Medical Technology Association of Australia

National Blood Authority
Patient blood management guidelines: Module 2 - Perioperative

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Medical Technology Association of Australia Limited
Level 12, 54 Miller Street
North Sydney NSW 2066 Australia
P: (02) 9900 0650
E: reception@mtaa.org.au
www.mtaa.org.au

MEDICAL TECHNOLOGY FOR A HEALTHIER AUSTRALIA

Contents

1. About the medical technology industry

The Medical Technology Association of Australia (MTAA) represents the manufacturers, exporters, importers and distributors of medical technology products in Australia. The medical technology industry manufactures a range of items that assist with patient blood management. These include lasers, microwave scalpels, argon-beam coagulators, items for minimally invasive surgery, ultra filtration devices, transfusion systems, vessel closure systems, cell processors and salvage devices that wash and save red blood cells. The medical technology industry had sales in Australia of $7.6 billion in 2009-10 and employs more than 17,500 people. It is strongly research-based, often working closely with healthcare professionals to design and develop products for improved patient benefit.

2. Perioperative module of the patient blood management guidelines

Patient blood management aims to improve clinical outcomes by avoiding unnecessary exposure to blood components. The three pillars of blood management outlined by the World Health Organization (WHO)[1] are:

- Optimizing the haemoglobin level by recognizing, detecting and treating anaemia in all clinical situations
- Understanding anaemia and harnessing the physiology of it, making it tolerable while optimization occurs
- Having a consistent approach to blood conservation.

Six new modules will replace the 2001 National Health and Medical Research Council/ Australian Society of Blood Transfusion (NHMRC/ASBT) Clinical practice guidelines on the use of blood components. The Patient blood management guidelines: Module 2 – Perioperative is the second guideline from the series and focuses on evidence-based patient blood management.

The use of patient blood management techniques optimises the use of donated blood and decreases the risks associated with blood transfusions. MTAA commends the National Blood Authority (NBA) for its extremely thorough review of the literature and the high standard of Module 2 and welcomes the chance to comment and provide feedback on the draft report. MTAA believes that one of the limitations of the draft is that there is little mention of the wide range of medical devices that can be used to enhance patient blood management and suggests that the guideline address this limitation. The draft Perioperative module consists of evidence-based guidelines. There is a large amount of published literature on the use of medical devices to minimise blood loss. This literature should be sourced, graded as per the NHMRC recommendations and included as part of the evidence-based guidelines. This information could be included in Section 3.1 (Effect of a perioperative patient blood management program). Intraoperative and post operative cell salvage are covered well.

The draft is accompanied by detailed technical reports and appendices. Evidence for recommendations was graded using National Health and Medical Research Council (NHMRC) guidelines that assess the quality of the evidence:

- Grade A: Body of evidence can be used to guide practice
- Grade B: Body of evidence can be used to guide practice in most situations

[1] WHO Resolution. Availability, safety and quality of blood products. 126th Session EB126.R14. Agenda item 4.16, 22 January 2010.

- Grade C: Body of evidence provides some support for recommendation(s) but care should be taken in its application
- Grade D: Body of evidence is weak and recommendations must be applied with caution.

MTAA provides recommendations that are relevant to the following sections of the draft Perioperative module:

No.	Grade	Recommendation	Section of document
R15	C	In adult patients undergoing surgery in which substantial blood loss is anticipated, intraoperative cell salvage is recommended	3.6
R20	C	In adult patients undergoing cardiac surgery or total knee arthroplasty, in whom significant post operative blood loss is anticipated, post operative cell salvage should be considered	3.6

MTAA made a previous submission to the National Safety and Quality Health Service Standards released by the Australian Commission on Safety and Quality in Healthcare (ACSQHC) in August 2010, recommending the inclusion of guidelines for blood conservation and alternatives to blood transfusion in the Blood and Blood Product Safety Standard (Standard 7). MTAA recommended that Standard 7 include the use of innovative medical technologies and surgical techniques to provide an alternative to transfusion[2].

3. Innovation and medical technology for blood conservation

The draft Perioperative module of the blood management guidelines is based on a systematic review of research published before July 2009. The technical reports provide a detailed overview of the literature including the author, quality of the study, type of study, population assessed, level of evidence and outcome(s). The draft states that there is need for further research to assess the use of emerging point-of-care technologies, for example devices that measure blood coagulation, to evaluate their use in patient blood management.

