CHAPTER 1
CONFRONTING BEWILDERING MEDICAL NEWS

Preview

Picture this: You are watching the evening news. "An authoritative new study," the announcer says, "shows that *flavonoids*—antioxidants found in plants, coffee, tea, and even chocolate—reduce postmenopausal women's risk of breast cancer by 45 percent!" Great news, indeed. This little bit of information, after all, immediately suggests an enjoyable way to ward off one of the diseases women fear most. So, if you are a woman, should you run to the supermarket and load up in the produce aisle? Should you brew a pot of coffee or tea or, perhaps, go to bed munching on a candy bar?[1]

You may, of course, have second thoughts. Some years ago, after all, a newspaper story had enticed you to get a prescription to fight your arthritis pain. But a short time after that, Merck had pulled *Vioxx* off the market, citing newly discovered and scary risks of blood clots, stroke, and heart attacks. You remember the feeling of betrayal at the time. So why should you believe anything now and reorganize your life once more because of those flavonoids? Better believe *nothing*, you may say, then you can't be let down in the end, can't be disappointed when a second study contradicts the results of the first.

That attitude, of course, puts you in a dilemma: If you simply ignore all those headline-grabbing research reports, you may miss the very findings that can *really* benefit your health! And that's why this book has been written. It urges you to make another choice: First, acquire the skills you need to ask the right questions of research reports; then use your new knowledge to judge for yourself whether their claims can be believed. You will be surprised to see how simple it can be. After having learned just a little bit about the major methods of research and the meaning of key statistical concepts that researchers employ, you will be able to read between the lines of their reports and find it quite easy to sift crucial truths from mere hype and outright lies. And if you are too busy to do this kind of work, there is another way. You can rely on the efforts of others who have dedicated themselves to judging the quality of medical news by employing the very type of statistical thinking this book recommends; later chapters will tell you who they are and where to find their reports.

PART I:
HOW NEW HEALTH-RELATED DATA ARE COLLECTED

Chapter 2: Observational Studies
Chapter 3: Controlled Experiments

Two alternative methods of research are used routinely to generate new knowledge about our health: the *observational study* and the *controlled experiment*. The two procedures provide data of rather different quality, but each method has its own strengths and weaknesses, which is why each is in common use. Regardless of the procedure chosen, however, much can go wrong when data are collected and analyzed. In this part of the book, we acquire the skills we need to recognize the types of errors that researchers may commit—by accident or design.

To help us assess the validity of new research reports and make the right decisions about our health, each of the next two chapters provides us with a *list of crucial questions* to ask. In the future, whenever those glowing press releases make their way into newspaper headlines and television sound bites, urging us to take advantage of another "medical breakthrough" yet, our checklist will tell us what to look out for. It will help us separate research results we can trust and act on from others we should doubt because some honest error has been made or, worse yet, someone is clearly trying to pull a fast one.

CHAPTER 2
OBSERVATIONAL STUDIES

Preview

Picture this: You have just contracted a miserable cold. Your neighbors show little sympathy. "Should have taken loads of vitamin C," they say, "just as we do. We haven't had a cold in years." You have heard this before; it is one of those pieces of folklore that collides with the facts as you know them. After all, you are not the type of person who falls for every bit of bunkum that comes along and runs with the herd. But this time you are too miserable to let it go. You are determined to get to the bottom of this, once and for all.

You decide to take the scientific approach. "Good health starts with good information," you say. You fashion a questionnaire, park yourself in front of the store across the street, along with your Kleenex box, and ask all the customers showing up during the hour before noon to answer a couple of questions about the past 5 years of their lives:

- How much vitamin C did you consume on a typical day?
- How many colds did you get in the average year?

Some people tell you to go fly a kite, of course, but those who do answer provide you with the results now summarized in Table 2.1. More than that! At a nearby college, a friendly statistician agrees to look at your data and offers to create a visual display of what your effort has wrought. You may never have heard of these concepts before, but now you know: Your data can be neatly illustrated with a *scatter diagram* and then summarized by a *regression line* drawn through the midst of them! Figure 2.1 shows the result.

In the *scatter diagram*, each person's pair of responses (like B's 0 units of vitamin C and 6 colds) is plotted as a fat dot, and the twenty-two dots as a group are summarized by the straight line, called a *regression line*, the downward slope of which clearly indicates that a greater consumption of vitamin C is associated with fewer colds. Your neighbors, it seems, have been right.

