AN INVESTIGATION OF THE EFFECT OF POUCH SIZE ON HAND REPOSITIONING
AND CONTAMINATION OF A MEDICAL DEVICE

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ABSTRACT

AN INVESTIGATION OF THE EFFECT OF POUCH SIZE ON HAND REPOSITIONING
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Three different pouch sizes were selected and filled with tongue depressors. Pouches were sized such that they maintained an aspect ratio of 6.4 when the pouch surface area was divided by the product surface area. Ninety-seven healthcare providers were each asked to present the tongue depressors of three pouch sizes into a simulated sterile field twice, for a total of six pouches per participant. Pouches and subjects' gloves were coated with Glitterbug cream, which fluoresces under black light, to serve as an indicator of contamination in post hoc analysis.

The rate of contamination and the number of times subjects changed the position of their hands while presenting items to the sterile field were recorded as dependent variables for analysis. A contamination rate of 11.6%, or 65 out of 582 trials, was observed in this study. Of the 65 trials, 32 were in large pouches (16.5% of those tested), 19 in medium pouches (9.8 % of those tested), and 14 in small pouches (7.2% of those tested). Pouch size had a significant effect on contamination rate (P=0.0108). Post hoc pairwise comparisons did not indicate a significant difference in the contamination rates generated when the medium pouch was compared with the small (P=0.6196) or the large (P=0.1123), but the large pouch was significantly more likely to be contaminated than the small (P=0.0130). Pouch size was also found to significantly affect the number of hand repositionings that personnel employed (P<0.0001). In this case, all post hoc, pairwise comparisons were significant (α=0.01). As expected, larger pouches induced a greater number of repositionings. Ramifications for design are discussed.

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Chapter 1: Hospital Acquired Infections

What is an HAI?

Definitions

Nosocomial is a word with etymology stemming from the Greek word for nurse, "nosokomia" [1]. The Food and Drug Administration Amendments Act defines a nosocomial infection as "an infection that is acquired while an individual is a patient at a hospital and was neither present nor incubating in the patient prior to receiving services in the hospital" [2]. The U.S. Centers for Disease Control and Prevention (CDC) specifies for surveillance purposes that an HAI is "a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s)" [3].

Nosocomial infections, or hospital-acquired infections (HAI) are often differentiated into sub-categories including: surgical site infections (SSIs), Urinary tract infections (UTI), nosocomial pneumonia, and bloodstream infections (BSIs) [3].

Causes

A study of over 498,998 patients from 1992 to 1998 revealed 29,041 nosocomial infections reported during that time. A total of 54% of those infections were surgical infections. Of the surgical infections, 68% were blood stream infections(BSI), nosocomial pneumonia, and urinary tract infections (UTI) [4]. Invasive medical devices played a role in many of these infections. Of 1,147 blood stream infections, 87% of these were due to central intravenous lines. Of 6,830 urinary tract infections, 97% occurred due to catheters [4]. In the Surveillance and Control of Pathogens of Epidemiologic Importance (SCOPE) project, intravenous catheters caused 23% of the blood stream infections observed in the 7.5-year-long study [5].

Statistics

In 1975, a twelve-month study by Haley et. al was done to monitor nosocomial infection rates from over 6,449 hospitals. Over the course of the year there were 37.7 million admissions, during which there were 2.1 million nosocomial infections reported. There was an infection rate of 5.7 per 100 in the study [6]. From 1992-1998, a study of 498,998 patients was done by Richards, who suggested an infection rate of 6.1 per 100 patients [4]. Klevens et. al utilized varied databases to estimate that in 2002, there were 1.7 million hospital-acquired infections in the United States, of which 244,385 were surgical site infections [7]. Klevens estimated nosocomial infection-related deaths from data taken from 1999-2003, suggesting that out of 1.7 million infections 99,987 patients died from the infection itself or related problems. Of these, 8,205 deaths were the result of surgical site infections and 30,665 from bloodstream infections.

The SCOPE project also performed a long-term surveillance of BSI rates from 1995-2002, similar to that of the NNIS data reported by Klevens et. al. In the SCOPE project, hospitals reported 60 cases of bloodstream infections (BSI) per 10,000 admissions [5]. Al-Rawajfah used 2003 data from the National Inpatient Sample database to similarly analyze nosocomial blood-stream infection rates in hospitals. Of the nearly eight million hospital admissions in the data set, there was a rate of 21.7 cases per 1,000 admissions, or 113,436 total. The death rate from these cases was 20.6% [8]. Table 1 summarizes the findings of varied studies related to HAIs.

