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Overview of Study Designs in Health

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CHAPTER OUTLINE

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- Study Designs
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 - Cohort Study Design
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Introduction

A fundamental purpose of research is to obtain knowledge. This may be to obtain descriptive information or identify new associations, in particular causal associations, to validate suspected associations, and to predict future events or new relationships. In the health sciences, such knowledge helps us to control, manipulate, prevent,

detect and treat medical conditions. All research requires a study design, that is, a plan or strategy. The study design identifies who the study participants will be, how they will be sampled and how many will be sampled, which in turn determines what and how measurements are taken, and the most appropriate analysis for answering the study

question. When the details of a study design are incorporated into a formal document, it is often referred to as the *study protocol*. In this chapter we introduce (1) qualitative research methods, such as focus groups, and (2) quantitative methods, which include **experimental study** designs, such as randomized clinical trials, and observational study designs, including the cohort, cross-sectional, case-control, and ecological study designs.

It is through scientific study that medical advances have occurred at a rapid rate in the last 100 years and have made possible great leaps in the general health of the public. Consider that global life expectancy at birth in 1800 was just 28.5 years (Ferguson, 2011) and in Canada in 2009 it was 80.7 years (World Development Indicators, 2011). This remarkable increase in life expectancy can be attributed in large part to scientific study and advances in health studies. Almost all of the research study designs described in this chapter have come into existence in the last two hundred years, and most have come into common research practice in the last 70 years.

Many factors go into making an excellent health researcher. Curiosity, ethics, objectivity, and a deep understanding of subject knowledge come to mind. However, one of the most important is the understanding of scientific methodology, including the many aspects of study design.

Background Concepts

Much of health research concerns developing an understanding between some “exposure” and “disease” or other health-related “outcome.” Exposure can have a wide range of meanings. For example, exposure could be an environmental toxin such as lead, a health-related behaviour such as smoking, a personality type, a genetic mutation, a dietary

pattern, a prevention program such as a smoking cessation program, a cancer screening program, or a treatment for a disease.

Similarly, disease or outcome in health studies can represent a multitude of different things, for example, getting a specific disease, having a disease recurrence after successful treatment, time to relapse, or death due to disease. We may start with disease-free individuals and investigate which exposures increase their likelihood of getting the disease, or start with diseased people and study what factors influence their recovery. What may be the endpoint (outcome) in one study may be a starting point (exposure) in another study. For example, one study may investigate whether smoking decreases quality of life, and another study may investigate whether quality of life impacts the survival of cancer patients.

Study designs are determined by how one chooses or samples and measures the exposures and disease or outcome states. Studies that have hypothesis and comparison groups which allow statistical testing to find out if a difference exists between groups or if an association exists between the exposure and disease or outcome are *quantitative* studies. Studies that are descriptive in which hypotheses are not tested are *qualitative* studies. Qualitative studies are used to discover new knowledge and answer questions which cannot be answered using quantitative study methods. Qualitative study methods are described in the second half of this chapter.

To understand how to relate exposure and disease/outcome in different study designs, it is important to develop some knowledge regarding measures of health. Some common health measures include incidence, prevalence, and mortality rates. To evaluate causal relationships we usually attempt to evaluate the risk or probability of disease/outcome in the exposed group and see if

it is different from the risk or probability in the unexposed group. In health studies, the optimum measure of risk or probability is obtained from incidence rates. *Incidence rate* is the number of new cases of disease in a defined population at risk per unit time. In the absence of such data, alternative health data are sometimes used. For example, if most of the people with the disease die of that specific disease after a relatively short period, then *prevalence proportion* or *mortality rates* may be used, *prevalence proportion* being the number of existing cases in a defined population at risk during one point in time (*point prevalence*) or during a period of time (*period prevalence*). In diseases that have a long duration, such as multiple sclerosis or arthritis, the prevalence proportion may be quite different from the incidence rates. *Mortality rate* is the number of deaths per population per unit of time. Mortality rates would not be a good surrogate for incidence data, if accurate cause-specific mortality data were not available or the disease was usually non-fatal. Different study designs provide different measures of health events, and thus provide different strengths of evidence for causal relationships. To control health-related events, we usually try to understand causal relationships, not mere correlations that might not be causal.

In some study settings, the researcher has control over which study participants receive or do not receive the “exposure” under study. These are *experimental study* designs and usually involve exposures thought to be safe. It would be unethical to administer a harmful exposure in a research study setting, for example, cigarette smoke to a non-smoker. Researchers investigating the effects of potentially harmful exposures must rely on observational studies. These are studies in which some of the study participants received the exposure under study due to self-selection or accident.

PRACTICAL TIP

Sometimes students and even some scientists think that to study the relationship between exposure and disease, the “unexposed” group must have zero exposure. Indeed, one scientist came onto the radio denouncing the INTERPHONE study investigating cell phone use and brain cancer (Interphone Group, 2010), because she said that no one in the control group was free of exposure. This thinking is not correct. It is valid to study the rate of disease over a range or gradient of exposures. For example, it is well-known that blood pressure or body mass index (BMI, weight in kilograms/height in metres squared) are determinants of health outcomes; yet no living human has a blood pressure or BMI of zero.

