



Medical Technology
Association of Australia



*National Safety and Quality Health Service Standards
Australian Commission on Safety and Quality in
Healthcare Consultation Paper*

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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

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1. Executive Summary

This submission is in response to the *National Safety and Quality Health Service Standards* released by the Australian Commission on Safety and Quality in Healthcare (ACSQHC) in August 2010. The Medical Technology Association of Australia (MTAA) welcomes the opportunity to comment on the paper and make specific recommendations. As a general comment MTAA would like to see criteria included for blood conservation and alternatives to blood transfusion, and the use of modern wound care devices to treat pressure ulcers.

MTAA recommends:

- Including guidelines for blood conservation and alternatives to blood transfusion in the Blood and Blood Product Safety Standard
- The use of modern wound care devices to treat pressure ulcers in the community (with funding via an Essential Care List scheme) in the Prevention and Management of Pressure Ulcers Standard.

This submission makes specific response to the question posed on Page 2 of the Consultation Paper: *Are there gaps in the Standards that should be addressed?*

2. About the Medical Technology Association of Australia and the medical technology industry

The Medical Technology Association of Australia (MTAA) represents the manufacturers, exporters, importers and distributors of medical technology products in Australia. Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability. Products range from commonplace, everyday items such as bandages and syringes, to high technology items such as cochlear implants and cardiac defibrillators and diagnostic imaging equipment. The medical technology industry manufactures many products that contribute to the health of Australians. These include devices to manage cardiac disease, diabetes and chronic obstructive pulmonary disease, as well as a range of devices for blood cell salvage and conservation and sub-acute medical products, including modern wound care devices. The medical technology industry had sales in Australia of more than \$7 billion in 2008/2009 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.

3. Comments on the ACSQHC Consultation Paper

The discussion paper: *National Safety and Quality Health Service Standards* outlines five initial Standards:

- Governance for Safety and Quality in Health Service Organisations
- Healthcare-Associated Infection
- Medication Safety
- Patient Identification and Procedure Matching
- Clinical Handover.

MTAA made a detailed submission in response to the Healthcare-Associated Infection and Medication Safety Standards in January 2010. The ACSQHC has released five new draft Standards. These cover areas that impact high numbers of

patients, have known gaps between the current situation and best-practice outcomes and are associated with known, achievable evidence-based strategies on which to base improvement. The five new draft Standards are:

- Partnering for Consumer Engagement
- Blood and Blood Product Safety
- Prevention and Management of Pressure Ulcers
- Recognising and Responding to Clinical Deterioration in Acute Health Care
- Preventing Falls and Harm from Falls.

MTAA makes specific response to:

- Blood and Blood Product Safety
- Prevention and Management of Pressure Ulcers.

The Commission is seeking feedback in relation to the following questions:

1. *Is the language and format of the Standards appropriate?*
2. *Are there gaps in the Standards that should be addressed?*
3. *Is there duplication that should be removed from the Standards?*
4. *General comment in relation to any one or all of the Standards.*

The Commission will submit a package of reforms for accreditation including the Standards and their use to Health Ministers in November 2010. If approved, implementation will commence in July 2011.

4. Standard 7. Blood and Blood Product Safety (BBP) Standard

The intention of Standard 7 is to ensure the safety of patients who receive blood and blood products. The Standard will be applied in conjunction with the *Governance for Safety and Quality in Health Service Organisations* requirements and *Partnering for Consumer Engagement*.

The Standard will apply from the point of the clinical decision to prescribe blood or blood products, to the administration or disposal of the blood. The Standard covers both blood (homologous and autologous whole blood, platelets, fresh frozen plasma, blood including red blood cells, cryoprecipitate and cryo-depleted plasma) and blood products (plasma derivatives and recombinant products excluding medication products).

The discussion paper outlines the role of each participant in ensuring that the requirements of the Standard are met. Participants include patients and carers who are required to provide accurate medical history and raise issues that may impact compliance and the clinical workforce who are required to administer blood products safely and appropriately and understand their responsibilities for blood product management. The discussion paper refers to the risks associated with the use of blood and lists the factors influencing the use of blood and blood products. These include:

- Recognizing the risks associated with contaminated blood products
- Changes in treatment options
- Changing environments for administration, including the administration of blood and blood products from home
- Understanding the role of blood components (rather than whole blood)

- An increase in the number of surgical interventions requiring blood – including organ transplantation
- An increase in the number of options for treating trauma patients
- Improving risk management resulting from the analysis of incident data
- An increase in the costs associated with the use of blood and blood products (including collection and administration)
- Recognition of consumer choice
- Emphasis on agendas of patient safety and quality.

