than truly negative findings, at least until controversy makes negative findings just as important and interesting as positive findings.

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Chapter 14

# Epidemiology, Medical Care, and the Health of the Community

Health and disease in the community are important concerns not only of medical and public health professionals but of the general public as well. To illustrate the important role of epidemiology in community health, two types of epidemiologic investigations will be described briefly—the time-honored investigation of infectious-disease epidemics and some recent efforts to detect unsuspected environmental hazards. Then, the limited effects of medical care on community health will be discussed. Screening for disease and other methods for increasing the beneficial effects of health care on the community will then be described.

### Investigation of Epidemics of Infectious Disease

Until a few decades ago, epidemiology had focused primarily on the infectious diseases, which have been the major scourges of mankind. Recently, in the more affluent nations, most infectious diseases

have been brought under reasonably good control, and the leading causes of death and disability have become the noninfectious conditions. Thus, in these areas, many epidemiologists' attention has been directed toward chronic degenerative and neoplastic diseases. Other diseases or conditions of great interest and importance include physical trauma or accidents, mental illness, and congenital defects. Additional concerns that have recently engaged the epidemiologist are studies of medical care and health services, and studies that focus on general health status irrespective of the particular diseases responsible for departures from good health.

Despite a shifting emphasis in the more affluent nations, infectious diseases remain extremely important problems in the "less developed" parts of the world. Furthermore, dangerous infectious-disease outbreaks continue to occur in industrialized nations. Even though the principal causes of many of these diseases are fairly well understood, epidemiologists, health officers, other physicians and public-health nurses are still called upon to investigate specific disease outbreaks to determine the particular conditions or factors that are responsible.

Investigation of the variety of epidemics that might occur cannot be described by a single step-by-step "cookbook" approach. However, certain principles are followed sufficiently often to deserve at least a brief summary here. The interested reader should consult Anderson et al. (1962) for more details.

The typical field investigation of an epidemic involves, first, a study of the cases. Clinical examination and appropriate laboratory tests are needed to determine or verify the diagnosis. Once the disease is identified, knowledge of the usual sources of infection and common modes of spread for that disease will help point the investigation toward the most likely explanations of the epidemic. A convenient reference book that summarizes the important information for most infectious diseases is *Control of Communicable Diseases in Man*, published by the American Public Health Association (Benenson (ed.), 1970).

In addition to verifying the diagnosis, the patients are studied further, usually by interview. Their basic characteristics such as age, sex, and occupation should be determined, as should the onset and



time course of the disease. Personal contacts at home, work, school, and other places, special events such as parties and trips, foods eaten, and exposures to other common vehicles are items that will frequently be inquired about, depending, of course, on the disease believed responsible for the outbreak. Particular emphasis should be placed on the time period when the patient was most probably infected. This period precedes the disease onset time by an interval equal to the usual incubation period for that disease.

The subsequent investigation will be guided by information gained from the known cases. For example, plotting the dates of disease onset graphically as in Figs. 5–7 (page 69), 5–8 (page 71), and 5–9 (page 72) will help determine if the epidemic had a point-source or involved person-to-person spread. Or, if the disease involves a gastrointestinal infection and several cases mention going to the same restaurant or party, further investigation of possible food contamination at the restaurant or party would be in order. Pursuing the party further, apparently well persons who also attended it might also be given appropriate laboratory tests to detect subclinical infection. Comparisons of what the infected and uninfected persons ate at the party will help determine which foods were contaminated. A good example of the simple analyses that are made to identify foods that serve as vehicles for infection is presented and discussed by Sartwell (1965).

Data analysis concerning possible causative factors for an epidemic will usually take the form either of an incidence study or a case-control study. In the former approach the incidence, or "attack" rates, of persons exposed to possible sources or vehicles are compared with those of persons not exposed. If the rates are much higher in the exposed, the source is highly suspect. In the case-control comparison, the suspect sources are those to which a much higher proportion of cases than controls were exposed.

