Community Medicine Epidemiology week 4 Study design part 1: Descriptive studies

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## Research

- It is a systematic investigation to develop or contribute to generalizable knowledge.
- \*• Research is an organized and systematic way of finding better answers to questions.

> Systematic: All & us should follow accertain pathwayseg: Iwant to do Prevalence on fife I diabetes 'n Jandan, theresearch assisted in agaba should Pick the same blocd investigation like People in Irbid, Amman, etc. . By doing the same blood tests & asking the same questions & using the same include exclude criteria. Ammise Iwill not have a productive research I like of interview of the same questions is using the same include exclude criteria. Ammise I will not have a productive research

## Research

★• Research is vital for the understanding of the problems that affect individuals, communities or health systems.

★ It allows for a systematic and scientific assessment or evaluation of problem and provides knowledge that allows for change to occur- change that improve the quality of health and health care.

X• No organization or health institution can grow or develop without the use of research.

## Research

- The basic function of research?is to answer
- why and how of a phenomenon,
- but searching answers to
  - what,
  - when,

Example: If we want to study diabetes' complications we need to answer couple of ques. like; - who does if affect (all patients or specific) - where is it occurring at? -> How can we control it?

• how much, etc., is also part of research endeavours.

## Medical Research

Lo If we're doing a medical

should be looking af the

Etiology (cause), risk factors,

research on cancer, we

- (how does it occurg) What stage
- It is a systematic process to better determine etiology,
   patho-physiology, epidemiology, diagnosis, therapy,
   prognosis and prevention.
   (wenced to have different reference rates from diff.
- Research is the very foundation of improved medical care.
- It can also provide evidence for policies and decisions on health development.

\*People with Prediabities are Now given metformin + a healthy diet in order to prevent or delay diabetes. [healthy life 1962 will bibling] \* People with Polyps have it remared to prevent colorectal cancer. [Polyps: 12,09] \*We can get our rinfo. by several ways & we should always have certain objectives in Areas of Research the research.

- Problem(s) discovery, finding
- Impact of the problem
- Epidemiology of the problem: Size, etiology / risk factors
- Pathogenesis
- Management
- Prevention

## STUDY METHODS: STEPS IN MEDICAL **RESEARCH** Science

- It is known to be a systematic study that follows a pattern and produces testable results.
- Thus scientific research must follow a step-by-step pathway that [ المقصود : اعلى خطوة بخطوة هنتان يكون البحث والله ع بدوره ما الله طل على على العل على We call this Study Methodology
- We call this **Study Methodology**

All studies should fallow acertain patturing like for egethical approved [ cajsion of the follow of the form of t