In specific response to the question: *Are there gaps in the Standards that should be addressed*, MTAA suggests that the Standards be expanded to include the use, where appropriate, of innovative medical technologies and surgical techniques to conserve blood and provide an alternative to transfusion. These have the capability to both decrease the demand for blood and decrease the risks associated with blood transfusion. The discussion paper does not mention the decrease in the number of blood donors in Australia and the increased need for blood that will occur with an ageing population who will require more blood for surgical procedures such as pacemaker implantation and joint replacement surgery. The increased demand for blood that will occur requires careful pre-planning and policy around blood conservation.

The discussion paper outlines four criteria for the Blood and Blood Products Standard:

1. Governance and systems for blood and blood product management (safe systems to minimise waste at all stages – storage, distribution and use)
2. Documentation of patient information (accurate record keeping, including transfusion history and indications for treatment)
3. Information for patients (including options and treatment risks)
4. Blood and blood product management (systems to obtain, prescribe, transport and administer blood appropriately, efficiently and safely).

The MTAA suggests that a fifth criterion be added which introduces guidelines for blood conservation and outlines alternatives to blood transfusion.

5. The need for Blood Conservation in Australia

Between 2007-2008 there were a total of 275,858 separations in Australia for transfusion of blood and gamma globulin (188,024 in the public system and 87,834 in the private system)¹. There are a limited number of blood donors in Australia. Only 3.3%² of the Australian population donates blood, whereas 33% of the population will require a blood transfusion over their lifespan³. Blood has a limited life span and blood components must be consistently replaced. Blood plasma has a lifespan of up to a year; however the life span of red blood cells is less than 42 days and the life span of blood platelets is less than 5 days. Additionally, donor and recipient blood types must be matched, which may be difficult for rarer blood types (e.g. AB-). Australia will face an increase in the need for blood and blood products that must be planned for. By 2050 the population of Australia will see the number of people aged

¹ 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.

² Australian Red Cross Blood Service. Percentage refers to the 2007/08 blood donor numbers as a proportion of the eligible Australian population.

³ Australian Red Cross Blood Service.

65-84 double and the number of people aged over 85 quadruple⁴. The dramatic increase in the number of elderly in the population 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). Australia will be challenged with increasing the number of donors to match the increase in demand for blood. This challenge emphasises the need for innovative strategies to conserve blood and decrease the number of blood transfusions.

An additional reason for adopting blood conservation strategies is that blood transfusions are not free of risks and side effects. While there has been a marked decrease in the risk of being infected with transmissible diseases such as Hepatitis B, Hepatitis C, AIDS/HIV over the last decades, infection control is still a challenge. While the risk of infection has decreased, the risk associated with human errors has not. These include misidentification of patients and samples, taking blood samples from incorrect patients and mis-transfusion of incompatible blood types.

Other risks include bacterial infection associated with transfusion, transfusion-associated suppression of the immune response and graft-versus-host transfusion reactions. A recent study that followed 3,842 cardiac surgery patients found that blood transfusions increased the risk of infection, renal failure and death. The study concluded that, in comparison to patients undergoing bloodless surgery, those undergoing blood transfusions had a dramatic increase in morbidity and mortality rates (Riddell et al., 2009). Given that 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 (Chelemer et al., 2002; Rogers et al., 2006), any efforts or devices that can minimize blood loss should be considered.

The cost of a blood transfusion is high, with costs including collection, preparation, storing, transporting and transfusion. Most of the costs associated with a blood transfusion are picked up by the hospital. Data from the US have shown that blood conservation programs can achieve large cost savings. Geisinger Medical Center began a blood conservation program in 2005 and reported a recorded savings of \$273,000 in its first six months of operation⁵. The Australian Red Cross Blood Service and two hospitals (Peter MacCallum Cancer Centre, Melbourne; Flinders Medical Centre, Adelaide) have partnered for a blood transfusion cost study. Mapping tools and analysis are being provided by Axel Hofmann of the Medical Society for Blood Management. Comprehensive cost information in the Australian setting has not previously been available. Preliminary results have found that the cost for transfusion of a single unit of red cells is approximately \$690 and the cost per patient transfused approximately \$2,300.

The discussion paper outlines findings by the Clinical Excellence Commission (CEC) which co-ordinates Blood Watch, a NSW transfusion medicine improvement program⁶. One of the priority focus areas is the appropriateness of blood component therapy. Recent audit data have found that:

- 12.7% of patients had surgery with low haemoglobin levels and the underlying cause of probable iron deficiency anaemia was not investigated or treated pre-operatively

⁴ Australia to 2050: future challenges. The Intergenerational Report 2010. Australian Government, January, 2010.