Study Designs

For a new study, the optimal study design is driven by the study question, the available population for study, resources, and the current state of research. Different study designs vary in cost, time required to conduct them, complexity, vulnerability to bias, and the evidence they contribute to establishing causal relationships. Although some study designs are more optimal than others, it is often not possible, feasible or even necessary to start off testing the study question/hypothesis with the most elaborate study design. Most study designs can contribute valuable information, if well-conducted and interpreted in light of their weaknesses. Scientific knowledge and causal relationships in health are rarely, if ever, advanced by one study in isolation. The scientific process is iterative and depends on replication of findings in different populations by different researchers in different settings using different approaches. Some examples of study questions which are suitably answered by the different study designs are presented in Table 6.1.

TABLE 6.1 Example Study Questions That can Appropriately be Answered by the Specific Study Design

Study Design	Study Question
Randomized controlled trial	Does vitamin E and beta carotene supplementation protect smokers against developing lung cancer?
Cohort	Does smoking cause lung cancer?
Case-control	Is childhood leukaemia associated with parental occupation during conception?
Cross-sectional/prevalence	What is the prevalence of cigarette smoking in Canadian high school students?
Ecological	Does the national intake of fat calories correlate with national breast cancer mortality rates in various countries around the world?

Randomized Controlled Trial (RCT)

The **randomized controlled trial** (RCT) is a study design often used to evaluate the therapeutic effects of treatments in diseased individuals, or the beneficial effects of a protective agent or screening procedure. This study design is *experimental* in that the researcher controls who receives the treatment or intervention, that is the “exposure”, and who gets the alternative. Those receiving the alternative are called the *controls*, and the alternative may consist of a placebo, no intervention, or the currently accepted treatment. A *placebo* is a simulated agent or sham procedure that has no specific intended therapeutic effect.

but is intended to make the recipient thinking that they might be receive treatment.

The RCT is a **prospective** study in that the study participants receive the intervention or become controls, and are then followed over time to determine the rates of the study outcome in both groups. A key element of the RCT is that study participants are randomly assigned into the intervention or control arms of the study. The components and flow of the RCT are illustrated in Figure 6.1. It is important to appreciate that the researcher does not get to pick and choose who gets the intervention and who does not. Such a practice could lead to selection bias, for example, this could occur when a researcher, who believes in the new treatment under study, assigns

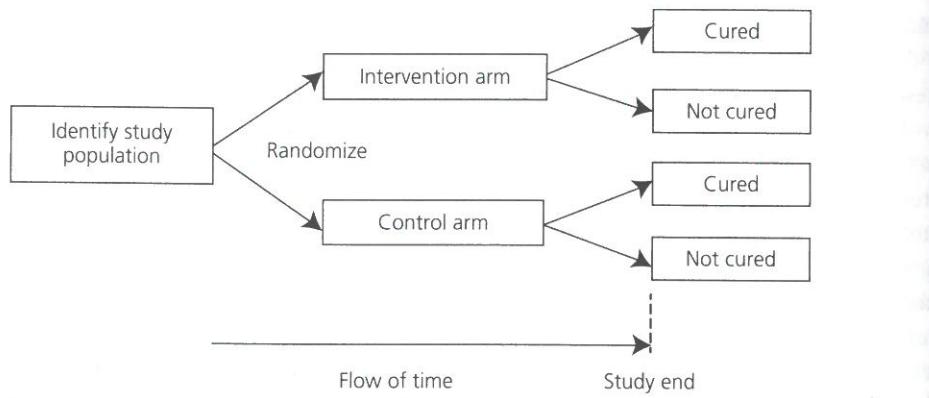


FIGURE 6.1 Components and flow of the randomized controlled trial

healthier patients to the treatment group and the sicker ones to the **control group**. In the properly randomized trial, the researcher has no control over who ends up in the intervention and control arms. In addition, when it is feasible, the evaluation of study outcome is done blinded to which study arm an individual belongs to. If randomization was successful and the study is sufficiently large, other factors which influence the study outcome, for example age and severity of disease on survival, are usually distributed roughly equally in both study arms and balance out in analysis. This is an example of *confounding* being controlled for in RCTs.

The “randomized controlled trial” (RCT) is sometimes referred to as a “randomized clinical trial”. The former name is preferred, because the RCT is often used to evaluate prevention pro-

grams to reduce subsequent disease in a healthy population. In this situation, the word "clinical" is not appropriate, because "clinical" usually refers to diagnosis and treatment of patients in medical practice.

Sometimes, some interventions are evaluated best at the community level. For example, the beneficial effect of fluoridation of drinking water on reducing dental disease (caries) was first convincingly demonstrated in randomized community trials. The impact of public health policies or teaching practices would be best evaluated when randomized to districts or classrooms, respectively. When the unit of randomization is a group of individuals sharing one or more defining characteristics, then the study is referred to as a *randomized community trial*.

6.1 Health Research in Action

A Cautionary Story

The randomized controlled trial is thought to be the ideal study because it reflects a true experiment, and true randomization can minimize confounding and selection bias. So how can one explain the following story?

