# A Collaborative Research Model in Family Practice

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Clinical settings in family practice represent an important area for much needed research in various aspects of primary care which to date have been largely neglected. Such settings provide the research setting of choice for studies involving pharmacotherapy of the psychoneuroses. Neither the individual researcher in an academic center nor the busy practicing family physician can alone undertake meaningful research efforts of this kind. A collaborative model combining the resources of a university medical center and practicing physicians in the community has been developed at the University of Pennsylvania. The structure, process and advantages of this collaborative research model are herein described.

The relatively recent establishment of Family Practice as the newest medical specialty has generated an increased concern for clinical research specifically directed to the family practice setting. As with other specialties, attention is now being directed to more effective ways in which family physicians can integrate both clinical and research perspectives into their daily work.

It is a well-accepted tenet of clinical research that treatment methods should be tested in those settings where they are to be regularly employed. One prominent area for such research involves pharmacotherapy for the psychoneuroses. Although some 60 percent of all prescriptions for minor tranquilizers are written for private family practice patients, most research in this area has ignored them.[1] This lack of research has been rationalized by appealing to the apparent clinical objectives and immediate patient needs confronting the family physician.

Since both practical and empirical data demonstrate the importance of drug studies in actual treatment settings, and since Family Practice is the first line of defense against mental illness,[2] there is little question that it is the research setting of choice for pharmacotherapy. The issue is not the desirability of such research, but rather the ability to devise research designs which can be adequately integrated with the busy office practice of family physicians. This article will describe the structure, process and advantages of a collaborative research model which has proved both feasible and productive.

## The Private Practice Research Group

A collaborative research organization has been developed at the University of Pennsylvania which involves resources of the university medical center as well as practicing family physicians and psychiatrists in the area. Through the Private Practice Research Group, the clinical skills of family physicians are combined with the technical competence of professional researchers. The collaboration of physicians in family and psychiatric practice (currently about 40) and a central research unit with personnel trained to design clinical trials and to collate, process, and analyze the patient trial data, has been shown to yield findings that will ultimately be of use to other clinicians, researchers, and the public at large. The organizational structure of this collaborative research group is illustrated in Figure 1.

Drug studies are initiated by the research unit. The principal concern is to obtain clinical data of good quality relating to the efficacy and safety of a particular medication. Clinical drug trials with new or experimental medications are normally undertaken if proper preliminary studies have been carried out and if there is sufficient expectation that the new medication would be of practical value to practicing physicians. To demonstrate such value, proposed drug studies usually include both an inert placebo control and an appropriate "active" control. With the ever-increasing assortment of neuroleptics now available to physicians, for example, new medications no longer achieve utility by being found superior to placebo.[3] The proffered medication must, in addition, display comparative benefits in the light of existing treatment options.

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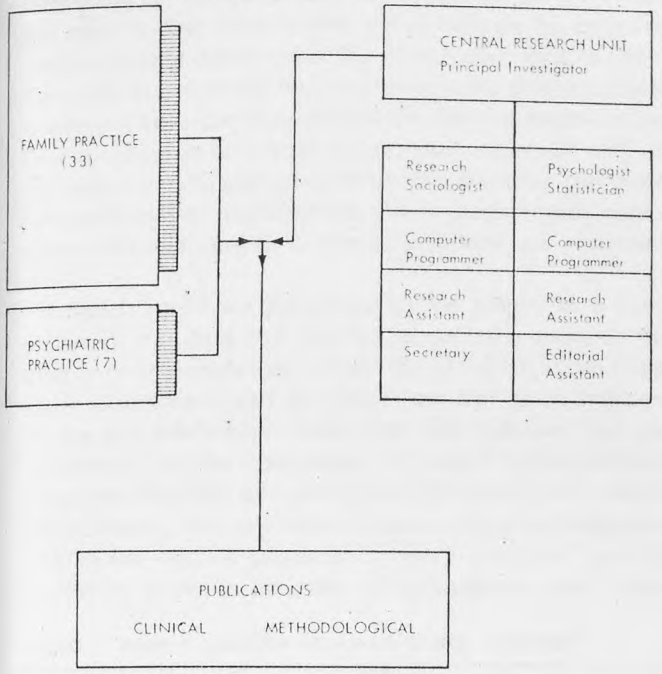
*Figure 1: private practice research group organization*




