

Tardive Dyskinesia and Informed Consent: Myths and Realities

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Tardive dyskinesia is a potentially irreversible neurologic syndrome secondary to long-term neuroleptic drug use. It is characterized by slow, rhythmical, automatic stereotyped movements particularly in the buccolingual masticatory area, extremities, and trunk muscles in patients who have received neuroleptic drugs for at least three months. Unlike other neurologic side effects to neuroleptic drugs, tardive dyskinesia is resistant to treatment with anticholinergic drugs. There is no generally effective treatment of tardive dyskinesia.¹

The prevalence of tardive dyskinesia varies widely in different studies but most likely is in the range of 10 to 20 percent of patients on maintenance neuroleptics. Of the total 10 to 20 percent of patients with tardive dyskinesia, less than 10 percent of them have severe abnormal movements with a fourth to a third of patients with the disorder showing moderately severe movements. While early studies suggested as many as 60 percent of cases of tardive dyskinesia were irreversible, more recent studies are more optimistic that frequent reversibility may be possible with early detection and discontinuation or reduction of neuroleptic medication. Confounding the detection and management of tardive dyskinesia is the fact that the very cause of the syndrome, neuroleptic drugs, also serves to mask it. Thus tardive dyskinesia is frequently not detected until the drugs are stopped or the dosage reduced. It is not clear what the relationship is between so-called withdrawal emergent dyskinesias and tardive dyskinesia that appears on a steady dose of neuroleptic.¹

However, it is clear that tardive dyskinesia is today a major public health issue in psychiatry.² We are talking about a sometimes irreversible, sometimes severe, sometimes grotesque neurologic disorder induced by long-term exposure to what is currently the best and, to many minds, the only effective treatment for schizophrenia.

It is no small wonder then that tardive dyskinesia has aroused a great deal of concern in the psychiatric community. Some have attempted to deny its existence, its irreversibility or its etiologic connection to neuroleptic

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drugs.^{3,4} Others have been alarmists to the other extreme, condemning the use of the drugs that have allowed for a productive life outside of institutions for large numbers of the chronically ill.

Amidst this clamor another important issue has been raised: patients must be informed of the risks of maintenance neuroleptic therapy, and patients who manifest signs of tardive dyskinesia must be informed of their condition. For example, Ayd has argued that patients on neuroleptics should be examined every three months for early signs of tardive dyskinesia and that unless physicians have obtained informed consent for the appropriate use of neuroleptics, physicians are at risk for negligence and malpractice suits.⁵

If this is the case, how can informed consent be best obtained from patients? Some investigators feel that written informed consent is mandatory for optimal protection of both patient and physician.^{6,7} Sovner has developed two informed consent forms, one for use with patients on continued maintenance neuroleptic therapy for longer than one year and another for patients who show signs of tardive dyskinesia and who clinically require further maintenance neuroleptics. Sovner believes these forms are appropriate for routine clinical use and reports their use has no negative effects on treatment compliance or the doctor patient relationship.⁶

The use of signed informed consent forms has been widely questioned, however.⁸ Whether the use of consent forms is without negative impact remains a question for empirical testing. There also is much reason to question the meaningfulness of a signed consent form both from the perspective of legal protection and in terms of how much knowledge actually may have been transferred from the written page to the patient.^{9,10,11}

The APA Task Force Report on Tardive Dyskinesia argues against the obtaining of routine written informed consent for the use of maintenance neuroleptics, citing a number of possible negative effects. The report argues that there are "differences between established pharmacologic treatments and invasive surgical, diagnostic, or experimental procedures" for which written consent forms are frequently used. Furthermore, the Task Force argues, written consent introduces a "potentially detrimental adversary quality to the physician-patient relationship. Finally, it is a precedent-setting step to routinely require written consent to institute an accepted non-experimental medicinal therapy." As an alternative to written informed consent the Task Force recommends documentation of a careful review of the indications and risks of prolonged neuroleptic treatment with the patient or family.¹

Unfortunately there are no more data to support the utility and safety of a meaningful oral informed review of risk/benefit ratios with patients than there are data to support the use of written consent forms in patients with or at risk for tardive dyskinesia.

