2020 Research Boot Camp Series

Presented by:
Research in Outcomes for Children's Surgery (ROCS)
Center for Children's Surgery

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Day 3:
Data Analysis and Results

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Series Schedule

- Day 1, Friday August 7th : "Designing Your Study and Protocol"
  - Study Design
  - Research Questions and Aims
- Day 2, Friday August 15th : "IRB Submission and Data Collection"
  - Human Subject Research
  - Required Training and Submission Guidelines
  - Database Variable Types
  - Data Management and Database Building: REDCap
- Day 3, Friday August 21st : "Data Analysis and Results"
  - Working with a Statistician
  - Preparing Data for Analysis
  - Presenting Your Results

Steps to Complete a Scholarly Project

STUDY DESIGNS

PROTOCOL AND IRB APPLICATION

DATA COLLECTION

DATA ENTRY & CLEANING

ANALYZE & INTERPRETATION OF RESULTS

Working with your Biostatistician

Overview

1. Involve us early
2. Education
3. Collaboration
4. Sample Size
5. Time
6. Scruples
7. Acknowledgement

1: Involve Us Early

- Involve the biostatistician early, starting with the design phase of your research

- Reach out to us early and often!

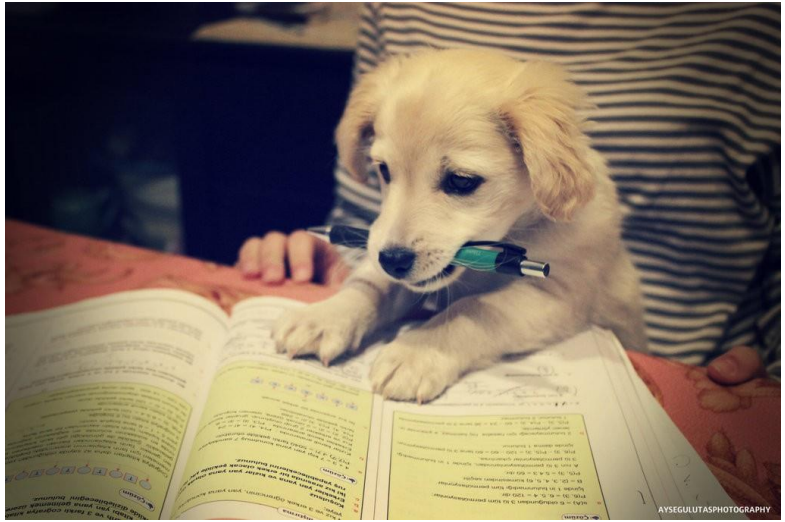
1: Involve Us Early

We Can Help:

- Be a sounding board for research ideas
- Identify the study question and specific aims
- Develop an analysis plan
- Calculate power and sample size
- Implement an analysis plan
- Provide:
    - results and methods of the analysis
    - statistical language for papers and proposals

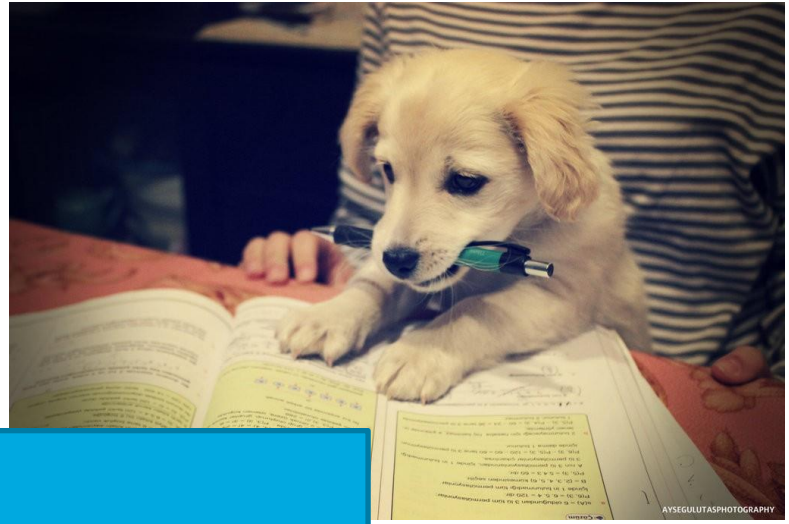
2: Education

- Plan for two-way educational process
- Often need to teach the biostatistician about your field of inquiry- disease process, anatomy, measurements/key variables
- Provide the biostatistician with background articles in your field



2: Education

- Plan for two-way educational process



We are excited to learn about your topic!

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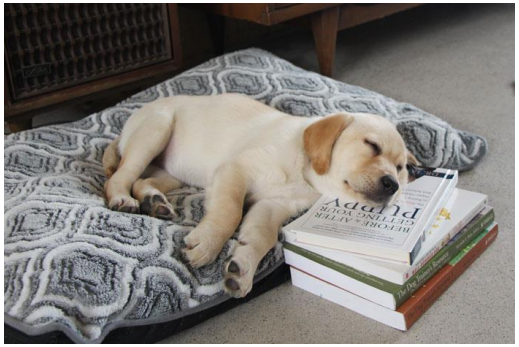
2: Education

- Do I have more than one primary outcome?
- Which of my outcomes is the focus of interest?
- Do I have preliminary data from previous studies?
- What does the literature review tell me I could expect in my control group?

2: Education



- What size of difference am I likely to observe?
- Do I have a restriction on patient numbers (due to timescale, rare disease, etc.)?
- What kind of data do I have?

