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(Inquiry into Obesity)
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KCI
The Clinical Advantage

KCI Medical Australia Pty Ltd.
Level 7
15 Orion Road
Lane Cove West NSW 2066
Australia

Tel +61 (0)2 9422 4322
Fax +61 (0)2 9422 4344
www.kci-medical.com

Executive Summary – Submitted by KCI Medical Australia Pty Ltd.

The prevalence of obesity is on the rise, both globally and in Australia. By 2025 it is estimated that 1 in 3 Australian adults will be obese. It is well documented through numerous clinical studies that obesity has a significant negative impact on many crippling disease such as diabetes, cardiovascular disease, a variety of cancers and osteoarthritis.

Significant complications for obese adults also occur in wound healing. The 2004-05 Australian Institute of Health and Welfare data reported 54.3 % of the 126,800 hospital admissions related to disease of skin or subcutaneous tissue occurred in individuals who were overweight or obese. In obese patients the wound healing process is often severely compromised. Obese patients are at risk of developing an acute wound post surgery (surgical site dehiscence) and also bear a higher risk of developing chronic wounds. In addition the capacity of an obese person to heal can be significantly impaired.

V.A.C.® Therapy System is a clinically proven therapy in advanced wound care to help promote wound healing while helping to decrease length of stay and incidence of complications. To date more than 2.8 million people have been successfully treated with VAC therapy worldwide. There have been over 550 published articles on V.A.C.® Therapy involving more than 6,400 patients. Whilst V.A.C.® Therapy System is funded in the USA through Medicare Part B and currently exists in Germany within a government funded pilot program, at this stage, there is no established funding pathway available for Australian patients through our own systems. There is currently however access for DVA Goldcard Holders and those persons with Private Insurance when agreed criteria are met.

The economic benefits of approving a pathway for the health care system are significant and include: reduced hospital admissions and length of stay post surgery reducing the significant burden of complex wound management on the Australian Health care system (please refer to the appendix for further evidence)

In line with the recommendations put forward by the HOR Standing Committee on Health and Ageing "End the Blame Game" report on the Inquiry into Health Funding, 2006, KCI Medical Australia recommends that:

- ✓ **Consideration be given to the simplification of the current funding arrangements** so that Australians with complex chronic wounds could have access in real time to effective wound healing therapies. The arrangement could be an expansion of the current DVA Goldcard RAP Schedule.

KCI Medical Australia further recommends that:

- ✓ **Consideration be given to the adoption of new funding mechanisms to allow equity of access** to technology which improves the health status for the individual while demonstrating savings to the health system in the form of either reduced admission periods or prevention of admission.

- ✓ **A solution is found that addresses the woundcare needs of the obese population** within the current renegotiation of the Australian Health care Agreements and COAG Health Reform.

- ✓ **That advanced wound therapies with level 1 clinical evidence** and demonstrated effectiveness in treating complex wounds be funded regardless of health treatment environment i.e hospital or community setting.

- ✓ **Establish an equipment and technology funding pathway** to allow hospitals and care providers to invest in equipment that will optimise the health status and treatment outcomes of this patient group.

Background : KCI Medical Australia Pty Ltd.

KCI Medical Australia Pty Ltd is part of a global medical technology company with leadership positions in advanced wound care and therapeutic surfaces. We design, manufacture, market and service a wide range of proprietary products which can help significantly improve clinical outcomes while helping to reduce the overall cost of patient care.

KCI Medical's heritage has been to focus on helping to treat patients and to prevent complications related to patient immobility. In 1995, KCI launched its largest innovation yet, the V.A.C.® Therapy System, which has been clinically proven to help promote wound healing while helping to decrease length of stay and incidence of complications. This advanced technology was introduced to Australia in 1997. To date over 2.8 million people worldwide have been successfully treated with V.A.C.® Therapy. There have been over 550 published articles on V.A.C.® Therapy involving more than 6,400 patients, addressing clinical, economic and quality of life benefits. KCI Medical Australia anticipates we will support in excess of 140,000 V.A.C.® Therapy days during 2008.

