NHS
Blood and Transplant

NHSBT Board

Cover Note Convalescent Plasma (CVP)

28 January 2021

Status: Official

1. Summary and Purpose of Paper

To provide an update on the Convalescent Plasma (CVP) Programme, including the key activities in Phase II and on the outcomes of the REMAP-CAP and RECOVERY clinical trials.

The situation is changing so rapidly following the announcement of the RECOVERY trial when collections were paused that we will present an update to the Board at the meeting.

2. Action Requested

For information only – no action required.

3. Background

At the last update the discussion focused on the challenge to open the new centres, the plan to maximise high titre donations and the scenario planning underway for the potential outcomes of the trials.

4. Detail of Report

Phase II of the Convalescent Plasma (CVP) Programme commenced in October 2020. The objectives in Phase II were to:

- Scale up end-to-end supply chain capacity to 7,500 units of CVP per week.
- Ensure provision of sufficient High Titre (HT) units for completion of the REMAP-CAP and RECOVERY trials.
- Increase donor centre footprint by ~10 new donor centres.
- Significantly increase the staffing base to support this work.
- Build flexibility in the donor centre network to enable agile repurposing of capacity (alongside other blood products) and to respond to localised COVID-19 outbreaks.

The original Phase I objectives were to supply 4,000 CVP units for two clinical trials (REMAP-CAP and RECOVERY), and to set up and scale collection, production and distribution of CVP to hospitals.

In Phase II, the programme has successfully created the capacity to collect ~10,450 CVP units per week, by expanding the number of donation slots available (5,503 bookable CVP donation slots w/c 11/01).

Sufficient HT units were collected to support both the REMAP-CAP and RECOVERY trials to completion. Across the two programme phases, over 60,000 CVP units were collected, with over 12,000 units issued to hospitals. A focus of Phase II was to maximise the amount of HT units, of which there are currently ~ 1,600 units in stock, (this excludes pre-validated stock).

Fourteen (14) new donor centres across England have been set up and are operational. Across both phases, 631 additional front-line staff (116 nurses and 515 donor carers) were recruited.

An Integrated Supply Process has been implemented to build flexibility and agility across the donor centre network. This enables a weekly exchange of capacity across blood products and between sites to respond to local demand.

Trial Outcomes

Recruitment to REMAP-CAP was paused on 7 January 2021. There was no overall benefit, however analysis is now being undertaken of whether any subgroups in intensive care benefit from CVP.

Recruitment to the convalescent plasma arm of the RECOVERY trial was temporarily paused on 15 January, following advice from the RECOVERY trial Data Monitoring Committee, after initial data showed no significant difference in the primary endpoint of 28-day patient mortality (18% amongst those receiving CVP vs. 18% usual care alone). Sub-group analysis is ongoing.

International trials are testing the efficacy of plasma for COVID-19 treatment very early in the disease (prior to hospitalisation). Early use may help the most vulnerable sub-groups, such as the elderly or those with weak immune systems. An Argentinian randomised control trial found that CVP use within 72 hours of symptom onset, before hospital admission, reduced the occurrence of severe COVID by about 50%. A similar UK trial is being discussed.

After discussion with DHSC, in view of the uncertainty of the potential benefit from plasma if used earlier in disease treatment, particularly for those who may not respond to vaccination, and given the optimal time for plasma collection being now, it was decided to recommense plasma collection. This will resume on 23 January, we have been asked to consider with others what a third trial in the UK might look like.

NHSBT is proactively communicating with its donor base through text messages, phone calls and social media. Staff are being supported through regular communications on trial outcomes and impacts and recognition of their hard work. An ongoing review of risk and investment exposure is also taking place, through engagement with partner and suppliers to review expenditure mitigate risk.

A further update will be provided at the Board meeting as this is moving so quickly.

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