Research design & study execution workshop series
Session 1

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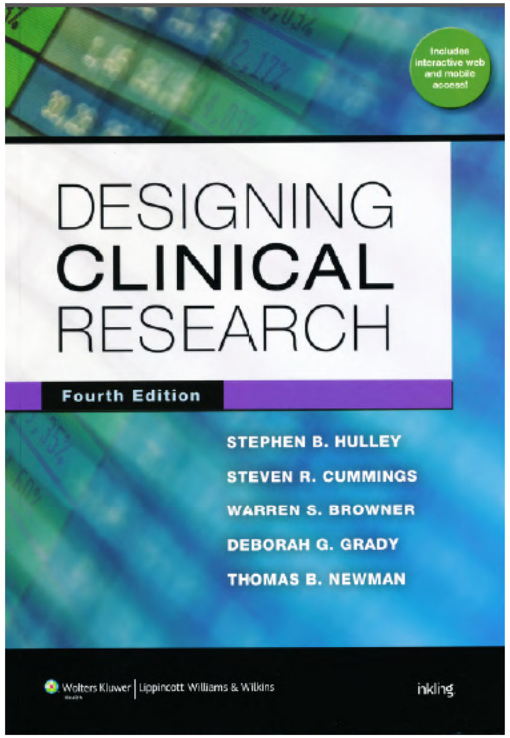
1. What makes a good research question?
2. Brief overview of study designs
3. What can Montage do for you?

What makes a good research question?

Background readings:

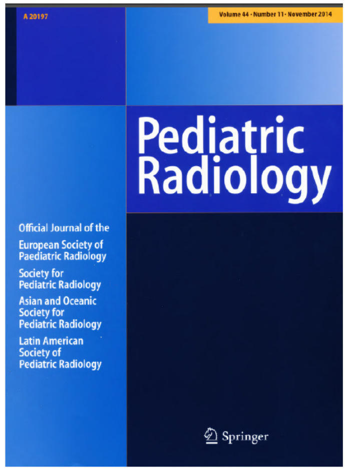
Chapter 1. Getting started: The Anatomy and Physiology of Clinical Research

Chapter 2. Conceiving the research question and developing the study plan



You have a great idea

A bunch of stuff happens



Your work gets published

You have a great idea

<u>Some unresolved issue exists</u>

I don’t think our practice guidelines make sense anymore…
I’m not convinced my colleague is right about that…
I think we can do this better…
I wonder what would happen if we did that…?
I think we might get better patient outcomes if we did this…

But, can you turn your great idea into a **research question**?

A **research question** is the question the research project is intended to answer

(Who, What, Where, When, Why, How much, How many)

Predictor	Outcome
Radiological finding	Clinical status of patient [has a disease, needs surgery, etc.]
Characteristic of the patient [age, sex, race, clinical history, etc.]	Radiological finding

“Is A associated with B in population C?”

Examples

“Is [ultrasound size of the appendix > 6mm] associated with [appendicitis (surgical outcome or clinical follow-up)] in [patients <18 years old who presented with abdominal pain?]”

“Is [increased ictal Neurolite/Ceretec SPECT focal brain uptake] associated with [focal cortical dysplasia] in [epilepsy patients < 18 years old]?”

“Is A associated with B in population C?”

Examples

“Is the type of playground surface (wood chips vs. recycled rubber chips) associated with the presence and type of forearm fracture (Buckle vs. complete) in [children 2-5 years old who had a radiograph following a playground fall]?”

“Is [high consumption of sugary drinks] associated with fatty liver [as diagnosed by ultrasound and/or MR elastography] in [7-18 year old, non-obese patients]?”

“Does A cause B in population C?”

Examples

“Does [exposure to radiation from CT scans] increase the [risk of brain tumors] in [patients 2-22 years old]?”

Good research questions are FINER

Feasible
Interesting
Novel
Ethical
Relevant

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Interesting
Novel
Ethical
Relevant

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

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Getting the answer intrigues you and your colleagues

Good research questions are FINER

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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

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A study the IRB will approve

Good research questions are FINER

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Relevant

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

You think you have a great idea...

