NHS
Manchester University
NHS Foundation Trust

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9 December 2020

Ms Alison Mutch OBE
HM Senior Coroner
Manchester South
1 Mount Tabor Street
Stockport
SK1 3AG

Via Email Only: [redacted]

Dear Ms Mutch

RE: Mrs Alison Jean Shirley JEANES deceased

I am writing on behalf of Sir Michael Deegan, Chief Executive, in response to your Regulation 28 Report sent to Manchester University NHS Foundation Trust ("the Trust") on 7th October 2020. Your report related to the death of Mrs Alison Jean Shirley Jeanes at Wythenshawe Hospital on 4th April 2020 and whose inquest was held on 14th September 2020.

Wythenshawe Hospital is part of the Trust's Wythenshawe, Trafford, Withington and Altrincham (WTWA) site.

I understand that you concluded that Mrs Jeanes suffered an accidental death, contributed to by a high INR level from anticoagulation. You concluded Mrs Jeanes' medical cause of death to be: *1a) Traumatic subdural haemorrhage on a background of anticoagulation; 2) Chronic kidney disease, vascular dementia, aortic stenosis*.

After hearing the evidence at inquest, you have raised the following matters of concern: -

1. *The inquest heard that whilst contact was made with the Neurosurgical team at Salford Royal Hospital on the day of her admission there was no conversation with a Doctor from that team until the day after her admission. As a result, there was no expert neuro input into her care for 24 hours. There was no evidence that there was any attempt to chase up contact earlier.*

2. *Mrs Jeanes was brought into hospital by ambulance at the direction of a GP who recognised that she had a suspected head injury and was on warfarin. The GP recognised that the NICE guidance suggests there is an 8-hour window for patients on warfarin with a suspected head injury. Her fall had been at 23.58 on 16th March. The inquest heard that she was triaged but her CT scan was not expedited and was not reported on until 11.45 almost 12 hours after the fall. There was no evidence of a system that would fast track such cases for a CT scan.*

3. *The inquest heard that haematology advice on the day of admission was to reduce her INR. This advice was reconfirmed by the neurosurgeons the following day. There were differences in the recommendations, and it was not entirely clear how that difference was being managed. In any event despite repeated attempts with Vitamin K Mrs Jeanes INR remained above the target. Further advice from the haematologist was not sought until 26th March some 9 days after her admission. It was unclear why that delay had occurred as the notes suggested it had been recognised that advice should have been sought previously but this had not been followed up. There was no evidence before the inquest of what system was in place or who would take responsibility for follow up in such a situation.*

I have sought to address each of your matters of concern in turn below: -

1. ***The inquest heard that whilst contact was made with the Neurosurgical team at Salford Royal Hospital on the day of her admission there was no conversation with a Doctor from that team until the day after her admission. As a result, there was no expert neuro input into her care for 24 hours. There was no evidence that there was any attempt to chase up contact earlier.***

Neurosurgical Advice from Salford Royal Hospital

Mrs Jeanes was referred to the Neurosurgical Coordinator on 17th March 2020, and the referral was followed up the next day. We have liaised with colleagues at Salford Royal NHS Foundation Trust; [redacted], Chief Officer and Medical Director, and [redacted], Clinical Director for Surgical Neurosciences. Having looked into this further, it appears that the standard of the record-keeping at Wythenshawe Hospital may have been such that when you heard evidence at the Inquest this gave rise to an incorrect assumption that the Neurosurgical team took a day to provide a plan, however from review of the records held by Salford Royal Hospital colleagues, it appears advice was in fact provided by Salford Royal Hospital Neurosurgical colleagues the same day that this was requested.

This then given rise to an additional concern around the standard of documentation at Wythenshawe Hospital in Mrs Jeanes' case. I have addressed this point below.