The Task Force recommendations can be understood as an effort to establish as routine practice a procedure viewed by most clinicians as "least

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restrictive." Sovner's recommendations can be seen as an attempt to provide legal protection for those psychiatrists treating the sickest of patients and fearful of being sued for administering the only treatment they believe to be effective. Since there are no hard data supporting the safety and efficacy of either approach, the unspoken fear is that a court may someday hand down a decision mandating one or another informed consent procedure that clinicians may find hard to live with.

With this background in mind, we have attempted to study the issue of informed consent and tardive dyskinesia in our ambulatory clinic for patients with chronic schizophrenia. The purpose of this article is to examine the extraordinary difficulties one faces in trying to do clinical research in an area fraught with emotion. We will not describe our results systematically, since our study is ongoing, but instead will try to explore the apparent myths and realities in the area of informed consent and tardive dyskinesia.

The Study

We are attempting to study the impact of two different informed consent procedures on patients with signs of tardive dyskinesia who are being maintained on neuroleptic drugs in the Cognitive Disorders Clinic at Western Psychiatric Institute and Clinic. While all patients at risk for tardive dyskinesia should ultimately provide informed consent for their treatment, we chose to study those patients manifesting abnormal movements. This group was chosen for our pilot study because of the belief that patients with tardive dyskinesia most urgently need to provide informed consent to drug treatment. Schizophrenic patients with tardive dyskinesia need to be aware that they are taking risks whether they maintain their medication dose, increase, decrease, or stop their medication.

Patients were selected for the study based on their having been identified by their primary therapist as having abnormal movements. The primary therapists included three psychiatrists and five psychiatric nurse clinicians. All such patients' charts were then carefully reviewed to assess the onset of abnormal movements and to rule out the possibility of having movement disorders occurring on a basis other than tardive dyskinesia. All patients suspected of manifesting tardive dyskinesia were then evaluated by two raters trained in the use of the Abnormal Involuntary Movement Scale (AIMS).¹² AIMS exams were scored independently by the two raters who observed the exam simultaneously. All patients scoring a mean of 2.5 or above on any one of the seven rated body areas, and whose movements could not be explained in other ways, were considered to have tardive dyskinesia.

After signing a consent form to participate in our study, the study patients were randomly divided into two groups. The *formal* group is presented with a written consent form, modified from Sovner's in an attempt to provide the clearest and most accurate information possible (Figure 1). The *informal* group receives no written forms but participates in a

Figure 1. Consent for: Patient with Tardive Dyskinesia

Dr./Nurse _____ has explained to me that I have/had a mental illness manifested by the following symptoms:

To treat my mental illness, the doctor/nurse recommends the continued treatment with _____, a neuroleptic drug. I have been informed that in the doctor's/nurse's opinion, no alternative type of drug therapy or any other form of therapy would be equally effective in improving/preventing a relapse of my mental illness. Studies of large numbers of other patients with my kind of illness have shown that there is about a 60 percent chance of relapse within one year if I stop my medicine. The chance of relapse if I continue on medicine is about 20 percent. In other words, the risk of relapsing is about three times as great if I stop my medicine.

The doctor/nurse has explained to me that I have abnormal movements of my mouth/tongue/face/body/extremities. I understand that these movements may have been caused by treatment with neuroleptic drugs which I have taken/am currently taking. I have been informed that little is known about the cause, course or treatment of these movements, although they may have some relationship to age and sex. Studies show that these movements occur to some degree in 10-20% of patients who take neuroleptic drugs over a year; in a small percentage of cases (about 3%) these movements were considered severe; although little is known about how long these movements may last, some studies suggest that many cases may be irreversible. However, more recent studies indicate that the movements do disappear if discovered early and if neuroleptic drugs are discontinued or reduced in dosage; there is no way to predict if my movements will change in severity or if new movements will appear if I remain on neuroleptics.

All my questions pertaining to my mental illness, its treatment, and my abnormal movements have been answered.

CROSS OUT A. OR B.

