NHS
Blood and Transplant

Convalescent Plasma Programme (CPP)

NHSBT Board Update: Pre-read

May 2020

V1.0

Introduction

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- The Convalescent Plasma programme commenced on 30th March
- The business case was submitted to DHSC on 8th April
- Funding for £17.9M was approved
- In light of the current COVID 19 epidemic, mobilisation and programme delivery have been at pace
- The business case assumed scale-up by mid-late May and up to 5,000 donors per week
- We have had to respond to changing circumstances, as the current epidemic and national response unfolds
- We will provide an update on the latest position at the Board meeting

Original programme objectives

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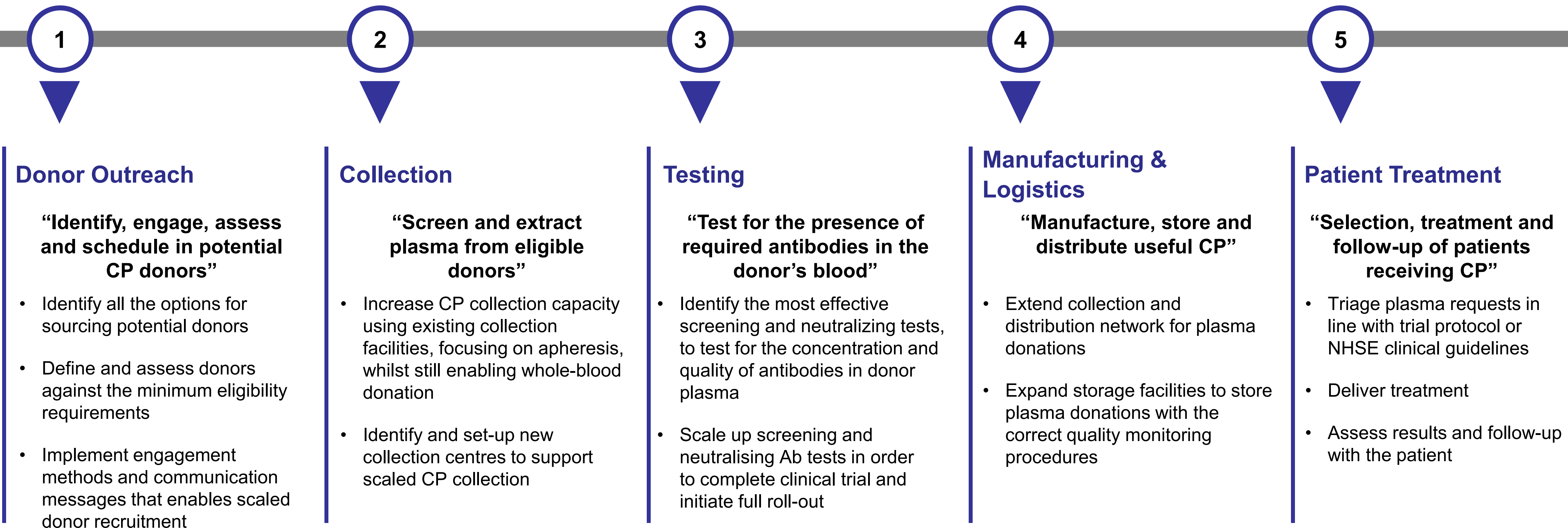

The supply target for the RECOVERY trial has changed since the programme initiation, and is now 10,000 units. The target for the REMAP CAP trial is still ~2,000 units

