NHS Blood and Transplant

NHSBT Board
January 26 2017

Platelet Strategy – Phase Two

1. Status – Public

2. EXECUTIVE SUMMARY

In September 2013 SaBTO recommended that the previously mandated requirement to meet at least 80% of platelet demand through apheresis should be rescinded on the basis of a re-evaluation of the vCJD risk associated with whole blood derived pooled platelets. In addition, the recommendation included a change from plasma to Platelet Additive Solution (PAS) for re-suspension of platelets. Following that recommendation from SaBTO, NHSBT has reduced production of apheresis platelets from 82% in 2013/14 to c57% by the end of 2016/17 and introduced PAS (Platelet Strategy - Phase One) reducing operating costs by c£2.2m per annum.

The Platelet Strategy - Phase Two project recommends to further reduce the proportion of platelets manufactured through apheresis from 57% of the total platelets (budget 2016/17) to 50% by early June 2017. The reason for this reduction is to drive further efficiencies in the supply chain as manufacturing platelets through apheresis is more expensive than by pooling buffy coats from whole blood donations (pooled platelets).

Reduction to 50% production of apheresis platelets will drive recurring savings of c£774,000 p.a. to be achieved by 2019/20 and require an investment of £1.045m (mainly redundancy costs in Blood Donation). The pay back of the investment would be three years. In addition, it would avoid c£1m investment as a result of the closure of the Leeds CBTU donor centre as the donor centre will not have to be relocated in the consolidation of Leeds-Sheffield. The proposed change will also release collection capacity in the donor centres to increase WB donations by c18,000[1] units supporting the delivery of one of Blood Donation strategic targets.

After six months, the project will evaluate if further reduction of production of apheresis platelets to 45-47% is possible by assessing impact on: a) level of A+B1 matching for Human Leucocyte Antigen (HLA) matched platelets, b) apheresis platelets on time in full provisioning performance (OTIF), c) progress on increasing WB collections in donor centres and d) extra costs in blood supply (e.g. NPT packs, CMV testing, inter centre movements).

3. ACTION REQUESTED

The Board is asked to approve the recommendation to reduce the level of apheresis platelets production to 50% in June 2017 and to evaluate further reductions to 45-47% after six months of implementation.

To achieve the reduction to 50% apheresis production, the Board is also asked to approve:

- Closure of the Leeds CBTU donor centre (four apheresis chairs and one WB chair) with the loss of 11.50 whole time equivalent (WTE) and the transfer of donors to the Leeds City Donor Centre.

- Reduction in apheresis capacity (equivalent to c15,000 apheresis appointments), with some of these appointments converted to collect more whole blood in donor centres. Reduction of apheresis appointments to impact all blood groups except A neg and AB neg. Operationally, this would be achieved by inviting A neg and AB neg platelet donors broadly at the same frequency as currently, whereas platelet donors from other blood groups will be invited less regularly.

- Non recurrent investment of £1.045m for staff redundancies, marketing and new incubators for Bacterial Screening in Colindale. The total net revenue savings over a five year period will be approximately £3.350m.

- Reduction of c14 WTE in blood donation mobile teams (in addition to Leeds CBTU closure) as more whole blood is collected in the donor centres using the freed-up apheresis capacity.

4. BACKGROUND

4.1. NHSBT currently manufactures platelet concentrates using two different methods, apheresis and whole blood derived. Apheresis platelets are single donor platelets manufactured using an automated collection system that can result in multiple platelet doses; typically two or three adult therapeutic doses (ATDs) can be collected from individual donors at each donation. This requires a dedicated panel of donors who attend donor centres. Whole blood derived platelets require the separation of the platelet rich ”buffy coat” layer between plasma and red cells in centrifuged units of whole blood. Four of these separated “buffy coats” are then pooled and further processed to produce one ATD.

4.2. NHSBT has, since 2009, supplied 80% of platelets requested by hospitals from apheresis collection. This followed a recommendation by SaBTO that the UK Blood Services should move to, as far as possible, 100% apheresis, but that as a minimum 80% of platelet demand should be met from apheresis. This was on the basis that single donor platelets constituted a lower vCJD risk as each unit exposes patients to fewer donors than those produced by pooling four whole blood donations. Prior to this time NHSBT had been producing around 40% of platelets by apheresis.