In respect of the referral to the Neurosurgical team at Salford Royal Hospital for specialist advice, Mrs Jeanes was referred to Neurosurgery on 17th March 2020, at 12.55 hours, via the on-call Administrator, in line with usual practice. The referral confirmed that the CT brain scan undertaken at 09.17 hours that day had shown a tiny focus of left frontal traumatic sub-arachnoid haemorrhage and a thin right-sided chronic subdural haematoma with minimal mass-effect on account of Mrs Jeanes' cerebral atrophy. The specialists at Salford Royal Hospital were advised that the INR was being reversed, i.e. with a view to reducing Mrs Jeanes' INR level. The international normalised ratio (INR) is a recommended method for reporting prothrombin time results for control of oral anticoagulation. Since adoption of the INR system, it has been usual practice to adjust the dose of Warfarin, or other Vitamin K antagonist, to maintain the INR within a therapeutic range.

The Neurosurgical team at Salford Royal Hospital reverted to the team at Wythenshawe Hospital the same day with a recommended plan that Mrs Jeanes' Warfarin should be held off for one week, with the decision as to whether/when to re-start this anticoagulation resting with the referring team at Wythenshawe Hospital, to be made after balancing of the risks and benefits. The Neurosurgical team at Salford Royal Hospital recommended local neuro-observation by the treating team at Wythenshawe Hospital, and it was deemed by the specialists that no neurosurgical intervention was required.

The next day, on 18th March 2020, at 10.40 hours, the treating team at Wythenshawe Hospital made a further referral to the Neurosurgical specialists at Salford Royal Hospital, again via Salford Royal Hospital's on-call Administrator. At that point, Mrs Jeanes' INR was noted to still be raised, at 2.4 (down from 8 on admission to Wythenshawe Hospital the previous day), following three doses of Vitamin K. The Neurosurgical Registrar doctor at Salford Royal Hospital again contacted the team at Wythenshawe Hospital the same day by telephone, with advice documented that it was noted that Mrs Jeanes had had three doses of Vitamin K, which had brought her INR down to 2.4. The use of mechanical prophylaxis (such as thromboembolic deterrent (TED) stockings) was recommended. The Neurosurgical Registrar advised the treating team to complete 48 hours of neurological observations for Mrs Jeanes, and to restart her Warfarin in two weeks' time. The advice was that there was no need to rescan Mrs Jeanes and that this would only be required if she suffered a deterioration, for instance in her motor score for diagnostic purposes. The advice from the previous day was reiterated insofar as Mrs Jeanes was not a candidate for neurosurgical intervention. The documentation from this call indicates that the local team at Wythenshawe Hospital was in agreement with the advice.

The Neurosurgical team at Salford Royal Hospital was again contacted on 26th March 2020, as Mrs Jeanes had been re-scanned due to a slight increase in her level of confusion (her Glasgow Coma Score, GCS, i.e. level of consciousness, was still 14). This scan showed a slight enlargement to the right-sided chronic subdural haematoma (though still with minimal mass effect i.e. this haematoma remained small) and a new small left-sided chronic subdural haematoma. Mrs Jeanes' INR remained elevated at 2. The Neurosurgical team at Salford Royal Hospital reiterated earlier advice that Mrs Jeanes was not a candidate for neurosurgical intervention.

Treatment Pathway for acute intracerebral haemorrhage

I ***enclose*** a copy of the *"Intracerebral haemorrhage: Greater Manchester care pathway and Neurosurgical referral guidelines"*. This is the treatment pathway used for all acute intracerebral haemorrhage patients in Greater Manchester, applicable to all relevant Trust staff/clinicians. Whilst implemented by the Greater Manchester Stroke Operational Delivery Network, the principles around referral to neurosurgery set out in this Standard Operating Procedure are applicable to any patient presenting with an intracerebral haemorrhage, i.e. as with Mrs Jeanes, who had not presented following a stroke.

This pathway acknowledges that around 10% of patients suffering an intracerebral haemorrhage are taking an anticoagulant at onset, and the emphasis is that after stabilising the patient, reversal of anticoagulation should be the first management priority. The pathway states that any history of premorbid anticoagulant use should be actively sought, scanned after confirmation and immediately reversed using locally agreed protocols.