It is hoped that investigation of the epidemic will reveal correctible problems. A major accomplishment would be the identification of infected persons who can continue to spread disease if not attended to, such as typhoid carriers working in restaurants or hospital employees with staphylococcal skin infections. The recognition of other factors leading to the spread of disease, such as

improper food-handling practices, contaminated water supplies, or segments of the population who have not received the usual vaccinations, can also lead to effective control measures.

### The Detection and Evaluation of Environmental Hazards

In recent years there has been considerable concern that we are poisoning ourselves with our technology. It is well known that our land, water, and air are being polluted by such substances as industrial wastes, exhaust products from burning fuels, trace metals, chemicals, pesticides, and radioactive materials. Furthermore, the population now ingests a variety of chemicals in such forms as preservatives and medicinal drugs.

What is less clear is the extent to which these substances affect human health. Epidemiologic studies can play an important role in the quantitative determination of the risks involved.

The usual investigations have employed standard epidemiologic methods to assess the relationship between specific substances, drugs, energy sources, or occupational exposures, and particular disease outcomes of interest. Examples are the Berlin, New Hampshire prevalence study of chronic respiratory disease in relation to air pollution and smoking, described in Chap. 6, the case-control study of thromboembolic disease in relation to oral contraceptives described in Chap. 7, and the cohort study of occupational exposure to x-ray described in Chap. 8. (For further examples, see Whittenberger, 1967, and Goldsmith, 1972).

These studies involve an assessment of environmental hazards that are *already under suspicion*. The proliferation of new chemicals and energy sources to which we are exposed has led to serious concern that there are many hazards that we are not aware of. Sometimes, unsuspected hazards come to light only after considerable damage has been done. A recent dramatic example involved the drug thalidomide which, when given as a tranquilizer to pregnant women, resulted in the birth of thousands of seriously deformed babies. Other classical cases were the occurrence of retrolental fibroplasia in premature infants who received oxygen therapy, and the development of bone cancers in radium-dial painters.

As a result of concern for the unsuspected, epidemiologists



have begun to work in a new area of research, sometimes called *monitoring*. The purpose of monitoring is to detect unsuspected adverse or undesired effects of components of the environment as soon as possible after these effects appear, and thus provide an "early warning system." Because broad areas are to be covered, this type of investigation usually involves initially a search for hypotheses. Suspicious relationships can then be subjected to more intensive study.

Much of the experience to date in monitoring environmental hazards has been gained from monitoring adverse reactions to medicinal drugs (Report of the International Conference on Adverse Reactions Reporting System, 1971). Despite careful testing of drugs before they are marketed, many drug reactions do not become recognized until the drug has been extensively used by large numbers of patients. Monitoring of drug reactions will be used to illustrate some of the methods to be described.

A number of methods or systems of monitoring are available. These have been tried with varying degrees of success. They involve the assembly and analysis of data on morbid events, usually, but not always, in relation to various exposures.

**Spontaneous Reporting Systems** Many hypotheses come from the observation by individual physicians of patients who develop what seems to be an adverse reaction to a drug. Ordinarily, if he is sufficiently concerned, the physician might report this to the drug manufacturer or publish a letter or brief case report in a medical journal.

Programs known as spontaneous reporting systems have been established to encourage physicians to send such reports to a central agency or clearing house where they can be assembled and evaluated. Examples are the reporting programs that have been set up by the Food and Drug Administration in the United States and the Committee on Safety of Drugs in the United Kingdom.

While some useful information has been obtained at low cost from spontaneous reports, certain deficiencies are apparent. Despite promotional efforts to get physicians to respond, the number of reports submitted and the amount of information contained in each report have often been disappointing. Furthermore, it is very difficult

for the physician to determine the cause of a serious untoward event in a single patient. While it could be an adverse effect of a drug, it could also be a worsening or complication of the disease being treated, or even the result of a different disease that has developed independently. Physicians tend to recognize and interpret as drug reactions events that they are familiar with in that regard, such as skin rash following penicillin therapy or aplastic anemia following chloramphenicol; they tend not to report unsuspected relationships. Finally, the lack of any "denominator" or "population-at-risk" information makes it difficult to determine whether the reaction might be rare or relatively common.