4.3. In September 2013 SaBTO reconsidered this recommendation following greater understanding of the risk of vCJD infectivity in whole blood and the prevalence of vCJD within the population. The recommendation of this review was that the 80% minimum provision of platelets by apheresis was no longer necessary and that both pooled whole blood derived and apheresis platelets should be re-suspended in Platelet Additive Solution (PAS).

4.4. The Platelet Strategy - Phase One project recommended reducing to 60% apheresis platelets and then, following implementation of 60% apheresis, undertaking a milestones review to evaluate potential further reductions.

4.5. This new project Platelet Strategy - Phase Two has evaluated the approach, costs/benefits and the risks of further reducing apheresis production from 57% of the total production in 2016/17 to 50% or 40%. The recommendation from this assessment is to reduce to 50% apheresis and to evaluate further reductions to 45-47% after six months of implementation. This has been agreed with all key internal stakeholders impacted by this decision: Blood Donation, Manufacturing & Logistics, Clinical and H&I.

5. PROPOSAL

The following table summarizes the main changes required in the operating model to enable the proposed reduction to 50% apheresis production.

Current position	Proposed change
People	
Blood Donation employ c300.4[1] WTE in donor centres to collect both platelets and whole blood (budget 2016/17).	Blood Donation will employ c290.0 WTE (10.4 WTE net reduction). This includes a reduction of 10.70[2] WTE from the closure of Leeds CBTU, increases in staffing in some donor centres to increase WB collections (5.90 WTE) and reduction of staffing in some donor centres (5.60 WTE).
Blood Donation employs 1,239 WTE in mobile teams to collect whole blood only (budget 2016/17).	Blood Donation will reduce c14 WTE in mobile teams over two years as more WB (c18,000 extra units) will be collected in the donor centres using freed up apheresis appointments
Manufacturing employs c815 WTE in processing, testing and hospital services.	Increase the number of staff in manufacturing in Colindale by 5 WTE to process both the extra pooled platelets and the extra red cells and reduce 1 WTE in Filton or Manchester.

[1] Figures excludes Bradford DC, and Leicester DC as they have separate business case and WEDC as platelets are not collected

[2] In addition, the donor centre manager post will be reduced bring total staffing reduction to 11.50 WTE

Current position	Proposed change
Process	
Approx. 114,000 donor appointments planned per year to produce c165,000 platelets through apheresis donations (2016/17 budget)	Approx. 99,000 appointments per year to be planned to reduce production of apheresis platelets. Number of appointments for production of A neg and AB neg apheresis platelets to be broadly maintained; the reduction will impact mainly on all other blood groups.
Filton is currently producing c1,000 pooled platelets per week, the 3 North sites c1,100 and Colindale c600. (NB: the three sites in the north will be consolidated into one from Sept'17).	All three manufacturing sites to process between 1,000 - 1,175 pools/week (depending on apheresis collection performance and demand)
Bacterial Screening equipment capacity (number of incubators): Manchester post north consolidation (20), Filton (23), and Colindale (20)	Move Bacterial Screening incubators to meet new production plans. Manchester (20), Filton (19), Colindale (26). Purchase 4 new incubators and a controller for Colindale[3].
Active tagging and tracking of Homozygous (HZ) donors in the Supply Chain No proactive management of Half Homozygous donors	Proactive tracking of the number of HZ and Half HZ appointments per week Donor Centres to start tagging some of the most used half-HZ donors. Central Planning Team to implement new process to retain donations from HZ and half HZ donors at the manufacturing sites up to day three.
Stock movement algorithm (SMA3) not differentiating between apheresis and pooled platelets to distribute platelets to the 15 Stock Holding Units (SHUs).	New Inventory Optimization Tool (IO) to account for variation in demand of apheresis vs. pooled platelets between SHUs and blood groups to ensure appropriate proportion is available by SHU to meet demand.

