

**Faculty of Health Sciences**  
**School of Nursing, Midwifery and Paramedicine**

**Determining Risk Factors for Surgical Wound Dehiscence: Development  
and Internal Validation of a Risk Assessment Tool**

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**This thesis is presented for the Degree of**

**Doctor of Philosophy**

**of**

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## Declaration

To the best of my knowledge and belief this thesis contains no material previously published by any other person except where due acknowledgement has been made.

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university.

Kylie Sandy-Hodgetts

A handwritten signature in black ink, appearing to read 'KSH', written in a cursive style.

Signature:

Date: Tuesday 22<sup>nd</sup> May 2018

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## Abstract

**Background:** The worldwide volume of surgery today is considerable and postoperative wound healing plays a significant part in facilitating a patient's recovery and rehabilitation. Whilst contemporary surgical procedures are relatively safe, complications such as surgical wound dehiscence (SWD) or breakdown of the incision site may occur despite advances in surgical techniques, infection control practices and wound care. Surgical wound dehiscence following any surgical procedure impacts on patient mortality and morbidity and significantly contributes to prolonged hospital stays and associated psychosocial stressors on individuals and their families. The impact of the cost burden for individuals and health providers is a further consideration. Risk factors associated with SWD include patient and non-patient related factors all of which may play a role in contributing to the occurrence of SWD, either independently or in combination across the patient's surgical journey. Whilst anecdotal accounts of this conundrum abound amongst the surgical and nursing fraternity, there is limited research about the influence of these factors in relation to SWD and how identification might be utilised in influencing clinical practice.

**Aims:** The principal aims of this study were to determine risk factors associated with SWD, develop a preoperative risk assessment tool for identification of patients at risk of surgical wound dehiscence, and test the tool in a clinical setting. Further to these aims was to test the tool for internal validity, predictive power and inter-rater reliability.

**Methodology:** The study consisted of two retrospective case control studies and one prospective case series validation. All three studies were reviewed and received Human Research Ethics Committee approval.

The first retrospective case control study was conducted to derive variables associated with SWD and to inform the development of a risk assessment tool. The sample was based upon a proportion of the surgical population 2010-2011 from Perth, Western Australia, who were receiving community nursing treatment for a SWD after discharge from the acute care setting. The control group was drawn from the acute care setting in matching each case with a control based on date and type of procedure.

The second retrospective case control study was conducted on a convenience sample in a Melbourne metropolitan hospital. An internal statistical validation was carried out using the receiver operator curve statistic (ROC), to determine the predictive power of the draft tool in an internal validation and prospective series.

The prospective consecutive series validation was conducted in an acute care setting in metropolitan Perth, to test the inter-rater reliability and predictive power of the tool. The participants of the validation were a portion of the colorectal surgery population at a single institute during a three month period in early 2016.

**Findings:** From the initial retrospective case control study, a baseline data set was derived consisting of 162 participants. Over half the sample was male, between 50 and 81 years of age, 37% were smokers and whilst not statistically significant, a distinct trend emerged towards an increased presence of chronic disease states. Following logistic regression and goodness of fit model testing, key patient related risk factors were identified; age (p 0.019, OR 0.3), diabetes (p 0.624, OR 2), previous surgery (p <0.001, OR 4), obesity (p 0.94, OR 1.4), smoking (p 0.387, OR 2), cardiovascular disease (p 0.381, OR 3) and peripheral arterial disease (p 0.501, OR 3). From the regression analysis, the beta coefficients of the associated variables were used to determine the risk score for each individual variable in the draft tool, the sum of which would provide a risk score for the patient.

Results from the second retrospective case control study (n = 57) conducted for the internal validation of the tool, yielded similar characteristics to the initial community nursing sample with the ROC analysis yielding a predictive power of the draft tool at 76% (AUC 0.768,  $p < 0.001$ ). The prospective clinical validation of the draft tool in the acute care setting with a convenience sample (n = 26) yielded a moderate predictive power for the ROC analysis (AUC 0.71,  $p < 0.001$ ) and high inter-rater reliability (100%). A cost analysis of the initial retrospective sample revealed a significant cost difference ( $p < 0.001$ ) between the clinical management of the infected group compared to the non-infected group. Overall the cost of managing 62 patients with SWD in the community nursing setting for up to a one year period was over \$56,000AUD.

**Conclusion:** Identification of at-risk patients for complications postoperatively is integral to improving health-related outcomes following surgery. This study combined factors previously identified from the literature associated with SWD to develop a conceptual framework and then study a cohort of patients with SWD. Many previously identified risk factors included chronic disease states such as CVD, diabetes, PAD and obesity were linked with SWD. Results of this study indicate that previous surgery in the same anatomical location was as a significant risk factor for SWD. Patients with this risk factor are four times more likely to incur a dehiscence.

A number of issues were identified during the course of this study. There was a lack of a standardised definition and a classification system for SWD for clinicians to use when reporting this outcome following surgery. This is coupled with a considerable dearth in the literature on the epidemiology and economic cost of SWD, which may indicate potential under reporting of this type of wound complication. There is considerable overlap of SWD with the definition of surgical site infection, which is also linked to misclassification and recognition.

Through this study a proposed framework conceptualising risk factors associated with SWD was developed which may inform future programmes of research and clinical education. Furthermore a novel draft risk assessment tool has been proposed and tested to reveal moderate predictive power. The draft risk tool may be worth considering for clinical practice following further testing and application in a much larger surgical cohort.

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### **List of Publications Resulting from the Study**

- Sandy-Hodgetts, K., Carville, K., & Leslie, G. (2013). Determining risk factors for surgical wound dehiscence: A review of the literature. *International Wound Journal*. 2013 May. doi:10.1111/iwj.12088.
- Sandy-Hodgetts, K., & Watts, R. (2013). Effectiveness of topical negative pressure in the prevention of surgical wound complications: A systematic review and meta-analysis protocol. *Joanna Briggs Institute Reports* 10.2013: 11(9):12-23. doi: 10.11124/jbisrir-2013-909.
- Sandy-Hodgetts, K., & Watts, R. (2015). Effectiveness of topical negative pressure in the prevention of surgical wound complications: A systematic review and meta-analysis. *Joanna Briggs Institute Database of Systematic Reviews & Implementation Reports* 2015 (13) 253 – 303. doi: 10.11124/jbisrir-2015-1687.
- Sandy-Hodgetts, K., Leslie, G. Lewin, G., & Carville, K. (2016). Surgical wound dehiscence in patients referred to a Western Australian community nursing service during 2010: Time and cost to healing. *Journal of Wound Care*, 25(7): 377-83. doi: 10.12968/jowc.2016.25.7.377.
- Sandy-Hodgetts, K., Ousey, K., & Howse, L. (2017). Top ten tips for management of surgical wound dehiscence. *Wounds International*, 8:11-15.

- Sandy-Hodgetts, K. (2017). The Sandy Grading System for surgical wound dehiscence classification: A new taxonomy. *Wounds International December 2017*.
- Sandy-Hodgetts, K., Co-Chair, Expert Advisory Panel (2017). World Union of Wound Healing Societies International Consensus Document. Surgical Wound Dehiscence: Improving preventions and outcomes (December 2017).

### **List of Oral Presentations Resulting from the Study**

- Sandy-Hodgetts, K. (2012). Title: *Surgical wound dehiscence: Current evidence for risk factors*. European Wound Management Association (EWMA) Annual Conference, May 2012, London, United Kingdom.
- Sandy-Hodgetts, K. (2014). Title: *Surgical site infection in the acute care setting: Latest evidence*. Australian Wound Management Association State Conference, November 2014 Perth, Western Australia.
- Sandy-Hodgetts, K. (2016). Title: *Surgical wound dehiscence: Current evidence and the challenges we face*. European Wound Management Association (EWMA) Annual Conference, May 2016, Bremen, Germany.
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- Sandy-Hodgetts, K. (2016). Title: *Development and internal validation of a surgical wound dehiscence risk assessment tool in the prediction of at risk patients*. (Free paper) National Wounds Australia Conference, November 2016, Melbourne, Australia.



- Sandy-Hodgetts, K. (2016). Title: *Surgical wound dehiscence: Evidence and risk factors*. (Invited plenary speaker) Wounds Australia, Perth State Conference, November 2016, Western Australia.
- Sandy-Hodgetts, K. (2016). Title: *Preoperative risk assessment tool for wound dehiscence in patients following abdominal surgery: Internal validation of the Perth Surgical Wound Dehiscence Risk Assessment Tool (PSWDRAT)* (Free paper) World Union of Wound Healing Societies (WUWHS), September 2016, Florence, Italy.
- Sandy-Hodgetts, K. (2016). Title: *Surgical wound dehiscence: The evidence and clinical challenges*. (Free paper) World Union of Wound Healing Societies (WUWHS), September 2016, Florence, Italy.
- Sandy-Hodgetts, K. (2016). Title: *Effectiveness of topical negative pressure in the prevention of surgical wound complications – A systematic review and meta-analysis*. (Free paper) World Union of Wound Healing Societies (WUWHS), September 2016, Florence, Italy.
- Sandy-Hodgetts, K. (2017). Title: *Surgical site infections across sectors –what can be done to improve prevention?* (Invited panel speaker) European Wound Management Association (EWMA) Annual Conference, Amsterdam, Netherlands.
- Sandy-Hodgetts, K. (2017). Title: *Preoperative risk assessment tool for wound dehiscence in patients following abdominal surgery: Internal validation of the Perth Surgical Wound Dehiscence Risk Assessment Tool (PSWDRAT)*. (Free paper) European Wound Management Association (EWMA) Annual Conference, May 2017, Amsterdam, Netherlands.
- Sandy-Hodgetts, K. (2017). Title: *Surgical wound dehiscence, infection and the nursing challenge & the effectiveness of topical negative pressure in the prevention of surgical wound dehiscence – A systematic review and meta-analysis*. (Invited speaker

and Co-Chair) Wounds International and World Union of Wound Healing Societies (WUWHS) International consensus panel meeting on surgical wound dehiscence, London Heathrow, United Kingdom.

- Sandy-Hodgetts, K. (2017). Title: *Surgical wound dehiscence, infection and the nursing challenge, can we achieve zero incidence?* (Invited speaker and Co-Editor) EWMA Surgical Site Infection Guidelines Document. Amsterdam, Netherlands.
- Sandy-Hodgetts, K. (2017). Title: *Surgical wound dehiscence and surgical site infection: State of play, current evidence for risk factors and prevention.* (Invited speaker) Acute Care Wound Conference, Royal Brisbane Women's Hospital, Brisbane, Queensland, Australia.

#### **Poster Presentations Resulting from the Study**

- Wound Management Innovation Cooperative Research Centre (WMICRC) National Conference. Adelaide 2013. *Risk factors for surgical wound dehiscence: A narrative review of the evidence.*
- Australian Wound Management Association National Conference, Gold Coast, Queensland, May 2014. *Effectiveness of topical negative pressure in the prevention of surgical wound complications: A Joanna Briggs Institute systematic review and meta-analysis.*
- Australian Wound Management Association (AWMA) State Conference Perth, Western Australia, November 2014. *Surgical site infection in the acute care setting: Latest evidence.*
- World Union of Wound Healing Societies (WUWHS), Florence, Italy, September 2016. *Effectiveness of topical negative pressure in the prevention of surgical wound complications: A systematic review and meta-analysis.*

- World Union of Wound Healing Societies (WUWHS), Florence, Italy, September 2016. *Preoperative risk assessment tool for wound dehiscence in patients following abdominal surgery: Internal validation of the Perth surgical wound dehiscence risk assessment tool (PSWDRAT).*

### **Abbreviations**

ACHI	Australian Classification of Health Interventions
ACSQHC	Australian Commission into Safety and Quality in Health Care
ANF	Australian Nursing Federation
ANOVA	Analysis of variance
ASA	American Society of Anaesthesiologists
AUC	Area under the curve
$\beta$	Beta coefficient
BMI	Body mass index
BP	Blood pressure
CABG	Coronary artery bypass grafting
CDC	Centers for Disease Control and Prevention, Atlanta, Georgia.
CEBM	Oxford Centre for Evidence-based Medicine
CeDAR	Carolinas equation determining associated risk
CI	Confidence interval
CNC	Clinical nurse consultant/coordinator

CNS	Community nursing service
COPD	Chronic obstructive pulmonary disease
CVD	Cardiovascular disease
DCS	Data collection sheet
DM	Diabetes mellitus
DSWI	Deep sternal wound infection
EN	Enrolled nurse
ERAS	Enhanced recovery after surgery
EuroSCORE	European system for cardiac operative risk evaluation
FiO <sub>2</sub>	Fraction of inspired oxygen
HCAI	Health care-associated infections
HREC	Human Research Ethics Committee
ICD	International Classification of Diseases
ICU	Intensive care unit
LIMA	Left internal mammary artery
LOS	Length of service
MRN	Medical record number
N	Newtons
NCCH	National Centre for Classification in Health
NHMRC	National Health and Medical Research Council
NHS	National Health Service (UK)
NNIS	National Nosocomial Infectious Surveillance System
NPWT	Negative pressure wound therapy

NSAIDs	Non-steroidal anti-inflammatory drugs
NYHA	New York Heart Association
OR	Odds ratio
PICF	Patient Information & Consent Form
POSSUM	Physiological and Operative Severity Score for EnUmeration of Mortality and Morbidity
PPO	Patient, phenomenon, outcome
PRISMA	Preferred reporting items for systematic reviews and meta-analyses
PAD	Peripheral arterial disease
RCT	Randomised control trial
RN	Registered nurse
ROC	Receiver operator curve
RTL	Reinforced tension line
SPSS	Statistical package for the social sciences
SSI	Surgical site infection
SWD	Surgical wound dehiscence
SWDRAT	Surgical wound dehiscence risk assessment tool
SWIPS	Sternal Wound Infection Prediction Scale
TKR	Total knee replacement
UK	United Kingdom
USA	United States of America
VHRWRT	Ventral Hernia Repair Wound Risk Tool

WHO

World Health Organization

## **Chapter One**

### **Introduction**

Timely and sustained postoperative wound healing is paramount for optimal patient outcomes following a surgical procedure. Contemporary surgical procedures are relatively safe, with some level of risk of postoperative complications, dependent upon the type of surgery and pre-existing patient-related factors (Spiliotis, 2010). However, from time to time postoperative complications occur, which impact on patient healing and impose ensuing costs on the health care sector in the course of their clinical management.

Surgical wound dehiscence (SWD) or incisional wound breakdown is a serious complication following surgery, which requires clinical expertise and considerable resources in the management of the patient and the resulting wound. A SWD has been defined as the rupture or splitting open of a previously closed surgical incision (Goldstein, 1984). Patients with a SWD may require additional surgery for secondary closure or prolonged periods of treatment from acute and community nursing services or medical practitioners as wound healing by secondary intention is facilitated. Consequently, SWD can lead to reduced patient wellbeing and quality of life (Sanger, et al., 2014), extended length of stay in the acute care setting or readmission (De Lissovoy, 2008), and the need for additional resources to manage the wound (Tanner, Aplin, Ball, Thomas, & Bankart, 2009).

Wound dehiscence is a possibility following any surgical procedure and numerous authors have reported the occurrence following orthopaedic, abdominal, cardiothoracic, and vascular surgery (Cevasco et al., 2011; Phan et al., 2012; Reilly, Twaddle, McIntosh, &

Kean, 2010; van Ramshorst et al., 2010; Webster, Neumayer, Smout, Horn, Daley, Henderson, et al., 2003; Weiland, Bay, & Del Sordi, 1998). The literature outlines some associations between SWD and patient comorbidities as well as types of surgical wound closure (Ceydeli, Rucinski & Wise 2005; De Vivo, 2010; Hadar, Melamed, Tzadikévitch-Geffen, & Yogev, 2011; Iavazzo et al., 2011; Mclaws, Irwig, Mock, Berry, & Gold, 1988; Ridderstolpe, Gill, Granfeldt, Ahlfeldt, & Rutberg, 2001; Smith, Mann & Dowell 2010; Weiland, Bay & Del Sordi., 1998). However, the validation of these associations as effective predictors for risk of SWD is limited across most surgical domains.

### **1.1. Background**

The first accounts in the historical record of surgical wound complications can be traced back to the origins of surgery itself. Although the term ‘dehiscence’ was not referred to in the literature until the early 20th century, the historical record recounts the existence of fistulae, open wounds secondary to trauma and wound breakdown following the early development of surgical practices (Haeger, 2000).

Early accounts of the surgical closure of the body, some 2,000 years before Christ, is described in the ancient Indian text *Sushruta Samhita*, which referred to the closing of incisions by cauterisation or the sewing of wounds (Haeger, 2000). Hippocrates (460–377 BC), referred to as the ‘father of medicine’, also described the assisted closure of opposing wound margins as primary intention and the spontaneous healing as secondary intention (Haeger, 2000). Another early account of suturing comes from ancient Egypt, where plant fibres, tendon or hair were used as suturing materials to close wounds resulting from battle injuries (Muffly, Tizzano, & Walters, 2011), and the Romans and Greeks also reported the use of sutures to close a wound (Haeger, 2000).



It is notable that not until after John Hunter's 1817 *Treatise on Blood, Inflammation and Gunshot Wounds*, did surgeons appear to develop an understanding of wound healing physiology, especially the role of inflammation in the healing process (Hunter, 1817). Hunter's careful observations and the use of the scientific method (systematic observation, measurement and experimentation) in medicine was instrumental in understanding impact of dilation on gunshot wounds in battle, of which he did not perform due to the increased chance of infection (Moore 2010). During the 19th century the scale of wound complications were more extensively documented. In particular, those that occurred as a result of infection or military endeavours. For example, necrotising infections of soft tissue as well as tetanus were reported to account for over 17,000 deaths during the American Civil War (Singhal, 2017).

During the late 1800s early infection prevention practices were influenced by Louis Pasteur's discovery of bacteria and the advent of bacteriology, which led to significant reductions in patient morbidity and mortality rates (Haeger, 2000). The American surgeon Halsted (1852–1922), initiated the sterilisation of instruments and the subsequent wearing of gloves, gowns, and masks, and he observed that the rate of surgical wound complications and death reduced dramatically as a result of these practices. In 1847, at Vienna's General Hospital maternity clinic, Hungarian obstetrician Ignaz Semmelweis, implemented handwashing before birthing procedures, which resulted in a substantial reduction of 'childbed fever' rates (Carter, 1983). Joseph Lister's implementation of antiseptics and the 'aseptic' technique in the late 1800s also contributed to a reduction in infection and mortality rates following surgery. As did frequent 'purification' of bedding, the need for nurses to wear washable dresses, and the use of carbolic acid before and during surgical procedures, which led to a reduction in the death rate of amputees from 48% to 15% over a 3 year period (Newsom, 2000).

Rapid amputation of limbs was considered the key to infection prevention during World War I. However, this practice became less urgent with the use of penicillin, during World War II, which brought about more appropriate wound care for the injured (Manring, Hawk, Calhoun, & Andersen, 2009a). During the Korean War, the administration of antibiotics, coupled with fast evacuation from the battle field, contributed to a reduction in the battle wound mortality rate from four to two percent (Manring, Hawk, Calhoun, & Andersen, 2009b).

Through the intervening years increasing sophistication and advances in surgical practice, diagnostic technologies and anti-infective pharmacological agents have improved postoperative outcomes for the surgical patient. However, SWD, which is often associated with infection, continues to be problematic. Often associated with wound dehiscence and considered a precursor is wound infection, a known contributor to delayed wound healing (Bucknall, Cox, & Ellis, 1982; Wolcott, 2008). Some patients with postoperative wound complications are readmitted to hospital for further surgical treatment such as debridement, or the use of more sophisticated techniques to assist in wound closure, such as topical negative pressure wound therapy (NPWT) which impacts on patient and health costs (Kilpadi & Cunningham, 2011).

It may appear that a symbiosis exists between wound dehiscence and infection. However, it could be argued that contemporary surgeons are challenged with the care of patients who are more complex than times past. These risks are associated with an increasing ageing population, and increase in chronic disease such as diabetes, cardiovascular disease and an obesity epidemic. The greater challenge today is in the management of complex patients and their ability to healing following surgery.

### **1.1.1 Epidemiology of Surgical Wound Dehiscence**

The worldwide volume of surgery is considerable with an estimated 312.9 million major surgical procedures carried out during 2012 (Weiser et al., 2016). Surgical wound dehiscence continues to pose a significant problem for the patient and healthcare professionals following any surgery (Spiliotis et al., 2009). While it may be clearly linked to infection in some cases, numerous other factors have been suggested to be associated with SWD. A number of studies (Buja et al., 2012; van Ramshorst, et al., 2010; Webster, Neumayer, Smout, Horn, Daley, Henderson, Khuri, et al., 2003; Uckay, Agostinho, Belaieff, Toutous-Trellu, Pietragmaggiori, Andres, Bernard, et al., 2011) have identified non-microbial related risk factors associated with wound dehiscence, yet, these factors need to be fully quantified in order to assist with the prediction of patients more likely to manifest SWD following surgery. It would be clinically advantageous to know what factors place the patient at risk of SWD prior to, during and after surgery and the magnitude of that risk.

Surgical wound dehiscence is often reported under the SSI terminology, and there is a substantial understanding of the economic impact of postoperative SSI in the acute care setting. For instance, in the United States of America (USA), SSIs comprise 33% of healthcare related infections, costing \$3.2 billion USD (AUD \$4.32 billion) per annum (Zimlichman et al., 2013). Whilst in the United Kingdom (UK), SSI constitutes 20% of all healthcare related infections and at least 5% of admitted patients will develop an SSI. In Europe the estimated costs for SSI range from €1.47bn to €9bn annually (Leaper et al., 2004), (AUD \$2.29 to \$12 billion). More recently Guest et al., (2015) reported the cost of managing unhealed wounds in the NHS as £3 billion per year (AUD \$5 billion), 11% attributable to surgical wounds. In Australia the estimated costs associated with SSI are close to \$268 million per year (McLaws & Taylor, 2003). Whilst some of these published reports

may be dated, they do give an indication of the cost impact of SSI to the healthcare settings. Despite the high reported costs with managing SSI in the acute care setting, there are limited published reports of the costs associated with clinical management of SWD in the community, where these wounds are often treated in the post discharge phase of the patient's journey (Tanner et al., 2009; Tanner, Kiernan, Leaper, Norrie, & Baggott., 2013).

Tanner et al. (2009) reported the average cost of treating wound infection in the community nursing setting in the UK was £10,523 per patient (AUD\$18,486). This included the primary care costs, organisational overheads and travel costs associated with district nurses' visits, ultrasound tests, and as well as hospital readmission costs. Whilst Tanner et al. (2009) provides a picture of a portion of the population, other reports of the post-discharge cost of managing SWD are yet to be forthcoming.

## **1.2. Problem Statement**

Currently there is limited research defining the frequency, aetiology and characteristics of SWD (Leaper, Tanner, & Kiernan, 2013; Spiliotis et al., 2009; Tanner, Aplin, Ball, Thomas, Bankart., 2009). Many of the factors associated with SWD could possibly be ameliorated, or at least, precautions introduced to reduce the likelihood of SWD, if the risk of SWD could be quantified and preventative strategies employed.

## **1.3. Research Aim**

The aim of the study was to determine risk factors associated with SWD, describe the costs associated with management of SWD in the community nursing setting, develop a draft

preoperative risk assessment tool, and conduct an internal statistical and clinical validation of the risk assessment tool.

#### **1.4. Objectives**

The specific objectives of the study were to:

- Determine the number of patients who received treatment for SWD in a community nursing setting (CNS) setting during 2010-11 and describe the costs associated with clinical management in the CNS.
- Identify the pre, intra and postoperative variables associated with SWD.
- Develop a preoperative SWD Risk Assessment Tool (SWDRAT).
- Test the draft SWDRAT for predictive power and undertake a preliminary internal validation.
- Determine the inter-rater reliability of the SWDRAT, and test the predictive power of the risk tool in a prospective series of surgical patients in the clinical setting.

#### **1.5. Significance of the Project**

It is anticipated that this research will contribute to the growing body of knowledge on the risk of SWD. Furthermore, the research sought to develop and validate a risk tool that identifies preoperatively patients who are at risk of SWD. The availability of a more inclusive and specific risk assessment tool for clinicians' preoperative use may have a significant impact on identification of risk and reduce the occurrence by optimising the prevention pathway for SWD. This would be of benefit to the patient and health care sector, as the opportunity to identify and manage the risk may lead to improved healing outcomes and

reduction in associated costs. Currently there are no validated, widely accepted, risk assessment tools that specifically identify patients at risk of SWD in the preoperative setting.

## **1.6. Overview of the Thesis**

The thesis is presented as a collection of seven chapters. The layout of the first three follows a traditional thesis format. The next two chapters discuss methods and results for the three separate studies conducted in an effort to identify characteristics associated with SWD and the associations between these and the prediction of SWD. In order for the reader to follow the development of these, each study is reported by method and results consecutively rather than describing all methods for each study together followed by all results in separate methods and results chapters.

Chapter One describes the background to the research, the problem statement that informed the research aims and objectives, and closes with the significance of the study. Chapter Two provides an exploration and critique of the literature and describes current knowledge of the frequency, aetiology and identified risk factors associated with SWD. Chapter Three describes a conceptual framework developed from the literature that underpins the research and discusses the focus of the study. Chapter Four describes the methodology and results for the two retrospective case control studies which led to the development of the risk tool. The methodology and results of a study which was conducted to determine the time and cost to healing of dehisced wounds are also presented. Chapter Five presents the methodology and results of the prospective clinical validation of the risk tool.

Chapter Six discusses the principal findings of the study and makes comparisons with the contemporary literature. Chapter Seven reports and discusses the study limitations, anticipated contributions to the field of inquiry and proposed significance of the study.

Finally, Chapter Seven also presents recommendations for future research and clinical recommendations regarding the identification of patients at risk of SWD

## **Chapter Two**

### **Literature Review**

#### **Introduction**

The objective of this review was to identify risk factors for SWD and critically evaluate the evidence in the literature. The review was undertaken to address two specific questions; first, what are the risk factors for SWD and secondly, have these risk factors been prospectively evaluated in a tool format to determine ‘at risk’ populations? This chapter explains the methodology of the review and the findings that relate to current risk indexes and patient related risk factors for SWD.

#### **2.1. Surgical Wound Dehiscence Defined**

For the purposes of the study, defining SWD was the first step in deriving the search terms and key words for the literature search. The literature revealed a number of definitions for the term ‘surgical wound dehiscence’. According to Goldstein (1984) SWD is the splitting apart of apposed margins following surgical closure. The CDC define a dehiscence as a deep SSI (Horan, 2013). Further to this, the CDC definition stipulates that a deep SSI is determined primarily by the following characteristics: it occurs within a 30-day period following surgery, has a purulent discharge, and has a surgical incision separation at the sutured margins (Horan, 2013). While the CDC definition was also referred to during the



literature search, the Goldstein definition does not have infection as its main criterion for dehiscence; it simply states the physical manifestation of SWD. Both definitions were taken into account during the evaluation and synthesis of the literature.

In the Australian acute care setting, SWD is classified under the ICD-10 code of T81.31 for wound dehiscence. The ICD-10 classification for T81.31 is defined as a disruption of the wound and/or dehiscence (World Health Organisation, 1992). Dehiscence may often be recorded in the medical record as a SSI (Spiliotis et al., 2009), and moreover, with very limited detail on the type of SSI, for example whether it is superficial or deep. This poses difficulties in ascertaining the type of SSI, or whether an associated SWD is present. The literature review included studies that employed any one of the above definitions when reporting SWD.

