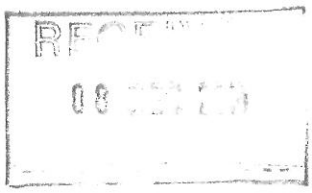
Tameside Hospital NHS
NHS Foundation Trust

Chief Executive Office
Silver Springs
Tameside General Hospital
Ashton-Under-Lyne
OL6 9RW

Our Ref: [redacted]

Date: 5 December 2014



Mr Pollard
Senior Coroner
Coroner's Court
1 Mount Tabor Street
Stockport
SK1 3AG

Dear Mr Pollard

Mary Fenton (deceased)

I write further to your letter dated 14 October 2014 enclosing a Regulation 28 Report issued at the conclusion of the inquest concerning the death of Mary Fenton, which took place on the 8 October 2014. I am very sorry that you found cause to issue this report and I hope to be able to address your concerns to your satisfaction in this letter.

I understand that during the Inquest a number of matters of concern were revealed. I have addressed each of your concerns as set out in Section 5 of your Regulation 28 Report in turn below. Please note that I have dealt with the concerns numbered 1, 6, 7 and 8 together as they all relate to the provision of pacing at the Trust and also concerns 4 and 5 together as they relate to the assessment of mental capacity and consent.

Dealing with the concerns raised in your Regulation 28 Report:

1. **Although Tameside Hospital holds itself out as performing pacemaker insertions, both temporary and permanent, no Cardiology Consultant is on call after 5:00 pm or at weekends. There is therefore no one available to the junior staff having the requisite levels of skill and expertise to advise.**

6. **Despite this being a major District General Hospital providing cardiology cover for a large proportion of the population of Greater Manchester, there is no-one with the skill or qualification to fit "temporary/permanent" pacing wires.**

7. **There were inexcusable and potentially catastrophic delays in inserting the pacing wires.**

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8. **It was demonstrated by the evidence that if there should be a situation where the placing of the pacing wires causes unforeseen problems (e.g. by causing bleeding within the pericardium leading to cardiac tamponade) there is a lack of adequate facilities to address that situation.**

Following the Inquest in to Mrs Fenton's death a review was undertaken by the Trust into the provision of pacing procedures out of hours. The Lead of the Cardiology Department was charged with organising an on call rota for pacing wires. The rota became operational on the 10 November 2014 and provides for a Consultant Cardiologist on-call to cover all emergency temporary pacing and pathway. The service is available 24 hours per day, every day of the year. The on-call rota for temporary pacing wires is shared with the hospital switchboard and CCU. The rota provides for out of hours cover by the following Consultant Cardiologists – [redacted] This is currently being provided with nursing support via the Night Nurse Practitioner and Level 2 / CCU nursing staff on shift.

There is also now a cardiac pacing room in theatre 4 and all equipment therein is operational. Relocation took place in September 2014 and this facility provides an in-hours and out of hours provision for all cardiac procedures, revisions and repairs and all Cardiologists are capable of carrying out emergency cardiac ultrasound to deal with very rare complications. Also, the old pacing room that the Trust was making use of is no longer required for pacing and the Trust is currently considering whether this could be used to expand the CCU area.

As a result of the review a Temporary Pacing Wire Pathway has also been created, a copy of which is attached.

2. **After 5:00 pm there is no facility for an echocardiogram to be performed at the hospital.**

Currently, the provision of echocardiogram services is undertaken as a day case service between the hours of 9.00am and 5.00pm and this existing service is provided by the specialist CRI technicians. Due to the existing capacity and demand for the service, the existing provision can only currently provide an in hours service. Echocardiograms are and have been undertaken by qualified Consultants and Staff Grade Doctors as and when required. Going forward, the recent external cardiology service review and your concerns following the inquest into the death of Mrs Fenton have formed the basis for a service review specifically around the provision of CRI services. As part of this review, the procurement of a portable echocardiogram machine and out of hour provision is being explored as part of the wider service developments.

