Patient attitudes to clozapine initiation

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Running title:
Abstract

Background
Clozapine is widely underused. No study has assessed views of patients suitable for, but not yet receiving, clozapine. We aimed to assess views of clozapine in patients eligible for clozapine but not yet prescribed it.

Methods
Semi-structured interviews with acutely unwell hospital inpatients.

Main Results
We interviewed 61 of 116 eligible patients and 50 (82%) answered all questions. At interview, 33 of 61 participants (54%) had heard of clozapine and 17 of 57 (30%) said they would take it if asked. Overall, 31 of 54 (57%) respondents said blood testing would not preclude them taking clozapine. The necessity for hospital admission was seen as the greatest barrier to receiving clozapine – 25 of 51 respondents (49%) stated this would be a reason for their refusing clozapine. Concerns about adverse effects of clozapine were considered sufficient to refuse clozapine in 23 of 53 (43.4%) respondents. Overall, 12 of 50 (24%) respondents felt that clozapine would be helpful to them.

Principal Conclusions
Patients’ acceptance of clozapine is likely to be improved by offering the opportunity to start clozapine at home and by improved education about the therapeutic benefits of clozapine and the management of its adverse effects. Blood testing does not appear to be an important barrier to the initiation of clozapine.

Keywords: clozapine, compliance, concordance, patient views
**Introduction**

Despite the established unique efficacy of clozapine in treatment-resistant schizophrenia, it remains under-prescribed (Howes et al., 2012). The reasons for this are not clear but perhaps are most likely to lie at the interface of the patient and prescriber. We have previously shown that the barriers psychiatry practitioners cited as most frequently preventing clozapine prescription are: patient refusal of regular blood testing; patient refusal of baseline blood testing; patient concerns about tolerability; medical complications; patient refusal of hospital admission; and the patient being unsure of efficacy (Gee et al., 2013). If one excludes co-morbid medical complications, the top five reasons that practitioners report for not prescribing clozapine are patient-related. This is at odds with research examining patient opinions of clozapine in which experiences expressed are overwhelming positive, with tolerability and the need for blood tests considered to be major problems far less frequently by patients than by clinicians (Taylor et al., 2000). However, there is a significant bias in that the rather limited available literature is confined to the opinions of patients who are *already* taking clozapine. By definition this cohort of patients will have consented to treatment and remained compliant with it. Surveys of existing patients could be said to confirm only what might otherwise be assumed. Therefore, in this study we surveyed the perhaps more relevant views of those patients who were eligible for, but not currently prescribed, clozapine, with the intention to better understand the patient-related barriers to clozapine initiation.
Method

The survey of patient attitudes to clozapine was approved by the trust’s Drug and Therapeutics Committee. Patients admitted to three acute psychiatric wards at the Bethlem Royal Hospital in London, UK in 2015 and 2016 were considered for inclusion in the study. Demographic details and compliance with eligibility criteria were gathered from clinical notes.

Eligibility criteria were:

- Admission to an acute ward at the Bethlem Royal Hospital
- Prescription of two or more antipsychotics over the course of the illness (up to and including the current prescription), each for at least 6 weeks and at a minimum effective dose
- Diagnosis of schizophrenia or schizoaffective disorder
- No previous trials of clozapine

Patients were approached for inclusion in the survey by the lead investigator (SG), and if consent was given then a face-to-face questionnaire administered (also by SG). Patients were first asked whether or not they had heard of clozapine. If they answered “no” then a brief paragraph detailing the indication for clozapine (an antipsychotic, used to treat the symptoms of schizophrenia described as a reduction in hallucinations, improvement in concentration and thinking), common side effects (constipation, drowsiness, hypersalivation, dizziness on standing, tachycardia) and rare side effects (a reduction in white blood cells) was read to them. They were fully informed of the need for blood testing and its frequency, and also that some people found clozapine to be the only medication
effective for them. This paragraph was also read to patients who replied that they had already heard of clozapine, if it became clear later in the interview that there were aspects of the treatment that they were either not aware of, or did not understand fully.

