

Pharmacists can improve consent to treatment documentation for detained psychiatric patients

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- **OBJECTIVE** — *To audit medical treatment requiring consent or a second opinion for detained psychiatric inpatients in a large psychiatric hospital.*
- **DESIGN** — *Retrospective examination of consent to treatment documentation and prescriptions on two occasions.*
- **SETTING** — *A 400-bed tertiary referral psychiatric hospital.*
- **OUTCOME MEASURES** — *Compliance with good practice and legal requirements of the Mental Health Act 1983.*
- **RESULTS** — *Significant increases in the proportion of patients whose treatment was fully authorised by their Mental Health Act Form 38 or 39 occurred due to pharmacists' monitoring and intervention. Some aspects of case note documentation improved following circulation of guidelines, but recording of mental capacity remained absent in two-thirds of cases and one-fifth of cases still had no case note entry about the patient's consent status.*
- **CONCLUSIONS** — *These results indicate a need for vigilance in ensuring that prescriptions for detained psychiatric patients beyond the first three months of compulsory treatment are always authorised by a Mental Health Act Form 38 or 39 and that the associated case note documentation has been completed. Pharmacists can play a valuable role in detecting and correcting errors.*

There is increasing interest in patient consent. Reasons for this include the rising number of claims against health care professionals and institutions, and increasing awareness of the need to respect patients' rights and preferences when making decisions about their care.¹ In order to give informed consent to medical treatment, a patient must first have the mental capacity to be able to give consent. They must be able to understand information, retain it and weigh it in the balance in order to reach a decision. The issue of informed consent for psychiatric patients is complicated by the fact that some patients, by virtue of mental illness, lack the mental capacity to make decisions about their psychiatric treatment. The current Mental Health Act 1983 (MHA), contains measures designed to protect the interests of detained patients who either lack capacity or refuse psychiatric treatment.

For patients detained under the MHA, the administration of medicine beyond the first three months of treatment requires the patient's consent or a second opinion.² Where the patient has the mental capacity to consent and does so, the responsible medical officer (RMO) (consultant psychiatrist looking after the patient) is required to complete a certificate of consent to treatment on an MHA Form 38. Where a patient lacks capacity or does not consent to treatment, a second opinion appointed doctor (SOAD) must authorise the treatment on an MHA Form 39. When changing a detained patient's medication, the RMO needs to check that the Form 38 or 39 covers any new medication prescribed for mental disorder. Full compliance with the requirements of Part IV of the MHA and the accompanying guidance given in the code of practice² is necessary to safeguard the rights and interests of patients and prevent them from being treated without proper lawful authority.

Our hospital provides specialist psychiatric treatment to over 200 detained patients in conditions of low and medium security. Most of these are tertiary referrals.

Patients, their representatives, purchasers and the Mental Health Act Commission (MHAC) all need assurance that we follow the requirements laid out in the code of practice. We therefore undertook an audit of current practice to produce such evidence. The main aims of the audit were to detect any discrepancies between consent to treatment or second opinion certificates and patients' current medical treatment, and to check that Form 38 was being completed as stipulated in the code of practice. We also sought evidence of a discussion of consent to treatment in patients' notes. The audit was undertaken in 1999 and repeated in 2001.

METHOD

Good practice standards were devised for assessing and recording the authorisation of medical treatment for detained patients with reference to the code of practice (see Panel 1, p178). For each detained patient, we examined the most recent Form 38 or 39 held by the hospital's Mental Health Act office. We studied the current prescription chart, the accompanying Form 38 or 39 and the RMO's case note entry made when a Form 38 was completed.

Data for the initial survey were collected between July and November 1999 and for the repeat audit between April and July 2001. The χ^2 test, with Yates correction and Fisher exact test were used for the statistical analysis.

