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Introduction to Epidemiological Study Design

Marco De Nardi

Outline

- Objectives
- The scope of epidemiology (*recap from previous training*)
- Exposures and outcome
- Confounder factor
- Epidemiological study design
  - Cross sectional study
  - Cohort study
  - Case-control study

- The scope of epidemiology (recap from previous training)

Epidemiology Definition

Epi = upon

Demos = population

Logos = study of

The study of how disease is distributed in populations and the factors that influence or determine this distribution.

Epidemiology, Third Edition, Leon Gordis

Key Word: Distribution

Distribution refers to the **frequency** and **pattern** of health and events in a population

Frequency -the number of events, and relationship to the size of population

Pattern – Occurrence of events by time, place, and person

Ex. *Time* patterns – annual, seasonal – *Temporal analysis*

Ex. *Place* patterns – rural, urban, - *Spatial analysis*

Key Words: Determinant & Health Related Events

Determinant (exposure or risk factor)	**Health Related Event (outcome of interest)**
Any physical, biological, social, cultural or behavioral factor that influences health	• Disease • Death • Injury • Disability • Decrease in animal production

Determinants (risk factors) ➔ Health related event (outcome)

Objectives of Epidemiology

- Identify the **etiology** or cause of disease
- Determine the **magnitude** of disease (impact) and **trends** over time and space
- Determine the **mode of transmission**
- Identify **risk factors** or **protective variables**
- Determine the role of the **environment**
- Identify potential **interventions/control measures**
- Evaluate the **impact** of prevention/control measures

Objectives of Epidemiology

- In epidemiology, measuring the occurrence of disease or other health related events in a population is **only one** of the possible objectives.
- Epidemiologists are also interested in assessing whether an **exposure is <u>associated</u> with a particular disease** (or other outcome of interest).

<u>Is the consumption of Aflatoxin associated with increased risk of liver cancer?</u>

Aflatoxin → **Liver cancer**

(Exposure) **(Outcome)**

Steps in an epidemiological study

1) The first step in an epidemiological study is to define the **hypothesis** to be tested (i.e. *Aflatoxin is associated with liver cancer*)

This should include a precise definition of the **exposure(s)** (*i.e. Aflatoxin*) and **outcome(s)** (i.e. *Liver cancer*) under study.

2) The next step is to decide which **study design** will be the most appropriate to test that specific study hypothesis.

- Exposures and outcomes

Exposures and outcomes

- In an epidemiogical study there is:

a) the **outcome of interest** (i.e. death/Sickness)

b) the **primary exposure** (or **risk factor**)

c) there my be **more than one risk factors** that influence the outcome of interest (some of which may be *potential confounders*)

- There is the need to measure more than one exposures

Exposures and outcomes

Risk Factors Associated with Contamination of Raw Milk by *Listeria monocytogenes* in Dairy Farms

M. SANAA, B. POUTREL,[1] J. L. MENARD,[2] and F. SERIEYS[2]
Epidemiology and Animal Health Management Laboratory
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7, avenue du Général-de-Gaulle
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Quiz 1: which may be some risk factors associated to the contamination of raw milk by Listeria monocytogenes?

- Poor quality of silage (pH >4.0) (*OR =5.64; P= .0005*),
- Inadequate frequency of cleaning the exercise area (*OR = 3.88; P =.0059*),
- Poor cow cleanliness (*OR = 5.91; P = .024*),
- Insufficient lighting of milking parlors (*OR = 4.57; P = .0093*) ,
- Incorrect disinfection of towels between milkings (*OR =2.93; P = .0326*)

Exposures and outcomes

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Quiz 2: how did they find what are the risk factors for Listerian Monocytogenes?

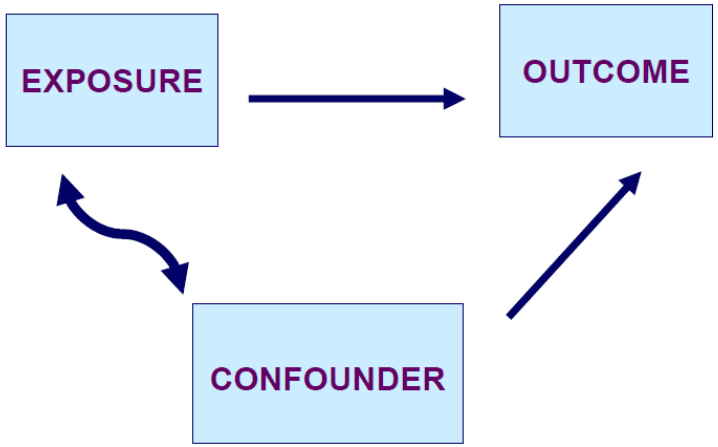
- A **case-control study** involving 128 selected dairy farms was conducted to assess the **association** of several suspected risk factors with the **odds** of contamination of raw milk by Listeria Monocytogenes.

