# Tropical Wound Dressing Protocols for Haemodialysis Central Venous Catheter Exit Sites: A Cross-over Randomised Controlled Trial

Thesis Submitted November 2015,

for the degree of

Masters of Nursing Science (Research)

Submitted By

Joleen McArdle
Bachelor of Nursing Science -James Cook University
Postgraduate Certificate of Nursing Science (Renal Nursing)-James Cook University

Panel
Principal Supervisor: Professor Anne Gardner
Co-Supervisor: Dr. Wendy Smyth
Co-Supervisor: Dr. Kristin Wicking
Research Student Monitor: Jeff Warner

# Statement on the contribution of others

Data collection support:

Nursing staff, Townsville Renal Services

Tropical Health Research Unit staff, The Townsville Hospital

Data entry support:

Ms Gail Abernethy

Statistical support:

Statistical advice about study design was provided as part of JCU support for HDR students

Financial support:

Private Practice Research and Education Trust Fund, The Townsville Hospital: $24237

Queensland Health Nursing and Midwifery Research Grant: $9768

Editorial support:

Paid editorial assistance was provided by the desktop publishing services of Kboodl Pty Ltd www.kboodl.com

in accordance with the Institute of Professional Editors' Guidelines for editing research theses' posted on the James Cook University Graduate Research School website at:

www.jcu.edu.au/graduate-research-school/enrolled-students/thesis-preparation,-submission-and-examination

# Acknowledgements

This trial was successfully undertaken with the assistance of numerous people and a massive team effort

Many thanks to the Tropical Health Research Unit. Without the drive and support of Dr Wendy Smyth and Professor Anne Gardner, this project would have never eventuated. Gail Abernethy's sense of humour and passion for SPSS assisted me through many hours of data entry!

The nursing staff of the Townsville renal services did a fantastic job collecting data over the trial duration. This did not falter even when faced with a massive category five cyclone

To my supervisors, Professor Anne Gardner, Dr Wendy Smyth and Dr Kristin Wicking-I can't thank you enough for all of your assistance and encouragement to get this thesis completed. I look forward to working on many more projects with you in the future.

# Abstract


## Tropical Wound Dressing Protocols for Haemodialysis

## Central Venous Catheter Exit Sites: A Cross-over

## Randomised Controlled Trial

**Background**

Exit sites of central venous catheters (CVC), often used to deliver haemodialysis, require meticulous care. Staff in a large regional North Queensland Renal Service found the recommended transparent dressing inappropriate because moisture build-up was thought to increase likelihood of infection or dressings not remaining intact. The use of an opaque dressing (used by the Renal Service) contradicted the State-wide infection control guidelines recommended at the time of the study. Minimal published evidence regarding CVC dressings in a tropical location was available when a literature review was undertaken.

**Aim**

To identify the most effective and safe dressing protocol for haemodialysis CVC exit sites in a tropical region. The null hypothesis was: There is no difference in effectiveness with the use of a transparent or combination dressing compared to an opaque dressing on CVC exit sites for patients undergoing haemodialysis in the tropics. Effectiveness was measured by intactness of dressings between haemodialysis episodes and by local (CVC exit site) and systemic infections.

**Methods**

Patients attending a regional North Queensland Renal Service with CVC access consented to participate in the prospective randomised, crossover trial (n=37). Five units from the Townsville Renal Service were included in the study. These units were located up to 900km from the central acute dialysis unit at the Townsville Hospital. Participants were randomly assigned to a specific sequence of transparent, opaque and combination dressings. Each dressing was used for six weeks then substituted in rotation. During dialysis, CVC sites were assessed by nurses for clinical signs of infection and dressing intactness.

**Results**

Numerous adverse reactions to the combination dressing early in the trial necessitated its removal from the rotation. Eight patients received only one type of dressing during the trial. The final sample size was 26 participants. The majority of the sample were Aboriginal and Torres strait Islander people (n=21). Statistical analysis was undertaken using Wilcoxon signed rank tests to evaluate the difference in the primary outcomes of intactness and infection between the opaque and transparent dressing. There were no statistical differences between intactness of the opaque and transparent dressing types ($z$=0.386, $p$=<0.700) or infection *($z$=-0.454, $p$=<0.650).*

**Implications for Clinical Practice**

This pilot study generated evidence regarding CVC dressings in tropical climate. The study also provided evidence for a unique population given the high number of Aboriginal and Torres Strait Islander Peoples. The study underlined the challenges of conducting a clinical trial. Combination dressing may not be suitable for the tropics due to the large number of reactions. Nurses in this setting can safely select either an opaque or transparent dressing until the study is replicated in other geographical locations with a larger sample size.

# Table of Contents

# Tables

# Abbreviations

| | |
|---|---|
| **AVF** | Arteriovenous Fistula |
| **CHRISP** | Centre for Health Related Infection Surveillance and Prevention |
| **CKD** | Chronic Kidney Disease |
| **CRBSI** | Catheter Related Blood Stream Infection |
| **CVC** | Central Venous Catheter |
| **ESKD** | End Stage Kidney Disease |
| **MVTR** | Moisture Vapour Transmission Rate |
| **RCT** | Randomised Controlled Trial |
| **THHS** | Townsville Hospital and Health Service |
| **TRS** | Townsville Renal Service |
| **TTH** | The Townsville Hospital |
| **WPI** | Work Place Instruction |

# Chapter 1 Introduction

## 1.1 Chapter introduction

This thesis reports a study that investigated the type of dressing most appropriate for use in the tropics to cover exit sites for patients receiving haemodialysis through a central venous access device. The research problem was identified while reviewing infection control guidelines pertaining to central venous device exit site care. Those guidelines recommended a different type of dressing than the dressing being used in the Townsville Renal Services (TRS). This chapter provides a brief background to the problem including a summary of an internal audit that demonstrated a need for the study and an overview of the thesis structure. The literature pertaining to the research problem is then examined in the next chapter. This is followed by the methods chapter. The methods chapter describes the methods used to answer the research questions. The fourth chapter details the results of the trial. The final chapter includes a discussion of the implications of the results, including recommendations arising from the trial in relation to future practice and research.

### 1.1.1 Chronic kidney disease and haemodialysis

Chronic kidney disease (CKD) is a disease that affects approximately one in 10 Australians (Australian Institute of Health and Welfare, 2014). It is classified in five stages: the 5$^{th}$ stage is the most severe stage with the kidneys having little or no function. This stage is classified as end stage kidney disease (ESKD). Patients suffering from ESKD die very quickly without a renal replacement therapy (RRT). Types of RRT include haemodialysis, peritoneal dialysis or kidney transplantation. Many patients select haemodialysis as their first choice for RRT. In Australia, 72% of all patients requiring some form of RRT are currently on haemodialysis (ANZDATA Registry, 2012). The number of patients requiring RRT is climbing at a rapid rate. The prevalence for treated ESKD is projected to double between 2011 and 2020 (Australian Institute of Health and Welfare, 2014). This increase in ESKD rates is due to an ageing population and an increase in diseases (such as diabetes) that cause renal failure (Cass et al., 2006). Diabetes is now the leading cause of renal failure (ANZDATA Registry, 2012).

Vascular access, either an arteriovenous fistula (AVF) or central venous catheter (CVC), is required for dialysis. The ‘gold standard’ vascular access for those

wishing to commence haemodialysis is a native AVF (National Kidney Foundation, 2006). A native AVF is constructed using the patient's own native tissue rather than a synthetic graft. However, several factors may make it difficult to establish an AVF in a timely manner. Such factors include patients with ESKD not being referred to the Renal Service sufficiently early. Many patients with ESKD are unaware that they are suffering from this condition because they remain asymptomatic until they require haemodialysis. The subsequent late referral to the Renal Service results in insufficient time to create a fistula prior to commencement of haemodialysis. An AVF takes six weeks to mature therefore the patient must have an AVF created at least six weeks before commencing haemodialysis. In some cases, an AVF creation may not be achievable because diseases such as diabetes and peripheral vascular disease hinder the construction and successful function of an AVF. As a result of the aforementioned factors some patients may require the insertion of a CVC for dialysis. In Queensland, Australia, it is estimated that 55% of all haemodialysis patients dialyse via a CVC on their first treatment (ANZDATA Registry, 2012). Due to the increase in predisposing chronic diseases, such as diabetes, the use of a CVC for dialysis access is inevitably going to increase.

### 1.1.2 Central venous catheters

Central venous catheters are catheters inserted percutaneously via the internal jugular or subclavian vein, with the catheter tip in the superior vena cava; less often they are inserted into the femoral vein. Central venous catheters are classified as either non-tunnelled or tunnelled. The non-tunnelled CVCs are generally described as temporary catheters and are for short term use (up to three weeks). Tunnelled catheters are cuffed and are inserted for long term use (more than three weeks) (Center for Disease Control, 2011), particularly if the patient is awaiting the creation or maturation of an AVF. Tunnelled CVCs are also indicated if the patient has poor vascular options and an AVF is not feasible. The purpose of the cuff is to provide "long term catheter stabilisation by stimulating growth of fibrous tissue which impedes the migration of organisms along the catheter's external surface, by creating a mechanical barrier" (Centre for Health Care Related Infection Surveillance and Prevention, 2007, p.2). Central venous catheters, although a lifesaving intervention, are not without risk and/or complication.

Infection of the CVC is a serious complication as well as being the most common complication (Besorab & Raja, 2007). O'Grady et al. (2002) state that the relative risk for bacteraemia in patients with a CVC is sevenfold that of the relative risk for those with an AVF. It has also been established that patients who undergo dialysis with a CVC have a threefold greater mortality rate than those who dialyse through an AVF, related to increased susceptibility to infection (National Kidney Foundation, 2006). Infectious complications relating to CVCs are the leading cause of death for patients receiving haemodialysis (ANZDATA Registry, 2012).

Whilst adverse patient outcomes are the most important sequelae of CVC infections, there are also implications for efficiency and resource usage. When reviewing the costs associated with infection within haemodialysis units, consideration should be given towards identifying cost-effective practices that could be adopted to improve the standard of care provided to patients and decrease infection rates. In Australia, the cost-per-infective episode is estimated to be as high as $20 000 (AUD) per patient (Collignon, Dreimanis, Beckingham, Roberts, & Gardner, 2007). In America the average cost is higher, around $22 000 (USD) (Harwood, Wilson, Thompson, Brown, & Young, 2008). In the majority of cases where a catheter related bloodstream infection (CRBSI) has occurred, the catheter will require removal. It is difficult to successfully salvage a CVC once a CRBSI has occurred, the successful salvage rate is claimed to be approximately 30% (Winterberger et al., 2011). This low success rate can most likely be attributed to a biofilm generated from fibrin and microbial products that forms in the catheter lumen within 24 hours of insertion (National Kidney Foundation, 2006). This biofilm plays a role in catheter resistant infections hence the catheter must be removed. Insertion of a new catheter generates significant additional cost and risk to the patient. Other factors contributing to the cost-per-infective episode include additional staff costs in caring for patients whose health is further compromised, and costs of medications used to treat the infection.

Causes of CVC infections include nasal colonisation with staphylococcus, other infective organisms, being older and having diabetes (Council, 2010). For patients receiving haemodialysis, however, the most likely source of infection is from skin contamination at the CVC insertion site. Standardised catheter exit site care is one of the most important factors in prevention of CRBSI (Centre for Health Care Related Infection Surveillance and Prevention & Tuberculosis Control, 2013a).

Patients with ESKD are particularly at risk of infections. This cohort of patients are often immunosuppressed as a result of uraemia causing immune dysfunction (Kato et al., 2008). Inserting a CVC into major blood vessels and leaving it in situ for an indefinite period of time is a major risk for infection: therefore it is vitally important to be vigilant with excellent exit site care. It is important that evidence-based protocols are developed to ensure the reduction of infections in this cohort of patients.

Skin integrity also becomes an issue. The high incidence of diabetes, uraemia, and oedema in patients with ESKD increases their risk of compromised skin integrity (Trotter, Brock, Schwaner, Conaway, & Burns, 2008). Therefore the type of dressing used on the CVC exit site is important to maintain skin integrity and is one of the infection control measures taken to prevent an infection that may result in the loss of the CVC for haemodialysis access. Management of the CVC exit site presents particular challenges in hot and humid climates and selecting the most appropriate permeable dressing to use can be difficult, as this study will demonstrate. The current study was undertaken in a tropical region, and this context is discussed in further detail in the next section.

## 1.2 Background to the study

Townsville, a regional city in tropical Australia, has an average daily temperature of 31ºC and average humidity of 70% (Bureau of Metereology, 2015). Townsville has two seasons: the "wet" season which runs from November to May and the "dry" season which is over the months of June to October. At the time of the study, the Townsville Renal Service (TRS) managed approximately 150 patients undergoing haemodialysis, most of whom were treated on an outpatient basis. The catchment area for this service is very extensive, stretching from Mornington Island in the north through Doomadgee, to Mount Isa in the west and south as far as Home Hill and beyond. This large catchment area has a high percentage of rural communities, unemployed people and Aboriginal and Torres Strait Islander peoples. These risk factors are further compounded by the attendant problems of living great distances from healthcare services, in particular the distance located from the Townsville Hospital renal service which may be located many hundreds of kilometres away on the coast.

These difficulties pose particular concern for the Aboriginal and Torres Strait Islander population dialysed within the service. There is a high proportion of this patient

cohort on dialysis (approximately 50% of patients dialysed) in part due to the prevalence of diabetes being much greater than that of the general Australian population (Kidney Health Australia, 2014). Additionally, there is a considerable proportion of Aboriginal and Torres Strait Islander peoples who are classified as late referrals to the renal service. Twenty-nine per cent of Aboriginal and Torres Strait Islander patients are referred late for dialysis compared with 22% of other Australian patients (Kidney Health Australia, 2014). This high rate of delayed referral to the renal service is due to the aforementioned issue of distance from healthcare services as many of the affected patients live in remote communities where they have limited access to CKD clinics. Hence the disease is not captured early enough to create an AVF for commencement of haemodialysis. This group of patients often require emergency haemodialysis as they are already unwell at the time of their first presentation and require the insertion of a CVC for immediate use. At any one time, approximately 35-40 patients of the TRS undertake haemodialysis using a CVC access. The majority of patients with a CVC are dialysed at the renal units that are located in Townsville. This equates to up to a quarter of the patients in Townsville using a CVC for haemodialysis. The majority of these patients are Aboriginal and Torres Strait Islander people.

Many patients receiving haemodialysis through a CVC live in homes without air conditioning or they work outdoors. Additionally there are issues with poor housing, inadequate sanitation and water supply, and sometimes homelessness across tropical north Queensland. Under these conditions, adhesiveness of the exit site dressing between dialysis sessions becomes a particular concern.

### 1.2.1 The research problem

At the time of the initial research conceptualisation, the Queensland Government's Centre for Health Related Infection Surveillance and Prevention (CHRISP) guidelines (2007) recommended that a transparent dressing such as IV3000™ be applied to the exit site of the CVC. The CHRISP guidelines recommended transparent dressings because they allowed for the continual observation of the exit site and because they assist in the protection, stabilisation and securement of the CVC. It should be noted, however, that the guidelines indicated that using this dressing was a recommendation only, as there was little evidence to determine the best type of dressing to be used for CVC exit sites. The CHRISP guidelines also

recommended that patient and environmental factors should be considered when deciding upon the dressing of choice for the patient. The TRS did not use the recommended transparent dressing but rather used Smith and Nephew's PRIMAPORE™, a non-transparent gauze-like dressing. The Townsville Hospital Renal Unit staff postulated that the transparent dressing led to the accumulation of excess moisture as a result of an increase in perspiration due to the warm climate. Staff surmised that this excess moisture increased the bacterial count which in turn enhanced the risk of infection. Alternatively, the PRIMAPORE™ dressing routinely used was perceived by the staff to have better breathability, hence decreasing the amount of moisture accumulation beneath the dressing. For these reasons the PRIMAPORE™ dressing was determined to be a more appropriate dressing in the Townsville Hospital Renal Unit context. However, this clinical decision was made without the benefit of research evidence to support the superiority of a gauze like dressing over a transparent type dressing.

An additional problem identified with the transparent dressing in the Townsville Renal Unit was the difficulty encountered during dressing changes. Two issues commonly occurred. The first issue related to the application of the dressing: the transparent dressing was not easy to apply over the CVC exit site. Upon removal of the adhesive guard the dressing often adhered to itself in places and was unable to be straightened and applied to the site without tearing it. The torn dressing would then have to be discarded. These discards resulted in unnecessary wastage and the resulting fiscal implications. The second issue arose when removing the dressing. The patient often complained of skin discomfort during dressing removal due to the strength of the adhesive.

Although staff had surmised PRIMAPORE™ was the better dressing, this dressing had also not been without its own problems. Patients often presented to the unit with a non-intact dressing and on occasion the dressing was absent. These issues led to compromised stability and security of the CVC. The exposure of the CVC site by a non-intact dressing also increased the likelihood of a CRBSI.

In 2007, as a senior nurse clinician, the author decided to explore the topic of CVC dressings in the tropics with the assistance of more experienced researchers given that no formal research had been undertaken in the TRS on this topic. It was decided to

review the published evidence about the most appropriate dressing to be used on CVC exit sites in the tropical climate and to review data pertaining to CVC infection rate and intactness of CVC dressing in the TRS. These audits are described in the following sections.

### 1.2.2 Infection rate audit

Preparatory to this study, and while the literature was being reviewed, the infection rates associated with CVC exit sites within the TRS for the previous two years were examined. These data were gathered from the state-wide infection control database for the period 1 April 2006 to 31 March 2008. Over this two-year timeframe, there were no wound swab confirmed local exit site infections but there were 26 bloodstream infections that met the Australian Council on Healthcare Standards criteria for healthcare-associated line-associated bloodstream infection (unpublished data). Of the causative microorganisms, 14 were Gram-positive, 11 were Gram-negative, and one was not classified. There were 12 *Staphylococcus aureus* infections, including four multi-resistant strains. The other Gram-positive organisms were *Staphylococcus epidermidis* and *Enterococcus faecalis*. Note that while *Staphylococcus epidermidis* is usually regarded as a contaminant, in this case it was deemed a pathogen. Gram-negative organisms were primarily *Enterobacteraciae species,* with two infections caused by *Klebsiella pneumoniae*, two by *Enterobacter cloacae* and one by *Serratia marcescens.* Other causative organisms were *Acinetobacter baumannii* (two infections), *Pseudomona aeruginosa* (two infections), *Stenotrophomonas maltophilia* (one infection) and *Bacillus cereus* (one infection). Although research often presents epidemiological data as rates of infections per CVC line days, such detail was not recorded by the TRS.

## 1.3 Dressing intactness audit

It was becoming clear from the literature review that there was little evidence to support either transparent or opaque dressing selection and so a randomised controlled trial was needed. However, further information would be required before embarking on such a trial. The current level of security of the PRIMAPORE™ dressings required accurate identification and the perception that the dressings did not stay in place required exploration. We also recognised that the link between non-intact

dressings and the development of local or systemic infection would require empirical measurement. An audit was planned to provide some of this information.

A prospective, observational audit design was used and two forms were developed to assist in the collection of relevant information. The outcome of the audit identified that there were some problems with the opaque dressings. Alarmingly, 43% of CVC dressings were not intact between dialysis episodes. The purpose of the dressing is to protect and stabilise the CVC, hence the dressing currently used could be a contributing factor to infection rates at that time.

## 1.4 Chapter summary

In this chapter the background to the study has been described. Complications, particularly infection, associated with CVCs for haemodialysis patients dialysing in a tropical environment have been discussed. Additionally the economic impact of these complications has been outlined. These issues have demonstrated the need for evidence based protocols for CVC exit care. An internal audit demonstrated that further exploration of the problem was needed. The next chapter presents the literature examined relating to CVC dressings for haemodialysis patients living in tropical environments and the subsequent development of a research question.

# Chapter 2 Literature review

## 2.1 Chapter introduction

As mentioned in the introduction chapter, The Townsville Hospital Renal Unit did not follow the CHRISP (2007) guidelines that recommended a transparent dressing be used on CVC exit sites. In this chapter the available national and international literature is examined with respect to whether or not there are any relationships between infection rates and the types of dressings used for CVCs in the tropics.

Initially a comprehensive literature review was undertaken in 2009 (McArdle & Gardner, 2009). This initial review of the literature informed the study and was updated in 2014.

## 2.2 Literature review process

There were over 100 articles reviewed in the initial literature search. An additional four relevant articles were found in the updated review. These four additional articles were: a systematic review by the Cochrane Collaboration (Webster, Gillies, O'Riordan, Sherriff, & Rickard, 2011), two Brazilian studies (Barros et al., 2009; Silveira, Braga, Garbin, & Galvão, 2010) and a 1997 (Treston-Aurand, Olmsted, Allen-Bridson, & Craig, 1997) study that was missed during the first literature review. The majority of articles initially reviewed pertained to peripheral cannulation exit sites or to CVC exit site care as a whole. It was identified from the literature that there were other factors, not just the type of dressing used that played a role in preventing infection. These factors included the frequency of dressing change and the solutions used to clean the exit site. The properties of the dressing, that is, the permeability of the dressing to moisture and the adhesiveness of the dressing were also explored in this review.

The search terms used for the literature review were: haemodialysis catheter, central venous catheter, exit site, dressings, IV3000™, transparent, PRIMAPORE™, gauze, tropics, tropical climate, wound care, sepsis and hospital in the home. The databases used for the search were: MD Consult, Blackwell, Cochrane, Ovid, Medline and CINAHL. The search was limited to English language papers. Initially date limits were set to examine literature after 2010, however due to the lack of recent studies

regarding this subject, all available literature was then searched regardless of the year of publication. These initial searches identified over 150 articles as on-line abstracts.

One hundred and thirty abstracts were rejected primarily because the papers related to other aspects of intravascular access management. Few relevant studies were found that were conducted with renal patients as the exclusive population. A large proportion of the abstracts pertained to oncology patients who have similar patterns of susceptibility to infection when compared to renal patients in relation to both disease and treatment processes therefore these articles were included in the review. Only those abstracts pertinent to CVC or cannula exit site infections or intactness of exit site dressings were obtained as full hard-copy articles.

In addition to examination of the peer-reviewed literature, grey literature was explored. Prior to the commencement of the trial the most relevant set of guidelines was published on the Queensland Health website (Centre for Health Care Related Infection Surveillance and Prevention, 2007). Although these guidelines have since been updated (Centre for Health Care Related Infection Surveillance and Prevention & Tuberculosis Control, 2013a, 2013b), the initial research problem was generated from the 2007 guidelines. Wound dressing manufacturers were also contacted with respect to information and recommendations about their products. The only manufacturer who stated that they had wound dressings demonstrating some success in warmer climates was 3M$^{TM}$. However, these dressings were specifically used to promote healing of complex wounds and were not deemed relevant to the study question. This manufacturer did have a transparent dressing with increased permeability that was recommended for use with peripheral cannulation sites but none with increased permeability for CVC exit sites. There was very little additional information about other suitable dressings from this company and from other dressing manufacturers contacted. Therefore no manufacturer literature was included in this literature review.

## 2.3 Summary of the excluded and retained articles

Overall, 34 full hard-copy articles were collected which were pertinent to CVC or cannula exit site infections in patients. However, six articles were based on CVC care as a whole and did not relate specifically to exit site dressings; therefore, these were not included in the review. These six articles were excluded at this stage and comprised two literature reviews providing recommendations for CVC care (Banton, 2006; Wittich,

2001), a study investigating infections in haemodialysis patients via CVC access or AV graft (Taylor et al., 1998), a study involving bone marrow recipients (Brandt, DePalma, Irwin, Shogan, & Lucke, 1996), an article evaluating a hospital-wide surveillance and intervention program to reduce incidence of blood stream infections caused by intravenous catheters (Collignon, et al., 2007), and an article describing a potential voluntary national surveillance system for bloodstream and vascular access infections of haemodialysis patients (Tokars, 2000).

The remaining 28 relevant articles all investigated exit site dressing care for CVC, with the majority comparing gauze and tape with a transparent dressings. Articles were reviewed and critiqued with particular attention to a number of confounding variables such as the types of dressing used (specifically if a gauze type dressing or transparent dressing was used), the sample population and the dressing protocols applied. The dressing protocols included factors such as frequency of dressing change, type of skin preparation used and if a securement device was used. Studies relating to dressing intactness on CVC exit sites and skin reactions to differing types of dressings were also of interest. Additionally articles were reviewed for any reference to management of exit site dressings under tropical conditions. Six of the studies included in the review were not included in the review tables as the studies did not specifically compare a gauze dressing with a transparent dressing. These articles were: a laboratory based experiment pertaining to different dressing types (Lin, Chen, Li, & Pan, 2009), a cross-sectional self-administered staff survey relating to CVC care (Bennett, Janko, & Whittington, 2005), a prospective observational audit of factors associated with CVC infection (Hughes, Gardner, & McArdle, 2011) and a prospective cohort study comparing rates of bacterial growth under dressings (Callahan & Wesorick, 1987) and, two studies undertaken with peripheral cannulas were included as the outcomes were of potential relevance (Callaghan, Copnell, & Johnston, 2002; Craven et al., 1985).

The remaining 22 articles included: two Cochrane reviews, one systematic review, one meta-analysis and six narrative literature reviews (see table 2.1.1). There were six RCTs identified (see table 2.1.2). Table 2.1.3 outlines six other studies which included non-randomised controlled trials, quasi-experimental, cohort studies, observational studies and audits. The three tables present a summary of 22 of the reviewed articles that have compared the use of a gauze type or gauze and tape dressing

to a transparent dressing on CVC exit sites. These tables provide details of the designs, samples, dressing types used and outcomes of interest relevant to this thesis.

