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DOI:

[10.1016/j.psycom.2022.100070](https://doi.org/10.1016/j.psycom.2022.100070)

Document Version

Publisher's PDF, also known as Version of record

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Citation for published version (APA):

Atkins, M., Taylor, D., Harland, R., Brewer, A., Williams, S., Chesney, E., & McGuire, P. (2022). Acceptability of point of care testing for antipsychotic medication levels in schizophrenia. *Psychiatry Research Communications*, [100070]. <https://doi.org/10.1016/j.psycom.2022.100070>

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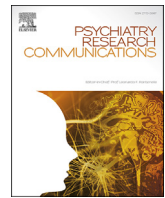
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Contents lists available at ScienceDirect

Psychiatry Research Communications

journal homepage: www.sciencedirect.com/journal/Psychiatry-Research-Communications

Acceptability of point of care testing for antipsychotic medication levels in schizophrenia



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ABSTRACT

We surveyed 106 patients with schizophrenia who were being treated with either oral clozapine or oral aripiprazole. For each patient, the plasma level of the medication was measured using i) a venous blood sample and a conventional lab-based assay and ii) a novel point of care assay that used a capillary blood sample taken with a fingerprick. Immediately after providing the two samples, participants completed a brief questionnaire. We also surveyed 10 members of staff who were directly involved in the care of these patients.

98% of patients found the capillary point-of-care approach acceptable, and 85% preferred it to the conventional venous blood procedure. 78% of patients said it was useful to have access to the result at the point of care (as opposed to at a later date), and 90% felt that POC testing improved clinical care. 83% said that the POC test made them feel more involved in their treatment. 100% of staff said their experience with the POC test was good, that it was easier than venous collection, and that it was very useful to receive the medication level while the patient was still in the clinic.

1. Introduction

Antipsychotic medications play a central role in the treatment of schizophrenia. In most patients these are given orally. However, even when prescribed at recommended doses, the blood level of these medications may not be optimal (Couchman et al., 2010; Bowskill et al., 2012). If the concentration is too low, the medication may not be effective (Taylor et al., 2021a). Conversely, if it is too high, patients are more likely to experience adverse effects (Varma et al., 2011). A further consideration is that many patients are reluctant to take antipsychotic medications (Gee et al., 2017) and may report that they are taking them when they are not (Haddad et al., 2014).

These issues may be addressed by regularly monitoring the blood levels of antipsychotic medications. However, although lab-based assays for measuring the antipsychotic levels have been available for many years, these are not widely used in routine clinical care (Kelly et al., 2018). This may partly be because some patients dislike having venepuncture from their arm. Another factor is that there is typically a delay

of 1–2 weeks before the result is available to the clinician, as samples have to be sent to a central laboratory for analysis.

Recently, it has become possible to measure antipsychotic medication levels using a small fingerprick sample of capillary blood (Kalaria and Kelly, 2019). Moreover, the analysis can be performed with a small portable device at the point of testing, providing a result in a few minutes (Boland and Dratcu, 2022). These Point of Care (POC) assays can be as accurate as conventional lab-based assays that use venous blood samples (Taylor et al., 2021b). However, while the POC approach has been evaluated from a technical perspective, its acceptability to patients with schizophrenia has not yet been formally evaluated.

In the present study, we addressed this issue by assessing the acceptability of POC testing to patients with schizophrenia and to staff involved in their clinical care. We studied two patient groups: first episode patients being treated with aripiprazole, and patients with treatment resistance being treated with clozapine. We tested the hypotheses that both patients and staff would find the POC approach more acceptable than the conventional venous blood sampling.

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<https://doi.org/10.1016/j.psycom.2022.100070>

Received 4 April 2022; Received in revised form 23 August 2022; Accepted 10 September 2022

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2. Method

2.1. Procedure

Patients who were providing a venous blood sample and a fingerprick capillary sample for the assessment of clozapine/aripiprazole levels were invited to complete a short questionnaire about the two testing procedures, which they completed after providing the two blood samples.

