UNIVERSITY OF CALGARY

Overview of Study Designs

Dr. Janet Aucoin, PhD

These lecture notes are based on others developed by myself and Dr. Brent Hagel

October 21, 2025

Learning Objectives

- To provide an introduction to the major epidemiologic study designs
- To distinguish the characteristics among major epidemiologic study designs

Resources


http://www.equator-network.org/
The EQUATOR Network | E...
View Favorites Tools Help
equator network
Enhancing the QUAlity and Transparency Of health Research
Home
Library
Toolkits
Courses & events
News
Blog
Librari
Your one-stop-shop for writing and publishing high-impac
find reporting guidelines | improve your writing | join our courses | run your own training course | enhance
Library for health research reporting
The Library contains a comprehensive searchable database of reporting guidelines and also links to other resources relevant to research reporting.
Search for reporting guidelines
Not sure which reporting guideline to use?
Reporting guidelines for mai study types
Randomised trials CONSORT Extensions
Observational studies STROBE Extensions
Systematic reviews PRISMA Extensions
Case reports CARE Extensions
Qualitative research SRQR COREQ
Diagnostic / prognostic studies STARD TRIPOD
Quality improvement studies SQUIRE

Understanding Epidemiologic Study Designs

- Identification of study designs is a key step in the design and critical appraisal of research
  - Bias can commonly be introduced due to study design defects
  - Identifying the study design begins the process of thinking through a study's vulnerability to error
- Descriptive v. analytic
  - Focus on goals, rather than design features
    - Not always clear
  - Risky starting point for study design classification.
- Experimental vs non-experimental
  - Experiment usually implies that the investigator manipulates the exposure assigned to the participants

Major Epidemiologic Study Designs

- Descriptive
  - Case report
  - Case series
- Analytic
  - Randomized
  - Non-Randomized
    - Quasi-Experimental
    - Cohort (Prospective/Retrospective)
    - Case-Control
    - Cross-Sectional
    - Ecological

Adapted from Koepsell and Weiss. Epidemiologic Methods: Studying the Occurrence of Illness. Oxford University Press 2003; P. 94

Determining the Study Design

1. Is the unit of analysis individual people or groups?
2. Is the study observational or interventional?
3. Is the directionality forward or backward?
4. Is the timing prospective or retrospective?
5. Is the exposure randomly assigned?

Descriptive Studies

- Undertaken without a specific hypothesis
- Can often be viewed as *Hypothesis Generating*
- Among the earliest studies on a new disease
  - Characterize disease entity
  - Quantify frequency and how it varies in relation to person, place, time

Descriptive Studies

- Case reports
  - "…careful, detailed report by one or more clinicians of the profile of a single patient." (Hennekens & Buring. Epidemiology in Medicine. Little Brown and Company, 1987; P. 18)

Primary Tuberculosis of Bone Mimicking a Lytic Bone Tumor

Scott D. Lemme, MD, Austin Kevin Raymond, MD,† Christopher P. Cannon, MD,‡ Anne N. Normand, MD,‡ Kimberly C. Smith, MD, MPH,*§ and Dennis P. M. Hughes, MD, PhD‖*

Summary: Causes of lytic bone lesions in children include benign, malignant, and infectious processes. Here, we present the case of a 3-year-old boy presenting with a lytic bone lesion and surrounding soft tissue mass sent for evaluation of possible malignancy versus osteomyelitis. Biopsy revealed granulomatous osteomyelitis, and subsequent purified protein derivative resulted in 20-mm induration. Lesion cultures eventually identified pan-sensitive *Mycobacterium tuberculosis*. We emphasize that tuberculosis can cause primary lytic bone lesions in children in the United States, even in the absence of pulmonary symptoms or known exposure, and advise clinicians to include mycobacterial cultures when analyzing biopsies of lytic bone lesions.

Key Words: Bone tumor, TB

(*J Pediatr Hematol Oncol* 2007;29:198–202)

Descriptive Studies

- Case series
  - Characteristics of a group of individuals with a given clinical outcome

Pediatric Fall Injuries in Agricultural Settings: A New Look at a Common Injury Control Problem

Objectives: *Children on farms experience high risks for fall injuries. This study characterized the causes and consequences of fall injuries in this pediatric population.* ***Methods:*** *A retrospective case series was assembled from registries in Canada and the United States. A new matrix was used to classify each fall according to initiating mechanisms and injuries sustained on impact.* ***Results:*** *Fall injuries accounted for 41% (484/1193) of the case series. Twenty percent of the fall injuries were into the path of a moving hazard (complex falls), and 91% of complex falls were related to farm production. Sixty-one percent of complex falls from heights occurred while children were not working. Fatalities and hospitalized injuries were overrepresented in the complex falls.* ***Conclusions:*** *Pediatric fall injuries were common. This analysis provides a novel look at this occupational injury control problem.* (J Occup Environ Med. *2007;49:461–468*)

UNIVERSITY OF CALGARY

Cuboid Nutcracker Fracture Due to Horseback Riding in Children

Case Series and Review of the Literature

Dimitri Ceroni, MD, Vicenzo De Rosa, MD, Geraldo De Coulon, MD, and André Kaelin, MD

Abstract: We report 4 cases of nutcracker fractures of the cuboid resulting from equestrian sport in pediatric population. These lesions are often consistent with a trauma in forced abduction of the forefoot. The particular mechanism of the cuboid fracture due to horseback riding in children is discussed. The methods used to radiographically evaluate the compression fracture of the cuboid and its associated injuries are presented. Left untreated, these fractures can lead to severe alterations in foot mechanics and function, such as to severe pain. In addition, the surgical treatment to correct the nutcracker fracture of the cuboid in our patients is presented.