Backdrop of the challenge

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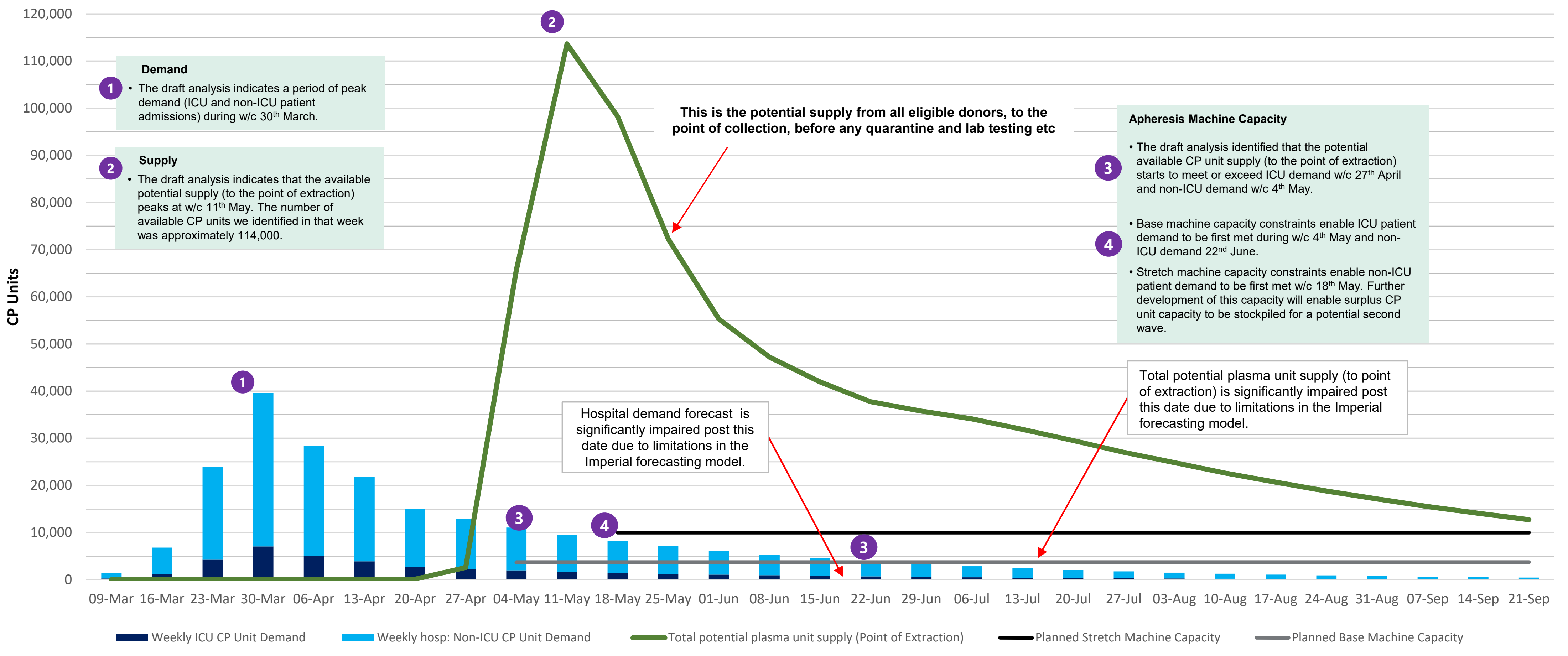

Subject to change as data is refreshed, additional actuals are included and assumptions amended

Convalescent plasma UK trial

- Patients admitted to ITU within last 48 hours
- Confirmed COVID
- CP versus standard care (+/- other randomised treatments)
- CP on study day 1 and day 2
- Primary outcome – number of organ support-free days up to D21
- REMAP-CAP outcomes plus other domain specific outcomes – arterial or venous thrombosis, SAEs
- Planned recruitment 2000 participants, approx. 1000 receive CP
- Intensive blood and respiratory sampling for a subgroup (400 participants)

Convalescent plasma UK trial

- Hospitalised patients
- Confirmed COVID
- CP versus standard care (+/- other randomised treatments)
- CP on study day 1 and day 2
- Primary outcome – 28 day mortality
- Other outcomes – need for ventilation, renal support, hospital stay
- Also thrombotic outcomes and Transfusion-related AEs usually reportable to SHOT
- Planned recruitment at least 5000 participants, 2500 receiving CP
- Substantial amendment submitted to include children

