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NHS
Salford Care Organisation
Northern Care Alliance NHS Group

If calling please ask for: [redacted]

Our ref: JS/SJB

Date: 20th November 2018

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Mr Walsh
HM Area Coroner
Manchester West
HM Coroner's Court
Paderborn House
Howell Croft North
Bolton
BL1 1QY

Dear Mr Walsh

RE: MR JOHN WAITE

I am writing to you on behalf of Sir David Dalton, Chief Executive, in response to your Regulation 28 Report sent to Salford Royal NHS Foundation Trust on 26 September 2018. Your report related to the death of Mr John Waite on 11 March 2018, whose inquest was concluded on 10 September 2018. At the outset please accept my sincere condolences to the family of Mr Waite.

Mr Waite's sad death was in part as a result of a haemorrhage following the removal of a femoral dialysis line, which you found to be a rare but recognised complication.

Following Mr Waite's death the Trust took steps to raise awareness of this issue with the UK Renal Association and British Renal Society and I am grateful to you for highlighting this case to these organisations so that national guidelines may be considered.

The Trust welcomes further guidance from the relevant national bodies and will further revise its protocols upon receipt of this.

The Trust is also grateful for your acknowledgment that a considerable amount of work has been undertaken in response to the concerns raised in Mr Walsh's case. However, within your Regulation 28 Report you asked the Trust to further review the policy and protocols in place since Mr Waite's

death to consider the constant visual observation of a patient for one hour following the removal of a central venous catheter (CVC).

There are a large range of CVC products available for different clinical indications. In considering our actions to address the specific issues identified in the prevention of future deaths notice, we have focussed on the CVCs used for the purpose of renal replacement therapy, however, our actions relating to training, competences, guidance and policies will incorporate all CVCs.

The Regulation 28 report also asked the Trust to review the Information Technology (IT) systems as you heard evidence that one witness had amended the author time of her electronic record to represent the time the action was taken, rather the time the note was made. The Trust agrees that all retrospective records should include the time of any action taken as well as the time the note was made.

Please find below details arising from the Trust's review of its policy and protocols in addition to its IT systems relevant to the circumstances of this death:

Review of policy and protocol related to the removal of central venous catheters
A CVC task and finish group was established in August 2018 with the first meeting taking place on September 6th 2018. Membership of the group includes medical and nursing staff from wards and departments that routinely use CVCs including Renal, Emergency Department, Critical Care, Medical High Care, Coronary Care, Anaesthetics, and also specialists who are able to inform the work of the group including infection control, education and training and the IV team. A key objective of the group is the review of documentation and guidance including the Trust CVC policy, development of a quick reference guide detailing the required observation post CVC removal (QRG), procedural checklists and EPR.

The policy is currently going through Trust approval processes and then will be widely disseminated.

Visual observations post CVC removal
The CVC task and finish group has reviewed all clinical incidents reported relating to central venous catheters since 2008. Over a 100 CVCs are inserted per month on average. Over 10 years there have been 150 safety reports relating to CVCs of which only 2 relate to bleeding post removal. One was Mr Waite's case. In the other a patient experienced a significant but non-fatal haemorrhage from a CVC line site forty eight hours after its removal.

We therefore feel that directly observing the patient for one hour post CVC removal would not provide assurance that haemorrhage leading to harm would not occur. Additionally, requiring staff to practise in this way may introduce unintended risks to other patients within the clinical area due to availability of staff.

We have introduced guidance for staff to undertake a risk assessment prior to removal of CVCs. If the patient is deemed to be high risk for haemorrhage post removal, the nurse will discuss the observation plan with the senior medical staff prior to line removal. This will include a review of the

timing of line removal (to ensure sufficient staff are available), location of the patient (avoid side rooms whenever possible), correction of bleeding abnormalities if required and observation plan which would include direct observation in the high risk patient group for 60 minutes and the formal recording of physiological observations every 15 minutes.

The patients will also be informed of the risk of bleeding post line removal and the need to remain supine for thirty minutes (when physically able) and then a further two hours of bed rest. Hourly intentional rounding is also carried out on all patients. A formal patient information sheet has been developed and is being tested with patients and families.

Location of CVCs
The practice in renal medicine is to use femoral veins to insert CVCs for renal replacement therapy. These patients often have difficult venous access and the veins in the neck are preserved wherever possible.

The practice of removing a CVC from a femoral vein differs to that of removal from a neck vein. This detail will be included in the Trust policy and protocols and in training provided.

A quick reference guide describing the procedure for removal of central lines used for the purpose of haemodialysis has been developed and is now available on the intranet. The Trust Central Venous Catheter Policy is being reviewed by the task and finish group and will link with the quick reference guide.

Electronic record keeping system
We would like to offer assurance that where alterations are made to the date and time of a clinical note that this is always clearly displayed in the header text of a document. The electronic record has a full audit trail of any corrections made. However when the note is "backdated" this can result in a note appearing before other written notes in the chronology of care.
I apologise that at the inquest the staff available did not have the in depth knowledge required to discuss the functionality within EPR to alter the date of documents. This functionality is not routinely taught to our teams so many users are not aware of it. The feedback from practitioners is that they believed this was the correct way to ensure their documents appeared at the time they met the patient, and this practice had spread through good intentions which were incorrectly applied.

A full investigation has been completed. We have not identified any episodes where an individual's care was adversely affected by a note being "backdated".

This functionality is a fundamental part of the electronic records and affects more than just documents. It has a number of essential and important uses so cannot be switched off.

We would expect, where retrospective notes are made, that these are recorded at the time of entry with clear reference that this is a retrospective note.

We are already incorporating a "date and time seen" field into our new documents so that they are authored at the correct time, but with a field to show if the time seen differed from the documentation time.

We have issued an urgent bulletin to all EPR users with guidance on how retrospective notes should be made (i.e. authored time not to be changed but captured as time written and annotated notes then to incorporate "written in retrospect, pt seen at time X").

We are also redesigning a number of individual user guides for EPR into a single Good Practice guide to address issues that may arise around the use of electronic patient records.

I hope that this response provides assurance to you and Mr Waite's family that Salford Royal Foundation Trust has worked hard and continues to focus on ensuring that lessons have been learned and improvements have been made.

Please do not hesitate to contact me if you require any further information in relation to our response.

Yours sincerely

James Sumner
Chief Officer, Salford Care Organisation

Enc: Exhibit A – Combined QRG and Visual Observation Chart