The pathway also sets out the criteria to be applied to inform decision-making around whether a patient should be referred acutely to the Neurosurgical Registrar on-call at Salford Royal Hospital. The pathway confirms that the Neurosurgical team on-call will then decide whether the patient should be transferred to Neurosurgery for further care.

The pathway sets out features that may indicate patients at high risk of deterioration in the hyperacute phase of an intracranial haemorrhage. These features include a GCS score of less than 8, airway/respiratory compromise, a decline in GCS by more than 2 points in the last 1-hour, posterior fossa intracranial haemorrhage with brainstem signs, and uncontrolled seizures. Mrs Jeanes did not exhibit any of these features that would have been indicators of her being at high risk of deterioration.

This pathway also indicates that the Physicians and Radiologists at each hospital must continue to make an assessment in each case as to whether further angiographic imaging is required and the urgency of this. For those patients meeting the criteria for referral to Neurosurgery, guidance may also be offered by the Neurosurgical on-call team. The pathway also sets out general guidance on the need or otherwise of imaging.

Patient Pass

Salford Royal Hospital is in the process of implementing a system called *"Patient Pass"*, which is designed to improve communication between referring hospitals and Salford Royal Hospital's special Neurosurgical unit. The electronic system will, as we understand it, seek to speed up referrals, supporting reliability in the clinical process and therefore improving patient safety, and providing a full audit trail for the purpose of information governance. Patient Pass will ensure there is a single accessible record of discussions which will minimise the risk of any issues around documentation, with a date/time-stamped referral and management plans being recorded in the system and available to access by the specialists at Salford Royal as well as the referring hospital. Patient Pass will also support speciality-specific decision-making and advice given, and the accessibility of that advice by the referring hospital, and the ability to refer back to previous referrals for the same patient. I understand that Patient Pass was due for implementation this year, however this had to be postponed as a result of the COVID-19 pandemic, and it is now expected to be implemented in 2021.

I hope the above provides you with assurance that the specialist Neurosurgical team at Salford Royal Hospital were proactively contacted for input, which was promptly provided to the local treating team at Wythenshawe Hospital. I am deeply sorry that the evidence you were provided with at the inquest led you to believe otherwise.

Trust Staff Preparation for Inquest

In the event that the oral witness evidence that you heard at Inquest did not provide you with the full information required around these points, I confirm that in September 2020 I issued, via the site Medical Directors for hospitals and Managed Clinical Services across the Trust, a reminder about the professional expectations of Trust staff when attending your Coroner's Court to give evidence in respect of Trust patients. With this, I reminded colleagues about the General Medical Council's guidance on *"Acting as a witness in legal proceedings"*, covering the expectations of doctors when giving evidence in a professional capacity. I reminded colleagues of the obligations on staff in this regard, including the need to be fully prepared before attending Court to give oral evidence, with access to and familiarity with the relevant entries in the clinical notes in order that you are provided with all relevant evidence to assist your inquiry and enable you to conclude Inquests satisfactorily.

Standard of Documentation at Wythenshawe Hospital

I sincerely apologise that the standard of documentation in Mrs Jeanes' clinical notes at Wythenshawe Hospital, specifically around the liaison with the Neurosurgical specialists at Salford Royal Hospital, appears to have been lacking in this case such that the evidence at inquest gave you the impression that there was no conversation with a doctor from that team until the day after Mrs Jeanes' admission to hospital, when in actual fact, as set out above, this was not the case. This clearly falls short of the standards that we as a Trust expect.

The Nursing and Midwifery Council's *"The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associations'* (2018) and the General Medical Council's *"Good Medical Practice"* (2013) set out the expected professional standards and responsibilities around clinical record-keeping. All patient-facing staff at the Trust are of course required to follow these fundamental principles.

In addition to this, the Trust also has its own local policy in respect of clinical record-keeping, which sets out the expected standards of documentation along with best practice guidelines relating to both paper and electronic records.