Some great progress has been made…

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National press coverage

First unit of CP collected at WEDC

First CP units go to hospital

Promotional video & social media campaign launched

DS2 machines arrive at Filton to enable in-house C19 testing…

New donor carers and nurses trained & operational

Freezer containers delivered to Filton

Achievements to 20th May

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1 Donor Outreach

- ✓ **Launched web-form** to enable scaled donor recruitment with **~34,000 completed forms to date**, and launched test & learn in Birmingham
- ✓ **Processed ~80,000 contact details** from PHE and web-form
- ✓ **More than doubled telephony outreach** capacity to 50 agents
- ✓ **Contacted ~27,000** potential donors
- ✓ Successfully booked **~2,600+ CP appointments**
- ✓ **Increased fill rates** from ~65% to an average of **94% over the next 7 days**
- ✓ **Initiated collaboration** with other organisations **to source additional potential donors** to contact (e.g. ZOE app)

2 Collection

- ✓ **Defined process for collection via apheresis** and **trained all existing staff across 23 DC's**
- ✓ **Collected ~1600 CP units in total** to date
- ✓ **Recruited 350+ new staff,** with ~117 already operational
- ✓ **Re-designed training** programme from 6 to 2 weeks
- ✓ **Creating 8 new CP collection pop-ups** within existing NHSBT real estate footprint, inc. MHRA
- ✓ **Deployed an additional 37 Trima machines** so far to expand capacity (out of 76)
- ✓ **Identified & contracted 3 new venues in London** to support scaled CP collection
- ✓ **Secured equipment and consumables** (inc. harnesses) to collect up to 85,000 CP units

3 C19 Testing

- ✓ Collaborated with PHE Porton, PHE Colindale and Oxford University on **evaluation of multiple assays and established a Bioarchive**
- ✓ Compared assay results and **selected EUROIMMUN assay for routine use**
- ✓ Made **decision on required antibody titre** for REMAP CAP trial
- ✓ **Procured 4 DS2 machines** to enable **in-house C19 antibody testing**
- ✓ **Secured a supply of EUROIMMUN test kits**
- ✓ Developed new and improved processes for **sample tube handling and data transmission**

4 Manufacturing & Logistics

- ✓ **Put in place manufacturing process for CP** with quality monitoring
- ✓ **Trained manufacturing staff** to issue and quality monitor
- ✓ **Changes to OBOS, Pulse and Hematos**
- ✓ **Processed ~225 CP units** to date
- ✓ **Released 67 CP units** to hospitals
- ✓ **Expanded freezer storage capacity** to store **~43,000 CP units**
- ✓ **Defined automated release process**
- ✓ **Recruited 25 manufacturing staff** for CP

5 Treatment

- ✓ **Protocol sign-off** for **REMAP CAP** and CP arm of trial launched on 27th Apr
- ✓ **Trained staff at 24** hospitals
- ✓ **15 hospitals on-boarded** to **REMAP CAP trial**
- ✓ **RECOVERY trial protocol agreed** and training of initial sites started