3: Collaboration

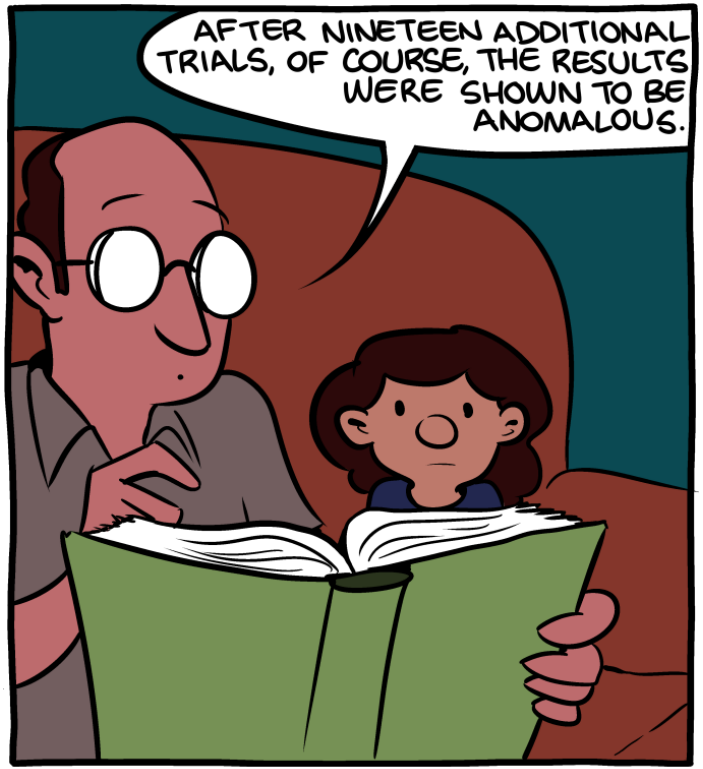
The biostatistician should collaborate in all parts of protocol development, not just the statistics

- Background
- Objectives
- Basic study design
- Study population
- Stratification/randomization
- Definition of treatments/endpoints
- Baseline/follow-up data collection
- Quality control
- Sample Size
- Statistical Analysis
- Organization
- Budget

4: Sample Size

To estimate sample size, you will need to know:

- Primary Hypothesis
- Effect size to be detected
- Study design
- Significance Level
- Outcome Measures
- Power
- Types of analyses
- Drop-out rate
- Estimated expected outcome in control group



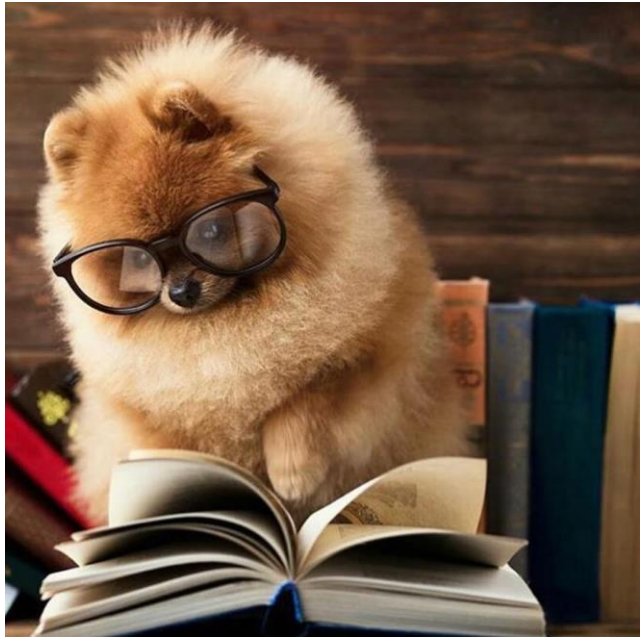
"The Tortoise And The Hare" is actually a fable about small sample sizes.

4: Sample Size

- Feasibility:
  - Are the numbers doable?
  - Do you have the time it will take to get that number?
- Everything is related:
  - Given a sample size and power, what is the effect size I can detect?
  - Given an effect size and sample size, what is the power?
- Ethics and safety of sample size

5: Time

- You need to give the biostatistician time to learn and work through the solutions
- They are typically working on a number of projects simultaneously
- Their time is usually much in demand



5: Time

- Plan ahead!
- We need at least 4 weeks from receiving data
    - **Your project is not our only project**
- Timing can change depending on data quality and unforeseen complexities

Request	General Timeframe
Power/Sample size alone	5-10 hours
Writing proposal and analysis plan	20-40 hours
Analysis (depending on complexity)	40-120 hours +

6: Scruples

Beware:

- Do not go on a fishing expedition with your biostatistician. Stick to the protocol objectives
- “If you torture the data enough, they will confess”

7. Authorship and Acknowledgement

- The biostatistician should be considered a **co-investigator**
- Budget for their time in grants
- Collaborate regularly with them throughout the study
- Consider them as co-authors on final papers- **usually 2nd author**
- Authorship guidelines : http://www.ucdenver.edu/academics/colleges/PublicHealth/research/centers/CBC/grants/Pages/Authorship.aspx

Steps to Complete a Scholarly Project

STUDY DESIGNS

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DATA COLLECTION

DATA ENTRY & CLEANING

ANALYZE & INTERPRETATION OF RESULTS

PUBLICATIONS

When it comes to your manuscript, we are here for you!

Manuscript Phase

In the analysis/publication phase:

- Talk with your biostatisticians about the most appropriate statistical analysis and data interpretation
- We value your input and always welcome questions!

Tables & Figures

- Tables and figures should be self-explanatory
- Avoid crowdedness and use clear symbols
- Consult biostatistician to create tables and figures
- Use other published papers as a guide

Methods & Results

- Rely on your biostatistician for these sections
- Takes biostatistician time to write up
- Always ask questions!

Questions?