Prostate specific-antigen testing (PSA) was adopted for screening men for prostate cancer in general medical practice in many western countries in the 1980s. This adoption took place without strong scientific evidence to support it. Recently, two large RCTs, the *European Randomized Study of Screening for Prostate Cancer* in Europe (Schroder et al., 2009) and the *Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial* (PLCO) in the United States (Andriole et al., 2009), evaluated whether annual screening with PSA reduced prostate mortality. The European study found that PSA screening significantly reduced prostate cancer

mortality, and the US PLCO found no reduction in mortality. These findings, with opposite conclusions, come from what is considered to be the highest type of study design. This is perplexing! What happened? The studies looked at the same question using similar study designs and came to opposite conclusions. It turns out that the populations under study were different. In Europe, PSA testing was not commonly carried out in routine practice. In the US, PSA testing is often routinely carried out in older men in annual checkups. In the PLCO control group a high proportion of men were getting PSA testing outside the trial. This lead the two groups to be similar with regard to the "exposure" under study and no difference in mortality could be found. Such studies are complex and interpretation is not always straightforward. Considerable thought needs to be given to all aspects of the study, from its design, conduct, analysis, and interpretation.

Cohort Study Design

In the *cohort study*, individuals without the disease of interest are sampled and they are classified according to whether they have the exposure of interest or not. They are then followed over time to see who develops disease and who does not (Figure 6.2). Cohort studies are sometimes referred to as prospective studies. The health measurements of primary interest are incidence rates, and these rates are compared between the exposed and unexposed groups. Sampling of study participants generally can take two approaches. *Population-based sampling* attempts to select participants so that they reflect the general population of interest or some component of it. This is useful for relatively common exposures. When an exposure is uncommon or rare, then sampling is often *exposure-based* to ensure adequate numbers of exposed individuals in the study. For example, to study the impact of inhaling high temperature combustion particles on respiratory cancers in firemen, one would not sample the general population, but rather would sample firemen and a comparison group similar to firemen except for the exposure under study, for example, policemen. Sometimes studies are

carried out using data that have been collected in the past. But even in these *historical cohort* studies, exposure measurements were made in disease-free individuals who were subsequently followed to determine if disease occurred at some later point in time.

Because cohort studies have exposures measured before disease has occurred, inferring causal associations between exposure and disease is more convincing than with other study designs in which the order of events is unclear. Cohort studies measure disease or outcome rates over time, and thus make possible estimation of rates of disease in the exposed and unexposed groups. This makes possible the direct calculation of risks related to exposures under study. In prospective cohort studies, more accurate and detailed measurements of exposures are possible than in retrospective studies.

However, the distribution of other factors that affect the outcome may differ between exposed and unexposed groups and may distort or *confound* the association under study. In cohort studies such potential confounders must be dealt with to obtain valid results. Some diseases have long incubation periods between exposure and disease, and a cohort study of

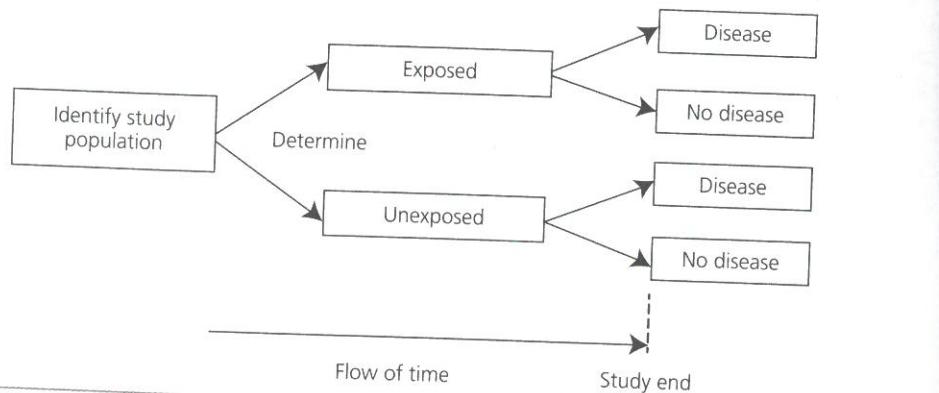


FIGURE 6.2 Components and flow of the cohort study

their relationship would require a long time. For example, it is estimated that the time between asbestos exposure and mesothelioma, a cancer of the lining of the thoracic cavity, is between 30 to 40 years. A cohort study of the association between asbestos exposure and mesothelioma may well span more than one researcher's career. Some diseases are uncommon or rare. A cohort study of such diseases would have to be very large to draw meaningful conclusions. Follow-up of cohort members must be done systematically and rigorously. Loss of follow-up can lead to biased study findings and must be minimized. However, this can be time-consuming and challenging because participants often move or lose interest in the study over time and drop out. For example, consider a study of the association between cigarette smoking and lung cancer survivorship. What will be the impact on the study conclusions if smoking in truth does lead to shorter survival, but smokers are more likely to quit the study before their follow-up is complete?

Case-control Study

In the **case-control study** cases from a specified population are sampled. Controls (non-

cases) who are free of the disease under study are also sampled. Ideally, the controls should come from the same referent population that gave rise to the cases. In other words, if controls had been diagnosed with the disease of interest, they should have a similar likelihood of being enrolled in the study as the cases in the study. Sometimes the controls are selected to be similar to cases with regard to some characteristics such as age, sex, race/ethnicity, socioeconomic status, or smoking status. This is called *matching*. Following enrollment in the study, the past exposures of cases and controls are measured (Figure 6.3). In the case-control study there is no carefully measured follow-up time, so it is not possible to directly calculate incidence rates and relative rates between exposed and unexposed groups. Instead in the case-control study, the measure of association is the exposure odds ratio, that is, the probability of exposure divided by the probability of no exposure in the cases versus in the controls.