Attrition on the CP donation pathway

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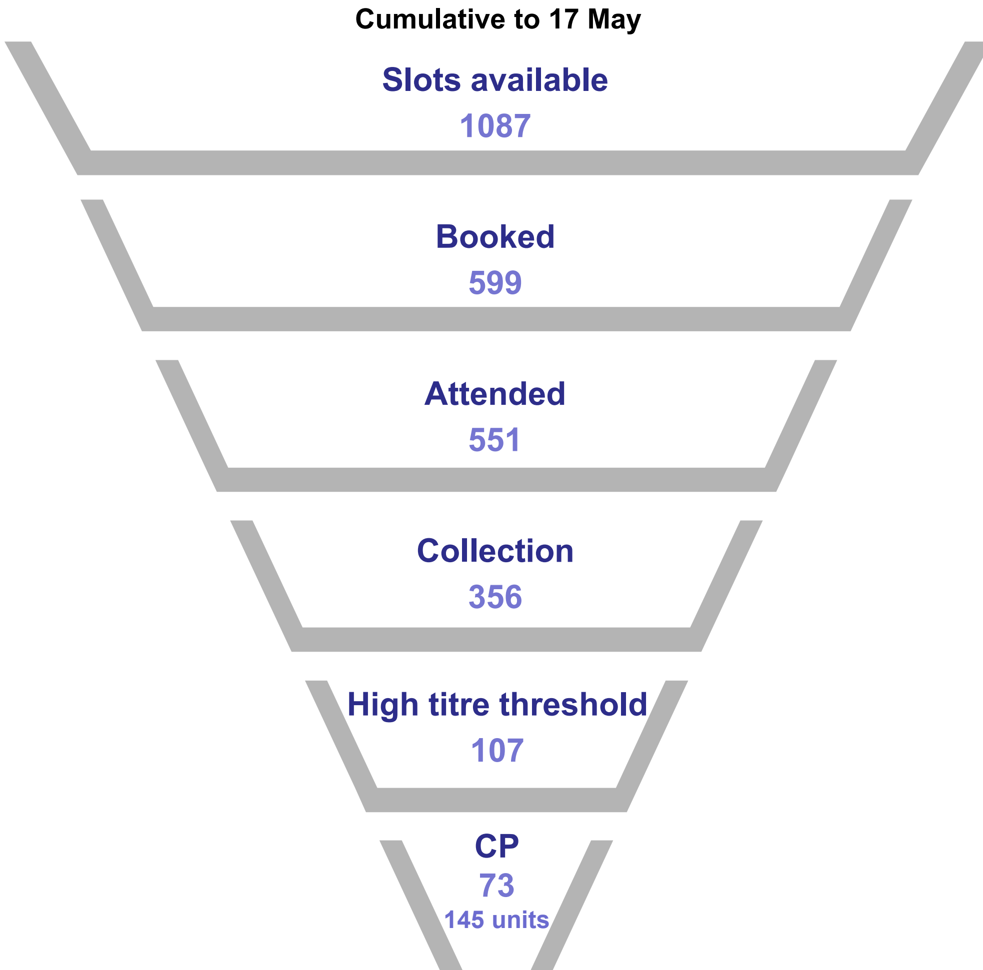

