NHS
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NHS Foundation Trust

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Mr Z Golombeck
HM Acting Area Coroner
HM Coroner's Office – Manchester City Area
PO Box 532
Manchester Town Hall
Albert Square
Manchester M60 2LA

Sent via email to: p.crosby@manchester.gov.uk

Dear Mr Golombeck

Re: David John SMITH – Regulation 28: Prevention of Future Deaths

I have now had the opportunity to look into the concerns you raise in respect of this case. Manchester Royal Infirmary acknowledge that the care received by Mr Smith fell below standard and have taken a number of actions following this case to ensure that care provided to our patients is always of the appropriate standard. The response required from Manchester University NHS Foundation Trust related to the following:

1. the consent process
2. recording of the CMV status

I have provided information on both points below as they are intrinsically linked.

Concerns were noted at Inquest regarding the lack of communication to Mr Smith regarding the donor's positive CMV status. There were also errors in correctly documenting the donor and recipient CMV status on the operation note leading to a failure to provide the recipient with the relevant medication. This was identified within the Trust's internal investigation and a number of actions were put in place to address this. I have provided the detail of these below.

It was acknowledged that the consent process regarding the communication of donor risks, particularly CMV status, needed to be more robust and comprehensive so that all recipients are fully informed before transplantation.

The consent process for transplantation has been strengthened all along the listing pathway, and all recipients are specifically informed during the assessment about CMV infection and its effects, morbidity and mortality. If they are being offered transplantation with a CMV positive kidney when they are CMV negative, they are considered high risk for developing CMV infection. This is discussed prior to transplantation with the recipient during the consent process and specifically documented.

Mr Smith's operation note had inaccuracies recorded with regard to donor kidney details as noted at Inquest. At the time of the transplant, some of the donor organ details were not available. In order to address this, a formal check process within 48 hours of transplantation and independent to the ward based team was implemented. This process is led by the Transplant Coordinators and includes a check of all donor and recipient documentation including the CMV status. This is then documented on the transplant flow chart. This process was reviewed after implementation, to ensure that it delivered the required assurance. Following this review, it was further amended in order to include the ward pharmacist providing a further independent check of the documentation as part of the established medication review process. This was considered to be a more seamless approach and provide a level of independence to the team reviewing the documentation. In order to support this, Pharmacists have been trained to confirm the CMV status from the original source i.e. the recipient status from ICE (electronic test results system) and the donor status from the National Electronic Offering System (EOS) form. I can confirm that this process remains in place.

The renal transplant patient discharge summary letter was also redesigned to incorporate relevant donor details including the donor and recipient CMV status. This was to provide a further level of assurance and robustness in the communication processes. It was also identified that operation notes are completed at the end of complex surgery and that could often be undertaken by on-call staff, therefore there was a requirement to review the electronic process for the completion of operation notes in order to reduce the risk of errors. I am able to confirm that following a review of the processes and systems in place, all transplant operation notes are commenced on a new operation template, so that there is no risk of transcription error. All operation notes are also reviewed by the responsible consultant after surgery for accuracy.

We acknowledge that the care of CMV patients can be complex and there is a requirement for expert overview and monitoring over an extended period of time for this cohort of patients. As a result of this, we undertook a review of the outpatient team and clinical follow up processes to look at creating continuity of care, and ensuring that there was overview of care at Transplant Nephrology Consultant level for patients with complex medical needs. In order to provide this in a robust and consistent way, a substantive post for a nephrologist with an interest in transplantation has been appointed to the Trust. A fourth nephrologist post for transplantation is planned and awaits business case and funding review.

As a further mechanism for the review and monitoring of the care of this complex cohort of patients, a weekly multi-disciplinary team meeting was established. This takes place on a Thursday afternoon and on review is working effectively and efficiently. Core attendees to the meeting include a Consultant Nephrologist, Consultant Virologist, Renal pharmacist and a senior nursing representative from the Transplant outpatients.

At the meeting, all virology results from the previous week are identified on reports from the virology lab and patients with positive results are presented and taking into account their clinical background, suggested management plans are drawn up.

Ever since this clinic was introduced there has been a demonstrable reduction in the number of CMV cases with the number of inpatient days of patients with CMV reducing from 162 to 38 after the introduction of the MDT. An audit of the impact of the clinic was presented at the Transplant Audit and Clinical Effectiveness day on 19 September 2019. A copy of the audit can be provided if required.

In order to support the appropriate provision of medication intervention, there is a process in place to identify for screening all patients due to stop prophylaxis; and the Pharmacy team generate a weekly report of those patients on CMV antiviral prophylaxis to confirm the appropriate dosing regime. This is further supported through the Virology team sending daily alerts to the Renal team listing all new CMV positive samples from renal patients.

These processes also ensure that all relevant information is provided for the discussions with recipient patients, in order for them to make an informed and educated decision regarding the consent process for the procedure. We acknowledge that the incomplete form in Mr Smith's case led to him not being aware of the CMV status of the donor, therefore he was unable to provide fully informed consent.

It is also worth noting that there is a virology and renal collaborative clinical research study on cellular immunity to CMV taking place, with the aim of improving patient management.

The Trust remains wholly committed to full implementation of the learning from this case, a case which is still raised and discussed at improvement meetings, and will continue to implement improvements based on the learning.

Please accept my assurances that lessons have been learned from this case and appropriate actions have been put in place to address the issues raised. If you require anything further then please do not hesitate to contact me.

Yours sincerely

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Joint Group Medical Director / Responsible Officer