Case-control studies are good for studying rare or uncommon diseases. Also, multiple exposures can be evaluated in one study. Generally, case-control studies are cheaper and faster to complete than their cohort counterparts.

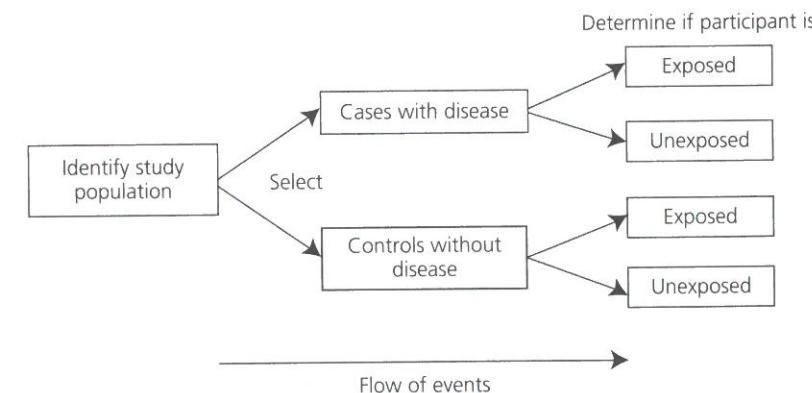


FIGURE 6.3 Components and sequence of events in a case-control study design

PRACTICAL TIP

When designing your own study, be careful to sample participants appropriately, based on the study design selected. If conducting a cohort or case-control study, be sure to sample your study participants consistently, either based on exposure for a cohort study or disease status for a case-control study, not a mixture of both. For example, a student wanted to study if having diabetes increases the risk of developing colorectal cancer using cohort data. Selected for study were colorectal cancer patients who had diabetes (exposure) and individuals who had not developed colorectal cancer (disease/outcome) during follow-up, who had or did not have diabetes. In this case, correct calculation of odds ratios or relative risks is not possible.

However, case-control studies are more vulnerable to biases than cohort and RCTs. Choosing unrepresentative case or control groups can lead to *selection bias*. This is especially likely when using hospital or medical system controls compared to using population-based samples drawn from the community at large because individuals who are sick and under medical care may well have had exposures different from the general

population. *Recall bias* occurs when cases, because of their illness, reflect more about their past exposures than healthy controls, and report past exposures in a manner that is systematically different than controls. For example, a mother of a baby born with a congenital abnormality may be more likely to report having been exposed to toxic substances than a healthy control.

Variations on Cohort and Case-control Study Designs

There are several variants of cohort and case control studies. For the cohort design, they include the nested case-control study, the case-cohort study, and the case-crossover study. These designs are advanced methods, which are not detailed further in this text. Further details can be found in standard epidemiologic textbooks, such as by Gordis (2009).

Cross-sectional or Prevalence Study

When a population is sampled and the exposure status and disease status are measured at the same time, the study design is called a **cross-sectional or prevalence study** (see Figure 6.4).

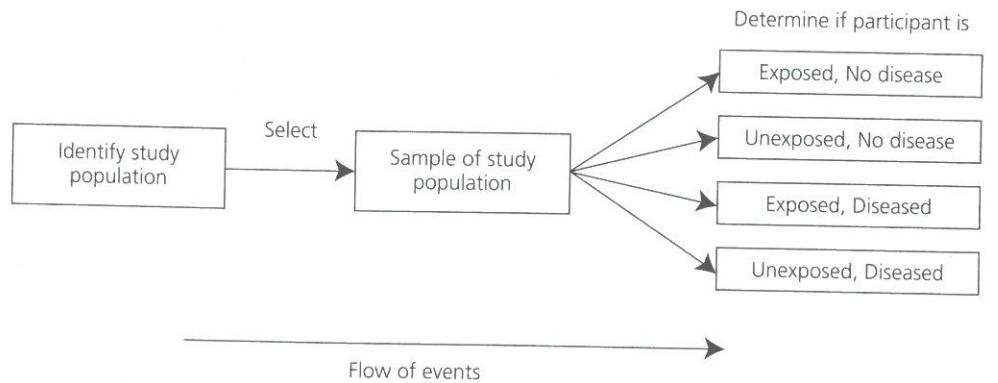


FIGURE 6.4 Contingency table stratifying exposure versus disease status for a cross-sectional study

This study design has a number of limitations. Because the element of time is not measured incidence rates cannot be calculated. As with the case-control study, associations are measured by the odds ratio. And, because temporal sequence is often unclear, that is, we don't know whether the exposure was followed by disease, or vice versa, arguing a causal relationship between exposure and disease is weak. When studying fatal diseases, cross-sectional studies are over represented by survivors, which may be unrepresentative of the disease in general, especially when studying disease etiology (cause). Many cross-sectional studies rely on self-reported disease status, which may not be as accurate as doctor-diagnosed disease status. Further, for rare or uncommon disease a large sample size is required.