What's a counfounder factor?

- Some factors may «***distort***» the relationship between primary exposure and outcomes. They «*step in the way*», acting as **counfounding factors**!

- For a factor to be regarded as a **confounder** the rules are:

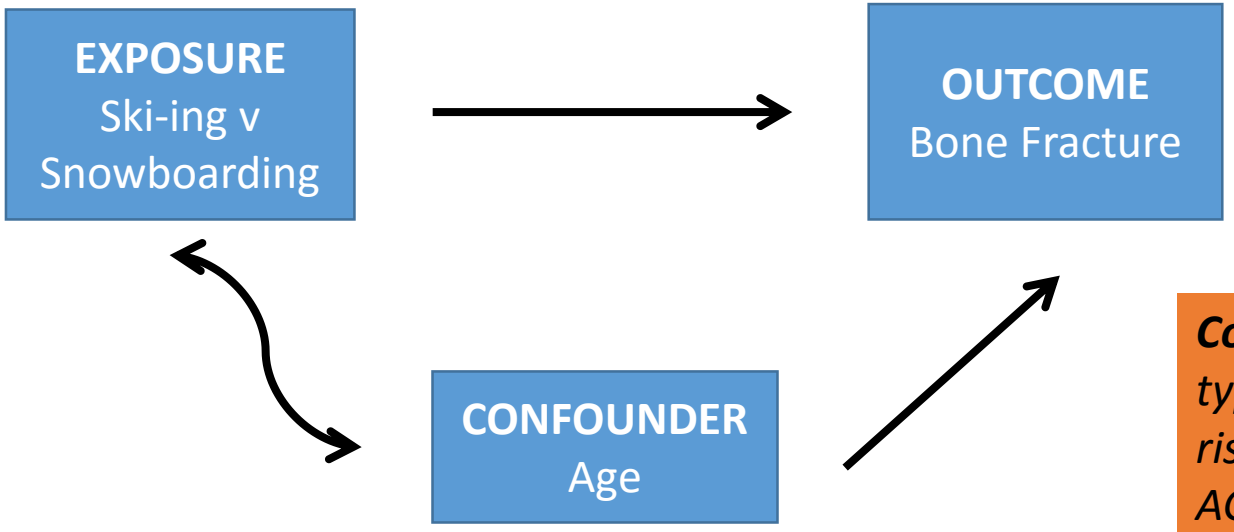
1. The factor must be associated with the exposure investigated
2. The factor must be independently associated with the outcome of interest



What's a counfounder factor?

Example: study of **fracture risk** in **skiers** verses **snowboarders**

Hypothesis: higher in skiers indicating a higher-risk sport?



Conclusion: *Association between type of winter sport and risk of fracture confounded by AGE*

- Epidemiological study designs

Epidemiological research

- **Laboratory based research**: procedures and strategies to understand mechanisms of health-related phenomena

- **Outbreak investigations**: study of outbreaks, in local populations, to identify agent(s), transmission mode(s), and possible control measure(s)

- **Population-based (field) research**: study of distribution, determinants, control measures of health-related phenomena in chosen populations, followed by application of suitable biostatistical techniques which may allow generalization of results

Adapted from: Study Designs in Epidemiology (Prof. Ahmed Mandil, University of Alexandria)

Data collection methods

- **Primary:** where the investigator is the first to collect the data. Merits: less measurement error, suits objectives of the study better. Disadvantage: costly, may not be feasible.

- **Secondary**: where the data is collected by OTHERS, for other purposes that those of the current study.

