



Role of the Medical Director

Beth Shaz, MD

Assistant Professor, Emory University School of Medicine

Director, Transfusion Services, Grady Memorial Hospital

Atlanta, GA

1.1.1 Medical Director Responsibilities

The blood bank or transfusion service shall have a medical director who is a *licensed physician* and *qualified* by education, training, and/or experience. The medical director shall have responsibility and authority for *all medical and technical policies, processes, and procedures* - including those that pertain to laboratory personnel and test performance - and for the consultative and support services that relate to the care and safety of donors and/or transfusion recipients. The medical director may delegate these responsibilities to another qualified physician; however, the medical director shall retain ultimate responsibility for medical director duties.

Organization Chart of a Clinical Laboratory

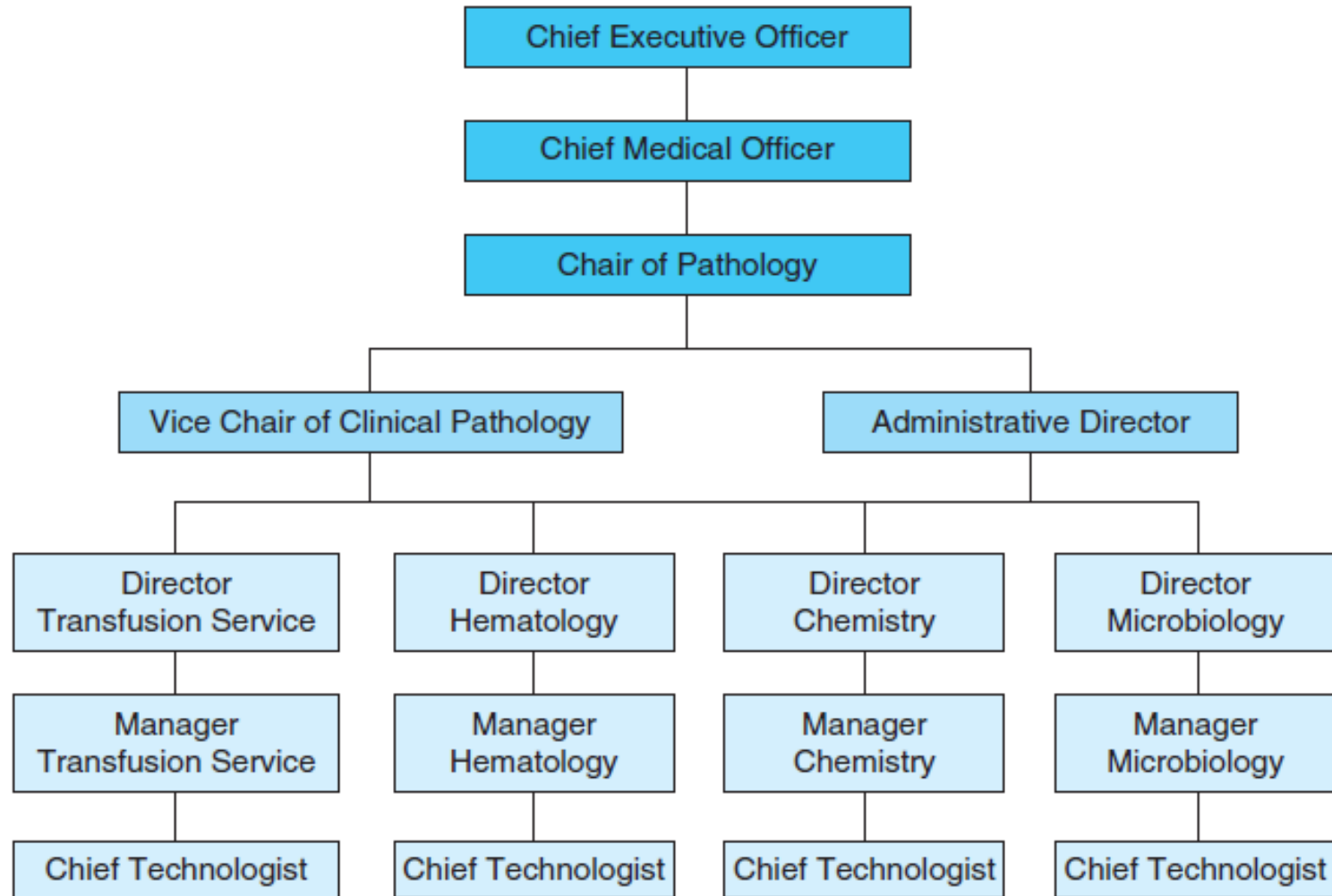


FIGURE 18.1 Organizational chart of a clinical laboratory.



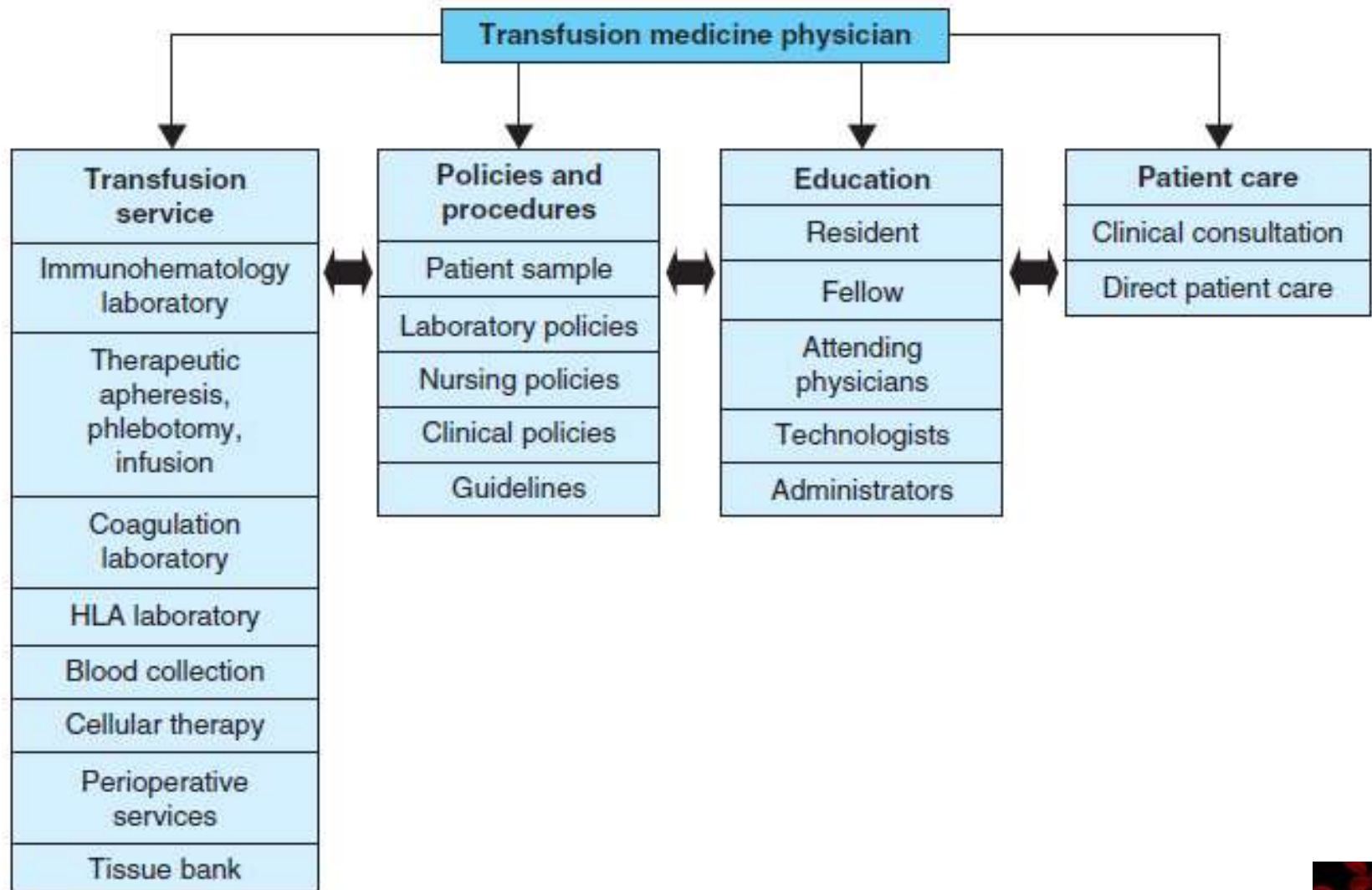


FIGURE 18.2 Transfusion service physician oversight.



