Yarmouk University

Community Medicine

Lec. 8 - Ecological & Cross Sectional Studies

Dr. Reema

Written By : Group B3

If you come by any mistake , please kindly report it to shaghafbatch@gmail.com

Observational Studies

Learning Objectives

- To describe the motivations for and the design of observational studies.
- To discuss early origins of the research question including case reports, case series, and ecologic studies.
- To describe the **cross-sectional study** design and its importance.

- Observational studies do not need interventions.
- -studies considered as an observational study :-
- 1-cross sectional study
- 2-cohort study
- 3-case control study
- 4-case series study

- -the interventional study is an experimental study(like you do sth on the participants and wait for result).

Case Reports and Case Series

Case Reports and Case Series

- Perhaps one of the most common and early origins of medical research questions is through careful observations by physicians and other health care providers of what they see during their clinical practice.
- Such individual-level observations can be documented in a case report, describing a particular clinical phenomenon in a single patient, or in a case series that describes more than one patient with similar problems.
- Both case reports and case series are considered the **simplest** of study designs (although some assert that they are merely "prestudy designs").

Case reports and case series :-

It means you like a case and you want to report it

Prestudy designs :-

It means when you see more than one case studies , u might start to do another observational study

أي أنها تعتبر بداية لدراسات أخرى

Case Reports and Case Series

- The **main objective** of case reports and case series is to provide a comprehensive and detailed description of the case(s) under observation.
- This allows other physicians to identify and potentially report similar cases from their practice, especially when they share geographic or specific clinical characteristics.

For example:

2015 witnessed an outbreak of the Zika virus in Latin America.

Despite the fact that case reports and case series are merely descriptive in nature with no reference group to make a strict comparison, the Brazilian case series was instrumental in the development of the CDC's guidelines (Fig. 7.1) for the evaluation and testing, by health care providers, of infants whose mothers traveled to or resided in an area with ongoing Zika virus transmission during their pregnancies (Fig. 7.2).

