Research design & study execution workshop series

Session 5

SEPTEMBER 9, 2015

General Q & A session

Progress report:
Football-related injury study

Sessions 1-4

- Identifying a “good” research question
- Review of common study designs
- Selecting appropriate study subjects
- Variables and their measurement

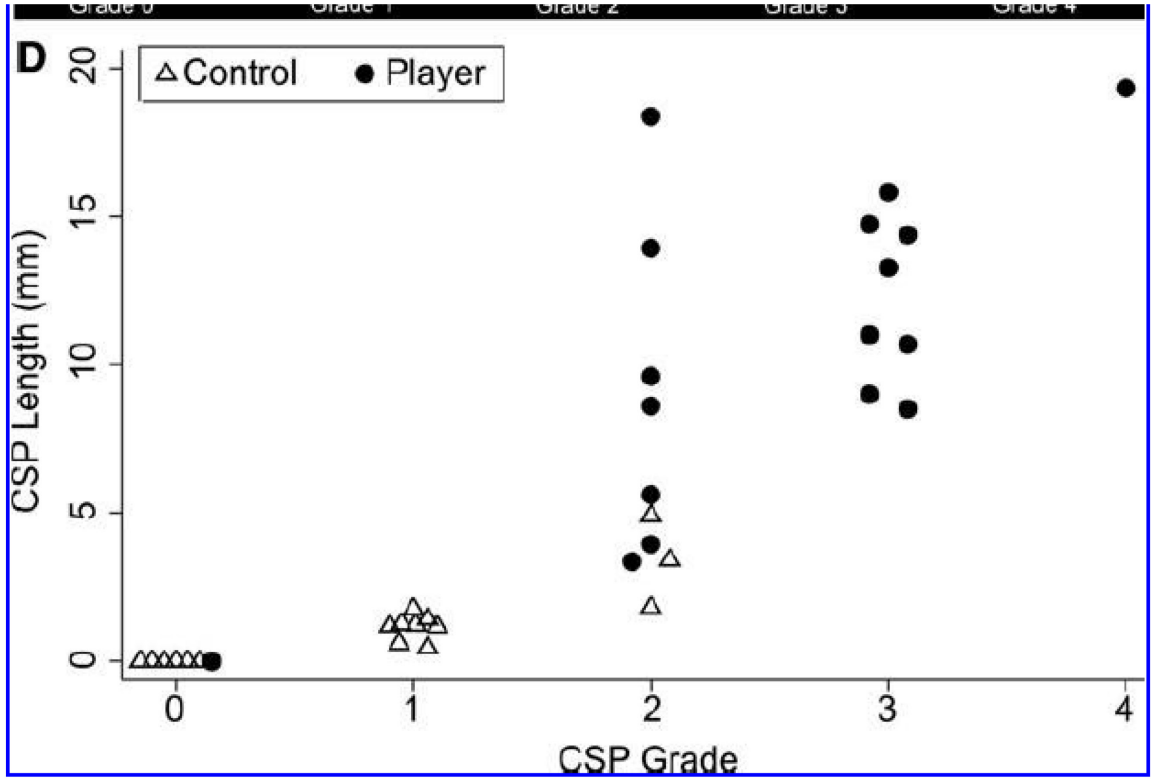
Case study: Football-related injuries

Variables and their measurement

Type of measurement	Characteristics of variable
Categorical	
Dichotomous	Two categories (alive or dead)
Nominal	Unordered categories (race, eye color)
Ordinal	Ordered categories with intervals that are not quantifiable (stage of disease)
Numeric	
Continuous	Infinite number of quantifiable intervals (height, weight, etc.)
Discrete	Limited number of quantifiable intervals (number of pregnancies, number of concussions)

Categorical
Dichotomous (Two categories)

Numerical
Continuous
(infinite number of quantifiable intervals)



Categorical
Ordinal (Ordered categories with intervals that are not quantifiable)

Numerical:

Discrete (Limited number of quantifiable intervals)

