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11 January 2020

Dear Sir,

Karen Winn Deceased – Regulation 28 (Prevention of Future Deaths)

Thank you for your letter regarding the investigation into the death of Mrs Karen Winn.

I have asked our Head of Deteriorating Patient, Acting Head of Patient Safety and Chief Nursing Information Officer to address the matters of concern that you have and the response is as follows;

Concern 1
Concern that a differential diagnosis of a rare and serious blood condition (haemolytic anaemia), although identified soon after admission, was not escalated to a Haematology Consultant at the time this diagnosis was made. It was a rare condition, which by its very nature should be treated with the support of haematology specialists. You are concerned that those specialists were unaware that a differential diagnosis of serious blood disorder had been made without their specialist input.

A meeting was convened with the Haematology Consultants to consider how escalation is achieved and how we can ensure that this is robust. Whilst there are specific criteria for the treatment of Autoimmune Haemolytic Anaemia, it is acknowledged that this is a rare condition. A flow pathway for Autoimmune Haemolytic Anaemia has been established, identifying investigations and treatment required, inclusive of referring to the haematology on call consultant. This flow pathway has been published on the Trust's 'Pink Book', a clinical reference point for all clinical staff, both internally and within the community (including GPs). This pathway will also be included in the 'Heads Up book' (HUB) which is currently being developed. This is a quick reference guide intended to provide junior clinicians with flowcharts and algorithms for emergent situations whilst waiting senior help; this book is still in its development stage and we are hoping that it will be available in 2021.

See appendix 1: Management of suspected autoimmune haemolytic anaemia flow chart

Concern 2

In addition, you are concerned that the automated VTE assessment system does not appear to be significantly robust. You are aware that the WSFT have taken steps to address the problem and have now placed the VTE assessment on the electronic Smart Zone 'to do list' and introduced an automated 14-hour consultant review function. However, you are concerned that as yet there is still no limit to the amount of times the automated 'pop-up' can be manually overridden and no automatic escalation process when it has been overridden a certain number of times.

Since Mrs Winn's death the Trust has made a number of changes designed to encourage the timely and accurate assessment of VTE risk, which includes guidance for prophylactic management. These changes were made in close consultation with subject matter experts, clinicians responsible for completing assessments at the point of care and the clinical informatics team. Some of these changes had already been scheduled for development and were accelerated as part of the critical incident investigation and some have been agreed following a review of the inquest feedback.

These changes include:

- **"Smartzone" alerting from point of admission –** the smart zone alerting provides a constant reminder that VTE assessment and management is required and provides a hyperlink to the document. The alert is deactivated on full completion.

- **Pop-up alerting when closing the patient record –** an additional alert is presented when closing a patient's chart with the ability to launch the assessment document or to return to the patient record for review before completing the assessment. The pop-up alert is now triggered when the clinician closes the chart rather than on opening which means that this person is less likely to override as they will have completed the primary purpose for opening the patient chart which would not necessarily have been to complete VTE. The alert is deactivated upon full completion.

- **Additional prompting displayed at point of first consultant review –** an additional field to confirm completion of the VTE assessment has been added to the template used to record the first review by a senior clinical decision-maker. Typically, this is recorded within the first 24 hours of admission.

- **Changes to the presentation of the pop-up alert at 24 hrs from admission (in development) –** the text, display and presentation of the pop-up alert indicating incompletion will be amended to indicate the urgent need to complete. The number of overrides to date will be indicated in the body of the text.

- **Appropriate alert presentation -** alerts are now presented to the appropriate staff group that have the ability (and responsibility) for completion of the assessment and prescribing of prophylaxis at appropriate times on the patient journey. This was identified as one of the factors contributing to high override rates. As an example, the alert now only appears for prescribers, where previously non-prescribers were presented with the alert and, in order to proceed, were required to record an override. This will in turn reduce the number of overrides occurring.

- **Discrete prompting within the body of the assessment –** clearer guidance has been added to the risk assessment. Haemolytic anaemia has been added explicitly to the 'thrombosis risk – patient related' section of the assessment document. The subsequent guidance displayed following completion of the assessment now includes a direct instruction to seek senior clinical guidance if needed.