**Table 2.1.1. Systematic and narrative literature reviews - In reverse date order and order of level of evidence**

| Reference | Design | Number of studies included | Types of dressings examined | Relevant Outcomes | Findings, in relation to dressing types |
|---|---|---|---|---|---|
| Webster, J., Gillies, D., O'Riordan, E., Sherriff, K., & Rickard, C. (2011). Gauze and tape and transparent polyurethane dressings for central venous catheters (Review). *Cochrane Database of Systematic Reviews, Issue 11. Art. No.: CD003827.* | Cochrane systematic review with meta-analysis | 6 | Transparent and gauze and tape | Infection | Studies reviewed associated gauze and tape with lower infection rates, however the studies were small and at risk of bias. Therefore recommended that further study needs to be undertaken. |
| McCann, M., & Moore, Z. E. (2010). Interventions for preventing infectious complications in haemodialysis patients with central venous catheters. *Cochrane Database of Systematic Reviews*(1), Art. No.: CD006894. | Cochrane systematic review | 10 | Transparent and Gauze | Infection | Transparent dressings do not decrease infection risk compared to a dry gauze dressing |
| Centre for Applied Nursing Research. (1998). *Central line dressing type and frequency: A systematic review*. Liverpool, NSW, Australia: Liverpool Health Service, Centre for Applied Nursing Research | Systematic review | 21 | Transparent and gauze | Infection | Inconclusive evidence exists to determine effectiveness of one particular type of dressing |

| Reference | Design | Number of studies included | Types of dressings examined | Relevant Outcomes | Findings, in relation to dressing types |
|---|---|---|---|---|---|
| Maki, D., & Mermel, L. (1997, April). *Transparent polyurethane dressings do not increase the risk of CVC related BSI: A meta-analysis of prospective randomised trials.* Paper presented at The Society for Healthcare Epidemiology of America, 7th Annual Scientific Meeting. | Meta-analysis | 7 | Gauze and transparent | Infection | Transparent semi-permeable adhesive polyurethane dressings used on high-risk, non-cuffed CVCs used for temporary access do not increase risk of CVC-related blood stream infections. |
| McArdle, J., & Gardner, A. (2009). A literature review of central venous catheter dressings: Implications for haemodialysis in the tropics. *Healthcare Infection, 14*(4), 139-146. | Narrative review | 17 | Gauze and transparent | Infection | No conclusive evidence to suggest infection rates are higher with a transparent dressing in a tropical climate |
| Danks, L. A. (2006). Central venous catheters: A review of skin cleansing and dressings. *British Journal of Nursing, 15*(12), 650-654. | Narrative review | | | | No conclusive evidence to suggest transparent dressing reduces or increases infection rates. The most important factor could be technique for dressing and central line care - a team approach to care is needed with strict policies (including staff education). |

| Reference | Design | Number of studies included | Types of dressings examined | Relevant Outcomes | Findings, in relation to dressing types |
|---|---|---|---|---|---|
| Theaker, C. (2005). Infection control issues in central venous catheter care. *Intensive and Critical Care Nursing, 21*(2), 99-109. | Narrative review | 7 | Transparent and gauze | Infection | Supports the use of gauze dressings. Argues transparent dressing increases the risk of infection due to promotion of moisture and bacterial proliferation. |
| Jones, A. (2004). Dressings for the management of catheter exit sites. *JAVA, 9*(1), 26-33. | Narrative review | 13 | Gauze, transparent and hydro colloid | Infection | No increased risk with highly permeable transparent dressing, and are easy to apply and remove. |
| Gillies, D., O'Riordan, E., Carr, D., O'Brien, I., Frost, J., & Gunning, R. (2003). Central venous catheter dressings: A systematic review. *Journal of Advanced Nursing, 44*(6), 623-632. | Narrative review | 8 | Transparent and gauze and tape | Infection | No conclusive evidence to support transparent dressing increasing infection rates; however this finding based on lack of sufficient sample size and no distinction made between tunnelled or non-tunnelled catheters in any of the included studies. |
| Safdar, N., Kluger, D. M., & Maki, D. G. (2002). A review of risk factors for catheter-related bloodstream infection caused by percutaneously inserted, noncuffed central venous catheters. *Medicine, 81*(6), 466-479. | Narrative review | 96 (11 compare dressing type) | Various | Infection | No conclusive evidence to support transparent dressings increasing infection rates |

**Table 2.1.2. Randomised controlled trials - In reverse date order and order of level of evidence**

| Reference | Design | Study Sample | Types of dressings examined | Relevant Outcomes | Findings |
|---|---|---|---|---|---|
| Barros, L. d. F. N. M. d., Arênas, V. G., Bettencourt, A. R. d. C., Diccini, S., Fram, D. S., Belasco, A. G. S., et al. (2009). Evaluation of two types of dressings used on central venous catheters for hemodialysis [English translation]. *Acta Paulista de Enfermagem, 22*, 481-486. | Randomised controlled trial | 66 haemodialysis patients with a CVC dialysing in Brazil. | Transparent dressing (tegaderm), gauze and tape (micropore) | Infection | Transparent dressing and insertion at a 90º angle had a higher rate of infection than gauze and tape |
| Trotter, B., Brock, J., Schwaner, S., Conaway, M., & Burns, S. (2008). Central venous catheter dressings put to the test. American Nurse Today, 3(4), 43-44. | Randomised controlled trial | 244 general medical and acute care American patients with a CVC | Gauze covered with tape, Gauze covered with transparent dressing, SorbaView transparent dressing | Intactness | Dressings changed three times a week. Sorbaview more likely to be intact and can be left for seven days before changing. Gauze and tape least likely to remain intact. |
| Le Corre, I., Delorme, M., & Cournoyer, S. (2003). A prospective randomized trial comparing a transparent dressing and dry gauze on the exit site of long term central venous catheters of hemodialysis patients. *Journal of Vascular Access, 4*, 56-61. | Prospective, randomized controlled trial, no blinding | 58 haemodialysis patients with long term central IV catheters | Transparent, gauze and tape<br>Transparent (IV 3000) standard sterile dry dressing with betadine | Infection | No observed increase in infection rate when using transparent dressing |

| Reference | Design | Study Sample | Types of dressings examined | Relevant Outcomes | Findings |
|---|---|---|---|---|---|
| Little, K., & Palmer, D. (1998). Central line exit sites: Which dressing? *Nursing Standard, 12*(48), 42-44. | Prospective, randomized controlled trial, no blinding. | 73 English hospital in-patients from ICU and Combined Gastroenterology Unit with a Central Line catheter. | Sterile dry dressing with betadine, Opsite, IV3000 | Infection | Found no significant differences in catheter-related sepsis rates between dressing types |
| Shivnan, J. C., McGuire, D., Freedman, S., Sharkazy, E., Bosserman, G., Larson, E., et al. (1991). A comparison of transparent adherent and dry sterile gauze dressings for long-term central catheters in patients undergoing bone marrow transplant. *Oncology Nursing Forum, 18*(8), 1349-1356. | Randomised controlled trial | 98 Bone marrow transplant patients with a CVC in a regional American hospital | Sterile gauze, a transparent dressing | Infection, Intactness and skin reactions | No difference in infection between the two dressings. Gauze dressing more likely to cause skin irritation and less likely to remain intact. |
| Conly, J. M., Grieves, K., & Peters, B. (1989). A prospective, randomized study comparing transparent and dry gauze dressings for central venous catheters. *Journal of Infectious Diseases, 159*(2), 310-319. | Prospective, randomized controlled trial, no blinding | 115 medical, surgical or paediatric patients having a central venous catheter for three or more days. | Transparent, gauze | Infection, Intactness | Transparent dressings were associated with significantly increased rates of insertion site colonization, local catheter-related infection, and systemic catheter-related sepsis. |

**Table 2.1.3. Other studies - In reverse date order and order of level of evidence**

| Reference | Design | Study Sample | Types of dressings examined | Relevant Outcomes | Findings |
|---|---|---|---|---|---|
| Jezova, L, Ziakova, K, Serfelova, R. (2012). Comparison of a Transparent Polyeurathane Film and Sterile Gauze as Dressing Materials for Central Venous Access. Journal of Nursing, Social Studies, Public Health and Rehabilitation, 1(2), 72-78. | Prospective quasi-experimental | 256 gastrointestinal, inflammatory disease of digestive tract, renal transplant surgical and other diagnosis patients with a CVC in Slovakia | Sterile gauze, semipermeable transparent | Infection, skin irritation | No statistical difference in the rates of infection between gauze and transparent. Higher rate of skin reaction with gauze |
| Dickerson, N., Horton, P., Smith, S., & Rose, R. C. (1989). Clinically significant central venous catheter infections in a community hospital: Association with type of dressing. *Journal of Infectious Diseases, 160*(4), 720-722. | Prospective cohort | 161 oncology, critical care and general medical patients with a CVC in a Tennessee community hospital | Transparent, gauze and tape, gauze covered by transparent, guaze covered by tape | Infection | Higher rates of infection with a transparent dressing |
| Petrosino, B., Becker, H., & Christian, B. (1988). Infection rates in central venous catheter dressings. *Oncology Nursing Forum, 15*(6), 709-717. | Prospective cohort study with 30 day follow up. | 41 oncology patients from two Texas hospitals having a first-time ICVC insertion | Two transparent (Tegaderm®, Op-Site®), Gauze or no dressing | Infection | Suggests transparent dressing have higher infection and sepsis rates when compared with gauze and/or no dressing, though not significantly. |

| Reference | Design | Study Sample | Types of dressings examined | Relevant Outcomes | Findings |
|---|---|---|---|---|---|
| Harwood, L., Wilson, B., Thompson, B., Brown, E., & Young, D. (2008). Predictors of hemodialysis central venous catheter exit-site infections. *CANNT Journal, 18*(2), 26-35. | Prospective observational study | 52 haemodialysis patients with a tunnelled CVC in a large academic hospital in Canada | Gauze type, semi permeable | Infection | Gauze type dressing associated with higher infection rate of CVC exit sites |
| Treston-Aurand, J., Olmsted, R., Allen-Bridson, K., & Craig, C. (1997). Impact of dressing materials on central venous catheter infection rates. *Journal of Intravenous Nursing, 20*(4), 201-206. | Retrospective audit | 3931 CVC insertions | Transparent, highly permeable transparent and gauze and tape | Infection | A 25% reduction in infection rates occurred when using a highly permeable transparent dressing |
| Silveira, R. C. d. C. P., Braga, F. T. M. M., Garbin, L. M., & Galvão, C. M. (2010). The use of polyurethane transparent film in indwelling central venous catheter. *Revista latino-americana de enfermagem, 18*(6), 1212-1220. | Prospective observational study | 10 hematopoetic stem cell transplant patients | Gauze until no exudate then transparent | Infection, skin reactions | Undertaken in tropical climate. More skin reactions and exit site infections associated with a transparent dressing. |

## 2.4 Types of dressing

The following section focuses on the relationships between the types of dressings and the outcomes of interest in this study (infection and intactness). Firstly the evidence indicating an increased risk of infection with transparent dressings will be discussed. Following this, the evidence indicating an increase of infection with a gauze type/gauze and tape dressing will be considered. In the third sub-section, the evidence indicating no preference between either a transparent dressing or gauze type/gauze and tape dressing will be reviewed. This section considers evidence for infection related to each type of dressing (transparent and opaque) in turn and then considers the evidence regarding intactness.

### 2.4.1 Increased risk of infection associated with transparent dressings

In studies contrasting types of dressings, the outcome most commonly examined was infection. Four primary studies conducted between 1985 and 2013 showed a clinical trend of an increased risk of catheter tip infection on CVC sites when using transparent polyurethane dressings compared to gauze dressings (Barros, et al., 2009; Conly, Grieves, & Peters, 1989; Dickerson, Horton, Smith, & Rose, 1989; Petrosino, Becker, & Christian, 1988), however the majority of these study findings did not reach the threshold for statistical significance. Conly, et al. (1989) did have statistically significant findings, although this study was undertaken with peripheral cannulas not a CVC.

The Brazilian Barros, et al. (2009) study found higher infection rates with transparent dressings when used on the exit sites of 66 haemodialysis patients; but these results did not reach statistical significance. The transparent dressing was changed every seven days compared with second daily with gauze and tape so it was not clear whether the inconsistency with time of dressing change influenced the rate of infection.

Dickerson, et al. (1989) also found a clinical trend towards higher rates of infection with a transparent dressing when compared to gauze and tape, in his prospective cohort study of 161 oncology patients. This finding was also reflected in the smaller prospective cohort study of 41 oncology patients by Petrosino, et al. (1988).

Only one study found higher infection rates for transparent polyurethane dressings to be statistically significant (Conly, et al., 1989). Conly's RCT included 79 medical, surgical and paediatric patients. During this trial 115 CVCs were monitored, and the majority of patients were using the CVC for parenteral nutrition purposes not for haemodialysis.

Of the ten systematic and narrative literature reviews examined pertaining to CVC care and infection, two (Theaker, 2005; Webster, et al., 2011) did not support the use of the transparent dressing when compared to gauze. Theaker's (2005) review of the literature found more evidence to support the use of gauze dressing, arguing that the transparent dressing increases the risk of infection due to promotion of moisture and bacterial proliferation beneath the dressing. Webster, et al. (2011) identified many other factors that contributed to infection rates such as site of insertion, age and duration of CVC catheterisation. When reviewing the evidence relating to the transparent dressing, Webster, et al. (2011) stated that a transparent dressing was associated with higher rates of local and systemic infections than a gauze and tape dressing, however they also concluded that the studies reviewed were small and at risk of bias.

### 2.4.2 Increased risk of infection associated with gauze/opaque dressings

Two articles were identified in the literature (Harwood, et al., 2008; Treston-Aurand, et al., 1997) that reported an increase in infection rates with a gauze type dressing. The aim of the Harwood, et al. (2008) Canadian observational study, was to identify predictors associated with confirmed CVC exit site infections rather than specifically comparing infection outcomes between gauze and transparent dressings. In this study 52 participants who had a tunnelled CVC were monitored. A transparent dressing was routinely used on CVC exit sites unless the participant could not tolerate it, then a dry gauze type dressing was used. The patient could also have three differing types of skin preparation depending on tolerance. The trial results did not indicate which type of skin preparation was used with what type of dressing. An additional limitation of this observational study is that there was a large number of nurses (70) employed within the unit who collected the data therefore the data could be at increased risk of perceptual error. The variety of dressing types, preparation solutions and providers introduces numerous confounding variables therefore it is difficult to ascertain which variable definitively contributed to the outcome.

Treston-Aurand, et al. (1997) in their retrospective audit of 3931 CVCs comparing gauze and tape with a transparent dressing on CVC exit sites found that a highly permeable transparent dressing reduced the incidence of infection by 25%. Potentially confounding factors such as site of insertion of the CVC and the type of CVC (i.e. tunnelled or non-tunnelled) which could be of significance in influencing the outcome were not specified.

### 2.4.3 No evidence to support either type of dressing

A meta-analysis of eight studies from the 1980s and 1990s failed to show any increase in the risk of CVC-related bloodstream infections (Maki & Mermel, 1997) with the use of a gauze type dressing over a transparent dressings.

Two systematic reviews also examined the literature (see table 2.1.1) and concluded there was no sufficient evidence to support either type of dressings as being better than the other at preventing infection. The Centre for Applied Nursing Research (1998) presented several studies that indicated transparent dressings may increase the risk of CVC related infections however overall this review could not definitively conclude that one type of dressing is more effective than another type. The second systematic review also had similar findings, concluding that "it is not feasible to determine which dressing was the most effective as there is insufficient quality data available to determine which dressing type has the lowest risk of catheter-related infections" (McCann & Moore, 2010, p.17). Safdar, Kluger, and Maki (2002) also reviewed the literature and performed a meta-analysis of RCTS that pertained to CVCs and infection rates. This review also reached the same conclusion as the two aforementioned reviews, concluding that transparent dressings do not materially increase the risk of CVC related bloodstream infections. Five of the six literature reviews included in table 2.1.1 also concluded that there is no conclusive evidence to determine whether transparent or gauze type dressings are more appropriate for use on CVC exit sites (Danks, 2006; Gillies et al., 2003; Jones, 2004; McArdle & Gardner, 2009; Safdar, et al., 2002).

There were three RCTs identified in the literature that found no difference in infection rates between a transparent dressing and a gauze type dressing. Shivnan et al. (1991) in their RCT comparing gauze with a transparent dressing on 98 bone marrow

transplant patients found no difference in infection rates. These findings are similar to those of Le Corre, Delorme, and Cournoyer (2003), and Little and Palmer (1998).

Jezova, Ziakova, and Serfelova (2012) undertook a large quasi-experimental study with 256 differing multiple diagnosis participants comparing sterile gauze and a semi-permeable transparent dressing on CVC exit sites. This study also found no difference in infection rates. The authors do not state how the dressings were assigned to each participant. The quality of the English translation of this article also creates confusion at various points throughout the article therefore it is difficult to obtain an accurate picture of the results.

Callaghan et al (2002) also conducted a large prospective cohort study. This study involved 364 children comparing infection rates when using a transparent dressing and gauze and tape on peripheral cannula sites. The study findings indicated no infection rate differences between the two dressings. Unlike a CVC, however, peripheral cannulas do not stay in-situ for more than a couple of days. Additionally this is a very different study population to a haemodialysis study population. Therefore the findings from Callaghan, et al. (2002) study need to be interpreted with caution for possible applicability to the haemodialysis patient population under consideration.

No articles were found that identified the use of the specific dressing used in the TRS (PRIMAPORE™) on CVC exit sites, and no other dressings apart from gauze and a transparent dressing were mentioned in retrieved articles. Additionally the brand of transparent dressing used in these studies varied and wasn't always an IV3000™ (transparent dressing used in the TRS). Therefore it is difficult to conclude that there is a single appropriate dressing that should be used on CVC exit sites. Gillies, et al. (2003) concur when they concluded "there is a high level of uncertainty of the risk of infection with the CVC dressing" (p.630). This conclusion is also stated in the CHRISP guidelines.

### 2.4.4 Intactness

Several authors reported on intactness. Four articles examined intactness as their outcome measures. Three articles supported the use of a transparent type dressing as the dressing more likely to remain intact (Callaghan, et al., 2002; Shivnan, et al., 1991; Silveira, et al., 2010). Conversely one article found that a gauze and tape dressing was the better choice to improve dressing intactness (Conly, et al., 1989).

Callaghan, et al. (2002), in their study of 364 children, found a transparent dressing more likely to remain intact than gauze and tape. However, as mentioned previously, the dressings were used for peripheral intravenous catheter sites not CVC exit sites. Therefore the findings may not be applicable to the population of interest.

Trotter, et al. (2008) conducted a large well designed RCT with 244 general medical/acute care patients in an American hospital. The CVC dressings were changed three times a week. The transparent dressing with cloth adhesive borders remained intact on 94% of occasions whereas the gauze and tape remained intact only 23% of the time. Shivnan, et al. (1991) undertook an RCT with 98 bone marrow transplant patients. This RCT was also well designed and had similar outcomes to Silveira, et al. (2010), finding transparent dressings more likely to remain intact on CVC exit sites.

In contrast to the findings in the three aforementioned articles, Conly, et al. (1989) found gauze and tape to be the better dressing of choice for intactness when compared to a transparent dressing on CVC exit sites in their RCT. The primary outcome measure in Conly's RCT was infection however statistical analysis was undertaken on the intactness of the two dressings. There was a statistically significant finding with 24% of patients who received the transparent dressing presenting with a non-intact dressing compared with only 2% of patients who used the gauze and tape dressing to be non-intact. It was also reported that loss of intactness (with both type of dressings) occurred predominately in patients who exhibited marked diaphoresis. In this study more male than female participants received a transparent dressing and, as mentioned previously this was not a cross-over study so it is difficult to ascertain if one dressing could be better suited for a particular gender, given the potential for increased hair and sweat in males.

### 2.4.5 Skin reactions

Adverse skin reactions to transparent and gauze type dressings were also of interest when reviewing the literature. Three articles were found that mentioned skin reactions. Shivnan, et al. (1991) and Jezova, et al. (2012) found gauze to cause more skin irritation. In contrast Le Corre, et al. (2003) found the transparent dressing to cause more skin irritation however it was postulated in this study that this may be due to not allowing sufficient time for the skin preparation solution to dry.

Harwood, et al. (2008) undertook an observational study involving haemodialysis participants with a tunnelled CVC. A transparent dressing was used on the CVC exit site unless not tolerated by the participant. It is interesting to note that out of 50 participants 18 used the gauze type dressing. Therefore it is assumed that over a third of participants could not tolerate the transparent dressing. The high usage of the gauze and tape dressing is not explored or explained in Harwood's study.

Based on the limited evidence found in the literature, and PRIMAPORE™ not being used in any of these trials, once again there is no definitive evidence to determine whether an opaque dressing (PRIMAPORE™) or a transparent dressing (IV3000™) is a more appropriate dressing for use in the TRS.

## 2.5 Dressing protocol

When examining evidence for overall dressing protocols, most articles appeared to indicate that dressing type was not the only factor to determine infection rates. There were three other frequently identified factors. The first factor mentioned in four studies was frequency of dressing change (Bennett, et al., 2005; Callahan & Wesorick, 1987; Centre for Applied Nursing Research, 1998; Harwood, et al., 2008); the permeability of dressing to moisture to prevent accumulation of fluid beneath the dressing (Lin, et al., 2009; Little & Palmer, 1998; Reynolds, Tebbs, & Elliott, 1997), and topical application of ointment such as mupuricin on the exit site (Banton, 2006; Fukunaga, Naritaka, Fukaya, Tabuse, & Nakamura, 2006; Theaker, 2005).

### 2.5.1 Frequency of dressing change

Bennett et al. (2005) and Callahan and Wesorick (1987) examined whether or not there is a correlation between the frequency of dressing change of CVC dressings and infection rates. Bennett's paper was based on a questionnaire survey that examined the current practices of Renal Units within Australia. The frequency of dressing change was therefore only reported as part of unit policy and there was no rationale or evidence based reason guiding the frequency of change.

Callahan and Wesorick (1987) examined the frequency of dressing change for a transparent dressing and supported use of transparent dressings. This, however, is a very old study and improvements in dressing properties mean that findings are no longer clinically relevant.

A systematic review by Centre for Applied Nursing Research (1998) identified seven articles found in the literature. These articles showed mixed results on whether or not the frequency of dressing change (either gauze or transparent) contributed to infection although they did find that the transparent dressings needed to be changed less frequently. Once again these are outdated studies

Harwood, et al. (2008) also supported weekly dressing changes. They found that infection was less likely to occur when the dressing was changed weekly versus second daily. Callahan and Wesorick (1987) found otherwise. In their prospective cohort study they used 39 volunteer participants and measured the bacterial growth under a transparent dressing. The dressings were not used on a CVC exit site and were placed on the backs of the participants and measured every 24 hours for bacterial growth. They noted a significant increase in bacteria after 48 hours, particularly with the participants who had oily skin and/or acne. This study indicated that a dressing should be changed more frequently and recommended that it may be more pertinent to find a skin preparation that has a longer lasting anti-bacterial affect. The major limitation of the study, which is acknowledged by Callahan and Wesorick (1987), is the lack of a comparison group wearing gauze dressings.

The finding by Callahan and Wesorick (1987) is one of the few that support more frequent dressing changes. The most common finding noted from reviewing these articles is that transparent dressings are preferable as they require less frequent dressing change, and are therefore more cost-effective. This finding is also consistent with the current Centre for Health Care Related Infection Surveillance and Prevention & Tuberculosis Control (2013a) that indicate transparent dressings can be left on for a longer duration of time than other types of dressings.

### 2.5.2 Securement of catheter and catheter insertion site

There is some evidence that catheter security is better when using transparent dressings than when using gauze dressings (Shivnan, et al., 1991; Tripepi-Bova, Woods, & Loach, 1997), and combining transparent dressings and a securement device reduce the incidence of phlebitis, infiltration and catheter dislodgements, most likely because of improved cannula stability (Tripepi-Bova, et al., 1997; Wood, 1997). These two articles relate to peripheral cannula stability. Although these studies are also dated, dislodgement is still an issue in today's health care setting. Certainly within the

Townsville Hospital Renal Unit, the patient often presents with a non-intact dressing which is an infection risk (Hughes, et al., 2011). The use of a securement device is often required, particularly with the femoral catheter as the dressing is not often strong enough to withstand the forces of having a catheter in such a mobile position.

In addition, the site of catheter insertion may also play a role. Theaker (2005), and Safdar and colleagues (2002), state that the insertion of a CVC using the subclavian approach results in lower infection rates than with the internal jugular approach. Femoral insertion, however, is the least favoured, as the rates of infection are much higher than the other two approaches (Center for Disease Control, 2011). This higher incidence of infection is thought to be due to bacteria harbouring in skin folds around the site of femoral insertion. However, more recent guidelines state the right internal jugular is now the insertion site of choice. The rationale for this preference is that the use of subclavian vein for CVC placement invariably leads to stenosis. This will in turn prevent the placement of an AVF in vessels that require adequate blood flow from the subclavian vein to develop into a successful haemodialysis access (Centre for Health Care Related Infection Surveillance and Prevention, 2007). The femoral vein is still at the highest risk of infection but has less chance of stenosing, hence, when deciding on an insertion site, the benefits and risks must be carefully considered.

### 2.5.3 Managing CVC exit site dressings in the tropics

No article reviewed made mention of dressings and infection rates in tropical climates. Several authors mentioned factors that are relevant such as level of diaphoresis (Jezova, et al., 2012; O'Grady, et al., 2002; Safdar, et al., 2002), moisture vapour transmission rate (MVTR) (Jones, 2004; Lin, et al., 2009) and factors related to climatic variation. Jones (2004) came closest to addressing climatic factors when mentioning that Craven and colleagues (1985) found in the summer months the rate of infection for those using a transparent dressing was higher than in the cooler months. However, like most of the evidence reviewed, this was a dated study.

