Methodology Series Module 7: Ecologic Studies and Natural Experiments

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Abstract

In this module, we have discussed study designs that have not been covered in the previous modules – ecologic studies and natural experiments. In an ecologic study, the unit of analysis is a group or aggregate rather than the individual. It may be the characteristics of districts, states, or countries. For example, per capita income across countries, income quintiles across districts, and proportion of college graduates in states. If the data already exist (such as global measures and prevalence of diseases, data sets such as the National Family Health Survey, census data), then ecologic studies are cheap and data are easy to collect. However, one needs to be aware of the “ecologic fallacy.” The researcher should not interpret ecologic level results at the individual level. In “natural experiments,” the researcher does not assign the exposure (as is the case in interventional studies) to the groups in the study. The exposure is assigned by a natural process. This may be due to existing policies or services (example, one city has laws against specific vehicles and the other city does not); changes in services or policies; or introduction of new laws (such helmet for bikers and seat-belts for cars). We would like to encourage researchers to explore the possibility of using these study designs to conduct studies.

Key Words: Ecologic studies, natural experiments, study design

Introduction

In the previous modules, we have discussed study designs that are generally used in clinical research. These can be broadly classified into two major categories: Observational and interventional studies. We have discussed cohort studies, cross-sectional studies, and case–control studies in the observational category. Furthermore, we also discussed clinical trials (randomized and nonrandomized) in the experimental category. In this module, we will discuss study designs that have not been covered in the previous modules – ecologic studies and natural experiments.

Ecologic Studies

In an ecologic study, the unit of analysis is a group or aggregate rather than the individual. It may be the characteristics of districts, states, or countries. For example, per capita income across countries, income quintiles across districts, proportion of college graduates in states. Actually, as clinical researchers, we often conduct ecologic studies. However, sometimes, we fail to acknowledge them as being “ecologic” in nature. We have provided some examples of these studies.

Examples of Ecologic Studies

Prentice et al. (1988)
The authors reported that there is strong correlation between dietary intake (of various caloric sources) and breast cancer incidence in 21 countries. They found that there was strong correlation in breast cancer incidence with national estimates of per capita intake of dietary fat in these countries. However, they did not find any such relation between other forms of caloric intake such as proteins and carbohydrates.

Pascal et al. (2013)
In this study, the authors assessed hospitalizations due to cardiovascular diseases, respiratory diseases, and cancers in an industrial region in the South of France. The exposure was the annual mean concentration of sulfur dioxide ($SO_2$) in 29 administrative districts of this region. They found that there was an excess risk of hospitalization for myocardial infarction in men and women who lived in districts with high or medium $SO_2$ levels compared with those living in reference levels. However, they did not find any excess risk for respiratory...
diseases. They concluded that industrial air pollution has an effect on the cardiovascular system; thus, there is a need to improve the air quality in this region.

**Parkhurst (2010)**

In this study, the author assessed the prevalence of human immunodeficiency virus (HIV) and socioeconomic parameters in 12 African countries. The author found that the HIV prevalence increased with wealth; this trend was observed particularly in lower-income countries. In nearly, all countries with gross domestic product (GDP) <US$ 2000, there was a significant trend in HIV prevalence across wealth quintiles. However, there was no such consistent relationship in countries with a GDP >US$ 2000. The author concluded that since both wealth and poverty can lead to change in behaviors, the interventions should be aimed at context-specific risks.

**What are the different types of group variables?**

In the first example, the group variable was per capita intake of dietary fat. This measure may have been calculated from some nutritional surveys (with the individuals reporting dietary intake). This is an example of “aggregate measure.” Some other examples could be median number of cigarettes per day, proportion of immigrants in districts, or proportion of minorities in cities.

In the second study, the group variable was mean concentration of SO\(_2\). This is an example of “environment measure.” Some other examples could be hardness of water, levels of other pollutants, or hours of sunlight in the country.

A third type of group variable is the “Global measure.” Some examples of this measure are human development index, gender equality measure, and GDP (gross and per capita). Some other global measure could be existing laws in the country (death penalty exists), policies present (example, free education for primary school, free antiretroviral treatment to HIV-infected individuals), etc.

**Why ecologic studies?**

- If the data already exist (such as global measures and prevalence of diseases, data sets such as National Family Health Survey, census data), these studies are cheap, and data are easy to collect
- These studies may be useful to generate hypotheses. For example, in the first example, the authors found a correlation between per capita intake of dietary fat and breast cancer incidence. This may be used to conduct clinical studies or molecular studies to evaluate the association between fat and breast cancer
- Sometimes, this is the only option available. For example, if we are interested to study the relation between GDP and prevalence of psoriasis (hypothetical example) across countries, we have use ecologic level data and it will be ecologic analysis.