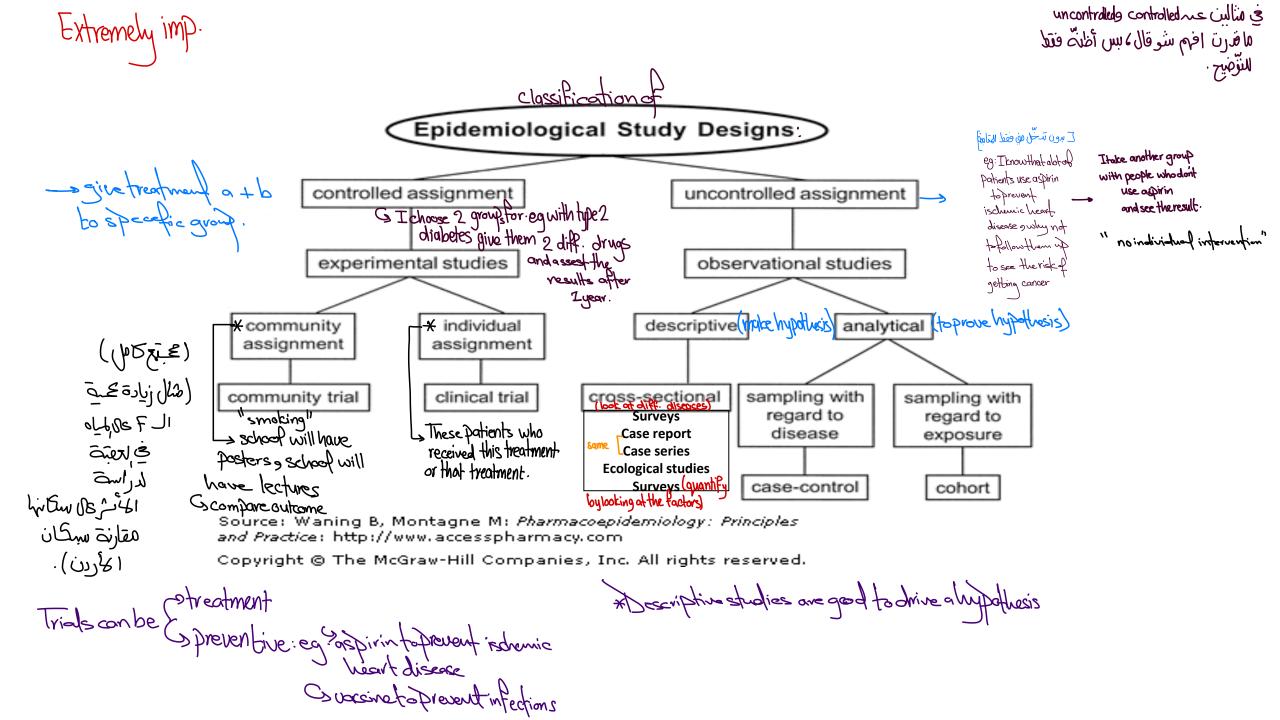
## Research Methods

- Research Methods are the tools and techniques for doing research.
- It covers all the steps from planning to carry out research till dissemination of the results.

Study design: Definition (pathway you select to do your study)

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.

Example: I choose cross-sectional studies to assest type I diabetes.



case report: apatient had undergone acomplicated surgery and I want to shave my out comes is observation case-series: summarizationalings from cases with similar problems. cross-section: understand the prevalence of clisease of a point in time. case confrat : group with vodiscose us group with discase (recliment consumptions) (cg Tsucceptibility to colorectal cancer ecological studies: correlations ( diff diseases with provision of fasting Altow are the descriptive studies good to drive ahupothesis?? Conservices: 20 potients with cerviced cancer 9 17 of them were tested to be the to HP virus and the drives alupothesis (listhere are before hip between HP+ cerviced cancer). Inthis are, Incedtedo an analytical study to dreck if it is avisk factor. \* cohorentstudy: follow up + incidence. incidence eg nonsmoke + hypo C> smoker us nonsmoker and hypothyrodism: incidence smoke + hypo  $\frac{20}{1000} |year \longrightarrow \frac{2}{100} = RR ijilitit$  $\frac{100}{1000} |year \longrightarrow \frac{10}{100} = \frac{5}{100}$ smoking increase the visk of disease by 5 times.

If we have a very rave disease like congenital heart disease // parkinson or any disease with prevalence besethen I. I need tomake follow up for 10 years mytaget 10 cases. [NOT FEASIBLE, Budget] That's why I don't use cohort instead I use the core control. case contral: start with people having a disease is and compare than to people with no disease. Zeabort: Nodiscare + exposed Nodisease + nonexposed Following (we can observe the exposed factors by looking at the history of the diseased person and compare it see who got the disease with people with nodisease). (can look for multiple diseases, with I risk factor).

## Observational epidemiology

- Provides information about disease patterns or drug use problems by various characteristics of person, place, and time.
- اهم نقطة • It also is used by epidemiologists to generate hypotheses regarding the causes of disease or drug use problems.

## Observational epidemiology

### a. Descriptive

Case reports and case series Descriptive analysis (Person place time) Ecological (correlational) Cross-sectional

