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Clinical Research by the Pract ing Physician: Why and How?

HAROLD B. HALEY, M.D.

The private practitioner in a community hospital can perform worthwhile and interesting research. In this presentation I am not referring to research that requires an electron microscope, a Ph.D. in biochemistry, or a tame computer. Rather, I am discussing the doctor's search for answers to questions which arise in practice when eye and brain are attuned to looking for them.

THE WHY

Why should a practicing physician want to do research? There are many reasons, any one of which can be of primary importance to the individual concerned. Some of them are: (1) An alert physician may observe a clinical phenomenon (a new symptom complex, an unusual response to a treatment or drug, etc.) and be stimulated to study it further to determine incidence, significance, or mechanisms involved. To make an observation and follow it up is, clinically, intellectual curiosity; philosophically, it is search for truth. (2) The sense of achievement and satisfaction of individually making a contribution to medical knowledge. We live in an age of big government, big business, big medicine, and big research. With conformity and bulk pushing in on all of us,

research is an area which the physician as a man an make a contribution to the ell-being of mankind. The care the patient is the primary goo a physician does for mankind. b research can in which provide another spl to do this. (3) Research serves as a means of keeping nan in the thought and mainstream of medic activity. Actual peri nance of rewledge of a search and current 1 specific area throug reading and neetings can attendance at related e of the dykeep one on top of s namic current chang in medicine than merely as a participant rath The search a passive onlooker. (for an answer can be ne secondarily a hobby in medicae, providing a focus of interest, a rea in which to daydream and the away from the immediate pressues of the day. For some physicians, research effort after years of suc ssful practice can provide a psychol gically needed shift of emphasis.

The strongest mativations for doing research are the vigorous stimulus it gives to one's practice, thinking, and living and the opportunity it gives the individual to contribute to medical progress.

For the inquisitive mind of the practicing physician to go beyond mere curiosity and sincerely join the

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search for truth, he must have a disciplined attitude and a compulsive feeling toward his research. Since his primary responsibility is care of patients, research time has many competitors — office hours, family time, recreation, etc. Choice must be made. Persistence is a major factor in achievement.

THE HOW

One type of research that fits the area of this discussion is based primarily on the record room, studying a series of cases in the local context against observations, findings, and results commonly reported from the large centers. Another type is research in which the physician-investigator either records specific clinical observations or carries out laboratory studies on clinical material. In this discussion I am specifically not referring to so-called clinical testing of new drugs. Recent unfortunate events have produced chaos of medical-legal, emotional, and other factors confusing this area. Clinical pharmacology, as a specific field, is developing new criteria and sounder procedures; but this will not be a fruitful area for many solo practitioners.

Record room — The recent provocative study from community hospitals in Rockford, Illinois, on results of different modes of treating cancer of the breast has stimulated studies by other groups and awakened considerable controversy.¹ This study appears to indicate that the type of

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operation performed for breast cancer doesn't affect the long-term results. Reanalysis of the same raw data was made by outside statisticians, who confirmed the conclusions of the original study.² This study clearly indicates the need for a statistically valid study of alternate cases to compare meaningfully the relative efficiency of radical mastectomy, simple mastectomy, and simple mastectomy plus X-irradiation in the treatment of breast cancer.

Compilation of experiences with conditions prevalent in a community can be worthwhile — e.g., farm injuries or infectious diseases localized to certain areas.

Reports at 5-year intervals by Snodgrass, Munn, and Flarity, from Rock County, Wisconsin, have provided valuable information on results of community hospital treatment of appendicitis and surgery of the gall bladder.^{3,4,5,6} These authors

2Shimkin, M. B.; Koppel, M.; Connelly, R. R.; and Cutler, S. J.: Simple and Radical Mastectomy for Breast Cancer: a Reanalysis of Smith's and Meyer's Report from Rockford, Ill., J. Nat. Cancer Inst., 27:1197-1215, November, 1961.

