

## DISCUSSION OF: "EPIDEMIOLOGIC CONTRIBUTIONS TO HEALTH SERVICES RESEARCH"

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Dr. Densen's stimulating paper (1) has highlighted a number of the critical issues involved in applying epidemiologic methods to health services research. Three important points in his talk merit particular emphasis: 1) the need for an objective patient classification system; 2) the need for appropriate comparison populations which were at comparable "risk" for receiving care, and 3) the need for more effective communication between epidemiologists and planners of health policy.

Dr. Densen began very appropriately with a reference to a 1925 paper by Wade Hampton Frost entitled, "Rendering Account in Public Health" (2). Frost's ideas are indeed astonishingly relevant to our thinking today. In this paper, for example, he spoke about the question of the effectiveness of school health programs and wrote, "Our cities have in recent years instituted regular medical inspection of school children, with vigorous efforts directed towards remedying certain obvious physical defects. I am not aware that anyone has even attempted as yet to demonstrate the ultimate effect of this work by a statistical analysis of mortality or of morbidity from the commonly reported diseases. Indeed, we have no definite and compact theory from which to deduce just where the results of this activity might be expected to show in such statistics. We may say, then, that we have neither a clearly defined theory nor adequate statistical experience to prove and measure the net result of this work upon the public health of any large community as a whole."

It is also of interest that when Frost read this paper at the 53rd Annual Meeting of the American Public Health Association in 1924, one of the formal discussants of this paper, Dr. Charles V. Chapin, commented, "Dr. Frost's earnest demand that the procedures of preventive medicine be placed on a firm scientific basis is well timed. Indeed, it would have been opportune at any time during the past forty years and, it is to be feared, will be equally needed for forty years to come." He went on to say, "I am very glad that Dr. Frost referred to school inspection as an instance, for it has always seemed to me that convincing evidence of real worth is lacking for much of the school health . . ." Today, over half a century since Frost's paper was published, little progress if any has been made in demonstrating the benefits of school health programs. Indeed, most of what Frost wrote in this paper remains highly relevant to our present day activities.

I should like to deal very briefly with four issues: 1) the relative value of process or outcome measures; 2) the problems of definition in health care; 3) the problem of availability of records for epidemiologic study and 4) the appropriateness of health services research as an activity for epidemiologists.

For some years, there has been considerable discussion as to whether process measurements are superior to outcome measurements for examining the effectiveness of health care. Process denotes the characteristics of the care provided and whether the care meets standards established by experts. Outcome, on the other hand, refers to the benefit accruing to the patient in terms of his health.

There are a number of problems associ-

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ated with process measures. In process studies, records of doctor-patient interactions may be examined to see if certain standards were met. However, even when standards are met and a process measurement is determined to be better in one health care setting than in another, these differences may not necessarily be reflected in the patients' health.

Another problem is that process measures are transient since they depend on expert medical opinion that tends to change with time and is often based more on conviction than on objective data. Thus, a process study of neonatal care units in the 1950's would probably have rated any nursery not providing 100 per cent oxygen to newborns as poor. It was only additional biologic and medical information which indicated that this practice was hazardous. A process study conducted after a link between high oxygen concentrations and retrolental fibroplasia had been demonstrated would obviously have to use a different standard for quality of care.

Outcome measures, on the other hand, look at the end results in terms of changes in the health status of the patient. Mortality and morbidity relating both to disease and complications as well as reduced or improved functional status are legitimate outcome measures. Since the critical question in health services research is whether a given form of health care does in fact alter the health of the individual receiving it, outcome measures are essential.

However, even those who agree that outcome measures are more desirable, often assert that they are too difficult to obtain in order to serve as practical endpoints in health care studies. While there are indeed major methodologic problems in using outcome measures, the challenge is not to avoid them but to solve them. For the epidemiologist, who studies the distribution of disease in populations, outcome measurements are the target and process measurements only become mean-

ingful after some health benefit has been demonstrated in the defined population receiving some type of health service. If no benefit is shown, one might argue that even if health services are ineffective, it would be better to provide them at less cost. However, this no longer lies within the realm of epidemiologic investigation.

In epidemiologic studies which aim at elucidating the etiology of disease, we often have problems documenting and quantifying the exposure to the possible etiologic agent and discriminating between exposure to one or multiple factors. Similarly, in health services research we have a significant problem identifying the specific components of care provided, quantifying them and discriminating between the effects of different components. All too often, this problem is not faced; instead, general non-specific descriptors are used such as "comprehensive," "multidisciplinary" and "primary" care. This approach however, merely evades a problem whose resolution is critical to the clear formulation of meaningful and researchable hypotheses.

This need to define the specific components of the health care provided leads to another point. Dr. Densen has indicated correctly that it is difficult to carry out randomized trials for entire systems of health care delivery. However, it would be unreasonable to discard randomized trials in health services research on this basis. Randomized trials are feasible if we randomize not whole systems of care but specific components. For example, the best approach today to resolving the question of the value of coronary care units might be to carry out a randomized trial with patients allocated to either a coronary care unit or to a regular bed. However, ethical and legal considerations preclude such a study in the United States today. The question, therefore, is not only whether "coronary care units" are effective but if they are, which specific component of the care in the units is having the beneficial effects? Conse-

quently, it is possible to set up a study in which patients are randomized into two types of coronary care units, which differ in the specific modalities of care provided.

