Problems of Long-term Informed Consent

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This study addresses problems arising with informed consent for long-term maintenance pharmacotherapy. Obtaining patient consent to neuroleptic treatment, with the risk of tardive dyskinesia, has raised questions about long-term recall and the competence of psychiatric patients as a special population.

The subjects were 32 adult outpatients, 16 were followed in the psychiatric clinic and 16 in the rheumatology, pulmonary, and neurology clinics. Structured interviews with these patients dealt with knowledge about relevant short-term and long-term medication side effects. Interview results were used to compare psychiatric and medical groups with respect to overall levels of comprehension. Two results were striking.

1. There was a remarkable similarity in the degree of comprehension between psychiatric and medical outpatient groups; this suggests that psychiatric patients need not be considered any less competent than medical outpatients in assimilating necessary medication information.

2. Patients in both groups were knowledgeable about short-term side effects, usually as a consequence of personal experience with them. However, their knowledge was consistently inadequate with regard to potential long-term side effects from their maintenance medication.

Current informed consent doctrine may presume a degree of recall and comprehension beyond the capabilities of most patients. The development of an appropriate doctor-patient relationship that reconciles the need for consent with patient limitations remains an important challenge for clinicians.

The responsibility for obtaining informed consent regarding tardive dyskinesia is perceived as a considerable burden to many clinicians grappling with other practical and potential difficulties attendant to neuroleptic use. Compliance problems, attempts to maintain a constructive relationship with often-difficult patients, and the physician's own concerns about preventing or managing tardive dyskinesia (TD) have already made the treatment of chronic psychotic states a complex task. And yet developing the patients' participation in his own treatment is recognized, pragmatically, as one of the most decisive factors in treatment. Ethically, Redlich and Mollica[1] state that "informed consent is the basis of all psychiatric intervention and that without it no psychiatric intervention is justified."

With so many unknowns surrounding TD—risk factors, pathophysiology, and treatment—one certainty is that the risk/benefit ratio for long-term neuroleptic treatment has been significantly

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altered. This change in the safety factor is frequently cited[2–4] as the reason for recommendations that TD information be a specific part of consent to neuroleptic treatment.

Exactly how consent should be obtained is not firmly established. The degree to which written documentation should be used varies widely in separate recommendations, as does the issue of when, during the course of treatment, specific TD risk consent (independent of basic consent for the antipsychotic agent) should be obtained. Table 1 summarizes the frequently cited sources of TD risk consent recommendations.

Guidelines are more uniform as to what information should be provided to the patient. Most authors[3,5,6] appear to be in general agreement that patients should be told the reasons neuroleptics are being prescribed; what alternative treatments might be available; how TD presents, how it relates to long-term medication use; the limitations of treatment, with the possibility of its irreversibility; what actions will be taken to prevent it. Finally, some concept of risk/benefit thinking—weighing benefits of treatment, consequences of discontinuing treatment, side effects, etc.—is generally suggested as part of the explanation.

Table 1
Consent Recommendations Regarding TD

Author	Medium	When
Ayd (1977)[2]		By 3 months
Sovner *et al.* (1978)[3]	Written	12 months
Deveaugh-Geiss (1979)[5]	Oral Written	Initially 4–6 weeks
Jeste and Wyatt (1980)[6]	Oral and progress note	3 months
APA Task Force (1980)[17]	Oral and progress note	
Gelenberg (1980)[4]	Oral and progress note	Initially
Stone (1981)[18]	Tape-record and written	

These guidelines, and recommendations and regulations for formal consent in general, have led to cynicism regarding patient's capabilities for recall and comprehension of relevent information. Poor recall after short-term surgical procedures (Robinson and Merav[7] found recall of only 42 percent of taped information four to six months after surgical consent) has been documented, with similar results being reported in many subsequent surveys and recall studies in a variety of clinical settings.[8,9] Some label the concept of informed consent a myth.[10,11] Although schemas for improving patient recall have been published,[12,13] Lidz *et al.*[14] in a review of the literature (p. 27) found the data to be sparse and the evidence conflicting.