Adapted from: Study Designs in Epidemiology (Prof. Ahmed Mandil, University of Alexandria)

Study design-definition

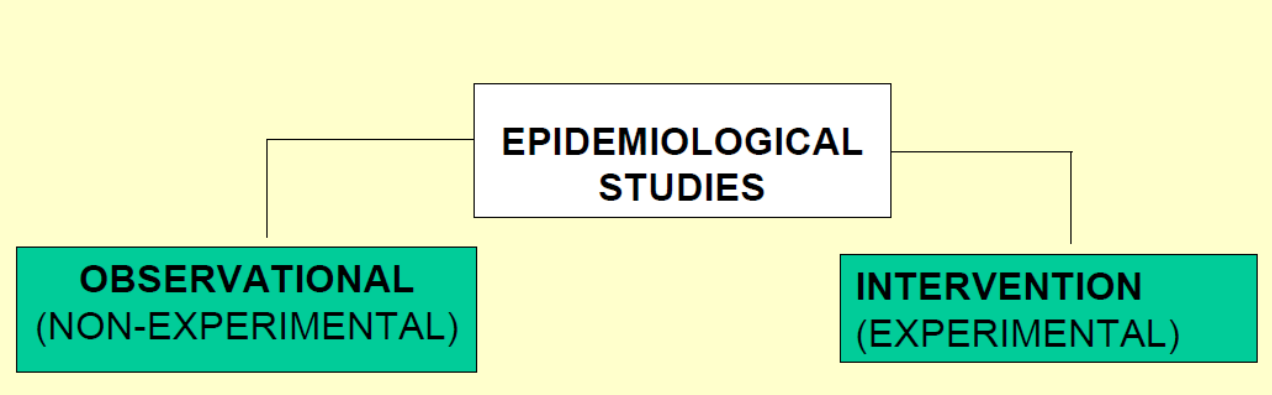
"A study design is a specific plan or protocol for conducting the study, which allows the investigator to translate the ***conceptual hypothesis*** *into an* ***operational one****."*

1) Hypothesis development
2) Study design to test the hypothesis
3) Epi study implementation to collect (primary) data
4) Data analysis
5) Confirm/refuse hypothesis

Adapted from: Study Designs in Epidemiology (Prof. Ahmed Mandil, University of Alexandria)