## **2.2. Literature Search Method**

Electronic searches of the literature were carried out on PubMed, Ovid MEDLINE (1945–2017), and Ovid CINAHL (1986–2017) using the following key terms; patients and surgical wound or wound breakdown surgical wound dehiscence or surgical site infection, risk factors surgical wound dehiscence. For the purposes of this study, publications included in the narrative review must have described the terms used to identify or define SWD. Those published studies that did not report the definition of SWD in their analysis were excluded.

For inclusion in the review, studies were required to meet the following criteria: be published in the English language, feature adult participants, be a primary research article using quantitative research methodology, and/or report results of risk factors obtained from retrospective or prospective data. The evaluation of the evidence was based upon the Oxford

Centre for Evidence-based Medicine Levels of Evidence (CEBM) (CEBM, 2009) which offered a number of advantages in comparison with other grading methods. The CEBM method provides a clear hierarchy of grades and incorporates grading for those studies that are most likely to be undertaken to determine risk factors, for example, cohort and case-control studies.

The grading system is as follows –

Level 1: systematic review of randomised control trials (RCT), individual RCTs and prospective cohort studies with good follow-up.

Level 2: systematic reviews with homogeneity of cohort studies, and retrospective cohort studies.

Level 3: case-control studies.

The review was carried out in line with the patient, phenomenon, outcome search strategy outlined by the Centre for Evidence Based Medicine (CEBM). The eligibility and critical evaluation process is outlined in Figure 2.1 using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Liberati et al., 2009) reporting standards as a frame of reference.

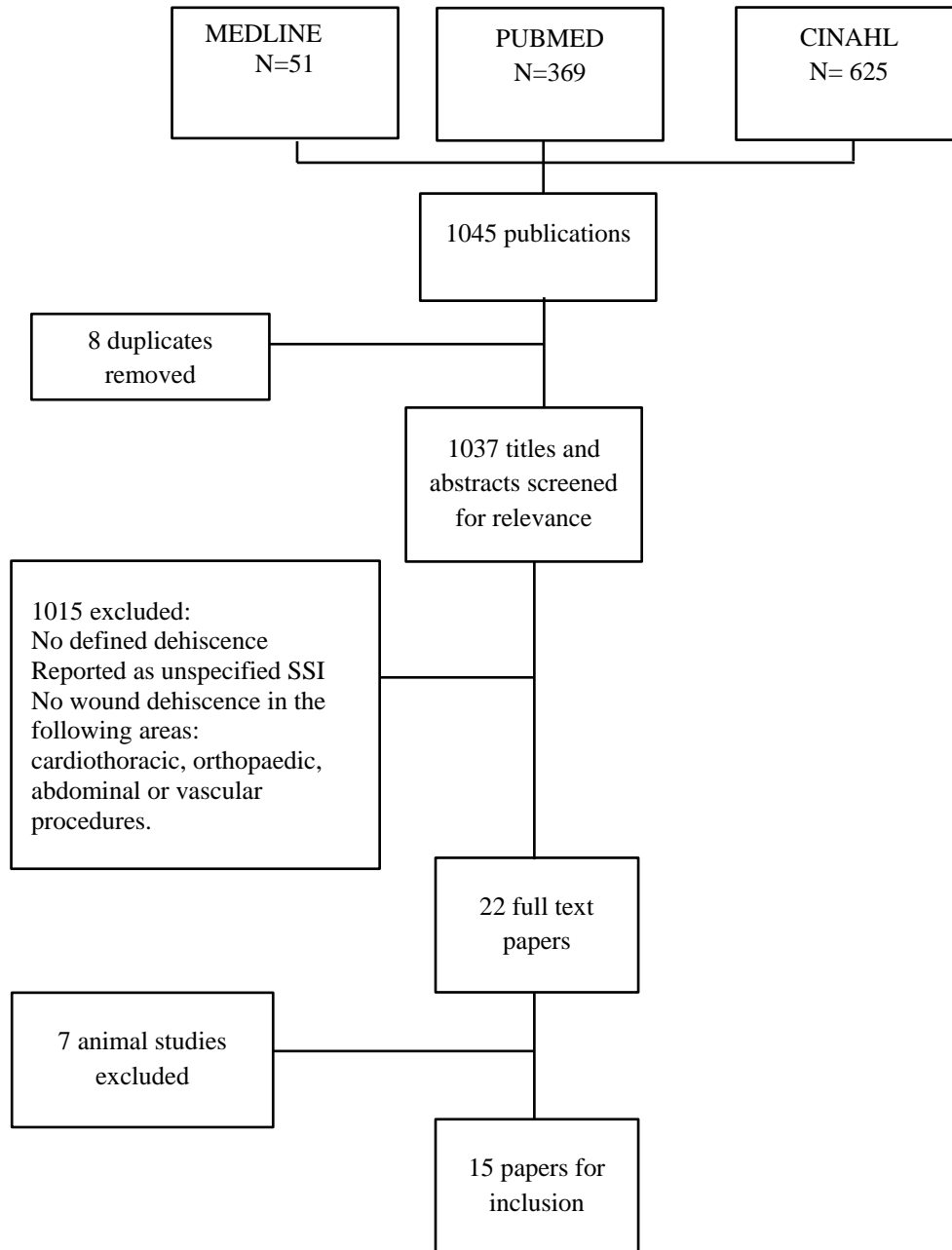


Figure 2.1. Flowchart for studies reviewed - adapted from PRISMA. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: Explanation and elaboration. Liberati, A., (2009) *Journal of Clinical Epidemiology*, 62(10), e1-34. Retrieved from <http://dx.doi.org/10.1016/j.jclinepi.2009.06.006>

### 2.2.1. Prevalence and Incidence of Surgical Wound Dehiscence

Surgical wound dehiscence may occur for many reasons. The literature reveals that SWD is related primarily to infection, even if a SWD may not be confirmed to microbial causes (Leaper et al., 2013; Tanner et al., 2013). Furthermore the literature indicates that clinicians use the term ‘SSI’ as a broad descriptor, at times, regardless of the type of SSI.

Of the 15 papers included for analysis the majority reported SWD in the context of the acute care setting. The occurrence of SWD following different surgical procedures has been reported as ranging between 1.3% and 9.3% (Table 2.1). The data in these studies were reported in accordance with the CDC’s SSI classification guidelines (Horan, 2013). Each surgical procedure’s prevalence data are listed below.

Table 2.1 Reported Prevalence of SWD

Procedure	Prevalence of SWD
Abdominal surgery – superficial dehiscence, deep dehiscence	0.4-3.5% (Mulligan, 2011; Niggebrugge, 1999; Riou, Cohen, & Johnson, 1992; Spiliotis et al., 2009; van Ramshorst et al., 2010; Webster et al., 2003)
Caesarean section	3% (De Vivo, 2010)
Sternal wound dehiscence following CABG	3% (John, 2008)
Hip prosthesis	3% (Smith, 2010)
Saphenous vein graft harvesting	9.3% (Biancari & Tiozzo, 2010a)

### **2.2.2. Abdominal Wound Dehiscence**

Wound dehiscence following abdominal surgery featured prominently in the literature. Abdominal wound dehiscence has the potential to lead to severe postoperative complications, with mortality rates reportedly as high as 45% (Fleischer, Rennert, & Ruhmer, 2000). The reported prevalence of abdominal dehiscence ranges from 0.4% to 3.5% (Mulligan, 2011; Niggebrugge, 1999; Riou, Cohen, & Johnson, 1992; Spiliotis, Tsiveriotis, Datsis, Vaxevanidou, Zacharis, Giafis, et al., 2009; van Ramshorst et al., 2010; Webster et al., 2003). Some SWD risk assessment models have been developed (van Ramshorst et al., 2010; Webster, Neumayer, Smout, Horn, Daley, Henderson, & Khuri, 2003) however, these models have yet to be fully validated in larger clinical settings and in a manner that can readily assist the prediction of which patients are more likely to experience SWD (Table 2.2).

Table 2.2 Risk Factors Associated with SWD

Author	Surgical domain	Variables of significance listed as a risk factor, statistical analysis method used and (p value where reported)
McDonald et al., 1989	Cardiothoracic surgery: sternotomy infection and dehiscence.	Multivariate analysis Female gender (p=0.03), Obesity (p=0.002), Diabetes (p=0.01), Prolonged postoperative ventilation (p=0.006).
Webster et al., 1996*	Abdominal surgery: abdominal wound dehiscence.	Logistic regression P <0.05 COPD (p=0.002), Postgraduate year of surgeon (PGY4) (p=0.003), Operative time (p=0.013), Emergency procedure (p<0.0011), Clean wound classification (p=0.0031), Superficial wound infection (p=0.0048), Deep wound infection (p<0.0011), Failure to wean from ventilator (p<0.0011), Current pneumonia (p=0.04).
Baskett et al., 1997	Cardiothoracic surgery: wound infection.	COPD (p=0.01)
Borger et al., 1998	Cardiothoracic surgery: deep sternal wound infection.	Diabetes, male, bilateral internal thoracic artery grafting may be contraindicated in diabetic patients.
Paletta et al., 2000	Vascular surgery: leg complications.	Multivariate analysis Female gender (p<0.001), Peripheral vascular disease (p<0.001).

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Ridderstolpe et al., 2001	Cardiothoracic surgery: Superficial and deep sternal wound complications.	<p>Superficial wound complications:  Univariate with ROC analysis  Age &lt;= 65 (p=0.006)  Age &lt;= 75 (p=0.020)  BMI &lt;= 30 (p&lt;0.001)  Diabetes (p=0.008)  Ventilator support (p=0.008)  Deep sternal infections/mediastinitis  BMI&lt;= 30 (p&lt;0.001)  Diabetes (p&lt;0.001)  Smoking (p&lt;0.001)  COPD (p&lt;0.001)  PVD (p&lt;0.001)  Reoperation – bleeding p=0.08)  Red blood cells – units (p=0.02)  Ventilator support (p=0.004).</p>
Salehi-Omran et al., 2007	Cardiothoracic surgery: superficial and deep sternal wound infection following CABG.	<p>Multivariate analysis  Female gender (p=0.05),  Preoperative hypertension (p=0.05),  Diabetes (p=0.05),  Obesity (p=0.05),  Prolonged intubation time (more than 48hrs) (p=0.05),  Re-exploration for bleeding (p=0.05),  Hypertension (p=0.05).</p>
Schimmer et al., 2008	Cardiothoracic surgery: sternal dehiscence and infection.	<p>Body mass indices greater than 30 kg/m2 (p=0.05),  New York Heart Association &lt; class III (p=0.07),</p>

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		<p>Impaired renal function (p=0.07),  Peripheral arterial disease (p&lt;0.001),  Immunosuppressant state (p&lt;0.001),  Sternal closure performed by an assistant doctor (p=0.004),  Postoperative bleeding p=0.03),  Transfusion of more than 5 red blood units (p=0.03),  Re-exploration for bleeding (p=0.001),  Postoperative delirium (p=0.01).</p>
Sharma et.al., 2009	Vascular leg complications	<p>Forward stepwise logistic regression  Female gender (p=0.008),  Renal insufficiency (p&lt;0.001),  Diabetes (p&lt;0.001),  BMI &lt;= 30kg/m<sup>2</sup> (p&lt;0.001),  PVD (p=0.09),  ICU stay &lt;72 hr (p=0.009).</p>
Van Ramshorst et al., 2010*	Abdominal surgery – abdominal wound dehiscence	<p>Multivariate stepwise logistic regression with backwards elimination  (p&lt;=0.05)  Age (p=0.02)  Male gender (p&lt;0.001)  Ascites (p&lt;0.01),  Wound infection (p&lt;0.001), Emergency surgery (0.001), CPD (p&lt;0.001),  type of surgery overall P value (p&lt;0.001),  Coughing (p&lt;0.001).</p>
Floros et al., 2011	Cardiothoracic surgery – deep sternal wound infection.	<p>Fisher’s Exact Test p value (p&lt;0.05)  Previous cardiac surgery (p=0.03),  BMI&lt;=30 (p=0.041),  Left ventricular ejection fraction (LVEF) &lt;=30 (p=0.01),  Homologous blood usage (p&lt;0.01).</p>

*Note.* \*Risk tool/prognostic models tested.



Webster et al. (2003) developed a prognostic risk model for SWD following a retrospective medical note audit of 17,044 patients who underwent a laparotomy during 1996-1998 (Webster et al., 2003). Following development of the risk model, an internal validation was conducted. Webster et al. (2003) determined a percentage risk prediction value for patients and suggested that this prognostic model could be used in a perioperative setting that included intra and postoperative factors such as operation time, emergency surgery, and wound infection as key predictors for SWD (Webster et al., 2003). However, research on further prospective validation of the prognostic model has not yet been published, nor have there been any published outcomes describing the inter-rater reliability of the prognostic model and clinical utility of the tool.

Van Ramshorst et al. (2010) developed and internally validated a risk model for wound dehiscence and identified several significant risk factors associated with dehiscence: age, male gender, emergency surgery, type of surgery, postoperative coughing, and wound infection (van Ramshorst et al., 2010). The findings of these authors were similar to those in Webster et al. (2003) results, with regard to the type of patient-related factors associated with SWD. Van Ramshorst et al. (2010) conducted a ROC analysis on the risk model which demonstrated a high predictive power of 91% (area under the curve [AUC] 0.91).

When comparing the findings of Webster et al. (2003) with those of van Ramshorst et al. (2010), the former revealed an increased risk of SWD after abdominal surgery when: the operative time was longer than six hours; a fourth-year postgraduate resident performed the surgery in lieu of a more experienced surgeon; the wound was a clean-wound classification; the presence of a wound infection was confirmed following surgery, and the patient spent extended time on a ventilator. These were confirmed as highly significant factors (Table 2.2).

Webster et al. (2003) cohort were patients who underwent laparotomies performed at 132 Veterans Affairs Medical Centres, with an average age of 60 years (L. Neumeyer, personal communication, 16 April 2012), whereas van Ramshorst et al.'s sample was recruited from the general surgical population. While van Ramshorst et al. (2010) and Webster et al. (2003) have made significant contributions to the field, a deficit remains in the availability of prospectively validated risk assessment tools for SWD that have demonstrated clinical utility and efficacy in the prediction of an at-risk population. As such the inclusion of these risk tools into the current study is restricted due to the absence of publications reporting validation.

The type of closure method and the suture materials used during surgery have been identified as a risk factor for abdominal wound complications by some authors (Ceydeli, 2005; Rucinski, Margolis, Panagopoulos, & Wise, 2001). Rucinski et al.'s (2001) meta-analysis reported continuous-mass (all-layer) closure with absorbable monofilament sutures to be the optimal closure technique after laparotomy for prevention of postoperative SWD complications. Similarly, Ceydeli et al.'s (2005) review supports this finding and the authors concluded that the optimal method of closure following a vertical midline laparotomy incision, was a mass closure using a simple running technique with number one or two absorbable monofilament suture and a suture length-to-wound ratio of 4:1. The type of suture material has also been subject to investigation in relation to the occurrence of SSI following surgery. A recent systematic review by Sandini et al. (2016) reported that triclosan-coated sutures have only a limited protective effect against SSI and that more level-one studies are required to investigate this matter (Sandini, Mattavelli, Nespoli, Uggeri, & Gianotti, 2016). Furthermore, these findings are also reflected in the work of Wu et al. (2017). However, other authors have reported different findings, with a reduced occurrence of SSI when using triclosan-coated sutures (Daoud, Edmiston, & Leaper, 2014). Whilst others have suggested

that a multifactorial approach in prevention of SSI is required, such as the implementation of care bundles (Tanner, Aplin, Ball, Thomas, Bankart., 2015; Waits et al., 2014).

Several authors have proposed that increased forces on the abdominal wall due to rises in intra-abdominal pressure, or oedema, may be of equal significance for SWD occurrence as compared with the method of closure for abdominal wounds (Ramneesh, Sheerin, Surinder, & Bir, 2014; van Ramshorst et al., 2010). Early studies on cadavers investigated whether a reinforced tension line (RTL) technique for abdominal wall closure was able to withstand increased tensile forces of up to 110 Newtons (N) in the epigastrium, 120N in the umbilicus and 100N in the hypogastrium (Hollinsky, Sandberg, & Kocijan, 2007). Interestingly, they found that in 77% of the non-reinforced (non-RTL) sites, sutures tore away from the tissues at a median load of 60N, which was a much lower force than that tolerated by the reinforced sites. Similarly, Agarwal et al. (2011) used continuous RTL technique in patients who underwent emergency midline laparotomies and found that the technique resulted in no dehiscence abdomens (Agarwal, 2011). Furthermore, 100 patients who were closed using a non-RTL continuous suture resulted in dehiscence abdomens ( $p=0.009$ ) compared to the RTL technique (Agarwal, 2011). The contemporary evidence would appear to suggest that the use of the RTL technique results in fewer dehiscence abdomens, however, the closure technique is at the discretion of the surgeon operating within the resources available to him or her and dependent upon the complexity of the surgery and the patient.

Abdominal wound dehiscence featured prominently in the literature with reported prevalence of this postoperative complication ranging from 0.4% to 3.5% (Mulligan, 2011; Niggebrugge, 1999; Riou, Cohen, & Johnson, 1992; Spiliotis, Tsiveriotis, Datsis, Vaxevanidou, Zacharis, Giafis, et al., 2009; van Ramshorst et al., 2010; Webster et al., 2003). Numerous risk factors have been identified in association with abdominal wound dehiscence and are summarised in Table 2.2, with wound infection reported by more than one author.

### 2.2.3 Cardiothoracic Wound Dehiscence

Coronary artery bypass grafting (CABG), is reported to be the most common procedure used by cardiothoracic surgeons in the ageing population for the treatment of the more serious consequences of cardiovascular disease (Diodato, 2014; Jahangiri, 2011). According to World Health Organisation (WHO), by 2030 cardiothoracic procedures will become more commonplace in treating an ageing population with pre-existing cardiovascular disease (CVD) (Mendis, 2011). Sternal wound dehiscence following a cardiothoracic procedure such as CABG, can result in lengthy hospital stays and increased morbidity and mortality rates in patients (Borger et al., 1998; El Oakley & Wright, 1996; Losanoff, Richman, & Jones, 2002; Ulicny & Hiratzka, 1991). Incidence of infection of median sternotomy wounds as reported in Europe ranges from 0.3% to 5% (Losanoff et al., 2002). In the UK, National Health Service (NHS) SSI surveillance data reported that in 2015–2016, 4.1% of cardiothoracic admissions experienced SSI following CABG (England, 2016). In Australia, SSI following CABG ranged from 0.7% in 2004 to 2.6% in 2011 (Si et al., 2014). In the USA, during the period 2006–2008, the reported rate of SSI following CABG was 2.8% (Edwards et al., 2009).

The most commonly reported predisposing factors identified in the literature for sternal wound dehiscence included: diabetes (Borger et al., 1998; McDonald, Brame, Sharp, & Eggerstedt, 1989; Salehi-Omran et al., 2007); female gender (McDonald et al., 1989; Ridderstolpe et al., 2001); and prolonged postoperative intubation of the patient (McDonald et al., 1989; Salehi-Omran et al., 2007) (Table 2.2). A retrospective review was conducted by Ridderstolpe et al. (2001) to investigate risk factors associated with surgical wound complications following cardiothoracic procedures. Sternal wound complications were

recorded for 9.7% of the study population. Of those complications, 6.4% were related to superficial infections, and 1.6% were deemed a deep sternal wound infection (DSWI), with 1.7% of the patients displaying postoperative mediastinitis (Ridderstolpe et al., 2001). Risk factors were divided into groups of preoperative, intraoperative and postoperative factors and of the total 42 variables identified across all three operative periods, 32 were associated with increased risk. The authors conducted a logistic regression analysis, and found the major independent predictors of sternal wound complications were: persons aged over 75, body mass index BMI greater than 30kg/m<sup>2</sup>, insulin-dependent diabetes, smoking, peripheral arterial disease (PAD), and those on prolonged ventilator support (Table 2.2). The authors concluded that with diligent post-discharge follow-up more sternal wound complications could be prevented.

Similar findings were also reported by Graf et al. (2010) following a retrospective review of patients who contracted DSWI post-CABG. Patients undergoing CABG surgery that were complicated by infection tripled the costs to the health care system (Graf et al., 2010). The reported median cost per patient was €36,261 compared to €13,356 for the non-infected patient (Graf et al., 2010). The costs for those patients with DSWI comprised ward care costs (24.7%), surgery costs (19%), intensive care unit (ICU) care (27.7%), laboratory tests (15%), and other costs not specified (13.6%). These findings emphasise the need for appropriate infection control measures for the prevention of DSWI, improved patient outcomes, and the consequent health cost containment (Graf et al., 2010).

As with abdominal surgery, the method of closure of cardiothoracic wounds has been investigated to determine if there is a correlation between closure method and postoperative complications such as SSI and SWD following CABG. A retrospective review compared two different products used in the closure of the sternum a 'figure of eight' technique and simple wire suture following CABG procedure. Tekumit et al. (2009) found that neither closure

technique showed any increased association with postoperative complications such as SWD (Tekumit, Cenal, Tataroglu, Uzun, & Akinci, 2009). More recently, Ozen et al. (2015) demonstrated that the use of cable instead of wire for sternal closure resulted in fewer postoperative SSIs and also reduced the length of hospital stay for the patient (Ozen, 2015). Wound dehiscence may be attributed to SSI as discussed by Graf et al. (2010) and Phan et al. (2012), both studies reported microbial presence as a factor contributing to wound dehiscence. One could propose that less than optimal surgical closure and the presence of infection could be doubly problematic.

#### **2.2.4. Orthopaedic Wound Dehiscence**

Surgical wound complications such as SWD are one of the major contributors to morbidity, prolongation of patient hospital stays and increased readmission rates following orthopaedic surgery (Singh, Nunn, & Mearns, 2006). Of considerable discourse in the orthopedic literature is the use or sutures of staples to close the incision line and its impact on postoperative complications.

Numerous studies have investigated the use of staples as compared to sutures, and the associations between these closure techniques and wound complications (Khan et al., 2006; Newman et al., 2011; Shetty et al., 2004; Smith, 2010). Smith et al. (2010) and Shetty et al. (2004) reported an increase in superficial wound infection occurrence with the use of staples as compared to sutures in closing incisions following hip or knee procedures. Other research has also demonstrated that the risk of developing infection following hip surgery is higher when patients' incisions have been closed with staples as compared to sutures ( $p=0.02$ ) (Smith, 2010). However, Newman et al. (2011) reported significantly fewer complications using staples as compared to sutures following total knee replacement (TKR) (Newman et al.,

2011). Khan reported the same outcomes of fewer complications using staples compared to sutures following hip replacement (Khan et al., 2006).

As is the case with other wound types, orthopaedic postoperative complications such as infection and SWD can lead to extended hospital stays, increased patient morbidity and an excessive fiscal burden for both patients and the health care system. While associations between wound closure methods and wound complications following orthopaedic surgery have been reported, there appears to be little in the way of risk assessment tools for clinicians to use in the preoperative setting for prediction of populations at risk of SWD.

### **2.2.5. Vascular Wound Dehiscence**

One of the more common complications following vascular surgery is wound infection and breakdown which reportedly contribute to the risk of amputation and to increased mortality rates (Calligaro et al., 1994; Kent, Bartek, Kuntz, Anninos, & Skillman, 1996; Nguyen et al., 2007; Pounds et al., 2005; Turtiainen et al., 2010). Reports of postoperative wound complications after vascular surgery are limited, however, some researchers describe rates of 10–20% following lower limb bypass grafting procedures (Inui, 2015), and 14% for high-risk patients following discharge (Wiseman et al., 2015). The incidence of SWD following harvesting of a saphenous vein graft for CABG was reportedly higher in patients that had been closed with staples as compared to sutures (Biancari & Tiozzo, 2010b). The findings of the Biancari and Tiozzo (2010) Cochrane review revealed the trials included in the systematic review were of sub-optimal methodological quality and were at risk of bias. Accordingly, the reviewers called for more stringent research to be carried out. Other studies have identified risk factors associated with infection following vascular surgery (Ott, Bange, Sohr, Teebken, & Mattner, 2013; Richet et al., 1991). Richet et al. (1991) reported that diabetes and previous vascular surgery were independent risk factors

for surgical wound infection following a vascular procedure (Richet et al., 1991). Ott et al., (2013) also identified independent risk predictors for surgical wound infection following vascular surgery (Ott et al., 2013). A four year retrospective cohort study conducted by Ott et al. (2013), in vascular surgery patients reported the odds ratios (OR) for wound infection risks among the following independent predictors: BMI great than 29 (OR 2.6), preoperative antibiotics (OR 2), immunosuppression (OR 2.8), and femoral grafting (OR 6.7).

### **2.3 Risk Factors for SWD**

Several authors across differing surgical disciplines have identified various factors associated with SWD such as: age, gender, ascites, jaundice, CVD, pneumonia, smoking and infection (Baskett, MacDougall, & Ross, 1999; Floros et al., 2011; Khan, Irshad, & Chaudhary, 2004; Schimmer et al., 2008; Sharma et al., 2009; van Ramshorst et al., 2010; Webster, Neumayer, Smout, Horn, Daley, Henderson, & Khuri, 2003). Some researchers have sought to identify associations between patient comorbidities and SWD across specific surgical domains. Van Ramshorst et al. (2010) and Webster et al. (2003) identified a suite of patient comorbidities associated with abdominal SWD. Webster et al. (2003) ranked the level of identified predisposing factors and developed a prognostic risk model for surgical patients.

Van Ramshorst et al. (2010) conducted a retrospective medical note audit of 1,452 patients and used a logistic regression analysis to determine independent risk factors associated with SWD following abdominal surgery. Van Ramshorst et al.'s (2010) analysis revealed the following variables as independent predictors of SWD: age, gender, emergency admission, type of surgical procedure, ascites, chronic obstructive pulmonary disease (COPD), coughing and wound infection.



Cardiothoracic researchers have identified potential causes and risk factors for sternal wound infection which include: age, gender, obesity, COPD and procedure-related factors such as duration of surgery, use of bilateral mammary graft, and reoperation for control of bleeding (Careaga et al., 2006; Ridderstolpe et al., 2001; Ulicny & Hiratzka, 1991). Baskett et al. (2005) reported that COPD was the only variable that was identified as a risk factor for DSWI and they stated that strict adherence to perioperative aseptic technique, attention to haemostasis, and precise sternal closure combined can result in a low incidence of mediastinitis (Baskett et al., 1999). Floros et al. (2011) reported that diabetes and obesity are associated with an increased risk of DSWI. Similarly, other researchers reported that obesity and diabetes were associated risk factors for SWD following a cardiothoracic procedure (Floros et al., 2011; Salehi-Omran et al., 2007) (Table 2.4). Whilst each surgical domain may differ due to type of procedure and treatment of the specific disease condition, several patient related comorbid and lifestyle risk factors associated with SWD have been identified that share commonality across domains. Risk factors for SWD cross both physiological and mechanical sectors of the patient state.

Mechanical factors are the external factors that may impact on the occurrence of SWD following surgery and these include: skin tensile strength (Broughton et al 2006), previous surgery in the same anatomical location (Levenson, 1965; Lindstedt & Sandblom, 1975; Broughton et al., 2006) and prolonged ventilation (Salehi-Omran et al., 2007). The physiological aspects include the patient related characteristics that may impact on the patient's ability to recover and follow the normal healing trajectory after surgery and they include: smoking chronic disease such as diabetes, obesity, cardiovascular disease, peripheral arterial diseases and intra operative factors such as tissue oxygenation, body warming and postoperative events such as infection.

