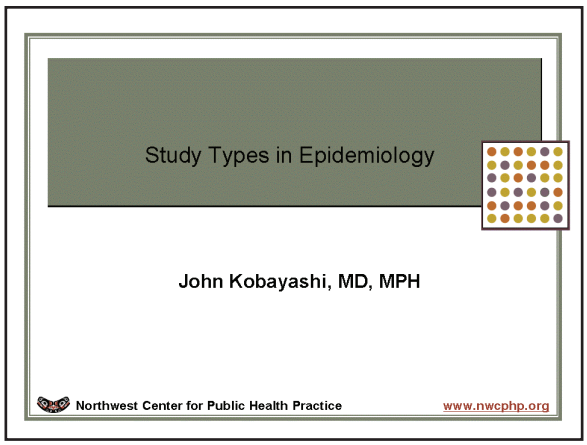
Study Types in Epidemiology

Transcript

Study Types in Epidemiology

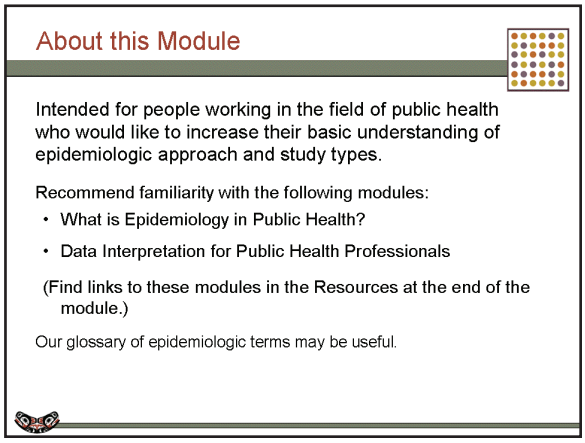
Welcome to "Study Types in Epidemiology." My name is John Kobayashi. I'm on the Clinical Faculty at the Northwest Center for Public Health Practice, at the School of Public Health and Community Medicine, University of Washington in Seattle. From 1982 to 2001, I was the state epidemiologist for Communicable Diseases at the Washington State Department of Health. Since 2001, I've also been the foreign adviser for the Field Epidemiology Training Program of Japan.



About this Module

The modules in the epidemiology series from the Northwest Center for Public Health Practice are intended for people working in the field of public health who are not epidemiologists, but who would like to increase their understanding of the epidemiologic approach to health and disease.

This module focuses on descriptive and analytic epidemiology and their respective study designs. Before you go on with this module, we recommend that you become familiar with the following modules, which you can find on the Center's Web site: What is Epidemiology in Public Health? and Data Interpretation for Public Health Professionals.



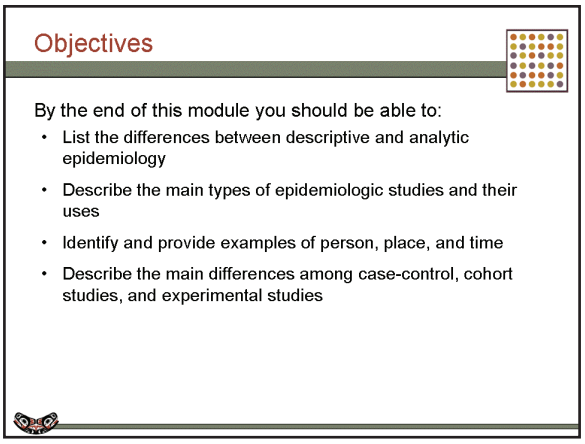
We introduce a number of new terms in this module. If you want to review their definitions, the glossary in the attachments link at the top of the screen may be useful.

Objectives

By now, you should be familiar with the overall approach of epidemiology, the use of various kinds of rates to measure disease frequency, and the various ways in which epidemiologic data can be presented.

This module offers an overview of descriptive and analytic epidemiology and the types of studies used to review and investigate disease occurrence and causes.

By the end of this module, you should be able to: list the differences between descriptive and analytic epidemiology, describe the main types of epidemiologic studies and their



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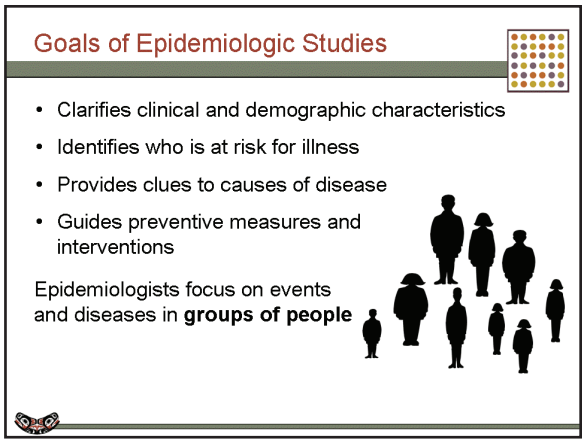
uses, identify and provide examples of person, place, and time, and describe the main differences among case-control, cohort studies, and experimental studies.