- A. REQUEST FOR TREATMENT: I hereby give my consent to start/continue treatment with _____, a neuroleptic drug, because I believe my mental illness represents a greater danger to my health and well being than do the abnormal movements which I have. I understand that periodic examinations will be conducted to determine whether or not the abnormal movements have become more severe, but in the absence of a drug-free trial, such an examination may not reveal whether the movements have worsened.
- B. REQUEST FOR TERMINATION OF DRUG THERAPY: I hereby request not to start/to discontinue neuroleptic drug treatment. I understand that the failure to take this type of drug therapy may lead to a relapse of my mental illness in which I might become incapacitated and need to be hospitalized.

I understand that I can at any time change my decision and request that neuroleptic drug therapy be discontinued/initiated. I also understand that my decision will not affect my future treatment in any way.

Signed: _____ Date: _____

I have examined the above individual and in my opinion this individual is capable of giving informed consent.

Signed: _____ Date: _____

discussion with the therapist aimed at covering the same material as in the written consent form.

Prior to being told about tardive dyskinesia, patients first responded to a questionnaire (Figure 2) assessing their baseline level of knowledge about their illness, its treatment, side effects in general and tardive dyskinesia in particular. Therapists then review the consent form with one group and discuss information orally with the second group. Following this, a decision is reached through discussion between the therapist and the patient to continue, alter, or stop drug therapy. The questionnaire about patient

Figure 2. Questionnaire

Patients on Neuroleptic Medication with Tardive Dyskinesia

1. Are you taking medication? _____ Yes _____ No
 2. Can you name your medication? _____
 3. Can you tell what dose of medication you are taking? _____
 4. Why are you given this medicine? _____
 5. What type of illness do you have? _____
 6. How does this medicine work? _____
 7. Do you take your medication regularly? _____
(Estimate Patient's Compliance)
 8. What risks would there be if you were to stop your medicine? _____
 9. What side effects do you notice with your medicine? _____
 10. Have you noticed that you have abnormal movements of your face, tongue, mouth or other parts of your body? _____ Yes _____ No
 11. Do you know what causes these abnormal movements? _____
 12. Do you know that there is a name for this kind of movement disorder? _____ Yes _____ No
 13. Do these movements bother you in any way? _____
 14. Do these movements bother anybody else? _____
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knowledge of tardive dyskinesia is repeated immediately following the procedure and again two months later.

The informed consent procedures are observed and recorded by one of the investigators. Selected cases are recorded on videotape. The patients are followed to observe apparent changes in clinician/patient relationship, missed appointments, discontinuation or reduction in medication against medical advice, and recurrence of psychotic symptoms and rehospitalization.

A control group was chosen by taking the next patient seen in the clinic following the presentation of the informed consent material to a study subject. The course of the control patients was followed looking at the same parameters as above.

Myths and Realities

Our preliminary results allow us to explore a number of apparent myths and realities surrounding the issue of informed consent and tardive dys-

kinesia. As we shall see, these myths and realities make the study of this important area particularly difficult.

Myth number 1: "Real" tardive dyskinesia rarely exists. While by now this would seem a dead issue, in preparing our study we learned this myth is very much alive. As noted above, we decided the study population would be those patients already identified as having tardive dyskinesia. Yet, members of our institute's research committee raised grave doubts that we would be able to find a reasonable number of patients in the outpatient schizophrenia clinic with "real" tardive dyskinesia.

While the presence of abnormal movements was not denied, it was suggested that most of them did not represent *true* tardive dyskinesia. Within this category of "not really tardive dyskinesia" were included mild abnormal movements of uncertain significance and abnormal movements that may be quite marked but not clearly caused by neuroleptics. This latter category may include stereotyped movements of schizophrenia, senility, chorea, torsion dystonia, and Huntington's Disease.

