A Comparison of the Efficacy of Three Methods of Antecubital Fossa Skin Disinfection Prior to Phlebotomy in Volunteer Blood Donors

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Abstract

Research suggests that many of the contaminating organisms that are responsible for transfusion related morbidity and mortality are components of normal skin flora that enter the blood product during collection at the time of venepuncture. A repeated measures, quasi-experimental design was used to investigate and compare the efficacy of three methods of antecubital fossa skin disinfection used for phlebotomy site preparation in volunteer blood donors.

Skin cultures were obtained using sterile Rodac contact plates applied to donors' arms before and after skin disinfection. Skin cleansing was performed using a double scrub no-touch-technique with one of three of the following commercially available antiseptic preparations: 1) a swab scrubstick saturated with povidone-iodine (0.75% titratable iodine) followed by a swab saturated with povidone-iodine (1% titratable iodine)(n=42) 2) a sponge with 2% chlorhexidine gluconate and 70% isopropyl alcohol followed by an applicator with 2% chlorhexidine gluconate and 70% isopropyl alcohol (n=42); or 3) a sponge with 70% isopropyl alcohol followed by an applicator with 2% iodine tincture (n=40). Culture plates were incubated at 35-36 degrees C and colonies counted at 24 and 48 hours pre and post skin disinfection.

Statistical analysis using repeated measures ANOVA indicated that there was no statistically significant difference in postdisinfection bacterial colony counts when comparing the effectiveness of the three antiseptic preparations for removing bacterial skin contamination prior to phlebotomy in volunteer blood donors. Recommendations for

nursing practice and future research are suggested.

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CHAPTER 1

Statement of the Problem

The prevention of transfusion related morbidity and mortality is a major aim of all health care workers involved in the manufacturing and delivery of blood and blood products to consumers throughout the world. Despite scientific advances in epidemiology, microbiology and infection control bacterial contamination of these products, with associated septic patient reactions, remains a well documented cause for concern (Anderson et al., 1986; Chiu et al., 1994; Goldman & Blajchman, 1991; Morrow et al., 1991; Puckett, 1986; Puckett, Davison, Entwistle, & Barbara, 1992; Wagner, Friedman & Dodd, 1994). Nurses have long held major responsibility and accountability during the collection and administration of these life saving products to patients. The Canadian Red Cross, the primary manufacturer of blood and blood products in Canada, employs nurses as the fundamental health care professionals responsible for the collection of these products from volunteer donors. Prevention of potential contamination during the collection process is therefore a major nursing responsibility.

Bacterial contamination of blood products can occur during collection, processing, storage and/or distribution (Puckett, 1986). However much research has suggested that many of the contaminating organisms are components of normal skin flora that enter the blood product during collection at the time of venepuncture (Block, 1983; Morrow et al., 1991; Puckett et al. 1992; Wagner et al., 1994).

To ensure that various blood cells are not traumatized during the collection

process a fairly large gauge needle is used for phlebotomy. These large bore needles frequently excise fragments of skin tissue, while traversing the skin, which are then introduced into the blood collection bag (Gibson & Norris, 1958; Morrow et al., 1991). Any bacterial contamination of the skin fragment then becomes a contaminant of the blood product. This problem is of special significance in products such as platelet concentrates. Platelets require room temperature storage at 20-24 degrees Celsius and may only be stored for periods of up to five days to ensure cell viability and to increase in vivo half life (Block, 1983; Chiu et al., 1994; Morrow et al., 1991; Puckett, 1986). Room temperature storage is a key factor that promotes bacterial proliferation and growth (Puckett, 1986). Collection staff also have a responsibility to protect the donor from bacterial invasion into the body during venepuncture. Strict attention to antiseptic preparation of the venepuncture site is therefore essential. As the skin cannot be sterilized or rendered free from all microbial flora it remains a weak link in the prevention of bacterial invasion of blood products and the donor.

Microorganisms on the skin can be reduced in numbers via physical removal through skin cleansing using friction and by killing them using bactericidal agents such as antiseptics (Russell, Hugo & Ayliffe, 1992). Therefore the method and antiseptic used in skin preparation prior to phlebotomy are of paramount importance in reducing the potential for bacterial contamination of blood products (Puckett et al., 1992).

Controversy continues to exist regarding the most effective antiseptic to use for skin disinfection prior to venepuncture. Currently nurses at the Canadian Red Cross employ a double scrub procedure using an iodophor compound for venepuncture site

preparation. However, various studies have questioned the efficacy of this solution as the most effective antiseptic available for this purpose (Goldblum, Ulrich, Goldman, Reed & Avasthi, 1983; King, Philip, & Price, 1963; Larson & Bobo, 1992; Maki, Ringer, & Alvarado, 1991; Strand, Wajsbort, & Sturmann, 1993). Improvements in phlebotomy site preparation may therefore assist in alleviating the potential for bacterial contamination of blood products with skin flora and thereby decrease morbidity and mortality related to post transfusion septicemia. Furthermore, improvements in skin preparation methods have direct significance for health care personnel who must perform invasive procedures for such purposes as intravenous cannulation, injections and blood culture collection.

Purpose

A salient question for nursing practice and the major aim of this research project is to investigate and compare the efficacy of three methods of antecubital fossa skin disinfection used for donor phlebotomy site preparation in volunteer blood donors. This was measured by skin surface cultures before and after arm preparation.

Significance of the Problem

In 1993/94 in Canada 1,045,749 units of whole blood, 115,418 units of apheresis plasma and 6,333 plateletpheresis products were collected by the Canadian Red Cross from volunteer blood donors. (Canadian Red Cross Society, 1995). Each unit of blood can be separated and made into various numbers of components including red cell concentrate, plasma, platelets and numerous specialized products (Rudmann, 1995). Each of these products can then be transfused. The number of transfusions of these products to Canadian patients in 1993/94 included 841,436 units of whole blood and red

blood cells, 348,971 units of platelets, 9598 units of apheresis platelets and 109,989 units of apheresis plasma (Canadian Red Cross Society, 1995). Protection from bacterial invasion of both the donor during the collection process and the recipient during transfusion is therefore a significant responsibility of health care personnel.

Although the incidence of post transfusion septicemia declined with the advent of closed plastic pack systems versus glass containers for collecting blood, the problem has not disappeared entirely (Puckett, 1992). As it is impossible to disinfect all layers of human skin and a skin tag is often thrust into the collection pack during venepuncture, investigators have found that human skin micro flora are a cause of contaminated blood products (Anderson et al., 1986; Chiu, et al., 1994; Dave, 1996; Puckett, 1986; Puckett et al., 1993; Punsalang, Heal & Murphy, 1989). Bacterial growth following contamination of a blood product is often thought to be inhibited by bactericidal properties inherent in blood itself, the bacteriostatic effects of the citrate in the anticoagulant and storage temperatures of 4 degrees Celsius or less which are not conducive to bacterial multiplication (Barbara, 1983; Puckett, 1986). However gram-negative rods such as *Pseudomonas* or *Enterobacter* are able to grow in citrated human blood and have a definite ability to grow at the usual blood storage temperature of four degrees Celsius (Puckett, 1986). Gram-positive organisms grow very poorly in cold temperatures (4 degrees Celsius) and rarely contaminate blood stored in these conditions (Puckett, 1986). However, this then poses a significant problem for platelet products stored at room temperature as the proliferation of both gram-positive and gram-negative organisms is not inhibited.

The bacterial contamination rate of blood products has been reported to range between 0% and 7% and is believed to be under-reported and under-recognized due to the difficulty in diagnosis associated with the similarity to febrile non-hemolytic transfusion reactions (FNHTR) (Blajchman, 1995; Block, 1983; Puckett, 1986; Sazama, 1994). It is now believed that cytokines released during storage of the blood product rather than bacterial invasion of the blood product is the cause of many of the symptoms associated with FNHTR (Blajchman, 1995). Chiu et al. (1994) reports that the risk of bacteremia in adult patients following platelet transfusion can be as high as 30% given that each adult generally receives six units of platelet concentrates per transfusion. Contaminated platelet transfusion is now the most common cause of transfusion-related sepsis (Punsalang et al., 1989). Sazama (1994) reports that the Canadian Red Cross Society first established a surveillance program for the microbial contamination of blood components in 1979. Blood component contamination rates since that time have ranged from 0.15% to 0.58% for red blood cells, and 0.15% to 0.89% for platelet concentrates with an overall rate of 0.3% (Sazama, 1994).

Post transfusion sepsis has the potential to carry with it significant patient morbidity and mortality. Symptoms which may begin to appear within thirty minutes of the initiation of the transfusion include shaking chills, fever, severe headache, pain in the abdomen and extremities often associated with vomiting and bloody diarrhea, and peripheral vasoconstriction (Anderson et al., 1986; Dave, Brett, MacLennan, & Shields, 1996; Gottlieb, 1993; Huestis, Bove, & Case, 1988). If unrecognized and not appropriately treated severe hypotension, tachycardia, disseminated intravascular

coagulation and death related to septic shock can ensue (Rudmann, 1995). Chiu et al. (1994) found that 40% of patients experiencing febrile episodes related to bacteremia following transfusion developed septic shock. Septic shock is partially due to the production and release of endotoxin from gram-negative bacteria (Gottlieb, 1993).

Although it is beyond the scope of this investigation, patient care and treatment requirements during and following these episodes are significant. Physical and psychological support of the patient as well as family members are essential. In an age where cost of patient care, treatment and hospital stay are closely scrutinized, another obvious sequela to transfusion of contaminated blood products is increased health care costs.

Bacterial contamination of the donor and of blood products remains a concern for health care professionals from collection to post transfusion. A frequently cited cause of this contamination is skin flora which enter the blood during phlebotomy. Methods to ensure the appropriate and adequate cleansing of donor skin prior to venepuncture remain a significant preventative measure that must be thoroughly investigated.

Sensitizing Framework

The basic framework underlying this investigation is not restricted to one particular conceptual framework or nursing theory. A generic approach utilizing a sensitizing framework with basic theoretical assumptions served as the basis for this study. The following assumptions served as the foundation for this investigation:

1. Patients have a right to the safest, highest quality and cost effective care, treatment and resources as is possible within the limits of current scientific knowledge.

2. Health care professionals have a responsibility to provide safe, cost effective, quality care and treatment to individuals.

3. Nurses, as health care professionals, have a responsibility to ensure the delivery of safe, cost effective, quality of care.

4. Transfusion of contaminated blood products is a complication of patient treatment that can be controlled.

5. The use of measures to prevent rather than treat post-transfusion septicemia is a goal of health care professionals.

6. Benefits from primary prevention of post-transfusion septicemia include decreased length of hospital stays, decreased health care costs, and decreased patient morbidity and mortality.

7. Nurses in their role in the collection of blood and blood products can reduce the risk of bacterial invasion of donors and associated blood products thereby contributing to the safest quality of care.

Study Questions

This quantitative research investigation explored the following questions:

1. Is there a significant difference, within each of the following three groups, in bacterial counts of the skin of the antecubital fossa in volunteer blood donors, before and after venepuncture site preparation, utilizing a double scrub procedure using each of the following methods of antiseptic applications:

a) a swab with povidone-iodine (0.75% titratable iodine) followed by a swab with povidone-iodine (1 % titratable iodine)

b) a sponge with 2% chlorhexidine gluconate and 70% isopropyl alcohol followed by an applicator with 2% chlorhexidine gluconate and 70% isopropyl alcohol

c) a sponge with 70% isopropyl alcohol followed by an applicator with 2% iodine tincture.

2. Is there a significant difference, across each of the three groups, in bacterial counts of the skin of the antecubital fossa in volunteer blood donors, following venepuncture site preparation, utilizing a double scrub procedure comparing the following three antiseptics applications:

a) a swab with povidone-iodine (0.75% titratable iodine) followed by a swab with povidone-iodine (1% titratable iodine)

b) a sponge with 2% chlohexidine gluconate and 70% isopropyl alcohol followed by an applicator with 2% chlorhexidine gluconate and 70% isopropyl alcohol.

c) a sponge with 70% isopropyl alcohol followed by an applicator with 2% iodine tincture.

Definition of Terms

Antiseptic:

A substance applied to living tissue that prevents or arrests the growth or action of microoganisms either by inhibiting their activity or by destroying them (Block, 1983)

Skin Disinfection:

Reduction in the numbers of bacteria on the skin through the application of bactericidal agents or antiseptics.

Double Scrub:

A method of donor skin preparation prior to phlebotomy as set out in the standard operating procedures of the Canadian Red Cross.

Post transfusion Septicemia:

A potential complication of blood product transfusion caused by bacterial invasion of the blood product (Blajchman, 1995).

Resident Skin Flora:

Organisms considered to be permanent residents of the skin. These include members of the groups *Staphylococci, Micrococci, Peptococci, Corynebacterium, Propionibacterium,* and *Acinetobacter* species (Larson, 1988; Noble, 1983).

Transient Skin Flora:

Organisms not demonstrated to be consistently present on the skin but can be picked up and colonize the skin during routine activities (Larson, 1988).

Summary

The continuing incidence of bacterial contamination of blood products remains a concern for health care professionals. Research has demonstrated that inadequate preparation of the venepuncture site prior to phlebotomy is one avenue by which microflora of the skin gain access to the blood product. Given appropriate storage conditions these microorganisms can rapidly multiply and produce endotoxins that can cause serious morbidity and mortality in patients receiving these transfusions. Nurses, responsible for preparation of the venepuncture site, must ensure that measures to promote the highest standards of skin disinfection are employed not only for the protection of the recipient of the transfused product but also for the donor. The aim of this investigation was to determine and compare the efficacy of three methods of skin disinfection used by nurses for donor phlebotomy site preparation in volunteer blood

donors. Results of this and similar investigations will assist in alleviating the morbidity and mortality associated with post transfusion septicemia as well as protect donors and patients who undergo invasive procedures from bacterial invasion of the body.

Chapter II--Review of the Literature

Introduction

This chapter will initially provide a brief historical perspective related to the events leading to our current state of knowledge on antiseptics and antiseptic practices. A discussion of the major types of microbial flora that are present on human skin, and their classification into transient versus resident flora is presented. The importance of skin disinfection for blood donors and its relationship to bacterial contamination of blood products is discussed. The effect of selected antiseptics and methods of skin disinfection on microbial flora is then provided. The chapter concludes with a summary of the literature review.

Historical Perspective

The term antiseptic was first referred to in a book written on the plague in the early 1700's which suggested that antiseptics might be valuable in counteracting the putrefication process (Russel et al., 1992). Following that time major advances were made in microbiology and aseptic practices which laid the basic foundation for skin disinfection protocols today.

In 1844, by means of a natural experiment, Ignaz Semmelweis noticed a striking difference in the rates of puerperal infection on maternity wards where midwives rather than medical students cared for patients (Jarvis, 1994). The incidence of death from child bed fever was strikingly higher on wards where medical students attended delivering

mothers. Semmelweis noted that these medical students dissected several cadavers daily whereas midwives did not and concluded that childbed fever was being transmitted on the hands of medical students (Sanford, 1992). He then ordered students to wash their hands in chlorinated lime after dissection and before attending to patients (Jarvis, 1994). The rate of infection and related death then markedly declined. Semmelweis had also noted an association between physician examination of a patient with a carcinoma of the uterus who had a foul smelling discharge and the development of puerperal fever in patients attended by the same physician following this (LaForce, 1993). He then concluded that both living and nonliving material could spread puerperal fever and insisted that students wash their hands between all patient examinations (LaForce, 1993). Semmelweis had essentially laid the foundation that demonstrated the importance of disinfection of the skin of the hands in preventing the transmission of infectious agents (Larson, 1993). Unfortunately Semmelweiss did not publish his findings for many years and the importance of skin disinfection in the prevention of disease transmission was not known by the medical community.

Although advances in infection control were not rapid over the next 100 years Sir Joseph Lister pioneered the search for antiseptics in the late 1800's (LeVeen, LeVeen & LeVeen, 1993). Lister was most intrigued by the work of Pasteur who had shown that air was contaminated with germs and that fermentation and putrefaction resulted from the growth of germs (LaForce, 1993). Lister packed the wounds of patients with severe fractures with lint soaked in carbolic acid, a substance a nearby town had used to treat a sewage problem (LaForce, 1993). Clinically dramatic improvements were now noticed in

wounds which would have otherwise been fatal. He then expanded this concept and used carbolic acid to clean his hands, equipment and operative sites prior to surgery (LaForce, 1993). Lister had therefore laid the foundation for the killing of bacteria on human skin or antisepsis.

Since the discoveries of Semmelweiss and Lister many advances have been made in the area of microbiology and antiseptics. Furthermore their discoveries have a direct link to the prevention of post transfusion septicemia and bacterial invasion of the donor through the appropriate and adequate cleansing of venepuncture sites with antiseptics prior to phlebotomy.

Microbial Skin Flora

The skin is richly inhabited with microbial flora that does not normally present any hazard to healthy individuals. The concept of resident versus transient flora was first described by Price in 1938. Resident flora are organisms that normally grow and reside on the skin and form a relatively consistent, permanent population (Russell, et al. 1991). These organisms are mainly nonpathogenic but may become opportunist and cause infection if transported into deeper tissues (Russel, et al., 1991). Price (1938) found that the size of the resident population normally found on the skin depends on a balance of bacterial multiplication and additions from various extraneous sources versus friction, washing and death of bacteria. Prolonged presence of contaminating bacteria on the skin can modify the resident population.

In contrast, transient flora are organisms that are deposited on the skin but do not

normally live and multiply there (Price, 1938; Russell, et al., 1991). Price suggests that these bacteria are gathered from extraneous sources and that there is no limit to the variety, both pathogenic and nonpathogenic, that can be present. Price also discovered that these bacteria are loosely attached to the skin by grease, fats and dirt and could be removed with relative ease by soap, water and friction. In contrast resident organisms are more firmly attached to the skin and require far more rigorous detergents or germicides for removal (Price, 1938). Price found that hands and arms harbored millions bacteria of which the majority were resident in nature. Resident organisms tend to be more difficult to remove. Strict attention to antiseptic preparation of the skin prior to injection or venepuncture is therefore essential.