Barros, et al. (2009) also raised concern about dressing performance when conducting a study in sub-tropical Sao-Paulo, Brazil comparing transparent dressings with a gauze and tape. In the findings of this study it is stated that the transparent film was “not feasible for patients with abundant sweating” (p.485). This statement was not elaborated on nor was any evidence provided to support this claim. References to the

suitability for a transparent dressing to be used when the patient is diaphoretic is also noted in the meta-analysis by Safdar, et al. (2002), O'Grady, et al. (2002) and Jezova, et al. (2012). However, once again there is no rationale provided in these articles to convince the reader why it is not suitable to use a transparent dressing where diaphoresis is occurring. Safdar, et al. (2002) meta-analysis states that a transparent dressing should not be used if the patient is diaphoretic or bleeding/oozing from the exit site. It is indicated that during these circumstances the risk of infection with a transparent dressing may increase. There are no references to any articles conducted in a tropical climate prior in Safdar, et al. (2002) meta-analysis. However they may not have examined this factor due to the lack of literature available relating to this topic. In summary, all of the aforementioned of these articles and reviews state it is not appropriate to use a transparent dressing if oozing or bleeding is present at the exit site. Many of the articles reviewed did not provide rationales as to why a transparent dressing is not suitable if sweating or bleeding is present. Betjes (2011, p.261) provides an explanation as to why this dressing may not be appropriate, stating that the permeability of a semipermeable adhesive dressing may be reduced by moist skin. This promotes maceration and infection of the exit site. This explanation is congruent with the clinical reasoning used by the nurses in the TRS in their decision to use the opaque dressing (PRIMAPORE™) instead of a transparent dressing (IV3000™).

An additional article made claims regarding the suitability of transparent dressings on CVC exit sites (Silveira, et al., 2010). This Brazilian study was an underpowered prospective observational study with a poor study design which aimed to assess the suitability of a polyurethane dressing on CVC exit sites in a tropical country. The study compared gauze and tape with a polyurethane dressing on ten participants. All participants had gauze changed daily until there was no exudate then changed to a transparent polyurethane dressing. The duration of time a participant used the gauze and tape was between four to six days and was changed daily. The transparent dressing was then used and changed every seven days. The transparent polyurethane dressing was used for an average of 15 days by each participant. Silveira, et al. (2010) concluded that although the study was not an RCT, there was sufficient evidence to raise concerns with using a transparent polyurethane dressing in a tropical climate. The presence of exudate made it not possible to use the transparent dressing for a number of days post CVC insertion. It is also stated that the appearance of erythema may be related to the

polyurethane dressing. However, this study has a weak design and it is not possible to determine if one dressing has contributed to signs of infection due to the variability of dressing duration of each dressing. The decision to change dressings was based on clinical grounds with no set criteria to follow. The English translation is at times confusing, especially in the results section. Therefore it is difficult to obtain an accurate overview of the study's outcomes. Silveira, et al. (2010) mentions other Brazilian studies that raise concern with dressing types for CVC exit sites in the tropics. Unfortunately it was not possible to obtain the studies referred to by Silveira as no English translation was available. These aforementioned studies were the only articles that included factors that might reflect specific consideration in tropical conditions.

In summary there are some limitations in research methodology in many studies when comparing infection rates between the gauze and transparent dressings. Of most importance is that unlike this RCT no trial specifically compared the use of the opaque PRIMAPORE™ with the transparent IV3000™ dressing and none of the trials were cross-over trials.

### 2.5.4 Application of findings from literature review to local context

When considering the most appropriate dressing for the Townsville patient, three factors have to be considered: adhesiveness, ease of application and removal, and the property of the dressing (i.e. MVTR). As mentioned in the introduction chapter, the Townsville catchment has a high percentage of rural communities, Aboriginal and Torres Strait Islander and unemployed people, with all the attendant problems of great distances from healthcare services, poor housing, inadequate sanitation and water supply, and sometimes homelessness. Under these conditions, adhesiveness of the exit site dressing between dialysis sessions becomes a particular concern. Given the significant percentage of haemodialysis patients in the TRS who frequently miss haemodialysis treatments, the adhesiveness of the dressing over time becomes even more important. Adhesiveness is also an issue when considering increased perspiration when living in a tropical climate.

The property of the dressing is also imperative when taking into consideration Townsville's hot and humid climate; in particular, MVTR needs to be examined. Although a moist environment is ideal for wound healing it can also promote infection (Theaker, 2005). The higher the MVTR from the dressing, the less sweat and skin

excretions will get trapped under the dressing. An accumulation of these excretions and moisture may lead to the loss of the adhesive bond and wrinkle formation in the dressing. In turn, this will allow for the passage of bacteria to the catheter resulting in irritant dermatitis or friction which may then increase susceptibility for infection (Jones, 2004). Lin, et al. (2009), in their study on the MVTR of gauze and a number of transparent dressings, have a similar opinion. Their study compared the differing MVTR of five types of dressings, including gauze, IV 3000™ and the combination dressing Tegaderm IV™ (two of the dressings used in our RCT) in differing temperatures and humidity settings. This trial was not performed on human participants, but it was performed in a laboratory setting. Fifty millilitre plastic centrifuge tubes containing 20ml of deionised water were used. The tubes were then covered by a dressing. The study found that in a setting of 37 degrees Celsius with a humidity of 30% or 60%, gauze had a higher MVTR followed by IV 3000™ and then Tegaderm IV™. As the humidity climbed to 90%, the IV 3000™'s MVTR improved to overtake the gauze, and again the lowest MVTR was the Tegaderm IV™. This study suggests transparent dressings may not necessarily increase infection rates as many of the current modern transparent dressings have a relatively high MVTR. However no evidence was found from studies involving human participants to support or refute this conclusion.

It is apparent from the published literature and from discussions with dressing manufacturers that the dressing permeability and its relation to moisture accumulation beneath the dressing needs to be examined (Jones, 2004; Little & Palmer, 1998; Reynolds, et al., 1997). Whilst it is true that transparent dressings enable direct visualisation, potentially reducing the need for dressing change, with its attendant problems of dislodgement of catheter and external contamination, the accumulation of moisture may increase risk of infection. These hypotheses have only been tested in small studies and ones that are at least a decade old with the exception of the more recent study by Lin, et al. (2009) in a non-human, laboratory condition only. Meta-analyses that investigated the hypothesis that there would be an increase in infections associated with use of transparent dressings did not support this hypothesis (Gillies, et al., 2003; Maki & Mermel, 1997). In addition, there was insufficient information available regarding the use of opaque dressings on CVC sites. For example, no articles were identified that examined the risk of bloodstream infection with the use of a PRIMAPORE™ dressing; all articles related to gauze as the only opaque dressing.

It is likely that the advent of highly permeable transparent dressing products, such as Tegaderm 1633™ dressing (Tegaderm and soft cloth surgical tape combined in a single dressing) and the OpSite IV3000™ dressing (sterile, water-proof and claimed in product information to transmit moisture eight times faster than standard film dressings (Smith & Nephew, 2015)) has overcome the potential catheter-related infection risks associated with the use of earlier occlusive film dressings. Unfortunately, most of the original research studies reviewed were over a decade old; therefore, it was difficult to gain an up-to-date insight into infection rates, and earlier studies are of questionable relevance with recent advancements in dressing properties.

## 2.6 Chapter Summary

It is evident from the literature that there is conflicting evidence regarding the most appropriate dressing to use on a CVC exit site. Whilst there were a number of articles that indicated a clinical trend towards a transparent dressing being associated with higher infection rates, the majority of the evidence indicated that there was inconclusive evidence regarding the most suitable type of dressing. The literature reviewed clearly indicated that the dressing type is only one of many factors involved in infection risk for bloodstream infections related to CVCs. In particular the frequency of dressing change, the site of CVC insertion, the use of a securement device, the MVTR of the dressing and the use of strict aseptic techniques in the placement and care of CVC sites is very important. However, the fact remains that, given the humid climate of the Townsville region and the subsequent increased perspiration, type of dressing is potentially a major factor associated with infection in patients receiving haemodialysis, but more research is needed.

The literature review identified a lack of empirical evidence to support changing the current dressing from opaque (PRIMAPORE™) to a transparent dressing. In particular, there was no available evidence about rates of infections for CVCs in the tropics or recommendations for the type of dressing that would be most suitable for the humid climate. No articles linked type of dressing, infection rates and the tropical climate. Silveira, et al. (2010) did voice concern about the use of a transparent dressing in a tropical climate as did Craven and colleagues (1985) who identified an increased infection rate associated with the use of transparent dressings on peripheral cannulas in the hotter summer months. However, this study is over 30 years old and may not be

relevant to current dressings. With recent advancements in dressing properties, the findings of the majority of the studies reviewed are outdated and therefore of little or no assistance. Overall, there was no evidence to definitively support any changes to the current CVC dressing practices (PRIMAPORE™ dressing) in the TRS.

This review has established that there is a paucity of information relating to the best type of dressing to use in tropical climates. An RCT is the most appropriate method of research to use to obtain this evidence as it is the "gold standard" of quantitative research (Polit & Beck, 2008) and produce a high level of quality evidence. The following chapter describes the method used in this study to answer the question: "Is an opaque dressing for CVC exit sites for patients undergoing haemodialysis in the tropics more effective than a transparent dressing?" Effectiveness will be measured by intactness of dressing between haemodialysis episodes and by local (CVC exit site) and systemic infections.

# Chapter 3 Methods

## 3.1 Chapter introduction

This chapter describes the methods used to investigate the study's aim of identifying the most effective CVC dressing for haemodialysis patients in the tropics, specifically if an opaque dressing is more likely to remain intact and/or have a lower infection rate than a transparent or combination dressing. This chapter provides details about the research methods, undertaken within a traditional positivist paradigm. The study settings, study design, sample, process, inclusion and exclusion criteria and interventions are outlined. Additionally, the conduct of the trial and ethical considerations including the ethical considerations regarding research with Aboriginal and Torres Strait Islander people are articulated. Finally, details pertaining to data collection, data management and data analyses are also presented.

## 3.2 Research question

This study was designed to explore the following research question: Is an opaque dressing for CVC exit sites for patients undergoing haemodialysis in the tropics more effective than a transparent or combination dressing? The null hypothesis was: There is no difference in effectiveness with the use of a transparent or combination dressing compared to an opaque dressing on CVC exit sites for patients undergoing haemodialysis in the tropics. Effectiveness was measured by intactness of dressings between haemodialysis episodes and by local (CVC exit site) and systemic infections. Intactness and infection are described in more detail in the 'Operational definitions of outcome measures' section later in this chapter.

## 3.3 Study settings

At the time of the study, the TRS served a large geographical area in North Queensland, Australia, of approximately 500,000 $km^2$. Using Townsville as a reference point, the area of coverage extended from Bowen (200km) in the south, to Cardwell (200km) in the North, and west to the Mt Isa region (900km), and included the northern Gulf of Carpentaria communities (900km). Several haemodialysis facilities provided renal services to such a widespread population. These facilities included an in-centre hospital haemodialysis unit at The Townsville Hospital (TTH), four satellite

haemodialysis units and a home therapies unit. The in-centre dialysis unit at TTH dialysed patients with acute renal failure as well as patients with chronic renal failure who required more extensive medical support than that able to be offered in the satellite haemodialysis units or in community settings. At the time of the study 96 patients dialysed at this in-centre unit. The largest of the four satellite units, located at North Ward (a suburb of Townsville), dialysed 44 patients at that time. The home therapies unit, also located at North Ward, provided training to those patients who wished to return home and perform either peritoneal dialysis or haemodialysis independently. The second satellite unit was located on Palm Island, just 63 km off the coast of Townsville, and dialysed three patients at the time of the study. The third unit was located at Home Hill (100km south of Townsville), where eight patients were dialysed. The final unit was the Mount Isa Satellite unit where 16 patients were dialysed. Patients often transferred between units, either temporarily or permanently for several reasons such as operational requirements, acuity and relocation, including temporary relocation to observe culturally significant rituals with extended family.

At the time of the study's commencement, there were no patients who met the inclusion criteria dialysing at the Palm Island satellite unit. Thus the study included participants from the in-centre dialysis unit at TTH and the North Ward, Home Hill and Mt Isa satellite units. However, only data from the North Ward satellite unit and the in-centre TTH unit were included in the final data analysis: the trial participants at Home Hill and Mt Isa had their CVCs removed before a second dressing type was trialled.

## 3.4 Study design

The study was a small scale, prospective, randomised trial with the intervention allocation blinded at the point of analysis only. This pilot study used a cross-over design with patient participants acting as their own controls which increased the efficiency of the trial by maximising the sample size because all participants were allocate to receive all treatments in a random sequence. Employing a cross-over design was ideal in this study due to the low numbers of participants available. A cross-over design can utilise fewer subjects than a parallel group design study to produce statistically significant results which are of clinical importance and relevance (Young, Contreras, Robert, Vogt, & Courtney, 2005). In many cross-over designs there is a washout period between the treatments to minimise carry over effects (Piantadosi, 2005). There was little need for a

washout period in this RCT, as unlike a drug trial there should be no lingering physiological effect of the dressing, therefore no carry over effect. It was recognised that infection can take a couple of days to develop but this very short period could be monitored separately. In addition, if a washout period had been incorporated between changes in dressing allocation, it would have been necessary to leave the CVC exit site uncovered for a period of time. Clearly this would not have been clinically appropriate as it would have exposed the patient to risks such as infection or trauma at the exit site.

Many RCTs are blinded to reduce awareness or expectancy bias (Polit & Beck, 2008). However it was not possible to blind the nursing staff or the participants to the dressings, given the difference in appearance of each of the the dressings. The recruiters were not involved in the randomisation process, therefore they did not know which dressings would be used first and in what sequence.

Participants were originally planned to receive each type of dressing for four weeks (a total of 12 weeks). The dressing would be changed at each dialysis session, with most patients being scheduled for a dialysis session three times a week. The rationale for the trial taking 12 weeks was based on best practice recommendations that CVCs should not be *in situ* long term; that is, longer than three months.(National Kidney Foundation, 2006). Thus a period of three months enabled a maximum data collection period without compromising patient safety. Recruitment commenced two weeks prior to the trial and continued up until one month after the commencement date of the first participants. Therefore, almost five months was allocated to the recruitment and data collection phases.

The main outcome measures were intactness of dressing between dialysis episodes, and local and systemic infection rates. It was anticipated the findings would provide preliminary guidance about the most suitable dressing for use in the tropics as well as definitive data on which to base sample size calculations for a future multi-site trial. Thus the design was appropriate for a pilot study (Polit & Beck, 2008).

## 3.5 Participants

### 3.5.1 Study population

The **patient population** was all TRS patients receiving haemodialysis through CVC access at TTH and three satellite units. The satellites included were the North

Ward, Home Hill and the Mt Isa dialysis units, as explained in the 'Study setting' section above.

This study had a unique patient population as it comprised a high proportion of Aboriginal and Torres Strait Islander patients (approximately 60%). As mentioned in the introduction chapter there are a large number of Aboriginal and Torres Strait Islander people living in the catchment area for the TRS and this patient cohort is particularly susceptible to renal failure due to the higher incidence of comorbities such as diabetes (Australian Institute of Health and Welfare, 2014). A number of the Aboriginal and Torres Strait Islander patients originate from areas outside of the Townsville Hospital and Health Service (THHS) such as Doomadgee and Mornington Island. Quite often these patients require emergency dialysis as they do not access medical services until they are very unwell and require dialysis. Since there are no dialysis services in these remote areas, the patients have to relocate to Townsville.

In addition to these emergency situations and because TTH is the tertiary referral hospital for the North Queensland region, there are quite a number of patients who dialyse via a CVC. Prior to commencing the trial, it was estimated that approximately 35 patients would be dialysed via CVC during period and that between 80% to 85% would consent to participate. Thus the convenience sample size for the study would be approximately 30 patients.

### 3.5.2 Study sample

The study was limited to all haemodialysis patients who dialysed via a CVC and attended a renal service within the THHS. No preparatory sample size calculations were undertaken as the total population was limited. Therefore the study was limited to those who fitted the eligibility criteria and who agreed to participate. The final sample size was the total patient population who came from Townsville in-patient centre, North Ward satellite unit, Home Hill and Mt Isa satellite unit. All patients with a CVC in these units agreed to participate.

Patients either had a tunnelled or a non-tunnelled catheter. Potentially, risk of infection and instability of dressing could differ, depending on the type of catheter. As mentioned in the introduction chapter, tunnelled catheters are far more stable due to the attached cuff which promotes growth of fibrous tissue around the catheter. Stratification of the sample into two groups was therefore planned for the purpose of randomisation

and statistical analysis to accommodate this potential variability. Again, however, no sample size calculation was possible.

### 3.5.3 Inclusion criteria

A patient was eligible for inclusion in the trial if they:

- Had a CVC and dialysed within the TRS
- Were at least 18 years of age
- Were able and willing to give informed consent

### 3.5.4 Exclusion criteria

A patient was excluded from the trial if they:

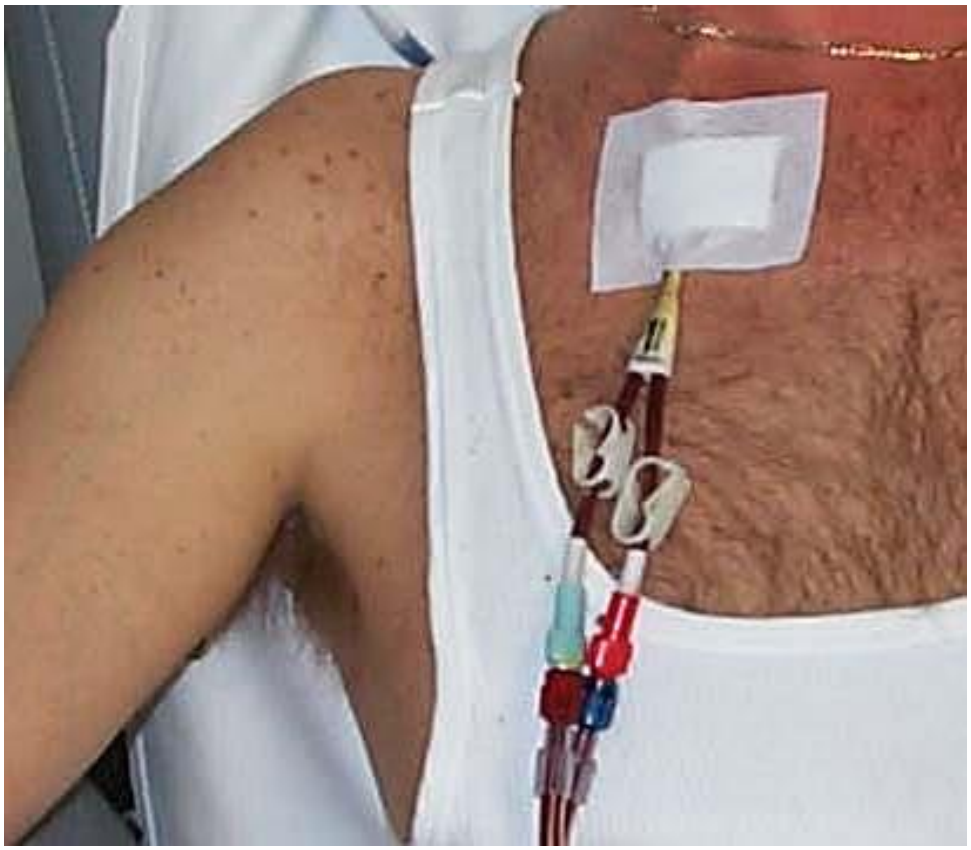
- Were not dialysing via a CVC
- Had a current exit site or CVC related bacteraemia at the time of commencement of the trial
- Were unable to give informed consent
- Chose not to participate

## 3.6 Interventions

### 3.6.1 Dressing types

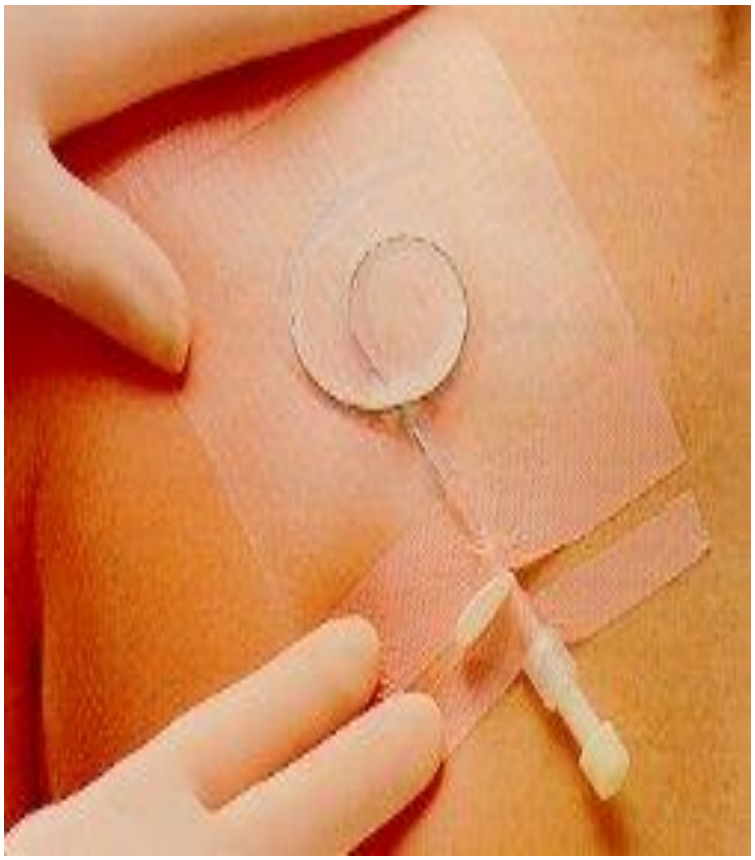
The three approved dressings used in this trial were:

- An opaque (or non-transparent) dressing, PRIMAPORE™ (Smith and Nephew). It is a white adhesive non-woven dressing. This dressing was standard practice for CVC site coverage in the TRS at the time of the trial.



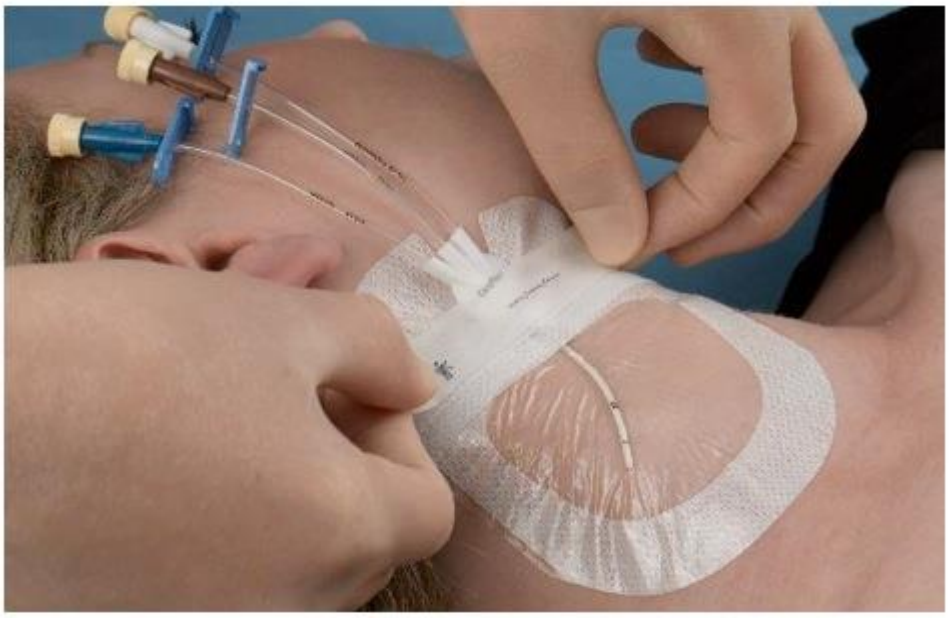
**Picture 1 Opaque dressing (PRIMAPORE™ )**

- A transparent dressing, (IV3000™, Smith and Nephew). This dressing allowed visualisation of the exit site and was the type of dressing recommended by the CHRISP guidelines as the dressing of choice for CVC exit sites at the time of the trial (Centre for Health Care Related Infection Surveillance and Prevention, 2007).



**Picture 2 Transparent dressing (IV 3000™ retrieved from: https://www.smith-nephew.com/belgie/producten-old/per-producttype/i-v--verbanden/iv3000-/)**

- A combination dressing, Tegaderm IV™ (3M). This dressing is opaque around the adhesive edges and transparent in the centre panel, which like the IV3000™, also allowed visualisation of the exit site. This dressing had not been used at all by the TRS prior to the trial. Representatives of the dressing manufacturer provided education to the nursing staff and observed nurses using the dressings following those in-services. A pre-test was undertaken on three patients to determine the dressing's suitability for inclusion in the trial. The pre-test was uneventful with no reported reactions or problems with dressing application and removal. However, shortly after commencement of the trial there were a number of adverse events which required the removal of this dressing from the trial. This problem is addressed later in the chapter (see 'Stopping guidelines' section).



**Picture 3 Combination dressing (Tegaderm IV™ retrieved from http://www.ivdressing.com/)**

## 3.7 Randomisation

The randomisation process utilised a web-based program for computer generated listing of random numbers, www.randomization.com, to determine the sequence of the cross-over allocation of patients to the three dressing types. Following consent, the participants were block randomised and stratifed into two groups: tunnelled or non-tunnelled catheter as described previously. Randomisation was carried out by researchers and research assistants who were not involved in the clinical care of the patients, nor in the recruiting process. Thus, the Principal Investigator and nurses in the renal unit were not involved in the randomisation process. See Table 3.1 for details about the possible randomisation sequencing at the commencement of the trial with the three dressing types.