6. BENEFITS CASE

6.1 There are significant financial benefits associated with the business changes proposed. Those benefits are described below.

6.2 Reduction in operating costs releasing approximately £774,000 per annum from 2019/2020. This is the net impact of:

- A reduction of operating costs in Blood Donation of c£1,361,000 per annum, of which c£620,000 are consumables and the rest are mainly pay costs.

[3] Extra incubators required to implement both the Supply Chain Modernisation changes in Manchester and the Platelets Strategy in 2017/18, otherwise expected recurring savings of £775k p.a. from the Platelets Strategy would have to be deferred by 6-8 months

- An increase in operating costs in Manufacturing and Logistics of c£587,000 to increase production of pooling platelets, of which £460,000 are consumables, £113,000 are extra staffing and transport costs and £14,000 are capital related charges.

6.3 Increase whole blood collections in donor centres, excluding Leicester, Bradford and the WEDC[4], from a forecast outturn of 220,000 to 238,000 by the end of 2017/18, supporting delivery of the Blood Supply 2020 strategy

6.4 Support the move towards an optimized end to end supply chain by building processing and Bacterial Screening testing capacity at Colindale reducing the number of platelets that would have to be moved daily from Filton/Manchester to Colindale Stock Holding Units.

6.5 Cost avoidance of c£1m as a result of the closure of the Leeds CBTU donor centre as the donor centre will not have to be relocated in the consolidation of Leeds-Sheffield.

7 OPTIONS ANALYSIS

7.1 Three options were considered:
- No change to apheresis collection
- Reduction of apheresis to 60%
- Reduction of apheresis to 40%

7.2 The decision not to pursue a reduction to 40% apheresis was based on the need to meet clinical needs for patients requiring apheresis platelets. Specifically:

- There are some key specialist components that rely upon apheresis platelets. Those include HLA matched / selected platelets, Human Platelet Antigen (HPA) specific platelets (including HPA-1a, -5b negative units for intrauterine / neonatal use) and platelet packs split into small volumes suitable for newborn babies (neonates) that are not HPA-1a, -5b negative. The simulation modelling indicates that if production of apheresis were to be reduced to 40%, the level of A+B1 matching would reduce by c10 p.p. towards 65% vs. current target of 75%. Whereas at 50% apheresis production with the proposed mitigation actions in this business case, it is expected that the levels of A+B1 matching could be broadly maintained at current levels[5].
- Following SaBTO's advice that apheresis and pooled platelets can be used interchangeably (excluding those listed in above), NHSBT also circulated a recommendation that apheresis platelets should be provided for all recipients under 16 years of age "where possible" and subsequently the wording of the NHSBT component portfolio has extended this to include young adults born on/after 01/01/1996.

4 Leicester and Bradford excluded as have separate business case for their relocation. WEDC not included in Platelets Strategy as the donor centre does not collect aphaeresis platelets
[5] At current levels of HLA demand

Similarly, British Society for Haematology (BSH) guidelines published in 2016 have included the NHSBT-derived statement that apheresis platelets should be provided for children “where possible” (not stating adults born on/after 01/01/96).

- Current demand for apheresis platelets ranges between 28-31% per month but there is large variability by location and blood group. This would make it challenging for NHSBT to have the right apheresis platelet in the right location at the right time if production were to be reduced to 40% given that the current stock movement algorithm does not distinguish between apheresis and pooled platelets. In addition, given NHSBT advice, which has been extrapolated to use apheresis for patients born on/after 01/01/1996 “where possible”, apheresis demand could grow by 1% p.a. in line with the growth of that cohort of patients, unless hospitals decide not to follow NHSBT and BSH advice once the differential pricing for apheresis vs. pooled platelets is introduced next financial year.
- In addition, at 40% apheresis production, NHSBT will incur additional costs, including NPT packs usage and additional CMV testing and there is a potential risk of falling below the price break volumes in the current harnesses contract.
- Detailed assessment of the options is included in the Detailed Business Case.
- After six months, the project will evaluate if further reduction of production of apheresis platelets to 45-47% is possible by assessing impact on:
    a) level of A+B1 matching for Human Leucocyte Antigen (HLA) matched platelets
    b) apheresis platelets on time in full provisioning performance (OTIF)
    c) progress on increasing WB collections in donor centres and d) extra costs in blood supply (e.g. NPT packs, CMV testing, inter centre movements).

