NHS
Blood and Transplant

Board Meeting in Public

Friday, 12 July 2024

Title of Paper	Patient Story- Pre-deposit Autologous Donation (PAD) Blood Donation: Rising to the Challenge	**Agenda No.**	2.1
Nature of Paper (tick one)	☒ Official (*Denotes that report contains information that needs to be protected, but equally, it can be shared where this is appropriate)*	☐ Official Sensitive *(Denotes that the report contains sensitive information and must be shared on a 'need to know' basis only)*	
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Lead Executive	Dee Thiruchelvam, Chief Nursing Officer		
Non-Executive Director Sponsor	(Insert name, if there is a NED Sponsor)		
Presented for (tick all that applies)	☐ Approval ☐ Assurance	☒ Information* ☐ Update	** See Note i*

Executive Summary (max 300 word count)

This patient story describes the experience of a 46-year-old patient with multiple myeloma, due to undergo autologous stem cell transplant. The patient has an extremely rare blood type (-D-) with no identified compatible donors or frozen units. Virology testing detected anti-HBc and anti-HBs with negative HbsAg, necessitating entecavir prophylaxis during chemotherapy. There were potential donors/donations overseas but not a realistic option at the time. Siblings donations were explored with no match.

Having achieved minimal residual disease negativity with quadruplet induction, NHSBT was approached to consider Pre-deposit Autologous Donation (PAD) where 1 or 2 units would be collected from the patient to be frozen to support future transfusions to the patient.

Under current Blood Collection processes, the patient would not meet the donor selection criteria due to myeloma, previously transfusion and evidence of past HBV infection. The patient had also donated once in 2017 and was permanently excluded (past HBV infection). Therefore, our existing processes for PAD require revision resulting in multiple deviations from current process in both blood donation, testing and processing.

Previously Considered by	
BSCARE	
Recommendation	*The Board is asked to note the contents of this paper*

Risk(s) identified (Link to Board Assurance Framework Risks)

Strategic risk 1 and 6

Strategic Objective(s) this paper relates to: [Click on all that apply]

☒ Collaborate with partners	☐ Invest in people and culture	☒ Drive innovation
☐ Modernise our operations	☐ Grow and diversify our donor base	

Appendices:	

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Pre-deposit Autologous Donation (PAD) Blood Donation: Rising to the Challenge

Overview of the case:

This is the case of a 46-year-old patient with multiple myeloma, due to undergo autologous stem cell transplant. Patient has an extremely rare blood type (-D-) with no identified compatible donors or frozen units. Virology testing detected anti-HBc and anti-HBs with negative HbsAg, necessitating entecavir prophylaxis during chemotherapy. There were potential donors/donations overseas but not a realistic option at the time. Sibling donations were explored with no match.

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Challenges and solutions

- Bespoke screening required (as standardised DSC questions not appropriate and would exclude as donor). Required bespoke consent approach, separate medical assessment and documentation.
- Inability to adhere to BSQR requirements for PAD.
- Patient specific bespoke Process Deviations (PDVs) required to facilitate, resulting in multiple deviations to current processes for Session Staff, involved staff all trained to new PDV.
- Donor safety and potential severity of adverse event – location and clinical support- the donation needed to happen in clinical area with support of the patient's team, and not within a blood donation centre.
- Donation would need to be segregated and assurance that donation would not enter blood supply chain to protect for patient use and in knowledge that testing was expected to generate biohazard and the necessary database amendments to allow freezing (storage) and validation/ review.
- Management of process was completed under a change control to ensure risk assessment and change control of bespoke process, including clinical risk assessment and venue assessment.
- Process completed under mobile team licence of Filton so that Blood donation could be performed outside the BD footprint as regulated by the CQC.

Outcome

A successful Whole Blood donation performed in March 2024. The clinic assessment post donation supported the collection of a further 2nd PAD for the same patient on 16th April 2024.

A full Audit trail has been retained (i.e. testing results). Frozen Red Cells; compatible with hospital LIMS further review in c6 months' time.

A revised SOP and MPD are currently in draft to enable future modifications for any further requests to facilitate PAD.

Considerations

This has been a unique process in that Blood Supply has facilitated a rare procedure for a patient by enabling this patient to donate blood for their future use. It has been a great experience for the BD colleagues involved and the feedback from the donor/ patient has been very positive. BD colleagues rarely meet the patient receiving the blood they are facilitating the donation of. It could not, however, be possible without the support functions across all aspects of the Blood Supply chain to enable this to happen. Recognition in particular to the below individuals and departments to enable this to proceed safely for both the patient and without impacting the safety of the wider blood supply chain.

Acknowledgements:

Chiara Vendramin – Consultant in Donor Medicine, Donor Medical Team
Clare McNally – Matron for Care Quality, Blood Supply (Nursing Directorate)
Cambridge Donor Centre Team, Quality Assurance, Rare Donor Team/Clinical Services, Testing, Manufacturing, Hospital Services, Microbiology Services, Digital Data and Technology Services, Logistics, National Frozen Blood Bank, Clinical Support Team, Cambridge University Hospital NHS Foundation Trust, Savant

This case will also be put forwards for presentation at

- British Blood Transfusion Society Annual Conference Sept 2024
- NHSBT Nursing Conference Nov 2024

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