Biostatistics Questions & Database Basics

Dan Eastwood, MS, Program Manager/Biostatistician

Medical College of Wisconsin, Division of Biostatistics

Friday, October 4, 2013

12:00-1:00 pm

Clinical Cancer Center-Room K

The Medical College of Wisconsin is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The Medical College of Wisconsin designates this live activity for a maximum of 1.0 *AMA PRA Category 1 Credit™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Hours of Participation for Allied Health Professionals

The Medical College of Wisconsin designates this activity for up to 1.0 hours of participation for continuing education for allied health professionals.

Financial Disclosure

- In accordance with the ACCME® standard for Commercial Support Number 6, all in control of content disclosed any relevant financial relationships. The following in control of content had **no** relevant financial relationships to disclose.

Name:	Role in Meeting:
Kwang Woo Ahn, PhD	Activity Director
Haley Montsma, BBA	Planning Committee
Dan Eastwood, MS	Presenter

Evaluation Forms

Your opinion matters!

Help us plan future meetings, by completing and submitting your evaluation forms.

Thank you.

Learning Objectives

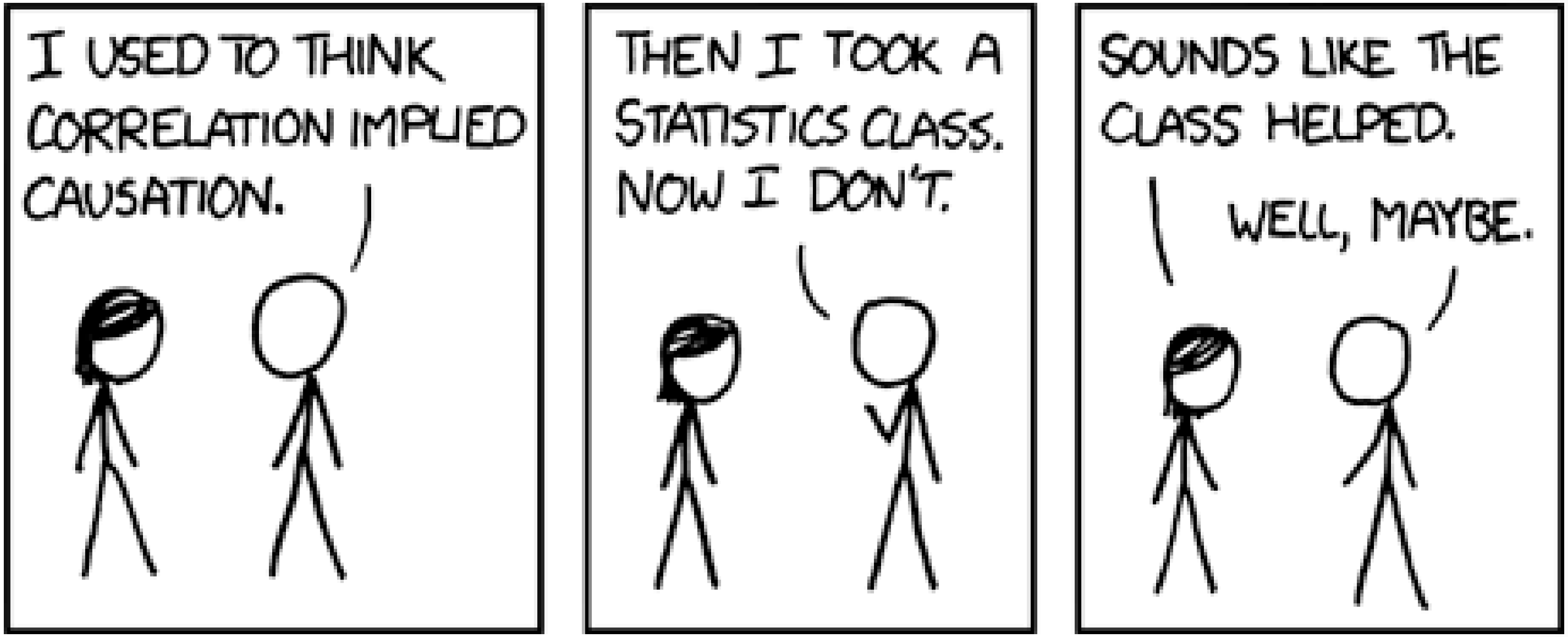
- Discover the capabilities and resources available within the Biostatistics Consulting Service
- Transition your research idea into a testable hypothesis
- Effectively organize research data
- Common data problems to avoid

(Getting Help for your)

Biostatistics Questions

Dan Eastwood, MS

Understanding Statistics


I USED TO THINK CORRELATION IMPLIED CAUSATION.
THEN I TOOK A STATISTICS CLASS. NOW I DON'T.
SOUNDS LIKE THE CLASS HELPED.
WELL, MAYBE.

http://xkcd.com/552/

Why Biostatistics Consulting?

- **Shared experience**
- Discuss your study
- Consider alternate views
- Formulate ideas into hypotheses

Why Biostatistics Consulting?

Why might you need help?

Why Biostatistics Consulting?

Why might you need help?

- “I’ve got this research idea about …”
- …
- …
- …
- …
- “The reviewers asked me to …”

Why Biostatistics Consulting?

Why might you need help?