Reality number 1: Tardive dyskinesia will be found if carefully looked for in a population exposed chronically to neuroleptic drugs. Our non-systematic search revealed 46 patients who met criteria for tardive dyskinesia as defined by Smith and associates.¹³ Only 2 of the 46 diagnoses of tardive dyskinesia were at all in question following a careful review of each case. In addition 26 more patients with mild to minimal abnormal movements were identified among an outpatient population of about 500 patients. Because AIMS exams were not performed on all patients, the actual prevalence of tardive dyskinesia in the clinic is probably well within the 10 to 20 percent range suggested by large literature reviews.¹

Once we convinced our research committee that tardive dyskinesia is a significant problem, we ran headlong into a second roadblock constructed of two myths. Nearly everyone agrees in principle with the basic assumption that patients need to be meaningfully informed about their condition, available treatment, and benefits and risks of such treatment and that patients should then participate with the clinician in making decisions about their continued treatment based on the preceding information. This study (based on those principles) was proposing to investigate the impact of two methods of imparting such information in arriving at such informed decisions with patients: a formal written procedure versus an informal discussion.

Myth numbers 2 and 3: If patients with tardive dyskinesia are informed of the risks of their medicine than either (a) large numbers of patients will stop their medicines, drop out of treatment, and consequently decompensate,⁷ or (b) patients previously unaware of the cause of their movements will sue.

The proposed study was thus criticized as attempting to put large numbers of seriously ill patients at risk for certain decompensation. It was accordingly implied that what we were proposing was unethical.

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Once the study was under way the issue subsequently took the form of concern by our primary therapists that participation could be dangerous for their patients. Therapists withheld three patients from the study who were seen as resistant patients who would use the information as an excuse for dropping out of treatment. Other patients may not have been referred to the study for the same reason, the therapist failing to bring the patients' movement disorders to the investigators' attention.

Reality number 2: To date there has not been an increased number of decompensations in the study population. Of 14 patients who have gone through the full informed consent procedure to date, two have been hospitalized over the last year with relapses apparently secondary to stopping their medications. Although these two patients agreed to continue on medication at the time of the informed consent procedure, both of them discontinued their neuroleptics on their own a short time later. One patient clearly made the decision to discontinue her medication at the time of the study procedure, although she kept this a secret from her therapist at the time. She previously had considered medication discontinuation because she had been doing so well, and the informed consent procedure apparently gave her the impetus to give it a try. After recovery from her relapse she subsequently insisted that she would have stopped her medicine even if she had never been involved in the informed consent procedure.

The second patient's non-compliance and relapse were not judged to be related to the informed consent procedure. This informing procedure appeared to have little impact on the patient as she did not understand the relationship between her illness, her movements, and her medication.

A third patient stopped his medications (with the agreement of the therapist) and has remained out of the hospital. All 14 patients remain active in the clinic.

By contrast, of 14 control patients, 5 were rehospitalized with relapses and two others were very erratic in their attendance at the clinic over the year. Most studies show that 30 to 40 percent of schizophrenic patients relapse over the course of a year.¹⁴

Therefore the reality may be that patients who are involved in a careful, meaningful discussion about their illness, treatment, and side effects may be more compliant and less likely to relapse. At this point no claims of causality may be made in this regard. But enough data does exist to disclaim the myth.

Reality number 3: You may get sued. Fear of litigation in the area of tardive dyskinesia is enormous and realistic. The notion exists that since many patients do not recognize their abnormal movements, it's best not to call the tardive dyskinesia to their attention. A similar argument is made against periodic drug withdrawal or dose reductions to improve early detection of tardive dyskinesia. It is feared that the physician who tells the patient of his tardive dyskinesia may be the physician to get sued. This "defensive medicine" may lead to poor practice such as not discussing patient's movements with them and not attempting periodic dose reductions.

Paradoxically, it is argued that poor practice may protect against malpractice suits.

The clinic had never been sued prior to the onset of our informed consent study. But the study did lead to a law suit. A 37-year-old man with a recent onset of rather marked tardive dyskinesia was recruited to the study. Prior to the information session he denied repeatedly any awareness of his abnormal mouth or arm movements. After a video-taped discussion with the patient about his movements, he noted he was quite worried about learning of the potential irreversibility and uncertain course of these movements. He elected to stop his medication against medical advice. A week later he mentioned reading about a large settlement received by a patient in Iowa with tardive dyskinesia.¹⁵ Within two weeks he felt anxious and requested resumption of low-dose neuroleptics. At that same time he announced to his therapist that he had consulted a lawyer who said he could sue for malpractice. Several months later the hospital was notified by his attorney that a suit against the institute was intended. Despite his intention to sue, the patient remained active in treatment, insisted he needed the medication, and was again undisturbed by his abnormal movements. Seven months after the informed consent procedure the patient announced he was dropping his law suit.

