

Psychiatry and the Law

The Need for Reinformed Consent with Continued Traditional Neuroleptic Treatment

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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

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

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long-term or maintenance neuroleptics (6). Psychiatrists' behaviour with respect to disclosure can reflect their difficulty in dealing with this negative side-effect of an otherwise 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 comprehend 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 retain 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 informed consent doctrine may presume a degree of recall and of comprehension that is beyond most patients' capability (16). Individuals with TD may acquire memory deficits subsequent to the disorder's development, and to some extent, these limitations may nullify previously obtained 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 forensic hospitals. The autonomy of the individual's functioning may, for example, be compromised by treatment that offers hope of freedom from incarceration, thereby affecting voluntariness—an essential component of informed consent (18).

Psychiatrists can use American case law to support individuals 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 psychiatric 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 options with respect to the atypical or nontraditional neuroleptics. Although as always, there is the potential for symptom breakthrough and relapse with the new medications, it is vital to inform patients about their expanded options. That is not to say that the move to the new medications will be automatic; many patients may elect to continue 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 increased 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 specifically related to consent and to TD have resulted in "new informed consent for TD" screening policies (24). The American Psychiatric Association (APA) has guidelines about TD (1,25,26) and a resource document, *Principles of Informed Consent in Psychiatry* (27). Concerns about liability have been described within the nursing profession (28). Rather than "formed" consent, we need to ensure that consent is "informed" and is part of a thoughtful and considered discussion between doctors and patients (4).

With the availability of clozapine in Canada in 1991, the opportunities have increased for individuals with psychosis to achieve a state of remission with negligible risk of developing TD. The price of this benefit, however, includes 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, concerns 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 qualified constitutional right to refuse psychotropic treatment exists. There is a central notion in Canadian law that individuals 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.

References

1. Benjamin S, Munetz MR. CMHC practices related to tardive dyskinesia screening and informed consent for neuroleptic drugs. *Hosp Community Psychiatry* 1994;45:343–6.
2. Deveaugh-Geiss J. Informed consent for neuroleptic therapy. *Am J Psychiatry* 1979;136:959–62.
3. Roth LH. Is it best to obtain informed consent from schizophrenic patients about the possible risk of drug treatment, for example, tardive dyskinesia, before initiating treatment or at a later date. *J Clin Psychopharmacol* 1983;3:207–8.
4. Munetz MR, Peterson GA. Documenting informed consent for treatment with neuroleptics: an alternative to the consent form. *Psychiatr Serv* 1996;47:302–3.
5. Benson PR. Informed consent: drug information disclosed to patients prescribed antipsychotic medication. *J Nerv Ment Dis* 1984;172:642–53.
6. Sadock BJ, Sadock VA. *Comprehensive textbook of psychiatry*. 7th ed. Philadelphia: Williams & Wilkins; 2000. p 2370.
7. Munetz MR, Schulz SC. Minimization and overreaction to tardive dyskinesia. *Schizophr Bull* 1986;12:168–72.
8. Lacro JP, Sewell DD, Warren K, Woody S, and others. Improving documentation of consent for neuroleptic therapy. *Hosp Community Psychiatry* 1994;45:176–8.
9. Tancredi LR. Malpractice and tardive dyskinesia: a conceptual dilemma. *J Clin Psychopharmacol* 1988;8(Suppl 4):S71–S765.
10. Munetz MR, Roth LH. Informing patients about tardive dyskinesia. *Arch Gen Psychiatry* 1985;42:866–71.
11. Ganguli R, Raghu U. Tardive dyskinesia. Impaired recall and informed consent. *J Clin Psychiatry* 1985;46:434–5.
12. Beck JC. Determining competency to assent to neuroleptic drug treatment. *Hosp Community Psychiatry* 1988;39:1106–8.
13. Jaffe R. Problems of long-term informed consent. *Bull Am Acad Psychiatry Law* 1986;14:163–9.
14. Jaffe R. Informed consent: recall about tardive dyskinesia. *Compr Psychiatry* 1981;22:434–7.
15. Kleinman I, Schachter D, Jeffries J, Goldhamer P. Informed consent and tardive dyskinesia: long-term follow up. *J Nerv Ment Dis* 1996;184:512–27.
16. Jeffries JJ. Ethical issues in drug selection for schizophrenia. *Can J Psychiatry* 1993;38(Suppl 3):S70–S74.
17. Kleinman I, Schachter D, Koritar E. Informed consent and tardive dyskinesia. *Am J Psychiatry* 1989;146:902–4.
18. Kleinman SB. Liberty and tardive dyskinesia: informed consent to antipsychotic medication in the forensic psychiatric hospital. *J Forensic Sci* 1990;35:1155–62.
19. Rennie v. Klein (1978), 720 F. 2d 266 (3d Cir 1988) 476 F Supp. 1294. 1309-1310 (D. NJ 1978).
20. Brabbins C, Butler J, Bentall R. Consent to neuroleptic medication for schizophrenia: clinical, ethical and legal issues. *Br J Psychiatry* 1996;168:540–4.
21. Clites v. Iowa (1982), 322 N.W. 2d 917 (Iowa CT App 1982).

22. Faigenbaum v. Oakland Medical Center (1985), 373 NW 2d 161 (Mich App 1985).
23. Hedin v. US (1988), US District Court No 5-83-3 (D Minn 1985) 2-2m TD.
24. Appelbaum PS, Schaffner K, Meisel A. Responsibility and compensation for tardive dyskinesia. *Am J Psychiatry* 1985;142:806-10.
25. Tardive dyskinesia: a task force report of the American Psychiatric Association. Washington (DC): American Psychiatric Association; 1992.
26. Butler B. Clinician's checklist to avoid liability for TD. In: Bloom H, Bay M, editors. *A practical guide to mental health, capacity and consent law of Ontario*. Scarborough (ON): Carswell, Thomson Professional Publishing; 1996.
27. Principles of informed consent in psychiatry. Resource document reference number 960001. Approved by the Board of Trustees. Washington (DC): The American Psychiatric Association; 1996.
28. Health Care Consent Act, 1996, SO c. Sched A, (s. 11[2,3]).



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