Retention of information during long-term treatments appears to be more problematic. While advocates of formal consent procedures could support a patient's "right to forget" side effects, risks, etc., once a short-term procedure is over, the goal in long-term pharmacotherapies would be a continued awareness of treatment issues by the patients (monitored and reinforced by periodic discussions) for as long as they take their medications. A more recent study[14] (pp. 189, 276, 320) suggests that long-term risks (like TD) remain significantly underdiscussed in inpatient and outpatient settings.

The goal of the present study was to identify the amount of information current outpatient groups at a university medical center had about their treatment. Particular focus was placed on issues of long-term effects (like TD) to answer two questions. First, does general knowledge about medication include long-term side effect information, or will the findings of gaps in long-term information be replicated? Second, recalling the work of Soskis[15] in showing psychiatric patients to be generally as informed as medical patients, how does a psychiatric outpatient group compare with a medical group in informed participation in long-term pharmacotherapy?

Methods

Thirty-two adult outpatients at the Temple University Health Sciences Center were seen in single, 5 to 10 minute, structured one-to-one interviews by me to explore their basic levels of knowledge of their medications. Patients were asked to provide demographic information including age, level of education, and duration of illness after formal diagnosis and identity of medications were obtained from the chart. The following questionnaire was then read to each patient:

1. What problems are you being treated for in the clinic?
2. How long have you attended the clinic?
3. What medications are you receiving? For how long? What dose?
4. How does the medication work to help you?
5. Does it have any side effects?
6. Are there any long-term side effects? This would be something that might happen after taking the medicine for several weeks or months.
7. How long will your doctor try to prevent the long-term side effect; treat the long-term effect?
8. Are you satisfied with the information about side effects that your doctor has given you?

All patients interviewed had received medication for at least three months and were on medication that had significant long-term risks. Sixteen psychiatric and medical patients were selected on the basis of these criteria, including all such patients presenting at their clinics on interviewing days. All were clinic, nonprivate patients and were interviewed in the offices in the psychiatry, rheumatology, pulmonary, and neurology clinics, just prior to their routine scheduled appointments. Sixteen were followed by psychiatry and were receiving neurolep-

Table 2
Medical Group: Short- and Long-term Risks

Medication	Short-term Risk	Long-term Risk
Phenytoin (N = 10)	Ataxia, slurred speech, interactions with alohol	*Gingival hypertrophy*, folate deficiency
Methysergide (N = 2)	Gastrointestinal (nausea and vomiting, cramping, diarrhea)	Behavior changes, weight gain, edema, *alopecia*, *retroperitoneal fibrosis*
Steroids (N = 4)	Peptic ulcer, mood changes	Steroid *diabetes*, Cushingoid syndrome, *osteoporosis*, *cataracts*

tic agents. The 16 medical patients and their medications are shown in Table 2. In psychiatry, 16 consecutive patients on neuroleptics attending medication clinic were interviewed. This service offers brief (15- to 20-minute) sessions for medication supervision of patients not receiving psychotherapy. The medical sample was obtained by 16 consecutive interviews in the neurology, pulmonary, and rheumatology clinics.

As shown in Table 2, all medical patients were receiving medications in which the early and late side effects correlate well with those of the neuroleptics. Possible long-term effects range from cosmetic impairment from Dilantin (comparable to TD in its cosmetic effects, when facial musculature is involved) to serious health risks with steroids and methysergide (Sansert) that can be compared with those more serious (and fortunately less common) TD effects, i.e., when gastrointestinal or respiratory muscles are involved.

Patient characteristics for both groups are shown in Table 3. No statistically significant differences were found between groups for age, education, or length of illness by chi-square of median splits ($\chi^2 = .03, .139, .125$, respectively). Chi-square for race and sex were likewise not significant ($\chi^2 = 3.28$ and $.126$, respectively).

Responses were evaluated on the basis of an ability to provide some, not necessarily all, correct information. For example, regarding the nature of illness, a correct response was scored for "I have hallucinations" as well as "schizophrenia" or "pulmonary fibrosis"; regarding side effects, some accurate description of one short- or long-term effect was required. No credit was given for a response that included incorrect information.

