Is a health study the answer for your community?

A guide for making informed decisions

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We dedicate this guide to the memory of Leslie J. Somos, who wrote the annotations to the three epidemiologic studies in Summer 2006. In 2009, after completing his MPH, Leslie was diagnosed with pancreatic cancer and passed in 2010. We miss him.

Thank you all.

Introduction

"No matter how good a study may be,
someone will have something bad to say about it.
And if it is a flawed study but people are organized,
it could move mountains."

– Dr. David Ozonoff, Boston University School of Public Health

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This *Health Studies Guide* is meant to assist community groups and individuals who think that some form of environmental health investigation or health study may be useful or necessary in their community. Readers of this guide may have environmental concerns such as drinking water contamination or concerns about a particular exposure that may be related to a health problem, such as the relation between emissions from a power plant and asthma in the community. People may suspect that a certain disease in their community, such as lupus, has an environmental cause or trigger. All of these may be reasons for wanting a health study.

However, a health study may not always be helpful in resolving an environmental problem in the community. The guide begins by helping readers to consider factors that might influence their decision about *whether* to do a health study. Readers are encouraged to define their goals carefully, consider whether a health study will be useful in meeting these goals, and, if so, to choose the appropriate kind of study.

The main chapters of this guide come in pairs.

- The first two chapters are useful early on—as you consider whether a health study will help you achieve your true objectives (Chapter 1), and, if so, what question you want the health study to answer for you (Chapter 2).
- Chapters 3 and 4 will guide you through the process of choosing the type of health study that best suits your needs. You might work back and forth between these two chapters.
- The next two chapters bookend the actual conduct of the study: Chapter 5 explains issues related to research methods that are important to consider during the planning stage, before your study begins, and Chapter 6 explains how to evaluate the strength of your study's results and think about what they mean. These two chapters may be challenging and may not be necessary for everyone who uses this guide, but they are important in producing and understanding study results.
- Finally, Chapter 7 discusses the roles of community members, government agencies, academic researchers, and others in community health studies.

This guide describes a wide menu of health studies and takes you through the process of choosing and designing a study, but it is not a complete how-to guide. For example, it does *not* explain how to do your own epidemiologic study or risk assessment, nor does it describe how to conduct a health survey. If that is your purpose, we list helpful resources in Appendix.

Most of the contributors to this guide are scientists who have worked with community groups for many years to address environmental health problems. We include insights from focus groups and interviews with community members as well as our own experiences with studies that did or did not resolve community problems. Because we know what it is like not to succeed, the authors believe it is worth discussing alternatives to traditional health studies that may help achieve community goals. We hope that this guide will be useful not only for those who are contemplating a study, but also for those who are involved in a study or are the subjects of one. It will help you think about your expectations for the study's findings, costs, and timeframe. Above all, if you decide on a health study you will want to organize and work with your entire community so that it is meaningful to you. A health study can easily end up on a shelf collecting dust.

Chapters 1 through 6 are designed to be used in the order presented but may also be read singly or in any order. Thought questions follow most chapters. A facilitator's manual to accompany the guide is being developed with questions, worksheets, and guidance for anyone leading a discussion as community group members explore their options. The *Health Studies Guide* is available online and in printed form.

As with any specialty, the area of public health and environmental health science has lots of jargon. We have created a glossary of big or jargon words that appear in the Guide. All words included in the glossary also appear in a Key Word text box at the beginning of each chapter, and in bold in the text. Like the other chapters, the glossary is its own file which can be downloaded as a pdf.

Chapter 1: What is a health study and why would you want one?

"We were hoping to find a connection between the path of the smoke and cancer in town. And we thought [the study] was going to reveal the link between the power plant and our high rates of cancer."

– Joe, Resident of Salem, Massachusetts

"It is not the study that is the problem. It is really the results. You don't know what you are going to get for results until you study it."

– Helen, Resident of Marblehead, Massachusetts

In the public health field, "health study" is a specific term for research looking at patterns of health and disease. However, for the purposes of this guide "health study" refers to *any type of study that can potentially provide information useful to community groups concerned with health or health risks related to environmental exposures*.

Key words

epidemiological study
exposure
latency
(health) outcome
probability

Most health studies are meant to answer a question, but this task immediately poses two challenges.

1) The clearer the question, the more likely it is that a study will be able to address it effectively. Joe from Salem wanted a health study to prove that the smoke from a nearby power plant was causing cancer in his community—a clear question. On the other hand, in the process of sharpening one question so that it can be answered, other concerns may get lost. For example, Joe and his neighbors were also concerned about respiratory diseases and heart problems. These concerns would not be addressed in a study focused on cancer.

2) Studies are meant to answer questions, but they do not necessarily give you the answer you are hoping for. When it turned out that the study in Salem was unable to link the power plant to cancer, Joe and many other residents felt frustrated and upset. Some did not trust the Department of Public Health or believe the results of the study. Others realized that the real reason they had wanted a study was to build a case for having stronger emission controls on the power plant. Even if it did not cause cancer, members of the community were certain it was harmful and wanted action. The negative results of the Salem study may have been more harmful than helpful to the group's goals in the long run.

Our goal in writing this guide is to help people who want a health study get the health study that will be useful to them. This chapter will help you recognize whether a health study is what you want or need.

Like Salem, many communities want studies that will help prove their case or provide evidence to strengthen an

argument. However, as we'll see throughout this guide, it is difficult to do a good study. Even when there is a real connection between an environmental problem and the health of the community, a study might fail to document the connection for many reasons—for example, it might be poorly designed, or it might not include enough people. And a study that shows no connection can cause new problems for the community.

> *I think it is really important when these studies are created to say . . . 'How will [the results] be used. . .?' To consider what the public perception is going to be, to look at the big picture . . . to think about, if it came out the way it did, it would be used against us. If I had had a chance to do that with the study . . . I would have said, 'Don't do it!'*
>
> – Erin, Resident of Salem, Massachusetts

Here are lists of some good and bad things that might come out of a health study:

Table 1.1 Possible Impacts of a Health Study

Positive things a health study might do:	Negative things a health study might do:
• Document disease and/or exposure • Demonstrate a relationship between exposure and disease • Educate residents about environmental health concerns • Generate media coverage and motivate the community • Be useful for political leverage in a campaign • Create an opportunity for members of your community to get involved • Be useful in community efforts to protect the health of future generations	• Document no significant relationship between a disease and exposure • Appear to show that there is no problem • Give permission to polluters to continue polluting • Lead to legal issues over confidentiality or lawsuits by polluters • Be used against your campaign or group • Overwhelm your organizing efforts and sap members' energy • Generate statistics that may undermine your efforts • Identify health problems that you are unprepared to deal with • Delay action while waiting for results

Your Reasons for Undertaking a Health Study

To write this guide, we interviewed individuals who had helped to initiate, organize, and conduct health studies. Although they expressed many different reasons for undertaking a study, these reasons fell broadly into two categories. Some people wanted to get information that would help them answer a question or understand a concern about a health issue in their community. Other people expressed a desire to get evidence or proof they could use in a larger campaign, or even just to build awareness and mobilize residents in their communities.

This is an important difference. If the motivation for a study is simply to get information, then the capacity of the study to provide that information will determine whether people's expectations are met. But matters become more complex if the desire for information is combined with goals related to an action plan or strategy to address an environmental concern: for example, forcing the closure of a polluting facility, preventing the siting of such a facility, ensuring enforcement of air or water standards, or forcing the cleanup of a contaminated site. In these instances, the study might be seen as a way to organize the community, educate people, and get them involved. Although studies may serve these purposes, if these are the *primary* reasons for doing a study there may be better ways to do this.

One of the first steps in determining whether a health study may be useful is to identify clearly your reasons for wanting a study. Here are two questions that will help sort out your motives:

Table 1.2 Your Motives for a Health Study

A. *What* do you want to know? That is, what is your *question or concern*?

Sample responses:
- How much soot from the power plant are we breathing?
- Is there too much illness in our community?
- Why are people sick?
- Is the mold in the school making our kids sick?

B. *Why* do you want to know? That is, what is your *goal*?

Sample responses:
- Stop the development
- Prove we were right
- Clean up the site
- Get compensation

If you can answer question A and your response is another question, such as the sample responses, this guide may help you identify a type of study that can answer your question. Studies are designed to answer questions, and a good study is well designed to answer *your* question. Even if you do not like the results, at least your question will have been addressed.

What about question B? *Why* do you want to know? To answer this question you would need to have a clearly defined goal in mind. If you already have a goal you should evaluate whether a health study of some kind can help you achieve it. It may not. Consider that a study may take much time and money and you may get results that put you farther from your goal. When the Salem study, conducted by a state agency, failed to link the power plant emissions with cancer, the power company used the study as evidence that its emissions were safe. According to residents, it was interpreted as permission to continue with "business as usual."

If you already have a goal you should evaluate whether a health study can help you achieve it. It may not.

If it is easier to name your goals than to identify what you want to know, a study may not be the best investment of time and resources.

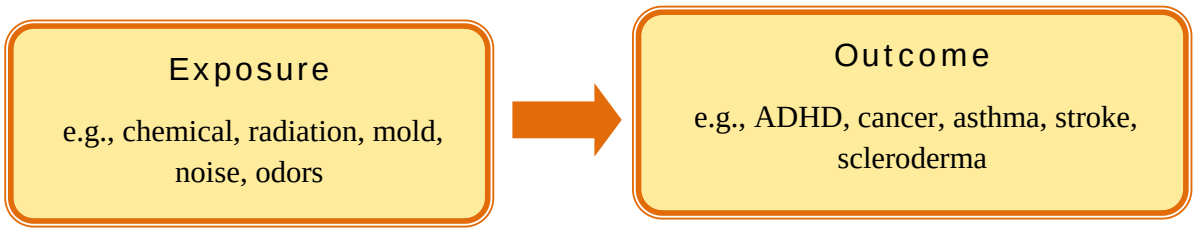
As we will see in Chapters 3 and 4, some studies are more complex than others. Studies that may be most appealing to a community—like the Salem study, which the residents hoped would connect cancer rates to the power plant—are often the most difficult to perform and interpret. On the other hand, some types of studies—like mapping disease occurrence—can be undertaken entirely by the community and provide important evidence that may further your goals. And, very often, a community needs only a relatively limited amount of information to be able to proceed, as described in a question like, *Are we being exposed to soot coming from the power plant?* The following chapters will describe a variety of ways to answer Type A questions.

The Basic Elements of a Research Question

If you are able to answer question A—What do you want to know?—you are on your way to framing a true research question, one that a study can be designed to answer. Chapter 2 will take you through the process of defining a research question. Here we'll introduce the vocabulary researchers use when they talk about research questions.

- ### Pollution and Disease—Also Known as Exposures and Outcomes

  Community members often express their concerns about *pollution* and *disease;* too much pollution, too much disease, or a suspicion that disease is caused by pollution. Often, community health studies try to answer a question about the relationship between something in the environment and a disease or other health effect. However, scientists talk more abstractly about *exposures* and *health outcomes* (often shortened to *outcomes*). To scientists, the term *health outcome* is more neutral than *health effect*, which suggests that a cause has already been established.



  Scientists use the term **exposure** to refer to any chemical pollutant or other stressor (for example, radiation or mold spores) that people may encounter. For the most part, researchers are concerned with exposures that people contact in their environments (*environmental exposures*) and that pose a threat to human health.

  Most health **outcomes** are conditions that we would identify as diseases (not to be confused with the result of a study, sometimes also called the outcome). Sometimes outcomes studied are more subtle than a disease. For example, a decreased level of a hormone in the body is an outcome, as is a slightly delayed reaction time that we wouldn't notice unless we measured it. In some cases these outcomes are too minor to be

diagnosed as a disease in an individual, but they are still of concern, especially when widespread in a population.

- Connecting Exposures to Outcomes

Some health studies are limited to measuring environmental pollution or to measuring the occurrence of diseases. More sophisticated and labor-intensive studies—which we call **epidemiologic studies**, and which will be discussed at length in later chapters—try to measure the *relationship* between a specific exposure and a health outcome. Based on accumulating scientific evidence from health studies, we now know of many relationships between specific exposures and health outcomes. Here are some well-known examples of exposures and associated outcomes: Remember, the exposure is what we think might cause the outcome.

Figure 1.1 Examples of Exposure-Disease Relationships

Exposure	→	Outcome
Lead (as measured in children's blood)	→	Lower IQ and learning disabilities
Poor air quality	→	Asthma and cardiovascular disease
Certain types of pesticides	→	Nervous system disorders
Diet high in salt and fatty foods	→	Heart disease
Cigarette smoking	→	Lung cancer

Epidemiologic studies try to measure the relationship between a specific exposure and a health outcome.

The exposures in this table range from things that are easy to measure (level of lead in the blood) to others that are more difficult to assess (contact with pesticides). The passage of time can also make it more difficult to link exposure to outcome: for example, it is often difficult to link cancer to past exposures because of cancer's long **latency**—the delay between the exposure that begins the process of cancer and the diagnosis of the disease.

For some chemicals, federal or state government standards have been set to limit people's exposures. Often these standards are maximum allowable concentrations in water or air. We can sometimes compare exposures in a community to these standards. Of course, standards are not perfect, and many standards allow exposure to pollutants at levels that some scientists think are unhealthy. Even more important, there are thousands of chemicals in commerce, and for most of them, no standards have been established.

Just as some exposures are more difficult to measure than others, some outcomes are more difficult to measure or define. For example, people may have asthma or a learning disability without having a diagnosis from a doctor. It is difficult to study an outcome in a population if

some cases are not identified. In contrast, death is a clear outcome, as is a diagnosis of lung cancer. In these instances, we can use death certificates or other data collected by the government (such as a state cancer registry as we'll explain in Chapter 4) to count outcomes, giving us solid information.

Most important, in any particular situation, the link from exposure to outcome is not a certainty—even if a disease is known to be related to an environmental exposure. For example, even though the relationship between cigarette smoking and lung cancer is well known, some people who smoke cigarettes all their lives will never get lung cancer. And smoking is not the only cause of lung cancer: some people who never smoked a cigarette will get this disease. What health studies have been able to demonstrate, though, is that on balance, smoking increases the **probability** that a person will get lung cancer. Most epidemiologic studies are designed to detect that increased probability, or risk, of a health outcome in a population.

A Health Study Is Not the Last Word

In public health investigations, there is a pattern of reassuring findings that do not lead to change. Cleaning up toxins in the environment costs money for business; treatment of cancer makes money for business. This political climate is simply not friendly to prevention.

— Terry, resident of Tuscon, Arizona[1]

Five well-established relationships between exposure and outcome are listed in Figure 1.1. These relationships are considered well established because they have been documented repeatedly in research studies over many years. A single study rarely provides enough evidence to change scientific understanding. Science works on accumulated evidence, and since any single study could be wrong, scientists (and policy makers) are generally reluctant to draw conclusions from one study. Thus you should not expect your health study to establish a definitive relationship between an exposure and an outcome.

In fact, even a mountain of scientific evidence is not always enough to provoke action. For example, it was first discovered that lead in children's blood was associated with learning problems decades ago, yet many, many studies were conducted before legislation was written in the United States to protect children from lead poisoning. This legislation was passed only because scientists and community members pressured politicians and executives in the lead industry to act on the scientific evidence. Science does not usually speak for itself. Only with organized community pressure and persistence will study findings be put to use.

Science, on its own, does nothing without the engine of community and political organization.

Neither agencies that conduct health studies nor academic researchers have the power, on their own, to change or enforce environmental health regulations. In fact, sometimes researchers who try actively to change policies or regulations are accused of being "junk scientists" or "activists," often by interests that are perfectly willing to hire different scientists to present different conclusions. Whether this is fair or not, it can harm a scientist's career as well as the community's cause. Scientists can provide crucial information about exposure and disease, but it is best left to legislators, educators, attorneys, advocates,

corporations, and communities to translate that information into changes that will improve public health. Science, on its own, does nothing without the engine of community and political organization.

Summing Up

Now that you've read this chapter, answer the questions below to help you think about your own situation. If you find that a health study is not the best strategy to meet your goals, or that your goals will best be met by organizing in your community or pressuring government or industry, don't be discouraged! You can make a persuasive argument even without health study findings to back you up. (See the Appendix on organizing resources.)

On the other hand, you may be more convinced than ever that your community needs a health study of some sort—anything from a relatively simple measurement of pollution at a facility to a complex epidemiologic study that will potentially identify causes of disease in the community. The next chapters will help you develop your research question and pick a study design that is most appropriate for your needs.

Key Points from Chapter 1

– The term "health study" may be used differently by scientists and community leaders.
– A good study is one that answers your question.
– Study results may be used against you.
– Studies can examine exposures, outcomes, or both.
– Science builds on evidence; one study is rarely enough to convince the scientific community.
– Science does not speak for itself.

Questions to Think About

– What do you want to know? What exposures or outcomes concern you most?

- What are your organizational/community goals?
- Will a health study help you achieve these goals?
- Look at the examples of positive and negative things that a study can do. In your case, what positive and negative outcomes could you expect from study results in your community?

Further Reading

– Rosner D., & Markowitz G. (2002) *Deceit and Denial: The Deadly Politics of Industrial Pollution*. Berkeley: University of California Press.

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Chapter 2 : Framing Your Concern as a Research Question

This chapter will help you focus your concern, framing it like a research question so that it can be addressed by one of the study types described in Chapters 3 and 4. Remember, a good study is one that is designed to answer your question—so now it is time to make sure you know what question you are asking. But as you learn more about different kinds of studies in later chapters you may also think about different ways to frame your question.

Before conducting a study researchers go through a process known informally as scoping; that is, defining the scope of the study. The scoping process should lead to a clear statement of your research question. In scoping a study, researchers answer these questions:

- What is the major concern we will address in our study?
- Whom do we want to study?
- Where and when do we want to do our study?

Key words

absorbed dose
ambient pollution
average daily dose
cancer registries
concentration
dermal exposure
disease cluster
dose
emissions
epidemiologic
epidemiology
hand-to-mouth
in utero
ingestion
inhalation
media
medium
micro-environment
parts per billion
parts per million
risk factors
route of exposure
source
surveillance
toxicology
toxicologist

Defining the problem: What is your concern?

In Chapter 1, we talked about the difference between an exposure (a pollutant or toxic substance) and a health outcome (a disease, or a condition, or even death). Now you can begin to think about whether the specific question you want answered is most related to exposure, outcome, or both (the exposure-outcome relationship).

Are you particularly concerned by an exposure, such as the presence of a particular chemical in the air, water, or soil, or a pollution source in your neighborhood? Or are you primarily concerned by a particular health problem in your community, such as leukemia, arthritis, or autism? Maybe you suspect a chemical exposure in the environment is making people sick and you want to study this connection. Perhaps a government agency such as the Agency of Toxic Substances and Disease Registry (ATSDR) has proposed a study and you want to evaluate it. See Table 2.1 for examples of concerns translated into study questions. Once you have clarified your concern, you will be in a position to choose the right type of study to look at your question.

Table 2.1. Examples of concerns to be addressed by a study

My concern is…	My study will address…
particulates emitted by a power plant in town	An **exposure**: Have we been exposed to something harmful?
too much breast cancer	An **outcome**: Are there more cases here than one would expect?
possible link between kids' poor school performance and our town's old lead water pipes	An **exposure-outcome relationship**: Is a harmful exposure affecting our health and well-being?

If your concern is an exposure…

Many people or communities are interested in a particular exposure of concern—for example, a chemical in the drinking water supply or visible pollution from a smokestack. People in these communities may suspect that the pollution has some impact on their health, but they are primarily concerned with identifying—and addressing—the exposure.