KCI Medical will describe the basic principles of wound healing and then explain why this process is complicated in the obese. Further we will provide the Committee with some examples of the difficult situations obese patients find themselves in and why resolution of such difficult wounds is compromised by structural deficiencies within the current health funding system. KCI believes that if the Government addressed the appropriate level of funding for wound care in the obese population and the general community the following benefits would accrue:-

- Reduced GP visits, attendances at clinics or community nurse visits
- Reduced need for long term involvement of Medical Specialists
- Reduced hospital admissions and bed days
- Reduced need for amputations,
- Reduced need for complex reconstructive surgeries
- Improved quality of life
- Faster return to normal function and productivity

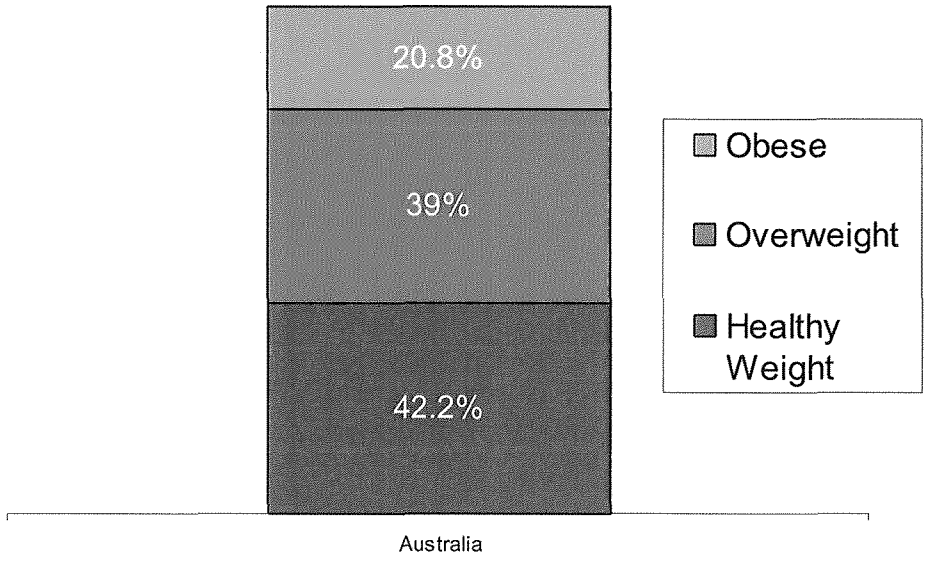
KCI Medical believes that all of these benefits:- financial, health outcome, resource utilisation and lifestyle, would far exceed any additional expenditures necessary to address the problem of complex wounds in the obese.

Complications of Obesity.

KCI Medical has noticed that obesity is an increasingly common factor of the complex acute and chronic wounds that we treat. Within the realm of health there is clinical evidence on the negative impacts obesity has in the areas of diabetes, cardiovascular disease, a variety of cancers and osteoarthritis. However KCI Medical Australia Pty. Ltd would like to draw to the Committee's attention another area where obesity has a major negative influence which has wide reaching implication for individuals, state and federal governments and the resources that we as a community share. This is the area of Wound care. The 2004-05 Australia Institute of Health and Welfare data reported 54.3 % of the 126,800 hospital admissions related to disease of skin or subcutaneous tissue occurred in individuals who were overweight or obese.

Exhibit 1: Prevalence of Obesity in the Australia Community, 2008.

BMI Classifications within the Australian Population 2008



International Obesity Taskforce, July 2008 – London

The International Obesity Taskforce estimates that by 2025, 1 in 3 adults in Australia will be obese

Please note BMI Definitions for Adults

For adults, overweight and obesity ranges are determined by using weight and height to calculate a number called the "body mass index" (BMI). BMI is used because, for most people, it correlates with their amount of body fat.

