CHAPTER ONE

INTRODUCTION TO RISK ASSESSMENT IN PUBLIC HEALTH

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Why did God invent risk assessment?
To give astrologers credibility!

—JOKE TOLD AT AN EPA RISK ASSESSMENT MEETING

Learning Objectives

Students who complete this chapter will be able to

1. Become familiar with the topic of risk assessment
2. Understand the process for developing this text
3. Understand the specific issues that relate to public health
4. Gain an overview of the book

Risk assessment is an important part of the training of environmental and occupational health (ENOH) students in schools of public health as well as in many programs in toxicology, environmental medicine, environmental engineering, and other fields of study. Most of the member schools of the Association of Schools of Public Health (ASPH) teach a risk assessment course. In some of the larger schools a student can select risk assessment as a major or minor. A number of texts on risk assessment are available; however, the Environmental and Occupational Health Council of ASPH asked us to write a book specifically designed to teach risk assessment for public health.

We are fortunate to be able to include in this book articles by a number of nationally and internationally recognized experts in the field who are on the faculties of many schools of public health. As a group we identified the major areas that are important for a public health graduate. We have also included a number of case studies to illustrate important principles and examples for our public health students.

Where to Begin?

When you woke up this morning and before leaving the comfort of your bed did you calculate the risk associated with each activity of the day ahead? Did you even know what you would be doing for the day—or, for that matter, think about risk at all? Looking at the day before, did you sum up the risks of what you experienced?

Unless we were in an accident or just missed one, few of us consciously think about risk. Few consider the risk of daily life, and fewer quantify those risks. Yet calculating risk, communicating risk, and managing risk in quantitative or qualitative ways are part of the human experience.

As this chapter was being written, one of us was in Bangkok, Thailand, and the other in Cape May, New Jersey. As each of us journeyed to our destination we thought more about finishing this chapter than about the risk associated with traveling, despite the very real hazards of how we traveled and where we were going.

For example, Thailand, though not the epicenter of SARS, was one of the first countries to record a death from the virus. West Nile Virus is now endemic in New Jersey, which for those with compromised immune systems can be deadly. In each country, and particularly during the summer months, exposure to the sun can lead to skin damage, sun poisoning, or skin cancer. Water pollution and air pollution are significant threats to populations in both locales, although to different degrees. Despite the vastly different cultures of Thailand and the United States, the hazards that concern public health professionals are quite similar.

While we did not quantify the risks associated with each of our journeys, we were aware of them and decided that the benefits outweighed the risks. For MR it was completing a research program that was set in Thailand beginning with the tsunami of 2004; for FE it was just sitting on the beach. Some of you would not have even considered flying more than 20 hours to Thailand, even though it is statistically less safe to drive to a more domestic destination. Others would not travel to Southeast Asia because of SARS, even though West Nile Virus has spread from the East Coast of the United States to the West in just a few years.

This illustrates that we face risks each day of our lives, whether we can quantify them, articulate them, or are even cognizant of them. Nevertheless, the exploration of risk can help inform priority setting, policy making, and decision making at global, national, regional, and local levels.

As we were putting the finishing touches on this chapter, the United States witnessed one of its worst natural disasters, Hurricane Katrina. This disaster made a previously hypothetical risk real. The physical and emotional devastation was undeniable, and the policy implications are only starting to emerge. For public health, it exposed a cultural bias of looking to the recent past (20 years) as a predictor of risk rather than a more comprehensive examination of the past (e.g., 100 years). It also exposed weaknesses in how the risk was managed from prevention to mitigation. Finally, it exposed how communicating risk-related information is itself a dangerous endeavor. At the core of this disaster, however, is the human dimension and a critical challenge to public health for this century: engaging the public to voluntarily take individual prophylactic action. We believe an informed public will be better equipped to understand and address risk, and we believe that an informed public health workforce is an essential first step.

What Is Risk?

For some risk means danger; for others, reward. It is a complex term that is best understood in context. In the investment world, risk is typically equated with reward, while in the insurance industry risk is equated with loss. These financial risks are very often quantifiable in terms of monetary gain or loss; for example, insurance risks are rooted in experience captured as actuarial data. For public health risk is usually framed as a potential harm to human health or the environment. Public health risk may have an actuarial component, but it is more likely to be based on a science and policy construct. Science is used to estimate the likelihood of the risk, while policy helps to define what is acceptable.

