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THE SUBJECTIVE EXPERIENCE OF THE RESEARCH PATIENT: AN INVESTIGATION OF PSYCHIATRIC OUTPATIENTS' REACTIONS TO THE RESEARCH TREATMENT SITUATION

LEE C. PARK, M.D.,[1] REGINA SLAUGHTER, M.S.S.W.,[1] LINO COVI, M.D.[1] AND HAZEN G. KNIFFIN, JR., M.D.[1]

INTRODUCTION

There has been a growing concern in the scientific community about the welfare of patients subjected to clinical research. Beecher (1) has presented extensive documentation of past abuses, and new policies have been implemented by the National Institutes of Health and other health agencies to assure that investigators carefully consider the risks involved, inform patients of the nature of procedures and obtain their permission to use the data obtained.

In this development, however, a most important consideration has been omitted, *i.e.*, how patients feel about being subjected to research methods and treatments. The present paper reports an attempt to evaluate the degree to which psychiatric patients are bothered by research procedures and by the idea and experience of being research subjects in a clinical setting in which permission for experimentation is not asked although research paraphernalia are obvious.

Although little is known about the subjective response of research patients, assumptions are often made about their attitudes, and some of these assumptions tend to inhibit attempts to learn from the patients how they really feel. Many investigators believe that the patient's awareness of the research nature of clinical tests or treatment might detract greatly from the success of an experiment. Fisher *et al.* (2) point out that patients, ". . . more often see themselves as being 'treated' rather than 'researched,' and this may provide a highly favorable setting for drug action. In many controlled experiments, the patients become definitely aware that they are participating in a research project (implying 'Let's see if the drugs will help you'), and such a perception could tend to inhibit drug action." Liberman (4) suggests that patients should not be forewarned of placebo administration since this "would engender suspicion and perhaps hostility in subjects, making them undesirable, if not unwilling, candidates for placebo research."

The present study is a systematic exploration of the patient's subjective experiences during the course of a drug study which was focused on methodology of psychopharmacological research.

SETTING

The ongoing drug study (November, 1962, to June, 1963), which is reported elsewhere (5), compared the clinical effectiveness of four agents: chlordiazepoxide, active placebo (atropine), inactive placebo and a chlordiazepoxide-atropine combination. Although the drug study itself is *not* the subject of this paper, a brief description of procedures influencing the patient's experience is given below.

The duration of the treatment was one week, with each patient receiving one of the

[1] The Henry Phipps Psychiatric Clinic, Johns Hopkins University School of Medicine, 601 N. Broadway, Baltimore, Maryland. This study was supported in part by United States Public Health Service Grant MH-04732.

four randomly assigned medications. The patient population consisted of 72[2] neurotic outpatients with manifest anxiety, age range 19–55 years (mean age, 31), who had been referred to the Henry Phipps Psychiatric Clinic Outpatient Department. Eighty-five per cent of the patients were rated as Hollingshead Social Class IV or V (31 patients Class IV and 30 Class V) (3). Thirty-six of the 72 patients stated this was their first psychiatric treatment experience; 27 had previously received treatment (chiefly pharmacotherapy); and the treatment history of the remaining nine patients was ambiguous.

The clinic social worker briefly screened each patient for referral to the drug study. Subsequently, the patient was seen in intensive evaluation by at least one and often by two experienced psychiatrists, occasionally along with a senior medical student. He was also asked to fill out a checklist describing expectations of therapist behavior, and the secretary-technician obtained information on ordinal position and social class. No reason was given to the patient for collection of these data nor for any of the subsequent forms administered. He was then given an appointment to return in a few days for the first treatment session and was advised to discontinue any psychotropic medication he may have been taking at least four days prior to that appointment. He was informed that he might be given a drug by his therapist and that the effectiveness of such a medication could not be judged unless he discontinued all medication. The research nature of the treatment program was not stated to the patient, and care was taken that no clear impression would be given that the treatment would be "different" or unusual.

