Psychiatry and the Law

The Need for Reinforced Consent with Continued Traditional Neuroleptic Treatment

Gary Chaimowitz, MB, ChB, FRCPC1, Graham D. Glancy, MB, ChB, FRCPsych2, Janice Blackburn, BA, LLB3

Abstract: In this paper, we discuss the effect of the increased availability of atypical antipsychotic medications on previously obtained informed consent for patients continuing on traditional antipsychotic medication. The availability of newer treatments with better side-effect profiles, especially the negligible risk of tardive dyskinesia, may place an onus on physicians to revisit the original informed consent. This entails providing accurate information about the possibilities that are opened up by these medications (and their risks and limitations). The issue is particularly important to patients who began taking traditional antipsychotic medication before the release of the newer atypical neuroleptics.

Résumé : Le besoin d’un nouveau consentement éclairé pour le traitement classique continu aux neuroleptiques
Dans cet article, nous discutons de l’effet de la disponibilité accrue des antipsychotiques atypiques sur le consentement éclairé obtenu antérieurement de patients qui continuent de prendre des antipsychotiques classiques. La disponibilité de nouveaux médicaments ayant de meilleurs profils d’effets secondaires, surtout le risque négligeable de dyskinésie tardive, peut imposer aux médecins la charge de revoir le consentement éclairé original.

Il s’ensuit de donner des renseignements exacts sur les possibilités qu’offrent ces médicaments (ainsi que leurs risques et limites). La question est particulièrement importante pour les patients qui ont commencé à prendre des antipsychotiques classiques avant l’apparition des nouveaux neuroleptiques atypiques.

Key Words: tardive dyskinesia, informed consent, atypical neuroleptics, traditional neuroleptics, medicolegal, medication side-effects

1Assistant Professor, Department of Psychiatry and Behavioural Neurosciences, McMaster University, Hamilton, Ontario.
2Assistant Clinical Professor, Department of Psychiatry and Behavioural Neurosciences, McMaster University, Hamilton, Ontario.
3Assistant Clinical Professor, Department of Psychiatry and Behavioural Neurosciences, McMaster University, Hamilton, Ontario.

Informed consent has become an explicit part of medical treatment. A review of 235 community mental health centres in the United States showed that 74 per cent had policies for informed consent for neuroleptics (1). This is predominantly the case when the treatment involves psychiatric medication, even though no greater onus exists at law. The perception that psychiatric medications are somehow “mind altering” and that they may be administered in a coercive environment contributes to the expectation of a high standard of informed consent in this domain. Capable patients have a right to receive information from their psychiatrists with respect to their illness, to risks and benefits of proposed treatment, and to treatment alternatives (as do the substitute decision-makers for incapable patients). Many jurisdictions have set up legal or paralegal procedures that deal with the mechanics of informed consent, determining the incapacity to decide about treatment and consequent substitute decision-making. The risk of tardive dyskinesia (TD) makes informed consent important in patients who receive traditional neuroleptics, particularly given its generally irreversible nature (2). Previously, some practitioners considered consent to be appropriate and informed even though it was obtained several weeks after the neuroleptics were administered (2,3). Studies of practice habits suggest less than complete disclosure about risks of TD (4,5).

The issue of informed consent in psychiatry has been examined and needs to be kept active, because many individuals who are receiving potentially hazardous yet helpful medication may be cognitively impaired and thus unlikely to fully comprehend the consent. Ironically, the medications with potentially harmful long-term effects may improve cognition enough to enable the provision of informed consent for their continued administration.