For our purposes, *risk* is defined as a function of hazard and exposure. Without either of these essential components risk is zero. For example, containers of drain cleaner are often found on supermarket shelves and in homes. The drain cleaner is hazardous, typically composed of caustic that is corrosive to skin if contact is made. If the container of drain cleaner is left unopened, the risk associated with the contained hazard is zero; no contact can be made with the contents. On the other hand, if the container is opened, the risk associated with using the drain cleaner can be determined; it will be greater than zero. How much greater than zero will depend on the exposure (such as length and frequency of use, concentration of the material, precautionary measures, and how it is used). This simple framework of risk is often made more complicated by perception and emotion.

To see how emotion drives outcome, consider asbestos. Asbestos, a naturally occurring fiber, is also hazardous. It is listed by the International Agency for Research on Cancer (IARC) as a known human carcinogen, particularly when it is in friable form. Parents panicked when it was determined that many schools built before the 1970s had used asbestos as a fireproofing material and that the U.S. Environmental Protection Agency (EPA) had estimated that approximately three million school children in 8,500 schools could be exposed to friable asbestos (Environmental Protection Agency, 1980). Panic led to a public policy initiative called the Asbestos School Hazard Abatement Act in Schools, which made federal funds available for asbestos abatement. No one should doubt that some schools were in dire need of repair and abatement. However, no one predicted that over the next two decades demands for asbestos abatement were made regardless of its condition. Ironically, in some instances indoor asbestos levels were higher after abatement than before because the process of asbestos removal causes it to become friable. In these instances, an alternative approach—containment—would have achieved an equivalent or better outcome. Finally, the asbestos-removal hysteria may have created a new cohort of asbestos-related disease victims: workers in the asbestos abatement industry.

In many respects, the public's reaction to a threat such as asbestos in schools is understandable. First, their children could be in danger, and parents are instinctively protective of their children. Second, it is human nature to react to health threats, whether real or perceived. These two human reactions are deeply ingrained instincts.

Why is risk perception important to the study of risk assessment? Simply because public policy is set before a public who may or may not be informed by the truth. In 1962 John F. Kennedy wrote:

> As every past generation has had to disenthrall itself from an inheritance of truisms and stereotypes, so in our own time we must move on from the reassuring repetition of stale phrases to a new, difficult, but essential confrontation with reality. For the great enemy of the truth is very often not the lie—deliberate, contrived, and dishonest—but the myth—persistent, persuasive, and unrealistic. Too often we hold fast to the clichés of our forebears. We subject all facts to a prefabricated set of interpretations. We enjoy the comfort of opinion without the discomfort of thought [Kennedy, 1962].

In the graduate introduction to environmental health course we teach, one of us (FE) routinely asks students to complete a questionnaire during the first class of the semester. This questionnaire, modeled after the Roper–NEETF Environmental Literacy survey, asks 15 questions on common environmental issues. The answers help students question their perceived environmental knowledge. One question asks about the cause of bird and fish entanglement. Over the course of five years 56 percent on average have answered that it is the six-pack rings; only 8 percent on average have given the correct answer: fishing lines. For the complete questionnaire, classes tend to answer about 35 percent of the questions correctly—a score slightly higher than that of the general public. The reason for this level of performance is quite simple: the images and information in the popular literature and television help perpetuate popular beliefs founded on a lack of environmental knowledge. So we focus on six-pack rings disposal rather than fishing lines and the result is—nothing. The behaviors that result in environmental risks associated with entanglements continue because we are focused on perception rather than reality. When the lack of environmental literacy is combined with priority setting, the results can lead to the funding of programs that may not represent the greatest opportunities for risk reduction.

Scientists at the USEPA (1987) discovered this truth during the course of an exercise that culminated in a report entitled *Unfinished Business.* Experts were asked to rank a number of risk-related issues and compare those rankings with priorities reflected in funding. We wish to emphasize that acknowledging perceptions is an important step toward understanding public concerns about a risk issue. In fact, the Presidential/Congressional Commission on Risk Assessment and Risk Management (1997a, 1997b) challenged the traditional approach to risk assessment. It incorporated the four steps of risk assessment—hazard assessment, dose response, exposure assessment, and risk characterization—into a more comprehensive framework that begins with understanding the context.