The Trust's separate health records management policy also emphasises that health records are essential for delivering quality and safety of patient care and highlights the legal obligations and responsibilities of individual staff members to comply with the legal requirements of health records legislation.

Training is provided to all clinical staff in respect of documentation in clinical records and the standard of record-keeping is monitored by way of regular audits.

2. ***Mrs Jeanes was brought into hospital by ambulance at the direction of a GP who recognised that she had a suspected head injury and was on warfarin. The GP recognised that the NICE guidance suggests there is an 8-hour window for patients on warfarin with a suspected head injury. Her fall had been at 23.58 on 16th March. The inquest heard that she was triaged but her CT scan was not expedited and was not reported on until 11.45 almost 12 hours after the fall. There was no evidence of a system that would fast track such cases for a CT scan.***

Emergency Department (ED) Team

Having reviewed the clinical notes, I confirm that Mrs Jeanes was brought to Wythenshawe Hospital's Emergency Department by ambulance on 17th March 2020, accompanied by her carer, following the fall at her Care Home. Mrs Jeanes was triaged within the Emergency Department at 05.29 hours as an *"unwell/collapsed"* adult and was triaged in the yellow category, indicating she should be seen within an hour. Mrs Jeanes' vital signs were normal on admission, as was her GCS, at 15/15. Mrs Jeanes was noted to have sustained bruising to the left side of her face and her carer confirmed that this was sustained from her previous fall on 13th March 2020 when she had previously attended the Emergency Department.

A nursing and risk assessment were completed at 07.30 hours on 17th March 2020, i.e. just over two hours after Mrs Jeanes' triage into the department. Clearly this is outside of the one-hour target according to her yellow triage category, and I am very sorry to note this. At the time of this assessment, Mrs Jeanes was scoring 1 on her Modified Early Warning Score (MEWS) due to a low temperature of 35.4 degrees. Mrs Jeanes was referred immediately to Wythenshawe Hospital's Older Persons Assessment Liaison (OPAL) Unit, based adjacent to the Emergency Department. Mrs Jeanes was seen by a doctor from the OPAL unit between 08.30 and 09.00 hours. Mrs Jeanes had bloods taken and a CT head scan was requested at 08.32 hours. This CT scan was completed at 09.16 hours (after the fall at 23.58 hours, which I note falls outside of the 8 hour target) and later reported by the Radiology team (please see below), showing a new intracranial bleed (compared to the previous CT scan undertaken on 13th March 2020). Mrs Jeanes' INR also returned with abnormal results, at 8.3, and the OPAL medical team was informed. At 10.05 hours, Emergency Department nursing documentation indicates that the doctors were awaiting the CT head scan results and were to prescribe Vitamin K with a view to lowering Mrs Jeanes' INR level. Vitamin K was given at approximately 11.00 hours. Mrs Jeanes was transferred from the Emergency Department to the Acute Medical Unit for further inpatient treatment.

I am sorry to note that Mrs Jeanes was not seen as urgently as required within the Emergency Department. I wonder if the category selected on Mrs Jeanes' triage within the Emergency Department, of *"unwell/collapsed"*, as opposed to flagging the presenting history of a fall and potential head injury, may have led to a failure to recognise the urgency with which she required medical review and a CT head scan.

Emergency Department Head Injury Pathway

I ***enclose*** the recently updated (in August 2020) local head injury pathway in place at Wythenshawe Hospital's Emergency Department, for use by clinical staff when assessing adult patients for a head injury and for documenting the assessment in the patient's clinical notes. This local pathway is in line with NICE guidance and serves to guide clinicians as to the steps to be undertaken to ensure a comprehensive assessment of patients presenting with a head injury. The local pathway specifically covers the indications for a CT scan and/or to contact the Neurosurgical specialists for advice and provides the template for documenting the outcome of CT scan/Neurosurgical advice in the clinical notes. This pathway also covers, in line with NICE guidance and as you point out, that in cases such as Mrs Jeanes', a CT scan is required within 8 hours of the injury.

