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Research in the Multispecialty Clinic

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of accruing 16,000 women, approximately 8,000 women entered the study in the first year. This study has the additional objectives of evaluating the expected benefit of tamoxifen on cardiovascular mortality and the incidence of bone fractures, as well as evaluating the risk-benefit ratios of tamoxifen prevention therapy.

In other breast cancer trials, we are departing from the conventional wisdom of treating all node-negative women equally. Our new protocols will use markers to assess a woman's risk of breast cancer recurrence and test appropriate therapies based on that risk. We will continue our evaluation of preoperative chemotherapy and the impact of the primary tumor response on outcome. We are also venturing into a clinical trial with a geriatric population. Despite representing a significant proportion of breast cancer patients, remarkably little reliable clinical data exists to guide physicians in the management of these patients.

One of the NSABP's most challenging trials is to evaluate the worth of preoperative multimodal therapy in patients with operable rectal cancer. In addition to evaluating the effect of preoperative therapy on survival, and disease-free survival, this study will assess whether patients can be converted to sphincter-saving surgical procedures by shrinkage of the primary tumor.

This description of our ongoing trials is evidence that the NSABP does not shy away from complex protocols if they have the potential to answer a clinically important question. Likewise, the community investigators have not been intimidated by the increasing complexity of some of our trials. The percentage of patients that community-based physicians enter onto NSABP protocols is consistently larger than university-based investigators, irrespective of the stage of the disease.

COMPLIANCE AND MOTIVATION

Entering patients onto a study is only one aspect of clinical research. Vital to the success of a study is compliance with protocol requirements. These requirements include 1) providing documentation of eligibility, 2) submitting data on patient adherence to therapy and follow-up testing, and 3) monitoring adverse drug reactions. By all criteria, community investigators have demonstrated their ability to successfully participate in clinical studies. In order to ensure a continuation of the distinguished research that the NSABP has performed, both community- and university-based NSABP investigators must also demonstrate the commitment to adhere to the highest standard of scientific conduct. The NSABP headquarters and membership are committed to the science of clinical trials and improvements in clinical practice through clinical research.

An important issue regarding community-based investigators is that they participate largely on a

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Table 1. NSABP accrual 1988–93

Comparison of accrual rates to NSABP protocols between university and cancer centers and community-based centers from 1988 to 1993.

Year	University & Cancer Centers	Community-Based Centers	Total
1988	1,619 (42.7%)	2,175 (57.3%)	3,794
1989	1,329 (38.6%)	2,109 (61.3%)	3,438
1990	1,843 (37.4%)	3,090 (62.6%)	4,933
1991	1,004 (46.5%)	1,156 (53.5%)	2,160
1992	1,534 (40.0%)	2,296 (60.0%)	3,830
1993 (Jan.-Sept.)	1,023 (34.8%)	1,916 (65.2%)	2,939
Total	8,352 (39.6%)	12,742 (60.4%)	21,094

Research in the Multispecialty Clinic

by Richard N. Re, M.D.

As the year 2000 approaches, researchers are making daily extraordinary advances in molecular genetics and in the understanding of pathogenesis of human disease. In the area of health care delivery, integrated models and physician group consolidation are increasing, and novel payment schemes are proliferating. At the same time, the government is proposing major health care reform. But because the specifics of this initiative are unknown, considerable uncertainty remains as to the form the health care system will assume.

Against this backdrop of frenzied activity, the physician, scientist, or administrator may wonder what place, if any, research has in the multispecialty clinic. This question becomes all the more poignant as margins from health care delivery fall, resulting in the decline of expendable income for research activities. At the same time, the National Institutes of Health and other federal funding agencies are finding it increasingly difficult to support a growing number of proposals for research activities. Indeed, it could be argued that research activities are a luxury the multispecialty clinic can no longer afford. This view, however, is incorrect.

THE BENEFITS OF RESEARCH

Now, more than ever, research forms an integral part of quality medical care, a view based on the fact that two major paradigm shifts are occurring simultaneously in the medical world. The first of these is the shift from physiology-based medicine to genetics-based medicine; and the second is the supplementation of clinical judgment with health services research. The first of these

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paradigm changes will fundamentally alter the physician's diagnostic and therapeutic armamentarium, while the second, particularly when coupled with new advances in information technology, will change how the physician uses that armamentarium. Despite the fact that margins and reimbursement will be constrained, the clinical application of molecular genetics and health services research will add value to the care the patient receives and confer a competitive advantage on organizations that embrace the new technologies.

