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PDQ EPIDEMIOLOGY

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To
Betty, Steven, Lisa, Scott, Heather, & Shoshana
and
Pam, Leigh, & Adam
and
Lenny & Sydney

PREFACE

Welcome to the wonderful world of epidemiology.

Just when you figured that you had mastered the mysteries of pulmonary blood flow, cardiac rhythms, electrolyte balance, gut motility, and cerebral anatomy, along came this strange guy in a tweed jacket muttering formulas, statistics, and foreign-sounding words like "relative risk," "positive predictive value," and "Mantel-Haenzel chi-square." He didn't look like a scientist; no dirty lab coat, scientific calculator, or long hair. He didn't look like a real doctor either; no clean lab coat, stethoscope, or designer length hair. Yet he had the arrogance to claim that he is both a clinician and a scientist—he is a Clinical Epidemiologist. Amid the hushed silence in the room you can overhear desperate whispers of, "What in the world is a clinical whatever-it-is-ologist?"

More particularly, why, in a world already overpopulated by physiologists, pharmacologists, pathologists, gerontologists, nephrologists, cardiologists, neurologists, and a dozen other relatively legitimate art forms, do we need yet another -ologist?

The answer, it seems, is that somewhere in that complex, compartmentalized world that lays claim to the human body as an object of study, common sense got lost in the shuffle. The reality is that, despite a tremendous explosion in biomedical science, we still know embarrassingly little about the workings of ourselves. No one knows the cause of most diseases, or the cure for that matter. No one can lay claim to the crystal ball that will predict accurately who, among a group of cancer or post-myocardial infarction patients, will survive a year. As a result, there is a considerable gap between the exact findings of the laboratory and the uncertain world of clinical medicine. This leaves enormous room for the dissemination of well-intended but useless tests, therapies, or theories.

Some examples may illustrate the point:

1. As we have been told by the media on countless occasions, dioxin is about the most lethal chemical known. A tiny dose causes mice to curl up and die; dioxins are teratogenic, mutagenic, and carcinogenic in the lab. Yet, despite all the tons of Agent Orange dumped over Vietnam and some large spills in places like Seveso, Italy, there is no evidence that they are a significant human carcinogen.
2. Conversely, cigarette smoking is easily the most lethal human carcinogen, measured in the number of lives lost. Yet it was long after good scientific evidence from human studies convinced everyone (except tobacco farmers and cigarette manufacturers) that it caused cancer that scientists were able to induce cancers in mice in the laboratory.
3. Clofibrate was a very popular lipid-reducing agent in the mid-1960s. There was abundant laboratory evidence that it would work as

claimed. Unfortunately, later randomized trials proved that the drug killed more people than it saved.

4. We like to think that the days of patent medicines and snake oil salesmen have passed. (However, one visit to your local drugstore to peruse the over-the-counter antiarthritis drugs, none of which contains anything more than aspirin and all of which cost 10 times as much, should dispel that myth.) Nevertheless, mainstream medicine is still susceptible to the legitimate and honest claims of success of new therapies based on experience with few patients. Many of these therapies are eventually proved to have no value. One case in point is gastric freezing. There were a number of case reports, involving a total of about 1,500 patients, that indicated that it would cure ulcers. It was only later that trials demonstrated that the procedure was useless.
5. Whatever happened to tonsillectomies? It seems as if five out of six adults over the age of 40 had their tonsils removed in childhood, but very few of our children have to endure this agony. Credit for the turnaround belongs to one of the neater epidemiologic studies. It was common wisdom in those days that roughly half of all kids needed their tonsils removed. These investigators started with about 400 kids who still had their tonsils, and shipped them around to a group of respected physicians. Sure enough, 45 percent of tonsils had to go. The researchers removed these "diseased" kids from the study and sent the remaining ones around again (to different physicians, of course). This time 46 percent of the tonsils were slated to go. Now, the kids who were left (who had been judged healthy by two sets of physicians by this time) were marched before a third group of doctors. Want to guess how many were said to need tonsillectomies? You got it—44 percent.