**b. Analytical** Case Control Cohort

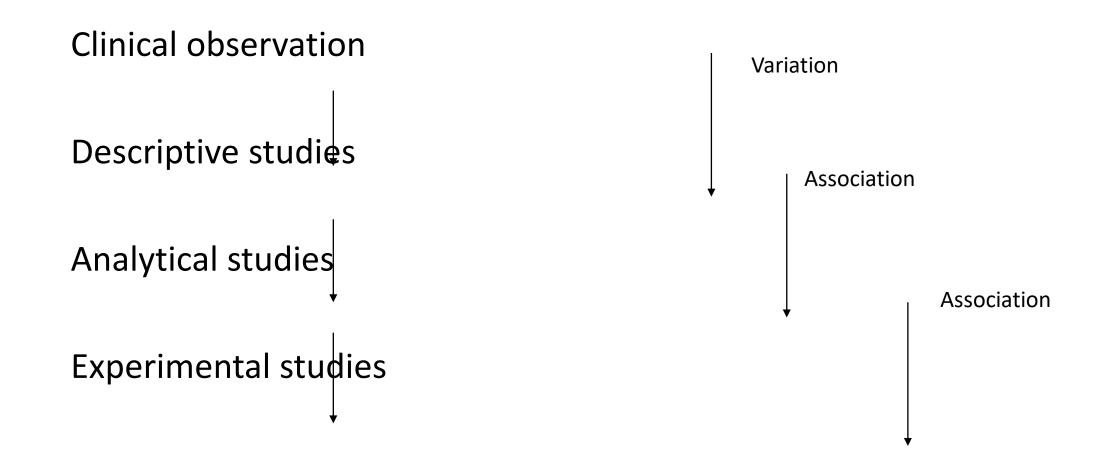
## Epidemiological studies

- Observational studies are descriptive or analytical in nature.
- Descriptive studies attempt to uncover and portray the occurrence of the condition or problem, whereas analytical studies determine the causes of the condition or problem.
- Investigators in observational studies may plan and identify variables to be measured, but human intervention is not a part of the process.
- Experimental studies, in contrast, involve intervention in ongoing processes to study any resulting change or difference.

## Observational epidemiology

- Descriptive studies: provide insight, data, and information about the course or patterns of disease or drug use problems in a population or group.
- Analytical studies are used to test cause—effect relationships, and they usually rely on the generation of new data.

## Epidemiological studies



## Does coffee causes pancreatic cancer

I am beginning to suspect that there is an association between coffee drinking and pancreatic cancer .....

I have seen a good number of cervical cancer patients positive for HPV...

Case series

Descriptive analysis

**Ecological study** 

Cross-sectional analysis

How to investigate this further?

Dr. Harald zur Hausen. Voyunecologist and a virologist V studied the relation between HAV + cerviced cancer V started a descriptive study V storted a descriptive stray V cross section - > prevalence - Analytical studies - > HPU is arisk for in hispotient (case control) cervical concer. (70%) VHe also developed avaccine to prevent cervice concer.

Never neglect any observation you get in your clinic

For example, if you prescribed a certain new drug to treat a specific disease, and after that, you observed some of the patients developed liver problems, and your colleague has also reported the same problem , then you should get back to the old medication

That is called challenged and rechallenged

" كُسُ أُدوب شَالوها مد لسوق (هيك أسباب

## Prospective vs. retrospective studies

## Prospective studies (more accurate)

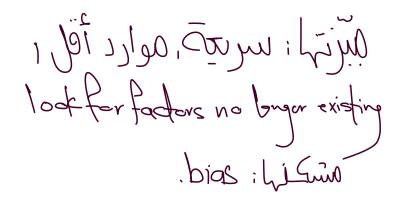
• Watches for outcomes, such as the development of a disease, during the study period and relates this to other factors such as suspected risk or protection factor(s).

Smoker

nonsmaker

- The outcome of interest should be common; otherwise, the number of outcomes observed will be too small to be statistically meaningful (indistinguishable from those that may have arisen by chance).
- All efforts should be made to avoid sources of bias such as the loss of individuals to follow up during the study.
- Prospective studies usually have fewer potential sources of bias and confounding than retrospective studies.

## Retrospective studies



- A looks backwards and examines exposures to suspected risk or protection factors in relation to an outcome that is established at the start of the study.
- Many valuable case-control studies, such as Lane and Claypon's 1926 investigation of risk factors for breast cancer, were retrospective investigations.
- Confounding factors and bias are more common in retrospective studies than in prospective studies.

### **Comparison of Retrospective and Prospective Approaches**

Retrospective	Prospective
Inexpensive to conduct	Expensive to conduct
Completed in a shorter time period	Completed over a longer time period
Easier to access a larger number of subjects	More difficult to access subjects and usually requires a larger number of subjects
Allows results to be obtained more quickly	Exposure status and diagnostic methods for disease may change
Useful for studying exposures that no longer occur	Loss of subjects from the study over time may be substantial
Information and data may be less complete and inaccurate	Information and data may be more complete and accurate
Subjects may not remember past information	Direct access to study subjects enhances reliability of data

