The Eurobloodpack
The IBTS Perspective.

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Presented on behalf of the Technical Committee of the Eurobloodpack Purchasing Group.

Eurobloodpack Purchasing Group

- The collaborators
  - The Netherlands - Sanquin Blood Supply Foundation
  - Irish Blood Transfusion Service
  - NHS Blood and Transplant
  - Northern Ireland Blood Transfusion Service
  - Scottish National Blood Transfusion Service
  - Welsh Blood Service

  - Plus...other future beneficiaries

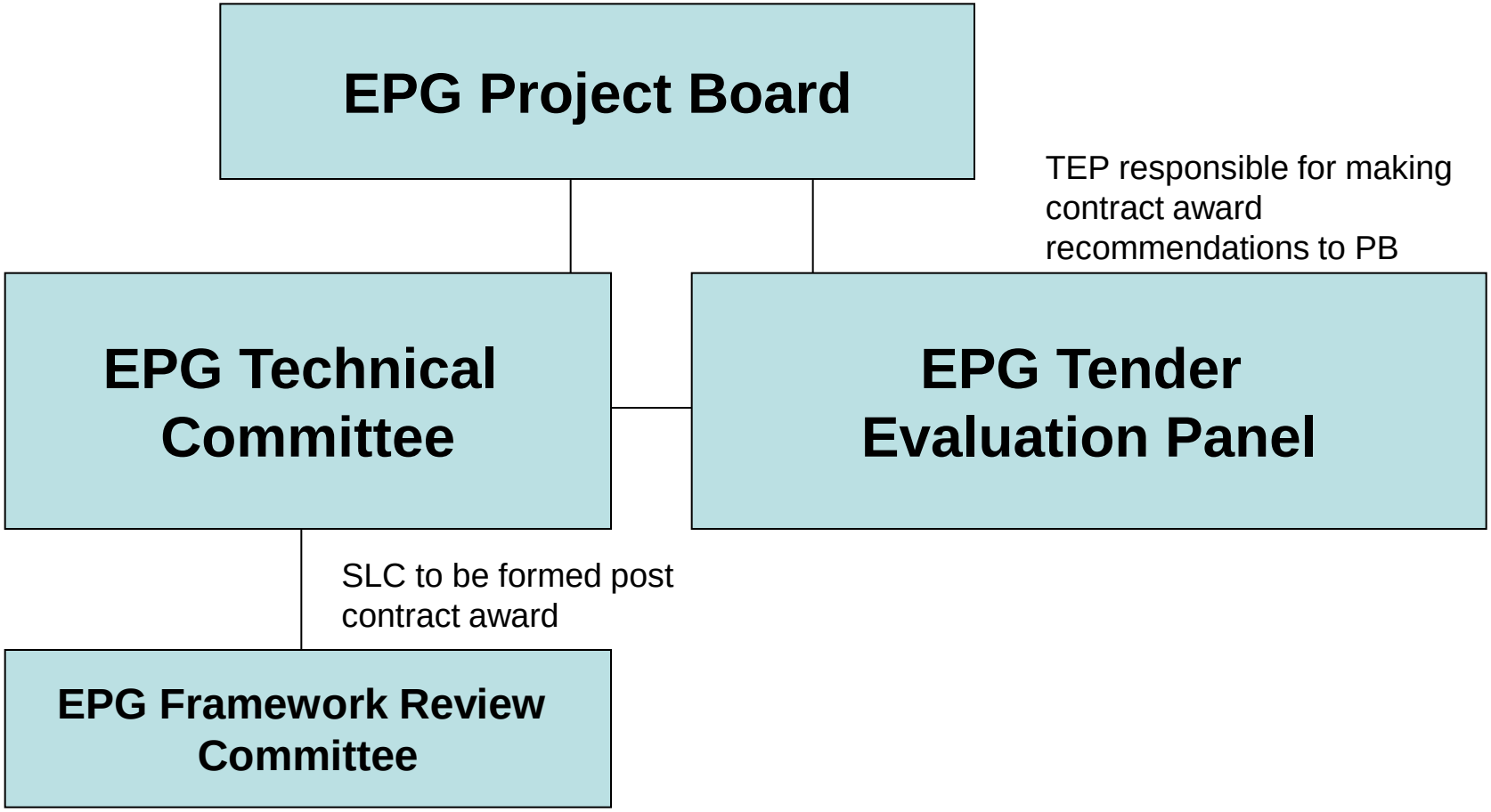
Eurobloodpack Project

<u>“4 pillars” which support the Project</u>

- **Use of standard Eurobloodpack specification**
- **Use of common validation protocols or principles (Sampson et al. Ver 1.7)**
- **Use of collaborative supplier audit reports**
- **Use of common pack fault monitoring system**
- **.**

Eurobloodpack Purchasing Group

- **Governance arrangements**