Steps to Complete a Scholarly Project

STUDY DESIGNS

PROTOCOL AND IRB APPLICATION

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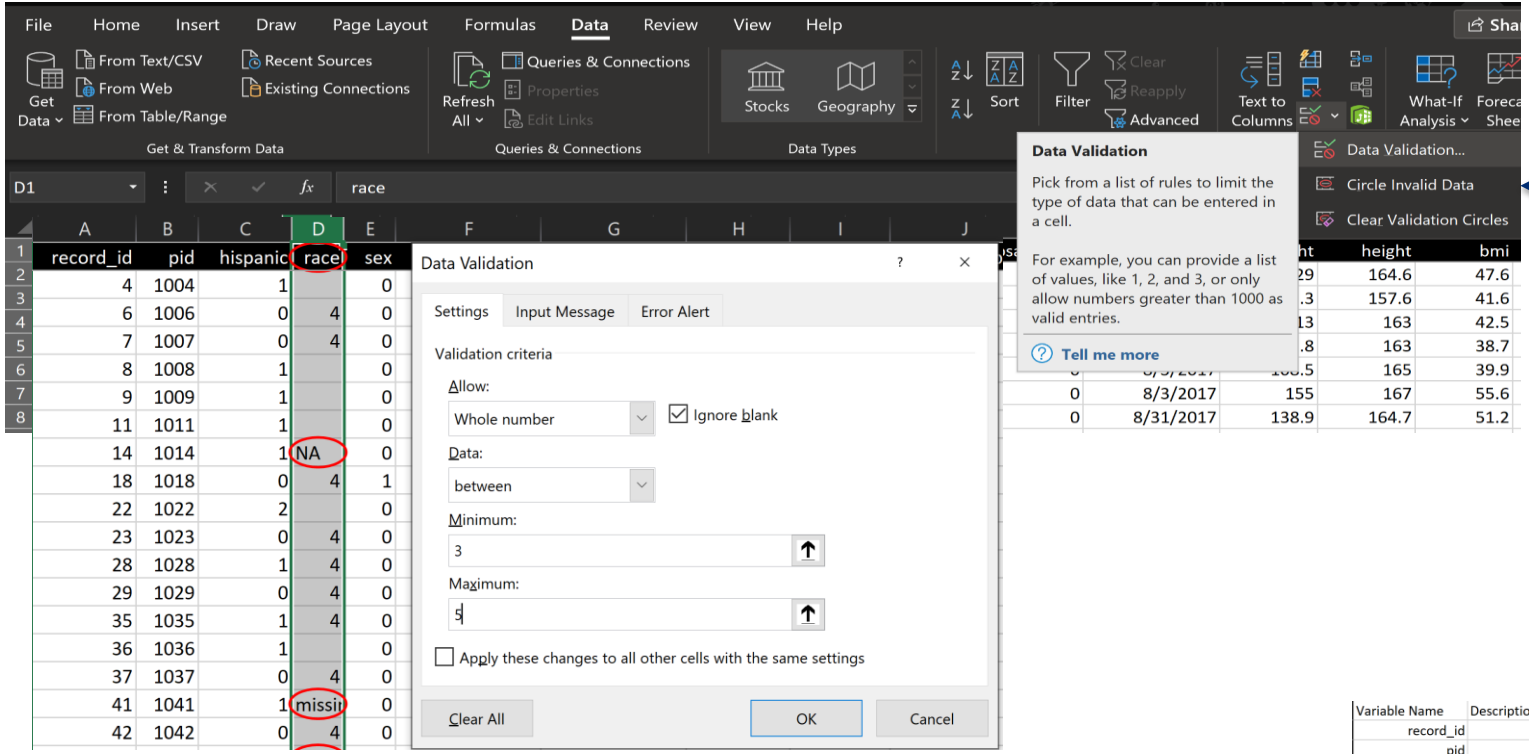
Getting Data Ready for your Statistician

First Step: Data Validation



Note: need to click after creating validation to see issues!

Variable Name	Description	Levels/Categories
record_id	record_id	
pid	pid	
hispanic	hispanic	1 = yes, 2 = no
race	race	3 = black, 4 = white, 5 = other
sex	sex	1 = male, 2 = female
dob	date of birth	
date_appt_1	date of first appt	
age	age at surgery	
insur_type	insurance type	1 = public, 2 = private, 3 = none