- **Safety dashboards** – the status of VTE assessment completion is shown against each patient on ward dashboards is displayed to clinical and operational teams. These provide "live" status reports and also enable a direct documentation link from the dashboard if required; a blank space identifies patients that have not had their VTE assessment completed.

- **Override notifications (in development)** – a notification will be sent to the Lead Consultant responsible for the patient indicating incomplete VTE assessments and management plans and the number of times this assessment alert has been overridden. These notifications will be issued after every twenty overrides (20/40/60 etc) and will be sent to the clinicians "Message Centre" inbox. Message Centre is a secure clinical messaging system embedded within the patient record system which would include clinical notifications, referrals and critical reminders.

See appendix 2: screenshots reflect some of the changes listed above

The Trust have considered the use of a hard stop to prevent continuing overriding of the alert once a maximum threshold has been reached. At this point we believe this is not in the patient's best interests as there are many clinical examples where it would not be appropriate to complete a VTE assessment especially in emergency situations. However, this option will remain under review and the current VTE compliance report is being amended to present the number of overrides and more detailed timings of completions to better inform future monitoring.

Finally, clinical guidelines have been updated for VTE (Prophylaxis for Venous Thromboembolism (VTE) in Adult Non-Pregnant Patients) which includes a section around risk factors. We have added the following risk factor; "*Conditions such as haemolytic anaemia and sickle cell disease"* to the relevant section of these guidelines and they are available on the staff intranet and are easily accessible.

Concern 3
You are concerned that if a Consultant, at an early review, has decided that prophylactic anticoagulation medication needs to be administered (even in the situation when an INR test is still awaited) that this is not clearly flagged on the patient electronic record in the Smart Zone, to act as a prompt for clinicians taking over that patient's care.

The narrative aspect of a clinician's plan cannot be 'pulled through' into the smart zone. However, the actions described in section 2 will ensure that an in-completed VTE assessment is recognised. Furthermore, the addition of the haemolytic anaemia prompting within the VTE assessment tool should aid ensuring that the clinicians are aware that this condition requires VTE prophylaxis consideration.