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Eurobloodpack Specification

Eurobloodpack Blood Collection System: 3 specific configurations

- Standard Top and Top Collection System for whole blood filtration;
- Standard Bottom and Top System for red cell concentrates (RCC) filtration;
- Bottom and Top System for RCC filtration with Integral Plasma Filter;
- Ref: Nightingale et al. Vox Sang 2011 Oct:101(3):250-4

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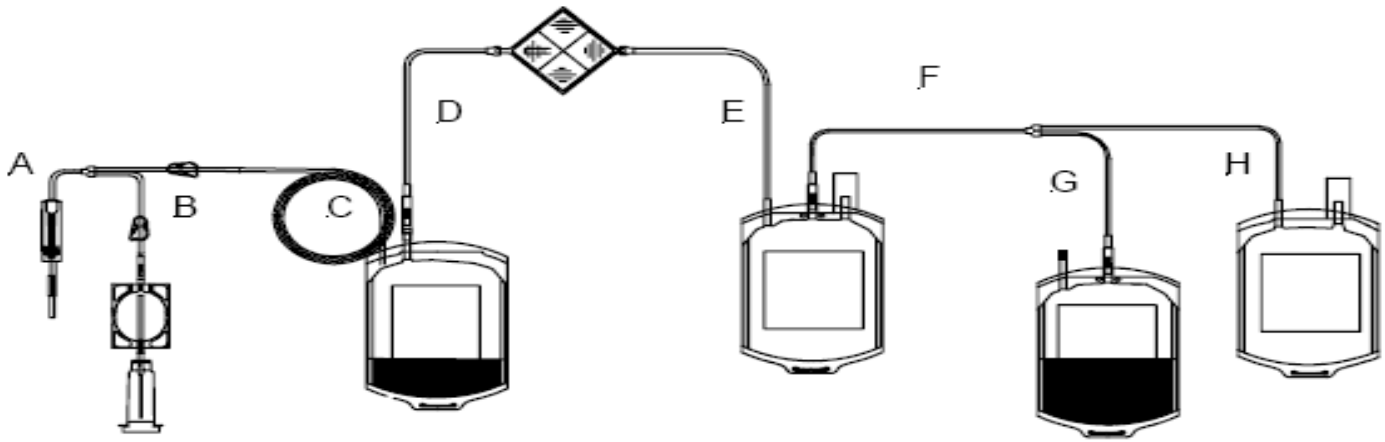
Figure 1 - Standard Top and Top Collection System for whole blood filtration



Dimensions (post sterilisation)		
Tube	***Length mm***	***Tolerance (±) mm***
A + C	1000	100
A	300	50
B	220	50
D	D + E = manufacturer defined	-
E	E = minimum 500	-
F	450	50
G	350	50
H	350	50

Volumes		
Detail	Specification	Tolerance (±)
Volume of anticoagulant in primary pack	66.5 ml	10%
Volume of additive in SAG-M pack or equivalent licensed OAS	105 ml	10%

