PUBLIC HEALTH AND THE RISK FACTOR

A History of an Uneven Medical Revolution

William G. Rothstein

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To
James C. Mohr

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PREFACE

Most laypeople, physicians, and other health professionals have a very different view of the relationship between personal behaviors and health and illness today than they did a century ago. At the beginning of the twentieth century, most people believed that their health was a matter of concern only when they were sick. By the end of the century, most people accepted the statistical evidence that specific behaviors and characteristics of healthy persons, called "risk factors," can increase the probability of developing disease, especially chronic disease. Most people also believe that making appropriate changes in their lifestyles, a concept associated with risk factors, can reduce the probability of the occurrence of disease. To facilitate this process, they expect health professionals, agencies concerned with public health, and the media to inform and educate the public about risk factors.

The acceptance of risk factors has produced changes in public health and medicine as profound as those that resulted from bacteriology and the germ theory of disease. The changes have been most evident in coronary heart disease, which was the major cause of death in the twentieth century and is the focus of this study. Yet the impact of the risk factor has been much more uneven than the germ theory. The risk factor concept has been controversial because of its statistical methodology, its multifactorial concept of disease etiology, and its effect on the economic interests of commercial, professional, and health organizations.

This study endeavors to explain in nontechnical language how one of the greatest revolutions in the understanding of health and disease could have produced such mixed outcomes. Although risk factors are a statistical concept, I have avoided all discussion of the mathematics involved. I have also refrained from using statistical terminology, although this has occasionally necessitated lengthier descriptions. Readers familiar with risk factor research will find that I have made little use of a popular statistical tool, meta-analyses. I believe that meta-analyses are based on the erroneous premise that methodological flaws in individual studies cancel each other when studies are combined. The history of the use of statistics in the social sciences, and I believe in medicine, provides convincing evidence to reject this assumption. Instead I have looked for agreement among studies that used the most rigorous methodologies.[1]

An anomaly of risk factor research is that many of the most useful quantitative studies are early ones. The early studies of the natural history of persons with risk factors occurred before medications were available and so provide the only longitudinal data on large numbers of persons with untreated risk factors. In studies of the treatment of risk factors, the protocols require that the experimental group receives the treatment being tested and the control group receives the standard available treatment. In the early studies of some widely accepted medications, the control groups received no treatment because there were no useful treatments. Today the control groups almost always receive an older treatment while the experimental groups receive the treatment being investigated. Today also, many members of both experimental and control groups are also being treated for other medical conditions. Consequently most persons in every group in these studies are receiving some kind of treatment and thus the studies have no true control groups.

Two other aspects of the statistics used in this study can be mentioned. Most historical epidemiological studies suffer from a paucity of trustworthy mortality and morbidity statistics. I believe that a major contribution of this study is the use of historical statistics of exceptionally high quality that are unknown to most scholars. In addition, erroneous reporting of cause of death has always been a major problem in coronary heart disease. However, studies have consistently found that reporting accuracy on death certificates is much greater for deaths below age 65, so I have focused on those age groups.

This study could not have been completed without the assistance of a number of persons. Professor James C. Mohr of the University of Oregon provided assistance in so many ways, including insightful readings of two drafts of the manuscript, that I cannot imagine its publication without his help. Doctor W. Bruce Fye of the Mayo Clinic explained the treatment and other aspects of coronary heart disease clearly and concisely and helped me avoid numerous errors. Edward Morman and the staff of the historical collections of the Welch Medical Library of the Johns Hopkins University were of great help in locating important historical materials. A journal article by Audrey Davis describing the influence of the life insurance industry on the practice of medicine provided the stimulus for this project, which grew in scope and depth as I realized its multifaceted implications.[2] I turned repeatedly to the writings of Rene J. Dubos, the great French-American bacteriologist, for enlightening explanations of multifactorial concepts of disease etiology. A grant from the Science, Technology, and Society program of the National Science Foundation enabled me to take a semester's

leave of absence that was invaluable early in the study. A subsequent sabbatical leave from the University of Maryland, Baltimore County, was of equal benefit. Professor Theodore Brown of the University of Rochester and Tim Madigan and others at the University of Rochester Press provided friendly assistance far beyond their formal responsibilities. Last, I would like to express my gratitude to my family, friends, colleagues, and students for cheerfully tolerating my preoccupation with this research for so many years.