8. ASSUMPTIONS

8.1 The current level of service to hospitals will be maintained or improved, including that the current level of matching for HLA grade A and B1 will be broadly maintained.

8.2 There is no difference between apheresis and buffy coat pooled platelets in terms of clinical efficacy.

8.3 Apheresis platelets will continue to be supplied for specific patients,

- Neonates and Paediatrics
- Patients requiring HLA/HPA matched or IgA deficient platelets
- Where possible, those patients born on/after 01/01/1996

8.4 No change to current shelf-life of platelets (maintained at seven days).

8.5 NHSBT will move to the provision of 100% HEV neg blood components in the first quarter 2017/18.

8.6 NHSBT will have rolled-out the new Inventory Optimization tool which includes the criterion to differentiate between apheresis and pooled platelets by the end of 2016/17.

9. FINANCIAL IMPACT ASSESSMENT

9.1 This section covers the 5-year financial impact of moving to the option to reduce apheresis production to 50% by early June 2017.

9.2 **Non recurring costs total £1,045,000**

- Redundancy costs in Blood Donation of £620,000. It assumes
    1. £255,000 for redundancy in Leeds CBTU (75% of the staff)
    2. £295,000 for redundancy in mobile teams (60% of the 14 WTE reduction in mobile teams)
    3. £70,000 for redundancy in donor centres with a reduction of staffing levels (2 WTE out of the expected reduction of 5.60 WTE)
- Marketing spend (above BAU) to drive donor recruitment in the donor centres: £290,000
- Equipment for the additional incubators and controllers and installation: £125,000
- Quality assurance resource (1 day/week): £10,000

9.3**. Five year savings in blood donation total £6,206,000**

- Reduction in apheresis harnesses costs: £2,723,000
- Closure of Leeds CBTU – pay savings: £1,723,000
- Pay savings from reduction of 14 WTE in mobile teams: £1,505,000
- Pay savings from reduction of 5.60 WTE in donor centres: £652,000
- Reduction in other consumables in blood donation: £259,000
- Reduction in venue costs in blood donation: £94,000
- Increase in pay costs of c5.90 WTE in Donor Centres: (£750)

9.4**. Five year costs in manufacturing total (£2,856,000)**

- Additional platelet filters: (£1,222,000)
- Extra staff in manufacturing (4 WTE): (£525,000)
- Additional sterile connecting devices: (£479,000)
- Additional PAS and PAS related consumables: (£443,000)
- Additional NPT packs: (£134,000)
- Capital charges on additional incubators: (£76,000)
- Additional transport costs: (£39,000)
- Reduction of apheresis related testing costs: £62,000

9.5 Total 5-year savings are £3,350,000. Pay back of the £1.045m investment estimated to be three years (27 months).

9.6 This financial forecast is based on a platelets demand forecast 2017-18 of 250,800 issues. Recurring savings would be higher if demand were to be higher than 250,800 and lower if demand were to be lower.

9.7 In addition to the above, further savings will be achieved through cost avoidance associated with the proposal to close the Leeds CBTU donor centre and not re-locate as part of the Leeds-Sheffield consolidation.

Table 1: Summary Financial Assessment

	Year 0 16/17 £'000	Year 1 17/18 £'000	Year 2 18/19 £'000	Year 3 19/20 £'000	Year 4 20/21 £'000	Year 5 21/22 £'000	Total 5-years £'000
Capital Requirement Purchases	(120)	-	-	-	-	-	(120)
Project Budget Expenditure	(270)	(430)	(225)	-	-	-	(925)
Project Support Costs			-	-	-	-	
Revenue Recurring (Costs)/Savings	-	335	726	788	788	788	3,426
Capital Charges (Increase)/Decrease	-	(16)	(16)	(15)	(15)	(14)	(76)
Revenue Income Increase/(Decrease)	-	-	-	-	-	-	-
Net Revenue	(270)	(111)	485	773	773	774	2,425
Cumulative (Payback period)	(390)	(501)	(15)	758	1,531	2,305	
Discounted Cash flow and 5 year NPV	(390)	(91)	468	711	687	664	2,048