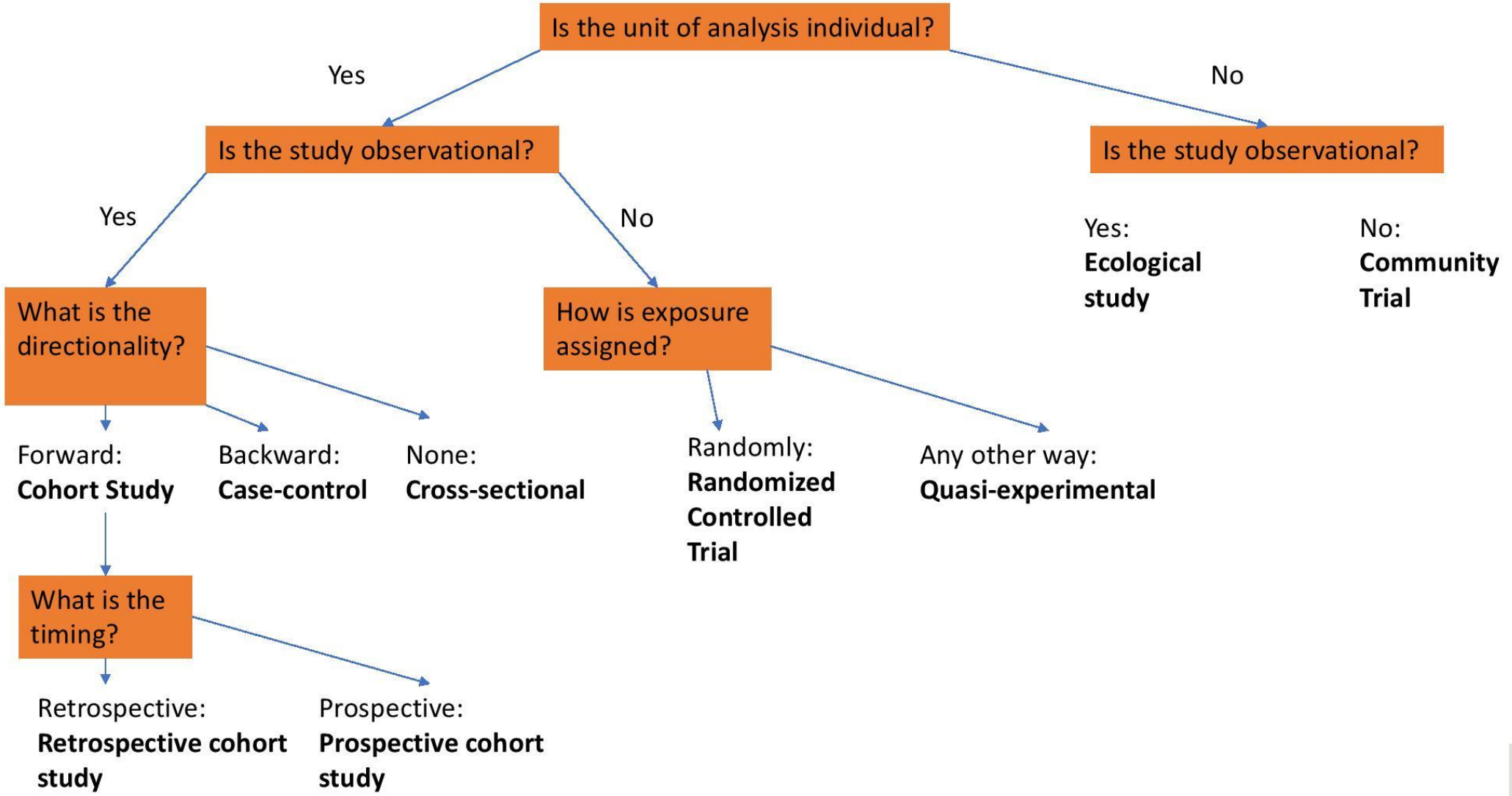
Key Words: children, compression, cuboid, horse riding, nutcracker fracture

(*J Pediatr Orthop* 2007;27:557–561)

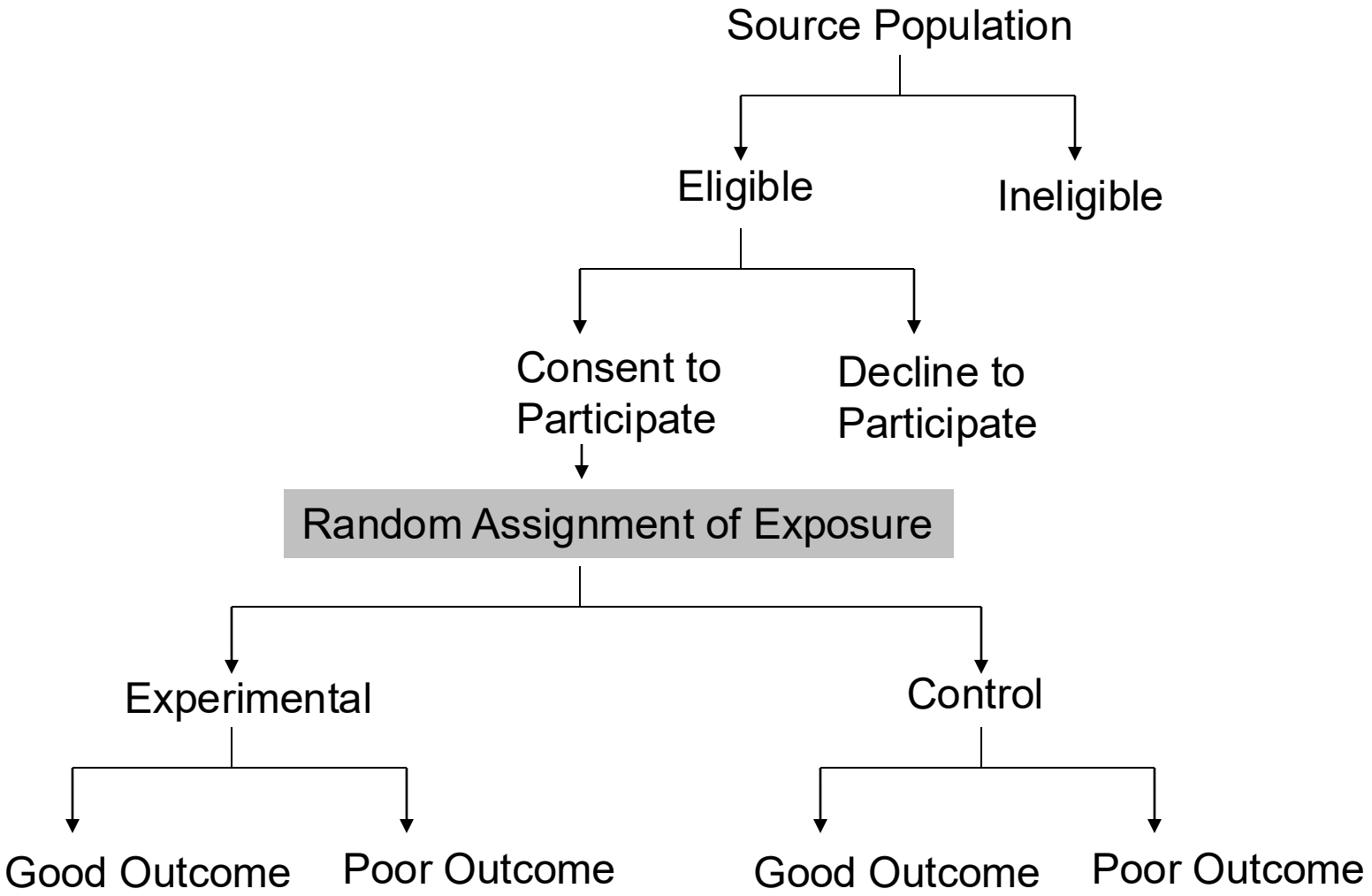
Analytic Studies

- Often undertaken to test a hypothesis
- Relate a health outcome to a potential determinant
  - Genetic
  - Environmental
  - Behavioural
- Does the determinant/exposure cause the outcome?

Analytic Studies



Randomized Controlled Trials



From Koepsell and Weiss. Epidemiologic Methods: Studying the Occurrence of Illness. Oxford University Press 2003; P. 94

A Randomized Controlled Trial of Home Injury Hazard Reduction: The HOME Injury Study

Kieran J. Phelan, MD, MS; Jane Khoury, PhD; Yingying Xu, MS; et al

UNIVERSITY OF CALGARY

Abstract

Objective To test the efficacy of installing safety devices in the homes of young children on total injury rates and on injuries deemed a priori modifiable by the installation of these devices.