Even if you are interested in the relationship between an exposure and an outcome, learning as much as you can about the exposures of concern to you is a good place to start. You may not have to go further to make your case, or what you learn may be helpful later in relating these exposures to health outcomes. Two questions may help you decide whether an exposure study is what you need:

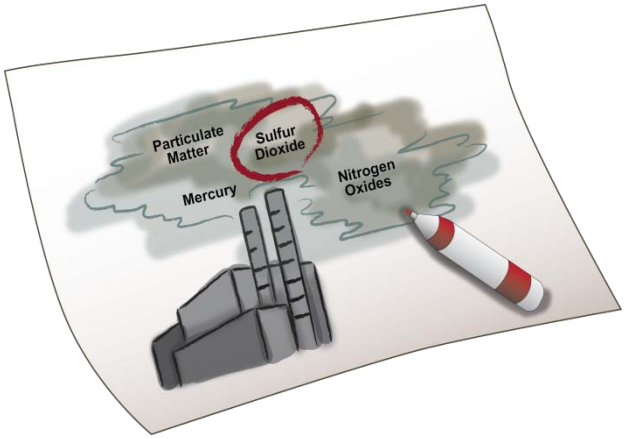
1) **Do standards exist for the exposure of concern?**

   For many substances the state or federal government has set standards corresponding to exposures that are considered *acceptable*. Of course, these standards may not truly be safe. Even so, the standards give you something to which you can compare your own exposure, a benchmark. If you find that your exposures are higher than the standards, you are more likely to get the government to agree that there is a problem. For example, some standards set limits on **emissions**: how much of a pollutant can be emitted legally from a power plant or from your car's tailpipe. Other standards restrict the amounts of **ambient pollution** allowed: for example, the concentration of a chemical in the outdoor environment, such as ozone or particulate matter in your town's air. Other standards address the concentration of pollutants in food (for example, mercury in tuna) or even in people (doctors regularly test children's blood for elevated lead levels). In each of these cases, a comparison of measurements against the existing standard may be enough to demonstrate that your concern is legitimate, from the point of

view of scientists and policy makers, and therefore deserving of action. The website of your state's Department of Environmental Protection is a good place to start if you're looking for an environmental standard.

2) **Can you narrow down the exposures of concern?**

If you are designing a new health study, you may be tempted to consider a number of exposures in your community—the waste site, the power plant, the drinking water, the food. While this reflects the reality in many communities, an exposure study is most feasible if it focuses on a particular source and, within that source, a narrow range of substances. Within a waste site are hundreds of chemicals. A coal-burning power plant emits a number of air pollutants (for example, sulfur dioxide, mercury, and particulate matter). Drinking water may contain a large number of possible contaminants, both biological (for example, bacteria) and chemical (for example, chlorine). Try to be as specific as possible. It is difficult for scientists to study more than one exposure at a time, so try to narrow your interests to those that are of most concern. It is very important to be able to clearly and consistently identify (and even measure) the exposure of interest.



An exposure study will try to answer other detailed questions such as: How close does one need to live to the site to be considered exposed? For how long? Suppose the people in one house had lived near the waste site for 30 years, while their next-door neighbors moved in last year. What is the difference in their exposures? Also think about how people come into contact with the exposure. For example, if you think the soil around a school is contaminated, why is that a concern? Does anyone actually touch the soil or come into contact with it?

For more details on understanding exposures in your community, see *Considering Your Question model of exposure and disease* on p.23, and the *Mapping* and *Studies of Exposure* sections of Chapter 4.

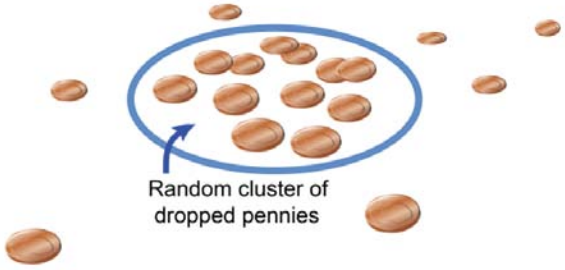
It is difficult for scientists to study more than one exposure at a time, so try to narrow your interests to those that are of most concern.

If your concern is a health outcome…

People are naturally concerned when they believe they see too much of a disease in their community. There are two basic ways people might think about "too much disease."

1) **Does my neighborhood have a disease cluster?** Sometimes people notice that a number of their neighbors have a specific illness (for example, childhood leukemia), so that there seem to be too many cases of the same disease in their neighborhood. Often these concerned residents plot the cases they are aware of on a map, and when they do this, they may see a geographic cluster of cases. Although this seems like a simple idea, in fact it is very hard to establish whether such a set of cases is a truly unusual **disease cluster** or is just part of the normal geographic variation in the occurrence of disease.

   Here is an analogy: If you toss 100 pennies up into the air and let them fall onto a carpet, you will see areas where the pennies cluster close together and areas where the pennies are spread out, but there is no particular meaning to this pattern. In the case of possible disease clusters, researchers use statistical methods to tell "real" statistically meaningful clusters from "random" ones, but these methods are out of the reach of most folks who are untrained in statistics. Even scientists often disagree about the results of cluster analyses. Public health agencies regularly receive requests from communities to assess whether cancer clusters exist, and, if so, what is causing them? These agencies often feel they *must* respond to cancer clusters with a study. Unfortunately, most cancer cluster studies are inconclusive: they fail to find a relationship between an exposure and the cancer, so they cannot say what is causing the cluster. The usual reason for this is that number of cases was too small to detect a relationship between exposure and disease, even if it really exists (more about this in Chapter 6). Ultimately, the study of a cluster of childhood leukemia in Woburn, Massachusetts in the late 1970s (see sidebar on next page) proved to be an exception to this general rule although there are still people who question the cause of leukemia in Woburn.



2) **What is the disease pattern in my region?** The other approach to thinking about whether there is "too much disease" in a given location is known as disease **surveillance.** In this context, *surveillance* means surveying the landscape of disease by systematically monitoring disease rates for geographic areas. For example, surveillance methods can be used to monitor and compare the rates of childhood leukemia across the 50 states, across the counties of one state, or across smaller areas defined by the US Census. All 50 states have **cancer registries** that collect information on cancer cases. It may be helpful to ask a public health professional to walk you through the cancer profile site or your state's cancer registry. Perhaps you should consider going door-to-door in your community to collect health outcome information directly from

Surveillance data are used to compare rates of disease on the level of state or county, whereas communities are usually concerned about disease clusters in a town or neighborhood.

your neighbors. A community survey may be the best way to measure the incidence of cancer or other outcomes such as birth defects, miscarriages, asthma, or autism that may not be well-documented in a state registry.

In general, surveillance data are used to compare rates of disease on the level of state or county, whereas communities are usually concerned about disease clusters in a town or neighborhood. It is possible to compare rates of disease for small areas using surveillance methods; however, there are significant difficulties. First, small Census areas don't necessarily match up with neighborhoods defined by the people who live there. Also, disease data are confidential: the cancer registry must protect the identity of individual cases, and that makes it difficult for ordinary people to get information for small local areas. Finally, just as it is hard to tell "real" and random disease clusters apart, it is difficult to tell "real" local peaks in disease rates from random ones in small populations.

Regardless of how you think about "too much disease," if your community is interested in a particular health outcome, try to define the outcome as clearly and consistently as you can. Some health outcomes are easier to identify than others. Cancer, for example, is diagnosed by a doctor and reported to a cancer registry; on the other hand, there are many different types of cancer, and most have unique causes. Therefore, just "cancer" is not specific enough as a health outcome. In order for a health outcome to be studied successfully, it must be clearly and consistently defined.

What if the outcome of concern to you—for example, stomachaches, flu-like symptoms, or skin rashes—is vague, short-lived, or hard to define? Many outcomes that are more frequent but less severe than cancer do not get counted or tracked, and this makes them harder to study. Even so, these symptoms or health conditions are worthy of investigation and challenge scientists to get creative.

Sidebar: Cancer Clusters and the Woburn Story

Some cancer cluster studies have gained significant public attention. For example, in the late 1970s, residents in Woburn, Massachusetts, raised concerns over environmental contaminants (particularly solvents in the water supply) and health. Suspecting higher than normal cancer rates, especially in children, residents went door to door to identify cases. They then mapped the cases using pins on a wall map, and by visual inspection it appeared that the cases were clustered in the eastern part of town (See Figure 2 under Mapping in Chapter 4.) In response to these concerns, the Massachusetts Department of Public Health, with help from the U.S. Centers for Disease Control and Prevention (CDC), investigated cancer incidence for childhood leukemia, liver cancer, and kidney cancer between 1969 and 1978. Analysis showed that childhood leukemia rates were elevated, specifically on the eastern side of town. Kidney cancer incidence was also higher than expected compared to national rates. However, the study reported that it could not link any particular environmental exposure to the elevated cancer (Parker & Rosen 1981). Meanwhile, two municipal water wells had been closed in 1979 after they were found to be contaminated by industrial chemicals.

Residents then initiated their own further study with researchers at Harvard School of Public Health to investigate whether use of tap water from public wells contaminated with solvents (trichloroethylene and perchloroethylene) was related to the cancers. Their research found an association between risk of childhood leukemia and maternal consumption of drinking water from two specific contaminated wells (Lagakos, Wessen, & Zellen, 1986). It also linked certain birth defects and fetal and infant death with consumption of this water. This community-initiated research brought national attention to the case,

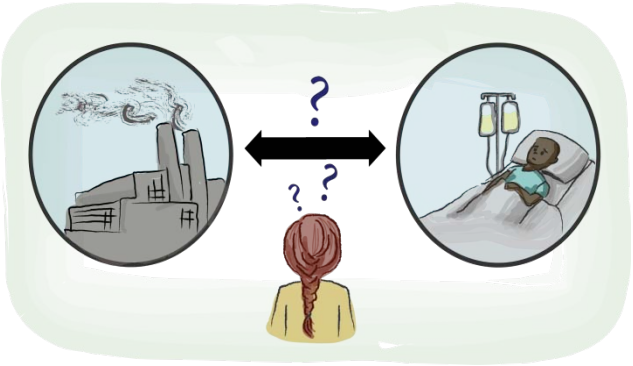
Sidebar: Cancer Clusters and the Woburn Story (*Continued*)

with the story being made into a book and movie, both entitled *A Civil Action* (Harr, 1996). More than 10 years later, the Massachusetts Department of Public Health published the results of a case-control study, which confirmed the results of the community study. Children whose mothers drank contaminated well water while pregnant had an eight-fold risk of cancer compared to children of mothers who had not been exposed (MDPH 1997).

The Woburn study is a rare example in which a cancer cluster was widely accepted as being connected with a particular exposure—yet even now many epidemiologists remain unconvinced. Clusters with small numbers of cases are extremely difficult for researchers to study, since most statistical tools are designed for large samples. Additionally, the role of chance in determining the location of cases means that clusters are difficult to distinguish from random groupings. For more detail, see *Statistical testing for the presence of clusters* in Chapter 6.

If your core concern is the relationship between an exposure and an outcome…

When a community has established that there is an excess of disease in the area, the next step is often to try to connect it back to an exposure. Some communities start at this point, with both an apparent excess of disease and an exposure they suspect caused the disease in their community, and want to investigate the connection between the two. That is, the primary concern is the relationship between the exposure and the outcome.



The question that often drives such people to want a health study is, "*Why* are we sick?" Built into this question is another question: "Why are we sick and other people are healthy?" At the heart of most health studies lies a comparison—between healthy and unhealthy or between exposed and unexposed. Usually we are comparing groups, for example, a group of people who have asthma compared to a group of people who do not; or a group of people who live near a power plant compared to a group of people who do not.

Some study types make a comparison between rates of disease in different groups, while others might compare levels of pollution. More complex studies, however, attempt to connect these two factors—to understand both *where disease is present* and *what caused it*, by comparing both the exposure *and* the disease in carefully selected groups. We call these studies **epidemiologic** studies. (The field of **epidemiology** began with the attempt to understand patterns of epidemic disease. The surveillance and cluster methods described above are also often referred to as epidemiologic studies,

At the heart of most health studies lies a comparison –between healthy and unhealthy or between exposed and unexposed.

but in this guide we will use this term when discussing study designs that specifically concern the *relationship* between exposure and outcome.)

For example, suppose we chose a group of people who are exposed to a hazardous chemical in their drinking water and another, similar group who have a different water supply and so are not exposed. We might then compare the rates of a bladder cancer in the two groups to see whether the exposed group is more likely to become ill than the unexposed group. If this occurs, it is strong evidence that the chemical in the water causes bladder cancer. To accomplish this, however, we needed to collect detailed data on both exposure and disease in the different groups. Not surprisingly, epidemiologic studies are far more difficult and complex than studies of exposure or outcome alone. In addition to the need to understand both exposure and outcome, making the link between disease cases and exposure requires statistical methods. Thus, as in Woburn, epidemiologic studies typically involve not only community members but also professionally trained researchers, statisticians, or government agencies.

In the laboratory, scientists who study toxic chemicals—**toxicologists**—try to determine whether a disease is connected to a particular exposure by giving chemicals to laboratory animals and observing what happens. But epidemiologists can't do experiments on people. Instead, epidemiologists investigate what has already happened: Who was exposed, when, and what were the health outcomes among the exposed and unexposed? Or they may watch as a situation develops; for example, following the lung development of children as they age in a city with polluted air compared to children in a city with cleaner air. Epidemiologists must try to take advantage of real-world experiments that are untidy, unsystematic, and not set up to provide easy answers. And, unlike lab rats, people in the real world are exposed to many different chemicals, stressors, and other **risk factor**s that may also contribute to disease, complicating the comparison between groups. This makes doing epidemiologic studies very challenging.

What is more, being exposed doesn't necessarily mean you will have the outcome, and having the outcome does not necessarily mean you were exposed. Some people get cancer due to genetic factors rather than environmental factors, and many people are exposed to toxic substances without ever getting cancer or any other health outcome.

Being exposed doesn't necessarily mean you'll have the outcome, and having the outcome doesn't necessarily mean you were exposed.

However, environmental health scientists are not satisfied with the explanation that some people are just unlucky or that "chance" is the reason some people are sick while others are healthy. They seek to understand all the reasons that might explain why people get disease. These may be genetic, behavioral, or environmental, or some combination of these.

If your community is interested in studying a link between a specific exposure and a specific outcome, first clearly define your exposure and your outcome. You will most likely want to enlist the aid of a researcher in this process. As you learn more in the next two chapters about the types of studies designed to examine exposures, outcomes, and their relationships, you may rethink the kind of concern you want to address.

Framing Your Research Question: *Who? When? Where?*

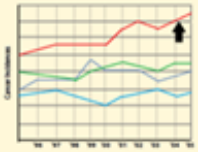
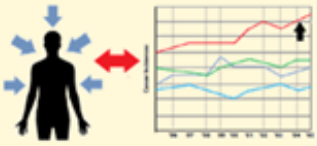
In an ideal world, we would like to understand the entire situation: the exposure, the disease, and the connection between them. But that is a difficult connection to make, and very often you do not need to go that far. As a practical matter, defining your research question may help you understand that you can achieve your goals by doing less rather than more.

For example, imagine you are in the community that is concerned about lead in drinking water: It will probably be enough for you, in collaboration with an academic partner or public health professional, just to document the *exposure* (lead), and to be able to describe or measure it. You don't need to show an *outcome* of lead exposure (which might be, for example, lowered IQ). This may be the best strategy for two reasons. First, there is a large research literature that documents the relationship between lead and IQ. And second, the presence of lead in drinking water is already carefully regulated by federal and state governments. In this situation, simply demonstrating the exposure might be enough to make your point. A health study that was capable of identifying a relationship between lead in your community's water and poor performance by children in school—an epidemiologic study—would take years and be very expensive. You might consider doing the *minimum* you can do to *achieve your goals*.

Table 2.2 adds a third column to Table 2.1 with examples of good research questions. In refining your core concern into a research question, try to specify the who, when, and where, as these examples have done.

You might consider doing the minimum you can do to *achieve your goals.*

Table 2.2: Sample concerns and research question

My concern is...	My study will address...	My research question is...
Particulates emitted by a power plant in town	An **exposure**: Have we been exposed to something harmful? 	Over the past 5 years, have people on the east side of town been exposed to high concentrations of airborne particulates emitted by the power plant?
Too many cases of breast cancer	An **outcome**: Are there more cases here than one would expect? 	Over the past 10 years, does our town have a higher rate of breast cancer in women than other, similar communities do?
Possible link between children's poor school performance and our town's old lead water pipes	An **exposure-outcome** relationship: Is a harmful exposure affecting our health and well-being? 	Is lead in our drinking water responsible for the current poor performance of local children in school?

Who is Your Study Population?

There are many ways to pose this question. Who is sick? Who do you think might be exposed to chemicals? Are you interested in workers and their occupational health? Children in a school? Residents on a street? An entire town or city? Is it a diverse population with regards to socioeconomic status, race, or ethnicity? Or are you interested in a small group of people who are relatively similar in income and education? If you are studying a fatal disease, are you interested in learning about those who have already died in addition to those who are living?

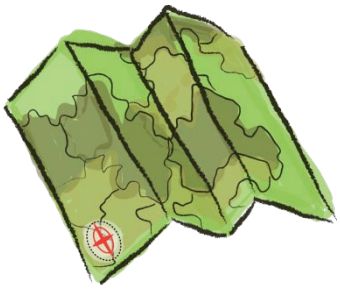
Whom you decide to include in your study will affect the number of people in the study, a very important factor because it affects the statistical power of the study to detect any association between exposure and outcome. This concept is discussed in detail in Chapters 5 and 6.

Finally, certain characteristics of the group you plan to study may affect the type of study you do or how you choose to do it. For instance, it may be difficult to learn about the experience and concerns of people who speak a different language, do not seek medical care, or are not comfortable talking to strangers. Once you have a population in mind to study, think about whether the questions you plan to ask are appropriate.

When Did Exposure and/or Disease Occur?

Some diseases people experience now are caused by exposures that happened years earlier. In order to study the disease today, we have to look back many years to think about what people were exposed to. Or we may want to study people who are not sick yet but are exposed to something in the environment and are concerned about becoming ill in the future. Are you interested in looking at what may happen in the future or at what has happened already? Perhaps you want to know about exposures and outcomes at this moment, like a photograph capturing everything *as is*. As far as exposures and health outcomes are concerned, what *did* happen, what *is* happening, and what *will* happen are all different questions that would point you to different study designs.

Where is Your Study Population Located?



If you are interested in a particular street or neighborhood, you may go door to door or search local records and data sources and involve local residents. However, if you want to study something that includes the entire city, state, or country, you may not be able to get personal data as easily and your study may include large numbers of people living in very different areas with very different environmental exposures. What factors will determine the geographic scope of your study population?