Other studies are initiated because clinicians and researchers have spotted a gap in our knowledge of available treatments. Clinical puzzlement over the inconsistent effects produced by a marketed antineurotic agent (Tybamate), for example, prompted us to undertake a controlled study of the drug which eliminated much of the confusion. Tybamate was found more effective than placebo *only* in those patients who expressed their anxiety mainly through somatic target symptoms, but not in patients who expressed their anxiety in psychological symptomatology.[4] Similarly, our lack of knowledge about the effectiveness of over-the-counter daytime sedatives prompted us to devise and implement a study in which, for the first time, such a drug was compared with both an established prescription agent and inert placebo.[2]

Thus far, clinical publications have been based on 15 antianxiety and 11 antidepressant trials ranging over most of the agents currently available for use in this field. The information obtained from these studies has generated a data bank of considerable size which has been used for methodological studies involving either prediction or hypothesis testing and draws on specific groups of patients across different drug trials.

## Process of Collaborative Research

The successful functioning of the Private Practice Research Group must initially reside in the recruitment of capable physicians with genuine research interests. Initial contacts and word of mouth referrals have gradually resulted in the active participation of many members of the American Academy of Family Physicians. Interest alone, however, does not make for the conduct of clinical research, and many "interested" physicians have been unable to participate in our drug trials. It is equally important that individual practices prove suitable for clinical research in terms of the physician's office procedures, the kinds of patients seen, and their receptiveness to participation in clinical drug trials. To determine whether an established office routine is, in fact, compatible with the requirements of clinical research, interested physicians first undertake a training trial. As preparation for the training trial, prospective researchers are brought to the central research unit, shown videotapes of typical anxious and depressed psychoneurotic patients, and given the opportunity to discuss both the content and the appropriate rating of the observed symptoms with psychiatrists and experienced family practitioners.

Beyond establishing the physician's capacity to detect and rate the symptoms of anxiety and depression, the training trial demonstrates whether he can make adequate scheduling arrangements for patients placed on the drug trial. Time is invariably an important factor; trial patients require additional time and a first visit, in particular, often requires at least a half hour. It is also during the training trial that the physician acquires familiarity with the research forms that both he and his patients must complete.[5,6] By the conclusion of the training trial, both the physician and the researchers monitoring his progress have a fair idea of whether he has treatment-suitable patients who attend him regularly, who can be committed to a clinical trial, and for whom sufficient time can be allotted. Only if these criteria have been satisfactorily met can the physician proceed to a "regular" clinical trial.

### The Clinical Trial and Patient Acceptance

In typical clinical trials, anxious or depressed patients are seen three or four times, usually at two week intervals. Prior to the first visit, patients are screened for trial criteria to determine their suitability for pharmacotherapy. If appropriate and sufficient symptomatology is present, the physician proceeds to schedule an initial study visit at which time the medication is dispensed.

Physicians have traditionally been advised to treat trial patients in the same way they would ordinarily treat them, and have had great latitude in determining how, and to what extent, these patients should be informed about the drug trial. When a medication not yet commercially available was being used, physicians often introduced it as "one of the newer, safe, not-yet-marketed drugs, received free from a pharmaceutical company, that I believe will help your nerves." If the medication was commercially available, physicians frequently told patients that they had recently received a "free" supply from the manufacturers. At their discretion they could tell patients about their affiliation with the University of Pennsylvania or the fact that the employment of the medication was part of "research" funded by the National Institute of Mental Health. FDA regulations stipulate that physicians must clearly inform patients that they will be participating in a drug trial and obtain their "informed consent" before administering the medication.[7] Thus, after formally explaining the nature and consequences of the drug trial, Private Practice Research Group physicians are now strongly urged to simply give their patients the choice of participating in the trial or receiving routine treatment.