- *An adult who has a BMI between 25 and 29.9 is considered overweight.*
- *An adult who has a BMI of 30 or higher is considered obese.*

http://www.cdc.gov/nccdphp/dnpa/obesity/defining.htm

Complex Wounds in Australia

One of the aims of wound healing is to restore the protective function of the skin by repairing the area of damage. This happens through a cascade of events which occur in a linear fashion. The wound healing process involves a series of cellular and biochemical events that ultimately lead to tissue repair and regeneration[1]. It is important to keep in mind that a person must have "capacity to heal" otherwise wound healing cannot progress. Systemic factors that impair a person's capacity to heal include:-Obesity, ageing, smoking, diabetes, malnutrition immunosuppressive and malignant disease states[2]. *More details on wound healing is available in the Appendices.*

Unfortunately, there is no national prevalence or incidence data that reflects the true incidence of wounds in Australia and consequently any subset data that relates to wounds in the obese is not available. However, KCI Medical has begun collecting data on factors that impair wound healing and obesity is recognised along with diabetes and smoking as the most frequently encountered co-morbidities in severe wounds.

Why is wound healing further complicated in the obese?

Obesity is associated with a number of effects on skin physiology:-

- Increased sweat gland activity can lead to over moistening of the skin. This can cause maceration and a further breakdown of the skin surrounding a wound.
- Friction and shear can cause alterations to the integrity of the skin where skin folds are present and two surfaces are in constant contact.
- Increased sweat gland activity can lead to an alteration in skin pH. Normal skin pH is designed to prevent the build up of foreign microorganisms surviving and causing skin irritations or infections.
- Healing requires a constant supply of oxygen for the creation of new tissue and new blood vessels. Reduced lymphatic flow, tissue oxygenation and blood flow can

[1] Traversa B, Sussman G (2001) The role of growth factors, cytokines and proteases in wound management. *Primary Intention* Vol 9. No 4. November 2001

[2] Grey, J.E., Stuart, E., Harding, K.G., 2006: "ABC of Wound Healing" Blackwell. UK.

reduce oxygen reaching the wound site, and can prevent waste materials being removed. A necessary process for wound healing.

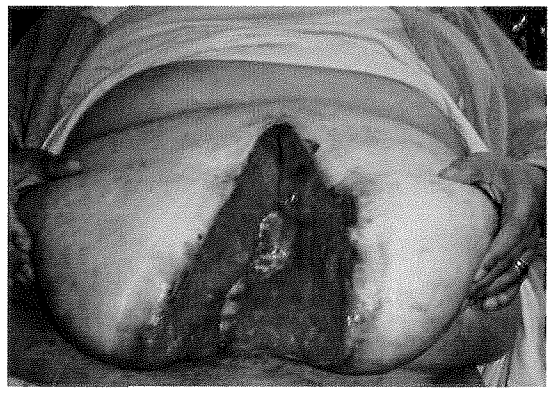
- An animal study (mice) identified that skin of obese mice may be found to be mechanically weaker compared with the skin of lean mice.
- Subcutaneous fat has less vascularity than muscle. The greater the depth of subcutaneous fat, the less vascularity there is.
- Obese patients are at high risk of developing Type 2 Diabetes. The difference in diabetic wound healing is defined as being complex[3].

In 2006-07 there were almost 2.1 million surgical procedures undertaken in Australian Hospitals, 908,000 within the public hospital system[4]. Abdominal surgeries alone including laparoscopic banding, cholecystectomy, hysterectomy and hernia operation accounted for 50,000 procedures last year. KCI Medical's experiences with even this small subset of surgical procedures undertaken reveal an immense cost to both the individual and the health system.

Audit data collected by KCI Medical Australia reveals an increasing incidence of patients with surgical site infections. KCI's current internal case files reveal a 38% incidence of obesity for surgically dehisced wounds. According to the 2004 British Medical Journal, "patients with surgical site infections or dehiscence stay in hospital on average about twice as long as uninfected patients and the total cost of care is more than doubled.