**Changes in Disease Frequency** If a population is being exposed to a new environmental hazard or to increased levels of an old hazard, suspicion can be aroused by monitoring disease frequency. Populations or special subgroups may be kept under systematic surveillance to determine time trends in incidence, prevalence, or mortality from any or all diseases. A good example is the monitoring of congenital malformations in newborn infants. The prevalence of various malformations among newborn infants in several cooperating hospitals can be recorded on a monthly basis. If the occurrence of one or more malformations shows a distinct increase beyond the fluctuations usually noted due to chance or seasonal variations, then an inquiry into prenatal exposures might be initiated, much as one would investigate an epidemic of infectious disease (Hook, 1972).

Although probably less accurate than special programs to monitor disease frequency, the surveillance of vital statistics can also provide useful information about changes in disease frequency. Increases in mortality rates in communities or increases in congenital malformations reported on birth certificates can provide useful clues that something is happening in the environment.

**Intensive Surveillance of Both Exposures and Disease** Procedures can be established to collect extensive information concerning both exposures and disease frequency. In this way a variety of exposure/disease relationships can be explored to look for unsuspected relationships and to develop quantitative information about known relationships. An example of this type of program is the



Community Health and Environmental Surveillance System (CHESS) of the Environmental Protection Agency, in which several components of air pollution and several measures of health and disease are measured in selected communities (Riggan et al., 1972). Examples in drug-reaction monitoring are the Boston Collaborative Drug Surveillance Program (Jick et al., 1970) which collects and analyzes data about drug administration and untoward events from several hospitals, and the Kaiser-Permanente Drug-Reaction Monitoring System, which emphasizes drug use and drug reactions in outpatients (Friedman et al., 1971).

## Limited Effects of Medical Care—Historical Perspective

With the impressive technical advances in medical care that have become available in recent decades, it is easy to forget that the quality and quantity of medical care have only a limited influence on community health. That medical care is not the only determinant of health is well illustrated by the observed long-term time trends in mortality from certain diseases. As will be shown, these trends appear to bear little relationship to changes in medical care.

One example is the marked decline in mortality from tuberculosis in the United States during the twentieth century (Fig. 14-1). As pointed out by Winkelstein (1972), the only treatment available at the beginning of this century was rest therapy in sanatoriums, accessible only to the wealthy. This was made available to all economic classes in the 1930's, and during the same decade, collapse therapy was introduced. Chemotherapy became widely available in the 1950's. Fig. 14-1 shows that the downward trend in mortality was clearly evident before these new therapies were widely applied. Winkelstein also cited data from a study by Terris (1948) showing that the isolation of cases in treatment facilities was probably not a major determinant of tuberculosis mortality. Thus, even though therapy and isolation of cases may have accentuated the decline shown in Fig. 14-1, other important factors must have been operating.

Other diseases have also shown major secular changes that are difficult to attribute to the benefits of medical care. For example, McKeown and Lowe (1966) presented a graphic picture of the

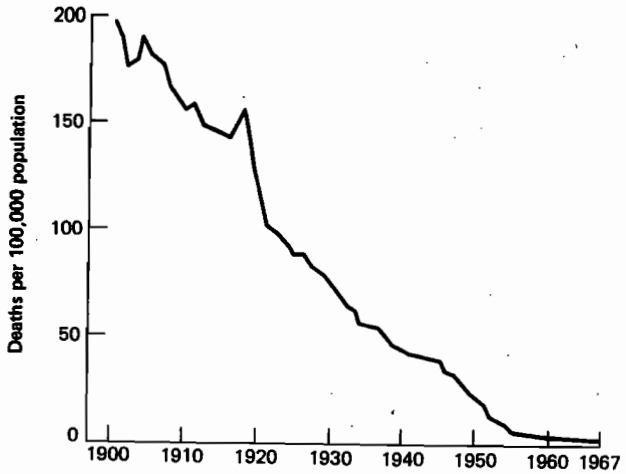


**Figure 14-1** Annual age-adjusted tuberculosis death rates per 100,000 population, death registration states of the United States, 1900–1967. (Adjusted to the age distribution of the U.S. population in 1940.) *(Reproduced, by permission, from Winkelstein, 1972.)*