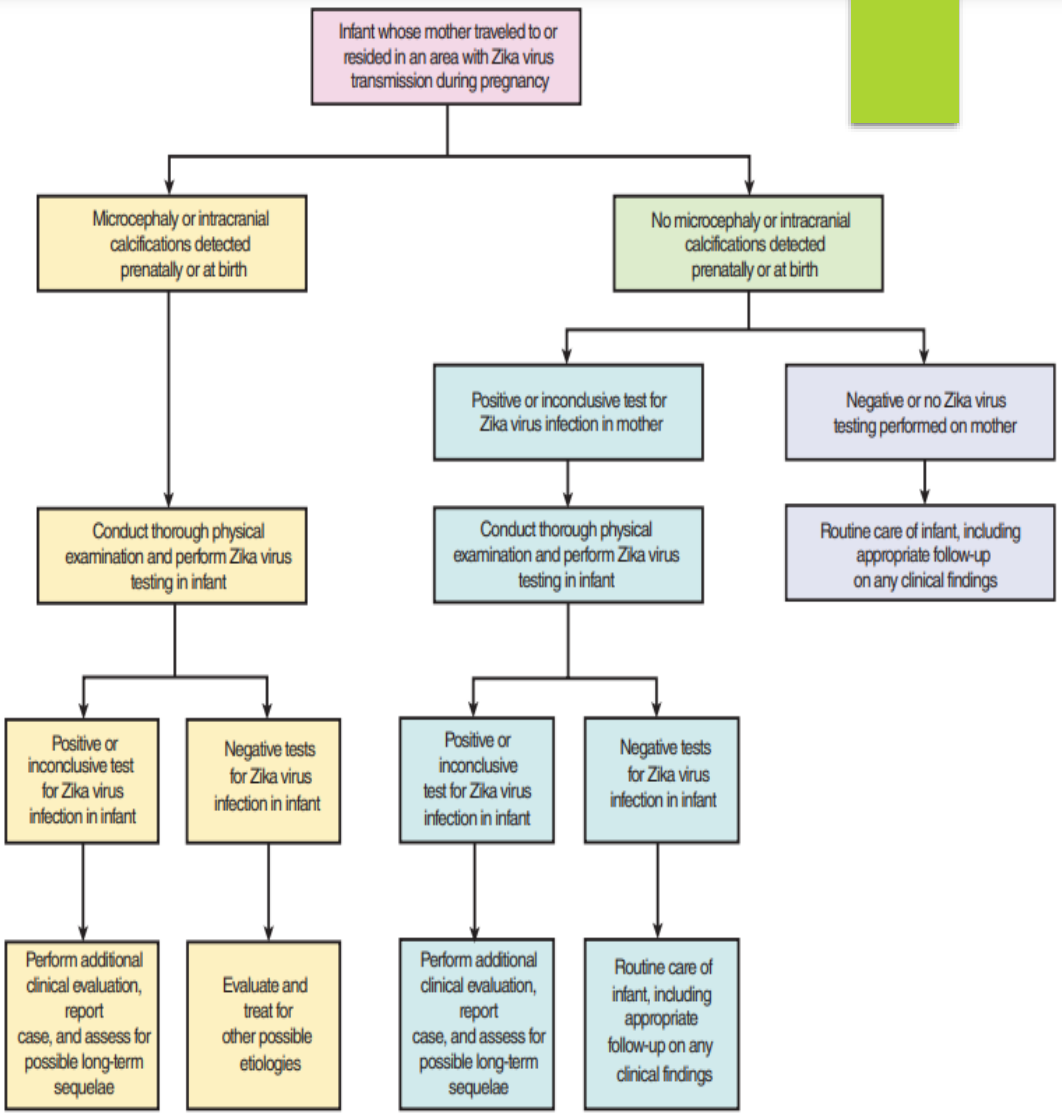


Fig. 7.1 Interim guidelines for the evaluation and testing of infants whose mothers traveled to or resided in an area with ongoing Zika virus transmission during their pregnancies. (Modified from Staples JE, Dziuban EJ, Fischer M, et al. Interim guidelines for the evaluation and testing of infants with possible congenital Zika virus infection—United States, 2016. *MMWR Morb Mortal Wkly Rep.* 2016;65:63–67.)

- حكت الدكتوره أنو الجدول مش من ضمن المطلوب والمخطط مش حفظ ولكن case report هو مثال بسيط على