All areas of human skin are inhabited by populations of microorganisms. Various characteristics on the skin surface determine the size and type of flora present. These include the state of hydration, the absence or presence of hair and hair follicles, the secretion of aqueous or lipid substances by eccrine, sebaceous or apocrine glands, skin temperature and skin pH (Noble, 1983). Depending on the variability of each of these factors they may either facilitate or prevent certain microbial growth. Noble postulates that the single most important factor in influencing skin flora is the degree of hydration. Increasing hydration results in dramatic increases in the number of microorganisms while drying the skin results in decreases (Noble, 1983). Therefore, the moist areas of the skin such as the head, thorax, armpits and perineum have the largest numbers of organisms while the drier areas such as the legs and arms support fewer colonies.

Although resident bacterial populations differ among individuals most will have at

least five of the following genera known to be resident of the skin: *Staphylococcus (S)*, *Micrococcus (M)*, *Peptococcus (P)*, *Corynebacterium (C)*, *Propionibacterium (Pr)* and *Acinetobacter (A)* (Jawetz, Melnick, Adelberg, Brooks, Butel & Ornston, 1989; Noble, 1983). In addition, the yeast Pityrosporum and the mite Demodex are frequently found (Noble, 1983).

Resident Populations

Staphylococcus Species

Staphylococcus epidermidis and *S. hominis* are the most prevalent and persistent aerobic, resident, nonsporeforming, gram-positive cocci found on the skin (Boyd & Hoerl, 1986; Noble, 1983). Both organisms are classified as coagulase negative staphylococci based on their inability to produce coagulase, a plasma-clotting protein (Boyd & Hoerl, 1986). These species are relatively resistant to salt and drying and are found on the dry areas of the skin such as the arms (Nester, McCarthy, Robers, Pearsall, 1973). *S. aureus*, normally known to be transient and coagulase positive can inhabit the skin and cause a variety of conditions such as impetigo, boils, carbuncles, abscesses and surgical wound infections (Nester et al., 1973).

Micrococcus Species

Although several species may be found, *M. luteus* and *M. varians* are the most common and numerous found on the skin (Noble, 1983). Like *Staphylococcus* these are also classified as aerobic, gram-positive cocci based on their ability to proliferate in the presence of air, their ability to retain dye on gram stain and their circular appearance arranged in pairs or groups when visualized microscopically (Nester, et al., 1973).

Micrococcus are nonpathogenic on the skin surface and play a major role in preventing the skin from pathogenic colonization (Nester et al. 1973). However, they can be opportunist pathogens in immunocompromised individuals causing such conditions as bacteremia, peritonitis, intracranial abscesses, septic arthritis and meningitis (Kloos & Bannerman, 1995).

Peptococcus Species

Only one species *P. saccharolyticus* is known to be resident on the skin (Noble, 1983). Peptococci are classified as anaerobic, opportunist, gram-positive cocci (Lancaster & Attebery, 1996, chap. 47). It is only found in about 20 % of people and therefore is not commonly studied (Noble, 1983). *Peptococcus* are an important cause of infections of the female genitalia, and head and neck including peridontitis, chronic otitis media, chronic sinusitis and brain abscess (Hillier & Moncla, 1995; Smith, 1980).

Corynebacterium Species

These aerobic organisms can be found fairly frequently on the skin of the forearm. Formerly called diphtheroids these organisms are small, nonsporeforming, opportunist, gram-positive rods of fairly low virulence (Nester et al, 1973; Boyd & Hoerl, 1986). Common species include *C. hofmannii, C. xerosis* and *C. diphtheriae* (Noble, 1983). *Corynebacteria* are known to cause diphtheria, pharyngitis, pneumonia, lymphadenitis and skin infections (Ryan, 1990).

Propionibacterium Species

These organisms are known to colonize the skin after puberty (Noble, 1983). The normal blood donor population is above the age of 17 and would therefore be expected to

harbour these organisms. The most common species found on the skin is *P. acnes* which is frequently isolated from acne lesions (Block, 1983). *Propionibacteria* can be occasionally associated with bacterial endocarditis in the severely immunocompromised (Ryan, 1990).

Acinetobacter Species

These are the only gram-negative bacilli found resident on the human skin (Noble, 1983). These organisms can be isolated from relatively dry areas of the skin, such as the forearm, in 20% of the population (Noble, 1983). One species, *Acinetobacter calcoaceticus* is being more frequently reported as an opportunist in a variety of hospital-related infections (Boyd & Hoerl, 1986). *Acinetobacter* cause pneumonia, urinary tract and soft tissue infections, and bacteremia related to contaminated intravenous catheters (Ryan, 1990).

Pityrosporum Species

These tiny yeasts are almost universally present on human skin. Two species are generally recognized *P. ovale and P. orbiculare* (Nester et al., 1973). Both species use fats present on the skin for growth (Nester et al., 1973). *Pityrosporum* are thought to cause a mild skin disease known as tinea versicolor which manifests as a scaly, patchy increase or decrease in skin pigment (Nester et al., 1973).

Demodex

The mite Demodex is an inhabitant of all humans (Noble, 1983). These obligate parasites inhabit hair follicles and sebaceous glands (Fritsche & Pfaller, 1995). This organism tends to proliferate when skin is damaged or conditions are abnormal and are

known to cause acne and blepharitis (Fritche & Pfaller, 1995).

Transient Populations

In a study by Puckett et al. (1992) skin swabs were taken from the arms of 782 blood donors to determine the presence of nonfermentative gram-negative rods. Organisms most frequently identified included *Pseudomonas spp, Flavobacterium spp* and *Moraxella*. Of the culture plates grown, 11.7% grew gram negative rods, 1.0% grew Pseudomonas spp and 0.3% grew *Pseudomonas fluorescens* specifically.

Organisms of the *Streptococcus* and *Neisseria* species are not known to be residents of human skin (Noble, 1983). However, as transients they can frequently grow and multiply when picked up during various activities.

Noble (1983) suggests that there are some age differences which influence normal flora of the body. Generally, the elderly tend to have a more restricted flora than young or middle-aged people and during puberty several flora changes also take place. Colonization with *Propionibacterium acnes, Propionibacterium avidum* and Pityrosporum occurs during puberty with women colonized slightly greater than men (Block, 1983).

In conclusion, the skin has both a resident and transient microbial population. Transient bacteria do not normally inhabit the skin but can become part of the skin population during routine activities. Resident populations are fairly stable colonies usually present on the skin. A transient organism may become resident given favourable conditions. Although not normally harmful, many of these organisms are opportunist pathogens and can cause disease if allowed to enter the body through various means such

as injection or venepuncture. There are some slight age variations in colonization of the skin. Methods to reduce the numbers of both categories of organisms on the skin are important prior to phlebotomy to prevent these organisms from entering both the donor and the blood product inevitably causing serious pathogenicity in both.

Importance of Skin Disinfection in Blood Donors

Microorganisms on the skin can be reduced in numbers by removing them physically, using friction with soap or another detergent and water or by killing them using a bactericidal agent (Russell et al., 1991). Transient bacteria are much more readily removed by cleansing with a detergent and water and are more easily destroyed using antiseptics than are resident bacteria (Russell, et al., 1991). It is essential that numbers of microorganisms on the skin be reduced prior to an invasive procedure. In blood collection this problem takes on additional significance because both the donor and the blood product recipient need to be protected from potentially harmful consequences of bacterial invasion.

Prior to invasive procedures in patients, health care personnel have adopted methods which combine friction and application of a bacteriostatic agent for skin preparation. In fact many commercial preparations now available not only contain various antiseptic combinations but also various ways they can be applied such as swabs, sponges and brushes. Both factors are considered essential in reducing microbial skin flora.

Blood donors frequently develop a life time pattern of making repeated frequent donations. After repeated venepuncture the phlebotomy site tends to become scarred and dimpled making adequate skin disinfection difficult (Blajchman, Ali & Richardson, 1994).

Microbial flora tend to collect in the dimpled areas of skin making access for disinfection purposes much more difficult. Gibson and Norris (1958) also reported that when a hollow needle is thrust through the skin the frequency of skin coring was nearly 70%. Attempts to avoid skin fragment removal by changing various aspects of the needle were unsuccessful. Thus the twofold problem is of special significance in blood collection where the health of the donor and recipient of the transfused product must be considered.

Bacterial Contamination of Blood Products

Sazama (1994) suggests that a new era in medical therapy began on November 14, 1914 when the first transfusion of citrated blood occurred. The first reported cases of transfusion-related sepsis occurred in the 1940's and 1950's (Sazama, 1994). During World War II the bacterial contamination rate of blood products was reported to be 8.5% or greater (Sazama, 1994). Blajchman (1995) reports that transfusion associated septic reactions during the 1940's were as high as 25%. During this time open glass systems were used for the collection and processing of donor blood and reusable containers were used for red cell transfusion (Blajchman, 1995). Since that time scientific advances have led to the replacement of glass bottles with closed system plastic collection packs. This has led to the hope and, for a time, the false sense of security of eliminating bacterial contamination of transfusion products (Blajchman, 1995). Although lower, today the contamination rate is reported to range between 0% and 7% (Sazama, 1994).

Bacterial invasion of blood products can occur either endogenously or exogenously. Endogenous contamination can occur from donor bacteremia during and

following illness or such procedures as dental work (Gottlieb, 1993). Exogenous contamination may occur inadvertently during all phases of collection, processing and transfusion of the blood product. Gottlieb states that the main cause of exogenous contamination is through inadequate skin preparation.

Whether bacteria introduced in collected blood will proliferate and cause harm to the recipient depends on the interplay of five factors:

I) the size of the inoculum introduced

ii) the type of bacterium and their ability to produce endotoxins

iii) the level of anti-bacterial factors present in the blood

iv) storage conditions for the blood product and

v) the health state of the recipient (Chiu et al., 1994; Morrow et al, 1991; Puckett, 1986; Sazama, 1994).

Logically , the greater the size of the inoculum the greater the chance for multiplication and overcoming of host defences as well as anti-bacterial factors present in the blood. However this is also dependent on the type of organism. In a study by Goddard, Jocobs and Manohithorajah (1973) growth of *Staphylococcus aureus*, *Staphylococcus epidermidis* and *Escherichia coli* introduced into 2.0 ml aliquots of platelet rich plasma was demonstrated from very small inocula. In another investigation by Myhre, Walker and White (1974) the introduction of greater sizes of inoculum of *Staphylococcus aureus, Staphylococcus epidermidis* and *Pseudomonas aeurginosa* into platelet packs were necessary for growth. Puckett (1986) inoculated very small numbers of *Pseudomonas aeurginosa, Pseudomonas putida, Pseudomonas fluorescens* and

Serratia liquefaciens, which are known to contaminate blood, and *Escherichia coli*, which is not normally implicated in bacterial contamination of blood, into pooled plasma. Results indicated that there was a much greater ability for the first four organisms to grow when compared to *Escherichia coli*. This demonstrates that both the size of the inoculum as well as the characteristics of the bacteria are important for bacterial proliferation. In addition, frequently blood products are transfused into recipients whose health and immune system are already compromised by disease, trauma or therapy itself. The recipients ability to overcome the invading organisms is therefore compromised.

The main microorganisms responsible for red blood cell contamination are reported by Sazama (1994) to include *Yersinia*, *Staphylococci*, *Micrococci*, *Bacillus* species, *diphtheroids*, *Streptococci*, *Paracolobactrum* species, *Pseudomonas aeruginosa* and *Escherichia freundii*. Certain bacteria such as *Aerobacter* species, *Staphylococci*, *diphtheroids*, *Streptococcus viridans* and *Pseudomonas aeurginosa* can completely overcome the bacteriostatic properties inherent in blood (Sazama, 1994). In addition Sazama reports that many of these bacteria grow well at refrigerator temperatures and use citrate as a substrate. For example *Pseudomonas fluorescens* and *Pseudomonas putida* generally grow well at varying temperatures including 4 degrees Celsius which is the standard storage temperature for red cell concentrates (Sazama, 1994). These organisms are called psychrophiles as they are capable of growth at temperatures of less than 5 degrees Celsius (Gottlieb, 1993). Gram-positive organisms such as *Staphylococcus* species, *Micrococcus* species, and *Streptococcus* species which frequently contaminate platelet products are known to grow well at temperatures of 22 to 24 degrees Celsius,

which is the typical storage temperature range for this product (Sazama, 1994).

Braude, Sanford, Bartlett and Mallery (1952) investigated the clinical significance of bacterial contaminants in transfused blood. It is noteworthy to mention that during this investigation glass bottles were utilized for the collection and storage of blood. Bacteria were cultured from 38 of the 1,697 bottles examined which represents a 2.24% contamination rate. The contaminants isolated most frequently were *Staphylococci*. The investigators concluded after sterility testing that the major source for this contamination was the air in the donor room. The clinical significance of transfusing these products was demonstrated by these investigators by transfusing blood heavily contaminated with *Staphylococci*, *Diphtheroids* or *Aerobacter aerogenes* into rabbits. Transfusions contaminated with *Staphylococci* and Diphtheroids produced fever in the rabbits but caused no further observable harm. However, transfusion of units contaminated with *Aerobacter* proved fatal in 11 out of 12 cases.

Sazama (1990) examined 256 deaths reported to the United States Food and drug Administration from 1976 through 1985 associated with transfusion. During this time frame an estimated total of 100 million units of red cells were transfused to 30 million patients (Sazama, 1990). Bacterial contamination of the blood product accounted for 10% or 26 of the fatalities (Sazama, 1990). Contaminated products involved both whole blood, including red cells, and platelets. Of the organisms implicated in the fatalities several are known to be either resident or transient on the skin including species of *Staphylococcus*, *Proprionibacterium*, and *Bacillus*. Nine of the fatalities were related to these organisms (Sazama, 1990).

Sazama (1994) discussed transfusion fatalities reported to the United States Food and Drug Administration due to bacterial contamination from 1976 to 1990. Although the number of transfusions was not reported for this period for comparison purposes, fatalities averaged three per year. Following the transfusion of platelets 28 fatal reactions were reported. For 17 of the fatalities gram-positive organisms such as *Staphylococcus epidermidis*, *Staphylococcus aureus*, *Streptococcus mitis*, and *Bacillus* species were implicated. For 11 of the fatalities gram-negative organisms such as *Klebsiella* species, *Serratia marcescens* and *Salmonella* species were implicated. For red blood cell transfusions 19 deaths were reported in the same time period. Six of the deaths were caused by gram-positive organisms such as *Staphylococcus aureus* and *epidermidis*, *Clostridium* species and *Propioni acnes*. For 13 of the deaths gram-negative organisms such as *Yersinia enterocolitica*, *Pseudomonas* species and *Escherichia cloacae* were implicated. Clinically, these patients first developed violent chills followed by high fever, tachycardia and eventually vascular collapse (Sazama, 1994). Other symptoms often reported that accompany bacterial sepsis include headache, back pain, marked hypotensive changes, vomiting and hematemesis accompanied by profuse bleeding confirmed to be disseminated intravascular coagulation (Sazama, 1994).

Frequently blood products are transfused into recipients whose health is already compromised by disease, trauma or therapy itself. The immune system is therefore unable to produce and mobilize sufficient defences to counteract even small numbers of invading organisms. The individual then succumbs to overwhelming bacteremia.

Bacterial contamination of blood is a problem that carries with it significant risk to

the recipient of these products. Many factors will interrelate to determine the nature and severity of the reaction. Health care professionals can assist in reducing this problem by utilizing methods that assist in preventing the possible contamination of these products.

Methods of Skin Disinfection--Antiseptic Preparations

This study investigated three antiseptic preparations namely: povidone-iodine; chlorhexidine and alcohol in combination; and alcohol and tincture of iodine in combination. Their efficacy in reducing bacterial counts when applied to the skin of volunteer blood donors were examined. These products were selected for study because currently the povidone-iodine and chlorhexidine/alcohol combinations are mandated as standard antiseptics for donor skin preparation at the Canadian Red Cross. The alcohol/tincture of iodine combination was reported by Goldman et al. (1997) to be superior to both products in decreasing bacterial arm counts, however, this is not currently an antiseptic that has been accepted for use by the CRCS. Larson (1988) suggests that the selection of an appropriate antiseptic solution must be based on four important factors:

I) the characteristics desired such as absorption through skin or mucous membranes, persistence, rapidity of reduction in flora and spectrum of microbial activity

ii) the evidence of safety and efficacy in its final formulation

iii) personnel (and donor) acceptance of the product and

iv) cost.

The properties, advantages and disadvantages of each antiseptic will be explored individually. The costs associated with using each antiseptic preparation are: iodine/iodine $.12 per donor; chlorhexidine/chlorhexidine $.45 per donor; and alcohol/tincture of

iodine $.44 per donor. There is a substantial price difference between the iodine preparation and the other two antiseptic combinations. If 60,000 units of blood were collected annually the cost of using iodine/iodine is $7200 and the cost for using each of the other two preparations is approximately $27,000. In this age of cost containment the advantages of using one of the more expensive products must be clearly justified.

The history of skin antiseptics is a story of new skin antiseptics enthusiastically embraced and uncritically adopted. Only over time have they been subjected to more critical evaluation and many eventually discarded. The effectiveness of each antiseptic is often a subject of great debate and controversy.

Povidone-Iodine

An iodophor such as povidone-iodine is a combination of iodine and a solubilizing agent or carrier called polyvinylpyrrolidone (Rutala, 1996). This compound provides a sustained-release reservoir of iodine and releases small amounts of free iodine in aqueous solution (Rutala, 1996). 'Free' iodine is the key ingredient that determines the bactericidal property of this compound (Rutala, 1996). Dilutions of povidone-iodine result in decreased iodine linkage to the carrier polymer with an increase in free iodine available for bactericidal purposes (Rutala, 1996).

The bactericidal effects are the result of cell wall penetration, oxidation and substitution of microbial contents with free iodine (Larson, 1988). Povidone-iodine has the broadest spectrum of any antimicrobial available and is effective against gram-positive and gram-negative bacteria, the tubercle bacillus, fungi, viruses as well as some activity against bacterial spores (Larson, 1988). However its antibacterial activity is reduced in

the presence of proteins such as in pus and exudates (Murphy, 1995). Larson (1988) reports that iodine must be on the skin for two minutes to allow release of free iodine and therefore maximum bactericidal effectiveness.

