NHS Blood and Transplant
Response to Regulation 28 Report for HM Coroner for Surrey.
Name: Mr Peter Clive Higson
DOB: 29/12/1949 (died 22/03/2013)
Hospital: Frimley Park Hospital
NHSBT Transfusion Related Acute Lung Injury (TRALI)
NHSBT Referral Reference Number: TOO-13-16-PH

1. Background

NHSBT received a Regulation 28 Report – Action to Prevent Future Deaths from HM Coroner from Surrey dated 23/10/13. The coroner had found the cause of death to be:
1a - Myocardial Infarction
2 – Acute Respiratory Distress Syndrome and treated Hodgkins Disease.

The inquest concluded that the deceased died from a complication of a necessary therapeutic procedure.

NHSBT was provided with the following clinical background by the Coroner: *"The deceased had suffered from Hodgkin's lymphoma. On 29th January 2013 he underwent an autologous stem cell transplant at University College Hospital, London after which he was discharged home. On 28th February 2013, he became very unwell and was admitted to Frimley Park Hospital and was treated for Pneumocystis Jiroveci Pneumonia with a 21 day course of Co-Trimoxazole and with Methylprednisolone. His chest remained an issue, however, and he underwent a platelet transfusion of 2 pools of platelets on 12th and 13th March which made matters worse. His clinical situation looked like a transfusion related acute lung injury which had a detrimental effect on his breathing and overall well-being. He slowly improved but towards the end of the Co-Trimoxazole course, it was learnt that he did not have the Pneumocystis infection. He died on 22nd March 2013."*

The Coroner raised the following concerns: *"The platelet transfusion (12th & 13th March 2013) following the stem cell transplant (28th January 2013) seemed to have a major detrimental effect on the deceased and features, of only chronologically, in the ultimate chain of causation leading to his death. A question arises as to whether there was any aspect of e.g., the stem cell transplant interacting with the platelet transfusion suggesting that on occasions such transfusion might be contra-indicated."*

NHSBT has compiled this report in response to HM Coroner's concerns.

2. Action Taken.

2.1 Immediate Corrective Action: For suspected TRALI cases, hospital clinicians contact NHS Blood and Transplant (NHSBT) and provide the clinical details and donation numbers potentially implicated to a designated TRALI expert within NHSBT (Dr [redacted] for London and South East Region). As the Coroner's report was the first notification NHSBT had received of this matter, Dr [redacted] contacted both [redacted] (Lead Transfusion Practitioner) and Professor [redacted] (Consultant Haematologist) at Frimley Park Hospital. Ms [redacted] and Prof [redacted] reviewed the case notes.

NHSBT were informed by [redacted] that platelets were transfused on 11th March 2013 at 19.10hrs and 13th March 2013 at 12.25hrs and 15.20hrs. The platelets transfused on 13th March 2013 were single donor apheresis platelets with the following donation numbers: G0525 1335 7413 A and G0525 1334 7540S.
The main episode of respiratory deterioration was documented on 14th March at 06.20hrs, 15 hours following the most recent transfusion on 13th March.

The first documentation of acute lung injury (ALI) suspected to be TRALI in the notes is on the 15th March at 12.22hrs so platelet transfusions subsequent to that time were not examined.

NHSBT records showed that the index apheresis platelet unit G0525 1335 7413 A was collected from a male apheresis donor (53 donations, 44 platelet donations). Donation G0525 1334 7540 S was collected from a female donor (35 donations, 9 platelet donations). As part of the TRALI preventive programme all female apheresis platelet donors are screened for leucocyte (white blood cell - WBC) antibodies. This female donor has been screened for leucocyte antibodies (white cell antibodies which can cause TRALI) and none were identified.

NHSBT has also recommended that the regulator of blood components, the Medicines and Healthcare products Regulatory Agency (MHRA) and the Serious Hazards of Transfusion (SHOT) UK haemovigilence scheme are informed of the Coroner's concerns.

2.2 Potential future preventative action: NHSBT has undertaken measures at least as stringent as international peers to reduce the risk of TRALI whilst ensuring that blood components are available for patients who need them. These measures have been successful in reducing the incidence of TRALI and are detailed in the appendix. Acute lung injury and acute / adult respiratory distress syndrome (ARDS) can be caused by other disorders such as a chest infection in the absence of transfusion.

It is also hypothesised that infection and other inflammatory processes may increase the risk of a patient suffering TRALI in the "two hit" hypothesis (see appendix for details).

The Coroner explicitly questioned whether the stem cell transplant or other factors may be a contraindication to platelet transfusion. National guidelines supported by randomised studies have suggested that the risk of adverse effects of transfusion (including TRALI) are outweighed by the benefits of reducing the risk of bleeding in patients with low platelet counts following chemotherapy and stem cell transplantation (BCSH 2003).

The presence of infection increases the risk of bleeding and hence, despite infection potentially increasing the low residual risk of TRALI, this is outweighed by the risk of bleeding if platelet transfusion is withheld.

NHSBT has recently specifically undertaken an international randomised study with NHS hospitals and other organisations investigating the benefits and risks of prophylactic platelet transfusions. Most of the patients in the study had received

autologous stem cell transplantation. This study concluded "*The results of our study support the need for the continued use of prophylaxis with platelet transfusion and show the benefit of such prophylaxis for reducing bleeding, as compared with no prophylaxis. A significant number of patients had bleeding despite prophylaxis*". (Stanworth et al 2013).

3. Conclusion

As the respiratory deterioration occurred more than 6 hours after the transfusion, the deceased in this case had other reasons for ALI / ARDS and as the female donor had no WBC antibodies the SHOT imputibility criteria would suggest that TRALI was unlikely. Recent studies and current guidelines suggest that the benefits of platelet transfusion in preventing bleeding following chemotherapy and stem cell transplantation outweigh the risk of the transfusions themselves. NHSBT undertakes measures to reduce the risk of TRALI that are at least as stringent as international peers. The MHRA and the SHOT haemovigilence scheme record adverse events including respiratory deterioration and, in conjunction with NHSBT and other organisations, identify potential additional interventions to prevent recurrence.

This response has been prepared by:

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Date: 6/12/2013