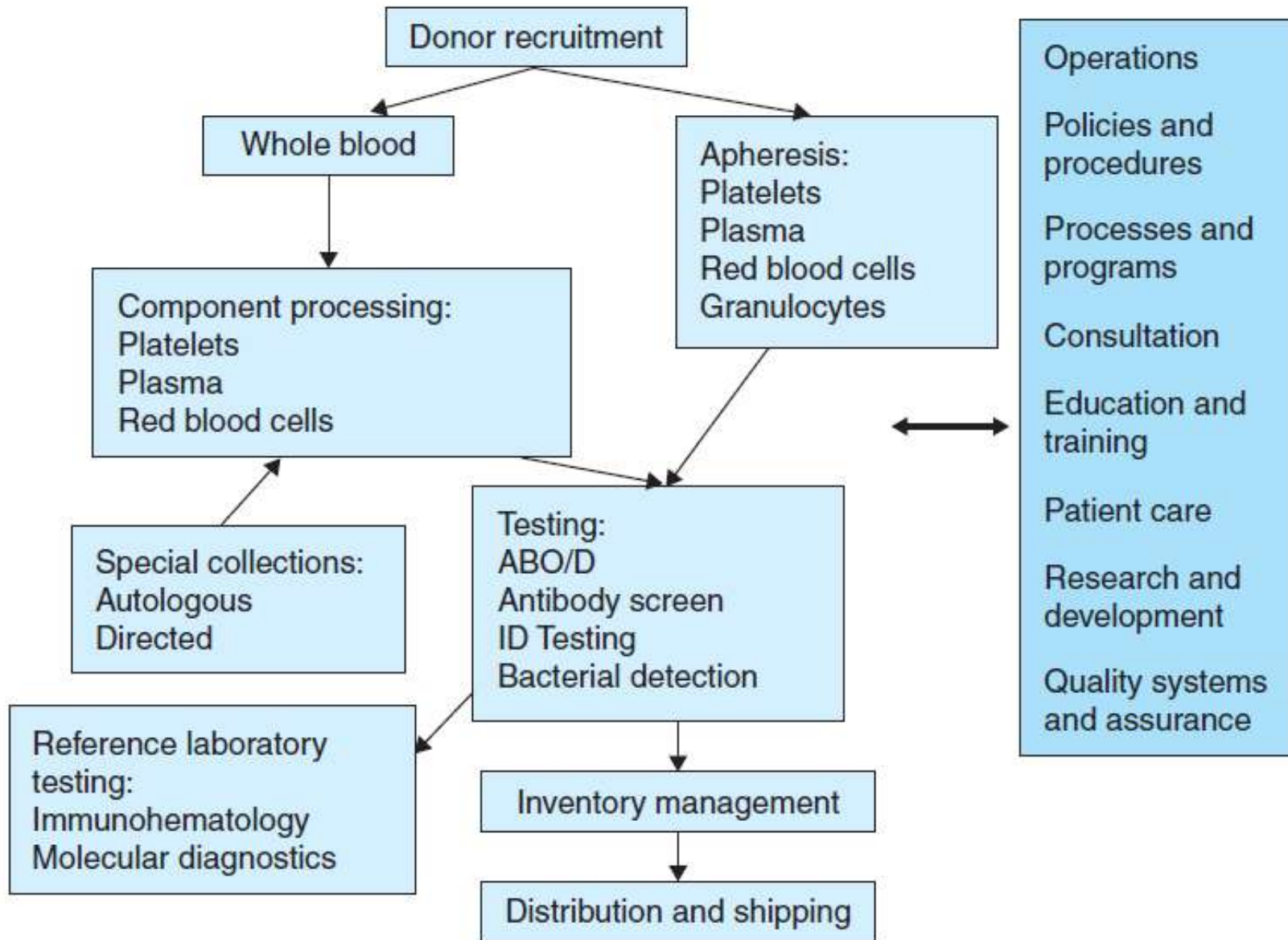
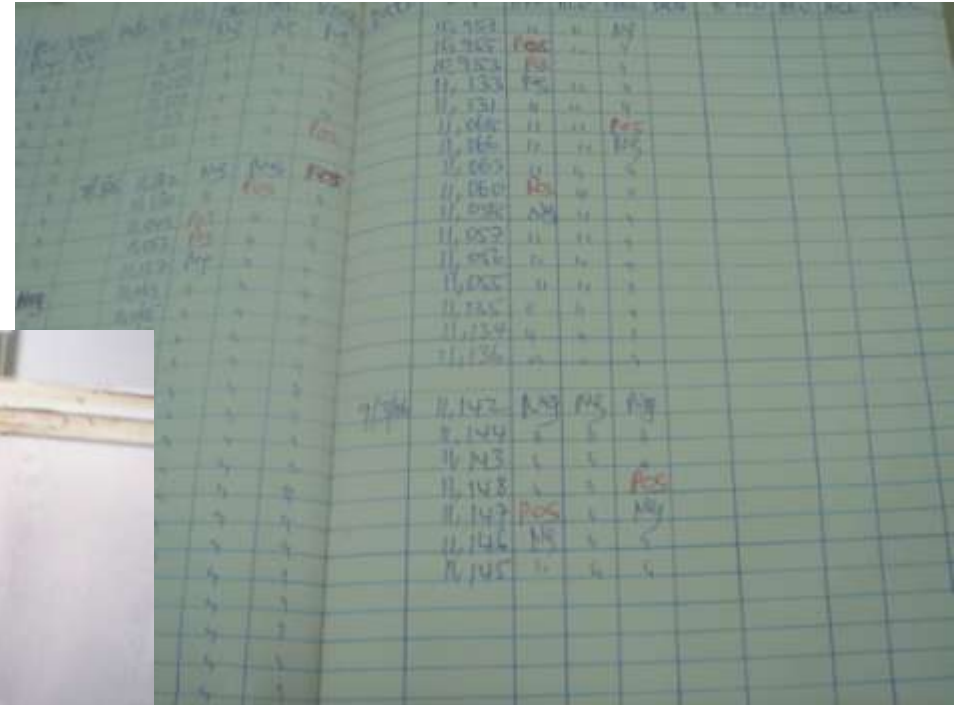


FIGURE 4.1 Physician oversight in the blood center.

AABB Standards



A handwritten inventory log on a grid notebook page. The log lists various items with their IDs, locations, and dates. Some items are marked with 'POS' in red ink.

ID	Location	Date	Status
11, 151			
11, 152			POS
11, 153			POS
11, 154			
11, 155			POS
11, 156			POS
11, 157			
11, 158			
11, 159			
11, 160			POS
11, 161			
11, 162			
11, 163			
11, 164			
11, 165			
11, 166			
11, 167			
11, 168			POS
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11, 200			



AABB Quality System Essentials

1. Organization
2. Resources
3. Equipment
4. Supplier & customer issues
5. Process control
6. Documents & records
7. Deviations, nonconformances, & complications
8. Assessments: internal & external
9. Process improvement
10. Facilities & safety

Leadership



- Passion, dedication and skill
- Making quality processes job #1
- Looking at 2nd and 3rd level reflection thought
 - Why, how, do we have a system in place
 - Data driven
 - Achieve consensus

Quality Assurance in the Hospital

- Ensure quality care, services and treatment are provided to patients
- Continuous operational improvement
- Have systems in place to collect data and monitor their performance
 - Blood product use
 - Hemolytic transfusion reactions
 - Audit particular areas
 - Turn around time
 - Specimen mislabeling
 - Wastage
 - Patient identification

Process Improvement Goals

Identify, investigate, correct, and prevent problems

Develop corrective and preventive action plans that include:

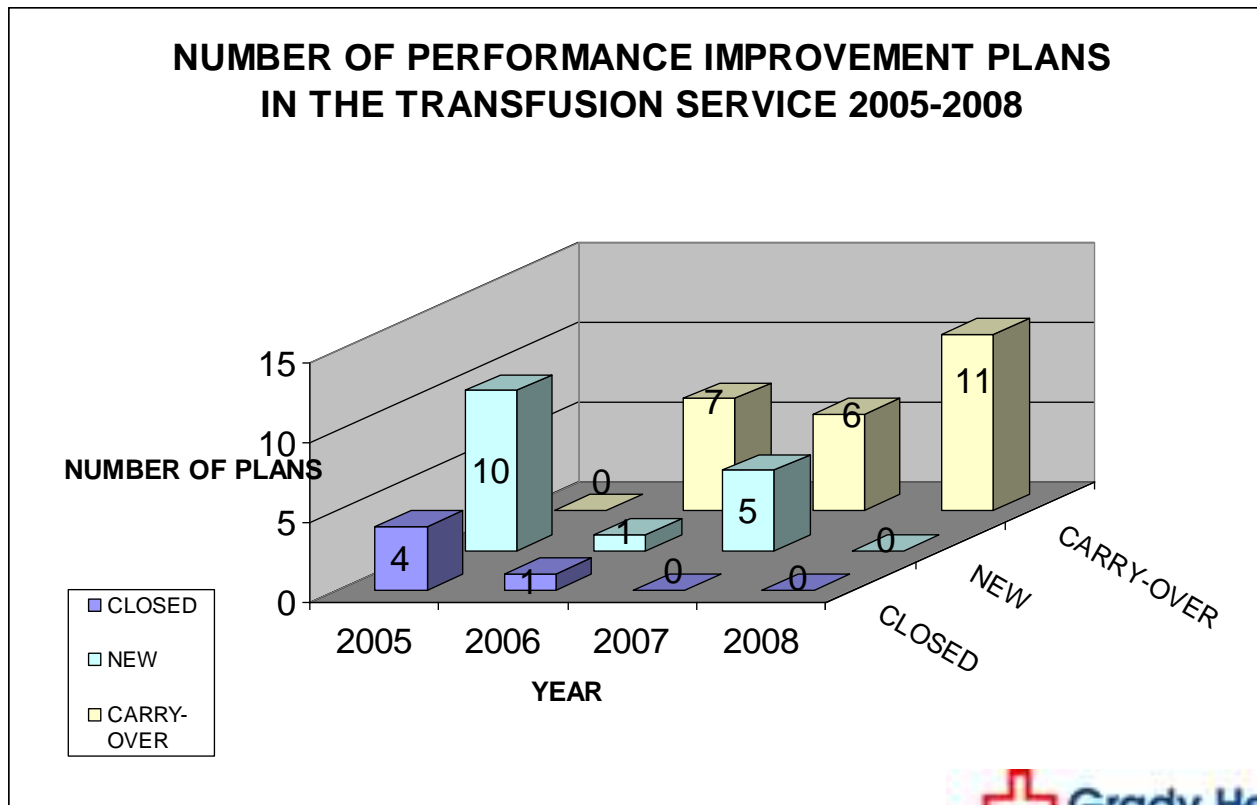
- Root cause analysis
- Identification and evaluation of solutions
- Data collection & evaluation
- Follow-up evaluation



Developed a performance improvement plan (PIP) database to track activities

Carry-over activities not finished into the next year

Review activities to aid in preparing departmental goals for next year



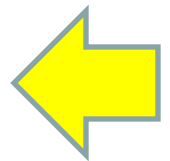
Process Improvement Goal

Massive Transfusion Protocol

Package	RBC (units)	Plasma (units)	Platelet apheresis	Cryo-pool (10 units)
Initial	6	6		
1	6	6	1	
2	6	6		2
3	6	6	1	
4	6	6		1
5	6	6	1	
6	6	6		1

Goals of the Massive Transfusion Protocol

- Early transfusion of coagulation factors and platelets
- Minimize coagulopathy
- Reduce total blood use by early correction of coagulopathy
- Reviewing laboratory data, turn around times, outcome, blood utilization, transfusion reaction rates



What did we need from the blood supplier

- Adequate group O RBC supply
- Adequate group AB plasma supply
- Adequate platelet supply
- Prepooled cryoprecipitate

What did we need in the blood bank

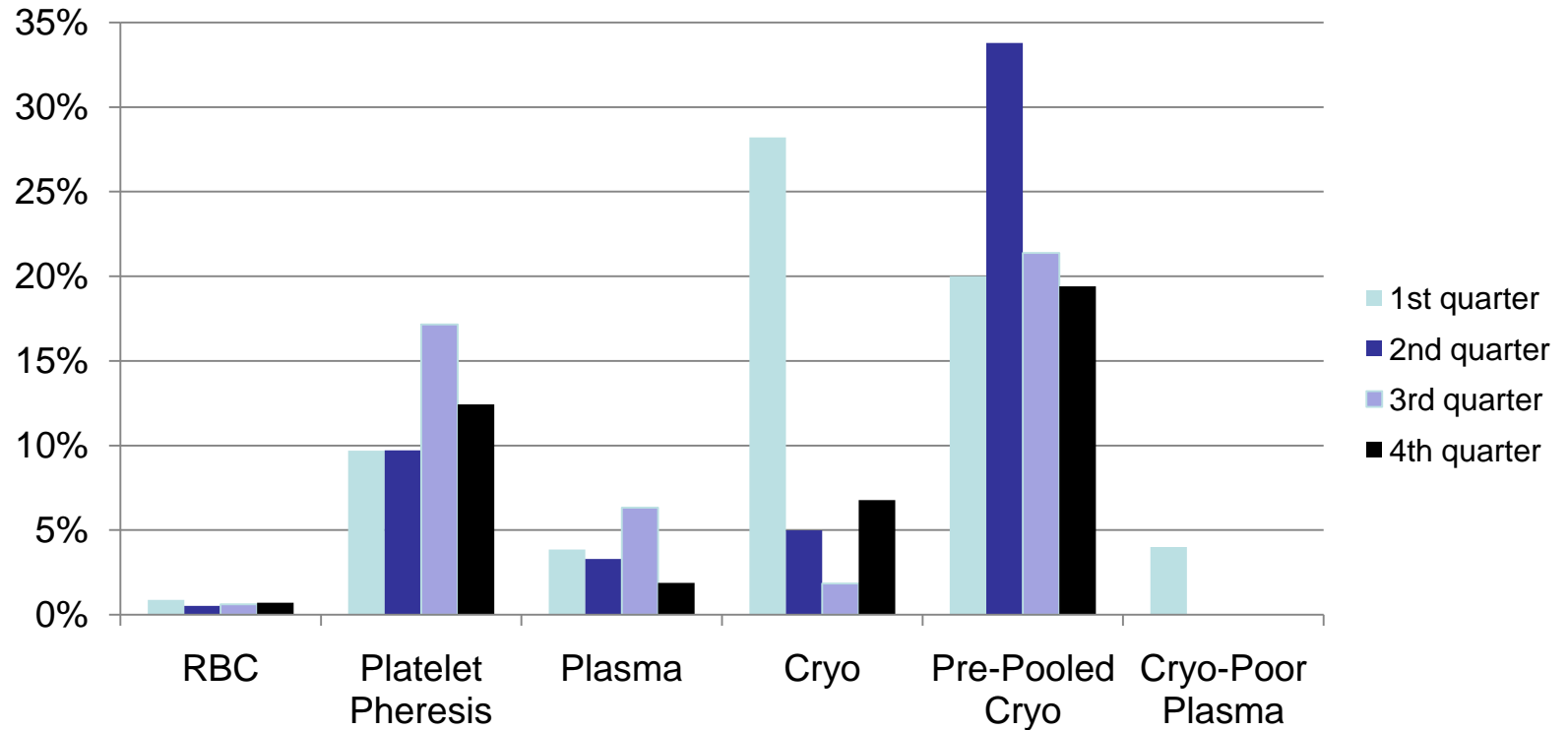
- Adequate personnel
- Adequate plasma thawers
- Quick and easy mechanism to issue blood products
- Adequate blood supply