Goals of Epidemiologic Studies

Epidemiology is a very common and important activity in public health departments. It clarifies clinical and demographic characteristics of diseases and conditions. It identifies who is at risk, and provides clues to the causes of disease. And finally, it guides preventive measures and interventions.

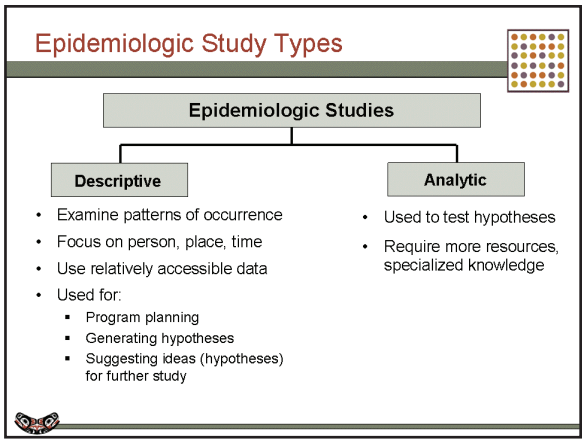
Before we go on, I want to emphasize an important point about epidemiologic studies. Unlike medical staff, who are concerned about the health of individuals, epidemiologists focus on the distribution and determinants of events and diseases in groups of people.



Epidemiologic Study Types

Epidemiologic activity is often divided into two types, descriptive and analytic, and each of these types of epidemiology uses specific kinds of studies.

Descriptive studies examine patterns of disease occurrence, with a focus on person, place, and time. These studies use relatively accessible data for program planning, to estimate caseloads, to determine the amount of public health resources needed, or to identify high risk groups. Many public health practitioners carry out descriptive epidemiologic studies within their jurisdictions. Epidemiologists also use descriptive studies to generate hypotheses that need to be confirmed or ruled out by analytic studies.



For example, early descriptive studies found that the majority of newly diagnosed AIDS cases in the United States were among young urban men, which led to the hypothesis that certain types of sexual behavior might cause AIDS.

Analytic studies are used to test hypotheses such as this. They are not usually planned or conducted at the local level, because these types of studies typically require more resources and knowledge than are available in a local agency. However, it's important that public health practitioners understand analytic study types in order to interpret these studies and make suggestions based on their own observations and experiences.

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The Five Ws of Epidemiology Studies

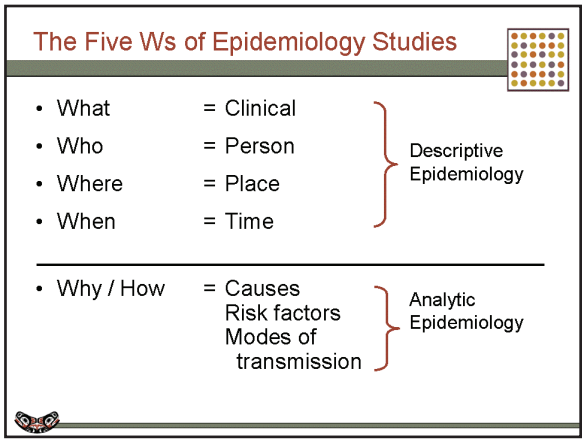
Epidemiologic studies ask five questions: what, who, where, when, and why. These five Ws remind us to organize questions about possible exposures (or risk factors).

What includes the diagnosis or clinical information.

Who, where, and when include person, place, and time information.

Why involves causes of disease, risk factors, and modes of transmission.

We study what, who, where, and when, or in other words, clinical data plus person, place, and time information, through descriptive epidemiology, which investigates the distribution of diseases or conditions.



We study why and how, or in other words, causes, risk factors, and modes of transmission, through analytic epidemiology, which investigates the determinants of diseases or conditions.

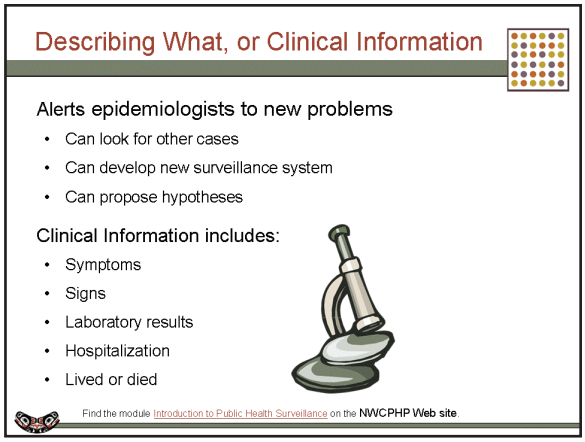
Let's look at the questions who, where, and when in a little more detail.