The Issue
TD is a serious and not-infrequent side-effect of traditional neuroleptics. The use of traditional neuroleptics has been widespread and covers many disorders, including schizophrenia, schizoaffective disorder, delusional disorder, mood disorders, as well as various other psychotic and nonpsychotic illnesses. The risk of TD has been estimated to range from 15 to 20 per cent in patients on
long-term or maintenance neuroleptics (6). Psychiatrists’
behaviour with respect to disclosure can reflect their diffi-
culty in dealing with this negative side-effect of an other-
wise helpful medication (7). Several basic practice issues
arise because of this connection; specifically, inappropriate
indications for neuroleptics, inadequate monitoring of
side-effects, error in diagnosis of TD and laxness, or even
misconduct, concerning the provision of informed
consent (8,9).

Studies of how patients on long-term neuroleptics com-
prehend the risks associated with their medication show
that they have less than full understanding (10,11). Some
of this lack of understanding stems from the transfer of
knowledge, possibly relating to lack of information that
was provided initially by the practitioner. Some of this,
however, may relate to the inability to comprehend or re-
tain information (12,13).

Acquiring information can be difficult for patients with
schizophrenia (14,15). Memory problems have been noted
in patients with TD (11). Further, it has been shown that
the informed consent in patients on maintenance dosages
of neuroleptic medication can be deficient with respect to
understanding long-term side-effects (13). Current in-
formed consent doctrine may presume a degree of recall
and of comprehension that is beyond most patients’ capa-
bility (16). Individuals with TD may acquire memory def-
cits subsequent to the disorder’s development, and to
some extent, these limitations may nullify previously ob-
tained informed consent. Consent as a process appears to
be more effective and satisfactory when taking place
within a therapeutic relationship (10). Kleinman has
shown that structuring the informed consent can lead to
increased knowledge and information retention (17).

Informed consent that concerns antipsychotic medication
and TD may be a topic of particular importance in foren-
sic hospitals. The autonomy of the individual’s function-
ing may, for example, be compromised by treatment that
offers hope of freedom from incarceration, thereby affect-
ing voluntariness—an essential component of informed
consent (18).

Psychiatrists can use American case law to support indi-
viduals who refuse psychotropic treatment, which is done
by encouraging the options of less intrusive therapy. In
Rennie v. Klein (19), a trial of lithium and antidepressant
was seen as less intrusive than a trial using psychotropic
medication in a patient who refuses medication. These
complex considerations point to the need to improve the
informed consent process for patients receiving psychiat-
ic medications (8,17,20). Ethical and legal issues about
the use of neuroleptics in patients with schizophrenia
abound (16,20). Certainly, if nothing else, it is necessary
to move beyond the more or less mechanical use of signed
consent forms and to come to grips with each patient’s
ability to learn about and understand the implications of
taking or not taking neuroleptics (14).

It is our contention that there is a duty to reinform patients
who are already being administered traditional
neuroleptics about the alternatives. In other words, we
need to inform patients who will be presented with and
who are receiving traditional neuroleptics about their op-
tions with respect to the atypical or nontraditional
neuroleptics. Although as always, there is the potential for
symptom breakthrough and relapse with the new medica-
tions, it is vital to inform patients about their expanded
options. That is not to say that the move to the new med-
cations will be automatic; many patients may elect to con-
tinue with traditional neuroleptic treatment. They may
still prefer the risk profile of the traditional neuroleptics,
compared with the newer. Yet, it has become increasingly
clear that our health-care system must now place in-
creased value and emphasis on informed consent. Clites v.
Iowa (21), Faigenbaum v. Oakland Medical Center (22)
and Hedin v. United States (23) are cases in which large
awards were made after plaintiffs developed TD. Written
consent was not required in Clites (21). Lawsuits that spe-
cifically related to consent and to TD have resulted in
“new informed consent for TD” screening policies (24).
The American Psychiatric Association (APA) has guide-
lines about TD (1,25,26) and a resource document, Prin-
ciples of Informed Consent in Psychiatry (27). Concerns
about liability have been described within the nursing pro-
fession (28). Rather than “formed” consent, we need to
ensure that consent is “informed” and is part of a thought-
ful and considered discussion between doctors and
patients (4).