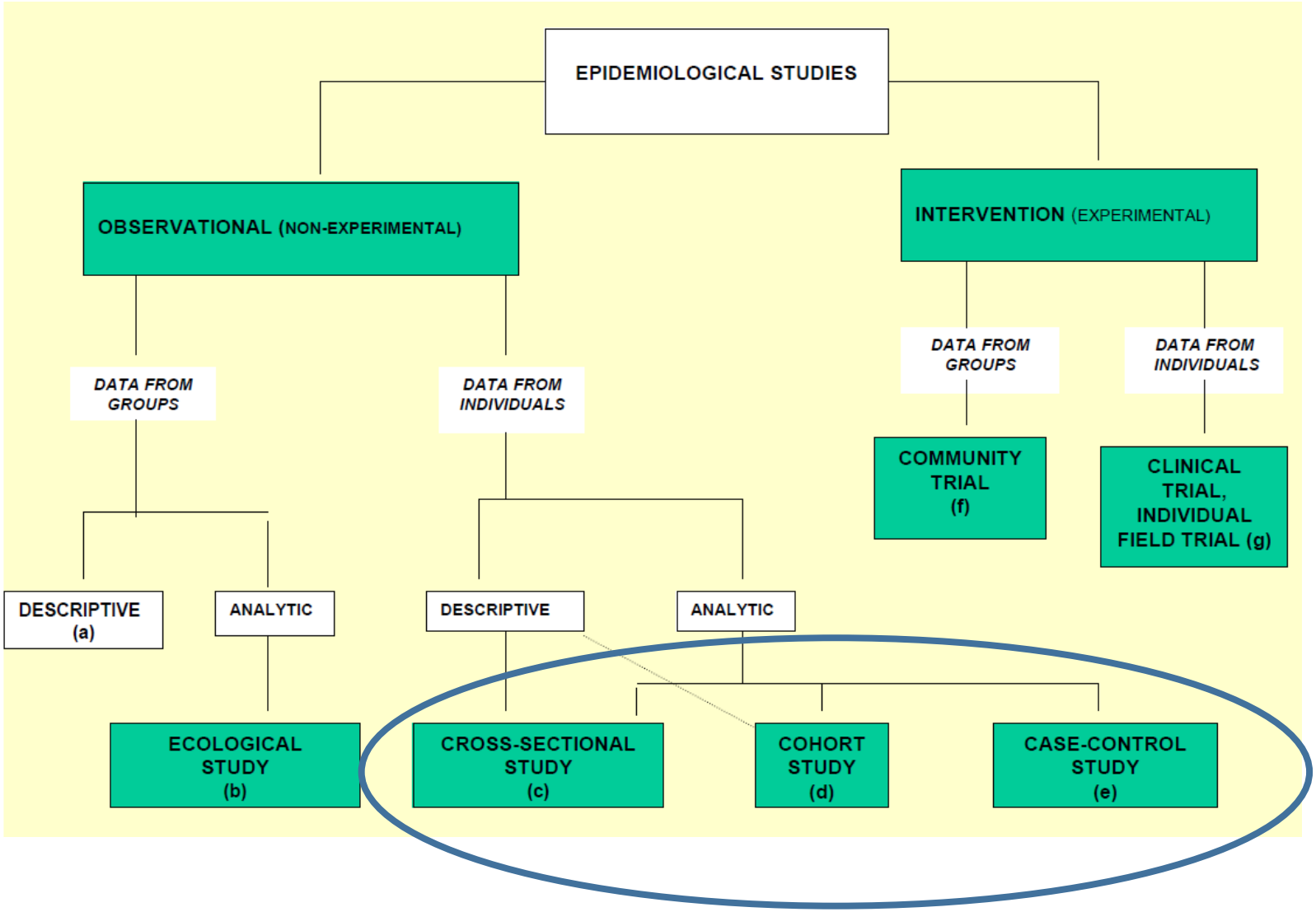
Classification of study design

There are two basic approaches to assessing whether an exposure is associated with a particular outcome: **observational** (non-experimental) and **intervention** (experimental).



We only **observe:** the role of the investigator is merely to observe what happens, noting who is exposed or unexposed and who has or has not developed the outcome of interest.

Researchers **allocate exposures** to individuals/communities:
in an experiment, investigators study the impact of varying some factor which they can control (i.e. treatments; reduce/removal smoking)