On arrival for his first treatment appointment, each patient completed various questionnaires, including a 64-item symptom checklist, an anxiety rating scale and a depression rating scale. He was then taken to a small experimental room, where a psychiatric resident was introduced as his therapist. On one wall of the room was a one-way mirror, clearly visible, measuring approximately four feet by two feet. A microphone protruded from the ceiling. The tape recorder was explicitly identified by the therapist, who explained that he found it useful to tape-record interviews rather than take notes; the one-way mirror was not mentioned.

The resident-therapist, who knew nothing of the patient, was required to elicit current complaints and history of present illness in an interview restricted to 15 to 30 minutes. He was instructed to obtain information concerning symptoms and complaints without getting involved in discussions of dynamics or other issues which might have significant therapeutic effect. After obtaining the information needed, he then recommended drug treatment, making rehearsed comments concerning relationship of dry mouth to improvement, the importance of taking the the medicine regularly and of not taking other medications. The patient was given an appointment slip for the subsequent appointment in one week, along with a bottle of medication, and was told to return the bottle with any unused capsules.

In the observation room two senior psychiatrists observed the interviews for the purpose of supervising the resident, particularly in his adherence to the rehearsed role behavior.

At the time of the subsequent and final drug study appointment one week later, the patient again completed the various forms and was then seen by the resident-therapist for approximately 15 minutes to evaluate change. A senior psychiatrist then interviewed the patient to investigate and record the patient's feelings about the medication and to advise him that the resident would not be available to see him in the future. This psychiatrist also re-evaluated the

[2] Due to missing data, only 71 of these patients were reported in the paper presenting the results of the drug study (5).

patient's condition so that he could be referred to a suitable further treatment program. The patient was seen again by the secretary-technician, who administered two questionnaires aimed at rating patient perceptions of the treating doctor.

METHOD AND RESULTS

At the conclusion of the above procedures, the patient was asked to wait until a social worker could speak to him. The worker, who had not seen the patient previously, explained that the chief of the clinic was conducting a survey of clinic services and had asked her to talk with each patient to find out what his expectation of treatment had been, whether he was satisfied with the way things had gone, what suggestions he had of ways things might be done differently and/or more effectively. In order to encourage in the patient a feeling of freedom to express negative feelings, the interview was presented as completely separate from any treatment program. Patients were reassured that their opinions were confidential, that any criticism, which was invited, would be considered in overall administrative planning of clinic services to patients in the future. A structured interview was conducted, with the social worker asking for information concerning the patients' reactions to the various research procedures. She attempted to be neutral in her expectations of results, even if privately entertaining some reservations about vigorous research procedures and resulting necessary postponements in pursuing individual treatment needs.

TABLE 1

Patient Awareness of Research

Awareness	*N*
Research definitely not involved	55
Research definitely involved	3
Research possibly involved	7
No opinion	3
Research probably not involved	4
Total	72
Research might be involved (Subtotal)	17

TABLE 2

Opinions about Participation as Research Subjects by the 17 Patients Who Felt Research Might Be Involved

Opinions	*N*
Very positive	0
Mildly positive	3
Neutral	7
Mildly negative	5
Very negative	2

The patients' attitudes about the various procedures were recorded and later jointly rated by the authors. Results of this assessment are reported below.

AWARENESS OF RESEARCH

After an initial period of questioning about attitudes prior to coming to the clinic and about general impressions, patients were asked specifically, "Do you think this was research?" If a patient seemed unable to grasp this question, he was asked if this was an experiment or if he had felt experimented on in any way. Almost all the patients had only a vague idea of what "research" or "experiment" could mean. The majority of patients did not acknowledge any awareness that research was involved at all (Table 1). Fifty-five of the 72 patients (76 per cent) felt that there was no research or experimentation, while only three patients (four per cent) were *sure* that research was a part of the program.

Of those 17 patients (24 per cent) who were willing to acknowledge the possibility that they might be part of a research program, none was strongly enthusiastic about the idea, whereas three were mildly positive, seven neutral, five mildly negative, and two very negative (Table 2). They tended to give differing reasons for concluding that research might be involved. For instance, one patient felt it was definitely research because two doctors asked the same questions. Another patient, who felt very clearly she

was part of a research program and who was mildly negative about it, stated that someone had told her this was research and that permission was asked and given. One patient stated that she automatically assumed there would be research if she came to Johns Hopkins, another that doctor changes and written forms implied research was involved for the purpose of deciding how to treat her. Only one patient stated that the purpose of research could be to compare his feelings with those of others, and no patient specifically indicated the primary purpose of the research was the study of medicines. On the other hand, as an example of explanations that research was *not* involved, one patient stated, "People in this clinic are treated like they are sick, so it's not research."