Acceptable Risk

Risk reduction as a public policy goal is laudable and implied in most government environmental and public health initiatives. The *protection of human health and the environment,* a common phrase found in many federal statutes, is based on a fundamental tenet: that of not harming health and therefore not increasing the risk to health. An extreme interpretation of this protective role is the notion of zero risk. Thus the answer to the question, Is zero risk achievable or even desirable? put bluntly is no. This statement might seem outrageous to some, but it is captured in the late Senator Patrick Moynihan's pithy statement, "Life is a risky proposition and it ends badly." The background risk for living on earth, which is bathed in radiation, means that zero risk is not achievable. Therefore, the notion of the desirability of zero risk is purely theoretical. So for that matter is total risk. There are just too many variables subject to constant change applied to a population base that is also changing. That notion alone presupposes that all of the variables and members of a population can be identified.

If zero risk is not achievable, then it follows that it would be reasonable to determine an acceptable level of incremental risk for an exposed population. In the United States an acceptable level of incremental risk has been defined as one in one million. While a one-in-one-million incremental risk of, for instance, cancer seems to most a reasonably low level, it too must have some context. If a policy decision were made that could subject the entire population to this level of risk, with a theoretical result of 280 cancers, public outcry would be unthinkable, despite the fact that one of every four people in the United States will be diagnosed with cancer in his or her lifetime. On the other hand, if we were to establish a strict policy that no pharmaceuticals should carry an incremental risk greater than one in one million, most anticancer drugs would not be marketable. Dr. Michael Gallo, a researcher at the University of Medicine and Dentistry of New Jersey and a cancer survivor, put it this way: "I dodged a lethal bullet, and thanks to a series of well-placed bullets. . . . I could have been a dead man. Thank God for toxicity."

At the root of risk, real or perceived, is an inbred personal basis for hazard assessment and by extension, if exposure is assumed, risk. We tend to assess personal risk from a qualitative basis, and each of us has a personal and somewhat unpredictable tolerance for risk. If it were possible to categorize lifestyles as risk seeking or risk averse, it would not be possible to categorically apply the same term consistently for each person. For example, one friend considers parasailing to be a sport that is not risky, but refuses to install natural gas as a home fuel source, opting instead to burn wood. He is familiar and proficient at parasailing but not familiar and therefore suspicious of natural gas. This illustrates that preferences can modify our views about risk. But there remain deep ingrained aversions to hazards that reside among all humans.

The British Broadcasting Company in cooperation with researchers at the London School of Hygiene and Tropical Medicine (2006) has been conducting a global survey of what people find disgusting. For images that appear to contain evidence of bodily fluids, excrement, lice, rats, cockroaches, bad smells, and sweaty people, respondents were asked to rank each image from one (not disgusting) to five (very disgusting). The researchers hypothesized that an ancient protective mechanism could evoke a behavioral aspect of human immuno-response to protect us from organisms that would use our bodies as a source of food or shelter (e.g., bacterial contamination or parasites). First surveyed were respondents from six countries; now anyone can take the survey and learn how their responses compare to others'. The researchers found that despite respondents' location, for similar images—one with and one without a disease threat, for example, towels, one with a blue stain, one with a yellow-brown stain, or a person, one healthy, one feverish—results were the same from every country tested. They found that a picture of a sick person was twice as disgusting as one of a healthy person, a picture of a yellow-brown stained towel was more than twice as disgusting as one with a blue stain, and a picture of a louse was more disgusting than one of a wasp, and so on. The researchers also found that women evidenced more disgust than men, which demonstrates that men can live in filth. On a more serious note, the researchers believe this is because women carry a double genetic burden (for themselves and their offspring). Overall, signs of disease and infection provoked more disgust, as did images linked to our sense of smell, which is often used to signal something that might be hazardous to eat, drink, or touch.

Risk Assessment Is Not New

The ancients institutionalized prophylactic behaviors to protect their populations. For example, the dietary laws of the ancient Hebrew people, commonly known as Mosaic Law, were a form of risk management in response to food-borne hazards. These and other precautionary instructions can be found in the book of Leviticus in the Old Testament.

The ancient Greeks believed that estimating risk was possible.

> We Athenians . . . take our decisions on policy and submit them to proper discussion. The worst thing is to rush into action before the consequences have been properly debated. . . . We are capable at the same time of taking risks and estimating them before hand [Thucydides (431 B.C.), 1954].