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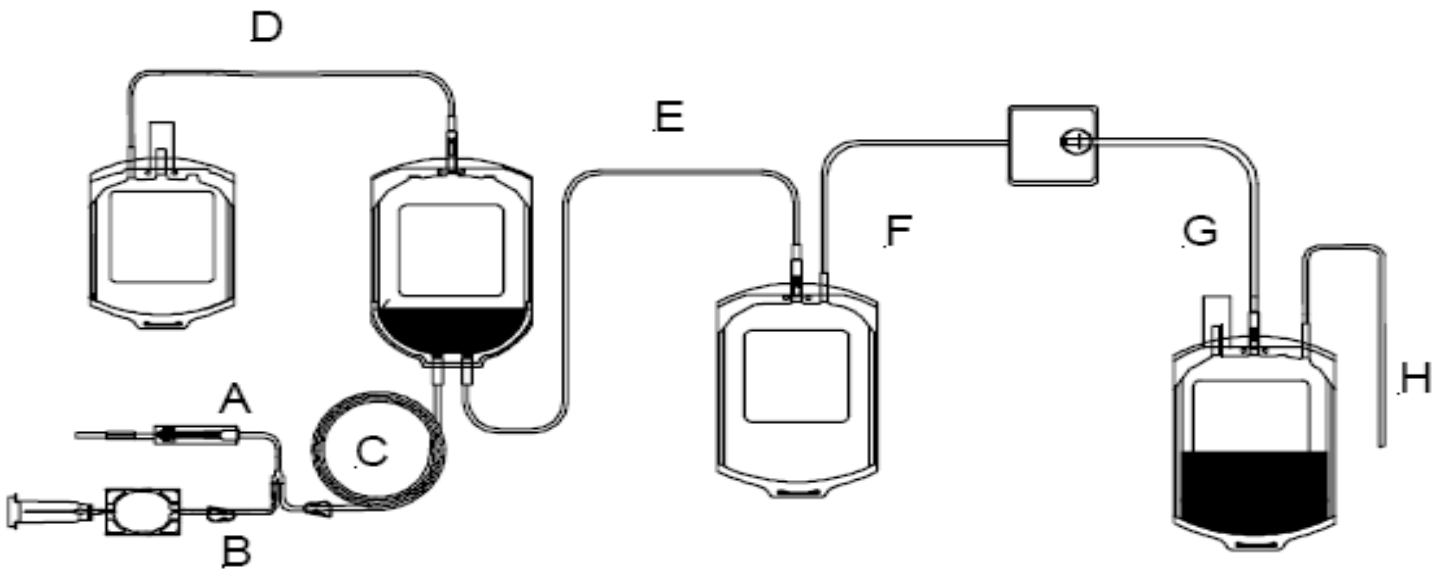
Figure 2 -Standard Bottom and Top System for RCC filtration



N.B. Donor line may enter the top of the primary bag

Dimensions (post sterilisation)		
Tube	***Length mm***	***Tolerance (±) mm***
A + C Donor line may be top or bottom entry to primary bag	1000	100
A	300	50
B	220	50
D	450	50
E*	450	50
F	F + G = manufacturer defined	-
G	G = minimum 500	-
H	200	50