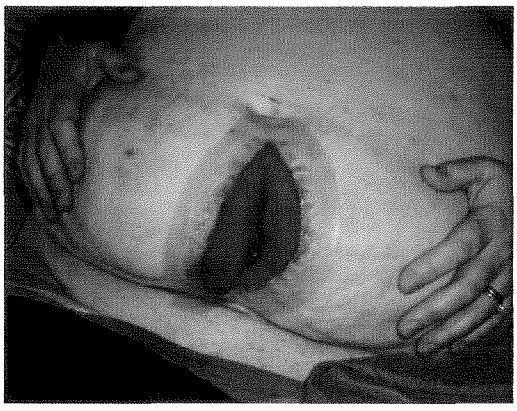
Exhibit 2: Case Example: Surgical Dehiscence Post Abdominal Surgery

This is an example of a surgical dehiscence post abdominal surgery for a malignant condition. This obese, diabetic, female patient was faced with months in hospital to address this large and complex wound. KCI Medical accepted this patient onto a trial we were undertaking and actually transferred her to her home environment where V.A.C.® Therapy was applied for 100 days. Her capacity to heal was severely compromised due to her complex co morbidities



[3] Sarsam S, Elliot J, Garrett K (2005) Management of Wound Complications From Caesarian Delivery *Obstetrical and Gynecological Survey* Vol 60 (7) July 2005 pp 462 - 473

[4] State of Our Hospitals Report June 2008. Australian Government Dept of Health and Ageing



Her treatment was successful and she achieved complete healing of her wound despite her health status. Once her wound was healed she was able to commence cancer treatment for her underlying condition.

In this case the hospital was relieved of a costly long term patient and the patient's quality of life was enhanced through faster healing and the opportunity to recover at home.

Why acute / surgical wounds occur in the obese?

Obese patients are at greater risk of developing an acute wound post-surgery. Some of the following considerations may apply:

- Yeast infections are a very common problem among the obese and often lead to maceration and moisture to build up.
- Friction and maceration play a role in enhancing the risk of the infection presenting itself.
- Obese patients have many folds in their skin that can give rise to both of these risk factors.
- Obese patients are at risk of seroma development*
- High glucose levels have been associated with surgical site infection rates in the immediate post operative period of obese patients.
- Obese patients are at a high risk of developing Type 2 diabetes[5].

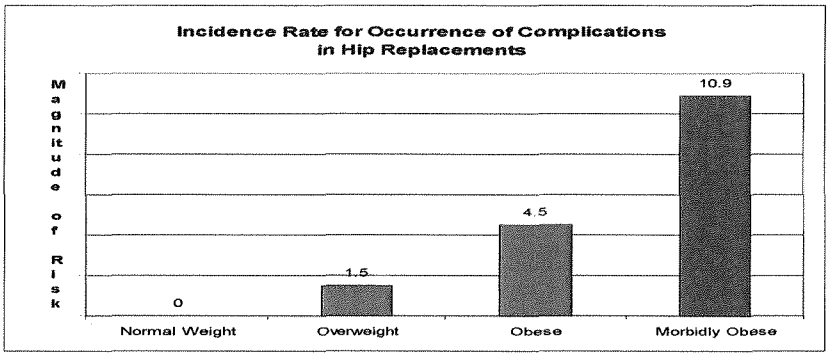
*Seroma - A mass or swelling caused by the localized accumulation of serum within a tissue or organ http://medical-dictionary.thefreedictionary.com

Recent studies from the researchers at Geneva University Hospital reveal a strong correlation between obesity and high rates of adverse events. The researchers documented the occurrence of one or more adverse events within 5 years after the first revision Total Hip Arthroplasty (THA)[6].

[5]. Sarsam S, Elliot J, Garrett K (2005) Management of Wound Complications From Caesarian Delivery *Obstetrical and Gynecological Survey* Vol 60 (7) July 2005 pp 462 - 473

[6] Lubbeke, A., et al. 2008:Outcomes of Obese and Nonobese Patients Undergoing Revision Total Hip Arthroplasty., Arthritis & Rheumatism (Arthritis Care & Research) , May 15, 2008; 59:5, pp. 738-745.