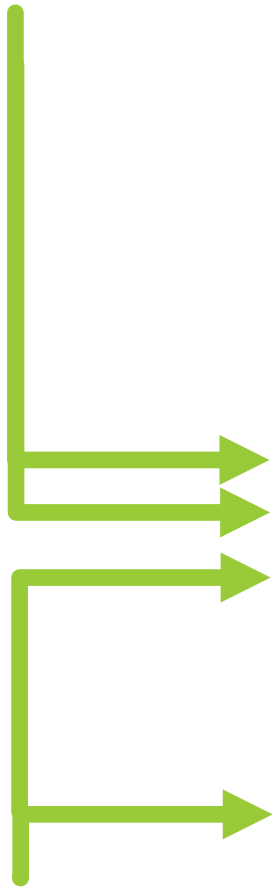


TABLE 1. CLINICAL CHARACTERISTICS

	Controls (n = 17)	*Players (n = 17)*
Age, years; mean (SD)	54.7 (15.8)	54.6 (15.8)
Male	17/17	17/17
Education, years; mean (SD)	17.3 (5.2)	17.7 (3.3)
MMSE; mean (SD)*	26.5 (4.5)	26.5 (2.5)
Total lifetime football exposure (childhood, high-school, college, pro), years; mean (SD)	N/A	17.3 (4.5)
Total pro-football exposure, years; mean (SD)	N/A	7.7 (3.8)
Patient reported repeated concussions	0/17	15/17
Patient reported at least one concussion with LOC	0/17	11/17
Pro-football position played	N/A	Defensive back (2), defensive end (1), defensive linebacker (6), defensive safety (1), long-snapper (1), offensive lineman (1), offensive tackle (4), offensive wide-receiver (1)
Years since retired from pro-football; mean (SD)	N/A	24.5 (15.5)
Clinical diagnoses (n)	MCI (9), AD (3), FTLD gene-carrier (2), bvFTD (1), HD (1), svPPA (1)	CPCS (5), MCI (6), HAND (1), cognitive disorder NOS (1), early-onset AD (1), mild dementia NOS (2), nfvPPA (1)

Categorical:

Nominal (Unordered categories)

Type of measurement	Characteristics of variable
Categorical	
Dichotomous	Gender (male)
Nominal	Type of pro-football position played (wide-receiver, lineman, etc.)
Ordinal	CSP category (1, 2, 3, 4, 5)
Numeric	
Continuous	Length of CSP (mm)
Discrete	Number of concussions

The study design + type of variables determine

- Information needs for sample size planning
- How the study data should be collected
- How you should code & record the data
- How you can analyze the data
- How you are able present the findings

Montage team sports challenge

Which of the following team sports resulted in the highest total number of **exams** and different **patients** with a sports-related injury/condition over the past 15 years?

	Exams	Patients
A. Baseball	267	209
B. Basketball	3046	2471
C. Football	**4766**	**3350**
D. Hockey	117	83
E. Soccer	946	751

One possible research question

Has the total number or nature of exams associated with football-related injuries changed over the past 15 years?

Study design: Time-series analysis

Title of study	Trends in football-related injuries investigated at a tertiary care children's hospital: 2000-2014
Research question	Has the total number or nature of exams associated with football-related injuries changed over the past 15 years?
Significance	Increased public awareness about the long-term impact of concussions, rules of football have changed, etc.
Study design	Time-series analysis
Subjects	Exams on 6-17 year old males (Jan 1, 1990-Dec 31, 2014) who reported playing football prior to the injury being investigated
Predictor variable(s)	Time period, age group
Outcome variable	Number and type of radiology procedures (defined by the modality and anatomical location of the injury)
Primary null hypothesis	No change in the overall number or type of exams associated with football-related injuries

Key problems with this research question

Proper identification of patients with football-related injuries (Feasible?)

Who will care about trends in football-related exam volumes over time? (Novel, Relevant?)

