NHS
Birmingham and Solihull
Mental Health
NHS Foundation Trust

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Mrs Louise Hunt
Senior Coroner for Birmingham and Solihull
50 Newton Street
Birmingham
B4 6NE

Our Ref:

Your Ref: Ian Allen

Date: 6 October 2020

Dear Mrs Hunt,

Re: Prevention of future death report Mr Ian Allen

Thank you for your letter of 17 August 2020 in relation to the concerns you had about Mr Allen's very sad death. I would like to personally offer my sincere condolences to Mr Allen's family. We have read and understood the points you have raised within your letter and have taken action in relation to this.

I felt it would be helpful to set out for you the existing governance around the prescribing and monitoring of Clozapine across our Trust before advising you of additional controls that we have established following the concerns that you have raised.

With regard to prescribing, monitoring and administering Clozapine we comply with the MHRA guidance and the guidance with regard to blood monitoring. There are a number of side effects of Clozapine and a particular risk with regard to agranulocytosis. As such, we follow a strict pre-initiation algorithm with regard to haematological monitoring. Full blood count is thereafter monitored weekly for 18 weeks, every 2 weeks for up to a year and monthly thereafter. Clinicians and pharmacy work with the National Monitoring Service in this regard. In relation to the monitoring of serum levels, we have followed the MHRA guidance. We undertake serum levels in a number of circumstances including whilst titrating the dose post initiation; where we have concerns regarding compliance or tolerability and where we are managing drug to drug interactions or changing smoking status. A key issue with regard to serum levels is that a trough sample must be taken in order to ensure 12 hours have elapsed since last dose of Clozapine and any deviation in relation to the 12 hour elapse period must be taken into account when clinically interpreting the results. The doses and serum levels needed to get the best clinical outcome are highly variable, and there are situations in which a high serum level (i.e. >600) is the lowest which can be used without there being a deterioration in the patient's mental state. Overall, it is important to consider the serum level as part of the overall clinical picture and balancing up all the various risks in the case, which are relevant to the particular patient.

Having considered the findings of the inquest of Mr Allen and the regulation 28 report, we have explored further opportunities to strengthen our existing systems as follows:-

1. **In February 2019 a blood test confirmed that Mr Allen had a high level of clozapine in his blood. This was not acted upon and no further blood test was taken. The clozapine dose was not adjusted as it should have been.**

We have commenced an audit of all patients prescribed Clozapine on Dr [redacted]'s caseload to ensure that there are no other patients for whom anomalous results have not been considered. In addition, we are in the process of issuing a practice alert to all of our Doctors reminding them of the importance of review when anomalous results are evident.

We have existing Multi-Disciplinary team meetings in place across our organisation and are now specifically strengthening the focus on physical health within these meetings utilising a quality improvement approach. This will provide an additional system for checking that periodic tests have taken place, ensuring that they are routinely acted upon when they are abnormal. Clozapine has now been added to this project to increase awareness.

In addition, we are working with our Post Graduate Medical Education training programme to utilise the learning from this regulation 28 report in the training of junior doctors on the use of clozapine and the importance of acting upon abnormal results where it is deemed necessary.

2. **There was no system in place at the time to ensure blood test results were escalated to the consultant to ensure action was taken.**

There is a system in place whereby anomalous results received are escalated to the Consultant, for example, via the Multi-Disciplinary Team meeting, the administrative staff in receipt of paper results or by junior medical staff who have checked electronic investigations; however on this occasion it appears that this failed. We have therefore put in place an additional control whereby our Information Team will send a report to the pharmacy Clozapine Lead of any results >600 so that these can be escalated directly to the Consultant and the Divisional Pharmacist so that appropriate action can be taken. This will include discussion and action where appropriate at the Multi-Disciplinary Team meeting.

3. There was a general lack of understanding at the inquest about the importance of monitoring clozapine levels and how frequently these levels should be monitored.

As you may be aware from the Mr [redacted]s evidence at inquest; the Trust is currently in the process of reviewing and updating the Trust Clozapine guidelines following the investigation carried out into Mr Allen's death. We understand that on 26 August 2020, in response to the Prevention of Future death reports from the Coroner there has now been an update in the MHRA guidance in relation to Clozapine.

The new guidelines published by MHRA are in fact similar to the current Trust guidance, although the wording of the monitoring level will be altered from 'may be useful' to 'must be carried out when attempting to determine adequate dose during initiation, to establish recent adherence, managing tolerability problems, managing drug on drug interactions or change in smoking status, when using higher doses and when there is a systemic infection'.

This guidance will be approved in November 2020 and once this has been completed, this will be disseminated round the Trust as a reminder to other staff to ensure that they are complying with the updated guidance. We have already provided all pharmacists with some additional training on Clozapine so we have more consistent advice and can respond quickly where necessary.

In addition, as we set out in response to your first point, further education will be built into the Post Graduate Medical Education programme to address any gaps in knowledge on clozapine. A safety alert is also being drafted and sent to all clinicians so that immediate action can be taken where necessary.

I would like to take this opportunity to say that we are taking this matter very seriously and are working hard to ensure that the correct processes are in place to support both learning for staff and ongoing care for patients who are prescribed clozapine to prevent re-occurrence. Patient safety is very important to us as an organisation.

If you require any further information, please do contact me.

Yours sincerely

[redacted]
Chief Executive