Research design & study execution workshop series Session 6

SEPTEMBER 16, 2015

Quick review of Sessions 1-5

- How to identify a "good" research question
- Common study designs: Pros & cons
- Selecting appropriate study subjects
- Understanding variables types and their measurement

Case study: Football-related injuries

Nuts and bolts of good data management: Part I

Data collection & data entry

If you have...

- 1. Identified a research question
- 2. Conducted a literature review
- 3. Picked an appropriate study design
- 4. Defined inclusion/exclusion criteria for subjects
- 5. Considered predictor and outcome variables

Next step: Work on creating a "smart" data collection system

Data management process

All of the steps required to create a clean data set ready to be analyzed

Three keys to success

- 1. Clarity
- 2. Consistency
- 3. Documentation

Concrete products

- 1. Dummy tables and figures for publication
- 2. Data collection instruments
- 3. Data entry forms (Excel files, etc.)
- 4. Data codebook/coding manuals
- 5. Study manual

Overview of the process

- 1. Collect the data
- 2. Enter the data
- 3. Combine and clean data files
- 4. Recode, transform and derive new variables
- 5. Document and archive raw data sets

Step 1. Data collection Methods

- Download existing data and use as is
- Extract information from existing medical records
- Conduct a survey (online, phone, mail, in person)
- Collect raw data from direct observations, etc.

Each has pros & cons

Step 1. Data collection Format

- Paper/pen
- Mobile devices (phones, tablets, etc.)
- Stationary computers

Each has pros & cons

Best practices

- Collect as little as possible
- Collect raw data
- Automate as much as possible
- Document the process

Step 2. Data entry Goals

- 1. Convert the information to electronic format
- 2. Maintain accuracy & integrity of the information
- 3. Prevent as many errors as possible up-front

Step 2. Data entry Methods & tools

- 1. Excel spreadsheet vs. data entry programs
- 2. Single vs. double data entry, one person or more?
- 3. Include logic checks & range checks
- 4. Define missing values, etc.

Best practices & "how-to" demo in Excel coming

Published example: NEISS

Home / Research & Statistics

National Electronic Injury Surveillance System (NEISS)

CPSC's National Electronic Injury Surveillance System (NEISS) is a national probability sample of hospitals in the U.S. and its territories. Patient information is collected from each NEISS hospital for every emergency visit involving an injury associated with consumer products. From this sample, the total number of product-related injuries treated in hospital emergency rooms nationwide can be estimated. This web access to NEISS allows certain estimates to be retrieved on-line. These estimates can be focused by setting some or all of the following variables (and an example of each):

- Date (one year maximum range; e.g., how many injuries were treated in 1996)
- · Product (e.g., how many bicycle injuries occurred)
- · Sex (e.g., how many injuries occurred to women)
- Age (e.g., how many injuries occurred to people aged 35-55)
- Diagnosis (e.g., how many lacerations occurred)
- · Disposition (e.g., how many people were admitted to the hospital)
- · Locale (e.g., how many injuries occurred at a school)
- · Body part (e.g., how many injuries involved the knee)



U.S. Consumer Product Safety Commission NEISS Hospitals



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Appendix D: NEISS Body Part Diagram



CODE BODY PART

Head Ear Eyeball Face (including eyelid, eye area, nose, and forehead) Mouth (including lips, tongue and teeth) Neck Shoulder Upper trunk (not including shoulders) Upper arm Elbow Lower Arm (not including elbow or wrist) Wrist Hand Finger Lower trunk Pubic region Upper leg Knee Lower leg (not including knee or ankle) Ankle Foot Toc 25-50% of Body

- All Parts of Body
- Not Stated
- 0 Internal

Appendix E: Summary of Other Codes

Code in months (preceded by the number 2) if patient is less than 2 years old. Code in years if patient is 2 years old or more.

201 = less than 8 weeks 206 = 6 months 218 = 18 months 002 = 2 years 022 = 22 years 045 = 45 years 078 = 78 years 102 = 102 years

000 = not recorded

Greater than 115 years, see guidance in introduction section of coding manual.

Gender

Age

1 = Male 2 = Female

2 = Female 0 = Not recorded

Injury Diagnosis See Appendices B and D

Body Part Affected See Appendices C and D

Disposition

- Treated and released or examined and released without treatment
- 2 = Treated and transferred to another hospital
- 4 = Treated and admitted for hospitalization (within same facility)
- 5 = Held for observation
- 6 = Left without being seen/Left against medical advice (AMA)
- 8 = Fatality, including DOA, died in the ED, brain dead
- 9 = Not recorded

Product Codes See alphabetic product code list.