Table 1 - Hospital Acquired Infections by Study

	Klevens	**Wisplinghoff**	**Al-Rawajifah**	**Haley**	**Richards**
# HAI	*1,737,125*	*--*	*--*	*2,148,485*	*29,041*
-BSI	*248,678*	*24,179*	*113,436 (21.7 cases per 1000)*	*102,950*	*4,117*
-SSI	*290,485*	*--*	*--*	*510,402*	*2,238*
-UTI	*561,667*	*--*	*--*	*902,732*	*6,830*
-Pnemonia	*250,205*	*--*	*--*	*226,968*	*--*
Study Population	*Not reported, data from 283 hospitals*	*Not reported, data from 42 hospitals*	*7,977,728 admissions*	*37,729,474 admissions*	*498,998 patients*
Study duration	*2002*	*1995-2002*	*2003*	*1975-1976*	*1992-1998*
Study Setting	*Hospital*	*Hospital*	*Hospital*	*Hospital*	*Medical-Surgical ICU*

Chapter 2: Medical Device Packaging

Medical Device Classifications

Medical devices are categorized the world over based on the level of risk associated with their use. In the US, medical devices are separated into three risk-based classes by the FDA. The first, *Class I*, refers to a device that is "not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health, and which does not present a potential unreasonable risk of illness of injury" [9]. The middle class, *Class II*, are devices that require special controls to ensure their safe use. The highest risk class, *Class III*, is different in that devices generally require a pre-market approval and are life-sustaining or supporting devices or implants.

The European Union (EU) has its own risk-based guidelines: I, IIa, IIb, and III, based on categories such as invasiveness and intended use, divided into various "Rules" which determine their classification. Canada similarly uses a Rule system, and has classifications from I to IV which represent low to high risk devices [10].

There are currently no uniform regulations with world-wide authority. The Global Harmonization Task Force (GHTF), a group of volunteers from regulatory and industry backgrounds, have published classifications based on risk. The GHTF defines risk in terms of: 1. The intended purpose of the medical device, 2. the effectiveness of risk management throughout the lifecycle of the product, 3. the end user, 4. the mode of operation, and 5. the employed technology [11]. The GHTF, with these inputs, classifies devices into category based on

necessity of regulatory control. Products are categorized from A to D, with A being the lowest

and D being the highest risk.

Examples of products are given within each category from the 2009 edition of the Wiley

Encyclopedia of Packaging Technology [11] (See Table 2):

Table 2 - Global Harmonization Task Force Classifications

Risk Type	Example of Product
A	Tongue Depressor
B	Hypodermic Needles
C	Lung Ventillators
D	Heart Valves

Survey of Nurse Perspectives of Medical Device Packaging

A survey conducted by the Institute of Packaging Professionals (IoPP) of subjects from

the Association of peri-Operative Registered Nurses (AORN) included "more than 200"

responses, providing insight into how medical device packages are perceived by those who use

them. "A high percentage" were aged 51 or older with 21+ years of experience in the field [12].

According to Neid, "nearly 60%" of the respondents were registered nurses (RN) with a

bachelor's education in nursing, and "about 2%" were licensed practical nurses (LPN).

According to the study, one of the issues that arose was that respondents didn't understand

packaging terminology. Exact numbers were not given in the article for the above percentages.

Participants' preferences were benchmarked as followed:

Table 3 – Operating Room nurse preference by packaging type

Header Bags	Flexible Pouches	Trays	Flexible packaging with lids (syringe)	Not Reported
14%	19%	60%	6%	1%

The respondents reported that they preferred double barrier packaging to single sterile barrier systems, especially in the case of implantable devices where the preference was 9 to 1 [12]. Although AORN cautions against tossing items into the sterile field (due to potentially puncturing the sterile drape or missing the field entirely) [13], 57% of respondents saw flipping/dumping into the sterile field as an acceptable method of presentation [12]. Header bags were reported as difficult to open, and chevron-style pouches were reported as "not understood" by operating room nurses with regard to opening.

Chapter 3: Aseptic Presentation

Nursing

The Bureau of Labor Statistics observes three pathways to becoming a Registered Nurse (RN). The first is a BSN (Bachelor of Science in Nursing) which comes from a 4-year degree program. The second is an ADN (Associates Degree in Nursing) which take 2-3 years to complete. The third, and final path, is a diploma program which is provided by a hospital and takes roughly 3 years to complete [14]. Registered Nurses work in various arenas. *Peri-operative nurses* are nurses who work in operating rooms and assist surgeons in surgery. *Ambulatory nurses* work in physicians' offices and deal with mainly preventative medicine. *Emergency or trauma nurses* tend to work in the emergency department and work with patients in life-threatening situations which require immediate care [14].

A licensed practical nurse (LPN) is licensed by a state board and primarily educated though junior colleges or community colleges. The LPN works primarily with patient bed-side care (bathing, feeding, giving injections) and takes patient information such as vital signs, weight, and blood pressure [15]. Licensed practical nurses work in a variety of healthcare settings, but some work in specialized areas such as a doctor's office and patient home healthcare. As part of their job, LPNs monitor adverse reactions in their patients and instruct the families of patients in simple nursing techniques [15].