10. Project approach and implementation

10.1 The approach to implementation will be through the Platelet Supply Project Board including key representation from Blood Donation, Manufacturing and Logistics, Clinical, Marketing and Communications, H&I, Quality and Finance. Governance of the project will be through the Manufacturing and Logistics Change Programme Board to the NHSBT Transformation Board. The Accountable Executive for the Platelet Supply Project will report to the Director of Manufacturing and Logistics. In addition, the Platelets Supply Project will also report into the Blood Donation Change Programme Board and the Director of Blood Donation.

10.2 Quality Assurance (QA) of the process will be achieved through the involvement of senior QA specialists from the organisation at each level of governance within the programme of work. A Quality lead has been nominated and will be a key member of the project and ensure all quality procedures including GMP, risk analysis, change control and quality standards are followed.

10.3 The scope of the project covers coordination of all activities relating to:

- Achievement of the apheresis reduction targets outlined
- Delivery of the increase of whole blood in donor centres
- Delivery of the reduction in staffing levels in Blood Donation
- Increase of pooling production in Manufacturing
- Development of detailed new production and collection plans assuming 50% apheresis production

10.4 Internal resources to support all project groups and activities are defined in the detailed business case for the project. Cross business support arrangements have been agreed and committed through the Transformation Programme Board on acceptance of the detailed business case ensuring engagement of all stakeholders and group services support. Those can also be found in the detailed business case.

10.5 The proposal for implementation is to reduce to 50% apheresis production in two stages. First, apheresis production will be reduced to c56% of total platelets by the end of February 2017 with the closure of Leeds CBTU donor centre and changes to bed configuration in Stoke Donor Centre. Thereafter, production will be further reduced to 50% apheresis in June 2017.

10.6 To achieve the increase in pooling capacity, the proposal is to increase pooling capacity in Colindale and Manchester and maintain the current pooling capacity in Filton to better align platelets production with demand. This will mean that all three manufacturing sites would broadly manufacture the same number of pooled platelets. It will also halve the current gap of pooled platelets for Colindale SHUs. The daily move of platelets from Filton to Colindale SHUs will continue given the shortfall of apheresis collections to serve Colindale SHUs demand.

10.7 To enable Colindale to pool more platelets, collections from the Hither Green and Surrey collection teams would be transported back directly to Colindale instead of Filton (via Tooting).

10.8 Table 2 below provides an outline of the project plan for the implementation of 50% apheresis, including key activities and milestones.

Table 2: Outline timetable

Key Deliverables, Milestones (M), Outputs (O)	Target Date	Tolerance
M1- Leeds CBTU closed and donors moved to Leeds City Donor Centre	Feb. 2017	+/- 30 days
M2 – Donor Centres to change their appointment grids and adjust invitation targets	Feb. 2017	+/- 30 days
M3- Agreed plan to increase production from 600 to 1,000-1,175 pooled platelets per week in Colindale	Feb. 2017	+ 30 days
M4 – Recruit extra staff in the Donor Centres with an increase in staffing levels	April 2017	+ 30 days
M5 – Reduce staffing levels in Donor Centres with reduced staffing levels	Sept. 2017	+ 30 days
M6 – Sign off marketing plan by Donor Centre to recruit WB donors in Donor Centres in 2017/18	Feb. 2017	+/- 30 days
M7 – Identify the half HZ donors that donor centres will have to tag in session (in addition to HZ donors) and manage in the supply chain as per HZ process	Mar. 2017	+/ - 60 days
M8 – Agree communication plan to staff and donors	Feb. 2017	+ / - 30 days
M9 – Recruit and train staff in Colindale to increase pooling capacity (5.00 WTE)	Mar 2017	+/- 30 days
M10- Install and validate additional 4 incubators and 1 controller in Colindale	Mar 2017	+/- 30 days
M11 – Transport to take WB collections from Hither Green and Surrey to Colindale instead of Filton	May 2017	+/- 30 days
M12 – Complete detailed collection and production plan with 50% of apheresis	April 2017	+/- 30 days
M13 – Implement Inventory Optimization module with criteria to manage apheresis and pooled platelets separately	Feb. 2017	+/- 90 days
M14 – Agree mobile teams reduction 18/19 or decide to reduce staffing in Donor Centres if increase in WB collections has not been achieved	Nov 2017	+/- 30 days
M15 – Install 2 additional incubators in Colindale and one extra controller (post SCM)	Nov 2017	+/- 30 days
M16 – Evaluate impact of reduction to 50% CD and assess if further reductions are achievable	Dec 2017	+/- 30 days
O1 – Reduce to 56% apheresis production	Feb. 2017	+/ - 30 days
O2 – Reduce to 50% apheresis production	June 2017	+/ - 30 days
O3 – Assessment of further reduction to 45-48%	Dec 2017	+/- 30 days
O4 – End of project report	Feb. 2018	+/- 30 days

