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> Lectures in Community Medicine For 4th Stage Students By **Dr. Hassan Baiee** 2010 – 2011

Lecture 6 Study Design

Study Designs:

- 1. Observational studies:
 - a- Descriptive studies:-
 - 1- Case report.
 - 2- Case series.
 - 3- Ecological studies (correlational)
 - 4- Cross-sectional (prevalence studies)
 - b- Analytical studies:-
 - 1- Case control studies (case references)
 - 2- Cohort studies (prospective studies)
- 2. Experimental studies (intervention studies):
 - a- Randomized controlled trials (Clinical trials)
 - b- Field trials
 - c- Community trials (Community intervention studies)

Observational studies:-

Allow nature to take its course: the investigator measures but does not intervene. They include descriptive or analytic studies.

A <u>descriptive study</u> is limited to a description of the occurrence of a disease in a population and is often the first step in an epidemiological investigation. An <u>analytic study</u> goes further by analyzing relationships between health status and other variables.

Advantages of descriptive studies:

- 1. They use already available data.
- 2. They are less expensive and less time-consuming.
- 3. They describe the pattern of disease occurrence.
- 4. They formulate research hypothesis.

Case reports:

Physician who sees unusual presentation of a common disease or a very rare disease and he describes the findings of this case, case description may take any relevant description of findings.

An unusual case may add to our knowledge, for example MI in very young person without ECG finding is unusual presentation of MI.

Case series (Clinical series):

When a group of cases of the same disease are reported but in this study we can not:

- Study the etiology of the disease
- Testing hypothesis
- Have a control group

But in this study it can help in generating hypothesis.

<u>Example:</u> vaginal ca is very rare in young females, if 10 cases were reported and studied it may help us to generate a hypothesis when we interrogated with stilbestrol taking during pregnancy among their mothers (this can be done by further studies).

Discovery of AIDS was a case series.

Many clinical studies are case series.

Advantages of case reports or case series:

- 1. Use available clinical data.
- 2. Detailed individual data.
- 3. Add to our knowledge.
- 4. Suggest need for investigation (hypothesis generation).

Disadvantages of case report or case series

- 1. May reflect experience of one person or one clinician.
- 2. No explicit comparison group.

Ecological Studies (correlational):

based on studying of a group of people not individual as in previous studies. Correlation data represent average exposure level rather than individual level so we do not have each person information.

Ecological studies can generate a hypothesis and need further confirmation, it provides just initial clues to causation.

<u>Example:</u> as meat consumption in different countries increases prevalence of ca colon increases, Cigarette smoking increases ca lung prevalence increases as well.

Advantages of Correlational Study:

- 1. They describe the disease in the entire population in relation to the factor of interest.
- 2. They use the correlation coefficient (r) to measure the association between the two variables of interest.
- 3. They are easy to do, inexpensive and can be conducted quickly.
- 4. They represent the first step in searching for exposure-disease relationship (generate hypothesis)
- 5. They use available data (administrative or other aggregate data).

Disadvantages of Correlational Study:

- 1. Correlation data represent average exposure level rather than actual individual values. Data on exposure and data on outcome are collected independently.
- 2. No assurance that persons with exposure (risk factor) of interest are the same ones with outcome (disease) of interest.
- 3. Inability to link exposure with the disease in particular individual.

<u>Cross-Sectional studies (prevalence studies or surveys):</u>

It is a study of a group of people at a point in time for the prevalence of a disease or an attribute in a well defined population but data is collected at individual levels. In this study the measurements of exposure and effect are made at the same time.

Survey either:

Or

Population survey = census

Sample survey

Advantages of cross sectional study:

- 1. Provide generalization from the sample to the population.
- 2. They are short term studies and not expensive.
- 3. Provide good information for the health problems and good for health planners to assess health care needs.
- 4. Used for generating hypothesis to be test in further studies.

Disadvantages of cross sectional study:

1. It is difficult to separate cause and effect because measurement of exposure and disease are made as one point of time and it is impossible to determined which came first.

2. Cases detected are prevalent cases (survivors) leading to survival bias cases cured or died are not detected.

3. Non response and this will affect the representation of the sample.