Describing What, or Clinical Information

Clinical information from a single or several ill persons has often been extremely important in alerting epidemiologists to a new problem. With this information, public health practitioners might look for other cases of the same type or establish some type of surveillance system to determine the extent of the problem. (You can find more information about surveillance systems in the module "Introduction to Surveillance.")

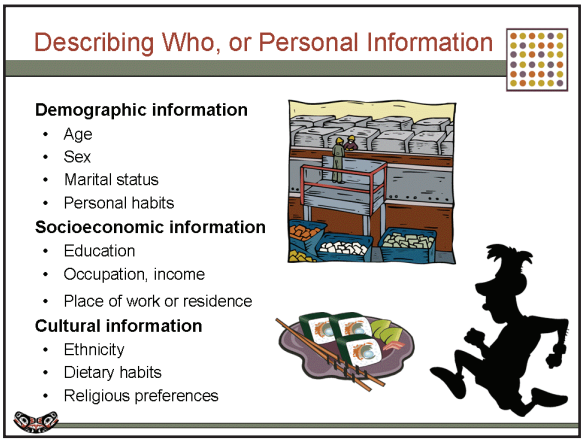
Public health practitioners might also use clinical information to propose a new idea or hypothesis for solving an existing problem, which could lead to an analytic study.

The "what," or clinical, information includes: symptoms (or a condition reported by the patient, such as pain), signs (or observed evidence of disease, such as blood in the stool), laboratory results, whether hospitalization was required, and whether the patient lived or died.



Describing Who, or Personal Information

Personal information about populations is another part of descriptive epidemiology.



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Personal information can be demographic, for example, age, sex, marital status, personal habits including exercise, smoking, alcohol use, and so on.

Personal information can also be socioeconomic, for example education, occupation, income, place of work, or residence.

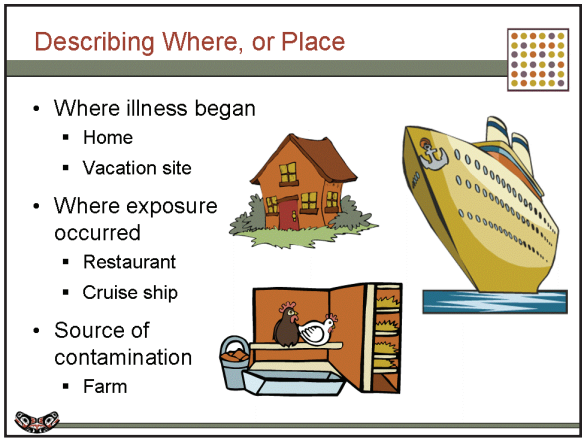
Finally, personal information can be cultural, which would include such categories as ethnicity, eating and dietary habits, and religious preferences.

Describing Where, or Place

Place information may include where people become sick, such as in the home or a vacation spot.

Place also includes where an exposure occurred, such as in a restaurant serving contaminated food or a cruise ship.

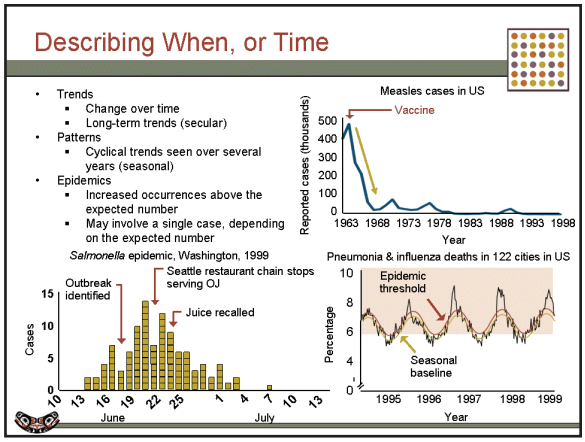
And finally, place also includes the source of contamination, such as a farm or a poultry-packing plant.



Describing When, or Time

Time information can be analyzed in three basic ways: trends, patterns, or epidemics.

A trend is a movement or change in something over time. Long-term trends of disease occurrence are called secular trends. We usually report them by year. This graph, for example, shows reported measles cases in the United States by year. Measles vaccine was first used in 1963. The graph shows the dramatic decrease in measles reports following the introduction of the vaccine.