Lab Quality Measurement 1

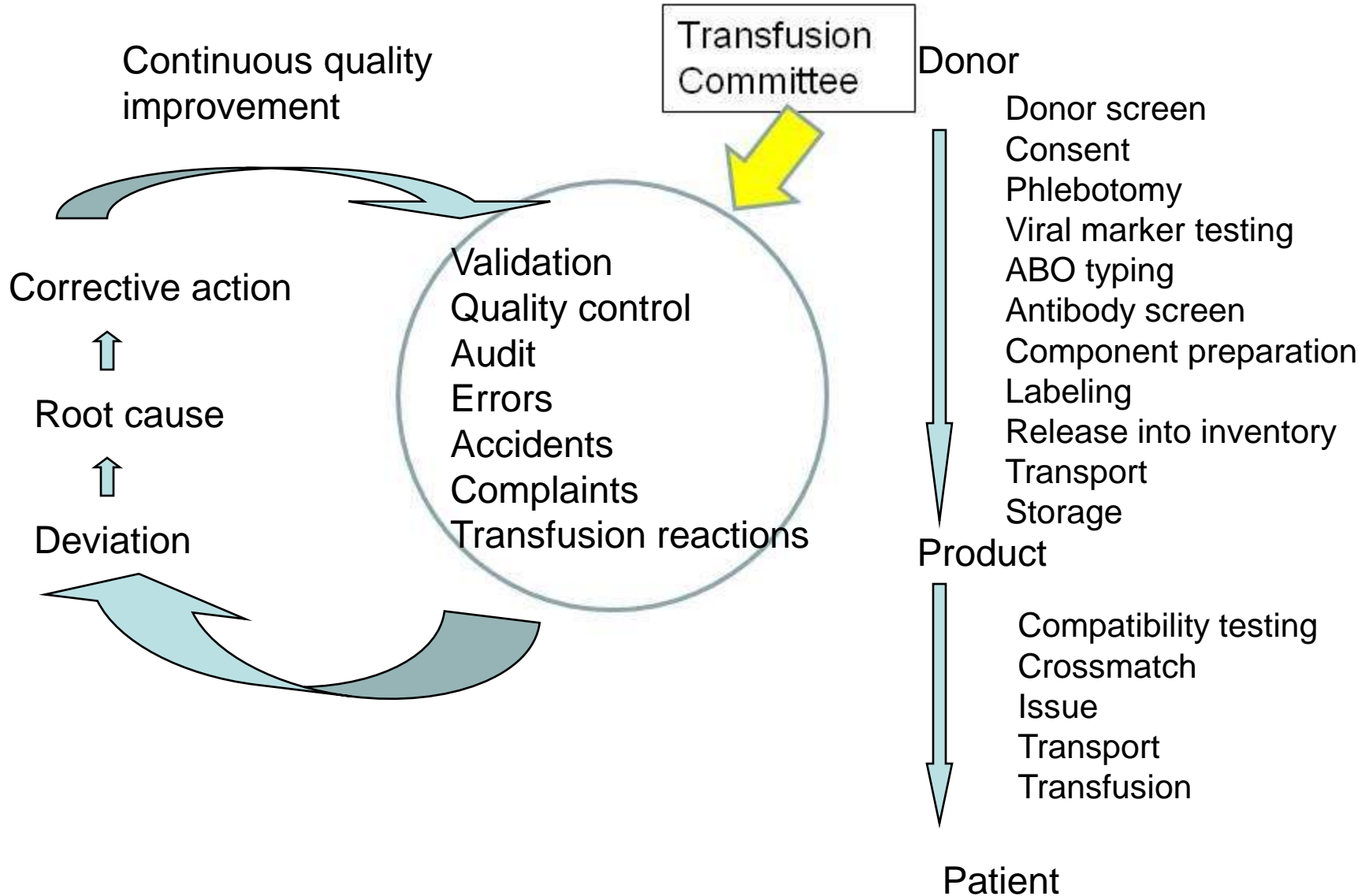
- Percentage of MTP cycles in which blood products are made available within 30 minutes and if they are delivered to the OR in a timely fashion (target > 90%).
- 74% of the packages were available within the designated target and 91% within 10 minutes, 98% within 30 minutes of the target.
- 31% of the packages were picked-up within the designated target and 69% within 10 minutes, 93% within 30 minutes of the target.

Lab Quality Measurement 2

- Number of wasted blood product units.



Continuous Quality Improvement



Transfusion Committee

- Members from departments that use blood products
 - Hematology, Surgery, Anesthesia, Obstetrics, Emergency room
- Members from the clinical laboratory
 - Blood bank
- Members from hospital administration
- Members from nursing



Monitor.....

- Blood supply
- Use and wastage of blood products
- Specimen mislabeling
- Turn around time for completing transfusion orders
- Documentation of patient identification and appropriate blood administration practice
- Transfusion reactions
- FDA reportable events
- Appropriateness of blood orders
- Use and maintenance of blood salvage equipment
- Use and maintenance of blood warmers

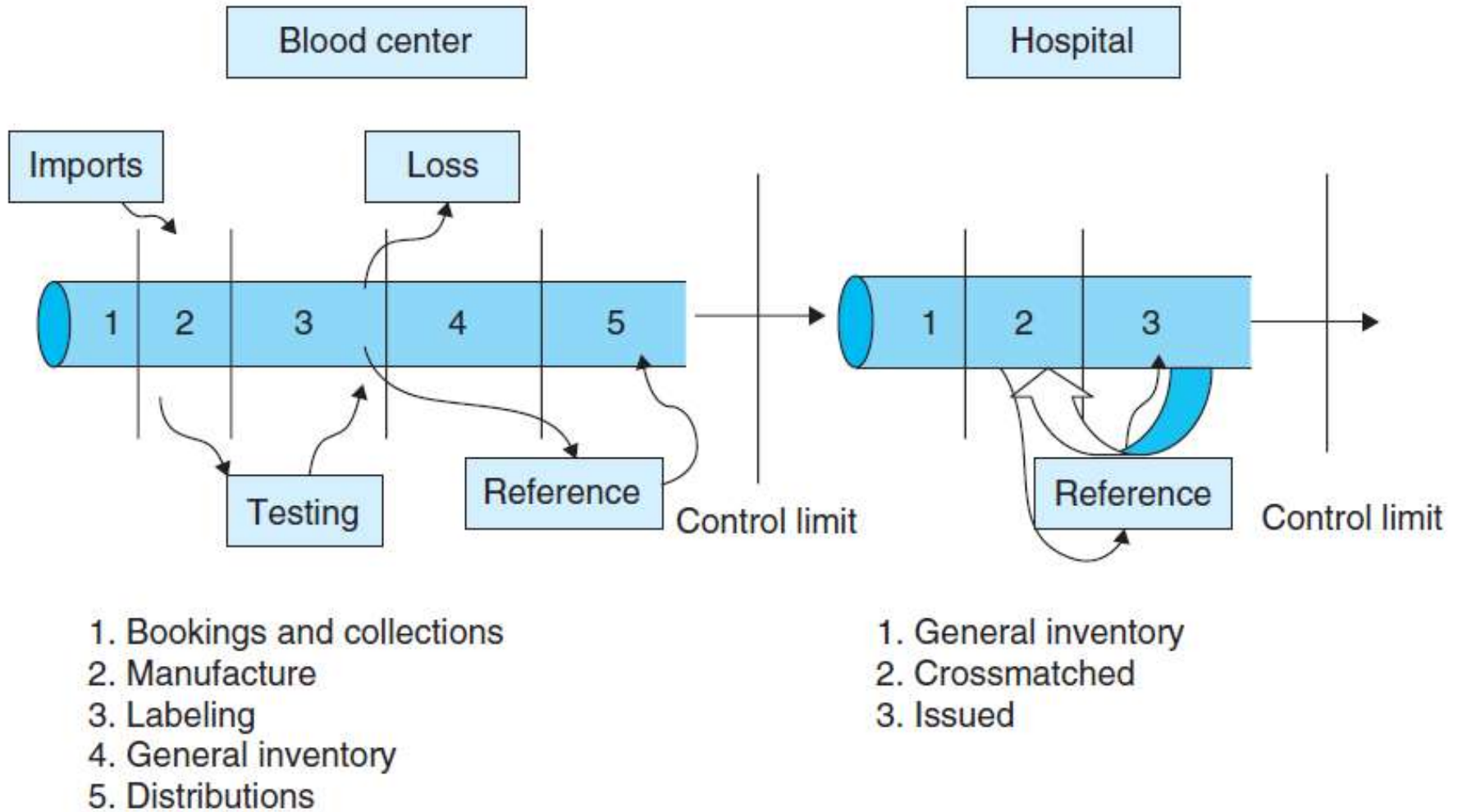


FIGURE 1.1 The Blood Pipeline.

