

## Chapter 5- Epidemiologic Principles and Methods

Epidemiology is defined as “the study of the distribution and determinants of disease frequency in human populations”.

First the epidemiologist must clearly define the disease so that there is no doubt whether a case should be counted or not. Some diseases are easier to identify than others- death from gunshot wound is easy to identify while hepatitis isn't.

In defining a disease they use the word “health outcome” as a description of what is being studied rather than “disease”. they may study high cholesterol, which isn't a disease but plays a role in heart disease.

When studying disease frequency it is important to not only count the number of cases but to also count the number in the population in order to determine a rate. When calculating a rate the denominator is usually the population at risk.

2 kinds of frequency measures:

- Incidence rates- the rate of new cases of a disease in a defined population over a defined period of time. For notifiable diseases it is ascertained by counting cases reported to the local or state health dept. and dividing by the population at risk. Incidence measures the probability that a healthy person in that population will develop the disease during that time. Incidence rates are useful in identifying causes of disease.
- Prevalence rates- the total number of cases existing in a defined population at a specific time. This is usually measured by a survey. For most diseases prevalence rates change slowly and are less useful for epidemiologic studies. They are most useful in assessing the societal impact of a disease and planning for healthcare services.

These are both related to each other but the relationship depends on how long people live with the disease. So a disease with high incidence can have low prevalence if people recover quickly or die fast. However, for chronic diseases which aren't lethal the prevalence will be much higher than the incidence.

- Death rates/ mortality rates are used as a measure of frequency for diseases that are usually fatal. For the most fatal diseases death rates are very close to incidence rates (pancreatic cancer). For diseases that many people survive the mortality rate is much smaller than the incidence rate (breast cancer). Death rates aren't useful as a measure of frequency for non fatal diseases (arthritis)
- Distribution of disease- comprised of the answers to who, when, and where questions. Who- characterizes the disease victims by factors such as age, sex, race, and SES- who is most likely to get it. When- looks for trends in disease frequency over time- is the frequency increasing, decreasing, or staying the same. This can also include seasonal variations in incidence- respiratory infections in winter. The when question is important in tracking the outbreak of infectious diseases. Epidemiologists construct **epidemic curves** by plotting the number of cases identified over a period of time. It compares the dates of onset with the dates of possible exposure to calculate an incubation period. Epidemic curves are typical for diseases that have been passed from one person to another. Where- looks at comparisons of disease frequency in different places and sometimes even urban vs. rural places.

Information on the distribution of disease gives clues about the determinants of disease. Ex. colon and rectum cancer is more common in industrialized countries than developing countries. This can be because of differences in diet- fat meat and dairy vs. fiber cereal and vegetables. But there are also other factors that play a role.

Epidemiology studies human populations, usually using observational rather than experimental methods. Another possible approach to investigating the causes of disease is the biomedical approach- using animal models of the disease. Each approach has pro and cons. Animal studies can be good because they show cause and effect while there are ethical issues doing it on humans. But then there is the question of if results can be applied to humans.

### **Kinds of Epidemiologic Studies**

Descriptive epidemiology- answers to the who, when and where questions that provide clues about the causes of a disease or the source of an outbreak. They form hypotheses and then test them out by conducting studies.

There can be prospective or retrospective studies.

**Prospective studies** start in the present and monitor a group into the future or they may start at a point in time from the past and look forward from there.

**Retrospective studies** look into the past for causes of diseases for which people currently suffer

In both cases they are looking for associations between exposure to the suspected causative factor and the disease/health outcome.

- Intervention studies- this is the only time epidemiologists do experiments. They are usually done to test a new treatment for a disease (chemotherapy for cancer) or a preventative measure (vaccine). In a clinical trial one group is exposed to the intervention while the control group isn't. They then watch and see if the intervention is effective. In testing treatments for serious disease, there must be enough doubt about the effectiveness of the intervention to justify withholding it from people who could be helped and enough evidence that it will not harm the people on whom it is tested.

The control group may get a placebo so subjects don't know whether they are getting the treatment or not. 1/3 of patients respond to a placebo as if it were the intervention- saying that it worked/ they feel side effects- this is called the placebo effect. They can also compare new treatment and old treatment. In order for the new drug to be considered effective it must have a higher response rate than the placebo.

Randomized, double blind is the best. Randomized means each subject is assigned to a group randomly, making the groups equal. Double blind means the subjects and the researcher don't know which group the patient is in.

When testing clinical trials the FDA requires that the safety and effectiveness of any new drug must be demonstrated in a properly conducted clinical trial before it can be approved for marketing.

Ex. 1954 field trial of the polio vaccine, physicians' health study- heart disease and aspirin and cancer and beta carotene- aspirin reduced heart disease beta

carotene had no effect on cancer, and Kingston- Newburgh study on fluoride on tooth decay.

- Cohort studies- a way of linking exposures to results by only observation (no intervening). A cohort study is the most accurate way of doing this. Cohort studies have large amounts of people who are healthy at the beginning of the study are asked about their exposures. Then over a period of time they wait to see if those exposed are more likely to develop the disease.

Ex. Framingham heart study, Doll-Hill and Hammond Horn study, Nurses' health study (50% higher risk for breast cancer while taking oral contraceptives, regular consumption of alcohol increases risk of breast cancer by 10-40%).

These studies are designed to determine the existence of an association between an exposure and a disease and also the strength of that association. The measure of the strength of association obtained by cohort studies and interventions is the **relative risk** which is the ratio of the incidence rate for people exposed to the factor to the incidence for unexposed people. A relative risk of 1.0 means that there is no association between the exposure and the disease. A value greater than 1.0 indicates an increased risk from exposure while a value less than 1.0 indicates a decreased risk.

- Case- Control studies- starts with people who are already ill and looks back to determine their exposure. These are more efficient than cohort studies because they focus on a smaller amount of people and can be completed relatively quickly. Cases (people who have the disease) are compared with controls (healthy people who match the cases) and they are asked the same questions.

Ex. Reye's syndrome- looking for the cause and they hypothesized that medicine given after viral infection was the cause. They realized that using aspirin during the initial infection caused the syndrome. Study on breast cancer- oral contraceptives increased breast cancer and the longer exposure the more likely to get breast cancer.

These studies estimate the strength of the association between exposure and disease by calculating an **odds ratio**- an estimate of what the relative risk would be if a cohort study had been done. This is calculated by dividing the ratio of exposed subjects to non exposed subjects in the case group by the ratio of exposed subjects to non exposed subjects in the control group.

- A smaller odds ratio or relative risk leads to a much less certain conclusion.