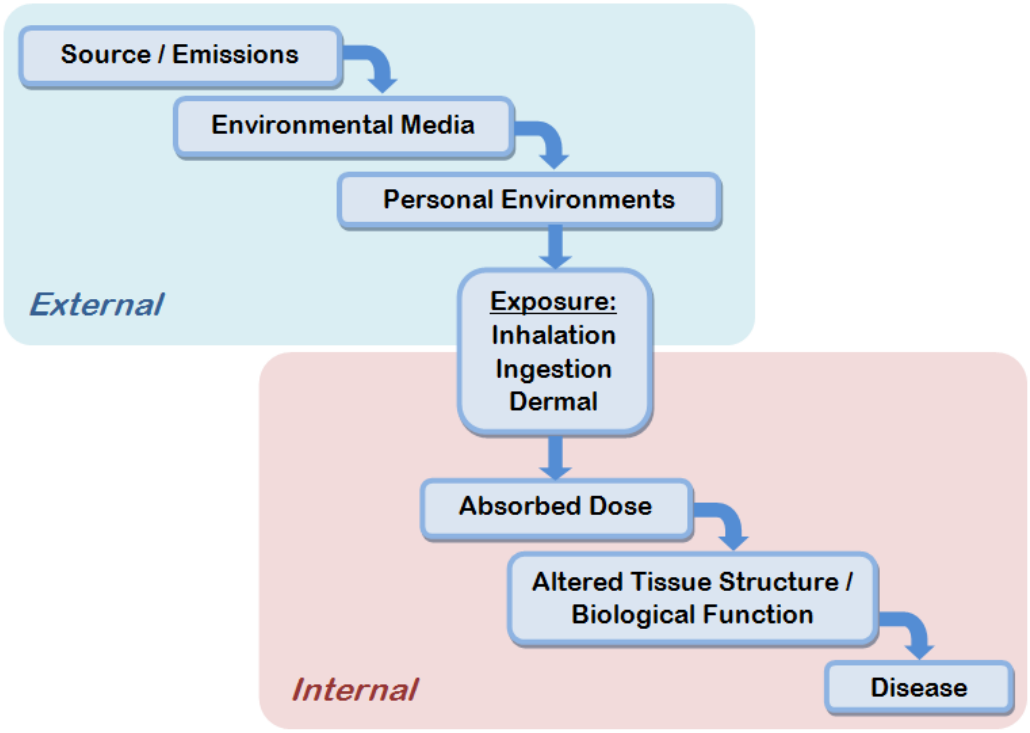
If you are driven by an exposure concern, consider where people are likely to be exposed. For example, if you are concerned about a landfill, how would you identify the potentially affected population in relation to the landfill? Or a drinking water supply? The who, where, and when questions are often related.

Considering your question with a model of exposure and disease

To pull these pieces together it may be helpful to consider your question in the context of the relationship that you think exists between the exposure and the health outcome. One way to do this is to sketch a diagram of how exposures and outcomes are generally linked (see Figure 2.1 below) and see which of these links your question addresses.

Our diagram is a model for how we understand the relationship between exposure and disease and helps us when designing a study. For example, considering how a pollutant or chemical travels in the air so that people are eventually exposed may help us choose where we to take environmental samples or what populations to include. (As we'll see in Chapter 5, many other factors, which we call *confounders*, may also be added to the model.)

Figure 2.1. A basic model for an exposure-related disease.



These models are most useful if you're concerned with an exposure or with an exposure and the related health outcomes. If you're primarily concerned with a health outcome but aren't aware of specific toxic exposures, you may not be able to complete every part of the model—but it will still help you understand what you should be looking for. Chapter 3 explains how certain study types focus on one or more aspects of the above model. An effective health study does not need to address all these components but knowing what it does and doesn't address will help you design your study and interpret results.

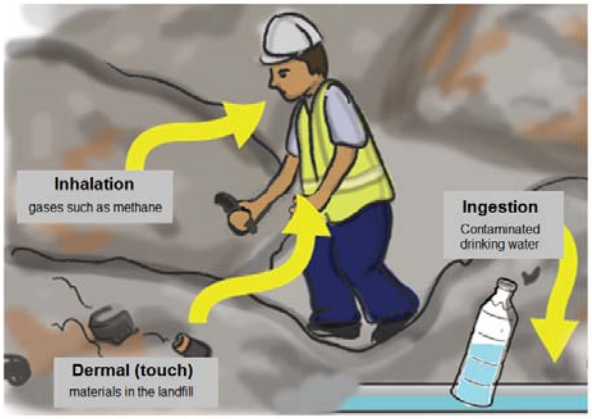
The figure starts with the **source** of the exposure—for example, a power plant that emits particulate-matter air pollution, or a house painted with lead paint.

Knowing what components a health study addresses and doesn't address will help you design your study and interpret results.

The next steps describe how a chemical or hazard makes its way into our bodies. First, what is the environmental **medium** (plural **media**) by which the hazard travels? Particulate air pollution is usually encountered by people in the air. Lead paint from a house may chip off into the soil, or it may be ground up into dust in the household. A groundwater contaminant like perchloroethylene (PCE) is transmitted through the water. Knowing the medium by which the hazard travels may require some background research. It is the key to understanding how people come into contact with the hazard, or how they are exposed.

The **personal environment** is the area immediately around the study population. For air pollution, we're not necessarily concerned with the air quality at the smokestack—we're worried about the air in our neighborhood or inside the home, school, or workplace. The micro-environment is often an ideal place to take an environmental sample; for example, lead paint that is ground into dust may find its way into the micro-environment of the living room.

One of the best reasons for using an exposure-disease model is that it forces us to think about the **route of exposure**. This is the pathway by which a hazard moves from the micro-environment into the body, and it is closely related to the medium by which the hazard moves. The most common routes of exposure are **inhalation** and **ingestion** (eating or drinking). Some types of hazards, like solvents, can enter the body through the skin, or **dermal exposure**.



In most cases, you will be concerned with inhalation or ingestion, and understanding these routes will clarify your research question. For example, let's say you are concerned about cadmium, a toxic metal in a landfill nearby. Many toxics (especially metals like cadmium) are not volatile, meaning, they are not likely to migrate from the land into the air. Therefore, inhalation is not a likely route of exposure. Unless you're working in the landfill, you are unlikely to be concerned with dermal exposure. What about ingestion? If the cadmium were to leach into the groundwater, and if your water came from a nearby well, that might be a source of exposure. On the other hand, if your drinking water is from a town water system located at a distance, ingestion may not be a relevant route.

In addition to these major routes of exposure, there are several others that might be considered. Anyone can be exposed ***in utero*** before they are born to toxic chemicals carried by the mother, or to which the mother is exposed. *In utero* exposure is a critical concern for childhood disease, and researchers are now beginning to understand that many adult diseases or conditions are related to *in utero* exposures. An important exposure route for children is **hand-to-mouth** behavior: Since young children spend a lot of time on the ground, and since they put their hands (and everything else) into their mouths, they often ingest things that adults don't. (Smokers can also be subject to significant hand-to-mouth exposure.) Some medical patients are directly exposed to chemicals **intravenously**, although this is usually in a carefully controlled setting.

The right-hand side of Figure 2.1 is the domain of **toxicology**, and we will review it lightly here. Toxicology is the study of how a particular chemical causes a particular change in biological function or tissue structure; toxicologists usually rely on animal studies, as well as other laboratory work, to explore these relationships.

The most important part of the right-hand side of our model is the **dose**. Knowing the route of exposure (for example, ingestion of contaminated water), the concentration in the medium (precisely how much chemical is in the water), and some extra information (how much water does a person drink in a day?), a researcher can attempt to calculate the amount of a chemical that enters a person's body in a given time. Toxicologists and medical researchers then try to understand the detailed mechanism by which some dose of a chemical causes disease.

The details of these steps are complex. However, one type of community study that will be discussed in Chapters 3 and 4, a body burden study, can directly measure the amount of a toxic chemical in the body (the **absorbed dose**)—through a blood test, urine test, or some other method.

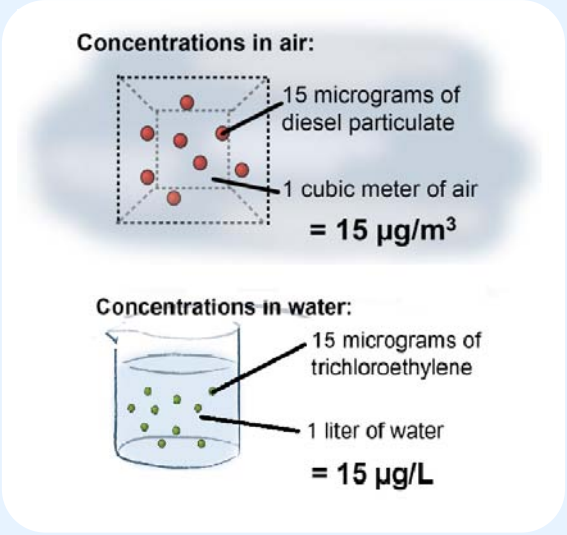
Missing from this model of exposure and disease is time. The timing of exposure in a person's life is extremely important (more in Chapter 5). Obviously, if the exposure occurs after the disease, it is unlikely that the disease is caused by exposure. But *when* a person is exposed may be even more important than the dose. There are critical windows of time, especially in fetal and adolescent development, where small exposures to some chemicals may have large effects.

Sidebar: Measuring chemicals: concentration and dose

In most of the study types that follow, the aim is to measure or estimate the amount of a hazard to which a community is exposed. These types of measurements fall into two basic categories—concentration in the environment and dose in the body—that relate to the diagram in Figure 2.1.

When we want to know how much of a chemical is in the environment, we measure a **concentration**: the amount of the chemical in the air, water, or soil. For example, the concentration of lead in soil is often measured in **ppm** (**parts** of lead **per million** parts of soil) or **ppb** (**parts per billion**). If we say that a sample of soil is contaminated with 200 ppm lead, we mean that for every million parts of soil, there are 200 parts of lead. Ppm and ppb are convenient and frequently used environmental measures.

Concentrations are often expressed a little differently for air and water. In air, we might express the weight of pollution in a volume of air: 15 micrograms (µg, a measure of weight or mass) of diesel particulate pollution in one cubic meter (m3) of air, or 15 µg/m3. In water, volumes are usually expressed in liters: for example, we might have 15 µg of trichloroethylene in a liter of water, or 15 µg/L.



Sidebar: Measuring chemicals: concentration and dose (*continued*)

When we want to measure how much of a toxic chemical enters the body, however, we need more information. The amount entering the body is called the **dose**, and it is most typically measured as an **average daily dose**: The amount of a chemical that a person takes in during an average day. For example, if your water is contaminated with 15 µg/L of trichloroethylene, and you drink two liters of water every day, your dose is 30 µg of trichloroethylene per day. (In practice, doses are often per kilogram of body weight, so that they can be compared between different people. We will see this type of dose in Chapter 4.)

Setting a Timeline

Finally, there is another important "when" question: When will you finish your study? Are you under pressure to produce results? Is there any specific deadline? Are you limited by your resources? It is important to set a realistic schedule for your work. It may be helpful to work backwards from a deadline, assigning times to each phase of the work, setting aside ample time to plan the study, gather data, and share results.

Summing Up

This chapter was intended to help develop your community health concern into a workable research question. Scoping begins by narrowing your research question and defining the concern: What is the problem? Can you translate your concern into terms of exposure, health outcomes, or both? Whom do you want to include in your study and why? Where is the focus of your investigation—a neighborhood, street, or town? Homes connected to a certain water supply? When did exposures and/or disease occur—is it ongoing? Is there a latency period between exposure and disease onset? Once you have your research question formulated into the terms of a health study and a clear understanding of what you want to know, you are ready to start considering which types of health studies can address your question.

Key Points from Chapter 2

– Understand the difference between an exposure and outcome and how a study can target either or both.
– Epidemiologic studies are time consuming and usually more expensive than other types of health studies because they combine the complexities of an exposure study and an outcome study with the extra difficulty of understanding how one caused the other.
– Simplify your study wherever possible. Remember the questions in Chapter 1: What is your goal, and what do you need from a study to advance that goal?
– The question posed by the study will determine what the study will address.

Further Reading

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Chapter 2 Worksheet: Developing a Research Question

Check the boxes and fill in the blanks using the sample responses as examples.

1. Identifying your concern(s) (**What**):

Are you concerned only about an exposure? ___ yes ___no

If yes, what exposure? _____

Are you concerned only about a health outcome? ___ yes ___no

If yes, what outcome? _____

Are you concerned about a possible link between an exposure and a health outcome?

___ yes ___no

If yes, what exposure? _____

And what outcome? _____

2. **Who** is the focus of concern?

What groups (for example, children ages 5-12, women under age 30, atomic energy workers)?

_____

_____

About how many people do you think are affected? A rough estimate is fine: Fewer than 100? hundreds? A thousand? Tens of thousands? Fill in an estimate for each:

_____ households

_____ adults

_____ children

4. **Where** is the concern? (for example, on my street, the school baseball field, areas near agricultural facilities)

_____

_____

5. **When** did the exposure or outcome (or both) occur?

_____

_____

6. State your research question.

_____

_____

Chapter 3 : A Menu of Health Studies

Which Type is the Best Match to Your Research Question?

"Is there a type of study that is most appropriate for what we are trying to accomplish? Really and truly there is not. . . . Nine out of ten, a health study will be telling you that your mind is playing tricks on you and you do not know what you are talking about."

– Emma, Resident of Louisiana

Considering the pros and cons of study types and knowing what information they can and cannot provide will help you develop a clear research strategy and avoid feeling as frustrated as Emma was. Below we have grouped some sample research questions under appropriate study types. Each type of study is sketched only briefly here. Longer descriptions appear in the next chapter. Community groups are unlikely to undertake three of the study types included here—environmental impact statements, risk assessments, and public health assessments. However, the community's insights and questions may be important in triggering, planning, and evaluating such studies.

Figure 3.1 summarizes the study types and the results they can produce. Use this chapter to match your question to a type of study or to stimulate your thinking about ways to refine your research question. Since only limited information is provided here, this will be a preliminary match. We encourage you to flip back and forth with Chapter 4 to read more about your chosen type of study. If you decide after reading further or talking with community or academic partners that your chosen study type is not a good fit, you can return to this chapter to pick another option.

You may find you have more than one question or that more than one type of study looks like a match to your question. That's OK—maybe you can think of a creative way to combine approaches. In real life, that is often what happens. On the other hand, if none of the questions sounds like your own, you might reconsider whether a health study will help you get what you really need.

Each type of study examines something slightly different, but for the most part they focus on exposures, outcomes, or both. As you will see, studies that focus on exposure or outcome alone tend to be less complicated.

Finally, each study type is shown in Figure 3.2 on the exposure-disease model presented in Chapter 2.

`

Figure 3.1 Summary of Study Types

Study Type ---------->	Results
(1) Mapping	
Exposure mapping	Map(s) of exposure
Outcome mapping	Map(s) of disease distribution
(2) Studies of Exposure	
Environmental monitoring	Concentrations in environmental media
Personal monitoring	Concentrations in immediate and personal surroundings
Body burden (biomonitoring) study	Concentrations in bodily tissue or fluid
Environmental impact statement	Description of environmental changes
(3) Studies of Outcome	
Community survey	Survey responses; may be qualitative
Analysis of registry data	Comparison of community disease or mortality rate with standard rate
(4) Studies of Exposure-Outcome Relationship (Epidemiologic Studies)	
Ecologic study	Correlation between exposure and disease
Cohort study	Relative Risk between exposed and unexposed groups
Case-control study	Odds Ratio between cases (have disease) and controls (no disease)
(5) Studies of Contaminated Sites	
Risk assessment	Characterization of hazard, estimates of health risk
Public health assessment	Exposure evaluation and health effects evaluation using collected data

`

(1) Mapping Studies (p.39)

Where are sources of environmental exposure located?

Exposure mapping can be done either by community groups or by scientists. It helps communities visualize sources of pollution, possibly identifying patterns of exposure. Some exposures are obvious; others will require that you get data from an environmental agency or other source. For example:

- *Some drinking water wells have been closed as a result of contamination. Where are these wells located in relation to people's homes, schools, etc.?*
- *Which neighborhoods are closest to the farms where sludge is sprayed?*
- *Are there childcare centers within walking distance of the highway?*

Where are the diseases occurring in our town?

Disease mapping can be done either by community groups or by scientists, and helps you visualize patterns in an area. However, mapping requires that you already have the data, perhaps collected from a door-to-door survey or looked up in a registry.

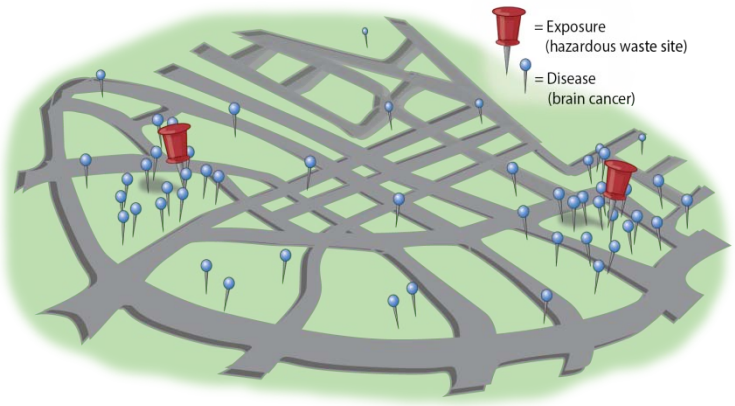
For example:

- *Where on our street or in our neighborhood are the lung cancer cases located?*
- *Where in our town are the greatest number of pedestrian fatalities?*
- *Where in our county are the leukemia cases located?*

Does there seem to be any pattern to the locations of exposures and outcomes in my community?

Just as **mapping** can be used to see the locations of exposures *or* health outcomes in your community, both can be captured on the same map.

- *The west side of town has more cases of brain cancer for its population than other neighborhoods. Does it also have more hazardous waste sites?*
- *Are there more breast cancer cases near the underground plume of contamination compared with areas with no ground water contamination?*
- *Do cases of cardiovascular disease mortality appear to be higher downwind of the coal-fired power plant?*



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(2) Studies of Exposure (p.45)

Are there toxic substances in the environment?

Environmental monitoring looks for and measures concentrations of chemicals or other toxicants in the environment. Depending on the availability of equipment and laboratories, samples of air, water, soil, or food can all be examined for evidence of contamination. For example:

- *Is there lead in my garden soil? How much?*
- *Is there mold in the air I am breathing? How much?*
- *Are there hazardous chemicals in my drinking water? Which ones and how much?*

Have we been exposed to pollutants? Are there toxic chemicals in my body?

A **body burden study** measures chemicals that are in a person's body. By taking samples of body tissue (blood, urine, saliva, hair, nails, or breast milk) some specific contaminants can be measured. These studies answer questions such as:

- *Is there lead in my blood? How much?*
- *Is there mercury in my hair? How much?*
- *Have I been exposed to PCBs? Is there evidence of them in my body?*

What will be the impacts of this land use?

An **environmental impact statement** is intended to describe the environmental impacts of a new development, such as a highway or building, or a modification of an old one, such as capping a landfill. Although this type of study is not strictly speaking an exposure study, it gives information that may be useful in thinking about exposure, by answering questions like these:

- *How will construction of this highway affect water runoff?*
- *How will building a power plant here affect the air quality in this area?*
- *How much will building a parking lot here increase traffic in locations where children are known to walk on their way to school?*

`

(3) Studies of Health Outcomes (p.53)

Are we sick?

A **community survey** can help you learn about what is happening in your area, either by going door to door or by making phone calls. Surveys can answer questions such as:

- *What health problems are residents of our street experiencing?*
- *What health problems are of concern to my neighborhood?*

Are we sicker than other, similar communities?

An **analysis of disease registry data or vital events data** lets you compare death rates or the rates of certain diseases—usually cancer—with those in other areas. For example, registry data can answer the questions:

- *Does our town have a higher rate of lung cancer than the state average?*
- *Does our county have a higher-than-expected rate of childhood leukemia?*
- *Are people dying younger in my city than in other cities?*

`

(4) Studies of the Exposure-Outcome Relationship (p.58)

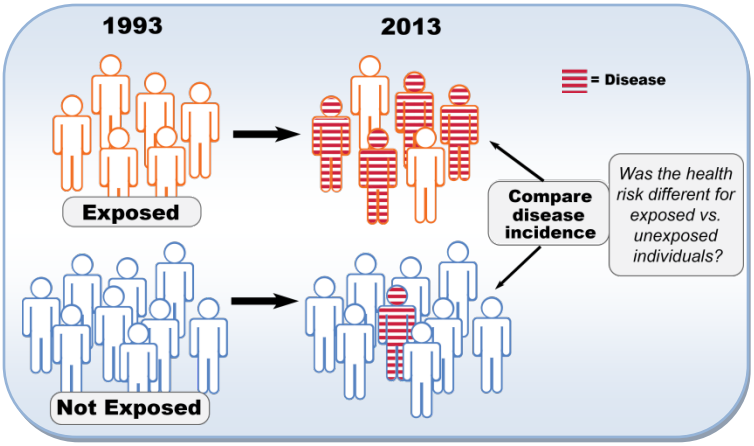
Are there more health problems in places where people are more highly exposed?