Sterile Technique

Phillips defines sterile technique as working within a sterile field, keeping microorganisms in a sterile field to an irreducible minimum [1]. The Association of Surgical Technologist (AST) study guide, which accompanies a training DVD, defines asepsis as

"absence of microbes." To achieve asepsis, the technologists practice sterile technique which they define as an "action taken to prevent microbial contamination of a sterile field." Similarly, the Association of peri-Operative Registered Nurses (AORN) defines aseptic technique as "methods by which contamination by microorganisms is prevented" [13].

Figure 1 - Operating Room Set-up
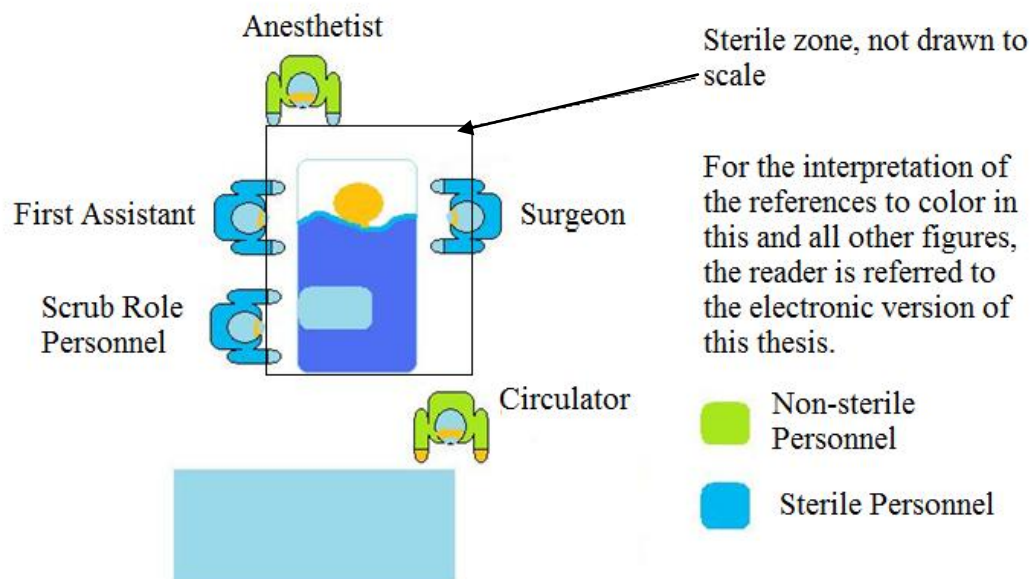
The above figure represents a basic operating room set-up. The individuals in green (circulator and nurse anesthetist) are not considered sterile personnel. The individuals in blue (first assistant, surgeon, and scrub role nurse/surgical tech) are considered sterile.

Nurses are not the only profession to occupy scrubbed and circulating roles. Surgical technologists are discussed in the next section.

The presentation

The circulating nurse takes the instrument from its non-sterile storage location .There are primarily two accepted methods of presenting the device within to the scrub nurse. In the first method, the circulating nurse will open the package (holding the outside of the package) while the scrub nurse removes the item in a quick, upward motion. This is commonly referred to as "picking." Alternatively, the circulating nurse will "thrust" the objects on to the sterile field [16]. This technique is often referred to as "bombing," "flipping," or "table tossing." The practice of flipping or tossing is disputed; AORN recommends against such action, while AST defines a method for successful introduction of devices by such means [17].

Figure 2 - Operating Room

Operating Room - Sterile personnel and Table in black

Back Table   Surgeon   Scrub Personnel   Anesthetist   Circulator
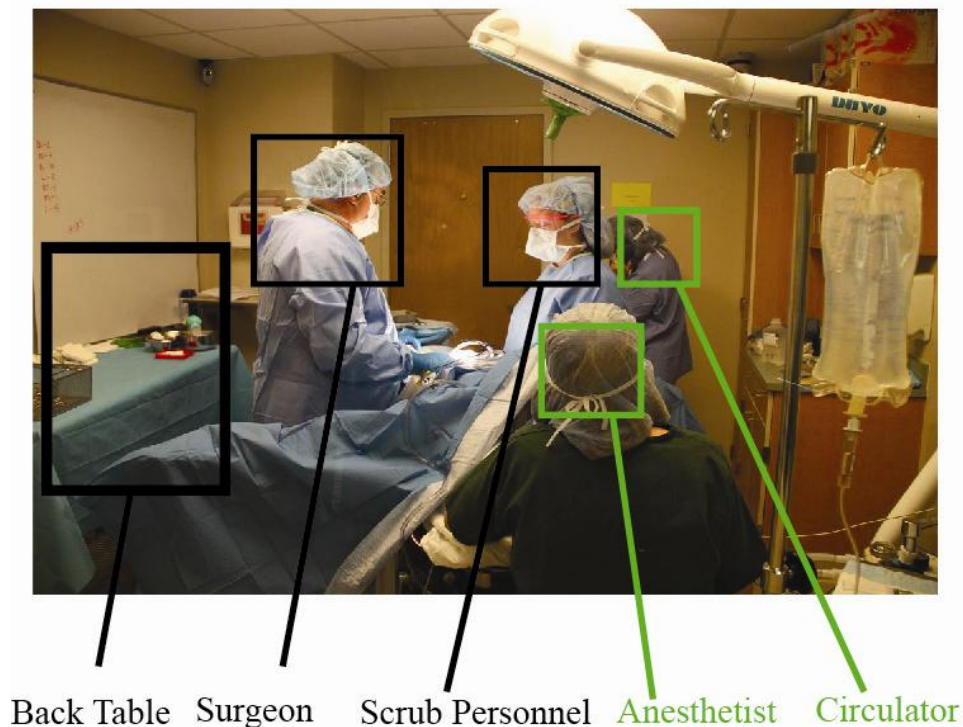
Association of periOperative Registered Nurses Recommendations