### **Case Reports and Case Series**

alla no usi ميمنة وأنا نقدمها **Case report** is detailed report by one or more clinicians of the profile of a single patient.  $\leftarrow \uparrow \uparrow \uparrow$ Example: 1961; pulmonary embolism 5 weeks after use on oral contraceptive. **Question:** Are women who develop pulmonary embolism more likely to have used oral contraceptives than women who did not develop the disease? **Case Series** describes the characteristics of a number of patients with a given disease. **Application:** Routine surveillance activities (accumulated case Z reports). Striking clustering of cases may suggest emergence of new diseases or epidemics

### Case report and case series

 Clinician finds unusual features of a disease or effects of a drug, or the patient's medical history, that lead to the formulation of a new research question or hypothesis Hammade et al. Journal of Medical Case Reports (2022) 16:386 https://doi.org/10.1186/s13256-022-03630-1 Journal of Medical Case Reports

#### **CASE REPORT**



Open Access

### Isolated giant renal hydatid cyst with a simple renal cyst appearance: a case report

Mohammed Hammade<sup>1\*</sup>, Sami Alhoulaiby<sup>1</sup> and Adnan Ahmed<sup>2</sup>

#### Abstract

**Background:** Isolated renal hydatid cysts of the kidney are a rare occurrence that account for about 2–3% of all hydatidoses. They can stay asymptomatic for years and could have a variable presentation on imaging techniques, which results in a challenging diagnostic process.

Case presentation: We report a 22-year-old Caucasian male with a large cyst on the upper pole of the left kidney that had no septations nor membrane calcifications on computed tomography, which led to mistakenly considering it a simple renal cyst. The true diagnosis was identified intraoperatively and proven postoperatively by pathology.

**Conclusions:** This case highlights the importance of keeping echinococcosis in mind when treating suspected renal cysts and tumors to avoid incorrect treatment and possible content spillage, anaphylaxis, and peritoneal dissemination.

Keywords: Isolated renal hydatid cyst, Renal echinococcosis

### Case Reports Case Rep Neurol

. 2017 Mar 20;9(1):44-48. doi: 10.1159/000460814. eCollection 2017 Jan-Apr.

A Case Report of Severe Delirium after Amantadine Withdrawal

Franz Marxreiter 1, Jürgen Winkler 1, Martin Uhl 2, Dominik Madžar 2 Affiliations expand PMID: 28611642 PMCID: PMC5465776 DOI: 10.1159/000460814 Free PMC article

Abstract

Amantadine is frequently used in addition to dopaminergic substances like dopamine agonists or L-Dopa in advanced Parkinson disease (PD). However, adverse effects like hallucinations limit its use. PD patients developing severe psychotic symptoms up of treatment with either dopaminergic substances and/or amantadine need to stop intake of any psychotropic substance. Here, report the case of a 71-year-old PD patient without previously known cognitive impairment. He presented with drug-induced psychotic symptoms due to changes in his therapeutic regimen (increase in COMT inhibitors, newly introduced MAO B inhibitor Also, amantadine had been part of his long-term medication for more than 2 years. The severity of his psychotic symptoms required a L-Dopa monotherapy. After changing his medication, the patient developed severe delirium that resolved rapidly a i.v. amantadine infusion, suggesting an amantadine withdrawal syndrome. Amantadine withdrawal syndrome is a rare adverse event that may present even in PD patients without cognitive impairment. This case report highlights the need for a gradual withdrawal of amantadine even if acute and severe psychotic symptoms are present. Moreover, this is the first report of a cognitively unimpaired patient developing an amantadine withdrawal syndrome.

Keywords: Amantadine; Amantadine withdrawal; Delirium; Parkinson disease; Psychotic symptoms.

Case Reports Transpl Int . 2002 Jul;15(7):374-6. doi: 10.1007/s00147-002-0426-9. Epub 2002 Jun 20. Colchicine myoneuropathy in a renal transplant patient

Peter Dupont 1, Ian Hunt, Lawrence Goldberg, Anthony Warrens Affiliations expand PMID: 12122515 DOI: 10.1007/s00147-002-0426-9

Abstract

Colchicine is widely employed for the treatment of gout in renal transplant patients where NSAIDs are contra-indicated and allopurinol prophylaxis is often avoided due to concomitant azathioprine immunosuppression. We report here a case of colchicine-induced myoneuropathy in a renal transplant recipient. Our patient had myalgia, muscle weakness, elevated creatine kinase levels, myopathic changes on electromyography and peripheral neuropathy. Withdrawal of colchicine resulted in recovery within 4 weeks. Renal transplant recipients are likely to be at greater risk of colchicine-induced myoneuropathy due to the unique concurrence of risk factors predisposing to toxicity in such patients. These risk factors include the high incidence of gout in this population, widespread use of colchicine as first-line therapy, impaired renal function and concomitant cyclosporin treatment. The diagnosis should be considered in any renal transplant recipient receiving the drug who develops myopathy. Prompt withdrawal of colchicine therapy should result in rapid clinical and biochemical improvement.