The review does not include new and emerging technologies due to the fact that the impact of these would not be reflected in the pre-2009 literature. MTAA recommends that the Perioperative module provide scope to include new and emerging technologies. The existing guidelines for blood management have not been updated since 2001. Major technological medical innovations occur within a ten year time window and should be considered.

The list of bodies consulted in the development of the draft does not include industry. MTAA believes that industry consultation is essential as the medical technology industry manufactures and distributes a range of devices that assist in blood management. For example practice point 13 (PP13, 3.6 of document) states that "*Intraoperative cell salvage requires a local procedural guideline that should include patient selection, use of equipment and reinfusion. All staff operating cell salvage devices should receive appropriate training, to ensure knowledge of the technique and proficiency in using it".* This type of guideline will require significant contribution from industry.

An ageing population will lead to an increase in the number of surgical interventions requiring blood (e.g. surgical procedures such as pacemaker implantation and joint replacement surgery). Treatment options change as do the environments for the administration of blood products (e.g. administration of blood products from home). Innovative medical technologies and surgical techniques to conserve blood provide an alternative to transfusion

[2] http://www.mtaa.org.au/pages/page308.asp.

in some cases. They have the capability to both decrease the demand for blood and the risks associated with blood transfusion.

4. The need for blood conservation in Australia

There were 275,858 separations in Australia between 2007-2008 for the transfusion of blood and gamma globulin[3]. By 2050 the population of Australia will see the number of people aged 65-84 double and the number of people aged over 85 quadruple(1). Only 3.3%[4] of the Australian population donates blood, whereas 33% of the population will require a blood transfusion over their lifetime[5]. Blood has a limited life span and blood components must be consistently replaced. An Australian study of 20,000 blood transfusions over a 10 year period in the Hunter New England region found that the use of stale blood is linked to infection and recommends a ban on all products over the age of 35 days [6].

Australia will face an increase in the need for blood and blood products that must be planned for. The increase in the number of elderly will lead to a corresponding increase in the demand for surgical procedures requiring large amounts of blood (e.g. liver transplants and complex cardiac procedures). These challenges emphasise the need for innovative strategies and the use of medical technology to conserve blood. An additional reason for adopting blood conservation strategies is that blood transfusions are not free of risks and side effects. There is a dose-response relationship associated with transfusion, i.e. an increase in the number of units is associated with an increase in infection and transfusion-related immunosuppression(2-3). Any surgical strategies or medical technologies that can be used to assist with minimising blood loss should be considered.

The Clinical Excellence Commission co-ordinates a transfusion medicine improvement program (Blood Watch) in NSW[7]. A priority focus area is the appropriateness of blood component therapy. Recent audit data have found that a high number of large rural and metropolitan hospitals are prescribing above the state average. Those hospitals performing best had quality systems in place that included the use of restrictive thresholds.

A report by the NBA notes that an increase in cardiac surgical procedures is a key indicator for increased demand and highlights several areas for investigation, one of which includes considering blood saving technologies(4). The report includes guidelines for the prioritization of red blood cell transfusion:

- Priority 1 includes resuscitation from life-threatening blood loss and emergency support
- Priority 2 includes semi-urgent surgery and anaemia
- Priority 3 includes elective surgery and nonsurgical anaemia.

The report states that *all* priority levels must consider alternatives to transfusion such as erythropoietin, iron therapy and red blood cell salvage.

The Western Australia Blood Management Project[8] is transitioning from blood transfusion as a default to patient blood management as a new standard of care. Multidisciplinary

[3] Chapter 10: Procedures for admitted patients supplementary tables (Australian hospital statistics 2007-08). Selected separation statistics for procedures in ACHI blocks, public and private hospitals, Australia.
[4] Australian Red Cross Blood Service. Percentage refers to the 2007/08 blood donor numbers as a proportion of the eligible Australian population.
[5] Australian Red Cross Blood Service.
[6] http://www.smh.com.au/national/stale-blood-linked-to-dangerous-infections-20101123-185r6.html.
[7] http://www.cec.health.nsw.gov.au/programs/blood-watch.html.
[8] http://www.nba.gov.au/conference08/presentations/pres8.pdf.

approaches are applied under each of the three pillars of blood management. Strategies include surgical techniques and the use of medical devices to minimise patient blood loss.