Care is taken in the methods employed to open and present items to the sterile field in order to minimize microbial risk to the sterile theater. Wrapped items, which come enveloped into the sterile theater, are unwrapped starting at the furthest-most flap, then at the sides, and finally at the flap nearest to the nurse [17]. See Figure 3 for the order in which items are unwrapped.

Figure 3 - Order in which wrapped items are unwrapped

With pouches, care must be taken that the edges of the pack do not curl in, as this may contaminate the contents of the pack [13]. The edges of the pack are not considered sterile, with the inner heat seal on the pouch being the line between an unsterile and sterile area [17] (see

Figure 4). For this reason, it is advised that the instrument not be slid across the lip of the pouch, which may result in contamination [17]. The Association of peri-Operative Registered Nurses (AORN) suggests that instruments not be tossed into the field, as the device may roll out of the sterile area or puncture the sterile drape [13]. Another possible result of tossing the device into the sterile field is that instruments like staplers may become damaged, or the surrounding air may be disturbed, leading to contaminants like dust entering the sterile field [1]. It has also been suggested that it is critical that unsterile objects do not extend over the sterile field during aseptic presentation [17].

Figure 4 - Line of Demarcation- Red areas indicate non sterile portions of the pouch
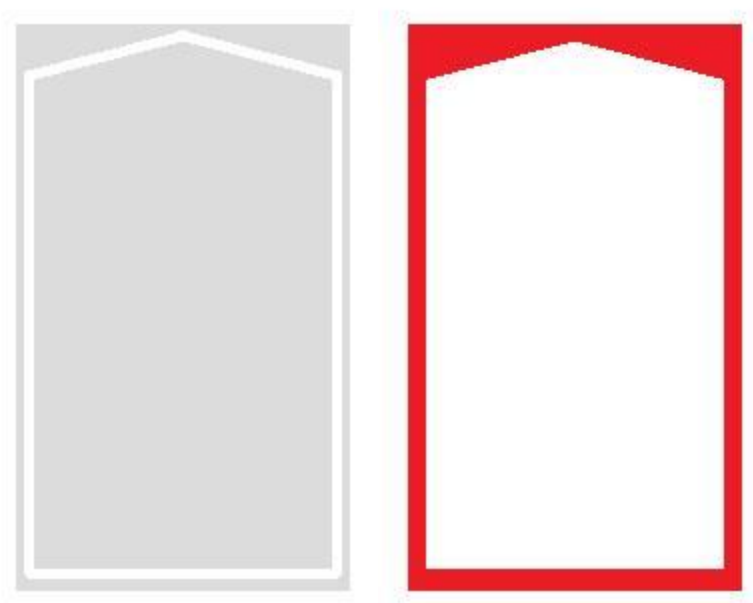
Fogg defines the boundary of the sterile field as extending to the edge of the draped table. Fogg defines a one inch non-sterile margin around the border of the wrapper [17].

Traffic

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There are also requirements regarding the proximity of personnel relative to the sterile field (see Figures 1 and 2). Scrubbed personnel should remain close to the sterile field [17]. Hands of the scrubbed personnel should remain above the waist level at all times [13]. The front of the gown, from the chest to the level of the sterile field is considered sterile. Sleeves are considered sterile from the cuff to two inches above the elbow. According to AORN, a sterile field "requires continuous visual observation" because "direct observation increases the likelihood of detecting a breach in sterility" [13]. Circulating nurses should be at least 12 inches away from the sterile field to lower the chances of contamination.