Adapted from: LSHTM, UK. Epidemiology MSc

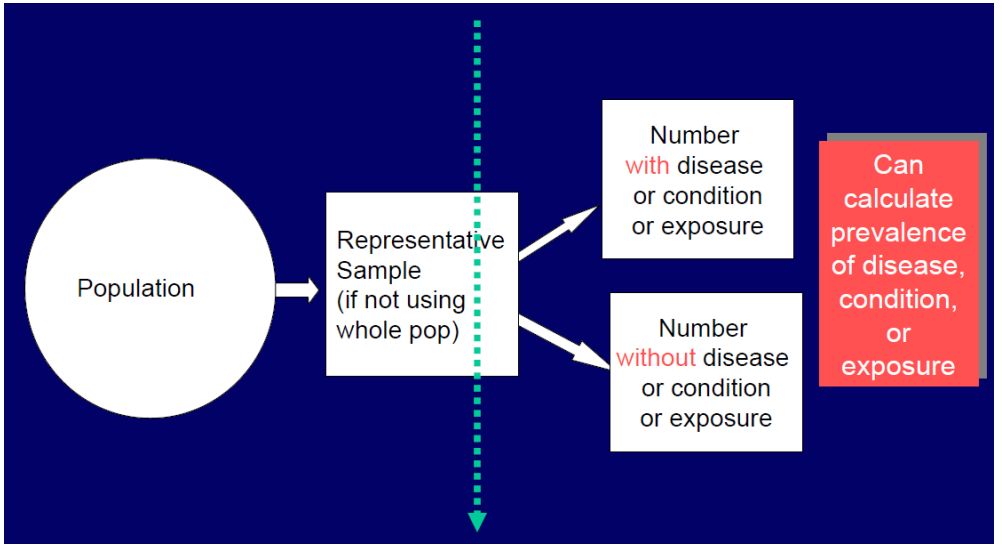
Cross sectional study

- One of the most frequently chosen study designs in veterinary epidemiology

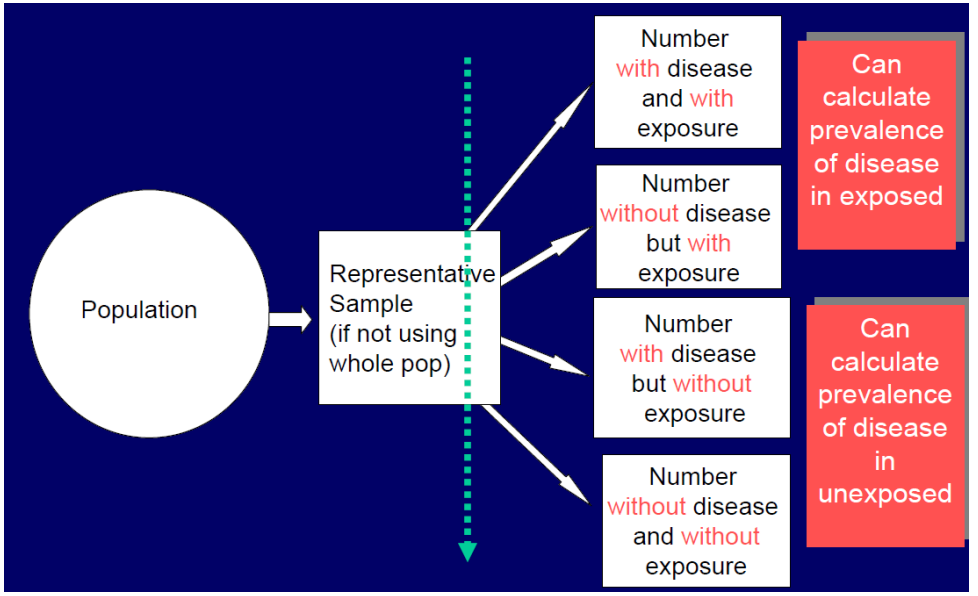
- Design is straightforward: a **sample** of individuals is selected from a previously defined (study) population and investigated (sampled) at a **particular point in time** to obtain simultaneously information on both the exposure(s) and outcome(s) of interest.

- The outcome frequency measure is the **Prevalence**

Cross sectional study **descriptive**



Cross sectional study **analytic**



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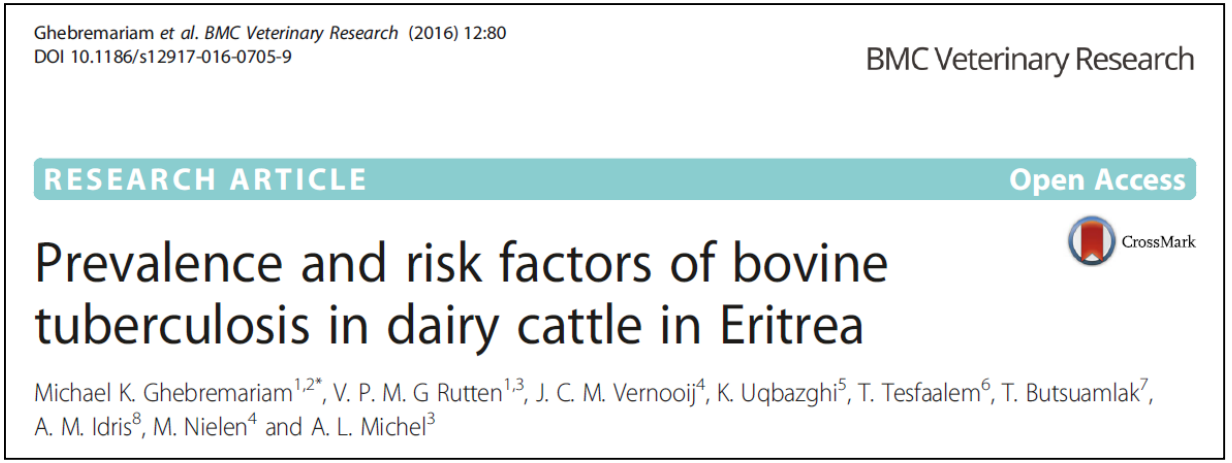
Cross sectional study-analytical



Ghebremariam *et al. BMC Veterinary Research* (2016) 12:80
DOI 10.1186/s12917-016-0705-9

BMC Veterinary Research

RESEARCH ARTICLE Open Access

Prevalence and risk factors of bovine tuberculosis in dairy cattle in Eritrea

Michael K. Ghebremariam[1,2*], V. P. M. G Rutten[1,3], J. C. M. Vernooij[4], K. Uqbazghi[5], T. Tesfaalem[6], T. Butsuamlak[7], A. M. Idris[8], M. Nielen[4] and A. L. Michel[3]

Results:

The BTB prevalences at animal and herd levels were: 21.5 % and 40.9 % in Maekel, 7.3 % and 10 % in Debub, and 0.2 % and 1.6 % in the Anseba region, respectively.