Patterns are cyclical trends seen consistently over several years, often as seasonal trends. This graph, for example, shows pneumonia and influenza deaths reported by 122 cities in the United States.

In this graph we also see peaks above the epidemic threshold. These peaks, corresponding to increased influenza activity, show influenza epidemics. Epidemics are increased occurrences of disease or conditions above the expected number for a particular time and place.

An epidemic may involve many cases, or it may involve a single case, depending on the expected number. For example, a single naturally acquired polio case in the United States would be an epidemic, since polio has been eliminated from the western hemisphere for many years.

This graph illustrates a Salmonella epidemic in Washington State in 1999, caused by contaminated orange juice. The effects of a rapid investigation and intervention are clearly demonstrated in this graph.

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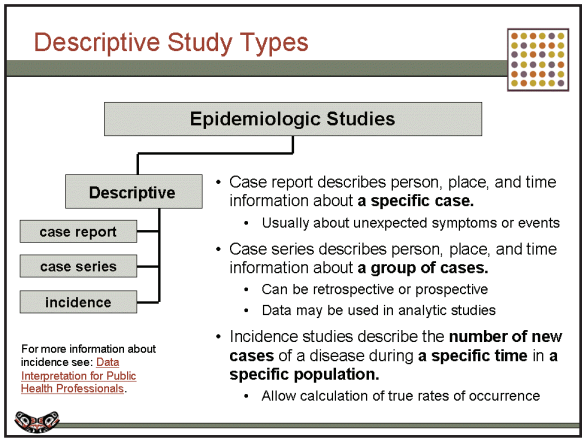
Now we will pause for the first of several interactive exercises about the material we have just covered. Please note that the exercises sometimes take several seconds to load.

Exercise 1

Descriptive Study Types



Descriptive studies, as the name implies, describe conditions or diseases. In particular, descriptive studies identify patterns in person, place, and time. Here are three of the most basic types: a case report, a case series, and an incidence study. These types of study involve no comparison group. They are merely descriptive.

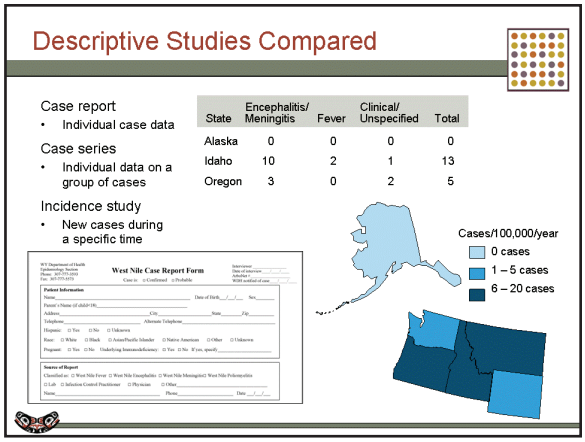
A case report is a detailed description of the person, place, and time information of a specific case of disease or condition. Case reports usually are about unexpected symptoms in a disease, an unexpected event while treating a patient, or unique therapeutic approaches.

A case series describes the person, place, and time information about a group of cases. It can be retrospective, looking back in time, or prospective, looking forward in time, and usually involves a small number of patients, such as those who were given similar treatment.

Case reports and series permit discovery of new diseases, unexpected effects, and provide data for generating hypotheses. Data from a case series may be used in analytic studies to investigate possible causal factors.

An incidence study describes the incidence, or number of new cases of a disease or condition, during a specific time in a specific population. One advantage of incidence studies is that they allow calculation of true rates of disease occurrence for a better estimation of risk.

Descriptive Studies Compared



Let's take a look at how these three descriptive study types relate to each other using West Nile virus as an example.

Remember, case reports describe individual data, perhaps on a form such as this one, or a report in a medical journal. West Nile virus in a transfusion or transplant recipient might be reported as a case report.

A case series for West Nile virus, on the other hand, might be presented in a table that lists and describes all West Nile cases in the Northwest.

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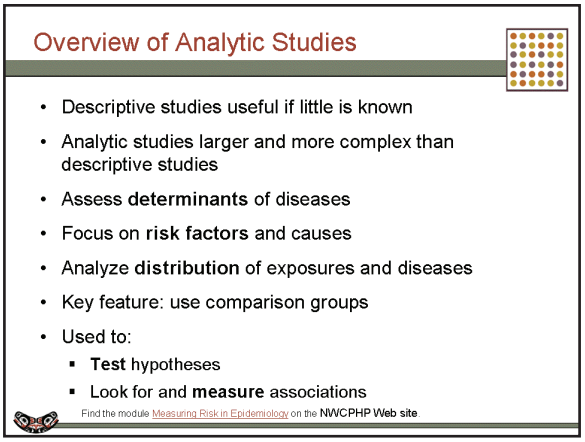
An incidence study could use a map to display all the new West Nile cases in the northwestern United States in 2006.