Thus, patients with tardive dyskinesia may sue if made to understand their condition, but maintaining a good relationship with one's patient is probably the best protection against a successful law suit. (At least that myth has not failed us yet.¹⁶)

Once the idea that obtaining informed consent may be dangerous to self or others (that is, psychiatrist or patients) is debunked, one arrives at the next problem, which we find much tougher to dispel.

Myth number 4: "You can inform schizophrenic patients all you want, they are still not going to understand what you are telling them . . . so how can you expect them to make a really informed decision?" As indicated above, this is a thorny issue. There is abundant literature to support the idea that patients in a medical or surgical setting often do not understand material they sign in routine informed consent procedures.^{9,10,11} There is ample reason to suspect schizophrenic patients will do no better than the medically ill, and some would argue that a priori they will do worse on the basis of their illness.^{7,17,18}

Yet the issue of competence is far from clear cut. The large majority of our schizophrenic population are presumed competent and act accordingly in their day-to-day affairs. In the group of 46 patients eligible for our study on the basis of their tardive dyskinesia, none had been adjudicated formally as incompetent. One patient was excluded formally from the study on the presumption of incompetence based on a profound Korsakoff's dementia and the lack of a responsible third party. Two other patients with dementia were not recruited to the study by the treating clinician who did not wish to involve them. Of the 14 patients so far actively involved in our study, none

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have been judged to have dementia and all are presumed to be competent. Yet how they came to make their decisions to continue or stop treatment is highly questionable.

Reality number 4: Most of our patients did not absorb the information we believed was most relevant for making an informed decision about their treatment. We tested our patients' knowledge of their medication, illness, and side effects immediately before, immediately after, and several months after the informed consent procedure. Prior to the informing procedures all patients knew they were taking medication, and most could name the medication, while only about half could state the dose they were taking. Prior to informing, few patients could adequately describe the nature of their illness (most could say they suffered from nerves or anxiety), and only half understood the risks of relapse if they stopped their meds. While half were aware of abnormal movements of some sort, only one of the 14 related the cause of the movements to his medication.

Striking is the lack of change in knowledge following both the formal written and informal verbal imparting of information. Patients typically picked up about three pieces of new information after being informed, one of which was forgotten by the time of requestioning several months later. After being informed, patients did know more about drug name and dose and about the name for their abnormal movement disorders. However, only 3 of the 13 patients, despite having been informed, learned that their movement disorder was probably caused by their neuroleptic medication.

Patients tried hard, and several learned to say "tardive dyskinesia" (one even learned to repeat the term to his attorney). But most decisions to continue or stop medications seemed affectively based rather than logically thought out. In fact many patients indicated before the informing procedure started that they could never stop their medication and pleaded to be allowed to stay on it. Interestingly, the two who stopped their medication against medical advice did so in a similar fashion. Each denied a direct connection between the informing and their drug discontinuation in the same way as each denied a connection between taking their medication and staying well.

Myth number 5: Written informed consent is the most effective way to insure and to document that the patient understands what you tell him or her and agrees with your treatment recommendations. As investigators we are prejudiced against consent forms. Five patients eligible for our study refused to sign a form consenting to participate in the study (that is, patients refused to sign a form allowing us to study informed consent forms with them). One of these patients became delusional about the consent form although she was willing to be involved with the study if she was not forced to sign any forms.

Therapists involved in the study also were uncomfortable with consent forms, especially the forms about tardive dyskinesia. Two approaches to handling the therapists' discomfort with the forms emerged. Some

therapists either read the forms aloud or handed the forms to the patient to read. The patients rarely asked more than a single question, and it was difficult to assess how much they really understood the information in the form. The second therapist approach to informing was to pretend the form was not there, to paraphrase in simpler language the meaning of the form, then at the end, after the patient had reached a treatment decision, to ask the patient to sign the form. The patients in these few instances rarely read the consent form. So this procedure ended up being nearly identical to the informal discussion procedure.