In adult dairy cattle the probability of positive reactivity in the SICTT test was highest in pregnant animals as compared to the other categories.

Cohort study

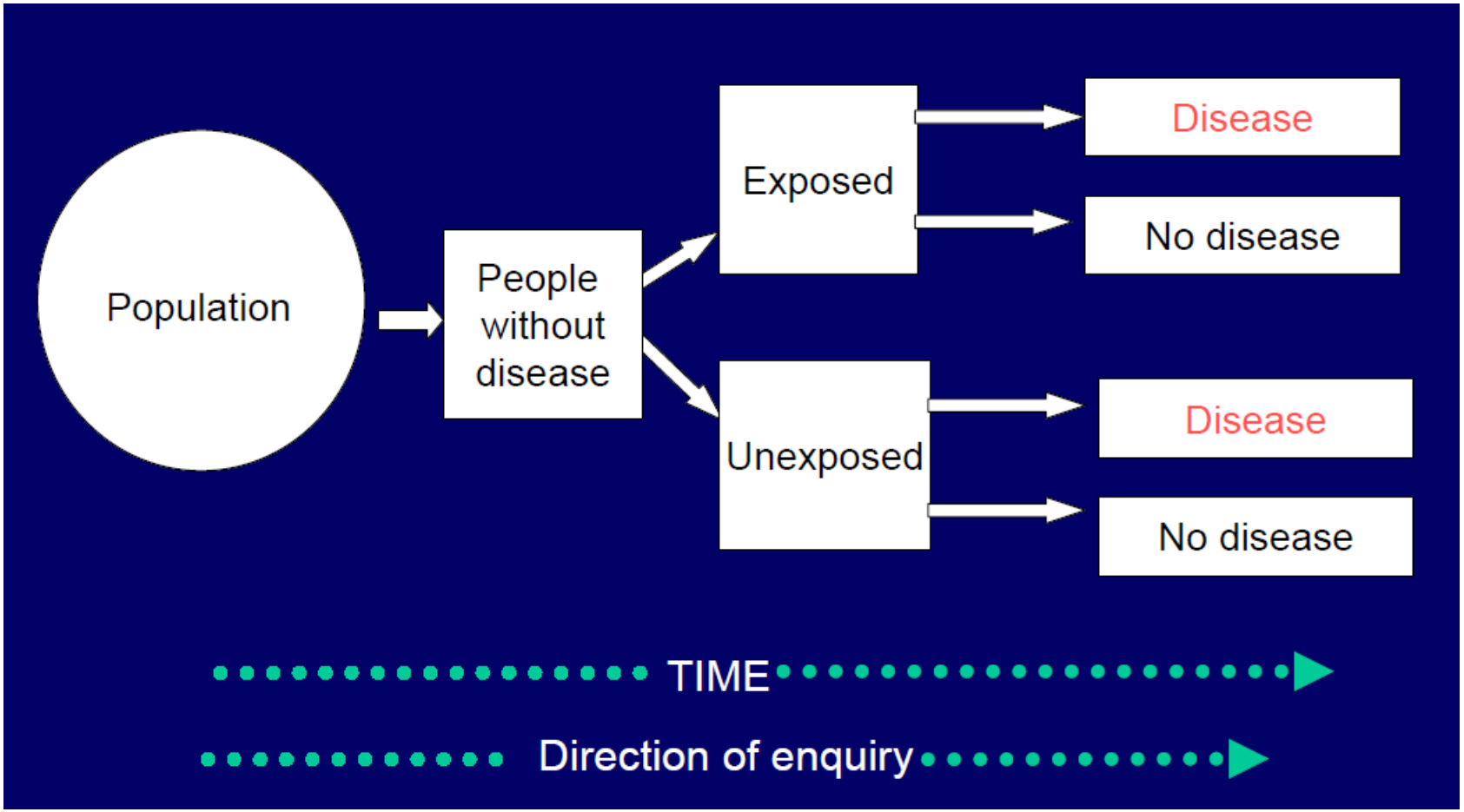
- Cohort studies are observational studies in which the starting point is the selection of a study population, or cohort. Information is obtained to determine which members of this cohort are exposed to the factor of interest (*i.e. poor hygiene condition in farm)*