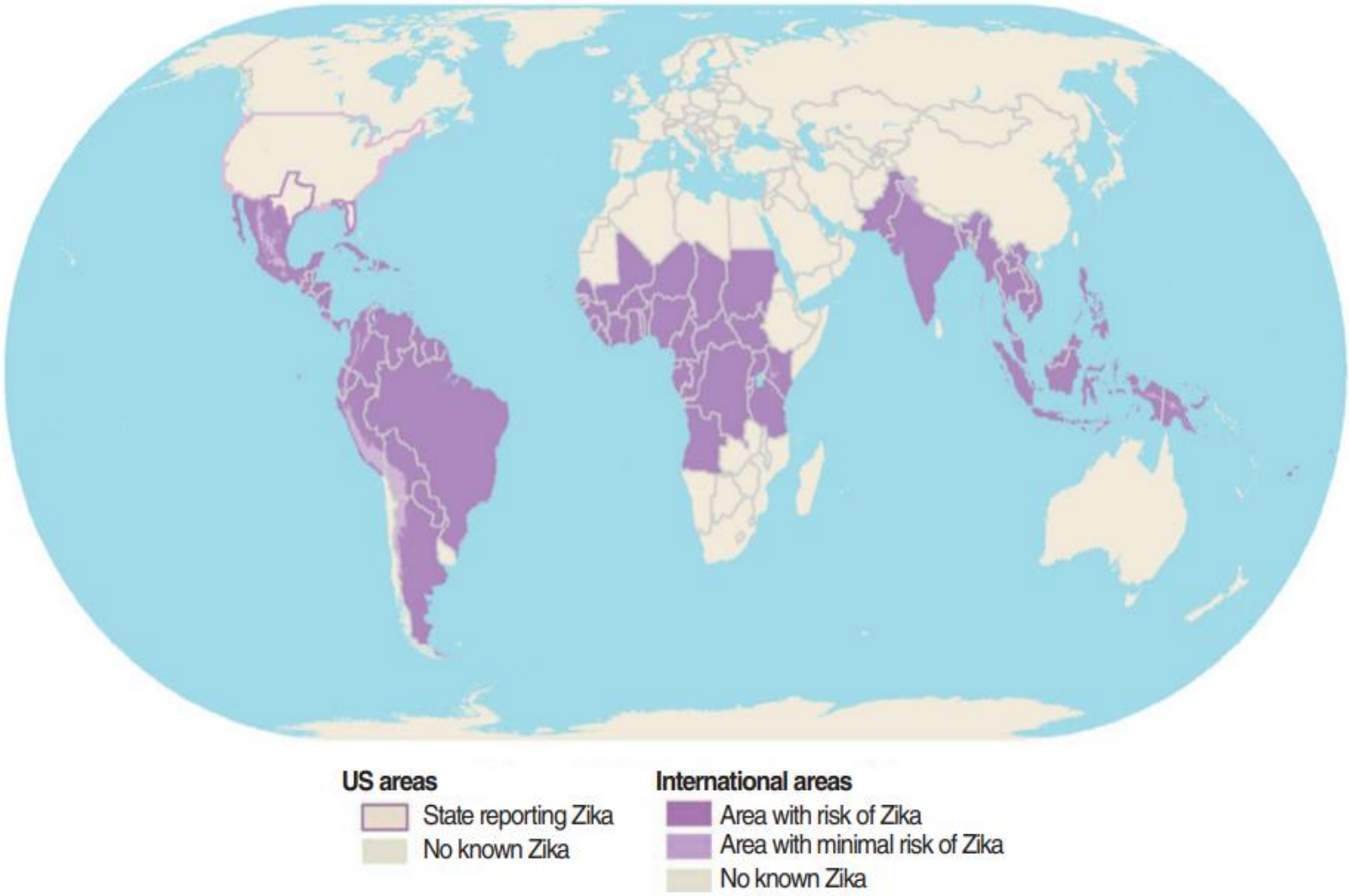


Fig. 7.2 World map of areas with risk of Zika virus. (From the Centers for Disease Control and Prevention. https://wwwnc.cdc.gov/travel/files/zika-areas-of-risk.pdf. Accessed July 24, 2017.)

Case Reports and Case Series (Cont..)

- Case reports and case series are key hypothesis-generating tools, especially when they are **simple, inexpensive, and easy** to conduct in the course of busy clinical settings.

- **Disadvantages:**
  - The lack of a comparison group is a major disadvantage.
  - The external validity (generalizability) is limited, given the biased selection of cases (all identified in clinical practice).
  - Any association observed in a case report, or a case series is prone to potentially unmeasured confounding unbeknown to the investigators

Disadvantages :-

1-there is no comparison between cohort studies and cross sectional study

2-findings in cases such as symptoms , I can't generalize in all patient to have the same symptoms or to treat them like that so external validity is missing

3- it means that results I cant generalize it or make from it a hypothesis.

Ecologic Studies

"ASSOCIATIONS ON POPULATION LEVEL"

Association based on population (group)

Ecologic Studies

- The first approach in determining whether an association exists may be a study of group characteristics, the so-called ecologic studies.

Ecologic studies give us a hint that there is an association ,that you have to further investigate in other designs

Why we do ecologic studies?

-we can build a hypothesis and start with it to investigate in other designs

ليش بلجأ الها بالأصل ؟

لانه تطبيقها سهل ,وسهولة الحصول على المعلومات بمجرد اخذها جاهزة حتى اشوف اذا association في

It's easy to take records (من مؤسسة الغذاء والدواء مثلا) of the consumption of certain medication at level of country then like it to a certain disease

- Ecologic Studies (Ex.):
- Fig. 7.3 shows the correlation of each country's level of chocolate consumption and its number of Nobel laureates per capita.

As seen in this figure, the higher the average chocolate consumption for a country, the higher the number of Nobel laureates per capita.

- Chocolate, high in dietary flavanols, is thought to improve cognitive function and reduce the risk of dementia.