These examples nicely illustrate the role of epidemiology these days—it comfortably fills the gaping chasm between the scientific wisdom of the wet laboratory and the clinical wisdom of the ward. The good news is that it isn't all that hard. Despite the fancy terminology, epidemiology is, above all, the science of common sense. (Its bedmate, biostatistics, isn't quite so straightforward. To decipher the arcane logic of statisticians, we heartily recommend another book in the *PDQ* series—*PDQ Statistics*. We're biased, of course, since we wrote it.)

The intent of this book is to translate the terminology of epidemiology into street talk, so that, we hope, the common sense of the methods will emerge. It's laid out a bit like a dictionary. Topics are grouped in logical, rather than alphabetic, order, so it would behoove you to tackle one section at a time. Chapter 1 is an introduction that goes into more detail about what epidemiology can and cannot do. Chapter 2 talks about experimental designs. Chapter 3 examines the issues in measurement, and Chapter 4 is devoted to the criteria of causation.

At the end of the second, third, and fourth chapters, we've provided guides to help you determine if articles that you have come across have made some basic mistakes in design or reasoning. As in our previous book, *PDQ Statistics*, we've called these illustrations "Convoluted Reasoning or Anti-Intellectual Pomposity Detectors," which we've abbreviated as "C.R.A.P. Detectors." This was done solely for the laudable purpose of conserving space, and anyone who reads any other meaning into this name reveals a low sense of humor; such people should enjoy this book.

We can't guarantee that your graduate degree will be mailed after you finish this book. Nevertheless, we hope that you will find all the fancy words a bit less intimidating.

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CONTENTS

1 INTRODUCTION TO EPIDEMIOLOGY

DEFINITIONS

Contrary to popular belief, epidemiology is *not* the study of skin diseases — the root word is epidemic, not epidermis. By the way, if you really want to impress your friends, the word *epidemic* comes from the Greek *epi*, meaning "among," and *demos*, meaning "the people." Some scholar defined epidemiology as "the study of the distribution and determinants of health-related states and events in populations and the application of this study to the control of health problems," which no doubt is about as clear and self-evident as a mortgage contract.

Fortunately, recent history is on our side. Before Legionnaires' disease came along, the only people who had ever heard of epidemiology were other epidemiologists. Now with AIDS (acquired immunodeficiency syndrome) on the rise, epidemiology is tops on the list of careers advocated by every high school guidance counselor.

We still haven't told you what it really is. That's a deliberate sidestep on our part: Epidemiology covers a whole range of activities from surveys of disease outbreaks to randomized trials of new drugs. Some would argue that the common basis of all epidemiology is methods rather than content, in contrast to most scientific disciplines. Two features of the methods of epidemiology differentiate it from most other branches of medical science: (1) in epidemiology the unit of observation is generally *groups of people* rather than individuals or other objects such as molecules, cells, or mice, and (2) epidemiology is concerned with *comparisons* of one group of people with another. Epidemiologists are always muttering about the control group. The real reason for this is that, in the primitive world inhabited by epidemiologists, we can't make any really good predictions about how people should respond under a given set of conditions; we need a control group of folks who are alike in every way *except* the variable of interest to provide some basis for comparison. After all, most theories of science make quantitative predictions about the relationship among a set of variables. Epidemiologic predictions may concern, for example, the action of a drug, and take the form "Hypothesis 1: It works," or "Hypothesis 2: It doesn't work."

Modern epidemiology incorporates both classical or analytic-descriptive epidemiology and clinical epidemiology, as we describe in this chapter. As Cassel has noted, epidemiology is an example of a discipline that has usefully expanded beyond its initial boundaries (kind of like the Sahara desert).