**Table 3.1 Original planned randomisation sequencing**

| Prior to start date | Wk 1 | Wk 2 | Wk 3 | Wk 4 | Wk 5 | Wk 6 | Wk 7 | Wk 8 | Wk 9 | Wk 10 | Wk 11 | Wk 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Recruitment | Opaque dressing four weeks | | | | Transparent dressing four weeks | | | | Combination dressing four weeks | | | |
| Recruitment | Opaque dressing four weeks | | | | Combination dressing four weeks | | | | Transparent dressing four weeks | | | |
| Recruitment | Transparent dressing four weeks | | | | Combination dressing four weeks | | | | Opaque dressing four weeks | | | |
| Recruitment | Transparent dressing four weeks | | | | Opaque dressing four weeks | | | | Combination dressing four weeks | | | |
| Recruitment | Combination dressing four weeks | | | | Opaque dressing four weeks | | | | Transparent dressing four weeks | | | |
| Recruitment | Combination dressing four weeks | | | | Transparent dressing four weeks | | | | Opaque dressing four weeks | | | |

## 3.8 Operational definitions of outcome measures (dependent variables)

The primary outcome of the trial was intactness of the dressing. Intactness was defined as all four edges of the dressing remaining adhered to the skin and was classified as '0' on the audit tool (see appendix A) Non-intactness was defined as one or more edges or corners of the dressing having lifted (classified 1, 2, 3 or 4 on the audit tool). Table 3.2 describes the classification and definitions of an intact and non-intact dressing.

The secondary outcome was the presence of infection, either clinical signs of infection or laboratory confirmed infections. Clinical signs of infections were assessed by the colour of the skin at the exit site and the presence or absence of a crust at the exit site, using the Twardowski scale (refer to Table 3.2). The Twardowski (Twardowski & Prowant, 1996) scale is described in full in the section addressing the data collection tools.

Laboratory confirmed infections were classified as local or systemic. Local infections were defined as either an exit site infection or a tunnel infection. Systemic infections were defined as a CRBSI. The definition and assessment of each of these three types of infections are described in turn.

Exit site infections were defined as local infection of the skin and soft tissue around the exit site. Erythema and purulent discharge with tenderness are typically present. Usually the subcutaneous tissue is not involved, although in some cases it may be affected (Oncu & Sakarya, 2002). Exit site infections were assessed by the use of the Twardowski scale (Twardowski & Prowant, 1996), which, as mentioned previously, will be described later in this chapter.

Tunnel infections were defined as an invasive painful soft tissue infection along the catheter tunnel superior to the cuff. Purulent discharge may be present through to the exit site (National Kidney Foundation, 2006). A diagnosis of confirmed tunnel infection requires a positive wound swab.

To diagnose a CRBSI, blood cultures must be taken. There must be a growth of $> 10^2$ colony forming units (cfu) from a catheter by quantification of broth culture and/or a growth of >15 cfu from a 5cm segment of catheter tip (Mermel et al., 2009).

Additionally the signs and symptoms of a CRBSI range in severity from minimal to life-threatening. These symptoms include fever, rigours, nausea, vomiting, back pain and changes in mental state. When a patient with a CVC presents with these clinical signs and symptoms without another confirmed source of infection, concerns should be raised that the catheter may be the source of infection. It is imperative that blood cultures are subsequently taken (Centre for Health Care Related Infection Surveillance and Prevention & Tuberculosis Control, 2013a). As CRBSI infections do not commonly occur and this was a pilot study with a small convenience sample, it was not expected there would be a statistically significant difference. Therefore only descriptive statistics, not inferential statistics were conducted in relation to presence of infection.

**Table 3.2 Dependent variable operational definitions**

| Dependent variable | Classification | Definition | Source of data |
|---|---|---|---|
| **Intactness** at time of dressing change according to Twardowski Scale (Twardowski & Prowant, 1996) | 0 | Dressing fully intact | Audit tool – completed by nurse at each dialysis session |
| | 1 | 1 edge/side off or rolled up | |
| | 2 | 2 edges/sides off or rolled up | |
| | 3 | 3 edges/sides off or rolled up | |
| | 4 | 4 edges/sides off or rolled up | |
| **Colour** of exit site at dressing change according to Twardowski Scale (Twardowski & Prowant, 1996) | A | Perfect | Audit tool-completed by nurse at each dialysis session |
| | B | Good | |
| | C | Equivocal | |
| | D | Infected or infection | |
| **Crust** at exit site at time of dressing change according to Twardowski Scale (Twardowski & Prowant, 1996) | A | Good | Audit tool-completed by nurse at each dialysis session |
| | B | Equivocal | |
| | C | Acute infection | |
| | D | Chronic infection | |

## 3.9 Ethical considerations

Approval was given from Human Research Ethics Committees of the Townsville Health Service District (approval number HREC/09/QTHS/121) and James Cook University (approval number HS3851) to perform this trial (see appendix B and C). The ethical considerations most important to this study were: informed consent, confidentiality of data, research involving Aboriginal and Torres Strait Islander people and adverse events. These will be discussed in turn.

### 3.9.1 Informed consent

All patients who agreed to participate in this trial provided their written consent. The guidelines from the National Health and Medical Research Council (NHMRC) about gaining consent from individuals in research state "consent should be a voluntary choice, and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation" (National Health and Medical Research Council, 2014, p.14). However, according to the NHMRC, consent is not just a matter of communicating information to participants. Participants should fully comprehend what is being asked of them. Nurses who approached patients about their potential participation in the trial received training about consent by experienced recruiters, following the *National Statement on Ethical Conduct in Human Research.* When approaching patients, these nurses who had been 'trained' in recruitment explained the voluntary nature of the consent and that patients would be able to withdraw their consent at any stage of the trial. To support the verbal information, all potential participants were provided with a Participant Information Sheet and Consent Form (D and E). Potential participants were encouraged to ask questions if they did not understand any aspect of the trial or required further information. All potential participants were encouraged to discuss their involvement in the trial with family members if they desired prior to signing consent forms.

The NHMRC (2014) guidelines also state that the information provided should be presented in a manner that is understandable by each participant and provide specific guidelines for potentially vulnerable populations, such as Aboriginal and Torres Strait Islander people. As this trial had a high percentage of Aboriginal and Torres Strait Islander participants, there were special considerations for consent and these are now explained.

### 3.9.2 Research involving Aboriginal and Torres Strait Islander peoples

The guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (National Health and Medical Research Council, 2003) articulate the values and ethics that should be taken into consideration when involving Aboriginal and Torres Strait Islanders people in a research project. The six values underpinning the guidelines are: spirit and integrity, reciprocity, respect, equality, survival and protection, and responsibility. The guidelines express the importance of these values to Aboriginal and Torres Strait Islander People. Failure to understand the importance of these values and to understand differing cultures endangers the quality and ethics of research (National Health and Medical Research Council, 2003). To ensure these guidelines were integrated into the research project, an Indigenous Health Professional was consulted during the preparatory phase of the trial process. The participant information sheets and consent forms were also reviewed by this Indigenous Health Professional to ensure cultural appropriateness for this cohort of patients. It was also important that nurses recruiting patients did so in a culturally appropriate manner. At the time this trial was conducted it was a mandatory requirement that all nurses in the THHS complete cultural awareness training early into their employment, therefore all nurses involved in recruiting had attended this course.

Some patients possessed limited literacy skills and often English was not their first language. The participant information sheets and consent forms were read carefully to all patients. Patients were encouraged to ask questions and discuss the trial with a family member or an Indigenous Liaison Officer before consenting. Several patients did take information away for further discussion with their families and no patients of Indigenous origin declined to consent.

### 3.9.3 Confidentiality of data

It is a NHMRC requirement to respect the privacy and confidentiality of patients who consent to participate in research (National Health and Medical Research Council, 2014). It was clearly explained to the patients who participated in the trial that all data would be treated as confidential. Copies of the signed consent forms were kept in participants' clinical notes during the trial for two reasons: first, to comply with NHMRC requirements and Queensland Privacy Legislation and second, so that there was a record of consenting to participate for all clinicians. Inpatient notes and pathology

results were accessed during the trial therefore demonstration of consent was important. It was an expectation that usual Queensland Health policy relating to confidentiality would be adhered to by all staff members, when accessing these data.

All paper-based data relating to the trial were stored within locked filing cabinets located within a secure office at TTH. Access to computer files was password restricted. A study identification number was assigned to each participant's data, however it was possible to re-identify the data should a need arise during data analysis. The register of study identification numbers matched to names was also kept in the aforementioned secure office at The Townsville Hospital. The data were only accessible to staff involved in the trial. At the completion of the trial, data were archived in a secure location at James Cook University for a period of seven years, as required by NHMRC guidelines.

### 3.9.4 Adverse events

In accordance with ethical requirements all adverse events were to be reported to the Human Research and Ethics Committees of the Townsville Health Service District and James Cook University. Skin reactions to dressings such as erythema, redness, pain or discharge, were a foreseeable potential adverse reaction. It was decided prior to the commencement of the trial that if a study participant developed a skin reaction to the transparent or combination dressing the dressing type would be changed immediately to the opaque dressing currently in use as standard practice. Should a study participant develop a skin reaction to the opaque dressing then the dressing would be changed to another dressing type based on clinical suitability. In this latter event, the dressing selected would not necessarily be one of the dressings used on the trial. During the course of the trial, several participants did develop reactions to one of the dressing types. This situation is discussed in the next section.

## 3.10 Stopping guidelines

During the first two weeks of the trial over 50% of patients randomised to the combination dressing developed a skin reaction. Human Research and Ethics Committees at the Townsville Hospital and James Cook University were notified of these adverse reactions and protocol changes were proposed. All changes to protocol were approved out of session by the committees to facilitate timely continuation of the

trial. This dressing was removed from future allocations, and this exclusion necessitated a modification to the study protocol. Instead of a patient receiving each of the three dressings, there would be a several alternate pathways depending on which dressing the patient had been randomised to receive first. The potential trial length (12 weeks) was retained for the majority of participants. A few participants had an 18 week trial duration. The amended process was:

1. Participants who had not yet trialled the now excluded dressing would extend the use of the other two dressings from four to six weeks. That is, they trialled two dressings for a period of six weeks each, to maximise data collection and exclude exposure to the problematic dressing.
2. Those participants who had been randomised to the now excluded dressing and did not have a reaction continued with that dressing for a period of six weeks (unless they developed a skin reaction in which case they went to pathway 3) and then continued on to the other two dressings for a period of six weeks each.
3. Those participants who developed reactions to the excluded dressing within the first two weeks were changed to the opaque dressing as per study protocol for adverse reactions. Data were collected on the opaque dressing for the remaining weeks of the first six week block. The participant would then move on to the next two dressings as per randomisation protocol.

Those few participants in pathways two and three had data collected for a total of 18 weeks and the majority of participants who did not trial the discontinued dressing had 12 weeks of data collected. In summary data collection continued for approximately three months per participant for most participants, with each participant having six weeks per dressing type with no washout period. The participants attended dialyis sessions up to three times a week therefore this provided up to 1620 episodes (540 in each group) for analysis. Table 3.3 demonstrates the actual randomisation sequencing following the implementation of the amended protocol.

This change of protocol to exclude the combination dressing also necessitated an alteration to the study research question. The research question proposed was: Is a non-transparent dressing for CVC exit sites for patients undergoing haemodialysis in the tropics more effective than a transparent dressing? There was no requirement to change the outcome measure. That is, effectiveness was still to be measured by intactness of dressing between haemodialysis episodes and by local (CVC exit site) and systemic

infections. The null hypothesis was also amended to: There will be no difference in effectiveness when comparing a transparent dressing with an opaque dressing on CVC exit sites on patients undergoing haemodialysis in the tropics.

**Table 3.3 Actual randomisation sequencing**

| New Pathway | Weeks 1-6 | Weeks 7-12 | Weeks 13-18 |
|---|---|---|---|
| Pathway1a | Opaque dressing six weeks | Transparent dressing six weeks | |
| Pathway 1b | Transparent dressing six weeks | Opaque dressing six weeks | |
| Pathway 2a | Combination dressing (no reactions) six weeks | Opaque dressing six weeks | Transparent dressing six weeks |
| Pathway2b | Combination dressing (no reactions) six weeks | Transparent dressing six weeks | Opaque dressing six weeks |
| Pathway 3a | Combination dressing (reaction) - changed to opaque (usual practice) for remainder of six weeks | Opaque dressing six weeks | Transparent dressing six weeks |
| Pathway 3b | Combination dressing (reaction) - changed to opaque (usual practice) for remainder of six weeks | Transparent dressing six weeks | Opaque dressing six weeks |

## 3.11 Data collection tools

Two forms were developed to assist in the collection of relevant information. The first form (see Appendix F), the demographic form, was completed once at the commencement of the trial. Demographic data collected included location of home town, age, gender, ethnicity, work and hobbies. Limited history was also recorded on this form and included: date the participant began dialysis; whether the participant was taking antibiotics prior to the trial, if they were an inpatient or an outpatient and base line information on the CVC exit site using the Twardowski (Twardowski & Prowant, 1996) assessment scale (see Appendix G). It was also recorded if the patient was diabetic and if so, whether he/she required medication to manage the diabetes. Table 3.4 outlines the operational definitions of the independent variables on the demographic data form.

The second form, the audit tool, was used to collect exit site information at each patient dialysis episode after the dressing was completed (Appendix A). These audit tools were printed on coloured paper as a visual prompt to remind staff which dressing to use. They were coloured: cream for the opaque dressing, orange for the transparent dressing and green for the combination dressing. This tool had been developed and tested prior to the trial in a previous audit (Hughes, et al., 2011). The previous audit included an opportunity for staff to review and edit the tool to identify what data collection was pertinent for use in the current trial. Minor changes were made based on staff feedback in preparation for the current trial.

The audit tool was divided into three sections and enabled information to be collected on:

1. Patient and catheter details on the day of dialysis. This included: insertion site of CVC, if tunnelled catheter used, date of catheter insertion, presence of sutures, at which unit the patient was dialysing, what dialysis location the audit was completed at, patient pain scale, body temperature, blood sugar level and most recent C-Reactive Protein (CRP) level.
2. Staff catheter dressing observations, including: type of dressing, whether the dressing was fully intact or had one to three sides off or was missing the dressing and if the patient had replaced the dressing.

3. Catheter exit site assessment. As explained in a previous publication (Hughes, et al., 2011), the Twardowski scale was used to assess CVC exit sites. This scale was adapted from the Peritoneal Dialysis Catheter Site Classification Guide (Baxter Healthcare Corporation, 1997; Twardowski & Prowant, 1996). This scale standardised scab or crust and colour assessment of a normal healed exit site. It is widely used in peritoneal dialysis as a standardised protocol for classifying the colour, crust, scab or discharge present around Tenckhoff catheter exit sites. This scale allows early identification and treatment of an exit site infection. While we could find no published validation studies of its performance as an assessment tool for either peritoneal dialysis or CVC exit sites, it has been recommended for trial in CVC exit site assessments (Harwood, et al., 2008). In the current study, the Twardowski scale classification chart was used to classify colour as either 'A' perfect, 'B' good, 'C' equivocal could be infected depending on discharge, or 'D' infected. Crust and scab with or without discharge was classified as either 'A' good, 'B' equivocal, 'C' acute infection, or 'D' chronic infection. A footnote was added to the audit sheet with the definition of crust and scab as defined in the original Twardowski scale. An area for recording active bleeding or other complications such as 'cuff visible' was available.

Additional data recorded on the audit tool pertained to infection. If there was a suspected local or systemic infection, swabs or blood cultures were taken and recorded on the audit tool. Table (3.5) provides a definition for all independent variables recorded on the audit tool.

**Table 3.4 Independent variables (demographic profile)**

| Independent Variable | Operational Definitions and Codes | Source of Data |
|---|---|---|
| Dressing type<br>• Transparent<br>• Opaque<br>• Combination | IV3000™, PRIMAPORE™<br>Tegaderm IV™ | Randomisation sequence |
| Gender | Male or Female | Patient interview |
| Culture | Aboriginal and Torres Strait Islander or not | Patient interview |
| Patient's home town | Town patient originated from if having to relocate to different town to receive Haemodialysis | Patient interview |

| Independent Variable | Operational Definitions and Codes | Source of Data |
|---|---|---|
| Current employment status | In paid employment or not | Patient interview |
| Diabetic | No or Yes.<br>If yes either diet controlled or medication controlled | Patient interview and medical notes |
| On antibiotics at consent | No or Yes | Patient interview and medical notes |
| Reason for use of antibiotics | Source of infection | Pathology results and medical records |
| Date of first dialysis | Date | Medical records |
| Inpatient at commencement of trial | Yes or No | Patient interview and medical notes |

**Table 3.5 Independent variables (audit tool)**

| Independent Variable | Operational Definitions and Codes | Source of Data |
|---|---|---|
| Catheter Position | Catheter insertion sites:<br>• Left Jugular (LJ)<br>• Right Jugular (RJ)<br>• Left Subclavian (LSC)<br>• Right Subclavian (RSC)<br>• Left Femoral (LF)<br>• Right Femoral (RF) | Medical note and nurse observation |
| Tunnelled catheter | Yes or No | Medical notes |
| Sutures present | Yes or No | Nurse observation |
| Dialysis location | Which health campus the patient is dialysing at:<br>• Inpatient at the Townsville Hospital (inpatient TTH)<br>• Outpatient at The Townsville Hospital (TTH)<br>• North Ward Health Campus (NWHC)<br>• Home Hill (HH)<br>• Mount Isa (MI) | Nurse |

| Independent Variable | Operational Definitions and Codes | Source of Data |
|---|---|---|
| Patient pain scale at exit site | Patient numerical pain rating from 0 (no pain) to 10 (extreme pain) | Patient interview |
| Body temperature | Patient body temperature | Thermometer reading |
| Blood sugar level | Patient blood sugar level | Glucometer reading |
| Most recent CRP level | Most recent C-Reactive Protein level | Pathology results |
| Does the dressing appear wet | Yes or No | Nurse observation |
| Has the patient replaced the dressing | Yes or No | Patient interview |
| Is the correct dressing in place | Yes or No | Nurse observation |
| Has a swab been taken today | Yes or No | Nurse |
| Has blood cultures been taken today | Yes or No | Nurse |
| Date of catheter insertion | Date of CVC insertion | Medical notes |
| Active bleeding at insertion site | Yes or No | Nurse observation |

## 3.12 Process

### 3.12.1 Pre-trial preparation

Nurses from all involved renal units performed the exit site dressings and participated in the data collection, including the assessment of the exit sites for signs of inflammation or infection. An education package was prepared to ensure the consistency of dressing techniques and exit site management. The package also contained education related to the consistency of data collection methods. In-services relating to the trial and data collection methods were also conducted in the Townsville, North Ward and Mt Isa renal units to ensure all staff had a common understanding about the trial. A number of senior nurses from across the participating sites were allocated to be research assistants to assist in data collection and monitoring dressing techniques These senior nurses received more detailed education regarding the trial, including extensive training on how to recruit patients to the trial. This training was led by the principal and co-investigatiors in small groups or one-on- one inservices. The senior nurses were allocated their own research folders with all tools needed in the day-

to-day running of the trial. Appendix H presents the table of contents of all information that was included in the research folders provided to the aforementioned senior nurses. These research related tasks were in addition to their usual duties as a clinical nurse, with some additional support for data collation provided by a research assistant employed within the Tropical Health Research Unit at TTH.

An existing workplace instruction (WPI) relating to initiation of haemodialysis via a CVC was reviewed prior to commencement of this study (Appendix I). As part of the WPI the dressing technique required for a CVC exit site was clearly outlined. The purpose of this WPI for this trial was to ensure consistency of dressing technique amongst nursing staff. Renal Unit staff were educated on the importance of adhering to this WPI by the Principal Investigator prior to the commencement of the trial. Random audits of CVC dressing technique were undertaken by the Principal Investigator and senior nurses twice weekly, using a previously hospital approved audit tool, to ensure adherence to study dressing protocol.

## 3.13 Combination dressing

As mentioned previously, the combination dressing was a new dressing not previously used within the TRS and a number of in-services were delivered in all units by representatives of the dressing company and by senior renal nurses. This education aimed to standardise the correct dressing application and removal techniques.

## 3.14 Data collection

A trial commencement date of 14$^{th}$ of November 2010 was agreed upon with senior clinical and management staff. The recruitment period began two weeks prior to the trial start date and continued for four weeks from the trial's commencement, allowing a total of six weeks for recruiting participants. This time allowed for inclusion of any new patients who commenced dialysis and met the inclusion criteria during this time. All staff were informed of these dates and, following randomisation of dressing sequence, the correct coloured audit tool was placed in each of the participant's chart by the Principal Investigator and by the senior nurses who were assigned as research assistants for the trial. These audit tools with the corresponding dressings were placed in containers in an easily visible and accessible location in the clinical area of each participating dialysis unit. The rationale was to ensure there were always spare

dressings and audit tools available to reduce the likelihood of the wrong dressing being used or an audit tool not being completed. Laminated colour copies of the modified Twardowski scale (Baxter Healthcare Corporation, 1997) were placed in the front of each participant's chart. This chart served a dual purpose as it was used for assessing CVC exit sites and it also acted as a prompt to remind staff which patients were participating in the trial.

Dressings were changed at each haemodialysis sessions (three times a week) and the audit tool completed. The research assistants and principal investigator collected the audit tools at the end of each week. When a participant was due to rotate to a different type of dressing, the Principal Investigator ensured the different coloured audit tool was placed in the participant's chart. As the majority of the participants commenced the trial at the same time, the transition from one dressing to the next was generally smooth.

## 3.15 Data management and missing data issues

Data from the audit tools were entered into an Excel spreadsheet (Microsoft Office 2003 and then imported into SPSS (Statistical Package for the Social Sciences, version 19). IBM Corp. Released 2010 IBM SPSS Statistics for Windows, version 19.0 Armonk, NY: IBM Corp. During this process any missing data were identified. There were two main reasons that data were missed, firstly, that nurses did not complete audit sheets and secondly, that patients did not attend scheduled dialysis sessions. For the first omission, data could often be retrieved by re-examining the participant's medical record and extracting data. If the second reason was confirmed then the appointment was recorded as a did not attend.

During this trial most of the participating units experienced major disruption to scheduled dialysis due to Cyclone Yasi, a severe tropical storm (McArdle, 2011). Fortunately during this frantic period, minimal data were lost because staff still managed to complete the audit tools for the majority of dialysis sessions, even when all dialysis sessions had been rescheduled.

## 3.16 Data analysis

Quantitative data were coded numerically and entered into the computerized Statistical Package for Social Sciences (SPSS Version 19 for Windows). Mean values

and standard deviations were used to describe numerical variables. Statistical analysis was undertaken as appropriate to the level of the data. To calculate the main outcome measure (intactness) a mean percentage for intactness was calculated for each participant for each dressing because the total number of times a participant presented for dialysis varied between participants. The percentage was calculated using the total number of dialysis episodes as the denominator and the numbers of times the dressing was deemed intact at presentation for dialysis as the numerator If the ordinal/interval data were normally distributed, Paired t-tests would be done. Where the ordinal/interval data were not normally distributed, Wilcoxon signed rank tests were performed as appropriate. For some comparisons, sample size was too small therefore no inferential statistical testing was undertaken.

Data analysis for a randomised controlled trial (RCT) is ideally based on 'intention to treat' allocation. Intention to treat is a strategy utilised to analyse data on participants in a RCT as part of the treatment group to which they were assigned even if they do not complete the intervention allocated to that group (Polit & Beck, 2008). Intention to treat analysis therefore reduces withdrawal bias caused by participant drop-outs (Schulz, Altman, & Moher, 2010) and when feasible, is therefore preferred over a per protocol analysis. However, in this study, a per protocol analysis approach was selected for several reasons. The trial sample was expected to be small in number. There were diverse reasons for non-completion, but none related to non-compliance by patients. Non-compliance is the most important reason for undertaking an 'intention to treat' analysis, because otherwise adverse effects may be underestimated in per protocol approach (Buttner & Mueller, 2011. p244-5). There was already some variability in the number of episodes of care for which data were available, because of non-attendance by patients for individual sessions for primarily cultural reasons and infrequently because data collection was not completed by staff. Due to the diversity of reasons for missing data and non-completion, it was difficult to estimate appropriate scores to be assigned in lieu of missing data. In a pilot study, complex statistical models of substitution for non-compliance are not feasible or appropriate. Therefore, the research team decided that the most useful analysis would be 'per protocol' with careful recording of reasons for non-completion, in particular. This approach was deemed to provide the most useful information for planning a later, larger multicentre trial. The Consolidated Standards on

Reporting of Clinical Trials (CONSORT guidelines) (Schulz, et al., 2010) were followed in presentation of results.

## 3.17 Chapter Summary

This chapter detailed the methods associated with the randomised crossover trial. The study settings in tropical North Queensland were described as was the study population, study sample and the inclusion and exclusion criteria. The study interventions were also outlined. Pictures of the three trial dressings used were provided. The randomisation process was presented, including the amended randomisation sequence that was required following the removal of the combination dressing from the trial. Ethical considerations were also discussed including the cultural considerations that were required due to the large proportion of Aboriginal and Torres Strait Islander participants who enrolled in this study. The collection, and management of the data, including the management of missing data was also detailed. Finally the planned method for data analysis was presented. The next chapter describes the results of the trial.

# Chapter 4 Results

## 4.1 Chapter introduction

In this chapter the results of the trial comparing the transparent and opaque dressings are presented. An overview of the demographics of all study participants is provided, including the participants who were later excluded from the comparative analysis because they only received one of the dressings; that is, they only received either the transparent or the opaque dressing. Also in this chapter the statistical analysis used to compare the opaque with the transparent dressings will be presented. Finally, a description of the participants who received the combination dressing and the adverse reactions that were associated with the use of this dressing will be provided.