Injury Intent

- 1 = Assault / intentional injury inflicted by one person on another person
- 2 = Self-inflicted injury (confirmed or suspected)
- 3 = Injury related to legal intervention / law enforcement activities
- 0 = Unintentional (accidental) injury or injury intent not determined / not recorded

Locale of Accident

- 1 = Home
- 2 = Farm/ranch
- 4 = Street or highway
- 5 = Other public property
- 6 = Mobile/Manufactured home
- 7 = Industrial
- 8 = School/Daycare
- 9 = Place of recreation or sports
- 0 = Not recorded

Fire Involvement

- Fire involvement and/or smoke inhalation - Fire Dept. attended
- 2 = Fire involvement and/or smoke inhalation - Fire Dept. did not attend
- 3 = Fire involvement and/or smoke inhalation - Fire Dept. attendance is not recorded
- 0 = No fire involvement or fire involvement not recorded

Occupational or Work-related

- Work-related; occurred on the job (excluding active military duty)
- 2 = Not work-related; did not occur on the job
- 3 = Work-related; active military duty
- 0 = Not recorded

Race

1 = White 2 = Black/African American 4 = Asian 5 = American Indian/Alaska Native 6 = Native Hawaiian/Pacific Islander 3 = Other 0 = Not stated in ER record

Appendix A: NEISS Coding Sheet

NEISS Coding Sheet		Treatment Date				
Hospital			Month Day	١	⁄ear	
Age/Birthdate Case Number	S e Diagnosis Bodypart x	First Product	Second Product	I L n o t c	F O	[∗] ? Raceother