1. Write it down
2. Get feedback from colleagues
3. Refine and revise

Produce a one-page outline

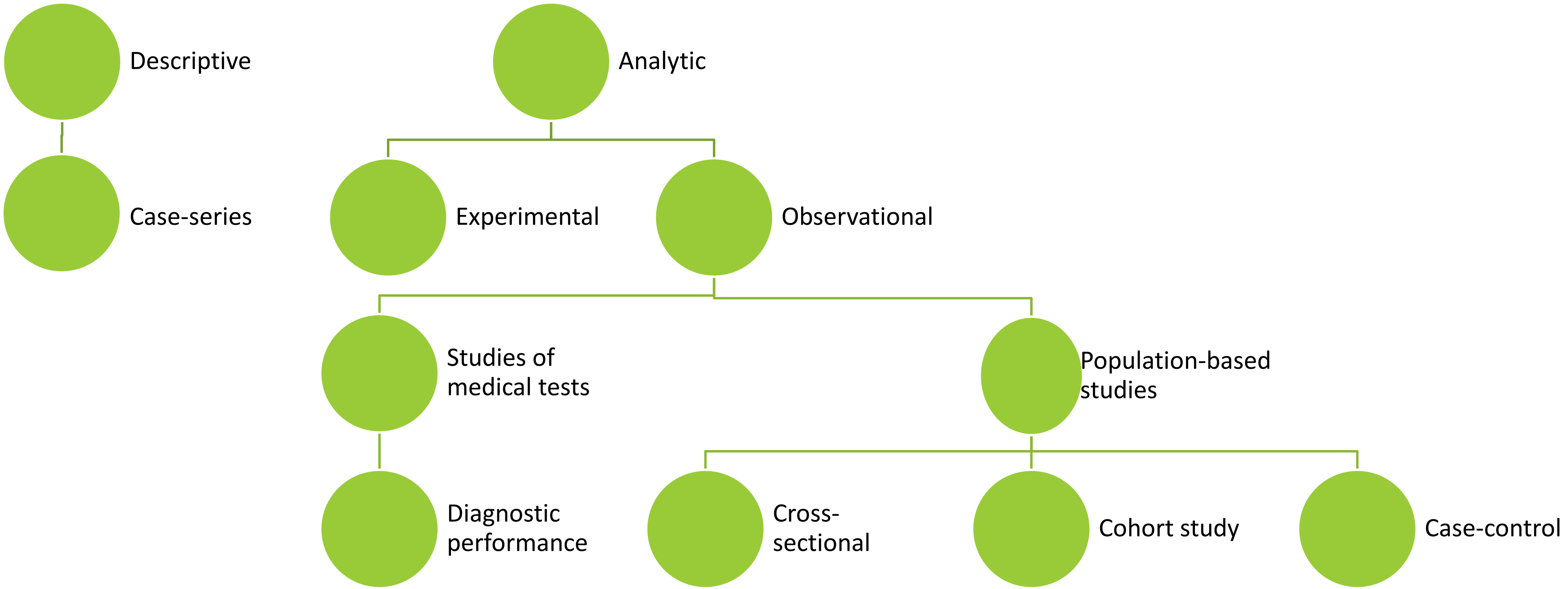
Title of study	
Research question	
Significance	
Study design	
Subjects	
Predictor variable(s)	
Outcome variable	
Primary null hypothesis	