3. **This patient was being kept alive by the use of isoprenaline. It transpires that there were severe shortages of this drug in the hospital but also nationally. I was told that this drug is produced as an unlicensed drug by NHS Pharmaceutical Productions. If so why do they not ensure sufficient supply?**

The Trust currently keeps a supply of 200 ampoules of Isoprenaline supplies in stock. This would last a patient approximately 17 calendar days if prescribed in the same dosage as that provided to Mrs Fenton. The Trust has replenished its stocks following the end of the national alert on the Isoprenaline shortage due to manufacturing difficulties in August/September 2014. Actions have also been taken to ensure that within Critical Care there is safe storage

and adequate medication and that staff regularly check this. The Principal Pharmacist and Critical Care Pharmacist undertake regular audits.

Where there is a shortage and we are unable to maintain supplies due to the national shortage every effort is made, both by the pharmacy team and the local network, to ensure that stocks are maintained. The Trust is aware that medicine shortages are occurring more frequently in the UK and globally for a variety of reasons. At any one day there can be 20-30 different products for which there are concerns about continuity of supply. Some of these have simple solutions but increasingly a large number have the potential to cause risks to patients. The guiding principle must be that appropriate medicines should be available for all patients. However, the role of our Chief Pharmacist is to ensure that no action is taken within the Trust which can exacerbate a medicines shortage within the greater NHS. The Trusts average stockholding for all products in our inventory is approximately three to four working weeks and stocks are typically replenished when minimum order stock levels are reached. As a Trust we are expected to work collaboratively across regions to avoid duplication of work on risk assessments, by sharing stock, seeking procurement alternatives and production of clinical advice, and our Chief Pharmacist reassures me that this was certainly done with Isoprenaline.

There are well developed systems in place to communicate shortages of drugs in a timely manner. Typically the information on a medicines shortage is derived from the pharmaceutical industry or from the Department of Health / NHS England or the Commercial Medicines Unit. They provide as much supporting information as possible to allow the Trust to take appropriate action in order to mitigate any possible effects on patient safety. This is very much a national and global issue which affects every hospital pharmacy in the UK and it is an issue on which an increasing amount of time is being spent in trying to resolve. All stakeholders in the pharmaceutical supply chain are aware of the current issues and the Trust understands that the NHS is exploring better ways to manage and communicate those situations. At present, the Trust is aware that a nationally available website is being developed for medicines shortages information which should contain up to date information on shortages, their duration and recommending actions that are available. However, if it is considered that the Trust should escalate local concerns nationally then I, supported by our Chief Pharmacist, will direct our concerns to the appropriate individuals at the Department of Health.

Also, the Trust does have a protocol in place which is followed when any shortage arises. This involves conducting a risk assessment to evaluate the potential effect of the shortage and the assessment takes account of the estimated duration of the shortage; usage figures; the availability of suitable alternative products; and the potential risk to patients. As you will appreciate, not all shortages will need further action but where the risk assessment supports further work on a long term critical shortage, the Trust's Pharmacy Department makes an estimate of the stock in hand within the entire organisation and of the time period this will cover. Where limited stock might lead to a restriction being placed on the use of a medicine, then this restriction will be discussed and agreed with the most relevant and appropriate Senior Doctor within the Trust. Thereafter, this will be communicated immediately to relevant hospital staff, to ensure patient safety and prevent medication errors. Please be assured that this protocol along with the other processes discussed above will be reiterated to the Trust's Pharmacy Department.

Please be assured that the Trust finds any shortage of drugs unacceptable and we are doing everything within our power to ensure such shortages do not impact upon the care our patients receive. The Trust does have a strong contingency plan in place and in the case of Mrs Fenton this was evidenced by the incident itself whereby the Trust utilised local networks to ensure continuity of supply. Following the inquest into the death of Mrs Fenton, the Trust has reviewed all incidents relating to the Pharmacy Department and we cannot identify a case where the Trust has not been able to supply either a medicine experiencing a shortage or a clinically appropriate and suitable agreed alternative for a patient. The Trust does realise that there might not always be a straightforward alternative but I would like to bring to your attention a recent example where there has been a national shortage of Acetylcysteine Injection which is used in every hospital centre for the management of a paracetamol overdose and is the standard treatment. This shortage has gone on for several weeks but has been managed effectively by hospitals sharing intelligence on stockholding and transferring stock between organisations if urgently required. Such a potentially significant shortage has not been perceived as an issue locally and the Trust has maintained their stocks.