### **2.3.1. Smoking**

Smoking is well documented as a negative factor for wound healing and in particular, it is associated with the occurrence of wound complications following surgery and, delayed wound healing is reportedly higher in smokers than non-smokers (de Blacam et al., 2012; Jorgensen, Kallehave, Christensen, Siana, & Gottrup, 1998; Kean, 2010; Lind, Kramhoft, & Bodtker, 1991; Sorensen, 2012; Sorensen, Karlsmark, & Gottrup, 2003). Ridderstolpe et al. (2001) identified smoking as a significant factor associated with patients who had DSWI following cardiothoracic surgery. Other researchers have demonstrated that reduced tissue oxygenation associated with smoking has a detrimental effect on the reparative cellular processes during healing and on neutrophil defence in the presence of pathogens (Hunt & Pai, 1972; Jorgensen et al., 1998). Furthermore, other research has demonstrated that the cessation of smoking prior to surgery results in improved healing outcomes with fewer wound complications when compared to patients who continue to smoke (Sorensen, 2012; Sorensen et al., 2003).

### **2.3.2. Diabetes**

Diabetes mellitus (DM), has a reported prevalence of 7% in Australian society (Tapp et al., 2003) and is estimated to affect over 1.8 million Australians (Whiting, Guariguata, Weil, & Shaw, 2011). Diabetes affects over 284 million people worldwide and this figure is expected to reach over 438 million by 2030 (Whiting et al., 2011). Persons with DM are at risk for impaired wound healing due the impact of diabetes on the metabolic and inflammatory pathways (Quinton, Lazzarini, Boyle, Russell, & Armstrong, 2015; Stotts, 2007). Glucose control is required for normal wound healing and in the case of patients with diabetes, hyperglycaemia can impair the healing process through interference with leukocyte function (Bagdade, Root, & Bulger, 1974; Nolan, Beaty, & Bagdade, 1978). It is now widely

recognised that the metabolic vascular and inflammatory complications that are associated with diabetes contribute to delayed wound healing (Falanga, 2005), and are also linked with impaired extracellular matrix expression, particularly in the case of chronic wounds (Loots et al., 1998), including impaired re-epithelisation and inhibited angiogenesis (Duraismy et al., 2001). These intrinsic factors place the patient at a distinct disadvantage for normal wound healing due to the reduced ability of the patient's physiology to cope with the reparative process after surgery.

Glucose control is also considered to be a risk factor associated with SSI, and several authors have demonstrated that glycaemic control is crucial during the pre-, intra- and postoperative period for optimal wound outcomes and reduced risk of infection (Kao & Phatak, 2013; Martindale & Deveney, 2013; Streeter, 2006). It should be recognised that patients undergoing major surgery may experience preoperative hyperglycaemia whether they are insulin-resistant or diabetic. In light of this and the current physiological relationship between both pre- and postoperative glucose levels and wound healing, it is critical that surgical patients be evaluated preoperatively and monitored for optimal glycaemic control, this being a key feature of the Enhanced Recovery After Surgery (ERAS) protocol (Li, Jin, Min, Liu, & Liu, 2017; Lv, Shao, & Zhou, 2012; Varadhan et al., 2010).

### **2.3.3. Obesity**

The clinical definition for obesity is a BMI greater than  $30\text{kg/m}^2$ , while severe obesity is defined as BMI greater than  $35\text{kg/m}^2$ , and morbid obesity as BMI greater than  $40\text{kg/m}^2$  (Encinosa, Bernard, Chen, & Steiner, 2006). Obesity is a global issue, and current estimates of the obesity rate are close to 13% of the world's population, which is equivalent to 1.9 billion adults; while the number of children worldwide under the age of five who are reportedly obese is 42 million (Ng et al., 2014). This global pandemic contributes to the

ensuing medical complications associated with obesity such as CVD, diabetes, musculoskeletal disorders and some cancers (Williams et al., 2009). Obesity or a BMI over 30kg/m<sup>2</sup> is a frequently reported significant risk factor associated with infection following surgery (de Blacam et al., 2012; Ridderstolpe et al., 2001; Salehi Omran et al., 2007; Schimmer et al., 2008; Sharma et al., 2009). Patients determined as morbidly obese (BMI greater than 40kg/m<sup>2</sup>) are considered to be at risk of post-surgical wound complications compared to those who are not classified as morbidly obese (Sood et al., 2015). Furthermore, patients undergoing bariatric surgery are considered to be at a higher risk of post-discharge complications such as infection or wound breakdown, due to the stress impact of high BMI on the body and are often readmitted following these complications (Chen, Stem, Schweitzer, Magnuson, & Lidor, 2015) including SWD.

#### **2.3.4. Body Temperature and Tissue Oxygenation**

It has been established in animal and human studies that there is a relationship between body warming and the occurrence of SSI following surgery, namely that a reduction in core body temperature results in an increased risk of postoperative infection (Johnson, 1971; Kurz, Sessler, & Lenhardt, 1996; Leaper, 2010b; Sheffield, Sessler, & Hunt, 1994). Surgical procedures occur in a cooler environment and often involve the injection of unwarmed fluids. Although this may not fully contribute to reduction in body temperature, often hypothermia is typical of unwarmed patients due to the failure of thermoregulatory defences in the operating room setting (Sessler, 2008). Perioperative hypothermia, a reduction in the core body temperature below 36 degrees Celsius or 96.8 Fahrenheit, is one of the most common risk factors for perioperative complications and SSI (Esnaola & Cole, 2011; Hopf, Hunt, West, Blomquist, Goodson, Jensen, Jonsson, Paty, Rabkin, Upton, von Smitten, et al., 1997; Seamon et al., 2012).

Several studies have demonstrated that mild perioperative hypothermia may promote infection by facilitation of thermoregulatory vasoconstriction, with a resultant decrease in subcutaneous oxygenation (Hopf, Hunt, West, Blomquist, Goodson, Jensen, Jonsson, Paty, Rabkin, Upton, & von Smitten, 1997; Kumar, Wong, Melling, & Leaper, 2005; Wong, Kumar, Bohra, Whetter, & Leaper, 2007). Melling et al. (2001) reported the findings of a randomised control trial which investigated the effects of postoperative warming on wound infection rates, and demonstrated a highly significant difference between the warmed and non-warmed groups ( $p=0.001$ ) (Melling, Ali, Scott, & Leaper, 2001). Subsequent research by Melling and Leaper (2006) demonstrated that patients who received warming for 2 hours postoperatively had significantly reduced pain scores compared to those who received 7 days of postoperative warming. Current surgical practices include pre and intraoperative warming as standard practice, as is well evidenced and reported in the WHO's *Global Guidelines on Prevention of Surgical Site Infection* (WHO 2016).

### **2.3.5. Skin Tensile Strength**

It has been proposed by researchers that skin tensile strength following closure of a surgical incision will never regain optimal strength, but attain 80% of original strength (Broughton, Janis, & Attinger, 2006; Levenson, 1965). Skin tensile strength is defined by Broughton et al. (2006) as a measurement of load capacity per unit. Peak tensile strength in human tissue is achieved approximately 60 days after injury following surgery (Postlethwait, Willigan, & Ulin, 1975). Collagen fibres are largely responsible for the tensile strength of the skin. Scars and reduced skin tensile strength resulting from surgical incisions may be among the major factors that contribute to postoperative dehiscence (Agarwal, 2011). This may be problematic when a subsequent incision is made in, or close proximity to a previous surgical incision. The reduced ability of collagen fibres to resist lateral tension, due to the reduced ability to form crosslinks following surgery, may impact the potential for optimal healing,

(Agarwal, 2011; Broughton et al., 2006). The use of abdominal binders to support and reduce the lateral tension on the incision line has been reported to reduce the occurrence of postoperative complications following laparotomies and has improved patient recovery (Zhang et al., 2016).

Over the past decade, postoperative incision management has improved with the use of advanced wound therapies such as negative pressure wound therapy (NPWT). Several quasi-RCTs report a reduction in postoperative complications such as SSI, which they attribute to the reduction of the lateral tension on the incision, and increased tissue perfusion (Banwell, Holten, & Martin, 1998; Bovill et al., 2008; Stannard, Gabriel, & Lehner, 2012; Stannard et al., 2006). However, large powered level 1 studies which provide irrefutable evidence for the prevention of SWD following surgery when utilising NPWT are required as stated in several systematic reviews and meta-analyses (Ingargiola, Daniali, & Lee, 2013; Sandy-Hodgetts, & Watts, 2015; Webster, Scuffham, Stankiewicz, & Chaboyer, 2014) and more recently in the World Health Organisation Guidelines on prevention of surgical site infection (WHO 2017).

### **2.3.6. Surgical Site Infection**

The precursor to SWD is often reported as SSI (Khan, Irshad, Chaudhary., 2004). It is reported that the most common pathogens associated with superficial SSI are *Staphylococcus aureus* and other flora common to the skin (Leaper, 2010). Often postoperative complications such as SSI and SWD occur between day 9 and 14 in the postoperative period, and these wounds are primarily managed in the community. The limited published data on the costs associated with the clinical management of this wound type has been noted by other authors, who attribute difficulties encountered may be due to a lack of standardised reporting methodology, classification, and diligent post-discharge surveillance (Leaper et al., 2013;

Leaper, 2010a; Sandy-Hodgetts, Leslie, Lewin, Hendrie, & Carville., 2016; Tanner et al., 2009).

Considering the concurrent association between SSI and SWD, it is possible that some clinicians, medical administrators and clinical coders record SWD as SSI without microbiological confirmation that infection is present. Hence, the nature and type of SSI remains undefined and especially more so if one uses the SSI term without further description (superficial or deep). When conducting analysis of the literature, it was difficult to identify the percentage of cases that are SWD of a non-microbial nature. Despite this reporting conundrum, the published costs associated with SSI may be considered a high cost burden to the acute care setting.

In the UK, SSI constitutes 20% of all hospital health care-associated infections (HCAI) and it is reported that at least 5% of patients will develop an SSI following surgery (Leaper et al., 2004). The concomitant economic costs are in part due to prolonged hospital stays or readmission costs, which in the UK are reportedly just under £90,000 per patient in the year 2000 (Reilly et al., 2001). In the USA, the estimated costs of SSI reportedly are US\$10 billion annually in direct and indirect medical costs (Urban, 2006). Furthermore, Urban et al. (2006) identified that the cost of superficial SSIs amounted to US\$400 per case, whereas DSWI cases could cost US \$30,000 per patient (Urban, 2006). In Europe it has been determined that the costs attributable to SSI range from €1.47 to €9.1 billion (Leaper, Reilly, Petrosillo, Geiss, Torres, & Berger, 2004). Leaper et al. (2004) suggest this considerable variance is due to inconsistencies in the data collection methods, surveillance criteria and variations in the surgical procedures. In Australia, the cost of SSI reportedly is AUD \$260 million per year (McLaws et al., 1988; McLaws & Taylor, 2003). However, the implicit costs associated with delays in healing and reduced quality of life for the patient, family, and the wider community are difficult to ascertain.

An Australian report published in 2003 by the Australian Commission into Safety and Quality in Health Care (ACSQH) stated that between 2% and 13% of patients in a hospital environment suffer from SSI (ACSQH, 2003). In the Australian context, the Hospital Infection Standardised Surveillance Program reviewed 10 hospitals in New South Wales and reported SSI rates following CABG to be 2.1% (McLaws & Taylor, 2003) (Table 2.4). These infections resulted in an estimated additional cost of AUD \$5,892 per patient for an extended length of stay of an average of 12 days. Wound infection following colorectal surgery was reportedly 12.7% and led to an extended patient stay of 16 days on average, with a cost of AUD \$8,066 per patient (McLaws & Taylor, 2003). Orthopaedic procedures such as a total hip replacement had a reported infection rate of 2%, an extended patient stay of seven days, and additional costs of \$3,767 allocated per patient (McLaws & Taylor, 2003). The SSI rates in TKR surgery were reported to be 9.8%, with an extended stay of 13.5 days, and resulted in a total cost of AUD \$6,520 per patient (McLaws & Taylor, 2003).

Table 2.3 Reported Rates of SSI in New South Wales (2000)

Surgical Domain	Surgical Procedure	Rate of SSI
Cardiac	Coronary artery bypass graft	2.1%
Obstetrics	Caesarean section	2.4%
Vascular	Abdominal aortic aneurysm repair	7.3%
Orthopaedics	Hip prosthesis	2%
	Knee prosthesis	9.8%
Colorectal	Procedure not specified	12.7%

Note. Adapted from *The Hospital Infection Standardised Surveillance Programme*. McLaws, M. & Taylor, P. (2003).

However, this data was obtained from the acute care setting, not the community setting, and as such, it is possible that the findings outlined above could be an underestimate of the total cost of SSI in Australia. A more recently published systematic review on the burden of healthcare associated infections (HAI) in Australian hospitals, has identified up to 60% of infections may not be reported and an associated dearth of peer reviewed literature



reporting the incidence of HAI's in Australia (Mitchell, Shaban, MacBeth, Wood & Russo 2017).

A SWD is a significant problem for patients, clinicians and the wider community. Management of these wound complications poses a continuous challenge. This review was carried out to identify studies that described and validated predisposing factors that may lead to post-surgical wound dehiscence. It is clear there is a lack of clarity or consensus in the definition for SWD, as SSI does not translate directly into wound dehiscence.

### **2.3.7. Risk Assessment Tools**

Risk assessment tools can provide the clinician with a method for identifying and mitigating a pre-determined level of risk within a specific setting. Various methods have been used to develop and validate risk tools. The work of Wasson et al. (1985) specifically suggests that a good prediction rule includes a clearly defined outcome not subject to selection bias, exact definitions of predictor variables, and predictors that are feasible and relevant (Wasson, Sox, Neff, & Goldman, 1985). Validation of the risk index is also an important component prior to extensive clinical application. Hence the limitations associated with the incorporation or clinical translation of Webster et al (2006) and Van Ramshorst et al (2010) models into this study. According to Haley et al. (1991), risk indices should be developed through multivariate analysis from a pool of variables that represent the most important underlying risks. This should be inclusive of potential risk factors collected and analysed, and formulated into a simple scale to test the predictive ability of the index through further validation.

There are numerous risk indices for SSI and they can be applied to the pre, intra and postoperative management of patients (Augenstein et al., 2015 ; Berger et al., 2013; Fisher, Bengero, Clapp, & Burgess, 2010; Fowler et al., 2005; Ivanov et al., 2006; Kohli et al., 2003;

Liang, Goodenough, Martindale, Roth, & Kao, 2015; Mangram, 1999; Nashef et al., 2002; Prytherch et al., 1998) and are listed in Table 2.3. These risk tools are primarily used in the cardiothoracic surgery domain, whilst the CeDAR (Augenstien 2015) and POSSUM (Prytherch 1998) tools are for general surgery (Table 2.3). Buja et al. (2012) discussed in a systematic review, several risk scales for the prediction of DSWI. Buja et al. (2012) described six different scales available for clinicians to use (EuroSCORE, Thoracic Surgeons Risk Score, Alfred Hospital Risk Index, Society of Thoracic Surgeons Risk Score and the Northern New England Cardiovascular Diseases Study Group Risk Score) of which, the factors could be classified into four categories; demographic, behavioural, baseline clinical conditions and operative risk factors. Buja et al. (2012) further commented that ease of use and application of the scales varied. However, there appears to be no risk tool yet inclusive of non-microbial factors related to SWD, specifically predicting SWD and not infection.

Most currently available risk assessment tools, models or indices collect operative data to determine the patient's level of risk for a complication such as SSI whilst in theatre or during postoperative recovery. While some of these tools cover factors that may be indicators of pre-existing comorbidities, for example the American Society of Anaesthesiologists (ASA) classification based on physical status and the New York Heart Association (NYHA) classification, these are primarily procedure-specific indicators that may not be reflective of the whole-patient condition. Hence a SWD risk tool incorporating intrinsic and extrinsic factors in the patient's journey maybe helpful, to gain preoperative understanding of the level of risk for SWD. This risk level may be used either to manage, modify or to mitigate non-modifiable risk factors for the patient's benefit.

Table 2.4 Risk Tools for Prediction of Surgical Site Infection Following Surgery

Risk tool	Clinical utility phase	Variables	Surgical area
Fowler Risk Index (Fowler et al., 2005)	Peri-operative	Age Caucasian BMI <40 30-40 Smoker Ejection fraction<=30 35-50 Hypcholesterolemia Hypertension Cerebral accident Chronic lung disease, mild, moderate, severe Immunosuppressive therapy PVD Cerebrovascular disease Previous CABG Diabetes Renal failure dialysis No dialysis Congestive heart failure (any) NYHA Class. IV Cardiogenic shock Anticoagulants Previous myocardial infarction Moderate or severe valvular insufficiency Valve surgery (any) Other procedures Single: non-cardiac (any) Single: Cardiac device Single: Cardiac device repair Multiple Distal anastomoses equal to 3 or 2 Perfusion time <300 (versus off pump) 200-300 (versus off pump) 100-200 (versus off pump) 1-100 (versus off pump) Emergent or urgent case (versus elective) Urgent case (versus elective) Unplanned CABG, angioplasty, or coronary artery stent placement within 6 hours of surgery Internal mammary artery used as a graft Primary incision: full sternotomy Balloon pump inserted peri-operatively or intraoperatively.	Cardiothoracic

Toronto Risk Score for Adverse Events (Ivanov et al., 2006)	Pre, intra and post operative	Age, gender, left ventricle grade (1-4), urgent, emergency, <1-month redo CABG, renal insufficiency, diabetes, PVD, COPD, postoperative length of stay, intensive care.	Cardiothoracic
European System for Cardiac Operative Risk Evaluation (EuroSCORE) (Nashef et al., 2002)	Peri-operative	Age, gender, renal impairment, extracardiac arteriopathy, poor mobility, previous cardiac surgery, chronic lung disease, active endocarditis, critical preoperative state, diabetes on insulin, New York Heart Association (NYHA) Class., CCS Class. 4 anginas, LC function, recent myocardial infarction, pulmonary hypertension, urgency (elective, emergency, salvage), isolated CABG, single non-CABG, 2 procedures, 3 procedures, surgery on thoracic aorta.	Cardiothoracic
CeDAR (Smartphone App) Carolinas Equation Determining Associated Risk following Ventral Hernia Repair (Augenstein et al., 2015)	Peri-operative	Tobacco use, active infection at surgery, previous VHR, uncontrolled diabetes, enterotomy/stoma, BMI<26kg/m2	General/colorectal Has functionality to calculate charges for variable hospital costs in USD
Ventral Hernia Repair Wound Risk Tool (VHRWRT) (Fischer, Wink, Tuggle, Nelson, & Kovach; 2015)	Peri-operative	Smoking, ASA score, surgery classification (clean, clean contaminated, contaminated, dirty, dirty/infected), BMI, diabetes, history of COPD, low albumin, age, operative time, component separation, panniculectomy, dependent functional status, intra-abdominal procedure	General surgery
Physiological and Operative Severity Score for Enumeration of Mortality and Morbidity (POSSUM) (Prytherch et al., 1998)	Peri-operative	Age Cardiac history Blood pressure (BP) Pulse rate Glasgow Coma Score Haemoglobin.	General surgery
Smartphone App: Cardiff Surgical Risk Score		White cell count Urea* K+* Na+* Electrocardiogram Operative severity Multiple procedures Total blood loss Peritoneal soiling Presence of malignancy Mode of surgery.	

Note.\*From venous blood sampling

## 2.4. Conclusion

Identified intrinsic risk factors such as uncontrolled patient comorbidities may contribute to delayed healing and subsequent dehiscence. Risk factors that were found to be commonly reported across different surgical procedures were age, high BMI, and diabetes. Other associated risk factors for SWD that span surgical domains (cardiothoracic, abdominal, orthopaedic, vascular) include: prolonged ventilator use, duration of procedure, perioperative warming, and impaired tissue oxygenation. In cardiothoracic surgery in particular, the focus has been primarily on identification of SSI risk and a number of risk tools have been developed, such as the Toronto Risk Index (Ivanov et al., 2006), EuroSCORE (Nashef et al., 2002), the NNIS System Risk Index (Russo & Spelman, 2002), and the Sternal Wound Infection Prediction Scale-R (SWIPS and SWIPS-R) (Hussey, Leeper, & Hynan, 1998). In general surgery, the advent of smart phone applications such as Carolinas Equation Determining Associated Risk following Ventral Hernia Repair (CeDAR) (Augenstein et al., 2015) and the Cardiff Risk Score (Prytherch et al., 1998) have application in the preoperative environment as they are specifically designed to determine the risk level of the patient for ventral hernia repair and general surgery risk respectively. Although similar risk factors were found to exist across all surgical groups for SWD, further analysis is required to demonstrate causal links, if any, for the identification of at-risk patients. Equally important is the need to identify the causes of wound dehiscence among cases.

The literature review highlighted a lack of consistency in the reporting of SWD. Further to this shortcoming was the absence of a consensus on definition for SWD used by clinicians. Moreover, there is a lack of a grading system for SWD that describes the severity of the wound breakdown. Although the CDC definition of deep SSI describes the clinical

signs and symptoms of the wound breakdown, there is a gap of descriptive parameters of the SWD characteristics such as; depth, length, and surface area of the dehisced wound, as well as other quantifiable measures that clinicians use to assess and inform the clinical management of the patient's wound. It would therefore appear beneficial to work towards a global consensus on definition and grading of SWD.

## **Chapter Three**

### **Conceptual Framework**

#### **Introduction**

A conceptual framework was developed to explain the current understanding of potential risk factors specifically related to SWD and more generally to wound healing following surgery, and to guide the direction of this research. This approach was taken to describe the interconnectedness of risk factors, as this was not forthcoming in the literature review, even though the evidence for physiological and mechanical factors in delayed or failed wound healing following surgery was extensive. Wound healing (complete and sustained wound closure) is the desired outcome however; the potential for SWD is a risk during the patient intraoperative and postoperative journey. Identification of risk factors prior to surgery may allow the clinician to implement preventative measures to assist in optimising patient outcomes.

This conceptual framework presents a patient-centric view and depicts the interdependence and dependence of potential risk factors that may influence the patient's risk profile during his/her surgical journey. The purpose of the conceptual framework is to provide a basis for the research question, and describe the interrelationships among concepts. Furthermore, the framework acts as a reference point for analysis. The conceptual framework identifies factors known to influence wound dehiscence and delayed healing. The use of concept mapping to visually represent the content of the subject and represent the spatial relationships between variables, assists in the creation of a flow for the process of knowledge acquisition (Jabareen, 2009).

Furthermore, the conceptual framework is constructed using symbols and links to demonstrate specific relationships within the visual schema. The framework also provides the researcher with a useful method of organising information and can create further lines of enquiry whilst providing an opportunity to gain knowledge on the subject matter. The framework (Figure 3.1) below presents the patient as the central focus and shows the interdependency as well as the dependency of the mechanical and physiological factors that can influence whether a patient may have a predisposition for SWD. These factors more often than not are linked to risk but any one factor has the potential to be an independent contributor to SWD.

Incisional wound healing by primary intention following surgery is assisted with the use of sutures, staples, glues, adhesive tape, wound dressings or NPWT. Failure of the wound to heal may be due to a number of reasons, from patient related physiological factors such as obesity (Chen et al 2015), diabetes (Streeter et al 2006), or poor nutrition (Stechmiller et al 2010), or mechanical reasons such as suture knot slippage, increased suture line tension, trauma or alterations in skin tensile strength near or on the incision line. Microbial organisms commonly associated with SSI include *Staphylococcus aureus* and other flora common to the skin (Leaper, 2010a). However, non-microbial causes for SWD such as trauma or fluid collections such as haematoma or seroma can predispose a patient to SWD (Figure 3.1).



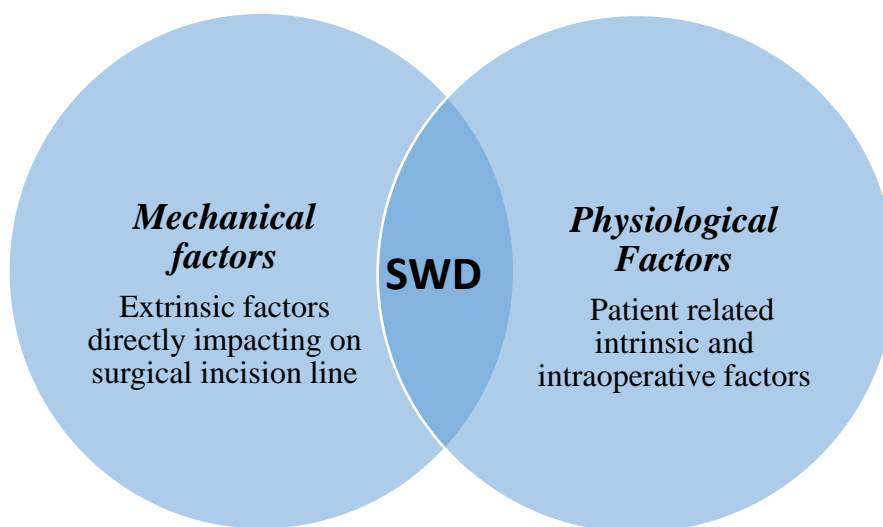


Figure 3.1. Venn diagram: Factors related to SWD

### **3.1. Physiological Factors**

The term ‘physiological factors’ refers to pre-existing patient comorbidities such as diabetes or high BMI (obesity), and physiological responses to known contributors to delayed wound healing, such as reduced tissue oxygenation and reduced core body temperature, as identified from the literature review (Table 3.1). Although the physiological factors such as comorbidities present in the preoperative period, they can also impact on the intra- and postoperative phases of the patient surgical journey. Several of these physiological factors, such as obesity and smoking, are well documented in relation to their impact on delayed wound healing. An example of this is the reported reduction of postoperative complication rates associated with smoking cessation prior to surgery (Durand, Berthelot, Cazorla, Farizon, & Lucht, 2013; Moller, Villebro, Pedersen, & Tonnesen, 2002; Sorensen, 2012).

Numerous authors have identified relationships between an increase in wound complications and compromised physiological responses such as reduced tissue oxygenation

(Gottrup, 2004b; Hunt & Pai, 1972; Leaper, 2007; Munoz-Price, Sands, & Lubarsky, 2013; Thibon et al., 2012); the effect of body warming during surgery (Leaper, 2006, 2007; Melling et al., 2001; Melling & Leaper, 2006); the impact of obesity (Williams et al., 2009), and hypoglycaemia (Jeon, Furuya, Berman, & Larson, 2012; Kao & Phatak, 2013). In addition, other known factors that delay healing, such as smoking, are intimately connected with the physiological responses to wound healing and have been described in Chapter Two. Causal links between the preoperative patient state and wound dehiscence remain to be clearly determined. For the purposes of this framework, however, factors that were identified in the literature as contributors to delayed post-surgery wound healing are described below (Table 3.1).

Table 3.1. Physiological Factors Associated with Delayed Wound Healing

Factors	Citations
Obesity	Chen et al., 2015; Sood et al., 2015; Williams et al., 2009.
Diabetes	Borger et al., 1998; Streeter, 2006.
Smoking	Gottrup, 1989; Kean, 2010; Moller et al., 2002; Sharma et al., 2009; Siana, Rex, & Sorensen, 2012; Sorensen et al., 2009.
Tissue oxygenation	Hopf, Hunt, West, Blomquist, Goodson, Jensen, Jonsson, Paty, Rabkin, Upton, & von Smitten, 1997; Gottrup, 2004; Hunt & Pai, 1972; Leaper, et al., 2007; Munoz-Price et al., 2013; Thibon et al., 2012.
Body warming	Kumar et al., 2005; Leaper, 2006, 2007; Melling et al., 2001; Wong et al., 2007.
Nutrition	Agarwal, 2011; Shepherd, 2003; Stechmiller, 2010; Todorovic, 2002
Time procedure (<2 hrs in theatre)	Salehi-Omran et al., 2007; Webster, Neumayer, Smout, Horn, Daley, Henderson, & Khuri, 2003.
Cardiopulmonary disease	Baskett et al., 1999; Celik, Kirbas, Gurer, Yildiz, & Isik, 2011; Gao et al., 2003; Ridderstolpe et al., 2001; van Ramshorst et al., 2010; Webster et al., 2003.
Cardiovascular disease	Heikkinen et al., 2005.
Peripheral vascular disease	Paletta et al., 2000; Ridderstolpe et al., 2001.
Superficial surgical site infection	Leaper et al., 2010a; Tanner et al., 2009; van Ramshorst et al., 2010; Webster, Neumayer, Smout, Horn, Daley, Henderson, & Khuri, 2003.