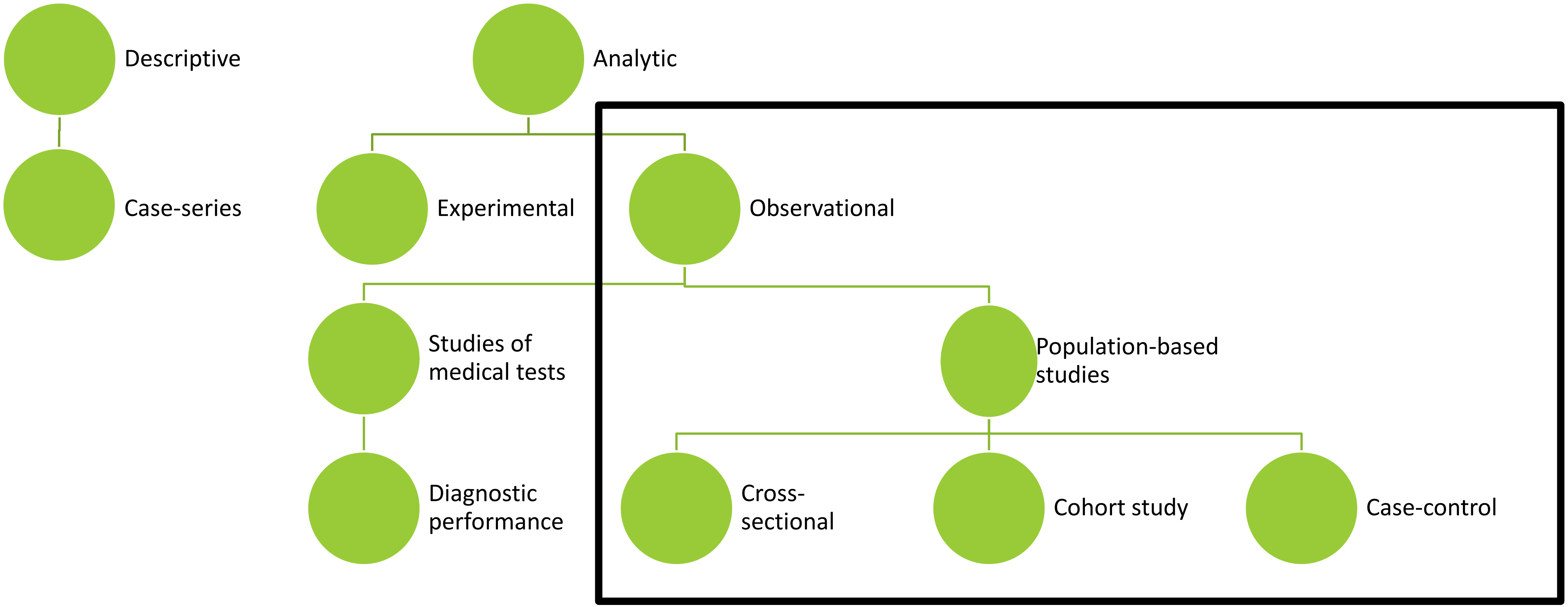
Title of study	Radiation exposure from CT scans in childhood and subsequent risk of leukemia and brain tumors: A retrospective cohort study
Research question	Does exposure to radiation from head CT scans increase the risk of leukemia and brain tumors in children <22 years old?
Significance	CT scans are commonly used in children, but ionizing radiation may increase the risk of certain types of cancers
Study design	Retrospective cohort study
Subjects	Children and young adults in the UK <22 years old who received head CT scans between 1985-2002
Predictor variable(s)	Gender, age, numbers and type of radiology procedures and estimated radiation dose
Outcome variable	Leukemia at least 2 years after the first CT Brain tumors at least 5 years after the first CT
Primary null hypothesis	Exposure to radiation from CT scans is not associated with increased risk of leukemia or brain tumors

Goals & learning objectives

* Name five characteristics of a good research question
* Formulate your own research question (one sentence)
* Start drafting a preliminary study outline (one-page)

General categories of study designs


Descriptive
Case-series
Analytic
Experimental
Observational
Studies of medical tests
Diagnostic performance
Population-based studies
Cross-sectional
Cohort study
Case-control