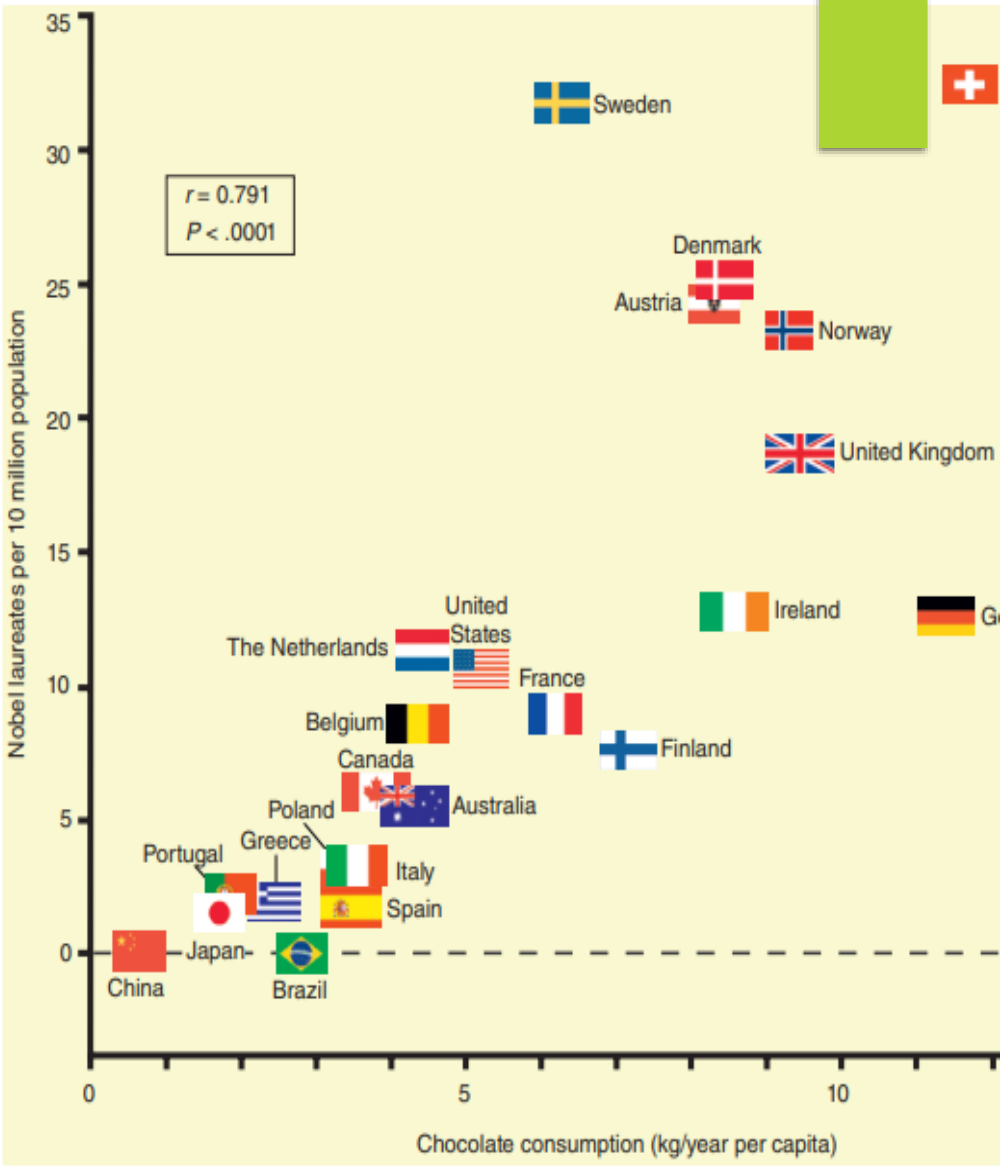


Fig. 7.3 Correlation between countries' annual per capita chocolate consumption and the number of Nobel laureates (From Messerli FH. Chocolate consumption, cognitive function, and Nobel laureates. *N Engl J Med.* 2012;367:1562–1564.)

- أهم شيء تعرف انه
- -لما شفنا ال chocolate consumption شفناها in general at level of country مش لكل حدا وهاي مشكلة ال ecologic studies

In this study we don't ask each one in the country about their chocolate consumption

-So, is eating chocolate increase cognitive ability?

I may test it in other designs to see if there is an association between chocolate consumption and cognitive ability.

Ecologic Studies

- We might therefore be tempted to conclude that chocolate consumption may be a **causal factor for being awarded a Nobel Prize**.
- The problem is that we do not know whether the individuals who won Nobel Prize in that country actually had a high chocolate intake.
- All we have are average values of chocolate consumption and the number of Nobel laureates per capita for each country.
- In fact, one might argue that, given the same overall picture, it is conceivable that those who won the Nobel Prize ate very little chocolate.
- Fig. 7.3 alone does not reveal whether this might be true; in effect, individuals in each country are characterized by the average figures (level of consumption and per capita Nobel laureates) for that country.
- No account is taken of variability between individuals in that country with regard to chocolate consumption.
- This problem is called the **ecologic fallacy**—we may be ascribing to members of a group some characteristic that they in fact do not possess as individuals.
- **ecologic fallacy , it is a problem in ecologic studies because we are talking about group, and we don't have individual data**
- This problem arises in an ecologic study because **data are only available for groups;** we do not have exposure and outcome data for each individual in the population

- Another example of ecologic studies; antibiotics consumption and the prevalence of certain disease may be there is an association exist or ecologic fallacy

Ecologic Studies

- Table 7.1 shows data from a study in Northern California exploring a possible relation between prenatal exposure to influenza during an influenza outbreak and the later development of acute lymphocytic leukemia in a child.

- The table shows incidence data for children who were not in utero during a flu outbreak and for children who were in utero in the first, second, or third trimester of the pregnancy during the outbreak.
- Below these figures, the data are presented as relative risks, with the risk being set at 1.0 for those who were not in utero during the outbreak and the other rates being set relative to this.
- The data indicate a high relative risk for leukemia in children who were in utero during the flu outbreak in the first trimester.