An **ecologic study** asks whether there is an association between some exposure and some health outcome across a set of geographic units (for example, towns, counties).

- *When I look at all the cities and towns of the state, do those with higher brain cancer rates also have a heavier burden of hazardous waste sites?*
- *Across the United States, do the counties that host a coal-fired power plant also have higher rates of asthma?*

What is the difference in disease risk among people who had a particular exposure and people who did not?

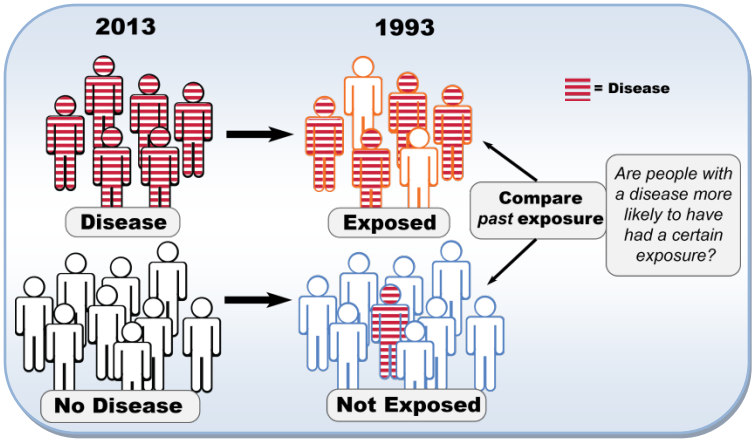
A **cohort study** follows people over time and compares a health risk among people who were exposed to the hazard to the health risk among people who were not exposed. For example:



- *Are the people who lived near a hazardous waste site 20 years ago more likely to have had cancer than people who lived far from the site?*
- *What will happen in the next five years to people who are exposed to this radiation source compared with people who are not exposed to it?*

Are people with a certain illness more likely than other people to have had some specific exposure in the past?

A **case-control study** compares people who have a specific illness or condition with people who do not. Case-control studies may ask:



- *Were adolescents who have learning disabilities more highly exposed to lead paint as toddlers than adolescents who do not have learning disabilities?*
- *What differences in lifestyle, behavior, genetics, or environmental exposures exist between women with breast cancer compared to women from my town who do not have breast cancer?*

`

(5) Studies of Contaminated Sites (p.64)

What chemical exposures are people likely to have from this site? What is the overall level of health risk from this site?

A **risk assessment** characterizes contamination at a site, estimates potential human exposures for a set of exposure scenarios, and provides estimates of the associated cancer risk and non-cancer health hazard.

- *What is the lifetime cancer risk of drinking well water contaminated with chemicals originating from this site?*
- *What is the non-cancer health hazard associated with teenagers' contact with chemicals while trespassing on the site?*

Are people exposed at this site? If so, are they exposed enough to take action? Will this exposure make people sick in the future?

A **public health assessment** looks into the details of exposure at a particular site, such as a hazardous waste site, and provides information from studies that have already been conducted regarding the hazards identified at the site.

- *What are people's actual exposures at this site?*
- *Have people's actual exposures to this site made them sick?*

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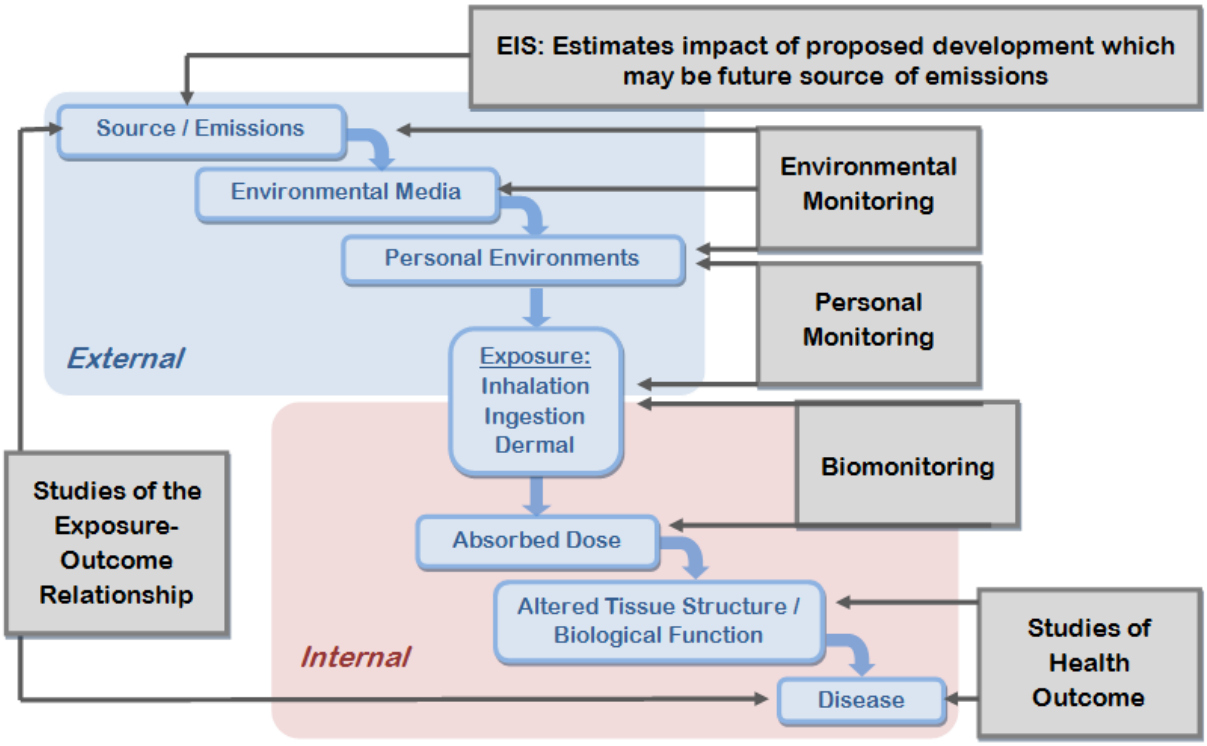
Figure 3.2 What Various Study Types Address in the Exposure-Disease Model



Summing Up

This chapter introduced you to the main study types and offered some examples of questions these studies are intended to answer. This was a preliminary exploration of the options available and an opportunity to see how closely your research question developed in Chapter 2 resembles some of the questions here, and if it fits into these study types. Perhaps you were able to narrow down a few potential options or perhaps you will want to go back and refine your research question. Chapter 4 will delve into more detail about these study types, including aspects of time and cost as well as provide resources to help further your understanding. This background knowledge will help you weigh your study options with a public health professional. Furthermore, familiarity with study designs, strengths, and limitations will inform your expectations for the study's results, if you decide to pursue a study, and give you the tools needed to communicate your study's goals and approach to others.

Key Points from Chapter 3

- Approach the menu of health study types with your research question formulated. Were you able to find a study type(s) with a research question similar to yours?
- Learn more about the study types that appealed to your question in Chapter 4 and return to this chapter if you don't find a good match or if your research question changes.

`

Chapter 4 : More about Each Type of Health Study

"We need to know the different types of health studies. And [researchers should] be direct!"

– Bea, Louisiana

You may now have a good idea of what you hope to learn from a health study and the type of study you need. In this chapter we work hard to be direct as we describe in more detail the 13 specific types of health studies listed on the menu.

Use this chapter like a reference book to accompany the Chapter 3 menu. If you know what you are looking for, such as Cohort Study, then by all means skip ahead. The chapter is organized into five main study categories outlined in Chapter 3:

Mapping
- Mapping exposure
- Mapping Disease
- Mapping both exposure and outcome

Studies of Exposure
- Environmental or personal exposure monitoring
- Body burden / biomonitoring
- Environmental impact statements

Studies of Outcome
- Community survey
- Analysis of registry data

Studies of the Exposure-Outcome Relationship
- Ecologic study
- Cohort study
- Case-control study

Studies of Contaminated Sites
- Risk assessment
- Public health assessment

At the end of this chapter is a summary table that compares the type of result and practical requirements of the various study designs described here. The requirements for time, cost, and expertise given in Table 4.1 (p.72) are only approximate, but they may give you a sense of whether you and your community group need outside support or can undertake the study on your own. We continue to define the term *health study* broadly, to include a variety of studies. In particular, we attempt to answer the following questions about each study type:

- How long might this study take to complete? Months? Years?

Key words

biomonitoring
case-control study
choropleth map
cohort study
community-based survey
controls
cross-sectional
crude
cumulative risk assessment
disease registry
dot density map
dot map
ecologic bias
endocrine disruptors
environmental monitoring
environmental standards
exposure assessment
geographic information system
odds
odds ratio
personal exposure monitoring
prevalence
probability
prospective cohort study
qualitative research methods
rate
ratio
reference concentration
reference dose
relative risk
retrospective cohort study
risk
risk assessment
risk factor
risk management
standardized incidence ratio
standardized rate ratio
threshold

- Can a community afford to pay for this with its own resources, or should it consider finding additional, external funding?
- Can a community group do this on its own? Is this the type of study that typically requires a toxicologist, epidemiologist, or other professional?
- What type of results might this study provide?
- What are the potential drawbacks of doing this study?

What do we mean by "type of results"?

Most of the studies described here yield *quantitative* results—that is, numbers. In some cases the numbers are simply the result of counting and adding up cases of disease. But as we have tried to convey, some kind of comparison is built into the design of most health studies. This is because simply measuring exposures or counting cases does not tell us whether what we are observing is unusual. In some cases we have to take the numeric result of our study and then compare it to a standard or number considered acceptable by regulatory agencies. In other instances, the more complicated study designs (epidemiological studies) have the comparison built into the study. Consequently, the result of the study is a more complicated calculation of odds, risk, or probabilities. The types of result you may expect for each study are briefly summarized here and described in Chapter 6 in greater detail.

Not all studies result in quantitative or numeric measurements. Some *qualitative* studies provide us with data in the form of narratives. For example, interviews and focus groups can produce information that may be very important and reflective of community concerns, but is not typically examined by environmental health scientists.

Mapping

A map is a way of visualizing patterns of exposure, illness, or both. The data for mapping health or environmental problems sometimes come from a community-based survey, but sometimes the mapping itself sparks residents to undertake a health survey. Mapping can be a very powerful tool—a picture truly is worth a thousand words—so it is especially important that they be accurate. This does not mean maps must be fancy. You can start with a map of a town that you might buy or draw yourself. Freely available electronic tools, such as Google Maps/Google Earth, have greatly expanded the possibilities for making and sharing maps electronically. You may even have access to computer software designed specifically to manage data linked to geographic locations and to create maps from the data. This type of software is called a **geographic information system (GIS).**

1. Mapping Exposure

GIS is a very sophisticated tool for making maps but a simple handmade map may be just as powerful. Whether you make your map using a GIS or a pencil, you want to be sure that your map presents your message in a way that is effective but not misleading.

Community groups commonly use maps to help identify sources of environmental pollutants or even routes of exposure. A simple map locating polluting facilities, or a map indicating the location of your town's drinking water wells, may help you visualize

patterns of pollution in your community. This type of map is called a **dot map**. The dot map in Figure 4.1 shows the locations of hazardous waste sites in Massachusetts.

Several publicly available databases published by US government agencies include information about specific sources of environmental exposures that can be useful in mapping pollution. The US EPA's Toxics Release Inventory (TRI) reports the quantities of several hundred toxic chemicals released by individual industrial facilities each year, and these data are available online. The US EPA's website also lists sites on the National Priorities List (that is, Superfund sites), with information about contamination and the status of cleanup; using latitude and longitude information from this website, you could plot these facilities in Google Maps. In addition, many states have publicly available environmental databases. In Massachusetts, for example, waste sites can be identified, including TRI sites, waste transfer stations, active and inactive landfills, and con

firmed federal and state-designated hazardous waste sites. The state also maintains a list of water supply wells closed due to contamination, and some towns monitor water supplies for certain pesticides used in agriculture. Residents can use this data to map exposures and environmental concerns in their communities, as in Figure 4.1. Dot maps provide preliminary information about potential exposures and are a good first step before undertaking a study that measures exposure or maps disease in a neighborhood.

For more details on data sources, see *Appendix: Accessing environmental health information*.

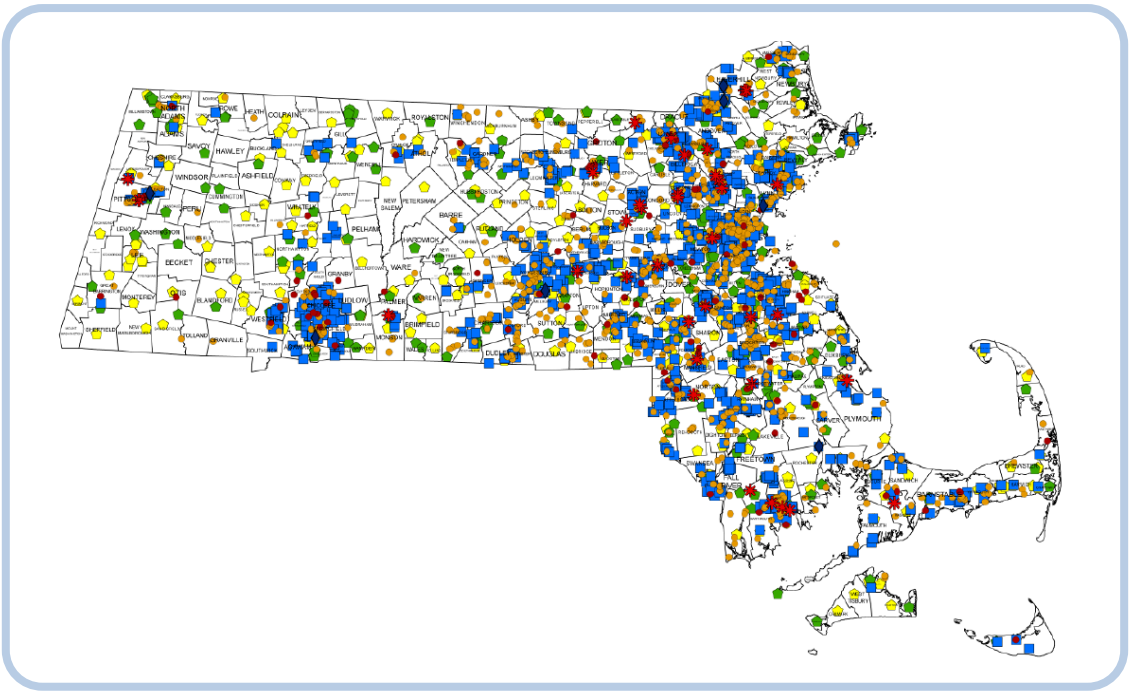


Figure 4.1: Hazardous waste sites, landfills, large-quantity waste generators, and solid waste incinerators in Massachusetts (data from Massachusetts Office of Geographic Information, 2010)

2. Mapping Disease: Cases or Prevalence and Rates

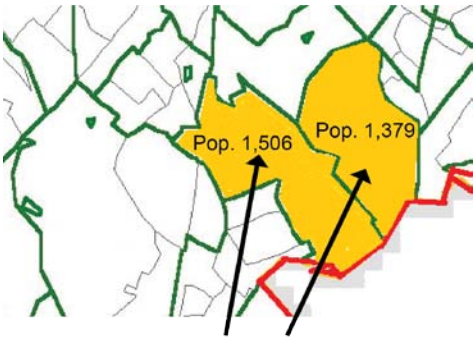
Two common methods of mapping disease are 1) dot maps showing the locations of cases or 2) shading maps reflecting different rates of disease across communities or geographic areas.

► Mapping Cases

> *"[Our group's health study] grew out of a simple cancer map that was drawn one night in a neighborhood meeting of over 300 people. In five streets, there were 110 pins on the map with someone in each household with active cancer at the time. And what we were trying to do is lay the groundwork to get the [Massachusetts Department of Public Health] to help us to do a study."*
>
> — Mike, Resident of Lee, Massachusetts

Mapping cases of illness is often the first step community members take towards conducting a health study. Most famously, the Woburn study (see sidebar, Chapter 2) started when concerned residents began placing pushpins on a city map to indicate cases of leukemia. This simple dot map showed clear patterns in the location of leukemia cases, which the community was eventually able to trace to solvent exposure in their drinking water. **For more details on the Woburn story, see "A Civil Action" under *Further Reading*.**

If you want to compare the number of sick people in different areas, then the populations of each area should be similar for this comparison to make sense. For example, if you mapped many cases of illness in a densely populated neighborhood but found no cases in an area where people don't actually live (for example, a large industrial park), this difference is not meaningful—although it may look impressive on your map. It may be helpful to find a map of the small Census units in your community (census tracts and census blocks) and then look up US Census data on the populations of these areas.



For a proper comparison, the populations of each area should be similar.

If you do find what looks like a cluster of cases, this does not tell you *why* there is a cluster. Community groups usually find that identifying a cluster leads to more questions about why there is a cluster, possibly suggesting an environmental problem—which is why mapping might lead to a bigger or better study. (See the discussion of clusters, and the sidebar about the Woburn case, in Chapter 2.) For most local community efforts, a dot map is a good start.

Sometimes, especially when plotting common diseases like asthma, there are too many cases to make a dot map practical. In such a case, mapmakers might use one dot to represent ten cases of asthma, or 50. On this type of map (called a **dot density map**), the dots no longer give exact locations of cases; instead, they refer to cases within some geographic area, like a county or a zip code. Although this map may give you a good sense of where disease is more common, it is more difficult to interpret without knowing the population of each area where there is a dot.