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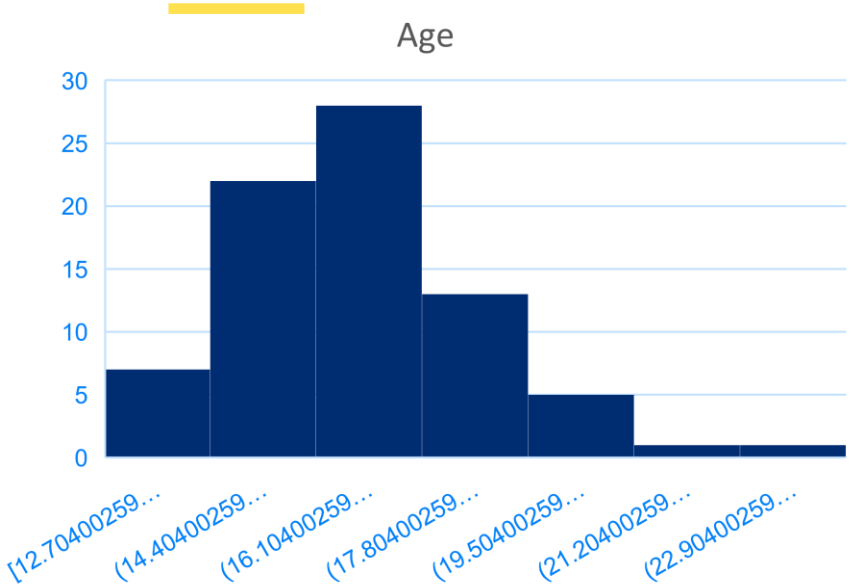
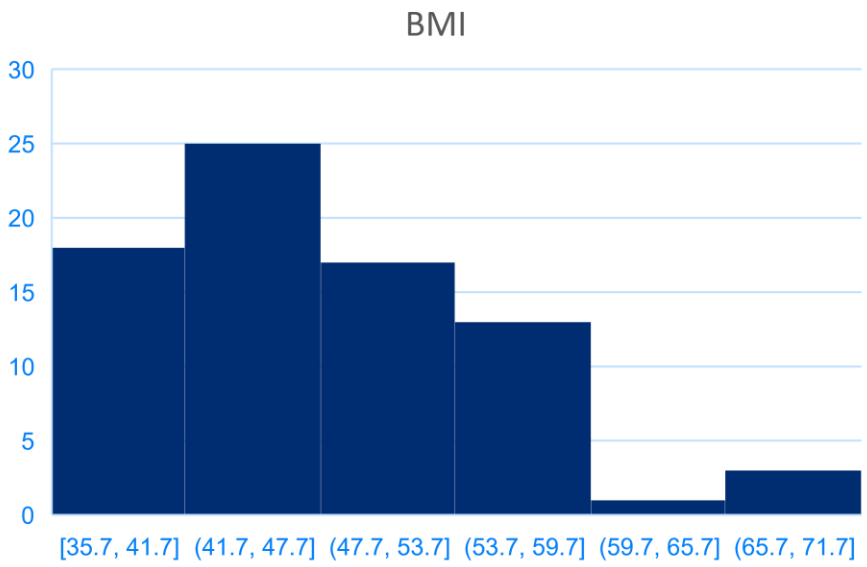
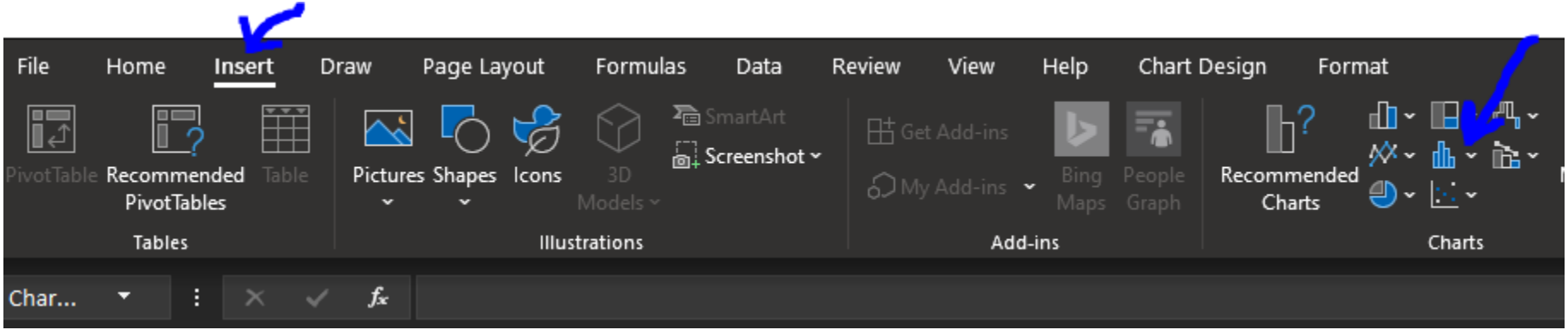
Plot your data!





How to make figures in case you need it:

- Highlight cell contents of the variable that you'd like to graph:



When you can do things on your own

- ✓For data cleaning and data validation
- ✓Check for missing data
- ✓Basic summary statistics only (no statistical testing)
- ✓When sample size is very large
- ✓When all data variables are normally distributed. Plot your data!
- ✓When all categorical variables have >5 individuals in all categories

When you can do things on your own

- ✓ For data cleaning and data validation
- ✓
- ✓
- ✓
- ✓
- ✓

⚠ Otherwise: ⚠

CONSULT A BIOSTATISTICIAN

Presenting your data: Table 1

ELSEVIER

Journal of Clinical Epidemiology 114 (2019) 125–132

Journal of Clinical Epidemiology

ORIGINAL ARTICLE

Who is in this study, anyway? Guidelines for a useful Table 1

Eleanor Hayes-Larson[a,*], Katrina L. Kezios[a], Stephen J. Mooney[b,c], Gina Lovasi[d]

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[b]*Harborview Injury Prevention & Research Center, University of Washington, Seattle, WA, USA*
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Accepted 10 June 2019; Published online 20 June 2019

Components of a Table 1.

		Columns	Rows	Cells
Basic Table 1 considerations		Total column *(EV)* Stratify by exposure (RCT/cohort/cross-sectional) or disease (case-control) *(IV)* Stratify controls by exposure (case-control) *(IV)* Consider column describing target population *(EV)*	Include rows for all variables included in final model *(IV)* Summarize variables as analyzed, rather than as-collected *(IV)* Consider including: - sampling variables and possible confounders *(IV)* - possible effect modifiers *(EV)*	Show n (%) for categorical variables (IV, EV) Show mean (SD) for continuous variables, but consider median (min/max or lower/upper quartile) for skewed data *(IV, EV)* Reduce visual clutter; round percentages to whole numbers
Analysis-specific considerations	Missing data	Show columns for complete and partial cases, or one imputed dataset *(IV)*	Include row for outcome variable *(IV)*	
	Sample weights		Include row showing distribution and range of sample weights *(IV, EV)*	Show unweighted n, weighted % *(IV, EV)*
	Clustered data	Show separate table for clusters and individuals *(EV)*	Include a row for n per cluster and sampling fraction *(EV)*	
	Interest in effect modification or interaction	Stratify by exposure and modifier *(IV)*	Show distribution of exposure and modifier in total column *(EV)*	

Abbreviations: *(IV)* denotes shows internal validity, *(EV)* denotes shows external validity, and *(IV, EV)* denotes shows both internal and external validity; RCT denotes randomized controlled trial; SD denotes standard deviation.

Example of a good Table one

Table 1. Demographics of patients stratified by preoperative diagnosis of obstructive sleep apnea (OSA)

Note: Data shown mean±sd, median [Q1,Q3], or n(%) dependent on distribution. P-value indicates difference between those with OSA and no OSA.