ما شرحته الدكتورة ,
But you must read it

TABLE 7.1 Average Annual Crude Incidence Rates and Relative Risks of Acute Lymphocytic Leukemia by Cohort and Trimester of Flu Exposure for Children Younger Than 5 Years, San Francisco/Oakland (1969–1973)

		FLU EXPOSURE			
		TRIMESTER			
	No Flu Exposure	1st	2nd	3rd	Tota
Incidence rates per 100,000	3.19	10.32	8.21	2.99	6.9
Relative risks	1.0	3.2	2.6	0.9	2.2

Modified from Austin DF, Karp S, Dworsky R, et al. Exces leukemia in cohorts of children born following influenza epidemics. *Am J Epidemiol.* 1977;10:77–83.

Ecologic Studies

- **What is the problem?**
- The authors themselves stated;
  - "The observed association is between pregnancy during an influenza epidemic and subsequent leukemia in the offspring of that pregnancy. **It is not known if the mothers of any of these children actually had influenza during their pregnancy**."
- What we are missing are *individual data* on exposure (influenza infection).

Ecologic Studies

- One might ask;
- **why didn't the investigators obtain the necessary exposure data?**

- The likely reason is that the investigators used birth certificates and data from a cancer registry; both types of data are relatively easy to obtain.
- This approach did not require follow-up of the children and direct contact with individual subjects. If we are impressed by these ecologic data, we might want to carry out a study specifically designed to explore the possible relationship of prenatal flu and leukemia. However, such a study would probably be considerably more difficult and more expensive to conduct.

Ecologic Studies

- In view of these problems, **are ecologic studies of value?**

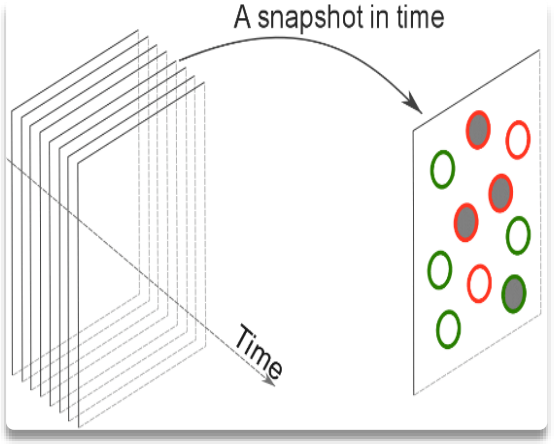
- Yes, they can suggest avenues of research that may be promising in casting light on etiologic relationships. In and of themselves, however, they do not demonstrate conclusively that a true association exists.

- When variability of an exposure is limited, ecologic correlations may provide a more valid answer with regard to the presence of an association than studies based on individuals

Cross-Sectional Studies

Cross-Sectional Studies

- Another common study design used in initially investigating the association between a specific exposure and a disease of interest is the cross-sectional study.



- This type of study design is called a cross-sectional study because both exposure and disease outcome are determined simultaneously for each study participant; it is as if we were viewing **a snapshot of the population at a certain point in time.**

Cross sectional studies divided to :

1-analitical :بتحاول تصل ل correlation between factor x , y but we cant confirm the causality

2-describtive

Cross-Sectional Studies

- study is seen in Fig. 7.5. We define a population and determine the presence or absence of exposure and the presence or absence of disease for each individual at the same time.
- Each subject then can be categorized into one of four possible subgroups.

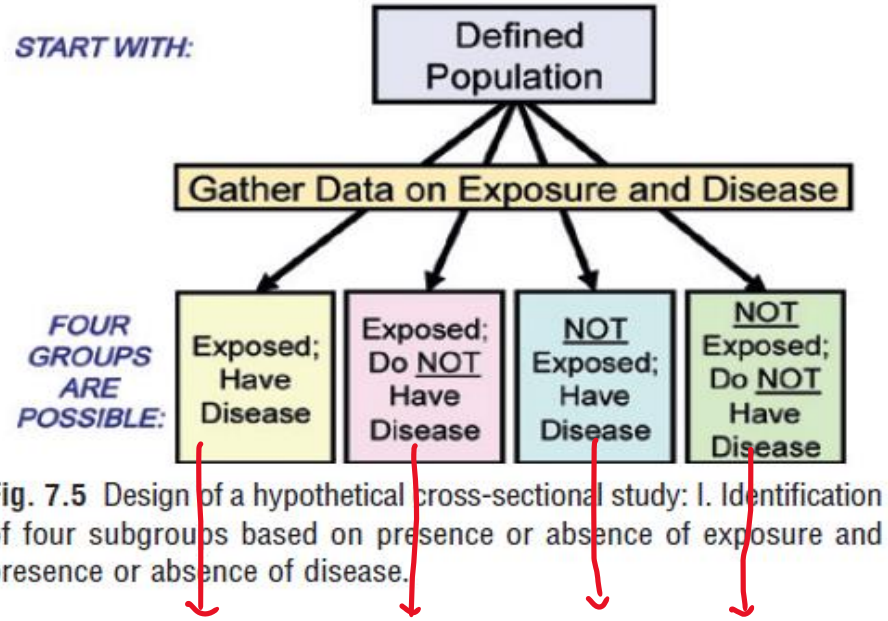


Fig. 7.5 Design of a hypothetical cross-sectional study: I. Identification of four subgroups based on presence or absence of exposure and presence or absence of disease.

