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Date: 1 March 2024

Mr Kevin McLoughlin
HM Senior Coroner
West Yorkshire (Eastern District)
HM Coroner's Service
71 Northgate
Wakefield
WF1 3BS

Dear Mr McLoughlin

Re: Inquest of Samantha Jade SHILLITO (dcd) – 28.04.1983 to 27.02.2022 – 1488090 – Case No. 28621

I am responding on behalf of Mid Yorkshire Teaching NHS Trust (MYTT; the Trust) to the Regulation 28 Report to Prevent Future Deaths that you issued to the Trust and the Royal College of Radiologists on 1st December 2023, upon conclusion of the above inquest.

The Matters of Concern raised in your report were:

1) *There were no relevant specialist consultants in the hospital on the night of Friday 25/2/22, during Saturday 26/2/22 or on Sunday 27/2/22. Ms Shillito had a NEWS score which would have triggered an escalation of her treatment, but she was neither reviewed, examined properly or subjected to further investigations (such as blood tests and/or a CT scan) to establish the cause of her deterioration. Evidence was heard at the inquest from a consultant hepatologist to the effect that this was a missed opportunity to initiate remedial action when her deterioration could have been halted and her condition improved.*

2) *The ascitic tap procedure was said to be commonly undertaken and was regarded as low risk. The inquest was, however, unable to establish the magnitude of the risks of bleeding, infection or perforation of surrounding structures by reference to the medical literature or statistical evidence. How then can it be said to be a low-risk procedure if the inherent risks have not been quantified? This was viewed as a national (if not international) problem, which requires published evidence to inform radiological practice.*

3) *The practice at the hospital was to obtain verbal consent to the procedure from the patient in the minutes before it took place. A consultant radiologist acknowledged that the risk of death was not mentioned to Ms Shillito. It is questionable whether this can be considered to be a patient's informed consent when the risks outlined are not reliably established, are not explained and the patient is not asked to sign a document. If there is a risk of death, irrespective of its rarity, the patient is entitled to be informed. This concern is highlighted when*

one considers the patient's medical condition and their likely emotional state, in circumstances which allow no time for reflection or discussion with other family members. It appears that no leaflet describing the ascitic tap procedure and the associated risks has been provided either by the Royal College of Radiologists or the hospital.

4) *Ms Shillito's family were not made aware of the seriousness of her underlying illness. No effective communication was provided to them even on Sunday 27 February to help them appreciate the gravity of her situation. Her husband and her mother informed the inquest that they had not been told that she might die. In consequence, the shock of her death on the evening of Sunday 27 February 2022 was all greater. It acknowledged that this concern did not contribute to Ms Shillito's death, but it underlines the need for compassion and candour when dealing with patients and their families.*

I would like to thank you for bringing these matters to MYTT's attention and for the additional time you've granted the Trust to provide its formal response. We have carefully considered and discussed the concerns you've raised and their implications for the Trust. Following a review of our processes, we will implement a number of measured actions in response as outlined below.

Weekend coverage by Consultants and responding to deteriorating NEWS

Specialist consultants are always available to be contacted out of hours and weekends if needed to provide advice and support for other clinical staff or to return directly to the hospital within a short time period if required. At any given time there are therefore varying numbers of specialists within the hospital grounds. Across specialties a minimum of 25 Consultants are present during weekends. Some specialities do have a fixed onsite 24/7 presence during and others provide an on call service with expectations of a direct return to site if needed within a maximum of 30 minutes.

The Trust also has escalation protocols in place to recognise when a patient's condition deteriorates, with appropriate response pathways prescribed. However, we know these protocols require regular review to be assured they are fit for purpose and are continually improved locally, and across the NHS. We undertake ongoing education with our teams of nursing, allied health professions (AHP) staff, and junior doctors so that when deterioration of patients occur, they promptly receive correct specialist input and treatment.

In addition we have recently introduced the Deteriorating Adult Response Team (DART) previously called the Critical Care Outreach Team (CCOT) as a 24/7 service. This multi professional team provides an initial response when patients with deteriorating NEWS are identified. Guidance for referral includes a NEWS of 7 or more, an increasing oxygen requirement of above 40%, or if there are any concerns about a patient deteriorating (irrespective of their NEWS / oxygen requirement).