1

INTRODUCTION

> Scientific uncertainty is an unavoidable limit that is inherent in scientific knowledge and in the methods by which scientific facts are established. Because scientific knowledge is basically probabilistic rather than absolute and provisional rather than final, it can never be devoid of uncertainty or the possibility of inaccuracy or incompleteness.[1]

One of the fundamental transformations in twentieth century public health and medicine has been the widespread acceptance of a new concept of the causes of chronic and degenerative disease. This is the lifestyle theory, which holds that an individual's state of health is affected by specific aspects of the manner of living of that individual. In the same way that an individual suffering from a disease must follow a prescribed regimen to recover from that disease, a healthy individual must engage in continuous activities that are an integral part of daily life in order to maintain health. According to the theory, the behaviors involved in healthy lifestyles can increase or decrease the probability that an individual will develop particular diseases.

The idea that the maintenance of health requires continuous personal care and attention is an ancient one and a basic precept of the Hippocratic writings. Until the twentieth century, however, the behaviors prescribed for maintaining health were vague, ill–defined, and usually in the

form of aphorisms: moderation in all things; early to bed and early to rise; an ounce of prevention is worth a pound of cure. The recommendations were rarely enlightening because they were neither internally consistent nor based on scientific investigations. Most healthy persons did not believe that the maintenance of health required a specific lifestyle and lived without much concern about the effects of their daily actions on future health. Furthermore, many illnesses were considered an unavoidable part of the normal pattern of life and therefore beyond human control: the infectious diseases of infancy and childhood; women's deaths, diseases, and disabilities resulting from childbearing and housework; workers' deaths, diseases, and disabilities produced by hazardous, unhealthy, and arduous working conditions; and the infirmities produced by aging. Even if the diseases or deaths were preventable, the great majority of people lacked the financial and other resources to make the necessary changes in their lifestyles to avoid them.

The lifestyle theory was made possible by the invention of the risk factor, a quantitative concept based on statistics that was introduced into life insurance at the turn of the twentieth century. *A risk factor is a pattern of behavior or physical characteristic of a group of individuals that increases the probability of the future occurrence of one or more diseases in that group relative to comparable groups without or with different levels of the behavior or characteristic.* (Although it will not be discussed here because of differences in usage and historical development, a carcinogen is a risk factor for cancer.)

Risk factors need not be directly involved in the disease process. In many cases the etiological process is unknown but risk factors are used as proxies for the unknown causes because they have predictive value. Some risk factors are indicators that can be measured accurately, inexpensively, safely, or with simple instruments. These are great virtues that reduce the possibility of harm to the patient, the time and effort of the health professional, and the cost to society. An example is build, the relationship of body weight to height, one of the first and most useful risk factors discovered by the life insurance industry.

When the risk factor and its statistical methodology became accepted as a method of investigation in the health sciences about 1960, it provided a new basis for understanding the relationship between a disease and its causes: (1) multiple factors internal and external to the individual are involved in the etiology of every disease; (2) the inherent limitations of scientific methodology mean that all of the etiological factors can never be identified or measured precisely[2] and; (3) statistical analyses can determine the degree to which a specific factor by itself or in conjunction with others can

increase or decrease the probability of occurrence of the disease. This approach is in striking contrast to the nineteenth-century doctrine of specific etiology, under which diseases were investigated as though they resulted from particular identifiable external causes, such as bacterial pathogens.

A social and intellectual revolution of this magnitude requires a number of basic discoveries and applications. The thesis of this study is that five historical innovations were necessary to produce the public health concept of the risk factor: (1) the development and adoption of probability and statistics as methods of quantifying the risk of death and disease and the benefits of treatment and public health measures; (2) the recognition that healthy lifestyles are essential to improve the health of the population; (3) the use of educational campaigns by public health departments to encourage the public to adopt healthy lifestyles; (4) the acceptance of probabilistic and multifactorial models of disease etiology; and (5) a disease, in this case coronary heart disease, that was so serious and prevalent as to warrant educational programs designed to change the lifestyles of the entire population.