Now, let's look at analytic studies.

Overview of Analytic Studies



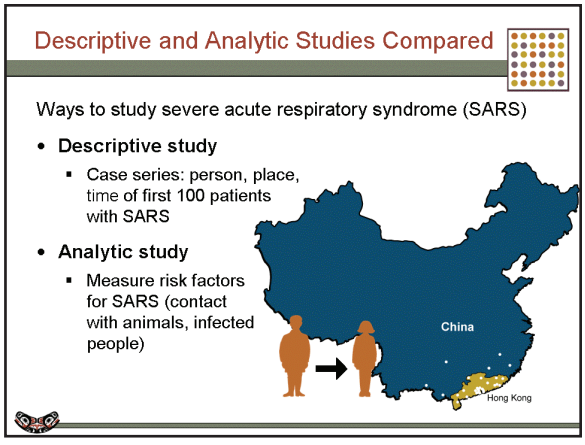
As you may recall, descriptive studies are useful if very little is known about a new disease or condition. They can be used to generate hypotheses on risk factors and causes of disease.

Analytic studies, on the other hand, are usually larger and more complex than descriptive studies. They're often used to assess determinants of diseases, focus on risk factors and causes, and analyze the distribution of exposures and diseases. A key feature of analytic studies is that they use comparison groups.

In contrast to descriptive studies, which generate hypotheses, analytic studies are used to test hypotheses. They are used to look for and measure associations.

(For more information on these kinds of measurements, see the module on Measuring Risk in Epidemiology.)

Descriptive and Analytic Studies Compared



To see how descriptive and analytic studies differ, let's look at ways to study severe acute respiratory syndrome, or SARS.

A descriptive study of SARS, for example, might be a case series describing person, place, and time information about the first 100 cases, or patients, with SARS.

In contrast, an analytic study might be used to measure risk factors for the reasons why people get SARS, such as contact with animals or infected people.

Types of Analytic Studies

Epidemiologists conduct two main types of analytic studies: experimental and observational.

Experimental studies use a randomized selection process. A process based on chance is used to assign study subjects to different exposure groups.

Experimental studies may be either clinical, such as studying a new drug to prevent influenza, or community-based, for example, studying the overall effectiveness of a new drug in preventing influenza in a community.

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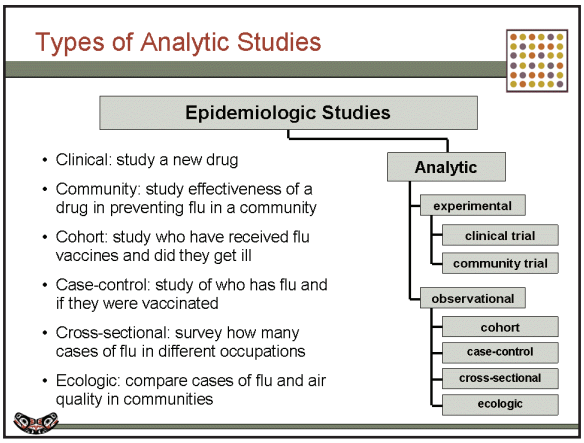


Unlike experimental studies, observational studies are non-randomized. In these studies the investigator does not assign exposures to the study subjects, but simply observes the patterns of exposure as they occur.

Observational studies fall into four categories: cohort, case control, cross-sectional, and ecologic.

Cohort studies observe groups of people who experience and who don't experience an exposure, such as flu vaccine, to compare how many in each group become ill, or in this case, get influenza.

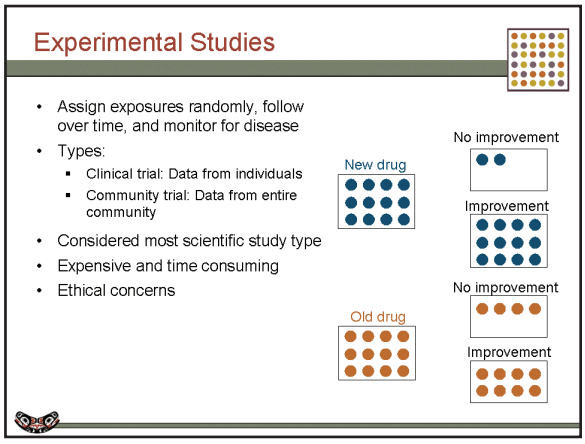
In contrast, in case-control studies the investigator compares a group of people who already are ill, such as with influenza, to a similar group who didn't get ill. The investigator records who had exposures of interest. In the case of influenza this includes who had been vaccinated.