RESULTS

A total of 201 forms (38 and 39) were audited in the first audit. Form 38 had been completed by the current RMO in 86 per cent of cases and was within the required time limit in 94 per cent of cases (see Table 1, p180). In 77 per cent of cases, there was a case note entry detailing the patient's consent to treatment but 8 per cent of entries were illegible. In only 6 per cent of case notes was there documentation of the patient's mental capacity to give consent and for only 31 per cent was there an

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Panel 1: Standards audited

Form 38

- The current RMO should sign Form 38
- Form 38 should be renewed annually or when the detention is renewed, whichever is more recent
- There should be a contemporaneous case note entry by the RMO stating that he or she has discussed the current prescription with the patient and the patient gives their consent to the treatment
- The case note entry should be legible
- The case note entry should indicate the patient has the capacity to give consent to treatment
- The case note entry should indicate that consent is informed
- Form 38 should be completed correctly and list the class of drug and BNF category, the route of administration, the maximum number of preparations per class, the maximum dosages, and if a patient is on antipsychotics, clozapine should be explicitly included or excluded
- A copy of the current Form 38 should be kept with the patient's current prescription chart
- Form 38 should cover all psychotropic medication including regular and as required drugs

Forms 39

- A copy of the current Form 39 should be kept with the patient's current prescription chart
- The Form 39 should cover all psychotropic medication including regular and as required drugs

entry indicating that the patient's consent was informed. Form 38 had been completed correctly in 79 per cent of cases, the most common errors being failure to specify the number of drugs in each category (15 per cent) or the route of administration (14 per cent). In 71 per cent of cases, Form 38 fully authorised the prescription. The most common omission was prescription of an unauthorised class of drugs (24 per cent).

Form 39 authorised the whole prescription in 71 per cent of cases, the most common omission being prescription of a drug dosage exceeding that authorised (19 per cent) (see Table 2, p180).

When the MHAC visited our hospital, they expressed concern at the first survey's results, especially the lack of case note entries documenting capacity and consent and the fact that over a quarter of detained patients were receiving unauthorised medication. Following presentation of the results of the initial audit, medical staff agreed good practice guidelines, based on the standards used in the audit, for completing Form 38 and 39 and a system whereby pharmacists regularly check that the forms authorise all prescribed medication was instituted. This was seen as a natural extension of current practice where pharmacists routinely monitor all prescriptions for hospital inpatients and identify problems or interventions that need to be resolved.

Pharmacists' checks of Form 38 In the month before the repeat hospital audit of consent to treatment, pharmacists found 23 patients on Form 38 were receiving unauthorised treatment. Some patients were receiving more than one unauthorised treatment. Prescribers were notified in writing of these discrepancies and for 19 patients, the discrepancies were corrected by the time of the hospital re-audit. Sometimes this involved a new Form 38 and for others the prescription was changed. For four patients, errors persisted despite the pharmacist informing the psychiatrist.

Pharmacists checks of Form 39 In the same month, there were 27 patients receiving

treatment not authorised by their Form 39. Again, some patients were receiving more than one unauthorised treatment. These were corrected by the time of the second audit for 21 patients, but errors persisted for six patients.

The 2001 repeat audit showed an increase in the total number of current forms (38 and 39) authorising medication to 222 patients. For those patients being treated on a Form 38 all case note entries about consent were legible, an improvement with respect to the 1999 audit (85/85 vs 66/72, Fisher exact 2-tailed $P < 0.01$). However, there was no significant increase in the proportion of patients with a case note entry of the RMO's discussion with the patient about the treatment plan. There was an increase in the proportion of patients with case note documentation of capacity to consent (38/105 vs 5/87, $\chi^2 = 23.7$, $P < 0.0001$). Documentation that consent was informed improved slightly but the improvement was not statistically significant. A higher proportion of both forms fully authorised the prescription (91/105 vs 67/94, $\chi^2 = 6.27$, $P < 0.05$) and (99/117 vs 76/107, $\chi^2 = 5.27$, $P < 0.05$). However, the re-audit failed to find a significant

improvement in the correct completion of Form 38.

DISCUSSION

This audit has highlighted a number of areas where clinical practice has improved with completion of the audit cycle as well as areas where there is room for further improvement.

The improvement seen at re-audit in the proportion of forms fully authorising the prescription clearly relates to the introduction of a system where pharmacy regularly check the forms and prescription charts. In the month before the repeat audit, pharmacists detected and informed the RMO of 54 instances of unauthorised medication and 44 (81 per cent) of these were rectified before the re-audit. The checking system needs to be ongoing since new discrepancies arise all the time. We recommend this practice of pharmacists collaborating with psychiatrists. We have learnt that putting systems in place to detect and correct errors is an effective way to improve clinical outcome.