obese and have diabetes

obese with no DM

NOT obese with DM

not obese no DM

Cross-Sectional Studies

- As seen in the 2 × 2 table in the top portion of Fig. 7.6, there will be:
  - *a* persons, who have been exposed and have the disease;
  - *b* persons, who have been exposed but do not have the disease;
  - *c* persons, who have the disease but have not been exposed;
  - *d* persons, who have neither been exposed nor have the disease.

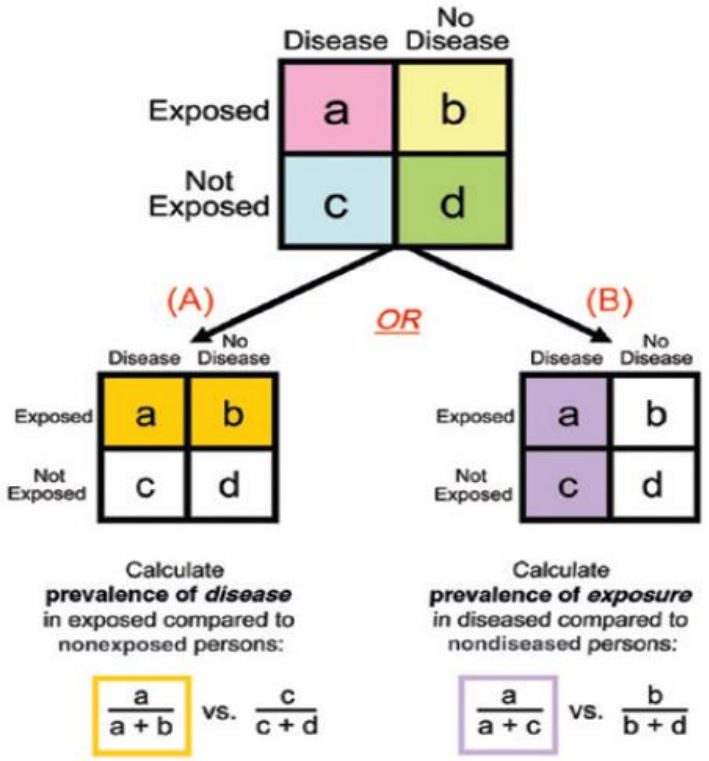


Fig. 7.6 Design of a hypothetical cross-sectional study—II: *(top)* A

لما سألنا عن factor A , factor B لكل مشارك بالدراسة
مثلا A: obesity
B: diabetes

سألنا عن نقطة زمنية معينة عشان اعرف ال Correlation و اذا بينهم علاقة

Cross-Sectional Studies

- In order to determine whether there is evidence of an association between exposure and disease from a cross-sectional study, we have a choice between two possible approaches, which in Fig. 7.6 are referred to as (A) and (B).
- If we use (A), we can calculate the prevalence of disease in persons with the exposure *(a/(a+b))* and compare it with the prevalence of disease in persons without the exposure (*c/(c+d)*).
- If we use (B), we can compare the prevalence of exposure in persons with the disease (*a/(a+c)*) to the prevalence of exposure in persons without the disease (*b/(b+d)*.