CLASSICAL EPIDEMIOLOGY

Over 100 years ago when the term epidemiology was first introduced in the *Oxford English Dictionary*, it referred to studying epidemics. The focus was on the study of factors that cause or are associated with disease. In one early and classic example from the mid-1800s, John Snow, a British physician, investigated the causes of the increased rates of cholera in certain areas of London. He observed that the disease was most prevalent in districts supplied with water by the Lambeth Company and the Southwark and Vauxhall Company, both of which obtained their water from a section of the Thames River that was extremely polluted with sewage. He also noted that the rate of new cases of cholera declined in those parts of the city supplied by Lambeth Company after it relocated to a less polluted section of the Thames. At the same time there was no change in the incidence of the disease in areas supplied by the Southwark and Vauxhall Company, which continued to draw its water from the heavily polluted section of the Thames. Snow was aware that a variety of factors other than water source (such as socioeconomic status and housing conditions, among others) could account for the differences in rates of disease between the two geographic areas. Snow's brilliance lay in his recognition of an opportunity to test his hypothesis that drinking water from the Southwark and Vauxhall Company increased the risk of cholera compared with the water supplied by the Lambeth Company. In his book, *On the Mode of Communication of Cholera*, Snow noted that

> Each company supplies both rich and poor, both large houses and small; there is no difference either in the condition or the occupation of the persons receiving the water of the different companies . . . . The (natural) experiment, too, was on the grandest scale. No fewer than three hundred thousand people of both sexes, of every age and occupation, and of every rank and station, from gentle folks down to the very poor, were divided into two groups without their choice, and, in most cases, without their knowledge; one group being supplied with water containing the sewage of London and amongst it, whatever might have come from the cholera patients, the other group having water quite free from such impurity. To turn this grand experiment to account, all that was required was to learn the supply of water to each individual house where a fatal attack of cholera might occur.

Walking from door to door (who ever said epidemiology is an armchair profession?), Snow documented the source of drinking water for every house where a death from cholera had taken place. In this way he determined that the polluted water, supplied by the Southwark and Vauxhall Company, was indeed responsible for the cholera epidemic.

This descriptive and analytic role of epidemiology continues to be important today in describing patterns of health and disease in communities, in contributing to our understanding of the natural history and clinical course of disease, and in identifying causal relationships. Classical epidemiology, sometimes referred to as "Big E" epidemiology, is associated with specific research approaches that are described in *Research Methodology*.

PERSON, PLACE, AND TIME

Classical epidemiology is concerned with three major variables that describe the features of the distribution of a disease or other health-related state: person, place, and time.

Person characteristics include such factors as gender (what we used to call "sex"), age, race, marital status, and socioeconomic status, among others. For example, some conditions may occur with greater frequency in one racial group than another, such as sickle cell anemia among blacks, thalassemia among Greeks and Italians, and Tay-Sachs disease among European Jews. Racial differences in the distribution of a disease can suggest a genetic root in the origins of the disorder.

The *place* or geographic distribution of a health-related outcome of interest can also be of importance in, for instance, understanding causal relationships or planning health services to meet the needs of a particular community. Geographic differences can suggest a role for factors such as climate or cultural practices, including diet, methods of food preparation, and food storage, in the promotion of a particular disease. For example, geographic comparisons from 39 countries demonstrate a strong correlation between breast cancer mortality rates and the intake of dietary fat (Fig. 1-1).