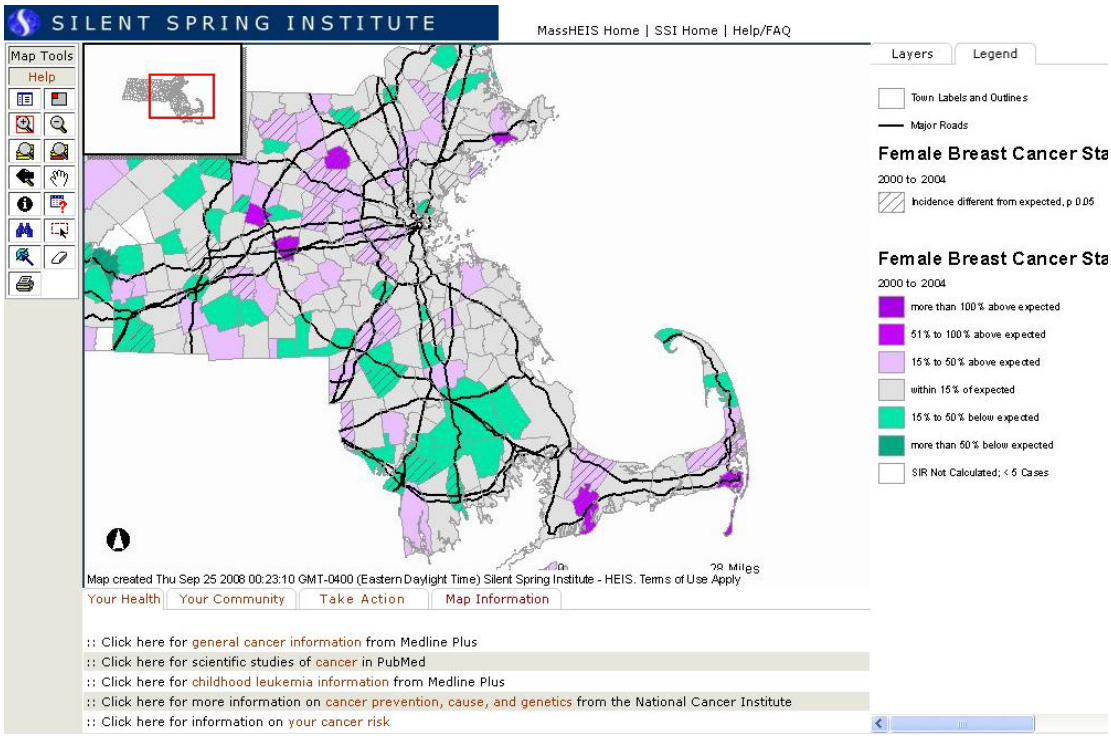
► Mapping: Prevalence and Rates

Comparing different communities with dot maps may be misleading, since only the *number of cases* is visible, while the underlying populations may be very different. Instead, we may need a map that presents the proportion of people with the disease—the **prevalence**—or the number of new cases of disease—the disease **rate**.

Most often, we present this type of data with a map in which different regions are colored or shaded to represent some information about the region. This type of map (technically known as a **choropleth map**) is familiar from election results, where shading represents political parties. If we were to shade different regions according to asthma prevalence—using darker blues for areas with higher asthma rates and lighter blue for lower rates—we could compare disease in different populations. The resulting map is extremely useful for showing how the burden of asthma in your community compares to other communities, rather than for creating a picture of where asthma is located in your community. Although this type of map is often made using GIS, it can be created by hand if the number of locations is not too large.

Many sources of data and mapping tools are available online to help you compare disease prevalence or rates. For example, many state cancer registries have online mapping tools with which you can visualize cancer rates by county, and a number of environmental health organizations have tools to help you map and analyze this data (Figure 4.2). (See *Studies of Health Outcomes* below for more information about using cancer registry data.)

Figure 4.2. Map of breast cancer rates in Massachusetts by county (http://www.silentspring.org).



3. Mapping Both Exposure and Disease

Overlaying a map of disease on a map of environmental hazards sounds like a commonsense way to detect environmental causes of disease. In practice, however, this turns out to be more complicated for two reasons.

1) There may be a considerable time lag between the exposure that began a disease process and the diagnosis of the disease. As already noted, cancer in particular has a long latency period. This means that the exposures of interest for today's cancer cases are not today's exposures but those of 20 or 30 years ago.

2) As time passes, people move around. Some people who were exposed years ago have moved away and will not appear on your map as cancer cases, even if they now have cancer. And some of today's cancer cases did not live in your community 20 or 30 years ago when their cancers began. Maps do not reflect individuals' movements into or out of a community over time. A citizen group in Monticello, Utah organized a mapping study in their community to investigate a suspected cancer cluster by mapping cases of lung cancer and exposure to uranium (see side bar on p.45).

Community groups are most likely to be mapping the locations of specific cases and specific facilities, all within a relatively small area. In this situation, the dot map is the most useful format to start with. In some cases, however, you may be able to combine map types—say, using a shaded map of air pollution as a base map, and adding information on asthma cases with dots. Remember, a map is just a way to visualize your data. Be creative: Even a choropleth map can be made by hand using colored pencils. If you do not have access to GIS, don't let this stop you from making maps.

Mapping Studies at a Glance:

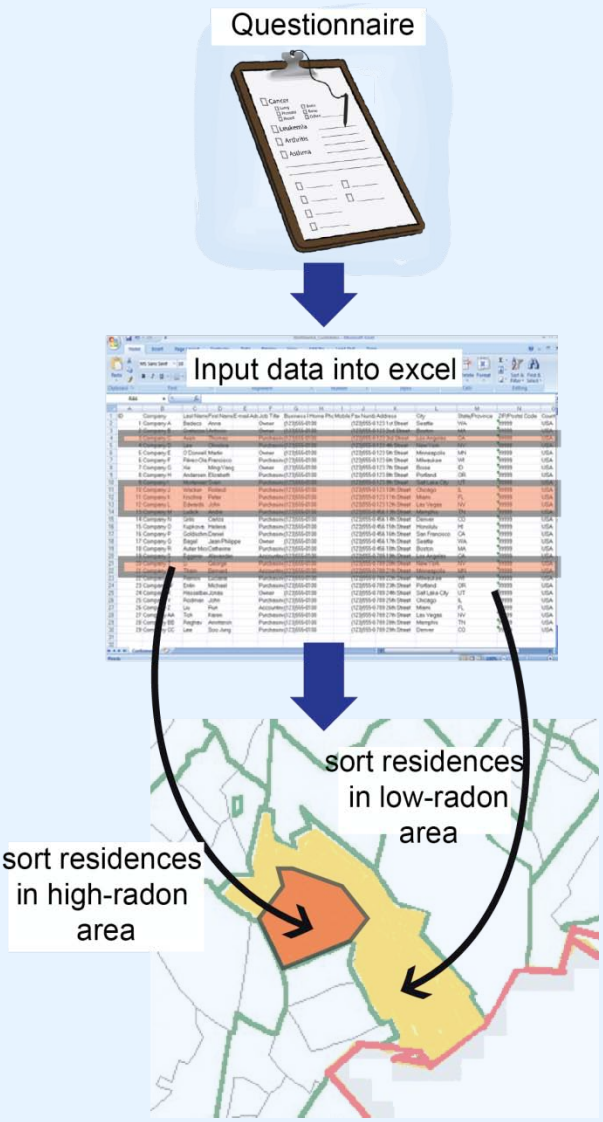
Study Type	Type of Result	Time	Cost	Expertise
Mapping of exposure, health outcome, or both	A visual representation of the patterns of exposures or outcome.	Can be very quick (hours) or longer (weeks or months), depending on the availability of the data you want to map and the type of map you want to create.	Can be free, can cost up to $1000	Some expert advice, maybe via phone or library; maybe access to GIS and someone trained to make maps.

Sidebar: A case-control analysis using data from a community survey in Monticello, Utah

In 1990 Monticello had a population of about 1,800, mostly Caucasian with some Native and Mexican American residents. The community is the site of a former uranium mill that received ore from several uranium mines in southeastern Utah from 1940 through 1962. Tailings—the wastes of milling the uranium ore—accumulated in large piles on the mill property, and dust from these tailings piles blew throughout the town for many years. As a result, there was considerable contamination of nearby residential property, grazing lands, and streams. In addition, mill tailings were used to make cement sidewalks and the grout used in fireplaces and chimneys of some homes.

The mill eventually closed, and the property was taken over by the U.S. Department of Energy until a plan for remediation could be put into effect. The town was designated a Superfund site, and widespread environmental testing and mapping were carried out in the early to mid-1990s. A cluster of leukemia had been identified in the late 1960s in one small part of town a short distance from the mill. This cluster was investigated by an epidemiologist from the Utah Department of Health, but the number of cases was small and no conclusions were drawn about exposure to uranium dust or other potential causes.

Monticello is a close-knit community, and many residents attend the traditional Fourth of July picnic. In the early 1990s, two concerned citizens, one of whom had lost her husband to cancer, decided to conduct a community health survey at the picnic. They developed a short questionnaire asking about residential and medical history, including cancer. The survey also included a simple question about smoking (smoker or nonsmoker). Although more than 250 questionnaires were completed, community residents were concerned because they did not have a plan to analyze the information they had collected. Fortunately, staff of the Boston University School of Public Health were working on a cooperative agreement with the Agency for Toxic Substances and Disease Registry in the mid-1990s, and they contacted the Monticello volunteers and offered to work with the citizens to analyze the data.



The first step was to enter the questionnaire results into a spreadsheet so that the individual responses could be sorted by residence, health problem, age, sex, smoking status, and so forth. Together, the residents and the researchers decided to focus on lung cancer and other radiation-related cancers in the analysis. Because a map detailing radon levels in soil had been created during the remedial investigation, each residence could be classified as being located either inside or outside a high-radon zone. Clearly, the data were not complete, …

Sidebar: A case-control analysis using data from a community survey in Monticello, Utah (*continued*)

…nor detailing radon levels in soil had been created during the remedial investigation, each residence could be classified as being located either inside or outside a high-radon zone. Clearly, the data were not complete, nor were the questionnaires from a random or scientifically drawn sample of the population. Nevertheless, the citizens had collected many responses and were anxious to see what, if anything, could be learned about disease patterns in Monticello as a result of their work.

The analysis documented an increased *odds* of lung cancer among those who lived in the high-radon area of the town, after accounting for the effect of smoking. Thus the analysis was suggestive of an association between residence in the high-radon area of Monticello and increased risk of lung cancer, although the report would not be considered publishable by most scientific journals. The point of the survey and the analysis, however, was not publication but action to prevent harmful exposure. The results were made public at one of the periodic community meetings about the progress of the remediation. Since the remediation plans were already under way, and many Monticello residential properties had already had uranium-contaminated soil removed, the survey simply strengthened the rationale for remediation.

Adapted from:
Clapp, R. W. (2002) Popular epidemiology in three contaminated communities. *Annals of the American Academy of Political and Social Science, 584,* 35–46

Studies of Exposure

Studies that attempt to quantify (either by measurement or estimation) human, environmental and even wildlife exposure to chemicals are generally referred to as **exposure assessments**. Two basic approaches are described here: measuring chemicals in the environment and measuring chemicals in people. Environmental impact statements are also included here; although they are not studies of exposure, they provide information about federal plans that may determine future exposures.

1. Environmental or Personal Exposure Monitoring Study

"We went out and did our own air sampling and because of that now the governmental agencies cannot send us away any more. They have to pay attention because the proof is in the pudding."

– Laura, Calcasieu Parish environmental activist and mother of two, Louisiana (Louisiana Bucket Brigade)

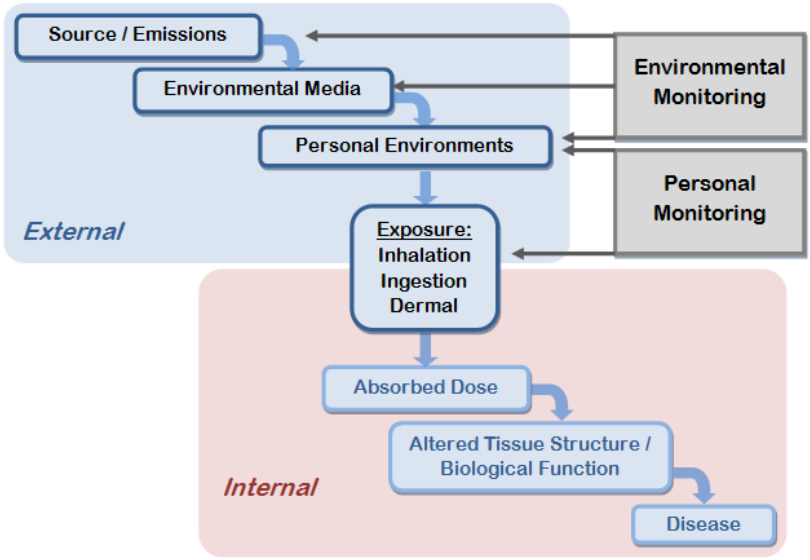
Previous studies conducted by scientists around the world have created a body of evidence documenting that certain environmental contaminants are hazardous to human health. For example, lead, mercury, PCBs, and dioxins are all widespread in the environment. All these chemicals are also well known to cause specific health problems.

One way to protect people from the effects of these contaminants is to prevent exposure; and one way to prevent exposure is to know where the contaminants are found in the environment, and at what concentrations. This is done by taking samples of air, water, or soil and analyzing them for the presence of specific chemicals. This is called **environmental monitoring**, especially if it is done routinely or more than once.

For example, the US Environmental Protection Agency has stationary air monitors installed across the nation to measure concentrations of specific air pollutants. The EPA is responsible for informing cities and states when measured concentrations exceed regulatory standards, thus posing a hazard to human health.

By measuring the concentration of chemicals or pollutants in the air we breathe, the water we drink, the soil in our gardens, or the dust in personal environments such as our homes or workplaces, scientists are able to estimate the quantity of a particular chemical that actually reaches an individual child or adult and how it may contribute to disease (see Figure 4.3). Sometimes this is done in the very immediate and specific environment of an individual. For example, working with researchers at Columbia University School of Public Health, high school students in Harlem, New York, attached air monitors to their backpacks to estimate how much diesel exhaust they inhaled on their daily route from home to school and back. This is an example of **personal exposure monitoring**, as data are collected by individuals measuring exposures in their immediate and personal surrounding. This type of monitoring is common in studies of workers in occupational settings.

Figure 4.3 Exposure-related disease model: Environmental monitoring



Community members can do some types of monitoring themselves at a relatively low cost. A famous example is the "Bucket Brigade." Using a specially designed bucket, community groups can take samples of air in their community and send the samples collected in a plastic bag to a lab for analysis. Denny Larson, a creator of the Bucket Brigade, explains that government monitoring devices are not typically located in highly industrial zones. Instead, they are often 10 or 20 miles away and may be upwind of the pollution sources. Thus when the public complains about bad smells and choking fumes, the regulatory authorities and industries may disagree and suggest the community needs data to demonstrate the problem. Bucket brigades

have been active in California, Ohio, Louisiana, Pennsylvania, and Texas with a proven track record of changing air pollution controls.

Once you've measured the amount of a chemical in the environment, how do you know if it's enough to cause a problem? Modern chemical methods can detect many chemicals at extraordinarily small concentrations (often in parts per trillion). Scientists often disagree about what human health effects occur at such low levels, if any. Ideally, you could compare your monitoring results to some reference or standard established by EPA or a state agency. Anything above a standard would indicate exposures that are considered to be unsafe (or at least not allowed). For more details, see sidebar, *Comparing Your Results to Standards on page 52.*

Environmental Monitoring at a Glance:

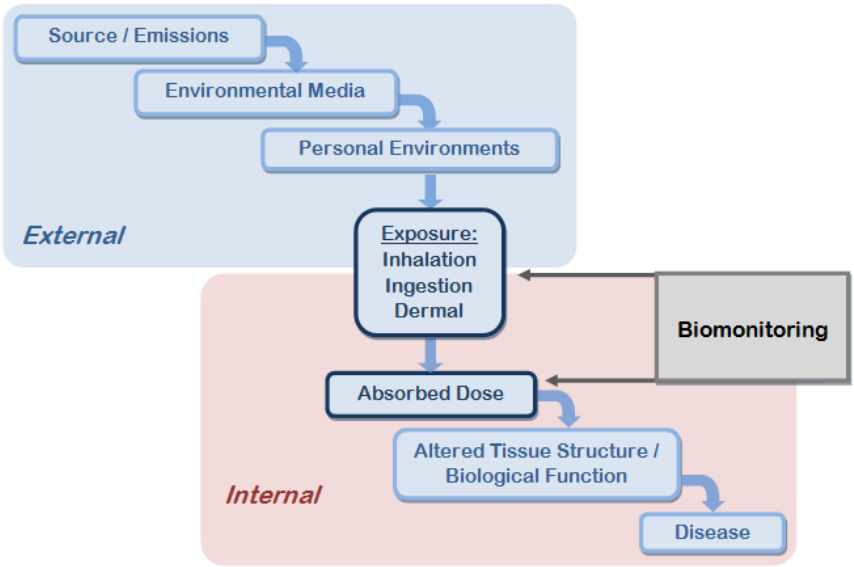
Study Type	Type of Result	Time	Cost	Expertise
Environmental Monitoring Study	Concentration of pollutant in environmental media (e.g., air, water, soil).	Probably six months to one year, including planning time	Varies; depends on what is measured, the equipment needed to measure, and laboratory analyses.	Sampling equipment and how to use it, depends on what you want to measure

2. Body Burdens and Biomonitoring

"It's very likely each of us is walking around with a cocktail of chemicals in our bodies."
– Erika Schreder, staff scientist for the Washington Toxics Coalition

There are tens of thousands of chemicals in our environment today. These chemicals can enter our bodies in the food we eat, the water we drink, and the air we breathe. Some chemicals can be absorbed through the skin. Scientists can now measure chemicals in our bodies in very small amounts. Measuring chemicals in the body is called **biomonitoring**, and it is being used more and more, for a number of purposes.

Figure 4.4 Exposure-related disease model: Biomonitoring



Biomonitoring can measure chemicals in body fluids or tissues. Measurements can also be made in something that is produced by the body, such as urine, breast milk, exhaled air, or even hair or fingernails. The concentration of a chemical detected in these ways is related to a person's body burden of the chemical—the total amount of the chemical the person is carrying in his or her body. Some chemicals rapidly change form once they enter the body, so sometimes biomonitoring methods don't measure the chemical itself but rather breakdown products, often referred to as metabolites of the chemical. You may think of them as sons or daughters of the "parent compound."

You are probably familiar with some common examples: We measure blood lead levels in children to make sure they are not exposed to unsafe levels of lead; we test people who appear to be driving while drunk, using a breathalyzer to measure alcohol in their breath; and we test urine samples for chemicals that indicate drug use. Above all, it is an important tool in identifying potentially harmful chemicals in people's bodies. Biomonitoring can help us understand what a person has been exposed to and how much of a chemical someone may have absorbed. Having this information could help people lower their exposures. In some instances, as with exposure monitoring, you may be able to find government standards (**reference doses**) which indicate what level of exposure is likely to be safe (see Sidebar, *Comparing Your Results to Standards,* p.52).

Unfortunately, for most chemicals, there is no consensus on what the levels found in peoples' bodies mean for their health. When a chemical is taken into the body, several things may happen. The chemical may be eliminated from the body immediately. Or it may be taken into the bloodstream, changed or broken down into other chemicals, or stored in body tissues. Some chemicals are stored in fat or bone and can accumulate in the body for years. Other chemicals are broken down rapidly and go out in urine within hours or days of exposure. It is harder to use biomonitoring to measure exposure to chemicals that break down quickly in the body. This is because the level of a chemical in blood and urine changes so quickly that the timing of testing is critical.

Biomonitoring has been used for many years to see if people are exposed to unsafe levels of chemicals in workplaces. But more and more, biomonitoring is being used for other purposes, partly because of advances in technology over the last 15 years.

Surveillance biomonitoring measures levels of chemicals in the general population rather than in a small group of people in a study. The only US national surveillance biomonitoring program is run by the US Centers for Disease Control and Prevention (CDC), and is designed to give information on what the average person in the US might be exposed to (See Chapter 7).

In recent years, some community groups have used biomonitoring, often working with university or government researchers. Usually such efforts stem from the belief that a local polluter, such as a manufacturing plant, is causing health problems. By showing higher-than-expected exposures, they hope to strengthen their call for cleanup and medical help.

