Guidelines for the Blood Transfusion Services

8.7: Generic protocol for the evaluation of blood packs for whole blood donations and apheresis collections

http://www.transfusionguidelines.org/red-book/chapter-8-evaluation-of-novel-blood-components-production-processes-and-blood-packs-generic-protocols/8-6-generic-protocol-for-the-evaluation-of-blood-packs-for-whole-blood-donations-and-apheresis-collections

8.7: Generic protocol for the evaluation of blood packs for whole blood donations and apheresis collections

8.7.1: Introduction

This protocol sets out in generic form the essential features of blood pack evaluations as required by the UK Blood Transfusion Services. National Services should exercise discretion in the extent to which the protocol should be applied; assessment of degree of novelty will assist in this (see table 8.1b). It may be appropriate to consider an abbreviated format, e.g. when the change to be evaluated represents the attachment of a filter to a pack assembly that is already in routine use, or where the change consists of a modified port access design. Section 8.8 provides additional guidance for the evaluation of novel plasticisers and additive solutions, where they are combined.

The protocol is not intended for use with packs for stem cell collection and storage, although the principles outlined may be helpful. The principles of this section apply to components produced from whole blood donations as well as whole blood itself and components from apheresis collections.

8.7.2: General principles

Each trial will be fully documented and will have a unique trial reference number. The key requirements are as follows:

- An evaluation outline: What type of pack is being investigated, where, when and the standards against which the assessment will be based.
- The evaluation objective: To demonstrate the packs are and remain free from defects and are suitable for the production and storage of components that meet current guidelines.
- Identification of any restrictions, e.g.:
    - situations where an evaluation would be required
    - agreement on ownership and release of the evaluation report with the supplier/manufacturer
    - limitations of the report and its distribution.
- How the trial will be controlled, e.g.:
    - the identity of the person/persons responsible for the trial and their reporting lines
    - sign-off procedures and authorities including concessionary changes
    - the trial protocol will be agreed with the supplier and any concessionary changes will require agreement in accordance with local procedures

- trials will be conducted in three phases. Satisfactory performance and sign-off in Phase 0 is a prerequisite to progression to Phase 1 and satisfactory performance in Phase 1 is a prerequisite to progression to Phase 2
- blood collected in Phase 0 will not be used for transfusion
- all components prepared in Phase 1 will be subject to routine quality monitoring tests
- components prepared in Phase 2 will be subjected to routine quality monitoring tests as defined in Table 8.1d and Chapter 7
- any testing that exceeds the minimum set out herein must be fully incorporated within the report.

- Confidentiality: Any data collected will normally be the property of the organisation performing the trial; blood pack suppliers/manufacturers who wish to release information arising from the trial will require confirmation in writing from the organisation performing the trial that they may do so.

- Quality monitoring: It is expected that packs evaluated under the trial protocol will be subject to routine quality monitoring and reporting procedures, e.g. pack faults, compliance with component specifications etc. It follows that any adverse findings during the trial would generate a corrective action.

A summary of the numbers to be tested for each evaluation or validation phase is given in Table 8.1d. The numbers given are the minimum required. More detail is given in the relevant sections below. Deviations from this number must be agreed in accordance with local procedures and consistent with section 8.7.1.

8.7.3: Phase 0: Evaluation

After an initial familiarisation with novel bag/filters (pre-Phase 0) the purpose of Phase 0 studies is to:

- assess suitability to progress to Phase 1

- determine suitable quality monitoring parameters

- disclose any quality problems that might prevent components collected or prepared in these packs from being used for transfusion.

Processing conditions used in the Phase 0 evaluation should be the same as those applied to Phase 1 and 2 evaluations.

8.7.3.1: Component quality monitoring

Starting donations and all final components will be tested for compliance with relevant parameters listed in the component specifications in these guidelines. Where relevant, additional assays should be performed as specified in the Red Book generic evaluation protocols for new or novel blood components and consistent with sections 8.2 - 8.6.

- Check for minimum / maximum volume or concentration limits (e.g. platelet count) stipulated for the blood bag system. These may vary between systems and should be built into validation tests.