I also ***enclose*** the *"Clinical Decision Support Tool"*, which contains a user friendly flow chart for use when assessing and treating adult patients presenting with head injuries, which covers the requirements around CT head scans being undertaken according to the patient's risk category, as well as the circumstances in which advice should be sought from Salford Royal Hospital's Neurosurgery team based on abnormality on the imaging. This tool is embedded within the Electronic Patient Record system used by clinicians in the Emergency Department as decision support software.

Radiology Team

Radiological imaging at Wythenshawe Hospital falls under the Managed Clinical Service of Clinical and Scientific Services, who have looked into this in respect of the CT scan and reporting pathway. Based on review of the Computer Radiology Information System (CRIS) it appears that the doctor on the ward submitted the request to the Radiology team at 08.32 hours on 17th March 2020, stating, *"89yo female presenting with unwitnessed fall with head injury on warfarin ?ICH"*, i.e. given that Mrs Jeanes had presented to hospital following a fall at her Care Home, querying whether she may be suffering from an intracranial haemorrhage and requesting a CT scan for this reason.

After the request was submitted by the ward at 08.32 hours, Mrs Jeanes attended Radiology and the scan was performed at 09.16 hours, i.e. within 44 minutes. This is within the required Key Performance Indicator (KPI)/target for imaging of this nature, which requires that for patients in the Emergency Department with a head injury, the required turnaround time from the scan being requested to being performed should be within an hour. The time from the scan being undertaken to a verified CT scan report being provided was two hours, with the report being verified at 11.16 hours, which the Radiology team accepts is one hour outside of the required KPI/target, according to which it is expected that CT scans of this nature requested by the Emergency Department are to be reported within an hour of the examination. The CT scan was reported by the Radiology Registrar doctor, under the supervision of the Consultant Radiologist. The report included a *"red alert"* indicating that the finding required review by the ward team. The case has been reviewed by the Trust's Clinical Director for Radiology, who notes and accepts the short delay in reporting the scan, adding that on review, it does not appear that this delay in reporting the scan would significantly have contributed to an adverse outcome for Mrs Jeanes.

Radiology Reporting Strategy

A local Trust policy, *"Division of Imaging Reporting Strategy"*, currently in draft, is in the process of being finalised, under the leadership of the Clinical and Scientific Services Managed Clinical Service. This policy will be applicable to all staff involved in diagnostic imaging examinations. This will be the first Division of Imaging Reporting Strategy for the Trust, the purpose of which is to set out the priorities, principles and ambitions for providing high-quality reports for service users over the next five years and, therefore, delivering the Division's vision and objectives. This Reporting Strategy is the plan through which the Division of Imaging will focus on the quality and safety of reporting structures. It will ensure that there are appropriate reporting pathways for all modalities across the Division and there is a harmonised approach to delivering this information to clinical teams. The Reporting Strategy will be applicable across all hospital sites and Managed Clinical Services Trust-wide.

This policy defines *"critical findings"* and *"urgent findings"*, which, based on the findings/results in imaging examinations require immediate or urgent communication with the referring clinicians, due to the findings reflecting conditions that are life threatening or require immediate change of management plan, or where the interpreting clinician reasonably believes may be seriously adverse to the patient's health and may not require immediate attention but, if not acted on, may worsen over time and possibly result in an adverse patient outcome.

The new Reporting Strategy, once finalised and ratified, will be used in conjunction with the Trust policy for requesting, review and actioning of diagnostic test results at the Trust, which is already embedded.