Participants were then asked whether they had ever been asked to take clozapine, and if so what the outcome was. They were asked whether they would consider taking clozapine now, were it to be offered to them.

Likert scales were used to assess patients’ opinions on the need for baseline blood tests, regular blood tests, side effects, and the potential need for hospital admission to initiate clozapine. Written descriptions were used to present the possible options, which ranged from ‘0’ (that doesn’t bother/worry me at all), ‘1’ (I’d be slightly bothered/worried but I’d still be willing to try it), ‘2’ (I’d be fairly bothered/worried but I’d still be willing to try it), ‘3’ (I’d be very bothered/worried but I’d still be willing to try it) to ‘4’ (I wouldn’t try clozapine because of this/the side effects). Participants were also asked whether starting clozapine at home would be preferable to being admitted to hospital in order to titrate the dose.

Finally, participants were asked to compare, as far as they were able, clozapine with medicines they had taken in the past, or were taking currently, and to rate how much they thought clozapine would help them. A Likert scale was again used to gather responses, ranging from ‘0’ (clozapine would be a lot less helpful than other medicines I’ve had), ‘1’ (clozapine would be slightly less helpful than other medicines I’ve had), ‘2’ (clozapine would be about the same as other medicines I’ve had), ‘3’ (clozapine would be a bit better than other medicines I’ve had), to ‘4’ (clozapine would be a lot better than other medicines I’ve had’). Where possible, their reasons for their answers were also noted.
Patients who fully or partially completed the questionnaire were designated ‘participants’, and patients who refused to take part, or could not be interviewed for other reasons were designated ‘non-participants’. Independent t-tests for continuous variables and Pearson’s chi-squared test for categorical variables were used to compare the demographics of patients in the participating and non-participating groups. All data were analysed using SPSS version 22. A copy of the questionnaire is available on request from the authors.
Results

In total, 468 patients admitted to the wards were assessed for entry into the study. Of these, 116 fulfilled the eligibility criteria for the study and of these 25% (29 of 116 patients) refused to take part, 5% (6 of 116 patients) were considered too unwell to provide informed consent, 10% (12 of 116 patients) were discharged before an interview could take place, and 7% (8 of 116 patients) were excluded for other reasons (predominantly a lack of sufficient English or transfer to another hospital before interview). The remaining 61 patients were considered ‘participants’ in the survey, and of these 82% (50 of 61 patients) answered all the questions asked, with a further 18% (11 of 61 patients) answering at least 1 question.

Demographics

Table 1 goes here

Questionnaire results
Just over half of the patients surveyed had heard of clozapine (54%, 33 of 61 patients), and a fifth (19%, 11 of 57 patients) recalled being asked to consider taking it as a treatment for their illness.

Table 2 goes here
A larger proportion of participants reported that if asked to take clozapine now, they would refuse (35%, 20 of 57 patients) although this was a narrow majority, with 30% (17 of 57 patients) saying that they would be willing to try it.

Table 3 goes here

Of those seventeen subjects that said they would take clozapine if it were offered to them now, fourteen provided further explanation. The most frequent theme (5 patients) that emerged was that the patient wanted their mental health to improve, and felt that clozapine would be helpful in this way:

“I want my mental health to recover”

“I need something in addition to my current medicines”

The next most common statements (4 patients) were related to trust in the opinion of the professionals caring for them:

“If it would help I’d take it. I trust the doctor’s opinion – if they say I need it then I’ll take it”

“I know it would do me good. I trust you.”

For patients who stated that they would not take clozapine, might take it or were not sure if they would take it if it were offered to them, 38 provided a more detailed response. The
most commonly cited reason (15 patients) for either refusing clozapine or being unsure about treatment was related to the side effects or blood monitoring, and of these most responses focussed on the effects on the white blood cells or the blood monitoring in some way (8 patients):

“There are more negatives than positives… the side effects”

“The constant monitoring. The side effects – salivation, drowsiness. I don’t like needles.”