Cross-sectional studies are a snapshot of a specific period in time, with the aim of finding the same kind of relationships as experimental studies, but often at less cost. A cross-sectional study of influenza might look at the number of cases at a specific time in different occupations involving indoor or outdoor work.

Ecologic studies look at group data, not individual data. In the case of influenza, an ecologic study might compare the rates of influenza cases in different Pacific Northwest counties with immunization levels in those counties.

We'll look at these different types of studies in more detail in the next few slides.

Experimental Studies



Experimental studies involve assigning subjects to exposures randomly and following them over time to determine if they develop or recover from disease. Experimental studies fall into two categories: clinical trials and community trials.

Clinical trials use data from individual people. The investigator randomly determines the type of exposure, for example, to a new drug to treat cancer. The study participants are then followed to determine the effect of treatment on them. People who received the new drug are compared with people who received an older drug or no drugs at all.

In community trials, on the other hand, the study group is the entire community, rather than individuals. Researchers might investigate whether a media campaign to reduce smoking was effective. The researchers would select a community to receive the media campaign. They would then compare the

smoking rates over time in this community with those in another community that did not to receive the intervention.

Many consider experimental studies to be the "gold standard" of epidemiology because they closely resemble experiments in scientific laboratories. However, experimental studies are frequently very expensive and take a long time to perform.

Also, ethical reasons may prevent performing experimental studies. For example, if a drug is suspected to have some value in preventing illness and death, it may be difficult to perform a clinical trial, which may involve randomly not giving the drug to some people.

Let's pause now while you answer some questions on what you have just learned.

Exercise 2

Observational Studies

Now let's look at the other main type of analytical study: observational studies.

In observational studies, the researcher does not determine who receives the exposure. The researcher simply observes or records the study participants and their outcomes.

Observational studies come in four main types: Cohort, case-control, cross-sectional, and ecologic.

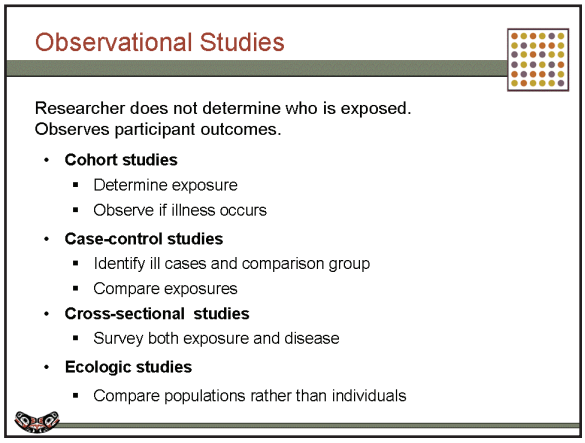
In cohort studies, researchers determine the study population's exposure and observe over time who gets ill.

In case-control studies researchers identify people who are ill and select or identify a comparison, or control group of people who aren't ill. Researchers then compare the prior exposures of the two groups.

In cross-sectional studies, researchers survey both the exposure and the condition or disease among individuals at a single moment in time.

In ecologic studies researchers survey the community level exposures and the condition or disease, but entire populations are compared rather than individuals.

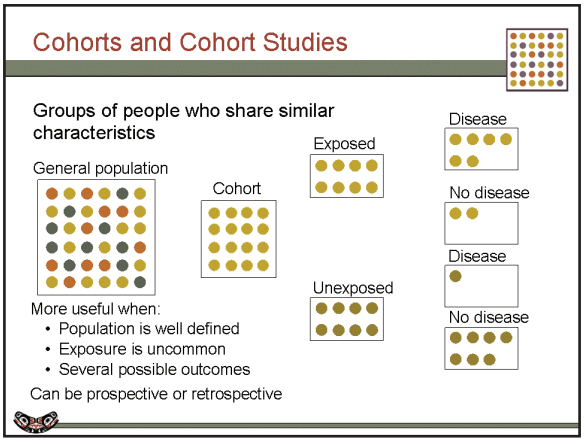
Let's take a more in-depth look at cross-sectional and ecologic studies.



Cohorts and Cohort Studies

Cohorts are groups of people who share similar characteristics. Cohort studies may involve people in the same school, church congregation, town, city, or occupation.

