AN INTRODUCTION TO EPIDEMIOLOGY

SECOND EDITION



Michael Alderson

An Introduction to Epidemiology

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SECOND EDITION



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Preface

Epidemiology has three main aims: to describe the distribution and size of disease problems in human populations; to identify aetiological factors in the pathogenesis of disease; to provide the data essential for the management, evaluation and planning of services for the prevention, control and treatment of disease. In order to fulfil these aims, three rather different classes of epidemiological study may be mounted.

- Descriptive studies concerned with observing the distribution and progression of disease in populations;
- Analytical studies concerned with investigating hypotheses suggested by the descriptive studies;
- (3) Experimental or intervention studies concerned with measuring the effect on the population of manipulating environmental influences thought to be harmful, or by introducing in a controlled way preventive, curative and ameliorative services.

This book describes the various approaches that can be made in following such paths of investigation.

Since routine mortality and morbidity statistics may provide background information for many studies and may be the sole source of data for some, two chapters are devoted to these issues. There follow chapters on the use of cross-sectional, retrospective and prospective studies, with examples in each of particular studies, the principles involved and some of the advantages and disadvantages of the different approaches. A further chapter deals with intervention studies, including preventive, clinical and medical-care trials. There then follow chapters dealing with the application of epidemiology to three very different topics: medical-care studies, genetics and occupational hazards. The final chapter provides some general comments on study design and the derivation of inferences from empirical data. For the second revision of this book the last three chapters are new additions to the text; chapters 4 and 5 have been rewritten, while all the others have been extensively revised.

Considerable emphasis is placed on study design in each chapter and attention is also paid to methods of analysis and the interpretation of data, particularly to certain statistical techniques that are used predominantly in the field of epidemiology. The intention is to indicate the relevance of these approaches, and to provide a guide to the literature and textbooks on statistics for readers wishing to explore these aspects further. The examples of published work that are quoted have been chosen to illustrate the methods of epidemiology. It is hoped that each example will help to stimulate interest in the subject, but no attempt has been made to provide a comprehensive cover of all the findings of epidemiological studies. The examples deal predominantly with the methods used in the study of chronic disease, the main field of work of epidemiologists in developed countries,

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together with an application of these methods to medical-care studies.

Epidemiology will be one of the sources of fresh data that may be of concern to everyone involved in the health-care field, whether these data relate to aetiology, means of prevention or modes of delivery of health care. It is suggested that many entrants into the health-care field (doctors, nurses, administrators and ancillary staff) should have some appreciation of the role of epidemiology and the underlying methods used in order to be able to read published work and interpret it. It is also hoped that a clear exposition of the various approaches used in epidemiology may stimulate a wider range of individuals to carry out their own, however limited, studies. In addition to the general acceptance that undergraduates should be introduced to this subject, there is a growing tendency to acknowledge that administrators in the health service should be trained in disciplines such as epidemiology. It is hoped that this book will provide a basic introduction to the subject suitable for this general readership who may not wish to study the subject any further. In addition the text should act as a useful basis for a more detailed course suitable for those entering into community medicine, and should also provide guidance for individuals in any branch of medicine who wish to carry out their own studies.

The stimulus to write this book came from the involvement in the teaching of medical and other students in the health field. This was reinforced by individuals bringing a range of fascinating problems for discussion. Each of these problems from the different branches of medicine has indicated the growing interest of many individuals working in the health service to carry out their own projects. It is hoped that this book will give assistance to such persons. These people are not named in the text, but a debt of gratitude is owed to them for the way in which the presentation of practical issues has stimulated thought. Hubble* drew attention to the relatively fine dividing line that separates plagiary from correctly attributed quotation, and original thought. It is obvious that the bulk of the ideas in this text have been distilled from contact with many colleagues over the past twenty years; in particular a debt of gratitude is owed to Robert Wofinden, Jerry Morris and Alwyn Smith. It is a pleasure to acknowledge the help from staff in the Medical Information Unit of Wessex Regional Health Authority, and the Division of Epidemiology in the Institute of Cancer Research.

I am most grateful for the help given by Elizabeth Horne, Senior Editor, Medical Books, and Steven Redwood, Production Services Manager, both of The Macmillan Press Ltd, and of Richard Powell, Editorial Consultant, in the preparation of this new edition.

Southampton, 1983

Michael Alderson

^{*}Hubble, D. (1974). Personal view. Br. med. J., 3, 623

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Definitions

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1 The Role of Epidemiology

Epidemiology may be defined as the study of the determinants of the incidence and prevalence of disease. This relatively simple definition has some extremely widespread implications. It immediately suggests that epidemiology may be used to identify the cause of disease, but it must be remembered that it is most unusual that there is a single cause for a disease without any other confounding or intervening factors playing a part. Thus the examination of the causation of disease may involve investigators in an extremely wide range of studies unravelling a complex tangle of factors. The consideration of factors influencing the prevalence of disease adds a different perspective to the role of epidemiology; the prevalence of disease (the measure of the extent to which a disease exists in a population at a point in time) is a combination of the incidence of the condition, the cure rate and the fatality from this condition. In order, therefore, to study the determinants of the prevalence of a condition, information about the incidence, the natural history of the disease and the impact of the health-care system on the disease is required. This involves studying the cause of disease, the identification of disease patterns, the population's attitudes to disease, their tendency to seek cure, the range of care provided and the impact of such care on the disease. The above definition thus acknowledges the activities of epidemiologists in a range of studies throughout the medical-care field in examining the functioning of the health-care system and its impact on the health of a population.