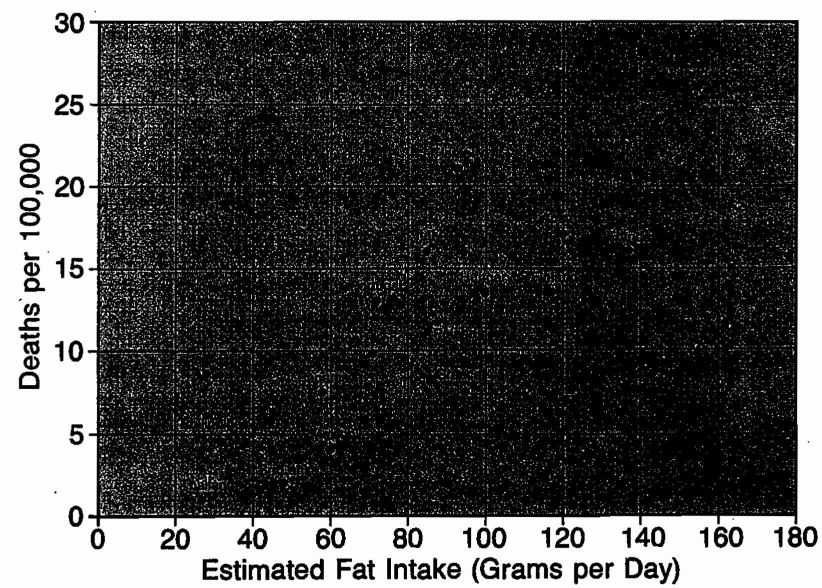

Figure 1-1 Geographic comparisons demonstrate a strong relationship between breast cancer mortality rates and the intake of dietary fat. (Data from Cohen LA. Diet and cancer. Sci Am 1987; 257:42-48.)

Variations in the *time* of occurrence of a particular disease can also indicate causal relationships among variables, although many different factors can account for the changes in disease distribution over time. For example, in many countries there has been a dramatic decline in the community incidence of dental caries over the past 20 years, which started with the gradual introduction of fluoride into community water systems, and of fluoride rinsing programs into the schools. Data from New Zealand show that a 12-year-old in 1971 would have had nine decayed, missing, or filled (DMF) teeth, whereas in 1983 the average 12-year-old had three DMF teeth (Fig. 1-2).

This strongly suggests a preventive role for fluoride, since no factors have been introduced simultaneously on such a massive scale that might otherwise explain the decline of tooth decay. This finding probably explains why more and more kids and Yuppies are wearing braces—dentists have to pay mortgages too!

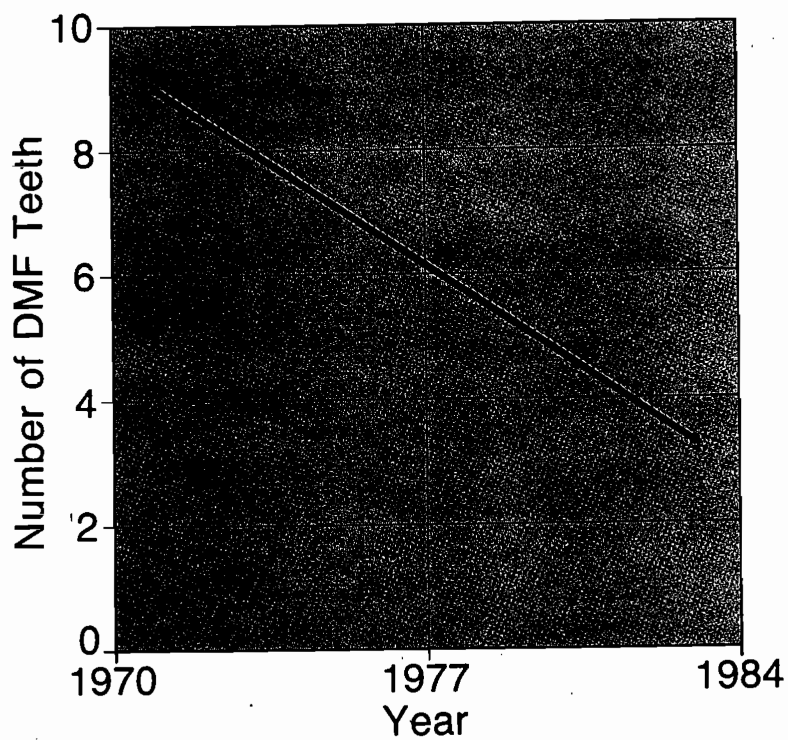

Figure 1-2 Time variable indicates causal relationship between decline in dental caries and the introduction of fluoride in New Zealand.

The variables of person, place, and time are important in understanding the nature of person-environment fit, a key construct in assessing the risk and protective factors that determine health status in groups of people.

CLINICAL EPIDEMIOLOGY

More recently, scientists such as Paul, Cassel, and Sackett and his colleagues, Feinstein, the Fletchers, and Wagner have formalized an additional branch of epidemiology termed **clinical epidemiology**. This approach applies the principles of epidemiology to the direct care of patients, sorting out research findings that are clinically useful from those that are primarily useful for tenure decisions. The hope is that this will result in more good and less harm to patients—a laudable goal.