decline in mortality from whooping cough in English children, similar to that shown for tuberculosis in Fig. 14-1. Mortality declined rather steadily from about 1,400 deaths per million per year in 1870 to a negligible number in the 1960's. Relevant medical landmarks during this decline were the identification of the causative organism in 1906, sulfonamide and antibiotic therapy, beginning in 1939, and the general availability of immunization beginning in 1952. By the time drug therapy and immunization became available, the whooping cough mortality rate was only a small fraction of what it had been in the late nineteenth century, when it was a very important cause of death.

The rather striking time trends over the last few decades in lung cancer and stomach cancer mortality rates (see Fig. 5-10, page 75) are also largely independent of the effects of medical care. To date, medical, surgical, and radiation therapy cannot save the lives of the vast majority of victims of these two malignancies.

It is obvious from these examples and from the usual incurability of the degenerative and neoplastic diseases that constitute most of our leading causes of death and disability, that if we are to bring



these conditions under control and improve the health and longevity of the population, we cannot rely solely on increasing the availability of medical care as we know it today. More important will be to improve our understanding of the environmental and social factors which foster these diseases and, using this knowledge, to apply effective preventive measures.

## Two Aspects of Disease Prevention

One approach to disease prevention is through medical care of individual patients. As an example of this approach, a simple method for preventing coronary heart disease, to be used in the clinic or physician's office, was described in Chap. 13. It involved, first, detecting individuals who are at high risk of developing the disease, and secondly, attempting to reduce their risk by changing their dietary and other habits and judiciously prescribing drugs, when indicated.

The second avenue of disease prevention does not focus on the individual. Rather, it involves large-scale social and environmental changes, such as improving housing conditions, requiring pasteurization of all milk sold commercially, or adding fluoride to community water supplies. For coronary heart disease, possible preventive approaches on this scale might include changing food processing to decrease the amount of saturated fat and cholesterol in animal food products, discouraging cigarette smoking by increased taxes or by other forms of persuasion well known to the advertising industry, or discovering the harmful agents in tobacco smoke and removing them, or banning automobiles from certain areas so as to force many people to walk or ride bicycles. These measures are listed here as examples of efforts that might be considered, not as proven practical approaches to the problem of coronary heart disease.

Because many people do not go to doctors routinely and because many others who do go either do not follow medical advice or find it extremely difficult to break pleasurable habits, one is forced into a rather pessimistic view about the impact that office preventive medicine can have on the health of the general population. Even special intensive programs to change patient behavior have not

proven to have as much long-term effect as has been hoped. For example, a variety of innovative methods have been tried to help people stop smoking cigarettes. Despite high initial success rates, follow-up one year later usually reveals that only about one-fifth of those originally treated still refrain from smoking.

The health-care professional must do what he can to help his patients. Certainly a success rate of one out of five is better than nothing. Nevertheless, since medical care often has so little impact on major health problems of the community, many believe that only large-scale social and environmental changes will be effective.

### The Physician's Limited View of Disease in the Community

One reason that medical care has less influence than one might expect is that much disease never comes to the attention of medical personnel. Using prevalence survey data obtained in Great Britain and the United States, White, Williams, and Greenberg (1961) showed how illness in the community gets filtered to various physicians and institutions in the medical-care system. As shown in Fig. 14-2, of 1,000 adults in the community, 750 report one or more illnesses each month. One-third of those with illnesses, or 250, consult a physician. Only 9, or 1.2 percent of the ill are admitted to a hospital, and only 5, or 0.7 percent, are referred to another physician. Particularly striking from the viewpoint of medical education is the fact that only one of these patients is seen at a university medical center.