## 4.2 Derivation of primary sample

All patients (n=37) who met the eligibility criteria agreed to participate in the trial and were randomly allocated to one of six possible cross-over sequences of three dressing types (see table 3.3 in Methods chaper). Very early in the trial seven participants allocated first to the combination dressing type developed adverse reactions to that dressing. This necessitated a change in the study protocol whereby the combination dressing was removed from future allocations and the trial essentially reverted to a comparison of two dressing types only (opaque and transparent).

The CONSORT diagram below (see Figure 4.1) details the recruitment, randomisation, allocation and completion of the trial. Data from 11 participants, were excluded from data analysis for a variety of reasons - these are discussed in turn. Three of the 11 participants were completely excluded from the trial prior to data being collected on either the opaque or the transparent dressing. First, one of these three participants was allocated to receive the transparent dressing first and was removed from analysis as protocol was not followed. This participant received multiple dressings at each dialysis (some of these dressings were not any trial dressings) due to clinical decisions made by nursing staff. The second excluded participant was randomised to receive the combination dressing first, but was excluded from analysis as the participant had a reaction to this dressing and then changed dialysis modality to peritoneal dialysis within the first 2 weeks of the trial. Consequently, her CVC was no longer required and was removed; this occurred before data pertaining to either the opaque or the

transparent dressings could be collected. The third excluded participant who exited the trial prior to commencement was one of the 13 participants who was allocated to receive opaque dressings followed by transparent dressings. This participant was excluded because he was diagnosed with a pre-existing infection.

The remaining eight other participants commenced the trial, however their data were also excluded because these further eight participants did not receive both transparent and opaque dressings as they ceased the trial early. The majority of these further eight participants who exited early from the trial did so because they changed dialysis access from a CVC to an arteriovenous fistula (AVF) meaning the CVC was no longer required for dialysis. Since this was a cross-over study design that required paired data, the data from those further eight participants were excluded from analysis.

Therefore 26 participants in total commenced and completed the trial, having received both transparent and opaque dressings and thus formed the primary sample for this analysis. As mentioned previously and as depicted in the CONSORT diagram (refer to figure 4.1), randomisation occurred in two sequences. The participant would have received either a transparent dressing followed by an opaque or *vice versa*.

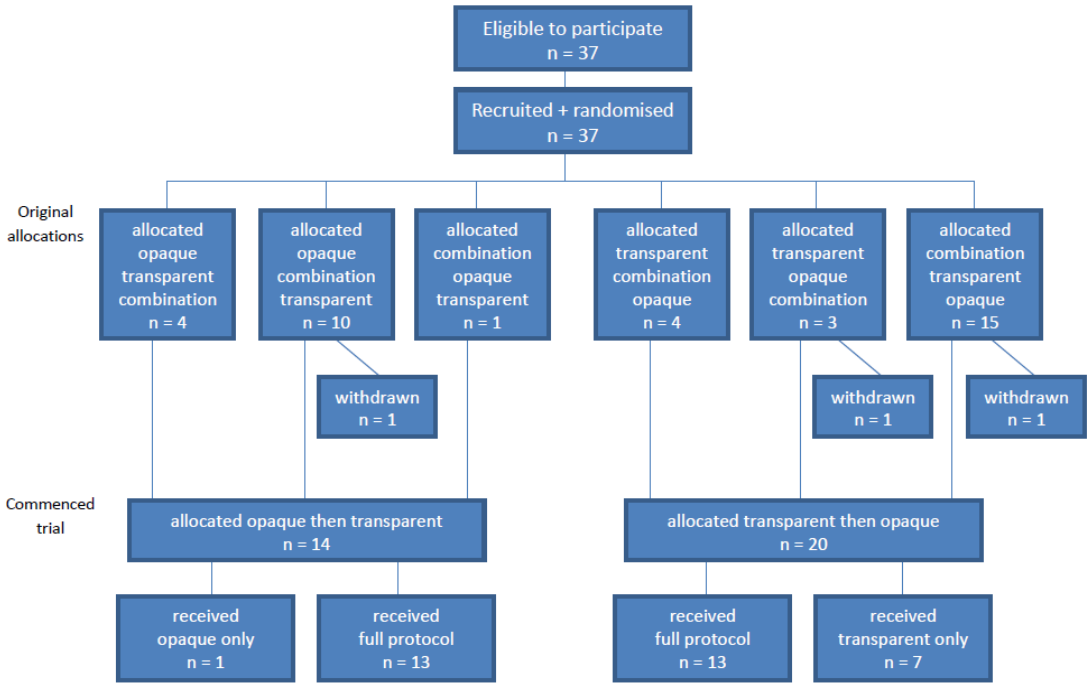



**Figure 4.1 CONSORT diagram**

## 4.3 Demographics

This section presents the demographics and the dialysis information at consent of the 26 participants who received the full revised protocol (primary sample). The demographics of the eight participants (non-completers) who commenced the trial but exited the trial early and were unable to be included in statistical analysis will then be presented followed by a comparison of the two groups. Table 4.1 displays the demographics between the participants who completed the trial (primary sample n=26), those who exited early (non-completers n=8) and of all participants (n=34)

## 4.4 Demographics of primary sample

In the primary sample of 26, there were two more female participants than males and the majority (n=21) were Aboriginal and/or Torres Strait Islander. Almost half of the participants (n=12) originated from Townsville, with smaller numbers of participants originating from Doomadgee (n=5), Mt Isa (n=2) and Ingham (n=2), respectively. The remaining five participants originated from five other differing locations. The mean age was 56.41 years (SD = 10.55; range 36-86 years). All were unemployed and stated they had no active hobbies.

**Table 4.1 Demographic characteristics - primary sample and non-completers**

| | Primary sample, full analysis n=26 | | Non-completers, excluded from full analysis n=8 | | All who commenced trial n=34 | |
|---|---|---|---|---|---|---|
| **Characteristic** | **Number** | **Percentage** | **Number** | **Percentage** | **Number** | **Percentage** |
| Sex | | | | | | |
| • Male | 12 | 46.2 | 2 | 25.0 | 14 | 41.2 |
| • Female | 14 | 53.8 | 6 | 75.0 | 20 | 58.8 |
| Age at consent | | | | | | |
| • ≤50 years | 9 | 34.6 | 2 | 25.0 | 11 | 32.4 |
| • 51-69 years | 14 | 53.8 | 4 | 50.0 | 18 | 52.9 |
| • ≥70 years | 3 | 11.6 | 2 | 25.0 | 5 | 14.7 |
| Ethnicity | | | | | | |
| • Aboriginal and/or Torres Strait Islander | 21 | 80.8 | 5 | 62.5 | 26 | 76.5 |
| • Non Aboriginal and/or Torres Strait Islander | 5 | 19.2 | 3 | 37.5 | 8 | 23.5 |
| Home town | | | | | | |
| • Townsville | 12 | 46.2 | 2 | 25.0 | 14 | 41.2 |
| • Doomadgee | 5 | 19.2 | 1 | 12.5 | 6 | 17.6 |
| • Mount Isa | 2 | 7.7 | 1 | 12.5 | 3 | 8.8 |
| • Ingham | 2 | 7.7 | 0 | 0 | 2 | 5.9 |
| • Other | 5 | 19.2 | 4 | 50.0 | 9 | 26.5 |

## 4.5 Dialysis information at the time of consent (primary sample)

At the time of consent, three quarters of the patients were diabetic with the majority taking medication to manage their diabetes (refer to Table 4.2). Over two thirds of the participants dialysed at TTH, with the remaining participants dialysing at the North Ward Satellite Unit. Almost half of the participants (n=12) had been on dialysis for over a year although all but one participant had their CVC in place for less than a year prior to consent. The most common site of the CVC was the right internal jugular vein (n=12, 46%). Another 19% (n= 5) of CVCs were inserted in the right femoral vein, followed by smaller percentages in the left internal jugular vein, right subclavian vein and left femoral veins. There were no catheters inserted in the left subclavian vein, and only two of the CVCs were non-tunnelled.

**Table 4.2 Dialysis characteristics - primary sample, non-completers, and all randomised**

| | **Primary sample, full analysis n=26** | | **Non-completers, excluded from full analysis n=8** | | **All commenced n=34** | |
|---|---|---|---|---|---|---|
| **Characteristic** | **Number** | **Percentage** | **Number** | **Percentage** | **Number** | **Percentage** |
| Location of dialysis service attended at consent | | | | | | |
| • The Townsville Hospital | 18 | 69.2 | 6 | 75.0 | 24 | 70.6 |
| • North Ward | 8 | 30.8 | 1 | 12.5 | 9 | 26.5 |
| • Mount Isa | 0 | 0 | 1 | 12.5 | 1 | 2.9 |
| Diabetes status | | | | | | |
| • Not diabetic | 1 | 3.8 | 2 | 25.0 | 3 | 8.8 |
| • Controlled by diet | 5 | 19.2 | 1 | 12.5 | 6 | 17.6 |
| • Controlled by medications | 20 | 76.9 | 5 | 62.5 | 25 | 73.6 |
| On antibiotics at consent | | | | | | |
| • Yes | 5 | 19.2 | 1 | 12.5 | 6 | 17.6 |
| • No | 21 | 80.8 | 7 | 87.5 | 28 | 82.4 |
| Date of catheter insertion | | | | | | |
| • >1 year | 1 | 3.8 | 1 | 12.5 | 2 | 5.9 |
| • ≤1year | 25 | 96.2 | 7 | 87.5 | 32 | 94.1 |

| | Primary sample, full analysis n=26 | | Non-completers, excluded from full analysis n=8 | | All commenced n=34 | |
|---|---|---|---|---|---|---|
| **Characteristic** | **Number** | **Percentage** | **Number** | **Percentage** | **Number** | **Percentage** |
| Catheter position | | | | | | |
| • Right jugular | 12 | 46.2 | 6 | 75.0 | 18 | 52.9 |
| • Left jugular | 4 | 15.4 | 0 | 0 | 4 | 11.8 |
| • Right subclavian | 4 | 15.4 | 2 | 25.0 | 6 | 17.6 |
| • Right femoral | 5 | 19.2 | 0 | 0 | 5 | 14.7 |
| • Left femoral | 1 | 3.8 | 0 | 0 | 1 | 2.9 |
| Tunnelled catheter | | | | | | |
| • Yes | 24 | 92.3 | 7 | 87.5 | 31 | 91.2 |
| • No | 2 | 7.7 | 1 | 12.5 | 3 | 8.8 |
| Length of time since first Dialysis | 12 | 46.2 | 3 | 37.5 | 15 | 44.1 |
| • >1 year | 14 | 53.8 | 5 | 62.5 | 19 | 55.9 |
| • ≤1 year | | | | | | |

## 4.6 Condition of CVC exit sites at consent

Patients' CVC exit sites were formally assessed using the Twardowski scale at the time of consent. The colour of the CVC exit site of most participants (n=22) in the primary sample was classified as good at this time (refer to Table 4.3). Four of the 26 participants had a classification of equivocal, none were classified as having an acute or chronic infection. With respect to the assessment of crust at the CVC exit sites, 12 participants were classified as 'good', meaning that there was no crust. The crust of eleven of the remaining 14 participants was classified as 'equivocal with three of the others showing some sign of acute infection. Thus, most CVC exit sites showed no signs of possible infection at the time of consent.

**Table 4.3 Primary sample characteristics at commencement of trial**

| Characteristic | Number | Percentage |
|---|---|---|
| Inpatient at commencement of trial | | |
| • Yes | 2 | 7.7 |
| • No | 24 | 92.3 |
| CVC exit site condition at consent | | |
| • Itchy | 1 | 3.8 |
| • Moist | 2 | 7.7 |
| • Natural | 23 | 88.5 |
| CVC exit site colour as classified at time of consent | | |
| • Perfect/good | 22 | 84.6 |
| • Equivocal/infected | 4 | 15.4 |
| CVC exit site crust classified at time of consent | | |
| • Good (no sign of infection) | 12 | 46.2 |
| • Equivocal/acute infection/chronic infection | 14 | 53.9 |

## 4.7 Comparison primary sample vs non-completers

As mentioned previously the combination dressing (Tegaderm IV™) data was removed from trial due to adverse events which necessitated a change in protocol to exclude the combination dressing. Therefore, analysis was done on the remaining two dressings which were the opaque (PRIMAPORE™) and transparent (IV3000™). As per

the CONSORT diagram (figure 4.1), there were seven participants who received transparent dressings only and one who received only the opaque dressing.

In comparison with the 26 participants in the primary samples, the eight participants who were not included in the data analysis (the non-completers) were fairly similar. The eight excluded participants were less likely than the included primary sample participants to be Aboriginal and Torres Strait Islander females with diabetes controlled by medication. The mean age of the excluded participants was 61.25 years meaning the excluded participants were a slightly older group than the primary sample. Similar to the primary sample of 26 participants, the eight excluded participants were more likely to have been on dialysis for less than a year and dialysing at TTH at the time of consent with a tunnelled right internal jugular CVC as their dialysis access. Location of the home town was evenly spread over a number of towns in the excluded eight participants compared to the 26 participants in the primary sample whose data was retained. There was only one person of the eight excluded participants that had an active hobby and none were employed.

## 4.8 Data analysis

The primary outcomes for the trial were intactness and infection. Although the CVCs were stratified into tunnelled and non-tunnelled for randomisation, only two non-tunnelled CVCs were included in the final primary sample. Due to the very small numbers the results from the two non-tunnelled catheters were aggregated with the tunnelled CVCs for data analysis. The results pertaining to intactness and infection are discussed in turn in this section.

## 4.9 Intactness

As mentioned previously, intactness was defined as all four edges of the dressing remaining adhered to the skin. If any edge had lifted the dressing was deemed to be non- intact. As mentioned in the methods section some data were missed due to participants failing to attend dialysis or, on occasion, an audit tool was not completed when a participant did attend dialysis. Intactness was therefore averaged out over the number of times the audit tool was completed. At the conclusion of the trial the mean percentage for intact dressings was calculated to be 68.84% for the transparent dressing and 68.15% for the opaque dressing. Statistical analysis was undertaken and as the

results were not normally distributed, Wilcoxon signed rank tests were used to evaluate the difference in intactness between the opaque and transparent dressings. The results indicated no statistical difference (z = 0.386, $p$=<0.700) between dressings (refer to Appendix J).

## 4.10 Infection

The secondary outcome of this trial was infection. Infection was recorded in two ways, classified as either clinical signs of infection or as laboratory confirmed infections.

### 4.10.1 Clinical signs of infection

As described previously, the clinical signs of infection were classified using the Twardowski scale for exit site colour and crust. A Wilcoxon signed rank test was also used to statistically analyse significant differences in colour and crust comparison between the two dressings. The results for the colour comparison were $z$ = -0.454 ($p$<0.650), indicating no significant difference (refer to Appendix K). The results for the crust comparison between the two dressings was $z$ = 1.650 ($p$ = < 0.099), also indicating no statistically significant difference between the opaque and transparent dressings (refer to Appendix L).

### 4.10.2 Laboratory confirmed infection

There were four confirmed catheter-related infections during the trial. All of these occurred whilst participants were in the transparent rotation of their randomisation sequence. The organisms responsible for the infections were:

1. *Staphylococcus aureus* (exit site)
2. *Achromobacter xylosoxidans* (exit site)
3. *Staphylococcus aureus* (exit and tip)
4. *Klebsilla pneumoniae* (blood culture) and *Aeromonas hydrophilia* (present in tip of CVC).

Two of these catheters were inserted in the RJ and one in the LF and RF respectively. As there were no infections in the opaque group, between group statistical analysis was not mathematically possible. As mentioned previously the non-tunnelled catheters were aggregated with the tunnelled catheters as the numbers were too low to

analyse separately. Non-tunnelled CVCs are at higher risk of infection (National Kidney Foundation, 2006) than tunnelled CVCs. None of the infections during this trial occurred with a non-tunnelled CVC. Note that one of the non-tunnelled CVCs was changed to a tunnelled catheter mid way through the trial.

## 4.11 Skin reactions to the transparent dressing

Nine patients experienced minor skin reactions to the transparent dressings over the duration of the trial. The nine events reported were localised skin reactions, skin tears and pruritis. All patients who experienced a minor reaction were changed to the opaque dressing as per study protocol and the skin condition was monitored carefully. All reactions were reported to the two relevant ethics committees. There were more female participants (66%) than males who reacted to the transparent dressing. Sixty-six percent of those who reacted were of Aboriginal or Torres Strait Islander descent (consistent with the high percentage of Aboriginal or Torres Strait Islander participants in the total sample). All patients who had a reaction to this type of dressing were medication controlled diabetics.

## 4.12 Adverse events associated with the combination dressing

As has already been reported, the initial intention of the RCT was to include a third dressing that combined both transparent and opaque qualities. There were early quite severe reactions to this dressing in seven patients, that is nearly 50% of those randomised to receive this dressing first in the original protocol (see table 3.1 in methods). Skin reactions were more serious than those encountered and reported in the previous section with the transparent dressing. So, whilst these data are not strictly relevant to the study outcomes from the revised study protocol, they are considered important to include at the end of this chapter as an ancillary finding. All reactions to the combination included localised itchiness and erythema, making the dressings difficult to tolerate. Blistering and moist broken areas occurred at two sites. Purulent discharge occurred at an additional two sites. One patient required resiting of the CVC access. Whilst there was no direct evidence that the skin reactions were due to the combination dressing, given the critical importance of venous access for patients receiving haemodialysis, the senior medical and nursing clinicians, in conjunction with the Chairperson of the Health Service Ethics Committee, decided that the combination

dressing should be removed from the study. Six of the seven participants who reacted were Aboriginal and Torres Strait Islander and six were medication controlled diabetics.

## 4.13 Demographics of participants who received the combination dressing

This group of participants who received the combination dressing were once again very similar to the primary sample of the 26 participants. The only difference was a slightly younger mean age which was 58.13 years compared to 61.25 years of age in the primary sample. There were a number of patients in this group who developed a reaction to this dressing. Their demographics will be discussed in the next section.

## 4.14 Other outcomes in patients who received the combination dressing

### 4.14.1 Adverse reactions

There were a total of seven reactions to the combination dressing within the first fortnight following trial commencement, of the fifteen participants who received the combination dressing before it was removed from the trial. The participants who reacted to the combination dressing were more likely to be not employed, female (63%, n=4), Aboriginal and Torres Strait Islander people, or medication controlled diabetic (86%, n=6). None of the seven participants who reacted to the combination dressing were inpatients and one was on antibiotics prior to the trial commencement. The majority of the reactions were local erythema, blisters, skin tears and itchiness under the dressing.

### 4.14.2 Participants who did not have adverse reactions

The eight participants who did not react to the combination dressings had similar demographic and clinical characteristics to the participants that did not react. There were more males (63%, n=5) who did not react than females (37%, n=3).

## 4.15 Chapter conclusion

In this chapter the demographics and clinical characteristics for the primary sample and the seven participants that did not complete the trial were described. The results for the primary sample were outlined first. There was no statistically significant difference in either intactness or infection when comparing the opaque and the

transparent dressings, however there was a clinical significance as all infections and skin reactions occurred during the transparent phase of the trial. The participant skin reactions to the transparent dressing were described.

The demographics and adverse reactions for the group of participants who received the combination dressing was also discussed as this group were initially included in the sample but had to be removed due to the number of adverse reactions which occurred in the first two weeks of the trial. These reactions necessitated a change in protocol and the combination dressing was removed from any subsequent randomisation rotations.

Based on the results of this trial, there is no evidence to change current dressing practice within the TRS to comply with the CHRISP guidelines of using a transparent dressing on CVC exit sites. The findings of this trial will be explored in the following chapter; the discussion chapter.

# Chapter 5 Discussion

## 5.1 Chapter introduction

The implications of the study's findings are discussed in this chapter. The findings from this crossover RCT did not demonstrate any significant difference in intactness between the two dressings. One dressing was associated with some CVC exit sit infections but the absolute number was small. Potential reasons for these findings will be discussed, within the context of the evidence known before the commencement of the trial, and that which has come to light since the trial was commenced. As this was a pilot study, the feasibility of conducting a similar trial across multiple sites in different climate zones will also be discussed. The strengths and limitations of this RCT, conducted in busy clinical settings, are then discussed and the chapter concludes with recommendations for future practice and research.

This RCT compared two dressings representing two main types of dressings available, that is an opaque and transparent. Both types are relatively inexpensive and commonly used for CVC exit site care in renal units Australia wide. No previous studies were identified in the literature that compared the use of these two dressings in any climate. Some studies found did use IV3000™, dressings; however they were often compared with a gauze or gauze-type dressing rather than specifically a PRIMAPORE™ dressing. This study therefore filled a gap in the literature to provide some evidence regarding the use of IV3000™, and PRIMAPORE™ dressings in a tropical renal unit. State departmental guidelines, at the time of the study (Centre for Health Care Related Infection Surveillance and Prevention, 2007), in the absence of any evidence to the contrary, recommended the use of transparent dressings on CVC exit sites. These guidelines have since been modified specifically for haemodialysis CVCs (Centre for Health Care Related Infection Surveillance and Prevention & Tuberculosis Control, 2013a) and do not recommend any specific dressing to be used on CVC exit sites. The guidelines now acknowledge that patient and environmental factors should be considered when choosing a dressing type. These updated guidelines are now more applicable to the current practice at the TRS. Although the results from the RCT determined that both the opaque and transparent dressings are safe to use with no statistically significant difference in intactness or infection rates, there were substantially more skin reactions to the transparent dressing, a clinically relevant

finding. This suggests that patient and environmental factors certainly need to be taken into consideration when choosing the most appropriate dressing for the renal patient. The main study aims are addressed first.

## 5.2 Intactness of dressings

The first aspect of effectiveness examined in this study was the ability of the dressings to remain intact over the CVC exit sites. It was clear that neither of the two dressing types used in the study was more likely to remain intact than the other. The mean % for intactness was calculated to be 68.84% for the transparent dressing and 68.15 % for the opaque dressing. The results obtained were not statistically significant ($z = 0.386$, $p$=<0.700). This RCT utilised the entire population of patients who were eligible to be included and, unlike any other study identified in the literature comparing transparent dressings with a gauze/gauze type dressing, this RCT was unique in study design as it was a cross-over design. Therefore each participant received both dressings. Both dressings were likely to be non-intact almost one-third of the time on the same patient. This is a grave finding from the clinical perspective. The dressing is the first line of defence against possible exit site infections because, if its intactness is breached, a passage for bacteria to enter into the body is created. Additionally, if the sutures were to break and the dressing does not stay intact as a secondary measure to secure the CVC, there is a chance the CVC may dislodge. Such an event could be potentially life threatening as the patient is at risk of exsanguination.

There are however, some studies that advocate no dressing on the CVC exit site. Olson et al (2004) compared the use of a sterile gauze with no dressing on CVC exit sites of 78 oncology patients and found no statistical difference in infection rates. Betjes (2011) and the Centre for Health Care Related Infection Surveillance and Prevention & Tuberculosis Control (2013b) also concludes that a well healed cuffed tunnelled CVC may not need a dressing. It is somewhat confusing, however, that there are now two CHRISP (state health) guidelines published in the same year. The above reference is the general guideline for tunnelled CVCs. There is an additional CHRISP guideline specifically in relation to haemodialysis catheters (Centre for Health Care Related Infection Surveillance and Prevention & Tuberculosis Control, 2013a). The haemodialysis guideline does not make mention of the recommendation for no dressing on a healed CVC. The practice of no dressing would be approached with caution in the

TRS due to the characteristics of the current patient population (for example, patients living in houses with inadequate sanitation and potential for homelessness).

There are few studies that examine dressing intactness reported in the literature. Chu, Adams, and Crawford (2013) examined intactness rates in an observational study of forty episodes of clinical practice The aim of the study was to decrease blood stream infections in haemodialysis patients with a CVC. The intactness rates were 80% before implementing a standardised protocol for CVC exit sites. The rate improved to 85% following implementation of the protocol, indicating that standardisation and staff education could improve intactness and infection rates. The type of dressing used is not stated. Trotter, et al. (2008) compared the intactness rates of a number of differing dressing types. The gauze and tape dressing used in that study had an intactness rate of 23%. Although this is a gauze dressing, it is not the same dressing (PRIMAPORE™) as used in this RCT. Additionally, all of the patients in that study were inpatients so were not subject to differing environmental variables of those experienced by the general outpatient haemodialysis population of the TRS.

In the audit by Hughes et al (2011) which was conducted in the TRS, that preceded the present study, the rate of non-intact opaque dressings was higher (43%), than during the RCT (32%). It is unclear why the intactness was poorer in this earlier audit. It may have been that more care was taken with the dressing during the RCT because there was a standardised protocol and training program. This was a similar occurrence as demonstrated in the aforementioned study by Chu, et al. (2013) which found a 5% increase in intactness rates following the implementation of a standardised dressing protocol.

There are several possible factors that may contribute to the loss of intactness of the dressings. Catheter position can be a likely cause. Femoral catheters sites in particular are often challenging in respect to maintaining intactness as femoral catheters are inserted in an area that is difficult to place a dressing due to hair growth and increased mobility. This risk is recognised through guidelines (Centre for Health Care Related Infection Surveillance and Prevention, 2007) (CHRISP) hence it is recommended patients with a femoral access remain in hospital whilst the femoral catheter remains in-situ. Jugular catheters that are inserted with the lumens running up the neck are also often difficult to place the dressing due to hair growth. Hair is a

difficult surface for dressings to adhere to adequately. This may explain a finding in the study conducted by Conly, et al. (1989) that recorded 24% of the 115 participants having a non-intact dressing with the use of a transparent dressing. The increased rate of non-intactness with the transparent dressing may be related to males being more likely to have increased hair growth and that more male than female participants received the transparent dressings. Hair removal for those patients with excess hair may need to be incorporated into unit protocols to improve intactness and ease of removal. An additional securement device such as a band placed around the head to secure the catheter lumens to the side of the head is also required for a jugular catheter that has been inserted with the lumens running up the neck. If left unsecured, the lumens tend to droop causing the dressing to loosen and trauma to occur at the exit site.