The repeat audit showed that completion of Form 38 remains a problem in some respects:

- Case note documentation of the discussion between the patient and the RMO about a treatment plan (absent in one-fifth of cases)
- Entries regarding patients' mental capacity (absent in almost two-thirds of cases) and entries stating consent was informed (absent in over half of patients)

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Table 1: Details of Form 38 audited in 1999 and 2001

Details audited	1999 n=94 n (%)	2001 n=105 n (%)	Statistical test
Form 38 signed by current RMO			
Yes	81 (86)	98 (93)	$\chi^2=2.08$
No	13 (14)	7 (7)	$P=0.15$
Date of Form 38 within required time limit			
Yes	88 (94)	96 (91)	$\chi^2=0.10$
No	6 (6)	9 (9)	$P=0.75$
Case note entry about patient's consent to treatment			
Yes	72 (77)	85 (81)	$\chi^2=0.19$
No	21 (23)	20 (19)	$P=0.66$
Case notes missing	1		
Case note entry legible			
Yes	66 (92)	85 (100)	Fisher exact
No	6 (8)	0 (0)	2-tailed
No entry or notes missing	22	20	$P<0.01$
Documentation of capacity to consent			
Yes	5 (6)	38 (36)	$\chi^2=23.7$
No	82 (94)	67 (64)	$P<0.0001$
Notes missing or illegible	7		
Entry stating consent is informed			
Yes	27 (31)	43 (41)	$\chi^2=1.61$
No	60 (69)	62 (59)	$P=0.20$
Notes missing or illegible	7		
Form 38 completed correctly			
Yes	74 (79)	84 (80)	$\chi^2=0.00$
No	20 (21)	21 (20)	$P=0.96$
Current Form 38 with prescription chart			
Yes	89 (96)	104 (99)	Fisher exact
No	4 (4)	1 (1)	2-tailed
Not applicable	1		$P=0.19$
Form 38 authorises current prescription			
Yes	67 (71)	91 (87)	$\chi^2=6.27$
No	27 (29)	14 (13)	$P<0.05$

● Form 38 was filled out incorrectly in one in five cases

It was disappointing to find that medical staff did not always follow the guidelines produced after the first audit. To try and remedy this, we have provided RMOs with individual feedback from the repeat audit highlighting errors made in the completion of Form 38, and pharmacists have been asked to carry out ongoing checks that Form 38 has been completed correctly. This is in addition to pharmacists checking that patients are only prescribed medication that is authorised by their Form 38 or 39.

The audit also stimulated a lively debate among pharmacists and psychiatrists about which medications require authorisation on the forms. Psychotropic medication clearly constitutes treatment for mental disorder but what about medication prescribed for the side-effects of psychotropics? Unofficially, the MHAC have indicated that medication which forms an integral part of the treatment plan requires authorisation and this includes some drugs used to treat side-effects, eg, anticholinergics for parkinsonism, valproate for clozapine-induced seizures and hyoscine for hypersalivation. However, laxatives prescribed for constipation caused by psychotropics are not considered to require authorisation. Official guidance from the MHAC would be welcomed.

Involving pharmacy in regularly checking prescriptions and MHA consent to treatment forms has resulted in increased workload for pharmacists. However, this new work is just an extension of pharmacy's role in detecting and correcting prescribing errors. We believe it is a worthwhile use of pharmacists' time and it has been well received by both our psychiatrists and the MHAC.

REFERENCES

1. Wirtz V, Dean B. Informed consent — what are the implications for pharmacists? *Pharm Pract* 2001;11:217–220.
2. Department of Health and Welsh Office. Mental Health Act code of practice. London: The Stationary Office; 1999.

Table 2: Details of Form 39 audited in 1999 and 2001

Details audited	1999 n=107 n (%)	2001 n=117 n (%)	Statistical test
Current Form 39 with prescription chart			
Yes	97 (93)	112 (96)	$\chi^2=0.26$
No	7 (7)	5 (4)	$P=0.61$
Not applicable	3		
Form 39 authorises current prescription			
Yes	76 (71)	99 (85)	$\chi^2=5.27$
No	31 (29)	18 (15)	$P<0.05$

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