Not only do just a portion of the sick get seen medically, but each medical specialty and medical setting attracts a selected group of patients out of all those seen. For example, in the outpatient clinic one is especially apt to encounter patients with mild acute and chronic illness and patients with symptoms for which no organic basis can be found. In the hospital, patients are, on the average, much more seriously ill with diseases that are farther advanced. As pointed out by White et al., "Each practitioner or administrator sees a biased sample of medical care problems presented to him; rarely has any individual, specialty or institution a broad appreciation of the ecology of medical care that enables unique and frequently



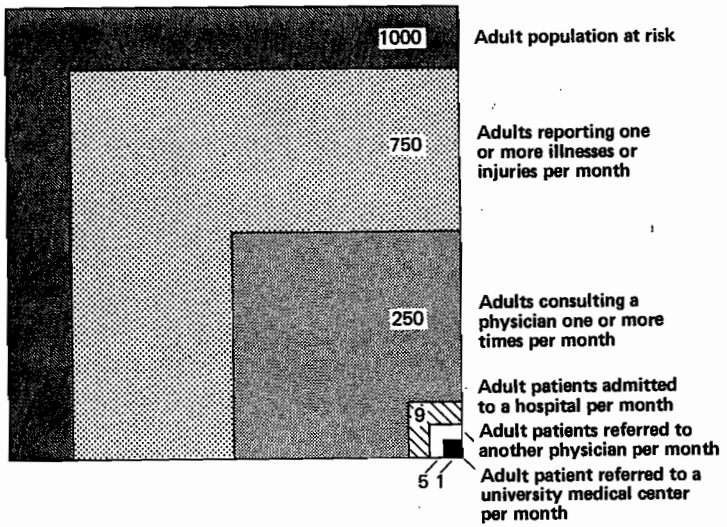


**Figure 14-2** Monthly prevalence estimates of illness in the community and the roles of physicians, hospitals, and University Medical Centers in the provision of medical care (adults 16 years of age and over). *(Reproduced, by permission, from White, Williams, and Greenberg, 1961.)*

isolated contributions to be seen in relation to those of others and to the over-all needs of the community."

### Efforts to Bring More Disease to Medical Attention: Screening

In the hope of increasing the impact of current medical knowledge and technology on disease in the community, medical and public health facilities have established *screening* programs to detect persons with early, mild, and asymptomatic disease.

As stated by Thorner and Remein (1961), "The basic purpose of screening for disease detection is to separate from a large group of apparently well persons those who have a high probability of having the disease under study, so that they may be given a diagnostic workup and, if diseased, brought to treatment." Since screening tests are designed to be applicable to large population groups, they

must be simple, rapid and inexpensive. As a result, they are generally less accurate and definitive than the examinations and tests used by physicians to arrive at a final diagnosis.

Screening is carried out in the belief that the detection of disease in an early or asymptomatic stage will lead to appropriate treatment which, in turn, will lead to less disability and/or mortality from the disease. After an initial period of enthusiasm in some quarters, considerable skepticism developed concerning the benefits of screening, based on doubts as to whether it would really lead to favorable modifications in the course of disease.

Critics pointed out that many persons with diseases discovered by screening did not receive adequate or appropriate treatment afterward. Or, even if the accepted treatment is given for some diseases detected by screening, such as mild maturity-onset diabetes mellitus, it has not been shown that persons so treated live happier, healthier, or longer lives. Also, persons correctly or incorrectly labeled as having a disease would be caused considerable worry and anxiety, often to no good purpose. Furthermore, careful analysis showed that apparently good results of screening could be misleading, due to self-selection for screening of those persons who take better care of themselves, or due to fallacies such as that pointed out in Chap. 10, page 148, wherein persons would *seem* to survive longer merely because the diagnosis was made earlier. Even ethical questions have been raised (McKeown, 1968) since in contrast to traditional medical care which is sought by the patient, disease detection by screening is initiated by medical or public health professionals, who, therefore, are under special obligation to make sure that screening does more good than harm.