Showering or perspiring could also cause the dressing to become wet and lose adhesiveness. The product information for the opaque dressing used in this crossover RCT recommends this dressing remains dry, as its adhesiveness becomes compromised if wet. This would not apply to the transparent dressing as it may be used whilst showering. However, increased perspiration may affect that dressing's adhesiveness as a transparent dressing is not recommended for use if a patient is diaphoretic (Barros, et al., 2009). Perspiration in the tropical climate is a frequent issue.

It could be postulated that missing dialysis sessions could also contribute to a loss of intactness due to an increase in time between dressing changes. The strength of adhesion may decline with increased length of time between dressing applications (Rippon, White, & Davies, 2007).

## 5.3 Infections related to transparent dressing

The second measure of dressing effectiveness examined in this study was clinical signs of infection and laboratory confirmed infections. The clinical signs of infection were classified using the Twardowski scale for exit site colour and crust. The results for the colour comparison between the two dressings were not statistically significant ($z$ = -0.454, $p$<0.650) nor was the comparison between the two dressings for crust ($z$ = 1.650, $p$ = <0.099). Four laboratory confirmed infections occurred during this trial when patients had the transparent dressing in place and none occurred with the opaque dressing. Based on these results one could conclude that transparent dressings are more prone to causing infections in the tropics, however the participant numbers are

too small to offer conclusive evidence. It was mathematically impossible to compare a zero incidence to an incidence of four with inferential statistical testing. Prior to this trial there was unpublished local TRS unit-based evidence that infections were not an uncommon occurrence when using the opaque dressing given that there were 26 infections over a 2 year period (Hughes, et al., 2011). In addition to this there were five infections during a four week period in the earlier published audit (Hughes, et al., 2011). These occurred with the use of the opaque dressing also used in this trial. Due to this prior evidence, the low number of participants and the short duration of this trial the author would be reluctant to definitively conclude that transparent dressings increased infection rates based on the data generated from this study. This potential risk certainly warrants further investigation with a larger sample size.

There are a number of other potential reasons why infections occurred during the transparent phase. These include the tropical climate and the moisture vapour transmission rate of the dressing.

## 5.4 Considerations particular to dressings in the tropics

The initial purpose for conducting this study was to determine if transparent dressings were more highly associated with infection in the tropical setting compared to opaque dressings. Previously, renal unit nurses suspected that transparent types of dressings were associated with infection in tropical areas, however a review of the literature identified that there was still very limited published evidence relating to CVC infections in the tropics (McArdle & Gardner, 2009). The only reported research is a very old study by Conly et al. (1989) who found higher infection rates with transparent polyurethane dressings compared to a gauze dressing. Callaghan and colleagues (2002), and two Brazilian studies by Barros, et al. (2009) and Silveira, et al. (2010) were the only articles found that made reference to tropical conditions. Callaghan proposed that elevated humidity caused moisture to accumulate beneath the dressing, thus increasing infection rates with peripheral cannula sites. Both Brazilian studies voiced concern about dressing performances in tropical environments. The Barros, et al. (2009) study and a meta-analysis on CVC dressings by Safdar and colleagues (2002) also mention that transparent dressings are not suitable for patients who perspire abundantly and, as mentioned previously, perspiration is a problematic issue in Townsville's hot and humid climate.

There is no conclusive evidence in the literature to support the premise that transparent dressings are associated with higher infection rates when used on CVC exit sites. There was more evidence found to support the argument there is no difference in infection rates between a transparent dressing and a gauze type dressing (Danks, 2006; Gillies, et al., 2003; Jezova, et al., 2012; Jones, 2004; Le Corre, et al., 2003; Little & Palmer, 1998; McArdle & Gardner, 2009; Safdar, et al., 2002; Shivnan, et al., 1991). However these findings need to be interpreted with caution for our setting, given that none of these articles pertained specifically to the tropics.

This trial was held over the "wet" season which has a mean daily maximum temperature above 31°C and a mean daily minimum temperature above 24°C. February is the most humid month with an average 9am humidity of 75% and a 3pm humidity of 67% (Bureau of Metereology, 2015). This trial was held over a particularly wet summer that had a number of significant weather events (e.g. tropical storms and cyclones) so the humidity may have played a part in causing infection. It is possible that the opaque dressing did have better breathability and allowed for evaporation of moisture. This is known as the moisture vapour transmission rate (MVTR).

## 5.5 Moisture vapour transmission rate of dressings

This concept was introduced in the literature review. The MTVR is a measure of the rate of how much water vapour will pass through a given area of material in a specific time and is determined by the difference in partial pressure of water vapour across a membrane (Thomas, Barry, Fram, & Phillips, 2011, p.484). It is calculated by the use of a Paddington cup technique. Approximately 20 ml of fluid is added to the Paddington cup and a dressing is clamped over the top. The cup is weighed and then placed in a chamber that maintains a stable temperature and humidity level for the required period of time. The cup is then reweighed to determine the moisture lost through evaporation (Thomas, et al., 2011). This value is expressed as g/m²/24h. For example, the MVTR of IV3000™ is quoted in the manufacturer's literature to be 11000g/m²/24h which is claimed to be up to eight times higher than other transparent dressings (Smith & Nephew, 2015). A MVTR for PRIMAPORE™ was unable to be located. There was very little literature available regarding MVTRs at the time the initial literature review was performed. Recently, the association between humidity and temperature has been more widely examined and it is argued that this can play a very

important role in dressing performance (Thomas, 2012). Some dressings rely on the permeability to water vapour to cope with sweating and or wound exudate. The permeability of the dressing combined with absorbency will determine the fluid handling capacity of the dressing. Considerable emphasis is now placed upon the MVTR and it is often quoted in scientific papers and manufacturers' literature, because it will influence wear times and therefore treatment costs.

In a review published since the completion of this trial, Thomas (2012) examined indwelling catheters of various types and the use of semi-permeable dressings. He summarised what was known about the accumulation of fluid beneath semi-permeable dressings that can facilitate bacterial proliferation. This proliferation may cause local infection or sepsis. Thomas recommended that local environmental conditions can greatly affect the MVTR of these products; therefore the MVTR should be taken into consideration when selecting dressings. He also raised the possibility that dressing data from one geographical location may not be transferable to another geographical location with differing temperatures or humidity levels.

Lin, et al. (2009) aimed to determine the MVTR of a number of commonly used transparent and gauze dressings at different temperatures and humidity levels. This was done in a laboratory setting simulating dressing contact with sweating skin. This study demonstrated that at temperatures below 36ºC and below 90% humidity, gauze had a higher MVTR when compared to a transparent dressing. Over the above parameters the transparent dressing performed better.

Many of the papers discussing the MVTR such as that by Lin, et al. (2009) are done in a laboratory setting which has limitations. In most laboratory tests, for practical reasons the temperature on both sides of a dressing will be the same; but in the clinical situation, due to the inherent heat produced by the body "a marked temperature gradient across the dressing will exist" (Thomas, 2012, p.336). This temperature gradient is likely to produce a misleading result. Although it appears that the MVTR may be a contributing factor to performance of dressings and potentially on infection rates in the tropics, there is not enough evidence in the literature to conclusively support this argument.

Although it is not possible to definitely correlate a link between transparent dressings and an increase in infection, it is important to note the number of skin

reactions associated with the transparent dressing compared to the opaque dressing that occurred during this crossover RCT. This is a finding that warrants further investigation

## 5.6 Other findings

There were other important but unanticipated findings from the study that warrant discussion. These relate to reactions from both the combined dressing (hence its exclusion from the study design) and less severe reactions to the transparent dressing. Contributing factors such as dressing regimens, adhesive types and associated allergies are considered below.

## 5.7 Reactions to the transparent and combined dressing

There were no reactions to the opaque dressing. Nine participants experienced reactions to the transparent dressing during the trial. These reactions took the form of skin tears, itchiness, urticaria, and non-intact skin. There was a significant number of skin reactions to the combination dressing initially proposed as being the third arm of the trial, hence it was completely removed from the RCT. Prior to commencement of this trial, the renal unit had very limited options for dressings as there was no requirement for other dressings to be used in the unit. The opaque dressing (PRIMAPORE™) was used the majority of the time and skin reactions were rare events in the renal unit.

### 5.7.1 Frequency of dressing change

In a study by Dykes (2007), several types of dressings were tested on volunteers. His study suggested that the skin damage was caused by removing the test products too frequently, in this case two to three times a week. Dykes suggested that it was not usual clinical practice to change dressings this often and it would be of more benefit to have a longer time between changes. Rippon et al. (2007) also suggested the period of time a dressing is *in situ* can determine how much skin-stripping will occur.

The renal unit's usual protocol is to change the CVC exit site dressing at each dialysis session; that is, to change the dressing three times a week. This frequency matches that found in Dykes's (2007) study. Renal patients, as mentioned previously in the introduction chapter often have difficulties with skin integrity, and so three times a

week was perhaps too frequent for the transparent and combination dressing to be changed.

### 5.7.2 Adhesives

After reviewing the literature to seek some possible explanation for the surprisingly high numbers of skin reactions to the transparent and combination dressings that occurred in the trial it became evident that there were many different types of dressing adhesives. However, no information was available from manufacturers regarding this aspect at the time this trial was undertaken.

Different types of adhesives are used in dressings. Polyeurathane dressings such as the transparent dressing used in this trial are prone to skin stripping (removal of part of the strata corneum) and maceration. This is due to the strength of the adhesive in this type of dressing (Rippon, et al., 2007). Skin stripping also causes blistering. Some participants experienced blistering with the use of the combination dressing. Suhng, Byun, Choi, Myung, and Choi (2011) explain that blistering occurs with dressing use when there is ongoing friction on the skin following the separation of the epidermis from the dermis. Suhng, et al. (2011) also outline the causes of and/or risk factors associated with skin stripping and blistering. These include comorbities such as diabetes and end-stage kidney disease. Only one of the 26 participants in the primary sample of end-stage kidney disease patients on haemodialysis from this crossover RCT was not a diabetic. Therefore this patient cohort is likely to be at a very high risk of skin-stripping and blistering.

### 5.7.3 Colophony

Another potential factor which may have contributed to the skin reactions experienced in this RCT is colophony. Colophony is a pine resin that is used in dressing adhesives. This has been known to cause contact dermatitis and other skin reactions such as rashes and blistering (Duteille, 2014). It is unknown how much colophony is used in the trial dressing as the manufacturer does not provide this information. Given the potential sensitivity of skin of the renal patient, patch testing of the skin prior to use of a transparent dressing may be advisable. Manufacturers should be encouraged to provide more detailed information pertaining to their products so consumers are better informed.

### 5.7.4 Skin preparation

There has been mention in the literature that skin preparation can contribute to skin reactions. Le Corre, et al. (2003) mentions skin reactions are caused by a practice of not allowing sufficient time for the chlorhexidine skin preparation to dry. In this trial the work place instruction for connecting a CVC line used in the study protocol clearly states that the skin must be dry before applying the dressing. Random audits were done to ensure that dressings were done per protocol or per work place instruction, therefore this is unlikely to have been a cause or contributing factor in this study.

The manufacturer of the combination dressing recommended the use of a barrier film such as Cavilon™ prior to the application of the dressing. The purpose of the film recommended by the company is to protect the skin from aggressive adhesives. The suggestion to use this film was provided by the manufacturer after the approval completion of the dressing protocol and would have required an amendment. The use of the barrier film may have decreased the number of reactions in this instance however as the barrier film had not been used previously as a skin preparation with any of the other dressings it was decided not to include the use of this product in this trial. Additionally inclusion of this product would have introduced another confounding variable. Therefore if we were to conduct a follow up trial amendments would be required to the study protocol when considering the inclusion of a new or transparent dressing. These amendments could possibly include:

- Changing the dressing once a week or only if clinically necessary
- Consideration of use of dressing adhesive prior to selecting dressings
- A more extensive pre-test of new dressings in the renal patient population (given their increased risk of skin breakdown)

Finally, it should be noted that there is also the possibility that dressing reactions are relatively common in clinical practice but go unreported as there does not appear to be a national or statewide reporting system for this type of incident. Therapeutics Goods Approval (TGA) for dressings is much less rigorous than that of drugs. There is no reporting system to TGA for adverse events relating to dressings. Therefore it is difficult to ascertain the commonality of dressing reactions due to this issue. A number of studies reviewed in the literature review chapter reported skin reactions as an outcome of interest (Jezova, et al., 2012; Le Corre, et al., 2003; Shivnan,

et al., 1991). A reporting system may assist in building a knowledge base that would guide in the selection of appropriate dressings.

## 5.8 Financial implications and patient/clinician dressing preference

The opaque dressing was the cheapest, and the transparent dressing was double the cost of the opaque dressing. The price of the more expensive dressing would be offset if the additional expense was proven to prevent a bacteraemia from occurring. The cost of a bacteraemia to the health service is several thousand dollars per episode (Collignon, et al., 2007). As mentioned previously the patient is also put at risk not only due to the infection but also due to the likely need for a new catheter to be inserted because in most cases the catheter cannot be salvaged (Winterberger, et al., 2011).

In terms of dressing properties and performance, the transparent dressing is splash proof and allows for the direct visualisation of the exit site, unlike the opaque dressing. Patients in the TRS often prefer to have a dressing which they can shower with, which is an issue with the opaque dressing as it is not waterproof. From past local clinical experience it was determined that the opaque dressing was also easier to apply and remove than the transparent dressing. As stated previously there was no statistical difference in intactness and infection rates between the transparent and opaque dressing therefore either dressing is appropriate for use on this patient cohort. However, as already discussed the transparent dressing had a high number of skin reactions whereas the opaque dressing had none throughout the trial period.

Although not finally included in the trial, the combination dressing was double the cost of the transparent so four times more expensive than the opaque dressing, This dressing, although most expensive, was well liked by staff. Feedback from staff during the period of time that the dressing had been included in the trial was that it was easy to apply, allowed for direct visualisation of the exit site and allowed the patients to shower as it was waterproof. Unfortunately, due to the number and type of adverse reactions to this dressing, it appears that, within the current dressing protocol it is not suitable for use for the patient cohort at the TRS. An amendment to the protocol to include the use of a barrier film or less frequent dressing change may warrant further investigation should this combination dressing be included in future trials.

## 5.9 Strengths of the study

This section will explore the strengths and limitations of this RCT in the context of internal and external validity processes. The strengths will be discussed first.

### 5.9.1 Internal validity

This study explored an area that has had very limited published evidence for comparison. This RCT was one of the first known studies to explore CVC dressings in a tropical Australian renal unit. It is one of a handful of studies that have been undertaken in a tropical climate more generally, when reviewing the international literature related to use of dressings. There were a large number of patients who identified as Aboriginal and Torres Strait Islander origin included in this trial. This is a unique population hence the trial provided an opportunity for valuable information to be collated regarding this group of patients.

Although this was a pilot study with small participant numbers it comprised the total patient population from the TRS therefore reducing the incidence of selection bias as all participicants who met inclusion criteria participated in the trial. Although the sample size was relatively small, this study utilised a cross-over design to maximise this sample size. No other studies found in the literature used a cross-over design.

The dressings used were commonly used and readily available. With the exception of the excluded combination dressing, the opaque and transparent dressings were familiar to the majority of staff as most had used the dressings prior to the trial. The dressings were randomly assigned to the participants. Although staff and patients were not blinded to the dressing, staff who participated in the consenting process were not involved in the the randomisation process therefore reducing potential bias. Additionally, initial data analysis was undertaken by someone without knowledge of the allocation arms.

The study was conducted in a busy clinical setting in the most humid time of the year with the assistance of experienced researchers to ensure the trial was conducted in an a rigorous and appropriate manner. Processes were implementated pre-trial to ensure that the nursing staff in a busy clinical setting were able to follow the study protocol easily. These processes included a pretest of the audit tool (Hughes, et al., 2011). This pretest assisted in refining data collection processes before the trial

commenced. Additionally this tested the instrumentation to ensure the reliability of it prior to the trial. The dressing audit also prepared the staff for the trial because they were already very familiar with the audit tool and how to correctly complete the required information. Another beneficial process was placing dressings in colour coded bins in a clearly visible place in the unit, which served to provide a constant visual reminder to staff to collect the correct dressing and colour coded audit tool.

A formal protocol for standardised CVC practices was implemented prior to the commencement of the trial. This was very important as it ensured that all participants received the same treatment. History is a threat to internal validity in cross-over designs (Polit & Beck, 2008). If an event occurs that affects the patients in one group and not another it will affect the outcome of the trial. The standardised protocol and random observational audits minimised any variations to the protocol. Pre-trial education using change management principles (Queensland Health, 2008) to inform all sites assisted in all aspects of the trial including consent processes and accurate completion of the audit tool.

All of the aforementioned processes assisted with data collection during Cyclone Yasi. During Cyclone Yasi, there were no data missed, all audit tools were completed despite how frantically busy the unit was. Ninety six dialysis patients had their entire dialysis schedule rearranged around the cyclone (McArdle, 2011) and the unit had to close for 24 hours during this extreme weather event. Dialysis hours were reduced from five hours to three hours to accommodate all 96 patients in over four shifts in one day, including the unit's first ever night shift. There were no data lost during this very difficult 24 hour period which is evidence of the strength of staff training processes.

A final strength to this RCT was the limited threats to construct validity as the outcomes and adverse events were based on physiological observations using validated tools, therefore not subject to researcher influence.

### 5.9.2 External validity

This pilot RCT was an appropriate design utilising the total population of the TRS service as its sample population. Multiple geographical locations were used which improves the generalisability of study results (Polit & Beck, 2008, p.205). The study included a high percentage of Aboriginal and Torres Strait Islander people, which

makes it more generalisable for a population not often studied. The study could be replicated again in similar settings and climates, with a similar but larger patient population because the study protocol and design are detailed, robust and well structured.

## 5.10 Limitations of the study

### 5.10.1 Internal validity

There were a number of limitations to this study.

One limitation related to the data available through normal charting process in this context. Line days can be a useful measure for calculating the prevalence of infections. However, this study did not include baseline denominator information about line days as it was not readily available and outside the scope of the current study. Incorporating this information into a future larger RCT would assist with more accurate measurement of infection and enable bloodstream infection rates to be monitored.

As previously discussed there were several participants who developed unexpected skin reactions to the combination dressing which limited the use of this dressing in the trial. The dressing manufacturer does recommend the use of Cavilon™ cream (their product) under the adhesive edge of the dressing for those patients who are susceptible to reactions. It was decided not to use this product as IV 3000™ or PRIMAPORE™ dressings do not require the use of any such skin preparation creams prior to application of the dressing and, as mentioned previously the dressing protocol had already been approved prior to the dressing company's recommendation to use the barrier film. Omission of this cream may have made a difference to the number of reactions to the combination dressing.

In terms of process limitations of the study, there were some processes that may have hindered the smooth running of the trial. Recruitment was staggered with the majority of participants recruited in the month prior to the trial so all commenced the trial at the same time. However, for clinical reasons unrelated to the study, some participants were recruited in the early weeks after the trial commenced. The participants who were recruited prior to commencement of the trial were less likely to have an error with the dressing changeover date as a set date facillitated changeover from one dressing to another with the majority of the sample changed on the one day.

Changeover was more likely to be missed if a participant consented after the intial trial commencement date. This issue may have been resolved if it had been possible to have a longer consenting time prior to the trial or with the employment of a dediated study research assistant.

A dedicated research assistant for the trial would have also assisted in the overall monitoring of the trial to ensure audit tools were completed at the beginning of every dialysis session. Audit tools were collected once a week and this neccessitated some retrospective completion of data. A dedicated research assistant could have checked audit tools for completetion at the end of every shift. A dedicated research assistant may have also assisted in other ways to reduce the amount of data that were missed during the trial. There were multiple units included in this trial as the participants often changed the location of dialysis. Commonly participants were transferred between dialysis units on the morning of their treatment. This process required the transfer of the participant's chart to the appropriate unit. Dialysis details would be faxed to the appropriate unit so dialysis could be commenced. Occasionally, the audit tool was not included in this transfer of dialysis details and the hard copies in the participants chart may not have arrived before the patient commenced dialysis. This did lead to some data being missed, however it was important that all haemodialysis units were included to increase the sample size

Following completion of this study, the THHS has transitioned to electronic medical records. All satellite units are to be included in this program. Electronic medical records will improve communication between the units as all units will have access to the patient's entire medical record. It would be anticipated that this transition to electronic charting would also facilitate reducing the amount of missing data should the trial be undertaken again.

It was difficult to ascertain at times if a participant had missing data or if the patient had failed to attend dialysis and therefore would not have had an audit completed on that day. When performing retrospective searches there was no or limited documentation to determine if the participant had failed to attend. Further education regarding documentation is required for nursing staff. In addition, a dedicated research assistant would have assisted in monitioring this issue.

An additional factor that affected the trial was the participant dropout rate. Dropouts have strong effects in cross-over trials (Polit & Beck, 2008) with the inability to analyse the data from participants who only received one dressing. There were eight participants who only received one dressing for various reasons. This decreased the sample size and reduced the statistical power of the study. Polit and Beck (2008) state that bias becomes a problem if the dropout rate is 20%. The participant drop-out rate in this trial from time of consent was 24%.

It was expected that there would be some non-completions in this RCT, particularly as CVCs are not a permanent haemodialysis access. A trial analysis based on intention to treat would have reduced the withdrawal bias that can be caused by drop outs, as all participants would have been analysed if they received both of the study dressings. However this small study provided several challenges related to randomisation and data analysis. The first challenge was the early identification of a high percentage of reactions to one dressing (almost 50% of those participants who received it), which required that this arm of the trial be removed altogether and the group allocation reorganised. The second challenge was due to having a small number of patients who consented and then received an incorrect dressing (that is, treatment). These errors were due to reasons unrelated to the efficacy of the treatment and so their removal was not likely to pose any potential withdrawal bias. Findings from the study should be considered in the context of potential over-estimation or under-estimation of treatment effect. The decision to analyse 'per protocol' may have over-estimated the overall effect of the intervention, whereas an 'intention to treat' based analysis would potentially under-estimate the overall effect of the intervention.

### 5.10.2 External validity

This research was specific to tropical northern Australia, with a high percentage of Aboriginal and Torres Strait Islander participants. The results may therefore not be generalizable to non-tropical areas of Australia or internationally.

It was anticipated that this pilot study would provide definitive data on which to base sample size calculations for a future large multi-site study with similar outcome measures (intactness and infections). It was not possible to calculate a sample size for the infection measure, due to no infections occurring with one dressing type in this study. With respect to the intactness measure, the small differences in intactness

(0.49%) between the opaque (68.15%) and transparent (68.64%) would require a very large sample size, which would be unreasonable and unachievable (email communication with statistics advisor, Mr Daniel Lindsay, James Cook University, 29/01/2016).

## 5.11 Recommendations

From the considerations of this study's findings, several recommendations for clinical practice, policy, patient education and future research are proposed. Clinical practice, policy and education recommendations are primarily aimed at local context given the small scale of the study. Several important findings provide a strong foundation for future national studies. These recommendations are presented in turn below.

### 5.11.1 Clinical practice and policy

**Recommendation 1: There should be no change to current practice locally with respect to the ongoing use of the opaque dressing (PRIMAPORE™).**

The dressing of choice within the TRS prior to commencement of the trial was the opaque product. This dressing is available in several sizes to suit the location of the CVC exit site, and is less expensive than either the transparent or combination types of dressings. The findings from this small scale RCT support the appropriateness of the opaque dressing in this setting and have raised concerns about skin reactions to some other dressings in this high risk population. The practice (of using opaque dressings) is no longer at odds with the revised Australian and Queensland health department guidelines; however, it is not consistent with the local procedure for care of vascular access devices more generally. Hence, there is a need to present the findings of the RCT to those responsible for the writing of this local procedure, and to consider a modification in this high risk population to ensure the preferential use of the opaque dressing within the renal unit. If, as a consequence of exploring this recommendation it is agreed that a transparent dressing type is suitable for selected patients, then the renal unit will need to re-assess its current procedure of changing these dressings at each haemodialysis session. It may well be that the unit's current policy of changing all

dressings at each session may have led to skin-stripping which was manifested as a skin reaction to the transparent dressing.

### 5.11.2 Patient Education

**Recommendation 2: If the continued use of the opaque dressing is approved for TRS renal patients, there needs to be consideration as to how to best advise the patients about the need to keep the dressing dry between haemodialysis sessions.**

Dressings that do not remain dry and intact between haemodialysis sessions pose an unacceptable risk of local and systemic infections. However, the patients of this renal service live in a hot, humid climate, often without air-conditioning, and their need for haemodialysis with a CVC will be long-term. Hence, there needs to be provisions for the patients to maintain their personal hygiene whilst protecting their CVCs. This recommendation will require involvement of the patients and their representatives about possible solutions. It is acknowledged that nurses need to be respectful of the needs and preferences of individual patients, in order to deliver person-centred care. It is likely in this patient cohort that patient education about care of a CVC will need to be delivered in a culturally appropriate format. Nurses may need some encouragement to identify ways to select appropriate patients to be more involved in their self-care, and teach them in the first instance how to change wet dressings after showers, and to replace dressings that become non-intact. Patients who undertake home haemodialysis are successfully taught how to care for their CVC at home, therefore these practices should be adopted for suitable patients who are on long-term haemodialysis at an incentre/satellite dialysis facility.