New Risks Arising from Common Public Health Practices

Public health as a discipline covers a wide range of topics. Public health measures or practices must, over time, be revaluated regarding their associated risks. It is common practice in many public water supplies to fluoridate water. In areas where people are served by an individual well, the family pediatrician or dentist often prescribes fluoride tablets for young children up to age 16. A recent National Academy of Sciences (NAS) report on fluoride in drinking water raised concerns about the current drinking water standard of 4 mg/L. There is, of course, concern about naturally occurring fluoride and the fluoride that is added to public water supplies to prevent dental caries. The American Dental Association (ADA) (as of March 22, 2006) continues to support community water fluoridation as a safe, beneficial, and cost-effective way to prevent tooth decay. The ADA cites the Centers for Disease Control and Prevention's proclamation that community water fluoridation is one of the ten greatest public health achievements of the twentieth century. EPA has set the drinking water standard for fluoride at 4 mg/L. The optimal concentration range for fluoride in drinking water to prevent tooth decay is 0.7 to 102 mg/L. This standard was set by the U.S. Public Health Service more than 40 years ago. In 2000 it was estimated that about 162 million people used artificially fluoridated water. There are a range of effects, from moderate staining of teeth to serious dental fluorosis, depending on the concentration of fluoride. There are studies presented in the NAS report on skeletal effects of fluoride exposure as well as a discussion on the possible association of fluoride and cancer. There are some studies that suggest a possible increased risk of osteosarcoma in rodents (NAS, 2006).

This illustrates important issues in public health risk assessment: that new information leads to new thinking about risks and that a single action, in this case the fluoridation of the water supply with its clear benefit, can in fact also have a risk associated with it (if the natural or background levels exceed, in the case of fluoride, the EPA standard of 4 mg/L).

Risk assessment has been described as both an art and a science. There are often specific benefits from certain risks. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), which dates back to 1947, is a good example. The Act regulates pesticides, and this Act plus the Food Quality Protection Act and the Federal Food, Drug and Cosmetic Act serve as the major regulations that set standards of risk for the food we eat. FIFRA requires an assessment of the risk and the benefits. Pesticides are economic poisons; we know they kill things—that is what they are specifically designed to do. What we need to be certain about in the regulation, and most important in the use of pesticides, is that the benefits far exceed the risks associated with a particular type of application.

Risk in Context

Six years ago MR was invited to make a presentation in West Africa at a conference called Challenges and Opportunities for Environmental Heath Research. MR was specifically asked to present the topic of risk assessment and the one-in-one million risk standard that is in place in the United States. After delivering what was thought to be an organized and thoughtful presentation, MR was quickly challenged by one of the meeting participants:

> Thank you, Dr. Robson, for your interesting and informative presentation. I enjoyed your talk, but I have a very hard time understanding the relevance of your talk to my work here in West Africa. I am a pediatrician in rural northern Ghana. I cannot comprehend one in one million risks. But let me give you some risks that I face every day. One in five of the children I treat will die from diarrheal disease before they are eight years old, and likely another one in five will die of malaria before they are eight. For me, two in five is a real risk, and one in one million is so far from what I live with every day that I do not know why you even bothered to come and make this presentation.

This is a true story and it illustrates the importance, especially for those of us in public health, to look at the context of the risk, to understand what risks are real, immediate, and of greatest concern to the public. It was hard to respond to the comments raised by the young pediatrician. It is clear that her work presents her with real risks that are immediate, real, and difficult to ameliorate. Public health students are there in the field in real risk situations. The risks are clearly greater than one in one million. While they may not deal with a two-in-five level of risk, they deal with far more serious and concrete risks than the very abstract one-in-one million risk that is cited so often in risk assessment texts, journal articles, and regulations.

In this text we include areas that are of direct public health concern, an overview of the risk process, the toxicological basis for risk assessment, specific populations and media, regulatory issues, ecological risk, the precautionary principle, and emerging issues such as PBPK modeling and biomarkers. We also include an important chapter on risk communication, often thought of as the fifth step in the risk assessment paradigm.

Thought Questions

1. What is a reasonable risk standard for public health?
2. When do we apply the risk standard?
3. How can the regulatory process be improved to account for improvements in analytical capabilities? What do we mean by the vanishing zero?
4. What are reasonable methods of assessing benefit in the risk assessment process?

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