The venous sample was sent to a central laboratory for analysis using LC-MS/MS assays for clozapine or aripiprazole. The fingerprick sample was analysed using a point of care (POC) device (MyCare™ Insite analyser, Saladax Biomedical, Inc., Bethlehem, PA) with an assay for capillary blood concentrations of clozapine (Taylor et al., 2021b) or aripiprazole.

3. Patient questionnaire format

The questionnaire comprised 5 questions (see Results). Two related to the POC approach, and three assessed its impact on the patient's clinical care.

3.1. Staff sample

The clinical staff who carried out the blood testing were invited to complete a questionnaire comprising 7 questions (see Results); four were related to the POC approach, and 3 to its impact on clinical care.

4. Results

4.1. Patient sample

Patients with schizophrenia (n = 106) who were being treated with either oral clozapine (n = 84) or oral aripiprazole (n = 22) in the South London and Maudsley (SLaM) NHS Foundation Trust (Table 1).

4.2. Staff sample

Clinical staff (n = 10) from the South London and Maudsley (SLaM) NHS Foundation Trust who were involved in the care of the participating patients. They comprised three psychiatrists, four Mental Health Nurses, and three clinical pharmacists.

4.3. Patient questionnaire

1. "How would you rate your experience of the finger-prick test?"

Of the patients taking aripiprazole, 59% answered very good, and the remaining 41% answered good. Of the patients taking clozapine, 39% answered very good, 41% answered good, 18% answered average, 2% answered poor.

2. "Which do you prefer – the finger-prick or taking a sample from your arm?"

Of those taking aripiprazole, 77% answered 'finger-prick', and the

remaining 23% answered 'blood sample from arm'. Of those taking clozapine, 88% answered 'finger-prick', and the remaining 12% answered 'blood sample from arm'.

3. "How useful is it for you to know your own clozapine/aripiprazole level when you visit the clinic?"

Of the patients taking aripiprazole, 96% answered useful, and 4% answered Indifferent. Of those taking clozapine, 74% answered useful, 25% answered indifferent, and 1% answered not useful.

4. a) "Do you believe this test provides you with better care?"

Of those taking aripiprazole, 100% answered yes. Of those taking clozapine, 88% answered yes, and the remaining 12% answered no.

b) : If 'yes', please explain why it provides you with better care"

Patients provided a variety of explanations including:

- a) *Ease of testing*. "only a finger-prick", "easier", "prefer finger prick", "less invasive", "an upgrade"
 - b) *Receiving the result immediately*. E.g. "better to know straight away", "advice on the spot, there and then", "instant results", "find out straight away and what to do next", "reassuring"
 - c) *Better understanding of the purpose of testing*. E.g. "Help with understanding", "communication clarity", "Better results, clear understanding", "I know more about what I'm having", "identify if you have been taking aripiprazole or if it's not working", "shows you if you're healthy", "it helps me to be aware"
 - d) *Feeling more involved in their care*. E.g. "felt involved", "very involving", "more feedback"
5. "Do you feel more involved in your care with this test?"

Of patients taking aripiprazole, 100% answered yes. Of those taking clozapine, 79% answered yes, and the remaining 21% answered no.

4.4. Staff questionnaire

1. "How was your experience of the finger-prick test?"

All staff (n = 10; 100%) answered 'good'.

2. "Was collecting blood this way easier, harder or no different from the usual method?"

All staff answered that the POC test was easier to administer.

3. "How useful was it to know the patients' antipsychotic level, when they visited the clinic?"

All staff felt that knowing the patient's medication level was 'very useful'.

4. "Do you think patients would prefer this way of testing?"

All staff answered they think patients would prefer finger-prick testing.

5. "What did you like about doing it this way?"

Staff gave qualitative answers, including: "patients prefer finger prick", "less blood", "less pain", "guaranteed to get a sample", "much easier to obtain a sample from patients with small or obscure veins", "I like that it is easier and more simpler than taking bloods" "able to take immediate action or escalate if required", "quicker

Table 1 Patient sample.