Thus, evaluation of screening programs requires carefully controlled experimental studies in which relevant disease outcomes are measured in a group receiving screening and compared to outcomes measured similarly in a comparable unscreened group. Any benefits found for screening programs should be compared to costs involved (McKeown and Knox, 1968; Wilson, 1968; Cochrane and Holland, 1971). Although it is more an evaluation of periodic comprehensive health checkups than of screening per se, the Kaiser-Permanente Multiphasic Health Checkup Evaluation Study, described in Chap. 9, illustrates the approach that is needed if



screening programs are to prove their merits. Other examples of well-controlled evaluations of screening or disease-detection methods are the study of breast cancer screening by the Health Insurance Plan of New York (Shapiro, Strax, and Venet, 1971) and the study of lung cancer screening by Brett (1971).

A generally accepted principle is that screening should only be done if it can be integrated with the medical-care program where it is carried out. In practice this means not only that adequate treatment, care, and follow-up be available for those who screen positive, but that the screening test results must be acceptable to the practicing physicians in the area. The characteristics of screening tests that relate to accuracy and acceptability will be discussed briefly.

Sensitivity and specificity, two measures of the accuracy of diagnostic tests, were defined in Chap. 13, page 192. These measures are also important features of screening tests. The relationship of a screening test to the final accurate diagnosis is conveniently shown in a fourfold table (see Table 14-1). In the table, *a* represents persons with the disease who are correctly labeled by the screening test. Persons denoted by *b* are *false positives*, since the test is positive but they do not have the disease. The letter *d* denotes persons free of disease who are correctly labeled by the test. The letter *c* represents *false negatives*, persons with the disease for whom the test is negative.

Sensitivity, the proportion of true positives that are labeled as positive, is thus $a/(a + c)$. Specificity, the proportion of true negatives that are labeled as negative is $d/(b + d)$. Both of these measures are important, since the test should detect as much disease as possible while avoiding false labeling. False negatives,

**Table 14-1 Relationship of Screening-Test Results to the Final Accurate Diagnosis**

| Screening test | Final diagnosis: Disease present | Final diagnosis: Disease absent | Total |
|---|---|---|---|
| Positive | $a$ | $b$ | $a + b$ |
| Negative | $c$ | $d$ | $c + d$ |
| Total | $a + c$ | $b + d$ | $a + b + c + d$ |

persons with undetected disease, may be deprived of valuable therapy. False positives, persons incorrectly labeled as diseased, are subject to needless worry and expensive diagnostic evaluations until their freedom from the disease is established. With all quantitative screening tests, the level above or below which a person is called positive will affect the sensitivity and specificity. Modifying this cutoff level to improve one of these characteristics will adversely affect the other.

Physicians evaluating patients who have been screened are especially sensitive to another measure, $a/(a + b)$, the proportion of positive tests that are true positives. Since physicians are usually asked to evaluate only the positive screenees, they understandably become irritated and critical of the screening program when most of their follow-up diagnostic evaluations turn out to be negative.

If the disease is infrequent in the population—and most chronic diseases are—even a screening test with a high degree of specificity will yield positives of which a large percentage turn out to be false. Thorner and Remein (1961) showed an example of a population of 10,000 with an assumed prevalence of diabetes mellitus of 1.5 percent, screened with a random blood glucose (not drawn at any particular time in relation to eating). Using a cutoff point of 130 mg percent, the test has been shown previously to have a sensitivity of 44.3 percent and a high specificity of 99.0 percent. The results are shown in Table 14-2. Note, that of the 164 positives, 98, or 60 percent, turn out to be false positives.