Regardless of these limitations, the cross-sectional study design is much used and makes important contributions. It is good for estimating the burden of exposures and diseases in populations, and because multiple exposures and diseases or outcomes can be investigated in one study, it is useful for exploring and discovering new associations. Some chronic diseases have an insidious onset, making accurate incidence of disease hard to measure. With these types of diseases, such as multiple sclerosis or dementia, cross-sectional studies provide an alternative to cohort studies. Generally, cross-sectional studies are relatively cheap and fast to conduct.

Cross-sectional studies also provide valuable information used to design cohort and case-control studies. For example, to calculate the sample size needed in a case-control study of genetic variations and disease, the prevalence of the genetic variants (polymorphisms) in the population is required. Such information often comes from cross-sectional studies.

Large national cross-sectional studies repeated over time play an important role in monitoring unhealthy exposures, behaviours and diseases, and

trends in them over time, and can provide a sense of whether current health promotion programs are working or are needed. An example of a cross-sectional study is the Canadian Health Measures Survey, which began collecting data in 2007 in two-year cycles. The survey collects direct physical measures, including blood and urine samples for laboratory testing, as well as data on environmental exposures to contaminants and infectious diseases, lifestyle characteristics, and the extent of chronic diseases. For each two-year collection period about 5500 participants across Canada between the ages of three and 79 are surveyed. The intended end users of this information are policy makers, health professionals, and researchers.

Ecological Studies

The studies described in this chapter so far, collect exposure and disease status data at the individual level. In **ecological studies**, we do not have individual level data, but data summarizing the exposure and/or disease in samples or populations. If we collect these summary data for a large number of samples or populations (usually ≥ 10) then we can statistically test if there is a correlation between exposure and disease. For example, one published ecologic study found that the density of fast food outlets in Ontario correlated significantly with cardiovascular mortality rates in the community (Alter and Eny, 2005).

PRACTICAL TIP

Some students mistakenly thinking that ecological studies have something to do with ecology, the study of the relationships between living organisms with each other and the environment. In the context of health studies, the ecological study design means something completely different.

Ecological studies are vulnerable to many weaknesses. For example, using ecological data it would be easy to demonstrate that the average number of cars per capita correlates with national average breast cancer incidence rates. However, common sense tells us that cars do not directly cause breast cancer. One important weakness of the ecological study design is the *ecological fallacy*; that is, results that apply at the group level may not apply at the individual level. Applied to the previous example, the study did not demonstrate that those individuals who had the cardiovascular deaths ate at fast-food outlets.

Sometimes the results of ecological studies are clearly wrong. For instance, the *Seven Countries Study of Hypertension and Stroke* found that hypertension was protective against stroke at the ecological level, whereas the individual level data confirmed the accepted association between hypertension and increase risk of stroke (Menotti et al., 1996).

Ecological studies can fail to control confounding variables and often present weak evidence supporting a causal relationship. For instance, in the previous example of fast-food restaurant-cardiovascular mortality, it may well be that some other aspects of life in the communities where there is a high density of fast-food restaurants are the direct causal links to heart attacks. In other words, if one forcibly closed fast-food restaurants, cardiovascular death rates may be unaffected.

Although ecological analysis can lead to spurious conclusions, they often do lead to important correct conclusions. In some situations, inter-country variations in an exposure are considerably larger than intra-country variations, and associations with disease are easier to identify. In addition, some exposures, such as health policies, food availability or smoking regulations, are administered at the group level and can only be studied with ecological designs. Because ecological studies are cheap and can be run quickly, they are a good early step in studying

hypothesized relationships or discovering new relationships.

Validity Pyramid of Quantitative Study Designs

Of the quantitative study designs, not all studies have equal potential for drawing valid conclusions. Some studies are more vulnerable to bias while some more closely reflect a true experiment and thus are considered to have a higher likelihood of producing valid or truthful findings.

Figure 6.5 attempts to represent an ordering of health study designs, working up from least to most potential validity. If the RCT is optimal, why not use the RCT design in all studies? Because it is unethical to expose individuals to harmful exposures. That is why almost all studies of potentially harmful exposures are observational. Non-serious exceptions sometimes occur, for example, in the study of the adverse effects of sleep deprivation in healthy volunteers. In addition, some exposures are more suitably administered to groups and the community trial design can be more appropriate than an RCT. Also, usually as one climbs up the Validity Pyramid, the studies become more complex, time-consuming, and expensive, so it makes sense to work one's way up from lower to higher study validity.

Some researchers do not like the idea of a "Validity Pyramid" because it might stigmatize studies lower in the pyramid. It is important to recognize that studies lower down the pyramid can produce valuable, valid information and lead to correct conclusions, but it is also important to be aware of their limitations. In medical science, no one study alone can irrefutably demonstrate a causal association. In the scientific process, validation of a new association by different researchers, in different settings, in different populations, and using different study designs, is much more

