THANK YOU!

Questions?
You can reach me at

Amanda Grady
agrady2@kumc.edu
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