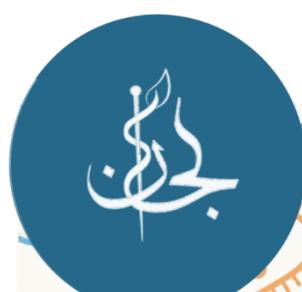




Subject: Scientific Research

Topic: Additional information lecture4

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CHAPTER 9 (Cross-Sectional Surveys)

9.1 Overview

-Cross-sectional surveys are **used to** :

- Describe communities
- Assess population needs
- Support program planning
- Monitor and evaluate programs
- Establish baseline data prior to the initiation of longitudinal studies

9.2 Representative Populations

-In some ways, cross-sectional studies use the simplest study design. The researcher just asks an adequate number of people-usually a few hundred-to complete a short questionnaire, and then those data are analyzed.

-Representativeness means that the researchers cannot simply ask friends, the fans attending a young football game, or individuals attending one chiropractic clinic to complete a survey and then assume that the results of the survey will be generalizable to all town residents.

9.3 KAP Surveys

- A KAP survey may be conducted with a representative sample of the patients of a hospital system or clinical practice, the clients of a community organization or business, the students or employees of a school district, the residents of a neighborhood or city, or the members of some other well-defined population.

KAP surveys can be particularly helpful for identifying gaps between what people know and how they act on that knowledge. **For example:**

- The adults in a KAP survey might demonstrate high knowledge about the benefits of exercise on cardiovascular health but at the same time indicate that they exercise rarely because a variety of perceived barriers prevent them from being as physically active as they know they ought to be for maximum fitness.

9.4 Repeated Cross-Sectional Surveys

-Some people may happen by chance to be selected for more than one round of surveying, but their answers to the different surveys are not linked.

-Repeated cross-sectional surveys can reveal trends in population-level metrics over time.but they don't allow for the examination of individual-level changes.

(A longitudinal cohort study is used to study individual participants over a lengthy period of time).

CHAPTER 10

10.1 Overview

-A case-control study is often the best study approach for identifying possible risk factors for a disease. This is specifically true when the disease is uncommon, **and a study of the general population would be unlikely to yield more than a few cases.**

10.2 Finding Cases and Controls

-Hospitals, speciality clinics, physicians' offices, public health agencies, disease registries, and disease support groups may be able to assist researchers in identifying individuals who are likely to meet the study's case definition.

Regardless of the source, in most situations these organizations will not release any information about individuals until a research project has received approval from an appropriate ethics oversight committee.

-Clinical manuals and publications stemming from previous studies of the disease can be helpful references for drafting and refining the inclusion and exclusion criteria. The case definition should include person, place and time (PPT) characteristics.

-Individuals who do not meet the case definition or the control definition must be excluded from the study. Excluded individuals may not meet one of the person, place, time criteria for inclusion, or they may have an intermediate or indeterminate disease status that prevents them from meeting either the case or the control definition.

10.3 Matching

-For both frequency matching and matched-pairs matching, it is important not to overmatch. The variables used as matching criteria cannot be considered as exposures during analysis. For example, suppose cases and controls are frequency matched based on the date of hospital admission, sex, and age. The case and control populations will therefore, by design, have the same proportion of admissions in April, the same percentages of males and females, and about the same mean age. As a result of this forced similarity, the study will not be able to examine whether cases are more or less likely than controls to require hospitalization in a certain month, to be males, or to be octogenarians. Additionally, when there are more matching characteristics, it can be difficult to find controls who meet all the matching criteria. The study population may end up being quite different from the general population because of the strict eligibility requirements, and this may limit the external validity of the study. Overmatching may also result in a statistical bias that obscures the relationship between an exposure and the disease.

10.4 Special Considerations

- Each type of study design has particular types of bias that are more likely to be problematic.
- This type of risk is particularly important in case-control studies.
- Example:
 - Adult cases in a study of night blindness may report that they rarely ate carrots as children. They may say this not because they never ate carrots but because they assume that they would have good vision as adults if they had eaten lots of vegetables high in vitamin A when they were younger. Alternatively, cases may overestimate childhood carrot intake. They may wonder why they developed high blindness when they have such fond memories of happily munching on carrot sticks every day at lunch in grade school. The reality may be that they ate carrots only once a month. Controls, on the other hand, are unlikely to have spent much time thinking about risk factors for poor eyesight. They may recall eating carrots sometimes rather than rarely or often.

-Because of recall bias, a study of night blindness might find a significant difference in the reported childhood consumption of carrots by cases and controls even if in reality there was no difference in the average diet of the two groups. Alternatively, the survey may fail to capture a true difference in dietary history. Although there is no way to prove that recall bias is occurring because of systematically different memories among cases and controls, the results of case-control studies must be interpreted cautiously in light of the possibility that differential recall may have influenced the findings.

10.5 Analysis: Odds Ratios (ORs)

- If 50% of the participants in a study report a history of exposure and 50% report no past exposure, then the odds of exposure are 50%/50% or 1.
- If 25% report having the exposure and 75% do not, then the odds are 25%/75% or 0.33.
- If 2% report being exposed in the past and 98% report not being exposed, then the odds are 2%/98%, or 0.02.
- In **contingency table**, the total number of cases in the study should be $a+c$, the total number of controls should be $b+d$, and the total number of participants should be $a+b+c+d$.
- For a case-control study, it is incorrect to say that “the exposed had a higher (or lower) rate of disease than the unexposed” because the rates of disease in exposed and unexposed participants are not known.

