When all else fails

A locally devised structured decision process for enforcing clozapine therapy

Stephen Pereira, Dominic Beer and Carol Paton

Aims and method A small minority of treatment-refractory patients who could benefit from treatment with clozapine, refuse to comply with blood tests or oral treatment. Treatment with clozapine can be enforced under the Mental Health Act.

Results An aide memoire was developed locally to guide clinicians through the process of enforcing clozapine treatment.

Clinical implications It is possible to enforce treatment with clozapine under the Mental Health Act, and so offer a valuable treatment option.

Approximately 60% of patients with treatment-refractory schizophrenia respond to clozapine (Kane, 1992). Such a high response rate cannot be dismissed in view of the lack of effective alternatives available to this patient group. The Mental Health Act Commission (MHAC) (MHAC, 1993) gives permission for haematological monitoring and the administration of clozapine to patients who have been detained and who are unwilling, or unable, to consent to treatment. There is, however, a lack of clarity over the practical aspects of such a treatment plan. The wider literature is not explicit as to how clozapine should be enforced, to whom and under what circumstances. It follows that clozapine treatment may not be pursued in many patients who could potentially benefit because of refusal to comply with blood tests or oral medication.

It has been suggested that one may "give clozapine and take the necessary blood samples despite the patients reluctance" (Barnes *et al*, 1996). Barnes also discusses the possible alternative of using electroconvulsive therapy (ECT) to gain temporary improvement before starting clozapine. Mortimer (1996) recommends compulsory treatment when the patient does not consent. This is after reviewing the alternatives such as "long-term detention in secure units, constant distress from active psychotic symptoms, serious danger to members of the public and life threatening catatonic episodes". Mortimer also advocates having "a fairly low threshold for insisting that vulnerable patients do have a proper trial of clozapine". The problem of managing patients encountered in clinical practice who fulfil the criteria for a trial of clozapine but adamantly refuse to cooperate are illustrated by the following case vignettes.

Patient A

Patient A was a 37-year-old male with a 17-year history of schizophrenia and numerous admissions to psychiatric units. He has a history of serious assault on nursing staff. His mental state stabilised five years ago with clozapine treatment to such an extent that he was transferred to a flat in a community project. However, a short while later he refused medication and blood tests. He was re-admitted under Section 3 of the Mental Health Act 1983 with persecutory delusions and auditory hallucinations and made attempts to sexually assault female nursing staff and female patients. Various attempts to educate and convince the patient to take clozapine failed. He required seclusion and control and restraint on occasions due to aggressive incidents. It was unsafe for him to have leave outside the ward. Conventional neuroleptic medication did not result in any improvement in his symptoms or behaviour. Psychological intervention was impossible due to his complete lack of engagement.

Patient B

Patient B was a 36-year-old female patient with an 18-year history of schizophrenia and numerous admissions to psychiatric units. Her mental state examination consistently revealed formal thought disorder and bizarre delusions. She had a history of gross sexual disinhibition resulting in inappropriate and indiscriminate choice of sexual partners and unsafe sex. She had abnormal cervical smear tests in the past, but refused to allow further investigations or examinations. She remained an in-patient under Section 3 of the Mental Health Act 1983 in an intensive care unit for one year with very little

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change in her mental state and many side-effects with conventional medication. Psychological interventions did not result in any improvement in her mental state or adherence with further physical investigations or with clozapine. She refused clozapine therapy due to delusions around giving blood and that clozapine tablets would give her AIDS. Various efforts to educate and convince the patient to take clozapine failed.

Because there is no nationally agreed protocol or detailed guidance, the following structured decision 'aide memoire' was developed locally, to ensure a balanced informed approach was taken each time enforcing treatment with clozapine was considered as a therapeutic option. This process requires a comprehensive assessment of the situation to take place before proceeding with enforced treatment with clozapine.

The patient's current mental state should be thoroughly assessed to exclude such factors as organicity, personality disorder, affective disorder, psychological events and over medication. There should be a thorough review of the patient's past treatment which includes previous mental state features, medication history and carer accounts. Lack of response to maximum *British National Formulary* (1998) dosages of conventional and atypical neuroleptics for an adequate duration, adjunctive treatments and psychological strategies should be determined. The patient, if informal, should be assessed for compulsory treatment under the Mental Health Act and transferred to an intensive care unit, if appropriate. Attempts should then be made to educate the patient and carers regarding clozapine over a period of time, followed by attempts to persuade and/or the offering of incentives such as leave or activities when safety permits. The patient should then be informed well in advance that medication and venepuncture may be enforced and that other medication will be stopped except emergency intra-muscular medication. All members of the multi-disciplinary team should fully discuss the proposed treatment plan. Consensus view is important. Risk–benefit factors in relation to the identified patient, other patients in the unit, staff and the procedure itself should be considered. The MHAC Second Opinion Appointed Doctor (SOAD) should be consulted. Relatives' views should be included in the formulation of the care plan if possible. The trusts managers should be made aware of any decision to proceed with enforced clozapine treatment. It would be appropriate in all cases to elicit the views of the United Kingdom Central Council for Nursing, Midwifery and Health Visiting, Royal College of Nursing and Medical Defence Union. Views of peers, experts and specialist units treating a large number of treatment-refractory patients with clozapine may also be elicited.