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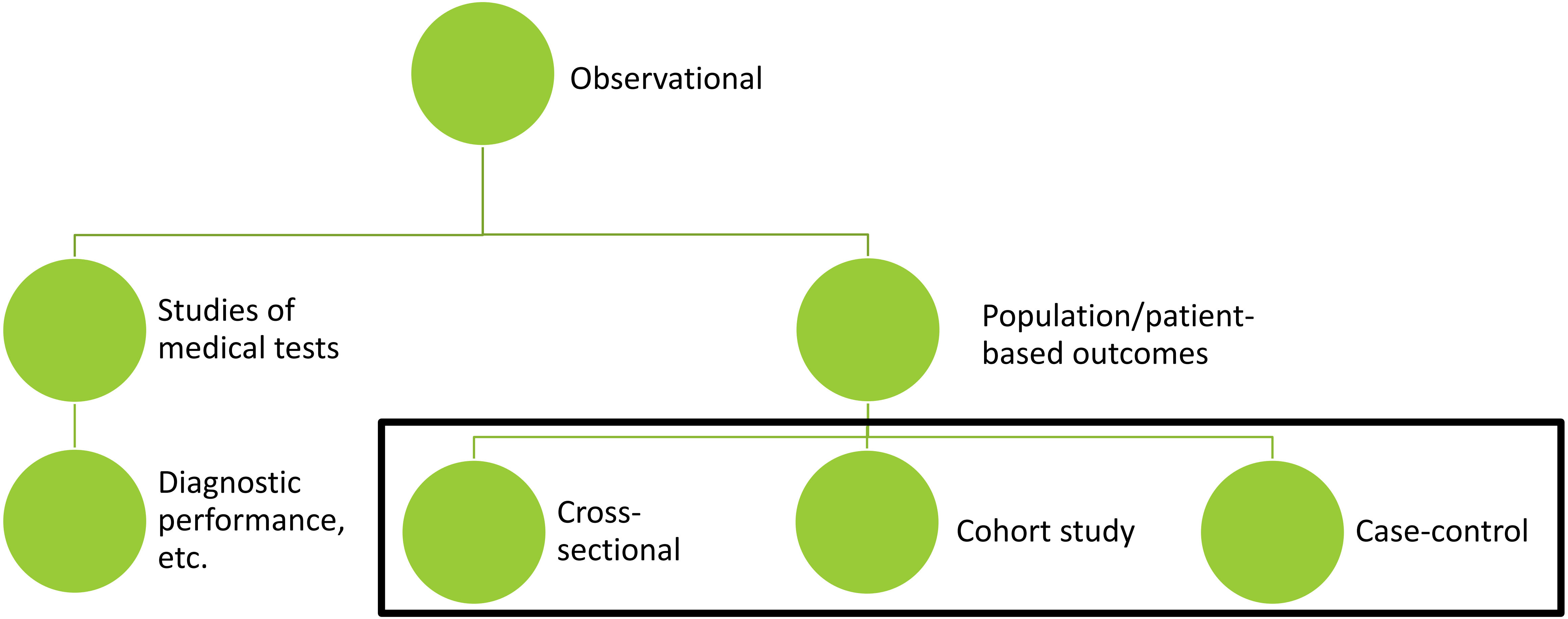

Observational
Studies of medical tests
Population/patient-based outcomes
Diagnostic performance, etc.
Cross-sectional
Cohort study
Case-control

Retrospective vs. prospective studies

Predictor	Outcome
Radiological finding	Clinical status of patient [has a disease, needs surgery, etc.]
Characteristic of the patient [age, sex, race, clinical history, etc.]	Radiological finding

Prospective

Predictor	Outcome
Radiological finding	Clinical status of patient [has a disease, needs surgery, etc.]
Characteristic of the patient [age, sex, race, clinical history, etc.]	Radiological finding

Study enrollment happens

Retrospective

Predictor	Outcome
Radiological finding	Clinical status of patient [has a disease, needs surgery, etc.]
Characteristic of the patient [age, sex, race, clinical history, etc.]	Radiological finding

Study enrollment happens

Type of study	Retrospective	Prospective
Cross-sectional	X	X
Cohort study	X	X
Case-control	X	

Cross-sectional study

Key design features

All measurements made at same point in time (snapshot); no follow-up

Implementation

1. Define selection criteria and recruit the population sample
2. Measure the predictor and outcome variables

Cross-sectional study

Strengths

Fast and inexpensive

Can calculate prevalence of a condition

Good for describing patterns in the distribution of variables (age, sex, race)

Weaknesses

Difficult to establish causal relationships (what came first?)