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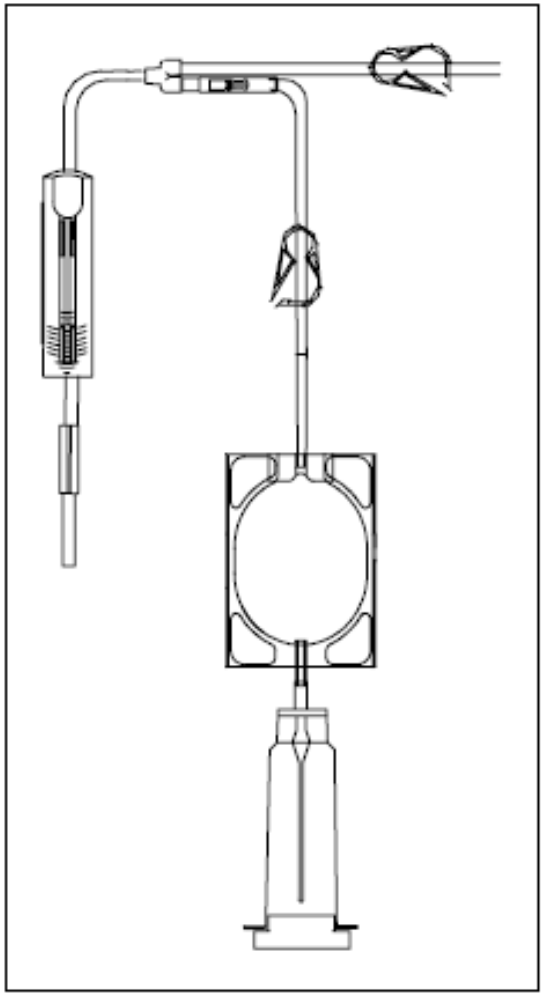
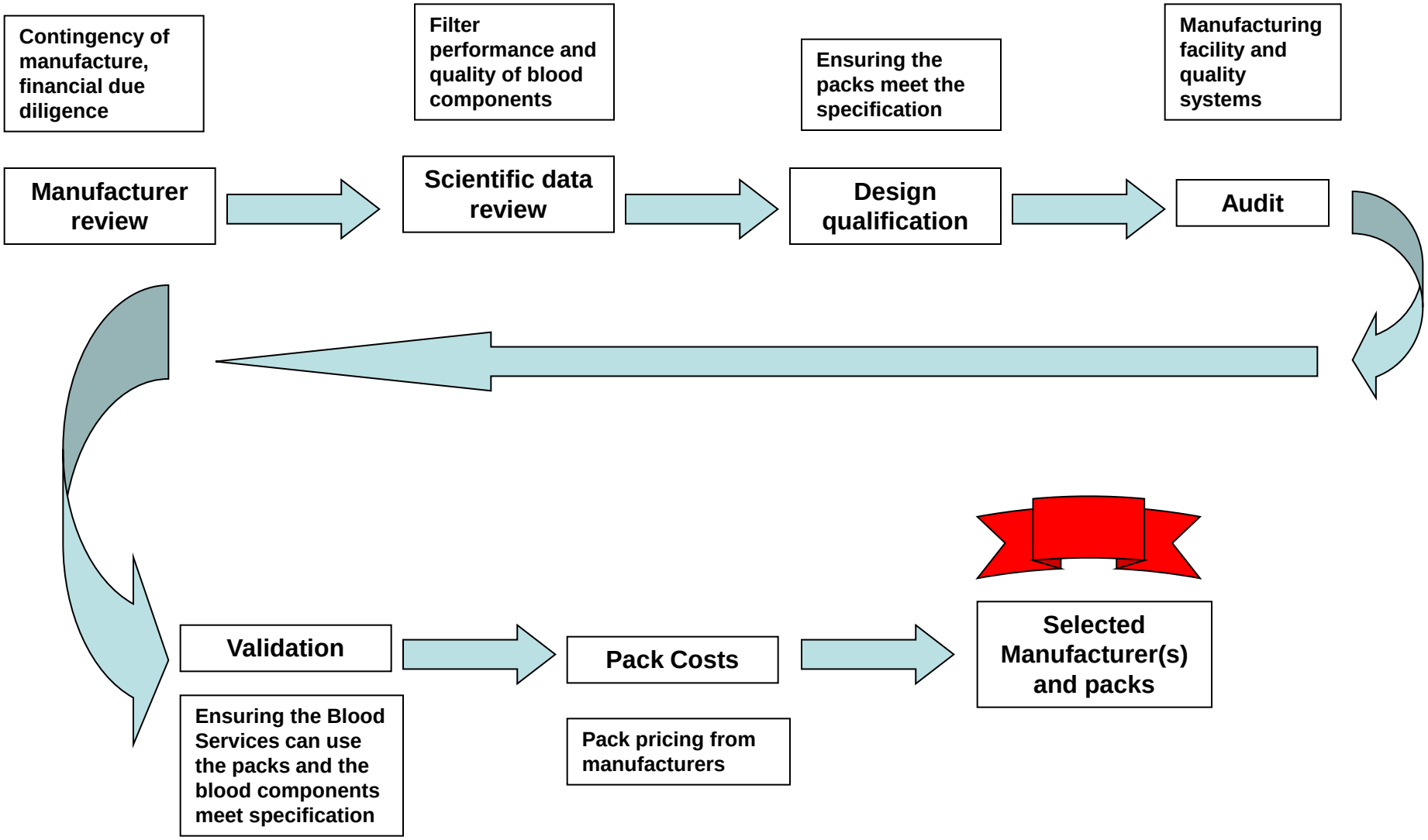
Figure 4 -Needle Assembly and Sample Site Coupler General Design
(applicable to TAT and BAT systems)