PubMed Disclaimer

## Case reports

- The most common type of study published in the medical literature.
- They note unusual medical occurrences, identify new diseases, and describe adverse effects from drug therapies.
- Clinical investigators can use challenge-rechallenge data to help establish causality.
- In this approach, administration of a drug (the challenge) might be suspected of producing a specific symptom (side effect or adverse reaction).
- Administration of the drug can be stopped to observe whether the side effect or adverse reaction diminishes.
- If it does, then administration of the drug can be resumed (the rechallenge) to observe whether the effect returns, suggesting a possible relationship between the two events.

Clinical Neurology and Neurosurgery Volume 99, Issue 4, December 1997, Pages 266-270 Clinical Neurology and Neurosurgery

Case report

### Acute onset of colchicine myoneuropathy in cardiac transplant recipients: case studies of three patients

Author links open overlay panel Sandeep S Rana a, Michael J Giuliani a, Chester V Oddis b, David Lacomis a c Abstract

Colchicine causes both muscle and peripheral nerve toxicity of subacute onset in patients with renal insufficiency. We report three cardiac transplant recipients, treated with colchicine for cyclosporin A (CyA)-induced gout, who developed acute weakness due to colchicine myoneuropathy. The onset of disabling weakness occurred over a 1–2 week period. All three patients had concomitant renal insufficiency and an elevated serum creatine kinase and two had elevated CyA levels at the time of presentation. Electromyography revealed features of myopathy and motor axonal neuropathy in all three patients. Two underwent muscle biopsy which confirmed the presence of sarcoplasmic vacuoles characteristic of colchicine-induced myopathy. All patients rapidly improved with either colchicine dose reduction or drug discontinuation. In conclusion, cardiac transplant recipients treated with CyA and colchicine may be at increased risk of developing colchicine-induced myoneuropathy especially in the setting of concurrent renal insufficiency. In patients with post-transplantation gouty arthritis, other treatment modalities are suggested; and if colchicine is administered, the dose should be reduced, CyA levels should be monitored closely and patients should be assessed for signs of neuromuscular toxicity.

### **CASE REPORT**

#### Open Access

Theok fo

# Syrian females with congenital adrenal hyperplasia: a case series

Nada Dehneh<sup>1\*</sup>, Rami Jarjour<sup>2,3</sup>, Sahar Idelbi<sup>4</sup>, Assad Alibrahem<sup>4,5</sup> and Sahar Al Fahoum<sup>1</sup>

#### Abstract

Background: One of the most common types of congenital adrenal hyperplasia is an autosomal recessive disorder with 21-hydroxylase deficiency. The classical form, defined by cortisol insufficiency, is accompanied by prenatal androgen excess causing variable masculinization degrees of external genitalia in babies with a 46, XX karyotype.

Cases presentation: These five case reports highlight the management of Syrian females aged between 0 and 32 years with congenital adrenal hyperplasia. Two of the patients have been raised as males, while two had reconstructive surgery and one had hormonal therapy. Becoming mother was achieved by two patients

**Conclusion:** The integrated treatment of females with classical congenital adrenal hyperplasia CAH, which includes appropriate surgical procedures and controlled hormonal therapy, gives these females the opportunity to live as they are, and perhaps as mothers in the future.

Keywords: Congenital adrenal hyperplasia, Syria, Case report

### Case-series: <u>Clinical case series</u> some as case report \* The 20-30 years we had many indications for several illnesses. \* In 60s-70 s with only clinical marri festations

 Usually a coherent and consecutive set of cases of a disease (or similar problem) which derive from either the practice of one or more health care professionals or a defined health care setting, e.g. a hospital or family practice.