CRITICAL APPRAISAL, DIAGNOSIS, AND MANAGEMENT

The behaviors of clinicians are based on their knowledge and beliefs about what actions are helpful in responding to a particular clinical problem; this knowledge may, in turn, be shaped by factors such as their prior experiences with similar problems, the advice of a trusted authority, and what they have read in scientific journals. These sources of information can lead to conclusions that may or may not be relevant, valid, and helpful in answering a particular clinical question. Clinical epidemiology offers clinicians specific criteria that can be applied to gauge the validity and usefulness of information they encounter when seeking to resolve a clinical problem. The buzzword for these criteria is **critical appraisal**.

TRENDS IN EPIDEMIOLOGY

As epidemiology has expanded to incorporate clinical decision making with classical or descriptive approaches, it has changed over time in regard to the nature of the diseases or health states with which it is concerned. The initial emphasis of epidemiology was on the study of infectious diseases of epidemic proportions, such as cholera and smallpox, at a time when communicable diseases plagued people everywhere and constituted the major health problem.

With improved hygiene and nutrition, advances in medical practice, and other factors, the major diseases have changed in most Western countries and are in a period of transition from infectious to chronic disease patterns in many developing nations. Epidemiology naturally followed this progression from its origins in the Age of Pestilence and Famine (infectious disease and starvation), through an Age of Receding Pandemics (decline in widespread epidemics), to an Age of Degenerative and Manmade Diseases (such as cancer, mental illness, occupational disorders, and cardiovascular disease).

About 1900 an eminent professor decreed that, given the natural history of physics, approximately 3 more years of research would solve all the remaining problems, but, in the process, he drastically underestimated the survival instincts of researchers. Epidemiologists have been equally adaptive, moving from infections to chronic diseases to drug trials (where the real money is!). However, in the last decade the wheel has come full circle with the onset of AIDS. As the disease spreads to pandemic proportions, it poses a new challenge to epidemiologists and other scientists (and guarantees many years of employment).

CURRENT APPLICATIONS OF EPIDEMIOLOGY

In case you're still confused about what this marvelous new (old) science is all about, this section provides some topical examples.

IDENTIFYING THE CAUSE OF A NEW SYNDROME

The late 1970s saw a number of cases of menstruating women who experienced a cluster of symptoms including fever, hypotension, and a rash that was followed by peeling of the skin. By 1980, 50 cases had been reported to the Centers for Disease Control in Atlanta and three women had died. Two questions required an urgent response: (1) Is this a new syndrome? and (2) What is causing it?

Through examination of the records, it was determined that these 50 cases were presenting a new clinical entity described by Langmuir as a "distinct clinical syndrome of marked severity and considerable clinical specificity." This syndrome was labeled "toxic shock syndrome."

The cause of the disease was established through a comparison of these women with a control group on a number of variables. There was no difference in their histories of sexually transmitted diseases, vaginal infections, frequency of intercourse, or intercourse during menstruation. On the other hand, 100 percent of the subjects used tampons, compared with 83 percent of the controls, and the women were significantly more likely to have used Rely brand tampons when compared with controls. That clinched it! In due course Rely brand tampons were withdrawn from the market.

This example demonstrates the strength of epidemiologic methods. Even given a relatively rare condition (toxic shock syndrome) associated with a very common practice (tampon use), it could nonetheless be established that tampon users had more than a tenfold greater risk of developing the condition compared with nontampon users.