11. RISKS

11.1 Detailed risk logs will be completed by the project team for all activities identified in the project plan, this will clearly identify GMP, donor and staff related risks and mitigating actions. All identified risks will be actively managed by the project team and any high level risks identified will be escalated to the Change Programme Board.

11.2 Current assessment of the project has identified key risks and these are outlined below.

11.3 A+B1 HLA matching levels

- There is a risk that the proposed mitigation actions to minimize the impact on levels of HLA matching are not enough or that there is a significant increase in the demand of HLA match above current levels or in the level of the complexity of patients' requests. This will result on the level of A+B1 match level to potentially fall below the actual performance of c70-72%.

- Mitigation: Project team will monitor both demand for HLA matched platelets and the monthly performance on A+B1 matched levels. If not enough, NHSBT could try to bring forward implementation of epitope matching to increase the pool of potential donors to match from.

11.4 Increase in WB collections in Donor Centres

- There is a risk that collections of WB in donor centres (excluding Bradford, Leicester and WEDC) are not increased by c18,000 units after the conversion of apheresis appointments into WB appointments or it takes longer than 10 months to achieve the increase. This will result in mobile team capacity reduction being delayed or having to replan reduction of staffing levels in Blood Donation and shift the reduction of staff from the mobile teams to the donor centres. This will likely lead to a delay in the delivery of part of the pay savings in Blood Donation.

- Mitigation: Targets by donor centre have been set using historical performance and donor potential analysis using Experian (consumer/demographics) data. Blood Donation and the Marketing and Communications Directorates will be leading the increase in WB collections as part of the Business Plan delivery. Project team to phase the marketing investment and to monitor delivery and review forecast/plans depending on progress.

11.5 Availability of apheresis platelets

- At 50% apheresis production, it will be more challenging to have the required apheresis platelets in all the SHUs at all times given the reduced number of apheresis platelets on the shelf. This could result in apheresis platelets not being available when required and having a negative impact on OTIF, potentially delaying patient treatment and increasing the number of complaints from hospitals.

- Mitigation: The new Inventory Optimization tool introduces an additional criterion in the stock algorithm to take into account the difference in demand for apheresis and pools by hospital/SHU to increase likelihood of meeting hospitals demand for apheresis platelets. Project team to monitor OTIF for platelets and discuss with Central Planning Team potential corrective actions if below expected levels. In addition, the introduction of differential pricing for apheresis and pooled platelets is expected to reduce overall apheresis demand although it may increase apheresis demand for certain blood groups (A neg apheresis platelets).

11.6 Split of accountability across the Blood Supply (Blood Donation, Manufacturing & Logistics, DTS and Marketing & Communications).

- Accountability for the delivery of the project is now split across four directorates, instead of two when the initial reduction from 82% to 57% was completed. Therefore, it is more time consuming to agree actions and targets and there is a risk of lack of coordination due to different priorities and lack of ownership.

- Mitigation: Ensure all team meetings and project boards have attendance from representatives from the four Directorates. Agree clear targets/actions for all key areas and monitor delivery.

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