“It kills white blood cells”

“The white cell thing sounds risky”

Other common themes included not believing that any medication was necessary at the moment (5 patients), being happy with the current medication (4 patients) and being unsure what the effects of clozapine might be (3 patients).

Table 4 goes here

When asked how they felt about having blood taken before starting clozapine, a narrow majority of participants (35%, 19 of 54 patients) reported that this wouldn’t bother them at all. The opposite answer, ‘I wouldn’t try clozapine because of this’ was the next most common response (32%, 17 of 54 patients). Proportionally more patients reported that
regular blood tests would put them off trying clozapine (41%, 22 of 54 patients), with 28% (15 of 54 patients) stating that this wouldn’t bother them at all. The side effects of clozapine were a barrier to clozapine for a substantial proportion of patients, with 43% (23 of 53 patients) saying that this would put them off clozapine entirely and 19% (10 of 53 patients) reporting that the side effects would worry them very much. In contrast, 17% (9 of 53 patients) said the side effects didn’t worry them at all, and 15% (8 of 53 patients) said they would be slightly worried. When asked how they would feel about coming into hospital in order to initiate clozapine, the largest proportion of patients (49%, 25 of 51 patients) said this would put them off trying clozapine. However, a significant proportion (29%, 15 of 51 patients) reported that being admitted in order to start clozapine wouldn’t bother them at all.

Figure 1 goes here

When asked which side effects particularly worried them, 30 patients gave more detailed answers. Of these, the most common side effect cited was dizziness or any cardiac complication (8 patients), followed by the effects on white blood cells (6 patients). Some patients expressed beliefs they held about the medicine both in general and in relation to side effects:

“I see other patients that drool, it means you are disabled.”

“The strength of the pill makes me worried about collapsing. You can’t miss a day of taking clozapine, so you are basically dependent on it.”
Others weighed the balance of side effects against the potential benefits:

“Medicines are there to improve and stay positive so I’m not worried about side effects.”

“I know other people who take clozapine. For them the psychosis is so bad the side effects are worth taking. It’s a balance for each individual. Therefore if I needed clozapine I wouldn’t care about the side effects because I would need it.”

“I’ve had drooling on amisulpride before, so I wouldn’t want this to happen again. I don’t need clozapine. But I recognise that if psychosis is really bad then people need clozapine and then for them any negative problems (having to have bloods done, the side effects, being admitted) are outweighed by the benefits. So the problem is people not having any insight into the severity of their psychosis.”

A clear majority of participants (67%, 34 of 51 patients) felt that starting clozapine at home would be better than being admitted to hospital, although a significant proportion (26%, 13 of 51 patients) disagreed (4 (8%) did not give an opinion).

Comments made by patients who stated that they would rather come into hospital to start a medicine than be at home included:

“I would be worried about starting clozapine at home because side effects wouldn’t be monitored.”
“A professional should be starting medicines so it is better to be in hospital for this, not at home.”

“If you feel ill it’s better to come into hospital for medicines to be started because that’s where the doctors are – it’s better to be with them.”

When asked to compare the likely effect of clozapine to other medicines they had taken, the majority of patients (32%, 16 of 50 patients) felt that it would be “a lot less helpful” for them, 3 (6%) felt it would be slightly less helpful, and 6 (12%) felt it would be “about the same”. Twelve participants (24%) thought clozapine would be “a bit better” (7, 14%) or “a lot better” (5, 10%). The second most common answer was “I don’t know” (20%, 10 of 50 patients). Three participants’ answers could not be classified.
Discussion

This study aimed to evaluate and categorise the opinions of potential clozapine patients on clozapine initiation, side effects and its potential effectiveness. The patients included were specifically selected as those who were not taking, and had not ever taken clozapine previously, and who were also acutely unwell. This group of patients were considered to reflect most accurately those that clinicians might expect to treat in daily practice and for whom clozapine might be considered the treatment of choice.

