Northern Ireland Blood Transfusion Service

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CROSS REFERENCES
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Key Change from Previous Revision:

This is a new Policy.

1 STATEMENT

NIBTS have undertaken routine bacterial testing of platelets (both buffy coat pooled and apheresis) using the BacT/ALERT system since 2000. Bacterial testing of platelets allows for a “7-day” product, whereas platelets which have not been tested require a 5-day shelf-life.

This policy aims to define the requirements for bacterial testing of platelets, the shelf-life of these products, and the release criteria required to prevent issue or transfusion of a contaminated unit. It also defines under what circumstances, and in which patient groups, NIBTS will continue to utilise a ‘5 day expiry’ product.

The Guidelines for the Blood Transfusion Services in the United Kingdom, 7th Edition 2005 (‘The Red Book’) allows for storage of platelets for up to seven days provided either bacterial testing or a licensed pathogen inactivation procedure has been carried out prior to transfusion. Any bacterial detection method should be sufficiently sensitive and used at a time appropriate to prevent clinically significant infection. Protocols must be in place for the management of reactive results.

The Blood Safety and Quality Regulation (BSQR 2005) state that the maximum storage time for platelet components is 5 days, or may be stored for 7 days in conjunction with detection or reduction of bacterial contamination.
2 OVERVIEW

Bacterial contamination of blood components presents a very real risk to transfusion recipients. Platelet components are more susceptible to bacterial growth as they are stored at room temperature (22°C ± 2°C), as opposed to refrigeration (4°C) used for red cells. The shelf life of platelets is 5 days which can present many problems for stock inventory and sufficiency of supply. Testing of platelet components for bacterial contamination can allow extension of the shelf life to 7 days. This may be particularly important in stock management over public holiday periods.

NIBTS has used the BacT/ALERT Classic System from 2000 to October 2009, with the BacT/ALERT Signature System installed in NIBTS in November 2009. Currently it is used in conjunction with BacT/VIEW. The BacT/ALERT system has been validated to screen platelet components for bacterial contamination. Platelets which have been tested on the system and show a negative result may be given a 7-day expiry. Platelet units which have not been bacterial tested must have a 5-day expiry date. It is clearly vital to have in place a robust system for checking of BacT/ALERT result prior to release of platelet unit, and an effective recall system, should a platelet flag ‘positive’ at any stage after issue of the unit to a hospital blood bank.

3 RESPONSIBILITY

The Medical Director, Laboratory Manager and Head of Regulatory Affairs & Compliance are responsible for informing policy on bacterial testing of platelets. Hospital Services, Bacteriology, Quality Control staff and on-call staff are responsible for complying with the relevant SOPs for testing, checking and issue of platelet components.

4 POLICY

4.1 Only platelets tested at 48 hours (or 72 hours – see 4.2) for bacterial contamination are eligible to have their shelf life extended to 7 days and BacT/ALERT results are used as a release criterion for extended life (7 day) platelets. Only platelets with a valid negative BacT/ALERT result at the time of issue can be issued after 5 days shelf-life.

4.2 Apheresis and buffy coat pooled platelets are sampled at 48 hours post donation, except in the case of apheresis platelets which have been bled on a Friday, and are therefore sampled at 72 hours post donation. Apheresis platelets are tested prior to any subsequent pack splits.

4.3 Platelets will be quarantined for 4-6 hours post-sampling.

4.4 When available, expired 5 day platelets and extended life 7 day platelets are re-cultured.

4.5 The appropriate volume (currently 7.5 mls) is inoculated into one aerobic and one anaerobic bottle.
4.6 Samples are incubated for 7 days (i.e. until day 9 platelet life)

4.7 Samples flagged as Positive should be managed as follows:

4.7.1 If the platelets have already been issued the recall procedure should be followed (QA070)

4.7.2 If the platelets are still within NIBTS the quarantine procedure should be followed.

4.7.3 It is important to ensure that all associated components (e.g. red cells, for a buffy coat pool) are also quarantined /recalled (QB013 and QB005).

4.7.4 If the platelets have already been transfused then the patient details should be obtained from the hospital blood bank and NIBTS medical consultant informed.

4.7.5 For each culture positive sample, recalled apheresis unit or recalled BC platelet unit and associated constituents, the following should be performed:

- BTA Culture
- Gram stain
- Sub culture
- Catalase, oxidase, staph latex
- ID to genus level

4.7.6 Confirmed (repeatable) positive result is defined by the same organism having been found in both the primary culture and the repeat culture of the original pack, sample pouch or related component. The medical consultant should be informed of the result and will determine if donor follow up investigations are required.

4.7.7 Unconfirmed (non repeatable) positive is defined where the follow up investigation of the component does not replicate the original positive result, no product or constituent is available for confirmatory testing and/or no transfusion reaction has been reported. An investigation should be undertaken to ascertain if the cause was operator contamination.

4.7.8 ‘Machine false positive’ is suggested by low positivity index, negative gram stain, negative sub-culture and, after reloading onto BacT/ALERT system, a negative result at 7 days.

4.8 Where a result becomes positive on the BacT/ALERT system, a procedure will be in place whereby key staff are notified immediately to ensure prompt and appropriate action.

4.9 For platelets which have been tested on the BacT/ALERT system, a current negative result will be required before PULSE can allow issue of the unit.

4.10 Although the majority of platelets will be tested on the BacT/ALERT system, there may be certain instances where this is not performed e.g. acute platelet
shortages where units are required immediately or specifically typed units (e.g. HPA-1a negative) which are required for immediate clinical use. Such units will carry an expiry date of 5 days.

4.11 ‘Under 16 policy’ – current policy is not to use platelets beyond 5 days for paediatric patients.

5 EQUALITY SCREENING OUTCOME

This policy has been drawn up and reviewed in the light of the statutory obligations contained within Section 75 of the Northern Ireland Act (1998). In line with the statutory duty of equality, this policy has been screened against particular criteria. If at any stage of the life of this policy there are any issues within the policy which are perceived by any party as creating adverse impacts on any of the groups under Section 75, that party should bring these to the attention of the Head of HR & Corporate Services.

6 TRAINING REQUIREMENTS

6.1 Hospital Services staff, Medical Consultant and any BMS undertaking on-call work should ‘read and understand’ this policy.