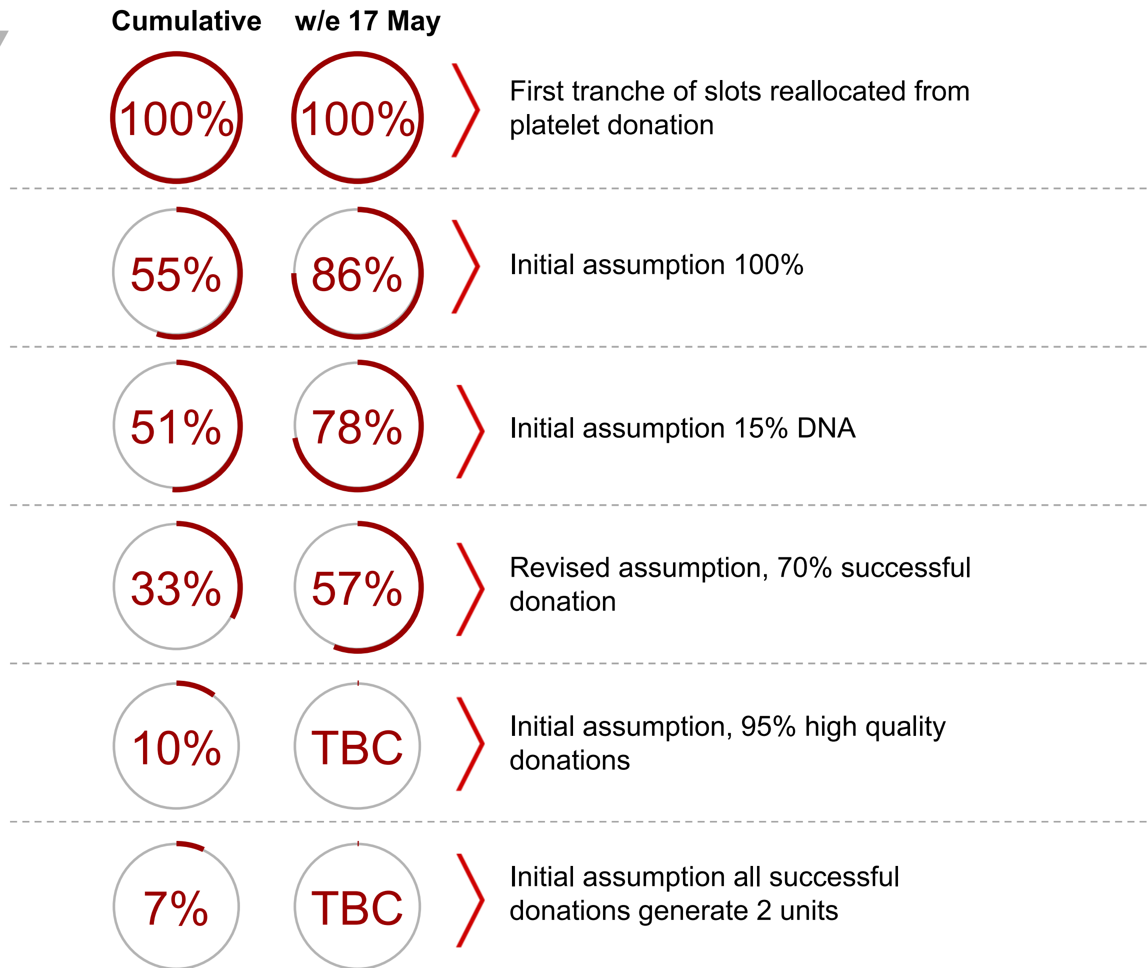

Interventions to address attrition

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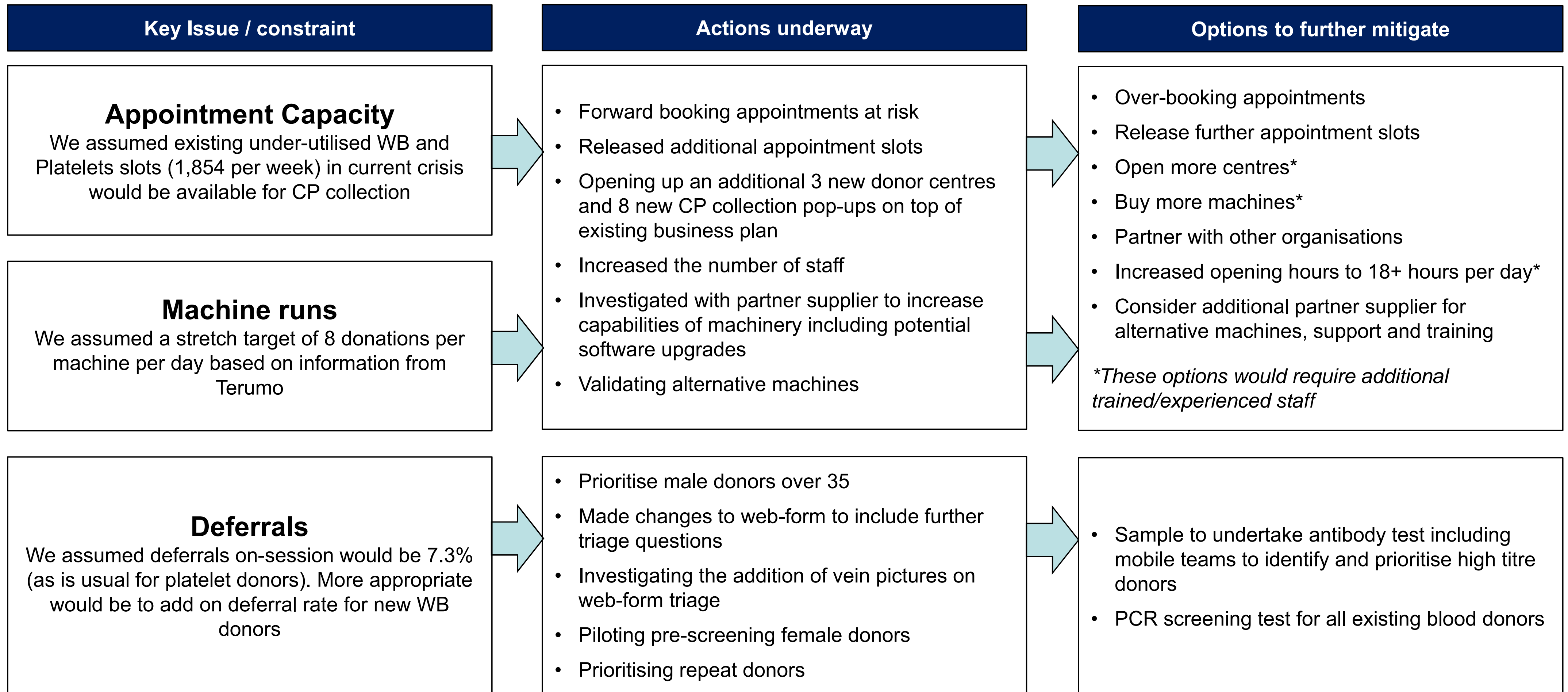