5. Medical technology for blood conservation and bloodless surgery

The aim of blood management is the appropriate use of blood via the adoption of a number of multidisciplinary strategies, for example cell salvage. A number of strategies are outlined in detail in the draft Perioperative module. Additionally, there are a number of other surgical techniques and medical devices that can be used to conserve blood and decrease the need for a transfusion. MTAA recommends that the Perioperative module include specific guidance on the use of medical devices for blood management.

The term 'bloodless surgery' does not mean that no blood is used, or that a blood transfusion is not given. Rather it refers to surgery performed without allogeneic blood (blood that is not the patient's own) and covers techniques for blood conservation and strategies for autologous blood transfusion (transfusion of the patient's own blood). A recent study that assessed blood transfusions in 741 patients reported that bloodless cardiac surgery is associated with a decrease in both morbidity and mortality and therefore advises limiting transfusions(5). Hospitals such as Englewood Hospital in the United States[9] have had a perfect record of no coronary artery bypass graft surgery mortalities following the introduction of bloodless surgery. The hospital performs a high proportion of complex patient cases and has an expected patient mortality rate of 2.26 percent. Nearly 80% of cardiac surgeries, including open heart surgery, are performed without blood transfusion.

An Australian study has compared operative mortality and early clinical outcomes in Jehovah's Witnesses undergoing bloodless cardiac surgery. Data were obtained from 5,353 patients, 49 of whom refused blood for religious reasons. The Jehovah's Witness group experienced significantly less bleeding (almost half compared to the control group). There were no differences in the operative mortality, intensive care or post operative length of stay between the two groups. The blood conservation protocol included the use of surgical technique to avoid bleeding and postoperative use of a cell-saver system(6).

6. The use of medical technology at each perioperative stage

There are a range of medical technologies that can be used in bloodless surgery or to minimise blood lost at each perioperative stage. Examples are provided below:

Preoperative Strategies

- Autologous donation (a patient donates their own blood prior to surgery)
- Control of anaesthetic and the depth of anaesthesia to control cardiac output and intravascular pressure.

Preoperative Devices

- Pediatric tubes for limited micro blood sampling in order to minimise the number and size of blood samples drawn for pre-surgical testing.

Intraoperative Strategies

- Use of minimally invasive surgical techniques for very small incisions
- Meticulous hemostasis, operative technique and surgical dissection
- Use of continuous blood parameter monitoring systems to provide continuous information on blood parameters

[9] http://www.englewoodhospital.com/ms_bloodless_home.asp.

- Use of local vasoconstrictors to decrease blood flow in localized regions
- Use of angiographic embolization to reduce blood supply in target regions
- Use of arterial embolization to occlude blood vessels
- Use of factors that stimulate features of the physiological process of wound closure.

Intraoperative Devices

- Mechanical occlusion of bleeding vessels using hemostatic clips, ligating clips, staples, sutures, tourniquets, modern wound care devices, surgical meshes, digital pressures and external bandages to cover bleeding tissue or to obstruct blood vessels either temporarily to decrease surgical site or to close vascular site access following catheterisation
- Use of biological haemostats and surgical sealants to enable meticulous haemostasis
- Use of endoscopic devices for minimally invasive procedures via very small incisions
- Local haemostats such as haemostatic matrices, solutions, patches, powder and sponges to cover a broad bleeding site and promote local coagulation by aiding platelet plug formation and/or fibrin clot formation
- Tissue adhesives or glues to seal off the incision/surgical wound to reduce bleeding, some tissue adhesives may contain ingredients such as fibrin to promote local coagulation to further promote hemostasis
- Use of modern surgical devices, such as haemostatic staplers which staple and cut tissues at the same time to reduce bleeding
- Use of medical devices for closure such as suture-mediated and clip-based vessel closure technologies designed to close vascular site access following catheterisation
- Electrocautery (thermal cautery)/electrosurgery which uses an electric current to heat a treatment instrument or probe and cauterises capillary vessels and small arteries minimising blood loss
- Laser surgery, laser energy is used to cut, vaporize, and simultaneously coagulate a targeted area without damaging nearby tissue. The technique increases coagulation by the promotion of clotting by localizing heat in bleeding vessels
- Microwave coagulating scalpels which concentrate a localized high-power microwave (electromagnetic) field that generates heat around the edge of a scalpel blade, microwave energy is absorbed in tissue and provides in-depth coagulation on vascular organs to reduce blood loss
- Argon-beam coagulators use a beam of ionized argon gas to conduct a high-frequency electric current to bleeding tissue with limited tissue contact and are used for hemostasis of surface and diffuse bleeding from internal tissue
- Harmonic scalpels use ultrasound to cut through tissue and seal blood vessels simultaneously, the scalpel ‘cuts’ through tissue and seals it using protein denaturisation by vibrating in the range of 20,000 Hz
- Technologies that deliver radiofrequency energy and saline to heat-induce tissue shrinkage and reduce bleeding
- Blood cell salvage and continuous autotransfusion systems to collect and process a patient’s own blood (see below).