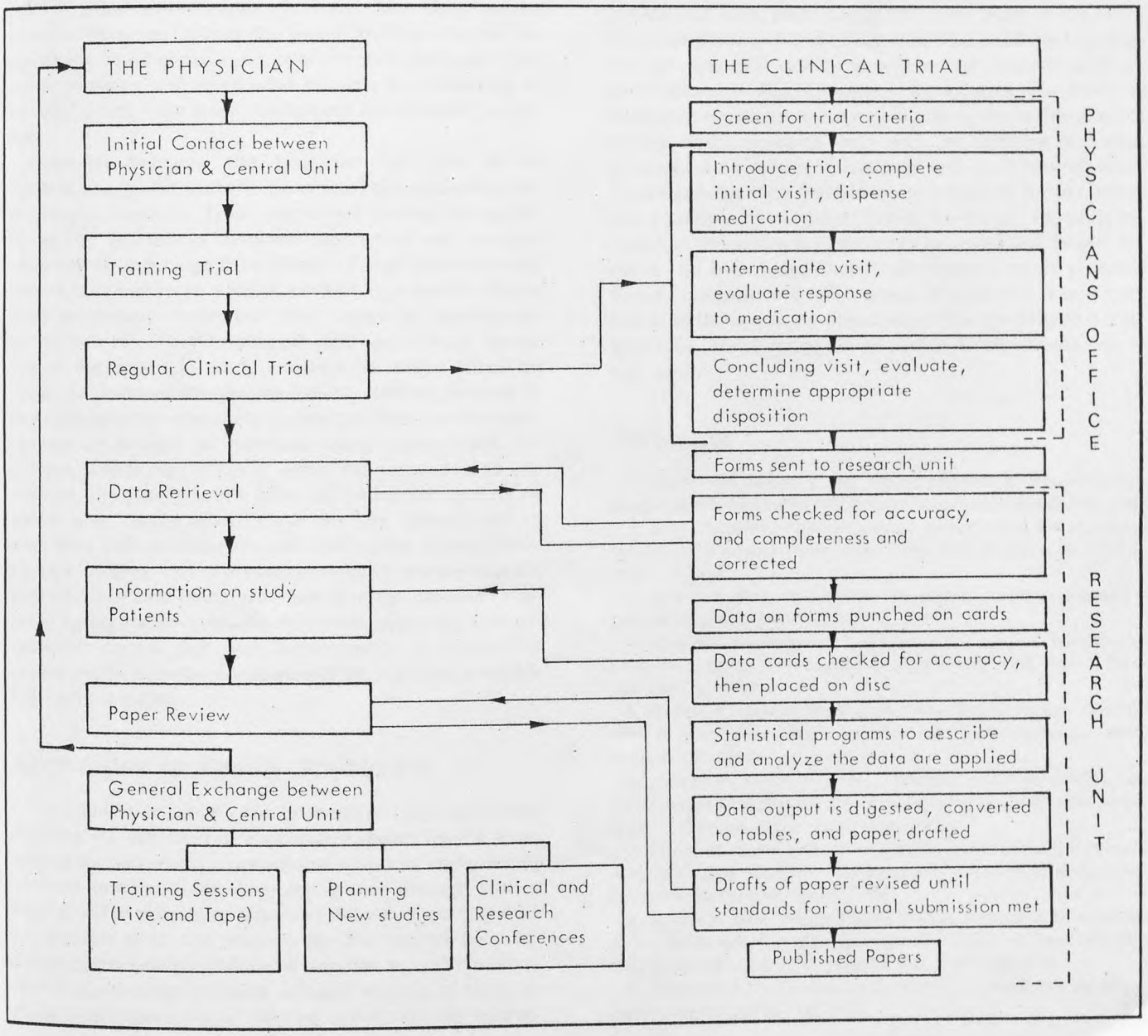
After the patient clearly understands and has agreed to participate in the clinical trial, the physician dispenses the medication, emphasizing that it is to be taken regularly and that remaining medication must be brought back at the next visit. Sufficient medication is dispensed so that the patient may be up to a week late for his next appointment and still be able to follow the prescribed dosage. Patients are additionally warned that mild side reactions such as, for example, drowsiness, may occur with the drug, but that such reactions are normal, generally transitory, and a sign that the medication is working. The patient will be allowed to reduce medication on his own, yet is generally discouraged

from doing so. The physician may advise the patient to call him after the first week of the trial to indicate his progress, and may at later dates adjust the dosage according to either the amount of reported improvement or the severity of side reactions. Our experience has shown that the degree of patient cooperation which physicians elicit relies not only on the patient's particular attitude toward the drug trial itself, but on the overall quality of the doctor-patient relationship. Where this relationship is strong, problems are extremely rare.[8]

Research forms are presented to the patient as a component of the drug trial needed to properly evaluate the drug, as helpful tools that will aid the physician in providing better patient care, and as a small "service" given in return for the free medication. Experience has indicated that patients rarely find the completion of research forms, primarily symptom checklists or mood scales, bothersome or threatening. Indeed, they are often viewed as positive indications of both the treating physician's "professionalism" and his interest in them as patients. At subsequent visits, these forms are used to assess the major dimensions of drug response — side effects, dosage deviation, and improvement, the latter rated both globally and by specific symptom measures by both the physician and the patient. When a patient's participation in the drug study is prematurely terminated, a disposition form is filled out summarizing the patient's response to the trial medication, the reason for premature termination, and any subsequent treatment the physician plans to institute.