Practical aspects of enforcement

Venepuncture

The patient may be approached with a control and restraint team in attendance, and requested to cooperate with the blood test. Any offer of incentives may be reinforced. If still refusing, the patient should be informed that restraint will be necessary in order to collect blood. The senior doctor should be present on the unit during this process.

Oral medication

Various methods can be tried, including offering clozapine in liquid form as a suspension under close supervision. The patient should be aware that the drink contains medication. The offer of incentives may be reinforced. If the patient still refuses to take clozapine, an intra-muscular neuroleptic can be given when the behaviour deteriorates to such extent that others are placed at risk.

After the procedure nursing staff should spend time with the patient to provide support and reinforce the need to cooperate with the treatment process. Nursing staff and junior doctors should feel supported during this process.

Discussion

It is crucial that the above described procedure is viewed in its proper context. Many patients take clozapine voluntarily and comply with blood monitoring. The need to enforce treatment applies to an extremely small number of patients. Enforcement would only apply to those who pose substantial risk of harm to others or to themselves through self-harm or neglect. Enforcement would be difficult on an open ward, so the patient may require transfer to a locked ward/psychiatric intensive care/secure rehabilitation unit, at least to initiate therapy.

Although the MHAC emphasises the role of the responsible medical officer, it is crucial that all members of the multi-disciplinary team are consulted and are in agreement with the enforced treatment. The role of the SOAD from the MHAC is also particularly important. The SOAD may give suggestions on the management of the patient which have been overlooked by the multi-disciplinary team, and provides an independent view which can be seen as such by both the patient and by any staff who may be opposed to clozapine treatment. The SOAD can also discuss the details of any medication regime necessary in the event of the patient refusing to ingest crushed clozapine.

The decision to enforce clozapine should be considered as a last option when all else fails. The method described here clearly has ethical,

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legal and clinical implications. Further discussion needs to take place to seek an agreed way forward in this important yet difficult area.

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Commentary: The risks of enforcing clozapine therapy

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Pereira *et al*'s paper (1999, this issue) is to be welcomed in that it highlights an area of clinical decision that requires a careful balance of short- and long-term risks and benefits in the individual patient. In this (necessarily) brief commentary I will concentrate on this aspect, and leave aside any ethical and medico-legal considerations.

The essence of this paper is a "locally devised structured decision process" for enforcing clozapine therapy in patients for whom it is indicated, but who are unwilling to take it. The paper presents a structured decision 'aide memoire', which is rather non-specific. For example, what constitutes a lack of response to previous antipsychotic medication is not defined in terms of adequate dosage, duration or adherence. Further, the authors recommend the broad canvassing of general views from colleagues and official bodies. However, there is a distinction to be made here between an informed second opinion relating to a particular patient, hearing of other clinicians' experience of starting patients on clozapine and informal discussion about the suggested approach.

Perhaps most critically, there is no mention of the need to elicit exactly why an individual patient might be currently reluctant to start clozapine. Depending on the reasons, the patient may be amenable to change through strategies such as reassurance and more detailed information about the potential hazards and advantages of the drug, or a psychological intervention, specifically cognitive–behavioural therapy, to improve aspects of insight or tackle a particular delusion (Barnes *et al*, 1996). Discussion between the patient and others already receiving clozapine may serve to allay concerns. Using such an approach in our in-patient service for treatment-resistant schizophrenia, along with patience and steady persuasion, we have usually achieved the goal of the patient eventually accepting treatment. If not, the risks, both short-term and long-term, of confrontation have generally been judged to outweigh the potential benefits, and the plan to administer clozapine has been abandoned, or at least postponed.

The possible short-term benefits of enforcing clozapine in a particular patient, in the manner described by Pereira *et al* are that a blood sample is obtained and clozapine treatment initiated. The risks include needle-stick injury, disruption of therapeutic relationships and problems asso-

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