⁵ http://www.geisinger.org/services/blood_cons/

⁶ <http://www.cec.health.nsw.gov.au/programs/blood-watch.html>

- A high number of patients had a transfusion, without a clinical indication for transfusion being noted in their medical record
- The standard dose for patients was two units, despite expert advice suggesting that after being provided with one unit, a patient should be re-assessed prior to a second unit being given
- A high number of large rural and metropolitan hospitals are prescribing above the state average
- Those hospitals performing best had 'quality systems' in place, including the use of restrictive thresholds.

A report by the National Blood Authority (NBA) (2007)⁷ considers a range of demographic factors to have an impact, including demographic change and the rate of growth in the proportion of people aged 65 and over. The report highlights several areas for investigation, one of which includes considering blood saving technologies. NBA points to the increase in the growth of surgical procedures used to treat cardiovascular disease as a key indicator for increased demand. The report includes guidelines for the prioritization of red blood cell transfusions. 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 cell salvage.

From an international perspective the World Health Organization (WHO)⁸ outlines three pillars of blood management:

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

The above findings are all relevant to the Australian context and support the inclusion of blood conservation strategies in the Blood and Blood Product Safety Standard.

6. Medical Technologies for Blood Conservation and Bloodless Surgery

There are a number of surgical techniques and medical devices that can be used to conserve blood and decrease the need for a transfusion. There are no public health standards in Australia that specifically deal with blood conservation. MTAA recommends that the Blood and Blood Product Safety Standard include specific guidance on the use of surgical techniques and medical devices to decrease blood loss, artificial haemoglobins, synthetic oxygen-carrying solutions and red cell salvage techniques. 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). It also covers techniques for blood conservation and strategies for autologous blood transfusion (transfusion of the

⁷ National Blood Authority – Fresh blood products. Products Benchmarking and Demand Drivers. Final Report, December, 2007.

⁸ WHO Resolution. Availability, safety and quality of blood products. 126th Session EB126.R14. Agenda item 4.16, 22 January 2010.

patient's own blood). The aim of blood management is the appropriate use of blood via the adoption of a number of multidisciplinary strategies (e.g. optimizing blood volume, minimizing blood loss, optimizing tolerance to anaemia) to reduce or avoid blood transfusions. Additionally, blood substitutes may be used to carry oxygen (oxygen therapeutics) or fill fluid volume (volume expanders). The examples below show the different strategies for blood conservation that can be put in place preoperatively, intraoperatively and postoperatively.

Strategies for Blood Conservation⁹

1. Preoperative Strategies

- Minimizing the number and size of blood samples drawn for presurgical testing
- Increasing preoperative red blood cell (RBC) mass using erythropoietin (EPO) and iron. EPO stimulates peripheral stem cells in the bone marrow to produce an increased number of red blood cells and increase the blood's ability to carry oxygen
- Autologous donation (a patient donates their own blood prior to surgery)
- Acute Normovolemic Hemodilution, withdrawing whole blood pre or post anaesthesia and replacing it with crystalloid/colloid to maintain normal blood volume. The blood is stored at room temperature in the operating room for up to 4 hours and reinfused if necessary
- Control of anaesthetic and the depth of anaesthesia to control cardiac output and intravascular pressure
- Correction of preoperative anaemia complications.

2. Intraoperative

- Meticulous hemostasis, operative technique and surgical dissection
- Staging of procedures to enable hemoglobin levels to recover
- Use of minimally invasive surgery
- Reduction of blood flow to skin
- Use of controlled hypotensive anesthesia
- Maintenance of normothermia
- Acute normovolemic hemodilution,
- Blood cell salvage
- Elevation of surgical site
- Clamping and cauterizing open blood vessels as quickly as possible
- Use of haemostatic surgical devices (electrocautery, lasers, microwave scalpel, argon-beam coagulator)
- Use of local vasoconstrictors to decrease blood flow in localized regions
- Use of angiographic embolization to reduce blood supply in target regions
- Use of tourniquets and modern wound care devices, glues and sealants to block puncture wounds and cover larger areas of exposed bleeding tissue
- Pharmacologic prophylaxis of bleeding (use of drugs to control bleeding and promote clotting and coagulation)
- Oxygen therapeutics (RBC substitutes) and the use of blood substitutes to expand blood volume to prevent shock
- Suture ligation of vessels
- Controlled hypotension and intentional lowering of arterial blood pressure to reduce blood loss.