ASSESSING THE RISKS ASSOCIATED WITH A HARMFUL EXPOSURE

Epidemiologic methods can be used to assess the risks to health that result from exposure to noxious agents. For example, with the worldwide use of nuclear reactors to generate power, the public, the nuclear power industry, and nuclear regulatory bodies are all extremely interested (obviously for different reasons) in determining the risks associated with exposure to the radioactive emissions resulting from a nuclear "accident" (a benign term for a malignant condition). These interests are not merely hypothetical or academic. In 1957 the first documented nuclear "accident," or substantial release of radioactivity from a nuclear power plant, occurred when a reactor caught fire at Sellafield on the Irish coast of Britain; in 1979 a nuclear accident occurred when a reactor was damaged at Three Mile Island; and in 1986 the most severe nuclear accident to date occurred at Chernobyl, in the USSR, when the graphite core of a reactor caught fire and caused the rupture or "meltdown" of fuel rods and the release of radioactive fission products into the atmosphere. Winds distributed the radioactive particles over large areas of Europe and the Northern Hemisphere.

It is of obvious importance to determine the immediate and long-term risks to the populations in the immediate vicinity of the accident and to those farther from the reactor (in other regions or countries). Fortunately, there is already a great deal of evidence available about the risks of cancer, childhood leukemia, birth defects, and so forth that result from exposure to high- and low-level radiation. By far the most extensive source of human evidence resulted from careful follow-up over the past 4 decades of the survivors of the Hiroshima and Nagasaki bombings. The basic strategy is to document, as carefully as possible, the radiation exposure of each individual and then compare the rate of onset of various diseases at different levels, from no exposure to a very high level. Other sources of evidence derive from the documented exposure of soldiers in the atom bomb tests of the 1950s, workers at the shipyards where nuclear submarines were serviced, populations exposed to the fallout clouds in Utah and Nevada, atomic workers, and even kids (now in their 40s) who put their feet in fluoroscopy machines at the local shoe store.

Based on this evidence, the scientists have predicted that there might be as many as 39,000 additional cancer deaths worldwide over the next 50 years. Since there are expected to be about 630 million deaths from cancer over the same period, the increase will not be detectable. Within the USSR, estimates range from 5,000 to 50,000 deaths against a background of 9.5 million cancer deaths; again, the difference would not be statistically significant. However, among the 24,000 people who lived within 15 km of the reactor site, the estimated excess number of cancers is 13, which raises the total to 624; this would be statistically detectable.

Epidemiologic studies have played a fundamental role in demonstrating the risk to health from such domestic exposures as smoking, nitrates in food, high dietary cholesterol, and occupational exposure to factors like asbestos, lead, and rubber. Conversely, epidemiologic methods have shown that there exists little evidence of harm from other exposures. For example, formaldehyde release from ureaformaldehyde foam insulation, "yellow rain" in Southeast Asia, video display terminals, and Love Canal have all, at one time or another, been featured prominently in news reports. Subsequent epidemiologic investigations, however, have revealed little in the way of measurable health problems from these highly publicized cases.

In turn, the identification of these risk factors may lead to the identification and effective treatment of those already exposed (e.g., screening and treatment for hypertension), and can suggest strategies for prevention (for example, guarantees of adequate income for single-parent families to prevent some childhood psychiatric disorders).

HOW TO DETERMINE IF A TREATMENT IS EFFECTIVE

You are a 33-year-old mother of two. Last week you noticed a small lump in one breast. With considerable apprehension you made an appointment with your family doctor. Today the doctor announced that your fear was justified; the lump is malignant. Your physician is recommending total mastectomy (a surgical procedure that involves amputation of the breast, but not of the underlying muscle and lymph nodes), and assures you that if you have this procedure your condition is almost certainly curable. A friend of yours had a diagnosis of breast cancer over 1 year ago, and her physician removed just enough tissue to eliminate the tumor (segmental mastectomy) and gave her radiation therapy. You are frightened by the disease and want the treatment that will be most effective in preventing a recurrence of the cancer. On the other hand, you are devastated at the prospect of losing your breast. Clearly, if the treatment your friend had is as effective as total mastectomy, it would be your treatment of choice.

How do you decide what to do? Being human, you likely would seek out other friends who have gone through the procedures. In the absence of friends there is still *Family Circle* and *Consumer Reports* (the latter, actually, does a good job of reporting medical research). However, if you or your close friends had access to Medline and a medical library, there is the option of seeking out the original articles.

