NHS Blood and Transplant

NHSBT Board
January 28 2016

Development of recommendations for use of HEV-negative blood components.

1. Status- public.

2. Executive Summary

Broad recommendations for provision of HEV-negative blood components were made by SaBTO in July 2015. The predicted demand was such that estimated costs could be absorbed in standard prices. Finalising detailed clinical guidance for hospitals took some of months of discussion between SaBTO members and the British Society for Bone Marrow Transplantation, and resulted in a significant increase in predicted demand, such that, with the agreement of the National Commissioning Group, a surcharge for HEV-negative components will be levied from April 2016 onwards. This detailed guidance was approved by SaBTO on 13th January 2016. The timing of the steps in the process in relation to budget building for 2016-17 has led to adverse comments from hospitals. Both UK Blood Services and DH have taken steps to improve cohesion in decision making, consultation and implementation, as detailed in the paper.

3. Action requested

The Board is asked to note

- **the chronology of events**
- **in particular, the steps taken to improve future decision-making and consultation**
- **the on-going limitations of clinical information regarding detailed usage of blood components.**

4. Purpose of the paper

This paper meets the Board's request for details of the decision-making process for use of HEV-negative blood components, and importantly, sets out recent actions by DH and UK Blood Services to improve the cohesion of future processes for producing and consulting on recommendations.

5. Background

5.1. During 2013, it was recognised that HEV prevalence was increasing in the UK, and there were reports of serious sequelae in transplant patients and instances of transfusion transmission. SaBTO therefore established a working group, chaired by myself, to bring forward recommendations regarding optimal protection of

patients, including provision of HEV tested blood components. This included a haematologist member of SaBTO, but not a stem cell transplant specialist.

5.2. The findings of the working group were presented to SaBTO in May 2015, at which it was agreed that further operational and health economic analysis was needed. On the basis of this work, led by Professor John Cairns, Health Economist on SaBTO, recommendations for provision of HEV-tested blood components were accepted by SaBTO at an Extraordinary meeting in July 2015. The main patient groups to receive HEV-negative components were stem cell and organ transplant patients. This was soon after publication of the Penrose report, and there was a wish to take steps to protect the most vulnerable patients without delay.

5.3. The recommendation at that point did not contain precise details of when HEV-negative components should be introduced in relation to the transplant, nor for how long they should be continued afterwards, but the unstated assumption was that they would be started at the time of the transplant procedure itself.

5.4. There was limited information available regarding the number of tested components which Blood Services would need to supply to meet this clinical need, but this was estimated to be approximately 50,000/year. On that quantity, Blood Services considered that they could absorb the costs without an increase in blood price/central funding. The recommendations were accepted on that basis by Health Ministers in England.

5.5. To produce detailed guidance which hospitals could use to prescribe/order HEV-negative components, a sub-group of SaBTO engaged with the British Society for Bone Marrow Transplantation. Their members felt strongly that tested components should be introduced at least 3 months in advance of the transplant, and at diagnosis for acute leukaemia patients potentially eligible for transplantation. The months of chemotherapy prior to transplant require heavy blood component support, notably with platelets. Such a policy would therefore increase greatly the number of units to be tested to meet clinical demand.

5.6. On the basis of this new information, NHSBT obtained agreement from the National Commissioning Group to place a surcharge of £17.18 on HEV-tested components. It was noted later that the stem cell expert on NCG had retired and had not yet been replaced.

5.7. The final guidance for the use of HEV-negative blood components was approved by SaBTO on 13th January 2016. This simplifies the guidance to recommend introduction of HEV-negative components for both stem cell and organ transplant patients from the time of listing for transplant.

5.8. Current estimates suggest that compliance with those would increase the number of tested components required to close to 300,000 at an approximate UK cost of £3M. However, the burden of costs will be concentrated in hospitals undertaking a high number of transplants, and some hospitals have raised concerns because of this.

5.9. Consideration of organ donor testing and monitoring of patients requires further work and consultation wih transplant centres through British Transplantation Society.

6. Actions to improve cohesion in decision making between SaBTO and UK Blood/Transplant Services.

6.1 Since the establishment of SaBTO in 2008, NHSBT has provided a series of secondees to the SaBTO secretariat for 18-24 months at a time. To provide

greater continuity, it has now been agreed to create a permanent post of Lead Scientist, Safety Policy, at PhD level, with 2-3 days/week allocated to SaBTO, and funded by the UK Forum. Internal recruitment is in progress, with a planned start date of 1st April 2016.

6.2 To provide greater support to the UK Blood Services advisory structure (Joint Professional Advisory Committee and its Standing Advisory Committees), and a closer link to SaBTO, the Lead Scientist, Safety Policy will devote the remainder of her/his time to supporting JPAC, and will be line managed by the JPAC Chair.

6.3 To ensure more structured consultation with hospitals on draft proposals for safety and other service changes, the Director of DTS, supported by the Medical and Research Director and others as necessary, will attend the Executive meetings of the National Blood Transfusion Committee, as well as its main committee as now.

6.4. DH are holding interviews in early February for the next Chair of SaBTO, and have increased support to the SaBTO secretariat.

6.5 The House of Commons Science and Technology Select Committee had previously recommended that senior managers in blood and transplant services should not chair SaBTO Working Groups (WG). At the SaBTO meeting on 13th January 2016, DH issued guidance for SaBTO Working Groups as an Annex to the current Code of Practice, along with the current safety framework. Specifically:

- where relevant to the issue under consideration, Working Groups should follow the SaBTO safety framework as far as possible, and ensure a completed copy of the framework accompanies their recommendations to the main committee
- where a WG is drafting guidance, the WG Chair should, where possible, have a professional background relevant for the audience to whom the guidance is primarily directed
- as well as co-opting external experts to Working Groups on a time-limited basis to assist with a particular piece of work, WG chairs should consider with members whether/how to involve wider stakeholder input. This could be through inviting stakeholder representatives to join a WG, contacting stakeholder organisations by correspondence to ask for their input or by circulating draft guidance to the intended audience for information and/or comment before final ratification by SaBTO
- working groups should present their recommendations/advice to the main committee for ratification before publishing. This includes clinical guidance. Ratification should ideally be via committee discussion at a full SaBTO meeting, but in circumstances where it needs to be expedited, it can be sought via correspondence, or exceptionally by Chair's action. WG Chairs should plan the most appropriate route for ratification of their group's work with the secretariat.

6.6 These changes planned by UK Blood Services and DH will improve cohesion in policy setting, consultation and implementation.

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