⁹ for further information see Goodnough et al., 2003; Towler, 2008, Waters, 2006

3. Postoperative

- Minimizing the number of blood draws and the quantity of blood drawn for testing, for example by using pediatric blood tubes for adult patients
- Treatment with EPO and iron
- Sedation and analgesia
- Positive pressure ventilation, muscle relaxation
- Controlled hypothermia
- Administration of medications to augment blood cell mass.

Examples of Medical Devices used for Blood Conservation

- Electrocautery (thermal cautery) (Geiger): an electric current is used to heat a treatment instrument or probe, which cauterizes capillary vessels and small arteries, minimizing blood loss
- Lasers: 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 scalpel: the device concentrates a localized high-power microwave (electromagnetic) field that generates heat around the edge of a scalpel blade. Microwave energy is absorbed in tissue and can provide in-depth coagulation during surgery on vascular organs
- Argon-beam coagulator: the device uses a beam of ionized argon gas to conduct a high-frequency electric current to bleeding tissue with limited tissue contact. It is used for hemostasis of surface and diffuse bleeding from internal tissue.

Specific Examples of Blood Cell Salvage used in Blood Conservation

The blood cell salvage technique involves 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. A range of procedures that assist in the salvaging of the patient's own whole blood perioperatively are listed below¹⁰:

- Cell processors and salvage devices that wash and save RBCs: These devices collect anticoagulated shed or recovered blood, wash and separate the RBCs by centrifugation and reinfuse the cells
- Direct transfusion: This salvage method is associated with cardiopulmonary bypass circuits or other circuits used in surgery, valve replacement, or surgical repair of vessels. Following bypass surgery the circuit contains a significant volume of diluted whole blood that can be harvested in transfer bags and re-infused into patients. Residual blood is fairly dilute and may contain contaminants
- 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 the patient's whole blood with all the blood elements and fractions including platelets, clotting factors, and plasma proteins. These devices do not totally remove potentially

¹⁰ for further information see Beckmann et al., 2007; Eichert et al., 2001; Freischlag, 2004; Sutton et al., 1993.

harmful contaminants; however, the effects of most are transient and reversible.

Hospitals such as Englewood Hospital in the United States¹¹ 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. The Englewood Hospital's Heart and Vascular Institute has a focus on blood conservation and avoidance of transfusions during surgery. Nearly 80% of cardiac surgeries at Englewood Hospital, including open heart surgery, aortic and valve cases and combined bypass and valve procedures, are performed without blood transfusion. 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 advises limiting transfusions (Whitson, 2010).

A recent Australian study 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 or intensive care or post operative length of stay between the two groups. The blood conservation protocol involved the use of surgical technique to avoid perioperative bleeding, intraoperative acute normovolaemic haemodilution, intraoperative administration of tranexamic acid, intra- and postoperative use of a cell-saver system, and post operative administration of folic acid, iron, and erythropoietin (Bhasker et al., 2010).

The increase in the demand for blood that will occur with an ageing population and the need to avoid adverse events associated with transfusion, make it important to for the Standard to include criteria for blood conservation. Medical devices have been developed to assist in salvaging the patient's own blood and can be used in cardiothoracic and vascular surgery. MTAAs suggests that criteria for use of these procedures and devices be included in the Blood and Blood Product Safety Standard.

7. Standard 8. Prevention and Management of Pressure Ulcers

The aim of Standard 8 is to prevent patients developing pressure ulcers and manage pressure ulcers when they occur in accordance with best practice guidelines. The Standard will be applied in conjunction with the *Governance for Safety and Quality in Health Service Organisations* requirements and *Partnering for Consumer Engagement* as specified in Standards 1 and 2.

Data from prevalence surveys conducted by Wounds West (Western Australia) show that the majority of pressure ulcers were acquired in a hospital setting and that pressure ulcers were the second largest group of wounds in public hospitals¹². In most cases pressure ulcers are preventable if all of the risk factors are included – e.g. skin integrity, mobility, age. The return on investment may be as high as 100:1 (Wakefield, 2009). The discussion paper acknowledges that patients who are managed in community-based or residential aged-care settings are at risk of pressure ulcers. A number of solutions to prevent and manage pressure ulcers are

¹¹ http://www.inglewoodhospital.com/ms_bloodless_home.asp.

¹² WA Health: Wounds West wound survey 2009: Key results at a glance.

available. There are a large number of specialist wound management products that can be used to treat pressure ulcers.