Blood Center Processes which Increase Costs yet Decreasing Adverse Events

- Universal pre-storage leukoreduction
- Universal irradiation
- NAT and micro-arrays expansion
 - Specialized donor profiles
- NAT for specialized populations
 - CMV, EBV, HHV-8
- Pathogen inactivation/reduction

Hospital transfusion committee must weigh the cost versus the benefit and communicate with the blood centers to optimize patient care while controlling costs

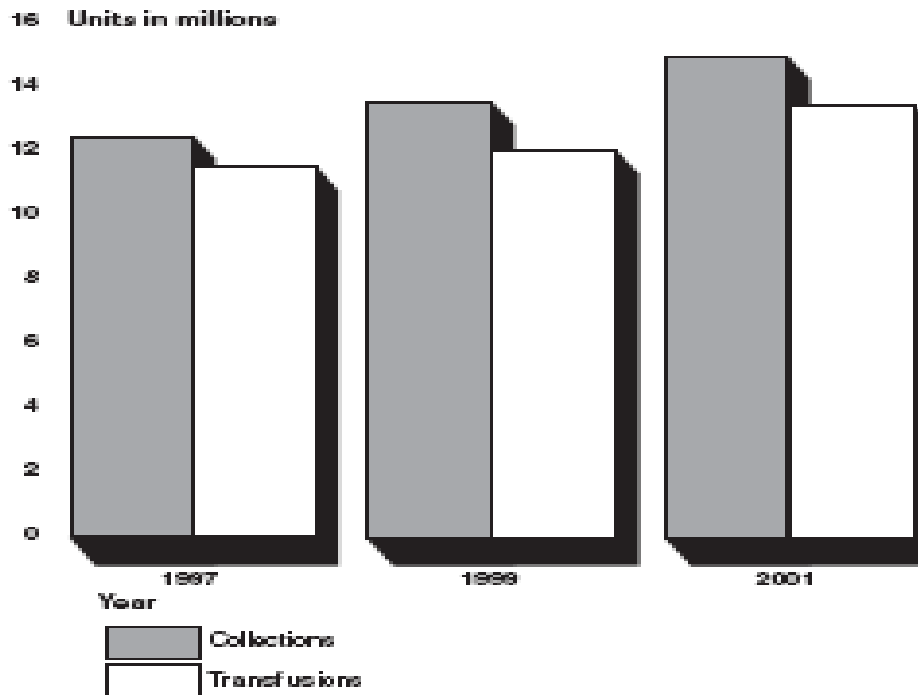
Changes in donor deferral which may effect the blood supply

- vCJD travel deferrals
- Chagas' testing
- High risk of alloimmunization resulting in TRALI

Blood center communicating blood shortages to the hospital

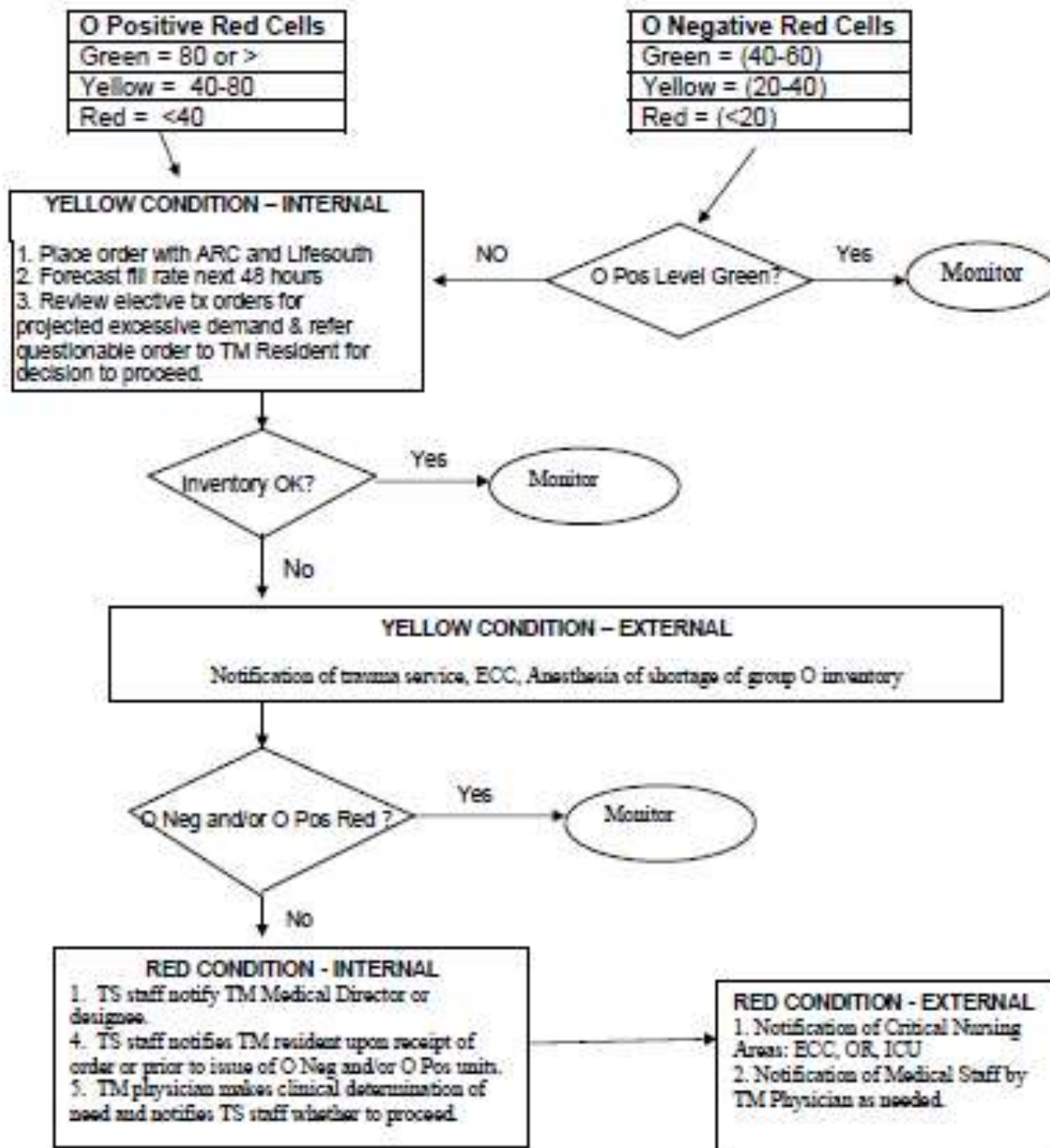
- “Shortages” need to be defined

Figure 1: Units of Blood Collected and Transfused, 1997 to 2001



Note: Collection data do not include autologous donations (that is, donations in which the blood donor and transfusion recipient are the same) of whole blood and red blood cells.

FLOWCHART OF THE EMERGENCY BLOOD MANAGEMENT PLAN (EBMP)



Audit Blood Administration Practice

- Reviews multiple steps in the process from specimen receipt, specimen testing, patient identification, transfusion
- Audits can be...
 - Prospective: occurring at the time of the event
 - Concurrent: occurring within 24 hours of the event
 - Retrospective: occurring after 24 hours of the event