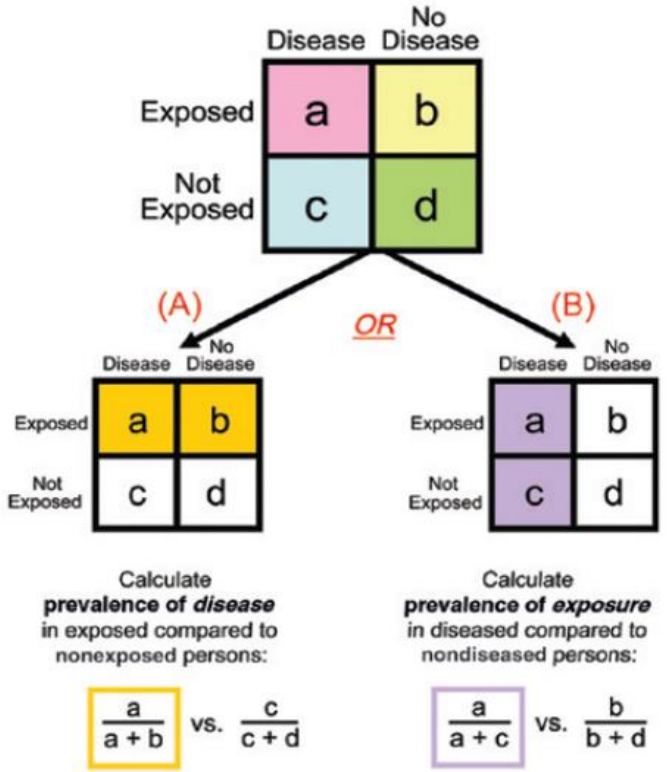


Fig. 7.6 Design of a hypothetical cross-sectional study—II: *(top)* A

*So in cross sectional study we try to measure the prevalence

*We do (A)or(B) depend on research question or focus on what you want

*in the previous slide we have a correlation not association because we don't know if A happens first or B so we cant say there is causality or there is a relation

لاني قاعد بدرس عند نقطة زمنية وحدة ما بعرف مين اجا اول

* يعني الTemporal relation الcausality ومن اهم نقاط ال
  cause before effect

Cross-Sectional Studies

=prevalence study

مثلا بهمني اعرف كم حدا بالمجتمع عندهDMوكم حدا منهم obese

- **Serial cross-sectional studies** are also useful to evaluate trends in disease prevalence over time in order to inform health care policy and planning.
  - كل سنة بعرف قديش انتشار السكري واذا زاد ناخذ اجراء
- Fig. 7.8 shows the temporal trends in adjusted prevalence of stages 3 and 4 CKD from NHANES 1988–1994 through 2011–2012, categorized by the presence or absence of diabetes.
- As shown in the figure, there was an initial increase in adjusted prevalence of stages 3 and 4 CKD that leveled off in the early 2000s among nondiabetic individuals but continued to increase in diabetic individuals.

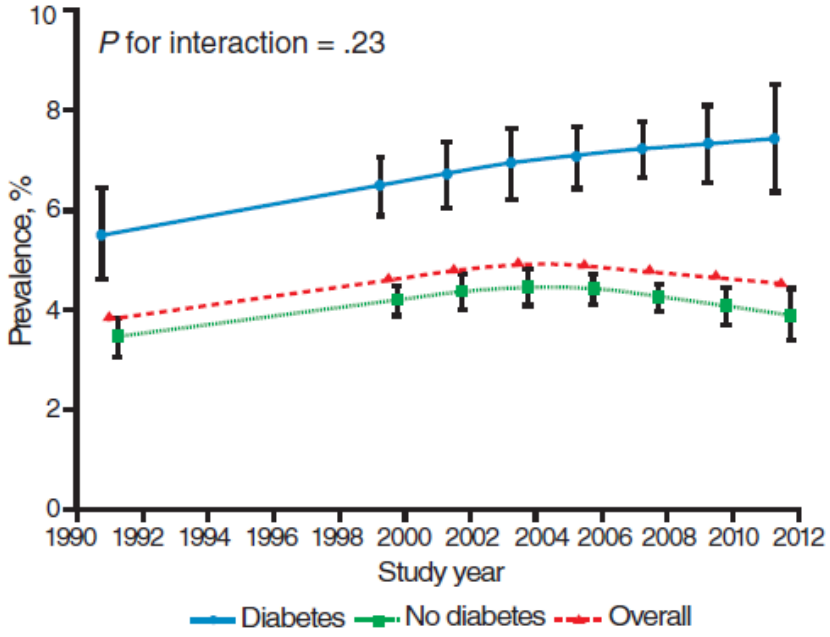


Fig. 7.8 Adjusted prevalence of stage 3 and 4 chronic kidney disease (estimated glomerular filtration rate of 15 to 59 mL/min/1.73 m^2 calculated with Chronic Kidney Disease Epidemiology Collaboration equation) in US adults, NHANES 1988–1994 through 2011–2012. (From Murphy D, McCulloch CE, Lin F, et al. Trends in prevalence of chronic kidney disease in the United States. *Ann Intern Med.* 2016;165:473–481.)