The discussion paper outlines specific roles in pressure ulcer prevention and management for patients and carers (compliance with ulcer prevention and treatment plans), clinical work force (implementation of prevention and management plans), and non-clinical workforce (to notify the clinical workforce where pressure ulcer injury is observed or when concerns exist).

The discussion paper outlines four criteria for the Prevention and Management of Pressure Ulcers Standard:

1. Governance and systems for the prevention and management of pressure ulcers (ensuring governance structures are place for prevention and management)
2. Screening for existing pressure ulcers
3. Prevention of pressure ulcers (screening for risk factors, developing prevention strategies)
4. Information for patients (risks, prevention strategies, management)

In specific response to the question: *Are there gaps in the Standards that should be addressed*, MTAA suggests that the criteria address the need for patients to have access to innovative wound care technology to treat pressure ulcers in the community setting. MTAA has developed a list of sub-acute medical consumables, known as the Essential Care List (ECL). The aim of the ECL is to enable subsidised access to essential care medical technologies that provide necessities to chronically ill or incapacitated patients in the community setting. The items intended for inclusion in the scheme are consumable, single use, non-implantable medical products, together with the hardware that the consumables are used with, essential to maintain an acceptable quality of life for afflicted patients who without government subsidy would not have adequate access to life supporting medical technology. Relevant to this submission is funding for modern wound care devices (MWCDs) to treat ulcers.

There is inconsistent funding across Australia for MWCD. While most states do not fund MWCD some do, but to a limited extent (in South Australia and Western Australia dressings are provided to a limited degree by home nursing services). Other products have varying levels of funding or subsidy. Where a product is not funded, patient access is limited to those with the capacity to pay, or at times, through the good graces of treating healthcare professionals. At the community level there is some funding provided by the Department of Veterans Affairs. In the 2009 Federal Budget the Government made a small but significant contribution to assist patients suffering from Epidermolysis Bullosa with a national dressing scheme worth \$16.4 million over four years from January 2010.

In the current scheme of reimbursement, a practice nurse is likely to be a major provider of wound care. In General Practitioner (GP) practices, a GP might charge the bulk-billing fee, the practice nurse may provide the wound care at a reimbursement of \$10, and the wound care product used would almost certainly be the lowest cost (mostly gauze) product because the GP picks up this cost. Thus the wound may take 2-3 months to heal, versus the 2-3 weeks with a MWCD (Gross, 2006).

The majority of Australians with pressure ulcers are probably most appropriately treated in the home care setting (with community nurses) or in the GP's office.

Current reimbursement systems do not provide for patients with chronic wounds or ulcers to be treated in the community setting without the burden of product costs falling heavily on the patient. Many with pressure ulcers are elderly with fixed incomes. In the case of wound care products patients must pay irrespective of their financial circumstances, thus becoming the 'informal funders' of their own care.

The current lack of systems for funding MWCDs in the community frequently drives patients into the hospital environment, shifting costs from Commonwealth to State Governments or from home care to nursing care. Elderly patients are likely to have co-morbidities and be more vulnerable to the complications associated with pressure ulcers and to the risks attendant in hospital treatment (e.g., infections). For many elderly people a hospital admission can be the catalyst for the loss of independence.

Modern wound care products deliver improved health outcomes and are usually less resource-intensive than traditional wound care, making them cost-effective. An Australian study by Gross and Graves (2006) found that patients with ulcers have significant gains in quality of life using the modern MWCDs compared with patients treated with standard gauze. International research has found that:

- MWCDs were associated with 28% higher probability of healing and a 0.02 QALY difference (Eglesias et al., 2004)
- A 2000 study compared Human skin graft (Apligraf) plus compression bandage to a standard Unna's Boot plus low compression bandage for hard to treat ulcers. They report overall healing rates of: Apligraf: 48% vs Standard: 25%. The mean difference in ulcer free period was Apligraf: 4.6 months versus standard: 1.8 months (Schonfeld et al., 2000)
- Wound vacuum dressing systems have been shown to lead to complete healing of complex wounds in 16 days, in comparison to conventional saline soaked gauze dressings which led to complete healing in 25 days (Perez et al., 2010)
- A randomized controlled trial in which 60 hospitalized patients with chronic leg ulcers were randomly assigned to treatment with a vacuum-assisted closure (VAC) device or conventional wound care techniques, found that the MWCD healed the ulcer 16 days faster. Furthermore, wound bed preparation during VAC therapy was also significantly shorter and the cost cheaper (Vuerstaek, 2006).

MTAA suggests that Prevention and Management of Pressure Ulcers Standard address the need for elderly patients to have timely, equitable access to modern wound care devices to treat pressure ulcers.

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