## Case-series: Clinical case series

- A case-series is, effectively, a register of cases.
- Analyse cases together to learn about the disease.
- Clinical case-series are of value in epidemiology for:
  - Studying symptoms and signs
  - Creating case definitions
  - Clinical education, audit and research

## Case series: Natural history and spectrum

• Helps professionals can build up a picture of the natural history of a disease

## Case series: Natural history and spectrum

- Population case-series is a systematic extension of this series but which includes additional cases, e.g. those dying without being seen by the clinicians.
- Add breadth to the understanding of the spectrum and natural history of disease.

## Case series: Limitations

Main limitation: no control group ? I read to compare them with other group tomake a conclusion.

Usually we cannot estimate the prevalence or incidence rate

- Breast cancer registry in Jordan: We cannot provide prevalence rates without:
- **1.** Population size
- 2. Time- period of data collection
- 3. All cases of breast cancer are registered

Siragely anothis

As a general statement: we cannot calculate incidence Exception is when all cases are reported in the country or the region.

For example, for calculation of the incidence of cancer in Jordan: Jordan National Cancer registry can generate data on the incidence.

All cancer cases in Jordan are reported to the Registry office.

No control group for comparison

بالتك المعلقة عش دقيقة كان الآن نأخذ مسكل المستشفيات ( للبن من من) ( كارتم يكون مسكل مكان وتل منطقة )

الدكتور عده اعتراض حلى فكي إله مطن لتدي زادد . . مد ١٩٩٧ م الحقن ؟؟ لاتلا بس بلينوا بتسجيل لي لات كالان كاليش\_ (يوم لم ٣٠٠ س)

## **Ecological studies**

Are studies in which information on the characteristics and/or exposures of individual members of the population groups are generally not obtained. Existing statistics are used to compare the mortality or morbidity experience of one or more populations with some overall index exposure. care is needed to avoid the 'ecological fallacy' where inappropriate conclusions are made from ecologic data

"world bank": huge amount of data for health care. t huge amount of data for health care. t huge amount of data on demography 9 environment.... (seepage 40)

# Ecological studies

• These studies are used to describe disease or drug use problems in relation to some factor of interest.

Comparing cigarette consumption with rates of cancer

Comparing Alcohol consumption with coronary heart disease mortality

• Ecological studies are the first identified strong relationships between disease and behavior.

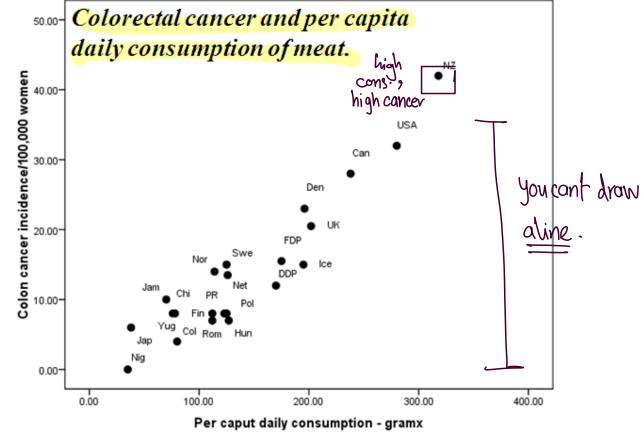
## **Ecological studies**

+ve correlation: risk factor -ve correlation: not arisk factor Sischemianter a

■In ecological studies the unit of analysis is some aggregate individuals rather than individual persons

Geographic areas or time period are often used as a basis for defining aggregates

The analysis centers on determining whether the ecological units with a high frequency of exposure are also unit with a high frequency of disease (+ve correlation) or a low frequency of disease (- ive correlation)



Adapted from: Int. J. Cancer 15:617, 1973

## Ecological (correlational studies)

- look for associations between exposures and outcomes in populations rather than in individuals.
- They use data that has already been collected.
- The measure of association between exposure and outcome is the correlation coefficent *r*.
- This is a measure of how linear the relationship is between the exposure and outcome variables. (Note that correational is a specific form of association and requires two continuous variables)

## Ecological (correlational studies)

Advantages of an ecological study

- 1. An ecological study is quick and cheap to conduct.
- 2. It can generate new hypotheses.
- 3. It can identify new risk factors.