A significant proportion of patients (46%) reported that they had never heard of clozapine, and 70% said they had never been asked to take it. We did not interrogate the clinical notes to establish whether this was the case, and arguably patients cannot be expected to recall all medicines that have been discussed with them in the past, but the lack of awareness by patients of the drug is striking and perhaps explains the low prescription rates of clozapine in our Trust (Howes, et al., 2012). Conversely, this lack of familiarity may be seen as encouraging, as patients do not necessarily enter into a conversation about clozapine with preconceived ideas about its benefits or disadvantages. Further to this, 46% of patients stated that they would either take clozapine were it to be offered to them, or that they were unsure. A minority (35%) rejected the idea outright.

We have previously found that clinicians consider patients’ refusal to undergo blood tests to be the main barrier to prescribing of clozapine (Gee, et al., 2013). In the present study, a high degree of concern was expressed by some patients about this, with 36% of participants...
stating that blood tests would put them off trying clozapine. However, this proportion does not represent the majority – the remainder felt that the blood tests presented no worry at all (31%) or that they would be worried only to some extent, but still willing to try clozapine (30%). Thus for 61% of patients eligible for clozapine blood testing was not a barrier to its use.

Also in our previous study, clinicians felt that the next most worrying aspect of clozapine therapy for patients was overall tolerability. We found 43% of patients to be unwilling to try clozapine because of adverse effects, although again the majority were either not worried at all, or worried but still open to considering treatment (53%).

When considering hospital admission as a barrier to patients willingly accepting clozapine treatment, 49% of patients stated that this would mean they would not want to try the medication. Of the remaining patients, almost a third (29%) did not feel this was a concern at all, and this was further reflected in a similar percentage actively wishing to be in hospital rather than at home to start clozapine (26%). Thus the main barrier to using clozapine is not blood testing but the apparent necessity to be admitted to start clozapine.

Finally, patients do not appear to consider clozapine to be as effective as the available data suggest it is, with 38% thinking it would be less helpful than other medicines they have previous taken, or were taking at the time of the study, just 24% thinking it would be better, and 12% considering it to be about the same. It is possible that patients were taking into
account the burden of side effects, hospital admission and blood monitoring when answering this question – and this perhaps makes it all the more relevant. Nonetheless, educating patients about the potential benefits of clozapine is likely to prove beneficial in the attempt to get more people on to clozapine.

To our knowledge, this is the first study to evaluate opinions about clozapine of patients who are not taking the drug, but who, in accordance with local and national guidelines (National Institute for Health and Clinical Excellence, 2010; Taylor et al., 2015), should be. Other authors have described the attitudes of patients who have already been established on clozapine, and these are overwhelmingly positive. Patients were repeatedly found not to mind the blood monitoring (Taylor, et al., 2000; Wolfson & Paton, 1996), to prefer clozapine to their previous medications (Waserman & Criollo, 2000; Wolfson & Paton, 1996), and to find it generally helpful for them when compared to other medicines – even when they were considered to lack insight into their condition (Castle et al., 2002). These studies cannot be said to represent the views of patients who are not taking clozapine, and therefore cannot help to address the issue of chronic under prescribing of the medication.

Our results do not show that patients are universally against the idea of clozapine, but that concerns about hospital admission, adverse effects and, to a lesser extent, blood monitoring are important. These concerns do not apply to every patient however, and patients vary in the degree to which they express concern about these aspects of treatment. It is clear that there is a need to increase patient awareness of the benefits of clozapine. We found in our survey that almost half of patients who would be considered eligible for clozapine treatment
had never heard of it, let alone knew anything about it. Clinicians should therefore be mindful not to assume that patients have prior knowledge of clozapine (either in terms of benefits or drawbacks). Rettenbacher et al. (Rettenbacher et al., 2004) found that patients with schizophrenia usually estimated other chronic diseases to be considerably worse than theirs, and so the authors suggested that patients might not take their illness seriously enough to consider taking medication to treat it. Regular discussions with healthcare professionals about schizophrenia and its treatment course with patients may improve this attitude, potentially increasing familiarity with clozapine and decreasing what might be considered a detrimental ‘fear of the unknown’. It may also be beneficial to move away from the practice of introducing the idea of an entirely new medication with unique monitoring requirements and side effects at the point of acute psychotic relapse. Instead, the treatment pathway for schizophrenia should be made transparent and clear to patients from the outset of illness. This may make easier initiating clozapine at a time of severe illness.
Limitations