Probability theory was devised in the seventeenth and eighteenth centuries as a technique for understanding the relative likelihood of alternative outcomes. Statistics developed in the eighteenth century as the quantitative and qualitative analysis of political entities such as states and cities. The two fields were brought together when probability theory was used to determine mortality rates for the population and for specific age and sex groups.

By the nineteenth century, convincing evidence existed that many social phenomena exhibited remarkable statistical regularities from year to year, including deaths, marriages, births, crimes, and suicides. These discoveries made it possible to apply the philosophy and methods of the natural sciences to study social phenomena quantitatively and contributed greatly to the development of public health and the social sciences. The life insurance industry was the first commercial enterprise to utilize this knowledge and developed mortality tables that placed life insurance on a sound financial basis. One basic actuarial principle was to adjust the premiums charged to specific groups, such as age and sex groups, to reflect statistical differences in their death rates. At the turn of the twentieth century, life insurance companies extended this principle to other characteristics, including occupations, build, and blood pressure, which they termed risk factors. Life insurance companies required physicians who examined their applicants to provide information on the applicants' medical risk factors, and the physicians soon applied this new knowledge to their private patients. The

adoption of risk factors by physicians was hindered by the lack of treatments and the incompatibility with widely accepted models of disease etiology.

Meanwhile, a new public health program of disease prevention based on the education and active participation of the public was being applied to infectious diseases. In the late nineteenth century, bacteriological investigations found that bacteria that caused diseases in humans were also sometimes present in drinking water, milk, sewage, and foods. Public health programs thereupon endeavored to destroy the bacteria in these sources or prevent them from coming into contact with humans. By the early 1900s, many of these programs were found to be insufficient or ineffective. Public health departments thereupon began to educate the public to change their lifestyles to avoid contact with the bacteria and to maintain a level of health that would enable them to resist the harmful effects of the bacteria.

During the first half of the twentieth century, the major causes of death changed from infectious diseases to chronic diseases of the middle aged and elderly. Coronary heart disease became the single most important cause of death in all advanced countries. Chronic diseases have a latency period measured in years, are incurable, and are often degenerative. In investigating the causes of chronic diseases, medical researchers were unable to discover any specific etiological factors comparable to bacterial pathogens in infectious diseases. Instead, they adopted the risk factor approach of the life insurance industry, which quickly became the accepted etiological model for chronic diseases.

Public health agencies combined the risk factor model of disease causation with their educational programs to encourage the population to change their lifestyles to modify risk factors for coronary heart disease. Private health organizations and commercial businesses also adopted educational and advertising programs concerning risk factors. Public acceptance of risk factors was enhanced by the consumer movement and the widespread application of statistical risk analysis to environmental hazards.

Despite its many achievements, the risk factor model has inherent limitations that produce controversy and conflict. The outcome of any statistical analysis concerning the risks imposed by a risk factor is a set of probabilities whose interpretation requires a subjective judgment. The same numerical level of risk may be perceived as dangerous by one group and minor by another. Similarly, if a treatment of a risk factor reduces the probability of contracting a disease by a given amount, one group may conclude that the reduction is meaningful while another may consider it trivial.

Various interest groups have used this characteristic of risk factors to influence public policies by exaggerating or minimizing the benefits of par-

ticular preventive programs and treatments. The major interest groups are organizations that sell commercial products such as foods, tobacco, and pharmaceuticals or provide services such as medical care, health information, and medical research. These organizations include private businesses and corporations, government agencies, medical societies, voluntary health associations, and academic health centers.

As a result, risk factors, which were thought to be scientific decisions based on statistical analyses of research investigations, have become enmeshed in controversies resulting from different interpretations of the statistical findings. The disputes are magnified by the strong and conflicting economic interests of the groups and organizations involved. A study of the history of this process can contribute to an understanding of the determination of health policies, the evolution of the health sciences and professions, and methods of scientific inquiry.