- “I’ve got this research idea about …”
- “How large should my sample be?”
- …
- …

- “A significant result! What does it mean?”
- “The reviewers asked me to …”

Why Biostatistics Consulting?

Why might you need help?

- “I’ve got this research idea about …”
- “How large should my sample be?”
- “I need help organizing my data.”
- “How do I perform a Chi-square test?”
- “A significant result! What does it mean?”
- “The reviewers asked me to …”

Questions for the Investigator

- What is your hypothesis?
- What is the design?
- What data are available?
- What is the plan for analysis?

Questions for the Investigator

What makes a good hypothesis? (1)

- A simple sentence. Null and alternate hypothesis should be evident
- Difference, equivalence, or agreement?
- No hypothesis? - a descriptive study
- Feasible design

Questions for the Investigator

What makes a good hypothesis? (2)

- The alternate hypothesis should be reasonable (power and clinical effect)
- Related factors (confounders)
- Preliminary data

It Never Hurts to Ask

Independent Samples	Sleep difficulty, Medication X?	Sleep difficulty, Medication Y?	Total
“No”	48	78	126
“Yes”	**136**	**106**	242
Total	**184**	**184**	368

Chi-Square test, p=0.0010,
Medication X 58%, Medication Y 74%

It Never Hurts to Ask

Paired Data	Med Y, No difficulties	Med Y, Sleep difficulties	Total
Med X, No difficulties	34	44	78
Med X, Sleep difficulties	14	92	106
Total	48	136	**184**

McNemar’s Test, p=0.0001,
paired data odds ratio = 44/14 = 3.14

Questions for the Investigator

What data resources are available?

- Understand your data
- Clinical data and public databases
- Data management

- Good data = good research

The Answers

What is the plan for analysis?

- Best methods for the available data
- Best data for the available methods
- Potential for other analyses

Biostatistics Consulting Service

How to find us:

- Schedule a meeting.
- Just “Drop-In”.
- Special Sessions.

- Ask Us.

Consulting Services Faculty

- Prakash Laud, PhD, Professor & Acting Director
  - Injury Research Center, Center for Patient Care and Outcomes Research, Bayesian statistical methodology
- Aniko Szabo, PhD, Associate Professor & BCS Director
  - Cancer statistics, genetics, clinical trials
- Sergey Tarima, PhD, Assistant Professor
  - Missing data problems, health service research
- Tao Wang, PhD, Associate Professor
  - Statistical genetics
- Jessica Pruszynski, PhD, Assistant Professor
  - Logistic regression, Cancer studies

Consulting Services Staff

- Dan Eastwood, MS, BCS Manager
  - Cancer studies, general biostatistics
- Alexis Visotcky, MS, Biostatistician
  - VA databases, REDCap
- Qun (Katelyn) Xiang, MS, Biostatistician
  - Large databases, pediatric data
- Shi (Heather) Zhao, MS, Biostatistician
  - Nutrition, Obstetric studies
- Haley Montsma, BBA, Administrator

What should you bring to a meeting?

- Ideas
- Protocol?
- Example of your data
- Electronic copy of your data?
- “The boss”

Services

Data entry (fee service).

Help with:

- Design
- Analysis
- Grant Preparation
- Reading Papers
- Reports
- Graphics
- Assistance with Public Databases
- Advice on Methods

Biostatistics Consulting Service

- We are now supported by the Medical College's *Clinical and Translational Science Institute* (CTSI)
- Biostatistics key function
- Monthly Lecture Series (more stats!): www.mcw.edu/biostatistics/LectureSeries.htm
- ***DATUM*** newsletter: www.mcw.edu/biostatistics/datum.htm

Biostatistics Consulting Service

CTSI services available to faculty, staff, and students working on Clinical and Translational Science Research at:

- MCW
- VA Medical Center
- Blood Center
- UW-Milwaukee
- Marquette
- Milwaukee School of Engineering

Free Drop-in Consulting

- **Medical College of Wisconsin**:
  Tuesdays and Thursdays
  Time: 1:00 PM—3:00 PM
  Building: Health Research Center
  Room: H2400 Biostatistics

- **MCW Cancer Center**
  Wednesdays 10:00 AM—12:00 PM
  Fridays 1:00 PM—3:00 PM
  Building: MCW Clinical Cancer Center
  Room: Clinical Trials Support Room
  CLCC: 3236 (Enter through C3233)

- **Froedtert Pavilion**:
  Mondays & Wednesdays
  Time: 1:00 PM—3:00 PM
  Building: Froedtert Pavilion
  Room: TRU Conference Room L742

- **Clement J. Zablocki VA Medical Center:**
  1st & 3rd Monday of the month
  Time: 9:00 AM—11:00 AM
  Building: 111, 5th Floor B-wing
  Room: 5423

- **Marquette University:**
  Every Tuesday
  Time: 8:30 AM—10:30 AM
  Building: School of Nursing, Clark Hall
  Room: Office of Research and Scholarship: 112D
  Contact: **Jessica Pruszynski, PhD** to make an appointment
  Please note: Priority given to MU Nursing and Dental School personnel