All iodophors have the potential to cause various side effects including contact dermatitis and more serious side effects such as acidosis and thyroid abnormalities if larger quantities are systemically absorbed (van Ketel & van den Berg, 1990). Van Ketel and van den Berg found that after patch testing eight patients with contact eczema caused by povidone-iodine containing compounds all but one patient showed a positive patch-test reaction to povidone-iodine. Other patch tests were done with Betadine preparations, potassium iodide and iodine tincture. All patients with positive reactions to Betadine preparations or povidone-iodine or both showed negative reactions to potassium iodide and to iodine tincture. These authors concluded that sensitization to povidone-iodine is more common than seems to be reported in the literature and that allergy to povidone-iodine seems not to be based on allergy to iodine.

LeVeen et al., (1993) report that available iodine is not responsible for the bactericidal properties of povidone-iodine and available iodine must be converted to free iodine for this effect. These authors also suggest that a 10% solution of povidone-iodine contains as little as 0.8 parts per million of free iodine which may not be sufficient to kill all bacteria. LeVeen et al. conclude that povidone-iodine is only a weak antiseptic and is only marginally acceptable as a skin disinfectant.

In 1963 King and Price repeatedly tested four iodophors to determine skin bactericidal effectiveness. The iodophors investigated included Ioclide, Virac, Ioprep and

Betadine. The serial basin hand-scrubbing technique was employed using five subjects. The procedure consisted of scrubbing the hands and arms of experienced subjects in a series of basins of sterile water then standardly applying the test antiseptic followed by washing the hands and arms with an antiseptic neutralizer to avoid antiseptic carry over into subsequent wash basins. Final scrubbing of hands and arms were done in another series of basins and serial bacterial counts of these washings were performed. Controls in the study included strength and temperature of the antiseptic solutions and the duration and method of applying it to the skin. These four iodophor antiseptics were tested 36 times and then results were compared with the use of 1% iodine in 70% alcohol and with ivory bar soap and brush. Results indicated that all iodophors were pleasant to use and did not cause skin, eye or nasal irritations. All iodophors were similar in their degerming effects and were more effective in this regard than a soap scrub alone. However when compared with a 1% iodine in 70% alcohol they were significantly less effective in their degerming abilities. These investigators concluded that although iodophors are more effective than soap and water they are inferior to 1% iodine in 70% alcohol.

Lilly and Lowbury (1971) compared the effectiveness of povidone-iodine (1% available iodine) in 70% alcohol with formulations of benzalkonium chloride, cetrimide, chlorhexidine and a control application of sterile water in reducing bacterial contamination of the hands. Each of the preparations were tested on five subjects. Repeat testing was performed for each preparation on different subjects in alternate weeks to allow return of normal skin flora. Bacterial counts were taken from standard handwashings taken before and after a two minute application of the test antiseptic. The culture medium and

sampling fluid contained appropriate neutralizers to prevent the effects of antiseptic carry over. These preparations were required to cause maximum reduction of bacteria after a single application which would resemble the technique used on an operative site. Both alcoholic povidone-iodine and chlorhexidine caused comparable reductions in skin flora and caused significantly greater reductions than benzalkonium chloride and cetrimide for this purpose.

Jacobsen, Grabe and Damm (1986) compared the effectiveness of povidone-iodine versus 70% isopropyl alcohol as a skin disinfectant in a prospective randomized study of 227 intravenous cannulations. Insertion techniques, cannulation time and culturing technique were all standardized so differences were attributed to the skin disinfectant alone. Patients were randomly divided into two groups based on the disinfectant utilized. The groups were comparable with regard to diagnosis, type of operation, type of anesthesia, age and sex. To evaluate possible errors of sampling and culturing, 60 unused catheters were cultured either immediately after opening or after eight hours. All were culture negative. Significantly lower ($P<0.01$) intraluminal contamination was found in the group using povidone-iodine (7.25%) as a skin disinfectant when compared with the alcohol (20.4%) contamination rate.

Thompson, Jowett, Flowell and Sutton (1989) in a study of 200 adult patients in a Coronary Care Unit concluded that they were unable to demonstrate the superiority of povidone-iodine versus 70% alcohol in decreasing the incidence of cannula-related thrombophlebitis caused by local infection or mechanical irritation from the cannula when using povidone-iodine versus 70% alcohol to cleanse the insertion site prior to

cannulation. Patients admitted to the Coronary Care Unit were randomly assigned to treatment groups. Catheters were inserted by house officers or nurses to resemble standard practice. Cannula were removed and cultured when signs of inflammation developed or just prior to discharge. Microbiologists processing the samples were unaware of the treatment group of each of the cannulae. The inflammation rate and the positive cannula culture rate of the iodine (test) and the alcohol group (control) were not statistically significant.

In a review of 10 published studies carried out from 1967 to 1993 Larson (1994) examined the effectiveness of skin disinfection products that were used for skin preparation prior to intravascular line insertion or phlebotomy for blood culture. In five of these studies comparisons were made between isopropyl alcohol and povidone-iodine. In three of the studies no significant differences between these products were found. In the two additional studies povidone-iodine was associated with lower colonization rates than isopropyl alcohol. When the combination of isopropyl alcohol and ethanol chlorhexidine versus isopropyl alcohol and povidone-iodine were compared the colonization rates were 2.7% and 13.7% respectively. Larson concluded that povidone-iodine is slightly better than isopropyl alcohol at reducing catheter colonization but products containing chlorhexidine held greater promise.

Stand, Wajsbort and Sturmann (1993) compared the effectiveness of iodine tincture versus povidone-iodine as skin preparation agents used to collect 8467 blood cultures. Blood culture contamination rates were used as the main outcome measure of effectiveness. To minimize procedure bias a pairwise comparisons-across-phases trial

design was utilized. Skin disinfection using iodophor occurred in phases one and three and using iodine tincture in phases two and four. All adult patients who presented to a large urban hospital who required blood culture collection during the study period were included. The blood culture collection procedure and culturing procedure were standardized. The contamination rate for blood cultures collected using povidone-iodine was 6.25% and for tincture of iodine 3.74%. This difference was statistically significant ($P<0.00001$). The authors suggested that tincture of iodine was therefore more effective than povidone-iodine when used as a skin antiseptic prior to blood culture.

Controversy exists in the literature regarding the effectiveness of povidone-iodine as a skin antiseptic. When compared to isopropyl alcohol, povidone-iodine seems to demonstrate superior performance in decreasing microbial flora. However povidone-iodine appears inferior when compared to preparations of tincture of iodine and chlorhexidine. The time factor involved for the release of free iodine from povidone-iodine, which is the effective antimicrobial agent, is also cause for concern in that povidone-iodine is only left on the skin for a maximum of one minute prior to venepuncture.

Isopropyl alcohol

In the course of this investigation isopropyl alcohol is not used alone as a skin antiseptic but is used in combination with either chlorhexidine or tincture of iodine. A combination product of chlorhexidine and alcohol is currently used at the CRCS only for donors allergic or sensitive to iodine. Alcohols applied to the skin are in common use as antiseptics. Alcohol derives its antimicrobial effect by denaturation of proteins (Larson,

1988). Isopropyl alcohol used in concentrations of 60% to 90% is rapidly bactericidal against gram-positive and gram-negative organisms and demonstrates good tuberculocidal, fungicidal and virucidal properties (Rutala, 1996). Isopropyl alcohol, however, is not sporicidal (Larson, 1988). Isopropyl alcohol is relatively inexpensive and is generally well received because of its colorlessness (Morton, 1993, p. 225). The major disadvantages of alcohol for skin antisepsis are its drying effects and its rapid rate of evaporation (Larson, 1988). Added emollients have assisted in decreasing these disadvantages by helping to minimize skin drying and slowing the drying time thereby increasing the contact time on the skin (Larson, 1988). Alcohol is said to be the most rapid acting of all the antiseptics however its effectiveness is diminished by the presence of organic matter (Larson, 1988).

In a review of the literature from 1967 to 1993 Larson (1994) concluded that isopropyl alcohol was inferior to povidone-iodine as a skin antiseptic. Results of a study conducted by Doebbeling, Stanley, Sheetz, Pfaller, Houston, Annis, Li and Wenzel (1992) comparing the effectiveness of chlorhexidine versus isopropyl alcohol for hand washing on the incidence of nosocomial infections in 1894 adult ICU patients found similar results. This prospective multiple-crossover study was conducted in three intensive care units of a large urban hospital over an eight month period. This study was not blinded nor was randomization attempted. Two handwashing systems were compared in the study, one involving a 4% solution of chlorhexidine gluconate and the other involving a 60% isopropyl alcohol hand rinsing agent with the optional use of a separate nonmedicated soap. Subjects in each of the two groups did not differ appreciably on selected

characteristics when examined. Education regarding appropriate use of each hand cleansing agent was provided to all staff. Culturing methods were standardized. The incidence of nosocomial infections when using chlorhexidine as a hand washing agent was 152 and 202 for alcohol. When hand cultures were obtained following hand washing with chlorhexidine or isopropyl alcohol the rate of hand carriage was higher in the isopropyl alcohol group for gram-negative organisms and fungi. Alcohol demonstrated slightly superior performance with gram-positive organisms. These authors concluded that chlorhexidine was superior to isopropyl alcohol as a hand antiseptic.

Grabe, Jacobsen and Damm (1985) in a prospective randomized study evaluated the effectiveness of 70% isopropyl alcohol versus no skin disinfectant prior to intravenous cannulation on intraluminal contamination rates. One hundred and eighty-seven surgical patients were randomly assigned to one of the two study groups. The two groups were comparable with regard to diagnosis, type of operation, type of anesthesia, age and sex. The type of cannula, persons and procedures for performing the cannulation and the culturing method were standardized. The intraluminal contamination rate following skin preparation with isopropyl alcohol was 22.6% and 22% after cannulation with no preceding skin disinfection. There was no significant difference between the two groups with respect to the contamination rate. The authors concluded that the use of 70% isopropyl alcohol as a skin antiseptic before intravenous cannulation did not prevent or even reduce intraluminal contamination.

Various studies have demonstrated the superiority of isopropyl alcohol over other antiseptic agents for skin preparation. Larson and Bobo (1992) evaluated the effect of

blood on the antimicrobial activity of 70% isopropyl alcohol, 70% ethyl alcohol and 0.5% chlorhexidine, detergent containing 7.5% povidone-iodine, detergent containing 4% chlorhexidine, a nonantimicrobial soap and no product used for hand washing. Seventy-two healthy adult volunteers were assigned by block randomization to one of the six treatment groups based on the product being tested. Subjects were tested on two occasions. The first test involved rubbing a measured amount of sterile sheep blood onto the hands of each subject and then air drying. Subjects then performed a standardized 15 second hand cleansing using the assigned product. This procedure was repeated three days later except that blood was not applied. Hands were cultured using a standardized procedure before and after application of the test product with and without blood. Colony-forming units (CFU) were then counted. Baseline CFU counts were not significantly different among subjects but post-treatment differences were significant ($P<0.05$). Results indicated that in the presence of blood the isopropyl alcohol and the ethyl alcohol resulted in significantly greater reductions in the number of colony-forming units when compared to the other products or no product. When no blood was present, isopropyl alcohol was associated with significantly greater reductions than other agents.

The literature basically suggests that alcohol is inferior to most other products as a skin antiseptic except in the presence of blood. In this study alcohol is not treated alone, but is used in combination with chlorhexidine and tincture of iodine. It may provide a more rapid reduction in bacterial counts due to its fast onset of action and may initially help in reducing bacterial counts if proteins such as blood are present on donor arms.

Chlorhexidine

Chlorhexidine as a skin antiseptic is used for the rapid disinfection of hands, operative sites and injection sites. Chlorhexidine derives its antimicrobial activity by causing disruption of microbial cell membranes and precipitation of cell contents (Larson, 1988). Although it has a fairly broad spectrum of activity it is known to be more effective against gram-positive than gram-negative organisms (Larson, 1988). It has also demonstrated little effect against the tubercle bacillus and fungi (Larson, 1988). Chlorhexidine has demonstrated good activity against many viruses (Larson, 1988). Although chlorhexidine demonstrates a fairly rapid onset of action within about 15 seconds it is not as rapid as isopropyl alcohol (Larson, 1988). However, one of the key properties that chlorhexidine is well known for is persistence (Larson, 1988). As a result of its strong affinity for the skin it remains active for up to six hours (Block, 1983; Larson, 1988). Chlorhexidine continues to demonstrate bactericidal properties in the presence of organic matter such as blood (Block, 1983). Chlorhexidine has a relatively low skin absorption, irritation and sensitization rate although concerns such as contact dermatitis and contact urticaria have been reported (Larson, 1988; Okano, Nomura, Hata, Okada, Sato, Kitano, Tashiro, Yoshimoto, Hama, Aoki, 1989). Larson (1988) suggests that the combination of the very rapid effect of alcohol and the persistence of chlorhexidine would be a desirable antiseptic preparation.

Studies comparing the effectiveness of chlorhexidine preparations as a skin antiseptic generally report the superior performance of this antiseptic. Maki, Ringer and Alvarado (1991) studied the efficacy of 10% povidone-iodine, 70% alcohol and 2%

aqueous chlorhexidine applied to 668 central venous and arterial catheter sites before insertion and every other day thereafter to determine the incidence of catheter-related infection. Adult patients admitted over a seven month period to a surgical intensive care unit at a large urban hospital participated in the study. At the time of insertion each catheter was randomly assigned to one of the three test groups. Sites were cultured before skin preparation and again at the time of catheter removal. Catheter cultures were also obtained at the time of removal. Sites were assessed and scored for inflammation at each dressing change. Microbiologists processing the cultures had no knowledge of the antiseptic group that the culture originated from. No significant differences between the groups were noted when inflammation was assessed. Catheters remained in place for a similar mean duration in each group. Overall 37 catheters (24 central venous and 13 arterial) demonstrated colonization. Central venous catheters in the chlorhexidine group were significantly less likely to show local catheter-related infection on removal when compared to the povidone-iodine group or the other two groups combined. The data for both central venous and arterial catheters demonstrated that chlorhexidine significantly prevented local catheter-related infections when compared to other products. The alcohol and povidone-iodine provided comparable protection against infection. Chlorhexidine was associated with the lowest incidence of local catheter-related infection and catheter-related bacteremia.

Champagne, Fussell and Scheifele (1984) compared the effectiveness of a solution of 0.5% chlorhexidine in 70% ethanol versus a two-step procedure using 70% isopropyl alcohol followed by either the chlorhexidine-ethanol combination or povidone-iodine in

reducing bacterial growth on forearms of neonates in isolettes. Results suggested that the two-step application of isopropyl alcohol followed by chlorhexidine-ethanol was most effective at decreasing bacterial growth.

Goldblum, Ulrich, Goldman, Reed and Avasthi (1983) also found favourable results when comparing the effects of betadine versus hibiclens (a chlorhexidine compound) on the microbial flora of hemodialysis patients. A total of 46 hemodialysis patients and 24 hemodialysis personnel were admitted to the study. Subjects were instructed not to use any germicidal agents on their skin during the study period. For the first 13 weeks of the study povidone-iodine was used for skin preparation prior to the hemodialysis procedure. For the next 13 week test period 4% chlorhexidine in a detergent base was used. Skin preparation procedures were standardized. Personnel scrubbed their own forearms using one of these solutions. Cultures were taken using Rodac contact plates once a week over the vascular access site for the hemodialysis patients. Hemodialysis personnel were cultured weekly as well. In addition, three times during each 13 week period patients and personnel were cultured at two and four hour intervals after skin disinfection during the course of a procedure. Pre-disinfection cultures for both staff and patients were not significantly different for the two study periods. Two and four hour patient post-disinfection colony counts demonstrated that a significantly greater reduction occurred with chlorhexidine use. The same result was found with staff for the two hour post-treatment cultures. Other results were not statistically significant. Chlorhexidine was found to be superior to Betadine in reducing bacterial counts and also had the advantage of a longer duration of activity which persisted throughout the hemodialysis procedure.

In a hand washing study by Lilly and Lowbury (1971) comparing 0.75% chlorhexidine digluconate and 3% hexachlorophane liquid, the hexachlorophane was found to be slightly superior in reducing resident skin flora. In this same study authors compared four preparations for effectiveness in disinfecting the skin of operative sites. The iodine/alcohol preparation and the chlorhexidine/alcohol preparation demonstrated equally good reduction in resident skin flora. Both of the antiseptic combinations were more effective in reducing skin flora than cetrimide or benzalkonium chloride.

In another hand washing study conducted by Nicolette, Boghossian and Borland (1990) 12 subjects hands were artificially contaminated with Micrococcus and Serratia organisms. Subjects and individual hands of subjects were randomly assigned to treatment groups. Each subject received all treatments. Two chlorhexidine handwash detergents and liquid soap were compared for both a rapid and sustained effect after a single contact and for a cumulative persistent effect after several contacts over four days. Application of the test organisms to the skin, handwashing technique and culturing method were standardized. Results for the single contact study indicated that chlorhexidine formulations were significantly better than soap in their activity against Micrococcus but were not more effective than soap in removing contamination with Serratia. Both chlorhexidine preparations demonstrated significant skin persistence.

Generally, chlorhexidine preparations have performed well in studies comparing the efficacy of this versus other antiseptic agents in reducing microbial contamination of the skin. Chlorhexidine is generally well tolerated after application and has a sustained duration of action.

Tincture of Iodine

Tincture of iodine is similar to povidone-iodine in its mode and rapidity of antibacterial action and spectrum of activity (Larson, 1988). However, free iodine is present in this antiseptic which leads to greater degerming properties when compared to povidone-iodine (Block, 1983). Tincture of iodine has a much greater potential than povidone-iodine to cause skin irritation, allergy, pain or toxic effects in sensitive individuals (Larson, 1988: van Ketel & van den Berg, 1990). Tincture of iodine has a dark reddish-brown color and has a tendency to stain skin and clothing if appropriate care is not taken.