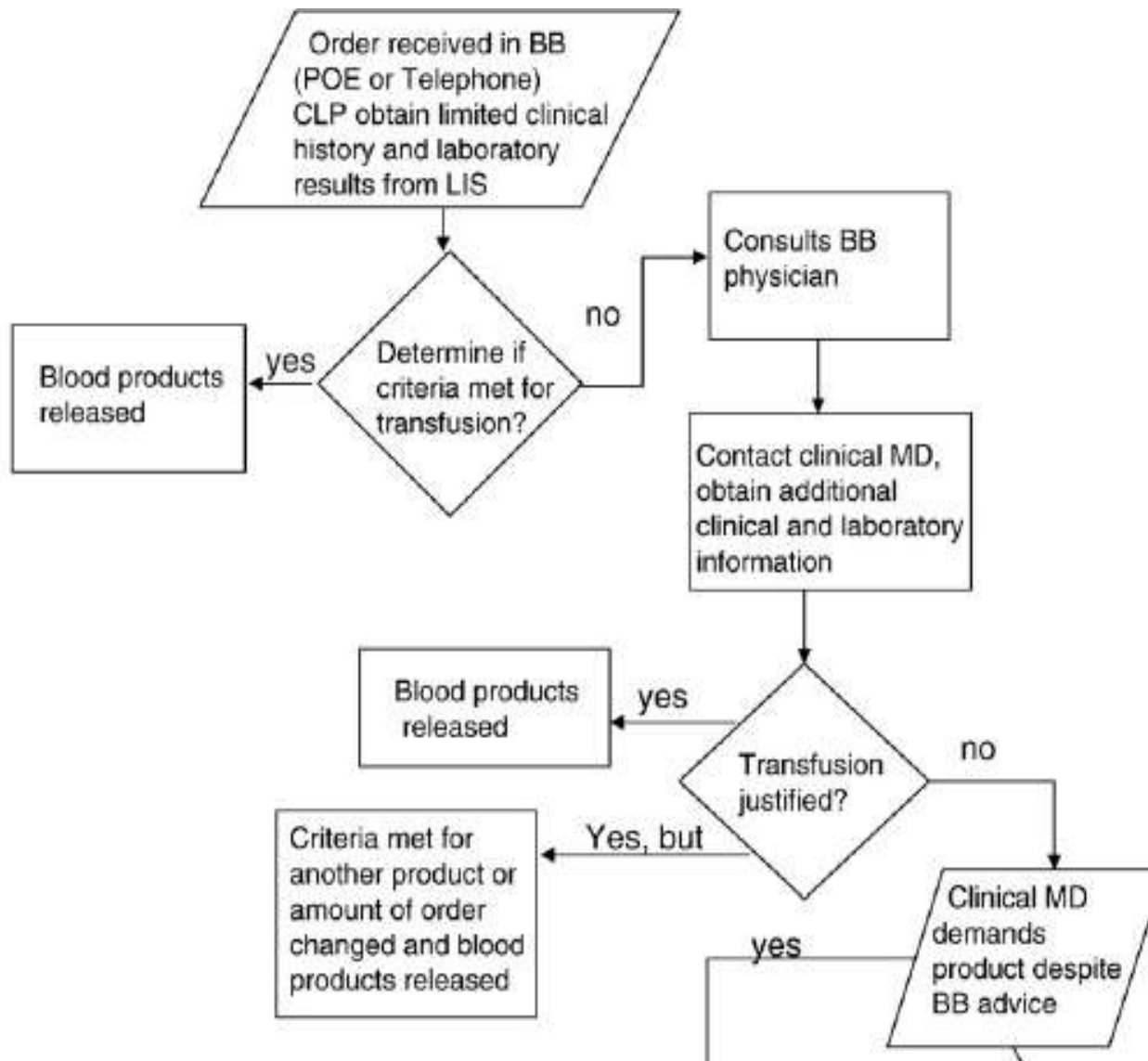
A Prospective Audit Program to Determine Blood Component Transfusion Appropriateness at a Large University Hospital: A 5-Year Experience

Grace N.C. Jackson, Cindi A. Snowden, and Alexander J. Indrikovs

Predetermined transfusion guidelines, pretransfusion approval, and transfusion audits are useful tools in the education of those ordering blood components, potentially resulting in the reduction of inappropriate use of blood components. Our institution requires mandatory prospective audits for a proportion (10%) of packed red blood cell unit orders and all orders for fresh frozen plasma, platelets, and cryoprecipitate. Cases where the blood bank physician recommends against a transfusion and the ordering physician concurs, or when blood components are released against blood bank's recommendation, are referred to the transfusion committee. Transfusion committee members review the medical records to determine the circumstances surrounding the transfusion request as well as patient outcomes relating to their receiving or not receiving the transfusion. We

analyzed 220 transfusion episodes brought before the transfusion committee from 2001 to 2005. The most requested blood component denied or changed was fresh frozen plasma. With only a few exceptions, the denial or change of blood components had no adverse effect on the patient. Nonetheless, these interventions were deemed appropriate by the transfusion committee. In most cases, blood components released based on the demand of the ordering physician, despite the advice of the blood bank physician, were deemed as inappropriate transfusions. This study therefore suggests that prospective audits of blood component orders can help reduce inappropriate transfusions and can be a valuable educational tool for the ordering physicians as well as for residents in training.

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Develop.....

- Transfusion practice guidelines
- Criteria for specific blood product use
- Blood administration procedures

Guidelines

- Product guidelines
 - RBC products
 - Platelet products
- Specialized patient population guidelines
 - Sickle Cell Disease
 - CMV in OLT
 - VIIa
 - Massive transfusion

Transfusion Practice Guidelines

- A model process follows:
 - An audit is performed in order to best understand current and established transfusion practices
 - Draft guidelines are created by a multidisciplinary team based on evidence in the literature.
 - Education of the ordering physicians and other members of the health care team ensues and is required to determined understandability and likelihood of implementation and compliance.
 - The guidelines revised, approved, adopted and implemented.
 - Periodically, repeat auditing is required to guarantee that the guidelines are being followed and continue to be appropriate.

GUIDELINES FOR BLOOD TRANSFUSION

These guidelines promote best practice regarding blood use within the Southern General Hospital. Recent audit revealed widespread differences in practice and confusion as to when and how to prescribe blood.

INDICATIONS FOR TRANSFUSION

1. Acute Blood Loss

An acute blood loss of greater than 20% of blood volume (about 1000 ml blood) will often need a transfusion. Do not delay ordering blood in situations where blood loss is acute and rapid. If blood loss is very rapid, the hospital **Major Hemorrhage Protocol** should be activated by dialing 3333.

2. For Surgical Patients

Consider transfusion if:

- Preoperative hemoglobin is less than 8 g/dl and the surgery is associated with the probability of major blood loss.
- Post-operative hemoglobin falls below 7 g/dl
- Preoperative anemia **MUST** be investigated, as medical management may be more appropriate than transfusion.

3. Anemia in Active Myocardial Infarction (Hb below 10 g/dl)

These patients are among the few who may benefit from a Hb above 80. Transfusion to an Hb of 10 g/dl is acceptable but to overshoot to 11 may be excessive. Evaluate effect of each unit as it is given.

4. Anemia in Other Patients (Hb below 10 g/dl but above 7 g/dl)

Consider transfusion in normovolemic patients **ONLY** if they have symptomatic anemia.

Symptoms and signs of anemia include:

- Shortness of breath for no other reason
- ST depression on ECG
- Angina
- Tachycardia for no other reason
- Syncope/postural hypotension

Transfusion above 10 g/dl is very rarely indicated and **WILL** be questioned by hematology staff.

- Think before transfusion. Blood is expensive and potentially dangerous if used inappropriately.
- Reasses after each unit is given. Do you need to give more?
- Stop if symptoms/signs shown above resolve.
- Stop if you have reached an adequate Hb i.e. above 8 g/dl in symptomless patients (10 g/dl in acute MI).