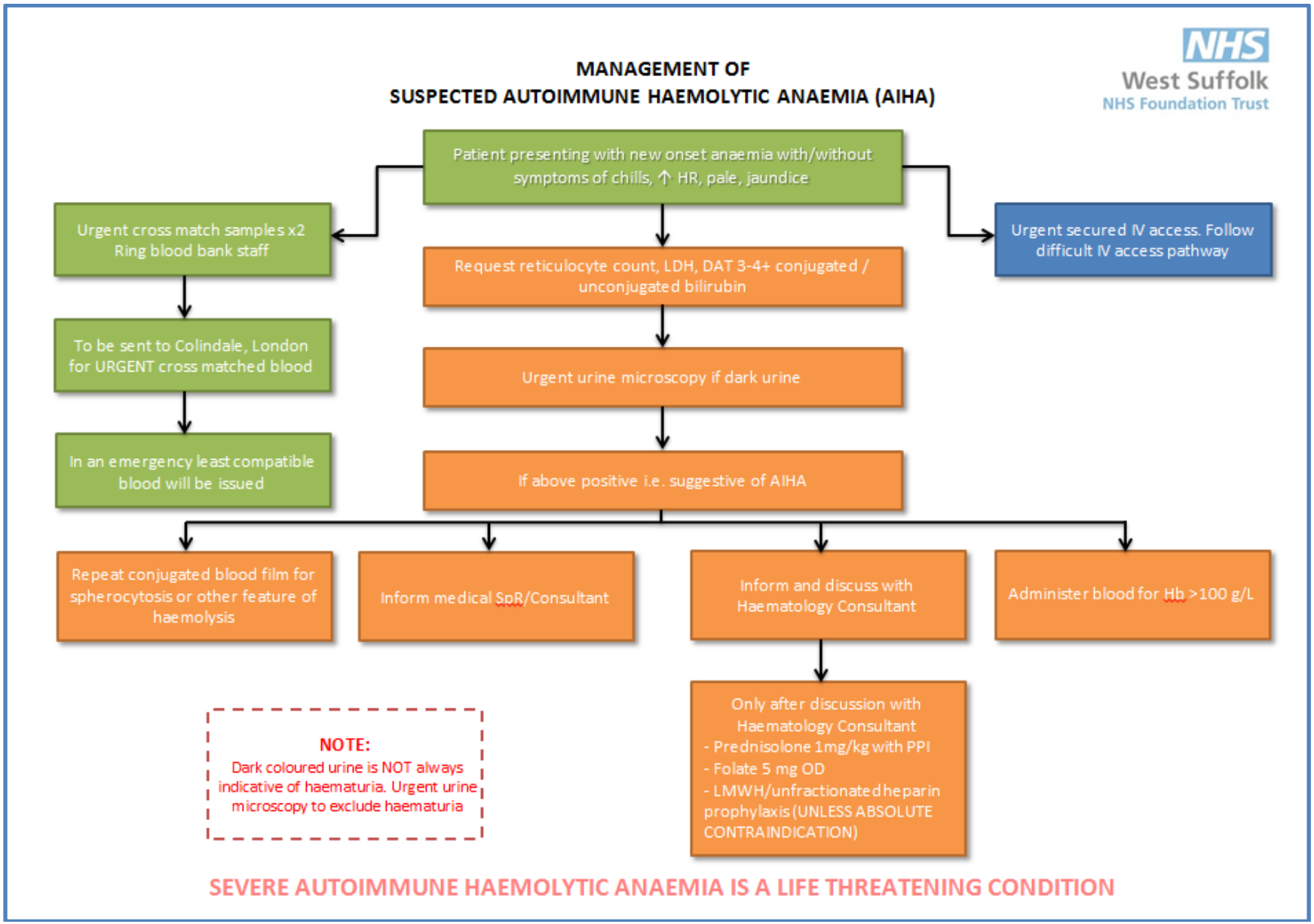
As part of the discussions within the Trust concerning this case it was agreed that whilst the initial consultant included in his plan VTE prophylaxis, if Mrs Winn's INR blood test was within normal parameters, it was a conscious decision over a weekend to withhold the prophylaxis because haematuria (blood in urine) was present. Over the weekend period different clinicians formed the same conclusion. This is not a thematic issue for the Trust, however, it is hoped that by addressing the issues around the VTE prophylaxis process described above, as well as a clear referral process and treatment required pathway for clinicians to follow would provide further assurance that the risk of reoccurrence would be minimalised. Smart zone alerting is restricted to indicating an omission, rather than providing a discrete instruction. Although this is often one and the same thing, in this case it would not be currently possible to provide the type of prompt suggested.

I hope that the above information and evidence provides you with a level of assurance in making your final decision and thank you for your consideration in this sad inquest.