Despite our therapists' discomfort with consent forms, they were surprisingly comfortable with verbally conveying pertinent information to the study patients. While the format varied (and consent forms were more tolerated than used as a tool), therapists made a valiant attempt to tell patients as clearly as possible the relevant information about schizophrenia, neuroleptic drugs, and tardive dyskinesia necessary for a "reasonable man" to make a decision about continued treatment. The information was presented, although not always in the context of the written form.

An interesting early finding in the study is that patients learned more from the informal than the formal procedure by about one item. While this is of uncertain significance, it does seem to dispel myth number 5.

Reality number 5: In our setting both patients and staff are uncomfortable with wordy, legalistic consent forms. Therapists seem to teach better and patients seem to learn better under a more informal procedure that may be just as meaningful from a legal point of view.*

Conclusions and Summary

As much as we all wish otherwise, tardive dyskinesia is a significant problem affecting 10 to 20 percent of patients maintained on neuroleptic drugs. In an ambulatory setting where the overwhelming majority of patients are legally competent, patients maintained on neuroleptics need to be informed of the risks as well as the benefits of such treatment. This is necessary not only for legal protection but also for ethical and clinical reasons.

Our experience trying to study two systematic approaches to obtaining the informed consent for treatment of patients with tardive dyskinesia suggests that such procedures can be conducted without being harmful to patients, therapists, or institutions. We have not seen patients stopping their medication en masse, decompensating at increased rates, or dropping out of treatment.

The impact of our study on clinic staff was more profound in many ways than on the patients we attempted to study. The staff was frightened to really sit down in a formal way and discuss an iatrogenic disorder with chronically ill patients. This has been handled in several ways. Therapists withheld patients with unstable clinical courses from the study on clinical grounds. It was argued, "How can you tell an extremely paranoid patient that his

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medicines are damaging his nervous system and making him twitch?" The entry of other patients into the study was delayed. The entire staff (*including the principal investigators*) was guilty of this procrastination. An interesting phenomena emerged from these procrastinations. Therapists began to talk more frequently to their patients about the relevance of tardive dyskinesia, and decisions about drug management were made by patients and staff *prior* to the patient's entry into the study. In some cases such decisions obviated their participation altogether. Paradoxically then (in order to avoid putting patients in the study), it is our impression that therapists began to tell more to their patients informally than they had previously. At the same time all persons in the clinic became more sensitive to early detection and intervention in new cases of tardive dyskinesia. The effect of such intervention was to keep patients out of the study. Such an unexpected result is clinically pleasing (even though it slowed down the research project).

An early concern by some therapists was that giving patients too much free choice was abrogating professional responsibility to advise patients as to what is best for them. It was important to clarify with the staff that obtaining informed consent is compatible with more than a simple description of the risks and benefits of treatment. The offering of a professional opinion is not incompatible with obtaining informed consent. As Ingelfinger noted, "a physician who merely spreads an array of vendibles in front of the patient and then says, 'Go ahead and choose, it's your life,' is guilty of shirking his duty, if not of malpractice."¹⁹ Giving a patient a part in treatment decisions does not free physicians from responsibility.

The one myth about informed consent and tardive dyskinesia, which (on the basis of preliminary data) seems a reality is that many schizophrenic patients do not understand, retain, and/or process the necessary information to make a "rational" decision about their treatment. The patients in general did not learn a great deal from a painstaking attempt to inform them. What they did learn was often steeped with confusion and colored by their mental state. While the study is too incomplete to make final conclusions, it is also our impression that patients do not learn very much from a formal procedure involving the reading and signing of a consent form.

It probably will turn out, as common sense would tell us, that the best way to obtain meaningfully informed consent is by *repeated* informal sharing of information within the context of a mutually trusting therapeutic relationship. Such relationships can be far more powerful in providing understanding than a signed consent form or documentation on a chart.

Instead of the perfunctory and meaningless signings of consent forms, the physician may consider the "education of the patient through the process of consent as a worthwhile therapeutic goal."²⁰

"If physicians listen to patients and spend time with them and their families, if they speak in a direct, honest, and forthright manner, in layman's terms, and if they avoid coercion of the building up of unrealistic expectations, they can scarcely fail to gain the patients' trust."²⁰

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