Surgical Technologists

A surgical technologist is a part of the operating room team and assists in the surgery. Education of surgical technologists includes certificates, diplomas, and associates degrees from junior colleges and community colleges [18]. Surgical technologists not only prepare the operating room's sterile and non-sterile equipment, but also prepare the patient for the surgery. Surgical technologists assist in the gowning process and present sterile items to scrubbed personnel in the sterile theater. Additional specializations are present which include the Surgical First Assistant and Circulator. Surgical First Assistants assist in the surgery in controlling blood flow and preventing hemorrhage (a process called homeostasis) [18]. Circulators are non-sterile personnel who operate in the sterile theater by presenting packages to sterile personnel. Hospitals are the primary employer of surgical technologists.

The AST guidelines start with wrapped instruments that are uncovered in a manner similar to the AORN recommendations (see page 16). Guidelines recommend that the integrity of the wrapper first be visually inspected. Flaps are opened first at the point furthest away from the surgical technologist, then at the sides, and finally at the nearest flap (See Figure 3 under the AORN guidelines on page 17). The document suggests that care be taken to not extend their hands over the sterile items [19]. Unlike Fogg, who references a 1" border on sterile wrappers, the AST suggests that a range of one to two-inch border around the wrapper is not considered sterile (See Figure 5). Additionally, excess material from wrappers extending below the table surface should not be brought back up, as they are considered non-sterile according to AST recommendations [19].

Figure 5 - Two-inch border along the edges of sterile field

Non-sterile margin between lines on sterile field.

AST recommends that "peel packs" be opened according to recommendations that are similar to those published by AORN. The integrity of the peel pack is checked and the package is oriented by grasping the opening edges in each hand. The sides are slowly separated and the item within is balanced such that it doesn't move to the edges of the package and, thus, become contaminated. The non-sterile surgical technologist is to maintain a safe distance of 12 inches from the sterile field (See Figure 1 for general OR set-up) when opening the package, and, in contrast to the AORN guides, the item is transferred by gently table-tossing it into the sterile field without crossing the boundary of the draped surface. Hands are retracted as soon as the item is airborne [19].

Similarly, opening small wrapped packages (similar in form to the gowning kit in Figure 3, but handheld and small in size) is a combination of the wrap opening and peel pack opening; integrity is checked and the flaps are opened in the order of furthest away, sides, and nearest without extending the hand over the sterile item. After the item is properly unwrapped, it is tossed gently into the sterile field and the hands are retracted when the item is airborne [19].

Traffic

As with AORN recommendations, AST suggests that the backs of sterile personnel (scrub nurse, surgeon, and surgical first assistant) should never be turned to the sterile field. Additionally, non-sterile personnel (circulating nurse and nurse anesthetist) and other non-sterile items should remain 12"-18" away from the sterile field and sterile personnel [19]. Non-sterile personnel must not pass between two sterile fields (i.e. a sterile basin and the draped patient). Sterile personnel must remain within the sterile area. AST recommends that if sterile personnel

must pass each other, it must be done facing front-to-front or back-to-back to prevent contamination [19].

Surgical Technology Principles and Practice, 5th Edition

Presentation

Yet another source for guidelines regarding aseptic presentation is the text *Surgical Technology Principles and Practice* [20]. According to this source, items packaged in sealed pouches are to be delivered directly to the scrub nurse/STSR (surgical technologist scrub role). Suture packets may be flipped into the field by peeling the pouch half-way, and then "popping open" the rest of the wrapper, propelling the item to the sterile field. *Surgical Technology Principles and Practice* also suggests that the person that presents in this type of fashion not cross the boundary of the drape [20]. Surgical technologists are also advised to not allow the item to slide across the opening of the pouch or the edges, as this contaminates the item (see Figure 4). A 1-inch margin around the edges of the wrap, as specified by the textbook, is not considered sterile. Sharps are presented directly to the individual in the scrub role and not directly to the field [20]. In addition, though many packages are designed such that items may be safely flipped into the field, large packs may not always facilitate this method and such items should be presented directly to the scrubbed personnel [20]. If there is any doubt of the sterility of the item, the item should be considered nonsterile [20].

Traffic

Sterile gowns are only considered sterile from mid-chest to the table level. The table is considered non-sterile below the surface of the table. Those who are scrubbed and in the sterile role must remain in the immediate area of the sterile field [20]. Nonsterile personnel must not

reach over the sterile field or pass between two sterile fields. Also, the sterile field must be created as soon as possible to the time of use [20]. Sterile personnel must pass other sterile personnel back to back or front to front; the back is not considered sterile as it cannot be constantly observed [20]. For this reason, one must not turn their back to the sterile field to prevent contamination.