Organizations participating in medical research may derive many benefits. First, the innovation brought to the clinical setting by research—be it a new clinical therapy or a new approach to health care—attracts and maintains an intellectually aggressive and aware medical staff, which can provide superior patient care.

Secondly, a research program supports a clinic's ongoing educational programs. It is difficult to conceive training high quality physicians in the absence of a research program. While medical education will in all probability be curtailed in coming years and subspecialty training slots will be reduced, all physicians and other health care providers still need to be well versed in the new basis of medicine. In addition, even physicians' assistants and primary care practitioners have a compelling need to be at least passingly familiar with techniques such as polymerase chain reaction technology, which is used in diagnosing disorders as diverse as chlamydia infection and cancer. On-site expertise in the new molecular genetics, as well as in the new areas of health care research, will help improve the education of the health care professionals of the future.

Finally, research provides access to novel technologies and therapies. It is highly unlikely that all technologies will be widely disseminated in the future. In coming years, scientific links between clinicians/scientists and basic scientists in universities and industry will, as in the past, provide improved access to new technologies with attendant benefits to patient care.

If research is coming under cost pressure, how is a clinic to institute and develop a research program? One way is to take advantage of the changes that occur in the science and practice of medicine. It is possible at a relatively low cost to establish a core molecular genetics laboratory that can provide intellectual and scientific support to multiple clinical disciplines while linking with similarly inclined laboratories nationwide.

Because molecular genetics touches virtually every facet of medicine, an investment in this area has wide applications for both research and clinical care in virtually all clinical disciplines. In our organization, the Alton Ochsner Medical Foundation in New Orleans, La., a relatively modest commitment to molecular genetics has already spun off a molecular genetics diagnostic laboratory, which uses polymerase chain reaction amplification, as well as more traditional hybridization techniques, to diagnose a wide range of conditions. A gene therapy initiative is also underway with important implications for the therapy of both the cancer patient and the patient suffering from cardiovascular disease. Thus, money spent in molecular genetics research will pay dividends in terms of an organization's ability to provide forefront diagnostic and therapeutic insights to many clinical services. This added value will be reflected in one fashion or another in the clinic's bottom line.

POTENTIAL OF MOLECULAR GENETICS RESEARCH

To see the wide ranging potential of this new genetics, one need only consider the sampling of gene-based technologies that are being adapted to clinical care , including molecular cloning, embryonal stem cell technology, and antisense oligonucleotides. Already, the National Institutes of Health is initiating programs to map those genes responsible for the largest part of the variance in blood pressure. Similar initiatives directed at gene influences on cholesterol and glucose metabolism are sure to follow. Networks of collaborating centers will one day be used to identify patients with the appropriate phenotypes and to then undertake to genotype them, either locally or at a central laboratory. This activity will have tremendous applications for the diagnosis and prevention of disease. The value that molecular genetics research and development can bring to a clinic is real.

HEALTH SERVICES RESEARCH

The case for health services research is even more obvious. As health care delivery systems become increasingly interdependent and integrated, the managers of the delivery system, as well as the purchasers of the care, must have valid information about the outcomes of care they provide. The analysis of the outcome of care requires that the patient's severity of illness be accurately measured and controlled. This is a major research challenge, which is only now yielding to the onslaught of health services research.

Already validated indices of the severity of patient disease have been developed and are finding wide application. In addition, the measurement of outcomes such as health status has advanced to the point where the technical success of procedures and their effect on the well-being of a patient can be assessed. Even more impressive are the new efforts to model delivery systems so that efficiencies can be introduced and the impact of new technologies estimated. Technology assessment is yet another branch of health services research and one that will find important implications for the research community and for management as well.

As an emerging discipline, health services research is multifaceted and is being advanced at multiple sites around the country. As with molecular genetics, networking will be required to link health services research units if productivity is to be maximized. Already, large consortia are being formed to develop the tools that will be necessary for applying health services research principles to health care delivery systems. The price of admission to these networks, like the price of admission to the molecular genetics diagnostic and therapeutic networks, will be the support of research and scholarly activities in these disciplines.