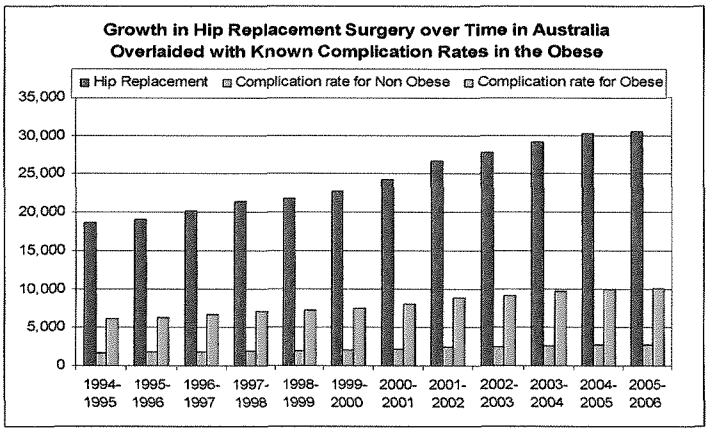
Exhibit 3: Surgical Complications Rates for the Obese Far Exceed the Non-Obese[6].



The incidence rate for occurrence of one or more adverse events rose with rising BMI. This increase was small between normal and overweight patients—1.5 times higher. Yet, it became significantly greater in the group with a BMI between 30 and 34.9—4.5 times higher than normal weight patients. And it escalated to an alarmingly increase in the group with a BMI of 35 or more—10.9 times higher. In these calculations, adjustments were performed for age, sex, and preoperative health status.

Overall, 20 complications occurred in 17 (33 percent) of the 52 obese patients, compared with 18 events in 13 (9 percent) of the 152 non-obese patients. In terms of specific complications, the incident rate was 4 times higher for surgical site infection[7].

Exhibit 4: International Data to the Growing Incidence of Complication Rates for THA .



Australian National Joint Replacement Registry Annual Report 2007, and Lubbeke, A., et al. 2008:Outcomes of Obese and Nonobese Patients Undergoing Revision Total Hip Arthroplasty., Arthritis & Rheumatism (Arthritis Care & Research) , May 15, 2008; 59:5, pp. 738-745.

[7] Lubbeke, A., et al. 2008:Outcomes of Obese and Nonobese Patients Undergoing Revision Total Hip Arthroplasty., Arthritis & Rheumatism (Arthritis Care & Research) , May 15, 2008; 59:5, pp. 738-745.

V.A.C.® Therapy has a substantial role to play in the management of surgical wounds, specifically in the management of infection, improved healing of wounds and delayed primary closure. In addition V.A.C.® Therapy enables an increased range of management options to be considered including the transfer of patients to lower cost settings.

Chronic Wounds in Australia

The current government estimates over 270,000 Australians suffer with a chronic wound each year. KCI's own market research suggests there are 200,000 Australians suffering from the three most common chronic wound types.

Of the many wounds in the community we estimate approximately 30,000 of those are of sufficient severity that they require admission to hospital for wound treatment since there are limited reimbursement avenues within the community setting. Unfortunately overweight and obese individuals are over-represented within this population.

Exhibit 5: Prevalence of Chronic Wounds in Australia, 2007.

	Total Chronic Wounds	Number Sufficiently Severe to Require V.A.C.® Therapy
Pressure Ulcers	113,287	12,949
Diabetic Ulcers	49,594	14,878
Vascular Ulcers	28,496	5,528

KCI Medical Australia Internal Research, 2007

Why chronic wounds occur in the obese

Obese patients are at greater risk of developing a chronic wound: Some of the following considerations may apply:

- The cardiovascular system is often under increased stress due to the extra activity that is needed to pump oxygenated blood to the extremities.
- Lymphoedema results from impedance of lymphatic flow. This can lead to decreased oxygen tension and macrophage function leading to fibrosis and a chronic inflammatory state.
- This gives rise to reduced tissue oxygenation in the lower limbs
- Chronic venous insufficiency can also reduce oxygen levels reaching the wound site, and prevent waste materials being removed
- This can lead to an imbalance in the chemical activity of the wound bed altering the sequence of events which promote wound healing.

- Obese patients are at high risk of developing Type 2 Diabetes. The difference in diabetic wound healing is defined as being complex[8].