As the various recommendations from professional organizations indicate, the practice of aseptic technique is not universal in its methodology (see Table 4). There is agreement, certainly, on the importance of maintaining the field and how one should approach it and sterile personnel in the sterile theater. The assertion that non-sterile objects should never be over the sterile field is agreed upon, but nuances such as which part of the pack is non-sterile and how one should get the package contents from the pack to the field are slightly different in nature. The following table summarizes some of these nuances in approach to aseptic presentation:

Table 4 - Differences between two sets of recommendations from AORN and AST

	AST	**AORN + supporting documents**
Wrappers	One to Two inch border	One inch border
Pouch pack delivery	12 inch distance, toss into field is acceptable	Should not be tossed into field
Sterile area of package	Advised to balance within the package when presenting, as the edges are contaminated	Line of demarcation between sterile and non-sterile*

*From the literature cited by AORN in each of the presentation guidelines

Chapter 4: Research into Routes of Contamination

Although many of the recommendations regarding sterile presentation appear to be based more on practice than on studies regarding the contamination of devices, data suggests that surgical devices serve as both a source of infection and a reservoir for them.

Studies regarding contamination of devices.

Contamination in the operating room has been studied in varied ways.

Exposure time

Minckley performed a study to characterize exposure time and handling of devices with regard to contamination. In her study of suture kits, Minckley confirmed or refuted contamination under specific conditions: a package that was dropped on the floor, a package from an open box of sutures, a package from a brand new box, and a package from a brand new box after aseptically washing the hands. In all conditions, no contamination was found. However, cultures taken prior to the study revealed bacterial growth in all 20 plates taken from the floor, 6 plates from the hands before washing, and 2 plates from the hands after washing. No sutures were contaminated despite the exposure to contaminants under the varied conditions [21].

Dalstrom et. al measured contamination to determine whether or not exposure time was a significant factor. Both Minckley and Dalstrom included the effects of open containers as a method of contamination. However, while Minckley looked at repeated use of packaging storage units, Dalstrom focused on the effect uncovered packaging and "traffic" in the room has on

contamination rates. In the study, 45 trays (three groups of 15) were measured over the course of four hours. Three groups consisted of the following: one group of uncovered trays in a locked room, one group of uncovered trays with a single individual walking past the tray every 10 minutes, and one group opened and covered with a sterile surgical towel in a locked room. Cultures were taken of the trays after 4 hours had elapsed. There was not a significant difference between the uncovered tray groups (p=0.69). Dalstrom found a statistically significant difference in contamination rates between a covered tray and uncovered tray over the course of 4 hours, with the contamination of the covered tray being significantly lower (p = 0.02) [22].

Aseptic Technique and devices

A study by Klapes et. al measured contamination rates of simulated surgical instruments (wrapped in towels) coming from the Central Sterile Supply. An overall contamination rate of 2.7% was found in the stainless steel strips, which were intended to simulate surgical instruments. Although there were no direct ties to a particular break in asepsis, contamination did occur. Thirty-six healthcare professionals, predominately nurses and surgical technicians from an operating room background (21/36), were involved in the study. Of the 119 samples used by the operating room group, 3.29% were found contaminated when samples were assayed [23]. Some departments experienced higher contamination rates than others, and the Operating Room group (with the most participants being from this background) produced the highest contamination rate.

Hall et. al. studied central venous catheter infections from a preparation angle. The practice of injecting saline into a pack to discharge static electricity is done as a preventative measure for microbial contamination. Hall's team hypothesized that this practice itself may lead

to contamination. However, the findings from the study suggested no significant difference between injected packs and those that had not been injected [24].

Jones et al. studied open versus closed staff-assisted gloving as a possible vector for contamination. Using Glitterbug Powder as a detector, Jones successfully hypothesized that the contact between the fingers and gloves in open staff-assisted gloving may be a source of contamination [25].

Gloves as contamination vector

Other researchers have investigated gloves as a mechanism as well. Davis et al used 100 patients undergoing primary knee and hip arthroplasty and observed a 14% (106/755) sample contamination rate. Twenty-five samples out of the 87 samples taken from the gloved fingertips of the surgeons revealed cultures of contamination [26]. Kong et al. performed a glove contamination study which observed the difference between two gloving methods: Method 1 involved the gloves being dropped into the opened gown pack prior to the staff member scrubbing in, and in Method 2, the staff member would scrub in after the gown pack was opened, and the gloves were presented to them. Gloves were put on using a closed technique in each case. It was found that the methods didn't differ significantly, with 67% and 63% contamination rates respectively for the first and second method. Contamination in this case seemed to stem from skin cells, water dripping into the sterile field from subject's hands, and the gown pack's exposure time to the open air [27].

Sørensen et al. monitored 10 shunt insertion operations in the early part of 2007. Many preventative anti-infection techniques were utilized including anti-microbial use, double gloving, and no-touch technique. The practices in the surgery were performed according to local preventative antimicrobial techniques (in Denmark). The surgeons, scrub nurses, and in 3 cases, the first assistant, made imprints of their gloves on agar plates for culturing. Sørensen found an alarming rate of contamination in the 10 surgeries the author monitored (100% for the surgeons, 60% for the scrub nurses), yet despite the high hand contamination rates, no infections occurred as a result [28].