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voluntary basis. Their involvement in clinical trials research is motivated by scientific, intellectual, and altruistic reasons. Their participation also enables them to bring state-of-the-art cancer management to their patients. Hence, it is imperative that we continue to provide adequate funding for conducting community-based clinical research. The NSABP will continue to seek funding through a variety of mechanisms and from a variety of sources to facilitate continued participation as well as expanded participation of community-based investigators in clinical research. This issue will become increasingly more important in a climate of health care reform and competition for health care dollars. Yet, in this climate, clinical research becomes even more important. It is only with scientifically verified results that physicians will be able to treat patients cost-effectively (i.e., they must know what works, how much it works, and at what cost). We know of no more efficient and effective mechanism for obtaining this information than through well-designed and sufficiently funded clinical trials. The concept of basing clinical practice on the science of medicine has evolved through this century. It must continue into the next.

ACCC's Collaborative Research Group

by Albert B. Einstein, Jr., M.D.

In 1990, the community's contribution to clinical research took another step forward. At the request of a number of ACCC members, the association launched its own Collaborative Research Group (CRG). This group has steadily increased in size and complexity, providing many member organizations involvement in quality clinical research trials from a number of pharmaceutical and biotechnology organizations.

The 60 member hospitals of ACCC's CRG are a powerful resource for clinical trials. Including one NCI Comprehensive Cancer Center, one academic cancer center, 20 of the larger CGOP institutions, and 18 CCOPs, the CRG provides access to more than 60,000 new cancer patients each year. CRG members have accrued 3,774 patients to NCI trials and 1,554 to other trials in 1993 alone through their existing affiliations with the national groups, including the Southwest Oncology Group, the Eastern Cooperative Oncology Group, the National Surgical Adjuvant Breast and Bowel Project, the Radiation Therapy Oncology Group, the Pediatric Oncology Group, the Cancer and Acute Leukemia Group B, and the North Central Cancer Treatment Group.

The group has a wide range of resources. Fifteen have operational BMT units with more than 350 patients treated each year. The group has 1,835 dedicated oncology unit beds, 2,359 oncology nurses, 425 medical oncologists, 192 radiation oncologists, and 167 data managers.

CRG ORGANIZATION

The CRG's multidisciplinary Steering Committee reviews new applicants for membership and conducts a thorough review of potential new protocols submitted by pharmaceutical and biotechnology corporate sponsors.

The idea is to assure that each protocol asks a legitimate and important scientific question and that the data collection requirements are within reason. The group is not interested in doing studies that are Phase IV marketing trials. It wants to be involved in and contribute to solid research activities.

The Steering Committee works with the sponsor, ascertains a price for participation in the trial, and notes problems with the trial (from eligibility requirements to data forms) that might prohibit the sponsor from achieving its goal. In at least one case, the group's recommendations were taken back to the FDA and eligibility requirements were loosened. Simplified contracting and billing procedures eliminate many of the hassles for both sponsors and sites.

Subsequent to the Steering Committee's approval, group members receive a copy of the protocol with a short Request for Proposal, which allows them to indicate whether or not they wish to participate, what conflicts their involvement might have with other protocol obligations, and to discuss their research experience. Sponsors then work with staff and the Steering Committee in making final site selections.

HIGH QUALITY

The CRG membership has won praise from corporate sponsors for its quality of data management. One corporate medical monitor has stated that there were no "data turkeys" among the ACCC group. "By that I mean that none of the sites gave us unacceptable data." Moreover, this same physician indicated that ACCC's sites had been the highest accruers to his study, exceeding prime sites which had been members of the study for twice as long.

As the group's reputation has grown, so have the number of corporations wishing to involve the CRG in studies.

ACCC Executive Director Lee E. Mortenson, D.P.A., has noted the emergence of two different approaches to working with the CRG. On the one hand, some organizations are coming with IND studies that they have had open for some time. These companies are often looking for high-quality sites to supplement ongoing efforts. On the other hand, a number of companies are approaching us about long-term relationships, involving group members in the development of studies, and in publications, in addition to implementation of the trials. This provides the high degree of interest and involvement many of our members have sought.

The CRG hopefully will provide participating ACCC members additional options for involvement in meaningful clinical research and for rapid access to new drugs for their patients.

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