### 3.2. Mechanical factors

Similarly, mechanical factors such as suture breakage, incisional trauma due to excessive coughing or vomiting potentially influence the occurrence of SWD (van Ramshorst

et al., 2010). Reduced skin tensile strength due to scarring may be a contributing factor in postoperative dehiscence, especially if an incision is made in, or close to, a previous incision. Furthermore, compromised dermal tensile strength may result due to reduced collagen deposition and synthesis following an incision, related to factors such as reduced tissue oxygenation (Gottrup, 2004a), poor nutrition (Stechmiller, 2010), smoking (Jorgensen et al., 1998), and diabetes (Black et al., 2003).

Mechanical factors as described in this conceptual framework (Table 3.2) may be divided into two groups, intraoperative and postoperative. The intraoperative group includes factors such as wound closure methods (interrupted or continuous closure, sutures or staples), incision closure performed by a senior or junior surgeon, and the class of surgery (clean, dirty or contaminated). Postoperative factors include trauma from a fall, excessive coughing or vomiting (which may place excess strain on suture lines).

Table 3.2. Mechanical Factors Associated with Delayed Wound Healing

Factors	References
Clean, clean-contaminated, contaminated, dirty surgery	Culver et al., 1991; Lilani, Jangale, Chowdhary, & Daver, 2005; Ortega et al., 2012.
Senior or junior surgeon closure	Hadar et al., 2011; Webster et al., 2003.
Scarring from previous surgery	Levenson, 1965; Lindstedt & Sandblom, 1975; Broughton et al., 2006.
Method of closure	Basha et al., 2010; Biancari & Tiozzo, 2010; Clay, Walsh, & Walsh, 2011; Smith, 2010; Tekumit et al., 2009; Tuuli et al., 2011; Wallace, Hernandez, Schlaerth, Nalick, & Morrow, 1980.
Haematoma and/or seroma	Cavadas & Baena-Montilla, 1995; Hoefler, DuBois, Ostrow, & Silver, 1990; Sakkary, 2012; Schwabegger, Ninkovic, Brenner, & Anderl, 1997; Srivastava, Basu, & Shukla, 2012.
Excessive coughing and/or vomiting	van Ramshorst et al., 2010.

### **3.3. The Patient Surgical Journey**

The aetiology of SWD is complex, with both physiological and mechanical factors affecting the likelihood of a patient acquiring SWD. The conceptual framework hypothesises that wound dehiscence can be explained theoretically by the following groups of factors: pre-existing comorbidities and lifestyle factors, intraoperative and postoperative factors (Figure 3.1). The patient journey begins some time before the surgical experience, often with health management of pre-existing comorbidities. While the surgical procedure may be only a brief event during a patient's lifetime, surgery has a long-lasting impact on the patient's recovery and rehabilitation especially when complicated by SWD. The patient journey in relation to factors that can lead to SWD is depicted in the conceptual framework below as consisting of three phases: preoperative, intraoperative and postoperative.

### Conceptual Framework for Surgical Wound Dehiscence

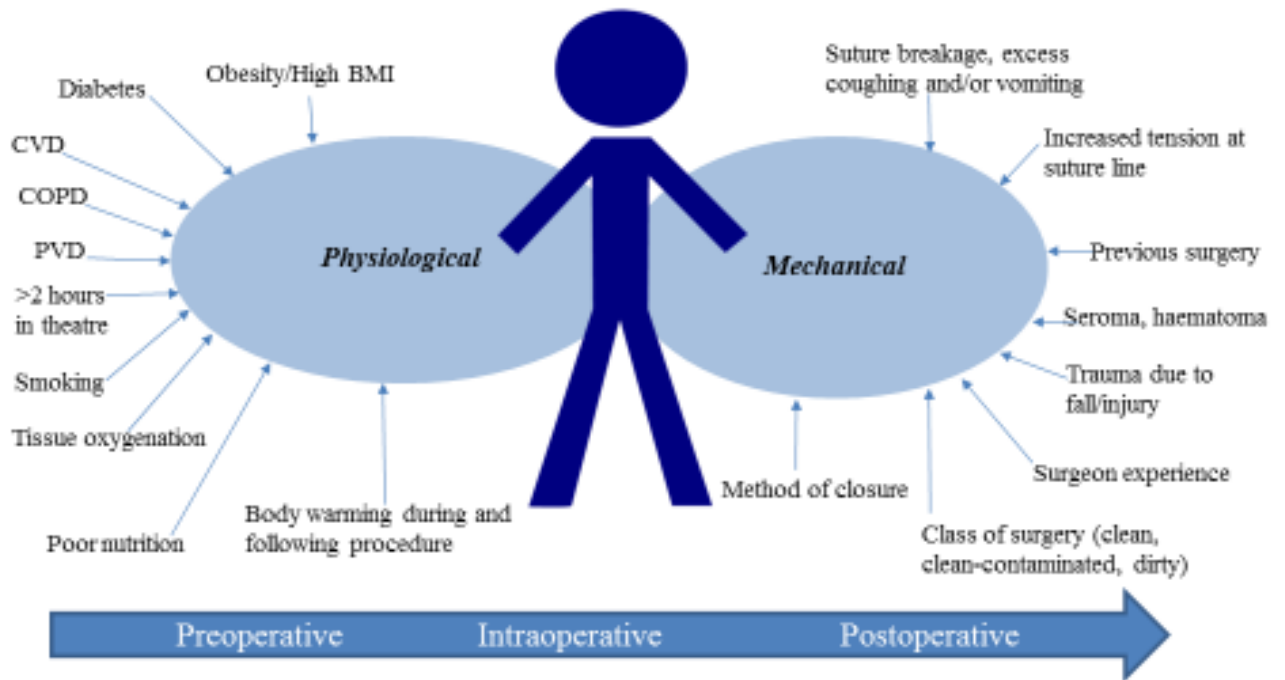


Figure 3.2 Conceptual framework for surgical wound dehiscence

The interconnectedness of the physiological and mechanical factors is problematic in the occurrence of SWD if both factors are present in the patient: for example, both obesity and scarring from previous surgery. While the intra and postoperative factors dominate the patient's post-surgical outcome, the physiological variables contribute to the patient's overall healing capacity.

### **3.4. Conclusion**

The conceptual framework highlights the physiological and mechanical risk factors and it is proposed that a combination of both, such as obesity and reduced skin tensile strength due to previous surgery, can compound the likelihood of a SWD. However, it is also anticipated that early intervention for control of predisposing physiological factors could reduce the risk associated with mechanical factors. For example, preoperative weight loss should reduce the stress on an incision associated with obesity. Furthermore, preoperative risk management of patients is projected to have a subsequent outcome on sustained wound healing during the postoperative period. Therefore, preoperative risk profiling of patients may predict the need for preventative interventions, as such, the development of a preoperative risk assessment tool became the prime focus for this study. The interconnectedness of the physiological and mechanical factors associated with SWD as reported in the literature, and further illustrated through the development of the conceptual framework, led to this particular design of the risk assessment tool.

## **Chapter Four**

### **Methods and Results: Two Retrospective Case Control Studies and a Descriptive Study to Determine Costs and Times to Wound Healing**

#### **Introduction**

The methodology and results for the four separate studies which were conducted are presented in Chapters Four and Five. Chapter Four presents the methodology and results for the two retrospective case-control studies, which led to the development and internal validation of a surgical wound dehiscence risk assessment tool. The methodology and results of a retrospective descriptive study which was conducted to determine the time and costs to healing of patients with dehisced wounds in the community are also presented. Chapter Five will describe the methodology and present the results for the subsequent prospective clinical validation of the risk assessment tool. Figure 4.1 outlines the research processes that are discussed in Chapters Four and Five.



**SWDRAT Development and Internal Validation  
(Chapter 4)**

- Conducted a case control study based on community nursing patients referred with a SWD – *Perth cohort*
- Conducted the following analyses: descriptive, univariate, cross-tabulation of variables, binary logistic regression
- Conducted analysis to determine time and cost of healing in the Perth cohort
- Drafted SWDRAT using *B* coefficients as the risk score of the variables
- Conducted an internal validation of the SWDRAT from a 2<sup>nd</sup> case-control sample derived from a Melbourne metropolitan hospital – *Melbourne cohort*
- Tested the SWDRAT predictive power, through Receiver Operator Curve (ROC) analysis.

**Prospective Clinical Validation and inter-rater  
Reliability of SWDRAT (Chapter 5)**

- Enrolled patients undergoing colorectal surgery
- Determined descriptive statistics and risk score of participants
- Tested inter-rater reliability of the SWDRAT
- Followed up participants day 3, 14 and 30 postoperatively
- Conducted ROC analysis on prospective sample
- Conducted ROC analysis on combined datasets.

Figure 4.1. SWDRAT development and internal validation

#### **4.1 Case control and descriptive study objectives**

The specific objectives of that underpinned the three studies presented in Chapter 4 components were to:

1. Determine the number of patients who received treatment for SWD in a community nursing setting (CNS) during 2010-11 and describe the costs associated with wound management by the CNS.
2. Identify the pre, intra and postoperative variables associated with SWD.
3. Develop a SWD preoperative risk assessment tool – the draft SWDRAT.
4. Test the draft SWDRAT for predictive power and undertake a preliminary internal validation.
5. Determine the inter-rater reliability of the SWDRAT, and test the predictive power of the risk tool in a prospective series of surgical patients in the clinical setting.

#### **4.2. Ethical Considerations and Consenting Processes**

Several ethical issues were considered in order to conduct the research. The primary ethical issues in the first retrospective case-control study and tool development process included obtaining the informed consent of patients referred to the CNS with a SWD during the period 2010–2011. Further to this were the data security and privacy considerations.

A Patient Information Sheet and Consent Form (Appendix 1) was sent to the potential case patients (those with a SWD history who had been referred to the CNS during the study time period) by the research department of the CNS. The Patient Information Sheet invited patients to participate in the study and requested access to the patients' community and hospital medical records for the study purposes, and sought their consent to publish de-identified aggregate data. This study was conducted according to the National Health and Medical

Research Council (NHMRC) *Code of Conduct for Responsible Research* guidelines (NHMRC 2007), and the Guidelines approved under Section 95A of the Privacy Act (NHMRC 1988) to protect the participants' identity and information. Measures to maintain the confidentiality of participants included de-identification of participants in the master database; source documentation kept in a separate location (locked filing cabinet in a locked office) from the master database; and results reported in aggregate form only.

In accordance with the Curtin University Research Data and Primary Materials Policy, the data were stored in a purpose-built institutional research drive. The research drive is password and firewall protected and has external server back-up facilities. To conform to Curtin University's policy on data storage, records will be kept for 5 years and then destroyed. Paper documents will be shredded via a secure shredding system and electronic data will be destroyed through erasing of hard drives (Curtin University, 2015).

Ethics approval was granted by Curtin University Human Research Ethics Committee (HREC) to conduct the retrospective study (HREC59/2012) and the prospective clinical validation at the lead site (referred to as Site 2), (HREC60/2012) (Appendix 2). Ethics approval was granted by the CNS to access participants' medical records with their consent (HRECECP074). Ethics approval was also obtained from the hospital referred to as Site 1, and reciprocal ethics approval came from the hospitals listed in Figure 4 as Sites 2, 3, 4, 5, 6. Outlined below are the ethics approvals obtained and the retrospective approval numbers are presented in Figure 4.2. The prospective validation of the study was approved as an amendment to the original ethics approval.

Six metropolitan hospital sites were identified as the discharge hospitals for the SWD community nursing patients. Ethics approvals were requested from and granted by the six referral hospitals to conduct the first component of the project (HREC EC2012/30, HREC 2013-060, HREC 1202, HREC 344, HREC R12/397 and HREC 609), with a waiver of consent for

controls. The waiver of consent was requested and granted at the six sites because the study was considered by the ethics committee to be low risk. In addition, source data were retained at the study site, and access to, as well as, control of data were managed by the study site employees.

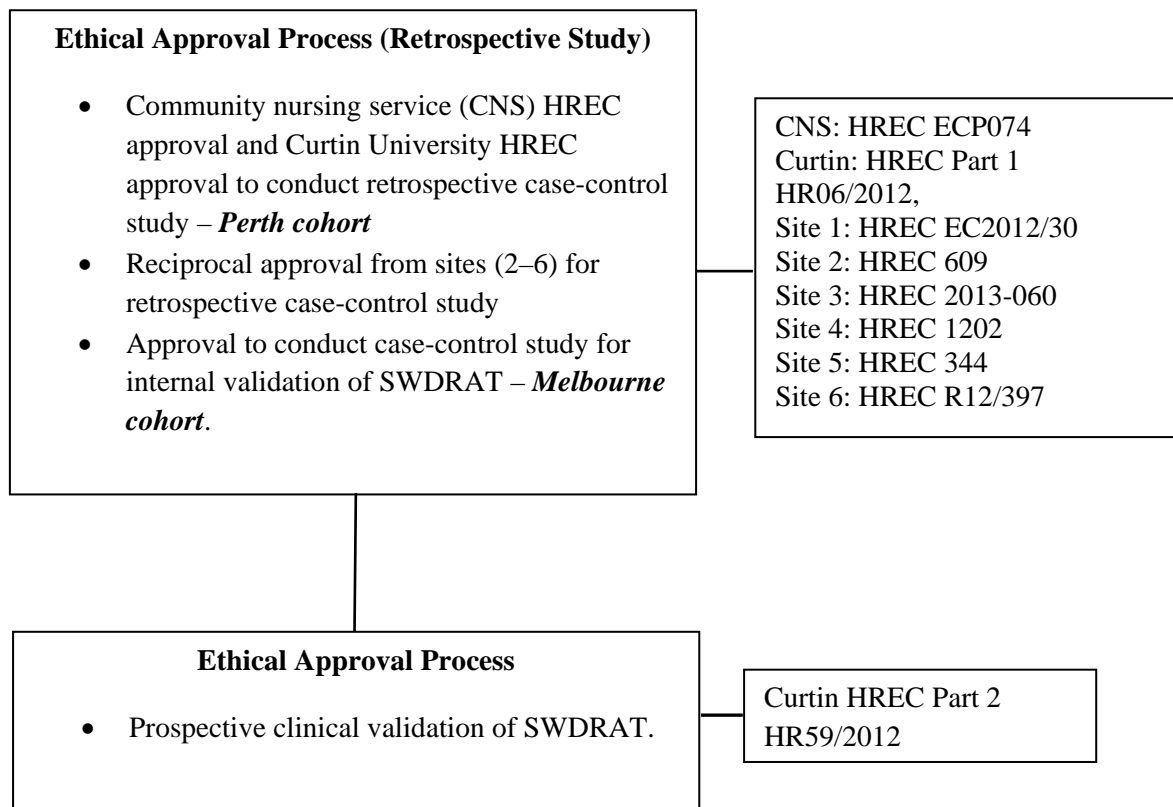


Figure 4.2. Human Research Ethics Committee approval process

#### 4.2.1. Ethical considerations: Retrospective case control study for internal validation of risk tool

Ethics approval was sought from a tertiary hospital in Melbourne to conduct the internal validation of the SWDRAT (HREC QA2014116). However, this component of the study was classified by the tertiary hospital HREC as a quality improvement project, as it dealt only with aggregated retrospective chart audit data. The researcher was granted ethics approval on a reciprocal basis to conduct the retrospective study.

#### **4.2.2. Ethical Considerations: Prospective Validation**

The main ethical issues for the prospective clinical validation described in Chapter Five were twofold: first was the need to seek the patient's informed consent to participate in the study and secondly, the need to maintain the confidentiality of the data. Prior to commencing the study, institutional ethics committee approval was granted from both the clinical site (HREC 609) and the supervising university (HREC 59/2012). To address the first ethical consideration, prior to their surgical procedure, patients were informed of the study and invited to participate during their preoperative consultation with the surgeon, after which written consent was obtained. An institutionally ethics-approved Patient Information Brochure and Consent Form (Appendix 2) was used to inform potential participants of the study and to seek consent from the patient to participate in the study. To address the ethical considerations concerning protection of data, several steps were implemented in the protocol to secure data. Only study personnel (clinical nurse consultant/supervisor and researcher) were permitted to use the data collection sheet (DCS).

Source documentation was stored in a locked filing cabinet in a locked office at the study site. Participant information was then de-identified and electronically stored in a purpose-built SPSS (Statistical Package for the Social Sciences) (IBM® SPSS® Version 20) database. The source documentation and the database were stored separately. In accordance with Curtin University's Data Management and Materials Policy (Curtin University, 2015), the database was kept in a locked office at Curtin University, firewall and password protected, with only study personnel permitted to access the information. Data is to be stored for five years and then destroyed. This was also according to the HREC conditions of approval and as per the study protocol.

### **4.3. Methodology: Retrospective Case Control Study Perth Cohort**

#### **4.3.1. Sample and Population**

The SWD study sample was derived from 416 patients who were referred to the CNS following discharge from Perth metropolitan hospitals, for treatment of a postoperative wound dehiscence during the period January 2010–2011. This group is referred to as the Perth cohort. The period from 2010–2011 in the CNS electronic database was searched by the organisation’s research department for patients coded as a SWD, using the International Classification of Diseases (ICD-10) coding T81.3. Following this initial screening, patients were mailed a Patient Information Sheet (Appendix 1) which outlined the aims and objectives of the study and extended an invitation to participate in the study. Patients who agreed to participate were asked to complete and return the accompanying Consent Form. The exclusion and inclusion criteria are outlined in Table 4.1. Excluded from this study were patients who had undergone a caesarean section as these were considered a discrete group with specific conditions outside the parameters of this study. Patients whom the CNS was unable to contact to establish their consent to participate were not included in the study.

The researcher and an expert wound management nurse employed by the CNS organisation, reviewed the consenting and available community patient records and excluded any from the sample that had been wrongly recorded as a SWD. Patients who were found on audit of their hospital records to have undergone an emergency surgical procedure were also excluded, as emergency admission is a well-established independent risk factor for SWD (Olsen et al., 2008; van Ramshorst et al., 2010; Waqar et al., 2005; Webster, Neumayer, Smout, Horn, Daley, Henderson, & Khuri, 2003) and if included, could have introduced a level of bias for other variables under consideration. Table 4.1 below summarises the study inclusion and exclusion criteria.

Table 4.1 Study Inclusion and Exclusion Criteria

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> <li>• Patient has reported SWD as per study definition</li> <li>• 18+ years</li> <li>• Consenting patients</li> </ul>	<ul style="list-style-type: none"> <li>• Under 18 years of age</li> <li>• Emergency admissions</li> <li>• C-section patients</li> <li>• No wound dehiscence recorded</li> </ul>

Six hospitals were identified as the sites where the SWD patients' surgeries were performed prior to referral to the CNS. Each referring hospital's theatre-management system was used to match each case with control patients. Up to three controls were matched to each case. Reports were generated by the theatre manager for control identification and were matched according to hospital, surgical procedure and date of procedure or as close as possible to the day of surgery for each identified case (within a month either side of the date). Controls were then cross-checked against the cases to rule out cases identified as controls. Once reports were completed and the medical records obtained, a retrospective case-control study was conducted on the Perth SWD cohort to determine risk factors associated with SWD.

#### **4.3.2. Data Collection: Community Nursing Service**

A data collection sheet (DCS) was created in an Excel spreadsheet format (Table 4.2) data collected consisted of patient related pre, intra and postoperative variables associated with wound healing complications and dehiscence, as identified in the literature review (Table 2.2 pg. 38). Commonly reported variables found to be associated with SWD in the literature, such as diabetes (Basha et al., 2010; Borger et al., 1998; McDonald et al., 1989; Ridderstolpe et al., 2001; Sharma et al., 2009) and postoperative infection (Biancari et al., 2012; Schimmer et al., 2008; van Ramshorst et al., 2010; Webster, Neumayer, Smout, Horn, Daley, Henderson, & Khuri, 2003) were incorporated into the data collection instrument used in this study (Table

4.2). Also incorporated were other reported variables found to be associated with SWD, such as smoking, alcohol consumption prior to surgery (Dahl et al., 2014; Fang, Hu, Endres, & Bradford, 2005; Kean, 2010; Makela, Kiviniemi, Juvonen, & Laitinen, 1995; Sorensen, Horby, Friis, Pilsgaard, & Jorgensen, 2002) and previous scarring (Johnson et al., 2005; Riou et al., 1992). These were included as known inhibitors of wound healing that pose a potential risk of SWD. The DCS grouped the risk factors into the preoperative, intraoperative and postoperative variables groups described previously in the conceptual framework.



Table 4.2. Data Collection Sheet: Variables

<i>Preoperative</i>	<i>Intraoperative</i>	<i>Postoperative</i>
Age (20–50, 51–80, 81+)	FiO <sub>2</sub> (readings were averaged during theatre time)	Days in intensive care unit
Gender		Vomiting (Y/N)
BMI (WHO): (<26, 27–30, 31+)	BP (mean arterial pressure pre- and during procedure)	Coughing (more than productive)
Weight (kg)	Body temperature Celsius	Body temperature Celsius
Height (cm)	Respiratory rate (average)	Day of dehiscence (postoperative day)
Diabetes (Y/N)	Use of warming blanket/Bair Hugger (Y/N)	Drain/s in situ (Y/N)
CVD (Y/N)	Prophylactic antibiotics (30 mins prior to procedure) (Y/N)	Day drain/s removed
PVD (Y/N)	Duration of bypass (CABG) (minutes)	Day light diet commenced
CPD (Y/N)	Duration of procedure (minutes)	Day post-op dressing removed
Smoking (Y/N)	Type of procedure	Exudate type (haemoserous, purulent, faecal)
Previous surgery in same anatomical location (Y/N)	Sutures used (Monocryl™, Vicryl™)	Wound pain (Y/N as reported in the ward patient notes)
Alcohol (Y/N)	Staples used (Y/N)	Infection (pathology confirmation)
NSAIDS (Y/N)	Tissue glue used (Y/N)	Pathogen identified (species.)
Corticosteroids (Y/N)	Closing method (continuous/interrupted and/or mass sutured closure)	Date of discharge
Fasting (No of Days)	Consultant or registrar-closed wound	
Paraplegia (Y/N)	Infection confirmed (Y/N)	
Hemiplegia (Y/N)	Dressing applied in theatre (Y/N)	
Immunosuppressed (Y/N)	Type of postoperative dressing (category)	
Cancer diagnosis (Y/N)		
White blood cell count (Y/N)		
Serum albumin value (mL)		
Body temperature Celsius		

Participants with missing clinical records were recorded as missing data. Data were sourced through a manual search of consenting patient and retrieved medical records, and recorded in the DCS (Table 4.2). Information was collected from the organisation’s written and electronic records and included the referral documents, wound assessment charts and care-plan progress notes. All data were entered into an Excel spreadsheet from the source documentation (DCS) and were further cleaned and transformed into a purpose designed database (IBM® SPSS® Version 20).

### **4.3.3. Data Collection: Hospital Medical Records**

Data collected from the participants' hospital medical records included the preoperative, perioperative and postoperative variables. Hospital records used for data collection included operation records; anaesthetic records; observation charts; general assessment charts; wound assessment charts; care plans; pathology reports; ward progress notes; clinical coding discharge summary sheets, and summary letters written by the attending medical officer. For those participants who had multiple surgical admissions, clinical coding discharge summaries were investigated to determine the reason for each admission and to ensure the correct admission date was matched to the relevant surgical procedure and to the referral discharge date to the CNS.

The ICD-10 (WHO, 1992) coding system and the hospital's internal coding system for surgical procedures, the Australian Classification of Health Interventions (ACHI) (ACHI, 2010), comprised the coding used to classify the cases. The ICD-10 and ACHI codes, as well as the name of the surgical procedure, were used to match controls. These codes were also cross-checked against the discharge summary to check for the correct procedure and date. Once a control was identified, the patient's medical record number (MRN) was cross-checked against the case MRN, to eliminate the possibility of a double-handling error (that is, a case being recorded as a control). A field journal was kept to record questions that arose and required further investigation or clarification with the supervisory team or medical records administrators. Cases and controls were de-identified by assigning an arbitrary code with no personal identifying information. Source documentation was kept separate from the de-identified database to maintain data security.

#### 4.3.4. Analysis

De-identified data were stored in Excel spreadsheets. The data were then cleaned, classified into either categorical or nominal format, and entered into the SPSS V.20 database for statistical analysis. The data were verified by the primary supervisor, who conducted an arbitrary audit of a sample of 10 cases to check for duplication and data entry errors. This process was carried out by cross-checking the DCS against the electronic database. Data such as BMI and age were categorised into ranges. Those variables that required a yes or no response were converted to binary format; the coding was 0=NO, 1=YES. For example, if the case had a pre-existing comorbidity such as CVD, then that case would be scored as 1. Missing data were assigned a 999 code.

Descriptive statistical analysis was carried out to determine the baseline characteristics of the sample (cases and controls), and to identify differences between and within the sample. Tests of significance (Chi-square analysis and Fisher's Exact Test) were conducted to determine if there were notable differences between the groups in relation to age, gender and BMI as well as the presence or absence of patient-related comorbidities. The various preoperative, perioperative and postoperative variables were then compared. Following tests of significance, those variables in the preoperative dataset with a *p* value of less than 0.05 were selected and used in a binary logistic regression model in order to identify independent risk factors associated with SWD. This protocol has been established by other researchers (Parsons, Jamrozik, Hobbs, & Thompson, 1994; van Ramshorst et al., 2010). A hierarchy of models was applied and a goodness of fit test conducted. Multiple regression analysis was conducted, with the final model yielding a goodness of fit as per the model summary  $R^2$  value as well as the Analysis of Variance test result. Following the selection of the model, the beta coefficients ( $\beta$ ) of the variables were used as the numerical value of the variable in the risk tool. Further

analysis was undertaken on the intra- and postoperative dataset but these variables were not included in the draft SWDRAT as they were considered independent of the preoperative setting.

#### **4.4. Methodology: Descriptive Study to Determine Costs and Time to Wound Healing**

##### **4.4.1. Study Design**

In order to determine the cost burden associated with the wound management of SWD cases referred to the CNS and recruited to this study, a descriptive cost study was conducted. For the purposes of the cost analysis, time to healing was defined as the period from the first wound management procedure until healing or discharge from the CNS.

##### **4.4.2. Data Collection**

Data was obtained from the CNS's written and electronic records for the cases recruited to the case control study as outlined above to determine the time and cost to wound healing. The primary measures were wound area (cm<sup>2</sup>) at referral; total length of service (in days); median length of service (in days); frequency of nursing visits and time taken to perform the procedure; time to healing or discharge from that episode of care (in days); dressings and other treatment consumables used (Table 4.3). Dressings were identified as either primary (in contact with the wound bed) or secondary (a dressing used to cover the primary dressing) and this was determined from the data collected from the wound care management plan. Length of service was determined by counting the number of days from the commencement of treatment on admission to the nursing service for that episode of care, until healing or discharge from the service for that episode of care. The duration of nursing visits was obtained from the recorded data in the organisation's electronic visit scheduling database. The presence of wound infection was determined by documented clinical signs and symptoms of the host response to infection

(redness, swelling, pain, erythema, purulent exudate). Furthermore, any available microbiology reports were also reviewed to confirm the presence of infection. Infection was further confirmed by the use of topical antimicrobial dressings in the care plan.