Design A nested, prospective, randomized controlled trial.

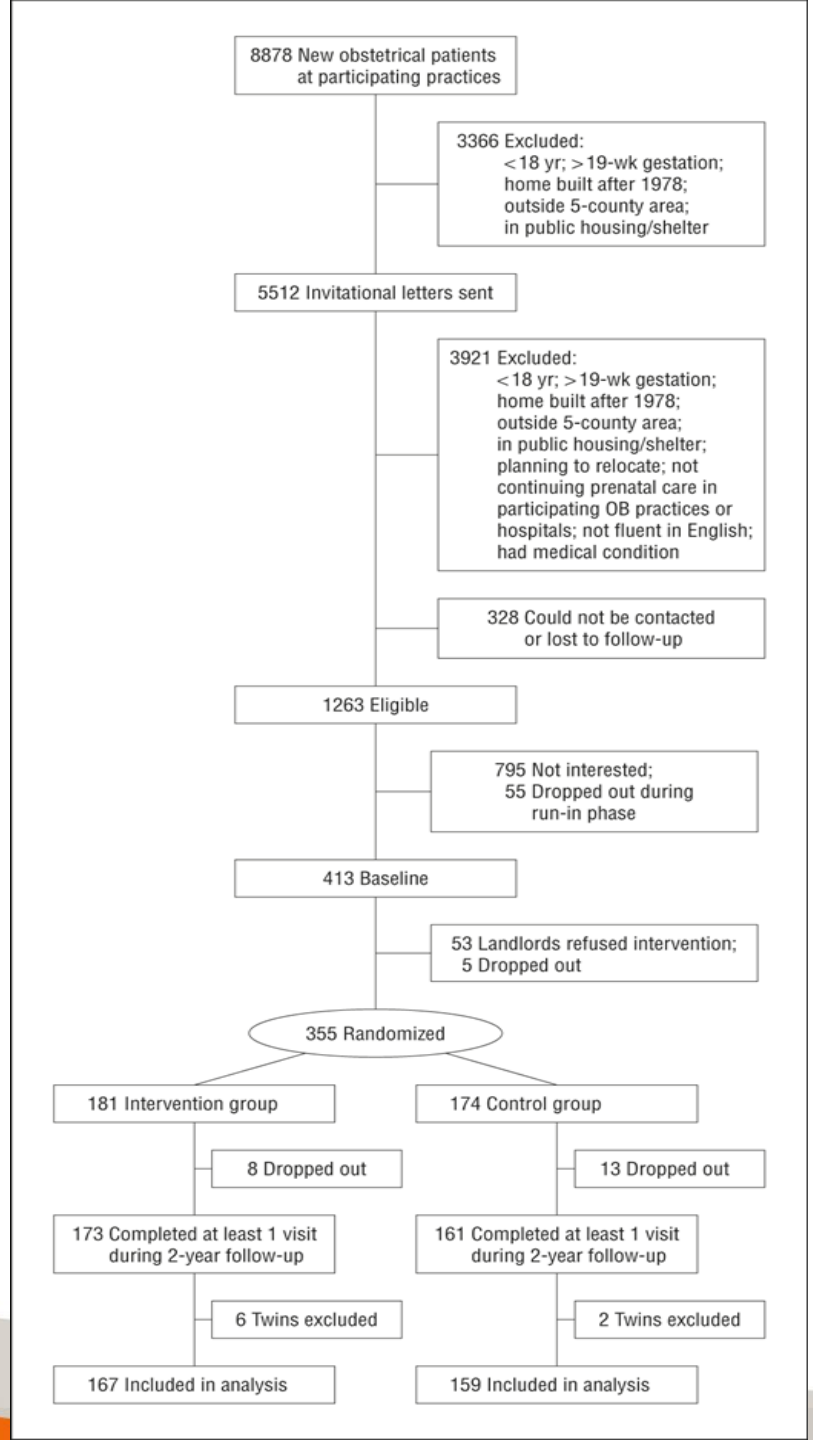
Setting Indoor environment of housing units.

Participants Mothers and their children from birth to 3 years old participating in the Home Observation and Measures of the Environment study. Among 8878 prenatal patients, 1263 (14.2%) were eligible, 413 (32.7%) agreed to participate, and 355 were randomly assigned to the intervention (n = 181) or control (n = 174) groups.

Intervention Installation of multiple passive measures (eg, stair gates, cabinet locks, and smoke detectors) to reduce exposure to injury hazards. Injury hazards were assessed at home visits by teams of trained research assistants using a validated survey.

Main Outcome Measure Modifiable and medically attended injury (ie, telephone calls, office visits, and emergency visits for injury).

Arch Pediatr Adolesc Med. 2011;165(4):339-345. doi:10.1001/archpediatrics.2011.29



UNIVERSITY OF CALGARY

Results The mean age of children at intervention was 6.3 months. Injury hazards were reduced in the intervention homes but not in the control homes at 1 and 2 years ($P < .004$). There was no difference in the rate for all medically attended injuries in intervention children compared with controls: 14.3 injuries (95% confidence interval [CI], 9.7-21.1 injuries) vs 20.8 injuries (95% CI, 14.4-29.9 injuries) per 100 child-years ($P = .17$); but there was a significant reduction in the rate of modifiable medically attended injuries in intervention children compared with controls: 2.3 injuries (95% CI, 1.0-5.5 injuries) vs 7.7 injuries (95% CI, 4.2-14.2 injuries) per 100 child-years ($P = .03$).

Conclusion An intervention to reduce exposure to hazards in homes led to a 70% reduction in the rate of modifiable medically attended injury.