3. ***The inquest heard that haematology advice on the day of admission was to reduce her INR. This advice was reconfirmed by the neuro surgeons the following day. There were differences in the recommendations, and it was not entirely clear how that difference was being managed. In any event despite repeated attempts with Vitamin K Mrs Jeanes INR remained above the target. Further advice from the haematologist was not sought until 26th March some 9 days after her admission. It was unclear why that delay had occurred as the notes suggested it had been recognised that advice should have been sought previously but this had not been followed up. There was no evidence before the inquest of what system was in place or who would take responsibility for follow up in such a situation.***

INR Monitoring

Mrs Jeanes' INR was at a level of 8.3 on admission to hospital and her case was appropriately discussed with the on-call Haematologist who advised administering Vitamin K, 10mg, with an aim of reducing the INR level to below 1.0. It was recommended that Octoplex could be administered if there were any concerns arising in respect of extension of the bleed.

Later on 17th March 2020, a repeat INR check after administration of Vitamin K remained elevated, at 6.3. As documented in the clinical notes, on 18th March 2020, the Neurosurgery specialists at Salford Royal Hospital, at 12.20 hours on 18th March 2020, recommended an INR of less than 1.2 on the balance of the risks and benefits in Mrs Jeanes' specific case. A further 15mg of Vitamin K was administered on 18th March 2020.

By 26th March 2020, noting that despite treatment with Vitamin K Mrs Jeanes' INR remained at 2, further advice was obtained from the Haematology team that day and on 27th March 2020, and a decision was made to give Octaplex, following which INR reduced to 1.5. Sadly however, Mrs Jeanes' condition rapidly deteriorated as a result of her subdural haematoma and confounded by significant frailty and comorbidities.

Guidance indicates that oral administration of Vitamin K will produce a significant fall in INR within 8-24 hours, and with Vitamin K administered intravenously the fall will be more rapid. Though Mrs Jeanes' INR level was brought down, I note that it unfortunately remained elevated beyond the recommended level despite administration of Vitamin K.

Advice from Haematology

The requirement is that the on-call or ward team should contact the Haematology specialists at Wythenshawe Hospital should they require advice. Patients should then be referred back to the Anticoagulant Clinic on discharge from hospital for follow-up care. The Trust has a Haematology service which is on-call 24 hours a day, 7 days a week. The Haematology team will advise on appropriate reversal of anticoagulation. It is the ward team's responsibility to follow-up and action such advice, and to refer back to Haematology should further specialist input be needed in the course of the patient's admission.

Clinical/ward teams are also clearly required to consider national guidance, such as that provided by NICE around oral anticoagulants, and that within the BNF. This guidance refers to the use of Vitamin K and specifically refers to the target INRs for adults for Warfarin and take into account the recommendations of the British Society for Haematology guidelines on oral anticoagulation with Warfarin. The national guidance is clear on the main adverse effect of all oral anticoagulants being haemorrhage, and that checking the INR and omitting doses when appropriate is essential.

The Trust's locally implemented *"Transfusion Policy"* also provides specific guidelines for the management of Warfarin reversal, produced in conjunction with the British Committee for Standards in Haematology *"Guidelines on oral Anticoagulation (Warfarin)"*. This Trust guidance refers to patients suffering from a bleed and the appropriate doses of Vitamin K to be used to reverse over-anticoagulation depending on INR. The guidance is clear that local ward teams should contact the Trust Haematologist if needed.

Trust clinicians are required to follow these standards. I am very sorry that, despite the efforts of the treating ward team at Wythenshawe Hospital, Mrs Jeanes' condition deteriorated, and she very sadly died.

We hope that the above provides you and Mrs Jeanes' family with assurance in respect of the matters of concern you had raised. The Trust is committed to ensuring patient safety is our priority. If you require any further information, please do not hesitate to contact us.

Yours sincerely

[redacted]
Joint Group Medical Director / Responsible Officer
GMC [redacted]

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Enclosures:

- *Greater Manchester Stroke Operational Delivery Network, "Intracerebral haemorrhage: Greater Manchester care pathway and Neurosurgical referral guidelines";*
- *Wythenshawe Emergency Department, "Adult Head Injury" Pathway;*
- *Wythenshawe Emergency Department, "Clinical Decision Support Tool, Adult Head Injury".*