Workflow for Eurobloodpack



IBTS Approach

- **Multiple bags for validation in a short timeframe**
- **EPG collaborative approach**
- **Division of testing/Pooling of results**
- **Risk assessment/Gap analysis**
- **Eurobloodpack™ validation scheme**

Design Qualification "Phase 0"

- Biochemical and Haematological analysis
- Reviewed by NHSBT CDL
- Main challenges were:
- Missing data; platelet storage (7day); different storage media.
- Which pack?

Design Qualification

- **Measured against Eurobloodpack specification ver. 3.7**
- **February – May 2012**
- **3 TAT and 4 BAT bags tested**
- **4 suppliers**

Design Qualification

- **Non-compliances in following:**
- Diversion pouch fill volume
- Labels not sufficiently tamperproof
- Line length differences
- IFU or symbiology being ambiguous or lacking
- Lack of barcodes on cartons

Audits

- 13 EPG Supplier audits Feb 2009 – May 2013
- 9 by Blood Service members; 4 by EPG in collaboration.
- 2 Majors; 20 others; 34 observations.
- Supplier feedback positive with all audits successfully closed out following agreed corrective actions.

IOQ/PQ Phase 1

- Optimisation in one IBTS centre only
- all bags passing DQ
- 6 weeks per bag (Apr 2012 to June 2012)
- IQ tests incl. upload onto Progesa.
- successful operation on collection/processing equipment.
- Destructive testing of primary components
- RC's LD in AS
- FFP for clinical use
- Buffy coats for platelet preparation (if BAT).

OQ/PQ Phase 2

- **Validation testing for:**
- **RC's LD in AS**
- **Platelet concentrates (if BAT).**
- **Cryoppt. for clinical use**
- **Platelets storage studies**
- **successful operation on collection/processing equipment.**
- **Compatible with customer requirements**
- **Absence of clinical SAE or SAR related to bag.**

EPG Analysis OQ/PQ

- **TC evaluation of EPG OQ/PQ phases 1 & 2 plus all relevant shared data (Sep/Oct 2012)**
- **125+/ up to 2,000 units transfused per bag**
- **Score DQ/OQ/PQ phase 1 & 2 results.**
- **Rank in order of quality.**

Overall Validation

Main Issues:

- Blood components non-compliance with legislation or local specifications.
- Lack of ability to comply with IFU
- Needle sheath, guard or plastic clamps unacceptable in routine use.

Further clarifications from suppliers resolved majority of issues.