- This enables the researchers to define groups of individuals by their exposure status (i.e. *a group animals kept in good hygiene condition* and *a group animals kept in poor hygiene condition*)

- The entire population is then followed up over time and the **incidence of the disease** in the exposed individuals is compared with the **incidence in those not exposed**

- Cohort studies have the ability of looking at **multiple outcomes**

Cohort study



Cohort study

A Cohort Study of Coagulase Negative Staphylococcal Mastitis in Selected Dairy Herds in Prince Edward Island

T. Jeffrey Davidson, Ian R. Dohoo, Alan W. Donald, Harry Hariharan and Kathy Collins

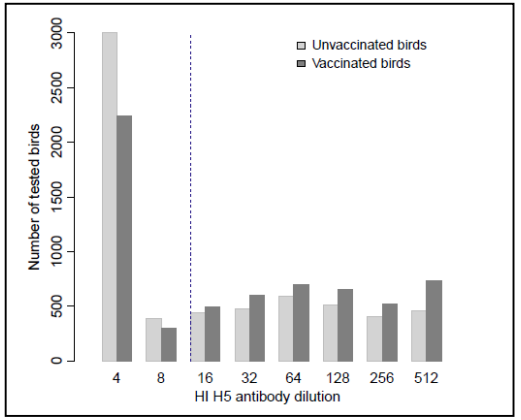
Transboundary and Emerging Diseases

Transboundary and Emerging Diseases

ORIGINAL ARTICLE

Descriptive Results of a Prospective Cohort Study of Avian Influenza in the Mekong River Delta of Viet Nam

Long V. Nguyen[1,2], M. Stevenson[1], B. Schauer[3], D. T. Nguyen[4], Q. D. Tran[3], T. N. Tien[3], P. T. T. Tran[2], G. Jones[5], D. Prattley[6] and R. Morris[1]



Our **objectives** were to (i) estimate the incidence of avian influenza virus infection and (ii) assess the efficacy of H5N1 vaccination programmes
as indicated by the presence of H5 antibody in vaccinated and unvaccinated poultry.

Results: A total of 17 968 swab and 14 878 blood samples were collected from 5476 birds over the study period. The overall **incidence rate** of H5 virus infection was 0.2 (95% CI 0.1–0.5) positive birds per 100 bird-months at risk.
Fifty (95% CI 48–52) birds per 100 tested birds were H5 HI positive in the **unvaccinated group** compared with 71 (95% CI 69–73) birds per 100 in the **vaccinated** group.