Tincture of iodine in combination with isopropyl alcohol has demonstrated excellent antimicrobial properties when used as a skin antiseptic. As previously discussed, Strand, Wajsbort and Sturmann (1993) report the superiority of 2% tincture of iodine vs povidone-iodine as a skin antiseptic prior to blood culture collection. The contamination rate for the blood cultures collected using iodine tincture was reported to be 3.74% and 6.25% for povidone-iodine. This difference was statistically significant.

Goldman, Roy, Frechette, Decary, Massicotte and Delage (1996) compared the efficacy of four different methods of blood donor phlebotomy site disinfection as measured by bacterial growth on contact plates. One hundred and ninety-six adult blood donors participated in the study. Results indicated that preparations with a combination of alcohol/tincture of iodine were significantly more effective than povidone-iodine or green soap/isopropyl alcohol preparations in reducing bacterial growth. Preparations with povidone-iodine and chorhexidine gluconate resulted in similar amounts of bacterial

growth following disinfection. However, significant to this investigation was that varying methods for applying each antiseptic preparation were used. This may in fact account for some of the difference in bacterial growth on contact plates as one method may be more superior than others in mechanically removing organisms from the skin.

Preparations that include tincture of iodine appear to have developed popularity in the literature as preparations for skin disinfection prior to invasive procedures. However tincture of iodine tends to be more staining to the skin and must be removed.

Effect of Method of Application of the Antiseptic

Studies are not consistent in their method of applying the antiseptic agent on the skin for cleansing purposes. Several studies suggest that this may be an important variable in reducing bacterial flora of the skin. In an unpublished study by Pleasant, Marni and Stehling (1994) for the Blood Systems Foundations in Scottsdale Arizona , three skin preparation products were compared for positive skin culture rates following arm preparation prior to phlebotomy in 300 blood donors. Skin preparation products included a sponge with 70% isopropyl alcohol followed by an applicator with 2% tincture of iodine; a swab with povidone-iodine followed by a swab with povidone-iodine; and a swab with 70% isopropyl alcohol followed by a swab with 2% tincture of iodine. Each skin preparation method was used for 100 donors. The positive skin culture rate was significantly lower for the skin preparation product using the sponge with 70% isopropyl alcohol followed by the 2% tincture of iodine applicator. The main bacteria cultured were *bacilli* and *Staphylococci.* This investigation also suggests that the effectiveness of skin preparation regimes varies not only with the type of antiseptic utilized but also with the

method used to apply the antiseptic. In this study a lower positive skin culture rate was evident using the alcohol/tincture of iodine sponge/applicator method than the alcohol/tincture of iodine swab/swab method.

In a study by Goldman et al. (1997) conducted at the Transfusion Centre of Quebec for the Canadian Red Cross Blood Services various methods of skin preparation were compared for effectiveness as measured by bacterial growth on contact plate cultures. A standard, mandated double scrub skin preparation method using a povidone-iodine swabstick followed by a povidone-iodine swabstick was compared to either a 70% isopropyl alcohol sponge followed by an ampule of 2% iodine tincture (n=126),or a sponge with green soap followed by an isopropyl alcohol swab (n =30) or a 0.5% chlorhexidine gluconate/70% isopropyl alcohol sponge followed by a 0.5% chlorhexidine gluconate/70% isopropyl alcohol ampule (n=40). Results indicated that there were significantly more bacterial colonies per plate after iodophor swab disinfection versus isopropyl alcohol sponge/tincture of iodine ampule disinfection. There were significantly more bacterial colonies per plate after green soap/isopropyl alcohol disinfection versus iodophor disinfection. Bacterial growth was similar for iodophor versus the chlorhexidine preparations. These investigators suggest that both the type of disinfectant and the method of application used may influence the effectiveness of the disinfection.

Summary

Since the discoveries of Semmelweiss and Lister major advances have been made in microbiology and infection control. As a result of the skin being richly inhabited with both resident and transient flora health care personnel must carefully cleanse the skin prior

to any invasive procedure. In the realm of blood collection and transfusion both the donor and the recipient of the blood product must be protected from these potentially opportunist pathogens. Although a false sense of security developed when closed blood collection systems were adopted, there still remains a well documented problem with the risk of significant patient morbidity and mortality. Many investigators have demonstrated that a primary reason for bacterial contamination of these products is related to inadequate skin disinfection of the donor venepuncture site prior to phlebotomy. Controversy continues to exist in the literature regarding the most effective skin disinfection regime for this purpose. This investigation will compare three methods of antecubital fossa skin cleansing prior to phlebotomy in an effort to find possible solutions to this concern. The following chapter describes the research approach including the study design, the population and sample selected, the data collection protocol, methods of data analysis and the ethical considerations employed in this investigation.

Chapter III--Methodology

Introduction

The major aim of this study was to investigate and compare the efficacy of three methods of antecubital fossa skin disinfection used for donor phlebotomy site preparation in volunteer blood donors. This was measured by skin surface cultures before and after arm preparation. This chapter describes the details of the study design, the population and sample, the sample recruitment procedure, the data collection protocol, the methods of data analysis and the ethical considerations for the study.

This quantitative research investigation utilized a repeated measures quasi-experimental design to investigate the proposed questions. A deliberate effort has been made to utilize similar methods and techniques as reported by Goldman et al. (1997) in their study entitled 'Evaluation of Donor Skin Disinfection Methods' carried out at the Canadian Red Cross Transfusion Centre of Quebec in Montreal. The combined results of these investigations will provide further evidence for consideration by the Canadian Red Cross when examining the issue of effective methods of skin disinfection prior to blood culture.

Similarities between the two studies exist in three of the skin preparation regimens being examined, namely, povidone-iodine/povidone-iodine, chlorhexidine-alcohol/chlorhexidine-alcohol and isopropyl alcohol/tincture of iodine and their application devices. Similarities also exist in the culturing method, using Rodac contact plates and the method of analysing the contact plate bacterial growth. Differences between the studies

exist in sample size and the use of povidone-iodine in the Quebec study for every donor (control). In the Quebec study the concentration of chlorhexidine that was used as a skin preparation agent was 0.5%. In this study the chlorhexidine concentration in the preparation was 2%. The Canadian Red Cross discontinued the use of 0.5% chlorhexidine as the distributor of this product reported superior bacterial reductions with the higher concentration. This study also utilized different agar ingredients to investigate growth of bacterial colonies. In addition this study did not attempt to assess the efficacy of 30 second versus 60 second scrubs as the 60 second scrub was found to be too irritating to donors arms. This study also did not attempt to examine and compare the sensitivity of culture plates versus a swab system as effective culturing methods but instead utilized the results of their comparison in selecting the best method.

Study Design

This study explored the efficacy of three methods of antecubital fossa skin disinfection used for donor phlebotomy site preparation in volunteer blood donors. Both before and following preparation of the venepuncture site, skin cultures were obtained by placing sterile contact plates on the antecubital fossa of these donors. Within two hours of collection culture plates were incubated at 35 to 36 degrees Celsius and bacterial colony counts were obtained at 24 and 48 hours. The major independent variable of interest in the study is the method of skin preparation utilized as this is the variable that will be manipulated during the investigation (Shelley, 1984). The dependent variable, or the effect that is presumed to be caused by manipulation of the independent variable, is the bacterial growth on contact culture plates (Polit & Hungler, 1991).

This study is classified as quasi-experimental in that like true experimental designs the independent variable, skin preparation method, was manipulated (Polit & Hungler, 1991). However this study lacks both randomization and a control group which are characteristics of true experiments (Polit & Hungler, 1991). Randomization is difficult to achieve in a natural setting such as the blood donor clinic because attendance for the purpose of blood donation is often a result of a pre-telephone conversation made by blood donor recruitment personnel to encourage donation. This call is only made to individuals who have a recorded history of donation but who have not done so for at least 56 days.

To control for potential procedural error only one skin preparation regimen was made available for study at any one time. Donors who provided consent to participate had skin preparation performed with the method selected during that time frame. However randomization for selection of the method to be used at any particular time was done. One skin preparation method was used for a total of approximately forty subjects and then the next method was instituted.

A repeated measure design was utilized in that pre-disinfection and post-disinfection cultures were measured and compared within each group as well as across the three different groups according to skin preparation regimen. Within group comparisons and across group comparisons for both pre-disinfection and post-disinfection cultures were made. Lack of a control group was based on the additional expense required for testing additional subjects and the lack of available funding for the project.

Population and Sample

The population for the study included all individuals in Winnipeg, Manitoba and

surrounding area who were eligible and who elected to donate a unit of whole blood during the time frame of the data collection. Data were collected on July 29 and 30, 1997. Eligibility to donate whole blood and therefore the inclusion criteria for the sample was based on the following factors:

1. ability to provide informed consent;
2. age range of 17 to 71 years;
3. a time interval of 56 days since last whole blood donation;
4. a generally good state of present and past health as determined by a health interview/screening procedure performed by a Registered Nurse with standards defined by the Donor Section Criteria Manual of the Canadian Red Cross Blood Services (Appendix A);
5. absence of stated lifestyle factors that predispose to the transmission of infectious organisms through blood transfusion as defined by the Donor Selection Criteria Manual of the Canadian Red Cross Blood Services;
6. a minimum hematocrit of 38%;
7. intent to donate a unit of whole blood;
8. attendance at the Winnipeg Centre clinic only.

Individuals who presented to the Red Cross Blood Services Donor Clinic located at 226 Osborne Street North, during the period the investigation was conducted and who met all sample inclusion criteria were invited to participate. Subjects sensitive or allergic to the skin preparation regimen being used at the time were omitted from the study. A total of 124 blood donors participated in the investigation. Subjects were divided into

three groups based on skin preparation regimen with 42 in the povidone-iodine group, 42 in the chlorhexidine group and 40 in the tincture of iodine group.

Nonprobability sampling using a convenience sample, which were subjects who presented for blood donation, was used for the investigation. Main population variables that would influence differences in the dependent variable included age, sex and number of previous donations. This data were collected for each subject and comparisons were made across groups.

To determine sample size, assistance was obtained from a Statistical Consultant affiliated with the Manitoba Nursing Research Institute. A power analysis was performed for the purpose of obtaining the largest sample size possible within the funding constraints. The level of significance was set at .05. The medium effect size, which is concerned with the strength of the relationship between research variables was 0.3 (Polit & Hungler, 1991). For a power of 80% a sample size of 36 subjects per group was determined. For a power of 90%, 48 subjects per group were required. A decision to include approximately 40 subjects per group with a total sample size of approximately 120 (N) therefore provided a power of between 80% to 90%.

Sample Recruitment Procedure

Blood donors who presented for purposes of blood donation during the data collection time frame were invited to participate in the study by Registered Nurses following completion of the health interview and after determining eligibility to donate based on sample inclusion criteria. Participants were introduced to the general nature of the study and provided with both an information sheet and a consent form describing the

details of the investigation (Appendix B). Potential participants were given an opportunity to seek clarification and ask questions during this time. Consent for participation was then obtained by having the participant sign and date the consent form and the Registered Nurse performing the health interview witness the consent. Consent to participate was again verbally confirmed by the nurse performing the phlebotomy prior to beginning the skin cleansing procedure.

Data Collection Protocol

One of three skin preparation regimens was utilized during separate data collection periods. Donors underwent the usual skin preparation and phlebotomy required to collect a unit of blood. During the time the blood was being collected skin preparation was completed by Registered Nurses on the arm not being used for phlebotomy. Skin preparation, for this investigation, occurred on the arm not being used for phlebotomy due to the strict no-touch technique required as well as the skin preparation solution required at present for use as regulated by industry standards. One of the following three skin disinfection methods was used on each subject:

1. A commercially prepared swab scrubstick saturated with povidone-iodine (0.75% titratable iodine) followed by a swab saturated with povidone-iodine (1% titratable iodine) (Appendix C)
2. A commercially prepared sponge with 2% chlorhexidine gluconate and 70% isopropyl alcohol followed by an applicator with 2% chlorhexidine gluconate and 70% isopropyl alcohol (Appendix D)
3. A commercially prepared sponge with 70% isopropyl alcohol followed by an applicator

with 2% iodine tincture (Appendix E).

Just prior to skin preparation a culture contact plate was applied to the antecubital fossa, for approximately three seconds, on the arm being used for the study.

Skin preparation on all subjects was performed by Registered Nurses who had been trained and annually certified by a Canadian Red Cross Clinical Instructor in the double scrub, no touch technique procedure used for skin preparation prior to phlebotomy for the collection of transfusable or fractionated products. Nurses were provided with an information sheet detailing the nature of the study, a review of the procedure for collection of the cultures and an opportunity to ask questions related to the methodology.

The two step skin preparation regime included:

1. Initially scrubbing the antecubital fossa approximately four centimeters (cm) in all directions from the potential intended site of venepuncture (an area 7.5 cm in diameter) for a minimum of 30 seconds using one of the identified products. This included either the povidone-iodine scrub swabstick, the sponge with 2% chlorhexidine gluconate/ 70% isopropyl alcohol or the sponge with 70% isopropyl alcohol. This scrub was timed for 30 seconds using a calibrated timing device.

2. Starting at the potential intended site of venepuncture and moving outward in a concentric spiral, for an area approximately 7.5 cm in diameter, the second product was applied, corresponding to the above solutions. This included either a swab with povidone-iodine (1% titratable iodine), an applicator with 2% chlorhexidine gluconate/70% isopropyl alcohol or an applicator with 2% tincture of iodine. This solution was then allowed to sit on the skin for a minimum of 30 seconds. Again timing

for 30 seconds was accomplished using a calibrated timing device (Canadian Red Cross, Blood Services, Standard Operating Procedure: Venepuncture; Nursing 180, Directive D94-038 Preparation of the Venepuncture Site (Double Scrub Procedure)). Immediately following the skin cleansing procedure a second culture contact plate was applied to this area for three seconds.

For purposes of identifying the source of the culture contact plates ABO labels were applied. ABO labels are affixed to each unit of blood collected and are unique identifying numbers used for blood traceability. Additionally each plate was coded with a number 1 or 2 indicating preprocedure culture versus postprocedure culture respectively. Culture plates were also coded with the letters A, B, or C indicating the povidone-iodine, chlorhexidine or tincture of iodine group respectively. Within two hours of culturing, all contact plates were delivered to the Quality Control Department of the Winnipeg Centre Blood Services for incubation at 35 to 36 degrees Celsius. Observation and recording of microbial growth occurred at 24 and 48 hours respectively by the main investigator and by trained staff of the Quality Control Department. Records for recording of the data were supplied by the investigator (Appendix F). The Quality Control Department staff performing the observations and recording were not aware of what skin preparation regimen was being tested at the time.

The culture contact plates contained a D/E neutralizing agar prepared by and obtained from PML Microbiologicals in Mississauga, Ontario. These plates were 65 mm diameter Rodac contact plates prepared using the ingredients as specified in Appendix G.

A certificate of quality for the D/E Neutralizing agar was obtained from the

supplier (Appendix G). Sheikh (1981), reports that neutralization is an important property of culture media when evaluating the bactericidal properties of antiseptics to eliminate the possibility of residual antiseptic action carry over into the recovery media. Sheikh (1981), tested and validated a similar identified neutralizing system for its neutralizing capacity for three antiseptics namely, Hibiclens (4% chlorhexidine gluconate), Betadine (7.5% povidone-iodine) and pHisohex (3% hexachlorophene). This system was also tested for its lack of inherent bactericidal action against *Staphylococcus aureus* and various gram-negative bacteria. This neutralizing system was found to be 100% effective in neutralizing all bacteriostatic carry-over and lacked bactericidal properties against all organisms tested.

The use of contact plates is a simple, effective and fast method for obtaining skin cultures. The agar surface of the plate is momentarily pressed on the skin, removed and incubated with bacterial colony counts taken directly from the plates (Ulrich, 1964; Williams, Gibson, Aitchison, Lever & Mackie, 1990). However, it must be born in mind that the contact plate samples only the most superficial layers of the skin and does not sample any layers below the skin surface which are also known to harbour microflora (Brown, Wenzel, Hendley, 1989; Williams et al., 1990).

Viable counts of organisms may be reported as numbers of colony-forming units (cfu) (Collens, Lyne & Grange, 1995). A viable count is based on the premise that a visible colony develops on the culture medium from each viable unit which may be one organism or a group of many (Collins et al., 1995). Bacterial colony counts were measured and recorded by the main investigator and the Quality Assurance staff of the

Canadian Red Cross. Colony-forming units were recorded for the pre-skin preparation at 24 and 48 hours. Post-preparation counts were also reported at 24 and 48 hours to allow sufficient time for even small amounts of bacterial growth. The presence of greater than 100 colony-forming units on culture plates was reported as Too Numerous To Count (TNTC) rather than the actual number. Difficulty was encountered in accurately counting individual colonies when greater than 100 colonies were present on any plate.

Demographic data collected for subjects participating in the study included age, gender and number of donations. This information was collected by the principle investigator from the registration information of donors who consented to participate. Review of the literature revealed that there are some slight differences in normal microbial skin flora as a result of age and sex. In addition repeated venepuncture in the antecubital fossa of donors who have multiple donations can cause scarring and dimpling of the skin making adequate skin disinfection more difficult. Therefore the variables of age, sex and number of donations were important factors that needed to be considered in determining if there were any significant differences in the study sample characteristics that might have affected the results.

Data Analysis

Demographic data were analyzed using descriptive statistics to allow comparisons for the three groups on the variables of age, sex and number of donations. Analysis of Variance (ANOVA) was used to test for differences in pre-disinfection colony counts across the three groups. The primary outcome measures of comparisons of groups for pre-disinfection and post-disinfection bacterial counts following application of each of the

three skin cleansing procedures were determined using repeated measures analysis of variance . Null hypotheses were as follows:

1. No differences were evident on pre-procedure bacterial colony counts for each of the three groups prior to the skin preparation regimen.

2. No differences were evident on pre-procedure versus post-procedure bacterial colony counts when comparing the use of povidone-iodine/povidone iodine, chlorhexidine-alcohol/chlorhexidine-alcohol or alcohol/tincture of iodine for the skin preparation regimen.