Contact

- Haley Montsma
- (414) 955-7439
- hmontsma@mcw.edu
- consult@mcw.edu

- Dan Eastwood, MS
- (414) 955-4855
- eastwood@mcw.edu
- consult@mcw.edu

www.mcw.edu/biostatsconsult.htm

Database Basics

Dan Eastwood, MS

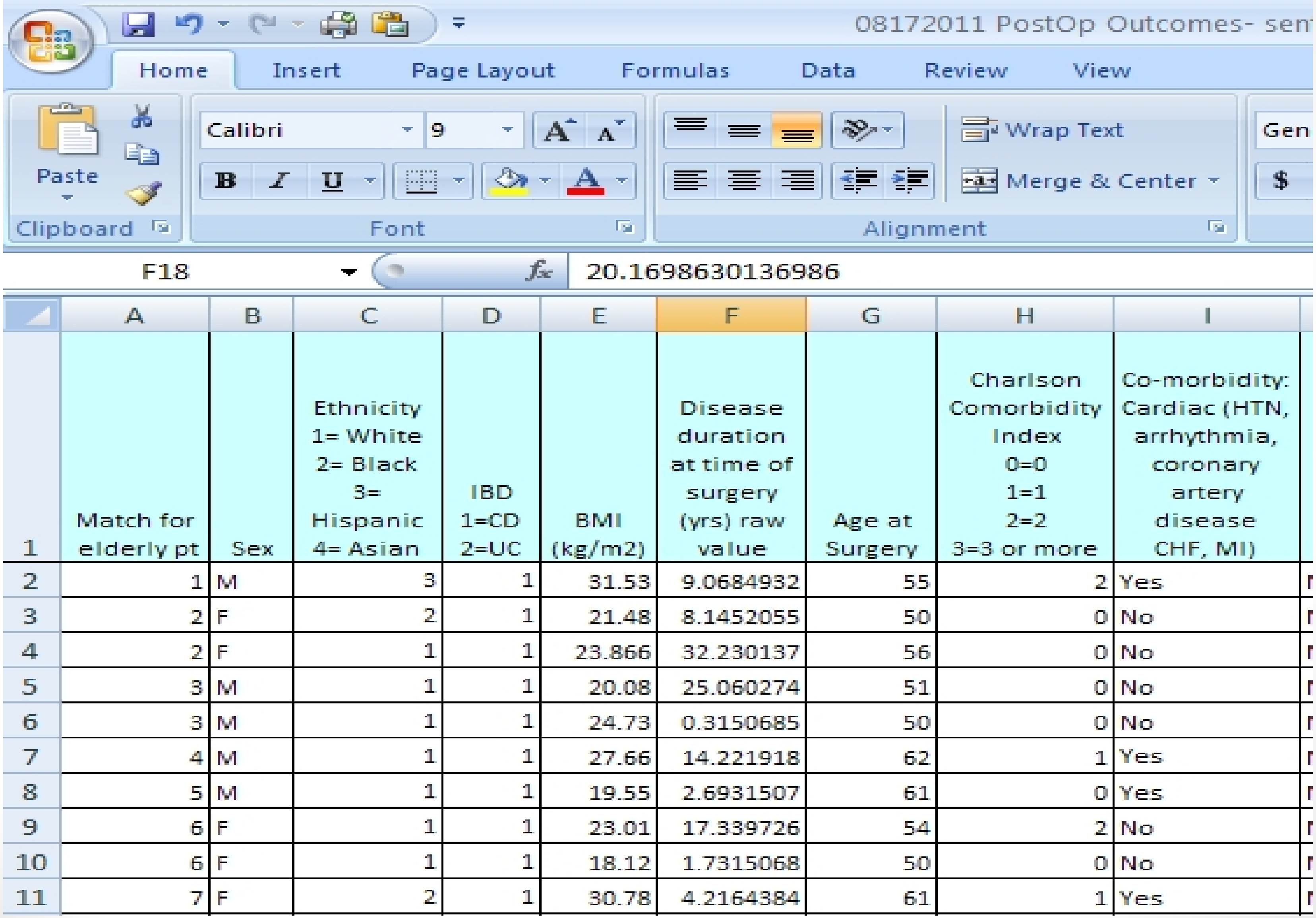
What is a Database?

- An organized collection of data
- Accessible in a computer
- Accessible in various ways
  - sortable
  - searchable
  - indexed

What is a Database?

- Well organized data enables good research
- Complex studies require careful organization
- Simple studies benefit from good organization

Is a spreadsheet a database?



F18 20.1698630136986

	A	B	C	D	E	F	G	H	I
1	Match for elderly pt	Sex	Ethnicity 1= White 2= Black 3= Hispanic 4= Asian	IBD 1=CD 2=UC	BMI (kg/m2)	Disease duration at time of surgery (yrs) raw value	Age at Surgery	Charlson Comorbidity Index 0=0 1=1 2=2 3=3 or more	Co-morbidity: Cardiac (HTN, arrhythmia, coronary artery disease CHF, MI)
2	1	M	3	1	31.53	9.0684932	55	2	Yes
3	2	F	2	1	21.48	8.1452055	50	0	No
4	2	F	1	1	23.866	32.230137	56	0	No
5	3	M	1	1	20.08	25.060274	51	0	No
6	3	M	1	1	24.73	0.3150685	50	0	No
7	4	M	1	1	27.66	14.221918	62	1	Yes
8	5	M	1	1	19.55	2.6931507	61	0	Yes
9	6	F	1	1	23.01	17.339726	54	2	No
10	6	F	1	1	18.12	1.7315068	50	0	No
11	7	F	2	1	30.78	4.2164384	61	1	Yes