# Ecological (Correlational studies) (talk about whole population Hedisease).

Disadvantages: (limitations)

- It is unable to control for confounding factors. This is often referred to as 'ecological fallacy', where two variables seem to be correlated but their relationship is in fact affected by cofounding factor(s). (روالي المحالي المحالي المحالي)
- 2. It cannot link exposure with disease in individuals as those with disease may not be expose.
- 3. Its use of average exposure levels masks more complicated relationships with disease.
- 4. Its units of study are populations not individuals. Therefore, the disease rates linked with population characteristics and the association observed at group level does not reflect association at individual level.

\* محكن تكون السبان احرى مماهمت سب على أكر س

#### Ecological (correlational studies)

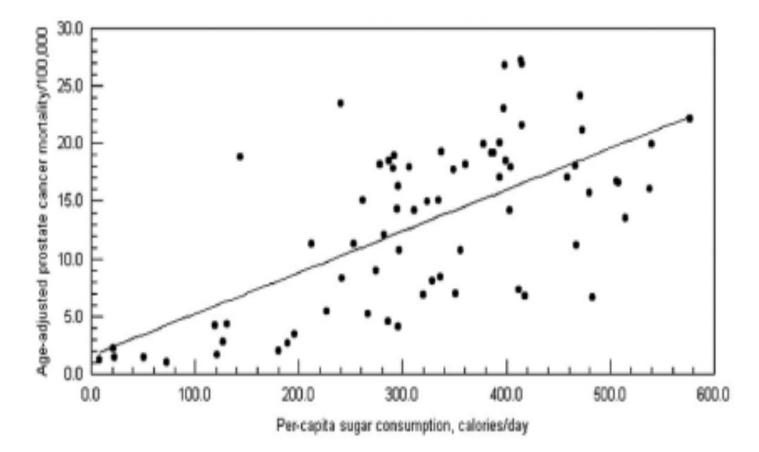


Fig. 1. Prostate cancer mortality versus sugar consumption in 71 countries.

CROSS-SECTIONAL STUDY DESIGN

 (look at very different illnesses)

 Sometimes called prevalence studies. <u>all cases ( p. 10 + 10, 10)</u>

- They are studies of total populations or population groups in which information is collected about the present and past characteristics, behaviors, or experiences of individuals.
- There are a number of advantages in performing a cross-sectional study.
- These studies involve a single data collection and, thus, are less expensive and more expedient to conduct.

Cross-sectional (or prevalence) studies we adapt screening bec. there are people relation is surveyed Are studies in which a defined population is surveyed and their disease or exposure status determined at one point in time

The prevalence rates of disease in the whole population as well as in those with and without the exposure under investigation can be determined

Cross-sectional studies are generally not suitable for a disease which is rare or of short duration as few people will have the disease at any one point in time Sweshould do incidence for these short studies

#### **CROSS-SECTIONAL STUDY DESIGN**

- Emphasis is on differences between groups at one point in time.
- They provide a one-time glimpse at the study population, showing the relative distribution of conditions, diseases, and injuries—and their attributes—in a group or population.
- Point prevalence versus Period prevalence

## Cross-sectional studies

- More effective in identifying chronic diseases and problems
- Less effective in identifying communicable diseases of short incubation periods and short durations.