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	А	В	C D	E	F	G	Н	1	J	K	L	Μ	1	N	0	Р	Q 🔺
1 (PSC Case #	trmt_date	age sex	race	diag	body_part dis	position loc	ation p	orod1	narrative	I I						
132	140926233	9/8/2014	6 Male	None listed	53	81	1	9	121	1 6 YOM- C	CONTUS LT	THIGH-	PAT PLAY	ED FOO	TBALL ;	FELL ONT	J KNEE A
133	141243741	9/19/2014	6 Male	None listed	53	79	1	9	121	1 6YOM PL	AYING ***	FOOTBA	ALL AND 1	FACKLED	SUSTA	INED A CO	NTUSION
134	141016874	9/18/2014	6 Male	White	53	33	1	0	121	1 6 YOM IN	IJURY TO A	ARM PLAY	YING FOC	OTBALL.	DX FOR	EARM COI	ITUSION
135	141040233	10/14/2014	6 Male	Black/African American	52	75	1	9	121	1 6 YOM TA	ACKLED AT	FOOTBA	ALL PRAC	TICE. D	CONC	USSION.	
136	140225928	2/8/2014	6 Male	White	55	92	1	0	121	1 6YOM BE	NT THUM	B BACK S	/P FALL V	VHILE PL	AYING	FOOTBALL	.; DISLOC
137	140640195	2/6/2014	6 Male	Other / Mixed Race	62	75	4	0	121	1 6 YOM PA	ASSED OU	T WHILE	PLAYING	FOOTBA	LL HIT I	HEAD ON '	THE FLOC
138	141225269	12/8/2014	6 Male	Black/African American	64	37	1	1	121	1 SPRAINED	D ANKLE 6	YO M FE	LL PLAYIN	IG FOOT	BALL A	T HOME	
139	150201631	11/25/2014	6 Male	Black/African American	59	76	1	1	121	1 6YOM PL	AYING FO	OTBALL A	AT HOME	WITH B	ROTHER	RS & FRIEN	IDS WAS
140	141203485	11/29/2014	6 Male	White	53	33	1	1	121	1 6YOM PL	AYING FO	OTBALL V	VITH DO	G @ GR/	NDMO	THER'S HO	JUSE, DO
141	140746090	7/15/2014	6 Male	Black/African American	57	30	1	0	121	1 6 YOM FE	ELL WHILE	PLAYING	FOOTBA	LL. DX:	FRACTU	JRE CLAVIO	CLE.
142	141148630	10/11/2014	6 Male	Other / Mixed Race	53	79	1	8	121	1 6YOM PL	AYING FO	OTBALL A	AT SCHOO	DL AND H	HIT HAR	D IN THE I	-OWER A
143	140904383	8/27/2014	6 Male	Black/African American	71	85	4	9	121	1 6YOM ST	ARTED FO	OTBALL	YESTERD	AY, HAS	INCREA	SED WOR	(OF BRE/
144	140143451	1/14/2014	6 Male	Black/African American	62	75	1	8	121	1 A 6YOM 9	SLIPPED &	FELL WH	IILE PLAY	ING FOC	TBALL I	N GYM CL	ASS AT S
145	140937706	9/6/2014	6 Female	White	57	32	1	1	121	1 6YOF WA	S PLAYING	G FOOTBA	ALL W SIB	LINGS A	ND FEL	L AND INJU	JRED ELB
146	141030674	9/30/2014	6 Male	White	64	37	1	8	121	1 6 YOM PL	AYING FO	OTBALL	AT SCHO	OL FELL	TWISTE	D ANKLE. I	OX ANKLE
147	141103517	10/13/2014	6 Male	White	57	30	1	0	121	1 6YOM PL	AYING FO	OTBALL;	DX FX CL	AVICLE			
148	140408929	3/29/2014	6 Female	Black/African American	64	35	1	0	121	1 6 YOF WA	AS PLAYIN	g footb	ALL WITH	I BROTH	IER AND	FRIEND S	HE FELL /
149	140557633	2/8/2014	6 Male	Black/African American	53	92	1	1	121	1 6 YOM C	ONTUSION	I TO FING	GER WHE	N PLAYII	NG FOO	TBALL	
150	141028287	10/7/2014	6 Male	White	59	76	1	9	121	1 6 YOM PL	AYING FO	OTBALL I	HIT IN TH	E EYE/F	ACE BY	ANOTHER	PLAYERS
151	140968169	9/17/2014	6 Male	None listed	64	37	1	0	121	1 6 YO M W	VAS PLAYI	NG FOOT	BALL WH	IEN SOM	IEONE J	UMPED O	N HIS AN
152	141213522	11/29/2014	6 Male	White	59	75	1	9	121	1 6 YOM PL	AYING FO	OTBALL I	INDOORS	WHEN	HE TRIP	PED AND	FELL HITT
153	140936713	8/30/2014	6 Male	White	53	92	1	9	121	1 6 YOM IN	IJURY TO F	INGER A	T FOOTB	ALL GAN	IE. DX F	INGER CO	NTUSION
154	141046574	10/15/2014	6 Female	Other / Mixed Race	57	33	1	9	121	1 6 YO FEM	IALE PLAY	ING FOO	TBALL. D	X RADIU	S FX		
155	141005282	9/28/2014	6 Male	Black/African American	59	76	1	9	121	1 6YOM HI	T HELMET	TO HELN	JET WHI	E PLAYI	NG FOO	TBALL, NO	W CUT (
156	140544020	5/7/2014	6 Mala	Other / Mixed Race	57	20	1	٩	171	1 6 YOM W			ΟΟΤΒΔΗ	GAME	MITH R		ς <i>δ</i> , γγ/δς 👗
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READY

Working example: Montage

Football-related injuries requiring radiologic imaging among 6- to 17-year olds treated in the emergency department of a children's hospital: 2013-2014 **Unsettled issue:** Conflicting claims about the frequency of severe football-related injuries among very young football players (6-11 years old)

Research question: Is <u>age</u> associated with the <u>type</u> or <u>severity</u> of football-related injuries among 6-17 year old males who visited the emergency room?

Null hypothesis: There is no association between age and the type or severity of football-related injuries

Subject selection

Inclusion criteria	N							
All exams completed Jan 1, 2000 through Dec 31, 2014 that had "football" mentioned anywhere in the report text								
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							

Dummy tables and figures

Characteristics of study population

Characteristic	Ν	%
Total number of exams	607	
Year of exam		
2013	269	44%
2014	338	56%
Total number of unique patients	463	
Age of patients (all exams)		
6-11 years	185	30%
12-17 years	422	70%

Characteristics of study population, cont.