For example, Anniston, Alabama used to be the site of a manufacturing plant that contaminated the area with chemicals called PCBs. A local community group worked with federal and state government agencies to collect blood from residents and test it for PCBs. The attorneys who were suing the company on behalf of residents arranged to test thousands more people. Anniston residents were shown to have higher PCB levels than would be expected, based on surveillance data from a broader population. The community group is using this fact to call for both cleanup

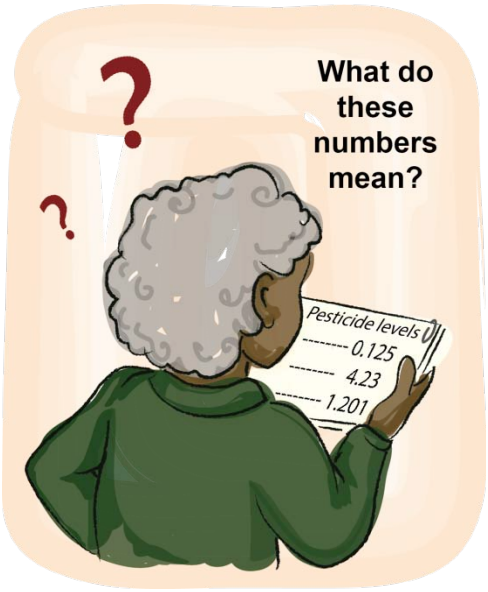
and compensation. Still, nobody knows how PCB exposure has affected the health of Anniston residents—or may in the future.

Environmental advocacy groups have also used biomonitoring to make the public more aware of chemical pollution. Hoping to make the issue newsworthy, these groups have tested small numbers of people—some famous and some ordinary. In 2003, the Environmental Working Group released *Body Burden: The Pollution in People*, a report that tested nine people for 210 chemicals. Later studies by the Environmental Working Group tested breast milk and the blood from newborn babies' umbilical cords. A May 2006 study by the Toxic Free Legacy Coalition in Washington tested the hair, blood, and urine of 10 Washington residents and used the results to call for reform of US chemical laws.

While these biomonitoring studies or projects do demonstrate that we all have foreign chemicals in our bodies, it is often unclear what the results mean for an individual's health. For most of the chemicals we can measure in our bodies, we do not have enough scientific information to say what levels cause harm or what the health effects may be. This sort of information comes from scientific studies, which can take years to conduct and even then may not give clear results. The mere presence of a chemical in the body does not mean it is causing harm. On the other hand, usual or average levels are not necessarily without risk or even without adverse effects.

This uncertainty creates difficult challenges. A study participant, knowing that his or her body has "elevated" levels of a chemical, may become confused and anxious about health risks. And, when study results are reported in the media, they can be confusing to the general public—who may want to use the information to make choices about products to buy or foods to eat.

In thinking about the ethical aspects of biomonitoring, it is important to consider how biomonitoring could harm individuals or communities. An individual might face a small risk of physical harm from having blood drawn. There could be emotional harm from not knowing what health problems might result from measured levels of a chemical. And many kinds of harm could result if a person's employer gets test results and uses them to make decisions about the individual's job. Similarly, testing a group of people, such as residents of a neighborhood where there is pollution, can lead to harm. The community may be stigmatized or discriminated against, or may see their property values go down (See Chapter 5). On the other hand, biomonitoring has great promise for telling us more about our exposure to chemicals.



Environmental or personal exposure assessments and body burden studies are most often used to characterize the level of exposure in a community. In these cases, just a handful of samples might be enough to give a rough idea of exposure levels. Body burden samples in particular can be difficult: They are often expensive to analyze; they require expertise; they may be invasive or even dangerous; and they may involve other difficulties (for example, getting the appropriate legal consent of the participants). Fortunately, just a few samples from different people may be enough to draw a comparison with the average (background) exposure or with other exposed populations.

Body Burden/ Biomonitoring Studies at a Glance:

Study Type	Type of Result	Time	Cost	Expertise
Body Burden/ Biomonitoring Study	Measure of concentrations of chemicals (e.g., parts per million of a chemical in blood) will tell you about exposures but not about health outcomes. Concentrations may be compared with national averages	Months, depending on how many people	Testing can cost up to $1000–2000 for some chemicals per a person. However, for certain chemicals with known associated health outcomes (for example, lead) people with health insurance may get tested by their doctors.	Medical expertise required for testing, laboratory analyses, and usually environmental health expertise required for interpretation.

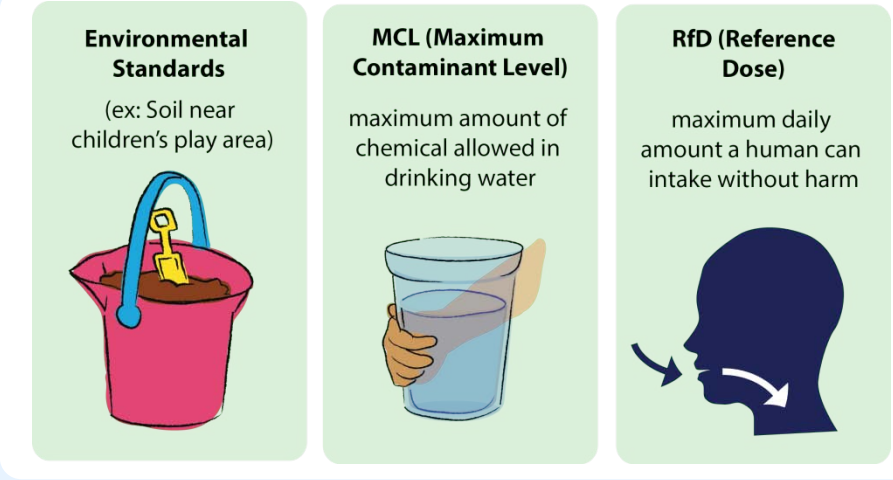
Sidebar: Comparing Your Results with Standards

Often when interpreting data on chemical concentrations found in the environment or in an individual's body, you will want to compare what you find with what is considered a "normal" or "safe" level. Regulatory agencies may have published exposures considered unsafe as defined by **environmental standards** or **reference doses or concentrations**.

Environmental standards or reference concentrations usually define concentrations considered safe in a particular environmental media (e.g., water or air) and should be interpreted according to how people come in contact with that media. For example, a state agency might publish a standard for the concentration of lead allowed in soil in the front yard of a home, and another, more stringent standard for the concentration of lead allowed in soil used to grow vegetables. These standards take into account different routes of exposure and different uses of the soil (consider the exposure model we discussed in Chapter 2).

Another example of a set of environmental standards are the Maximum Contaminant Level (MCL) standards created by EPA to set the maximum amount of a chemical legally allowable in drinking water. For example, the MCL for arsenic is 10 ppb (parts per billion). If you measure arsenic in your drinking water and find concentrations above the MCL, action must be taken. *In general, environmental standards are enforceable legal limits.*

In contrast with a *concentration* in the environment, a *dose* measures the amount of a hazardous agent introduced into the body in a given time period (see Chapter 2). Measurements of doses require somewhat more information than environmental concentrations: for example, knowing a person's daily dose of arsenic requires knowledge of the amount of arsenic inhaled or ingested, such as in drinking water (the environmental concentration), as well as detailed knowledge of the amount of water that person takes in each day (on average). Doses can sometimes be estimated from biomonitoring data. As a standard for comparison, the US EPA publishes a **Reference Dose** (or **Reference Concentration**, abbreviated **RfD or RfC**) for many chemicals. The reference dose is the *maximum* amount a human can take in, every day, on average, without suffering any adverse health effects. That is, the reference dose is intended to be a *safe* dose of a chemical to which people may be exposed without harm for their lifetime.



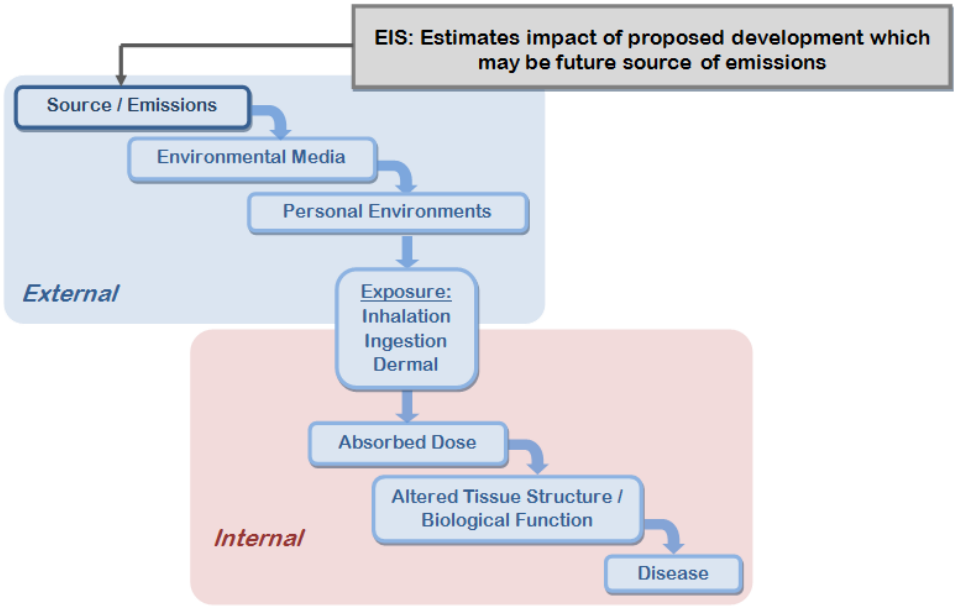
A reference dose, unlike an environmental standard, is not usually enforceable by law. However, if an exposure assessment demonstrates that a person is likely to be exceeding the reference dose, an agency may be forced to take action. These data will be more powerful with biomonitoring data demonstrating that, in fact, the person has been exposed and that concentrations of the chemical can be measured in their body.

Environmental standards are set by many state and federal agencies. The details of standards, as well as the scientific research backing them up, is typically available on the web. For more information on where to get standards and the agencies that publish them, see Chapter 7.

Environmental Impact Statement

Strictly speaking, an Environmental Impact Statement (EIS) is not a study of exposure. But we include environmental impact statements in this guide because they may ultimately affect exposures to people, and community groups are often in the position of having to interpret them. An EIS is an evaluation of a proposed action—such as the construction of an incinerator, power plant, highway, train tracks, or landfill that is to be located in a community—with a consideration of alternatives. Federal law written in 1969 under the National Environmental Policy Act (NEPA) requires that an EIS be produced for any action *by a federal agency* that may have significant environmental impacts. Many states have similar laws for actions by state agencies.

Figure 4.5. Exposure-related disease model: Environmental Impact Statement



Environmental Impact Statements are often published in the Federal Register and the public is given an opportunity to comment. The examination of alternatives is often where community groups can participate, since what residents and government agencies consider to be viable alternatives may not be the same. It is also important that the community participate in identifying possible negative effects of a proposed action that may not have been included in the EIS, such as social effects that are not easy to quantify. The results of an EIS are likely to directly influence decisions on whether or not to proceed with a proposal.

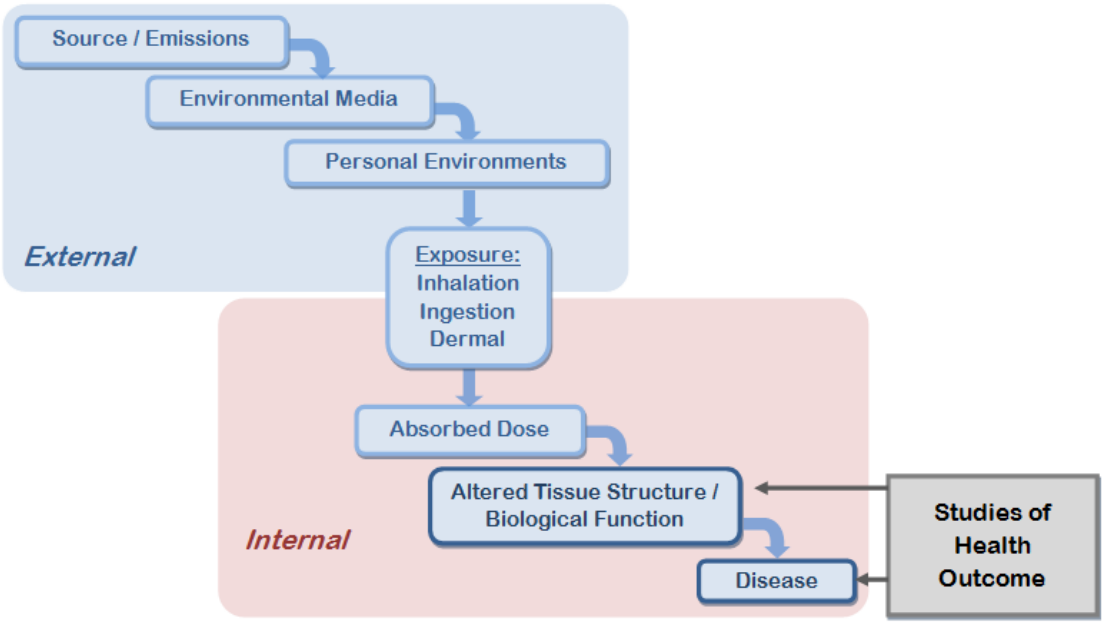
Environmental Impact Statements at a Glance

Study Type	Type of Result	Time	Cost	Expertise
Environmental Impact Statement†	description of environmental changes	1-2 years	Several thousand or more	Produced by a regulatory agency

Studies of Health Outcomes

An epidemiologic study can look at patterns of disease in a population, or disease frequency, by gathering health data on individuals in a community. Two epidemiologic approaches described here are simple studies of health outcomes. One relies on the collection of data using surveys of individuals or families; the other considers rates of disease in a population using existing information, usually collected by government agencies. In addition to epidemiologic approaches, simple mapping can be a highly effective tool for understanding local patterns of illness, as already described.

Figure 4.6 Exposure-related disease model: Studies of Health Outcomes



1. Community Survey

I initiated the health study... went around and got the surveys from door to door, and we all know how horrendous that can be. . . I then, with the aid of my neighbor and dear friend, went to Senator Kennedy's office and got to speak with his aide, who heard the story, felt that there was a reason to have a health study and convinced [Kennedy] of it. ...we had 81 families involved; every single person's medical history dating back 30 years.

– Rosie, Western Massachusetts

Large community health survey efforts—in which community members respond to a questionnaire about their health—are often conducted by community members, sometimes with the help of scientists. Health surveys that are initiated and conducted by community members—like Rosie, quoted above—can be very useful for documenting community concerns and health problems. Such **community-based surveys** can influence decision-making that may result in the clean-up of a site, or can lead to further studies to identify the source of a health problem. A community health survey may generate a large volume of information, and some expertise in data analysis may be needed to make sense of it all. The sidebar on p.45 describes an example of the effectiveness of a simple community health survey conducted by two residents in Monticello, Utah, concerned about a cancer cluster.

There are several potential drawbacks of community surveys. For one, they do not include residents who have moved away from the community, unless a special effort is made to track down past residents. They also do not usually include a comparison population, to give some context for the responses of community members. Some surveys are basically **cross-sectional studies**—that is, they ask questions about both exposures and health outcomes at same time—and this is an important limitation, since exposures precede the outcomes to which they are linked, sometimes by many years. However, depending on the exposure of interest, it may be possible to collect data on past exposures and give some temporal context to a specific exposure and adverse health outcome.

Surveys can be distributed on paper or can be computer-based.

Reports about community-based surveys are rarely accepted by scientific publications and are often attacked as unscientific. This is usually because the number or respondents is small, and the respondents are not a random sample of the population (which may result in confounding or bias; see Chapters 5 and 6 for an explanation of why these concerns matter). Further, many scientists tend to assume, rightly or wrongly, that if a community member is asking a question, he or she might steer the respondent's answer in a direction that would help the community group achieve some goal (for example, demonstrating that something is making people sick). Still, community-based surveys *can* provide a lot of information. Usually surveys are designed so that people check boxes and answer multiple-choice questions. Such surveys do not require a lot of handwriting, and the data can be analyzed quantitatively (that is, by counting answers).

However, some questions may be open-ended (without predetermined responses). This technique is exploratory, and the information they yield is descriptive, rather than numerical. These methods are known as **qualitative research methods**. Such questions result in qualitative data and stories that may be very important and relevant to community concerns; typically, environmental health scientists consider such information to be "anecdotal" and not representative of the population.

Community Survey at a Glance

Study Type	Type of Result	Time	Cost	Expertise
Community survey	Lots of data. How you analyze it will depend on the questions you want answers to	You probably want to consider six months to a year at a minimum, including the time to design the survey, administer it and analyze the data. The size of the study population and the length of the survey will also affect study duration	Lots of time, the cost of paper and photocopying, possibly postage	It will be helpful for the community to get a professional help with developing and analyzing the survey, even if volunteers actually collect the data (i.e., go door knocking).

2. Analysis of Disease Registry Data or Vital Events Data

When the Marblehead cancer registry was [published] . . . we had statistically significant rates of breast cancer, melanoma and leukemia. . . . That ended up being a local bombshell. . . . That galvanized the local cancer prevention project. It gave everybody a reason for acting. It gave instant credibility to people who were emotionally concerned about something.

– Elissa, Marblehead, Massachusetts

One way to begin asking questions about your town's health is by looking at databases of certain health outcomes in order to evaluate whether rates of disease are elevated in a community compared to others. Databases of cases of a disease diagnosed by a physician are called **disease registries**, and they are usually managed by a state or federal agency. The most useful registries are population-based: that is, they try to include all the cases of a particular disease from a defined population, such as the population of a state. For example, in each state, cancer cases are reported to a central statewide registry from various medical facilities, including hospitals, doctors' offices, radiation treatment facilities, surgical centers, and pathology laboratories. This information includes the type of cancer diagnosed and its location or site within the body (for example, lung, breast, colon), the severity (stage) of the cancer at the time of diagnosis, and in some cases the kinds of treatment that patients receive. In Massachusetts cancer statistics—at the city or town level for multi-year periods—are regularly published by the Department of Public Health. Usually when cancer statistics are published, each city or county is reported as compared with the state, for a particular type of cancer or all cancers.

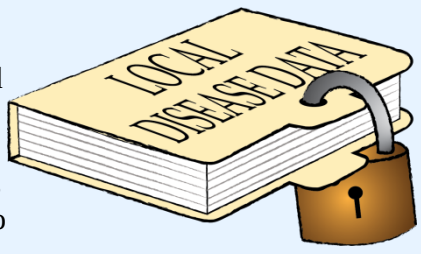
Case data are not published for small areas (such as neighborhoods) or short time periods because the cases are judged to be potentially individually identifiable and often there are very few cases of any particular cancer. Members of the public might obtain lung cancer data at the town level, for example, or data for a period of years, but they cannot obtain individually identifiable case records. Keep in mind that there is a time lag before cases are entered into a registry, and they don't always capture cases of people who move out of state or are just outside the area included in the registry. To be granted permission to use individual-level data, researchers pledge to maintain its confidentiality. Funding and support for these cancer registries comes from the states and from the US Centers for Disease Control & Prevention.

More on protecting data

"The cancer incidence data was owned– lock, stock, and barrel– by [the State Department of Public Health], and they wouldn't release it. They'd release averages across big chunks of town, but nothing we could map."

--Frank, Natick, Massachusetts

Getting information from the government is not easy if government officials do not want you to have the information or if they are simply understaffed. Furthermore, if you are concerned about cancers in your particular neighborhood, the cancer rates for your city or town may not reflect a problem in your small area. In order to protect the identities of people with cancer, states are often reluctant to provide disease data that are more specific to location (for example, census tract, neighborhood or street).



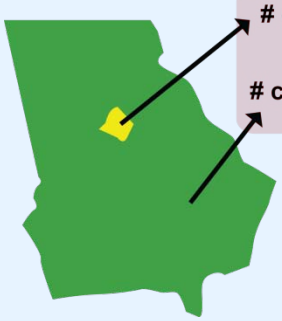
Other than cancer, the list of disease registries varies from state to state. For example, some states have registries for autism, adult blood lead level, trauma, occupational lung disease, or other health outcomes. In Massachusetts, where there is concern about high occurrence of lupus (systemic lupus erythematosus), two legislators introduced bills to fund the establishment of a registry, as well as education, screening, and prevention services for lupus and related connective tissue diseases. Both bills explicitly call for funding to set up a statewide lupus registry and conduct scientific research on lupus and related diseases. The bills currently await action in committees. Of course, there are many more diseases and conditions for which there are no registries, including conditions that are transient, difficult to diagnose, or underreported.