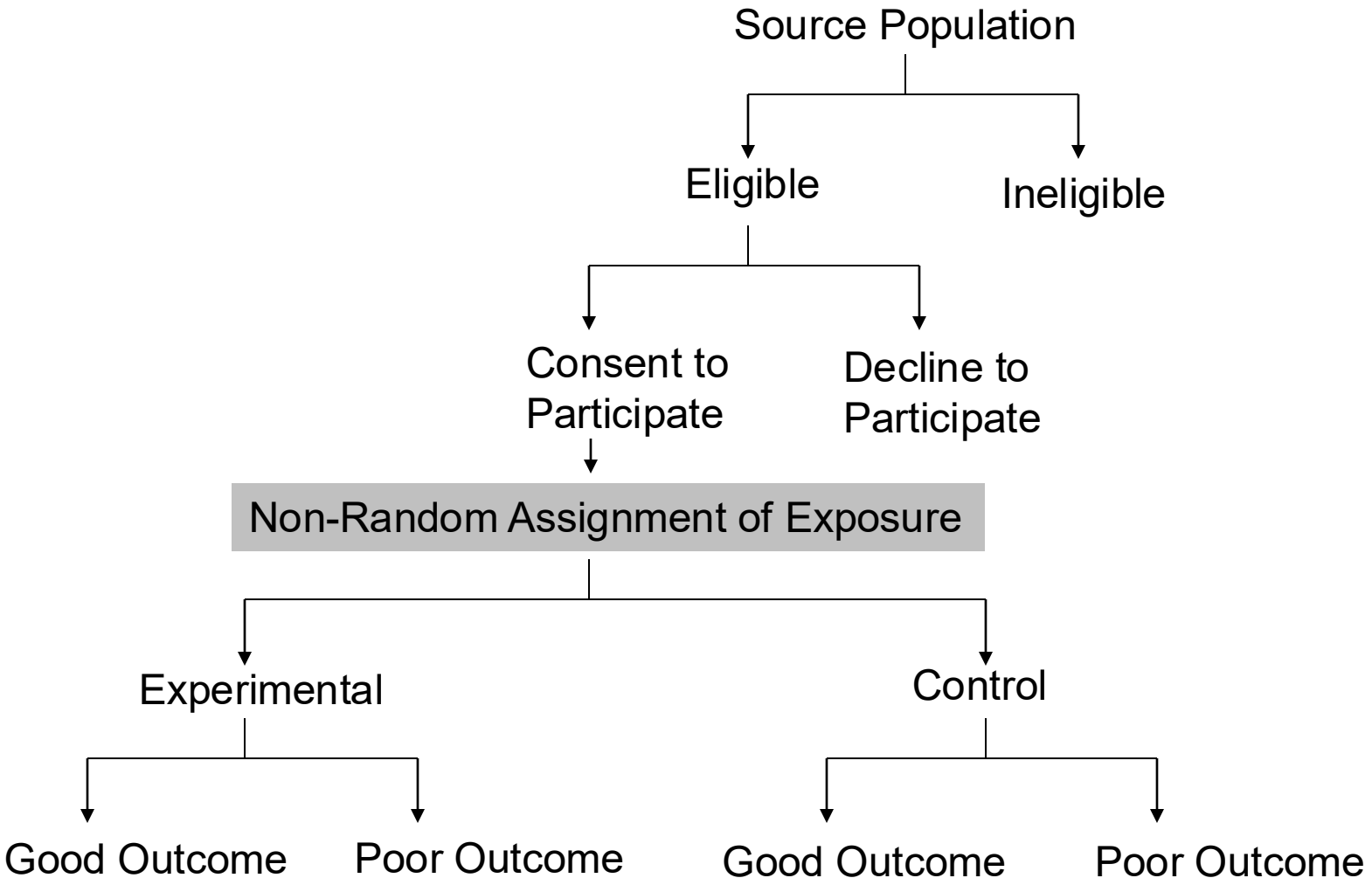
Arch Pediatr Adolesc Med. 2011;165(4):339-345. doi:10.1001/archpediatrics.2011.29

Non-Randomized Studies

- Quasi Experimental
- Cohort
  - Retrospective
  - Prospective
- Case-control
- Cross-sectional

- Ecological

Quasi-Experimental



Adapted from Koepsell and Weiss. Epidemiologic Methods: Studying the Occurrence of Illness. Oxford University Press 2003; P. 94

EDWARDS H., WALSH A., COURTNEY M., MONAGHAN S., WILSON J. & YOUNG J. (2007) Improving paediatric nurses' knowledge and attitudes in childhood fever management. *Journal of Advanced Nursing* 57(3), 257–269
doi: 10.1111/j.1365-2648.2006.04077.x

Abstract

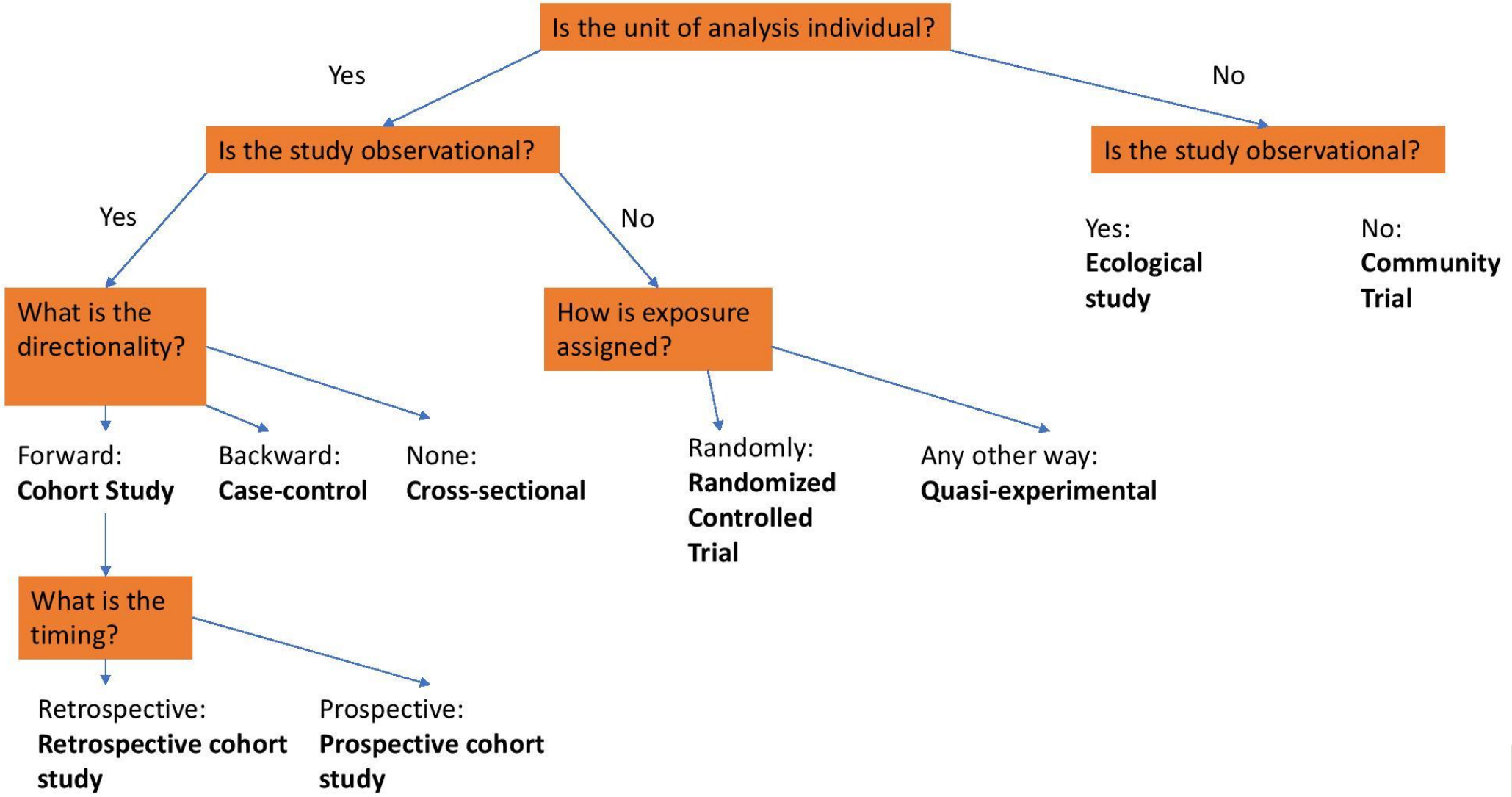
Title. Improving paediatric nurses' knowledge and attitudes in childhood fever management

Aim. This paper reports an evaluation of the effectiveness of a peer education programme in developing paediatric nurses' evidence-based knowledge and attitudes towards fever management and the sustainability of these changes.