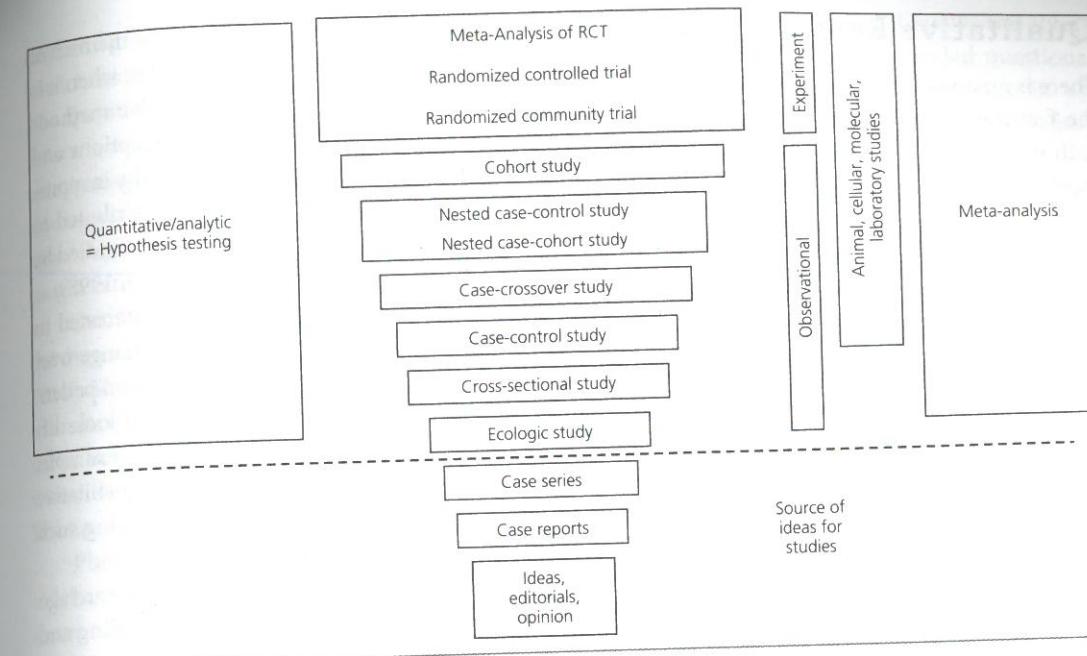


FIGURE 6.5 Pyramid of validity for quantitative health studies

convincing than an isolated finding, regardless of what study design was used.

Some have incorrectly argued that only the RCT can demonstrate a causal relationship because it is the only truly experimental study design for health studies of human populations. However, there is no doubt in the scientific community that smoking causes lung cancer, and yet no RCT was ever conducted to test this hypothesis. The first strong evidence for a link between smoking and lung cancer came from case-control studies followed by cohort studies in the 1940s and 1950s, which occurred before we had an understanding of the biological effects of smoking carcinogens on tumor suppressor genes and oncogenes.

Pilot or Feasibility Studies

Sometimes, to support a larger, more expensive, time-consuming, and complex study, prelimin-

ary studies are conducted to get information prior to carrying out the larger more definitive study. They may test the logistics of running the larger study so as to improve its quality and efficiency. **Pilot or feasibility studies** are not large enough to have enough statistical power to answer the specific proposed study question. Pilot studies may identify optimal methods for conducting the study, and sometimes evaluate whether a larger study is even feasible or affordable. Pilot studies may obtain data to more accurately calculate the sample size and study recruitment period for the larger study. This may entail measuring the frequency of the exposure of interest in the study population and the ability to recruit participants into the study, or to recruit cases in a case-control study. A pilot study may pre-test research tools, such as measurement instruments. Simply put, a pilot study may be said to "work out the bugs" before launching the larger study.

Qualitative Research

There is no one simple definition that describes all the features of qualitative research and different authors describe qualitative research in different ways. The following paragraphs provide a sense of what qualitative research is and does.

Qualitative research attempts to find out what is going on, what is happening, and the nature of "something" from the perspective of those involved in the situation under study (Bouma, Wilkinson, and Ling, 2009). In contrast to the ideal RCT setting, qualitative research is used to study what happens in the everyday world.

Qualitative research can involve feelings and impressions, which by their nature are not readily described numerically. This is in contrast to **quantitative research**, which involves measurements and numeric (statistical) descriptions of distributions or relationships between factors. Answers to questions such as how much, how often, what proportion, and what rate, involve counting and numbers, and by their nature entail quantitative research. The study question determines whether quantitative or qualitative methods are more appropriate.

Qualitative research can focus on beliefs and perceptions of truth that individuals have. Such things are difficult to quantify and measure at the population level. Consider studying the concerns and issues that people who are terminally ill have. Attempting to evaluate such issues with a structured close-ended quantitative questionnaire would not be effective as it would fail to capture many important concerns, many of which cannot be easily expressed in such a format.

Subjective "meaning" influences how individuals make decisions regarding health-related matters. Qualitative research attempts to interpret such subjective meanings and understand how they explain health-related behaviours (Green and Britten, 1998). For example, some individuals,

though already underweight, perceive themselves to have issues with their body, and diet when it is detrimental to their health. Qualitative methods can be used to investigate such perceptions and their link to eating disorders. Similarly, inappropriate use of some medications are attributed to patient perceptions, which can best be studied by qualitative methods (Green and Britten, 1998).

Qualitative researchers are also interested in the *process*, that is, how "meanings" change over time, and *interaction*, for example, between patient and physician. In addition, "reality" can look different from different perspectives, for example, from the physician's and patient's views. Qualitative health researchers are interested in studying such *relativism* (Green and Britten, 1998).