Good research questions are FINER

Feasible

Interesting

Novel

Ethical

Relevant

- Adequate number of subjects
- Adequate technical expertise
- Affordable in time and money
- Manageable in scope
- Fundable

Good research questions are FINER

Feasible

Interesting

Novel

Ethical

Relevant

Getting the answer intrigues you and your colleagues

Good research questions are FINER

Feasible

Interesting

Novel

Ethical

Relevant

- Provides new findings
- Confirms, refutes, or extends previous findings
- May lead to innovations in concepts of health and disease, medical practice, or methodologies

Good research questions are FINER

Feasible

Interesting

Novel

Ethical

Relevant

A study the IRB will approve

Good research questions are FINER

Feasible

Interesting

Novel

Ethical

Relevant

- Likely to have significant impacts on scientific knowledge, clinical practice, or health policy
- May influence directions of future research

Conclusion:

Need to propose a slightly different research question that meets all FINER criteria

Literature search required
Discussions with colleagues

Why do a literature search?

- To help you clarify your research question
- To ensure that your study hasn't been done (published) before
- To identify key limitations of the previous studies
- To help you design a stronger study (better design, subject selection, etc.)
- To identify standard ways of measuring key variables
- To identify accepted statistical analysis techniques
- To identify compelling methods of data presentation

Medical literature

- Overview of pediatric football injuries [common and unusual imaging presentations, diagnosis & treatment plans]

- Studies of injuries occurring in specific anatomical sites and/or specific diagnosis [recent focus on brain injuries and concussions in youth]

Medical literature

- Prospective studies about the incidence of injuries in specific geographical areas, organized leagues and/or by levels of play [greater focus on high school or college-age players]

- One nationally-representative study of football-related injuries among 6-17 year olds treated in emergency departments (2000-2007) (Nation et al., 2011)

Internet/popular press

- “Game changers: Stats, stories and what communities are doing to protect young athletes” (Aug 2013, Safe Kids Worldwide)
- Conflicting claims about the risks of serious injury associated with playing youth football (Atlantic Monthly, Pop-Warner)
- Focus on traumatic brain injuries & concussions

Information gaps:

Studies focused on youth football players (particularly under 12)

- Few studies on the incidence of football-related injuries
- Lack of detailed information about injury severity
- Little focus on potentially serious injuries (other than traumatic brain injuries & concussions)

New idea:

Football-related injuries requiring radiologic imaging among 6- 17-year olds treated in the emergency department of a children's hospital: 2013-2014

Does this meet the FINER criteria?

Title of study	**Football-related injuries requiring radiologic imaging among 6- 17-year olds treated in the emergency department of a children's hospital: 2013-2014**
Research question	Does the type and severity of football-related injuries vary by age among youth football players?
Significance	Football is a highly popular sport, despite the risk of injuries. Conflicting claims have been made about the risk of severe injury to young players, particularly children under 12.
Study design	Cross-sectional study
Subjects	6-17 year old males who came to the emergency department as a result of an football-related injury and needed an imaging exam (Jan 1, 2013-Dec 31, 2014)
Predictor variable(s)	Age; age category (6-11 vs 12-17 year olds)
Outcome variable	Anatomical location and severity of the injury
Primary null hypothesis	No association between age and the type or severity of football-related injuries

Is this feasible?

Selection of subjects: New football-related injuries

- Use ‘status’ identifier (Inpatient, Outpatient, Emergency)
- Quick review of 607 report texts found “injury”

To do:

Verify how status indicator data was captured by Montage (2013-2014)
Check for multiple visits by the same patient
Check for multiple exams on the same patient on the same day
Decide how to handle and exclude as needed

Subject selection

Inclusion criteria	**N**
All exams completed Jan 1, 2000 through Dec 31, 2014 that had “football” mentioned anywhere in the report text	**4766**
Exclusion criteria	4159
Exams done outside Children’s DC location	120
All females	158
Patients outside the 6-17 year old age range	153
Patient status not clearly classified (all years prior to 2013)	3516
Inpatients and outpatients	212
Final sample size (# of exams in emergency patients)	**607**

Is this feasible?