Our study included only a small number of patients from a single hospital and so our findings may or may not be generalizable to patients in other units or countries. It is almost important to be aware that patient views, expressed in the abstract (in response to a questionnaire) may differ markedly from actions and opinions taken in reality.

It is vitally important that clinicians are aware of the views of patients regarding medication in chronic conditions, such as schizophrenia, as it provides the basis of the appropriate approach necessary to overcome the sometimes considerable obstacles to prescribing clozapine effectively. We have shown that awareness of clozapine amongst patients was generally low, especially considering that these patients would be eligible for clozapine treatment on the basis of their clinical record. Patients were largely unaware of the clinical benefits of clozapine. There is a need for increased patient awareness of the role of clozapine, and this may include initiatives such as the use of patient advocates to educate fellow patients about medication, and services supporting the initiation of clozapine at home.
Declarations of Interest

DT has received speaker honoraria from Janssen, Servier, Otsuka and Lundbeck and is on the following advisory boards: Servier, Lundbeck and Sunovion. Research funding has been received from Janssen, Lundbeck and BMS. SS and SG do not have any potential conflicts of interest.
References


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<tr>
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<th>Total cohort, n = 116</th>
<th>Participants, n = 61</th>
<th>Non-participants, n = 55</th>
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<td>43 (19 - 76)</td>
<td>42 (20 – 71)</td>
<td>44 (19 – 76)</td>
<td>0.31</td>
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<td>Gender, male (%)</td>
<td>84 (72)</td>
<td>48 (79)</td>
<td>36 (66)</td>
<td>0.05</td>
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<tr>
<td>Ethnicity, n (%)</td>
<td></td>
<td></td>
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<td></td>
</tr>
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<td>White</td>
<td>31 (27)</td>
<td>18 (30)</td>
<td>13 (24)</td>
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<td>Black</td>
<td>62 (53)</td>
<td>31 (51)</td>
<td>31 (56)</td>
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<td>Asian</td>
<td>12 (10)</td>
<td>4 (7)</td>
<td>8 (15)</td>
<td></td>
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<td>Mixed or other</td>
<td>11 (9)</td>
<td>8 (13)</td>
<td>3 (5)</td>
<td></td>
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<td>Mean days between admission and interview (range)</td>
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<td>11 (0 – 61)</td>
<td>15 (1 – 68)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Schizophrenia</td>
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<td>45 (74)</td>
<td>43 (78)</td>
<td>0.15</td>
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<td>Schizoaffective disorder</td>
<td>28 (24)</td>
<td>16 (26)</td>
<td>12 (22)</td>
<td></td>
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<tr>
<td>Interview outcome, n (%)</td>
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<td></td>
<td></td>
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<tr>
<td>Fully answered</td>
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<td></td>
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<tr>
<td>Refused</td>
<td>29 (25)</td>
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<td></td>
</tr>
<tr>
<td>Unwell</td>
<td>6 (5)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discharged</td>
<td>12 (10)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Other</td>
<td>8 (7)</td>
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Table 2. Responses to ‘Have you heard of a medication called clozapine?’

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Yes,</th>
<th>No,</th>
<th>Don’t know,</th>
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<tr>
<td></td>
<td>n</td>
<td>(%)</td>
<td>(%)</td>
<td>(%)</td>
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<tr>
<td>Have you heard of clozapine?</td>
<td>61</td>
<td>33 (54)</td>
<td>26 (43)</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Have you ever been asked to take</td>
<td>57</td>
<td>11 (19)</td>
<td>40 (70)</td>
<td>6 (11)</td>
</tr>
<tr>
<td>clozapine?</td>
<td></td>
<td></td>
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Table 3. Responses to ‘If you were asked to take clozapine now, how would you respond?’