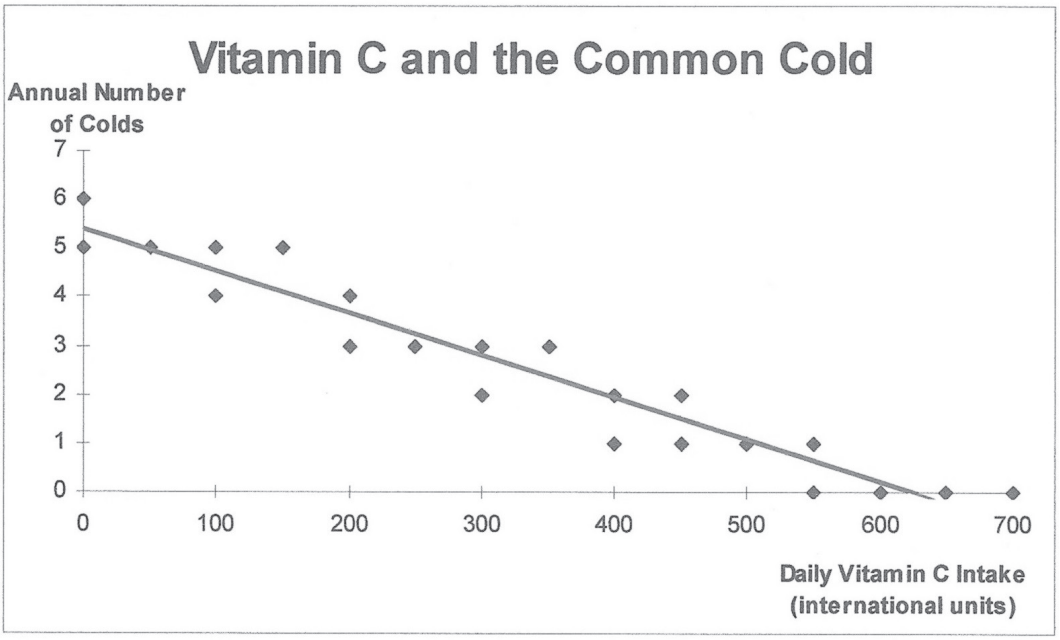
Let the local media get hold of that little diagram and the consequences are easy to predict. "Is your health stuck in the slow lane?" the newspapers will ask. "Stop colds with vitamin C!" And can't you just hear the announcer on the evening news: "A new *observational study* completed today confirms what many of us have long believed…."

And yet, as this chapter will show, your Table 2.1 evidence, along with its fancy illustration in Figure 2.1, doesn't prove a thing. More likely than not, despite your good intentions, your conclusion is garbage, gibberish, gobbledygook. Your study is the type that

Table 2.1 Vitamin C Consumption and Incidence of the Common Cold

Person	Vitamin C Consumption (international units per day)	Number of Colds (annual average)	Person	Vitamin C Consumption (international units per day)	Number of Colds (annual average)
A	300	3	O	250	3
B	0	6	P	550	1
C	100	5	Q	50	5
D	600	0	R	400	1
E	350	3	S	650	0
F	450	2	T	200	3
G	150	5	U	0	5
H	400	2	V	300	2
I	700	0	W	550	0
J	500	1	X	100	4
N	200	4	Y	450	1

Figure 2.1 Scatter Diagram and Regression Line



fools people all the time and that should be discarded as quickly as possible. By the end of this chapter, when you have acquired a checklist of crucial questions to ask of research reports, you will understand the reason for this harsh assessment. In case you can't wait, here is one of them:

Your study ignored so-called *confounding factors*, other variables that could just as well explain how often people are attacked by the common cold. The lower incidence of colds among the consumers of more rather than less vitamin C, for example, could have been the result of dozens of other causes, such as their being younger and generally healthier, being compulsive hand washers, sleeping many more hours, drinking huge quantities of water, exercising regularly, or, perhaps, quite inadvertently eating a lot of zinc! Any one of these and other factors, *and even pure chance*, might explain the result illustrated in our graph. And that would make any conclusion about *vitamin C* preventing colds utterly unfounded. But all too often, studies with similar flaws make it into the headlines; the rest of this chapter will show you how not to be bamboozled by them.