Costs of dressings and other wound treatment consumables, such as cleansing solutions, dressing packs, sterile scissors or other instruments, adhesive tape or bandages, supplied as recorded in the patient's wound care plan, were individually calculated per patient. Calculations were based upon the number of dressings and consumables used, according to the organisation's contract pricing for 2010, which was the year the study participants received nursing services. Nursing time involved direct patient contact time for required dressing changes and did not include organisational overheads or nurse travel time and associated vehicle costs. Costs calculated were actual costs and were not based on economic models. Nursing costs were determined as per the hourly award rate as specified by the Australian Nursing Federation (ANF) Award Pay Scales 2010 (downloaded from <http://www.anfvic.asn.au/multiversions/39682/FileName/NursesAward.pdf>).

Table 4.3. Data Collection Table

Variable	Unit of measure
Age	Years
Gender	M/F
Length of service (LOS)	Days
Minimum wound size	cm <sup>2</sup>
Maximum wound size	cm <sup>2</sup>
Minimum nursing visits	Days
Maximum nursing visits	Days
Nurse: RN/EN/CNS	Hourly rate \$
Wound cleansing (dressing packs include scissors, saline, gauze and forceps)	Per unit \$
Dressings (type of dressing, brand of dressing, frequency of changes)	Per unit \$
Wound infection	Yes or No

Source documentation was collected and stored electronically in Microsoft Office Excel 2013®, and kept separate from the de-identified database. Data were de-identified, cleaned and transposed into a purpose-built IBM® SPSS® V.20 main database.

#### 4.4.3. Analysis

Descriptive statistical analysis was carried out to describe the patient, wound and treatment-related characteristics. Tests of significance (Chi-squared and T-tests) were also carried out to identify if there were significant differences in time and cost to healing between the infected and non-infected wound groups.

## **4.5. Methodology: Surgical Wound Dehiscence Risk Assessment Tool Internal Validation**

### **Melbourne Cohort**

#### **4.5.1. Study Design**

Following logistic regression and identification of independent variables associated with SWD in the initial Perth cohort study, the SWDRAT was constructed and ready for internal validation. A retrospective medical note audit was conducted on a convenience sample of patients at a metropolitan hospital in Melbourne to determine the internal predictive power of the risk assessment tool. As six Perth sites were participating in the study, this was a measure conducted to eliminate sample bias. Predictive validation was conducted in order to determine the “effectiveness of a test in predicting an individual’s performance in specified activities” (Anastasi & Urbina 1997, p.118). According to Minichiello, predictive validity involves the examination of the relationships between the measurement and an event that may occur in the future (Minichiello, 1999). The rationale behind the statistical validation was to determine the predictive power of the tool, as well as to detect other discrepancies in the data that could be further investigated prior to a validation in the clinical setting.

#### **4.5.2. Data Collection**

The records of patients who potentially could fit the criteria of this study were screened via a theatre-management system-generated report by the theatre manager at a major Melbourne tertiary public hospital. Screening criteria included patients who were coded as having a SWD ICD-10: T81.30 during the period 2012–2014 following a surgical procedure. Information was collected as per the Perth cohort DCS. Patients were retrospectively scored according to the draft SWDRAT and the risk score and outcome were recorded in a purposefully designed

database. Cases were scored between the minimum and maximum of the tool range and the outcome was recorded in binary form: Y=1, N=0.

#### **4.5.3. Analysis**

Descriptive statistical analysis was carried out to determine the characteristics of the sample, and to identify differences between and within the samples. Tests of significance (Chi-squared, T-test) were conducted to determine if there were notable differences between the groups in relation to age, gender, BMI and other patient-related comorbidities.

#### **4.5.4. Receiver Operator Curve Analysis**

To assess the predictive power of the risk assessment tool a ROC analysis was conducted. A ROC is a statistical analysis for testing the predictive power of a certain diagnostics test. The area under the curve (AUC) statistic of the ROC test is able to detect the true positive rate (sensitivity), and the false positive rate (specificity) for different cut-off points of a parameter (Greiner, Pfeiffer, & Smith, 2000). Furthermore, the ROC test can provide an assessment of the predictive power of a certain tool, given a specific outcome. Each case and control was assigned a risk score based on summation of the beta coefficients from the regression analysis. The ROC analysis was done using IBM® SPSS® V.20.



## **4.6. Results: Retrospective Case Control Perth Cohort**

### **4.6.1. Sample Characteristics and Preoperative Variables**

Initially, 416 patients referred to the CNS were identified as candidates for the Perth retrospective study and of those 416 potential participants, 39 had since died. Consequently, letters were sent to 377 patients informing them of the study and inviting them to participate. The response rate for letters sent (n=377) was 59% (n=223). Of the letters sent out, 154 were returned unopened due to a change of address. Of the 223 patients who responded, 145 consented to participate, 25 were duplicates and 53 declined. The CNS medical records of these participants were audited to confirm a SWD diagnosis: 26 were excluded as they did not meet the criteria for a SWD; the CNS records were unable to be located for study access for 57, while a further eight patients had a post-caesarean section dehiscence and were thus excluded as per the study criteria (Figure 4.3). It is interesting to note the number of cases that were originally identified as a SWD, yet were found on a hand search of the participant's documentation to be misclassified, an issue noted by others in the literature review.

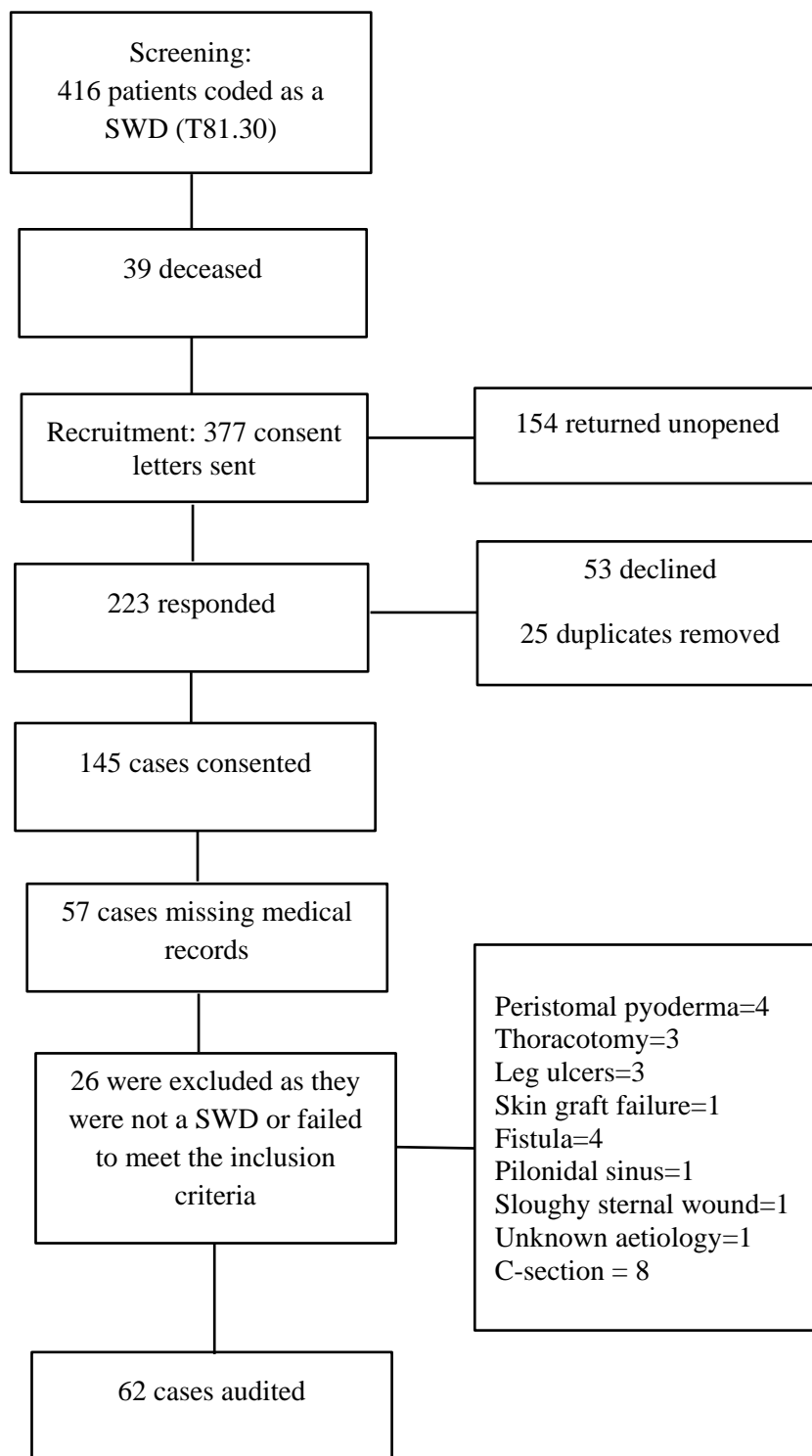


Figure 4.3. Patient recruitment flowchart Perth cohort

The final overall study sample consisted of 62 confirmed SWD cases that had consented to participate in the study. Controls were matched to the SWD cases by hospital, date and type of procedure; for every case there was at least one control, with a maximum of three controls

per case. The time range for the match was within a month either side of the date of the procedure.

Table 4.4. Descriptive Statistics Preoperative Variables - Perth Cohort

		Surgical wound dehiscence				
		Cases (n= 62)		Controls (n=100)		
		n	%	n	%	<i>p</i> *
Age	20–50 years	9	14.5%	34	34.0%	<i>0.019</i>
	51–80 years	48	77.4%	56	56.0%	<i>0.098</i>
	81+ years	5	8.1%	10	10.0%	<i>0.693</i>
Gender	Male	34	54.8%	57	57.0%	<i>0.897</i>
	Female	27	43.5%	43	43.0%	<i>0.905</i>
	Transgender	1	1.6%	0	0.0%	
BMI	<26	5	13.5%	19	34.5%	<i>0.143</i>
	27–30	15	40.5%	18	32.7%	<i>0.212</i>
	31+	17	45.9%	18	32.7%	<i>0.076</i>
<i>Missing data</i>		36	<i>59%</i>	51	<i>51%</i>	
Smoker		27	49.1%	33	33.3%	<i>0.055</i>
Previous surgery <sup>1</sup>		12	19%	4	4%	<i>0.038</i>
CVD		26	49.1%	33	33.0%	<i>0.052</i>
<i>Missing data</i>		8	<i>14%</i>			
CPD		12	26.1%	17	17.0%	<i>0.201</i>
Diabetes		15	27.8%	17	17.0%	<i>0.116</i>
<i>Missing data</i>		7	<i>12%</i>			
PAD		16	31.4%	12	12.0%	<i>0.004</i>
<i>Missing data</i>		10	<i>17%</i>			

*Note.* \*The Chi-square statistic is significant at the .05 level and tests for differences between the case and controls. 1. In the same anatomical location.

Amongst the sample, over half the SWD cases were male, with the majority 51 to 80 years old, and this male dominance was consistently reflected in the control group. Interestingly there was a statistically significant difference between cases and controls in the younger age

category (20–50 years), with younger patients among the controls, as compared to the cases ( $p=0.019$ ). Among the entire sample, 21% were in the high BMI group (31+). Whilst this was not statistically significant, there was a clear trend towards the higher BMI category in the overall sample and in particular, the cases. In the entire sample, 37% were smokers, with more smokers found among the cases as compared to the controls. Interestingly, 19% of the cases had a previous surgical incision in the same anatomical location that had dehisced, which was significantly different between the case and controls ( $p=0.003$ ). A trend was found across the cases towards an increased presence of chronic disease states. Among the cases, 49% had CVD compared to 33% of controls, 26% had cardiopulmonary disease (CPD) compared to 17% of the controls, and 27% had diabetes compared to 17% of the controls (Table 4.4). However, a statistically significant difference was found between cases and controls in relation to PAD, of which, 31% of the cases has PAD compared to 12% of the controls ( $p=0.004$ ).

Following the CNS and hospital retrospective cases control data collection, SWD participants were grouped by surgical procedure based on sample characteristics as follows:

1. Abdominal (laparotomy, hemi-colectomy, appendectomy, Hartmann's procedure)
2. Orthopaedic (TKR, elbow replacement, washout and debridement)
3. Breast (insertion/removal of tissue expander, mastectomy, incision and drainage of abscess)
4. Cardiothoracic (CABG, valve replacement, sternotomy, washout)
5. Vascular (femoral popliteal bypass).

In terms of the anatomical location of the SWD, the majority of the sample was of abdominal origin (48%), followed by orthopaedic procedures (30%), breast procedures (11%), cardiothoracic procedures (8%), and vascular procedures (4.8%). The surgical procedures are reported in Table 4.5.

Table 4.5. List of Surgical Procedures Perth Cohort

Surgical procedure	Case	Control
	n=62 ( <i>group %</i> )	n=100 ( <i>group %</i> )
<b>Abdominal Group</b>	<b>n=30 (48%)</b>	<b>n=48 (48%)</b>
Division of adhesions	1 (3%)	2 (4%)
Colectomy	1 (3%)	1 (2%)
Hemi colectomy	4 (13%)	2 (4%)
Hartmann's procedure	3 (10%)	4 (8%)
Exploratory laparotomy	8 (26%)	36 (75%)
Anterior resection	5 (16%)	2 (4%)
Hernia mesh repair	5 (16%)	1 (2%)
Washout for infection	3 (10%)	0 (0%)
<b>Orthopaedic Group</b>	<b>n= 19 (30%)</b>	<b>n=26 (26%)</b>
Total knee replacement	2 (10%)	12 (46%)
Washout and debridement	8 (42%)	10 (38%)
Elbow replacement	2 (10%)	1 (3%)
Knee revision	3 (15%)	3 (11%)
Below the knee amputation	2 (10%)	0 (0%)
<b>Breast Group</b>	<b>n=7 (11%)</b>	<b>n=10 (10%)</b>
Mastectomy	4 (57%)	7 (70%)
Drainage of abscess	1 (14%)	2 (28%)
Insertion/removal of tissue expander	2 (28%)	1 (14%)
<b>Cardiothoracic Group</b>	<b>n=5 (8%)</b>	<b>n=8 (8%)</b>
CABG + LIMA	3 (60%)	5 (62.5%)
Valve replacement	1 (20%)	3 (37.5%)
Sternotomy washout	1 (20%)	0 (0%)
<b>Vascular Group</b>	<b>n=3 (4.8%)</b>	<b>n= 8 (8%)</b>
Femoral popliteal bypass	3 (4%)	8 (8%)

#### 4.6.2. Abdominal Group

A total of 30 cases were recorded as having an SWD following surgery in the abdominal region (general or colorectal surgery). Of those 30 cases, 20% had a cancer diagnosis (stage not

specified) and had not received chemotherapy prior to surgery. In the abdominal case sample, 26% had an exploratory laparotomy, 16% had an anterior resection and 16% had a hernia mesh repair (Table 4.5). Other surgical procedures among the abdominal group included Hartmann’s procedure (10%) and debridement with washout (10%). A total of 48 controls were matched to the 30 cases of abdominal wound dehiscence. The factors found to be significantly different between the abdominal cases and controls were: age ( $p=0.02$ ), CVD ( $p=0.016$ ), PAD ( $p=0.032$ ), and previous surgery ( $p=0.009$ ) (Table 4.6).

Table 4.6. Chi-square Test for Difference: Surgical Grouping versus Preoperative Risk Factors

	Surgical Procedures				
	Cases and Controls (n=162)				
	Abdominal (n=78)	Breast (n=17)	Cardio (n=13)	Ortho (n=45)	Vascular (n=11)
Age	0.002 <sup>*, a</sup>	0.382 <sup>a, b</sup>	0.338 <sup>a, b</sup>	0.157 <sup>a, b</sup>	0.195 <sup>a, cb</sup>
Gender	0.407 <sup>a, b</sup>	N/A	0.782 <sup>a, b</sup>	0.557 <sup>a</sup>	0.486 <sup>a, b</sup>
BMI	0.199 <sup>a</sup>	MD	0.788 <sup>a, b</sup>	0.888 <sup>a</sup>	0.449 <sup>a, b</sup>
CVD	0.016 <sup>*</sup>	0.338 <sup>a, b</sup>	0.214 <sup>a, b</sup>	0.067 <sup>a</sup>	0.611 <sup>a</sup>
COPD	0.424 <sup>a</sup>	0.740 <sup>a, b</sup>	0.011 <sup>*, a, b</sup>	0.574 <sup>a</sup>	0.475 <sup>a</sup>
Diabetes	0.089	MD	0.026 <sup>*, b</sup>	0.510 <sup>a</sup>	0.377 <sup>a</sup>
PAD	0.032 <sup>*, a</sup>	MD	0.087 <sup>a, b</sup>	0.001 <sup>*, a</sup>	0.931 <sup>a, b</sup>
Smoking	0.082	0.251 <sup>a, b</sup>	0.387 <sup>a</sup>	0.874 <sup>a</sup>	0.218 <sup>a</sup>
Previous surgery <sup>1</sup>	0.009 <sup>*, a</sup>			0.083 <sup>a, b</sup>	

Note. <sup>\*</sup>The Chi-square statistic is significant at the .05 level. <sup>a</sup> More than 20% of cells in this sub-table have expected cell counts below 5 due to missing data. <sup>b</sup> Chi-square results may be invalid. MD = missing data. N/A= not applicable. 1. In the same anatomical location.

### 4.6.3. Orthopaedic Group

In the orthopaedic group, 19 cases were recorded as having had an SWD. There were no hip replacement/revision-related cases. In the orthopaedic group, 42% of cases underwent a washout and debridement subsequent to a total knee replacement (TKR) procedure, 10% had a TKR, 15% had a knee revision procedure and 10% had an elbow replacement (Table 4.5). In the

same group, 35% had CVD, 14% CPD, 42% PAD, and 14% had a previous surgical procedure in the same anatomical location. Four within the group were smokers and two were patients with diabetes. For the 19 cases, 24 controls were matched as follows: knee washout/debridement (n=10); elbow replacement (n=1); below-the-knee amputation (n=0), and TKR (n=12). The only comorbidity that was significantly different between the cases and controls was PAD ( $p=0.001$ ).

#### **4.6.4. Breast Group**

A total of seven cases had an SWD following a breast-related procedure. In this group there were no significant differences in age between cases and controls. The seven breast procedures were matched to 10 controls. No statistically significant differences in patient-related or lifestyle factors were identified between cases and controls. Among the sample, 11% had a SWD following breast surgery and within the breast group, 57% had a mastectomy and 28% had a dehiscence following removal of a tissue expansion device.

#### **4.6.5. Cardiothoracic Group**

A total of five cases had a SWD following a cardiothoracic procedure. Of the five cases, all had diabetes and CVD, and one case had PAD. The three SWD cases for the cardiothoracic group were matched to eight controls. The significant difference between the cases and controls in relation to pre-existing comorbidities was the presence of COPD ( $p=0.011$ ) and diabetes ( $p=0.026$ ) (Table 4.5). Among the cardiothoracic cases (n=5), three patients underwent a CABG with left internal mammary artery harvesting (CABG+LIMA), one patient had a valve replacement (no type specified in the medical notes), and one patient had a sternotomy washout out due to mediastinitis.

#### **4.6.6. Vascular Group**

Five cases in the vascular group were recorded as having had a SWD, of the five cases: three had CVD, one with COPD, two were diabetic and two were smokers. Furthermore, one case had Crohn's disease and one had diverticulitis. No other comorbidities were present in this group. For the five cases there were 11 controls, matched by date and procedure.

In summary, the SWD cases consisted of older males and females with pre-existing lifestyle and comorbid risk factors such as smoking and diabetes, with a trend towards a high BMI. In particular, the majority of cases had undergone a previous surgical procedure in the same anatomical region, and close to half were smokers. In contrast, the control group's baseline characteristics featured a younger cohort with less chronic disease, lower numbers of smokers, and lower occurrence of previous surgeries.

#### **4.6.7. Intraoperative Risk Factors**

Intraoperative risk factors measured and recorded for the study are reported in Table 4.7. All surgical groups were combined and analysed for intraoperative risk factors, due to the small samples within each group.



Table 4.7. Descriptive Statistics: Intraoperative Variables Perth Cohort

Variable	Intraoperative variables					
	Case (n=62)			Control (n=100)		
		%	Median		%	Median
Mass closure <sup>a</sup>	13	20.0%		17	17.0%	
Staples	20	32%		26	26%	0.859
Mesh	1	1.6%		2	2%	
Surgical closure	Consultant	33	53%	86	86%	0.276
	Registrar	9	14%	14	14%	
	Missing data	20	32%	0		
Duration of procedure (hrs)			2.8			3.0
<1.0	0			0		
1-3	33	63%		73	73%	
3.5-6	16	30%		17	17%	
6.5-9	3	5%		7	7%	
9+	0			3	3%	
Missing data	10	16%		0		
Prophylactic antibiotics (30 minutes prior to surgery)	11	17%		5	5%	0.07
Missing data	5	8%		7	7%	
% BP reduction <sup>b</sup>			21			20
Missing data	7	11%		7	7%	0.073
O2 saturation (procedure)			99.0			99.0
Missing data	7	11%		0		0.263
Intraoperative warming	29	46%		43	43%	0.245
Missing data	8	12%		2	2%	

Note. \* Students T-test. <sup>a</sup> Mass closure is defined as closure of abdominal wall with a single suture. <sup>b</sup> Difference between mean arterial pressure (MAP) prior to procedure and following procedure.

The use of staples was the most frequently used wound closure method in both the case and controls across all the surgical groups (Table 4.7). The consultant closed the incision more frequently than did the junior surgeon in both the case and control groups and there was no significant difference between cases and controls. The duration of the procedure was collected from the anaesthetic record in the medical notes; it was recorded in minutes and converted to categories based on hours for data analysis. Again, for the purposes of analysis of this variable,

all surgical groups were combined. Cases that underwent a CABG procedure unsurprisingly had a longer procedural time of three or more hours. The majority of the sample had a procedure duration of between one and four hours. Prophylactic antibiotics were administered 30 minutes prior to surgery for 17% of cases and 7% of controls. While this is not statistically significant, it is interesting to note a higher likelihood of antibiotic administration in the cases than in the controls.

Both blood pressure (BP) reduction (measured through percentage reduction in mean arterial pressure) and average oxygen saturation recordings yielded no statistical significance between cases and controls. Likewise for the application of intraoperative warming devices.

#### **4.6.8. Postoperative Risk Factors**

Postoperative risk factors were also recorded for the study. There were no statistically significant different outcomes between the cases and controls in the sample for coughing or vomiting. However, wound infection was statistically significant between cases and controls ( $p < 0.001$ ) (Table 4.8) with 46% of cases with an SSI.

Table 4.8. Descriptive Statistics: Postoperative Variables Perth Cohort

Postoperative variables general					
	Case (n=62)	%	Control (n =100)	%	<i>p</i>
Coughing	14	22%	15	15%	<i>0.163</i>
Vomiting	9	14%	10	10%	<i>0.331</i>
Wound infection <sup>a</sup>	29	46%	1	1%	<i>&lt;0.001</i>
Wound pain <sup>b</sup>	28	45%	0	0%	<i>&lt;0.001</i>

*Note.* <sup>a</sup>Confirmed through pathology report and as recorded in ward notes. <sup>b</sup>Wound pain as described in medical notes, no validated pain scoring method used.

Where possible, pathology and/or microbiology reports were audited for confirmation of wound infection. The documented clinical signs and symptoms of wound infection, and the recorded postoperative management, with the use of antimicrobial dressings (such as silver or cadexomer iodine), were deemed as evidence of clinical management of wound infection, and classified as such. Among the cases, several wound assessment characteristics consistent with signs and symptoms of inflammation (redness, swelling, pain, erythema, and exudate) were reported. Although inflammation is related to the wound healing trajectory, it is also a clinical indicator of infection (Carville 2017). Wound pain was reported in 45% of cases; it was documented in the medical record as an observational account, without the use of validated pain assessment tools or scales (Table 4.8).

Table 4.9. Descriptive Statistics: Wound Specific Perth Cohort

Postoperative variables – wound-specific					
	Case (n=62)	%	Control (n =100)	%	<i>p</i>
Wound erythema	16	25%	0	0	<0.001
Wound oedema	4	6%	0	0	0.007
Wound haematoma	0	0	0	0	N/A
Wound seroma	4	6%	0	0	0.007
Exudate, sanguineous	25	40%	0	0	<0.001
Exudate, haemoserous	16	25%	0	0	<0.001
Exudate, purulent	9	14%	0	0	<0.001
Exudate, faecal	1	2%	0	0	0.184

Wound-specific characteristics, as listed in Table 4.9, were found to be significantly different between cases and controls. Wound erythema was reported in 25% of cases, with none reported among the controls. Post-procedure seroma formation was recorded in 6% of cases, whereas in the control group no seroma formation was recorded. Among the postoperative wound specific variables recorded, the statistically significant factors associated with SWD were erythema ( $p<0.001$ ), sanguineous exudate ( $p<0.001$ ), haemoserous exudate ( $p<0.001$ ), and purulent exudate ( $p<0.001$ ).

#### 4.6.9. Missing Data

Missing data was a significant issue in conducting this phase of the study, a recognised limitation of retrospective case control methodology. To limit this potential problem, the records that were accessed were audited completely to source the information required (patient admission forms, patient discharge forms, clinical coding sheets, ward progress notes, medical

chart notes, operating/ theatre report/s, anaesthetic charts and postoperative recovery room charts).

The following percentages of data were missing:

1. Case preoperative variables: BMI 59% (n=36), CVD 14% (n=8), diabetes 12% (n=7), and PAD 17% (n=10). Intraoperative variables with missing data were: duration of procedure 16% (n=10), BP reduction 11% (n=7), and oxygen saturation 11% (n=7).
2. Controls preoperative variable: BMI 51% (n=51). Intraoperative variables with missing data were: prophylactic antibiotics 7% (n=7), BP reduction 7% (n=7), and intraoperative warming 2% (n=2).

The main reasons for missing data were a lack of documentation of the variable of interest in the medical record, and missing chart records within the patient files at the study sites.

#### 4.7. Results: Descriptive Study to Determine Costs and Time to Wound Healing

To determine the actual costs of managing SWD in the CNS setting for the 62 cases identified during the first case-control study, a descriptive cost study was conducted. The majority of patients (84%) were discharged from service within 6 weeks, and 15% were discharged within 3 months (Table 4.10).

Table 4.10. Duration of Treatment by Community Nursing Service

Wound duration	n	SWD
<6 weeks	52	84% (47% n= 24 treated for infection)
6 weeks to <3 months	9	15% (63% n= 6 treated for infection)
3 months+	1	1 patient

Among the 62 cases, the minimum length of service was one day, with a maximum of 308 days and a median length of service of 18 days. The minimum wound area (cm<sup>2</sup>) at referral was 1cm<sup>2</sup>, with the largest measuring 144cm<sup>2</sup>, and the median area being 9cm<sup>2</sup>. The frequency

of nursing visits was determined by calculating the number of recorded visits in the organisation's electronic ComCare database (Silver Chain 2011). The minimum number of visits was one, the maximum 55 and the median number of nursing visits was 15.

#### 4.7.1. Wound Dressings Used

A range of contemporary dressings was used for both primary and secondary applications. Fixation in the form of bandages or adhesive tape was used in some cases. Among the non-antimicrobial dressings, foam dressings made up the greatest number of primary dressings used (36%), followed by Hydrofiber® (gelling fibre) dressings. Silver and other antimicrobial dressings accounted for 54% of primary dressings used (Figures 4.4 and 4.5).