Current headline Programme risks

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Risk	Mitigation
Non delivery against published timeline Damaging NHSBT reputation	• Carry out detailed planning and ensure plans are reviewed by the experts and key stakeholders in each of the capability areas – stress testing as appropriate and gaining buy-in from relevant levels of the organisation from work stream through to Programme Board • Plans reviewed regularly and reported through Programme governance
Sustainability of Collection because of other competing priorities / challenges Unable to achieve published target	• Integrating the plan with WB and Platelets to maximise capacity • Over recruit Collection staff to mitigate the impact of staff sickness • Increase capacity with new sites and plasma only capability • Explore ways to increase training capacity to limit the impact on BAU and enable greater numbers to be trained in shorter time periods • Recruit those with skills that mean not all training is required
Missing peak collection opportunity Unable build stock levels of CP in advance of second wave	• Increase capacity with new sites and plasma only capability • Exploring pre-screening and taking samples more rapidly to identify high titre donors that are suitable • Ramp up/full collection capacity across all existing donor centres prior to new centres being operational
Uncertain environment, planning at risk Assumptions in modelling may be incorrect e.g. timing of second "wave"	• Develop forecast model utilising all Government data and working with National agencies • Make "No Regrets" decisions based on NHSBT subject matter experts • Proactive stakeholder and supplier engagement

Programme governance overview

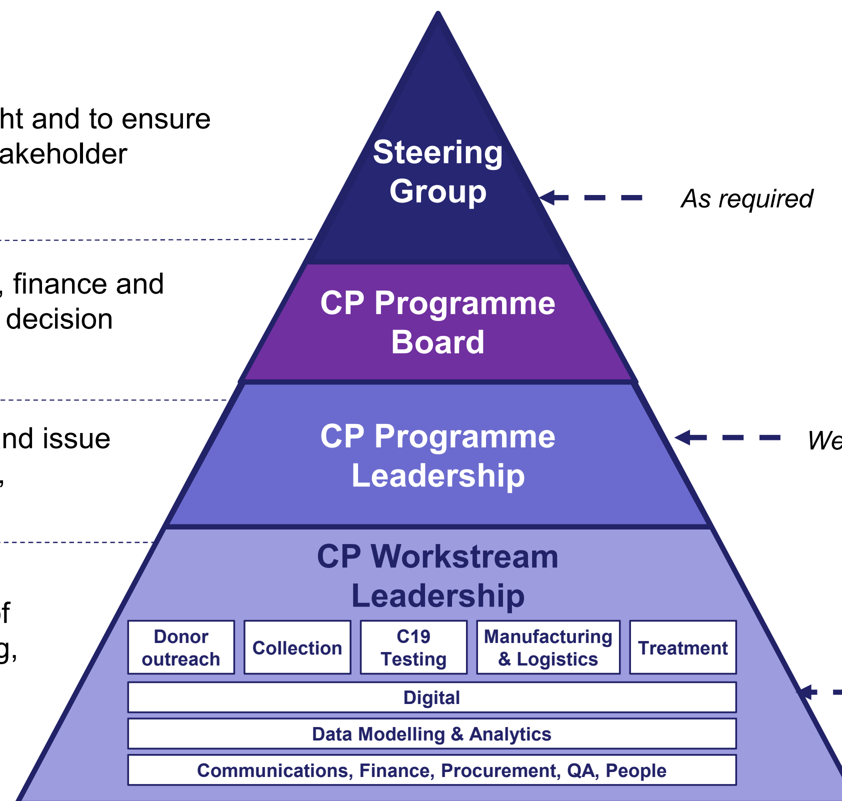
Responsibilities	Governance Forums	Advisory Groups

Fortnightly: Responsible for Programme Oversight and to ensure alignment with strategic objectives. Board level Stakeholder engagement and management.