3. No differences were evident on post-procedure bacterial colony counts when comparing treatment groups using povidone-iodine/povidone-iodine, chlorhexidine-alcohol/chlorhexidine-alcohol or alcohol/tincture of iodine.

Statistical software utilized to assist in the analysis of data was Statistical Package for the Social Sciences (SPSS) available through the Manitoba Nursing Research Institute (SPSS Inc., 1997). Statistical advice and guidance was obtained through the use of a Statistical Consultant again from the Manitoba Nursing Research Institute.

Analysis of Variance (ANOVA) is a parametric procedure used to test the significance of differences between group means (Polit & Hungler, 1991). Using repeated measures ANOVA the means of three or more groups can be compared (Polit & Hungler, 1991). The statistic computed using ANOVA is the F-ratio statistic which contrasts the variation between treatment groups and the variation within treatment groups (Polit & Hungler, 1991). Polit and Hungler (1991) state that "if the differences between groups receiving different treatments is large relative to fluctuations within groups, then it is

possible to establish the probability that the treatment is related to, or resulted in, the group differences" (p. 443).

Ethical Considerations

Prior to conducting this investigation this study was approved by the Ethical Review committee of the Faculty of Nursing, University of Manitoba (Appendix H). In addition, consent to conduct the study at the Canadian Red Cross Blood Services, Winnipeg Centre was requested and granted by the Centre Director (Appendix I).

Informed consent was obtained from all study participants by having them read, sign and date a prepared consent form detailing the nature of the investigation (Appendix B). Additional written information that detailed the nature of the study was provided along with the consent to each potential participant. Both the consent and the information sheet emphasized the voluntary nature of participation, the freedom to withdraw at any time during the course of the investigation without penalty and the minimal potential risks or benefits to study participants. Participants were provided the opportunity to ask questions regarding the investigation to the Registered Nurses obtaining the consent in a private screening room. Registered Nurses signed as witnesses to the informed consent. Registered Nurses performing the scrub procedures again verified consent verbally prior to initiating the additional skin disinfection protocol. Participants were invited to obtain a summary of the research results.

A written information sheet detailing the nature of the investigation and stating the voluntary nature of participation was distributed to all staff working in the Clinic Operations Department at the Canadian Red Cross Blood Services on the days of the

investigation (Appendix J). Opportunity was provided to ask questions of the principle investigator. The voluntary nature of participation in the study without risk or benefit was emphasized. Nurses were given control over temporarily discontinuing data collection during busy clinic periods.

Confidentiality of subjects was protected using ABO label numbers only. ABO labels were applied to each culture plate and consent form. The ABO label was used to trace the demographic information of each study participant. Access to donor information through the use of ABO labels is restricted to CRCS employees who, at the time of employment, sign strict confidentiality agreements.

Access to raw uncoded data was restricted to the principle investigator. Data for statistical analysis and discussion had been previously coded using ABO label number. Data and consents will be stored for seven years in a separate locked cabinet and then destroyed.

Summary

This quantitative, quasi-experimental investigation was designed to assess and compare the efficacy of three methods of antecubital fossa skin disinfection prior to phlebotomy in volunteer blood donors. This investigation was modelled after a similar investigation conducted by Goldman et al. (1997) at the Transfusion Centre of Quebec in Montreal. The similarities and differences between the two studies were highlighted. Details of the population, sample size, inclusion criteria, study design, data collection protocol and data analysis have been provided. Factors considered in the ethical protection of human subjects have also been presented. The following chapter provides

details of the results of the investigation.

Chapter IV--Results of the Investigation

Introduction

This chapter provides a discussion of the findings of the investigation. The study sample characteristics are described in relation to the variables of age, gender and number of previous blood donations. Differences between the three treatment groups in relation to these three variables are highlighted. A comparison of three treatment methods on the outcome measure of colony counts using repeated measures analysis of variance is described.

Data for this study were obtained over a two day period on July 29 and 30, 1997. Data for the investigation were analysed using SPSS, a statistical software package (SPSS Inc., 1997). Statistical consultation was obtained through the Manitoba Nursing Research Institute.

Sample Characteristics

A total of 124 subjects were included in the results of the study. One hundred and twenty-nine people initially participated in the investigation. Two of the above individuals were excluded from the study due to inadvertent contamination of the agar plates while measuring colony counts. Three other subjects were excluded from the results because careful examination of the raw data revealed that the observations from these three participants were recorded on the incorrect group observation record. To avoid possible errors in the data these subjects were excluded.

Subjects were divided into groups based on the antiseptic skin preparation being

tested. Group A, the povidone-iodine/povidone-iodine subjects had a total of 42 participants. Group B, the chlorhexidine/chlorhexidine subjects had a total of 42 participants. Group C, the alcohol/tincture of iodine subjects had a total of 40 participants.

Subjects ranged in age from 17 to 69 years with a mean age of 42.5 years (Table 1). Participants were required to be a minimum of 17 years old and a maximum of 71 years old to be a blood donor and therefore participate in the study. The mean age of subjects in Group A, B and C was 43.0, 42.26 and 42.18 years of age respectively. Analysis of variance to compare treatment groups on the variable of age indicated that there was no significant difference (F=0.047; p=0.954) for the groups. An alpha level of 0.05 was used for all statistical tests.

Seventy-nine (63.7%) of the total number of subjects were men. Forty-five (36.3%) of the subjects were women. In group A were 22 men and 20 women, group B 28 and 14, and in group C 29 and 11 respectively (Table 1). A Pearson Chi-Square test indicated that there was no statistically significant differences when comparing the groups (chi square= 3.827; p=0.148) on the variable of gender.

The number of previous donations for subjects ranged from 0 to 169. The mean number of previous donations made by the subjects was 38.27. The average number of previous donations made by subjects in Group A, B and C were 35.6, 44.6 and 34.4 respectively (Table 1). Analysis of variance to compare treatment groups with respect to number of previous donations indicated that there was no significant difference (F=1.025; p=0.362) between the groups. Although the variable of number of previous donations is

not normally distributed the Central Limit Theorem indicates that for sample sizes over 10 to 20 the normality assumption is unnecessary as ANOVA is robust in regard to assumptions about distributions (Norman & Streiner, 1994).

Statistical analysis suggests that groups are relatively similar with respect to age, gender and number of previous donations of subjects. Results of treatment effects should therefore not be attributed to any major differences in these variables.

Table 1

Demographic Data

Variable	Category	Group A (n=42)	Group B (n=42)	Group C (n=40)	Total Group (N=124)
Age	**Mean Age**	43.0	42.26	42.18	42.48
	Minimum	17	20	17	17
	Maximum	68	68	69	69
Gender	**No. of Males**	22	28	29	79
	No. of Females	20	14	11	45
Number of Previous Donations	**Mean**	35.57	44.64	34.42	38.27
	Minimum	0	1	1	0
	Maximum	115	169	107	169

Pre-disinfection and Post-disinfection Bacterial Colony Descriptive Data

Group A consisted of 42 subjects who had skin disinfection performed using povidone-iodine/povidone-iodine. Pre-disinfection colony counts at 24 and 48 hours ranged from 0 to Too Numerous to Count (TNTC) colony-forming units (cfu).

Colony counts 100 or greater were extremely difficult to accurately count so all cases of colony counts 100 or greater were assigned the maximum value of 100 for statistical analysis purposes. The mean colony count at pre-disinfection 24 and 48 hours were 34.86 cfu and 45.38 cfu respectively. Post-disinfection colony counts at 24 and 48 hours ranged from 0 to 12 cfu and 0 to 100 cfu. Mean colony counts for these same time intervals were 1.19 cfu and 4.10 cfu respectively (Table 2).

Group B consisted of 42 subjects who had skin disinfection performed using chlorhexidine-alcohol/chlorhexidine-alcohol. Pre-disinfection colony counts at 24 and 48 hours ranged from 0 to TNTC cfu. Mean colony counts for these groups for these time periods were 28.71 cfu and 39.40 cfu respectively. Post-disinfection colony counts for 24 and 48 hours ranged from 0 to 7 cfu with mean colony counts for these time periods of 0.71 cfu and 0.95 cfu (Table 2).

Group C consisted of 40 subjects who had skin disinfection performed using alcohol/tincture of iodine. Pre-disinfection colony counts at 24 and 48 hours ranged from 0 to TNTC cfu. Mean colony counts for these groups were 27.05 cfu and 41.48 cfu respectively. Post-disinfection colony counts at 24 and 48 hours ranged from 0 to 100 cfu. It was interesting to note that all post-disinfection colony counts from subjects in group C ranged from 0 to 7 with the exception of one subject who had post-disinfection colony counts of 28 and 100 cfu at 24 and 48 hours. This subject also had high pre-disinfection colony counts of TNTC at both time measurement intervals. Mean post-disinfection colony counts for 24 and 48 hours were 1.18 cfu and 3.23 cfu (Table 2). Table 3 presents information regarding the frequency of bacterial colonies per plate.

Table 2

Group Data for Mean Bacterial Colony Counts

	Group A	Group B	Group C	Total
Pre 24 Hour cfu	34.86	28.71	27.05	30.26
Pre 48 Hour cfu	45.38	39.40	41.48	42.10
Post 24 Hour cfu	1.19	0.71	1.18	1.02
Post 48 hour cfu	4.10	0.95	3.23	2.75

Table 3

Postdisinfection Frequency of Bacterial Colonies per Plate by Group

	Group A		Group B		Group C	
Hours	**24**	**48**	**24**	**48**	**24**	**48**
Colony Counts						
0	21	16	29	24	26	21
1-10	20	24	13	18	13	18
11-20	1	1	0	0	0	0
over 20	0	1	0	0	1	1

Treatment Effect Results

Null hypothesis # 1 stated that no differences were evident on pre-procedure bacterial colony counts for each of the three groups prior to the skin preparation regimen. To test this hypothesis, one-way ANOVA testing was utilized. No statistically significant differences were found when comparing groups for the pre-procedure 24 hour ($F=0.601$; $p=0.550$) and 48 hour counts ($F=0.260$; $p=0.771$) (Table 4). Therefore groups were comparable in pre-procedure counts and the first null hypothesis was accepted. These results were confirmed using General Linear Model Repeated Measures Analysis of Variance when examining groups at 24 and 48 hour predisinfection intervals ($F=0.603$; $p=0.549$ for 24 hour comparisons) ($F=0.471$; $p=0.626$ for 48 hour comparisons) (Table 5).

Null hypothesis #2 stated that no differences were evident on pre-procedure versus post-procedure bacterial colony counts when comparing the use of povidone-iodine/povidone-iodine, chlorhexidine-alcohol/chlorhexidine-alcohol and alcohol/tincture of iodine skin preparation regimens. Using General Linear Model repeated measures ANOVA, comparisons were made of the 24 hour pre-disinfection versus post-disinfection and 48 hour pre-disinfection versus postdisinfection counts for groups. Results indicated that there was a statisitically significant difference when comparing the 24 hour pre-disinfection versus post-disinfection and 48 hour pre-disinfection versus post-disinfection colony counts for the groups ($F=93.739$; $p<0.001$, for 24 hours) ($F=133.873$; $p<0.001$, for 48 hours) (Table 6). Therefore the second null hypothesis was rejected. All antiseptics demonstrated that they were effective in decreasing bacterial colony counts. Based on

Table 4

ANOVA--Preprocedure Counts

	SS	df	Mean Square	F	Sig.
Pre cfu 24 hour	1400.13	2	700.06	0.601	0.550
Pre cfu 48 hour	772.840	2	386.42	0.260	0.771

Table 5

Repeated Measures ANOVA--Preprocedure Counts

	SS	df	Mean Square	F	Sig.
Pre cfu 24 hour	735.978	2	367.989	0.603	0.549
Pre cfu 48 hour	873.785	2	436.892	0.471	0.626

Table 6

Repeated Measures ANOVA--Test of Effectiveness of Antiseptics

Source	SS	df	Mean Square	F	Sig
Pre and Post 24 hour	52765.38	1	52765.38	93.739	0.000
Pre and Post 48 hour	95850.82	1	95850.82	133.873	0.000

these results it is apparent that bacteria on the skin are reduced in number by application of an antiseptic agent.

Null hypothesis #3 stated that no differences were evident on post-procedure bacterial colony counts when comparing treatment groups using povidone-iodine/povidone-iodine, chlorhexidine-alcohol/chlorhexidine-alcohol and alcohol/tincture of iodine. The General Linear Model repeated measures Analysis of Variance was again used to test this. No statistically significant difference was found when analysing this treatment effect (F= 0.595; p=0.553, for 24 hours) (F=0.084; p=0.920, for 48 hours) (Table 7). The third null hypothesis was therefore accepted. Each of the antiseptic preparations demonstated similar effectiveness in their ability to reduce bacterial contamination of the skin.

Table 7

Repeated Measures ANOVA--Test of Comparison of Effectiveness of Antiseptics

Source	SS	df	Mean Square	F	Sig
24 Hour Time* Group	670.255	2	335.127	0.595	0.553
48 Hour Time* Group	119.806	2	59.903	0.084	0.920

In conclusion, results indicated that there were statistically significant differences in pre-disinfection versus post-disinfection colony counts for all treatment groups. Furthermore, each of the antiseptic preparations demonstrated similar effectiveness in their

ability to reduce bacterial contamination of the arm.

Summary

In conclusion, the three antiseptic skin cleansing preparations were comparable in their ability to reduce bacterial contamination of the skin prior to phlebotomy. Prior to an invasive procedure these three antiseptic preparations demonstrated effectiveness in decreasing bacterial contamination of the arm. Subjects in the three groups were comparable for the variables of age, gender and number of previous donations which the literature indicated may have some effect on microbial flora. The similarity in the three groups for these variables rules out the possibility that any treatment effects were related to differences in sample characteristics. The pre-disinfection 24 and pre-disinfection 48 hour bacterial colony counts also did not show any significant differences between groups. This also suggests that treatment effects were not influenced by prior differences in the study sample characteristics.

The following chapter discusses the results of this investigation in comparison to results from similar studies. The limitations of the study are explored. Implications this investigation has for current and future nursing practice are highlighted. Suggestions for future research in this area are provided.

Chapter V--Discussion

This chapter provides a discussion of the results of the investigation in relation to the main purpose for the research. A comparison is presented of the findings of this study with other salient research in the area. The limitations of the study are outlined. Implications for nursing practice and suggestions for further research in the area are highlighted.

Discussion of Treatment Effects

The major aim of this study was to investigate and compare the efficacy of three methods of antecubital fossa skin disinfection used for donor phlebotomy site preparation in volunteer blood donors. Two major research questions were investigated. The first question investigated the effectiveness of each antiseptic preparation in reducing bacterial growth following disinfection. Significant differences were found on colony counts within subjects. The greatest difference in mean bacterial colony counts occurred between the pre- and post-disinfection stages. All antiseptic products were therefore effective in decreasing bacterial contamination of the arm prior to venepuncture.

The second research question compared the effectiveness of the three antiseptic preparations. The results of this investigation suggested that there were no significant differences in the effectiveness of these three products when using reduction in surface bacterial colony counts as the primary outcome measure. All three antiseptic preparations effectively reduced the number of bacteria present on the skin following disinfection and should therefore assist in preventing the contamination of blood products during

collection.

Of interest, however, is the method by which the antiseptic agents were applied to the skin. This purpose for this study was to investigate the effects of antiseptic preparations that were currently being used by the CRCS for skin preparation and one new product. Therefore, control over the method of application of the antiseptic was not possible. The chlorhexidine/alcohol combination and the alcohol/tincture of iodine combination were applied using exactly the same devices, namely a sponge followed by an applicator. The povidone-iodine/povidone-iodine combination was applied using swabsticks. It is difficult, based on these results, to determine if mode of application of the antiseptic influenced the results or if just the antiseptic product itself was the significant factor in bacterial reduction.

The methodology in this investigation was similar to that employed by Goldman et al. (1997). Goldman and associates found that the isopropyl alcohol/tincture of iodine demonstrated significantly greater reductions in bacterial growth than either the chlorhexidine/alcohol or the povidone-iodine combinations. However there were no significant differences in bacterial growth after disinfection between the povidone-iodine and the chlorhexidine/alcohol groups. This latter result is consistent with the findings of this investigation. Both studies utilized the same methods for application of the test antiseptic preparations so this would not account for any differences in results. Goldman and colleagues used a 0.5% concentration of chlorhexidine while this investigation used a 2% concentration as the supplier of this product reported greater bactericidal effects with the higher concentration. The comparable effectiveness of tincture of iodine and

alcohol/chlorhexidine in the current study may be related to the higher concentration of the chlorhexidine employed. Differences in the results of these two studies may also be related to the differences in the culture media employed. Initially, for the purposes of this investigation, the same agar used by Goldman and associates was to be used. However, once prepared and during quality control of the agar preparation, PML Laboratories reported that this particular agar was inhibiting the growth of salient skin microorganisms. A decision was then made to use an agar preparation that had an established record for growth of skin microorganisms for the purposes of this investigation. This may account for the differences in the results reported by the two studies.

Goldman et al. (1997) did not investigate the samples to determine if treatment groups were similar with respect to age, gender and number of previous donations. These three factors are known to play a role in bacterial colonization of the skin. Treatment groups in this investigation were similar with respect to these three variables. This factor may also account for differing results in the studies.

Other research in this area present differing views on the comparable effectiveness of these products. Strand et al. (1993) found that tincture of iodine was more effective than povidone-iodine when used as a skin antiseptic prior to blood culture collection. The main outcome measure for this investigation was blood culture contamination rates rather than skin surface bacterial colony counts. To be comparable this investigation would have had to examine blood product contamination rates, which is difficult to monitor given the nature of the current standard approved collection packs and rapid release of blood products from blood banks. Shahar, Wohl-Gottesman and Shenkman (1990) suggest that

blood culture contamination rates may not be related to the venepuncture site preparation but may be more related to later stages of laboratory handling and processing.