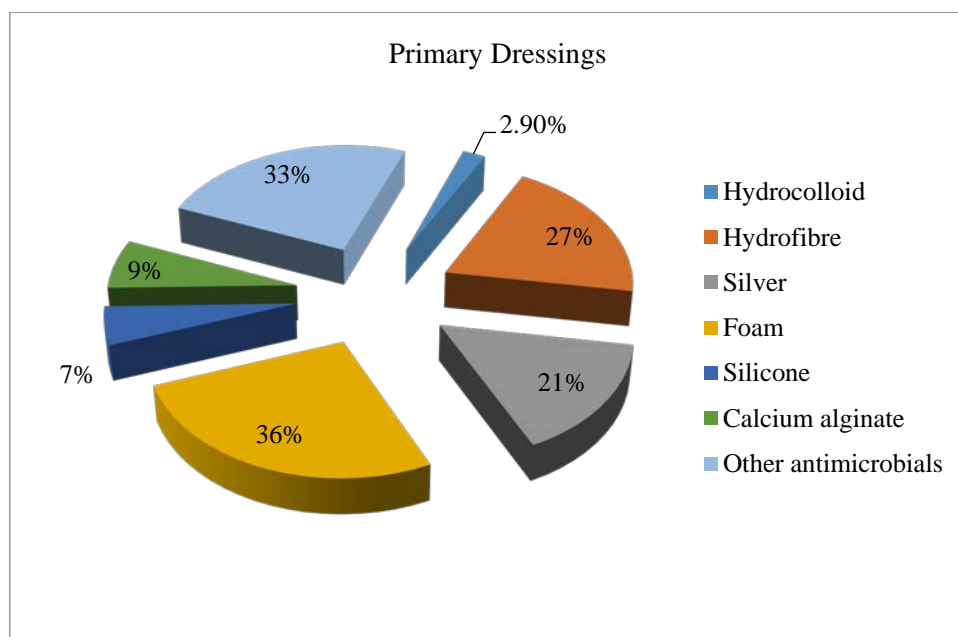


Figure 4.4. Primary dressings Perth cohort

When a secondary dressing was required the most common dressings used were dry dressings, foam dressings, film dressings and silicone dressings. Fixation bandages or adhesive tapes were used in 6.6% of cases. Where a silver-impregnated foam dressing was used, it was categorised under 'silver' not foam, due to its antimicrobial properties.

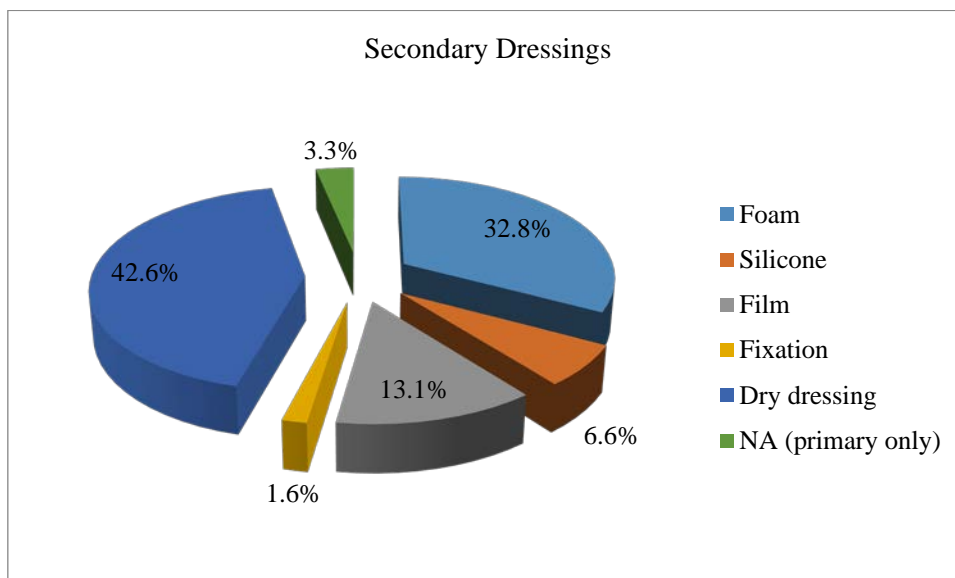


Figure 4.5. Secondary dressings Perth cohort

There were no cases recruited to this study who received NPWT dressings or devices. Due to CNS funding protocols during the period 2010–2011, all patients with NPWT were managed by acute-care hospital-in-the-home programs and were not referred to the CNS. The costs for NPWT dressings and devices were subsequently absorbed by the acute care setting. Among the group that healed in less than six weeks, 47% received topical antimicrobial dressings or solutions for the treatment of an identified or clinically suspected wound infection (see Table 4.10).

Table 4.11. Number of Cases with Wound Infection Perth Cohort

Surgical group (n=62)	n (cases)	n Infection	% Infection
Abdominal	30	18	29%
Orthopaedic	17	7	11%
Breast	7	1	1.6%
Cardiothoracic	5	0	0%
Vascular	3	3	5%
Total	62	29	46.7%

Among those who healed in less than six weeks, 47% were treated for infection by the CNS. Among those who took between six weeks and three months to heal, 63% received antimicrobial dressings or solutions. One patient had not healed within the year. Within the abdominal group (n=18), 60% received antimicrobial dressings for management of wound infection and among the overall cases, 50% were treated with topical antimicrobial dressings or solutions for infection. A total of 31 cases were recorded as having standard-treatment wound care with no infection present.

#### **4.7.2. Cost of Wound Care**

The estimated total cost of wound dressings and other consumables for 62 cases with confirmed SWD was over AUD \$20,000 (Table 4.12). The total cost of nursing time for cases was AUD \$35,695 with a median cost per case of AUD \$509. The cost of dressings, consumables and nursing time in managing cases with infection was AUD \$37,940, with a median cost of AUD \$1,025 (Table 4.12). Community nursing service organisational overheads and travel costs associated with home visits by nurses were not factored into the analysis.



Table 4.12. Community Nursing Costs Associated with Clinical Management of SWD Perth Cohort

Type of cost	Min	Mean	Median	Max	Total AUD
Dressing cost <sup>1</sup>	\$34		\$294	\$1,790	\$20,591
Nursing cost <sup>2</sup>	\$129		\$509	\$1,424	\$35,695
Infected patient (dressing and nursing cost)	\$100	\$674	\$1,025	\$5,277	\$37,940
Non-infected patient (dressing and nursing cost)	\$28	\$519	\$509	\$647	\$18,346
<i>Overall cost</i> <sup>3</sup>	\$163		\$804	\$3,214	\$56,286

Note. 1. Total dressing costs include primary, secondary and tertiary dressing cost, cleansing, dressing packs and scissors.

2. As determined by ANF 2010 nursing rates (<http://www.anfvic.asn.au/multiversions/39682/FileName/NursesAward.pdf>), does not include organisational costs or vehicle maintenance costs.

3. Overall cost includes nursing and dressing costs for the entire sample.

### 4.7.3. Cost of Infection

The presence of infection impacted on patients' time to heal, as there was a statistically significant difference between cases and controls ( $p=0.001$ ). The use of antimicrobial dressings and the associated nursing time for infection accounted for 67% of the overall nursing and dressing costs. Per case, the cost for treating infection was 60% more than a non-infected case; the average cost per case to treat the infected wound was AUD \$1,025 (Table 4.13). The infected group took the longest to heal.

In summary, among the cases that were treated for infection, 47% of the wounds healed within a six week time frame and 63% healed within three months of treatment. Of the cases who were admitted to CNS care, close to half were treated for wound infection, which accounted for over 60% of the costs to the CNS in the sample. Although the data reported in this section are actual costs associated with nursing time and treatment products alone, the results highlighted the fact that those with infection took longer to heal and were more costly to manage than the non-infected group.

#### 4.8. Risk Assessment Tool Development

As reported in the descriptive statistics for cases and controls (Table 4.6) low sample sizes were reported for the cardiothoracic (n=11), orthopaedic (n=45), vascular (n=11) and breast (n=17) groups. The abdominal group had the largest sample size (n=78). Therefore it was decided that tool development focus would be the abdominal surgical group. The rationale for this decision was based upon the presence in this group of the minimum sample sizes that would be required to produce statistically meaningful results and that abdominal wound dehiscence features prominently in the literature which would assist in underpinning the design of the draft SWDRAT on an abdominal wound dehiscence model.

The risk factors found in the literature review and the initial findings from the first case control study, conducted in the CNS setting, assisted in guiding the process of selecting which variables were to be incorporated into the SWDRAT. The case control variables of prime interest were those identified in the preoperative period as these were considered to be the most helpful in predicting risk prior to surgery. A univariate analysis was used to determine variables of significance for the subsequent multivariate regression model. The results of the univariate analysis are shown in Table 4.13 below. In the abdominal group the variables that were of significance were age ( $p=0.002$ ), CVD ( $p=0.016$ ), PAD ( $p=0.032$ ), and previous abdominal surgery ( $p=0.009$ ). The significant variables derived from the univariate analysis were entered into a multiple regression equation to determine which variables were significant independent risk factors for SWD. The preoperative variables (BMI, diabetes, CPD, gender, and smoking) did not yield a statistically significant result, thus were not used in the regression analysis.

Table 4.13. Chi-squared Test for Significance: Abdominal Group — Perth Cohort

Pearson's Chi-squared	Abdominal (n=76)
Age	0.002 <sup>*, a</sup>
Gender	0.407 <sup>a, b</sup>
BMI	0.199 <sup>a</sup>
CVD	0.016 <sup>*</sup>
CPD	0.424 <sup>a</sup>
Diabetes	0.089
PAD	0.032 <sup>*, a</sup>
Smoking	0.082
Previous surgery <sup>1</sup>	0.009 <sup>*a</sup>

*Note.* \*The Chi-square statistic is significant at the .05 level. <sup>a</sup> More than 20% of cells in this sub-table have expected cell counts below 5 due to missing data. <sup>b</sup> Chi-square results may be invalid. 1. In the same anatomical location.

#### 4.8.1. Logistic Regression Model and Goodness of Fit

Logistic regression can be utilised for retrospective studies that require differentiation from the control group (O'Gorman & Woolson, 1993). A hierarchy of models was obtained from a stepwise procedure and the beta coefficients of the variables of significance were used to assign scores to each of the risk variables (Table 4.14). Variables of significance entered in the model were age (category), CVD, PAD, and previous surgery in the same anatomical region; the dependent variable was dehiscence (Table 4.14).

Table 4.14. Regression Model and Coefficients

\*in the same anatomical location

Model	Unstandardised Coefficients		Standardised Coefficients	T	Sig.	95.0% Confidence Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
1 (Constant)	0.805	0.160		5.043	0.001	0.474	1.136
Previous surgery*	0.930	0.088	0.919	10.55	0.001	0.747	1.112
CVD	0.042	0.111	0.035	0.381	0.707	-0.187	0.272
PAD	0.079	0.116	0.057	0.684	0.501	-0.161	0.319
AGE	0.098	0.076	0.108	1.298	0.208	-0.059	0.256

Dependent:  
Dehiscence

The model used to determine the draft risk assessment tool appeared robust according to the goodness-of-fit test, with a resultant R value of 0.93 (Table 4.15).

Table 4.15. Regression Model Summary Results

\*in the same anatomical location

Logistic regression input model summary <sup>b</sup>									
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	R Square Change	F Change	df1	df2	Sig. F Change
1	0.930 <sup>a</sup>	0.865	0.848	0.197	0.865	49.325	3	23	0.001

a. Predictors: (Constant), PAD, Previous surgery\*, CVD  
b. Dependent Variable: Dehiscence.

The results of the ANOVA test for the multiple regression analysis yielded previous surgery as the only independent predictor for SWD ( $p < 0.001$ ) (Table 4.15).

Table 4.16. ANOVA Logistic Regression

		ANOVA <sup>a</sup>				
Model		Sum of Squares	Df	Mean Square	F	Sig.
1	Regression	5.770	3	1.923	49.325	0.001 <sup>b</sup>
	Residual	0.897	23	0.039		
	Total	6.667	26			

a. Dependent Variable: Dehiscence

b. Predictors: (Constant), PAD, previous surgery\*, CVD).

\*in the same anatomical location

In the light of other research on the known impact of patient-related comorbidities and lifestyle habits on delayed healing (Sorensen et al., 2003; Streeter, 2006; Stryker et al., 2013; Williams et al., 2009) and the trends noted in the initial analysis, the following additional variables were added (gender, BMI, CPD, diabetes, smoking) to the draft SWDRAT. The beta coefficients from these variables were derived using Log (OR) from the odds ratios. Once the beta coefficients for all variables were derived, the risk tool was constructed using the non-standardised beta coefficients as the assigned score for the variables (Table 4.17).

Table 4.17. Risk Scores: Preoperative Variables

Variable	Odds ratio	$\beta$ coefficient	P value
Previous surgery*	4	2.20	0.001
Age			
19–50	0.3	0.165	0.019
51–80	1	0.550	0.098
81+	0.5	0.104	0.693
CVD	3	1.65	0.381
PAD	3	1.65	0.501
Diabetes	2	1.10	0.624
BMI			
$\leq 26$	0.4	0.220	0.736
27–30	1.25	0.690	0.505
31+	1.4	0.773	0.947
Smoking	2	1.10	0.387

\*in the same anatomical location

Following the findings reported above, a draft risk assessment tool was created (Table 4.18).

Table 4.18. Draft surgical wound dehiscence risk assessment tool (SWDRAT)

Variable	Risk Score
Age 19–50	0.165
Age 51–80	0.550
Age 81+	0.104
BMI $< 26$	0.220
BMI 27–30	0.690
BMI 31+	0.773
Diabetes	1.10
CVD	1.65
PAD	1.65
Previous surgery	2.20
Smoking	1.10

Once the draft SWDRAT was completed, the tool (Appendix 4) was then tested for predictive power on a test dataset obtained from the Melbourne cohort.

## 4.9. Results: SWDRAT Internal Validation Melbourne Cohort

### 4.9.1. Sample Characteristics

A retrospective case control study was conducted at a metropolitan hospital in Melbourne to determine the predictive power and internal validity of the draft SWDRAT. The recruitment process for the cases and controls for that component of the study are outlined in Figure 4.4 and 4.5, followed by the descriptive statistics of the sample (cases and controls) as presented in Table 4.19.

A T81.30 coding search for SWD was conducted to determine those patients who had incurred SWD following a surgical procedure. Controls were sought to match cases on a one to one basis determined by date and type of procedure. One hundred and eighty one patients were identified and 128 records retrieved, the remaining 53 medical records were unable to be retrieved. The internal validation sample consisted of 56% males and 43% females (Table 4.19).

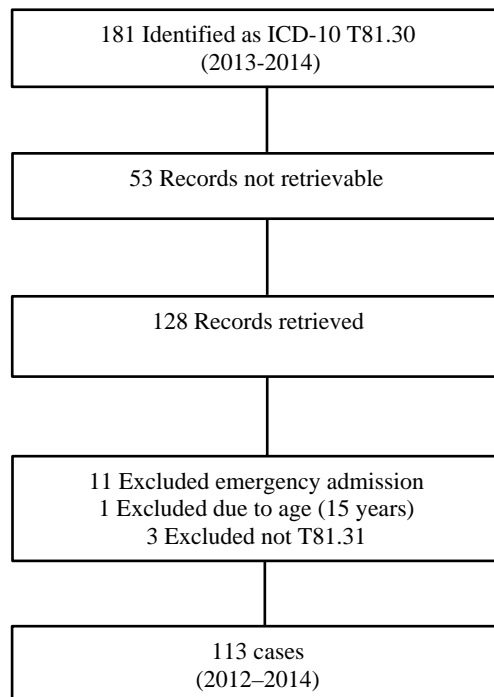


Figure 4.6. Protocol cases recruitment Melbourne cohort

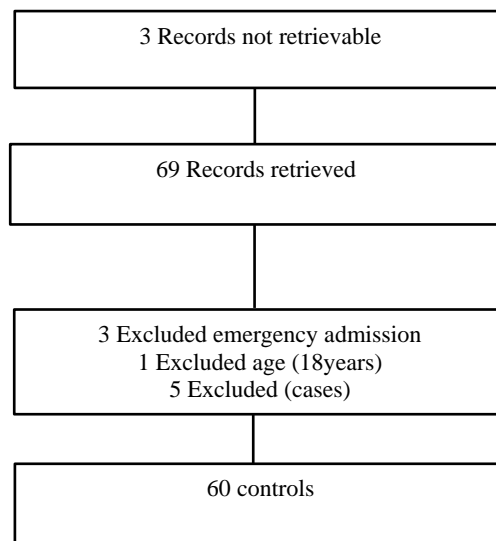


Figure 4.7. Protocol controls recruitment Melbourne cohort

In the validation sample, 32% of cases had diabetes compared to 18.3% of controls, and the majority of cases had previous surgery in the same anatomical location (80%) (Table 4.19). The validation sample age groupings were similar to the Perth cohort, with the majority in the 51 to 80 years of age category. Among the cases, 39% had a BMI greater than 31, similar to the Perth cohort (49% of cases).



Table 4.19. Descriptive Statistics Melbourne Cohort

Variable		Validation sample				Case vs controls
		Case		Control		<i>p</i>
		<i>n</i>	%	<i>n</i>	%	
Gender	Female	49	43.4%	27	45.0%	<i>0.750</i>
	Male	64	56.6%	33	55.0%	
Age	20–50	26	23.0%	27	45.0%	<i>0.080</i>
	51–80	76	67.3%	29	48.3%	
	81+	11	9.7%	4	6.7%	
BMI	<26	12	10%	8	13%	<i>0.376</i>
	27–30	15	13%	5	8%	
	31+	44	39%	14	23%	
Diabetes		37	32.7%	11	18.3%	<i>0.039</i>
Previous surgery*		91	80.5%	17	28.3%	<i>&lt;0.001</i>
PAD		14	12.4%	2	3.3%	<i>0.005</i>
CVD		29	25.7%	0	0.0%	<i>&lt;0.001</i>
Smoker		45	39.8%	13	21.7%	<i>0.007</i>
Total		113	100.0%	60	100.0%	

\*in the same anatomical location

Among the cases, 39% were smokers compared to 21.7% of the controls. The Melbourne validation sample was similar in many respects to the Perth cohort, particularly with regard to the presence of pre-existing comorbidities such as diabetes, CVD and PAD, as well as similar lifestyle factors, such as high BMI and smoking.

Table 4.20. Descriptive Statistics: Surgical Groups Melbourne Cohort

		Validation Group														
		Abdominal n = 54 (30%)			Cardiothoracic n = 18 (10%)			Vascular n = 27 (15%)			Orthopaedic n = 27 (15%)			Other n = 50 (28%)		
		case control			case control			case control			case control			case control		
		<i>p</i>			<i>p</i>			<i>p</i>			<i>p</i>			<i>p</i>		
Gender	female	18	11		4	4		5	3		11	1		14	8	
	male	17	8		8	2		9	10		10	5		20	8	
TOTAL		35	19	0.590	12	6	0.180 <sup>a</sup>	14	13	0.472 <sup>a</sup>	21	6	0.121 <sup>a</sup>	34	16	0.558
AGE	20–50	8	7		0	3		0	4		8	4		9	9	
	51–80	21	10		10	3		11	7		12	2		21	7	
	81+	1	2	0.381 <sup>a</sup>	2	0	0.022 <sup>a,b</sup>	3	2	0.080 <sup>a</sup>	1	0	0.438 <sup>a,b</sup>	4	0	0.075 <sup>a</sup>
BMI	26	2	4		3	1		3	2		2	0		2	4	
	26–30	3	1		0	1		3	0		2	1		7	5	
	31+	18	7	0.253 <sup>a</sup>	6	3	0.364 <sup>a,b</sup>	4	2	0.452 <sup>a,c</sup>	4	1	0.659 <sup>a,b</sup>	14	1	0.015 <sup>a,*</sup>
Diabetes		13	4	0.489	5	0	0.063	9	4	0.089 <sup>a</sup>	4	1	0.859 <sup>a</sup>	9	2	0.266 <sup>a</sup>
PAD		0	0	NA	1	0	0.467 <sup>a,b</sup>	11	2	<0.001*	1	0	0.586 <sup>a,b</sup>	1	0	0.488 <sup>a,b</sup>
CVD		4	0	0.097 <sup>a</sup>	10	0	0.001 <sup>a,*</sup>	12	0	<0.001*	2	0	0.432 <sup>a,b</sup>	1	0	0.488 <sup>a,b</sup>
Smoker		15	4	0.110	4	0	0.109 <sup>a</sup>	8	5	0.032	7	1	0.430 <sup>a</sup>	11	3	0.318 <sup>a</sup>
Previous surgery		28	9	0.003*	12	1	<0.001 <sup>a</sup>	13	2	<0.001*	13	0	0.007 <sup>a,*</sup>	25	5	0.004*

Note. Results are based on non-empty rows and columns in each innermost sub-table.

\*The Chi-square statistic is significant at the .05 level. a. More than 20% of cells in this sub-table have expected cell counts below 5. Chi-square results may be invalid. b. The minimum expected cell count in this sub-table is below one. Chi-square results may be invalid.

Among the validation sample, 20% of cases had undergone abdominal surgery (n= 35), 12% orthopaedic surgery (n=21), 8% vascular surgery (n=14), and 6% cardiothoracic procedures (n=18) (Table 4.17). The remainder (n=35) of the cases were classified as other surgery; plastic surgery (n=20); neurosurgery (n=3, spinal; n=1, urology; n=1, maxillofacial surgery; n=2, transplant; n=8), and they were excluded from analysis beyond descriptive statistics. As the SWDRAT was based on the abdominal sample, it was this group that was used for the tool validation purposes. Within the abdominal sample used for validation of the tool, 80% of cases had a previous surgery in the same anatomical location whereas only 40% of controls had previous surgery (Table 4.20).

Table 4.21. Comparative statistics - Perth and Melbourne Cohorts

Variable		Abdominal group			
		Validation Cohort		Perth Cohort	
		Case	Control	Case	Control
		n=35	n=22	n= 30	n=48
		n %	n %	n %	n %
Gender	Female	18 51%	12 54%	12 40%	22 45%
	Male	17 48%	10 45%	17 56%	26 54%
Diabetes		13 37%	5 22%	8 26%	6 12%
BMI	<26	2 5%	5 22%	2 6%	6 12%
	26-30	3 8%	2 9%	7 23%	5 10%
	31+	18 51%	7 31%	10 33%	6 12%
Previous surgery*		28 80%	9 40%	9 30%	0
PAD		0	0	5 16%	2 4%
CVD		4 11%	0	14 46%	12 25%
Smoker		15 42%	4 18%	16 53%	16 33%

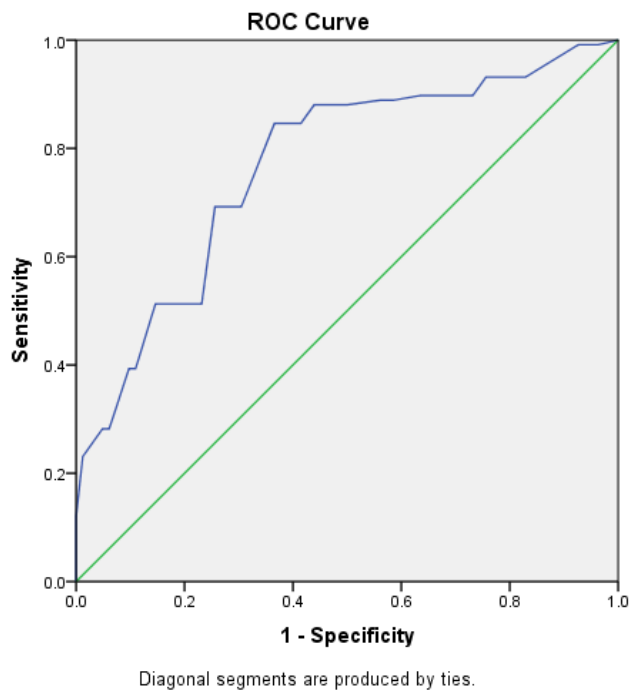
\* in the same anatomical location

Among the cases, 42% were smokers compared to 18% in the control group (Table 4.21). In the abdominal cases group (n=35), 11% had CVD, and no cases recorded PAD. While the Melbourne cohort was not identical to the Perth cohort, the overall similarities between the two groups were consistent.

#### 4.9.2. SWDRAT Predictive Power

Risk scores were determined by summing the beta coefficients of selected variables as per the draft SWDRAT. Patients could score from 0 to a maximum of 9.02 points. Following the descriptive analysis of the internal validity sample, a ROC analysis was conducted to determine the sensitivity and predictive power of the draft SWDRAT. The AUC statistics were

used to determine the predictive power of the risk tool against the validation sample. Furthermore, the AUC statistic was used to determine the cut-off points for the risk score (Figure 4.6).



Area Under the Curve				
Test Result Variable(s): Risk score				
Area	Std. Error <sup>a</sup>	Asymptotic Sig. <sup>b</sup>	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.768	.034	.000	.701	.834

*Note.* The test result variable(s): Risk score has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased...a. Under the non-parametric assumption. Null hypothesis: true area = 0.5.

Figure 4.8 Receiver Operator Curve (ROC) statistics — Melbourne cohort

From the ROC analysis, the predictive power of the draft SWDRAT across the validation sample was 76%. The receiver operator characteristic AUC statistic is a plot of false positives against true positives for all cut-off values. The AUC statistic for a perfect test is 1.0 (Hajian-

Tilaki 2013). The SWDRAT was found to have reasonable predictive power; however, caution is required with regard to this finding, due to the low sample sizes.

#### **4.10. Conclusion**

This chapter has described the methods and results of the first component of the study which included the development and internal validation of a draft risk assessment tool for SWD. The pre, intra and postoperative factors related to SWD in the sample were also described. While variables such as diabetes and high BMI did not yield statistical significance across the Perth and Melbourne cohorts, there was a substantial trend towards a correlation of high BMI, diabetes and SWD. Of particular note was the statistically significant link between previous surgery and the occurrence of SWD across the Perth and Melbourne cohorts. A draft preoperative surgical wound dehiscence risk assessment tool (SWDRAT) was developed to assist clinicians to identify patients at risk of SWD in the preoperative clinical setting. An initial validation, as derived from an ROC test, yielded a predictive power of 76% for the draft SWDRAT. It is acknowledged the findings from the intra- and postoperative datasets may require further investigation, and perhaps development of specific risk tools for those clinical settings and this is discussed in research recommendations at the end of this thesis.

A descriptive cost study of the Perth cohort revealed considerable healing time and associated cost differences between those who were treated for infection and those without infection. Clinical management of a wound dehiscence in the community setting averaged \$1,025 per patient, whilst the non-infected patient was substantially lower on average \$509. Moreover the healing times were significantly different ( $p > 0.001$ ) between the infected and non-infected patient, with the infected patient taking a longer time to heal.

Building on the initial findings of the literature review and the findings from the case-controls studies, the internal validity of the SWDRAT was considered to require further testing

in a clinical setting. Preliminary assessment of the tool's clinical utility, inter-rater reliability and further predictive power of the SWDRAT in a combined prospective sample are reported in the following chapter.

## **Chapter Five**

### **Methods and Results Prospective Clinical Validation**

#### **Introduction**

The findings from the internal statistical validation of the SWDRAT as presented in Chapter Four, identified the need for further testing of the tool in a prospective clinical setting. This chapter describes both the methodology and findings of a clinical validation of the SWDRAT which was conducted amongst a cohort of patients who underwent abdominal colorectal surgery in an acute care setting. The aim of this part of the study was to determine the clinical utility, inter-rater reliability and predictive power of the risk assessment tool.

#### **5.1 Methodology**

##### **5.1.1. Study Design and Sample**

Following the development of the SWDRAT, which was outlined in Chapter 4, it was decided to conduct further prospective testing in a clinical setting to determine inter-rater reliability, predictive power and more specifically, clinical utility. The prospective sample was derived from a cohort of patients admitted to a private metropolitan hospital in Perth, who were scheduled to undergo an elective abdominal procedure and were recruited and consented as a consecutive series (Figure 5.1).