Clinical epidemiology figures prominently in the review. The methods of clinical epidemiology have contributed much to the assessment of the effectiveness of particular treatments. In the case of breast cancer the primary issue is whether there is any greater chance of survival with total versus segmental mastectomy. The question of effectiveness must be clearly defined, including both the specifics of the treatment and the particular cases to which it is applied. For example, segmental surgery may be just as effective in treating early stage breast cancer, whereas it may well be ineffective in treating later stage breast cancer after the malignant cells have spread beyond the immediate area.

Some additional concerns may relate to the side effects. If there is no difference in survival between two treatments, it becomes a tradeoff between the short-term discomfort from chemotherapy or hair loss from radiation against the disfigurement and disability from the loss of the breast. An approach that may help when examining side effects is to seek out information about the differences in psychological adjustment following total mastectomy versus segmental mastectomy and radiation therapy.

The best data on whether a treatment does more good than harm come from an experimental study design called the **randomized controlled trial (RCT)**. Here, patients with the disorder are randomly allocated to receive either the experimental treatment or conventional therapy (or a placebo), and then followed up so that the clinically relevant outcomes of the disease and treatment can be described and compared (see *Research Methodology* for more complete details of the RCT design). If you were the woman in our breast cancer example, and if, in an improbably objective frame of mind, you wanted to apply epidemiologic principles to determine the treatment of choice, you would want to know if any RCTs had been conducted comparing total mastectomy to more conservative surgery and radiation therapy.

As it turns out, there are several such trials. A recent one found that segmental mastectomy, with or without radiation, was superior to total mastectomy (Fig. 1-3). More women remained disease-free and more women were still alive 5 years after the procedure, whether or not the cancer had recurred. So, your literature search would give you the ammunition to say that segmental mastectomy not only is less disfiguring, but also likely leads to a better outcome.

HOW TO IDENTIFY HEALTH SERVICE UTILIZATION NEEDS AND TRENDS

Modern epidemiology plays an important role in the development of methods that can be used to describe health services and to test alternative ways to "deliver the goods." As an example, one often-debated health service question concerns the effect of health insurance coverage on the health services used by poor and near-poor populations. Conservatives claim that allowing people free access to health care services will open the

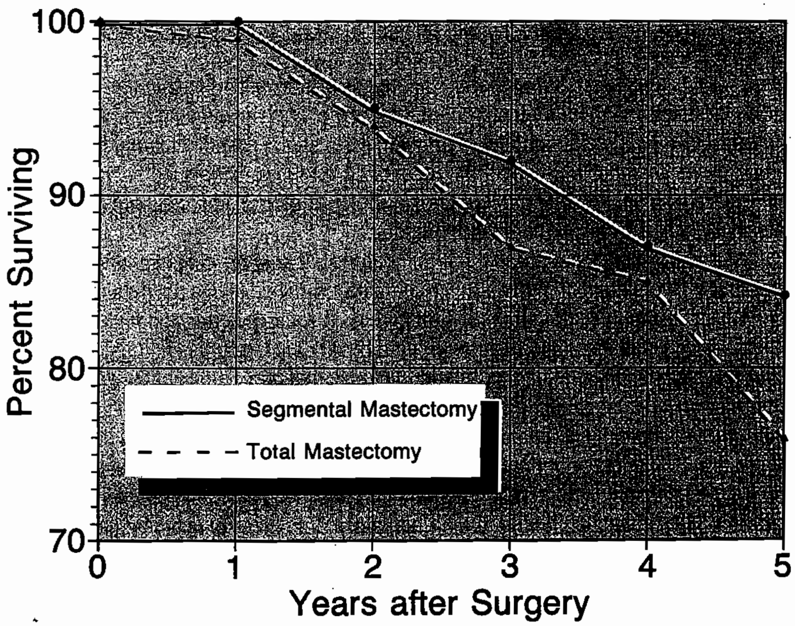

Figure 1-3 Data from a randomized controlled trial showing survival rates following segmental and total mastectomies.

floodgates and result in massive increases in health care costs. In so doing they ignore two kinds of data: (1) the several decades of experience in Canada and western Europe that provide ample demonstration that there is a practical ceiling on use of health services, and (2) the unpleasant experience of cooling one's heels in a doctor's waiting room, thumbing 10-year-old copies of *Reader's Digest*. The idea that people would prefer this to doing almost anything else is bizarre. By contrast, socialists live in their own version of utopia, where all are equal — in access, income, and reason. In socialist heaven no clear-thinking individual would dare to take undue advantage of free health care services, and utilization rates would not differ regardless of the method of payment.