**Recommendation 3: Formalised ongoing education about CVC exit site care, supported by written protocols to guide practice, needs to be implemented in a sustainable way.**

The written protocol and work instruction developed for this RCT was instrumental in standardising the care of the CVC exit sites. However, given the ongoing turnover of nurses within the TRS, and the limited number of experienced renal nurses, education about CVC exit site care needs to be formalised, and delivered at regular intervals throughout each year. The Clinical Nurse Consultant and Nurse Educator in the TRS can then observe nurses' techniques on actual patients. Such formalised education will go further than the current expectation that all nurses commencing in the TRS complete a skills checklist about the use of a CVC for

haemodialysis before they are deemed competent to independently access a CVC for haemodialysis. Some progress toward this recommendation has already been made: following the RCT, it was agreed that all nurses should complete this skills checklist annually to ensure their practices remain consistent with the formalised protocol for care of a CVC. Additional education that incorporates the findings of this RCT for this patient population will equip the renal nurses to provide evidence-based care, and they will be able to convey this information, for example, to student and newly-graduated nurses who rotate through the TRS.

### 5.11.3 Research

**Recommendation 4: Lessons learned from conducting this RCT in a busy clinical area need to be incorporated into future research into the topic.**

This RCT was always conceived as a pilot study for a larger multi-site RCT; as such there are several lessons learned that need to be incorporated into future research. This pilot study demonstrated the value of using data collection tools that had been tested in this setting, and the value of written protocols for the care of the CVC exit sites. One of the limitations identified during the conduct of the study was the absence of a full-time research assistant dedicated to the trial. It is strongly recommended that future RCTs be resourced to include a dedicated research assistant to collect and check data collection forms in real time, and to oversee the changeover of dressing types. This would help to minimise missing data. A dedicated research assistant could also help with checking that the work instructions for applying and removing the dressings are consistently applied. Perhaps a research assistant could also assist with undertaking a patch skin test of dressings with participants to minimise adverse reactions. With respect to the properties of dressings to be used in future studies, it is suggested that company representatives provide a greater level of detail about the ingredients in the dressing adhesives and the moisture vapour transmission rates of their products. Of course, the need to protect commercial in-confidence information is respected – however, in order to make an informed choice of products to trial, it is reasonable for both clinicians and supply officers to insist on full product disclosure about adhesive components and MVTR.

**Recommendation 5: A multi-site RCT needs to be undertaken to compare different dressing types in tropical and temperate climate settings.**

As the results of this trial were inconclusive, a larger multisite-trial should be conducted over a longer period of time to further evaluate the use of transparent, opaque and combination dressings focussing on infection and intactness as the primary outcomes. A multi-site comparison trial that includes renal units in tropical climates and renal units in non-tropical climates could lead to more conclusive results. Other confounding variables, such as different intervals between dressing changes and different dressing products would need to be controlled or measured to enable multi-factorial statistical analysis. However, as previously discussed (see section 5.10.2), an extremely large sample size would need to be recruited to such a study.

Although there was no statistically significant difference in intactness or infection rates in this RCT, there were a number of skin reactions to the transparent dressings and the combination dressing; therefore a safety trial may need to be conducted prior to the commencement of another trial. It may be pertinent to use a barrier film prior to applying particular dressings as is now being recommended by the manufacturers of the combination dressing used during this RCT. This barrier film may reduce the number of skin reactions experienced with the transparent and the combination dressing. A larger multi-site RCT could also explore other variables such as the frequency of dressing changes. An opaque dressing will still need to be changed at each haemodialysis session; however, transparent dressings that have remained intact are designed to be left in place for a longer period of time.

## 5.12 Conclusion

This thesis has described a small cross-over RCT that was conducted in a tropical region to address the paucity of high-quality evidence about the most effective dressing to use on CVC exit sites for haemodialysis patients. The background of the study was explained as were the methods used in the trial.

The cross-over RCT found no evidence to support change of practice locally. The results of this trial, although not statistically significant, were clinically significant given the number of infections and skin reactions that occurred during the transparent dressing phase of the trial.

Both dressings were found to be non-intact almost one-third of the time. It may be that the position of the catheter and excess hair may have contributed to this problem. Therefore it would be pertinent to determine, on an individual basis, the need to use a catheter securement device or remove excess hair so the dressing can adhere to the skin more securely.

It is evident from the literature that there are other variables, not exclusively the type of dressing that may contribute to intactness and infection rates. This includes such factors as frequency of dressing change, the properties of the dressing and other dressing protocols.

The state health guidelines have since been updated to recommend patient and environmental factors be taken into consideration when choosing the most appropriate dressing for use on a haemodialysis CVC exit site. The PRIMAPORE™ dressing is not always preferable to meet patient hygiene needs as they cannot shower with this dressing on. Patient education regarding CVC care and how to change their dressing may assist in many instances in negating this problem.

If the TRS decided, after reviewing the local evidence to adopt the use of a transparent dressing, it would be required that we: educate staff and patients about signs and symptoms of potential skin reactions, change unit protocol to use a protective barrier cream before application of the dressing, and potentially decrease the frequency of dressing change to reduce potential skin trauma.

The thesis concluded with recommendations for further investigations to determine the most effective dressing type and dressing protocol for use on haemodialysis CVC exit sites in the tropics. Finally, a multi-site randomised controlled trial, ideally conducted within different climate zones, comparing transparent and opaque dressings was proposed to address some of the limitations of the pilot cross-over RCT. While rate of infection is the most important outcome measure, an adequately powered study would require a very long data collection period and intactness of dressings remains an appropriate first study outcome.

# References


ANZDATA Registry. (2012). *The thirty fifth annual report: Australia and New Zealand Dialysis and Transplant Registry*. Adelaide, South Australia: Australia and New Zealand Dialysis and Transplant Registry.

Australian Institute of Health and Welfare. (2014). *Projections of the prevalence of treated end-stage kidney disease in Australia 2012-2020*. Canberra: Australian Institute of Health and Welfare.

Banton, J. (2006). Techniques to prevent central venous catheter infections: Products, research, and recommendations. *Nutrition in Clinical Practice, 21*(1), 56-61.

Barros, L. d. F. N. M. d., Arênas, V. G., Bettencourt, A. R. d. C., Diccini, S., Fram, D. S., Belasco, A. G. S., et al. (2009). Evaluation of two types of dressings used on central venous catheters for hemodialysis [English translation]. *Acta Paulista de Enfermagem, 22*, 481-486.

Baxter Healthcare Corporation. (1997). *Peritoneal dialysis catheter exit site classification guide*. Deerfield; IL: Baxter.

Bennett, P. N., Janko, A., & Whittington, T. (2005). Central venous dialysis catheter care: An Australian survey. *Renal Society of Australasia Journal, 1*(2), 50-57.

Besorab, A., & Raja, R. (2007). Vascular access for hemodialysis. In J. Daugardis, P. Blake & T. Ing (Eds.), *Handbook of dialysis* (4th ed.). Philadelphia: Lippincott Williams & Wilkins.

Betjes, M. (2011). Prevention of catheter-related bloodstream infection in patients on hemodialysis. *Nephrology, 7*, 257-265.

Brandt, B., DePalma, J., Irwin, M., Shogan, J., & Lucke, J. F. (1996). Comparison of central venous catheter dressings in bone marrow transplant recipients. *Oncology Nursing Forum, 23*(5), 829-836.

Bureau of Metereology. (2015, 5th February). Climate statistics for Australian locations - Monthly climate statistics. Summary statistics Townsville Aero. Retrieved 9th February, 2015, from http://www.bom.gov.au/climate/averages/tables/cw_032040.shtml

Callaghan, S., Copnell, B., & Johnston, L. (2002). Comparison of two methods of peripheral intravenous cannula securement in the pediatric setting. *Journal of Infusion Nursing, 25*(4), 256-264.

Callahan, J. L., & Wesorick, B. (1987). Bacterial growth under a transparent dressing. *American Journal of Infection Control, 15*(6), 231-237.

Cass, A., Chadban, S., Gallagher, M., Howard, K., Jones, A., McDonald, S., et al. (2006). *The economic impact of end-stage kidney disease in Australia: Projections to 2020*. Sydney, Australia: Kidney Health Australia.

Center for Disease Control. (2011). *Guidelines for the prevention of intravascular catheter-related infections*. Atlanta, GA: Department of Health and Human Services.

Centre for Applied Nursing Research. (1998). *Central line dressing type and frequency: A systematic review*. Liverpool, NSW, Australia: Liverpool Health Service, Centre for Applied Nursing Research.

Centre for Health Care Related Infection Surveillance and Prevention. (2007). *Queensland Government's Centre for Health Related Infections Surveillance and Prevention Guidelines*. Brisbane, Australia: Queensland Health.

Centre for Health Care Related Infection Surveillance and Prevention & Tuberculosis Control. (2013a). *Guideline. Haemodialysis Catheters (Version 2)*. Brisbane, Australia: Queensland Government Department of Health.

Centre for Health Care Related Infection Surveillance and Prevention & Tuberculosis Control. (2013b). *Guideline. Tunnelled central venous catheters (Version 2)*. Brisbane, Australia: Queensland Government Department of Health.

Chu, G., Adams, K., & Crawford, S. (2013). Improving catheter-related blood stream infection in haemodialysis patients using a practice development framework. *Renal Society of Australasia Journal, 9*(1), 16-21.

Collignon, P., Dreimanis, D., Beckingham, W., Roberts, J., & Gardner, A. (2007). Intravascular catheter bloodstream infections: an effective and sustained hospital-wide prevention program over 8 years. *Medical Journal of Australia, 187*(10), 551-554.

Conly, J. M., Grieves, K., & Peters, B. (1989). A prospective, randomized study comparing transparent and dry gauze dressings for central venous catheters. *Journal of Infectious Diseases, 159*(2), 310-319.

Council, N. H. a. M. R. (2010). *Australian guidelines for the prevention and control of infection in healthcare*. Canberra, Australia: Commonwealth of Australia.

Craven, D. E., Lichtenberg, D. A., Kunches, L. M., McDonough, A. T., Gonzalez, M. I., Heeren, T. C., et al. (1985). A randomized study comparing a transparent polyurethane dressing to a dry gauze dressing for peripheral intravenous catheter sites. *Infection Control, 6*(9), 361-366.

Danks, L. A. (2006). Central venous catheters: A review of skin cleansing and dressings. *British Journal of Nursing, 15*(12), 650-654.

Dickerson, N., Horton, P., Smith, S., & Rose, R. C. (1989). Clinically significant central venous catheter infections in a community hospital: Association with type of dressing. *Journal of Infectious Diseases, 160*(4), 720-722.

Duteille, F. (2014). Preventing skin-stripping and blistering using a non-adherent perforated ethylene methyl acrylate film dressing: A case study evaluation. *Wounds UK, 10*(3), 88-93.

Dykes, P. (2007). The effect of adhesive dressing edges on cutaneous irritancy and skin barrier function. *Journal of Wound Care, 16*, 97-100.

Fukunaga, A., Naritaka, H., Fukaya, R., Tabuse, M., & Nakamura, T. (2006). Our method of povidone-iodine ointment and gauze dressings reduced catheter-related infection in serious cases. *Dermatology, 212 Suppl 1*, 47-52.

Gillies, D., O'Riordan, E., Carr, D., O'Brien, I., Frost, J., & Gunning, R. (2003). Central venous catheter dressings: A systematic review. *Journal of Advanced Nursing, 44*(6), 623-632.

Harwood, L., Wilson, B., Thompson, B., Brown, E., & Young, D. (2008). Predictors of hemodialysis central venous catheter exit-site infections. *CANNT Journal, 18*(2), 26-35.

Hughes, K., Gardner, A., & McArdle, J. (2011). Audit of factors associated with the intactness of central venous catheter exit site dressings for northern Australian haemodialysis patients. *Renal Society of Australasia Journal, 7*(3), 108-114.

Jezova, L., Ziakova, K., & Serfelova, R. (2012). Comparison of a transparent polyeurathane film and sterile gauze as dressing materials for central venous access. *Journal of Nursing, Social Studies, Public Health and Rehabilitation, 1*(2), 72-78.

Jones, A. (2004). Dressings for the management of catheter exit sites. *JAVA, 9*(1), 26-33.

Kato, S., Chmielewski, M., Honda, H., Pecoits-Filho, Matsuo, S., Yuzawa, Y., et al. (2008). Aspects of immune dysfunction in end-stage renal disease. *Clinical Journal of the American Society of Nephrology, 3*, 1526-1533.

Kidney Health Australia. (2014). Kidney Fast Facts. Retrieved from http://www.kidney.org.au/LinkClick.aspx?fileticket=mlGlKiLUaic%3d&tabid=609&mid=1727

Le Corre, I., Delorme, M., & Cournoyer, S. (2003). A prospective randomized trial comparing a transparent dressing and dry gauze on the exit site of long term central venous catheters of hemodialysis patients. *Journal of Vascular Access, 4*, 56-61.

Lin, Y. S., Chen, J., Li, Q., & Pan, K. P. (2009). Moisture vapor transmission rates of various transparent dressings at different temperatures and humidities. *Chinese Medical Journal, 122*(8), 927-930.

Little, K., & Palmer, D. (1998). Central line exit sites: Which dressing? *Nursing Standard, 12*(48), 42-44.

Maki, D., & Mermel, L. (1997, April). *Transparent polyurethane dressings do not increase the risk of CVC related BSI: A meta-analysis of prospective randomised trials.* Paper presented at the The Society for Healthcare Epidemiology of America, 7th Annual Scientific Meeting.

McArdle, J. (2011). Cyclone Yasi: Dialysis mission impossible. *Renal Society of Australasia Journal, 7*(3), 76-78.

McArdle, J., & Gardner, A. (2009). A literature review of central venous catheter dressings: Implications for haemodialysis in the tropics. *Healthcare Infection, 14*(4), 139-146.

McCann, M., & Moore, Z. E. (2010). Interventions for preventing infectious complications in haemodialysis patients with central venous catheters. *Cochrane Database of Systematic Reviews*(1), Art. No.: CD006894.

Mermel, L. A., Allon, M., Bouza, E., Craven, D. E., Flynn, P., O'Grady, N. P., et al. (2009). Clinical practice guidelines for the diagnosis and management of intravascular catheter-related infection: 2009 update by the Infectious Diseases Society of America.[Erratum appears in Clin Infect Dis. 2010 Feb 1;50(3):457], [Erratum appears in Clin Infect Dis. 2010 Apr 1;50(7):1079 Note: Dosage error in article text]. *Clinical Infectious Diseases, 49*(1), 1-45.

National Health and Medical Research Council. (2003). *Values and ethics: Guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research*. Canberra, ACT, Australia: Australian Government.

National Health and Medical Research Council. (2014). *National statement on ethical conduct in human research 2007*. Canberra, ACT: Australian Government.

National Kidney Foundation. (2006). *Updates, clinical practice guidelines and recommendations*. Boston, MA: National Kidney Foundation.

O'Grady, N. P., Alexander, M., Dellinger, E. P., Gerberding, J. L., Heard, S. O., Maki, D. G., et al. (2002). Guidelines for the prevention of intravascular catheter-related infections. *Pediatrics, 110*(5), e51.

Olson, K., Rennie, R. P., Hanson, J., Ryan, M., Goilpin, J., Falsetti, M., et al. (2004). Evaluation of a no-dressing intervention for tunneled central venous catheter exit sites. *Journal of Infusion Nursing, 27*(1), 37-44.

Oncu, S., & Sakarya, S. (2002). Central venous catheter-related infections: An overview with specific emphasis on diagnosis, prevention and management. *The Internet Journal of Anesthesiology, 7*(1).

Petrosino, B., Becker, H., & Christian, B. (1988). Infection rates in central venous catheter dressings. *Oncology Nursing Forum, 15*(6), 709-717.

Piantadosi, S. (2005). *Clinical trials: A methodologic perspective* (2nd ed.). Hoboken, NJ: Wiley-Interscience.

Polit, D. F., & Beck, C. T. (2008). *Nursing research: Generating and assessing evidence for nursing practice*. Philadelphia: Wolters Kluwer Health.

Queensland Health. (2008). *Modelling contemporary nursing and midwifery: a framework for shaping professional practice*. Brisbane, Australia: Queensland Government.

Reynolds, M. G., Tebbs, S. E., & Elliott, T. S. (1997). Do dressings with increased permeability reduce the incidence of central venous catheter related sepsis? *Intensive and Critical Care Nursing, 13*(1), 26-29.

Rippon, M., White, R., & Davies, P. (2007). Skin adhesives and their role in wound dressings. *Wounds UK, 3*(4), 76-86.

Safdar, N., Kluger, D. M., & Maki, D. G. (2002). A review of risk factors for catheter-related bloodstream infection caused by percutaneously inserted, noncuffed central venous catheters. *Medicine, 81*(6), 466-479.

Schulz, K. F., Altman, D. G., & Moher, D. (2010). CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomised trials. *British Medical Journal, 340*, 698-702.

Shivnan, J. C., McGuire, D., Freedman, S., Sharkazy, E., Bosserman, G., Larson, E., et al. (1991). A comparison of transparent adherent and dry sterile gauze dressings for long-term central catheters in patients undergoing bone marrow transplant. *Oncology Nursing Forum, 18*(8), 1349-1356.

Silveira, R. C. d. C. P., Braga, F. T. M. M., Garbin, L. M., & Galvão, C. M. (2010). The use of polyurethane transparent film in indwelling central venous catheter. *Revista latino-americana de enfermagem, 18*(6), 1212-1220.

Smith & Nephew. (2015). IV3000 Product Range. Retrieved 21 October, 2015, from www.smith-nephew.com/australia/healthcare/products/products-types/iv-care--product-range/

Suhng, E. A., Byun, J. Y., Choi, Y. W., Myung, K. B., & Choi, H. Y. (2011). A case of allergic contact dermatitis due to DuoDERM Extrathin®. *Annals of Dermatology, 23*(Suppl 3), S387-S389.

Taylor, G. D., McKenzie, M., Buchanan-Chell, M., Caballo, L., Chui, L., & Kowalewska-Grochowska, K. (1998). Central venous catheters as a source of hemodialysis-related bacteremia. *Infection Control and Hospital Epidemiology, 19*(9), 643-646.

Theaker, C. (2005). Infection control issues in central venous catheter care. *Intensive and Critical Care Nursing, 21*(2), 99-109.

Thomas, S. (2012). The effect of weather and other environmental factors on the performance of surgical dressings. *Wounds, 24*(12), 335-338.

Thomas, S., Barry, L., Fram, P., & Phillips, P. (2011). The effect of temperature and humidity on the permeability of film dressings. *Journal of Wound Care, 20*(10), 484-489.

Tokars, J. (2000). Description of a new surveillance system for bloodstream and vascular access infections in outpatient hemodialysis centers. *Semin Dial, 13*, 97-100.

Treston-Aurand, J., Olmsted, R., Allen-Bridson, K., & Craig, C. (1997). Impact of dressing materials on central venous catheter infection rates. *Journal of Intravenous Nursing, 20*(4), 201-206.

Tripepi-Bova, K. A., Woods, K. D., & Loach, M. C. (1997). A comparison of transparent polyurethane and dry gauze dressings for peripheral i.v. catheter sites: Rates of phlebitis, infiltration, and dislodgment by patients. *American Journal of Critical Care, 6*(5), 377-381.

Trotter, B., Brock, J., Schwaner, S., Conaway, M., & Burns, S. (2008). Central venous catheter dressings put to the test. *American Nurse Today, 3*(4), 43-44.

Twardowski, Z. J., & Prowant, B. F. (1996). Classification of normal and diseased exit sites. *Peritoneal Dialysis International, 16*, 32-50.

Webster, J., Gillies, D., O'Riordan, E., Sherriff, K., & Rickard, C. (2011). Gauze and tape and transparent polyurethane dressings for central venous catheters (Review). *Cochrane Database of Systematic Reviews, Issue 11. Art. No.: CD003827. DOI: 10.1002/14651858.CD003827.pub2*.

Winterberger, C., Epaulard, O., Hincky-Vitrat, V., Brion, J., Recule, C., Francois, P., et al. (2011). Outcome of central venous catheter-related bacteraeia according to compliance with guidelines: Experience with 91 episodes. *Journal of Hospital Infection, 80*(3), 245-251.

Wittich, E. (2001). Maintaining an optimum haemocatheter exit site. *Journal of Renal Care, 27*, 81-82.

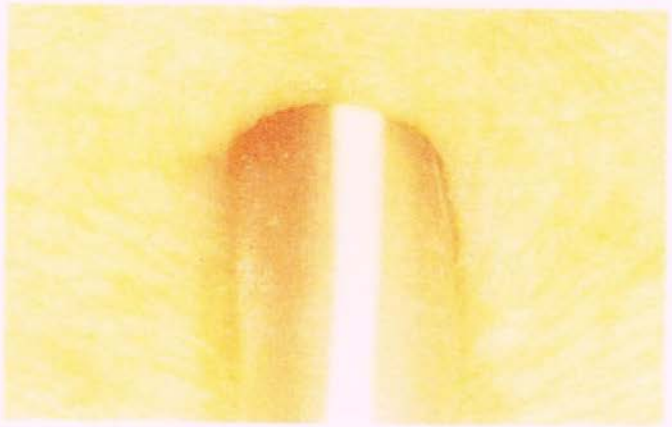
Wood, D. (1997). A comparative study of two securement techniques for short peripheral intravenous catheters. *Journal of Intravenous Nursing, 20*(6), 280-285.

Young, E. J., Contreras, G., Robert, N. E., Vogt, N. J., & Courtney, T. M. (2005). Incidence and influencing factors associated with exit site infections in temporary catheters for hemodialysis and apheresis. *Nephrology Nursing Journal, 32*(1), 41-50.

# Appendices

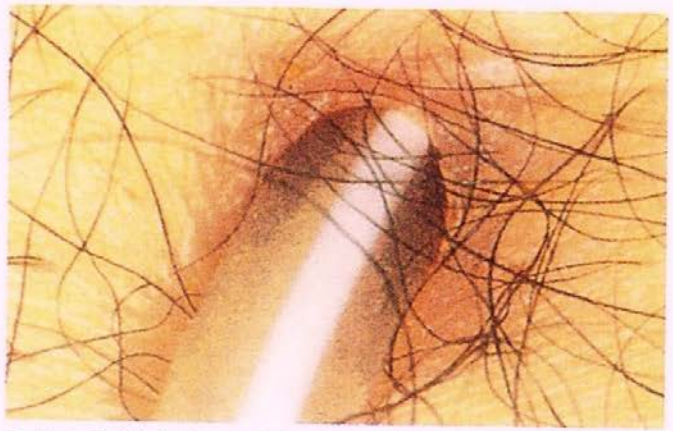
## Appendix A – Twardowski scale

A.



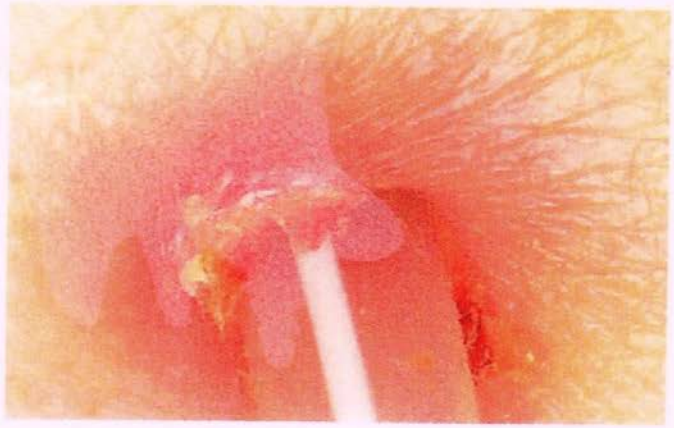
Perfect exit. Natural skin color.

B.



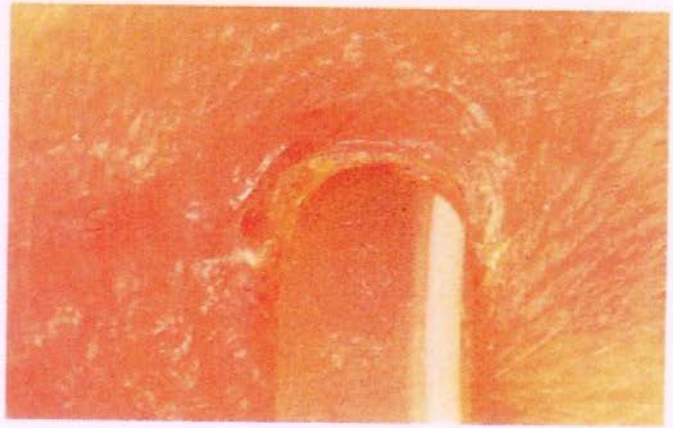
Good exit. Purplish discoloration of the skin at the exit site.

C.



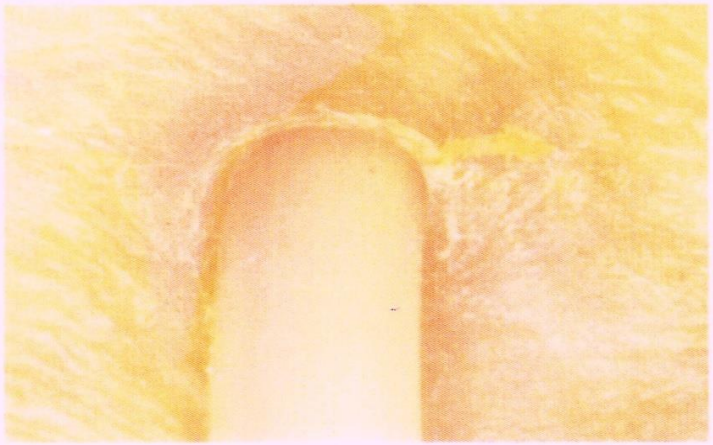
Equivocal exit (based upon color only). Erythema (red, <13mm) at the exit site. This exit could be infected, depending on drainage and presence of exuberant granulation tissue in the sinus.

D.