Pleasant et al. (1994) also report the superiority of the alcohol/tincture of iodine when applied using the sponge/applicator combination over both povidone-iodine applied using swabs and alcohol/tincture of iodine using swabs. Bacterial skin cultures before and after disinfection were used as the primary outcome measure. The result of greater effectiveness using the alcohol/tincture of iodine combination may in fact be more related to the method by which the antiseptic was applied than the actual antiseptic properties. It is difficult to evaluate the methodology employed in this study as the investigation was not published.

Maki et al. (1991), based on the results of their study, advocate the use of chlorhexidine preparations over povidone-iodine preparations for skin disinfection before insertion of an intravascular device and for postinsertion care. These investigators suggest that the effectiveness of the chlorhexidine in preventing catheter-related infections is probably related to the sustained duration of action of this antiseptic. Thus chlorhexidine may be especially appropriate for situations that require long-term placement of intravascular devices.

Lily and Lowbury (1971) found that povidone-iodine and alcoholic chlorhexidine were equally as effective in disinfecting the skin of hands. These results were similar to the findings of this investigation but employed a method that obtained bacterial cultures from standard handwashings taken immediately before and after the application of the disinfectant.

Controversy continues to exist in the literature regarding effectiveness of antiseptic agents. Studies vary in their method of application of the test antiseptic, culturing medium and technique employed, and primary outcome measure of antiseptic effectiveness. Differences in the results of this study in comparison to other studies may be attributed to these variables.

Limitations of the Study

This study employed a different mechanism for application of one of the test antiseptic preparations. It is therefore difficult from the results to determine if the application device had any effect on the efficacy of the antiseptic product. No conclusions can therefore be drawn from this research regarding whether the antiseptic preparation or the application device influenced bacterial colonization rates. Any inferences made from these results must take this factor into consideration.

All nurses employed at the CRCS and certified in the double scrub no-touch technique, who wanted to participate in the study, performed the arm cleansing and culturing of donor arms. It is reasonable to assume that all nurses would therefore be performing the arm cleansing according to standard protocol. However, slight variation in technique by individual nurses may have had implications for the results.

The sample size for the investigation was 124 subjects with approximately 40 subjects per treatment group. A larger sample size might have demonstrated differences in treatment effects and results similar to other research in the area. However, there is no reason to believe that this sample is not representative of the blood donor population in general as subjects age, gender and number of previous donations covered the spectrum of

what would normally be expected in blood donors. Lack of available funding for the research project required that a conservative sample size be utilized.

Implications for Nursing Practice

Nurses performing skin cleansing prior to an invasive procedure have a responsibility to ensure that effective methods for bacterial reduction of the skin are employed. The three antiseptic products tested in this investigation were effective in decreasing the bacterial contamination of the arm prior to phlebotomy. This continues to be an important nursing measure for protection of the donor or patient from the harmful effects of potential opportunist pathogens.

Based on the results of this study, all three test antiseptic preparations were equally effective in decreasing bacterial colonization. Focus for the selection of an antiseptic product for use prior to an invasive procedure could now be related to such factors as the acceptability of these products to donors/patients, the ease of application of the product, the preference of the nurse for mode of application, and the cost. These factors take on significance in a setting, such as a blood donor clinic, where customer service is paramount. Many problems arise with the use of products that are iodine based due to the staining qualities of this antiseptic. It is not uncommon to have this antiseptic preparation splatter on donor's clothing resulting in inconvenience to the donor and laundering or replacement expenses for the blood collection facility. In addition if visible droplets of iodine contact the blood collection bag, industry regulations stipulate that this blood cannot be used for transfusion . This can result in the loss of many units of blood that could have been used for transfusion. Additionally, the cost of using an antiseptic can

become a factor for consideration. The cheapest of the three antiseptics tested is the povidone-iodine combination at $0.12 per donor. This is approximately $0.30 per donor cheaper than each of the other products. If the antibiotic preparations are equally effective it is reasonable to assume that the preparation with the least cost would be used.

Recommendations for Future Research

Currently there is a paucity of research that investigates the effects of the method of application of the antiseptic product. There is potential to examine both the effectiveness of the method of application and such factors as the preference of nurses/donors, and ease of application of a particular method. Further research could also investigate whether a double scrub versus single scrub procedure, for donor arm preparation, is more effective in reducing bacterial contamination.

Further studies using large sample sizes, similar culturing techniques and outcome measures need to be conducted. This is especially relevant considering the controversy that continues to exist over the effectiveness of antiseptic products. Controlling for any possibility of variability in the method by which the skin cleansing and culturing were performed would be an important consideration to enable this to be ruled out as a variable that could affect results.

Summary

The results of this study indicate that continuing to utilize antiseptic skin preparation methods prior to an invasive procedure significantly reduces the degree of bacterial contamination of the site and therefore may assist in preventing opportunist pathogen infection of both the donor and the blood product. Results also indicated that

there were no differences in effectiveness of the three preparations tested in reducing bacterial colony counts on the arm. The results of this investigation may be used to reinforce to care providers the importance of skin disinfection prior to an invasive procedure. These results may also be used to select the type of antiseptic preparation product used prior to venepuncture in blood donors, based on the cost-effectiveness of the product, given that all preparations were equally effective in decreasing bacterial contamination.

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APPENDIX A

HEALTH ASSESSMENT QUESTIONNAIRE

APPENDIX B:

INFORMED CONSENT

Canadian Red Cross

RECORD OF DONATION

I.D. Card Imprint	Clinic Site	Clinic Date Day / Month / Year
	Donor I.D.	Birth Date Day / Month / Year
	Surname	
	First Name and Initial	Title
	Home Phone ( ) -	Business Phone ( ) - / Sex

Apt.	Street Address	City	Prov.	Postal Code

Alert Code	Def. Code	Date Eligible	Special Information	Pref. Lang	New I.D. Card

Preferred Clinic	# Previous Donations	Zero Recall	Blood Group: Rh	$CuSO_4$ P / F	Hgb/Hct A / D	Wh. Bld	Plasma	Plts.	Auto.	Specs.	Other

BP	Pulse	Skin Lesions Yes / No	Perm. Deferral	Alert Code	Delete	Temp. Deferral	Duration Days	Pack Type	Pack Lot	Bleed Time Start / Stop

	Temp.	Comments:

PLACE BAR CODED LABEL HERE

UNIT LABEL	Reg. Initials	Donor Accepted Y N	1st Venepunc. Initials L / R	2nd Venepunc. Initials L / R	Bleed Time Initials	Labeling Init.
	Tech. Initials	R.N. Signature				Verification Init.

ANSWER YES OR NO TO QUESTIONS 1 TO 11

UNIT LABEL

YES	NO		
☐	☐	1.	a) Are you feeling well today?
☐	☐		b) Do you have a cold, flu, sore throat, fever, infection or allergy problem today?
		2.	In the last three days have you:
☐	☐		a) taken any medicine or drugs (pills including Aspirin or shots), other than birth control pills and vitamins?
☐	☐		b) had dental work?
		3.	In the last 3 months have you:
☐	☐		a) had a vaccination?
☐	☐		b) if female, breast-fed a baby?
☐	☐		c) taken Accutane for skin problems?
		4.	In the last 6 months have you:
☐	☐		a) been under a doctor's care, had surgery, taken Cyclomen (Danazol)?
☐	☐		b) if female, been pregnant?
☐	☐		c) taken Proscar for prostate problems or Methotrexate?
		5.	In the last 12 months have you:
☐	☐		a) had a tattoo, ear piercing, skin piercing, acupuncture, electrolysis, graft, injury from a needle, or come in contact with someone else's blood?
☐	☐		b) had a rabies shot?
☐	☐		c) had close contact with a person who has had hepatitis or yellow jaundice?
☐	☐	6.	a) Have you ever taken Tegison or Soriatane for skin problems?
☐	☐		b) Have you ever received human pituitary gonadotrophin hormone (sometimes used for treatment of infertility or to promote weight loss) or human pituitary growth hormone?
☐	☐		c) Have you ever received a corneal or dura mater (brain covering) graft?
		7.	Have you ever had:
☐	☐		a) yellow jaundice (other than at birth), hepatitis or liver problems?
☐	☐		b) epilepsy, coma, stroke, convulsions or fainting?
☐	☐		c) heart or blood pressure problems or heart surgery?
☐	☐		d) cancer, diabetes, ulcerative colitis or Crohn's disease?
☐	☐		e) kidney, lung or blood problems?
☐	☐		f) Chagas' disease, babesiosis or leishmaniasis?
☐	☐	8.	Are you aware of a diagnosis of Creutzfeldt-Jakob Disease among any of your blood relatives (parent, child, sibling)?
☐	☐	9.	a) Have you ever had malaria?
☐	☐		b) In the last three years, have you been outside Canada, the U.S. or Europe?
☐	☐	10.	Have you ever had an AIDS test other than for donating blood?
☐	☐	11.	Have you ever given blood elsewhere in Canada or under a different name?

STOP HERE

DO NOT ANSWER QUESTIONS 12 TO 27

☐	☐	12.	a) Do you have AIDS?
☐	☐		b) Have you ever had a positive test for the AIDS virus?
☐	☐	13.	Have you used cocaine within the last 12 months?
☐	☐	14.	Have you ever taken illegal drugs or illegal steroids with a needle even one time?
☐	☐	15.	At any time since 1977, have you taken money or drugs for sex?
☐	☐	16.	Male donors: Have you had sex with a man, even one time since 1977?
☐	☐	17.	Have you ever taken clotting factor concentrates for a bleeding disorder such as hemophilia?
☐	☐	18.	Have you had sex with anyone who has AIDS or has tested positive for the AIDS virus?
☐	☐	19.	Female donors: In the past 12 months, have you had sex with a man who had sex, even one time since 1977 with another man?
☐	☐	20.	Have you had sex in the last 12 months with anyone who has ever taken illegal drugs or illegal steroids with a needle?
☐	☐	21.	At any time in the last 12 months, have you paid money or drugs for sex?
☐	☐	22.	At any time in the last 12 months, have you had sex with anyone who has taken money or drugs for sex?
☐	☐	23.	Have you had sex in the last 12 months with anyone who has taken clotting factor concentrates?
☐	☐	24.	In the last 12 months, have you had or been treated for syphilis or gonorrhea?
☐	☐	25	In the last 12 months, have you received blood or blood products by transfusion for any reason, such as an accident or surgery?
☐	☐	26	In the past 12 months, have you had sex with someone whose sexual background you don't know?
☐	☐	27.	a) Were you born in or have you lived in any of the following countries since 1977: Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger or Nigeria?
☐	☐		b) If you have traveled to any of those countries since 1977, did you receive a blood transfusion or any medical treatment with a product made from blood?
☐	☐		c) Have you had sexual contact with anyone who was born in or lived in these countries since 1977?

I have read and understand the information about how the AIDS virus may spread by donated blood and plasma. I agree not to donate blood, plasma, platelets or white cells, if I believe there is a chance this might spread the AIDS virus. I understand the procedure and any side effects and complications associated with my (whole blood), (plasmapheresis), (cytapheresis) donation. I understand that my blood will be tested for hepatitis, syphilis, AIDS and other factors to make the blood supply safer. I understand that my positive test results will be given to me in confidence, that they will be reported to Public Health if required by law. I have answered all questions truthfully. I agree to donate blood for use as decided by Red Cross. Please call the Red Cross Centre if after giving a donation you decide for any reason your blood should not be used.
Optional: My results may be forwarded to my family doctor, whose name is:

Doctor: _____ Address: _____

Date: _____ Donor Signature: _____

Donor Informed Consent
For a Study on the Effectiveness of Antiseptic Skin Cleansing Methods

I, _____ (printed name), have read and understood the information inviting me to be a participant in a research investigation that will explore the effectiveness of three methods of antiseptic skin cleansing prior to venepuncture. I understand that this study is being conducted by a graduate student as part of a Master of Nursing thesis who is also the Clinic Operations Manager for the Canadian Red Cross Blood Services. I am aware that this study has been approved by the Ethical Review Committee of the Faculty of Nursing.

I give consent to have an additional arm cleansing procedure using either iodine, chlorhexidine, alcohol or a combination of these ingredients. I will make the nurse, doing the skin cleansing, aware of allergies or sensitivities I have to any of these products. I agree to allow a culture contact plate to be applied to my skin for several seconds both before and after the skin cleansing.

I understand that the costs to me as a study participant are minimal and involve subjecting my arm to another skin cleansing procedure. I also understand that the benefits to me as a participant are minimal but results will help improve the safety of the blood supply by exploring measures to decrease the risk of bacterial contamination.

I understand that my participation in the study will be confidential and known only to the researchers in the project and to the Canadian Red Cross staff collecting the blood. I agree to allow data regarding my age, gender and number of donations be obtained from my Registration sheet to allow analysis of the study population. This data will be confidentially stored by the main researcher in a separate locked cabinet for seven years. I also understand that my participation is strictly voluntary and I am free to withdraw at any time during the course of the investigation without penalty.

I have had an opportunity to have all my questions answered regarding my participation in the study. By signing below I hereby give consent for participation.

I agree to participate in this project.

Participants Signature _____ Date:_____

Witness Signature: _____ Date_____

Study Conducted by: RaeAnn Thibeault, Graduate Student, Faculty of Nursing, University of Manitoba

EXPLANATION FOR A STUDY ON THE EFFECTIVENESS OF ANTISEPTIC SKIN CLEANSING METHODS

Please let us take this opportunity to invite you to participate in a study that will explore the effectiveness of three methods of antiseptic skin cleansing prior to venepuncture. This study is being conducted as a part of a Master of Nursing thesis by a graduate student affiliated with the University of Manitoba. This individual is also the Clinic Operations Manager for Blood Services at the Canadian Red Cross. This study has been approved by the Ethical Review Committee of the Faculty of Nursing, University of Manitoba.

If you agree to participate in the study a Registered Nurse will perform the standard procedures required to collect a unit of blood. In addition, your arm, that is not currently being used to collect the blood, will undergo another skin cleansing procedure using one of three antiseptics. The possible antiseptics include preparations of : iodine, chlorhexidine, and alcohol or a combination of these ingredients. All of these antiseptics are used routinely as skin cleansing agents in health care. However if you have an allergy to any of these three preparations it is important that you identify this to the Registered Nurse performing the skin cleansing. A skin culture will be taken both before and after the antiseptic scrub is performed by placing a small plate on your arm for several seconds. These culture plates will be analysed by the Quality Control Laboratory at the Canadian Red Cross to determine the effectiveness of the skin preparation.

The costs and benefits to you as a study participant are minimal. The cost involves subjecting your arm to another skin cleansing procedure. No pain will be involved and no side effects should occur. Results of this study will however benefit patients who receive blood transfusions in that measures that may possibly improve the safety of the blood supply by decreasing the risk of bacterial contamination will be explored.

Your participation in the study will be confidential and known only to the researchers in the project who are listed below and to the Canadian Red Cross staff collecting the blood. Your participation is strictly voluntary and you may choose to withdraw your consent at any time during the course of the study, without penalty. If you wish a summary of results to be sent to you at the end of the study please complete the attached form. If you have questions or concerns please contact RaeAnn Thibeault at 982-7385.

We value your contribution to this research. Thank you.

Main Investigator:	RaeAnn Thibeault, Graduate Student, Faculty of Nursing University of Manitoba
Thesis Committee	Dr. Erna Schilder, Committee Chair, Faculty of Nursing, University of Manitoba Phone: 474-9664

A STUDY ON THE EFFECTIVENESS OF ANTISEPTIC SKIN CLEANSING METHODS

At the completion of the study I would like a summary of the results mailed to me by the main researcher.

Name: ----------

Address: ----------

Thank you for your participation.

Study conducted by: RaeAnn Thibeault, Faculty of Nursing, University of Manitoba
982-7385

APPENDIX C:

MATERIAL SAFETY DATA SHEETS--
POVIDONE-IODINE

ID # #4434

Material Safety Data Sheet

May be used to comply with OSHA's Hazard Communication Standard, 29 CFR 1910.1200. Standard must be consulted for specific requirements. 5 8125 #S48050

U.S. Department of Labor
Occupational Safety and Health Administration
(Non-Mandatory Form)
Form Approved
OMB No. 1218-0072

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable, or no information is available, the space must be marked to indicate that.
POVIDONE IODINE 0.75% SCRUB NP	

Section I

Manufacturer's Name NICE-PAK PRODUCTS, INC.	Emergency Telephone Number (914) 365-1700
Address (Number, Street, City, State, and ZIP Code) TWO NICE-PAK PARK ORANGEBURG, NY 10962-1376	Telephone Number for Information (914) 365-1700
	Date Prepared REVISED JULY 24, 1989
	Signature of Preparer (Optional) J Genovese

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
POVIDONE IODINE POLY (1-(2-OXO-1-Pyrrolidinyl) (ethylene) iodine complex - CAS #25655418 (no TL/TWA established).				

Section III — Physical/Chemical Characteristics

Boiling Point	212°F	Specific Gravity (H_2O = 1) @ 25°/4°C	1.02 ± 5%
Vapor Pressure (mm Hg.)	N/A	Melting Point	N/A
Vapor Density (AIR = 1)	N/A	Evaporation Rate (Butyl Acetate = 1)	N/A

Solubility in Water: SOLUBLE

Appearance and Odor: DARK REDDISH BROWN LIQUID. FAINT IODINE ODOR

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	N/A	Flammable Limits	LEL N/A	UEL N/A

Extinguishing Media: WATER/FOAM/CO_2/DRY CHEMICAL

Special Fire Fighting Procedures: N/A

Unusual Fire and Explosion Hazards: MAY EMIT TOXIC FUMES OF IODINE IN A FIRE

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid
	Stable	X	

Incompatibility (*Materials to Avoid*): ALKALIES AND REDUCING AGENTS

Hazardous Decomposition or Byproducts: EMITS IODINE VAPORS @ HIGH TEMPERATURES

Hazardous Polymerization	May Occur		Conditions to Avoid
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Skin? TOPICALLY APPLIED Ingestion?

Health Hazards (*Acute and Chronic*): N/A

Carcinogenicity: N/A NTP? IARC Monographs? OSHA Regulated?

Signs and Symptoms of Exposure: SAFE AS A TOPICAL ANTIMICROBIAL AGENT

Medical Conditions Generally Aggravated by Exposure: MAY BE IRRITATING IF SPLASHED IN EYES. FLUSH WITH WATER FOR AT LEAST 15 MINUTES.