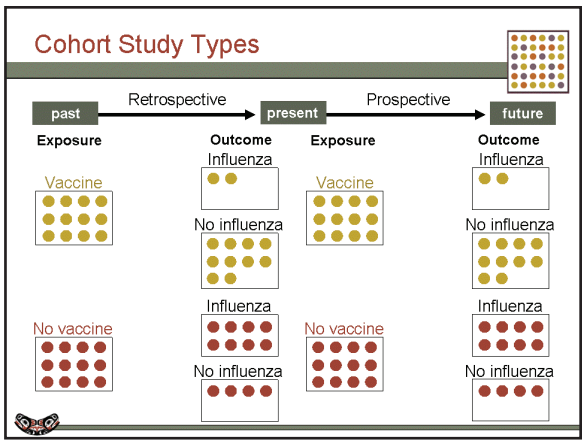
In cohort studies, people under investigation are divided into two groups, depending on whether they were exposed



to something. The exposed and unexposed groups are observed to determine and compare the proportion of each group that develops the disease.

Cohort studies may be more useful when the study population is well defined, if the exposure is uncommon, or if there are several possible outcomes from the exposure. Cohort studies can be prospective or retrospective.

Cohort Study Types



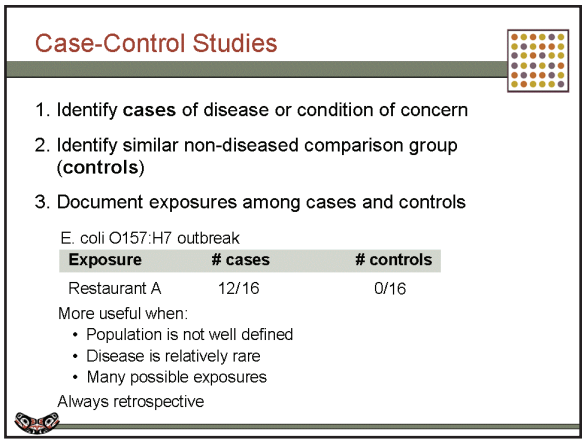
Prospective cohort studies are those in which the investigation is performed starting with exposures in the present and looking forward to outcomes in the future. Retrospective cohort studies, on the other hand, start with exposures in the past, and then look forward to outcomes in the more recent past or the present.

For example, when a new influenza vaccine is developed, scientists may study a cohort of individuals, some of whom receive the vaccine, and some who do not. This cohort, or group, of people can be followed prospectively over the next influenza season to see what proportion of those vaccinated or not vaccinated become ill with influenza.

On the other hand, if an influenza outbreak occurs in a nursing home, a retrospective cohort study might be done to determine if influenza vaccination was protective. Immunization records at the nursing home would be reviewed to see who had received influenza vaccinations in the past. To determine if the vaccine provided protection against influenza, the nursing home records would also be reviewed—to see what proportions of vaccinated and unvaccinated residents developed influenza.

Similar cohort studies might be done following food borne outbreaks, such as in people who become ill at a church supper or a wedding reception.

Case-Control Studies



The second type of observational study is the case-control study. This involves selecting people with a particular disease or condition. These people are called "cases."

Another group of people are selected who don't have the disease. These are called "controls." Ideally, the controls are similar to the cases in every way, except they do not have the disease or condition of concern. Information is collected from the cases and the controls to document and compare their exposures.

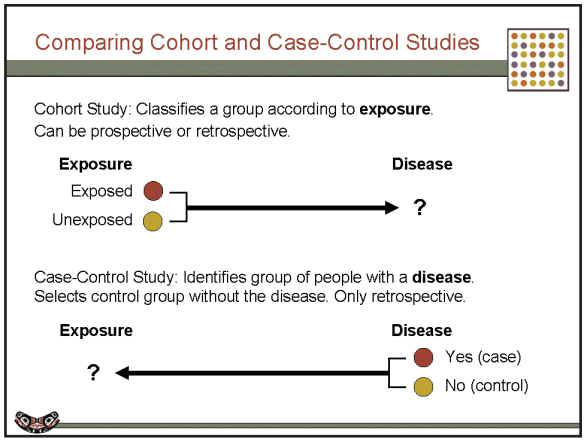
Let's look at an example of an *E. coli* O157:H7 outbreak.

In this example, 16 people became ill with gastroenteritis. Of these, 12 had eaten at Restaurant A prior to their illness.

A group of 16 well people were selected as a control group. These people had the same age and lived in the same neighborhood as the ill people. They differed only in that they were well. In comparing the possible exposures of the two groups, researchers found that none of the control group had eaten at restaurant A. This finding suggests that restaurant A was the outbreak source.

Case-control studies may be more useful when the study population is not well defined, if the disease is relatively rare, or if there are many possible exposures for a disease. Case-control studies are always retrospective.