Handling Pouches

Smith et al. studied contamination on individually wrapped screws in double barrier packages. Each screw was individually bagged, with a non-sterile "cover" to be opened by the scout (circulating) nurse (See Figure 1 on page 14 regarding personnel and sterility). Smith prepared and cultured petri dishes from the exterior of the pouch, the table over which the package was opened, and the scrub nurse's hand. It was found that 24 of the 50 packages had colony forming units on the exterior package, 7 of the 50 petri dishes from the opening area had contamination, and the scrub nurse's hand showed more than 100 colony forming units of microorganisms [29].

Crick et al. also studied contamination on screws that were packaged in banks or individually wrapped. However, unlike Smith's team, Crick utilized Glitterbug cream (Brevis Corporation, Salt Lake City, UT) to characterize contamination in these double-wrapped screws. Five theater nurses opened up 20 individual double-wrapped screws and 1 screw bank (a single container containing multiple screws). The number of screws in the screw bank was not explicitly stated in the study. Nurses applied a new application of the Glitterbug cream to their bare hands after every 10 packages. Samples were not analyzed if the nurse had believed contamination occurred (as, in the OR, the package would have been discarded and not used). Five screw banks were opened using similar methodology as the individually wrapped screws. One sample (inner pack) out of 100 was found to be contaminated with the cream. The inner packet was stipulated by Crick to have occurred from brushing against the outside of the non-sterile layer in the individually wrapped screws. No screw banks were contaminated [30].

Package handling studies produce interesting questions. Previous work by Smith et. al. [29] and Crick et. al. [30] has suggested the possibility that aseptic presentation is one possible route of contamination, but further information is needed. Crick concluded that opening individually wrapped items (in his study, surgical screws versus screw banks), potentially increases risk for contamination in the sterile theater. Smith saw the spread of microbes as a result of opening the package itself, and even the scrub nurse in his study had contaminated hands.

This suggests that packages that require more handling enhance the likelihood of contamination. It follows then that if larger packages are harder to control and maintain aseptic technique (securing the opening edges of the pouch to prevent the flaps from curling in), package size may influence handling and, in turn, rates of contamination. Smith found cultures on the hands of the circulator (Figure 1 on page 14), suggesting that if the device were to come into contact with the hands, contamination could possibly occur. Crick, in his study, stated his observation of the cream on the outer and inner packages: "We assessed this pattern as being consistent with the inside packaging having rubbed over an area of the outer packet that had been touched before the removal of the inside packet" [30].

Chapter 5: Materials and Methods

The major objective of this study was to understand how pouch size impacts a nurse's ability to aseptically present devices to the sterile field. To do so, we asked healthcare professionals involved in asepsis to present the contents of three sizes of pouch to a simulated sterile field using methods adapted from Crick et al. [30]. Dependent variables for analysis included: the number of times nurses repositioned their hands in order to successfully open packages and the presence or absence of contamination on the items presented.

Materials

- Glitterbug® Potion Pump Bottle Brevis Corporation (Salt Lake City, UT)

- Glitterbug® Glowbar UVA Lamp Brevis Corporation (Salt Lake City, UT)

- Paint Brushes   Loew-Cornell (Englewood, NJ)

- Paint roller from Quick Solutions (Cleveland, OH)

- Chevron-style pouches

    o Poly film: PET/LDPE coextruded layer

    o Uncoated Tyvek layer

    o Small pouch- 3" x 8" poly/Tyvek pouch (198) Oliver-Tolas Healthcare Packaging (Grand Rapids, MI)

    o Medium pouch- 10" x 9-5/8" poly/Tyvek pouch (198) Oliver-Tolas Healthcare Packaging (Grand Rapids, MI)

    o Large pouch- 16" x 10-1/2" poly/Tyvek pouch (198) Oliver-Tolas Healthcare Packaging (Grand Rapids, MI)

- Cases of Sterling Nitrile Powder-Free Exam Gloves, Kimberly-Clark (Roswell, GA)

- Tongue Depressors, Unknown Manufacturer, Provided by Cardinal Health

- Sterilization Wrap (Simulated Sterile Field) Kimberly-Clark (Roswell, GA)

- Sealing machine: Vertrod Impulse Sealer, 260°F, 3 seconds

- Folding Camera Holder

    o Grid cell size: 1 cm x 1 cm

- Corel Draw X3 Version 13

- Digital Camera

- Video cameras

Methods

Preparation

Packages were cut manually to size, filled with tongue depressors, and sealed with an impulse sealer (Vertrod model 14BP-WE, 260°F, 3 seconds) in the laboratory. Sterile fields were cut from sterilization wrap to the dimensions of 28.5" by 15". The size was chosen based on material availability, and the fact that sterile fields of this size exist in an OR setting.

Tongue depressors were selected as an affordable, porous medical device that provided adequate contrast to detect the Glitterbug under the UVA lamp (Brevis Corporation, Salt Lake City, UT). Using a white or grey colored device would have made the detection of trace amounts of cream difficult, so a neutral color which didn't cause these problems was desirable.