While the collection of trial data occurs solely within the physician's office, it is the central research unit which trains him in clinical research procedures and which receives and processes the data collected in his practice. The physician's role within the total research operation is shown in greater detail in Figure 2. This diagram follows the physician's various contact points with the research unit and traces all the steps involved in the conduct of a clinical trial as it progresses from the physician's office to the research unit. The interplay between physicians and researchers is described as a flow chart.

*Figure 2: private practice research group operation*



## Communications

The physician's participation in a drug trial does not terminate with the collection of the completed study forms. Several contact points remain between him and the central research unit. Initially, there is a check to determine the accuracy and completeness of the data. Particular attention is paid to whether the physician's patients have met all the study criteria, and whether the physician's own clinical assessments of the same patient are internally consistent. When discrepancies arise, the physician is contacted and appropriate corrections made.

When the study data from all the physicians participating in a drug study have been collected and processed, each one receives a summary evaluation providing him with a "feedback" about his own patient responses. This tells the physician which medication each of his patients received, systematically lists the amount of improvement and incidence of side effects reported by each, and allows him to compare his own results with those obtained in the practices of the other study physicians. As the final piece of contact generated by a drug study, each participating physician receives a draft of the paper which has been based on the trial data. Physicians review the paper, indicate whether the statistically based conclusions conform with their own clinical impressions, and often offer possible interpretations of the data which have been overlooked by research personnel.

Exchanges between the physician and the central research unit go beyond the process of data gathering and assessment, however. These exchanges attempt to capitalize on the differences between the clinical and research perspectives, and range from filmed clinical interviews and patient observation to clinical conferences which discuss pharmacotherapy treatment and research conferences which consider methodological and procedural issues. Typical exchanges in such conferences might focus on "gaps" in pharmacotherapy treatment, difficult patients to treat, examples of unusually successful cases, or the comparative advantages of different rating scales. Such exchanges, which may occur at either the research unit laboratories, the practitioner's office or university conference rooms, give participating physicians the opportunity to share their own experiences with colleagues while obtaining new insights into the management of psychoneurotic patients. Since data reflect no more than the physician's capacity to accurately evaluate treatment response, it is extremely important that such opportunities to discuss the various problem areas encountered be regularly available and easily initiated.

## Advantages to Family Physicians

The ultimate improvement in medical care, specifically regarding the selection of appropriate agents for the treatment of the symptoms of emotional illness, is undoubtedly the most important objective being met through clinical drug trials. For the family physician, however, participation in a program of clinical research like the one we have described offers several additional benefits as well. Involvement in a university-affiliated research effort is certainly an educational experience of the first order, and the instruction received at research meetings and conferences may be used to acquire postgraduate education credits from the American Academy of Family Physicians.

Formal instruction of family physicians is of value, however, only insofar as it can be translated into practical clinical gains,[9] and there is no doubt that in terms of this kind of research program, the most valuable "education" occurs in the clinical conduct of the drug trials. It is through implementing well-designed drug trials that the physician sharpens his sensitivity to the different symptom dimensions of neurotic illness and acquires a practical body of knowledge about the nature of psychotropic drug use by *experiencing* the differential effectiveness of different psychotropic agents. Moreover, participation in such collaborative research gives the physician the extended clinical opportunity to understand more thoroughly his patients with emotional difficulties, an opportunity that can be supplemented by proficient use of the measuring instruments put at his disposal.

One must note, lastly, that collaborative research with other clinicians and researchers can be a gratifying experience in its own right. As co-authors of papers based on the clinical trial data, participating clinicians share in the sense of accomplishment and recognition that published findings of high scientific quality generate. The content of these publications is also important: by locating the kinds of treatment responses that are particular to the family practice setting, and contrasting them with the different responses encountered in different treatment settings, it contributes to the knowledge base that will be necessary to further define the academic discipline of Family Medicine. Certainly research in this area will continue to be important, largely because the knowledge that results from it offers potential benefit not only to a select group of academic researchers, but to all the practicing physicians in the specialty that is responsible for delivering a large part of primary health care in our nation.

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