Postoperative Devices

- Pediatric tubes for limited micro blood sampling in order to minimise the number and size of blood samples drawn for pre-surgical testing
- Blood cell salvage.

Additional to this, the guidelines do not appear to cover the use of pharmaceutical agents within the blood management process, for example blood-volume replacements such as crystalloids and colloids etc. All of the strategies and devices listed above are backed up by research. It is beyond the scope of this response to include all of the evidence-based

literature for each device. This literature should be sourced and included in the draft Perioperative module.

7. Blood cell salvage for blood conservation

Blood cell salvage techniques involve collecting blood during a surgical procedure, citrating it to prevent coagulation, filtering it, washing it with saline, concentrating it and returning it to the patient. Cell salvage can be used in a wide range of surgical procedures, including cardiac and orthopaedic operations. Processes that assist in salvaging the patient's own whole blood perioperatively are listed below (7-10):

- Cell processors and salvage devices that wash and save red blood cells: these devices collect anticoagulated shed or recovered blood, wash and separate the red blood cells by centrifugation and re-infuse the cells.
- Direct transfusion: this salvage method is associated with cardiopulmonary bypass circuits or other circuits used in surgery such as coronary artery bypass grafts, valve replacement, or surgical repair of vessels. Following bypass surgery the circuit contains a significant volume of diluted whole blood that can be harvested and re-infused.
- Ultrafiltration of whole blood: ultrafiltration devices filter anticoagulated whole blood and remove excess non-cellular plasma water, low molecular weight solutes, platelet inhibitors and some particulate matter through hemoconcentration, including waste substances, making concentrated whole blood available for reinfusion. Hemofilter devices return whole blood with all the blood elements and fractions including platelets, clotting factors, and plasma proteins.

8. Future directions

The draft Perioperative module asks for feedback on areas for future reference (page 61). In contrast to pharmaceuticals medical devices undergo rapid innovation. The draft needs to include within its guidelines mechanisms for the consideration of new innovative devices and technologies for blood management. Some of these types of technologies are listed below:

- Blood flow monitors which use ultrasound to measure blood flow from the heart and adjust the amount of blood to give during surgery
- A get produced from squid and shellfish that is placed into the sinuses after surgery to control nasal bleeding
- Smart suction systems to reduce blood loss during cardiovascular surgery
- Advanced bandages, dressings and gauzes that control severe bleeding using positively charged chitosan which attracts the outer membranes of red blood cells, which are negatively charged leading to localized clotting
- Dressings that make use of natural blood clotters such as kaolin clay
- Diagnostic tools that analyse hemostasis to determine the need for transfusion
- Advanced fibrin sealants containing blood clotting factors that are applied to wound surfaces to stop bleeding
- Specialised valves to seal interventional devices and minimise blood loss.

9. Conclusion

The need to avoid adverse events due to transfusion, coupled with an increase in blood needs, has led to an emphasis on blood conservation. Medical devices have been developed to assist in minimising salvaging the patient's own blood and are used frequently in cardiothoracic and vascular surgery. The increase in the demand for blood and the need to

avoid adverse events associated with transfusion, make it important to for the Perioperative module to include criteria for blood conservation that outline the types of medical devices that can assist in blood conservation and evidence-based guidelines for their use.

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