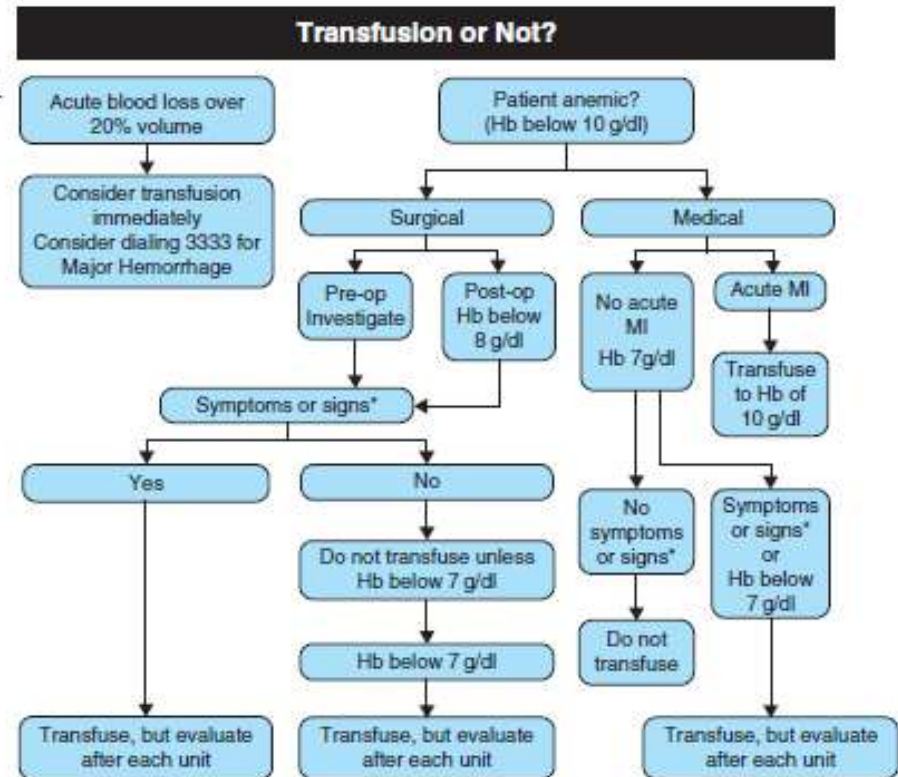
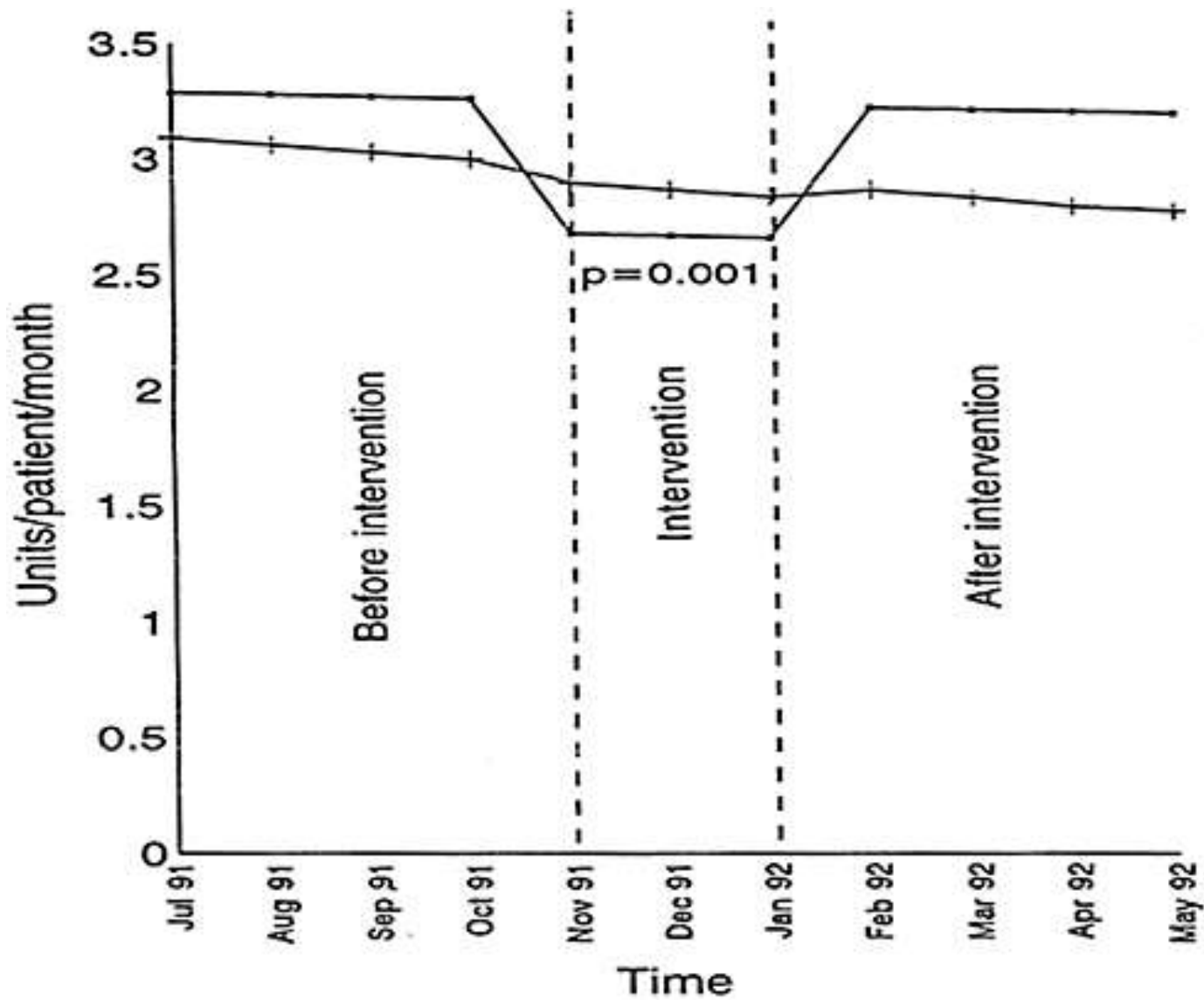


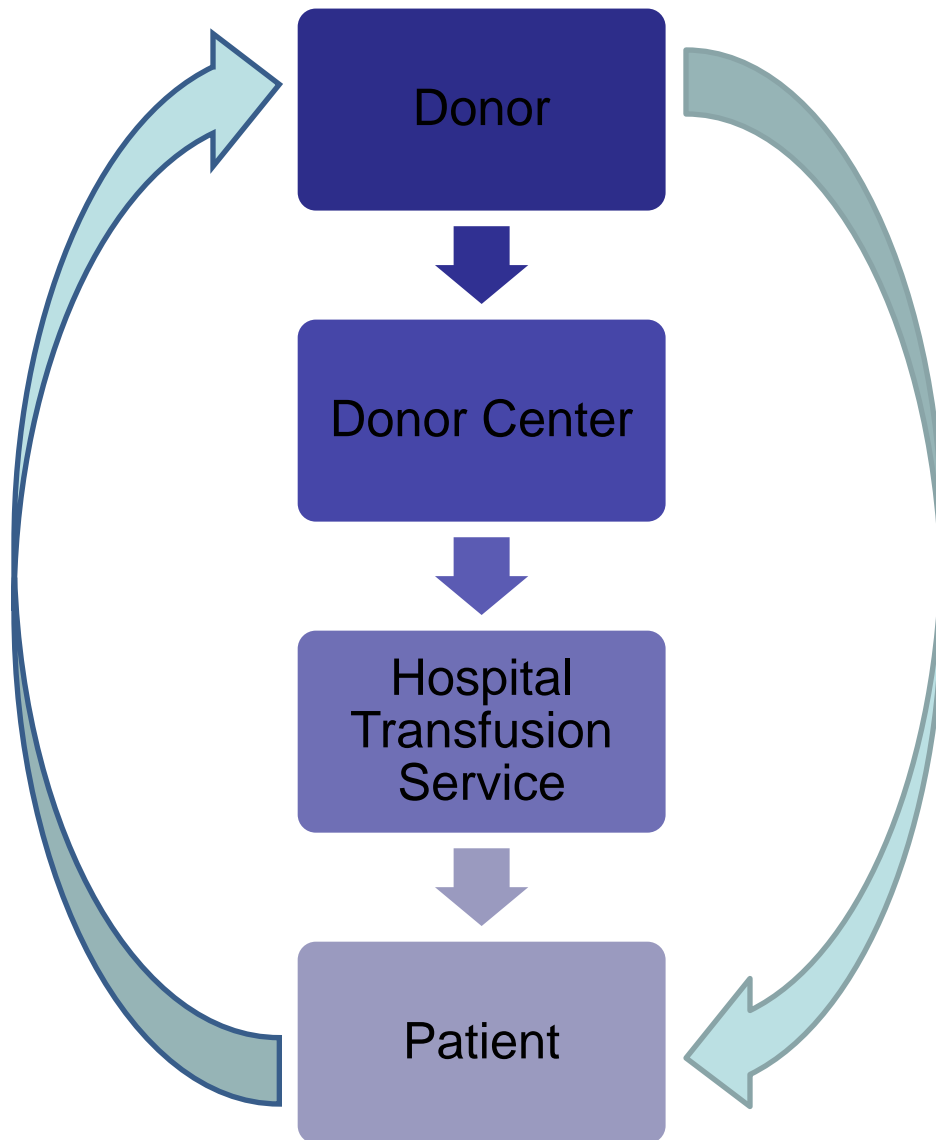
FIGURE 28.1 An example of RBC transfusion guidelines. From Garrioch M, Sandbach J, Pirie E *et al.* (2004). Reducing red cell transfusion by audit, education and a new guideline in a large teaching hospital. *Transfusion Med* 14, 25–31.