Sixteen patients thought the program involved teaching of students or training of residents, expressing a generally neutral to mildly negative attitude toward this possibility. In addition, 11 patients thought that the one-week program was essentially an evaluation and felt generally neutral about this possibility.

However, a statistically significant majority of patients viewed the program primarily as treatment and were satisfied with it ($p < .01$). When asked to express their overall feelings on a five-point scale, 18 patients expressed strong satisfaction, 28 mild satisfaction, three were neutral, 14 were mildly unsatisfied, and nine very unsatisfied (Table 3). Satisfaction could not be shown to be related to prior treatment experience, to degree of improvement expected at the time of initial clinic contact or to any specific study procedure. Patients had indicated improvement expected at initial contact on a five-point scale: 31 patients had expected "a complete cure"; 33 to be "a good deal better"; six "a little better"; none "not much better"; one, "no improvement" and one, no response.

PERCEPTION OF SPECIFIC RESEARCH PROCEDURES

The patients were asked to comment on specific facets of the research program: treating doctor, change of treating doctor, forms, tape recorder, screen, and as contrast questions they were asked to comment on

TABLE 3

Patient Perception of Research Procedures

	Attitudes or Degrees of Enthusiasm about Various Aspects of Research					Total*	χ^2‡	p
	Very Enthusiastic	Enthusiastic	Neutral	Dissatisfied	Very Dissatisfied			
Total program	18	28	3	14	9	72	6.72	<.01
Treating doctor	21	21	10	13	7	72	6.13	<.02
Doctor change†	1	3	32	17	19	72	13.35	<.01
One-way screen	0	2	12	18	7	39	12.41	<.01
Tape recorder	0	6	41	16	4	67	2.52	—
Forms	4	15	25	25	2	71	.69	—
Administration	1	23	34	7	7	72	1.13	—
Clinic location	1	11	45	14	0	71	.01	—

* The total in some rows is less than the sample size of 72 because of patients being unaware of the item (in the case of the screen and recorder) or giving unclassified responses (one each about forms and clinic location).

† This item refers to termination of contact with the treating doctor after completion of the drug study.

‡ In order to satisfy assumptions of chi-square, very enthusiastic and enthusiastic categories were combined, dissatisfied and very dissatisfied were combined, and neutral responses were distributed evenly between the resulting two categories.

the supposedly relatively neutral subjects of administration and location of the clinic (Table 3). They were asked to indicate positive, neutral or negative feelings about these items on a five-point scale. Significantly positive reactions were reported only regarding the treating doctor ($p < .02$). It is noteworthy that no patient indicated awareness of role-playing by the treating doctor. Reactions were significantly negative concerning change of doctors ($p < .01$) and screen ($p < .01$). There were relatively neutral reactions to administrative procedures, location of the clinic and filling out forms, with responses to the tape recorder showing a slight tendency to be negative.

Patients were also asked to give opinions as to the purposes for using forms, tape recorder and screen. Their responses were grouped in the following three categories: primarily beneficial to the doctor, primarily helpful to the patient, and beneficial to both doctor and patient (Table 4). Of the 45 patients who were able to give clear explanations for the use of forms, 31 (43 per cent) felt they were for study by the treating doctor; nine (13 per cent) thought they were specifically to help the patient understand himself or express how he felt; and five (seven per cent) thought the forms were for both the doctor's and patient's use and benefit. With regard to the real purpose of the forms, to evaluate change in distress from visit to visit, only 11 patients (15 per cent) indicated that the forms might have to do with evaluation of feelings or symptoms, and only eight individuals (11 per cent) noted that filling out forms on more than one occasion could be for the purpose of evaluating change.