	All (n=77)	OSA (n=41)	No OSA (n=36)	p-value ⚠
Age (years)	16.9 ± 2.0	17.3 ± 2.1	16.4 ± 1.8	0.05
Sex				0.01
Females	53 (69%)	23 (56%)	30 (83%)	
Males	24 (31%)	18 (44%)	6 (17%)	
Hispanic	38 (49%)	20 (49%)	18 (50%)	0.91
Race				0.06
White	36 (47%)	17 (41%)	19 (53%)	
Black	13 (17%)	11 (27%)	2 (5%)	
Other	3 (4%)	2 (5%)	1 (3%)	
Missing	25 (32%)	11 (27%)	14 (39%)	
Insurance				0.49
Public	52 (68%)	30 (73%)	22 (61%)	
Private	22 (29%)	10 (24%)	12 (33%)	
None	3 (4%)	1 (2%)	2 (6%)	
BMI (median [Q1,Q3])	47.0 [42.3, 52.8]	47.7 [43.2, 55.1]	46.5 [42.1, 52.5]	<0.001

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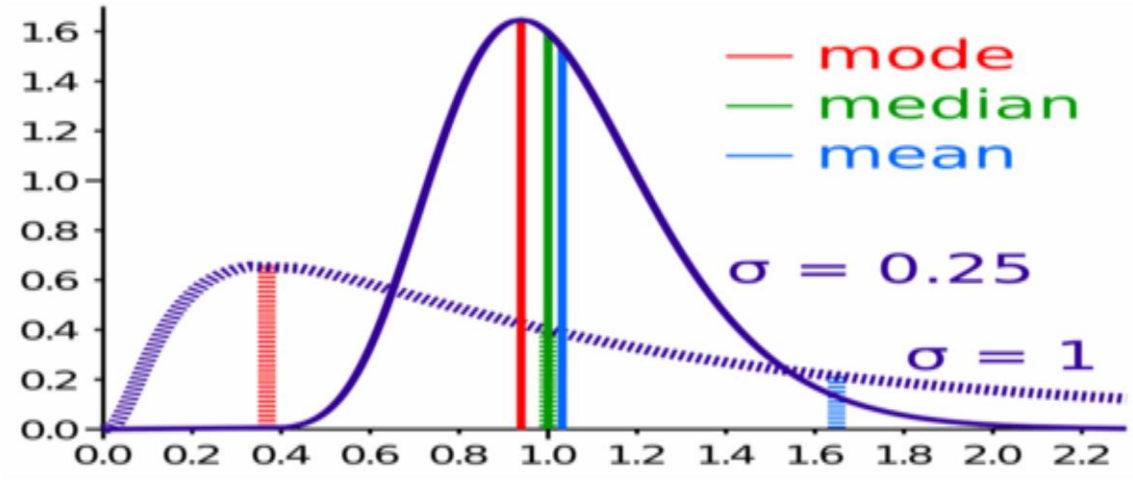
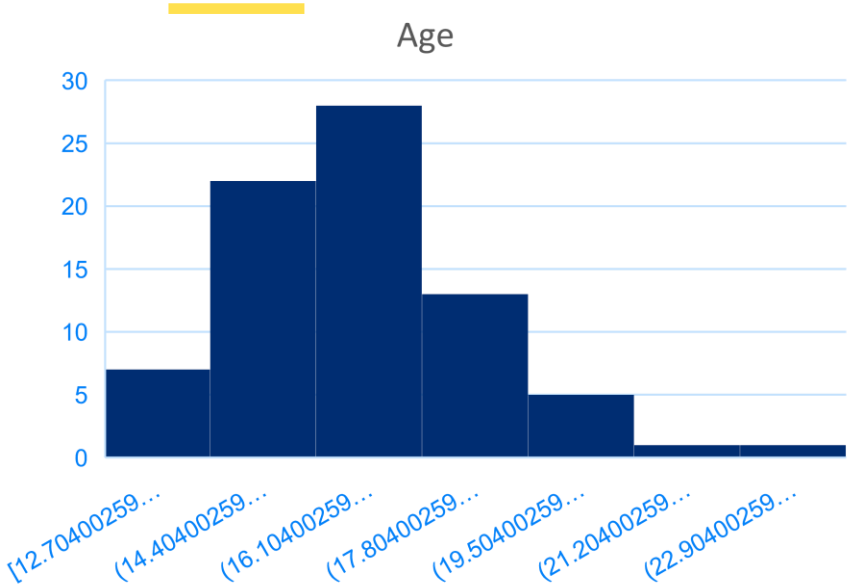
Mean (SD) or Median [IQR]: Check the Distribution of the data!

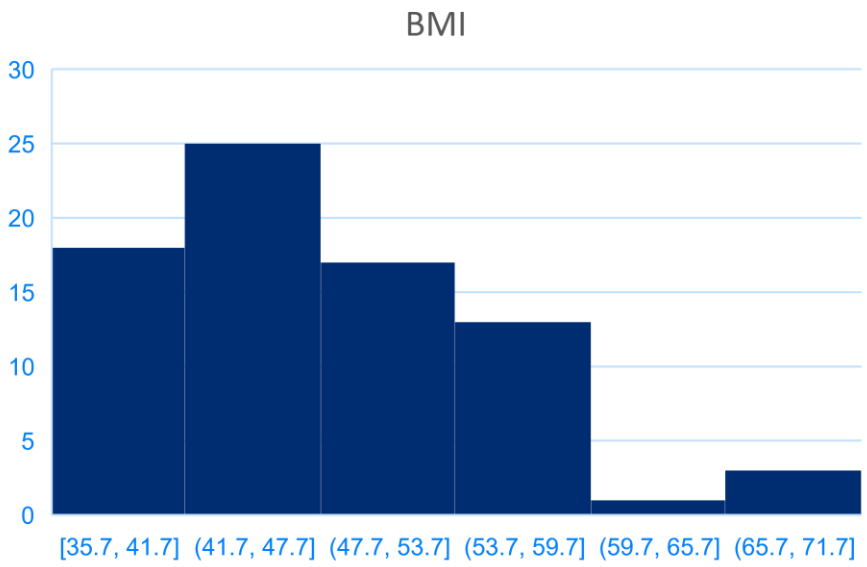


Comparison of mean, median and mode of two log-normal distributions with different skewness.

https://www.diffen.com/difference/Mean_vs_Median

Plot your data!