Spreadsheet vs. Database

- Spreadsheets have few or no rules
- Databases have strict rules
- Rules make spreadsheets more like a database

Spreadsheet vs. Database

- Use a database program to enforce rules
- Additional capability of databases
- A simple database can be viewed in a “flat” or “table” form (a single spreadsheet)

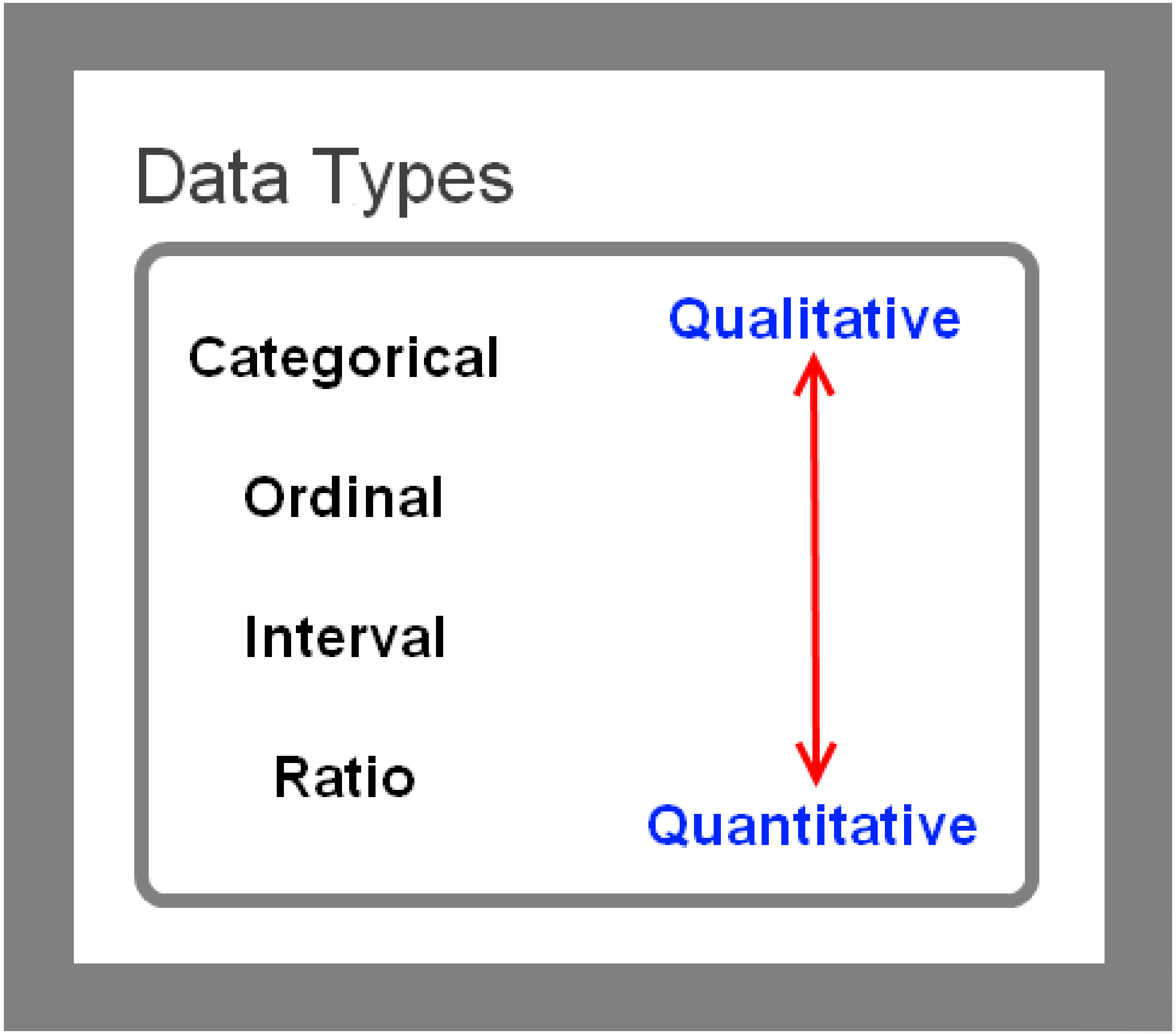
Spreadsheet vs. Database

- Spreadsheets are prone to copy/paste, partial sorting, and other entry errors
  - Errors may be uncorrectable
  - Errors may be undetectable
- Changes to databases are generally reversible
  - Queries display data in different ways
  - Revert to original
  - Errors are more easily detected

What goes into a database?