Emergency and First Aid Procedures: IF INGESTED, DO NOT INDUCE VOMITING. DRINK LARGE AMOUNTS OF WATER, EGG WHITES OR GELATIN SOLUTION. GET MEDICAL ATTENTION.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled: TAKE UP WITH ABSORPTIVE MATERIAL AND DISPOSE AS PER LOCAL REGULATIONS. DILUTE AND NEUTRALIZE WITH SODIUM THIOSULFATE SOLUTION, IF NECESSARY.

Waste Disposal Method: VIA LICENSED CONTRACTOR TO LANDFILL OR INCINERATOR.

Precautions to Be Taken in Handling and Storing: AVOID STORING AT EXTREME TEMPERATURES

Other Precautions: N/A

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): N/A

Ventilation	Local Exhaust: N/A	Special: N/A	
	Mechanical (*General*): N/A	Other: N/A	

Protective Gloves: GLOVES IF HANDLING LIQUID

Eye Protection: PROTECTIVE EYE WEAR

Other Protective Clothing or Equipment: N/A

Work/Hygienic Practices: N/A

• USGPO 1986-491-529/45775

B40701 - B40600 - C12400 - S41350 - S41425 - L57725

ID # 4089

Material Safety Data Sheet

May be used to comply with OSHA's Hazard Communication Standard, 29 CFR 1910.1200. Standard must be consulted for specific requirements.

U.S. Department of Labor
Occupational Safety and Health Administration
(Non-Mandatory Form)
Form Approved
OMB No. 1218-0072

IDENTITY (As Used on Label and List): POVIDONE IODINE SOLUTION, U.S.P.

Note: Blank spaces are not permitted. If any item is not applicable, or no information is available, the space must be marked to indicate that.

Section I

Manufacturer's Name: NICE-PAK PRODUCTS, INC.	Emergency Telephone Number: (914) 365-1700
Address (Number, Street, City, State, and ZIP Code): TWO NICE-PAK PARK, ORANGEBURG, NY 10962-1376	Telephone Number for Information: (914) 365-1700
	Date Prepared: 3/17/92 (REVISED)
	Signature of Preparer (optional): J.J. GENOVESE

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
POVIDONE IODINE				
POLY[1-(2-OXO-1-PYRROLIDINYL) ETHYLENE] IODINE COMPLEX - CAS #25655418(NO TLV;TWA ESTABLISHED)				

Section III — Physical/Chemical Characteristics

Boiling Point	212°	Specific Gravity (H_2O = 1) 025°/4°C	1.027
Vapor Pressure (mm Hg.)	N/A	Melting Point	N/A
Vapor Density (AIR = 1)	N/A	Evaporation Rate (Butyl Acetate = 1)	N/A

Solubility in Water: SOLUBLE

Appearance and Odor: DARK REDDISH BROWN LIQUID. FAINT IODINE ODOR

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used) N/A	Flammable Limits N/A	LEL N/A	UEL N/A

Extinguishing Media: WATER/FOAM/ CO2/DRY CHEMICAL

Special Fire Fighting Procedures: N/A

Unusual Fire and Explosion Hazards: MAY EMIT TOXIC FUMES OF IODINE IN A FIRE.

B40801 - B40701 - C12460 - 541350 - L57735

Section V — Reactivity Data

Stability	Unstable			Conditions to Avoid
	Stable		X	

Incompatibility (Materials to Avoid): ALKALIES AND REDUCING AGENTS

Hazardous Decomposition or Byproducts: EMITS IODINE VAPORS @ HIGH TEMPERATURES

Hazardous Polymerization	May Occur			Conditions to Avoid
	Will Not Occur		X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Skin? TOPICALLY APPLIED Ingestion?

Health Hazards (Acute and Chronic): N/A

Carcinogenicity: N/A NTP? IARC Monographs? OSHA Regulated?

Signs and Symptoms of Exposure: SAFE AS A TOPICAL ANTIMICROBIAL AGENT

Medical Conditions Generally Aggravated by Exposure: MAY BE IRRITATING IF SPLASHED IN EYES. FLUSH WITH WATER FOR AT LEAST 15 MINUTES.

Emergency and First Aid Procedures: IF INGESTED, DO NOT INDUCE VOMITING. DRINK LARGE AMOUNTS OF WATER, EGG WHITES OR GELATIN SOLUTION. GET MEDICAL ATTENTION.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material is Released or Spilled: TAKE UP WITH ABSORPTIVE MATERIAL AND DISPOSE AS PER LOCAL REGULATIONS. DILUTE AND NEUTRALIZE WITH SODIUM THIOSULFATE SOLUTION, IF NECESSARY.

Waste Disposal Method: VIA LICENSED CONTRACTOR TO LANDFILL OR INCINERATOR

Precautions to Be Taken in Handling and Storing: AVOID STORING AT EXTREME TEMPERATURES

Other Precautions: N/A

Section VIII — Control Measures

Respiratory Protection (Specify Type): N/A

Ventilation	Local Exhaust	N/A	Special	N/A
	Mechanical (General)	N/A	Other	N/A

Protective Gloves: GLOVES IF HANDLING LIQUID Eye Protection: PROTECTIVE EYE WEAR

Other Protective Clothing or Equipment: N/A

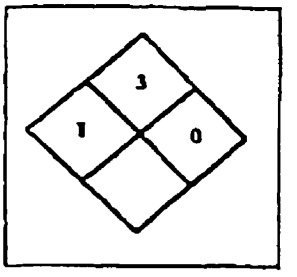
Work/Hygienic Practices: N/A

APPENDIX D:

MATERIAL SAFETY DATA SHEETS-- CHLORHEXIDINE GLUCONATE

MEDI-FLEX HOSPITAL PRODUCTS, INC.

MATERIAL SAFETY DATA SHEET



SECTION I. IDENTIFICATION

Trade Name:	ChloraPrep 2.0%	**Vendor:**	Medi-Flex Hospital Products
Chemical Family:	Mixture	**Revision No.**	Original
Date Revised:	6/11/96		

Dot Information

Shipping Name:	Isopropanol or Isopropyl Alcohol
Hazard Class:	Flammable liquid 3
UN/NA Number:	UN 1219

SECTION II. INGREDIENTS

CAS #	67-63-0
Dot Hazard Class:	Flammable liquid

Principle Hazardous Component(s)

	Health Hazard	**%**	**Exposure Limits in Air (ACGIH)**
IPA	Irritant: eye.	70% Weight	400 ppm (PEL/TLV)
Chlorhexidine Gluconate		2% W/V	

SECTION III. PHYSICAL DATA

Boiling Point:	N/A	**Melting Point:**	Unknown
Vapor Pressure:	N/A	**Specific Gravity:**	0.880
Vapor Density:	N/A	**% Volatile by volume:**	100
Solubility in Water:	Complete	**Evaporation Rate:**	Unknown
Appearance & Odor:	Clear, colorless liquid	**pH**	7.0 - 7.5

SECTION IV. FIRE AND EXPLOSION DATA

Flash Point:	67° F TCC
Explosive Limits:	N/A
Extinguishing Media:	Water fog, alcohol foam, carbon dioxide, dry chemical halogenated agents.
Special Fire Fighting Procedures:	Self-contained breathing apparatus with full facepiece and protective

clothing.

Unusual Fire and Explosion Hazard: May explode if exposed to extreme heat or flame.

SECTION V. REACTIVITY DATA

Stability:	Stable; vapors are violent.
Incompatibility:	Oxidizing materials
Hazardous polymerization:	Will not occur.
Hazardous Decomposition Products:	Carbon dioxide, carbon monoxide, nitrogen oxides, ammonia
Conditions to avoid:	Extreme heat or flame.

SECTION VI. TOXICOLOGICAL PROPERTIES

Threshold Limit Value: (TWA) N/A

Toxicity Information: TSCA (Toxic Substances Control Act) Regulations 40 CFR 710: All ingredients are on the TSCA Section 8(b) inventory. CERCLA and SARA regulations (40 CFR 355.370 and 372): This product does not contain any chemicals subject to the reporting requirements of SARA Section 313.

Hazard & First Aid

Skin:	Wash material off the skin with copious amounts of water. If redness, itching or a burning sensation develops, seek medical attention and discontinue use. See product label.
Eyes:	Flush with copious amounts of water. After initial flushing remove any contact lenses and continue flushing for at least 15 minutes. Have eyes examined and treated by medical personnel immediately. See product label. May irritate skin the causing dermatitis.
Ingestion:	Give individual at least two glasses of water to drink. If gastrointestinal symptoms develop, consult medical personnel. (Never give anything by mouth to an unconscious person) Acute LD50 in rat is 19.1 ml/kg in males and 26.6 ml/kg in females.
Inhalation:	Remove victim to well ventilated area. If not breathing, administer artificial respiration, preferably mouth to mouth. If breathing is labored, give oxygen. Consult medical personnel.

SECTION VII. PREVENTIVE MEASURES

Eye Protection:	Goggles. Full faceshield in addition if splashing is possible.
Gloves:	Rubber.
Respiratory:	If needed, use MSHA-NIOSH approved respirator for organic vapors.
Ventilation:	As need to stay below exposure limits.
Other:	Apron.

Handling & storage: Avoid prolonged exposure (ingestion, inhalation, or skin). Avoid breathing vapors. Store in a cool dry, well-ventilated area. Keep container closed. Wear protective equipment.

Spills Procedure: For small spills, mop up and rinse to sewer serviced by a wastewater treatment facility. For large spills, eliminate sources of ignition and ventilate spill area. Wear skin, eye and respiratory protection during cleanup. Soak up liquid with absorbent and shovel into waste container. Cover container and remove from work area. Wash residue from spill area with water and flush to sewer serviced by a wastewater treatment facility.

Waste Disposal: Discarded products is not a hazardous waste under RCRA, 40 CFR 261

SECTION VIII. FIRST AID MEASURES

Skin: Wash material off the skin with copious amounts of water. If redness or a burning sensation develops, seek medical attention and discontinue use. See product Label.

Eyes: Flush with copious amounts of water. After initial flushing remove any contact lenses and continue flushing for at least 15 minutes. Have eyes examined and treated by medical personnel immediately. See product label.

Ingestion: Give individual at least two glasses of water to drink. If gastrointestinal symptoms develop, consult medical personnel. (Never give anything by mouth to an unconscious person) Acute LD50 in rat is 19.1 ml/kg in males and 26.6 ml/kg in females.

Inhalation: Remove victim to well ventilated area. If not breathing, administer artificial respiration, preferably mouth to mouth. If breathing is labored, give oxygen. Consult medical personnel.

SECTION IX. PREPARATION INFORMATION

MEDI-FLEX HOSPITAL PRODUCTS, INC.
19 Butterfield Trail Blvd.
El Paso, Texas 79906

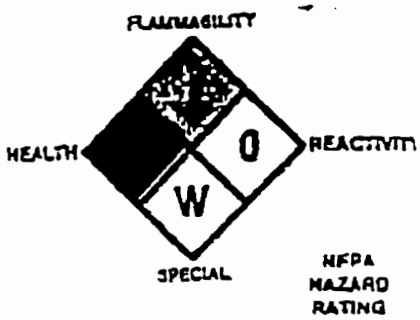
PHONE: (915) 778-6421
MSDS DATE: 6/11/96
PREPARED BY: Pat McGrath

ACGIH: American Conference of Governmental Industrial Hygienist.
IARC: International Agency for Research on Cancer: Monographs.
OSHA: Occupational Safety and Health Administration.
NTP: National Toxicology Program: Annual Report on Carcinogens.
PEL: Permissible Exposure Level (OSHA).
TLV: Threshold Limit Value.
TWA: Time Weighted Averages over 8 hours.

APPENDIX E:

MATERIAL SAFETY DATA SHEETS-- ALCOHOL AND TINCTURE OF IODINE

MEDI-FLEX HOSPITAL PRODUCTS
MATERIAL SAFETY DATA SHEET



SECTION I — IDENTIFICATION

TRADE NAME: SEPP 70% Isopropyl Alcohol
CROSS REFERENCE:
FORMULA:
VENDOR: Medi-Flex Hospital Products
REVISION NO: 1
DATE REVISED: 8-29-85

SECTION II — HAZARDOUS INGREDIENTS

MATERIAL: Isopropyl Alcohol
% WEIGHT: 70
NATURE OF HAZARD:

SECTION III — PHYSICAL DATA

BOILING POINT: Unknown
VAPOR PRESSURE:
VAPOR DENSITY:
WATER SOLUBILITY: Complete
APPEARANCE & ODOR: Clear, colorless liquid
MELTING POINT:
SPECIFIC GRAVITY: Unknown
% VOLATILE BY VOL: 100
EVAPORATION RATE:

SECTION IV — FIRE & EXPLOSION DATA

FLASHPOINT: 67°F
EXPLOSIVE LIMITS:
EXTINGUISHING MEDIA: Dry chemical, carbon dioxide, alcohol foam and water spray. Water should be used to cool fire exposed containers and to disperse unignited vapors.

SPECIAL FIRE-FIGHTING PROCEDURES: Remove all sources of ignition.

UNUSUAL FIRE & EXPLOSION HAZARDS: May explode if exposed to extreme heat or flame.

SECTION V — HEALTH HAZARD & EMERGENCY

THRESHOLD LIMIT VALUE: 400ppm
HAZARDS & FIRST AID PROCEDURES:

Inhalation: Remove victim to fresh air, call a physician.

Skin Absorption: Flush with flowing water for 15 minutes. Call physician Eye exam if irritation exists.

Swallowing: Ingestion rarely produces serious toxic affects. If ingested in quantity, call physician.

SEPP 70Z ISOPROPYL ALCOHOL REV. 1

SECTION VI — REACTIVITY

STABILITY: Stable
INCOMPATIBILITY: Oxidizing materials
HAZARDOUS POLYMERIZATION: Will not occur
HAZARDOUS DECOMPOSITION PRODUCTS:
CONDITIONS TO AVOID: Extreme heat or flame

SECTION VII — SPILL & DISPOSAL

SPILL PROCEDURES: Wear protective equipment. Remove all sources of ignition Absorb spill with an inert material. Dispose of as given below.

DISPOSAL PROCEDURES: Incineration is preferred, however, dispose of in accordance with RCRA and applicable state and local regulations.

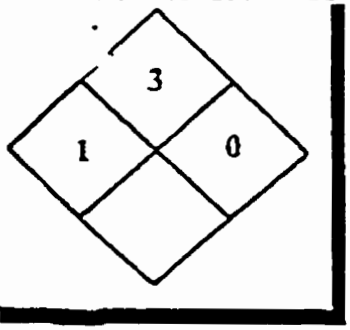
SECTION VIII — PROTECTION DATA

EYE: Safety glasses
GLOVES:
RESPIRATORY:
VENTILATION: None beyond normal good room ventilation.
OTHER:

SECTION IX — HANDLING & STORAGE

Store in a cool, well-ventilated place away from all sources of ignition. Keep container closed. Wear protective equipment.

SECTION X — MISCELLANEOUS DATA



MEDI-FLEX
QUALITY THROUGH INNOVATION

MATERIAL SAFETY DATA SHEET

SECTION I PRODUCT INFORMATION

Trade Name:	Sepp Iodine Tincture, 2%	**Vendor:**	Medi-Flex Hospital Products
Chemical Family:	Mixture	**Revision No.**	2
Date Revised:	5/27/92		

Dot Information

Shipping Name:	Flammable liquid, n.o.s.
Hazard Class:	Flammable liquid.
UN/NA Number:	UN 1993.

SECTION II HAZARDOUS INGREDIENTS

Material:	Ethanol	Iodine
CAS #	64-17-5	7553-56-2
Dot Hazard Class:	Flammable liquid	

Principle Hazardous Component(s)

	Health Hazard	%	Exposure Limits in Air (ACGIH)
Ethanol	Irritant: eye.	47% V/V	1000 ppm (PEL/TLV)
Iodine	Irritant: eye, skin, inhalation.	2% W/V	0.1 ppm (TWA)

SECTION III PHYSICAL DATA

Boiling Point:	Approximately 177°F	**Melting Point:**	N/A
Vapor Pressure:	40 mm Hg @ 19°C	**Specific Gravity:**	0.92
Vapor Density:	Unknown (Air = 1.0)	**% Volatile by volume:**	98%
Solubility in Water:	Complete/soluble	**Evaporation Rate:**	2.5 (Butyl Acetate = 1.0)
Appearance & Odor:	Deep red solution, typical odor of iodine tincture (iodine odor).		

SECTION IV FIRE AND EXPLOSION HAZARD

Flash Point:	90°F
Flammable Limits in air:	3.3 - 19 % by volume.
Extinguishing Media:	Use water spray, carbon dioxide, dry chemical, alcohol-type or universal-type foams.
Special Fire Fighting Procedures:	Use self-contained breathing apparatus and proper safety equipment.

MEDI-FLEX HOSPITAL PRODUCTS, INC. • 19 Butterfield Trail Boulevard • El Paso, Texas 79906 • 915-778-6421 • FAX: 915-778-6425

Unusual Fire and Explosion Hazard: Iodine fumes (ethanol).

SECTION V REACTIVITY DATA

Stability:	Stable
Hazardous Polymerization:	Will not occur.
Materials/Conditions to avoid:	High temperatures.
Hazardous Decomposition Products:	Iodine.

SECTION VI TOXICOLOGICAL PROPERTIES

Threshold Limit Value: 0.1 ppm (TWA) (Iodine) & 1000 ppm (PEL/TLV) (Ethanol)

Hazards & First Aid: May cause irritation to eyes, skin, and mucous membranes. Over exposure symptoms reflect Iodine overexposure. Chronic exposure may induce hyperthyroidism.

Carcinogenic Listing

NTP:	No.
IARC Monograph:	No.
OSHA 29 CFR 1910:	No.

Entry Route(s)	Effects of Overexposure	
Inhalation:	Acute exposure:	Irritation of nasal passages and lungs.
	Chronic exposure:	Unknown.
Contact:	Acute exposure:	Irritation of skin and eyes.
	Chronic exposure:	Unknown.
Ingestion:	Acute exposure:	Ingestion of large amounts may cause nausea, diarrhea, vomiting, drowsiness, pain and loss of consciousness.
	Chronic exposure:	Unknown.