<table>
<thead>
<tr>
<th>If you were asked to take clozapine now, how would you respond?</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I’d take it</td>
<td>17 (30)</td>
</tr>
<tr>
<td>I wouldn’t take it</td>
<td>20 (35)</td>
</tr>
<tr>
<td>I might take it</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Don’t know</td>
<td>7 (12)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (2)</td>
</tr>
</tbody>
</table>
Table 4. Responses to Likert scale-measured questions

<table>
<thead>
<tr>
<th>How would you feel about having blood taken before starting clozapine?</th>
<th>That doesn’t bother/worry me at all</th>
<th>I’d be slightly bothered/worried but would still try clozapine</th>
<th>I’d be fairly bothered/worried but would still try clozapine</th>
<th>I’d be very bothered/worried but would still try clozapine</th>
<th>I wouldn’t try clozapine because of this</th>
<th>Don’t know</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
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<tr>
<td>54</td>
<td>19 (35)</td>
<td>6 (11)</td>
<td>5 (9)</td>
<td>5 (9)</td>
<td>17 (32)</td>
<td>1 (2)</td>
<td>1 (2)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>How would you feel about having blood taken regularly whilst taking clozapine?</th>
<th>That doesn’t bother/worry me at all</th>
<th>I’d be slightly bothered/worried but would still try clozapine</th>
<th>I’d be fairly bothered/worried but would still try clozapine</th>
<th>I’d be very bothered/worried but would still try clozapine</th>
<th>I wouldn’t try clozapine because of this</th>
<th>Don’t know</th>
<th>Other</th>
</tr>
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<tbody>
<tr>
<td>N</td>
<td>N (%)</td>
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<td>N (%)</td>
<td>N (%)</td>
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<tr>
<td>54</td>
<td>15 (28)</td>
<td>5 (9)</td>
<td>4 (7)</td>
<td>7 (13)</td>
<td>22 (41)</td>
<td>0 (0)</td>
<td>1 (2)</td>
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<table>
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<tr>
<th>How much do the side effects of clozapine worry you?</th>
<th>That doesn’t bother/worry me at all</th>
<th>I’d be slightly bothered/worried but would still try clozapine</th>
<th>I’d be fairly bothered/worried but would still try clozapine</th>
<th>I’d be very bothered/worried but would still try clozapine</th>
<th>I wouldn’t try clozapine because of this</th>
<th>Don’t know</th>
<th>Other</th>
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<tbody>
<tr>
<td>N</td>
<td>N (%)</td>
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<tr>
<td>53</td>
<td>9 (17)</td>
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<td>1 (2)</td>
<td>10 (19)</td>
<td>23 (43)</td>
<td>2 (4)</td>
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</table>

<table>
<thead>
<tr>
<th>How would you feel about being admitted to hospital in order to start clozapine?</th>
<th>That doesn’t bother/worry me at all</th>
<th>I’d be slightly bothered/worried but would still try clozapine</th>
<th>I’d be fairly bothered/worried but would still try clozapine</th>
<th>I’d be very bothered/worried but would still try clozapine</th>
<th>I wouldn’t try clozapine because of this</th>
<th>Don’t know</th>
<th>Other</th>
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<tr>
<td>N</td>
<td>N (%)</td>
<td>N (%)</td>
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<td>51</td>
<td>15 (29)</td>
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<td>7 (14)</td>
<td>3 (6)</td>
<td>25 (49)</td>
<td>0 (0)</td>
<td>1 (1)</td>
</tr>
</tbody>
</table>
Figure 1 Responses to questionnaire, shown as percentage of responses for each question

- How would you feel about having blood taken before starting clozapine?
- How would you feel about having blood taken regularly whilst taking clozapine?
- How much do the side effects of clozapine worry you?
- How would you feel about being admitted to hospital in order to start clozapine?