## **Research in Patient Care**

The responsibility for educating future physicians in the care of patients lies with the modern medical center, and therefore such institutions must continually revise standards for patient care. Research in patient care is necessary to establish criteria for judging the quality of contemporary instruction in clinical medicine, and can create as healthy an attitude of inquiry toward patient care as has been established in the traditional areas of biomedical research. On these assumptions, the Association of American Medical Colleges sponsored a seminar on research in patient care (1-5 March 1965, Chicago, Illinois).

Morton Bogdonoff (Duke University) defined present clinical research in leading departments of internal medicine as increasingly reductionistic and elegant. Research in patient care must meet the challenge of rigor and elegance if it is to become a productive academic enterprise.

Edmund Pellegrino (University of Kentucky) defined research in patient care as "a critical inquiry into all aspects of and the results of the process of delivering care to patients," a unique interdisciplinary task which unites the attitude and skills of the clinical investigator with those of the social scientist. Some faculty members oppose patient-care research, claiming it is mystical research; others say that patient care is a mystique that cannot be researched. Still others criticize its lack of intellectual challenge. However, the multiple phenomena of patient care require use of methods which can deal with multiple variables; therefore inferential analysis is more appropriate than in laboratory research.

Other barriers to patient-care research are difference in languages used by the clinician and the social scientist; differing interpretations of such basic concepts as reliability and validity; the principle of uncertainty; and the misconception that research in patient care is easy. These problems are illustrated in the literature. In many studies, investigators have settled for what is measurable rather than what is significant; limited hypotheses are rarely tested; and a method is used because it is available, not because it can best answer a question.

Meetings

Jack Elinson (Columbia University) characterized patient-care research as sociomedical research to which the principles of scientific method apply. The researcher in patient care, no less than the laboratory researcher, must deal with problems of reliability and validity, sampling, generalizability, experimental design, and control. Another problem in this research is lack of consensus on end results of patient care. The medical scientist regards changes in tissues as end results, whereas the social scientist emphasizes changes in capacity to function individually and socially. Physicians define reasons for seeking medical care narrowly, in terms of disease, whereas sociological, psychological, and economic factors are often predominant.

It is necessary to distinguish between the process of patient care and its end results and to relate the two in patient-care research. The commonly stated targets of patient care are death, disease, disability, discomfort, and dissatisfaction (the five D's). However, these must be operationally defined to contribute to research.

Donald Riedel (Blue Cross Association) reviewed the assessment of technical performance. In most studies, the observed practice is compared, explicitly or implicitly, with some designated scale of accepted or "good" standards. Direct observational studies present difficult problems in sampling, observer bias, cost, and reproducibility. Indirect studies, made on the basis of medical records, are more convenient but may turn into studies of the quality of records rather than of patient care. The most difficult task in evaluating technical performance is choosing standards for comparison and devising methods for applying the standards appropriately. Variation in criteria and in techniques of applying them can lead to differing conclusions as to the level of technical performance. Reproducible ratings for specific components of care are readily obtained, but to combine these into other than a very broad classification such as "good," "fair," and "poor" is difficult.

Paul M. Densen (New York City Department of Health) discussed the strategy of evaluating patient care. A series of measurements are required, depending upon whether the problem is to be analyzed from the point of view of the physician, the patient, or the community. Attempts to establish arbitrary standards focus attention on particular problems but suffer from the deficiencies inherent in any average. Knowledge of variation around the average is much more informative. The hospital tissue committee and later Professional Activities Study the evolved as mechanisms for analyzing this variation. These two approaches raise questions which then require systematic follow-up.

Studies of end results have been extended to the medical audit, but problems arise when the relationship between treatment and patient outcome is not as clear cut as it is in obstetrics and surgery. It is here that research in measuring the quality of patient care is needed. Systematic effort to identify assumptions underlying any medical audit will provide sound questions for research. Also, research in the natural history of disease is intimately related to the medical audit process. Scientific measurement of the quality of patient care awaits development of a systematic classification of the functional status of the patient.

Count D. Gibson, Jr. (Tufts University), reviewed the ecology of medical care, emphasizing the significance of the environment for the patient-care process. In his study in which home care and office care for cases of acute illness were compared, important differences were observed in treatment, performance, and subjective reaction of medical students serving as "physicians," and in the subjective reactions of mothers of the pediatric patients.

Robert J. Haggerty (University of Rochester) and Jerry A. Solon (University of Pittsburgh) reported on studies of use of medical services and patterns of medical care; in these studies the common-sense approach is supplanted by accurate information to be used for organizing and providing services in accord with patient needs. These studies identify the characteristics of the patient population, their patterns of obtaining care, and the factors that determine their patterns of care, and show that use of medical services follows definite patterns and is not a random affair.