Often quantitative and qualitative research go hand-in-hand to develop true understanding and successful application of knowledge. For example, an RCT (quantitative research) suggests that annual screening for colorectal cancer using flexible sigmoidoscopy examination of the bowel significantly reduces deaths due to colorectal cancer (Weissfeld et al., 2012). Flexible sigmoidoscopy involves inserting a flexible endoscope through the rectum and visually inspecting the large bowel for abnormalities. Attempts to implement flexible sigmoidoscopy screening into public health practice may have disappointingly low participation rates and thus fail to provide the benefits projected from the RCT results. This is where *qualitative research* is invaluable. It can listen to individuals in the target population to find out the reasons why they are not participating in a flexible sigmoidoscopy screening program. Lack of participation may be due to a fear of discomfort, embarrassment, poor transportation availability, unaffordable costs. The researchers would not have been able to explain the failure of the program and how to modify it effectively, if they had not asked the right questions and listened to responses. In this case, researchers could use in-depth interviews

or focus groups to identify the reasons for low participation.

Quantitative health studies usually have the outcome as the primary study focus (e.g. cure vs. no cure in response to treatment), whereas qualitative studies evaluate the process or natural history of how one gets to the outcome (why was diagnosis not sought earlier when the disease was more curable).

Qualitative data has the *natural setting* as the direct source of data (Neutens and Rubinson, 2010). The researcher wants to study the situation in context so they often go to the location under study because situations can be best understood when they are directly observed (Neutens and Rubinson, 2010).

Phenomenologism is the idea that individuals have a voice, that understanding their story is essential to understanding social issues (Bouma, Wilkinson, and Ling, 2009). Qualitative researchers who are trying to understand a phenomenon do not only want to understand the individual's feelings, thoughts, and perspective, but also that of those in the participant's life. For example, in developing a complete understanding of the end-of-life experience of a terminal patient, the patient's spouse, family and friends, would also be interviewed. By talking to all stakeholders, new issues, concerns or understandings may arise. Most qualitative researchers use the *phenomenological perspective* (Neutens and Rubinson, 2010).

Methods Used in Qualitative Research

Qualitative research uses many methodological approaches, a few of which are outlined below. In many qualitative studies, multiple approaches are used.

1. A fundamental method for data collection is the **in-depth interview**, in which the researcher talks with the study participant

about the study themes. Usually the interviewer does not use close-ended questions, but rather engages the interviewee in an open-ended conversation to extract ideas and interpretations.

2. Often individuals are interviewed in groups called **focus groups**. This can be particularly useful when individuals are reluctant to offer opinions or when it is inappropriate to ask questions on an individual level, for example, when asking about poor health services. Usually a moderator acts as a group leader directing discussion to make sure all planned topics are covered. Group size is often around five to 12 individuals.
3. What people actually do is often different from what they say they do. For this reason observing them can be an important source of data. **Observation** is a discovery-oriented approach in which data are collected in the natural setting, minimally influenced by the researcher. In some situations, observation is the optimal choice of study, for example, in the study of infants or dementia patients. The observation method can be unstructured or structured. In the **unstructured** method a digital camera, recorder, or an alternative method may be used to record events. Unstructured observations are best used to generate hypotheses. In contrast, **structured observation** studies are set up more formally. The researcher can pre-select activities to focus on and methods of data documentation (Neutens and Rubinson, 2010). Recording of activities, events, and behaviours can be continuous, or focus on the duration of a particular event, or the count or frequency of a specific behaviour, or what is happening at specific intervals. For example, the length of time physicians spend listening to a patient's problems during an office visit could be measured by structured

observation, and time can be measured by stopwatch. Whether physicians consistently ask patients if they smoke and recommend smoking cessation programs to smokers could be evaluated by using frequency count recording. Structured observational studies may employ pre-prepared data entry forms, which anticipate important responses and simplify data collection.

Consistency and high quality observer data collection requires development of a detailed observation manual, observer orientation and training, all of which have to be adequately completed prior to onset of the study.

In order to develop a thorough understanding of a program, a qualitative researcher might obtain a detailed description of the program setting, that is the physical environment it occurs in, program activities and participant behaviours, informal interactions and unplanned activities, nonverbal communications, and unobtrusive measures (Neutens and Rubinson, 2010). In a study of smoking cessation, searching garbage for evidence of cigarette butts is an example of an unobtrusive measure.

Participant observer. Sometimes the qualitative researcher does not stay a detached observer, but rather participates to a varying degree in the group or program under study. Such methods have advantages and may allow greater access to information, often more accurate information, and provides deeper insights into what is going on, frequently stimulating new ideas. Participant observation has disadvantages. It may also alter behaviours so that the researcher is no longer observing what would have taken place if they had not participated. Ethical issues may arise if participant observation is carried out in a way that deceives study participants. Observer acceptance into a group

depends on establishing social relationships, which may lead to emotional involvement and loss of objectivity. In addition, because observations cannot be documented as events unfold, data recording occurs at some later time, relying on memory, and can be incomplete and inaccurate. An example of participant observation is the following: To study the issues and problems facing patients in long-term care homes, a participant observer could pose as a staff member.