In addition, some of the factors previously mentioned may also affect whether a wound has the potential to become chronic including; alteration in pH, repeated friction and shear, poor oxygenation and maceration (both increasing the risk of infection) and the aforementioned risk of developing diabetes.

Exhibit 6: An Example of a Leg Ulcer Encountered in Overweight or Obese Patients.

Leg ulcers can be particularly painful wounds and occur frequently in patients that are obese or overweight. Other factors such as vascular insufficiency, diabetes and smoking further contribute to the problem.

Photograph courtesy of:
WoundHeal Australia Pty Ltd

Implications of Obesity for Hospitals and Health Workers

Experts agree that Healthcare Systems including Australia's are going to be overwhelmed by weight-related hospitalisations from knee replacements through to heart attacks and strokes[9]. In the USA, the calculable health care costs of the obese are in excess of $117 billion annually[10].

A growing area of the health expenditure for the obese that KCI draws to the attention of the Committee is the increasing equipment costs and the need to decrease the risk of injury to both the patient and the caregiver when managing the larger patient. Large patients are difficult to turn and position, suffer issues with immobility, pain and oedema and are at significantly higher risk of developing pressure ulcers. The initial financial outlay needed to adequately equip facilities to meet the particular needs of bariatric patients and the staff who provide their care can be significant[11].

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[8] Sarsam S, Elliot J, Garrett K (2005) Management of Wound Complications From Cesarian Delivery *Obstetrical and Gynecological Survey* Vol 60 (7) July 2005 pp 462 - 473

[9] Stewart S, Tikellis G, Carrington C, Walker K, O'Dea K. *Australia's future 'Fat Bomb':* A report on the long-term consequences of Australia's expanding waistline on cardiovascular disease. April 2008, BHRI, Melbourne, Australia

[10] Buchwald, H. Bariatric Surgery for Morbid Obesity: Health Implications for Patients, Health Professionals, and Third-Party Payers – Consensus Statement. 2004

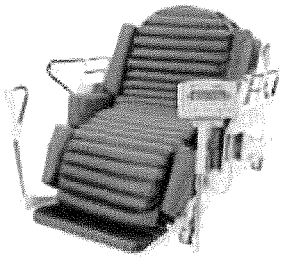
[11] NSW Health Guidelines for the Management of Occupational Health and Safety (OHS) Issues Associated with the Management of Bariatric (Severely Obese) Patients August 2005/

Considerations that need to be addressed include:-

- Hospital corridors and door frames need to be wide enough for wheel chairs and equipment specific to bariatric patients
- Operating Theatre tables with maximum weight limits beyond 350kg
- Ground floor locations should be preferred
- Patients require to have fresh air and sunlight (Vitamin D) particularly during an extended admission
- Moving walkways between departments for those who need to be pushed from one department to another and for those who can't make the distance.
- Rooms need to be large enough to accommodate bariatric equipment which would likely include:-

-BariAir Profiling bed with Air comfort mattress	380kg
-Mobile Electric Liko Hoist	300kg
-Scales for Hoist	200kg
-Wheelchair scales	500kg
-Electronic bed/trolley scales	300kg
-Wheelchairs	318kg
-Walking Frames	298kg
-Commodes	300kg
-Static chairs	318kg

Exhibit 8: KCI's Combined Risk Management Bed and Therapy System for the Care of the Obese Patient.



The patient can be weighed, washed, x- rayed, and transported whilst lying on the BariAir Risk Management Bed.

Additionally the bed can used to position the patient while they are still in it to become either a chair or a lifting device to allow the patient to stand without causing injury to either the patient or the staff involved in the patient's care.