Yours sincerely

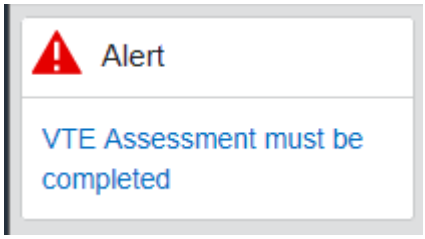
[redacted]
Chief Executive

Appendix 1

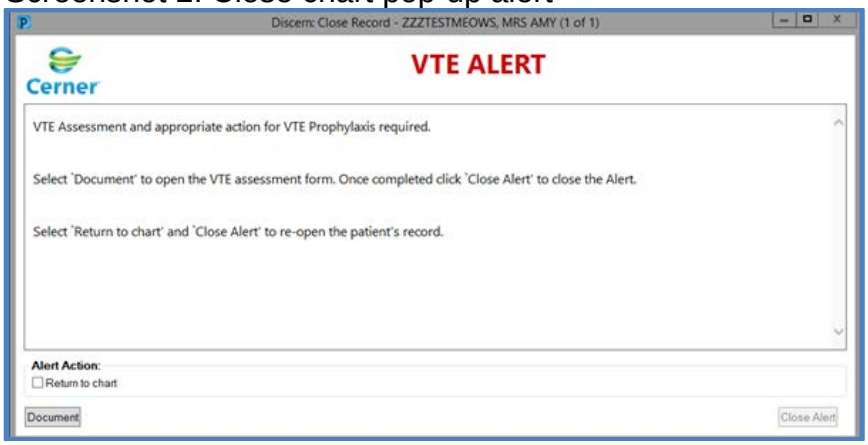

MANAGEMENT OF
SUSPECTED AUTOIMMUNE HAEMOLYTIC ANAEMIA (AIHA)
NHS
West Suffolk
NHS Foundation Trust
Patient presenting with new onset anaemia with/without symptoms of chills, ↑ HR, pale, jaundice
Urgent cross match samples x2
Ring blood bank staff
Request reticulocyte count, LDH, DAT 3-4+ conjugated / unconjugated bilirubin
Urgent secured IV access. Follow difficult IV access pathway
To be sent to Colindale, London for URGENT cross matched blood
Urgent urine microscopy if dark urine
In an emergency least compatible blood will be issued
If above positive i.e. suggestive of AIHA
Repeat conjugated blood film for spherocytosis or other feature of haemolysis
Inform medical SpR/Consultant
Inform and discuss with Haematology Consultant
Administer blood for Hb >100 g/L
NOTE:
Dark coloured urine is NOT always indicative of haematuria. Urgent urine microscopy to exclude haematuria
Only after discussion with Haematology Consultant
- Prednisolone 1mg/kg with PPI
- Folate 5 mg OD
- LMWH/unfractionated heparin prophylaxis (UNLESS ABSOLUTE CONTRAINDICATION)
SEVERE AUTOIMMUNE HAEMOLYTIC ANAEMIA IS A LIFE THREATENING CONDITION

Appendix 2 – e-Care Screenshots

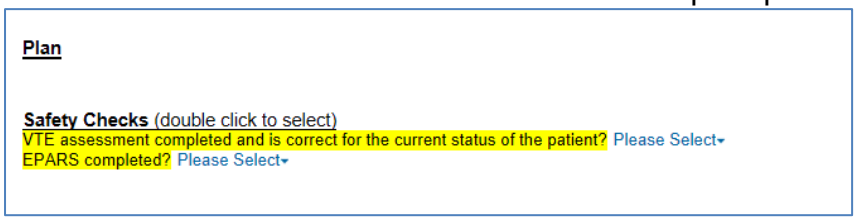
Screen shot 1: Smartzone alert



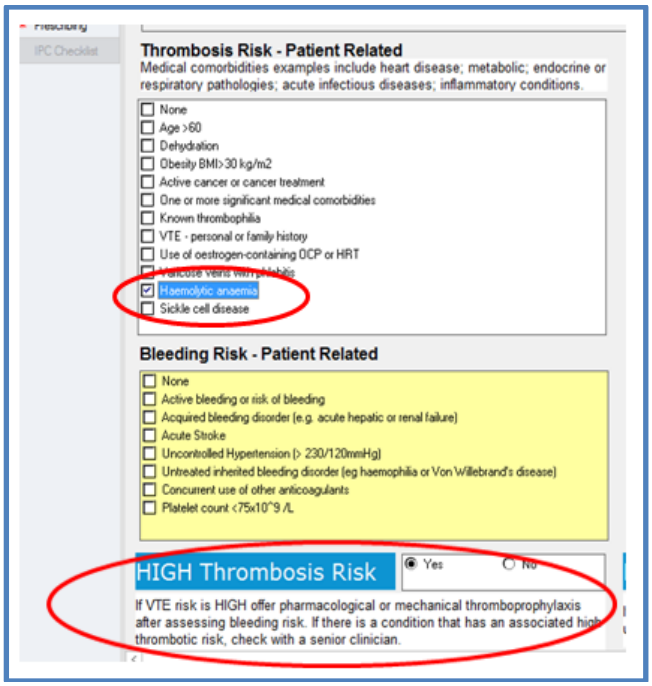
Screenshot 2: Close chart pop-up alert



Screen shot 3: First consultant review additional prompt



Screen shot 4: VTE assessment detail



Screen shot 5: Doctors Safety Dashboard