Background. In general, paediatric nurses' fever management knowledge seems to be mediocre. They believe fever to be harmful, causing febrile convulsions and brain damage. Antipyretics are administered to prevent febrile convulsions and alternate antipyretics are given when temperatures are not reduced.

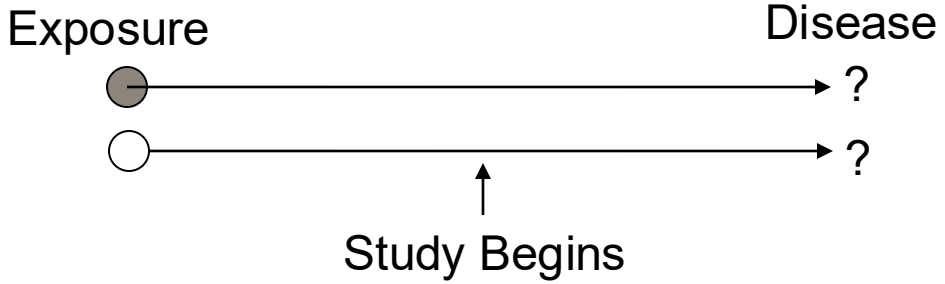
Method. A quasi-experiment was conducted from August 2002 to March 2003. An experimental group of Registered Nurses received the peer education programme and peer support and education were promoted for those unable to attend the sessions. A control group continued its normal practices. Seventy-seven nurses were eligible to attend the programme; 74·0% attended at least one session, 52% two or more. Questionnaire data were collected 1 month before and 1 and 4 months after the peer education programme from 56·3% to 77·8% of eligible experimental and 40·9% to 51·6% of eligible control group nurses.

Analytic Studies

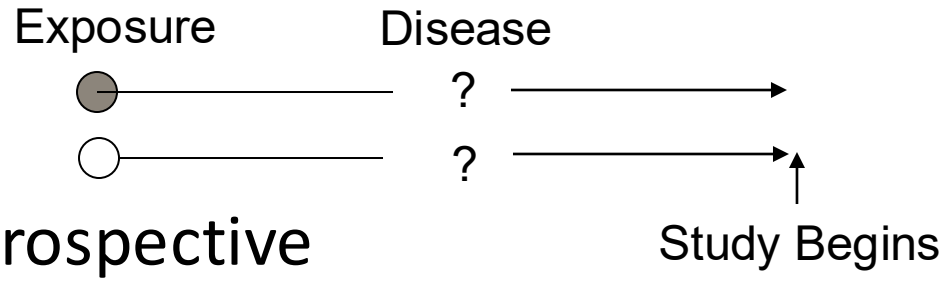


Cohort Study

- Study groups defined in terms of exposure and followed to determine frequency of outcome
- Prospective or concurrent Cohort Study



- Retrospective or historical Cohort Study



- Studies can have both prospective and retrospective components

From Hennekens & Buring. Epidemiology in Medicine. Little Brown and Company, 1987; P. 24

The Relationship Between Birth Weight and Childhood Asthma

A Population-Based Cohort Study

Don D. Sin, MD, MPH; Sheldon Spier, MD; Larry W. Svenson, BSc; Don P. Schopflocher, PhD; Ambikaipakan Senthilselvan, PhD; Robert L. Cowie, MD; S. F. Paul Man, MD

Background: Because obesity promotes inflammation and imposes mechanical constraints to the airways, a high birth weight may be a risk factor for asthma in childhood. However, to our knowledge, few studies have examined this potential relationship.

Objective: To determine the relationship between high birth weight and risk of emergency visits for asthma during childhood.

Design: Population-based cohort study.

Setting: Alberta, Canada.

Participants: All neonates born at term (≥37 weeks) between April 1, 1985, and March 31, 1988, in Alberta (N=83595). We divided the cohort into birth-weight categories: low (<2.5 kg), normal (2.5-4.5 kg), or high (>4.5 kg). The cohort was observed prospectively for 10 years.

Main Outcome Measure: Comparison of risk of emergency visits for asthma over 10 years across the birth-weight categories.

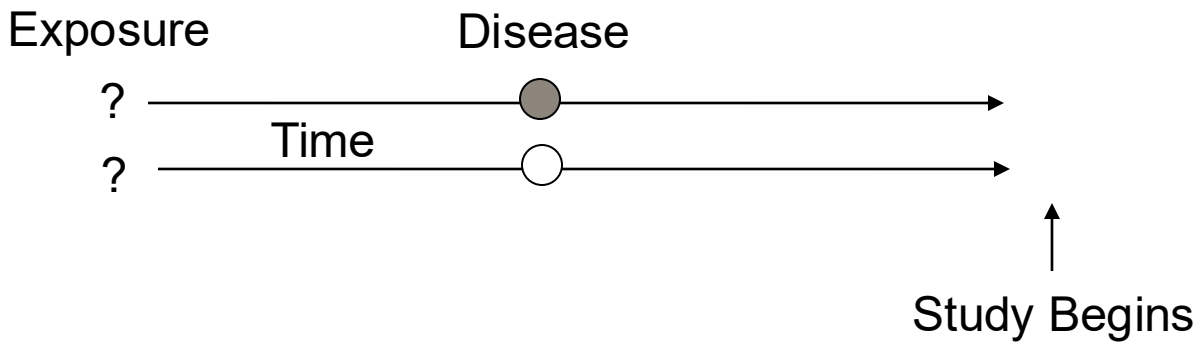
Results: Neonates born with a high birth weight had a significantly increased risk of emergency visits for asthma during childhood compared with neonates born with a normal birth weight (relative risk [RR], 1.16; 95% confidence interval [CI], 1.04-1.29). The relationship between birth weight and emergency visits for asthma beyond a birth weight of 4.5 kg was linear, such that every increment of 0.10 kg in birth weight was associated with an additional 10% (95% CI, 2%-19%) increase in the risk of emergency visits for asthma. Other factors associated with an elevated risk for emergency asthma visits during childhood included male sex (RR, 1.26; 95% CI, 1.22-1.30), aboriginal status (RR, 1.20; 95% CI, 1.11-1.29), and low-income status (RR, 1.11; 95% CI, 1.06-1.16).

Conclusions: A high, but not low, birth weight is a risk factor for increased emergency visits during childhood. The risk increases linearly beyond a birth weight of 4.5 kg.

