NHS
Birmingham and Solihull
Mental Health
NHS Foundation Trust

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Date: 4 September 2023

Mrs Louise Hunt
HM Senior Coroner for Birmingham and Solihull
Steelhouse Lane,
BIRMINGHAM B4 6BJ

Dear Mrs Hunt,

RE: Prevention of Future Deaths Report for Mr Khalid Mohammed Hussian (deceased)

Further to the Prevention of Future Deaths Report dated 12th July 2023, the Trust has now had an opportunity to review the Matters of Concern you have raised within the same. I would first like to begin by offering my sincere condolences to the Family of Mr Hussain for his very sad loss. As a Trust we have taken your concerns very seriously and have aim to act on these issues as quickly as possible to ensure lessons are learned to benefit other patients in the future. I will respond to each issue in turn;

1. **Monitoring of clozapine levels**

All blood test results including plasma clozapine assays are available from within Rio by a link to the 'ICE' results system provided by the laboratory.

In addition, all raised plasma clozapine assay results are reported to a specialist report that pharmacy staff have access to. These results are reviewed by the trust lead clozapine pharmacists. Where appropriate, the lead clozapine pharmacists contact the responsible clinician and team manager to highlight the result and need for the patient's clozapine treatment to be reviewed, particularly regarding dosage. It is especially important to ensure the result is 'trough' value i.e. the sample was taken around 12 hours following the last dose. This ensures accurate interpretation.

A number of training elements are being planned:

1. A recorded webinar by a consultant psychiatrist and pharmacist with significant experience in the use of clozapine will be taking place on 8 September 2023 and will be available for all clinical staff to improve the knowledge around clozapine including

interpreting plasma levels and what to do with them. This will also be available on the Trust Intranet for anyone who cannot attend on that date.

2. Development of a series of e-learning modules on the trust e-learning platform form the Learn It Online resource www.learnitonline.co.uk. Clinical staff will be able to access these as part of their on-going training to improve knowledge around clozapine. This is anticipated that the team will be able to take this to the Learning and Development Team by September 2023.

3. The Trust has multidisciplinary experts on the subject of clozapine. There is also expertise in the Pharmacy Clozapine Team; to support follow up of raised clozapine plasma assays but more importantly to support all teams involved with the use of clozapine with training in the handling of clozapine and promotion of the trust clozapine prescribing guidelines and procedures. This team is expected to be established by September 2023. All these colleagues will be made known to staff for any advice that is needed. Staff can also ask for help through their manager, who can signpost them accordingly. This will help improve the skills and experience in responding to results on clozapine levels appropriately with the care of the patient at the centre of all decisions.

2. Medication Changes

As part of the learning there will be clear guidance on prescribing on the electronic system and communication of how best to do this when a dose change is required.

Where a clinician may be new to the Trust there will be clear instructions to ask for support at the time of need and the line manager, team managers and clinical director will have processes in place to guide them to ensure they have the right advice.

The staff involved in this case are being asked to have reflective conversations around learning from this case.

3. How to record high clozapine levels

All blood test results are made available to staff in the ICE system, which is provided to us by our pathology service provider. This system is used both for ordering tests and reviewing results. It is accessed from within Rio and in patient context, so all staff have ready access to results. In common with most other systems, abnormal results are indicated within the system along with the normal reference range.

Clozapine levels are the only lab result which have a mechanism of routine reporting of high levels with pharmacy review and as such it has the greatest safeguards around it of any test used by BSMHFT.

The additional steps which are also mentioned in point one will ensure that clinicians will understand how to interpret results and actions are taken, in cases where this is necessary.

4. Understanding of clozapine

The Training is aimed to be in place to ensure that staff are confident in the use of clozapine and its monitoring in the future. We have sent an email to all prescribers about the need to record about decisions of care following a clozapine result that may be out of range, the need to ensure there is clinical review and this is documented.

5. August 2020 Regulation 28 Report

Following the last PFD in August 2020 the Trust made significant changes to the processes and procedures surrounding clozapine and its use. However this case has highlighted areas of learning. Consequently, the Trust has now put into place an urgent learning session along with future planned training and development to ensure staff keep up to date with this and learning is refreshed, alongside other additional support systems that have previously been introduced.

6. Quality of internal investigation process

Serious Incident investigations are carried out under the Serious Incident Framework (2015) and are conducted for the purposes of learning to prevent recurrence. As part of this investigation expert opinion was sought from our Specialist Clozapine Pharmacist; [redacted] [redacted], which were included within the body of the RCA and reflect a number of the issues you have raised.

As a Trust we would like to assure you that we have governance processes in place which provides oversight of the quality of our serious incident investigations and input into the recommendations based on the learning the investigation has found.

In this case the learning points were:

- The system for escalation of clozapine levels and monitoring and implementation of plan were not followed.
- Record keeping was not of a standard as expected.
- Clinicians were not clear on coordination of prescribing, ordering and delivery processes as part of EPMA and discussion via MDT was not used to clarify and ensure prompt action.
- There was a lack of understanding of how clozapine levels are to be interpreted and actioned.

On this occasion the following actions were identified and carried out:

- For there to be a review of the governance processes for the management of clozapine using the safety summit approach. In the short term as a mitigator the pharmacy team have prioritised the reviewing of the assay levels and the communication to consultants
- To improve the quality of record keeping the division has been working to establish a set of MDT standards is therefore recommended that the lead for this work provides an update to the local governance committee on progress and that the team manager ensures the projector is fixed and in the meanwhile alternative methods used to ensure this is done to a good standard.
- Given the service users care needs; a carers assessment should have been offered to the family. As a Trust this is a recognised area of improvement across all services and to support this piece of work there will be a review of the carer engagement tool. However, in the short term the team should have bespoke session from our carer engagement team.

7. Pharmacy Resourcing

As already mentioned in the first point, the Trust is developing a specialist Pharmacy Clozapine Team which will be closely linked into the trust multidisciplinary team,gro which should assist in ensuring that any concerns in the future will be acted upon and that where areas are identified where there is a lack of understanding, this team can support with learning to ensure that Service Users receive the best possible care.

Yours sincerely,

Chief Executive