This Therapy System addresses the specific needs of a Bariatric patient and the health workers caring for them:-

- Pulsating Air Suspension Therapy^{SM} aids in the prevention and treatment of pressure ulcers.
- Pressure Relief Therapy helps prevent skin breakdown.
- Expandable bed width adapts to different patient sizes, resulting in improved comfort, safety and dignified care.
- Cardiac chair improves ease of patient positioning and reduces risk to nursing staff.
- Percussion assists in mobilizing pulmonary secretions.
- Continuous turning up to 20° aids in patient positioning, promote comfort and shift pressure points.
- Battery backup provides two hours of uninterrupted operation during transport and power outages.
- The unique GORE-TEX® fabric sheet offers superior moisture vapor permeability while serving as an effective barrier to liquid and bacteria and provides an excellent microclimate for patients skin

Summary

KCI Medical's propriety product V.A.C.® Therapy has a significant role to play in addressing acute, complex and chronic wounds – particularly those in the obese as its mechanisms of action work to overcome the individual's own impaired capacity to heal. The adoption of the technology is increasing within the hospital systems, public and private, despite the fact that a large segment of the community is denied access to the technology due either to hospital funding constraints or the unavailability of a reimbursement pathway when the patient is not in hospital. The effectiveness of the technology has been demonstrated in the community setting as evidenced by Exhibit 2. However in usual circumstances, only DVA Goldcard holders and some third-party payers or privately insured patients are able to access the technology in the community – the current situation is neither equitable nor just.

KCI Medical's BariAir Therapy System and other bariatric equipment have been meeting international demand to effectively care for the obese patient in hospital and community settings. To date however, the Australian Health System has been slow to adopt these systems and products, due primarily to lack of funding.

KCI believes the Committee is in an ideal position to promote the need to set aside specific funds to reimburse health expenditures directly related to the management of quality outcomes for the obese. A funding pathway that addresses the management of both acute and chronic wounds and a reimbursement process whereby hospitals and care facilities could access equipment to 1) care for the obese; and 2) protect care providers; would be significant steps forward that would positively impact on the quality of life for this population group while offsetting the current health system expenditures that result from the increased incidence of GP visits, attendances at clinics or community nurse visits, the long term involvement of Medical Specialists, the requirement for extended hospital admissions, amputations and complex reconstructive surgeries.

With support from Government, KCI Medical would like to deliver improved quality of life and faster return to normal function and productivity to this growing population group while offering faster, effective and cost-efficiencies to the health care system.

Recommendations

In line with the recommendations put forward by the HOR Standing Committee on Health and Ageing "End the Blame Game" report on the Inquiry into Health Funding, 2006, KCI Medical Australia would recommend that:

- ✓ **Consideration be given to the simplification of the current funding arrangements** so that Australians with complex chronic wounds could have access in real time to effective wound healing therapies. The arrangement could be an expansion of the current DVA Goldcard RAP Schedule.
- ✓ **Consideration be given to the adoption of new funding mechanisms to allow equity of access** to technology which improves the health status for the individual while demonstrating savings to the health system in the form of either reduced admission periods or prevention of admission.
- ✓ **A solution is found that addresses the woundcare needs of the obese population** within the current renegotiation of the Australian Health care Agreements and COAG Health Reform.
- ✓ **That advanced wound therapies with level 1 clinical evidence** and demonstrated effectiveness in treating complex wounds in the overweight and obese be funded regardless of health treatment environment i.e hospital or community setting.
- ✓ **Establish an equipment and technology funding pathway** to allow hospitals and care providers to invest in equipment that will optimise the health status and treatment outcomes of this patient group.

Prepared by:

Mr. Peter Hickey
Managing Director
KCI Medical Australia Pty Ltd
Phone 02 9422 4310
Email: phickey@kci-medical.com

