Chapter 2
QUALITY SYSTEMS FOR CLINICAL TRANSFUSION

PRACTICE POINTS

• Safe patient care relies on a safe hospital system.

• It is important that the entire transfusion (‘vein to vein’) chain is traceable. This means that the blood establishment and the hospital blood bank should have a clear documentation and archive of all critical steps.

• Haemovigilance systems provide valuable data on the occurrence of transfusion-related adverse events and as a result drives initiatives to enhance the safety of the transfusion process.
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2.1 ESTABLISHING A QUALITY SYSTEM

Blood transfusion may be a life-saving treatment for patients but is not without risk. Safe transfusion is dependent on having a safe and reliable blood supply, and also a safe clinical transfusion process. All healthcare institutions that transfuse blood should have policies and procedures in place for every step of the clinical transfusion process. Appropriate and correct systems aid in the safety of patients.

Management commitment and support are essential in ensuring that a hospital quality system for clinical practice is developed and supported, and that all staff understand the importance of quality and the consequences for patients of failure in the quality system.

2.1.1 Establishing a system and procedures to support the implementation of the guidelines

Guidelines are a supportive set of indicators and motivators to implement rational practice on an evidence base. They are an integral part of a larger system to manage the quality of operations in daily practice, allowing proper standardization, consistency of implementation of processes and procedures, and monitoring and evaluation to be able to continuously improve.

To be able to demonstrate good clinical practice, documentation of what is to be done and what has been done is paramount. The hospital quality system on the clinical use of blood should include standard operating procedures for the following stages in the clinical transfusion process and, ideally, standard outcome documentation such as a transfusion reaction report form.

It is important to transfuse blood based on evidence. All hospitals require a blood transfusion policy based on the national guidelines for effective and rational use of blood products. The policy is determined by the Hospital Transfusion Committee (HTC) and endorsed by the hospital executive or board.

2.1.2 Key elements for hospital transfusion policy

Managerial

- A hospital transfusion policy in compliance with the National Guidelines for Transfusion Practice.
- Strategies to implement the policy and achieve the goals set based on a National Quality (QS) and Quality Management System (QMS) e.g. standards and guidelines, annual quality plan.

Operational

- Operational system based on written instructions, e.g. standard operating procedures (working instructions) and equipment operating procedures.
- Key elements of a management and quality system are standard procedures for all stages of the clinical transfusion process:
  a. Ordering blood and blood products in routine and emergency situations.
  b. The selection and compatibility procedure.
  c. Issue of blood and blood products.
  d. Storage and transportation of blood and blood products.
  e. Administration of blood and blood products.
  f. Recording all transfusions in patient records including indication and consent.
  g. Monitoring the patient before, during and after transfusion.
  h. Management, investigation and recording of transfusion reactions.

- Efficient system for transportation and storage of blood and blood products in the clinical setting (cold chain).
- Practical outcome documents to allow appropriate communication, monitoring and evaluation, for example:
  a. Availability of standard blood request form.
b. Availability of blood ordering schedule.
c. Availability of transfusion reaction report form.
d. A standard consent form which includes transfusion consent.
e. A standard compatibility test form.
f. Clinical indications for transfusion.
g. A standard checklist for monitoring the patient.

Annexes 4 and 5 include guidance on the monitoring of the transfused patient, and investigating and recording acute transfusion reactions.

The decision to transfuse blood or blood components must be based on a careful assessment of clinical and laboratory findings which indicate that a transfusion is necessary to save life or prevent significant morbidity.

Responsibility for the decision to transfuse rests with individual prescribers of blood, although this may be made in consultation with the National Blood Transfusion Service.

2.2 TRACEABILITY

Traceability is an essential element of haemovigilance. The blood component manufacturer, the hospital blood bank and hospital wards must keep records to trace from which donor or donors a specific patient has received a blood product, and when this took place. The documents of this administration must be kept for at least 10 years depending on national regulations.

The purpose of this documentation is that after a post transfusion infection a contaminated donor can be traced. Also recipients of products from recognised contaminated donors must be able to be traced to any recipient.

2.3 HAEMOVIGILANCE

Haemovigilance is the observing, recording, analysing and reporting of transfusions when something goes wrong; and using the lessons learned to take action to avoid it going wrong again.

It is important that the entire transfusion (‘vein to vein’) chain is traceable. This means that the blood establishment and the hospital blood bank should have a clear documentation and archive of all critical steps.

NBTS has responsibility for documentation of donor identification and any donor adverse events. The hospitals have responsibility for the documentation of clinical decision making, compatibility testing and patient outcomes including adverse events. Investigation of adverse events is a joint responsibility.

Haemovigilance is the assurance and registration / documentation of this entire process. In the hospital it is preferably guided by the haemovigilance coordinator. This person collects all data and provides them to the provincial or regional blood establishment coordinator after processing of these data. The data collected from the associated hospitals are provided to the national coordinator in a compiled form.

2.4 MAXIMUM BLOOD ORDERING SCHEDULE

A Group & Screen or cross-match should be performed for all surgical patients at predictable risk of bleeding and in those patients where uncommon and unexpected bleeding may be catastrophic. The hospital transfusion laboratory must give special consideration to patients with a positive antibody screen.

A Maximum Blood Order Schedule (MBOS) can be used to gauge expected blood use for patients undergoing a specific procedure and assists in ordering blood. Institutional factors affect the format of an MBOS and include:

- The presence of an onsite laboratory and whether it is staffed 24 hours a day or not,
- The availability of blood and blood products and distance from Transfusion Service,
- The availability of O erythrocyte units, and
- Clinical demand, clinical specialties and local surgical practice.

2.5 HOSPITAL TRANSFUSION COMMITTEE

The Hospital Transfusion Committee (HTC) has a role in ensuring clinical governance and risk management, appropriate use of precious blood products and to improve patient care and safety.

All major hospitals should have or establish a HTC (or equivalent) for oversight and governance of transfusion practice. The HTC should:

- monitor and improve transfusion practice,
- promote appropriate use of blood,
- report and investigate adverse events and transfusion reactions,
- monitor blood utilisation, stock availability and wastage.
• provide an active forum to facilitate communication between those involved with transfusion,
• ensure implementation of the Kingdom of Cambodia National Transfusion Guidelines,
• review on an annual basis MBOS, and
• promote transfusion training and education activities.

The HTC should meet on a regular basis and at least quarterly.

The membership of the HTC should include a range of health professionals involved in transfusion, including physicians, nurses, transfusion staff, hospital administration, and other personnel as needed. The chair of the committee should report to the hospital executive so that practice changes can be endorsed and authorized.

Both clinical and laboratory perspectives are critical in obtaining the safest and most practical policies for transfusion activities. The members of the HTC can help provide this input on behalf of, and preferably in collaboration with, members of their own departments.

The HTC has a role in reviewing blood stock supply and demand data. This may include the management of blood shortages and the use of a MBOS. The HTC also has a role in reviewing the cold chain management for storage, handling and transportation of blood components.

See Annex 1. Hospital Transfusion Committee Terms of Reference

See Annex 2. Indicators for monitoring and evaluation of the Hospital transfusion chain.