-Usually about 50% of participants in a case-control study are cases even if cases make up less than 1% of the community from which the study population was drawn. As a result, the prevalence of disease among exposed persons in the study population could be 70% even when the prevalence of disease among exposed persons in the community from which participants were drawn is less than 1%. Because the study population is usually not representative of the community as a whole, case-control studies are unable to estimate rates of disease among the exposed and unexposed.

-A ratio of the number of times the case was exposed and the control was not (b) to the number of times the control was exposed and the case was not (c) provides an estimate for a special type of **matched-pairs odds ratio**

- When $b/c > 1$ and the 95% confidence interval does not overlap 1, cases were more likely than controls to have been exposed. This implies that the exposure is risky.
- When $b/c < 1$ and the 95% confidence interval does not overlap 1, cases were less likely than controls to have had the exposure. This implies that the exposure is protective.
- When the 95% confidence interval for b/c includes 1, there is no statistically significant association between the disease and the exposure.

CHAPTER 11

10.1 overview

-Because information is collected from individuals at multiple points in time, researchers can know with certainty which exposures were present in individual participants before the onset of new disease.

11.2 Types of Cohort Studies

-Recruiting based on exposure status makes retrospective and prospective cohort Studies the optimal study approaches for uncommon exposures

-Participants in Longitudinal cohort studies are recruited based on membership in a well-defined source population. Longitudinal cohorts may follow all the residents of one town, a representative sample of members of one professional organization, or a cohort of students recruited from the same university.

-For retrospective and prospective cohort Studies, the members of the two comparison groups should be similar except for their exposure status. For example:

- A retrospective cohort study might compare industrial workers exposed to a certain chemical to workers in a plant that does not use the chemical. It would not be valid to compare factory workers to office managers.
- A prospective cohort study might compare health outcomes in children with high blood lead levels and low blood lead levels who attend the same

elementary school. It would not be as helpful to examine the impact of blood lead levels if the exposed students were from one primary school and the unexposed were from another school. Any differences in health observed might be due to differences in socioeconomic status rather than lead exposure.

-Retrospective studies establish baseline information from birth records, school records, medical files, occupational records, or other sources that may be decades old.

Prospective and longitudinal cohort studies have a different time orientation than retrospective studies. Prospective and longitudinal studies collect baseline data about exposures and outcomes in the present and follow the cohort to some point in the future.

Because all cohort studies examine incident (new) disease, retrospective and prospective studies must be able to demonstrate that the outcome of interest was not present in any members of the cohort at baseline. A retrospective cohort study that looks at the causes of death after the baseline assessment will have no trouble proving that the outcome—death—was not present at the time of the initial assessment. It is more challenging to conduct a retrospective study when the outcome of interest is a condition that may have been present at baseline but not documented.

Individual participants in longitudinal studies are usually assessed at baseline for several exposures and diseases. Then they are followed forward in time to determine the incidence rate for one or more outcomes of interest. A participant with a history of breast cancer at the baseline exam would need to be excluded from any analyses of breast cancer incidence. However, that person could be included in studies of heart disease incidence if she did not have heart disease at the baseline exam.

Longitudinal studies may use a **fixed population** in which all participants start the study at the same time and no one is allowed to join later. Alternatively, they may use a **dynamic population** (also called an **open population**) with rolling admission and replacement of dropouts (Figure 11-4). For dynamic populations, the time to follow up is usually based on individual participants' dates of enrollment rather than on a fixed calendar date.

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Several variants of longitudinal studies measure the same individuals repeatedly over time, as longitudinal cohort studies do. These studies may be called **time series studies** or **panel studies**. Surveillance systems that are designed to monitor whole populations over an extended period of time, often using continuous data collection rather than discrete time points, may also use a cohort approach. However, studies that measure individuals randomly sampled from the same populations at different points in time (that is, repeated cross-sectional surveys) are not using a cohort study approach, because they do not necessarily capture the same individuals in each round of questioning.

11.3 Special Considerations

11.3 Special Considerations

For a prospective cohort study that will recruit participants based on exposure status, the first step is to identify two accessible source populations: one for individuals with the exposure of interest and one for those without the exposure. For a longitudinal cohort study, the first step is to select a source population. For a retrospective study, the first step is to identify a source of existing records that can provide baseline data of adequate quality. In some situations, existing records may provide all required follow-up data, and no contact with the individuals whose files are being examined is required. (For some historic studies, this is the only option available because all of the "participants" are already deceased.) For retrospective studies that require contact with individuals, a method for contacting the people identified in historic records must be developed, tested, and shown to result in a reasonable participation rate.

Alternatively, if the goal is to conduct secondary analysis of existing data, the first step is to identify an existing source of data. The secondary analysis of existing data is the most cost-effective way to examine study questions when a completed or ongoing cohort study has assessed the exposures and outcomes of interest and electronic data files are available to outside researchers for analysis.

For prospective and longitudinal cohort studies, decisions must be made about how often follow-up data collection will take place and how long the study (or at least the first wave of the study) will continue. Because **loss to follow-up** of participants before the end of the study period is a major concern of studies that follow participants forward in time, researchers must develop strategies that minimize the burden of participation while maximizing interest in continuing to participate. Some studies may increase retention rates by offering participants free medical tests or other incentives. Sufficient motivation may also be provided by reminders of the significant impact of the disease on affected persons and their family members or by notifications of the important discoveries being made as a result of their continued participation.

Once source populations have been identified, plans for data collection can be made. Survey instruments and other assessments for cohort studies must establish exposure and disease status for all participants at baseline and at follow-up. All participants must complete the same assessments in order to prevent the information bias that might result when exposed participants are more thoroughly examined for disease