THE MAN AND QUALITY IN CLINICAL INVESTIGATION

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The complete title of this address is as follows: The man and quality in clinical investigation; the allegory of the brackish water, i.e., the clinical investigator as an estuarial species; or growth, common sense, and ethics. There is no doubt that the members of the American Society for Clinical Investigation have concerned themselves with the man and quality of investigation. It is appropriate, therefore, to look for those policies which may guarantee such quality in the future. Since judgment of the present is difficult and prophecy is treacherous, other methods of evaluation of potential future policies may be tried. From nature itself, and by the use of allegory, it may be possible to describe controversial problems in the quiet and objective language of the biologist. Thus the field of clinical investigation may be described allegorically in a timeless manner by study of the dynamic concepts of the botanist, Professor Merritt L. Fernald (1).

In the study of fresh tidal estuaries and shores, Fernald found that certain plants, such as genus *Lilaeopsis*, were distributed widely throughout the world. Critical observations of the plants and their environment led Fernald to a remarkable theory to explain the wide distribution and location of these species. First, these plants occurred only in brackish tidal estuaries, where the regular action of tide alternately flooded and left bare the inner shores of streams and inlets twice a day with essentially fresh water. Second, the plants which could tolerate such daily changes were limited in number. It was also apparent that continental shelves had been submerged and then elevated, which processes rendered certain areas dry or completely submerged in salt water. There always remained, however, a brackish tidal estuary in a new location and the same plant growth apparently migrated with the changing estuary. Thus, the concept is advanced by Fernald that the tidal estuary, in spite of its dynamic change in salinity twice a day, is a reproducible medium for plant growth that is more constant than land, which may be inundated by salt water, and more constant than the sea bottom, which may be elevated and left dry.

The application of this concept to clinical investigation is immediately apparent, as indicated in Figure 1. Thus, the clinical investigator is bathed daily in the salt water of clinical medicine and the fresh water of biology and other sciences. Relatively few choose to tolerate such daily changes in medium. Or, as expressed in old terminology, some like fresh, some like salt, some like brackish and millimols exalt. Accordingly, the medium for clinical investigation may well be defined as dynamic and brackish. If new discoveries submerge or elevate continental shelves of existing knowledge, there always remains an estuary where clinical medicine and biology meet, but in a new location. The faculty of the clinical investigator to work in a tidal estuary, to move promptly to the correct salinity develops (in this estuarial-species-of-scientist) remarkable degrees of hardness, adaptability, humility, and considerable intellectual honesty.

To continue the allegoric analysis of clinical investigation, the hypothesis is here advanced that the finest quality of this research is produced, not by one estuarial species, but by the symbiotic growth of three closely related species. The total number of each species may be large in a research group. For simplicity, only a single symbiotic unit of three species will be considered here as related to function, selection, growth requirements, growth antagonists, and factors modifying quality of productive research.

A symbiotic unit is defined hypothetically as composed of three persons of integrity and ability whose major function in life is the production of outstanding clinical research. The administrator, at the base of the unit, is the most complex of the species and has roots in medicine, science, his institution, and the community. The senior investigator, supported by the functions of the administrator, is the major productive unit, but, in turn, is required to support the junior investigator who is maturing. Thus, the concept is advanced that the weight of the two investigative persons is supported by the administrator, as shown in Table I.

The administrator may be described by a variety of synonymous terms such as director, leader, soul of the clinic (2), guardian of freedoms, professor, etc. He may conduct research himself. However, his administrative role is indeed a responsible one, since it concerns recruitment of capable investigators and advising them on their own growth (or careers). The administrator may indicate fields for research by the choice of investigators whose interests are known. He then gives freedom for the conduct of research but judges the quality of results and of men. The cultivation of growth of investigation and of the investigator, without directing the research, is probably the most delicate metabolic equilibrium of the symbiosis. Further, the administrator is concerned with the environment, or culture medium, for growth of investigators and investigation, the translation of research...
Beginning, then, with a junior investigator of integrity and ability, it is important to examine the requirements for his growth that will lead to quality of results. The following requirements appear essential. There must be a clear responsibility to produce research of quality. This is one biologic stimulus that relates to survival of the species. Manifestly, time and scholarship are required for productivity. For normal growth of the species, certain freedoms appear to be essential, such as freedom to speak the truth, freedom to choose research problems, associates, and institution; freedom to teach and to care for patients. In addition, stimulating colleagues contribute indefinable growth factors of catalytic nature.

Potential growth antagonists are readily recognized of both quantitative and qualitative variety. Quantitatively, growth and productive investigation are inhibited by lack of time for research and scholarship, and by financial distress. Growth may be adversely influenced by requirement to publish substandard or incomplete results. Some of these data can be plowed back into the culture medium as fertilizer. Growth that is abnormal, bizarre, or neoplastic, and research that is substandard may be related to an attempt to obtain wealth through practice, by selection of a research problem because of ease of financial support or by the sequelae that may result from misrepresentation of data in order to obtain support. Another group of factors that appear catalytic in producing abnormal growth in investigators include: ectopic administrative demands, traces of regimentation, unpredictable and unexplained changes in environment, command performances, fund raising, and politics.

One factor requires special definition since it appears to influence development of the investigator and especially the kind of research he chooses. This factor is the duration of support of the investigator. Research can be arbitrarily divided into three kinds, as follows: (1) short-range problems with small risk—these may be easily described in advance; (2) medium-range problems with
moderate risk—these may be difficult to describe in advance; (3) long-range problems with large risk—these may be impossible and undesirable to describe in advance. The hypothesis is advanced here that an investigator will have maximum opportunity for mature growth and productivity if all three kinds of research are proceeding simultaneously. It is observed, however, that short-term support tends to encourage short-range problems at the expense of other kinds. Thus, the duration of support to be optimum would permit growth of roots of varying depth, so that productivity may be planned over a range of from one year to many years for full fruition, as shown in Figure 2.

In summary, an attempt has been made to describe the field of clinical investigation in terms of the brackish mixture of clinical medicine, biology, and other disciplines. Although data obtained by allegoric analysis can not be interpreted in great detail, it is believed that the quality of clinical investigation begins and ends with men of high integrity, ability, and inquiry. Similarly, it is the man that requires selection and support for his long-term growth. It is proposed that the organization of clinical investigation may be described as a symbiotic unit of at least three persons serving, respectively, as administrator, senior investigator, and junior investigator. The functions of each of these are considered as related to the proper growth of the investigators so that the finest quality of research is possible.

The following conclusions are generic. If the allegoric analysis has virtue and if it is true in part, then, from the objective language of the biologist, policies may be evolved that are constructive and based on common sense. And, if ethics represent a codification of common sense, one may develop a sound ethical basis for evaluating the controversial problems of today that will influence the quality of clinical investigation of the future.

BIBLIOGRAPHY