Results

The numbers of correct responses to the interview questions are summarized in Table 4; two findings were striking. First, both medical and psychiatric groups appear to have been comprised of fairly well-informed patients. Scores were quite high and quite similar, question by question, for naming medications, knowing the dose, having some insight as to illness, and providing a connection between medication and symptom relief. Knowledge of at least one short-term side effect was, again, impressive and similar across both groups. Although the questions regarding side effects were asked in an impersonal way (i.e., "Does the medicine have

Table 3
Patient Characteristics

Patients	Age	Race	Sex	Mean Education (years)	Length of Illness (median, years)
Psychiatry (N = 16)	39 (22–64)	5 white 11 black	8 male 8 female	12.25 (8–17)	5 (.25–20)
Medicine (N = 16)	38 (23–62)	1 white 15 black	7 male 9 female	11.6 (9–20)	7 (.25–40)

Table 4
Psychiatric Versus Medical Group—Patients Providing Correct Responses

	Psychiatric (N = 16)	Medical (N = 16)
Name	16	15
Dose	14	15
How medicine helps	15	14
Short-term effects	12	11
Long-term effects	3	1
Prevention	2	0
Total	62	56 ($\chi^2 = 2.85$ $p > .05$, NS)
Insight into illness	15	16
Satisfaction with information	13	12 ($\chi^2 = .183$ $p > .5$, NS)

any side effects?"), a large number—10 of 12 psychiatric and 8 of the 11 medical patients responding correctly—chose to personalize their response and were answering out of personal experience. This reaction, which has been noted elsewhere,[16] took such form as "it makes me restless (stiff, sleepy, gain weight, etc.)." The final high scores for satisfaction with their doctor's explanations were not surprising, given both groups' ability to intelligently discuss their treatments. As noted in Table 4, responses regarding medicines were not statistically significant between groups in a 2×6 table ($\chi^2 = 2.85$, $p > .05$). Degree of insight showed no significant difference by inspection.

The second striking finding was the scoring for long-term side effects and for prevention/management issues; again similar, but here quite poor, with four of 32 subjects able to detail any long-term effects and 2 knowledgeable about prevention issues. (No correlation existed between responses to these two questions.) Again, the one correct response in the medical group reflected a patient's personal experience—a woman on Dilantin who indicated a friend, also on Dilantin, had developed some gingival hypertrophy.

Discussion

This study is limited by the fact that no specific information was available as to how much, if any, information was presented by the various physicians involved. As each patient was treated in a clinic setting for a chronic illness, each had seen more than one physician. The data presented are only a survey of patient knowledge at a given time.

As a survey, the results appear to support the findings of Soskis[15] that psychiatric patients are as knowledgeable as medical patients. They likewise support the impression of Geller[8] that this level of knowledge is often inadequate.

The fact that the psychiatric patients were attending a medication clinic raises two issues: First, while this group would have a clinic experience quite similar to that of the medical patients (i.e., medication adjustment or change based on symptom and side effect changes), the primary focus on medication may have given these patients more knowledge about medication than is usual in psychiatric patients receiving traditional

therapy that includes medication. Whether such patients are, in fact, more knowledgeable than other psychiatric patients is a question that must be addressed in further comparative studies. Second, by utilizing those patients who might be best able to answer medication questions, the discrepancy in knowledge about short- versus long-term effects may have been maximized. We cannot be sure that other groups would display the knowledge of short-term effects shown by our patients. On the other hand, it would be unlikely that other populations would show a different relationship between knowledge of short- and long-term effects, i.e., little knowledge of short-term effects and extensive knowledge of long-term effects. Indeed, these results were quite consistent with the findings of Lidz *et al.*[14] in their observations of inpatients and outpatients receiving neuroleptics.

Ensuring competent, truly informed consent, problematic in all treatment areas, appears to be particularly challenging with chronic treatments. This study supports the impression that patients are learning best from experience—the discomfort of an unpleasant side effect or the repeated medication discussions and prescriptions. The prospect for education about TD by either of these modalities—experiencing the discomfort or raising the spectre of an irreversible movement disorder at every visit—is at variance with clinical goals and realities.

The complex interactions between the doctor-patient relationships and informed consent doctrine are beyond the scope of this article. A return to a more fiduciary or paternalistic relationship in psychiatry cannot, of course, be expected or desired. It can be concluded that the difficulties in developing informed patients challenges us to be informed of the issues involved. The identification of those patients for whom alternatives to long-term neuroleptic treatment exist is clearly more important than ever, both to reduce the incidence of TD for them and to justify its risk in those who require them.

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