Arch Pediatr Adolesc Med. 2004;158:60-64

Case-control Studies

- Subjects are selected on outcome status (disease / no disease)
- Look back to determine exposure status



- There can be prospective data collection in a case-control study

From Hennekens & Buring. Epidemiology in Medicine. Little Brown and Company, 1987; P. 24

Factors Associated With Refusal of Childhood Vaccines Among Parents of School-aged Children

A Case-Control Study

Daniel A. Salmon, PhD, MPH; Lawrence H. Moulton, PhD; Saad B. Omer, MBBS, MPH; M. Patricia deHart, ScD; Shannon Stokley, MPH; Neal A. Halsey, MD

Background: The rate of nonmedical exemptions to school immunization requirements has been increasing, and children with exemptions have contributed to outbreaks of vaccine-preventable diseases.

Objectives: To determine why parents claim nonmedical exemptions and to explore differences in perceptions of vaccines and vaccine information sources between parents of exempt and fully vaccinated children.

Design: Case-control study.

Setting: Colorado, Massachusetts, Missouri, and Washington.

Participants: Surveys were mailed to the parents of 815 exempt children (cases) and 1630 fully vaccinated children (controls randomly selected from the same grade and school) recruited from 112 private and public elementary schools. Surveys were completed by 2435 parents (56.1%).

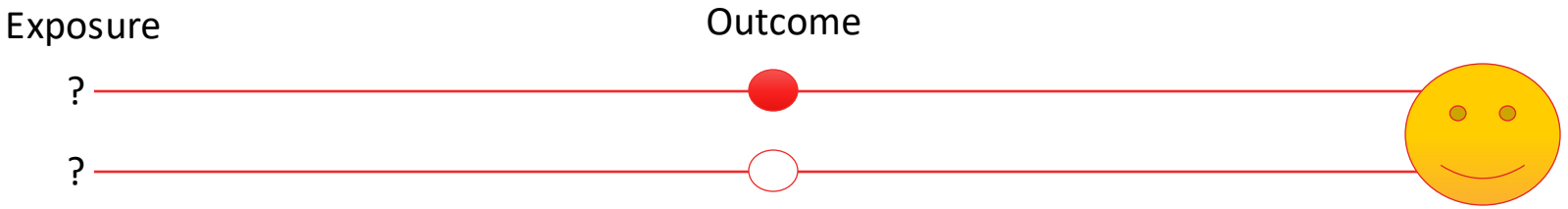
Main Outcome Measures: Parental reports.

Results: Most children (209 [75.5%] of 277) with nonmedical exemptions received at least some vaccines. The most common vaccine not received was varicella (147 [53.1%] of 277 exempt children). The most common reason stated for requesting exemptions (190 [69%] of 277) was concern that the vaccines might cause harm. Parents of exempt children were significantly more likely than parents of vaccinated children to report low perceived vaccine safety and efficacy, a low level of trust in the government, and low perceived susceptibility to and severity of vaccine-preventable diseases. Parents of exempt children were significantly less likely to report confidence in medical, public health, and government sources for vaccine information and were more likely to report confidence in alternative medicine professionals than parents of vaccinated children.

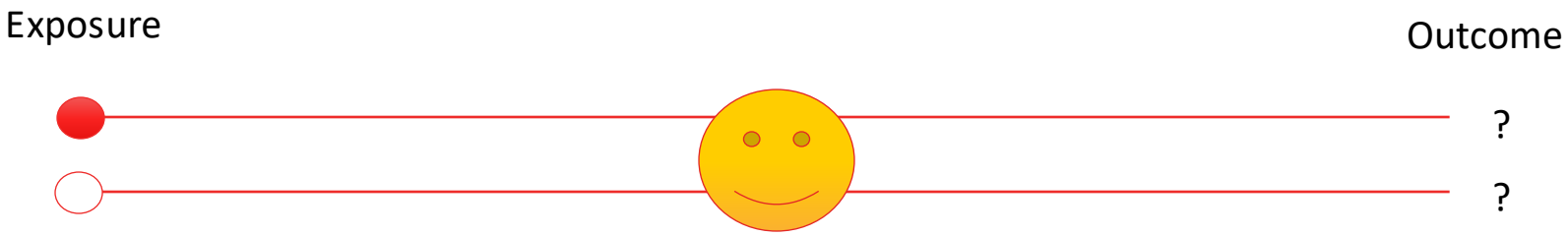
Conclusion: Continued efforts must be made to educate parents about the utility and safety of vaccines, especially parents requesting nonmedical exemptions to school immunization requirements.

Arch Pediatr Adolesc Med. 2005;159:470-476

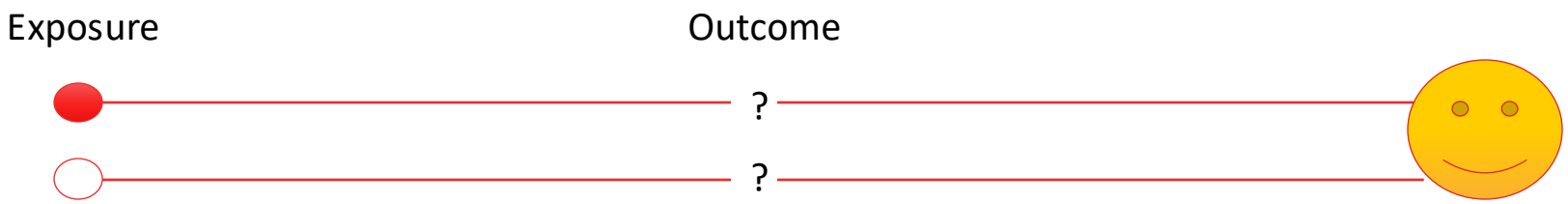
Case-Control Study



Prospective Cohort Study



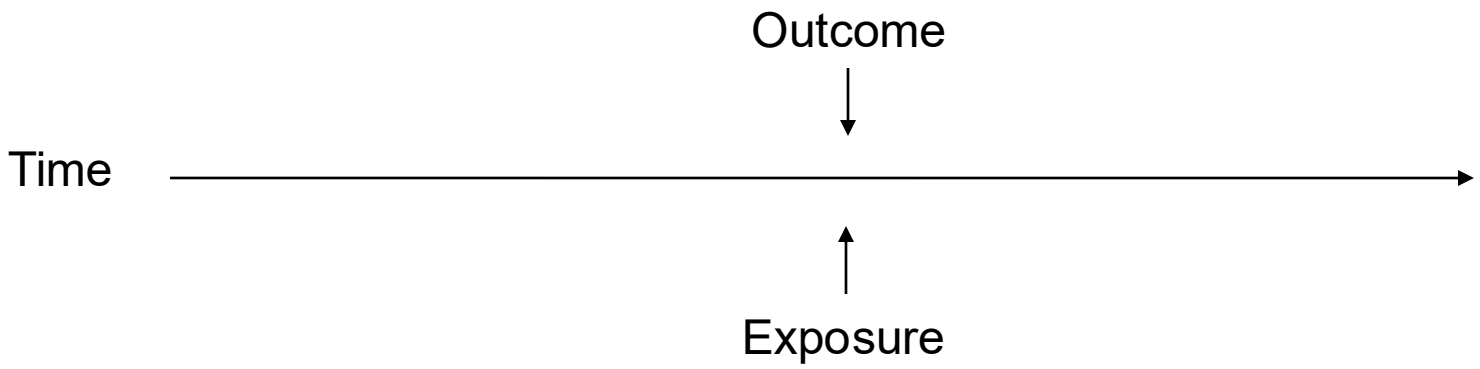
Retrospective Cohort Study



Adapted from Hennekens & Buring. Epidemiology in Medicine. 1987
and from slides by Dr. Kirsten Fiest