Avedis Donabedian (University of Michigan) outlined the components of the medical care process-recognition of need for care by the patient or those who are responsible for him; the decision to seek care; the process of seeking care; assuming the sick role; diagnostic and therapeutic decisionmaking by the providers of care; relations between the patient and the providers of care; relations among the multiple sources of care and the recipient; maintaining care; and, finally, terminating care. The quantitative aspect of the medical care process is reflected in studies of the use of medical services. The qualitative aspect is reflected in research in the quality of care, either with respect to process or end results.

Kerr L. White (Johns Hopkins University; chairman of the seminar) presented an overview of research in patient care, which he considers but one component of the entire system of health services. The system has five major components which may be studied-personnel; institutions; organization and administration; financing, payment, and economics; and objectives. Research in medical care may be directed at one of five levels in the entire system-patients' need for care, patients' demand for services, use of the services, outcome, and satisfaction. Similar to other forms of research, the design and methods are determined by the units to be observed-episode of illness or of care, the "visit" or "admission," the patient and his care in time and place, the disease, the family, the institution, or the community. The denominator of any study must be clearly defined because the research so often consists of comparisons between otherwise similar groups. The techniques of epidemiology are most useful here.

Research in medical care uses four types of data—administrative, personal, medical, and behavioral. The major sources of bias in research in patient care are selective bias, the uncertainty effect, the Hawthorne effect, the placebo effect, observer variation, observer error, and sampling errors. Research in patient care can be classified broadly into two major typesthe case history method and the cohort method. Within the broad classification, there are four types of studies: descriptive, not based on specific hypotheses, and involving observation of unplanned events; analytic, based on specific hypotheses and observation of unplanned events; experimental, directed by specific hypotheses and using controls to deal with irrelevant variables; and evaluation studies, which require stated objectives and often must rely on comparison groups rather than true controls.

The primary emphasis in patient care research should be on "research." It is irrelevant to debate whether "laboratory" research is more scientific or important than "patient-care" research. Each requires knowledge and critical application of both the rules of logic and the methods of science. Lacking these, an activity may well advance "patient care" but it is not "patient-care research."

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## Nucleation Phenomena

Theoretical and experimental aspects of nucleation phenomena were reviewed at an international symposium held at Case Institute of Technology, Cleveland, Ohio, 7–9 April 1965. The major areas covered were atmospheric and solid state physics, analytical and physical chemistry, metallurgy, ceramics, polymer science, and biological systems. In addition to the 10 invited review lectures, 26 short papers covering recent research in the field were presented.

In the opening lecture W. Dunning (University of Bristol) outlined the current status of classical nucleation theory. He pointed out that the best correlation between theory and experiment can be expected for tightly bound clusters where partition functions can be evaluated. He also suggested that new experimental techniques currently being developed should enable a critical evaluation of cluster theories within the next decade.

The problem of nuclear size in the weak interaction limit was also dis-

cussed by J. Cahn (M.I.T.). His formulation, developed from a consideration of the spinodal, led to a formalism postulating the development of periodic concentration fluctuations. In the extreme weak binding limit, therefore, the issue of critical nucleus size, with its corresponding physical enigmas, is avoided. Periodic spinodal composition fluctuations have now been observed in many systems, including the inorganic glasses and metal alloys.

Several papers were presented in the area of statistical methods. F. Goodrich (California Research Corp.) demonstrated that it should be possible in certain cases to determine the kinetics of the nucleation and growth stages by a statistical analysis of the particle size and its standard deviation. This approach is still in its initial stages and, as Goodrich pointed out, is in need of experimental tests. Although an initial paper on the subject has been published, the method was unfamiliar to many scientists present and as a result of the presentation, several participants in the area of ceramics and metals expressed an interest in applying this analysis to data which had been accumulated, but which were not amenable to standard approaches. Thus, it appears that the symposium in at least one case did fulfill its aim to bring the theoretician into contact with experimental data and vice versa. In a contributed paper on irreversible thermodynamics, K. Russell (M.I.T.) showed that subcritical growing nuclei follow a reaction path which is one or two degrees cooler than the ambient temperature. This point seems particularly interesting in view of the controversy which existed a few years ago on the relative temperatures of molecular clusters.

The experimental technique which appears to be emerging as a new method of evaluating nucleation theories is the use of nozzles for condensing vapors. Several papers were devoted to the experimental design, data, and theory of operation for such nozzles. Up to now, however, definitive data are only starting to be obtained. D. Turnbull (Harvard University) felt that experimental studies of crystal nucleation from liquids could also yield suitable data for an assessment of nucleation theory. He reviewed the main methods of studying melt-solid transitions.

Most of the other papers fell into one of two categories. In the first category, experimental evidence was compared with theory which was considerably modified for application to the