SECTION VII PREVENTIVE MEASURES

Protection Information:

Eye Protection:	Goggles.
Gloves:	Plastic.
Respiratory:	Combination acid gas and organic respirator if TLV exceeded.
Ventilation:	As need to stay below exposure limits.
Other:	As necessary to protect clothing from stains.

Handling & storage: FLAMMABLE! Keep away from heat, sparks, and open flames. Store in cool, dry and well ventilated location. Use with adequate ventilation to keep below PEL/TLV limits. Avoid contact with skin and eyes; do not inhale vapors; do not take orally.

Spills or Leaks: Eliminate all sources of ignition. Absorb spilled material with vermiculite or floor absorbent and ventilate area. Shovel or sweep into a DOT approved container and seal.

Waste Disposal: Waste material is an EPA Characteristic Hazardous Waste (D001) due to ignitability of the mixture. Therefore, it must be disposed of at an EPA-approved disposal facility and must comply with all local, state and federal regulations.

SECTION VIII FIRST AID MEASURES

Eyes: Flush with water for 15 minutes. Seek professional assistance.

Ingestion: Seek professional assistance or call Poison Control Center immediately.

Inhalation: Remove from exposure. Seek professional assistance.

Skin: Remove contaminated clothing. Wash skin.

SECTION IX PREPARATION INFORMATION

MEDI-FLEX HOSPITAL PRODUCTS, INC.
19 Butterfield Trail Boulevard
El Paso, Texas 79906

PHONE: (915) 778-6421
MSDS DATE: May 27, 1992
Prepared by: Tim Delmont

ACGIH:	American Conference of Governmental Industrial Hygienist.
IARC:	International Agency for Research on Cancer: Monographs.
OSHA:	Occupational Safety and Health Administration.
NTP:	National Toxicology Program: Annual Report on Carcinogens.
PEL:	Permissible Exposure Level (OSHA).
TLV:	Threshold Limit Value.
TWA:	Time Weighted Averages over 8 hours.

This information is, to the best of our knowledge, accurate. Medi-Flex furnishes this information in good faith, but without warranty, representation or guarantee of its accuracy, completeness, or reliability.

APPENDIX F:

OBSERVATION RECORDS

A STUDY ON THE EFFECTIVENESS OF ANTISEPTIC SKIN PREPARATIONS

Record of Demographic Profile

Number	ABO Label Number	Age	Gender	Number of Donations

A STUDY ON THE EFFECTIVENESS OF ANTISEPTIC SKIN PREPARATION METHODS

Observation Record--Group A

No.	ABO Label Number	Pre-prep CFU*--24	Pre-prep CFU*--48	Post-prep CFU*--24	Post-prep CFU*--48

*Colony Forming Units--Group A

A STUDY ON THE EFFECTIVENESS OF ANTISEPTIC SKIN PREPARATION METHODS

Observation Record--Group B

No.	ABO Label Number	Pre-prep CFU*--24	Pre-prep CFU*--48	Post-prep CFU*--24	Post-prep CFU*--48

*Colony Forming Units--Group B

A STUDY ON THE EFFECTIVENESS OF ANTISEPTIC SKIN PREPARATION METHODS

Observation Record--Group C

No.	ABO Label Number	Pre-prep CFU*--24	Pre-prep CFU*--48	Post-prep CFU*--24	Post-prep CFU*--48

*Colony Forming Units--Group C

APPENDIX G:

D/E NEUTRALIZING AGAR

D/E NEUTRALIZING AGAR

FORMULA:

Approximate, per liter of deionized filtered water.

Pancreatic Digest of Casein	5.00 g
Yeast Extract	2.50
Dextrose	10.00
Sodium Thioglycollate	1.00
Sodium Thiosulfate	6.00
Sodium Bisulfite	2.50
Lecithin (Soybean)	7.00
Polysorbate 80	5.00
Brom Cresol Purple	0.02
Agar	15.00

Final pH 7.6 ± 0.2 at 25°C

QUALITY CONTROL RESULTS:

Microorganisms Used (ATCC®#):	Incubation Temp	Incubation Atmos	Incubation Time (Hrs)	Results
Bacillus cereus (PML #158)	35°C	Aero	18-24	Growth
Bacillus subtilis (6633)	35°C	Aero	18-24	Growth
Escherichia coli (8739)	35°C	Aero	18-24	Growth
Pseudomonas aeruginosa (9027)	35°C	Aero	18-24	Growth
Salmonella choleraesuis ssp. *choleraesuis* (14028)	35°C	Aero	18-24	Growth
Staphylococcus aureus (6538)	35°C	Aero	18-24	Growth

®American Type Culture Collection, 12301 Parklawn Drive, Rockville, MD 20852

PHYSICAL CHARACTERISTICS:

APPEARANCE:	Opaque, lavender
GEL STRENGTH:	Medium firm

PRODUCT INFORMATION

D/E NEUTRALIZING AGAR

[redacted]

Use: Agar medium used for the testing and neutralizing of antiseptics and disenfectants.

Description: D/E Neutralizing Agar is capable of neutralizing a broad spectrum of antiseptic and disenfectant chemicals including quaternary ammonium compounds, phenolics, iodine, chlorine preparations, mercurials, formaldehyde and glutaraldehyde. It can determine the bactericidal capability of disenfectants and therefore is well suited for environmental sampling.

Formula per Liter:

Pancreatic Digest of Casein	5.0 g
Yeast Extract	2.5
Dextrose	10.0
Sodium Thioglycollate	1.0
Sodium Thiosulfate	6.0
Sodium Bisulfite	2.5
Polysorbate 80	5.0
Lecithin	7.0
Bromcresol Purple	0.02
Agar	15.0

Final pH : 7.6 +/- 0.2 at 25 C

Preparation: Mix 54 grams of the medium in one liter of purified water until evenly dispersed. Heat with repeated stirring and boil for one minute to dissolve completely. Dispense and autoclave for 15 minutes at 121C.

Quality Control Specifications:

1. The powder is homogeneous, moist, lumpy and bluish grey.
2. Visually the prepared medium at 45-50 C is opaque and lavender.
3. Expected cultural response after 40-48 hours at 35 C.

Microorganism	Growth
Bacillus subtilis ATCC 6633	Good to excellen
Escherichia coli ATCC 25922	Good to exccelle
Pseudomonas aeruginosa ATCC 27853	Good to excellen
Salmonella typhimurium ATCC 14082	Good to excellen

Storage: Store the dehydrated medium in a low humidity environment at 2 to 8 C. Keep the container closed and protected from moisture and light. The dehydrated medium should be discarded if it is hard or if the color has changed from the original bluish grey color.

Packaging: Container sizes available: 1, 5, 25 & 100 lbs; 500 gm & 10 kg

References:

1. CSMA Proceedings, 1970.

CERTIFICATE OF QUALITY

D/E NEUTRALIZING AGAR

Catalog No. P8045

97 071029M November 7, 1997

PROCEDURES:

RESULTS:

Bacillus cereus (PML #158)	Growth, good
Bacillus subtilis (6633)	Growth, good
Escherichia coli (8739)	Growth, good
Pseudomonas aeruginosa (9027)	Growth, good
Salmonella cholerasuis ssp. *cholerasuis* (14028)	Growth, good
Staphylococcus aureus (6538)	Growth, good

NOTE:

PHYSICAL CHARACTERISTICS:

	Opaque, lavender	Passed inspection after 7 days
	Medium firm	NA
	16 ml, Contact	

PML microbiologicals

QUALITY ASSURANCE

APPENDIX H:

ETHICAL APPROVAL

The University of Manitoba

FACULTY OF NURSING
ETHICAL REVIEW COMMITTEE

APPROVAL FORM

Proposal Number N#97/03

Proposal Title: "A COMPARISON OF THE EFFICACY OF THREE METHODS OF ANTECUBITAL FOSSA SKIN DISINFECTION PRIOR TO PHLEBOTOMY IN VOLUNTEER BLOOD DONORS."

Name and Title of Researcher(s): RAEANN THIBEAULT
MASTER OF NURSING GRADUATE STUDENT
FACULTY OF NURSING UNIVERSITY OF MANITOBA

Date of Review: JANUARY 06, 1997.

APPROVED BY THE COMMITTEE: JANUARY 16, 1997.

Comments: APPROVED WITH SUBMITTED CHANGES DATED JANUARY 16, 1997.

Date: JANUARY 16, 1997.

Karen I. Chalmers, PhD, RN — Chairperson
Associate Professor
University of Manitoba Faculty of Nursing

Position

NOTE:
Any significant changes in the proposal should be reported to the Chairperson for the Ethical Review Committee's consideration, in advance of implementation of such changes.

Revised: 92/05/08/se

APPENDIX I:

ACCESS PERMISSION

115 Woodside Crescent
Winnipeg, Manitoba
R3W 1B5

November 28, 1996

Mr. Steve Tyson
Acting Centre Director
Canadian Red Cross Blood Services
226 Osborne Street North
Winnipeg, Manitoba

Dear Steve,

As you are aware I am currently completing a thesis in partial fulfilment of the degree of Master of Nursing. The purpose of this letter is to request permission to conduct a research investigation at the Winnipeg Centre Blood Donor Clinic. The results of this investigation should jointly benefit the Canadian Red Cross Blood Services and patients who receive transfusion therapy.

The major purpose of this study is to investigate and compare the efficacy of three methods of antecubital fossa skin disinfection prior to phlebotomy in volunteer blood donors. Skin disinfection methods will be evaluated using cultures obtained from donors' arms before and after skin disinfection. Approximately 100 donors will be invited to participate in the project. Attached please find information outlining the nature of the proposed investigation . The Ethical Review Committee of the Faculty of Nursing, University of Manitoba is responsible for reviewing and approving research proposals based on ethical considerations as well as scientific merit. Approval from this committee is mandatory prior to proceeding.

Resources and materials that will be required to carry out the investigation include:
1) 30 iodine swab scrub sticks and swabs (currently in use)
2) 30 Frepp sponges and Sepp applicators (currently in use for donors allergic to iodine)
3) Screening nurses will be asked to obtain informed consent from donors for participation in the study. This will occur following the health interview. Consents will be prepared prior to the investigation.
4) Nurses performing venepuncture will be requested to prepare all participants arms using one of three skin disinfection methods. Bacterial cultures will be obtained by these nurses before and after skin preparation.
5) The Quality Control Laboratory is agreeable to incubating all culture plates and counting and recording bacterial colonies at 24 and 48 hours.
As the principal investigator I will be available for immediate consultation with staff or participants should the need arise.

It is my hope that results from this research will suggest measures that can be considered in our constant effort to improve the safety of the blood supply . Thank you for your consideration of

my request to conduct this investigation at the Winnipeg Blood Centre.

Sincerely,

RaeAnn Thibeault
Graduate Student,
Faculty of Nursing
University of Manitoba

APPROVAL TO CONDUCT STUDY AT THE CANADIAN RED CROSS, WINNIPEG CENTRE, BLOOD SERVICES DONOR CLINIC

I hereby grant permission for RaeAnn Thibeault, Graduate Student, Faculty of Nursing, University of Manitoba to conduct a study titled 'A Comparison of the Efficacy of Three Methods of Antecubital Fossa Skin Disinfection Prior to Phlebotomy in Volunteer Blood Donors' at the Canadian Red Cross, Winnipeg Blood Services. I understand that this investigation is done in partial fulfillment of the degree of Masters of Nursing.

Steve Tyson,
Acting Centre Director

29 Nov 96
Date

APPENDIX J:

INFORMATION FOR CANADIAN RED CROSS STAFF

EXPLANATION FOR CANADIAN RED CROSS STAFF OF A STUDY ON THE EFFECTIVENESS OF THREE METHODS OF ANTECUBITAL FOSSA SKIN DISINFECTION

In the near future I will be conducting a research investigation examining the efficacy of three methods of antecubital fossa skin disinfection prior to phlebotomy in volunteer blood donors. This study has been approved by the Ethical Review Committee of the Faculty of Nursing as well as Steve Tyson, Acting Centre Director of Winnipeg Centre. This study is being conducted as part of my requirements towards the degree of Masters of Nursing from the University of Manitoba..

To conduct this investigation I am requesting the assistance of the Registered Nurses working in the Centre clinic on designated days. Participation in the study by nurses is strictly voluntary and you may freely decide whether or not you wish to particpate. Participation is strictly without penalty or benefit.

Assistance from Registered nurses will be required for:
1. Obtaining informed consent from prospective subjects who will be Whole Blood Donors only (Consent forms have been prepared and will be available in the screening rooms--see attached)
2. Performing an additional antecubital fossa scrub (on the arm not currently being used for venepuncture) on volunteer subjects using one of three preparations including povidone iodine--povidone iodine; alcohol--tincture of iodine; or chlorhexidine gluconate--chlorhexidine gluconate combinations and
3. Applying a culture contact plate to volunteer subjects arms before and after the scrub procedure and labelling these plates.
This data will be collected from approximately 120 subjects in total over a period of approximately six days to allow nurses to collect data during less busy clinic times.

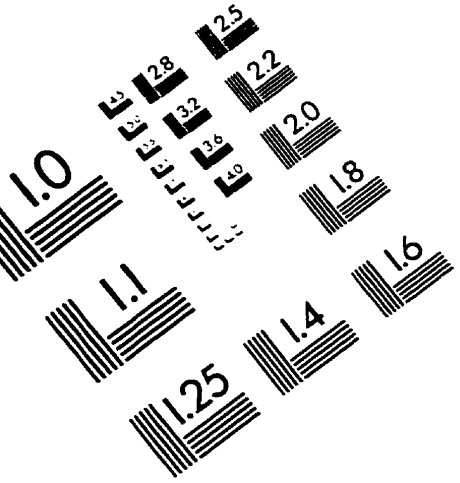
During the course of the investigation nurses have the right to decide that due to various circumstances, such as a busy clinic, the investigation needs to be stopped for a period of time. I will be available prior to and during the course of the investigation to answer any questions you may have.

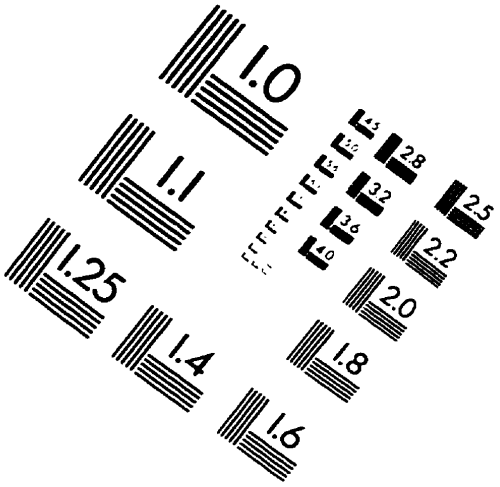
Please let me take this opportunity to thank each of you for your assistance, support and encouragement during the course of this investigation. The contributions of all Registered Nurses will be gratefully acknowledged in the thesis. At the conclusion of the investigation a summary of findings will be made available to all staff.

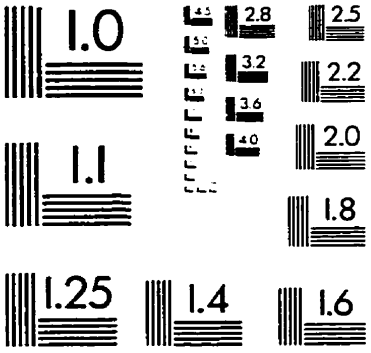
Thank you for your assistance.

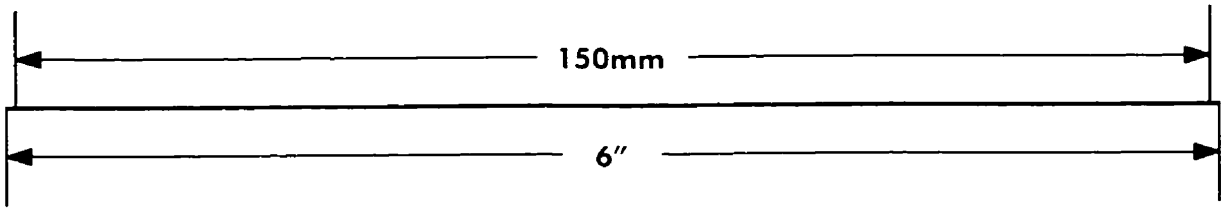
RaeAnn Thibeault

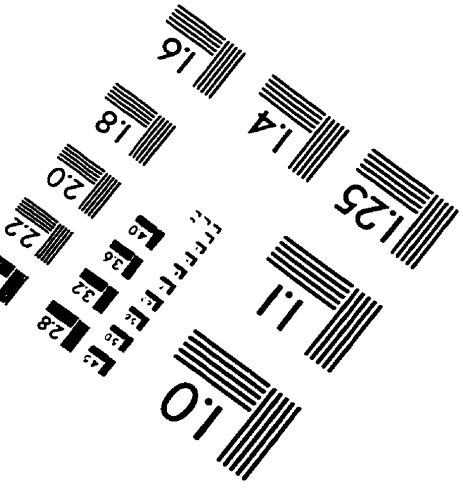
IMAGE EVALUATION
TEST TARGET (QA-3)

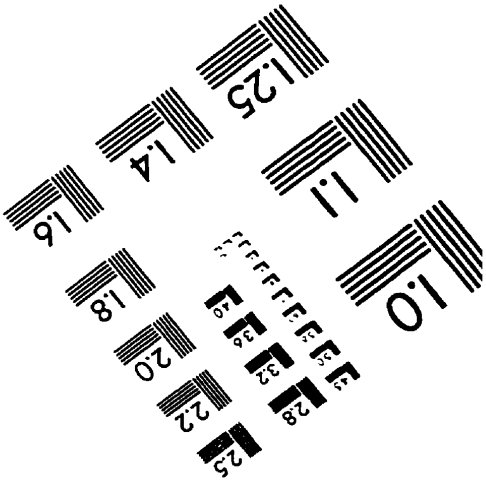












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