1.1 Who Practices Epidemiology?

There is a very small but steadily growing proportion of the total manpower in the health field identifying themselves as trained epidemiologists. Although many of the studies discussed in this book have been carried out by 'professional epidemiologists', it is important to point out that many studies have been done by individuals working primarily in other branches of medicine. Recently, classic work has been carried out in general practice and by hospital staff. Pickles (1939) described a whole series of studies carried out in a rural practice in the Yorkshire dales. By the use of relatively simple methods relying on careful documentation and analysis of observations, he provided unique contributions on the spread of a number of infectious diseases. Fry (1966, 1974) has patiently documented the health problems of patients in an urban practice and reported on the natural history of a range of acute and chronic diseases. A major extension of such work in general practice has been the large-scale study on oral contraceptives involving 23 000 users, an equal number of controls and records provided by 1400 general practitioners whose activity was co-ordinated by Dr Clifford Kay (1974). Gregg (1941) noticed a change in the proportion of children referred to his clinic in Australia with certain eye defects; this stimulated him to initiate studies on the association between material rubella and congenital abnormality of the subsequently born child. More recently Burkitt (1962), while working as a surgeon in East Africa, was responsible for the identification of a new form of malignant disease; he then launched studies of its epidemiology.

These examples are arbitrarily selected from a wide range of studies that have been carried out by clinicians either in the primary medical-care or in the hospital field. They indicate that there is no need to consider that epidemiology is a branch of medical science only practised by a restricted group of specially trained individuals. Over the past few years increasing emphasis has been placed on the need for administrators in the health service to be trained in disciplines such as epidemiology. This is an indication of the acceptance of the application of these techniques to the study of medical problems and the contribution that such studies can make to the management and planning of the delivery of health-care services.

The points argue for a wide range of individuals being familiar with the general principles of epidemiological studies. Epidemiology will be one of the sources of fresh data that will be of concern to everyone in the health field whether these data relate to aetiology, means of prevention or modes of delivery of health care. It is on these grounds therefore that all categories of health-service staff should have some appreciation of the role of epidemiology and the underlying methods in order to be able to read published work and interpret it. The medical field undergoes continuous change and therefore the most important aspect of training is not the accumulation of facts, but the acquisition of the ability to accept fresh information, and judge whether the findings warrant change in practice.

Apart from facilitating the interpretation of other people's findings, it is possible that a description of the methods of epidemiology may stimulate the use of these techniques by a wider range of individu'.ls. Some of the work discussed in later chapters has been carried out using the minimum of facilities. Useful studies can be done either by examining the routinely available data, or by collecting a restricted amount of information and analysing this in a relatively simple way; the resources required for many worthwhile studies are slight compared with research in other fields. The emphasis is mainly on the need for careful planning and consideration of the issues involved, the collection of observations of known accuracy and the careful interpretation of such material.

1.2 Development of Epidemiology

The foundations of epidemiology were laid in the nineteenth century, when a few classic studies made a major contribution to the saving of life. This work was particularly concerned with infectious diseases. However, even at that time there was an awareness of the need to look at the influence of the environment. Other studies early in the nineteenth century demonstrated the influence of occupation on morbidity and mortality, and also the effect

on health of the general environment and social conditions. Thackrah (1832) produced a lengthy book on the effects of arts, trades and professions on health, while Chadwick (1842) in his report on the sanitary condition of the labouring population in Great Britain discussed the influence on health of drainage, ventilation, overcrowding in dwellings, low income and poor diet.

A misconception that has lingered too long is that epidemiology is primarily concerned with infectious diseases. From the start it was recognised that the onset of disease can be due to an infective agent; this was associated with an awareness of the important influence of physical, emotional, social and genetic factors. In developed countries the majority of health-care problems now stem from chronic disease and the bulk of the examples in the following chapters are related to studies on chronic disease. The basic techniques for studying infectious disease are similar. However, due consideration must always be given to the relative influence of the prime aetiological agent, the 'vehicle' for transmitting it, the associated factors affecting risk of development of a disease and the host's reponse to the disease.

1.3 Four Categories of Study

Epidemiology involves four different categories of study. The first one is descriptive: for example, 'Who gets heart disease?' National data have been used to examine the mortality from heart disease in different countries in relation to some of the characteristics of the individuals who died and other basic items available in the mortality data (for instance the fatality rates in relation to age, sex, time of year and secular trend). This limited material has then been supplemented by population surveys, which have looked at the prevalence of identified heart disease.

A second category of study is hypothesis testing, for instance exploring the question 'Does diet influence heart disease?'. National mortality rates have been contrasted with estimates of intake *per capita* of various nutrients. This has been followed by the examination of the reported diets of persons with heart disease and of control subjects. A more precise examination may occur with the measurement of the habitual diet in a large number of subjects and their follow up to determine which individuals develop heart disease in relation to initial categorisation of diet.