- Type of data, formatting
- The “bad” list
- Factors and variables
- Sample units or observations?
- Multiple tables and linked tables

Statistical Qualities of Data



Data Types

Categorical

Ordinal

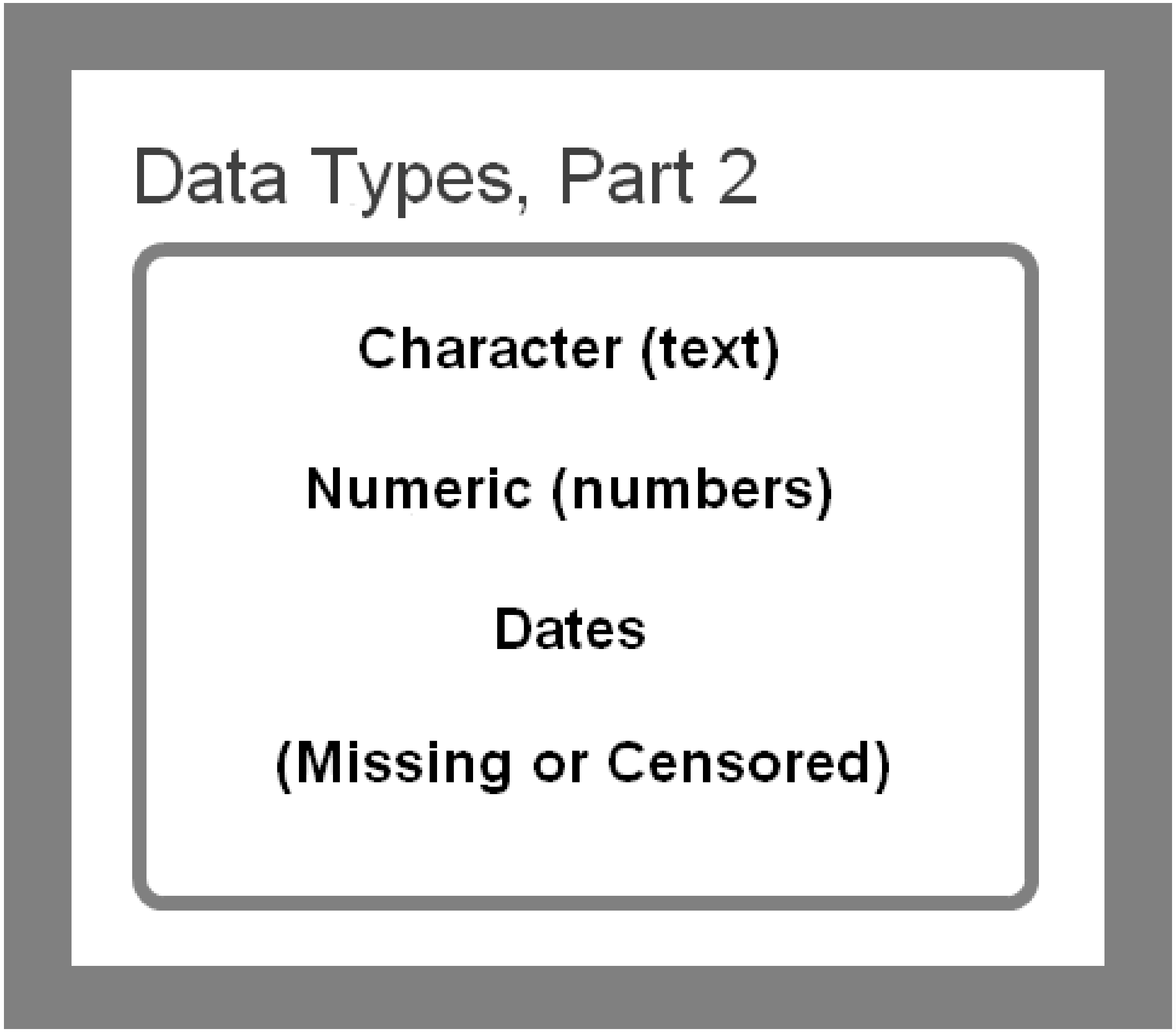
Interval

Ratio

Qualitative

Quantitative

Computational Qualities of Data



Data Types, Part 2

Character (text)

