NHSBT Cover Note Convalescent Plasma (CP)
26th November 2020

Status: Final

1. Objectives

NHSBT has been asked to scale up collection capacity of Convalescent Programme in preparation for a potential 2nd wave, whilst establishing a sustainable operating model. The aim in Phase II is to build additional capacity into the programme to collect up to 7,500 CP units per week, alongside the capability to flex the collection footprint in response to localised outbreaks.

The original Phase I requirement was to scale collection in order to supply 4,000 CP units for two clinical trials: RECOVERY and REMAP-CAP, and to begin building a stock reserve.

2. Programme Update

The Convalescent Plasma Programme began Phase II in October 2020.

Since then, the CP programme has successfully collected over 40,000 units of convalescent plasma, of which over 10,000 are validated High Titre (HT) units. Sufficient CP has been collected to support both trials to completion and the programme is on schedule to generate the target 7,500 CP units per week by the end of November.

Ten (10) new plasma donor sites have been opened so far in November, with a further two (2) sites due to open by the end of November, and a further four (4) sites by mid-December. Training is being delivered to approx. three hundred new joiners. The programme is working to further improve training turnaround times without compromising quality, in order to speed up future staff deployments and accelerate capacity building.

There are three main areas of challenge for which active mitigations are in place.

1. Due to the speed with which new centres have been opened, the resilience of some centres in early stages of start-up are low with potential single points of failure. There are several efficiency, recruitment and training initiatives in-flight to strengthen resilience.

2. If Convalescent Plasma therapy proves successful, demand is projected to significantly outstrip supply. The programme is bringing new capacity online, optimising operations and investigating further scaling opportunities. This includes a critical focus on increasing the quantity of High Titre donations collected.

3. The proximity of the trial completion dates presents the urgent need to simultaneously plan programme responses for the treatment proving to be effective or not. Planning for both potential outcomes is underway.

3. Trial Progress

Randomisations have increased over recent weeks, in line with rising hospitalisations. The current trajectories for trial completion are:

- RECOVERY trial: by the end of November with results announced mid-December 2020 (previously reported as early 2021)
- REMAP-CAP trial: by the end of December with results reported early January 2021

The Therapeutics Task Force is leading engagement with RAPID C-19 and other stakeholder groups to develop the clinical commissioning policy and governance systems for managing supply and demand. The aim is to have protocols in place within a week of trial completion.

4. Post-trial Plans

If the trial proves Convalescent Plasma to be an effective therapeutic treatment, it is projected that demand will exceed the rate at which stocks can be replenished. To mitigate against this, several initiatives to scale capacity and focus attention on High Titre donors have been designed and are being rolled out. These are:

- Deploying additional machines to increase capacity
- Implementing off-session sampling to identify High Titre donors
- Increased collaboration with hospitals to recruit patients who are potential High Titre donors
- Investigating options for further scaling through a potential Phase III.

If Convalescent Plasma is determined by the trial to be unsuitable as a therapeutic treatment, it will be necessary to demobilise and repurpose programme infrastructure and staff.

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Convalescent Plasma