The exclusion criteria included those who declined to participate, pregnant females, and those patients with a postoperative open abdomen or delayed primary closure. Laparoscopic procedures and patients who underwent emergency procedures were also excluded.

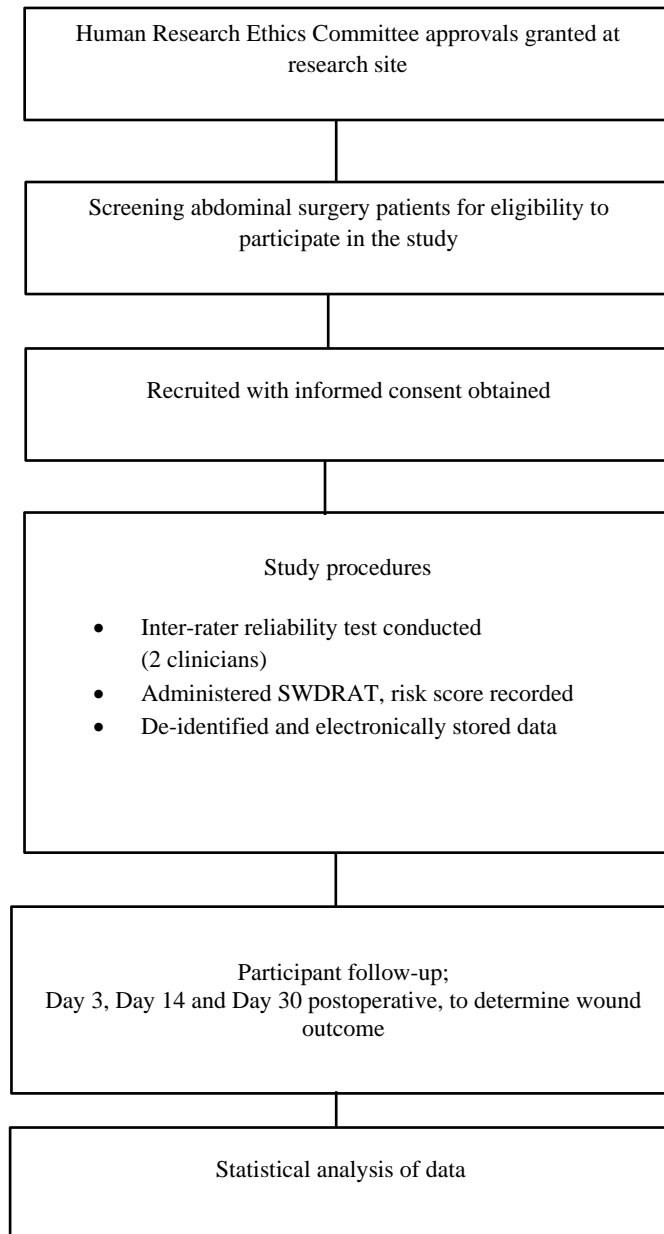


Figure 5.1. Prospective validation protocol



### 5.1.2. Data Collection

The study instrument used for data collection was the SWDRAT as outlined in Chapter Four, Table 4.14 and (Appendix 4). The risk score assessment was completed in the preoperative phase by the Clinical Nurse Consultant. Once the patient had consented (consented patients are referred to as 'participants' from hereon), the data were collected during the initial surgical consultation. The participant was then scored for risk by summation of the beta coefficients, and the information recorded on the SWDRAT. For example, if a participant had diabetes, a BMI of 31+ and was a smoker, his or her total score was calculated as  $(1.10 + 0.773 + 1.10 = 2.97)$  as per the risk score tool. Once the scores were calculated, the information was then de-identified from the source documentation and stored in an electronic database (IBM® SPSS® V.20) for further analysis.

All participants were followed up postoperatively on day 3, 14 and 30, to determine whether they had a wound dehiscence. In the event the participant had a dehiscence this was recorded in the outcome box as '1'. The participant follow-up at each point on the time line was conducted in the surgical wards, and in the outpatient clinics, in liaison with the clinical nurses, surgeons and the clinical nurse consultant (CNC). The primary clinical outcome (dehiscence or not) was recorded in the database in binary format (Yes = 1 or No = 0). The incision was sighted by a CNC and this nurse's clinical judgement determined whether the participant had incurred a wound dehiscence within the study definition. The length of the dehiscence was recorded (cm), as well as any depth to the sutured margin separation (cm), using a wound-specific ruler. Any separation of the sutured margins was deemed an event. Source documentation was kept separate from the de-identified database for security purposes.

### **5.1.3. Inter-rater Reliability**

The reliability of a measurement determines the consistency, repeatability and reproducibility of the instrument being used (Richman, 1980). Inter-rater reliability is a measure of how consistent two or more independent raters are in their judgement (Goodwin & Prescott, 1981). Concordance among raters is essential to the establishment of inter-rater reliability. If the raters do not agree, the tool may be insufficient or the raters require further training and clarification on the measurement. The inter-rater reliability of the risk assessment tool in this study was tested using a previously published protocol (Sanada et al., 2004).

Two nurses were trained on the use of the risk assessment tool. The nurses (one an experienced wound nurse practitioner and the other a CNC) were given an hour's training on the use of the tool and then completed risk score calculations on a case series (10 scenarios), independently of each other. A reference rater (experienced wound nurse practitioner) had scored the series of ten case studies with the SWDRAT. The reference rater disclosed his/her score and if there were any discrepancies these were discussed. Anecdotal feedback was sought from the raters as to the clinical utility of the score. There was 100% concordance of ratings between the nurses and the expert practitioner.

### **5.1.4. Analysis**

Descriptive statistical analysis was conducted to determine the prospective sample characteristics. Further descriptive analysis included investigation of wound characteristics. Tests of significance (Chi-square analysis and Fisher's Exact Test) were conducted to determine differences within the group in relation to age, gender, and BMI, as well as differences among other patient-related comorbidities as recorded in the risk assessment tool. A one-tailed T-test was used to test for differences between the dehisced and non-dehisced group. A ROC analysis was conducted to further determine the predictive power of the tool in the clinical setting. The

methodology was identical to the initial ROC analysis conducted for the internal validation of the SWDRAT, as discussed in Chapter Four.

## 5.2. Prospective Clinical Validation Results

Over the data collection period, 26 participants were recruited to the study. All patients who were invited to participate and were eligible for recruitment consented to participate. However, during the six month data collection period, recruitment was hindered by cancelled theatre lists and the principal surgeon's unscheduled leave period due to illness, which contributed to the overall low convenience sample size. Figure 5.2 reports the recruitment process and results.

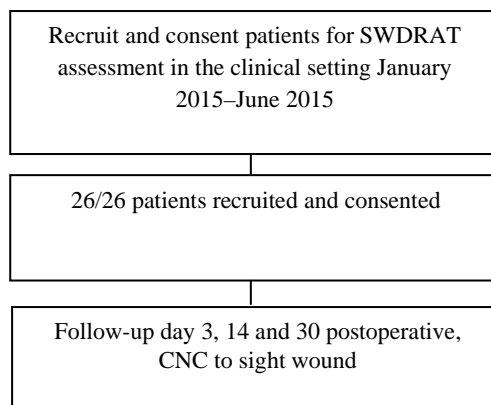


Figure 5.2. Patient recruitment flowchart

Among the 26 participants who were recruited to the study, 42% were male and 58% female (Table 5.1). Half of the group (50%) had a previous surgical scar in the area that was to undergo another surgical incision, while all participants had a confirmed diagnosis of colorectal cancer.

Table 5.1. Descriptive Statistics: Prospective Sample

Variable		n	%	Dehiscence
Age	19–20	1	3.8%	0
	21–50	11	42%	0
	51–80	13	50%	5
	81+	1	3.8%	0
Gender	Male	11	42%	2
	Female	15	58%	3
TOTAL		26	100%	5 (19%)
BMI	<26	11	42%	1
	26–30	9	34%	2
	31+	5	19%	1
Diabetes		4	15%	0
Previous surgery		13	50%	1
CVD		4	15%	1
PAD		1	3.8%	1
Smoker		1	3.8%	0

*Note.* Results are based on non-empty rows and columns in each innermost sub-table.

\*. The Chi-square statistic is significant at the .05 level.

a. More than 20% of cells in this sub-table have expected cell counts below 5. Chi-square results may be invalid.

b. The minimum expected cell count in this sub-table is below one. Chi-square results may be invalid.

Although not of statistical significance, several trends were evident. The majority of participants were in the 51–80 age bracket, there were fewer males than females and 42% of the sample had a low BMI of under 26kg/m<sup>2</sup>. Of the total sample 19% (n=5) of participants had a wound dehiscence following surgery. Participants were scored for risk of SWD prospectively during the initial surgical consult. The risk scores for participants are reported in Table 5.2.

Table 5.2. Risk Score Grouping of Participants

SWDRAT Score	(n)	Dehiscence	
		Y	N
0-3	11	1	10
3.1-6	6	3	3
6.1-9.02	9	1	8

Among the 26 participants, five incurred a dehiscence following surgery; they were in the 51–80 years old category, two of them male and three female. One participant had undergone previous surgery in the same anatomical location, while one had CVD, and another had PAD. The majority of participants, 43%, scored between 0 - 3.9, followed by 34% of participants scoring in the 6.1–9.02 group, and 23% in the 3.1–6 group (Table 5.2).

Characteristics of the dehiscence for the five participants were collected and are reported in Table 5.3. The degree of dehiscence for each of the five participants involved the separation of the subcutaneous layers and these were not classified by the CNC as a deep or organ-space dehiscence.

Table 5.3. Dehiscence Characteristics Prospective Cohort

Location of dehiscence along midline laparotomy incision	Length	Width	Depth
1. Proximal end incision	2cm	2cm	1cm
2. Distal end incision	1cm	0.5cm	0.5cm
3. Distal end incision	2cm	1cm	0.5cm
4. Distal end incision	3cm	1cm	1cm
5. Distal end incision	1cm	1cm	0.5cm

As reported in Table 5.3, the majority of the dehisced wounds were at the distal end of the incision and the average length was 1.8 cm, average width 1.1cm, and depth 0.7cm. Two of the wounds had a confirmed wound infection and the pathology reports identified the primary

pathogen as *Staphylococcus aureus*. Interestingly, 50% of the sample had undergone previous surgery in the same anatomical region.

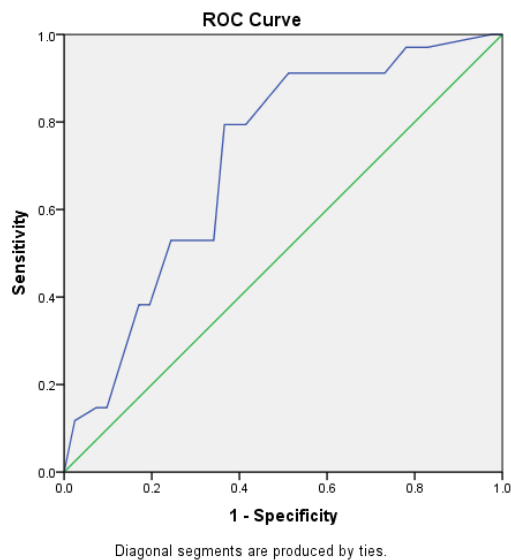
### 5.2.1. ROC Analysis: Combined Dataset

As previously described in Chapter Four, the SWDRAT was tested for internal validity in a sample population in Melbourne and then subsequent ROC analysis was conducted on the abdominal cohort only. Following completion of the prospective study, a subsequent test dataset was created (due to low numbers from the prospective cohort), to combine both the internal validation cohort (Melbourne cohort) and the prospective clinical cohort to further determine the predictive power in a larger sample. The descriptive statistics for the combined dataset are reported in Table 5.4.

Table 5.4. Descriptive Statistics Combined Dataset

Variable	n	%
Age		
20–50	19	34%
51–80	34	62%
81+	2	5%
Gender		
Male	24	45%
Female	31	54%
	TOTAL	55
BMI		
<26	15	27%
26–30	13	23%
31+	27	49%
Diabetes	17	30%
CVD	8	14%
PAD	1	1.8%
Previous surgery	41	74%
Smoker	16	29%

The combined data test set consisted of a sample size of 75, of which 45% were males and 54% females (Table 5.4). Both datasets were comparable in the proportion of males to females, percentage of participants with diabetes and those who had undergone previous surgery, as well as those with the diagnosis of CVD. Of the sample, 22% had diabetes and interestingly, a high proportion (74%) had previous surgery in the same anatomical location. As with the approach used for the Melbourne cohort a ROC analysis was undertaken using the combined dataset. The results are reported in Figure 5.3.




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Area Under the Curve

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Test Result Variable(s): Risk score

Area	Std. Error <sup>a</sup>	Asymptotic Sig. <sup>b</sup>	Asymptotic 95% Confidence Interval (CI)	
			Lower Bound	Upper Bound
.714	.060	.001	.597	.831

The test result variable(s): Risk score has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased.

a. Under the non-parametric assumption

b. Null hypothesis: true area = 0.5.

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Figure 5.3. ROC Curve combined dataset

The combined dataset analysis confirmed the predictive power of the risk assessment tool at 71% (Figure 5.3) (CI 95%, 0.597–0.831). These results were similar to the initial ROC analysis of the Melbourne cohort for predictive power, that is, 76% (CI 95%, 0.701–0.834) on the first test and 71% predictive power on the combined dataset. The ROC test on the combined dataset yielded a moderate predictive power for the SWDRAT. However, given the small sample size and the somewhat heterogeneous nature of the combined dataset, further testing of the SWDRAT is required on a larger patient group, to eliminate sampling issues.

### **5.3. Conclusion**

A prospective internal validation was conducted to determine the predictive power and inter-rater reliability of the draft SWDRAT. This chapter has described the methods and results of the prospective clinical validation and predictive power of the SWDRAT. Of the 26 participants in the prospective clinical validation, the majority were females (57%), and 67% of the entire sample had undergone previous surgery in the same anatomical location. Of those predicted to be at risk of SWD (high risk score), only 1 out of the 9 high risk participants incurred a dehiscence in the prospective series, this patient also had previous surgery in the same anatomical location. Within the medium risk group, half incurred a dehiscence and in the low risk group one incurred a dehiscence. It would appear that the sensitivity and specificity of the tool requires further work for accurate prediction of SWD.

A combined dataset (Melbourne cohort and prospective clinical validation) was used to conduct a further ROC analysis. The combined dataset had an almost even distribution of males (45%) and females (54%), of which 49% had a BMI of 31 or greater, a similar proportion to that in the original Perth cohort (46%). From the ROC analysis of the combined dataset, the AUC statistic of 71% revealed that the SWDRAT had moderate predictive power. Anecdotal accounts from clinicians during the study revealed the ease of use of the SWDRAT during the initial



surgical consult with the patients. The inter-rater reliability proved high between two raters and the expert clinician with different nursing experience. Chapter Six will discuss these findings in light of the contemporary literature.

## **Chapter Six**

### **Discussion**

#### **Introduction**

Timely and sustained postoperative wound healing plays a significant role in optimising a patient's postoperative recovery and rehabilitation. It has been established that SWD contributes to increased morbidity and mortality and to implicit and explicit costs for individuals and health care providers (Leaper et al., 2004; McLaws et al., 1988; Phan et al., 2012; van Ramshorst et al., 2010; Webster et al., 2003). Explicit costs result from prolonged hospitalisation, the need for community nursing support services, and the wound management consumables required to manage the problem (Graf et al., 2010; Lissovoy, 2008; Reilly et al., 2001; Ridderstolpe et al., 2001; Urban, 2006). Implicit costs are the psychosocial impact on patient wellbeing; delays in returning to employment; reduced capacity for self-care, and limitations in returning to self-management of activities of daily living (Ghoneim & O'Hara, 2016; Spiliotis et al., 2009; Tanner, Aplin, Ball, Thomas, Bankart., 2009).

Surgical wound dehiscence is a complex wound management issue that requires evidence-based wound management and resources to optimise patient outcomes. This study determined risk factors associated with SWD and used these findings to develop a preoperative risk assessment tool (SWDRAT), which underwent subsequent preliminary statistical and prospective internal validation. The novel SWDRAT (Appendix 4), that resulted includes 11 factors associated with SWD. The identification of these may assist in recognising patients that may be predisposed to surgical wound breakdown. The objectives of this study are addressed in the discussion that follows.

**1. Determine the number of patients being treated for SWD in a community nursing setting (CNS) setting during 2010-2011 and the costs associated with the clinical management of SWD in the CNS.**

Four hundred and sixteen patients were initially identified from the community nursing setting database as receiving treatment for SWD following discharge from the acute setting in metropolitan Perth. Further investigation of the 145 consented cases revealed 62 cases with a confirmed diagnosis of SWD. Close to 25% of the original sample were misdiagnosed and this conundrum has also been observed by others in their work (Guest et al, 2015). The SWD cases consisted of older males and females with pre-existing lifestyle and comorbidity risk factors such as smoking and diabetes, with a trend towards a high BMI. In particular, the majority of cases had undergone a previous surgical procedure in the same anatomical region, and close to half were smokers. In contrast, the comparison control group of 100 participant's baseline characteristics featured a younger cohort with less chronic disease, lower numbers of smokers, and lower occurrence of previous surgeries.

The baseline characteristics of the Perth cases in this study were not too dissimilar from the findings of others who have reported obesity, diabetes and older age as contributing factors of those who had a SWD (Guest et al., 2015; Tanner et al., 2009; van Ramshorst et al., 2010; Webster et al., 2003). Whilst these findings are not surprising, it may be reflective of a wider global problem for wound complications. That being patients with chronic disease states, obesity, and an aging population of which underpin delayed wound healing, suddenly become doubly problematic when linked with extrinsic risk factors in the intraoperative environment or poor postoperative management. The burden of SWD remains to be reported and understood, however the findings of this study have confirmed similar factors that complicate wound healing in the chronic wound.

A descriptive cost study was also conducted to determine the wound management costs associated with the treatment of SWD identified in the community cohort recruited to the first case control study. Calculations were based upon contract pricing of wound care consumables and nursing services for 2010–2011 the period during which data for this cohort was collected. One of the key findings of the cost analysis was the median cost of wound management (nursing time, dressings, and other consumables used) for a patient with a SWD in a community nursing setting, which was AUD \$509 for the non-infected patient, as compared to AUD \$1,025 for those receiving antimicrobial dressings for treatment of clinical infection. The portion of the sample receiving treatment for infection was close to half (n=29), which accounted for over 60% of the costs to the CNS in the sample. In this study, the cost of managing wound dehiscence with an infection were double that of a non-infected dehiscence. Of note were the higher costs associated with the increased frequency of nursing visits in the infected wound group compared to the non-infected group. Several other authors (Byrne et al., 1994; Noel, Hollyoak, & Galloway, 1997; Reilly et al., 2001; Tanner et al., 2009) have reported similar findings associated with increased costs of care and the delay in healing times for infected wounds.

Although this study did not investigate the additional explicit costs associated with the clinical management of SWD, such as organisational overheads and the travel costs of visiting nurses, they need to be considered. Other researchers such as Tanner et al. (2009) found the average cost per patient of treating wound infection following discharge was £10,523 in the UK, including primary care costs, organisational overheads and travel costs associated with district nurses' visits, ultrasound tests, and hospital readmission costs. While comparison of this study with Tanner's work is somewhat constrained due to differences in data collection and analysis methods, it is highly likely that the costs associated with SWD as reported in this thesis may be an underestimate, given the omission of organisational overhead costs and any associated acute

care costs. Tanner et al. (2009) proposed that the key to capturing the associated costs of treating SSI, including SWD, is robust reporting and post-discharge surveillance programs that should extend to at least 30 days following discharge. Publication of community care costs in managing SWD was found to be very limited in the literature, and this was identified as a gap in this study which substantially limits the ability to benchmark findings.

Researchers in the USA (Smith et al., 2004) found that patients with SSI following elective colorectal surgery accumulated a mean cost of USD \$6,200 on home health expenses related to wound care. These authors reported that treatment of an SSI among 45 patients cost USD \$124,000, and this was acknowledged by the authors as a conservative estimate; however, SSI and SWD were conflated in this report. Similarly, the annual cost of SSI in Europe and the UK exceeds €1.4-19 billion (Leaper et al., 2004) and £930 million (Plowman et al., 2001) respectively, again with no distinction made between SSI and SWD. In Australia however, the annual cost of SSI is reported at AUD\$268 million (McLaws & Taylor, 2003). Moreover, these costs reportedly refer to the acute care setting, not the community nursing setting, where the clinical management of SWD may require lengthy episodes of care.

Further to the first component of this study was the identified absence of a global consensus around the definition and classification of SWD. This was surprising, considering that dehiscence imposes a significant burden on health care systems, and has an equally heavy impact on patient wellbeing. Too often in the literature SSI was used as the umbrella term for postoperative complications, with little detail on the nature of the SSI or whether or not it resulted in an actual SWD. In addition, there is much discourse with regards to the difficulties encountered in synthesising the data collected due to reporting inconsistencies and a lack of standardised definition across published data sets, including a standardised definition for SWD as distinct to SSI (Leaper et al., 2004; Sandy-Hodgetts et al., 2016; Sandy-Hodgetts., et al 2018). Mitchell, et al. (2017) has called for national standardisation of recording and reporting

health care acquired infection surveillance to improve our scope and understanding of the problem in Australia. From the lack of published data available it would appear that a national approach is required to address the problem (ACSQHC 2017). This study has contributed to the growing body of knowledge in this area (Sandy-Hodgetts et al., 2016), however there remains a considerable dearth of level-one published studies that report the incidence and prevalence of the problem in the community nursing setting (Leaper et al., 2013; Tanner et al., 2009; Tanner et al., 2013; Sandy-Hodgetts et al., 2018). The greater challenge remains in elucidating the scope of the issue, the snapshot provided in this study may be indicative of a wider problem.

This study has identified the number of SWD cases in a selective community cohort. It has also demonstrated a non-microbial component of SWD, similar to Uckay et al. (2011) findings. Furthermore the study has demonstrated the importance of determining whether wound infection has contributed to or has occurred subsequently to SWD. The identification of the aetiology of the SWD underpins the appropriate clinical management of the wound dehiscence. Inconsistencies in reporting and classification of SSI and SWD, can lead to spurious results and potential misrepresentation of the scope of the clinical problem (Leaper et al., 2013; Tanner et al., 2009). This global discrepancy clearly needs addressing for reports of prevalence and incidence rates of SWD must be independent of SSI rates. A SWD definition and classification consensus will facilitate correct identification and reporting of SWD.

## **2. Identify the pre, intra and postoperative variables associated with SWD.**

A critical appraisal of the literature was conducted, and individual risk factors associated with SWD were identified. Pre-existing patient-related comorbidities such as diabetes, CVD and high BMI featured prominently in the literature (Borger et al., 1998; Streeter, 2006; Williams et al., 2009).

Researchers have determined that the experience of the surgeon, as well as the closure method is related to the occurrence of SWD (van Ramshorst et al., 2010; Webster et al., 2003). The findings from the first case control study, which focused on the Perth cohort, yielded findings similar to those of others in the field in relation to the presence of risk factors such as increased age and CVD, which were of statistical significance in this study as well as the work of others (van Ramshorst et al., 2010; Webster et al., 2003). Whilst the findings of this study did not yield a statistically significant result in relation to diabetes and high BMI, trends were evident to suggest that a BMI of 30kg/m<sup>2</sup> and above is associated with the occurrence of SWD.

Whilst the literature reports that in the cardiothoracic group, the experience of the surgeon was also noted to be of significance in relation to SWD (Buja et al., 2012), a similar trend was noted in the results of this study's Perth cohort, although this was not statistically significant. Also found in the cardiothoracic group, females were more likely to incur a SWD following a procedure (Borger et al., 1998; Salehi-Omran et al., 2007; Sharma et al., 2009) although not of statistical significance, a similar trend was also noted in this study.

Overall, the preoperative risk factors associated with SWD identified in this study were found to be consistent with the findings of others in the field and included age, high BMI, cardiovascular disease, peripheral arterial disease and smoking, (van Ramshorst et al., 2010; Webster, Neumayer, Smout, Horn, Daley, Henderson, & Khuri, 2003). What yielded a high statistical significance in this study was the presence of previous surgery in the same anatomical location as the study surgery. This study has demonstrated that previous surgery in the same location as an independent predictor of SWD.

The first case control study and the literature review led to the development of a patient-centric conceptual framework that synthesised the pre, intra and postoperative risk factors associated with SWD, (Figure 3.2, Chapter Three). A conceptual framework for SWD had not previously been described; this is a new contribution to the field and one which may provide a

benchmark for future research. In using a conceptual framework, risk factors for SWD were identified and supported their inclusion in the draft preoperative SWDRAT.

### **3. Develop a SWD Risk Assessment Tool (SWDRAT).**

The preoperative SWDRAT that resulted from the study is a unique risk assessment tool in the early stages of development. The risk tool addresses the patient risk prior to surgery with the focus on pre-existing comorbidities and lifestyle factors that may impact the healing capacity of the patient. Although numerous patient risk indices or models are available for identification of postoperative complications such as SSI, to date there have been none that focus specifically on SWD. Available risk assessment tools which include; the Toronto Risk Index (Kohli et al., 2003); the NNIS (Emori, 1991); the Alfred Hospital Risk Index (Russo & Spelman, 2002); the SWIPS (Hussey et al., 1998); the Fowler Index (Fowler et al., 2005), and the EuroSCORE (Nashef et al., 2002), tend to be related to specific surgical domains or have dedicated focus on infection risk. More recently, there has been the advent of web or smart phone based applications for some of these tools such as CeDAR (Augenstein et al., 2015) and Cardiff Medical Apps Surgical Risk (Prytherch et al., 1998). Whilst these risk tools are available for clinicians they focus primarily on infection risk and not SWD. This is where the SWDRAT differs from current available risk tools.

One of the major findings from the retrospective case control regression analysis was the identification of an independent risk predictor for the occurrence of SWD, which was previous surgery in the same anatomical location. The odds ratio of this independent risk predictor revealed that patients who had undergone previous surgery in the same anatomical location were four times more likely to incur a SWD than those who had not (OR:4, 95% C.I 0.747-1.112,  $p<0.001$ ) (see Table 4.19 in Chapter Four). This appears to be the first report of an empirical measure and subsequent statistical testing of this variable in the context of an association of SWD and previous surgery in the same anatomical location. Authors have



reported this factor as part of the baseline characteristics of their sample under examination (Floros et al., 2011; Agarwal et al., 2011; Zhang et al., 2016), however further statistical analysis to examine the correlation between this factor in relation to SWD, and its predictive relationship to SWD has not been forthcoming. The question remains; is this independent risk factor alone enough to place the patient at immediate risk notwithstanding other risk factors? Further investigation in larger cohorts to test this assumption is warranted as is the need to conduct multicentre validations as per other risk tools such as the EuroSCORE (Nashef et al, 2002) or CeDAR (Augustein et al, 2015).