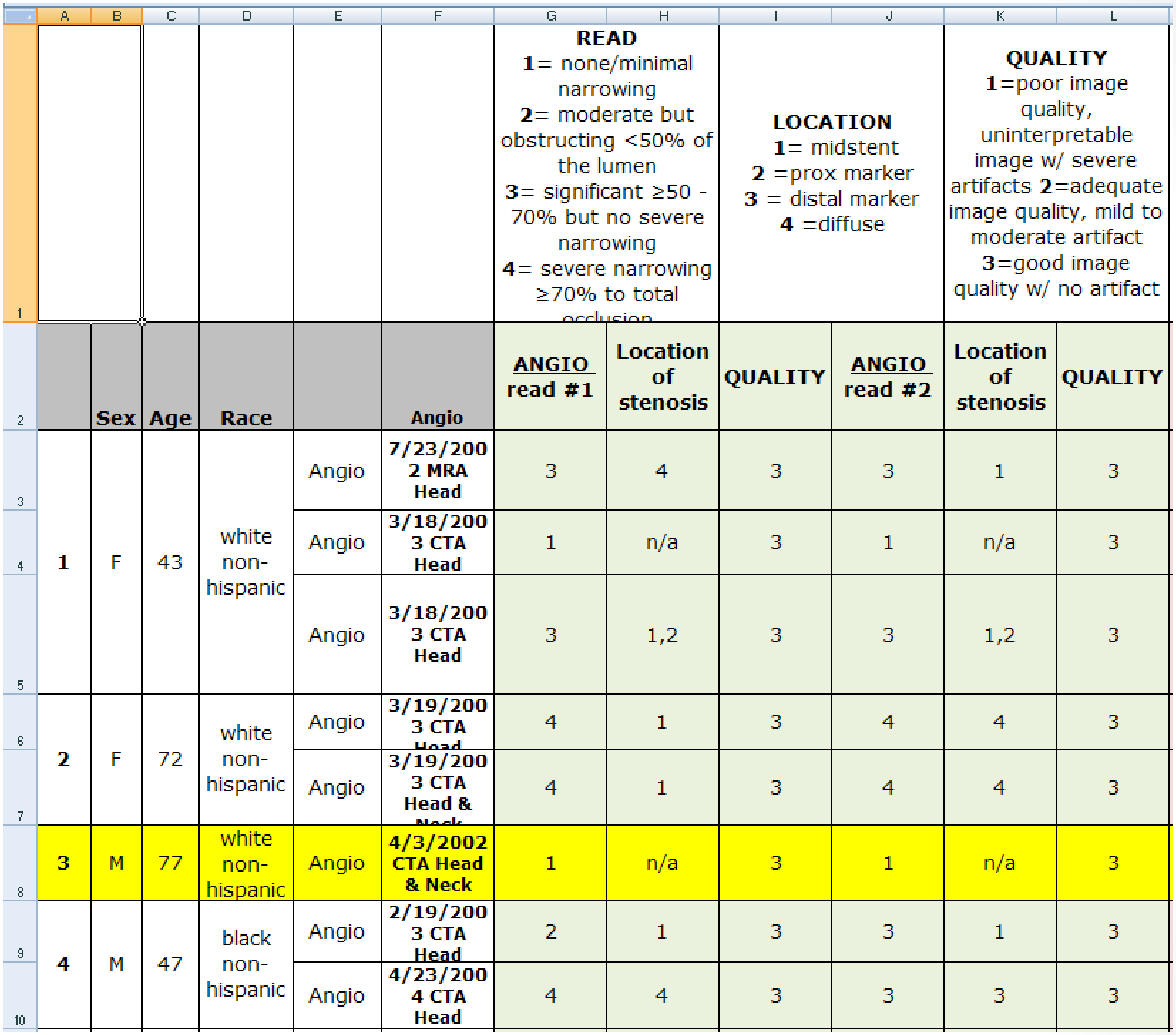
Numeric (numbers)

Dates

(Missing or Censored)