³Snodgrass, T. J.; Munn, W. A.; and Flarity, T. H.: Thirty-five-Year Survey of Appendicitis in Rock County, Wis., Wisconsin Med. J., 42:298-392, September, 1943.

⁴Flarity, T. H.; Raube, H. A.; Munn, W. A.; and Snodgrass, T. J.: Gallbladder Series (Survey in Rock County, Wis.), *Wisconsin Med. J.*, 44:984-987, October, 1945.

⁵Snodgrass, T. J.; Munn, W. A.; and Flarity, T. H.: Research Project on Appendicitis in Rock County, Wis., *Wisconsin Med. J.*, 47: 388-394, April, 1948.

⁶Snodgrass, T. J.; Munn, W. A.; and Flarity, T. H.: Surgery of the Gallbladder: a Study of the Results of Surgical Treatment in Rock County, Wis, AMA Arch. Surg., 61: 199-210, August, 1950.

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¹Smith, S. S.; and Meyer, A. C.: Cancer of the Breast in Rockford, Ill., Amer. J. Surg., 98:653-656, November, 1959.

point out the importance of evaluation at the community level, where most surgery is performed under circumstances unlike those in major medical centers where most reports come from. Studies such as these can be immensely educational to the original investigator and provide interesting clinical information to other physicians as well.

Library - Since research is a discipline requiring training and/or guidance, the primary problem for the physician is how to get started. The most important requirement is to observe patients and consciously look for problems to be studied. Once an idea has been considered and reconsidered, access to a good medical library is essential. A day or two spent in a medical center with the Index Medicus, Chemical Abstracts, Biological Abstracts, Science Citation Index, Excerpta Medica, and other indices can be most valuable. The American Medical Association maintains a library service which, in response to a request from an A.M.A. member on his letterhead, searches the literature and compiles bibliographies on specific subjects, as well as lending books and journals. The American College of Surgeons, which maintains a library devoted to the history of medicine and surgery, will assist research in this area. A package library service on clinical subjects which is maintained by the Texas Medical Association Memorial Library (1801 North Lamar Boulevard, Austin 1. Texas) is accessible also to Fellows of the College. The American Dental Association serv entists on an interlibrary loan ba The National Library of Medicin developing a computer service v a will greatly facilitate the gath 2 of material in specific areas of arch. It also lends books and pu hes some bibliographies which available on an interlibrary bas Various commercial book serie uch as major encyclopedias, and blications of such companies as e W. F. Prior Co., Inc., include al acting or photostat services. The pervisor of the e local public medical section of library will help obtain pertinent publications. ind most good research can be fou a good librarian. With the ra development of inexpensive h -quality copy Dect expansion techniques we can ocopy services. of reprint and ph itly, medical Lastly, and impousually most school libraries at willing to help the lumni.

Collaboration an cooperation urticular study The how of a may require collabe ation with anhe pathologist, other individual. radiologist, and diretor of laboratories in your hose tal will be the ones most often is olved. I have been impressed with the amount of interest these people have in this kind of study. Many times arrangements for serum tests, histological preparations, and the like can be made with them. The science departments of local small colleges might on occasion also be interested in collaborative studies.

A major source of help is the expert working in the field of your

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interest. Such an individual can be identified from the bibliography you will be accumulating or from local reputation. When you have lived with your idea long enough and have done sufficient reading to have knowledge and understanding of the field, you may write this person of your desire to meet with him. Such an arrangement may be made during a vacation; or, at a medical meeting, you may approach a speaker at the end of his presentation of material on a subject related to yours. I have been tremendously impressed with the good will and free exchange of information among scientists. Of course, you must be serious, know your field, and be conscious of the time of the person you are approaching. A consultant's time should not be imposed upon until one has done extensive reading and planning and some actual work on the project. Until an investigator gets his hands dirty in it, no problem has real meaning for him.