The use of a tape recorder was the only procedure for which an explanation was given to the patients; they were told that it was being used so that the doctor could be relieved of taking notes. With this background, 43 patients (60 per cent) said the tape recorder was primarily for personal use by the doctor, with only two patients

TABLE 4

Patient Ideas as to Who Benefits from Research Procedures (N = 72)

Procedure	Patients' Opinions			
	Dr. Benefits	Patient + Dr. Benefit	Patient Benefits	Unclear or No Response
Forms	31	5	9	27
Tape recorder	43	7	2	20
Screen	32	0	0	40

(three per cent) of the opinion that the tape recorder was primarily for their own benefit and seven (ten per cent) feeling the recorder was useful both to them and to the doctor. Of the remaining 20 patients, five denied awareness of the tape recorder and 15 could not suggest any explanation for its presence. There was only one complaint relating the recorder to possible breach of confidentiality and none specifically relating the forms or the screen to confidentiality.

When questioned about the possible presence of a one-way screen, 39 of the 72 patients (54 per cent) acknowledged that they had recognized it. It is interesting to note that although the mirror was quite large and its nature obvious, only two patients (three per cent) had spontaneously indicated to the doctor during a treatment interview that they had noticed it. None of the patients felt that the screen was for a purpose directly helpful to the patient, while 32 individuals (82 per cent of 39 patients) felt it was useful to the doctor for observation of the patient and/or his behavior; 14 of these patients specifically stated that it was for observation of the patient when he was *alone* in the room. Seven patients who were aware of the screen gave no explanation for its use.

PRINCIPAL COMPLAINT ABOUT THE RESEARCH PROGRAM.

Each patient was asked to state his overall chief complaint about the program (Table 5). Of the 72 patients, 28 individuals (39 per

TABLE 5
Principal Complaint about the Research Program

Complaint	*N*
Doctor	
Wanted more time to talk with doctor	14
Wanted more advice from doctor	5
Disliked change of doctors	9
Subtotal	28
Improvement	
Improvement nil or inadequate	11
Drug treatment no good	4
Wrong drug	1
Evaluation only	2
Subtotal	18
Miscellaneous	7
No complaints	19
Total	72

cent) had chief complaints which specifically involved the treating doctor: 14 patients wanted more time to talk with the doctor; five wanted more advice from him; and nine stated that they were chiefly bothered by the change of doctors. Eighteen patients (25 per cent) complained about degree of improvement: 11 stated that improvement was either nil or inadequate; four individuals further added that they wanted treatment other than drugs; one patient wanted a different drug; and two patients complained that they had only been evaluated so far. There were seven (ten per cent) other miscellaneous complaints. Nineteen patients (26 per cent) stated that they had no complaints.

When asked to state overall chief complaint, the patients did not complain about specific research procedures, research in general, confidentiality, or the possibility placebos were administered. Rather, the responses indicated that the patients were primarily concerned with the doctor in terms of time, communication to and from him and doctor change, and with degree of improvement, rather than with other research procedures and paraphernalia.

DISCUSSION

Results of the study were unexpected. The purposes of the study were to determine the degree to which patients were bothered by research procedures and by the idea and experience of being research subjects. We were surprised to learn that the large majority of patients did not even recognize the program involved research and that, instead of being greatly distressed about research procedures, their concerns appeared to be primarily about their relationship with the treating doctor and about issues involving degree of improvement. In general, it appears that special research procedures may not have been of much greater importance to these patients than other peripheral issues such as administrative procedures, physical comfort and the like in any psychotherapeutic program.

The most important factors involved in the patients' perceptions of and reactions to research and to research procedures appear to be prior expectations of help, along with lack of knowledge enabling them to distinguish research from treatment. The great majority of these patients, who were of low socioeconomic status and who had not been followed in intensive psychotherapy in the past, were characterized by lack of sophistication with regard to any specific pattern to expect in a psychotherapeutic situation yet with overall expectation of either "a complete cure" or to be "a good deal better." They tended to assume that anything which was happening was part of routine treatment in a low-cost psychiatric clinic. Furthermore, some patients were even able to "use" research procedures as treatment. Thus, 14 patients felt that checking out forms was helpful to them in gaining an understanding of their symptomatology; nine patients felt that the tape recorder was helpful and, surprisingly, two patients actually indicated a positive reaction to the use of the one-way screen. From the "realistic" point of view of the research staff, the one-week program appeared to be quite obviously "research," some aspects of which could be seen as at the "subjects'" expense; the "patients" on the other hand, with their deep-set expectation of "therapy," that is, of help, perceived

the program as individually focused on their need for help. Similarly, E. Meyer[3] found that, although several patients with Myasthenia gravis were specifically informed they were research subjects in a controlled study, they later referred to the research as their "treatment."