Characteristic	Ν	%
Region of body part injured		
Lower extremity	305	50%
Upper extremity	200	33%
Trunk	62	10%
Head, neck & face	39	6%
Severity of injury		
Mild		
Severe		

Number of exams by month



Number of exams by month



Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec

Numerical

Discrete (Limited number of quantifiable intervals)

Categorical Ordinal (Ordered categories)

Number of exams by age



Number of exams by age



Region of body injured by age category





Montage data: Football injuries (2013-2014: ER, 6-17 year old males)

	Α	В	С	D	E	F	G	Н	I	J	К	L	М	Ν
1	Patient Sex	Patient Age	Organization	Patient Status	mrna	acca	Exam Completed Date	year	month	Exam Code	Report Text			
2	Male	13	СН	Emergency	20674900	2706182	11/22/2014 13:44	2014	11	HAND3	AP right Hand with 2 Views fifth digit His	story: {1	3 yo s/p foot	ball injury to
3	Male	12	CH	Emergency	20383774	2677867	9/20/2014 18:31	2014	9	CTRAUMABR	Examination: CT of the head without con	ntrast. H	istory: Hit pla	ying football
4	Male	11	СН	Emergency	20427354	2518004	9/14/2013 14:30	2013	9	KNEE3	Addendum BeginsInitial report incomple	te. Com	plete report a	s follows: H
5	Male	11	СН	Emergency	20427354	2518005	9/14/2013 14:30	2013	9	FEMUR	Addendum BeginsInitial report incomple	te. Com	plete report a	s follows: H
6	Male	9	CH	Emergency	20535503	2721171	12/27/2014 9:43	2014	12	FINGER	AP left Hand with 2 Views fourth digit H	istory: s	/p football inju	ury yesterda
7	Male	19	CH	Emergency	20133004	2719927	12/23/2014 15:44	2014	12	UEXT	HISTORY: 19-year-old male with footba	all helme	t to thigh one	month agon
8	Male	12	СН	Emergency	20433798	2716117	12/15/2014 16:40	2014	12	KNEES	4 views right knee History: {football inju	iry} Com	parison: None	e Findings:B
9	Male	14	СН	Emergency	20380881	2715666	12/15/2014 0:01	2014	12	HAND3	3 views right hand History: {football hel	met to h	and} Compari	ison: None F
10	Male	12	СН	Emergency	20421615	2715287	12/13/2014 11:15	2014	12	HAND3	3 views right hand History: Playing foot	ball, hyp	erextended ri	ght third fing
11	Male	17	OT	Outpatient	20655764	2714531	12/11/2014 16:39	2014	12	KNEE3	RIGHT KNEE SERIES 12/11/2014 4:39	PM CLI	NICAL INDIC	ATION: 17-
12	Male	16	CNI	Inpatient	20286919	2712859	12/8/2014 16:38	2014	12	FINGER	XR, finger(s), minimum of two views HIS	STORY:	Football injury	y in August.
13	Male	11	CH	Emergency	20657925	2710734	12/3/2014 17:37	2014	12	FINGER	AP left Hand with 2 Views index finger H	listory:	s/p playing fo	otball, L ind
14	Male	12	СН	Emergency	20410999	2709997	12/2/2014 12:29	2014	12	KNEES	XR, knee; complete, four or more views		RY: Fell playir	ng football 2
15	Male	6	СН	Emergency	20833664	2709336	12/1/2014 10:21	2014	12	FOOT3	3 views right foot History: Injured right	foot play	ring football ye	esterday Co
16	Male	10	CH	Emergency	20504139	2709297	12/1/2014 9:20	2014	12	FINGER	AP RIGHT HAND WITH 2 VIEWS THE	RIGHT 1	THIRD FINGE	R History:
17	Male	16	CH	Emergency	20256331	2709176	11/30/2014 18:25	2014	11	FORARM	2 views left forearm History: s/p footba	III injury (Comparison: N	None Finding
18	Male	14	СН	Emergency	20639803	2708968	11/29/2014 16:32	2014	11	FINGER	AP right Hand with 2 Views thumb Histo	ry: Jam	med thumb in	ito ground d
10														

Next steps: Classification of body parts

- Body part classification system created & applied
- 2. Confirm decisions (2nd radiologist)
- 3. Apply to all exams (need more information than exam codes?)

Next steps: Injury classification

- 1. Create injury classification system
- 2. Document & pretest the system
- 3. Apply the system (2 radiologists?)

Data management defined

All of the steps required to create a clean data set ready to be analyzed

Five parts of the process

- 1. Collect the data
- 2. Enter the data
- 3. Combine and clean data files
- 4. Recode, transform and derive new variables
- 5. Document and archive raw data sets

Three keys to success

- 1. Clarity
- 2. Consistency
- 3. Documentation

Next week

Nuts and bolts of good data management: Part II

(Data cleaning, recoding, archiving)