Clinical observation-My interest in the subject of this paper arose in 1956 when, at the American Medical Association convention, while studying the scientific exhibits, I came across one by Dr. A. W. Graham, of Chisholm, Minnesota. Dr. Graham was a small-town practitioner, still active although in his seventies. His exhibit consisted of hand-lettered posters, in considerable contrast to a plush, heavily artistic government-agency exhibit located next to his. Dr. Graham's exhibit was based on the fact that for 39 years he recorded blood pressures on his patients. This meant

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that he recorded pressures in three generations of some families. He recorded the pressures of children of hypertensive parents. He had previously published a significant study showing a gradual increase in blood pressure as children became older. This was based on yearly examination of children in school from ages five to 16.7 He had clinical fun with this throughout his practice. He also was presenting a longitudinal study in depth of information not usually available. This term "clinical fun" is one possible description of the enthusiasm and pleasure that some physician-investigators derive from their productive efforts.

We have had a recent personal example of an exercise in clinical observation. A patient admitted with acute large-bowel obstruction underwent emergency surgery for relief of obstruction. Two further laparotomies were necessary for repeated obstruction. No definite point of obstruction was ever seen. The operative note at time of the first obstruction stated that two gallons of ascitic fluid were removed from the patient. This occurred in a municipal hospital, and at change of service a few weeks later the oncoming team recognized that the patient had clinical myxedema. In the patient presenting with acute intestinal obstruction, myxedema had not been clinically obvious; when new doc-

⁷Graham, A. W.; Hines, E. A., Jr.; and Gage, R. P.: Blood Pressures in Children Between the Ages of Five and Sixteen Years, *Amer. J. Dis. Child.*, 69:203-207, April, 1945.

tors came on and looked at the unobstructed patient for the first time, the clinical diagnosis was made and confirmed by laboratory studies. This aroused interest: Could the intestinal obstruction have been due to myxedematous changes in the wall of the intestine, and what was the significance of the two gallons of ascitic fluid? Examination of the hospital records found one other case of proven myxedema with ascites. This then led to search of the literature and the finding that there were a few isolated reports of myxedema with ascites and a very small number of cases of intestinal obstruction apparently due to myxedema. Review of the literature and analysis of our two cases demonstrated, first of all, that these complications of myxedema do occur and, secondly, that the ascitic fluid in myxedema is a high-protein, high-specific gravity fluid. This is not the world's most significant medical finding. On the other hand, it was worthwhile to put it together and to call this specific entity to the attention of other physicians.8

Our best example is a tragic one. That is the story of thalidomide. A doctor in Germany in a comparatively short period of time, saw

three newborn infants ic congenital malforr comelia.9.10 To him than a coincidence. something in common infants and found t mothers had taken tha in pregnancy. This w ical observation follow that led to an answer. had been alerted, sire tions were made in sev Presumably, as a result malformations have be One can't help specu possibility that still me tions might have behad this entity been relier by some other doct a small number of ca equally as good a detect

th a specifon — phowas more looked for nong these all three mide early astute clinby thought nce doctors ir observa-| countries. this, many prevented. ing on the malformaprevented gnized ears observing and being ve.

SUMMARY

The possible research role of the private practitioner in the community hospital is discussed. The why and the how are exploit it. A few of many available examples are discussed to show the pl sician that this approach can enrich is clinical activity and to stimulate him to efforts in this direction.

⁸Haley, H. B.; Leigh, C.; Bronsky, D., and Waldstein, S. S.: Ascites and Intestinal Obstruction in Myxedema, AMA Arch. Surg., 85:328-333, August, 1962.

⁹Lenz, W. and Knapp, K.: Thalidomide Embryopathy, Deutsch Mal. Wschr., 87: 1232-1242, June, 1962; AMA Arch. Environ Health, 5:100-105, August, 1962.

¹⁰Taussig, H. B.: The Thalidomide Syndrome, Sci. Amer., 207:29-35, August, 1962.