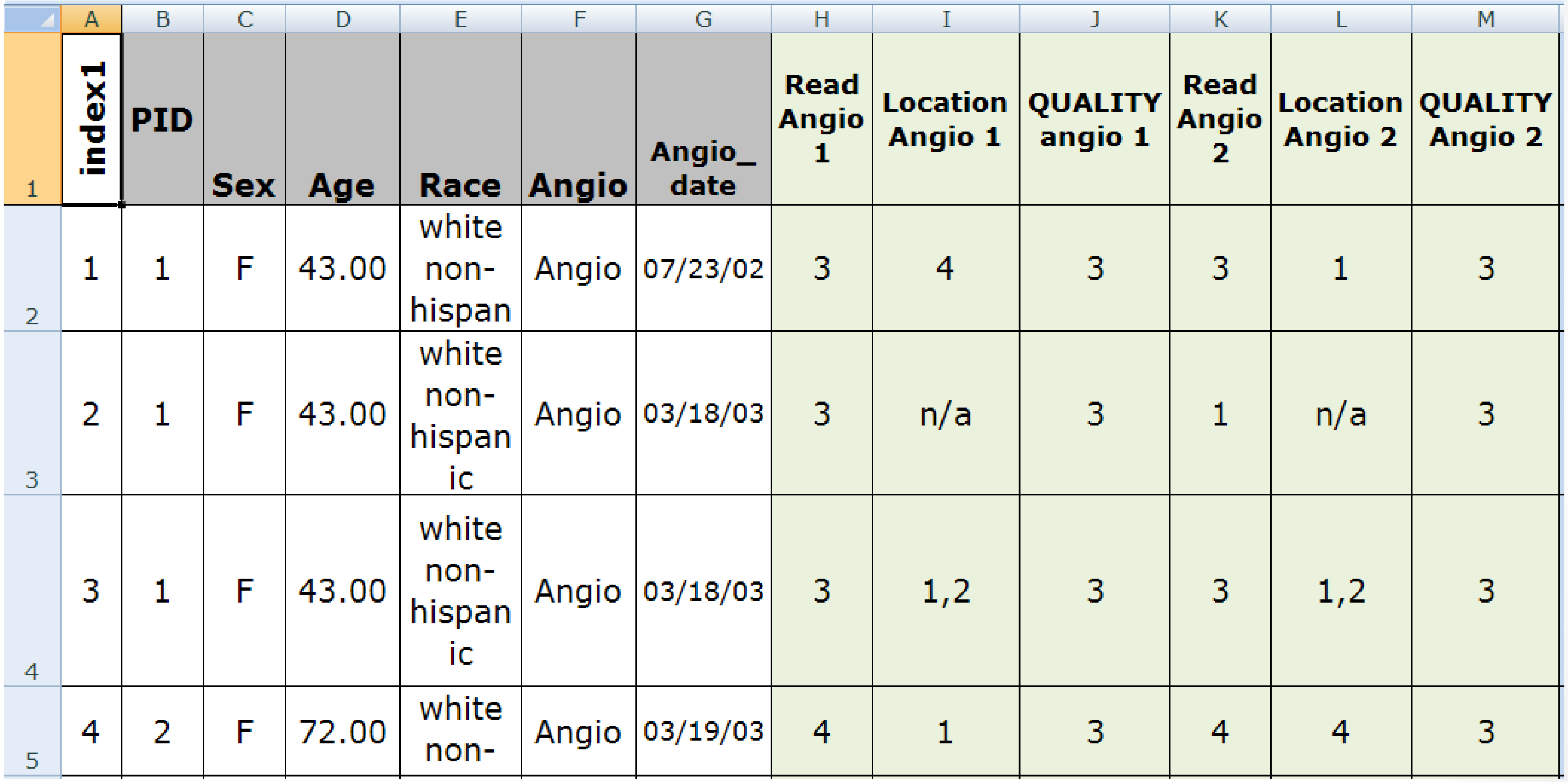
The List of Bad Things

- More than one value in a single cell
- Mixed character and numbers
- Merged cells
- Color coding
- UPPER and lower case text are different
- Confused coding or formats
- “Prettifying” is generally unhelpful
- Identifying information (try to minimize)



	A	B	C	D	E	F	G	H	I	J	K	L
1							**READ** **1**= none/minimal narrowing **2**= moderate but obstructing <50% of the lumen **3**= significant ≥50 - 70% but no severe narrowing **4**= severe narrowing ≥70% to total occlusion		**LOCATION** **1**= midstent **2** =prox marker **3** = distal marker **4** =diffuse		**QUALITY** **1**=poor image quality, uninterpretable image w/ severe artifacts **2**=adequate image quality, mild to moderate artifact **3**=good image quality w/ no artifact	
2		**Sex**	**Age**	**Race**		**Angio**	**ANGIO read #1**	**Location of stenosis**	**QUALITY**	**ANGIO read #2**	**Location of stenosis**	**QUALITY**
3	**1**	F	43	white non-hispanic	Angio	**7/23/2002 MRA Head**	3	4	3	3	1	3
4					Angio	**3/18/2003 CTA Head**	1	n/a	3	1	n/a	3
5					Angio	**3/18/2003 CTA Head**	3	1,2	3	3	1,2	3
6	**2**	F	72	white non-hispanic	Angio	**3/19/2003 CTA Head**	4	1	3	4	4	3
7					Angio	**3/19/2003 CTA Head & Neck**	4	1	3	4	4	3
8	**3**	M	77	white non-hispanic	Angio	**4/3/2002 CTA Head & Neck**	1	n/a	3	1	n/a	3
9	**4**	M	47	black non-hispanic	Angio	**2/19/2003 CTA Head**	2	1	3	3	1	3
10					Angio	**4/23/2004 CTA Head**	4	4	3	3	3	3

Better now?



	A	B	C	D	E	F	G	H	I	J	K	L	M
1	index1	PID	Sex	Age	Race	Angio	Angio_date	Read Angio 1	Location Angio 1	QUALITY angio 1	Read Angio 2	Location Angio 2	QUALITY Angio 2
2	1	1	F	43.00	white non-hispan	Angio	07/23/02	3	4	3	3	1	3
3	2	1	F	43.00	white non-hispanic	Angio	03/18/03	3	n/a	3	1	n/a	3
4	3	1	F	43.00	white non-hispanic	Angio	03/18/03	3	1,2	3	3	1,2	3
5	4	2	F	72.00	white non-	Angio	03/19/03	4	1	3	4	4	3

Variables

- Short yet meaningful names
  - Top row of spreadsheet
  - Longer description or labels elsewhere

- Create a “key” to formatted values
  - ex: 1=‘yes’, 2=‘no’ :: 1=‘treatment’, 0=‘control’
  - Usually on a different sheet