The question may be raised as to how the formulation on the part of the research social worker affected the responses of the patients. Despite precautions, subjects of low socioeconomic status may have perceived this as an investigation with possible unfavorable implications for their doctors. As a result of their positive feelings toward the doctors, they may have tended to give a more optimistic picture of their reactions than they would have under different demand characteristics (6). These considerations may explain such surprising statements protective of the doctor as that by one patient that permission was asked and given to do research on her.

The results of this study suggest a number of recommendations with regard to clinical research. First, the data strongly suggest a patient will be surprisingly accepting of bothersome research procedures if he can count on a continuing relationship with an expert he trusts. In setting up a research program, one need not be so concerned with patient reaction to research paraphernalia as to take careful consideration of duration and intensity of "therapist" or "researcher" contact with the "patient" or "subject."

Second, the importance of being honest and straightforward with patients should be considered in setting up research procedures. We tend to become inappropriately secretive because of our own apprehensions that the patient might discern the experimental nature of procedures and/or might be able to infer that our primary purposes may be research findings rather than immediate alleviation of distress. For example, patients were not informed of the use of a one-way screen; although more than 50 per cent of the patients observed the screen, they did not deduce that they were subjects of a research project. However, they did tend to see the screen as a secretive tool for learning about patients when off guard. It is quite possible that they would have reacted less negatively to this item if the research team had been explicit about it, as was the case with the tape recorder. Along this line, perhaps too often patients are studied with rigid methods designed for nonhuman subjects, without taking advantage of the special intellectual capabilities that make them qualified in many studies to be included to some extent as members of the research team. This concept is supported by the present study as well as by a study of placebo response by Park and Covi (7) in which patients accepted treatment and responded with a wealth of subjective material after having been forewarned they were to be given placebo.

Third, the naive acceptance by patients of even obvious research procedures as treatment, along with suggestions in this and other studies that keeping patients unaware of the nature of the research can sometimes by inhibitory rather than helpful to research goals, lends added support to Beecher's (1) conclusion that we must be exceedingly careful not to take advantage of patients' trust and that this concern need not necessarily interfere with medical progress. Furthermore, the obtaining of the patient's written consent does not remove from the investigator primary moral responsibility for the welfare of the patient.

Finally, these data recommend a critical attitude toward preconceived notions. The preconceived idea in this study was that patients would be distressed by research procedures. Another hidden preconceived notion later became evident: patients would know what research might be. It is important to test some of these widely accepted biases, often such basic assumptions that they are not verbalized and are thus difficult to question and test objectively. This difficulty

[3] Personal communication, 1965.

may explain the lack of studies in the literature on certain topics which are considered "obvious."

SUMMARY

This is a study of reactions to research as reported by 72 neurotic outpatients subjested to multiple research procedures in an ongoing drug study, including double-blind drug prescription, evaluations by several interviewers, role-playing by treating doctors, unexpected change of treating doctor after two interviews, completion of multiple forms, and observation and recording of interviews.

It was found that 55 of the 72 patients (76 per cent) had no notion whatsoever that research goals were involved. Rather, they perceived the procedures as diagnostic, teaching and treatment.

Patients' primary concerns appeared to be with the treating doctor, the change of doctors and degree of improvement, rather than with research procedures. In clinical research, a focal issue for the patient remains the doctor-patient relationship. Therefore, careful consideration should be given to this factor in setting up even a brief, controlled psychopharmacological study. Elevating a patient from the role of experimental subject to that of evaluator of aspects of a research project can help avoid ethical risks and at the same time can result in valuable information which might not have been available through multitudes of formal "tests." The data also indicate the importance of examining afresh some deeply and widely held preconceived biases concerning patient perceptions in clinical research settings.

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