Weekly: Accountable for Programme governance, finance and control. NHSBT Exec Team point of escalation for decision making and escalation of issues and key risks.

Daily: Resource allocation, workstream and risk and issue escalation, providing direction and daily decisions, prioritisation and focus.

Daily: Workstream delivery, timely management of risks and issues to enable agreed decision making, managing workstream plans and status reporting



As required

Clinical Advisory Board
Providing ethical and clinical inputs to decisions

Weekly engagement

Devolved Blood Services
Knowledge sharing and collaboration across workstreams

Nominated members

Financial update as of 20th May

NHS Blood and Transplant

Initial Target Scenario 85,000 units	Estimate Provided to DHSC (£'K)	Forecast total cost (£'K)	Forecast additional cost* (£'K)	Forecast absorbed cost** (£'K)	Currently Incurred (£'K)	Comment
Project Staffing including Deloitte	£1,500	£1,300	£1,300		£602	Deloitte Costs anticipated to be £1.2M
Temporary Donor Centres	£500	£300	£300		£185	
Training, PPE, Freezers etc.	£500	£300	£300		£193	4 Freezers delivered to Filton + Racking & Contronics
Storage & Distibution	£0	£687	£687		£568	Freight, Transport Boxes, Warehousing
Donation Couches	£250	£122	£122		£122	Based on 35 chairs + 30 adaptive pads
Other one-off costs	£0	£300	£300		£206	Including 4 x DS2 Analysers
TOTAL PROJECT/ SET-UP COSTS	**£2,750**	**£3,009**	**£3,009**		**£1,875**	
Test Kits***	£2,580	£1,060	£1,060		£18	Micro, NAT, HLA/HPA Antibody, COVID antibody
Consumables***	£3,615	£3,277	£3,277		£62	Harness, Transfer Packs etc.
MTHS Staff	£310	£314	£82	£232	36	Part of cost absorbed in baseline establisment
H&I Staff	£0	£340	£340		6	
Blood Donation Staff	£2,975	£2,975	£2,329	£646	212	
TOTAL PRODUCTION COSTS	**£9,480**	**£7,966**	**7,089**	**878**	**396**	
Donor Recruitment (Based on £50 per donor)	**£2,125**	**£1,500**	**£1,500**		**£55**	Includes cost of NCC Agents & Allowance for Marketing
CONTIGENCY	**£3,590**					25%
TOTAL ESTIMATED COST	**£17,945**	**£12,475**	**£11,598**	**£878**	**£2,326**	

- *Cost due to be charged directly to the project
- ** Cost absorbed within baseline budgets initially i.e. Utilisation of current staff
- ***Incurred cost for Test Kits and consumables charged to project in line with units collected

- Project on track to deliver 85k units within financial envelope of estimate provided to DHSC.
- Forecast has reduced from £12.8M to £12.5M (excluding contingency) due to further clarity on Estates costs and Deloitte costs. Not currently forecasting to use contingency.

Summary

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- The team have achieved a huge amount in the 8 weeks since programme launch
- The current environment has meant that the programme has needed to operate in a different way to the traditional NHSBT approach
- Decision making has had to be fast, bold and based on untested assumptions
- The programme is forecast to deliver the 85,000 units within the financial envelop, but there are challenges in scaling up and balancing business as usual
- Discussions are ongoing with the Programme Board and Steering Group on the appropriate pace and scale
- The programme must be considered within the wider context of DHSC responses to the current epidemic
- Any next steps and decisions on the strategic direction for NHSBT need to consider other potential responses, such as the role of Hyperimmune Globulin, as the two are inter-linked