The routine collection of vital records—birth and death certificates—has a much longer history than do disease registries. Rates of overall mortality, premature mortality (i.e., death before age 65) and infant mortality have long been considered the most basic indicators of the health of populations (these rates are higher in the world's low-income countries, for example, compared with higher-income countries). Every state maintains vital records. Unlike disease, death is not private: death certificates are public records, and this means that you can get death data even for small areas. Nationwide county-level data for overall mortality and infant mortality are available online from the US Census.

Epidemiologists use surveillance data to compare rates of disease (or mortality) across locations, such as the towns of a state. However, the overall rate of most diseases is strongly influenced by the age of a population. For example, lung cancer is more common in older age groups, and thus if Town A's population is older than Town B's population, we would expect to see a higher rate of lung cancer in Town A for that reason alone. What we would really like to know is how much of the difference is due to an exposure or other cause, as opposed to simply reflecting the age makeup of the two towns.

Sidebar: Calculating the SIR for Macon, Georgia

The Rollins School of Public Health at Emory University in Atlanta maintains Georgia's State Cancer Registry online at http://www.cancer-rates.info/ga/index.php. A large amount of data in the registry is accessible to the public online free of charge. The registry reports that Macon County's age-adjusted cancer incidence rate for all types of cancer was 527.68 cases per 100,000 people during 2004-2008. Over the same period, the age-adjusted cancer incidence rate for the state of Georgia was 485.81 cases per 100,000 people. The age-adjustment reflects that the rates have been standardized for differences in age distributions between the population of Macon compared to the state population.



 # cancer cases in Macon
÷
 # cancer cases in Georgia
x 100 = SIR

To calculate the SIR, we divide the observed cases by the expected number of cases.

In this example we are comparing the observed rate in Macon with the rate we would expect to see across Georgia (the state rate).

SIR =527.68/485.81 x 100 = 109

The cancer incidence rate in Macon County is 9% higher than would be expected given the state rate of Georgia.

Analyzing registry data is a popular study design primarily because of its low cost and the relative ease with which data can be obtained. Federal health agencies such as the Agency for Toxic Substances and Disease Registry (ATSDR) and state health agencies have increasingly turned to this method when faced with health issues under public and/or political scrutiny. Furthermore, this method cuts out any reliance on participant recruitment to obtain information, which saves time and is deemed by many in the field to be a "cleaner" study design. To account for the average age of a population, epidemiologists use a variety of techniques to compare rates of disease or death across locations. What these statistical measures have in common is that they are *standardized*, meaning we have accounted for differences in the distribution of age of populations. These techniques produce a ratio—either a **standardized rate ratio (SRR)** or a **standardized incidence ratio (SIR)**. In both instances the ratio represents a comparison between what we are seeing, for example actual number of cancer cases in Macon, GA, and what we would expect to see when compared to a reference population such as the State of Georgia. The SIR is a ratio that compares the actual number of cases in Macon with the expected number in the denominator representing Georgia as a whole. A ratio of 100 (ratios are commonly multiplied by 100) means that there is no difference between Macon and the state. A ratio of less than 100 means that we observed fewer cancers than we would expect, and greater than 100 means more. For example, and SIR of 125 means that the number of cases is 25 percent higher than would be expected based on the rate in the reference population. An example of SIR calculation can be found in the following sidebar.

We use the example of SIR as a statistical tool because the SIR has practical advantages for community groups. First, only the total number of cases in a community is needed to calculate the SIR, rather than the number of cases by age group. This is important, because age-specific case data may not be available given the state agency's rules to maintain the confidentiality of disease records. The SIR is also easier for community members to interpret, since it directly addresses the question of concern: Is there more illness here than expected?

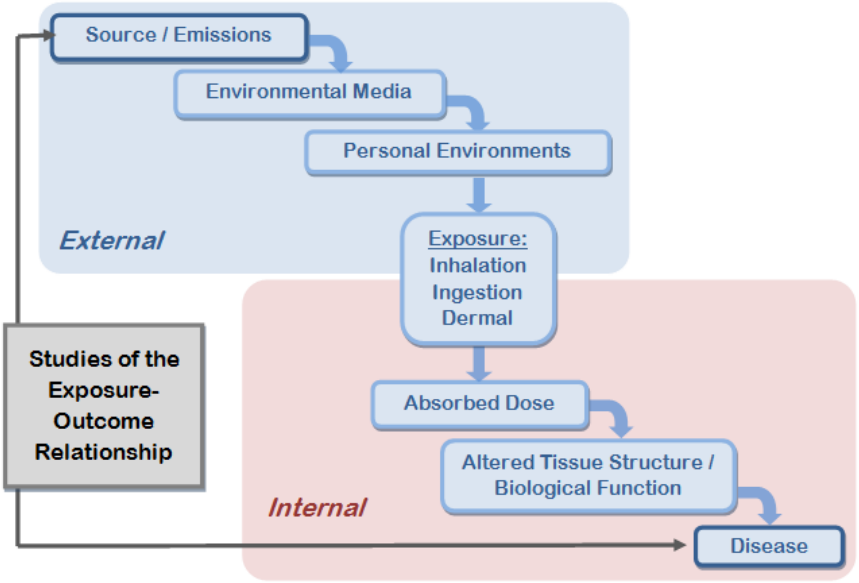
The main thing to keep in mind is that local disease rates that have *not* been standardized (sometimes called ***crude*** *rates*) are not directly comparable. Rates of many diseases differ not only by age group but also by gender. However, gender differences are usually addressed by reporting separately for males and females. When the outcome we are talking about is death, we talk about standardized mortality ratios (SMR). It's calculated the same way as an SIR.

Analysis of Registry Data or Vital Events Data at a Glance

Study Type	Type of Result	Time	Cost	Expertise
Analysis of Registry or Vital Events Data	Provides comparisons of disease or death rates between different areas, often reported as a Standardized Incidence Ratio (SIR), SMR or SRR.	Can be relatively quick, although getting the data can be difficult	Very low. The data should be free of charge and the primary cost is time	Depending on how the data are packaged, it may be done by community members, or with assistance of someone with knowledge of statistics to interpret what are considered significant elevations

Studies of the Exposure-Outcome Relationship

Figure 4.7. Exposure-related disease model: Exposure-Outcome Relationship



We describe here three classic epidemiologic study designs for examining the relationship between an exposure and an outcome. The first, a community-level **ecologic study**, asks whether communities with higher exposure to a hazard also have higher rates of some disease or condition. The last two approaches use data on individual people rather than communities:

- A **cohort study** compares the disease experience of exposed individuals to that of unexposed individuals. A cohort study asks: Other things being equal, are exposed people more likely than unexposed people to get sick?
- A **case-control study** does just the reverse, comparing the exposure experience of cases to that of a comparison group (**controls**). A case-control study asks: Other things being equal, are cases more likely than controls to have been exposed?

1. Ecologic Study

An ecologic study is a type of epidemiologic study that does not rely on data about individual people (as cohort and case-control studies do; see below), but rather on data about places and the populations who live there. The researchers gather environmental data about places (for example, counties) and they gather health data on the populations that live in those places. In analyzing the data, researchers document whether there is a relationship between community-level exposures and community-level rates of a particular health outcome. For example, across US counties, is the asthma rate higher in counties where the concentration of particulate air pollution is higher?

The ecologic study design is often criticized because results at the population level (such as a county) may not be interpreted as estimates of *individual* health risk. It is true that the relationship between exposure and disease at the individual level may be wildly different than at the population level. This limitation and potential flaw of ecologic

studies is known as **ecologic bias.** Thus a community-level correlation between an exposure and an outcome cannot be interpreted to mean that the exposure and the outcome are similarly correlated at the individual level, much less that the exposure causes the outcome. For example, it may be true that where there is more pollution there is more asthma, but it may also be true that the people who have asthma smoke cigarettes and do not live in the most polluted areas. So, what appears to be an association in the big picture is not an association when you look at each person. Still, the results of ecologic studies are sometimes seen as suggestive, and you may find such results useful in arguing for an individual-level case-control or cohort study in your community.

An ecologic study may be **cross-sectional**, using data on exposure and disease at the same time point, or the exposure data may be drawn from an earlier time period than the disease data. Like maps, ecologic studies do not reflect individuals' movements into or out of a community over time, though US Census data on residential mobility can give you an idea of how much coming and going has occurred in your community.

For community members concerned about a health issue, an ecologic study has a more basic limitation. It is a way to think about patterns and make comparisons across a whole set of populations or locations, not to think about a single local area—an ecologic study can't give you new information about what is going on *within* your own community. As a general rule, within your own community it is more useful to map environmental features and individual cases of disease, and look for patterns at the individual as opposed to group level.

Ecologic Studies at a Glance

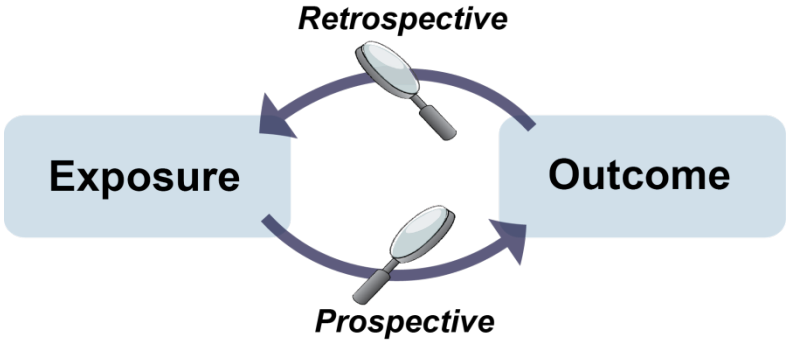
Study Type	Type of Result	Time	Cost	Expertise
Ecologic Study	Provides measures of association, usually a risk ratio or percent risk, comparing the risk of disease in the exposed population compared with risk in the unexposed population.	Depending who is doing the study the process could last months to a year or more. Often an ecologic study will require getting data from registry or vital events databases, along with data on population demographics and exposure sources (environmental hazards).	Relatively low for a study that examines both exposures and outcomes. The cost will probably be in getting the assistance of someone (professor, student, or government staff) to analyze the data	Someone with knowledge of study design and statistics to calculate correlations that may or may not exist between exposure and outcome at the community level

2. Cohort Study

A cohort study includes two groups of individuals: people who have been exposed to the hazard being studied and people who have not been exposed. The study is designed to compare the experience of the two groups on a health outcome (for example, lung cancer). There are two major types of cohort studies.

A **retrospective cohort study** begins *after* the health outcome of concern has occurred. Both diseased and non-diseased individuals are enrolled in the study but the investigator does not know which individuals are which. (In research lingo, the investigator is ***blinded*** to the health status of the study participants and does not know if they are cases or not.)

A **prospective cohort study** begins *before* any of the study participants have been diagnosed with the health outcome of concern. The investigators wait—sometimes for many years—for outcomes to occur, and then they compare the exposure experience of the people who became ill, and those who did not. Keeping participants engaged in the cohort over years is sometimes one of the challenges of this study design. If they move, die of other causes, or simply don't want to participate any longer, they are considered "lost." A prospective cohort study gives researchers flexibility to study multiple outcomes and multiple risk factors over a long period.



The statistical analysis in a cohort study asks: other things being equal, are exposed individuals more likely than unexposed individuals to get sick? The investigators calculate the risk of lung cancer in the exposed cohort and the risk of lung cancer in the unexposed cohort, and they compare the two risks in a ratio, with the exposed group in the numerator. This ratio is called a **relative risk**. For example, in a cohort study of smoking and lung cancer, a relative risk of 5.0 would mean that smokers are 5 times more likely than nonsmokers to be diagnosed with lung cancer. (A relative risk of 1.0 means that there is no difference in the cancer risk of the two groups.) We will come back to the "other things being equal" concept in Chapter 5.

Cohort studies are expensive and require a lot of expertise, but they provide solid results if you have the time and money. For community groups, time may be an even bigger concern than money. Some cohort studies last for months and others last for years. Among the most famous cohort studies is the Framingham Heart Study, which has been going on for over 60 years. The Framingham Study is a prospective cohort study: it follows cohort members into the future, looking at both exposures and health outcomes (see sidebar, p.62).

One advantage of prospective studies is that assessment of exposures and health outcome is usually accurate. However, if exposures don't have an effect until many years later, there are no quick answers about the harm they cause. Of all epidemiologic study designs, prospective cohort studies are the least likely to answer a community's question in a timely manner. Moreover, by the time we get an answer, the damage has already

been done, right before our eyes. When community members are concerned that they are sick from an exposure that occurred in the past, it is generally more useful to look to the past for answers.

Retrospective cohort studies attempt to measure the relationship between an existing or past health outcome and an exposure that occurred even earlier. A disadvantage of the retrospective study is the reliance on historical data—for example, emissions data or air quality measurements—and people's recollection of events related to health and exposure. The retrospective cohort study design has also been used in occupational settings, where past exposures are more consistent and better remembered than in residential or outdoor settings and may even have been documented.

In Massachusetts, a retrospective cohort study design was used to assess the risk of certain cancers associated with childhood exposures to chemical wastes from an industrial site in the town of Ashland. The Massachusetts Department of Public Health assembled a cohort of 1,387 Ashland residents and former residents who had been 10 to 18 years old during the period from 1965 to 1985, the time of greatest opportunity for exposure to the Nyanza Chemical Waste Dump site. Local children had routinely played on and near the site, contacting both waste lagoons and a small stream (dubbed Chemical Brook) into which partially treated chemical wastes were dumped (Massachusetts Department of Public Health, 2006). This retrospective cohort study was undertaken after Ashland residents documented five cases of soft tissue sarcoma in young men who had played on the site as children. The study took 7 years to conduct and cost $800,000. The findings indicated that cancer risk was two to three times greater among study participants who had contact with the contaminated water bodies.

Sidebar: The Framingham Heart Study (a prospective cohort study)

Over sixty years ago it was apparent that death and disability from cardiovascular disease were rapidly increasing in the US. What factors were contributing to this rise?

The Town of Framingham, Massachusetts, was selected as a study site in1948. Over five thousand healthy residents between 30 and 60 years of age were enrolled as the first cohort of participants.

Every two to four years participants in the cohort are given extensive medical examinations, including a medical history and blood tests assessing multiple aspects of their current health status. The study, which continues today, has contributed much valuable information to public health. Among many things it demonstrated that smokers are at increased risk of having a heart attack or experiencing sudden death. Further, the risk was found to be related to the number of cigarettes smoked each day, and smoking cessation was found to promptly halve the risk compared to the risk among those who continued to smoke.

www.framingham.com

Cohort Study at a Glance

Study Type	Type of Result	Time	Cost	Expertise
Cohort Study	Provides measures of association, usually a risk or rate ratio comparing the risk of disease in the exposed population with risk in the unexposed population. Can be used to study more than one disease in the cohort (for example, stroke, heart attack, and death in Framingham)	Retrospective cohort studies are likely to last one year at a minimum, more likely five or more years. A prospective cohort study could easily be a decade or more.	Both types of cohort study are likely to cost in the hundreds of thousands (if not millions) of dollars. Enrolling people in studies of this type usually requires that they be compensated, and large numbers of individuals are likely to be necessary	This type of study would be difficult to pursue without someone trained in epidemiologic methods, probably at the doctoral level (a professor or professional researcher), and will also likely rely on the infrastructure of a large research institution (with an IRB, See Chapter 5).

3. Case-Control Study

A case-control study enrolls two groups of individuals: a set of people who have a specific health outcome or disease (the cases); and a set of people (the controls) who are a sample drawn from the same population or location that produced the cases. A clear definition of the health outcome being studied (a case definition) is essential. Researchers conducting a case-control study attempt to identify and enroll every case in a specific population or location, and then work to enroll one or more controls per case. Controls *usually* do not have the disease in question.

The statistical analysis in a case-control study asks: other things being equal, are cases more likely than controls to have been exposed to the exposure being studied? (The "other things being equal" concept is taken up in Chapter 5.) The investigators calculate the odds of exposure among the cases and the odds of exposure among the controls, and then they compare the two odds in a ratio, with the cases in the numerator. This ratio is called an **odds ratio**.

Thus, in a case-control study of smoking and lung cancer, an odds ratio of 5.0 would be interpreted to mean that smokers are 5 times as likely as nonsmokers to be diagnosed with lung cancer. In fact, odds ratios for environmental exposures are typically much lower than 5.0, often less than twofold. (Like a relative risk, an odds ratio of 1.0 is interpreted to mean that there is no difference in the cancer risk of the two groups.) For statistical reasons, a study that enrolls two or three controls per case, rather than just one, has a greater capacity to detect a modest difference in risk between the two groups, if in fact there is a difference.

Unlike a prospective cohort study, which can become a vehicle to study more than one health outcome and multiple exposures, a case-control study can address only one health outcome. Because a case-control study is an expensive proposition, this study design is typically used to document, in human beings, an association for which there is prior evidence in laboratory studies, and which has substantial public health implications.

However, the case-control design is sometimes used in addressing community concerns about a specific health outcome and exposure. For example, both the case-control study of leukemia risk associated with consumption of public drinking water in Woburn, Massachusetts, described in

Chapter 2, and the Monticello, Utah, case-control study described on p.45 began with community surveys of cases of illness.

Case-Control Study at a Glance

Study Type	Type of Result	Time	Cost	Expertise
Case-control Study	Provides measures of association, usually an odds ratio comparing the odds of having been exposed to a hazard of interest among the cases with the odds of exposure among the controls. Case-control studies can be used to study more than one exposure at a time among cases and controls	Case-control studies are likely to take several years	Case-control studies are likely to cost in the hundreds of thousands of dollars, if not millions. Enrolling cases and controls often requires contact with people who have an illness and those who don't (and may have little motivation to participate in a study), and it is customary to compensate people for participation. Case-control analyses using existing data will cost less.	This type of study would be difficult to pursue without someone trained in epidemiologic methods, probably at the doctoral level (i.e., a professor or professional researcher) and will also likely rely on the infrastructure of a large research institution (with an IRB, See Chapter 5).

Side Bar: Risks and ratios

What is the likelihood that something will happen? We may talk about the **probability** it will happen as 1 in 5 (0.20, or 20%), for example. But in health studies, we often use the word **risk** instead—for example, a 20 percent risk of injury—although risk still refers probability. Another way to express the same probability is with an **odds**, which is familiar from gambling terminology: If a horse has a 1 in 5 probability of winning (20%), we say the odds that the horse will win are 1 to 4 (that is, four chances of losing for every one chance of winning). All of these measures—probability, risk, and odds—are ways of quantifying likelihood.

In epidemiology, different study designs use different expressions of probability: A cohort study expresses likelihoods as risks, while a case-control study expresses likelihoods as odds. The numerical result of each type of study, however, is usually a **ratio** of probabilities. In a cohort study, this is most often a risk ratio (or relative risk): a **risk ratio** of 2.0 tells us that the risk of the health outcome in the exposed group is twice the risk in the unexposed. In a case-control study, the result is usually expressed as an odds ratio: an **odds ratio** of 2.0 tells us that the exposed group has double the odds of the health outcome as the unexposed. At a basic level, the interpretation of these ratios—whether odds ratio or risk ratio—is the same.