Outcome variables: Injury classification system

- Applied coding methodology used by NEISS studies and mapped all exam codes (>100) to body parts and then back to four major regions

To do:

Develop a clear plan for coding all exams as injured (yes/no), type & severity of injury

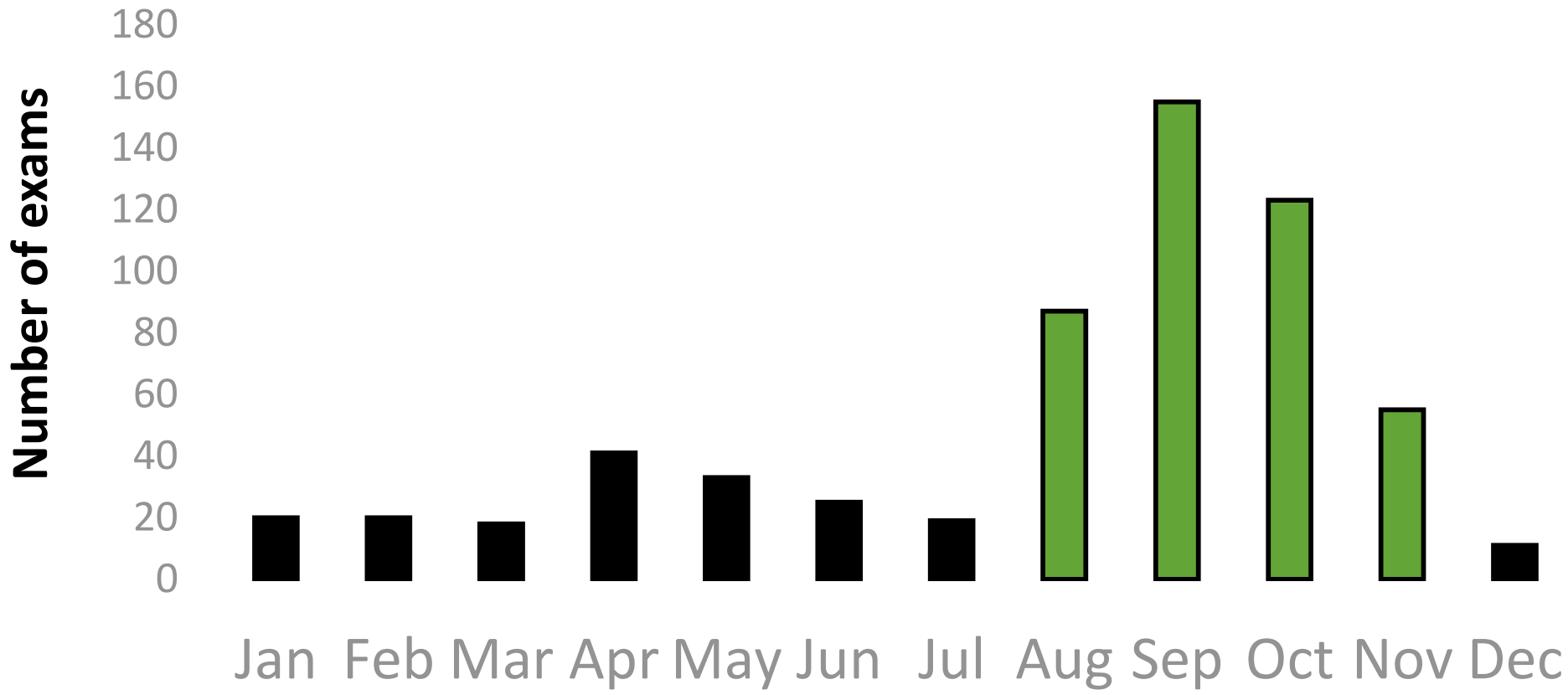
Current assessment of new research question

Is this feasible?	Yes, with more help
Is this interesting?	Yes
Is this novel?	Yes, with more help
Is this ethical?	Yes
Is this relevant?	Yes, with more help

