REGULATION 28 REPORT TO PREVENT FUTURE DEATHS

THIS REPORT IS BEING SENT TO: The Secretary of State for Health and Social Care, 39 Victoria Street, London SW1H 0EU; The National Institute for Health and Care Excellence, 10 Spring Gardens, London, SW1A 2BU; and Greater Manchester Health and Social Care Partnership. 4th Floor, 3 Piccadilly Place, Manchester, M1 3BN.

CORONER

I am Adrian Farrow, Assistant Coroner for Manchester South.

CORONER'S LEGAL POWERS

I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.
http://www.legislation.gov.uk/ukpga/2009/25/schedule/5/paragraph/7
http://www.legislation.gov.uk/uksi/2013/1629/part/7/made

INVESTIGATION and INQUEST

On the 2nd August 2019, an inquest was opened into the death of Maureen Waterfall, who died on 26th July 2019 at Willow Wood Hospice at Mellor Rd, Ashton-under-Lyne OL6 6SL, at the age of 72 years. The investigation concluded with an inquest which I heard on 18th December 2019 and which concluded with a Conclusion that Mrs Waterfall died from the consequences of a brain injury sustained during a fall which were complicated by the previous use of prescribed Edoxaban.

CIRCUMSTANCES OF THE DEATH

Mrs Waterfall had a successful heart operation at the Liverpool Heart and Chest Hospital in November 2018. As part of the post-operative treatment, an anticoagulant, Edoxaban, was prescribed.

Mrs Waterfall fell at home on the morning of 12th July 2019 shortly before 9.00am. She sustained an injury to the back of her head which bled and she went, accompanied by a friend, to the Accident and Emergency Department of Tameside General Hospital. She was seen in triage promptly and the inquest heard that the fact of her anticoagulant medication was noted and in consequence, because of the head injury, a CT scan was ordered at triage stage, rather than awaiting review by a doctor.

The CT scan was performed at 12.07pm, but before the CT scan was reviewed by the A&E Consultant at the time of his examination of Mrs Waterfall at about 1.10pm, Mrs Waterfall's condition deteriorated. The CT scan showed a subdural haematoma and she was moved to the resuscitation unit.

After consultation with a neurosurgeon at Salford Royal Hospital and the haematologist at Tameside General Hospital and the decision was made to administer Prothrombin complex as an antidote to the Edoxaban.

The inquest heard that Edoxaban has no currently licensed antidote. Prothrombin complex is not specific to Edoxaban and its effectiveness is difficult to assess and monitor.

Mrs Waterfall did not respond to the Prothrombin complex and her condition was such that when the second CT scan was reviewed, there was no surgical intervention which would have been viable and she was moved to the intensive care unit at Tameside General Hospital. Whilst she had a period of brief raised consciousness the following day, her condition did not improve and she was transferred with the agreement of her family to Willow Wood Hospice on 15th July, where she remained until her death on 26th July 2019.

A post mortem examination concluded that Mrs Waterfall died as a consequence of:

1)a) Subdural haematoma

CORONER'S CONCERNS

During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you.

The **MATTERS OF CONCERN** are as follows. –

1. I heard evidence from [redacted] Clinical Director of Neurosciences at Salford Royal Hospital. He told me that Edoxaban was one of the new anticoagulant drugs, but of those with which he is familiar, it is differentiated by the fact that there is no currently licensed antidote. He is aware of clinical trials being undertaken of such an antidote.

2. The inquest was told that head injury patients who are prescribed Exodaban are at greater risk of continued bleeding to the brain than other patients as the absence of a specific antidote makes the reversal of the anticoagulant medication less certain. As with other newer anticoagulant drugs, there is little ability to monitor the effectiveness of the antidote. It was unclear if that understanding had been shared widely amongst non-tertiary centres to assist them in managing such patients.
   The inquest was told that, at SRFT which is a tertiary centre for neuro surgery/ neurology they have taken steps to set a target for the use of anticoagulant antidote drugs at 90 minutes from presentation. It was unclear if this target was feeding into development of a national protocol. It was unclear how in the absence of national guidance that information was being shared with DGHs which rely on tertiary centres for expertise. At TGH there was no clear target time for the administration of anti-coagulations.

3. I heard that there is no national standard guidance about the storage of supplies of anticoagulant antidote drugs. As a result, as in this case at Tameside General Hospital Accident and Emergency Department they were not kept at the resuscitation unit, but rather they were kept in the haematology department

ACTION SHOULD BE TAKEN

In my opinion action should be taken to prevent future deaths and I believe you and your organisation have the power to take such action.

YOUR RESPONSE

You are under a duty to respond to this report within 56 days of the date of this report, namely by **24th February 2019**. I, the coroner, may extend the period.

Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed

COPIES and PUBLICATION

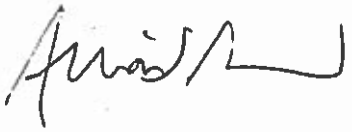
I have sent a copy of my report to the Chief Coroner and to [redacted] on behalf of the family.

I have sent a copy of my report to The Medical Director, Tameside and Glossop Integrated NHS Trust, Fountain St, Ashton-under-Lyne OL6 9RW who may find it useful or of interest.

I am also under a duty to send the Chief Coroner a copy of your response.

The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.

Dated: 30th December 2019.

Signature: 

Adrian Farrow HM Assistant Coroner, Manchester South.