#### **4. Test the draft SWDRAT for predictive power and undertake a preliminary internal validation.**

The draft SWDRAT was internally validated among a retrospective sample of 75 patients and subsequently prospectively clinically validated in a consecutive series of 26 participants. The predictive power of the tool as determined by the ROC analysis in the internal validation sample was 76%, which was moderately strong. Further testing of a combined dataset (the prospective cohort and the abdominal cohort from the retrospective sample) yielded 71% power. When comparing the predictive power of the SWDRAT to other available risk tools the results are varied. This may be due to the lack of homogeneity between test samples, sample size differences and non-comparable outcomes of other risk tools which restricts the ability to directly compare predictive power of other tools such as the EuroSCORE or van Ramshorst's et al., (2010) across published studies. However, in light of this, when compared to the predictive power of Ramshorst et al.'s. (2010) model of 91%, the predictive power of the SWDRAT is considerably lower. Further validation studies of the van Ramshorst et al (2010) risk model's predictive power in other clinical settings were not found in the literature. Across a consecutive series of 78 patients, the EuroSCORE yielded a predictive power for mortality of 74% (Holinksi et al., 2015). Comparison of the SWDRAT to the EuroSCORE is somewhat difficult as

EuroSCORE is measuring mortality rates whereas the SWDRAT is measuring SWD. It is interesting to note, however, in observation of the work that has been conducted on the EuroSCORE, that the SWDRAT would require extensive multisite validations, similar to the EuroSCORE, to ensure the predictive power of the tool for real clinical efficacy.

**5. Determine the inter-rater reliability of the SWDRAT, and test the predictive power of the risk tool in a prospective series of surgical patients in the clinical setting.**

This study has reported that the inter-rater reliability test of the SWDRAT yielded 100% agreement between raters who participated in the testing of the tool, however the number of participants was low. Of importance were the anecdotal accounts by surgeons and nurses of how easy it was to use the tool and incorporate the SWDRAT into daily clinical practice. This suggests that the SWDRAT may translate easily into clinical practice, and could be readily adopted by practitioners in the field. However, the prospective validation of the SWDRAT on a consecutive series of patients and subsequent ROC analysis on the combined data set yielded a moderate predictive power of 71%. Whilst this was encouraging the level of predictive power was deemed less than desirable for optimal clinical practice outcomes. Moreover, extrapolation to the wider clinical setting is limited due to the small sample size recruited to the consecutive series sample during the internal validation of the tool. The results indicate that further testing and analysis is required to improve the predictive power of the tool and acceptance across a range of clinical settings.

Perceived clinical benefits of additional and expansive validation testing the SWDRAT are anticipated to include:

1. Focussed assessment of preoperative risks for dehiscence (Figure 6.1).
2. Inclusion an independent risk factor for SWD not previously reported, which is previous surgery in the same anatomical location.

3. An opportunity for clinicians to implement preventive strategies preoperatively once risk is identified.

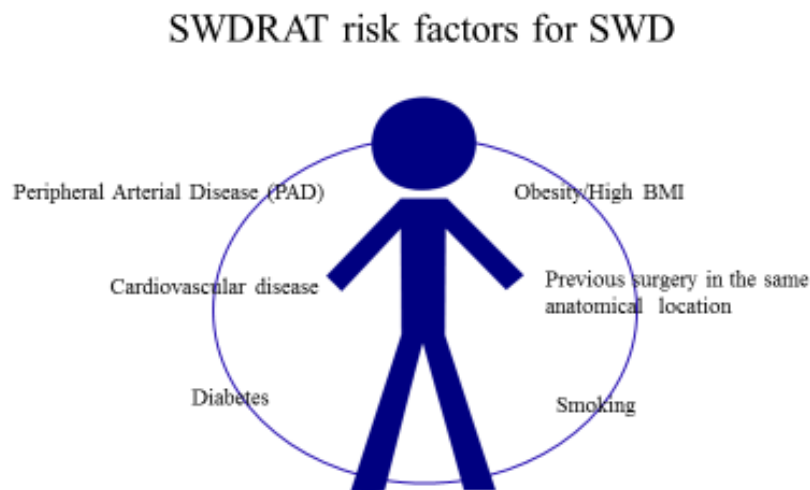


Figure 6.1 SWDRAT - identified preoperative risk factors for SWD

Figure 6.2 outlines a proposed clinical pathway which illustrates how the SWDRAT might inform clinical practice if further validations support the value of the tool. This incorporates identification of potential risk, implementation of preoperative management of key risk factors (e.g. weight loss, smoking cessation, diabetes control, alternate surgical plan to avoid existing surgical incision) and close intraoperative and postoperative management, dressing support of the incision line (Zhang et al., 2016), and if problems do occur, a care plan that extends beyond patient discharge. The rationale behind the clinical pathway is to facilitate research translation into clinical practice as has been widely adopted by others in translation of research findings into clinical practice (Curtis, et al., 2016; Rubio et al., 2010; Wuchner, 2014; Soria et al., 2005).

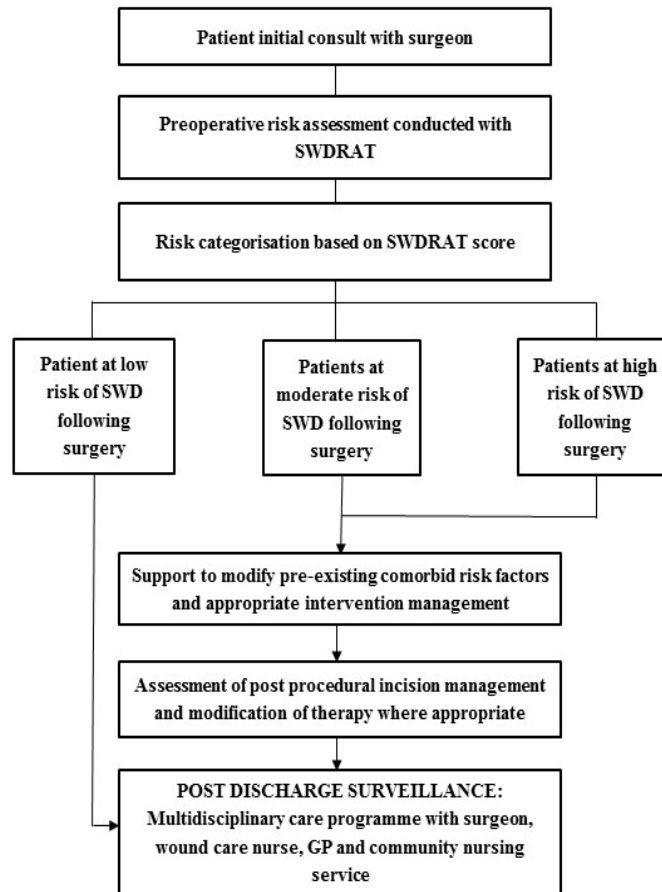


Figure 6.2. SWD screening and identification algorithm for acute care setting

## 6.2 Conclusion

Surgical wound dehiscence is a complex wound management issue that requires evidence-based wound management, and resources to optimise patient outcomes. This study has revealed new findings in relation to the aetiology of SWD and has highlighted the issues surrounding the classification and reporting of this wound type. The draft SWDRAT offers a new risk tool for the clinician’s armamentarium in the preoperative assessment of the surgical patient.

## Chapter Seven

### Conclusion and Recommendations

#### Introduction

The purpose of this study was to determine risk factors for SWD, and to develop and internally validate a risk assessment tool for the identification of patients at risk of SWD. This thesis has reported on the development and preliminary validation of a SWDRAT in response to the occurrence of SWD cases who were being treated in a community nursing setting in Perth, following discharge from the acute care setting. The findings have determined that patients at risk of SWD are considerably more likely to have pre-existing comorbidities such as CVD and PAD and have associated poor lifestyle factors such as smoking and obesity. Moreover, those patients who have undergone previous surgery in the same anatomical location are at greater risk of SWD than those who have not.

While the SWDRAT was anecdotally well accepted by clinicians, with high inter-rater reliability demonstrated between two raters in the preliminary validation, more research is still needed to further validate the SWDRAT in the expanded clinical setting, in order to establish a systematic approach to SWD screening, and improve the identification of high-risk patients. This study has confirmed much of what is already reported in the literature, particularly in regards to the preoperative risk factors which informed the development of the risk assessment tool. Identification of at-risk patients with a validated risk tool creates opportunities to explore preventive approaches rather than having to manage the resulting wound complication.

## **7.1. Study Limitations**

There are several study limitations that could complicate the generalisation of findings and use of the draft SWDRAT in the wider population.

### **7.1.1. Study sample, data collection, analysis, and tool development**

The sample comprised patients who were referred to the CNS following hospital discharge. The data collection obtained from the initial Perth cohort was restricted to patients referred to the CNS and so did not include those patients who received care from other health providers, such as hospitals or other home primary care services, nor did it cover those who may have been readmitted to the acute care setting.

The study therefore represents a proportion of the total surgical population which had a SWD during the period 2010–2011 in metropolitan Perth, Western Australia. This represents a potential bias in the initial sample as it is not inclusive of all patients who may have had a SWD. Therefore, one may assume that findings in relation to the time and cost to healing are limited to the study population only (CNS), and may not be a true reflection of the costs and time to healing in the wider population. The small study size is a limitation in regards to the statistical analysis of the study findings. While multiple studies have reported statistically significant associations of variables such as diabetes and high BMI with SWD in large cohorts (Ridderstolpe et al., 2001; Salehi-Omran et al., 2007; van Ramshorst et al., 2010; Webster, Neumayer, Smout, Horn, Daley, Henderson, & Khuri, 2003) this study failed to yield similar statistically significant findings.

However, trends linking the occurrence of SWD and pre-existing comorbidities such as diabetes and high BMI were apparent in the Perth cohort results. The lack of medical records, incomplete documentation in those medical records sourced in the first and second case controlled studies, and the misclassification of wound types, all contributed to shortcomings in

the robustness of the subsequent tool development, and highlighted the inherent weakness of a retrospective methodology. The ability to build a more robust tool from the modelling data was limited and impacted on the study outcomes. Whilst a ROC of 71% is encouraging, this is not sufficient to be an appropriate level for clinical use. Another limitation is the focus of the tool on the abdominal surgery domain which may not necessarily be reflective of other surgical areas such as orthopaedics, cardiothoracic or vascular surgery. It is possible that one risk assessment tool may not suit all surgery types and therefore other surgery specific tools may need to be designed to be fit for purpose.

### **7.1.2. Definition inconsistencies**

A contentious issue discussed in this body of work and reported by others in the literature is the lack of standardised classification and reporting of SWD and its relationship with SSI (Leaper et al., 2013; Tanner et al., 2013; Tanner, Aplin, Ball, Thomas, & Bankart., 2009). There is also a need for a specific grading system for SWD that includes non-microbial aetiologies for SWD. A major problem encountered during the literature review and data collection phase of the study, which hindered the collection of a complete dataset, was the inconsistencies in the methods of reporting SWD. This is a direct limitation of the study itself, and certainly impacted on the findings due to incomplete or missing data collected from the Perth and Melbourne case control cohorts. What has become apparent from this study is the need for improved reporting of SWD, as compared to the reporting of SSI. This can only be achieved through the education of health care providers in regards to the importance of accurate reporting of microbial and non-microbial aetiologies of SWD. The development of the conceptual framework can certainly guide this education.

Other discrepancies that impacted on the study were noted to be:

1. Inconsistencies in clinical coding within the written acute care medical record.
2. Incorrect clinical descriptions of wound types.
3. Incomplete record keeping and inadequate reporting.

In the light of this study, several recommendations for further research are made and discussed as follows.

## **7.2. Recommendations**

The study has demonstrated the need for rigorous and consistent classification in the identification and classification of SWD. Close to 25% of patients in the original sample were misclassified as to their diagnosis and excluded from the analysis due to this conundrum. Incorrect diagnosis may have flow-on effects for the patient, for clinical practice, and for the wider health care setting. The recommendations below have been developed around three key areas; definition, education, risk tool development and education.

### **7.2.1. Definition and classification of SWD**

The following recommendations for future research in regards to the definition and classification of SWD are proposed and they are the need to;

1. Establish a global consensus on the definition of SWD, both microbial and non-microbial in origin.
2. Develop a new SWD grading system to assist clinicians in the diagnosis and management of SWD in the acute and community care settings.
3. Test the SWD grading system for inter-rater reliability and clinical utility in these respective settings.



### **7.2.2 SWDRAT development**

The following recommendations for future research in regards to the SWDRAT are proposed;

1. Further develop the SWDRAT with larger cohorts of patients.
2. Conduct prospective testing (multi-site) of the SWDRAT in the clinical setting, in larger cohorts of surgical patients, which may improve the predictive power, and enhance the sensitivity and specificity of the SWDRAT.
3. Conduct comparative analysis of the SWDRAT against National Nosocomial Infection Surveillance System (NNIS) to assess the performance of the draft SWDRAT in larger datasets.
4. Determine the risk stratification for SWD to enable risk profiling of patients prior to surgery, as informed through the use of the tool.

### **7.2.3 Clinical education in SWD and algorithm development**

Educational programs based on an agreed definition and grading system that enables the clinician to identify and grade an SWD, would allow the clinician to select the appropriate patient-specific treatment required to improve clinical outcomes. The following recommendations for future research in regards to the delivery of clinical education and the development and use of a care algorithm are proposed and they are;

1. Develop and conduct education and training programs in relation to the defining and reporting of SWD, and the use of a specific grading system for SWD, as informed by the conceptual framework.

2. Implement a clinical algorithm as proposed in Figure 6.1 in the acute care setting to facilitate the identification of at risk patients in the preoperative period and inform postoperative wound care management.

### **7.3. Conclusion**

Several key outcomes have resulted from this study that has attempted to address the knowledge gaps. The findings of this research have contributed a refined understanding in the form of the conceptual framework and the SWDRAT which will expand understanding of the aetiologies and the preoperative risk factors that potentially lead to SWD. The preliminary internal validation draft SWDRAT demonstrated a potential for effective risk assessment and affords opportunities for implementation of preventative strategies. Ultimately the full impact and significance of this study will be evident amongst patients preparing for, and during their surgical journey.

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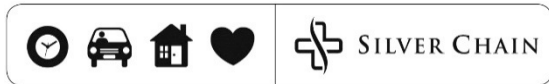
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*Every reasonable effort has been made to acknowledge the owners of copyright material. I would be pleased to hear from any copyright owner who has been omitted or incorrectly acknowledged.*

## Appendix 1. Patient Information and Consent Form (PICF)



Date

Name and Address

Dear xxxxxx

My name is Professor Gill Lewin, Director of Research at Silver Chain. I am writing to let you know about an important study on surgical wound breakdown that is about to be conducted by Silver Chain and Curtin University. The study is important because it is designed to determine whether it is possible to predict the risk of wound breakdown post- surgery and therefore how it can be made less likely.

The study will be conducted by comparing the medical records (both Silver Chain and hospital records) of people whose wound broke down with those of people who had a similar operation in the same hospital but whose wound healed with no problems. The research team includes researchers from both Silver Chain and Curtin University and the project is being managed on a day to day basis by Kylie Sandy-Hodgetts, who will also be writing it up as her PhD.

According to Silver Chain records you received care between 1 January 2010 and 31 December 2010 because of post-surgery wound breakdown. For this study, we would like your permission to extract information from your records at Silver Chain and the hospital where you had your surgery. Only information that is directly relevant to your surgery, the post-surgical complications and the care you received will be extracted from your records. Further information about the study, and how we will ensure your privacy is not breached, can be found in the enclosed information statement and consent form.

Your participation in this study will be very much appreciated and will make a significant contribution to ensuring that fewer people experience the trauma and discomfort of wound breakdown. Please read the attached information sheet and sign and return the consent form in the envelope provided, if you are willing to be part of the study.

If you have any questions about this study please don't hesitate to contact the Researcher; ,Kylie Sandy-Hodgetts on 9266 2212.

Yours sincerely

Professor Gill Lewin  
Director of Research



## Surgical Wound Dehiscence Study

### PATIENT CONSENT FORM

- I have read the information statement about this study and any questions I have asked have been answered to my satisfaction.
- I agree to consent to allow the researcher, Ms Kylie Sandy-Hodgetts, access to my Silver Chain and hospital medical record information required to conduct this study, realising that I may withdraw at any time, without affecting the Silver Chain services I receive now or in the future.
- I agree that the information collected for this study may be published, provided that I am not identifiable.

**SIGNED** \_\_\_\_\_

*Participant*

\_\_\_\_\_

*Researcher*

**NAME** \_\_\_\_\_

*(BLOCK LETTERS)*

\_\_\_\_\_

*(BLOCK LETTERS)*

**DATE** \_\_\_\_\_

\_\_\_\_\_

## Appendix 2. St John of God Participant Information and Consent Form (PICF)

As research can often take many years, it is probable that there will not be any information from research conducted on your tissues that will have specific relevance to your health. However, in some instances the research conducted may reveal information that has health implications for you, your family or descendants. In those cases we may contact you. We will only do this if the information is reliable and there is something that can be done with the information. We shall also ensure that you are directed to appropriate care if required. You and you alone may choose what happens as a result of this new information.

**If you want to change your mind**

Please tell us by writing to the address below, if you wish to withdraw your consent, which you are free to do at anytime. If you do this, we will write back to acknowledge your wishes and to confirm the removal of your health information.

**Further information**

If you would like independent advice about the research or if you would like to lodge a complaint, please contact:

St John of God Health Care Ethics Committee  
T: 08 9382 6940  
Curtin University Human Research Ethics Committee  
T: 08 9266 2784

### About St John of God Health Care

St John of God Health Care is a Catholic not-for-profit health care provider, with hospitals, home nursing and pathology services, as well as Social Outreach Services which reach out to people experiencing disadvantage to improve health and wellbeing.

We strive to serve the common good by providing holistic, ethical and person centred care and support. We aim to go beyond quality care to provide an experience for people that honours their dignity, is compassionate and affirming and leaves them with a reason to hope.

This study is in partnership with



wound management innovation CRC



Australian Government  
Department of Industry  
Business



ST JOHN OF GOD  
Health Care

Ground Floor, 12 Kings Park Road  
West Perth, WA 6005  
T: 08 9213 3636 F: 08 9213 3668  
E: info@sjog.org.au  
www.sjog.org.au



ST JOHN OF GOD  
Health Care



Curtin University

### Surgical Wound Study

Information brochure & frequently asked questions



Hospitality | Compassion | Respect | Justice | Excellence





We undertake medical research to improve our understanding of diseases and find better ways to prevent or treat them. This is done by studying medical information and investigating clinical outcomes. Medical information is collected from people like you for research. Surgery today is a relatively safe procedure, however from time to time complications may occur. St John of God Health Care is working in partnership with Curtin University to collect information about your surgery and how your wound has healed after the surgery. To conduct research we need to access specific health information about you that is relevant to medical research.

**The purpose of this brochure is to:**

- A) Inform you of our ongoing need to do research into the prevention or treatment of a medical condition and to;
- B) Ask your permission to give us consent to access your health records where required.

Please consider the following information carefully before making a decision. If you decide to give us your consent, it is advisable that you tell your family of your decision and why you chose to support medical research in this way.

Please note:

- You are not obliged to give us consent in regard to anything in item b) above
- Your decision will not affect your care in anyway

The following is important information that you need to know. Please read it carefully.

**Confidentiality**

The identification of your health information will be kept in strict confidence for viewing by authorised people only. You cannot be identified from your information as the data will be coded in such a way that does not identify you.

**What will be done with your information?**

Your health information will be used only for bona fide research studies. In the longer term we may wish to collect information on your health. This would involve contacting your local General Practitioner (GP) or other medical providers. If it is not possible to gather information from these sources, we may also wish to contact you directly by a follow up phone call.

**Keeping within acceptable community standards**

All the research we do has to be approved by a Human Research Ethics Committee certified by the National Health & Medical Research Council. The NMHRC is responsible to the Commonwealth Minister for Health. This is to give you assurance that your health information will be used for only genuine medical research with foreseeable community benefits.

**Collaboration with other research bodies**

Where appropriate your health information may be sent interstate or overseas for collaborative research purposes. This can only happen when we are sure that requisite approvals have been obtained and the necessary ethical and privacy safeguards are in place.

**Commercial gain from use of your information**

The law in Australia dictates that you may not be rewarded financially for consenting for your health information to be used in research.

We are however, allowed to profit from research outcomes that are ultimately successfully commercialised. Any money we receive from commercial ventures is always put back into medical research.

**Results of Research**

The research conducted using your health information may be published in medical journals or presented at scientific meetings in the future, but you will not be identifiable in any such publications.

The results of the research performed on your health information are intended to improve our understanding of wound healing following surgery and so provide general benefit to the community.



## School of Nursing and Midwifery

### Participant Information Sheet

My name is Kylie Sandy-Hodgetts. I am currently completing a piece of research for my PhD at Curtin University, School of Nursing and Midwifery.

Surgery today in modern hospitals is usually a relatively safe procedure with minimal complications and extended stays. From time to time unpredictable events do occur that involve a certain level of risk, of which your surgeon would have discussed with you prior to your surgery. What this study will do is attempt to identify those risks associated with surgery and document these in order to improve practice and patient's overall wellbeing following surgery.

Participation in this study will involve your surgeon or clinician completing a draft diagnostic tool and the researcher following up with you once your surgery is complete. This will include a follow up phone call within a two week time frame to check the progress of your surgical wound healing.

#### **Please note:**

- Taking part is voluntary and you can withdraw at any time without any problem.
- Your withdrawal will not affect you in any way.
- Your privacy is greatly respected and any information that could identify you will be removed.
- The researcher has signed a confidentiality form and cannot share information about you with any person.
- All information will be stored confidentially with a code at Curtin University of Technology for 5 years. After this time information will be destroyed.

#### **Your role**

In this study your role as a participant will involve a follow up consultation or phone call with the researcher after your surgery for 2-weeks to record the outcome of your surgery, in particular your surgical site wound.

#### **Consent to Participate**

Your involvement in the research is entirely voluntary. You have the right to withdraw at any stage without affecting your rights or my responsibilities. When you have signed the consent form I will assume that you have agreed to participate and allow me to use your data in this research. The data will be assigned a case number and there will be no record of your identity so as to protect your privacy.

**Confidentiality**

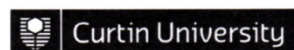
The information will be kept separate from your personal details, and I will only have access to this. The data collection sheets will not have your name or any other identifying information on it and in adherence to university policy, the datasheets will be kept in a locked cabinet and password protected database for 5 years, before it is destroyed.

**Further information**

This study has been approved by the Curtin University Human Research Ethics Committee and Saint John of God Hospital Human Ethics Research Committee. If you have any concerns about the conduct of the study or your rights as a research participant, please contact Prof Stephan Millett, Chairman of the Curtin University HREC, via (08) 9266 2784 [rph.hrec@health.wa.gov.au](mailto:rph.hrec@health.wa.gov.au) and quote the ethics approval number (HR59/2012).

Thankyou very much for your involvement in the research, your participation is greatly appreciated.

## Appendix 3. Ethics Approval Curtin University



### Memorandum

<b>To</b>	Adjunct Professor Keryln Carville, School of Nursing and Midwifery
<b>From</b>	Professor Stephan Millett, Chair, Human Research Ethics Committee
<b>Subject</b>	Protocol Approval <b>HR 06/2012</b>
<b>Date</b>	29 February 2012
<b>Copy</b>	Professor Gavin Leslie, School of Nursing and Midwifery Mrs Kylie Sandy-Hodgetts, School of Nursing and Midwifery Graduate Studies Officer, Faculty of Health Sciences

Office of Research and Development  
**Human Research Ethics Committee**

**TELEPHONE** 9266 2784  
**FACSIMILE** 9266 3793  
**EMAIL** hrec@curtin.edu.au

Thank you for your application submitted to the Human Research Ethics Committee (HREC) for the project titled "Risk factors for surgical wound dehiscence and the development of a surgical wound dehiscence risk tool - Phase 1". The Committee notes the prior approval by Silver Chain HREC (EC Applic 074) and has reviewed your application consistent with Chapter 5.3 of the *National Statement on Ethical Conduct in Human Research*.

- You have ethics clearance to undertake Phase 1 of the research as stated in your proposal.
- The approval number for your project is **HR 06/2012**. Please quote this number in any future correspondence.
- Approval of this project is for a period of twelve months **28-02-2012** to **28-02-2013**. To renew this approval a completed Form B (attached) must be submitted before the expiry date **28-02-2013**.
- If you are a Higher Degree by Research student, data collection must not begin before your Application for Candidacy is approved by your Faculty Graduate Studies Committee.
- The following standard statement **must be** included in the information sheet to participants:  
*This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR 06/2012). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au.*

Applicants should note the following:

It is the policy of the HREC to conduct random audits on a percentage of approved projects. These audits may be conducted at any time after the project starts. In cases where the HREC considers that there may be a risk of adverse events, or where participants may be especially vulnerable, the HREC may request the chief investigator to provide an outcomes report, including information on follow-up of participants. The attached **FORM B** should be completed and returned to the Secretary, HREC, C/- Office of Research & Development:

When the project has finished, or

- If at any time during the twelve months changes/amendments occur, or
- If a serious or unexpected adverse event occurs, or
- 14 days prior to the expiry date if renewal is required.
- An application for renewal may be made with a Form B three years running, after which a new application form (Form A), providing comprehensive details, must be submitted.

Yours sincerely,

Professor Stephan Millett  
Chair Human Research Ethics Committee

**Memorandum**

<b>To</b>	Adjunct Professor Keryln Carville, School of Nursing and Midwifery
<b>From</b>	Professor Stephan Millett, Chair, Human Research Ethics Committee
<b>Subject</b>	Protocol Approval <b>HR 59/2012</b>
<b>Date</b>	22 June 2012
<b>Copy</b>	Professor Gavin Leslie, School of Nursing and Midwifery Mrs Kylie Sandy-Hodgetts, School of Nursing and Midwifery

Office of Research and Development  
**Human Research Ethics Committee**

**TELEPHONE** 9266 2784  
**FACSIMILE** 9266 3793  
**EMAIL** hrec@curtin.edu.au

Thank you for your application submitted to the Human Research Ethics Committee (HREC) for the project titled "*Risk factors for surgical wound dehiscence and the development of a surgical wound dehiscence risk tool - Phase 2*". The Committee notes the prior approval by Royal Perth Hospital HREC (EC2012/039) and has reviewed your application consistent with Chapter 5.3 of the *National Statement on Ethical Conduct in Human Research*.

- You have ethics clearance to undertake the research as stated in your proposal.
- The approval number for your project is **HR 59/2012**. Please quote this number in any future correspondence.
- Approval of this project is for a period of twelve months **22-06-2012** to **22-06-2013**. To renew this approval a completed Form B (attached) must be submitted before the expiry date **22-06-2013**.
- If you are a Higher Degree by Research student, data collection must not begin before your Application for Candidacy is approved by your Faculty Graduate Studies Committee.
- The following standard statement **must be** included in the information sheet to participants:

*This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR 59/2012). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au.*

Applicants should note the following:

It is the policy of the HREC to conduct random audits on a percentage of approved projects. These audits may be conducted at any time after the project starts. In cases where the HREC considers that there may be a risk of adverse events, or where participants may be especially vulnerable, the HREC may request the chief investigator to provide an outcomes report, including information on follow-up of participants.

The attached **FORM B** should be completed and returned to the Secretary, HREC, C/- Office of Research & Development:

When the project has finished, or

- If at any time during the twelve months changes/amendments occur, or
- If a serious or unexpected adverse event occurs, or
- 14 days prior to the expiry date if renewal is required.
- An application for renewal may be made with a Form B three years running, after which a new application form (Form A), providing comprehensive details, must be submitted.

Yours sincerely,



*SM* Professor Stephan Millett  
Chair Human Research Ethics Committee

**Appendix 4. Surgical Wound Dehiscence Risk Assessment Tool (SWDRAT)**

Variable	Risk score	Participant score
1. Diabetes	1.10	
2. Previous surgery in the same anatomical location about to undergo surgery?	2.20	
3. Age 21-50	0.165	
4. Age 51-80	0.550	
5. Age 81+	0.104	
6. BMI <26	0.220	
7. BMI 26-30	0.690	
8. BMI 31+	0.773	
9. Cardiovascular disease	1.65	
10. Peripheral arterial disease	1.65	
11. Smoker	1.10	
	<b>TOTAL</b>	

<b>Risk/Outcome</b>
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