East Lancashire Hospitals
NHS Trust
A University Teaching Trust

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12th July 2024

Dr James Adeley
HM Senior Coroner
Lancashire and Blackburn with Darwen
[redacted]

Sent via email only

Dear Dr Adeley

Regulation 28 Report – Response by East Lancashire Hospitals NHS Trust
Inquest relating to the death of Antony Waring

This letter comprises the formal response of East Lancashire Hospitals NHS Trust ("the Trust") pursuant to section 7(2) to Schedule 5 of the Coroners and Justice Act 2009 and Regulation 29 Coroners (Investigations) Regulations 2013, to the issues raised in the Regulation 28 Report to Prevent Future Deaths, dated 17 May 2024, made following the inquest into the death of Antony Waring, which concluded on 12 April 2024.

I would like to start the response by offering our sincere condolences to Antony's family for their loss. The Trust fully accepts the findings of HM Coroner and are truly sorry that Antony did not receive the treatment and care we would expect him to receive.

The Prevention of Future Deaths report identifies a number of areas of concern, and I will address these in this response, with details of the actions we have undertaken and those that we plan to undertake in the near future, along with details of the improvements made to date.

Matters of Concern

(1) The Trust made no progress on the introduction of an SOP recommended in the internal review for almost 4 years. A draft SOP had been proposed in the weeks leading up to the inquest.

Response

I am pleased to confirm that the Trust's SOP for 'Minimising the risks of supra-pubic catheter insertion in complex cases of patients who have had previous abdominal or bladder surgery' has now been approved and ratified following the inquest hearing.

The Trust would like to assure both HM Coroner and Antony's family that the SOP has been embedded as an additional safety mechanism as a result of additional learning. Following the evidence heard at Mr Waring's inquest the Trust has reflected on the guidance that was in place at the time and made the necessary changes to the clinical processes. The Trust SOP does not replace the British Association of Urological Surgeons ("BAUS") SPC (suprapubic catheter) 2020 guidelines but is to be used in conjunction, with careful consideration of the individual patient on a case by case basis.

The SOP is for all healthcare professionals involved in the assessment, planning and insertion of a suprapubic catheter in 'non-routine', complex cases where a patient has a previous history of bowel, bladder or abdominal laparoscopic surgery, and is in accordance with the BAUS suprapubic catheter practice guidelines.

As an organisation we constantly strive to improve patient safety and I can confirm these changes have been confirmed by both the Urology and Radiology Departments. In order to ensure the SOP is fully embedded, an assurance process is now in place for monitoring and escalation, with regular audits being introduced and associated assurance reporting.

The Clinical Director for Urology has confirmed that all clinical staff are aware of the new guidance and how it is implemented. This process will be audited annually by the Clinical Director and any deviation from policy will be escalated as part of the Trust's incident reporting framework. I am advised that since Mr Waring's inquest an SPC incident was raised and a Patient Safety Review undertaken, which confirmed that all appropriate steps were taken and the BAUS SPC 2020 guidelines followed.

(2) The expert evidence at the inquest was that the Trust's proposed action plan using CT scanning at an unspecified time before a suprapubic catheter insertion was sub optimal and inferior to ultrasound as bowel may move between the date of the CT scan and the catheter insertion.

Response

As indicated above at point (1), the Trust has reflected on the evidence presented at Mr Waring's inquest and changes have been made to clinical processes in place with the introduction of the SOP for 'Minimising the risks of supra-pubic catheter insertion in complex cases of patients who have had previous abdominal or bladder surgery'.

With regards to the concern regarding ultrasound scanning I can confirm that under the new SOP complex SPC insertions are now listed as a scheduled joint procedure with a Consultant Urological Surgeon and Consultant Radiologist in the theatre suite at Royal Blackburn Hospital. This will ensure the availability and presence of a Consultant Radiologist (with expertise in ultrasound scanning) and the ultrasound scanner itself.

These patients will be listed as 'complex SPC catheter insertion' and the procedure will be undertaken by the designated responsible Consultant Urologist who has seen and counselled the patient (rather than being placed on a core/pooled urology waiting list).
The new process under the SOP is specifically applicable to those who are at higher risk of bowel injury during SPC insertion and include those:

- who have undergone previous lower abdominal surgery, bowel surgery (including laparoscopic surgery, where the bladder has been mobilized), bladder reconstruction procedure, complex open or laparoscopic pelvic/gynaecological surgery;
- with a lower abdominal scar where the nature of previous surgery is not known; and

- where there is an inability to distend the bladder sufficiently.

All routine, non-complex SPC insertions will continue to be undertaken in compliance with the British Association of Urological Surgeons (BAUS) guidelines for the insertion of SPC 2020.

(3) in the four years since Antony Waring's death, the Trust has not provided a single ultrasound teaching session provided by the Trust to any consultant who is not capable of using ultrasound.

Response

I can confirm that Suprapubic Catheter placement is only performed by clinicians who are trained and confident to perform that procedure.

All Consultant Urologists are trained to scan patients to a standard level, however cases such as Mr Waring's are extremely rare and complex, and requires a level of scanning expertise and skill that is practically not feasible to train Urology Consultants up to. Therefore on these occasions a Consultant Radiologist is now required to use the ultrasound scanner as indicated above.

Under the new processes in place at the Trust, complex SPC insertions are listed as a scheduled joint procedure with a Consultant Radiologists who is trained and has the expertise to use USS (ultrasound scanning).

(4) the allocation of high-risk patients to Core Lists where a specific ancillary prophylactic measure such as ultrasound is left to either chance or to an administrator.

Response

By way of assurance I would like to clarify the process the Trust has in place for identifying high-risk patient procedures and ensuring theatre lists ('Core Lists') are managed appropriately.

I can confirm that weekly meetings are scheduled to review each individual theatre list and these are attended and led by the Trust's Clinical Director for Urology. At each weekly meeting the individual theatre list for the next two weeks is reviewed, looking at each individual patient case and ensuring that these are suitable.

Once the lists are fully booked, a finalised theatre list is sent to the treating clinician who will check the suitability of patients as well in advance of the surgery taking place.

On the day of the procedure itself, a pre-list check and brief is already embedded within theatres In which equipment is discussed including if the ultrasound machine is required, and the Surgeon receives this list in advance. A post-list debrief also takes places to identify any concerns or any opportunities for learning.

(5) The expert evidence at the inquest was that the research provided on the risk of complications after insertion of a suprapubic catheter into patients with lower abdominal surgery is inappropriate the patient such as Antony Waring and provides false reassurance as to the level of risk posed to these patients.

Response

The Trust has reflected on the evidence and research presented at the inquest, and has subsequently introduced changes to clinical processes as outlined above.

I hope that I have provided reassurances around the steps that we have taken to address the issues of concern contained within your report. I would like to assure you that the Trust takes your concerns extremely seriously, and, as a learning organisation, constantly strives to improve the clinical services it delivers to patients.

Our thoughts remain with Antony's family.

Yours sincerely,

Martin Hodgson
Chief Executive Officer