أزرق ←بزيد prevalence | أخضر: زاد ورجع نزل ليش ؟لنكون عملنا intervention

TABLE 1 Strengths and Weaknesses of Cross-Sectional Studies

Strengths	Relatively quick and inexpensive to conduct
	No ethical difficulties
	Data on all variables are only collected at one time point
	Multiple outcomes and exposures can be studied
	Easy for generating hypotheses
	Many findings can be used to create an in-depth research study
Weaknesses	Unable to measure the incidence
	Difficult to make a causal inference
	Associations identified might be difficult to interpret
	Unable to investigate the temporal relation between outcomes and risk factors
	Not good for studying rare diseases
	Susceptible to biases such as nonresponse bias and recall bias

لانه ما في Intervention

هاظ صعب وبكون بالدراسات المعقدة

ما بقدر اعرف← مين قبل الثاني اذا DMاول او ال obesity

Bias

Important when we critic paper

- Investigators should be aware of bias when planning a cross-sectional study.
- Bias may be defined as any systematic error in a study that results in an incorrect estimate of the true effect of an exposure on the outcome of interest.
- There are many types of bias in clinical studies, but for simplicity, they can be broadly grouped into two categories:
  - Selection bias
  - Information bias.

TABLE 3 Common Types of Biases and Their Definitions in Clinical Studies

Selection bias	
Sampling bias	Some individuals within a target population are more likely to be selected for inclusion than others
Allocation bias	There is a systematic difference between participants in exposed and unexposed groups
Loss-to-follow-up bias	Some individuals lost to follow-up differ from those who were not lost to follow-up with respect to the exposure and outcome
Nonresponse bias	There is a systematic difference between responders (ie, people who complete a survey) and nonresponders (ie, people who do not complete a survey)
Prevalence-incidence bias	Also known as Neyman bias. It is a selection bias in which individuals with severe or mild disease (or both) are excluded
Information bias	
Observer bias	The investigator's prior knowledge of the disease status or treatment of the subject leads the researcher to ask questions or assess the subject differently
Interviewer bias	The tendency of the interviewer to obtain answers that support preconceived notions
Recall bias	Participants recall information on exposure differentially depending on their outcome status or recall information regarding their outcome dependent on their exposure
Detection bias	Systematic differences between groups in how outcomes are determined

Bias divided into
1-selection bias
2- information bias

1-selection bias :
a-sampling bias زي اني اوخذ اول سطر من الطلاب اللي بالقاعة

مثال :
بدي اشوف ال Prevalence of HTN, household يعني بدي اشوف ال
ف رحت الف عالبيوت من الساعة 8 للساعة 11 الصيح وكل الناس بالدوام واللي بالبيوت هما الكبار اللي اغلبهم عندهم ضغط فهون العينة اللي اخذت منها المعلومات بتكون غلط

B- allocation bias
- دراسات سريرية
- بال interventional study
- لمل اعمل جروبين واحد اعطيه الدوا والثاني ما اعطيه لازم يكون توزيع المرضى عالجروبين عشوائي بحيث يكونوا متماثلين

c- loss of follow up bias : in longitidunal study not in cross sectional
In case control or cohort

ممكن بعض العينة يبطل بدهم يكملو او يطلعوا برا البلد او يموتو فهون بخسر المتابعة للعينة

D-non response bias

E- prevalence- incidence bias

- هسا ال Cross sectional study هي ال prevalence
يعني بتقيس عند Point of time عشان نعرف الانتشار
-Now prevalence depend on incidence and duration

لذالك كل ما طول المرض ممكن اقدر اعمله

Detection in the prevalence even if the incidence is low

There is equation for prevalence
Prevalence =incidence *duration
في فيديو يوتيوب احضروه حتحمله

Prevalence اللي يموتوا من السكري بسرعة ما بلحق اني ارصدهم بال

2- information bias :
A-observer bias بطرح السؤال بالطريقة اللي بدو اياها هون بأثر عالسؤال
B –interviewer bias هون بعمل مقابلة بسمع الجواب بالطريقة اللي انا بدي اياها
يعني بعملInterpretation للاشي اللي سمعه او شافه بالطريقة اللي هوا شايفها او بتخدم مصلحته
C-recall bias present in more than one design like case control , cross section
يعني المشكلة هون نتيجة النسيان مثلا اذا سألت ام ابنها لساته مريض عن الادوية اللي بيوخذها حتتذكر بينما لو سألت ام ابنها صارله فتره متشافي احتمال ما تتذكر فبالحالة هاي انا ما قدرت اعرف الدوا اللي سبب في تحسن حالة الطفل واعمل عليه دراستي

-D-detection bias :divided into systematic error and random error(5%)

-systematic : systematic كل انواع ال biasاللي شفناها هيا

لانه أثرها حيكون موجود عكل عملية البحث

-random error I cant control

الها علاقة بال

-mood

- الوضع

-كيفية فهم السؤال

:Detection bias مثال على ال

بقيس الكوليسترول بجهاز معين دائما بزيد مثلا وحدتين