NHS Blood and Transplant

Board Meeting

July 2018

Update paper - Understanding the implications for Haemoglobin screening of the INTERVAL and COMPARE studies

1. Status – Official

2. Executive Summary

A paper was presented to the Board in January showing that the unpublished results of the COMPARE study confirmed the findings of the INTERVAL trial. Namely that around 9% donors are accepted for donation with a haemoglobin (Hb) result that was below the Blood Safety and Quality Regulations (BSQR) limits when compared with a gold standard (a full blood count or FBC). The implications of this was that there is a risk that, without changing our processes, we could inadvertently bleed a donor, who is already significantly anaemic, resulting in harm to them.

The paper detailed a number of further actions that were required to mitigate this risk. These were:

- Immediate action to improve practice in the use of copper sulphate.
- Implement use of capillary analyte in place of venous in the secondary test.

Additionally, it was recommended that a pilot, screening women under 50 with the capillary HemoCue as a first line test, was also carried out in case the improved copper sulphate testing did not mitigate the risk sufficiently. The latter two actions were piloted on 5000 donors to understand the implications of a larger roll out on donors and the blood supply chain.

These actions have now been completed with further data generated on the risk mitigation they provide and the implications of implementation. The recommendation mitigates the main clinical risk of inappropriately bleeding a donor with anaemia (reduced by 38%) with a small increase in the number of deferrals (to 7.3%). The pilot screening women under 50 gave no additional safety benefits.

The Executive Team has agreed that the next steps are:

- To accept the improved copper sulphate testing on all donors and to continue this practice.

- We roll out a secondary capillary HemoCue test (in place of the current venous test) on donors who fail the copper sulphate test as quickly as feasible.
- We do not implement testing all women under 50yrs with a primary capillary HemoCue test.

The paper in January also recommended a long-term preferred option of post-donation testing for Hb on automated analysers with the use of a prediction algorithm to estimate the Hb value over time or trajectory after donation. The funding to commence this work was approved in May 2018 and is now part of a formal strategic change project alongside transforming the new donor pathway.

3. Action Requested

The Board is asked to note the mitigation of the clinical risk provided by these actions at the expenses of a small increase in donors being deferred.

4. Purpose of the Paper

This paper concludes the work to recommend appropriate solutions to mitigate the risk of inappropriately bleeding donors who are clinically anaemic.

5. Background

A paper was presented to the Board in January showing the unpublished results of COMPARE confirm the findings of the INTERVAL trial in the rates of donors accepted with a haemoglobin result below the BSQR limits. The implications of these results showed that there is a risk that, without changing our processes, we could inadvertently bleed a donor, who is already anaemic, resulting in harm to them and non-compliant with BSQR. Since January, we have considered several options to mitigate this risk which are discussed below.

5.1 Immediate action to improve practice in the use of copper sulphate

We assessed how we perform the copper sulphate test to assess best practice and because of that review, we updated our process to reduce the risk of ambiguity and misinterpretation leading to inappropriate acceptance. There is now **one** definition of a pass. Any other result is a fail. In addition, there is now only one attempt at copper sulphate testing and if the result is a fail the donor has a secondary test performed.

We tested a full blood count post-donation on approximately 5000 donors to assess the false acceptance rate with the revised copper sulphate process together with a secondary capillary HemoCue. The data showed that improving the practice around copper sulphate testing has reduced the numbers of donors inappropriately bled by 39% from a rate of 13.8% to 8.4% in women and by 38% from a rate of 5.5% to 3.4% for men. In addition, most inappropriately bled donors now have a Hb very close to the threshold values with only around 0.3% or 3/1000 having a Hb 10-20g/L under the threshold and none with Hb 20g/L lower than the threshold. These changes have therefore mitigated the inappropriate collection of blood from donors with significantly low haemoglobin levels.

5.2 Implement use of capillary analyte in place of venous in the secondary test.
This revised copper sulphate screening process has been implemented on all session nationally and we have found that, without changing the secondary test, this has significantly increased the number of secondary tests required. When the secondary test is a venous HemoCue this causes overrunning sessions and enforced overtime for donation teams. This further strengthens the need to use a capillary method as the secondary test as well as being quicker and less expensive.

5.3 Pilot screening women under 50 with a, first line, capillary HemoCue test.
Capillary testing of women under 50 was trialled on three teams. The results showed that the rate of inappropriate bleeding dropped by 32% to 9.4%. This was not as low as the rate of 8.4% achieved by a combination of copper sulphate and capillary Hb as a secondary test. The average deferral rate for this group of donors was 21.4%. There is therefore no advantage the adoption of this strategy. This would have a significant impact on the donor base and incur substantial costs to recover sufficient donors. We do not recommend this as an option.

6.0 Impact Assessment

6.1 Donor base

The recommended option does however present the challenge of how to bring back higher numbers of donors who have come to donate and unexpectedly been deferred for a low Hb. It is important that these donors are retained to minimise the pressure on donor recruitment. The starts at the point the donor is told of the deferral, the rationale and the need to return. Whilst this is already part of current practice, we will need to improve this dialogue with the donor. We will also develop a clear pathway for those individuals who have been deferred. This will start with an individual letter or email sent to the deferred donor thanking them for coming, apologising to them for not being able to take their donation and reinforcing the reasons as to why this was so. There will also be a clear message that they will receive a text or call nearer the date of the end of the deferral asking them to attend. Learning from both arms of the INTERVAL study indicates that this should be a personalised call before the end of the deferral period with an offer to book an appointment there and then, this will be especially important for donors with ‘vulnerable’ blood groups. If this communication is unsuccessful then the donor will join our regular reactivation programme.

A review of the current donor retention rates for those donors who are deferred for low Hb results shows that 66% of donors return to donate within 12 months. The costs of the recommendations are therefore based on this and are £393k as detailed below. However, the above measures should increase the number of donors returning. The table below shows the impact on the numbers (and costs of recruiting) new donors required depending on the retention achieved. Retaining 10% more donors more than halves the recruitment costs needed to replace these lost donors.

Actuals	Baseline 66%	70% Return	75% Return
Total Annual Donor Loss	4819	3420	1673
Total Annual O- Donor Loss	606	441	235
NDA Needed O- Up Method	8742	6361	3384
Recruitment Cost (£45 NDA)	£393,395	£286,224	£152,260

6.2 Operational & Supply Planning

To protect supply and achieve collection BP targets especially in the vulnerable groups of O neg and B neg, a two-month period is required to complete the following essential activity:

- review of planning activity to ensure daily capacity planned is enough to achieve appointment slots booked required to achieve the business plan at blood group level
- update of planning assumptions for all planned sessions based on the revised deferral rate of 7.3% for low Hb
- update of invitation process algorithms to ensure increased volume of donors are invited
- review of on session processes to ensure that planning assumptions around current operational throughput can be achieved, or that alternative options for securing capacity are identified.
- review the required donor base depending on the effectiveness of the retention plan for those additional donors that will be deferred due to low Hb.

The cost of additional HemoCue machines (£42,161) was absorbed in the 17/18 financial year.

7.0 Implementation

This will be managed via a staggered roll out on a team by team basis which started with some more pilot teams starting 16th July. This will allow us to more accurately monitor the impact on sufficiency and take actions as required. This, coupled with the planning actions described, above means that we will need two months to complete the planning actions and up to a further 6 months to complete a full roll out with the larger scale roll out being planned from October.

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