Cross-sectional Study

- Outcome and exposure status determined at same point in time
- Participants selected without knowledge of exposure or outcome status



From Koepsell and Weiss. Epidemiologic Methods: Studying the Occurrence of Illness. Oxford University Press 2003; P. 94

Relationship of Physical Activity and Television Watching With Body Weight and Level of Fatness Among Children

Results From the Third National Health and Nutrition Examination Survey

Ross E. Andersen, PhD; Carlos J. Crespo, DrPH, MS; Susan J. Bartlett, PhD
Lawrence J. Cheskin, MD; Michael Pratt, MD, MPH

Context.—Physical inactivity contributes to weight gain in adults, but whether this relationship is true for children of different ethnic groups is not well established.

Objective.—To assess participation in vigorous activity and television watching habits and their relationship to body weight and fatness in US children.

Design.—Nationally representative cross-sectional survey with an in-person interview and medical examination.

Setting and Participants.—Between 1988 and 1994, 4063 children aged 8 through 16 years were examined as part of the National Health and Nutrition Examination Survey III. Mexican Americans and non-Hispanic blacks were oversampled to produce reliable estimates for these groups.

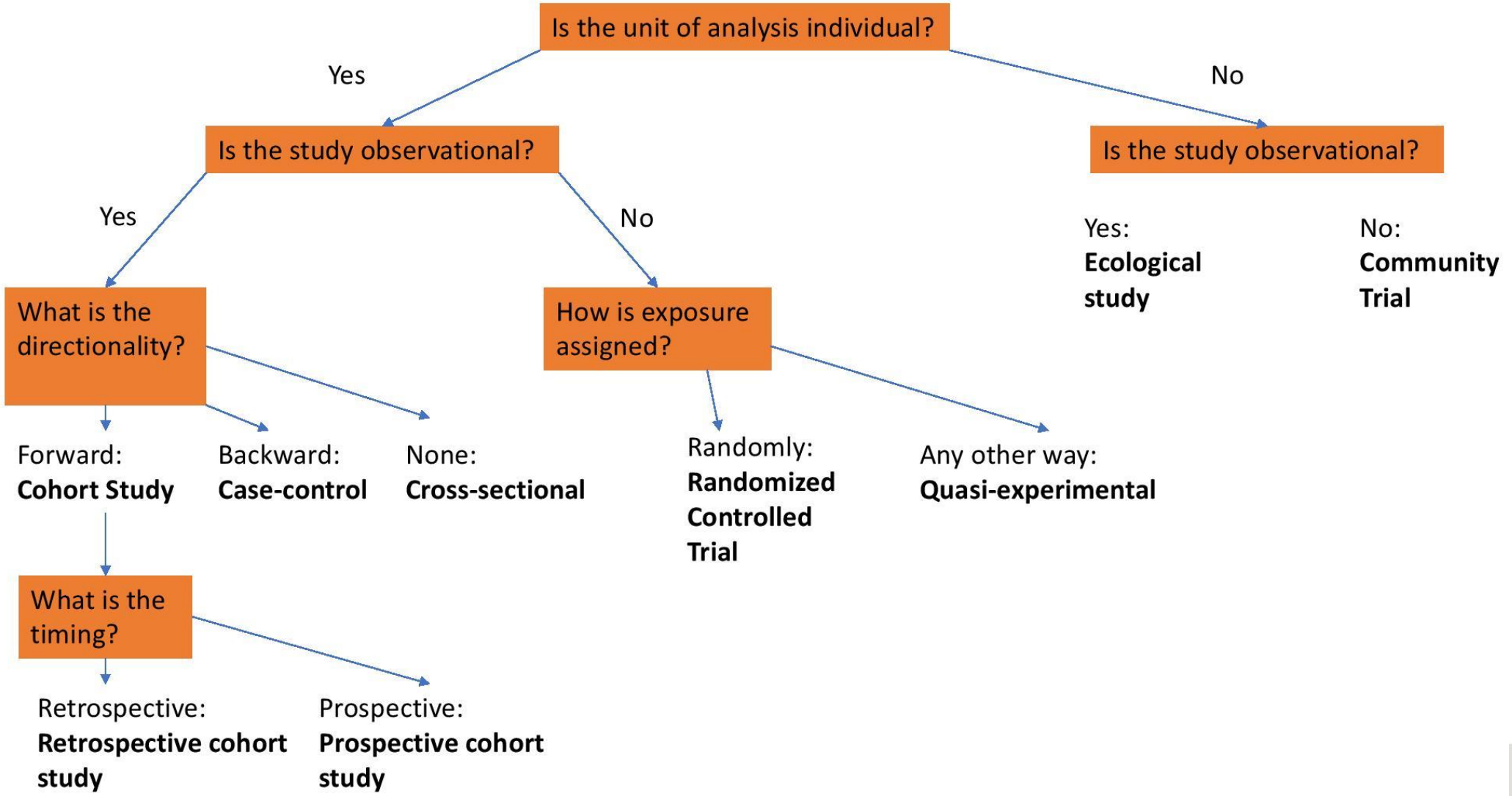
Main Outcome Measures.—Episodes of weekly vigorous activity and daily hours of television watched, and their relationship to body mass index and body fatness.

Results.—Eighty percent of US children reported performing 3 or more bouts of vigorous activity each week. This rate was lower in non-Hispanic black and Mexican American girls (69% and 73%, respectively). Twenty percent of US children participated in 2 or fewer bouts of vigorous activity per week, and the rate was higher in girls (26%) than in boys (17%). Overall, 26% of US children watched 4 or more hours of television per day and 67% watched at least 2 hours per day. Non-Hispanic black children had the highest rates of watching 4 or more hours of television per day (42%). Boys and girls who watch 4 or more hours of television each day had greater body fat ($P<.001$) and had a greater body mass index ($P<.001$) than those who watched less than 2 hours per day.

Conclusions.—Many US children watch a great deal of television and are inadequately vigorously active. Vigorous activity levels are lowest among girls, non-Hispanic blacks, and Mexican Americans. Intervention strategies to promote lifelong physical activity among US children are needed to stem the adverse health consequences of inactivity.