Epidemiologic inquiry depends on the availability of medical and vital records, both for their data as well as for a basis for the ascertainment of patients for subsequent interview and study. The great contributions of epidemiology to our understanding of disease have been based on such data. In recent years, however, a legitimate concern for privacy and confidentiality has made many types of epidemiologic investigation progressively more difficult to carry out if not totally impossible. There is no question that the legitimate rights of patients must be protected by providing adequate safeguards for confidentiality of data and informed consent and that epidemiologists, like all medical investigators, must give serious thought to the ethical issues involved in their studies. However, we have become faced with extreme positions which if carried to their logical conclusions threaten the viability of most epidemiologic research in this country. The solution may well rest in enacting federal and state legislation to insure the availability of medical and vital records for legitimate medical and epidemiologic investigation.

Society has a vital stake in such studies. Society as well as the affected individual, bears the cost of disease and its aftermath. Consequently, society must insure that a reasonable approach will prevail in which patients will be protected while the advancement of human knowledge through epidemiologic investigation will be facilitated. This will be accomplished only when our legislators become aware of the seriousness of this problem and the value of epidemiologic research for the health of the community. They are likely to gain this awareness only if motivated epidemiologists take the initiative in educating the legislators who draft laws dealing with

protection of patients and the confidentiality of medical records and press strongly for reasonable legislation that will accomplish both ends. If epidemiologists remain silent and fail to take concerted action to protect the future of epidemiologic research, we will pay an enormous price in the years to come.

Finally, the question of the appropriateness of health services research for epidemiologists. All too often there is a feeling among epidemiologists that epidemiologic studies which are oriented to elucidating etiologic factors are "true" epidemiology, while studies applying epidemiologic methods to the study of health services are second class. If, however, epidemiology is defined as the study of the distribution of diseases in populations and the factors which influence the observed distributions, then any such factors including health services are legitimate subjects for investigation. As long as these studies are carried out with conceptual and methodologic rigor, they are fitting areas of activity for the best available talents in the field of epidemiology.

The application of epidemiologic methods to health services research is a natural step. In etiologically oriented studies (figure 1) we focus on relationship of risk factors to rates of disease, but take into account the role of other variables including health care either by adjusting or

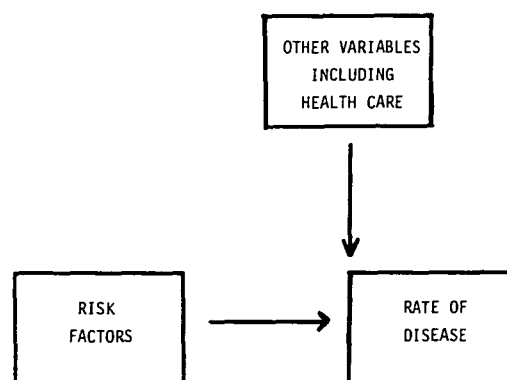


FIGURE 1. Etiologically oriented studies.

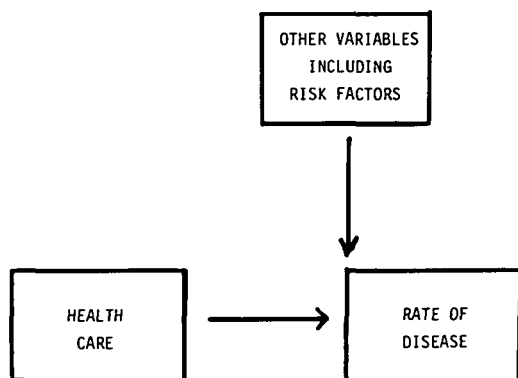


FIGURE 2. Epidemiologically oriented health care studies.

stratifying for them. In epidemiologically oriented health care studies (figure 2) the main issue is the relationship of health care to rates of disease or of complications. In this case we also consider other variables as in etiologically oriented studies, but the risk factors for the disease are among the other variables considered. Thus the issues of study design and the methodologic challenges are similar in both types of research activity.

It is important to point out that there are in fact two distinct types of studies involving epidemiology which bear on the evaluation and planning of health services. The first, often referred to as health services research, comprises studies which are specifically designed to test hypotheses relating to the evaluation of the effectiveness of health programs. However, one should not lose sight of the fact that much of the epidemiologic data gathered in etiologically oriented studies also have clear application to the health services area. For example, a knowledge of the differences in the rates of hospital admissions for whites and blacks for acute myocardial infarction would be essential before expanding the size of coronary care units in predominantly black areas.

However, despite the relevance to health

services planning of much epidemiologic data which were initially obtained for other purposes, there has been in general a failure to utilize such data for rational program planning. While it is easy to blame this failure on political and economic interests, part of the responsibility must surely rest with the failure of epidemiologists to translate their data into a language comprehensible to those in the planning area, to point out to the planners which epidemiologic data are relevant to them and to be willing to work with the planners in interpreting these data in a manner appropriate to their planning responsibility.

When deluged with reams of computer printout or pages of complex tables, it is unreasonable to expect planners with little sophistication in epidemiology to be able to intelligently apply such data. They require the expert assistance of epidemiologists interested in having these data utilized in planning health programs. Since society supports the epidemiologic investigations which we carry out, I believe it is our social obligation to apply our findings to the health problems of society not only by identifying etiologic agents of disease and developing new methods of prevention, but also by providing the basis for rational planning and evaluation of health services.

In closing, we might best quote the words of Louis Pasteur which are particularly relevant to this issue. Pasteur wrote, "There are not two sciences. There is only science and the application of science and these two activities are linked as the fruit is to the tree."

#### REFERENCES

1. Densen PM: Epidemiologic contributions to health services research. *Am J Epidemiol* 104:478-488, 1976
2. Frost WH: Rendering account in public health. *Am J Public Health* 15:394-396, 1925