Cross-sectional study

Many examples…

Patient characteristic [A] is associated

with radiological finding [B] in population [C]

Radiological finding [A] is associated

with patient characteristic [B] in population [C]

Retrospective cohort study

Key design features

Two measurements: Predictors [time passes] outcomes

Implementation

1. Identify a suitable existing cohort
2. Collect predictor variable data
3. Collect outcome data

Retrospective cohort study

Strengths

Establish time-sequence of events

Calculate incidence of outcome

Less costly and time consuming than prospective cohort study

Weaknesses

Limited control over approach to sampling, follow-up & quality of measurements

Retrospective cohort study

Radiation exposure from CT scans in childhood and subsequent risk for leukemia and brain tumors: A retrospective cohort study

Pearce MS, et al. Lancet 2012; 380:499-505.

Case-control study

Key design features

Always retrospective; outcomes defined first; predictors measured

Implementation

1. Select the sample of cases
2. Select the sample of controls
3. Measure the predictor variables

Case-control study

Strengths

Efficient for rare outcomes, inexpensive

Useful for generating hypotheses

Weaknesses

Can only study one outcome

Susceptible to bias (sampling and retrospective measurements)

Case-control study

Severity of playground fractures:

Play equipment versus standing height falls

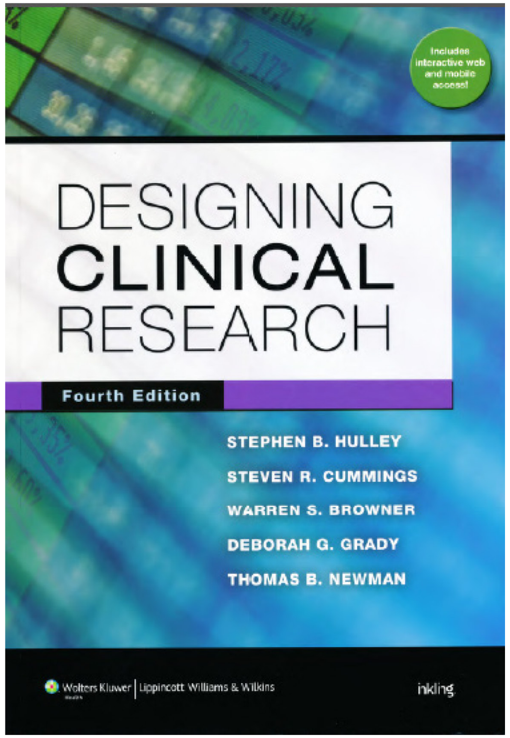
Fissel D, et al. Injury Prevention 2005; 11:337-339.

Study designs

Background readings:

Chapter 7. Designing cross-sectional and cohort studies

Chapter 8. Designing case-control studies



Goals & learning objectives

* List major categories of study designs

* Explain the key difference between prospective and retrospective studies

* List 3 common types of population-based study designs

* Identify the design of a study you would like to do

What can Montage do for you?

Key variables accessible in Montage

Patient factors (age, sex)

Location of service (DC vs. Shady Grove)

Type of exam (exam code, CPT code)

Time/date stamps (exam completed, exam read, exam started, exam ordered)

Clinician (Ordering physician, reading radiologist)

Report text (clinical history & impressions)

Montage can help you systematically…

1. Identify a case series of patients with specific image findings or outcomes
2. Construct a cohort of patients for a retrospective cross-sectional study
3. Construct a cohort of patients for a retrospective cohort study
4. Identify cases and control patients for a case-control study
5. Assess feasibility (sample size planning)

Etc.

Title of study	
Research question	Does exposure to radiation from head CT scans increase the risk of childhood leukemia and brain cancer?
Significance	CT scans are commonly used in children, but ionizing radiation may increase the risk of cancers
Study design	Retrospective cohort study
Subjects	Children and young adults in the UK <22 years old who received head CT scans between 1985-2002
Predictor variable(s)	Gender, age, numbers and type of radiology procedures and estimated radiation dose
Outcome variable	Leukemia at least 2 years after the first CT Brain tumors at least 5 years after the first CT
Primary null hypothesis	Exposure to radiation from CT scans is not associated with increased risk of leukemia or cancer

Next steps:

Formulate your research question
Draft study outline
Test-drive Montage