Pack defects scored based on historical data

Final Tender Evaluation

- **Shortlist by Tender Evaluation Committee based on:**
  - **Quality score (Technical Committee)**
  - **Price**
- **Shortlist to 3 suppliers per bag type (final)**
- **IBTS contracted for one of each bag type**

Key Milestones (2012/13)

Second Supplier Assessment	Jan 2012
Supplier Audits 2012	Jan – Mar
Completion of validation	Oct 2012
ITT tender evaluation	Nov 2012
Award recommendations (from EBA)	Nov 2012
Implementation plan	Dec 2012
Board approval	Jan 2013
Award of contract	May 2013
Implementation	May – Aug 2013

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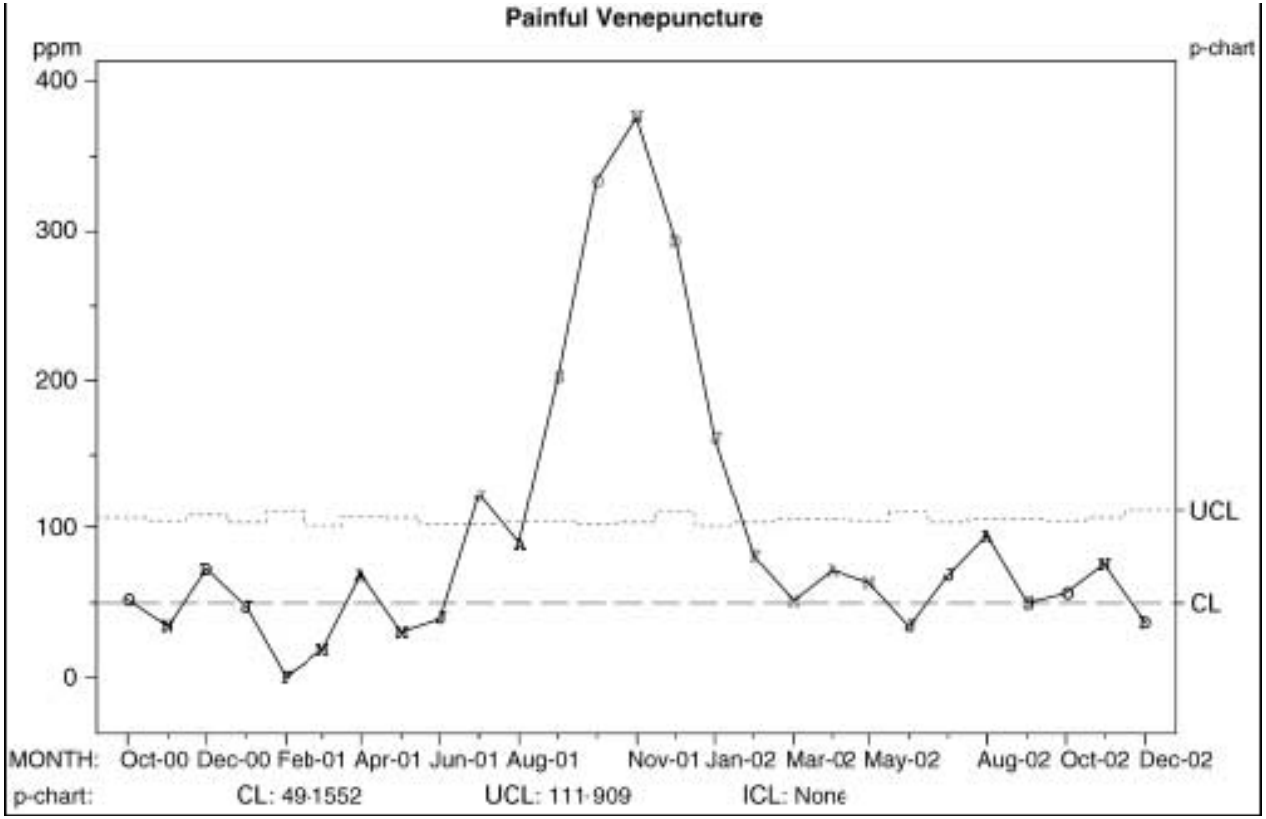
Next steps from Sept 2013

- ✓ Framework Review Committee – ongoing monitoring
- ✓ Change control process - specification
- ✓ QC results resource
- ✓ Blood pack defect monitoring tool

Blood Pack Fault Monitoring



Beckman N, Nicholson G, Ashford M, Hambleton R. Blood Pack Fault Monitoring. Vox Sanguinis 2004 87, 272-279