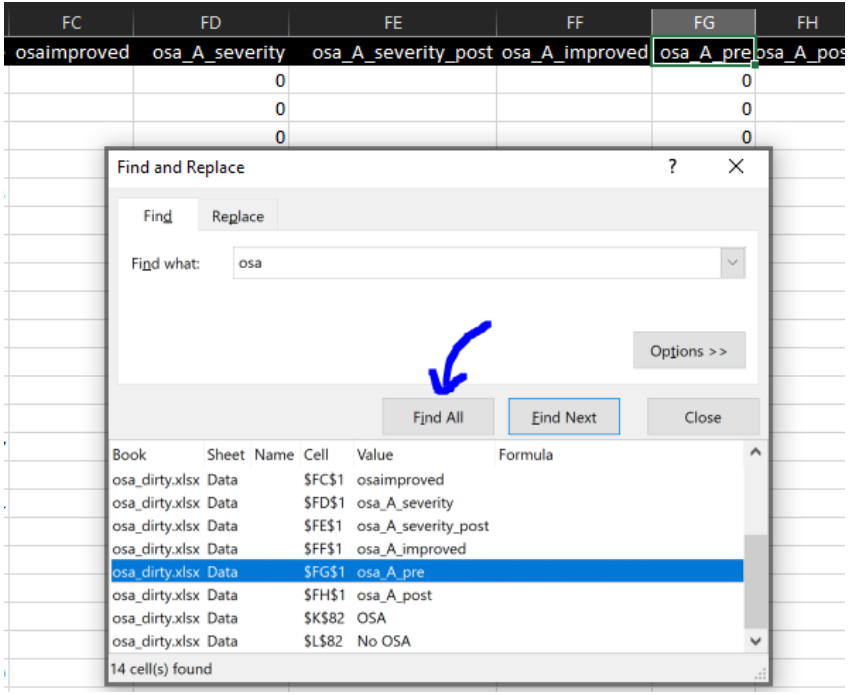
Calculating Summary Statistics in Excel

- SUM, AVERAGE, MAX, MIN, MODE, MEDIAN, COUNT, STDEV are some of the main functions
- These are used as functions in a cell using =funct(cell #'s)
- Stratification by exposure or disease status by adding "IFS" to end of summary measure

- A few good references:
  - https://www.online-tech-tips.com/ms-office-tips/excel-average-median-mode-formulas/
  - https://www.techrepublic.com/blog/10-things/10-tips-for-summarizing-excel-data/

Finding variables of interest

Using **ctrl+F** or **'Find & Select'** in large databases along with **'Find All'** option



A	B	C	D	E	F	G	H
record_id	pid	hispanic	race	sex	dob	date_appt_1	age i

Summary Statistics: The basics

_1	age	insur_type	aphics_complete	osa_A_pre	
19	20.101713	1	2	1	
19	16.227575	2	2	1	
			All	sd %	OS
		total N	77		
		Age (years	= AVERAGE(H2:H78)		
		Sex	AVERAGE(**number1**, [number2], ..		
		Females			

Helpful Tip:
Always press **'Enter'** before clicking out of an equation cell to avoid affecting cell contents!

Summary Statistics Stratified: Averages

=AVERAGEIF(K2:K78,1,H2:H78)

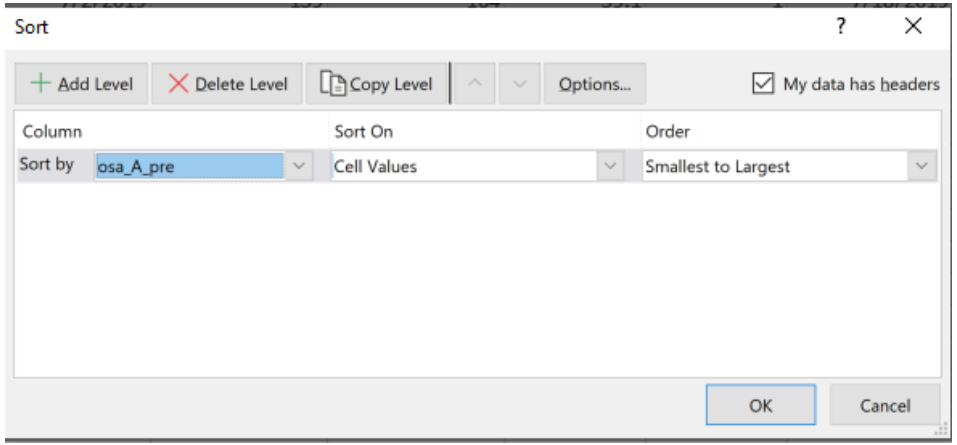
AVERAGEIF(range, criteria, [average_range])

E			H	I	J	K
sex	dob	date_appt_1		age_insur_type	aphics_complete	osa_A_pre
0	7/6/2001	6/29/2017	15.981163	3	2	0
0	1/3/2001	8/17/2017	16.618981	2	2	0

- Stratification criteria comes first, then the value you want to summarize

Summary Statistics Stratified

- Some summary statistics (i.e. sd) do not have “IFS” options – sort on stratifying variable for future summaries
- Home -> ‘Sort & Filter’ -> ‘Custom Sort’



Summary Statistics Stratified: Standard Deviation

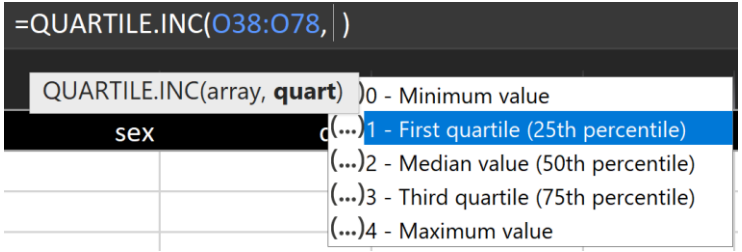
=STDEV(H38:H78)