#### **CROSS-SECTIONAL STUDY DESIGN**

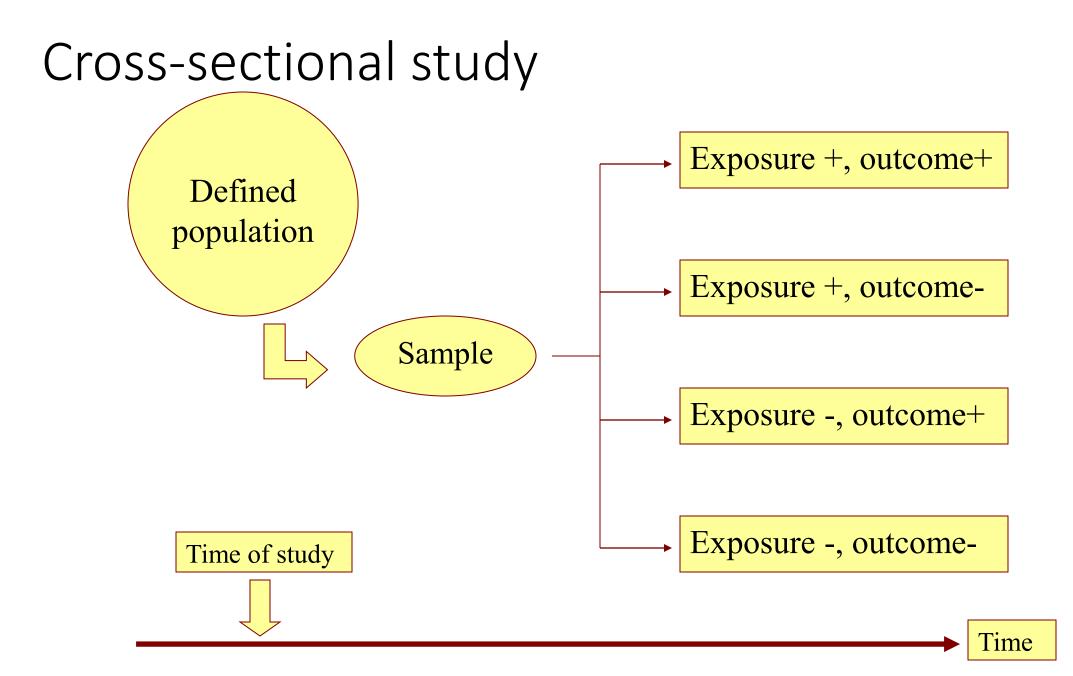
- They provide information and data useful for the planning of health services and medical programs.
- Assessment of the burden of diseases or healthcare programs leads to setting priorities at the organization, local or national levels.

 They are based on a sample of the whole population and do not rely on individuals presenting themselves for medical treatment

#### **Cross-sectional (or prevalence) studies**

It is often difficult to separate cause and effect as the measurement of exposure and disease at any one point in time

Cross-sectional studies are often used as an initial exploration of a hypothesis prior to conducting a case-control or follow-up study



# Two by two table

Exposure	Outcome		
	Yes	No	Total
Yes	а	b	a + b
No	С	d	c + d
Total	a + c	b + d	a+b+c+d

Prevalence of outcome in exposed= a / a + bPrevalence of outcome in non-exposed= c / c + dPrevalence Rate Ratio (PRR) = $= \frac{a / a + b}{c / c + d}$ 

## Cross-sectional study

#### Prevalence of and Factors Associated With Persistent Pain Following Breast Cancer Surgery

JAMA. 2009;302(18):1985-1992

**Objective** To examine prevalence of and factors associated with persistent pain after surgical treatment for breast cancer.

**Design, Setting, and Patients** A nationwide cross-sectional questionnaire study of 3754 women aged 18 to 70 years who received surgery and adjuvant therapy (if indicated) for primary breast cancer in Denmark between January 1, 2005, and December 31, 2006. A study questionnaire was sent to the women between January and April 2008.

# Cross-sectional study

	Outcome		
Chemotherapy	With pain	Without pain	Total
Yes	664	556	1220
No	879	1088	1967
Total	1543	1644	3187

Prevalence of pain among chemotherapy = 664/ 1220 = 54.4%

Prevalence of pain among no chemotherapy = 879 / 1967 = 44.7%Prevalence Rate Ratio (PRR) = = 54.4 / 44.7 = 1.22

#### Cross-sectional survey of CHD among male by physical activity

	Number examined	Number with CHD	prevalence
Not			
physically			
active	89	14	157.2/1000
Physically			
active	90	3	33.3/1000

#### Cross-sectional studies: advantages

- Relatively quick (combe expensive when you have investigatione)
  Data on all variables is only collected once.
- Sample size depends on the question
- Standard measures used
- Prevalence estimated
- The prevalence of disease or other health related characteristics are important in public health for assessing the burden of disease in a specified population and in planning and allocating health resources.
- Good for descriptive analyses and for generating hypotheses

## **Cross-sectional studies**

Disadvantages:

 Disadvantages:
 They cannot show cause-effect relationships.
 They cannot show cause-effect relationships. temporal\_

Difficult to determine whether the outcome followed exposure in time or exposure resulted from the outcome.

If the sample is not representative, results are representative only of the individuals who participate in the study

Example prevalence of sickle cell anaemia in the Easter region of the KSA does not represent the who country.

- Not suitable for studying rare diseases or diseases with a short duration. •
- Unable to measure incidence •
- Associations identified may be difficult to interpret. •
- Susceptible to bias due to low response and misclassification •

-> we can't find this velationship except in 2 cases a genetic factor.