- More data means earlier detection, fewer losses and greater safety

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Summary

- This and similar projects will deliver significant benefits in the future
- Benefits are not only financial – there is great merit in simplicity of design and manufacture for both the manufacturer and the Blood Services
- Sharing the burden of evaluation, validation and audit using common approaches reduces timescales and costs

Thank you

EPG Technical Committee

- Dirk de Korte (Chair)
- Gordon Nicholson
- Tom Finn
- Doris Campbell
- Josje Koolen
- Kevin McColl
- Russell Hambleton
- Graham Rowe
- Rebecca Cardigan
- Neil Beckman
- Mark Nightingale
- Barbara Mullin
- Arlene Davidson
- Daniel Kirkbride
- Sonja Curd
- Samantha Rainbird
- Belinda Pelle
- Saber Bashir

IBTS Red Cells (BAT)

- Volume: 278ml ± 13ml.(231ml – 355ml)
- Residual Leucocyte content: < 1.0 x 10^6/unit (Average: 0.13 ± 0.13 x 10^6/unit)
- Haematocrit: 0.618 ± 0.013 L/L. (Allowed range: 0.5 – 0.7 L/L)
- Haemoglobin content: Average 54.6 ± 4.3 g/unit (Specification: > 40.0 g/unit)
- % Haemolysis at expiry: 0.15 ± 0.06% red cell mass. (Specification: < 0.8%)

IBTS Red Cells (TAT)

- Volume: 300ml ± 17ml.(231ml – 355ml)
- Residual Leucocyte content: < 1.0 x 10^6/unit (Average: 0.14 ± 0.18 x 10^6/unit)
- Haematocrit: 0.605 ± 0.029 L/L. (Allowed range: 0.5 – 0.7 L/L)
- Haemoglobin content: Average 56.7 ± 5.5 g/unit (Specification: > 40.0 g/unit)
- % Haemolysis at expiry: 0.26 ± 0.17% red cell mass. (Specification: < 0.8%)

Fresh Frozen Plasma

(O.N. Hold)

- **Volume: 299ml ± 14ml.(220ml – 340ml)**
- **Residual Leucocyte content: < 1.0 x 10^6/unit (Average: 0.02 ± 0.02 x 10^6/unit *limit of detection*)**
- **Residual Red Cell content: < 6.0 x 10^9/Litre: < *limit of detection***
- **Residual Platelet content: < 50 x 10^9/litre: < *limit of detection***
- **Factor VIIIc content: > 0.7iu/ml: Average 0.83 ± 0.18iu/ml**

IBTS Buffy Coats

- Volume: 45ml ± 3ml.(39ml – 55ml)
- Residual Leucocyte content: > 1.6 x 10^9/unit (Average: 2.2 ± 0.6 x 10^9/unit)
- Residual Platelet content: ≥ 60 x 10^9/unit (Average: 99 ± 21 x 10^9/unit)
- Haematocrit: 0.48 ± 0.05 L/L. (Allowed range: 0.37 – 0.64 L/L)
- Haemoglobin content: Average 6.6 ± 1.1 g/unit (Specification: < 9.5 g/unit)

Platelet Concentrates (4BC/PAS)

- **Volume: 288ml ± 10ml.(150ml – 400ml)**
- **Residual Leucocyte content: < 1.0 x 10^6/unit (Average: 0.08 ± 0.05 x 10^6/unit)**
- **Residual Red Cell content: < 4.0 x 10^9/Litre: < *limit of detection***
- **Platelet content: > 240 x 10^9/unit (< 450 x 10^9/unit) Average: 350 ± 54x 10^9/unit**
- **pH (22°C) at expiry (Day 8): >6.4. (Average:7.37 ± 0.04)**
- **% Platelet Recovery from BC pool: > 80% (Average: 85.8 ± 3.4%)**
- **[illegible] at expiry (Average score: 2 to 3)**