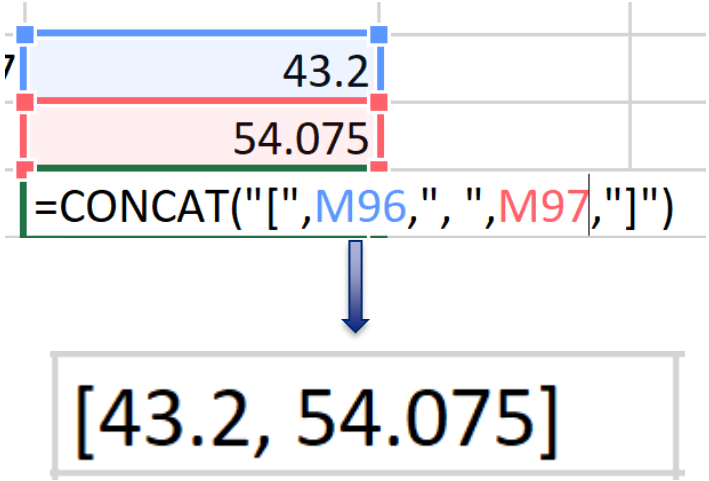
E	F	G	H	I	J	K
sex	dob	date_appt_1	age	insur_type	aphics_complete	osa_A_pre
0	3/28/2004	6/27/2019	15.24729	1	2	0
1	4/28/2002	7/18/2019	17.221435	1	2	0
0	3/24/2006	7/25/2019	13.336231	2	2	0
1	5/4/2001	6/8/2017	16.096155	1	2	1
1	10/15/1999	6/15/2017	17.667714	1	2	1

- Remember the Custom Sort from before!!

Median and IQR

- Use median [Q1, Q3] when data is skewed
- IQR or [Q1, Q3] = range of data between 25th and 75th Percentiles
- Median does not have IFS option (need to sort prior like sd)





A	B	C	D	E	F	G	H
record_id	pid	hispanic	race	sex	dob	date_appt_1	age i

Categorical Variables

H	I	J	K
age	insur_type	aphics_complete	osa_A_pre
.101713	1	2	1
.227575	2	2	1
		All	sd %
	total N	=COUNT(K2:K78)	
	Age (years)	16.91028854	
	Sex		

	All	sd %
total N	77	
Age (years)	16.91028854	
Sex		
Females		
Males		
Hispanic		
Race		
White	=COUNTIF(D2:D78,4)	
Black	COUNTIF(range, criteria)	
Other	3	
Missing	=COUNTIF(D3:D78,"")	

Check for continuous variables also!

Summary Statistics Stratified: Counts

=COUNTIFS(K2:K78,1,D2:D78,4)

COUNTIFS(criteria_range1, criteria1, [criteria_range2, **criteria2**], [criteria_range3, ...])

panic	race	sex	dob	date_appt_1	age	insur_type	aphics_complete	osa_A_pre
1		0	7/6/2001	6/29/2017	15.981163	3	2	0
0	4	0	1/3/2001	8/17/2017	16.618981	2	2	0

- Stratification criteria comes first, then the value you want to summarize

Testing for group differences

- Test type for group differences are based on a few main things:
  - Number of groups being compared (2 vs 3+ have different tests)
  - Type of variable (categorical, continuous)
  - Are the Values Paired? (pre/post differences, matched case control studies)
  - Distribution of Variable (normally distributed, skewed)
  - Sample Size (small sample invalidate many tests)
- Formula -> more functions -> statistical
- *T.test*: for testing differences between 2 groups in ***normally distributed continuous*** variables
- *Chi.Square*: for testing group differences in **categorical variables** ***with sufficient cell sizes (>5 per category!!)***

CAUTION!!!:
Just because a p-value comes out does not mean you've used the correct test for your data! Check with your statistician before reporting/publishing anything!

T-test

Function Library | Defined Names | Formula Auditi

fx =T.TEST(H2:H37,H38:H78, 2,

T.TEST(array1, array2, tails, **type**)

- Paired
- 2 - Two-sample equal variance (homoscedastic)
- 3 - Two-sample unequal variance (heteroscedastic)

T.TEST performs a paired t-Test

D	E							
ace	sex	dob	dat			plete	osa_A_pre	date
3	0	7/1/2003			2	2	1	7/5/2018
4	1	9/11/2001	6/7/2018	16.736826	2	2	1	6/7/2018
3	0	3/24/2001	9/13/2018	17.473208	1	2	1	9/13/2018

Chi-Square Test

- compare number of individuals observed to number of individuals expected if summarized together (i.e. the overall proportions)

Gender			
observed	no osa	osa	total
f	30	23	53
m	6	18	24
	36	41	77
expected	no osa	osa	
f	=L100/L102*J102		
m	11.22077922	12.779221	

observed	no osa	osa
f	30	23
m	6	18
expected	no osa	osa
f	24.77922078	28.22077922
m	11.22077922	12.77922078

= CHISQ.TEST(F99:G100,F103:G104)

CHISQ.TEST(actual_range, **expected_range**)

⚠ CAUTION! ⚠

observed	no osa	osa
f	30	23
m	6	18

expected	no osa	osa
f	24.77922078	28.22077922
m	11.22077922	12.77922078

= CHISQ.TEST(F99:G100,F103:G104)

CHISQ.TEST(actual_range, **expected_range**)

p-value
0.010039922

	Observed	Expected
F OSA	23	28.22077922
M OSA	18	12.77922078
F No OSA	30	24.77922078
M no OSA	6	11.22077922