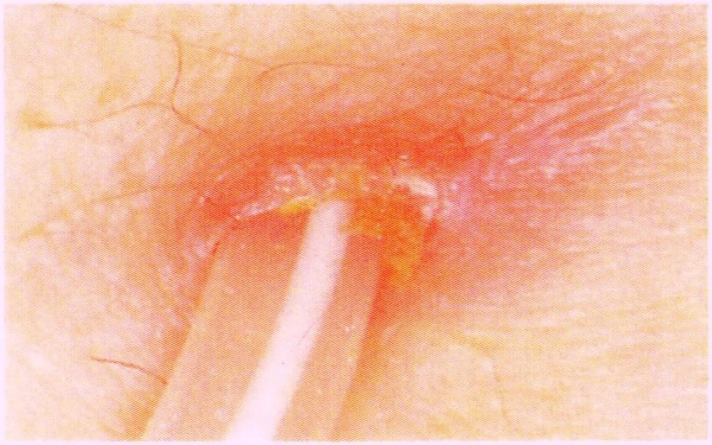
Infected exit. Erythema (red) greater than 13mm in diameter; swelling present.

A.



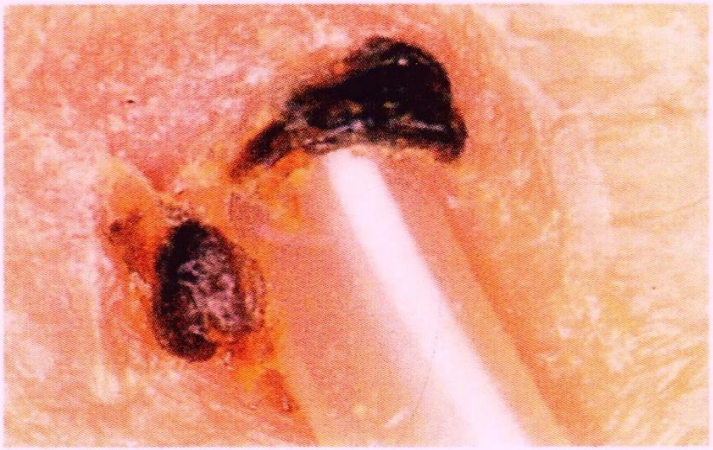
Good exit. Small crust.

B.



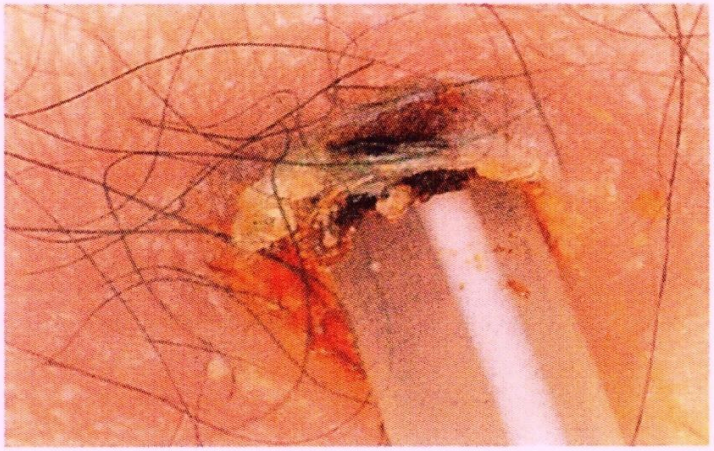
Equivocal exit. Small crust.

C.



Acute infection. Scab at the exit.

D.



Chronic infection. Large crust with scab and partially dried drainage.

# Appendix B – Audit tool

This audit refers to Patient with PSN _____

Dressing for use this audit week _____

Please complete the following audit tool questions for patient undergoing dialysis.

| **Please complete these patient details for each dialysis episode (write date of dialysis in right column)** | | **Date** ___/___/___/ | **Date** __/___/___/ | **Date** ___/___/___/ |
|---|---|---|---|---|
| Q1. | Catheter position? Write either RJ, LJ, RSC, LSC, RF, or LF (see notes at bottom of page) | | | |
| Q2. | Tunneled catheter? Write 'Yes' or 'No' | | | |
| Q3. | Sutures present? Write 'Yes' or 'No' | | | |
| Q4. | Where Dialysing? Write inpt TTH or TTH or NW or MI | | | |
| Q5. | Patient pain scale at exit site? Write a number between 0 (no pain) and 10 (extreme pain) | | | |
| Q6. | Body Temperature? (0C) | | | |
| Q7. | Blood Sugar Level? (mmol/L) | | | |
| Q8. | Most recent CRP result | | | |
| **These 5 questions refer to staff catheter dressing observations** | | | | |
| Q9. | Intactness of dressing? Please write number from 0 to 4 that corresponds to the intactness of the dressing (see scale below).<br>0 → Dressing fully intact ( all sides Sealed)<br>1 → 1 edge/side off or rolled up<br>2 → 2 side/edges off or rolled up<br>3 → 3 sides/edges off or rolled up<br>4 → No dressing | | | |
| Q10. | If Primapore is the dressing wet? Write 'Yes' or 'No' If IV 3000 or tegaderm is there a fluid collection under the dressing? Write 'Yes' or 'No' | | | |
| Q11. | Has patient replaced the dressing? Write 'Yes' or' No' | | | |
| Q12. | Was the correct dressing in place? Write Yes or No | | | |
| Q13. | Has a swab been taken today? Write 'Yes' or' No' | | | |
| Q14. | Have blood cultures been taken today? Write 'Yes' or' No' | | | |
| **The next 5 questions refer to the catheter exit site** | | | | |
| Q15. | Date of catheter insertion?( may have changed since last run) | ___/___/___/ | ___/___/___/ | ___/___/___/ |
| Q16. | Skin area condition under dressing? Moist, rash , itchy, bleeding, intact etc. | | | |
| Q17. | Colour classification of exit site (refer to colour chart). Write either A, B, C, or D | | | |
| Q18. | Crust* and scab** classification of exit site (refer to colour chart). Write either A, B, C, or D (* and ** - see notes at bottom of page) | | | |
| Q19. | Active bleeding at exit site? Write 'Yes' or 'No' | | | |
| Q20. | Any other comment eg. Cuff visible | | | |

Notes: J-Right Jugular, LJ- Left Jugular, RSC- Right Subclavicle, LSC- Left Subclavicle, F– Right Femoral, LF- Left Femoral
Crust defined as pale or dark yellow hardened drainage.
*Scab defined as hardened serum and blood

## Appendix C – Townsville Health Service District ethics approval

This administrative form has been removed

## Appendix D – James Cook University ethics approval

This administrative form
has been removed

## Appendix E – Patient information sheet


# Townsville Health Service District

**PATIENT INFORMATION SHEET**

**PROTOCOL NAME:**

Wound dressing protocols for haemodialysis central venous catheter exit sites in the tropics: A pilot study.

## INVESTIGATORS:

Ms Joleen McArdle, Prof Anne Gardner, Dr Wendy Smyth and Dr Robert Norton

You are invited to take part in a study investigating the most suitable dressing type and appropriate dressing protocol for central venous catheter (CVC) exit sites in the tropics. The research team requests your involvement because you are undergoing haemodialysis through a central venous catheter. If you agree to participate in the study, the nursing staff will dress your CVC exit site with three dressings in turn, each dressing for 4 weeks. Neither you nor the nurse will choose the order in which each dressing is used– this will be decided by a process called randomization and will be undertaken by the research team. (Randomization means that every participant has an equal chance of receiving either dressing first.) The dressings, all of which are accepted as appropriate dressings for CVC sites, will be supplied to you by the Hospital without charge. During the weeks that you participate in the study, nurses will collect information about your care including information about the way that the dressing remains in place between dialysis treatments.

If you wish to participate in the study, we ask that you indicate your agreement and sign the attached consent form. There is no payment for your involvement in this research. We do not foresee any risks by your involvement in this study, and there are no immediate benefits to your health care associated with your involvement. If you wish to withdraw from the study at any time, you may do so without giving a reason, and this will not have any adverse impact on the treatment you receive.

All data obtained will remain confidential, and will be securely stored throughout the course of the study within locked cupboards and filing cabinets within a locked office, to which only the researchers have access. Any computer files will be password-protected, accessible only to the researchers. You will not be identifiable in any reports, publications or presentations arising from the study.

This study has been reviewed and approved by the Townsville Health Service District Human Research Ethics Committee. Should you wish to discuss the study with someone not directly involved, particularly in relation to matters concerning policies, information about the conduct of the study or your rights as a participant; or should you wish to make an independent complaint you can contact the Chairperson, Townsville Health Service District Human Research Ethics Committee via email at TSV-Ethics-Committee@health.qld.gov.au or telephone (07) 4796 1140.

**INVESTIGATOR CONTACT NAME:** Ms Joleen McArdle
**INVESTIGATOR CONTACT TELEPHONE NO.** 07 4796 3522
**DATED:** June 2010
**SIGNATURE OF CONTACT INVESTIGATOR:**

## Appendix F – Patient consent form


# Townsville Health Service District

**PATIENT CONSENT FORM**

**PROTOCOL NAME:**

Wound dressing protocols for haemodialysis central venous catheter exit sites in the tropics: A pilot study.

## INVESTIGATORS:

Ms Joleen McArdle, Prof Anne Gardner, Dr Wendy Smyth and Dr Robert Norton

1. The nature and purpose of the research project has been explained to me. I understand it, and agree to take part.
2. I have been given an Information Sheet which explains the purpose of the study, the possible benefits, and the possible risks.
3. I understand that I may not directly benefit from taking part in the trial.
4. I understand that, while information gained during the study may be published, I will not be identified and my personal results will remain confidential.
5. I understand that I can withdraw from the study at any stage and that it will not affect my medical care, now or in the future.
6. I understand the statement concerning payment to me for taking part in this study, which is contained in the Information Sheet.
7. I have had the opportunity to discuss taking part in this investigation with a family member or friend.

**NAME OF SUBJECT:** _____

**SIGNED:** _____

**DATED:** _____

I certify that I have explained the study to the patient/volunteer and consider that he/she understands what is involved.

**SIGNATURE OF INVESTIGATORS:** _____

# Appendix G – Demographic profile

**Demographic profile of TTH peritoneal and haemodialysis patients receiving haemodialysis via CVC catheter**

**Patient cover sheet;** To be completed by consenting Research Assistant

Is the patient allergic to any dressings/tape?

| If Yes consult with a Principal-Investigator before placing on trial |
|---|

Q1. Patient UR #: _____

Q2. Date of Birth: _____

Q3. Gender?
- ☐ Male
- ☐ Female

Q4. Culture?
- ☐ Identifies ATSI
- ☐ Australian or other
- ☐ Does not speak English

Q5. Patient's home town?: _____

Q6. Accommodation while in Townsville?_____

Q7. Current Employment status?:
- ☐ Not working
- ☐ Paid work outdoors (How many hours / day? _____)
- ☐ Paid work indoors (How many hours / day? _____ )

Q8. Currently does the patient have any active hobbies (a regular activity for more than 15 minutes)?
- ☐ No
- ☐ Yes

(Describe_____;
How many minutes / day? _____)

Q9. Diabetic?
- ☐ No
- ☐ Yes, but diet controlled
- ☐ Yes, on medication either tabs or insulin

Q10. Date of Ist ever dialysis? (any Type) _____/_____/_____/

Q11. Is the patient a in-patient when commencing trial (days)
- ☐ No
- ☐ Yes (Number days already inpt? _____)

Q12. Is the patient currently on AB'S?

☐ No
☐ Yes (Days on _____ drug _____ dose _____)

Q13. Why have the AB'S been commenced? _____

Q14. Please complete before commencing trial dressing.
Base line of site and skin area.

Date of Insertion of current CVC

---

How does the skin area under the current dressing look?
Moist, rash, itchy, bleeding, natural etc.

---

Colour classification of exit site (refer to colour chart).
Write either *A*, *B*, *C*, or *D* or comment

---

Crust* and scab** classification of exit site (refer to colour chart).
Write either *A*, *B*, *C*, or *D* (* and ** - see notes at bottom of audit tool) or comment

---

Active bleeding at exit site? Write '*Yes'* or '*No'*

---

Any other comment eg. Cuff visible

---

**NOW**

**Call Randomisation Phone Number: 47 96 25 65**

Note date and time of call: _____

Operator whom you spoke with: _____

Participant Study Number (PSN) _____
(given to you by randomization call centre)

**This patient is to use these dressings in this order while they are a consenting participant in the Renal CVC Dressing Trial**

Week 1 to 4 Dressing_____ Start Date _____

Week 5 to 8 Dressing_____ Start Date _____

Week 8 to 11 Dressing_____ Start Date _____

Signature of Renal Staff Research Assistant_____

# Appendix H – CVC trial staff education and resource folder table of contents

**Central Venous Catheter Exit Site Dressing Trial**

**Staff Education and Resource Folder**

**Table of Contents**

**Part A. The background information about the study**

- Study title, investigators, funding sources
- Summary of study

**Part B. Information about the study for staff of Renal Unit**

- Frequently Asked Questions
- PowerPoint presentations about the study
- Everyone's roles in the study

**Part C. Patient and nurse involvement during the study**

- Patient information and consent forms
- Flow chart of processes
- Patient demographics documentation at time of recruitment to trial
- Workplace Instructions for CVC connection
- Workplace instruction for CVC disconnection
- Audit tool for dialysis treatment

**Part D. Miscellaneous**

- Product information - *Primapore*
- Product information - *IV3000*
- Product information – *tegaderm IV*
- Twardowski scale – *Classification chart*
- Other background literature

# Appendix I – WPI

Queensland Government
Queensland Health

**TOWNSVILLE HEALTH SERVICE DISTRICT**

**WORKPLACE INSTRUCTIONS - RENAL UNIT**

**THSDWPI090072 v1**

| | |
|---|---|
| **TITLE** | Initiation of Haemodialysis using a Central Venous Catheter (CVC) |
| **DESCRIPTION** | Connection of the Haemodialysis Patient using a CVC Access |
| **TARGET AUDIENCE** | Renal Unit Nursing Staff |

**Alert/ Guidelines & Special Considerations:**

- Maintain asepsis
- Prior to commencement:
  - observe for general signs and symptoms of infection
  - observe the exit site for infection
  - observe catheter kinking / movement
  - prepares patient for commencement
- Note the condition of the sutures / dressing that keeps the catheter immobile at the exit site
- Notify RMO/Treating Dr. if necessary
- Check for Skin preparation allergies
- Check x-ray post initial insertion if temporary catheter except femoral
- Catheters should not be accessed for purposes other than haemodialysis unless it is an emergency.
- Betadine may be used instead of Chlorhexidine to sterilise caps and ports, if contraindicated by the manufacturer.

**PURPOSE / OBJECTIVE:**

- To remove excess fluid, electrolytes and toxins for the patients' wellbeing until a permanent access is created and ready for use
- When there is a sudden loss of an established vascular access.

**REQUIREMENTS / EQUIPMENT**

- Sterile Dressing pack
- Syringes - 2 x 2ml, 1 x 5ml, 2 x 10ml, 1 x 20ml
- 4 pkt sterile gauze
- 1 x Primapore dressing
- Chlorhexidine
- 2 x sterile gloves
- Blue sheet
- 2 x 10ml saline 0.9%
- 2 x 5ml heparin 5000u/s /5ml or clexane dose
- 1 x 18 gauge needle
- Sterile drapes as required
- Add what you require eg. For blood taking or I.V drugs or fluids.** If you need to take blood for coagulation purposes, take a further 20mls of blood (after removing the heparin) then return it immediately once blood is taken. **

**PROCESS**

- Wash hands and open sterile equipment onto sterile tray. Open Saline and Heparin ampoules – these are not to be placed on sterile tray.
- Place blue sheets under catheter ends and loosen dressing. Position patient's head to one side. Scrub hands, use sterile towel to dry and don gloves.
- Remove used dressing with forceps. Don sterile towels under catheter ends and over side of patient's face and hair. Apply Chlorhexidine soaked gauze around catheter ends for a minimum of 1 minute.
- Clean insertion site with Chlorhexidine and dry. Observe and report any exit-site infections to the Doctor
- Apply dressing to cover insertion site and sutures. Remove gloves and replace with new ones.
- Draw up saline in the 10ml syringes and the prescribed heparin loading dose in 5ml syringe, remaining heparin to be drawn up in 20ml syringe. Remove Chlorhexidine soaked gauze, using forceps, unscrew bung and discard (ensuring catheter clamp is closed first). Attach 3ml syringe to each port.
- While using gauze to hold catheter, unclamp and withdraw 3mls of blood, clamp and discard.
- Attach 10ml syringe of saline to port, unclamp and withdraw slightly, flush catheter assessing its patency and clamp.
- Repeat process for other side.
- Add heparin to the lumen that is going to be the venous side for the dialysis treatment, flush well.

**Troubleshooting**

- If unable to withdraw lock from catheter do not flush in, discuss with senior Nurse or Medical Officer. Note how many mls were able to be removed, if partially obstructed
- If catheter has become dislodged and cuff is protruding (permcath), or sutures fallen out (temporary catheter), do not use until medical officer has been notified, as the catheter may no longer being in the correct position.

**REVIEW OF DOCUMENT: New**

## MARKETING/COMMUNICATION

| | |
|---|---|
| Marketing/Communication Responsibility | NUM – renal<br>CNC – renal<br>NE – renal<br>A copy to be placed on the renal unit 'I' drive |
| Marketing/Communication Strategy | This will be noted in the minutes of a staff unit meeting.<br>The original signed copy |

## AUDIT STRATEGY

| | |
|---|---|
| Level of Risk | **Medium Risk** |
| Audit Strategy | Report in PRIME clinical incidence reporting system |
| Audit Tool Attached | Not Applicable |
| Audit Date | Not Applicable |
| Audit Responsibility | Not Applicable |
| Key Elements/Indicators/Outcomes | Central Venous Line will remain patent and free from organisms for the duration its of usage |

## REVIEW STRATEGY

| | |
|---|---|
| Minor Review Date 1 (1Year) | Feb 2011 |
| Minor Review Date 2 (2 Years) | Feb 2012 |
| Major Review Date (3 Years) | Feb 2013 |
| Review Responsibility | CNC or Educator |

## PUBLISHING INFORMATION

| | |
|---|---|
| Version | 1 |
| Version Date | Nov 2009 |
| Effective Date | Feb 2010 |
| Author/s, Position & Business Area | Vicki Nebbia – A/Nurse Educator Clinical - Renal |
| Key Stakeholders who reviewed *this version*, Position & Business Area | Amy Burrows, NUM Renal<br>Jolie McArdle – A/CNC Renal<br>CN Hartig – Renal<br>Clinical, Registered and Enrolled Nurses in the renal Unit |

| | |
|---|---|
| Replacement for | N/A |
| Information Source | • Bard Access Systems. (2003). Polyurethane Haemodialysis/ Aphaeresis Catheters – Nursing Procedure Manual. Retrieved from http://www.bardaccess.com/pdfs/nursing/ng-hemoglide-hemosplit.pdf 5 March 2008<br>• Daugirdas, J.T. etal, (2007), Handbook of Dialysis,4th edition. Lippincott Williams and Wilkins. Sydney. P 84-86.<br>• Harris, D., Elder, G. Kairaitis, L. & Rangan, G. (2005) *Basic Clinical Dialysis,* McGraw Hill Medical, Sydney.<br>• Levy, J., Morgan. J. & Brown, E. (2004) O*xford Handbook of Dialysis.* Oxford University Press, New York<br>• Smith, T. (2007) *Renal Nursing 3rd edition*. Sydney: Bailliere Tindall.<br>• Caring for Australians with Renal Impairment (CARI) guidelines<br>• Queensland Nursing Council 2005. |
| Further Reading | Nil |
| EQuIP and other Standards | EQuIP 4 Clinical 1.1.1, 1.1.2,<br>Health Drugs and Poisons Regulations 1996.<br>Health Services Act 1991 |

**Endorsed by:**

**Amy Burrows A/NUM**

Signature…….....**ON FILE**..... Date.....

**Joleen Mc Ardle A/CNC**

Signature…….....**ON FILE**..... Date.....

**Approval**

**Simon Mitchell –Nursing Director IOM & ES**

Signature…….....**ON FILE**..... Date.....

**Dr George Kan – Director of Nephrology**

Signature…….....**ON FILE**..... Date.....

# Appendix J – SPSS output for intactness

**Descriptive Statistics**

| | N | Mean | Std. Deviation | Minimum | Maximum | Percentiles | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | 25th | 50th (Median) | 75th |
| transparent number intact divided by number of audits | 26 | 68.64 | 26.166 | 0 | 100 | 49.17 | 75.96 | 88.13 |
| opaque number intact divided by number of audits | 26 | 68.15 | 24.185 | 0 | 100 | 57.31 | 73.86 | 81.77 |

## Wilcoxon Signed Ranks Test

**Ranks**

| | | N | Mean Rank | Sum of Ranks |
|---|---|---|---|---|
| opaque number intact divided by number of audits - transparent number intact divided by number of audits | Negative Ranks | 12[a] | 13.63 | 163.50 |
| | Positive Ranks | 12[b] | 11.38 | 136.50 |
| | Ties | 2[c] | | |
| | Total | 26 | | |

a. opaque number intact divided by number of audits < transparent number intact divided by number of audits
b. opaque number intact divided by number of audits > transparent number intact divided by number of audits
c. opaque number intact divided by number of audits = transparent number intact divided by number of audits

**Test Statistics[a]**

| | opaque number intact divided by number of audits - transparent number intact divided by number of audits |
|---|---|
| Z | -.386[b] |
| Asymp. Sig. (2-tailed) | .700 |

a. Wilcoxon Signed Ranks Test
b. Based on positive ranks.

# Appendix K – SPSS output for colour

**Descriptive Statistics**

| | N | Mean | Std. Deviation | Minimum | Maximum | Percentiles | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | 25th | 50th (Median) | 75th |
| COMPUTE colourTinfectionpercent_26=(ITT_Tcolour / ITT_Taudit) * 100 | 26 | 10.30 | 19.360 | 0 | 71 | .00 | .00 | 10.83 |
| COMPUTE colourOinfectionpercent_26=(ITT_Ocolour / ITT_Oaudit) * 100 | 26 | 13.30 | 25.268 | 0 | 100 | .00 | .00 | 20.00 |

## Wilcoxon Signed Ranks Test

**Ranks**

| | | N | Mean Rank | Sum of Ranks |
|---|---|---|---|---|
| COMPUTE colourOinfectionpercent_26=(ITT_Ocolour / ITT_Oaudit) * 100 - COMPUTE colourTinfectionpercent_26=(ITT_Tcolour / ITT_Taudit) * 100 | Negative Ranks | 6[a] | 6.50 | 39.00 |
| | Positive Ranks | 7[b] | 7.43 | 52.00 |
| | Ties | 13[c] | | |
| | Total | 26 | | |

a. COMPUTE colourOinfectionpercent_26=(ITT_Ocolour / ITT_Oaudit) * 100 < COMPUTE colourTinfectionpercent_26=(ITT_Tcolour / ITT_Taudit) * 100
b. COMPUTE colourOinfectionpercent_26=(ITT_Ocolour / ITT_Oaudit) * 100 > COMPUTE colourTinfectionpercent_26=(ITT_Tcolour / ITT_Taudit) * 100
c. COMPUTE colourOinfectionpercent_26=(ITT_Ocolour / ITT_Oaudit) * 100 = COMPUTE colourTinfectionpercent_26=(ITT_Tcolour / ITT_Taudit) * 100

**Test Statistics[a]**

| | COMPUTE colourOinfectionpercent_26=(ITT_Ocolour / ITT_Oaudit) * 100 - COMPUTE colourTinfectionpercent_26=(ITT_Tcolour / ITT_Taudit) * 100 |
|---|---|
| Z | -.454[b] |
| Asymp. Sig. (2-tailed) | .650 |

a. Wilcoxon Signed Ranks Test
b. Based on negative ranks.

# Appendix L – SPSS output for crust

**Descriptive Statistics**

| | N | Mean | Std. Deviation | Minimum | Maximum | Percentiles | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | 25th | 50th (Median) | 75th |
| COMPUTE crustTpercent_26=(ITT_Tcrust / ITT_Taudit) * 100 | 26 | 31.81 | 35.658 | 0 | 100 | .00 | 25.00 | 42.71 |
| COMPUTE crustOpercent_26=(ITT_Ocrust / ITT_Oaudit) * 100 | 26 | 24.43 | 31.440 | 0 | 100 | .00 | 2.63 | 43.81 |

## Wilcoxon Signed Ranks Test

**Ranks**

| | | N | Mean Rank | Sum of Ranks |
|---|---|---|---|---|
| COMPUTE crustOpercent_26=(ITT_Ocrust / ITT_Oaudit) * 100 - COMPUTE crustTpercent_26=(ITT_Tcrust / ITT_Taudit) * 100 | Negative Ranks | 12[a] | 11.33 | 136.00 |
| | Positive Ranks | 7[b] | 7.71 | 54.00 |
| | Ties | 7[c] | | |
| | Total | 26 | | |

a. COMPUTE crustOpercent_26=(ITT_Ocrust / ITT_Oaudit) * 100 < COMPUTE crustTpercent_26=(ITT_Tcrust / ITT_Taudit) * 100
b. COMPUTE crustOpercent_26=(ITT_Ocrust / ITT_Oaudit) * 100 > COMPUTE crustTpercent_26=(ITT_Tcrust / ITT_Taudit) * 100
c. COMPUTE crustOpercent_26=(ITT_Ocrust / ITT_Oaudit) * 100 = COMPUTE crustTpercent_26=(ITT_Tcrust / ITT_Taudit) * 100

**Test Statistics[a]**

| | COMPUTE crustOpercent_26=(ITT_Ocrust / ITT_Oaudit) * 100 - COMPUTE crustTpercent_26=(ITT_Tcrust / ITT_Taudit) * 100 |
|---|---|
| Z | -1.650[b] |
| Asymp. Sig. (2-tailed) | .099 |

a. Wilcoxon Signed Ranks Test
b. Based on positive ranks.