Obviously, truth lies somewhere in between these extremes. Taube and Rupp conducted a study to assess the effect of Medicaid coverage on access to ambulatory mental health care for the poor and near-poor under 65 years of age. Analyzing data from the National Medical Care Utilization and Expenditure Survey, they found that the poor and near-poor with continuous Medicaid coverage used almost twice as much service as the poor and near-poor not enrolled in Medicaid (Fig. 1-4).

They concluded that the higher probability of use in those covered by Medicaid reflects the impact of the increased financial accessibility to needed mental health services. (This is a fine demonstration of the art of sciencemanship. Take an obvious and self-evident conclusion from the data, and clothe it in big obscure words so it sounds profound.)

This is only one example. Our personal favorite, which neatly skewers

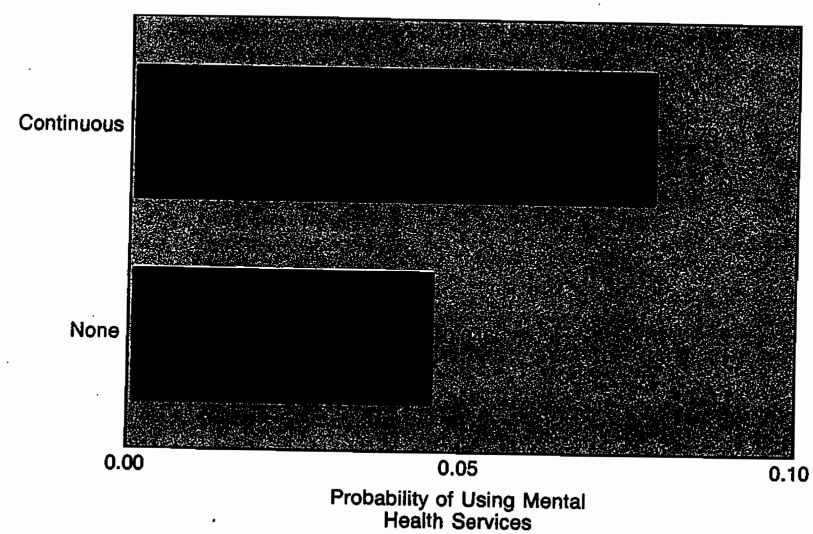

Figure 1-4 Data showing the effect of Medicaid coverage on access to ambulatory health care for the poor and near-poor populations under 65 years.

those who assume that every additional dollar spent on health care is a dollar well spent, is the repeated demonstration (in Scandinavia, Israel, and Canada) that when the doctors go on a protracted strike, the mortality rate drops.

Some other variations on this theme are *health economics*, which combines epidemiologic and economic methods to examine the cost-effectiveness of alternative models of delivery, and *policy analysis*, which seeks to link research findings to change in health policy.

SUMMARY

Epidemiology is a combination of knowledge and research methods concerned with the distribution and determinants of health and illness in populations, and with contributors to health and control of health problems. It comprises an analytic, descriptive component termed *classical epidemiology*, and a component concerned with critical appraisal of the research literature and diagnosis and management of illness, which is termed *clinical epidemiology*.

Modern epidemiology contributes to defining new clinical syndromes and their causes, as well as to completing the picture of the natural history and clinical course of a disease. It assists in the identification of the health risks associated with particular exposures and suggests strategies for disease prevention. It provides the criteria and methodology for determining if a treatment is effective and for describing and identifying health services needs and trends. Epidemiology has application to a range of health-related disciplines and has benefited from the contributions of a variety of professions.

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