If the descriptive and hypothesis-testing studies point to a particular factor being of importance in the development of the disease, these studies may be followed by a third phase—an intervention study. For example, work has been carried out to test whether an actual alteration of diet in individuals has any effect on the incidence, recurrence rate or fatality from heart disease.

These three main categories of epidemiological study may each require, as a preliminary phase, a fourth and rather different approach—that is, a method study. As with any other research work, before embarking on a definitive study there may be a need to refine the techniques required in the

applied study. For example, in order to examine the diet of a large number of individuals, there is the need to develop a technique for assessing diet that is reliable and valid, and yet sufficiently simple to be applied in the field to a large number of subjects.

Method studies involving the development of data-collection techniques may also lead to improved disease categorisation. For example, epidemiological, clinical and pathological work has indicated that Hodgkin's disease may be a heterogeneous collection of conditions. The ability to distinguish between these types of Hodgkin's disease may be a necessary preliminary to aetiological studies (MacMahon, 1966). Other work may suggest that a 'condition' does not really exist. Examination of the X-rays of 132 subjects with dysphagia by eight observers resulted in variation of between 6 and 59 per cent of the subjects being reported as having a web (Elwood and Pitman, 1966). This suggests that the Patterson–Kelly syndrome may be nothing more than a variation in observers' interpretations of barium swallows.

1.4 Need for Numeracy

Considerable emphasis is placed on study design in each of the chapters and attention is also paid to the methods of analysis and interpretation of collected data. Epidemiology is essentially a multidisciplinary approach, and in particular relies heavily on numerical techniques. Each chapter ends with brief consideration of some of the relevant statistical techniques. This is not intended to serve as a text of statistical techniques, but merely to indicate the relevance of statistical method and in particular to emphasise those methods that are of special use in epidemiological studies. Some of the techniques, such as the calculation of relative risk or proportional mortality, are not generally dealt with in the standard books on statistics. These techniques are therefore given more emphasis, and only the most cursory mention is made of those statistical approaches that have been fully dealt with elsewhere. One of the reasons for including the sections on statistics is to indicate the specific methods appropriate in the various categories of epidemiological study. This should facilitate communication between the research worker and the statistician. It must be emphasised that when statistical advice is required, this should be sought at an early stage in planning a study and not when the material has all been collected and an attempt is being made to interpret it. Armitage (1971) has suggested that 'statisticians are in too short a supply to act as collaborators in more than a fraction of all statistically orientated studies in medical research'. There is a need therefore for those mounting epidemiological studies or attempting to interpret the work of others to appreciate the relevance of certain statistical techniques in the handling of material.

The advent of the microprocessor makes it increasingly likely that many epidemiologists will have access to calculating facilities that can directly handle the range of statistical tests usually required. Rothman and Boice (1979) have set out in a clear fashion the algebra and program listings for the

range of conventional tests in a form suitable for use in a handheld programmable calculator. The statistical sections in each of the chapters in this book provide a guide to the relevance of the various techniques and some of the problems of application and interpretation of results. These aspects are more important to the general reader than the details of the method of calculation.

1.5 Different Approaches to the Consideration of Epidemiology

Epidemiology could be considered under the applications it may have, such as the definition of disease groups, the unravelling of primary and associated aetiological factors in the causation of disease, and the delineation of the natural history of disease. Another approach is to describe the findings of epidemiology in relation to disease entities, such as malignant, heart and respiratory diseases. A third approach is to describe the methods of epidemiology, illustrating these by the different categories of use (thereby indicating some selected findings from the application of such methods).

This is the approach that has been used in this book, but this should in no way suggest that a study of the methods of epidemiology in isolation is of merit. The approach has been deliberately chosen, however, in an attempt to interest a wide range of individuals in the use of such methods, whatever their particular field of work. In this book, there has not been any attempt to provide a comprehensive account of the findings of epidemiology in relation to every major category of disease problem. This is chiefly because the approach selected only provides a discussion of the findings as part of a consideration of particular problems of study design and interpretation of results; also it is felt that the findings of epidemiology cannot be looked at in isolation. For instance, when considering malignant diseases, epidemiology can provide background information and some extremely interesting pointers to the causes of various malignant diseases and the steps that can be taken to prevent these diseases. Even the descriptive data on the disease in question requires support from clinical and pathological studies to indicate the specific nature of the condition. A discussion of the natural history of the disease should not really be divorced from the consideration of the various methods of treatment for each particular malignant disease, and a detailed assessment of the outcome of treatment. Such an approach calls for integrated topic teaching rather than the isolated presentation of the findings of epidemiological studies. Factual information is provided in a number of books (see further reading lists) on the epidemiology of particular diseases, and data are being augmented all the time by fresh studies reported in the literature.

Even in the absence of any clear knowledge of the underlying cause of disease, epidemiology may help to unravel the 'vehicle' responsible for the transmission of the disease (whether this is due to infection, exposure to physical and/or chemical factors, or is genetically determined). Such studies are pursued not merely to add to the general body of medical knowledge, but