8.7.3.2: Goods inward inspection

- Check that appropriate storage information is shown on the packaging.

- Check the condition of packaging on receipt. Document damaged cartons and examine contents to assess the extent of any damage.

8.7.3.3: Quality assurance pack conformance inspection

Unless otherwise indicated, the following inspection will be performed and documented for all packs to be used in Phase 0 of the trial:

- pack batch number (eye-readable and machine-readable)
- pack type number (eye-readable and machine-readable)
- base label integrity and compliance with Chapter 26 of these guidelines for the uniform labelling of blood and blood components
- base label adherence (a sample of 20 at each temperature)
    - +22°C for 1 week
    - +4°C for 1 week
    - +4°C for 1 day, followed by –25°C for 1 week
- donation number, component type and blood group label adherence (a sample of 20 at each temperature)
    - +22°C for 1 week
    - +4°C for 1 week
    - +4°C for 1 day, followed by –25°C for 1 week
- seals, seams and welds satisfactory
    - absence of leaks
    - anticoagulant/additive free from turbidity, particulate matter and inclusions
- if the inspection requires removal of packs from their overwraps, either repackage and use according to the manufacturer's instructions or perform the examination immediately prior to donation
- check for acceptable handling and storage characteristics of unopened cartons of packs from receipt, through storage to use at sessions.

8.7.3.4: Checks to be performed by collection teams

Collection teams will follow routine procedures for recording pack faults, but additionally should comment on:

- ease of overwrap opening
- integrity of overwrap
- accuracy of instructions for use at time of collection
- acceptability of needle characteristics
- suitability of tubing (length and flexibility)
- general suitability.

8.7.3.5: Checks to be performed by processing team

The processing team will follow routine procedures for recording pack faults, but may additionally wish to comment on:

- breakage rates following freezing
- heat seal failures (in-house seals)
- suitability of tubing (length and flexibility)
- ease of cannula breakage
- ability to sterile dock (during secondary processing)
- integrity of join, following local, current, procedure
- compatibility with instructions for device for sterile connection
- assess compatibility with current protocol for packaging of frozen packs
- inspection of packs after overnight storage at 4°C.

When the minimum number of packs has been evaluated, the individual or group responsible for the trial will prepare and submit a Phase 0 report.

8.7.4: Phase 1: Validation

The purpose of this phase is to allow:

- staff to familiarise themselves with the packs and any associated equipment
- the generation of quality monitoring data
- the development of an appreciation of the suitability of the packs for routine use, i.e. progression to Phase 2 trial.

Phase 1 of the validation process normally will require not less than 125 packs to be tested at the centre undertaking the trial. Deviations from this number must be agreed in accordance with local procedures.

It is expected that a smaller number of packs will be used for familiarisation in other centres. This phase will include the finalisation of standard operating procedures (SOPs) for use in Phase 2.

Blood components produced during Phase 1 may be used therapeutically where they comply with appropriate release criteria.

8.7.4.1: Component quality monitoring

Starting donations and all final components will be tested for compliance with relevant parameters listed in the component specifications in these guidelines.

8.7.4.2: Goods inward inspection

- Check that appropriate storage information is shown on the packaging.
- Check the condition of packaging on receipt. Document damaged cartons and examine contents to assess the extent of any damage.

8.7.4.3: Quality assurance pack conformance inspection

Unless otherwise indicated, the following inspection will be performed and documented for all packs to be used in Phase 1 of the trial:

- pack batch number (eye-readable and machine-readable)
- pack type number (eye-readable and machine-readable)
- base label integrity
- seals, seams and welds satisfactory
    - absence of leaks
    - anticoagulant/additive free from turbidity, particulate matter and inclusions
- if the inspection requires removal of packs from their overwraps, either repackage and use according to the manufacturer's instructions or discard
- check for acceptable handling and storage characteristics of unopened cartons of packs from receipt, through storage to use at sessions.