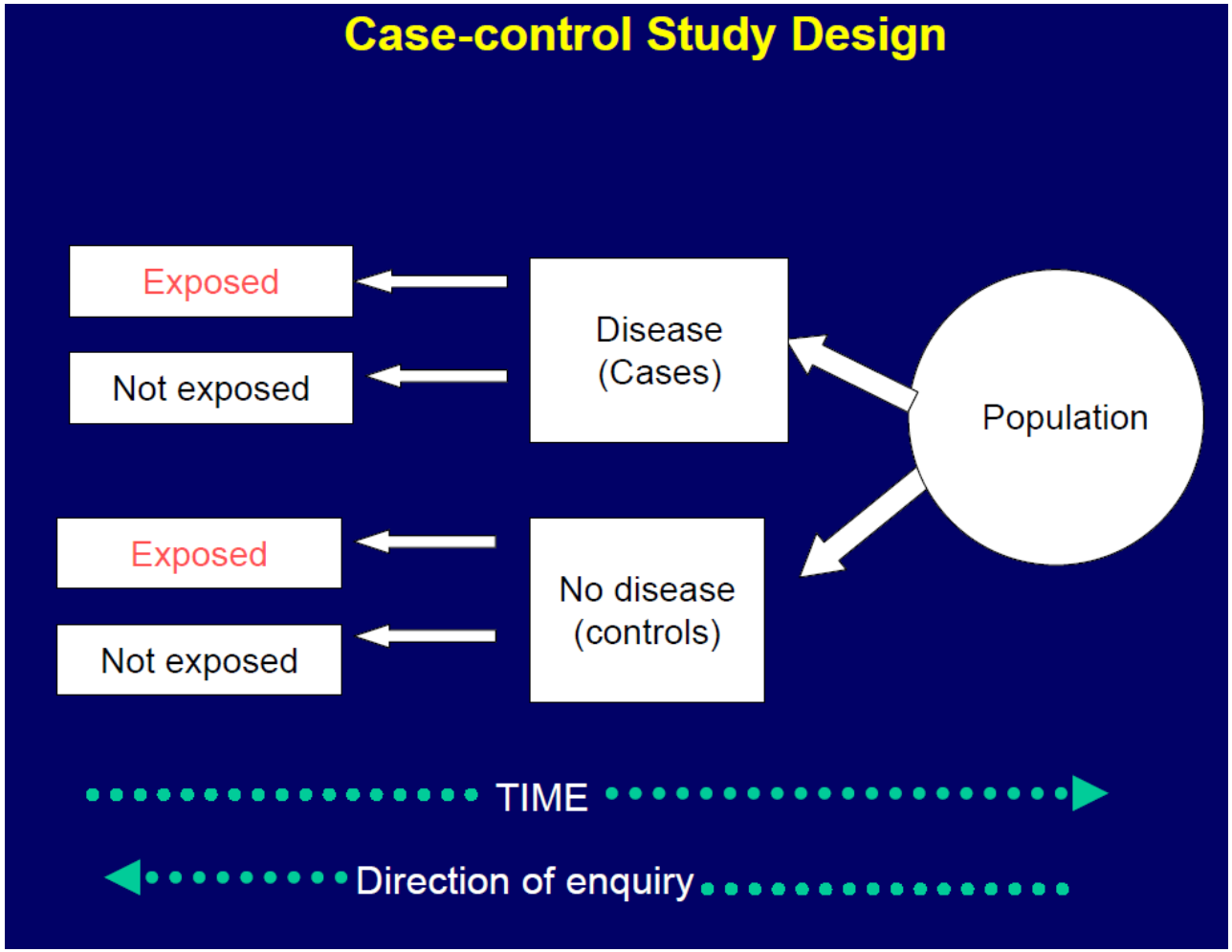
Case control study

- Case–control studies are observational studies in which the starting point is the identification of '**cases**' of the disease (or condition) of interest, and of suitable '**controls**' without that disease (or condition).

- Cases and controls are then compared to assess whether there were any differences in their **past exposure to putative risk factors** (i.e. the *odds* of exposure in cases is then compared with the *odds* of exposure in controls)

- Although a case-control study is limited to 1 outcome, **many different exposures** can be measured

Case control study



Case control study

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Design: From September to December 1989, we detected 40 herds with bulk milk contaminated by L. monocytogenes (**cases**); After selecting the first 40 herds, we engaged in a preliminary study comparing those herds with 80 other herds for which milk was not contaminated by Listeria spp (**control**). These two groups were compared for different factors.

Results:

- Poor quality of silage (pH >4.0) (*OR =5.64; P= .0005*),
- Inadequate frequency of cleaning the exercise area (*OR = 3.88; P =.0059*),
- Poor cow cleanliness (*OR = 5.91; P = .024*),
- Insufficient lighting of milking parlors (*OR = 4.57; P = .0093*) ,
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Measures of disease frequency and exposure effect in analytic study designs

Type of analytical study	*Measure of disease (outcome) occurrence*	*Measure of exposure effect*
Ecological	Rate, Risk, Prevalence	Correlation or Regression Coefficient
Cross-sectional	Prevalence	Prevalence Ratio, Prevalence Difference, Odds Ratio
Cohort	Rate, Risk , Odds, Mean or Median	Rate Ratio, Risk Ratio, Odds Ratio, Rate Difference, Risk Difference, Vaccine Efficacy, Difference between Means or Medians
Case-control	None[1]	Odds Ratio,Vaccine Efficacy,

- **Round table discussion**: what are the advantages and disadvantages of different types of epidemiological studies?

What design to choose?

- Need to consider:

- Rarity of outcome
- Rarity of exposure
- More than one outcome?
- More than one exposure?
- Interested in time relationships between exposure and outcome?

Application of different studies

	Ecological	Cross-sectional	Case-control	Cohort
Investigation of rare disease	++++	-	+++++	-
Investigation of rare exposures	++	-	-	+++++
Examining multiple outcomes	+	++	-	+++++
Studying multiple exposures	++	++	++++	+++
Measurement of time relationship between exposure and outcome	+	-	+	+++++
Direct measurement of incidence	-	-	+ [1]	+++++

Adapted from: LSHTM, UK. Epidemiology MSc

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Thanks