Patients being treated with clozapine	(n = 84)
Male/Female	55/29
Age (years)	47 (21–75)
Duration of clozapine treatment (months)	144 (12–192)
Patients being treated with aripiprazole (n=22)	11/11
Male/Female	
Age (years)	30 (20–63)
Duration of aripiprazole treatment (months)	15 months (2 - 36)

results and can make changes to medication asap”

6. “Was there anything you didn't like about doing it this way?”

Staff gave qualitative answers, including:

“some patients complained of pain”, “it just takes practice with the technique of drawing the blood but once you have practiced it is fine”, “nothing, this way is very easy and quick”, “anomalous results need to be repeated requiring a 2nd fingerprick to be performed”

7. “Did knowing the level immediately allow you to provide better care?”

Staff gave qualitative answers, including:

“Relevant”, “unnecessary discomfort to patients”, “medication changes discussed face to face”, “doctors informed straight away”, “non-compliance can be identified, and we know what is happening with the patient at that moment rather than later”, “immediate results, allowing discussing then and there in the clinic, there is also no need to chase results from the laboratory after the clinic”, “facilitated faster changes to prescription and allowed the patient to be informed on their clozapine levels at the time of consultation”

5. Discussion

Our findings indicate that patients with schizophrenia find POC testing for antipsychotic medication levels highly acceptable and prefer it to conventional venous blood sampling. These findings were not specific to a particular patient group or medication: the acceptability in patients with treatment resistance taking clozapine was similar to that in first episode patients being treated with aripiprazole, despite the two groups being very different in age, duration of illness and antipsychotic treatment. We also found that clinical staff preferred the POC approach to venous sampling. These findings are consistent with data from a previous study in schizophrenia which demonstrated a patient preference for POC testing for physical health monitoring (Butler et al., 2020).

Our findings have implications for the application of POC testing in mental health care. If this approach is more acceptable to patients and staff than conventional blood monitoring, it should be easier to include the regular monitoring of medication levels in routine clinical practice. At present, monitoring of antipsychotic levels in the management of schizophrenia is mainly limited to treatment with clozapine, but monitoring could improve the safety and effectiveness of all antipsychotic medications. In the absence of monitoring, there is a risk that patients are given doses of medication that are either too low to be effective, or too high, increasing the likelihood of side effects.

Poor treatment adherence is a major issue in the clinical management of schizophrenia (Bitter et al., 2015). Monitoring medication blood levels allows clinicians to assess adherence more accurately than by asking patients (Day et al., 2005). The finding that POC testing is acceptable to patients is likely to facilitate the clinical implementation of monitoring. A further challenge in the management of schizophrenia is a lack of engagement with clinical services (Dixon et al., 2016). Our data suggest that using a POC approach can lead to patients feeling more involved in their care. This could help to improve their engagement with their clinical team, which has a critical bearing on outcomes in schizophrenia (Sendt et al., 2015; Morken et al., 2008).

Author statement

Matthew Atkins: Conceptualization, methodology, Supervision, Writing - Original Draft **David Taylor:** Writing - Review & Editing **Robert Harland:** Methodology **Aaron Brewer:** Methodology **Sophie Williams:** Methodology **Edward Chesney:** Methodology **Philip**

McGuire: Conceptualization, Writing - Review & Editing.

Ethics statement

This investigation was defined as a service development by our local Drug and Therapeutics Committee. Our trust policies dictate that medicines-related audits and service developments are considered by the Drug and Therapeutics and approved or modified by that committee. Ethical committee approval is only sought when it is considered to be appropriate by the Drug and Therapeutics Committee. In the case of this investigation, the committee approved it as a service development not requiring ethical committee approval or formal written consent from potential participants (SLAMDTC2020/3). All patients who had the fingerprick procedure by point of care were asked if they were willing to participate in this short survey. Only those who gave verbal consent were provided with the questionnaire to complete.

Funding

No funding was received for this study.

Declaration of competing interest

There are no conflicts of interest.

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