CHAPTER 3
CONTROLLED EXPERIMENTS

Preview

A few decades ago, before it was known that most stomach ulcers were caused by *Helicobacter pylori*, a bacterium susceptible to antibiotics, many people suffered from such ulcers without an end in sight and many a doctor looked in vain for a cure. But then Dr. O. H. Wangensteen made an experiment and proposed a revolutionary new ulcer treatment: The patient swallows a balloon into which a refrigerant liquid is pumped, which freezes the stomach. In response, the digestive process shuts down temporarily, giving the stomach a chance to heal. The physician had performed this experiment, he said, on 24 patients of his choice and all were cured. The prestigious *Journal of the American Medical Association* published his report.[1]

But critics scoffed. They thought this was a *bad* experiment, for lots of reasons. For one thing, the doctor's experimental subjects had *not* been selected at random from the entire population of ulcer sufferers; the doctor's tiny *convenience sample* could easily have consisted of patients who would have become better even without the procedure. (Unlike the general population of ulcer sufferers, Dr. Wangensteen's patients, for example, might just happen to have had simultaneous ear infections and, unbeknownst to anyone, their ear treatment with antibiotics could have improved their ulcers at the same time.) For another, even if such *confounding factors* did not influence the results of the gastric freezing experiment, neither the doctor who ran the experiment nor his patients could be trusted to be *objective* observers. The doctor would have had a strong self-interest in the success of his procedure and might have exaggerated the rate of cure. The patients could well have experienced a psychological reduction in symptoms, at least for a short time, merely because they knew themselves to be subjects in a new and exciting experiment. Worst of all, this experiment was not a *controlled* experiment, which requires a comparison of otherwise identical patients who do receive a new treatment with others who do not.

Interestingly, before long, another physician, Dr. J. M. Ruffin, performed an alternative and much more rigorous test.[2] He randomly selected 160 ulcer patients and, by another random procedure, divided them into an *experimental group* and a *control group*. (Such *randomization* deals with the confounding problem. It lets extraneous factors operate during the experiment but assures—by virtue of the random selection of subjects from a target population and their subsequent random assignment to experimental and control

groups—that the outcome in each group has an equal chance to be enhanced or handicapped by these extraneous factors.) In addition, Dr. Ruffin performed a *double-blind experiment*. All patients were made to swallow the balloon and were given the impression that they underwent the gastric freezing procedure. However, some 82 patients in the *experimental* group received the genuine procedure, while some 78 patients in the *control* group underwent a fake procedure during which a bypass valve diverted the refrigerant. More than that! The doctors who performed the procedure, just like their patients, had no idea about who belonged to which group; only the statisticians knew what was going on.

The results of this second experiment were instructive: After the procedure, 76 percent of patients in the experimental group showed improvement or no symptoms; 68 percent of patients in the control group were similarly classified. The difference was found to be *not statistically significant*, which, as we will see, is a fancy way of saying that the observed difference could easily have been produced by chance. Indeed, such was Dr. Ruffin's conclusion and, as expected under the circumstances, patients in both groups relapsed over time at about the same rate. Dr. Wangensteen's procedure was termed useless; there was no reason to believe that gastric freezing cured ulcers.

This chapter gives us the lowdown on what it is that makes for good or bad experiments. In the process, we develop a second list of questions to use whenever we encounter health-related advice derived from an experiment rather than an observational study. And, thus, once again, we acquire the ability to spot useless advice right off the bat.

NOTES

Chapter 1: Confronting Bewildering Medical News

[1] The flavonoids story introducing this chapter's Preview has been adapted from Tufts University, *Health & Nutrition Letter*, June 2006.

Chapter 3: Controlled Experiments

[1] Owen H. Wangensteen et al., "Achieving 'Physiological Gastrectomy' By Gastric Freezing," *The Journal of the American Medical Association*, vol.180, 1962, pp. 439-444.

[2] J. M. Ruffin et al., "A Cooperative Double-Blind Evaluation of Gastric 'Freezing' in the Treatment of Duodenal Ulcer," *The New England Journal of Medicine*, vol. 281, 1969, pp. 16-19.