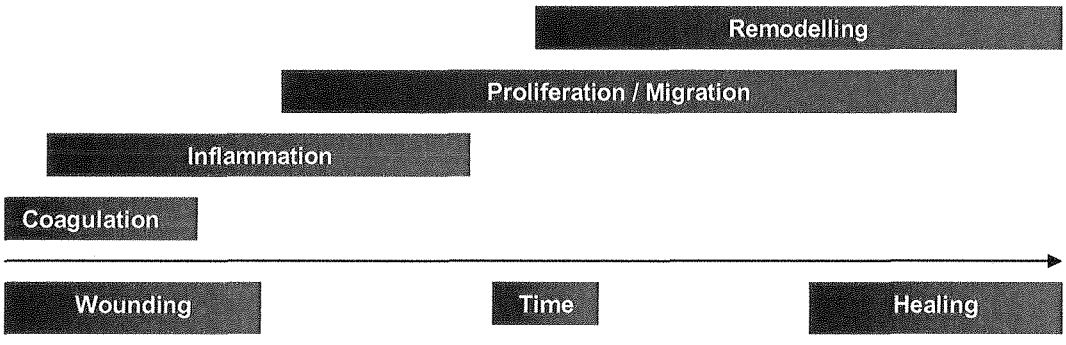
Ms. Cathy-Lyn Burnard
Reimbursement Business Development
KCI Medical Australia Pty Ltd
Mobile 0438 67 4542
Email: cburnard@kci-medical.com

Appendices: Normal pattern of wound healing

One of the primary functions of the skin is protection. This comes in many forms –providing a physical barrier, waterproofing, providing bacterial defense and absorbing light. It is also often quoted as being the largest organ in the body.

One of the aims of wound healing is to restore the protective function of the skin by repairing the area of damage. This happens through a cascade of events which occur in a linear fashion. The time this takes depends on a number of factors, including but not limited to, location of the wound, volume of tissue loss and co-morbidities of the patient - of which obesity is included. As described by Traversa and Sussman (2001), the wound healing process involves a series of cellular and biochemical events that ultimately lead to tissue repair and regeneration.

Carville K, (2005) further describes wound healing as 'a complex sequence of events' and in the following diagram this sequence of events has been further broken down into four distinct stages: Coagulation, Inflammation, Proliferation/ Migration and Remodelling.



The above cascade of events occurs in sequence to enable acute wound healing to occur. If this process is altered or there is an imbalance in the microscopic, chemical activity occurring within the wound bed – then healing has the potential to stall and a wound can be described as being 'chronic'. Hughes (2002) recognises this and suggests that 'Impaired healing occurs when syntheses and processes do not switch on or off at appropriate times and a failure of signalling or regulatory factors at any stage can lead to impaired healing.'

This leads us to the conclusion that the wound healing physiology can be incredibly complex. Hughes (2002) and Timmons (2006) acknowledge this and suggest that wound healing science has a very wide scope requiring investigation at the macroscopic, tissue and microscopic, cellular level.

References

Carville K. (2005) *Wound Care Manual* (5th Ed) Silver Chain Nursing Association Western Australia

Enser M and Avery N (1984) Mechanical and chemical properties of the skin and its collagen from lean and obese hyperglycaemic (ob/ob) mice. Diabetologica Vol 27 pgs 44-49

Hughes M A (2002) The Science of Wound Healing. The European Wound Healing Course Handbook. Positif Press, Oxford.

http://medical-dictionary.thefreedictionary.com
www.medscape.com/viewarticle/564201_6)
http://www.cdc.gov/nccdphp/dnpa/obesity/defining.htm

Sarsam S, Elliot J, Garrett K (2005) Management of Wound Complications From Cesarian Delivery *Obstetrical and Gynecological Survey* Vol 60 (7) July 2005 pp 462 - 473

Shermak M, Rotellini- Coltvet L Chang D (2008) Seroma Development following Body Contouring Surgery for Massive Weight Loss: Patient Risk Factors and Treatment Strategies *Plastic and Reconstructive Surgery* vol 122 (1) July 2008 pp 280-288

Timmons J (2006) Skin function and wound healing physiology. Wounds Essentials 1: 8-17.

Traversa B, Sussman G (2001) The role of growth factors, cytokines and proteases in wound management. *Primary Intention* Vol 9. No 4. November 2001

Yosipovitch G, DeVore A, Dawn A (2007) Obesity and the skin: Skin physiology and skin manifestations of obesity. *Journal of American Academy of Dermatology* Vol 56 No 6 June 2007

Zerr K, Furnay A, et al (1997) Clucos Control lowers the risk of wound infections in diabetic after open heart operations. Annals of Thoracic Surgery. 1997 Vol 63, 356 - 361