We have augmented this service and also launched the Call 4 Concern patient safety initiative (based on Martha's rule). This enables a patient or family member to seek help or advice if a patient's condition deteriorates. A new phone number is publicised on wards which connects to members of DART for a response. Patients and family members can call for help or advice if:

- they see a noticeable change or deterioration in the patient's clinical condition
- they feel a healthcare team has not recognised or responded appropriately to this deterioration.

When DART receives a Call 4 Concern the team will review the patient's notes, observations and NEWS2 scores on PPM+. They will then advise the ward team and/or directly support ongoing management of the patient's care.

Quantifying the risks of ascitic tap procedure

As an organisation that provides healthcare, we rely on various sources of information to enable us to quantify the risks of any procedure. The majority of this information is sourced from guidance issued by specialist societies, royal colleges, or developed through literature evidence base/local audits etc. In the instance where there is an absence of specific quantifiable risks, best practice is to inform patients of potential complications with indicative likelihoods of these occurring. For an ascitic tap it is felt to be very low risk based on the experience and judgement of the health professionals involved. Decisions to proceed with an intervention would also be balanced against the risk of not proceeding with an intervention

At the inquest you specifically noted that the Trust did not, and indeed could not, provide definitive advice to Ms Shillito quantifying the magnitude of the risks of bleeding, infection or perforation of the surrounding structure, in relation to the ascitic tap procedure. You also noted that this was a national (if not international) problem, requiring published evidence to inform radiological practice.

Therefore to address this concern fully, we welcome any advice from the Royal College of Radiologists (also issued with this regulation 28). In the interim, however, we continue to work with our clinical teams to support appropriate risk/benefit assessments by the healthcare professional and consideration of these risks/benefits with patients prior to a procedure.

Consenting for ascitic tap procedure

As you are aware, the process of consenting a patient for a procedure is an ongoing one that starts with a conversation with the patient about treatment options and culminates with the signing of the consent form. The form itself is merely the final "ok" from the patient to go ahead after a number of steps have taken place over a length of time, to obtain fully informed consent from the patient.

All treatment/interventional options ranging from the most benign non-invasive option such as a prescription for antibiotics or a blood test, to a highly invasive procedure, require informed consent from a patient before commencement, whether that consent is implied, verbal or written. It is generally accepted that the greater the impact of a known risk occurring, the more important fully informed and documented consent is obtained from the patient. Arguably the risk of death, no matter how remote, exists with almost every treatment and many diagnostic interventions offered. However, it would not be practicable for written consent to be obtained in every instance and, for many treatment options, verbal consent is deemed acceptable clinical practice.

With regard to patient information leaflets, we do use patient information leaflets for many procedures but not universally for those procedures that are perceived to be very low risk. I acknowledge that in my own exploration of this concern I have identified several NHS Trusts which have information leaflets for a diagnostic ascitic tap procedure (needle removal of a small amount of fluid) and/or the more invasive paracentesis (usually implied as insertion of a drain to remove larger volumes of fluid). None of those leaflets specifically mention the risk of death. We will, however, review our patient safety leaflets in accordance with relevant guidance from professional bodies such as the Royal College of Radiologists and British Society of Interventional Radiology to

ensure we are supporting patients with the most contemporary medical advice to help make best informed shared decisions about their care.

Communication with families

I fully recognise the requirement for compassion and candour with patients and families as part of their medical care experience. I am sorry that our communications with Ms Shillito's family fell below the high standard we strive to achieve, and that they were entitled to expect. The Trust has wholeheartedly embraced the NHS's changed methodology for investigating patient incidents / events through the new national Patient Safety Incident Response Framework (PSIRF), where patients and families have a greater voice and involvement. Aligned with this philosophy, the Trust is actively promoting a more compassionate and inclusive approach by staff/clinicians in all communications with patients and their families. We continue to work with our healthcare professional team members to embed this change in order to ensure appropriate communication with patients and their families regarding the care they receive occurs.

In closing, I acknowledge that your concerns arose out of your investigation into the death of Ms Shillito, and on behalf of Mid Yorkshire Teaching NHS Trust, I would like to take this opportunity to offer our sincere condolences once again to Ms Shillito's family in relation to her death and the impact this has had on them.

Yours sincerely

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Chief Medical Officer