**What is the problem with ecologic studies?**

- The analyses of ecologic studies may require expertise (such as handling Geographic Information System, confounding variables). Thus, it is important to consult a methodologist or a statistician before initiating these studies
- Ecologic fallacy: This is an important concern in ecologic studies. Let us understand this fallacy. We have conducted a study to assess the relation between psoriasis and socioeconomic status (SES). We find that districts with a higher proportion of the upper SES individuals have a high prevalence of psoriasis. One should not conclude immediately that higher SES is associated with psoriasis. This will be an example of “ecologic fallacy.” We have interpreted ecologic level analysis at the individual level.

**Natural Experiments**

Although they are called natural experiments, the researcher does not assign the exposure (as is the case in interventional studies) to the groups in the study. The exposure is assigned by a natural process. This may be due to existing policies or services (example, one city has laws against specific vehicles and the other city does not), changes in services or policies, or introduction of new laws (such helmet for bikers and seat-belts for cars). The difference in outcomes in these groups (two or more with different types or levels of exposure) is assessed. The assessment can be (1) simultaneously between two or more groups with different policies/services/any other form of exposure or (2) pre-post assessment after the change in policy/service/other exposure.

**Examples of Natural Experiment Studies**

**Cole et al. (1987)**

The authors evaluated eye injuries in the United Kingdom before and after the introduction of seat belt laws. They evaluated 381 injuries during two time periods (time period one: August 1, 1981–January 31, 1983 – 18 months; time period two: February 1, 1983–July 31, 1984). They found that the proportion of road traffic accidents as a cause of eye injuries reduced from 17.1% in the preseat belt legislation period to 6% in the postseat belt legislation period. Thus, they concluded that “seat belt law” was effective in reducing serious ocular morbidity.

**Cheng et al. (1997)**

The authors evaluated the changes in health-care utilization in Taiwan after the introduction of Universal Health Insurance. They evaluated physician visits, hospital admissions, and emergency department visits before and after the implementation of the policy in a
cohort of individuals. They found that individuals who were insured after the implementation of the program were significantly more likely to make outpatient visits, emergency department visits, and get admitted in the hospitals, and compared with the time period before the implementation of the insurance program. However, there were no significant changes in the hospital admissions and emergency department visits in those that were insured before the National Insurance Programmes. Thus, they concluded that introduction of the program reduced barriers for health-care access.

Evans et al. (2016)
The authors evaluated the association between socioeconomic factors and time to revascularization in patients with acute myocardial infarction after redesigning the services. They analyzed data from two cohorts – 24 months before and after the date of change of services (the cutoff was kept very close to the date of change). They found that in the preintervention period, the adjusted risk for revascularization was significantly lower in the most deprived quintile compared with the least deprived quintile. However, the difference in the rates was not statistically significant between the two quintiles in the postintervention period. Thus, they concluded that access to revascularization was not different in different socioeconomic categories after redesigning the services.

**What are the advantages of natural experiments?**
- They can be used in situations when it is not ethical to assign exposures. For example, it will unethical to design an interventional study to assess the role of helmets in prevention of head injuries
- These studies can be used to evaluate policies and laws
- The results from these studies are useful for advocating changes in policies.

**Learning points in natural experiments**
- The principles of study design should be adhered to. For example, if the researcher wants to compare two groups at the same time (in two different areas/cities), then it is a cross-sectional comparison. However, the researcher may choose to use a cohort design to compare the two groups
- One may also use ecologic data for natural experiments. For example, the researcher can assess the number of outcomes every year before the introduction of policy and compare with the number of outcomes every year after the introduction of policy
- Although these studies may give some evidence of the role of policy change, it may not be enough for causal inference.

**Additional Points**
In addition to these study designs, another important quantitative study is the diagnostic study. The diagnostic study design can be used to assess the diagnostic properties of a new test or diagnostic algorithms. These properties include sensitivity, specificity, positive predictive value, and negative predictive value. A detailed explanation of these terms and methods for these parameters will be discussed in the biostatistics module.

**Summary**
We would like to encourage researchers to explore the possibility of using these study designs to conduct studies. In some of these studies, data collection and management may be relatively easy. For example, if the researcher proposes to conduct an ecologic study based on published data, the data can be collected in an office (using a computer), addressing ethical issues may be easy, and the study can be completed at a lower cost.

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**Conflicts of interest**
There are no conflicts of interest.

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