4. **There was a failure of the medical staff to assess and/or document the mental capacity of the patient**

5. **There was a failure of the medical staff to obtain "consent" to treatment or to document why such consent was unavailable and why they were "self-consenting".**

The Trust has employed a specialist nurse in safeguarding adults, MCA and DOLS to support medical and nursing staff and to ensure that a thorough and correct assessment relating to mental capacity is completed and that any decisions made are made in the best interests of the patient. During 2013/14 the Trust has seen a significant increase in activity (146%) and profile of adult safeguarding. Therefore, an assertive training programme has been put in place and we have seen over 828 staff trained to date. The Trust's solicitor, Weightmans have also been utilised in providing training and they have provided an extensive training course throughout the year titled "The Legal Principles of the Mental Health Act; Mental Capacity Act and Deprivation of Liberty".

The Trust's Policy for Consent to Examination or Treatment deals with the obtaining of consent for treatment, in situations where the patient has capacity and in situations where it is deemed the patient lacks capacity. I can only apologise for the actions of the particular individuals concerned in the care of Mrs Fenton in that the Trust's Policy does not appear to have been followed in these circumstances. I have described the actions that are being taken in respect of the individuals concerned further below.

10. **There was very poor communication between staff and other staff, and between staff and the family of the deceased and the patient herself (e.g. in relation to DNAR notice, consent forms etc.).**

The Trust is striving to improve communication between clinicians, patients and family members. The Trust has created a bedside booklet, available for patients and relatives – "Patient Safety – Keeping you safe during your stay in hospital". This empowers patients and their families to ask questions.

In May 2014 the DNACPR policy was reviewed in line with *R (on the application of David Tracey) v Cambridge University Hospitals NHS Foundation Trust* to involve discussion with patients/their families. A DVD was created and is available on the Trust's intranet. The review of the policy was promoted through screensavers, to inform staff of the new policy.

A patient leaflet was created in August 2014 by the Lead Resuscitation Officer. This document, entitled "Decisions about cardiopulmonary resuscitation" provides information as to what CPR is, in what circumstances it is relevant to an individual patient and how decisions are made.

The current Trust policy dealing with decisions relating to DNACPR, which was updated in November 2014, stresses the importance of clear, accurate and honest communication with the patient and (unless the patient has requested confidentiality) those close to the patient, including provision of information and checking their understanding of what has been explained.

As to the actions of the particular staff involved in the care of Mrs Fenton, and with particular reference to the assessment and documentation of mental capacity, consent and communication, we have reminded the clinicians of the relevant policies and advised them that we will be rolling out refresher training. All Cardiology staff have also been informed by the Lead Consultant Cardiologist that no usage of Isoprenaline should be permitted in the CCU / Ward 31 without the consent of a Consultant Cardiologist / the on-call Cardiologist for pacing out of hours.

You also requested that the Trust issue a warning to all medical staff as to their duties to report matters to Her Majesty's Coroner and the circumstances in which this duty arises. I have attached a copy of the warning that has been issued to all medical staff as a result of your request.

I do hope that I have addressed your concerns and that I have reassured you that the steps taken by the Trust will prevent the recurrence of a similar set of circumstances as those in the case of Mrs Fenton.

Should you have any further questions arising from the contents of this letter please do not hesitate to contact me. I am again sorry that your investigation into this death caused you such significant concern to issue a Regulation 28 Report but I hope that you are now reassured.

Yours sincerely

[redacted]

Karen James
Chief Executive