Preliminary results

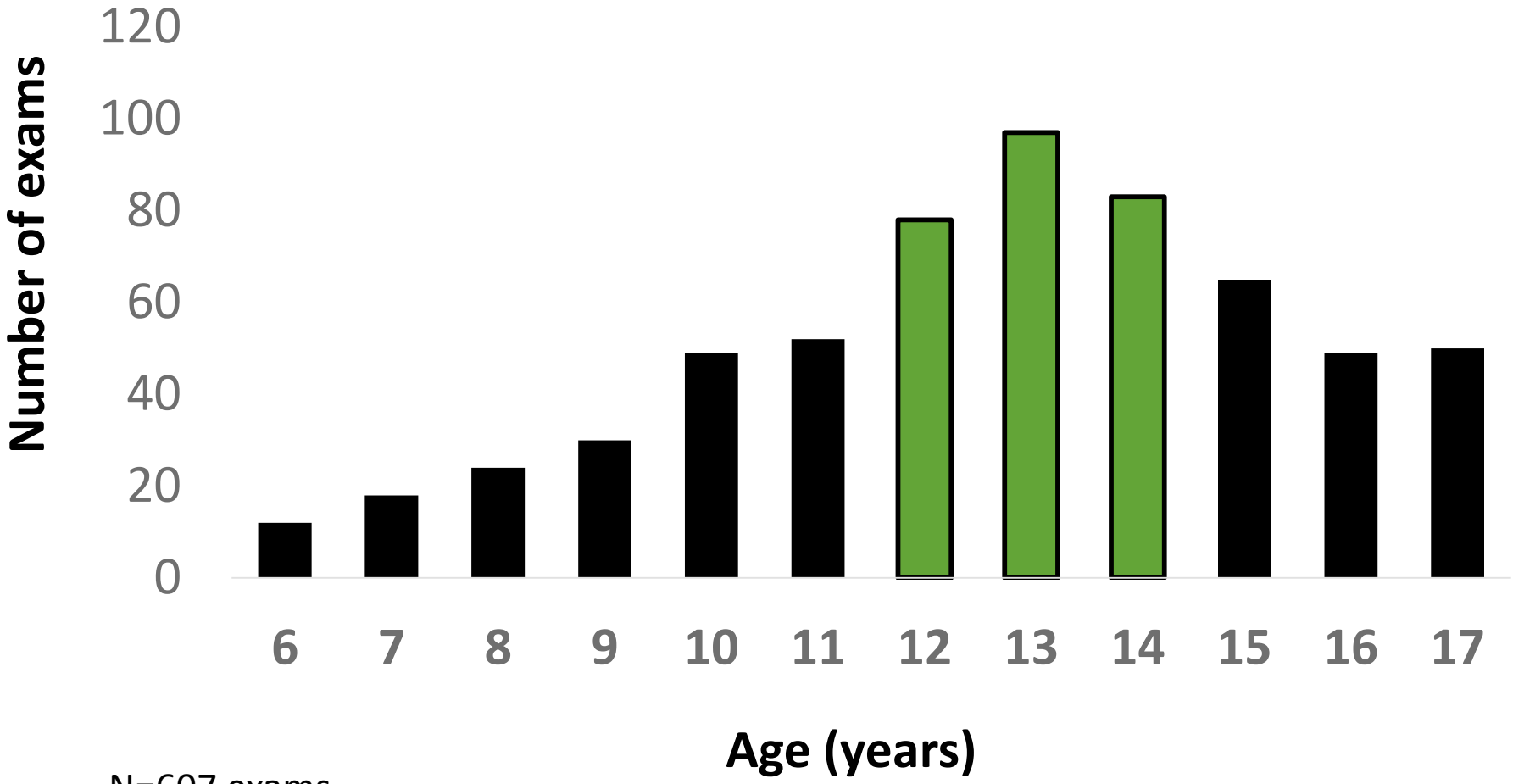
A total of **463** different male 6-17 year old patients who were seen in the emergency department for a football-related injury in 2013 and 2014 required imaging exams

The highest number of football-related injuries occurred during the fall football season (August-November)