4. Some qualitative research involves **document study**, in which institutional, public, or personal documents are systematically reviewed. For example, Rosella and colleagues (2013) incorporated document analysis into their study of developing Canadian public health policies for the H1N1 pandemics of 2009. When novel infectious disease outbreaks occur, public health policies are made rapidly, with uncertainty, and can have unexpected consequence. This study examined four highly debated issues, including use of adjuvanted vaccine in pregnant women, vaccination of priority groups, school closures and personal protective equipment. Across Canada, 40 public health officials and scientific experts were interviewed, and 76 pandemic policy documents were reviewed. Among other things, the study concluded that clarification of roles and responsibilities and improved transparency would lead to reduced duplication and improved public credibility.
5. **Ethnography** is the method of identifying and describing social and cultural groups and subgroups (Liamputpong, 2013). Ethnography initially was most used in social anthropology to study non-Western populations, and more recently it has been adopted by sociology to describe subgroups in modern contemporary societies. Ethnographic

methodologies are now applied by qualitative researchers in medical and health research.

Techniques for collecting qualitative data include field notes, participants' written words, photography, videos, and official statistics (Neutens and Rubinson, 2010). Field notes are the mainstay of qualitative research and are used to capture all information thought to be of any value. Field notes start with descriptive details of when and where an event took place, who was there, and what happened, including interactions between people. Quotations of what people said are documented. Observer insights and reflections are also recorded.

Qualitative versus Quantitative

Is quantitative research superior to qualitative research? This is not a sensible question. It cannot be said that one is better than the other, because they seek to answer different questions and get at different knowledge claims, both of which are important. Qualitative research is used to study how family, community, cultural, and other factors influence the attitudes, beliefs, motivations, and preferences of medical care providers and patients, and can provide an understanding of how evidence from quantitative studies can be turned into practice (Green and Britten, 1998). Whereas quantitative research is used to identify measurable numeric relationships and patterns,

which may range from simple to complex, between "exposures" and health outcomes, and can quantify the burden of disease.

In addition, in health research the two approaches often work together. Preliminary qualitative studies can provide important information, which can improve the design of subsequent quantitative study. Often a study that starts out as a qualitative study can transition into a quantitative study. Consider the earlier example of low uptake of flexible sigmoidoscopy screening for colorectal cancer. Once the qualitative study finds the reasons for poor uptake of screening, a quantitative study is used to estimate the proportions of each reason, and look at the relationship between different reasons and the impact of combined reasons, and identify which sociodemographic groups are at highest risk to have these reasons for lack of screening.

Regarding quantitative versus qualitative, although one is not more important than the other, they do use different study approaches and require different skill sets to conduct. It should be noted that although some lines of medical research are triggered by anecdote, a case report, or a case series report, these should not be thought of as representing typical qualitative research. Green describes qualitative research as a rigorous process that entails "explicit sampling strategies, systematic analysis of data, and commitment to examining counter explanations" (Green and Britten, 1998).

Summary

- Study design refers to the study plan or strategy.
- The study question/hypothesis should drive the study design.
- Many different study designs exist, and they fundamentally differ in how they sample
- the population under study and collect the exposure and disease/outcome data.
- Qualitative studies do not have a comparison group and do not test hypotheses, but are useful for idea development and hypothesis generation.

In contrast, most quantitative studies with comparison groups are hypothesis testing.

- In experimental study designs, such as RCTs and community trials, the researcher has control over which study participants receive the exposure under study.
- The impact of adverse or harmful exposures on populations is studied using observational study designs, of which cohort and case-

Review Questions

1. A graduate student in her MSC thesis defence was asked: "To answer your thesis question, what is the most appropriate study design?" The student thought about it and replied: "It depends on your point of view and who

control studies represent two of the most commonly used study designs.

- Different study designs vary in their vulnerability to biases.
- Qualitative research can answer questions and find out answers that quantitative studies cannot, and can help make implementation of evidence-based knowledge from quantitative studies more successful.

is doing the study." Do you agree or disagree with the student's answer? Why?

2. If the RCT is the optimal study design and comes closest of epidemiological studies to the experimental design, why not use it all the time?

Recommended Readings and Websites

Standard texts on research methods

Jacobsen, K.H. (2012) *Introduction to Health Research Methods: A Practical Guide*. Sudbury, Massachusetts: Jones & Bartlett Learning.

Free Books on the Internet

They contain useful information. However, some of them do contain mistakes, as almost all books do, so read critically.

Bonita, R., Beaglehole, R., and Kjellström, T. (2006) *World Health Organization. Basic Epidemiology*. 2nd ed. Geneva: World Health Organization.

Neutens, J.J., and Rubinson, L. (2010) *Research Techniques for the Health Sciences*. 4th ed. San Francisco: Benjamin Cummings.

Coggon, D., Rose, G.A., and Barker, D.J.P. (2003) *Epidemiology for the Uninitiated*. 5th ed. London: BMJ Books.

(This book was initially published as a series of articles in the journal Lancet. The articles are still available online as separate postings.)

Pearce, N. (2005) *A Short Introduction to Epidemiology*. 2nd ed. Wellington, New Zealand: Centre for Public Health Research.

World Health Organization. Regional Office for the Western Pacific (2001) *Health Research*

Methodology: A Guide for Training in Research Methods. 2nd ed. Manila: World Health Organization, Regional Office for the Western Pacific.

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