NHS
Blood and Transplant

Dear Colleague

Re: Notification from The Department for Health and Social Care (DHSC) of the Ministerial decision to accept SaBTO's recommendations on vCJD Risk Reduction Measures in England, Wales and Scotland for Plasma and Platelet Recipients Born on or after 1st January 1996

The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) has recommended that it is appropriate to withdraw two specific variant Creutzfeldt-Jakob (vCJD) control measures on plasma and platelets.

The Minister has made an announcement to Parliament that the committee's recommendations have been accepted and DHSC has now instructed NHSBT to introduce the operational changes required.

The purpose of this communication is to advise you of the steps that NHSBT is taking and actions required from you to implement this change.

1. <u>Plasma components</u> (fresh frozen plasma (FFP) and cryoprecipitate (cryo))
The SaBTO recommendations mean that it is no longer necessary for NHSBT to import plasma as a vCJD risk-reduction measure and we can begin the process of sourcing plasma for all patients from UK donors. This will effectively remove the current distinction for selection of plasma components based on whether the patient was born before/after 1st January 1996.

All other vCJD control measures remain in place, including leucodepletion to reduce the number of white blood cells which are considered to contain most of the infectious agent that causes vCJD.

NHSBT is now taking steps to bring this change into effect in our component portfolio. This is a significant change and one which we have advised DHSC we believe will take around 8 - 12 months to enact.

In particular:
- We will be increasing the number of plasma donations collected from UK donors
- We will be undertaking a number of infrastructure changes within NHSBT's systems and processes to meet anticipated demand for UK plasma components
- We are working with relevant stakeholders to understand what, if any, continuing requirement there may be to pathogen inactivate UK plasma components for any recipients of UK plasma components
  Note: The pathogen inactivation of imported plasma was introduced to manage the general risk of viral transmissions from plasma sourced from outside the UK; the import requirement was introduced as a separate safety measure to manage the specific vCJD risk.

ACTIONS REQUESTED FROM HOSPITALS:
- That you **take no immediate action** in relation to your FFP/cryo ordering practice/s as a result of this change

- That you **continue to order** MBFFP and MBcryo components as per current practice

This will allow NHSBT
- To maintain our current component provision to you
- To agree/define necessary component/safety specifications and requirements and
- To make the necessary internal changes for the future move to a UK-only plasma supply.

This is a transitional period and we undertake to keep hospitals regularly informed as the transition progresses. Your understanding and co-operation with our request is very much appreciated.

2. Platelet components

The SaBTO recommendations remove the requirement for patients born on or after 1st January 1996 to receive apheresis (single-donor) platelets whenever possible. This change means that patients who would have been recommended to receive apheresis platelets can now receive pooled platelets (i.e. platelets retrieved from several whole blood donations and pooled into an adult therapeutic dose suspended in platelet additive solution (PAS)).

In practice platelets with neonatal/infant specification will likely be apheresis to ensure they fulfil other requirements (from second time donors, PANTS-tested etc). Similarly HLA and HPA selected platelets will be apheresis derived.

In the longer term we expect this to result in changes in the respective demand for pooled and apheresis platelets, which are considered to be equivalent in terms of component efficacy.

ACTION REQUESTED FROM HOSPITALS:
- If you feel that this change is likely to result in a change to your current ordering pattern or demand for platelets (whether apheresis or pooled platelets) please contact your NHSBT Customer Services Manager or Patient Blood Management Practitioner to discuss further.
  This will allow NHSBT to develop plans to ensure sufficiency of supply whilst undertaking these changes.

3. Component pricing

DHSC commissions NHSBT's prices and services through the annual National Commissioning Group (NCG) process.

Due to the timing of this announcement, it has not been possible to include any price revisions in the NCG process for the 2020-2021 financial year which concludes on 13th September 2019. It has therefore been agreed with DHSC that any interim/in-year pricing changes will be agreed under NCG governance outside of the normal NCG timetable. Trusts will be advised of the outcome of this process in due course.

4. Next Steps

This change presents NHSBT with a number of logistical and operational challenges as we transition from our current operating model to meet the new requirements. Implementation will be an ongoing process and, for changes related to plasma, we have indicated an 8 - 12 month implementation/transition timeframe to DHSC.

In particular, we are keen to work in partnership with you in order to maintain sufficiency of plasma/cryoprecipitate and to avoid any unplanned changes in demand from non-UK to UK plasma components.

- We are therefore committed to keeping hospitals regularly informed as matters progress.
- We are keen to understand how hospitals are likely to react to these changes in the medium to longer term. We suggest that you discuss this with your Hospital Transfusion Team to consider your potential future ordering requirements. Our Customer Service Managers and/or Patient Blood Management Practitioners will be making contact with you to better understand the impacts of these changes.

5. Further information

If you require any further information on this change, please consult with your local Customer Service Manager or Patient Blood Management Practitioner in the first instance. If there are any other particular matters related to this change, please contact us at NHSBT.customerservice@nhsbt.nhs.uk

Yours sincerely

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