Sheffield Teaching Hospitals NHS
NHS Foundation Trust

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Our Ref: AJC/PB

7 October 2015

Private & Confidential
Ms Mundy
HM Coroner
South Yorkshire (East District)
Coroner's Court and Office
Crown Court
College Road
Doncaster
DN1 3HS

Dear Ms Mundy

Re: William Arthur Bows (Deceased) – Report to Prevent Future Deaths

I write with the Trust's response to your Report under Regulation 28 of the Coroners (Investigations) Regulations 2013 enclosed with your letter of 29 July, received on 3 August 2015.

Sheffield Teaching Hospitals NHS Foundation Trust (STHFT) was not present at the inquest and so this letter is based on the summary in your report and a review of Mr Bow's medical records and our relevant policies and procedures. In your report you raise two areas of concern and I shall deal with these in turn.

1. **There was no evidence of any protocols in place or guidance for advising primary care providers of the need to closely monitor patients who have been prescribed amiodarone, particularly in relation to liver function tests, thyroid tests and respiratory difficulties.**

I am pleased to reassure you that there is and was an appropriate policy in place. The Shared Care Protocol for Amiodarone was initially developed in Sheffield in 2007 by the cardiology team in conjunction with the then Sheffield PCT. It has been revised several times since, so that it was the third edition that was current at the time of the prescription (Appendix 1). It was subsequently revised further in 2014, a version developed by Dr Sheridan, Consultant Cardiologist, STHFT and Richard Crosby, Head of Primary Care Clinical Support, NHS West and South Yorkshire and Bassetlaw CSU.

The protocol is designed for use by both primary and secondary care clinicians to enable the safe and appropriate continuation of care of patients initiated on amiodarone in hospital. It sets out the responsibilities of the primary and secondary care clinicians to ensure appropriate consent, dosage, baseline testing and ongoing monitoring. The monitoring specifically confirms the need for liver function tests, thyroid tests and the need to ask about breathlessness and non-productive

cough at each review relating to possible pulmonary toxicity. It also confirms the further tests to be undertaken if there is suspected pulmonary toxicity.

The amiodarone in this case, was initially prescribed by STHFT on 16 October 2013 whilst the patient was an in-patient, following development of atrial fibrillation. It was determined by the cardiologists that this should continue post discharge, and this was confirmed via the in-patient discharge summary dated 20 October 2013, a copy of which is documented to have been given to the patient and also will have been sent to the GP (in Sheffield this goes to GPs electronically, but is printed off and sent to practices outside of Sheffield). This correspondence also referred the GP to an internet link to the Shared Care Protocol and also summarised the hospital physician and GP responsibilities (Appendix 2).

A further letter was sent to the GP on 5 November 2013 (Appendix 3) which included the following:

"Post operatively he developed atrial fibrillation and therefore was started on treatment with amiodarone. This is to be continued in the community and we would be grateful if you could carry out the tests as per the agreed protocol. We will see Mr Bows in clinic in 6 weeks time with an ECG on arrival where further decisions regarding the amiodarone can be made."

As is transpired the amiodarone was then stopped with immediate effect (as the patient had reverted to a sinus rhythm) at the out-patient appointment referred to, which took place on 27 November 2013. This was confirmed to the patient during that appointment and the plan was also communicated to the GP by letter of 29 November 2013 (Appendix 4).

2. **With regard to the development of amiodarone toxicity, I heard evidence that should this complication develop it usually does so within the first twelve months or so of commencing this drug and linked with (1) above, there was nothing before me to suggest primary care providers, or indeed secondary care prescribers, were taking steps to ensure there was adequate monitoring during this period.**

This Trust would be responsible for baseline monitoring and monitoring during the loading dose. From review of the medical records the appropriate tests were carried out. It is not known what reviews were undertaken in the community, but monitoring tests are largely undertaken at 6 and 12 months, unless there is any suspected pulmonary toxicity or other side effects in the meantime. The patient was on the amiodarone prescribed by STHFT for around 6 weeks.

I therefore believe that an appropriate protocol was in place at the time of the prescription of amiodarone and that this was followed during the inpatient stay and communicated to the GP. Since this case, but not because of it, to further improve the safety of patients taking amiodarone, an Amiodarone Passport and Patient Handheld Information Booklet has been developed which provides key information about the drug, including the monitoring regime and the potential life threatening side effects (Appendix 5).

I hope that the above satisfies you that the Trust has an appropriate policy in place, part of which is to ensure that this is also communicated to GPs. Please do not hesitate to contact me if I can be of any further assistance or provide any further information in respect of these issues.

Yours sincerely

Andrew Cash.

Sir Andrew Cash OBE
Chief Executive

cc [redacted]

Enc.