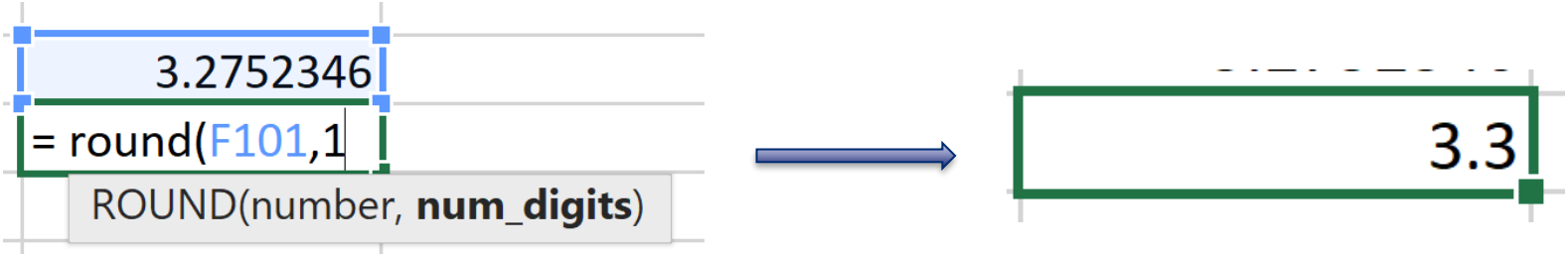
=CHISQ.TEST(F84:F87,G84:G87

CHISQ.TEST(actual_range, **expected_range**)

p-value
0.084756395

Rounding Reported Numbers

- Only need enough digits after decimal points to show magnitude of difference
- P-values 2 digits after decimal point
- Percents can be whole numbers
- Continuous values 1-3 depending on range of data



Questions?

Now Reproduce the Table!

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BMI (median [Q1,Q3])	47 [42.3, 52.8]	47.7 [43.2, 55.1]	46.8 [42.1, 52.5]

Bonus Material

"We've got the Big Data report, we did the competitive analysis, and *nobody* thought to include *cats?!*"

PNAS PNAS

Female hurricanes are deadlier than male hurricanes

Kiju Jung[a,1], Sharon Shavitt[a,b,1], Madhu Viswanathan[a,c], and Joseph M. Hilbe[d]

Do people judge hurricane risks in the context of gender-based expectations? We use more than six decades of death rates from US hurricanes to show that feminine-named hurricanes cause significantly more deaths than do masculine-named hurricanes. Laboratory experiments indicate that this is because hurricane names lead to gender-based expectations about severity and this, in turn, guides respondents' preparedness to take protective action. This finding indicates an unfortunate and unintended consequence of the gendered naming of hurricanes, with important implications for policymakers, media practitioners, and the general public concerning hurricane communication and preparedness.

PNAS PNAS

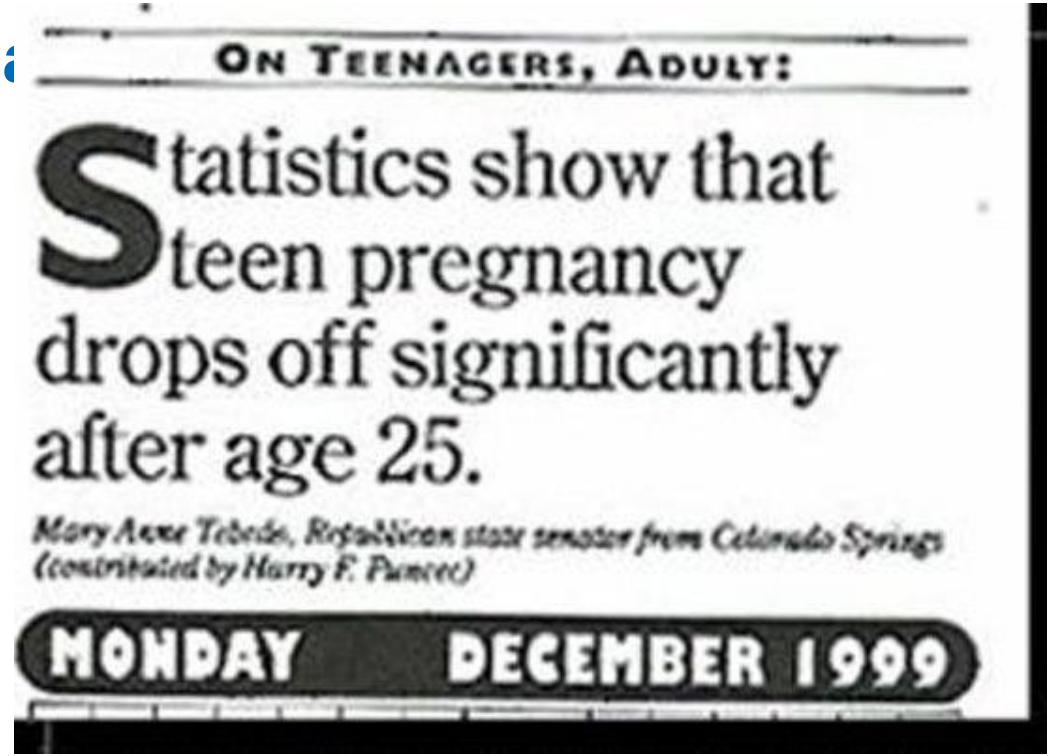
Female hurricanes are deadlier than male hurricanes

Kiju Jung[a,1], Sharon Shavitt[a,b,1], Madhu Viswanathan[a,c], and Joseph M. Hilbe[d]

Do people judge hurricane risks in the context of gender-based expectations? We use more than six decades of death rates from US hurricanes to show that feminine-named hurricanes cause significantly more deaths than do masculine-named hurricanes. Laboratory experiments indicate that this is because hurricane names lead to gender-based expectations about severity and this, in turn, guides respondents' preparedness to take protective action. This finding indicates an unfortunate and unintended consequence of the gendered naming of hurricanes, with important implications for policymakers, media practitioners, and the general public concerning hurricane communication and preparedness.

Hurricanes before 1979 were more likely to be named female names and hurricanes over time have become less deadly

Bonus Ma



ON TEENAGERS, ADULT:

Statistics show that teen pregnancy drops off significantly after age 25.

Mary Anne Tebede, Republican state senator from Colorado Springs (contributed by Harry F. Pancec)

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Thank you!