If, in order to decrease the number of false positives, the screening level is raised to 180 mg percent, the specificity will now

**Table 14-2 Results of Screening for Diabetes Mellitus in a Population of 10,000***

| Screening test | Final Diagnosis | | Total |
|---|---|---|---|
| | Diabetic | Not diabetic | |
| Positive | 66 | 98 | 164 |
| Negative | 84 | 9,752 | 9,836 |
| Total | 150 | 9,850 | 10,000 |

*In this population the disease prevalence is 1.5%, and the sensitivity and specificity of the test are 44.3% and 99.0%, respectively.

*Source:* Data from Thorner and Remein (1961).



be 99.8 percent. The test will now yield only 54 positives, of whom only 20, or 37 percent, are false positive. However, there is a marked decrease in sensitivity. Only 34 of the 150 diabetics will be detected.

If the disease prevalence is higher, a larger proportion of positives will be true positives. One strategy for increasing the prevalence of disease in the population screened is to restrict screening to high-risk individuals. For example, screening for diabetes by measuring blood sugar may be carried out only among persons who are obese or who have a family history of the disease.

### Broadening the Concept of Screening

Although formal screening programs were initially directed primarily at the early detection of single specific diseases, the screening concept has expanded in recent years to encompass *screening for high risk* and *multiphasic screening*.

**Screening for High Risk** As more emphasis is being placed on disease prevention, community programs for disease control may well include screening programs to detect persons at high risk of developing disease. In this way, preventive measures can be applied before the disease occurs. For example, pilot programs are now underway in industry and communities to identify persons with coronary risk factors such as high serum-cholesterol and blood-pressure levels, so that myocardial infarction and other manifestations of coronary heart disease can be prevented. The long-term effects of these programs need to be evaluated.

Before setting up such a program it is necessary, as with screening for frank disease, to make sure that suitable care and follow-up will be available for positive screenees. That is, the screening must fit in with the local medical care program so that something more than patient anxiety will result.

**Multiphasic Screening** It is more efficient to screen for a variety of diseases at one time than to carry out separate screening programs for single diseases. Fostered by the development of automated testing procedures, *multiphasic* screening programs are becoming widespread.

Multiphasic screening or multiphasic health testing is being viewed increasingly as having greater utility than just in the detec-

tion of asymptomatic disease (Thorner, 1969). It has been shown to be an efficient and economical component of periodic health checkups for patients both with and without known disease. Used in this way, multiphasic screening of high quality appears to be acceptable to both physicians and patients, and it conserves physician time and other medical-care resources (Collen, 1971).

Multiphasic health testing is also seen now as an important component of a new mode of entry of patients into medical care. With the trend toward prepayment or government payment for medical care, the traditional economic barrier, the fee for service, is disappearing. To prevent a resultant overloading of the medical-care system and to assure appropriate allocation of physician time to the care of the sick, Garfield (1970) has proposed a new system of organization for medical care. He suggested that patients not acutely ill enter the system in a way that would utilize multiphasic health testing to help determine the nature of the problem and the appropriate facility to which the patient should be referred.

### Evaluating a Changing Health-Care System

We are living in a period of great change in health care. Spurred by technological and socioeconomic advances, many old methods are being questioned or discarded and new approaches are being introduced.

Innovations can and should be evaluated by well-controlled experiments, whenever possible. Where particular circumstances or meager resources prohibit rigorous experiments, less-formal evaluations such as before/after comparisons can be conducted. However, careful attention should then be paid to extraneous influences and biasing factors that may affect the apparent outcomes of the innovation.

A few of the health care issues of current interest are modes of payment for services, the use of nurses and other paramedical personnel for tasks traditionally performed by physicians, the content and frequency of health checkups and community screening programs, control of drug overuse and abuse, and provision of optimal care for persons living in inner cities and remote rural areas. Defining and describing these problems, and identifying and evaluating possible solutions all involve studies of health-related characteristics, events, and outcomes in groups of people.



Whether these studies are labeled as "epidemiology," or "medical-care research," or "health-services research" makes little difference. What is important is that we be guided by careful observations and wise judgment to make necessary improvements while preserving the many good methods and approaches that we now have.

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