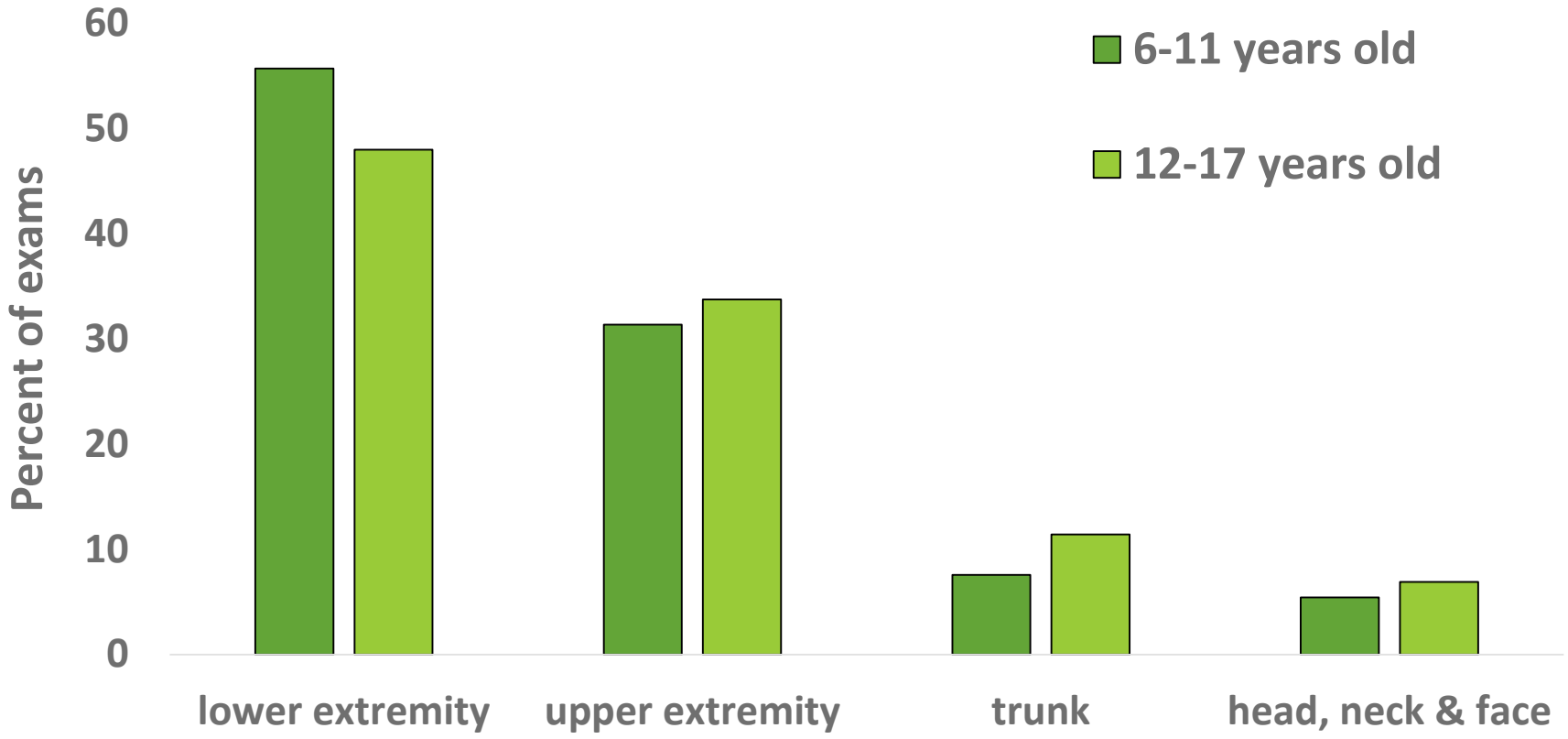
N=607 exams

The highest number of football-related injuries occurred in 12-to 14-year olds



N=607 exams

The lower extremities were the most commonly imaged body parts



commonly imaged body parts
(80% of all exams – all ages)

Knee
Ankle
Shoulder
Hand
Finger
Lower arm
Wrist
Lower trunk
Elbow

Part of body	Freq.	Percent	Cum.
knee	85	14.00	14.00
ankle	71	11.70	25.70
shoulder	64	10.54	36.24
hand	61	10.05	46.29
finger	58	9.56	55.85
lower arm	47	7.74	63.59
wrist	39	6.43	70.02
lower trunk	31	5.11	75.12
elbow	30	4.94	80.07
upper trunk	28	4.61	84.68
neck	25	4.12	88.80
foot	24	3.95	92.75
lower leg	16	2.64	95.39
head	10	1.65	97.03
upper arm	6	0.99	98.02
face	4	0.66	98.68
pubic region	3	0.49	99.18
upper leg	3	0.49	99.67
not stated	1	0.16	99.84
toe	1	0.16	100.00
Total	607	100.00	

Any questions?

Thoughts on how to improve the proposed study?

Next week

Nuts and bolts of good data management