JAMA. 1998;279:938-942

Analytic Studies



Ecological Study

- Data from entire populations compared for outcome frequency
- Joint distribution of exposure and disease not available

Ecological (correlation) Study

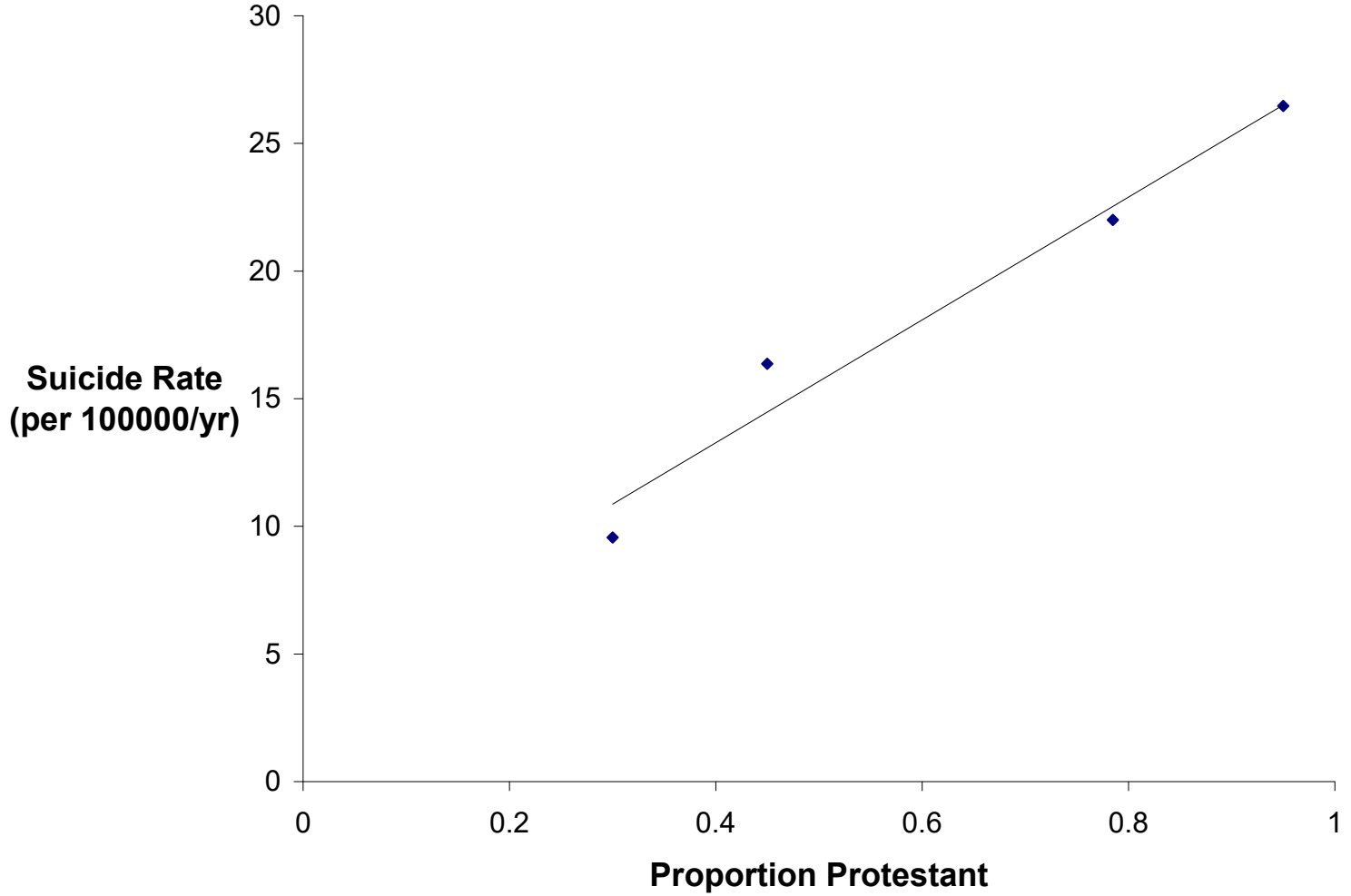


Figure. Suicide rate (Y, 10^5/year) by proportion Protestant (X) for four groups of Prussian provinces, 1883-1890.
Morgenstern. “Ecologic Studies”, in Rothman and Greenland: Modern Epidemiology 1998, p. 467
Adapted from Durkheim E. Suicide: a Study in Sociology. New York: Free Press, 1951.

Environmental tobacco smoke and the epidemic of asthma in children: the role of cigarette use

Renee D. Goodwin, PhD, MPH

Background: Asthma is the most common chronic disease affecting youth worldwide. The prevalence of asthma has increased at least 3-fold during the past several decades. The reason for this increase remains unknown.

Objective: To examine one possible factor that may be affecting the increase in prevalence of asthma among youth.

Methods: Data on the incidence of asthma among youth were aggregated using the National Health Interview Survey (sample of 4,500 children) and were compared on an ecologic level with data on cigarette consumption in the United States from 1900 to 2003 from the American Lung Association.

Results: Our results suggest a parallel increase in the rates of cigarette use among adults and asthma in children. These findings show an increase in cigarette use during the past 4 birth cohorts, with subsequent leveling off at a population level with a progressively more prominent increase in cigarette use among women in the United States.

Conclusion: We present one possible factor that may be contributing to the epidemic of childhood asthma. We hypothesize that (1) there has been a marked increase in smoking during the past century, (2) this increase in smoking has resulted in a substantial increase in exposure to environmental tobacco smoke among children, and (3) increased exposure to environmental tobacco smoke has contributed to the increase in childhood asthma. Data on trends in cigarette use among adults and asthma prevalence among children during the past century are presented as ecological evidence in support of this hypothesis. Future studies will be needed to confirm these findings with community-level analyses in a variety of geographic regions.

Ann Allergy Asthma Immunol. 2007;98:447–454.

In-class Activity

Assign one of the study designs outlined in the lecture to each study description

1. Investigators are interested in the relationship between diet and heart disease. They obtain data from a number of countries on the average annual meat intake as well as each country's administrative data on deaths from heart disease.

2. The relationship between alcohol consumption and the risk of injury is studied using data from the emergency department. The blood alcohol level of individuals who have an injury is determined. The investigators select a random sample of patients who do not have an injury, but are in the ED for another reason and, in turn, measure their BAC. The investigators then compare the prevalence of high vs. low BAC in the injured and uninjured group.

3. A number of soccer teams were assigned at random to receive a pre-season training program incorporating the use of a wobble board to increase balance and proprioception. The remaining teams received a standard pre-season fitness program. The rate of injuries in the wobble board group was compared with the standard fitness training group.

4. Investigators enrol a group of ice hockey athletes at the start of the season to determine what effect wearing a mouth guard has on dental injuries. At the end of the regular season, the rate of dental injuries in the mouth guard group is compared with the rate in the no mouth guard group.

5. Investigators select all patients presenting to an Emergency Department with a skiing injury and describe their characteristics and the type and nature of the injuries.

6. Investigators are interested in the relationship between obesity and asthma. They randomly call people and ask those with children if the child has asthma and the age, height and weight of the child.

7. In a study that began in 1965, a group of 5,000 adults in New York were asked about alcohol consumption. The occurrence of cancer was studied in this group between 1981 and 1995.

8. The personnel records from a number of insulation manufacturing plants were obtained for the period 1970-1975. During this time period, the number of lung cancer deaths was compared between this group of employees and a comparable group of employees not exposed to insulation manufacturing.

UNIVERSITY OF CALGARY

Thank You!

janet.aucoin1@ucalgary.ca