Comparing Cohort and Case-Control Studies

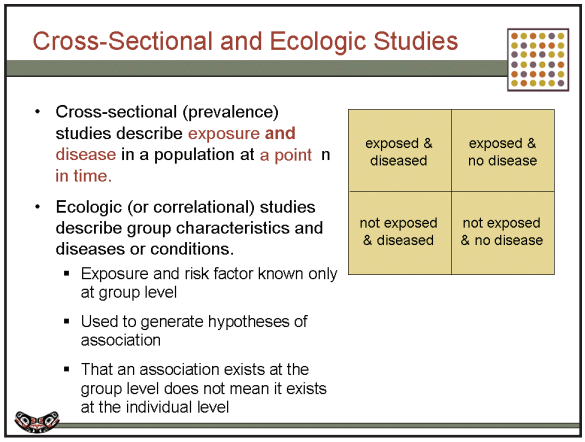


Let's review a bit about these two types of analytic studies.

Cohort studies start out by classifying a group of people according to an exposure. Then, the investigator determines whether the exposed and unexposed people develop a disease or not. Cohort studies can be either prospective, following a group over time, or retrospective, looking at what happened to the group in the past.

In case-control studies, the investigator identifies a group of people with a disease. Then the investigator selects a comparison or control group without the disease. The two groups are compared and analyzed for exposures. Because case-control studies begin with people who are sick or not sick, and interview people about previous exposures, they can only be retrospective.

Cross-Sectional and Ecologic Studies



In contrast to an incidence study, which looks at new cases over time, cross-sectional, or prevalence, studies describe a population at a specific point in time. You can think of them as a snapshot of the population. They're called cross-sectional because they look at both the exposure and the condition or disease. They're called prevalence studies because they look at the amount of a disease or condition at a moment in time. The investigator defines a population and identifies the presence or absence of exposure and disease for each individual. Each individual is categorized into one of four possible groups: exposed and having the disease, exposed and not having the disease, not exposed and having the disease, and not exposed and not having the disease. A cross-sectional study can be used

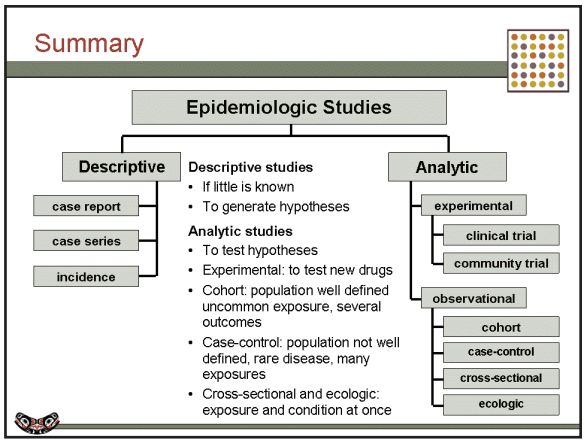
to assess the prevalence of acute or chronic conditions in a population, and it may suggest a possible risk factor for a disease.

Ecologic studies focus on groups, rather than on separate individuals. Exposure and risk factors are known only at the group level. An example would be the correlation between average air pollution concentrations in different cities in the Northwest and chronic lung disease in these same cities. Ecologic studies may be used to generate or test hypotheses of an association between exposure and disease. One potential problem with ecologic studies is that just because an association exists between exposure and disease at the group level, it does not mean that a similar association exists at the individual level.

Let's pause now while you answer some questions on what you have just learned.

Exercise 3

Summary



In summary, epidemiologic investigations involve two types of studies: descriptive and analytical.

Descriptive studies are more useful if little is known about a new disease or condition. They can also be used to generate hypotheses on risk factors and causes of disease. Descriptive study types include the case report, cases series, and incidence studies.

Analytic studies, on the other hand, should be performed if hypotheses exist for risk factors and diseases, and if these hypotheses need to be tested. Analytic studies fall into two categories: experimental and observational.

Experimental studies, which include clinical and community trials, may be used to study the effects of new drugs or vaccines. However, observational analytic studies of drugs are also performed, especially after drugs or vaccines are licensed.

Observational studies fall into four different types.

Cohort studies may be more useful when the study population is well defined, if the exposure is uncommon, or if there are several possible outcomes from the exposure. Cohort studies can be either prospective or retrospective.

Case-control studies may be more useful when the study population is not well defined, if the disease is relatively rare, or if there are many possible exposures for a disease. Case-control studies are always retrospective.

Cross-sectional, or prevalence, studies look at individual exposures and conditions at the same time. Ecologic studies look at exposures and conditions at the same time, but at the community level. Both of these study types look for the same kind of relationships that might be shown by an analytic study, but often at less cost.

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Resources

If you would like to learn more about the concepts in this module, you might want to explore some of the resources listed here.

Now, if you're ready, please go on to the final assessment.

Final Assessment