Durability Of Change in Transfusion Practice

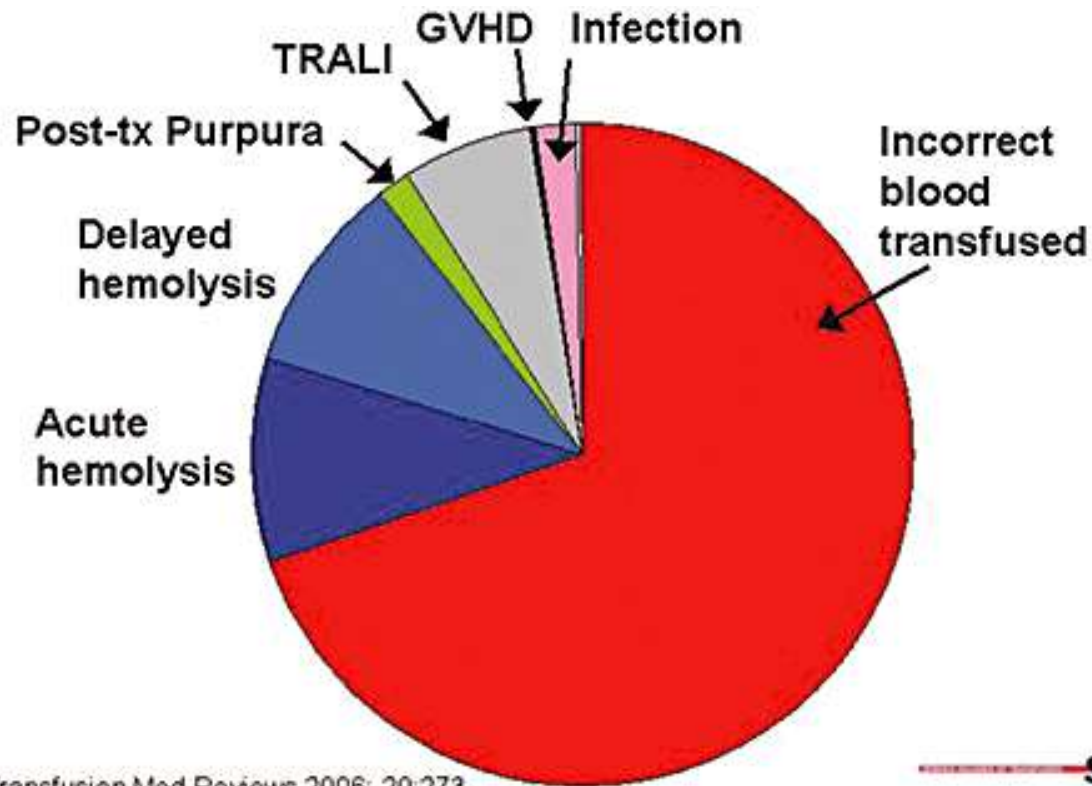


Guidelines on the need for phenotype matched products

- RBC Phenotype/ genotype matching
- Currently routine RBC phenotype matching occurs in the selection of appropriate units for Sickle Cell Disease patients
- Requires appropriate communication between the blood center , hospital transfusion service , and patient care area to have the units available when the patient requires them



Transfusion reactions



How is the hospital going to prevent ABO incompatible transfusions?

- Barcode technology
- RFID technology
- Blood-loc
- Two specimens until type-specific blood is issued

Fig. 1. The pyramid of human error and patient risk for pre-transfusion specimen collection. Line “A” = refusal to accept mislabeled specimens—represents the first line of defense against errors in sample collection. Line “B” = comparing blood group results on the current sample with historical records—represents the second line of defense against sample

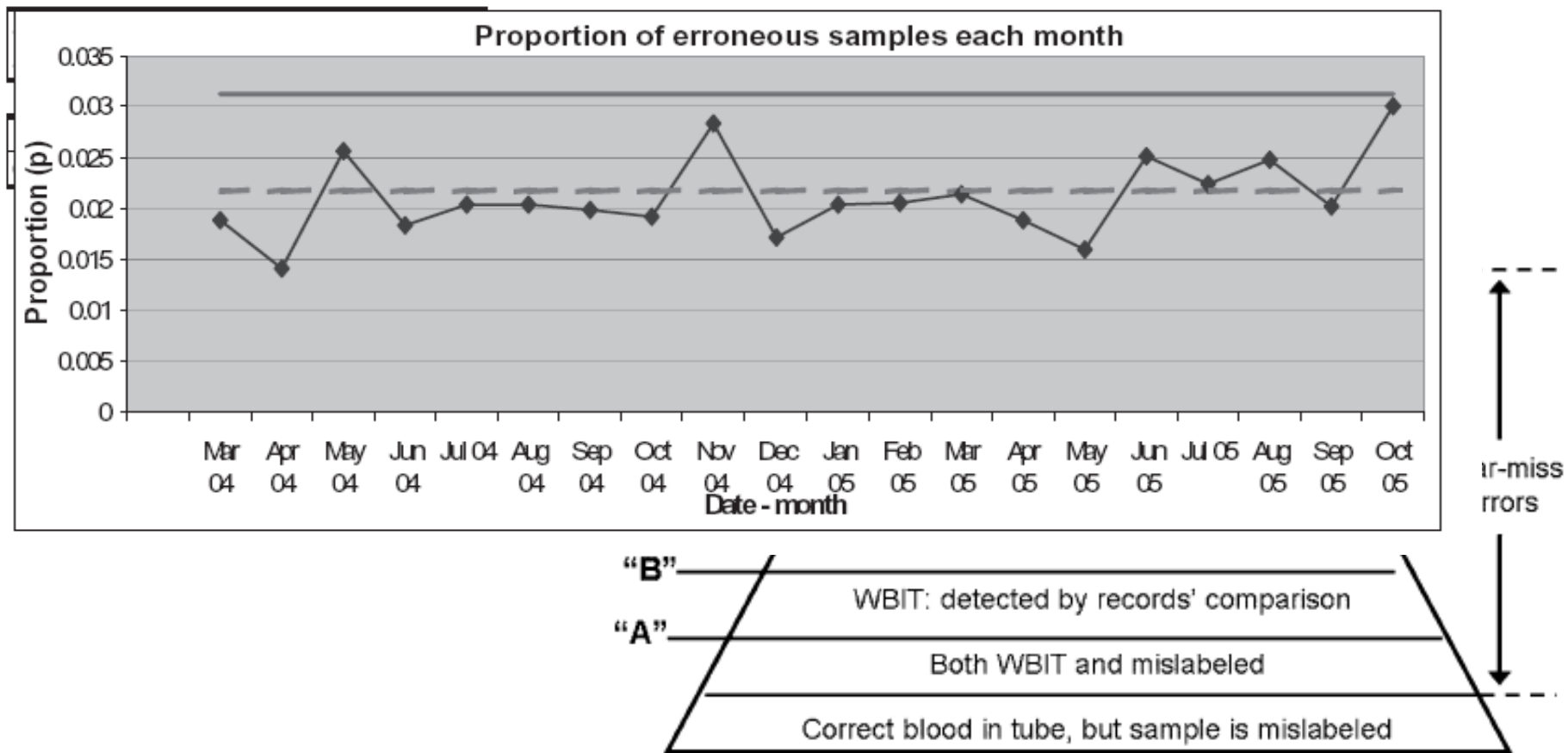
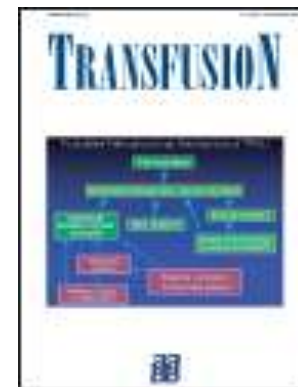


TABLE 1. Recommended criteria for TRALI and possible TRALI

1. TRALI criteria
 - a. ALI
 - i. Acute onset
 - ii. Hypoxemia
Research setting:
 $\text{PaO}_2/\text{FiO}_2 \leq 300$,
or $\text{SpO}_2 < 90\%$ on room air
Nonresearch setting:
 $\text{PaO}_2/\text{FiO}_2 \leq 300$
or $\text{SpO}_2 < 90\%$ on room air
or other clinical evidence of hypoxemia
 - iii. Bilateral infiltrates on frontal chest radiograph
 - iv. No evidence of left atrial hypertension (i.e., circulatory overload)
 - b. No preexisting ALI before transfusion
 - c. During or within 6 hr of transfusion
 - d. No temporal relationship to an alternative risk factor for ALI
2. Possible TRALI
 - a. ALI
 - b. No preexisting ALI before transfusion
 - c. During or within 6 hr of transfusion
 - d. A clear temporal relationship to an alternative risk factor for ALI

Canadian Consensus Conference 2004



Transfusion
December 2004

Communication for adverse events between the transfusion service and blood center

- TRALI work up and donor deferral
 - Signs and symptoms of TRALI
 - Specimens and information to send to the donor center for the appropriate work up of both the donor and the patient

The transfusion committee.....

- Must create a committee of involved members who represent those who use blood products and the blood bank
- Must create performance measures to demonstrate improved patient care and patient outcome
- Must collaborate to improve blood transfusion practice in the hospital

Medical Director Overview

- Policies/ processes/ procedures
- Provision of a safe and adequate blood supply
- Blood administration including informed consent
- Transfusion adverse reactions including investigation of system failures and additional evaluation
- Peri- and intra-operative blood management
- Therapeutic apheresis and phlebotomy