8.7.4.4: Checks to be performed by collection teams

Collection teams will follow routine procedures for recording pack faults, but additionally should comment on:

- ease of overwrap opening
- integrity of overwrap
- accuracy of instructions for use at time of collection
- acceptability of needle characteristics
- suitability of tubing (length and flexibility)
- general suitability.

8.7.4.5: Checks to be performed by processing team

The processing team will follow routine procedures for recording pack faults, but may additionally wish to comment on:

- breakage rates following freezing
- heat seal failures (in-house seals)
- suitability of tubing (length and flexibility)
- ease of cannula breakage
- ability to sterile dock (during secondary processing)
- integrity of join, following local, current, procedure
- compatibility with instructions for device for sterile connection

- assess compatibility with current protocol for packaging of frozen packs
- inspection of packs after overnight storage at 4°C.

8.7.4.6: End users

Set up a process by which users will feedback information on acceptability of the packs for use. This would involve blood bank and ward/theatre staff. Obtain details on:
Blood bank issues:

- acceptability to end users
- acceptability of number and condition of bleed line samples
- crossmatch/other label adherence
- leak and breakage rates.

Ward/theatre staff issues:

- general acceptability
- accessibility of ports for giving sets
- leak and breakage rates.

When the minimum number of packs has been evaluated, the individual or group responsible for the trial will prepare and submit a Phase 1 report.

8.7.5: Phase 2: Evaluation

A minimum of 2000 packs from each of two batches for whole blood collection processes or 300 sets for apheresis collection will be used in this phase to allow data on consistency of manufacture to be collected.

Relevant SOPs will be available before commencing Phase 2. Customer communication and any associated training will also have been done by this date.

Blood components produced during Phase 2 may be used therapeutically where they comply with the normal release criteria.

8.7.5.1: Goods inward inspection

- Check that appropriate storage information is shown on the packaging.
- Check the condition of packaging on receipt. Document damaged cartons and examine contents to assess the extent of any damage.

8.7.5.2: Quality assurance pack conformance inspection

Unless otherwise indicated, the following inspection will be performed and documented for packs to be used in Phase 2 of the trial:

- pack batch number (eye-readable and machine-readable)

- pack type number (eye-readable and machine-readable)
- base label integrity
- seals, seams and welds satisfactory
- absence of leaks
- anticoagulant/additive free from turbidity, particulate matter and inclusions.

8.7.5.3: Checks to be performed by collection teams

Collection teams will follow routine procedures for recording pack faults, but additionally should comment on:

- ease of overwrap opening
- integrity of overwrap
- accuracy of instructions for use at time of collection
- acceptability of needle characteristics
- suitability of tubing (length and flexibility)
- general suitability.

8.7.5.4: Checks to be performed by processing team

The processing team will follow routine procedures for recording pack faults, but may additionally wish to comment on:

- breakage rates following freezing
- heat seal failures (in-house seals)
- suitability of tubing (length and flexibility)
- ease of cannula breakage
- ability to sterile dock (during secondary processing)
- integrity of join, following local, current, procedure
- compatibility with instructions for device for sterile connection
- assess compatibility with current protocol for packaging of frozen packs
- inspection of packs after overnight storage at 4°C.

8.7.5.5: Component quality monitoring

A minimum of 1% of components (or as determined by statistical process monitoring) produced for whole blood collection processes or 300 of each component (one of each relevant component per procedure) for apheresis collection will be subjected to routine quality monitoring for parameters specified in this book. Deviation from the protocol must be consistent with section 8.7.1.

8.7.5.6: End users

Set up a process by which users will feedback information on acceptability of the packs for use. This would involve blood bank and ward/theatre staff. Obtain details on:
Blood bank issues:

- acceptability to end users
- acceptability of number and condition of bleed line samples
- crossmatch/other label adherence
- leak and breakage rates.

Ward/Theatre staff issues:

- general acceptability
- accessibility of ports for giving sets
- leak and breakage rates.

On completion, the individual or group responsible for the trial will prepare and submit a Phase 2 report on the suitability for use of the blood pack system within the service undertaking the trial.