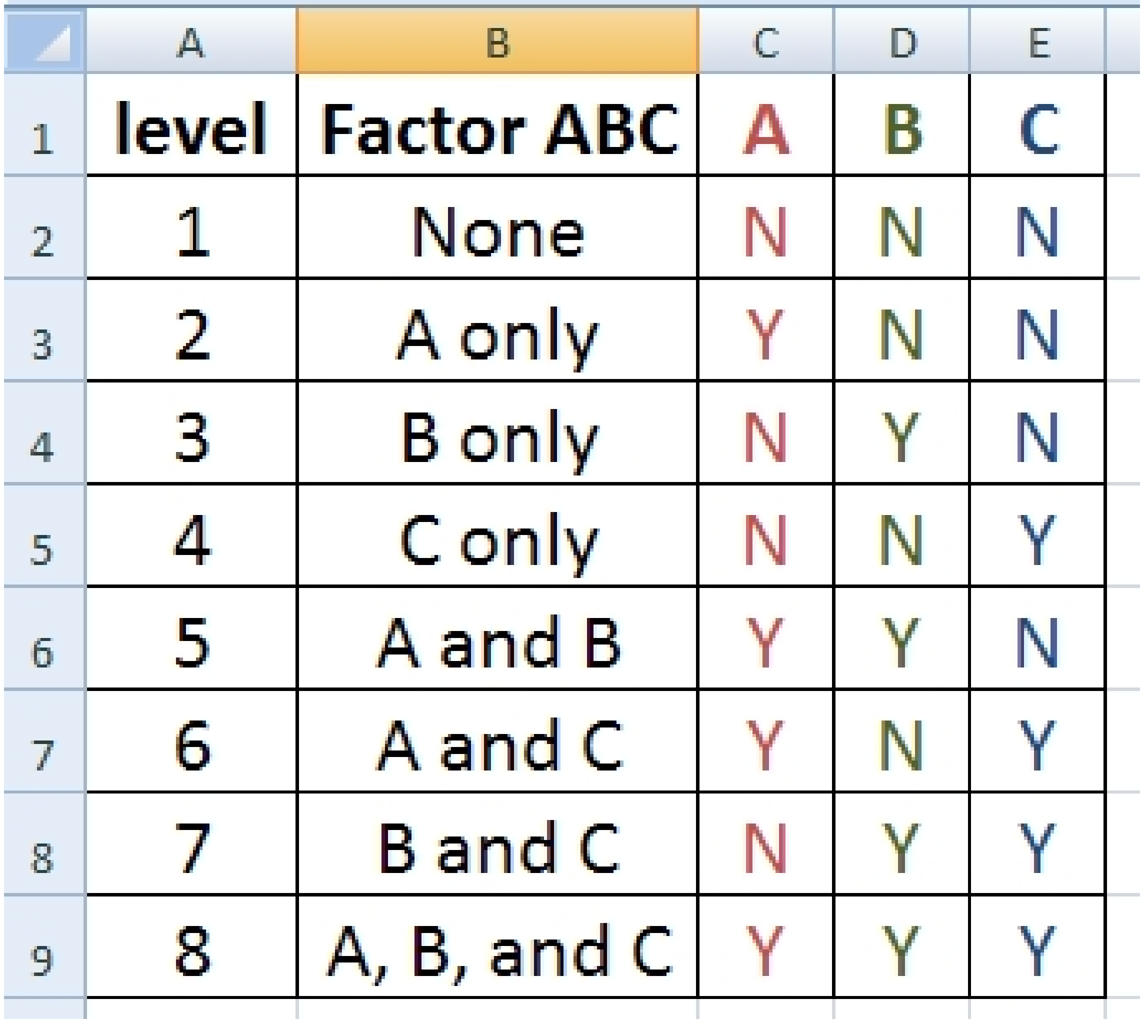
Factors & Variables

- A factor is a complete description of one contributing element in the analysis

- A variable is a representation of a factor, or part of a factor, as used in the analysis

- A factor may be described by several variables (ie: dummy variables)

Factors & Variables



level	Factor ABC	A	B	C
1	None	N	N	N
2	A only	Y	N	N
3	B only	N	Y	N
4	C only	N	N	Y
5	A and B	Y	Y	N
6	A and C	Y	N	Y
7	B and C	N	Y	Y
8	A, B, and C	Y	Y	Y

Sample Units & Observations

- Depends on Study Design
- Usually one row of data per sample unit
  - ie: one row per patient
  - “wide” layout
  - side-to-side scrolling problems
- Sometimes one row per observation
  - “long” layout
  - wasted space with demographics

Wide Layout

Study ID	Sex	Age	Group	SBP1	DBP1	SBP2	DBP2	SBP3	DBP3
1	M	56	Treatment	136	82	130	84	148	82
2	F	65	Placebo	138	95	22	88	120	76
3	M	76	Treatment	124	88	130	88	136	80
4	M	77	Treatment	120	84	140	78	122	84
5	F	54	Placebo	126	86	124	80	134	n/a

Long Layout

Study ID	Visit	Sex	Age	Group	SBP	DBP
1	1	M	56	T	136	82
1	2	M	56	T	130	84
1	3	M	56	T	148	82
2	1	F	65	P	138	95
2	2	F	65	P	22	88
2	3	F	65	P	120	76
3	1	M	76	T	124	88
3	2	M	76	T	130	88
3	3	M	76	T	136	80
4	1	M	77	T	120	84
4	2	M	77	T	140	78
4	3	M	77	T	122	84
5	1	F	54	P	126	86
5	2	F	54	P	124	80
5	3	F	54	P	134	n/a

Multiple Tables

Demographics and Clinical Data with linking index variable

Study ID	Sex	Age	Group
1	M	56	Treatment
2	F	65	Placebo
3	M	76	Treatment
4	M	77	Treatment
5	F	54	Placebo

Study ID	Visit	SBP	DBP
1	1	136	82
1	2	130	84
1	3	148	82
2	1	138	95
2	2	22	88
2	3	120	76
3	1	124	88
3	2	130	88
3	3	136	80
4	1	120	84
4	2	140	78
4	3	122	84
5	1	126	86
5	2	124	80
5	3	134	n/a

Database Programs

- **Microsoft Access**
  - Everybody has it
  - Nobody uses it

Database Programs

REDCap
Research Electronic Data Capture

- REDCap
  - web based
  - secure server
  - survey package (no more Survey Monkey)
  - 267 institutional partners
  - 20K+ studies, 30K+ end users
  - project-redcap.org
- Contact for more information:
  - Mark Oium, moium@mcw.edu, 805-2051

Concluding Remarks

- Have a plan for your data
- You can “pilot” a database at the same time you gather pilot data for a study
- Good data leads to good research

Questions?