With the availability of clozapine in Canada in 1991, the
opportunities have increased for individuals with psycho-
sis to achieve a state of remission with negligible risk of
developing TD. The price of this benefit, however, in-
cludes the added (though low) risk of life-threatening
blood dyscrasias, as well as other potential unwanted
effects.

Since clozapine, various nontraditional, or atypical
neuroleptics, have been available for treating psychoses.
In this country, these medications include risperidone,
olanzapine and quetiapine. Their use and availability have
increased steadily over the past few years; however, con-
cerns about other side-effects are emerging. When they
become available in Canada, quick-acting forms, as well
as intramuscular short or depot preparations, may further
increase their use.

Although some of the limitations of these medications
have to be acknowledged, we cannot dispute that, among
the advantages they offer, there is the much reduced risk
of TD. Concern about physician liability is a key reason
why psychotropic (neuroleptic) drug use is restricted. The
common law doctrine of battery provides a remedy in
damages for deliberate touching or for invasions of bodily
integrity to which the victim (patient) has not consented
or which in any other way are not legally permitted.
American case law supports the proposition that a qual-
ified constitutional right to refuse psychotropic treatment
exists. There is a central notion in Canadian law that indi-
viduals retain the right to security of the person, to bodily
integrity and to freedom from nonconsensual medical
treatment. The Ontario Court of Appeal has stated that
“few medical procedures can be more intrusive than the
forcible injection of powerful mind-altering drugs which
are often accompanied by severe and sometimes irreversible adverse side-effects” (20,27).

The United States appears to have paid due attention to this area, with justification. Other countries may look to U.S. experiences and adapt them to create their own policies. The awareness of the legal requirement for consent exists, but the policies and the implementation of these requirements may be less than appropriate in certain circumstances. Informed consent to treatment includes several components: nature of the treatment, expected risks and benefits of the treatment, alternative courses of action and the likely consequences of not having the treatment (28). In addition, there is an assumption of an assessment of competency to consent or to refuse with legal procedures available for the incompetent patient.

The availability of new treatments with potentially less harmful side-effects than previous treatments should ease in informing patients about traditional neuroleptics and about their new choices in the current health-care environment—an environment that stresses the requirements of informed consent. The newer-generation antipsychotic medications are alternatives with reduced, different, or arguably better, side-effect profiles. Even so, the new medications reveal a set of side-effects that, too, may require a risk–benefit evaluation. This raises the question of the perishability of informed consent given by patients on maintenance medication in a climate of changing treatment options. We should not forget that newer, seemingly safe medications may reveal more serious side-effects. The previous informed consent may become invalid or, at least, less valid than before. Given the potential liability issues surrounding TD, it may be appropriate and prudent to reexamine informed consent with patients in light of recent scientific and legal developments. It will be critical to document these discussions carefully, particularly if the capable patient elects to remain on the older, arguably more hazardous medication. Reinforcing consent would require assessing the patient’s capacity to make treatment decisions about the medication being proposed by the physician and then providing the patient with the necessary information to make the appropriate treatment decision. Clinicians must convey information about possible risks and benefits of both types of drugs, old and new.

Certainly, some patients need to learn that the new neuroleptics could help. The onus remains on physicians to determine that sufficient information has been provided and has been comprehended. The physician is expected to convey this knowledge about the medications, including the risks of and nature of TD. Moreover, it is prudent to document the discussion and consent.

**Conclusion**

The availability of new antipsychotic medications with reduced TD risks will affect previously obtained informed consent. This reinforces the importance of obtaining appropriate informed consent when neuroleptic or antipsychotic medications are prescribed. Specifically, in psychiatric patients, informed consent is a process rather than a “form” and, similar to all consent, assists the patient with understanding the issues. Physicians should consider reinforcing all patients who are receiving traditional antipsychotic medication, including those who are asymptomatic and side-effect free. As newer medications become available and as current medications display previous, unrecognized side-effects, consent should be revisited.

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