Table 4.1 Summary of Outcome Measures by Study Design

Study Type	Measure	Interpretation
Analysis of Registry Data	Standard Incidence Rate (SIR)	Ratio between incident rate of study population to rate of reference population (i.e. county vs. state cancer rate)
Cohort Study	Risk Ratio	Ratio between disease rate in exposed group to rate in unexposed group (e.g. rate of disease in group who lives near a chemical company vs. a group that does not)
Case Control	Odds Ratio	Ratio between the proportion of cases and proportion of controls that share a specific exposure (e.g. rate of cases vs. controls born to mothers who lived near a contaminated site).

Studies of Contaminated Sites

Contaminated sites, of course, are important potential sources of exposure, especially to nearby residents such as the schoolchildren who played on the Nyanza site described above. Two major approaches to *estimating* the health risks associated with contaminated sites are described here. These types of studies are generally undertaken by government agencies or consulting firms. In fact, it is highly unlikely that a community group would conduct these types of studies on their own, nor would they necessarily want to. However, when agencies or firms conduct these studies community members should have the opportunity to contribute local knowledge during the process that can greatly improve the quality of these assessments.

1. Risk Assessments

"People don't understand modeling. . . . It has been a bit of an uphill battle at times to deal with the fact that people say, 'Oh this is just a model. It is not real. It is just a model.'"

– Helen, Marblehead, MA

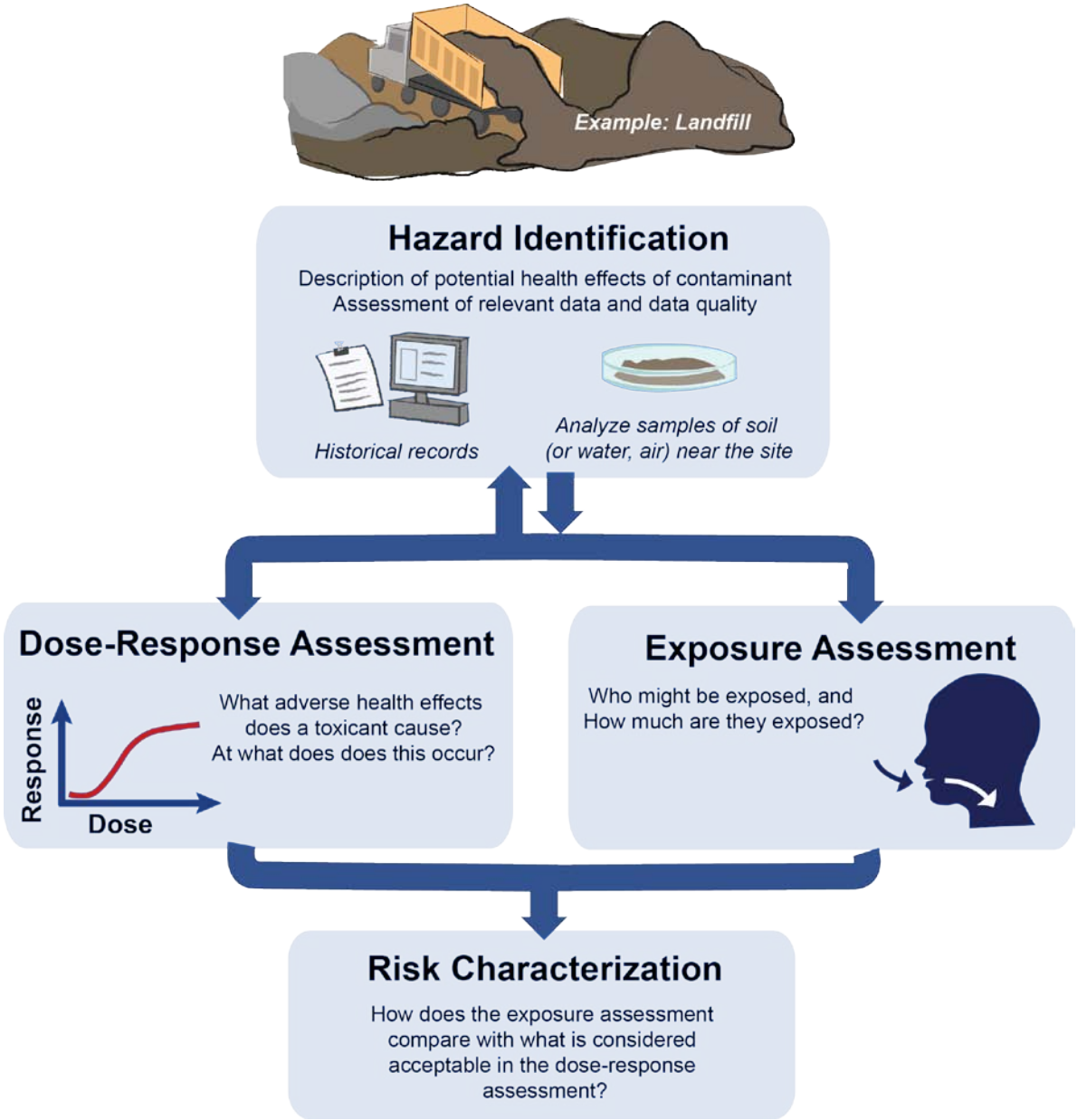
A **risk assessment** estimates the potential health risks associated with a specific site or activity (for example, emissions from a power plant). Helen was referring to a mathematical model used in a risk assessment when she described community members' difficulty understanding models. *Estimating* risk is not the same as *measuring* risk in a case-control or cohort study. A risk assessment does not examine the health of *actual people* living near a site. Instead, it *estimates* the health risks to hypothetical people or a general population, given a set of assumptions about people, their exposures, and the toxicity of what they are exposed to.

Risk assessment is typically performed by government agencies rather than by community groups or academic researchers, but we include it because this type of study is often conducted in response to community concerns about a polluting industry or a contaminated site. US EPA regularly conducts risk assessments at Superfund sites, and

state departments of public health often conduct risk assessments to estimate health effects of an industrial site or a state-regulated waste site (see Chapter 7).

Generally, a risk assessment is structured in four steps (see Figure 4.8). We'll use the example of a landfill. The risk assessor first determines what chemicals are present at the landfill that may be of concern for human health. She may do this by looking at historical records for who used the landfill, as well as analyzing samples of water, soil, and air on and near the site. This step is known as *hazard identification*. For each chemical of concern, the risk assessor would then look for data on the toxicity of each chemical that is present. This is known as *dose-response assessment* (that is, assessing the relationship between various doses and the corresponding toxic response in the body). During this process the risk assessor would examine the known cancer risk of each chemical (if any) as distinct from the non-cancer health effects of each chemical (see sidebar, p.68).

Figure 4.8. Structure of a Risk Assessment



For risk information on cancer and non-cancer effects, the likely source would be toxicity values (cancer potency factors and reference doses, described in the sidebar) published by the US EPA. A risk assessor can simply look up these values on the Internet. However, in most instances there will be chemicals on a site for which *no* cancer potency factor or reference dose has been derived. In such instances the risk assessor may calculate their own toxicity value using the scientific literature describing the chemical's toxicity in a variety of studies. (This is an area where community groups may want to be assured that all of the literature has been included in such an analysis, and not just literature showing high or low toxicity.)

The next step is called the *exposure assessment*, characterizing the ways people come into contact with the site. Do people drink water that has been contaminated by chemicals from the landfill? Does the wind carry dust into their vegetable gardens? Do children cut through the landfill on their way to school? The risk assessor quantifies the answers to these questions to estimate people's doses of each chemical by various exposure routes (inhalation, ingestion, dermal). Estimation of exposure may include computer models of both the exposures (leaching from the landfill into drinking water supplies) and people's behavior (drinking 16 oz of water daily for 10 years). Ideally, this process is meant to arrive at results similar to what we would find if we performed environmental monitoring and biomonitoring studies as described earlier.

Sidebar: About dose-response assessment

Common sense tells us that, as a general rule, a higher dose will have a greater toxic effect. But this leaves two key questions: How much difference does the dose make? And is there any dose that has no toxic effect at all?

When describing a non-cancer effect, scientists start with the assumption that there is a **threshold**—a level of exposure below which there will be no toxic effect. Agencies like EPA use the threshold to calculate a **reference dose**. This is a dose that is expected to cause no adverse human health effects over a lifetime of exposure. In simple terms, this is a "safe" dose. To derive a reference dose, scientists start from a dose that showed no effect, or minimal effect, in a study—preferably a study in human beings but more often a study in rodents. Then scientists divide the starting dose by a series of uncertainty factors, to be sure that the reference dose is low enough that it will cause no harm in humans. (See sidebar, *Comparing Your Results with Standards*, on p 52.)

By contrast, when evaluating a carcinogen, risk assessors usually assume that there is *not* a threshold—that, in principle, a single molecule of a carcinogenic chemical could kick off the cancer process. Therefore, there is no reference dose for a carcinogen. Instead, the carcinogenic risk is captured in a *cancer slope factor*, which describes the additional lifetime cancer risk for each additional unit of dose. In other words, this is an estimate of the carcinogenic potency of the chemical. Scientists use data from epidemiologic studies to derive the cancer slope factor, if such studies have been done; if not, then the slope factor is derived from animal data.

In both of these cases, we assume that a larger dose will increase the risk (or will increase the severity of the disease). While generally true, this is not always the case. In particular, chemicals called **endocrine disruptors** are thought to mimic the body's natural hormones. Current research indicates that some endocrine disruptors can cause greater harm at very low doses than at higher doses. These effects are more likely to be seen in carefully controlled animal studies, rather than in community health studies, but they do represent a challenge to the traditional assumptions behind risk assessment.

Finally, the risk assessor estimates human health **risk** by bringing together all of the previous steps. This final step is called *risk characterization* (see Figure 4.8). The risk characterization

includes an estimate of the incremental cancer risk over a lifetime from the assumed activities (it is good for community members to confirm that activities assumed by risk assessors accurately portray actual activities), considering all of the chemicals present on the site. The risk characterization also compares the estimated dose of each chemical from the assumed activities to the reference dose for the chemical (for non-cancer health outcomes), in a ratio. A ratio greater than 1.0 indicates that the "safe" dose has been exceeded. Usually, the results of a risk assessment contribute directly to a decision about how to manage the site (**risk management**).

A common critique of risk assessments, by both scientists and community groups, is that the assumptions made during the process have a large impact on the outcome. For example, the toxicity of most chemicals has not been tested directly in human beings—most cancer potency factors and reference doses are derived from laboratory data on animals. Similarly, site risk assessors make assumptions about how—and how much—people come into contact with the site. Finally, risk assessment assumes that individual chemicals act separately. The process simply sums up the effects of individual chemicals; it does not take account of different effects from exposure to multiple chemicals, or the interaction of these chemicals in the body.

A recent report published by the National Research Council's *Committee on Improving Risk Analysis Approaches Used by the U.S. EPA* articulates these shortcomings of risk assessment, and many others. US EPA has recently funded scientists to attempt to develop analytic techniques for understanding the combined effects of multiple chemicals interacting over time. Additionally, people who experience social stress in their lives (racism, violence, oppression) may be more vulnerable to the effects of chemical exposures. Attempts to account for these multiple chemicals, types of exposures, and risk factors are loosely referred to **cumulative risk assessments**. While the need for cumulative risk assessment has been clearly articulated by scientists and communities alike, we are a long way from knowing how to conduct such assessments.

Risk Assessment at a Glance

Study Type	Type of Result	Time	Cost	Expertise
Risk Assessment	Provides estimates of risk or hazard for non-cancer health outcomes, or a life-time cancer risk from exposure to carcinogens.	Risk Assessments should take months to a year to conduct, depending on who is doing the assessment and the complexity of the site.	The major cost of a risk assessment is the expertise. Risk assessments are usually conducted by a professional risk assessor. In some instances where environmental samples are collected, equipment and laboratory analyses will add to the cost. Generally, a risk assessment should cost as little as nothing (if expert donates their time) to tens of thousands of dollars (for a firm to do an assessment requiring environmental monitoring).	A risk assessor could be trained in a variety of fields, from toxicology to epidemiology. They may have no formal scientific education beyond a bachelor's degree, but are likely to have a Master's degree or professional certification.

2. Public Health Assessments

While risk assessments are typically done by EPA, public health assessments are typically done by the Agency for Toxic Substances and Disease Registry (ATSDR). ATSDR is part of the US Centers for Disease Control and Prevention. The US Congress established ATSDR in 1980 to assess the presence and nature of health hazards at specific, federally designated hazardous waste sites. The public health assessment process may be triggered by a site's listing on the National Priorities List or a specific request from a community member or another government agency. The purpose of the process is to find out whether people have been, are being, or may be exposed to hazardous substances and, if so, whether that exposure is harmful, or potentially harmful, and should therefore be stopped or reduced (ATSDR 2005).

The public health assessment process involves multiple steps but consists of two primary technical components—*the exposure evaluation* and the *health effects evaluation*. These two components lead to conclusions and recommendations identifying specific, appropriate public health actions to prevent harmful exposures. Public health assessments also have a specific step for addressing community concerns. The health assessor must address each community health concern about particular contaminants in their report. The ATSDR website has a very complete description of the process for conducting public health assessments. Additionally, they have made available nearly 2,700 public health assessments and health consultations published since October 1, 2004, in all fifty states and US territories. As of the writing of this guide, the most recent public health assessment to be published is focused on Frit Industries in Walnut Ridge, Lawrence County, Arkansas. The Public Health Assessment (PHA) was prepared by the Arkansas Department of Public Health, with funding from ATSDR, and published on April 8, 2011. Frit Industries facility in Arkansas recycles hazardous waste materials to make zinc fertilizer products for use in agriculture. The results of the 21-page PHA are summarized here to give readers a flavor of what the results of a public health assessment might look like:

ATSDR reached two separate conclusions in this PHA regarding current and past exposures and based on the environmental data and cancer statistics (or health outcome) data:

1. Based upon all environmental data reviewed for sediment, surface water, groundwater, air, and soil, exposure pathways still exists for incidental skin (dermal) contact and accidental ingestion of the on-site soil on the Frit Industries property. After evaluation of the elevated levels of cadmium and zinc in the soil, ADH/ATSDR concludes that *current* exposure to elevated levels of cadmium and zinc in the on-site soil through skin contact and accidental ingestion at Frit Industries is not expected to harm people's health (*i.e.*, exposure to site-related contaminants might have occurred in the past or is still occurring, but the exposures are not at levels likely to cause adverse health effects).

2. Based upon information and historical data previously reviewed, there may have been a completed exposure pathway to *past* contaminants found in surface water and surface soil at Frit Industries. ADH cannot currently conclude whether *past* exposure to elevated levels of cadmium, chromium, lead and zinc in the contaminated surface water and surface soil from Frit Industries could harm people's health. The lack of information

before and after the 1979 fire makes it difficult to discern what part of the surrounding community was potentially exposed.

The health outcome data, evaluated in response to community concerns, indicate an increase between cancer rates in Lawrence County as compared to the state. Yet due to the high prevalence of smokers in Lawrence County records, ADH cannot currently conclude whether *past* exposure to chemicals from Frit Industries alone could harm people's health because the cancer incidence factors are not conclusive in relation to this site. It is likely that the increased rates of lung/bronchus and other cancers may be due to the increased prevalence of smoking in the county compared to state rates. Limited health or personal data from the past, such as individual smoking habits, residential activity, exposure, and occupational histories, make it difficult to fully assess whether or not the site has had sole adverse impacts on human health within the community. Additionally, only a few residents would have been likely to have had past exposure to site COCs, which would not account for the increase in county cancer rates.

The Public Health Assessment of Frit Industries concludes with the recommendation that no further action is needed.

Public Health Assessment at a Glance

Study Type	Type of Result	Time	Cost	Expertise
Public Health Assessment	A written report on exposure and health data, or the compilation of several separate health consultations. The conclusion is in the form of a qualitative judgment of current or past health risk to nearby residents, with recommendations for future actions, that is based on readily available environmental testing	A public health assessment could take months to a couple of years	Since public health assessments are conducted by the ATSDR, they should not cost anything to community groups who request or are the subjects of a public health assessment	Federal agents, physicians, data analysts all usually employed by the federal ATSDR or the state agencies with whom they have cooperative agreements

Summing Up

Because the results of a single health study are rarely considered definitive, it is very common for more than one study to be conducted to address a single community concern. Usually residents and researchers rely on a combination of study types. For example, residents in Pittsfield, Massachusetts, concerned about the health effects of exposure to PCBs went door to door conducting a *community-based health survey.* They wanted to document health problems and concerns in their neighborhoods. At the same time, the EPA was working on a *risk assessment* to estimate potential exposures to PCBs from a variety of sources in Pittsfield and to

estimate the health risks. Both study types have their value. Depending on your organization and resources, you may want to pursue more than one option at a time.

Remember, however, that in many instances you may already have all the information you need at your fingertips. For instance, if you are concerned about emissions from a power plant, and you already know that asthma rates in your community are higher than they should be, or that concentrations of particulate matter already exceed levels determined to be safe by the Environmental Protection Agency, then what you need is to get existing information into the hands of people with the power to effect change. If you already have the evidence you need to accomplish your goal, more research may not be the answer.

Table 4.2: Practical requirements of various study designs

Study Type	Type of Result	Time	Cost	Expertise
Mapping				
Mapping of exposure, health outcomes, or both	Map(s)	⌛	$	📘
Studies of Exposure				
Environmental Monitoring Study	Concentrations in environmental media	⌛	$$	📘📘📘📘
Body Burden Study	Concentrations in bodily tissue or fluid	⌛	$$$	📘📘📘
Environmental Impact Statement	Description of environmental changes	⌛⌛⌛	$$$	📘📘📘📘
Studies of Outcome				
Community Survey	Survey responses; maybe qualitative	⌛⌛	$	📘📘
Analysis of Registry or Vital Events Data	SIR, SMR	⌛	$	📘📘
Studies of the Exposure-Outcome Relationship				
Ecologic Study *	Correlation	⌛⌛⌛	$$	📘📘
Cohort Study *	Relative risk	⌛⌛⌛⌛	$$$$	📘📘📘📘
Case-control Study *	Odds ratio	⌛⌛⌛⌛	$$$$	📘📘📘📘
Studies of Contaminated Sites				
Risk Assessment		⌛⌛	$$	📘📘
Public Health Assessment		⌛⌛	$$	📘📘

* Epidemiologic studies

⌛ = weeks or a few months

⌛⌛⌛⌛ = at least a few years

$ = hundreds to $1,000

$$$$ = hundreds of thousands or more

📘 = some expert advice, maybe via phone or library

📘📘📘📘 = a consulting firm, or team of university or government professionals

Key Points from Chapter 4

– Have your research question in mind as you consider your study options. Which design will give you the types of results, fit within an appropriate timeframe and stay within budget given your community's goals and resources?

– Community research studies benefit from the partnership of community groups and scientific experts from academia or a health agency. Expert consultations can be as simple as an email or phone call for small-scale studies or develop into collaborations in which community leaders and scientists work together to design, implement, and interpret a health study.

– Familiarity with the terminology and structure of health studies will give you more confidence to contribute to the process, help set realistic expectations, and stave off exasperation when things don't go as planned.

– Plan ahead. Know the boundaries of your resources and the logistics you're seeking in a study design (time, cost, workforce, etc).

Further Reading

On Woburn:

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On endocrine disruption, dose-response assessment, and complex environmental exposures:

Colborn, T., Dumanoski, D., & Myers, J. P. (1996) *Our stolen future: Are we threatening our fertility, intelligence and survival? – a scientific detective story*. New York: Plume.

On toxicology, cancer, and risk assessment:

Steingraber, S. (2010). *Living downstream: An ecologist's personal investigation of cancer and the environment (2nd ed.)*. Cambridge, MA: Da Capo Press.

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