Participants

Ninety-nine healthcare providers were recruited and tested at one of the following venues: the 58th Annual Association of perio-Operative Registered Nurses (AORN) Congress (Philadelphia, PA), the 2011 Annual Meeting of the Association of Surgical Technologists (San Francisco, CA) or the Pontiac Regional Medical Center (Pontiac, MI) using procedures and documents approved as part of IRB 11-102 (see Appendix B for all IRB approved forms).

In accordance with approved policies, participants had to be: at least 18 years of age; have no history of skin condition (e.g. latex allergy or eczema); currently be employed as, or have a history of employment as, a healthcare professional and be willing to be digitally recorded.

Upon arrival, each participant signed a consent form (See Appendix B) and was assigned a participant number. All data was tied to participant number and not name. Although all participants were digitally recorded, enabling review of biomechanical approach, participants could indicate that they were not willing to have these images shown publically. As such, each participant had a sticker affixed to the lab coat that they wore during testing; a red sticker indicated that the participant did not consent to have their images shown publically, while those with yellow stickers had consented.

Following this, participants' were asked to fill out basic demographic information including: age , gender and information regarding employment history (see Appendix B).

To characterize the size of each subject's hands, researcher asked each subject to lay their dominant hand (or hand of choice if ambidextrous) flat on a grid system of known proportions (Figure 6), and a digital picture was recorded. These images were analyzed post hoc using photographic methods employed to characterize anthropometrics in prior research (DTI, 2002 b; Wong and Whishaw, 2004; de la Fuente, 2006). Hand breadth was measured using the distance between the metacarpal II and V area of the hand as described in de la Fuente's work [31]. Measurements were done using Corel Draw X3 VERSION 13. Images were scaled by resizing the picture until the gridded cells measured 1 cm by 1cm.

Figure 6 - Measuring Grid for Hands

Testing

Each participant was asked to aseptically present the contents of six chevron pouches (tongue depressors) to a simulated sterile field measuring 15" x 28.5". Three sizes of chevron pouch were used: 3" x 8" (small), 10" x 9-5/8" (medium), and 16" x 10-1/2" (large). Each participant

opened each size twice, for a total of six openings per participant. Order of presentation was randomized to mitigate any effect of fatigue or run order.

Randomization was performed using a six-sided die. Each side of the die was assigned to one trial as presented in Table 5:

Table 5 - Randomization

Trial	Side of die to which each trial is assigned
Small pouch 1	1
Small pouch 2	2
Medium pouch 1	3
Medium pouch 2	4
Large pouch 1	5
Large pouch 2	6

In order to determine the order of presentation for each subject, the die was rolled until each side of the die had resulted. For example, if a small pouch (2) had already been drawn, the die would be rerolled until a new number was obtained.

Figure 7 - Chevron-style pouch (Left to right: large, medium, small)

Pouches were filled with tongue depressors such that the "aspect ratio" (i.e. surface area of the pouch/ surface area of the tongue depressors) was approximately equal for all three sizes. The surface area of one side of one tongue depressor was 3.75 sq-in. The surface area of one side of the 3"x8" pouch was 24 sq-in. Therefore, the aspect ratio between the two is approximately (24/3.75) = 6.4. This ratio was maintained throughout the experiment by cutting the medium and large pouches to an appropriate length. Table 6 provides the number of tongue depressors per pouch size as well as the aspect ratio for each.

Table 6 - Aspect Ratio (Width versus Number Devices)

Pouch	Dimensions (width x length), inches	Area of one side	Number of Tongue Depressors	Surface Area of Tongue Depressors	Aspect ratio Area of pouch/Area of Tongue depressors
Small	3" x 8"	24 in^2	1	3.75 in^2	6.4
Medium	10" x 9-5/8"	96.25 in^2	4	15 in^2	6.4
Large	16" x 10-1/2"	168 in^2	7	26.25 in^2	6.4

In order to simulate and measure "contamination" of package contents (i.e. tongue depressors) the methodology developed by Crick et al. [30] was adapted in the following ways. Gloves were added to the study to facilitate a time efficient manner to do multiple trials and to enhance the consistency of coverage of the microbial simulation (Glitterbug Potion) between each trial. This differs from the Crick team, who instructed subjects to reapply the cream directly to their skin after every 10 trials. To ensure consistent application of the cream, the gloves were coated with a specific number of pumps of the bottle after each trial (see Table 7). Each glove

received 2 pumps of cream. See Table 7 - Amount of cream per pouch" for more detail on pumps of cream for equivalent quantities.

To simulate contamination that would occur if a device were to brush the outside of the pouches, cream was applied to the pouch as well. All test pouches were coated immediately preceding testing with Glitterbug ® Potion (Brevis Corporation, Salt Lake City, UT). Applications of the Glitterbug cream were applied to the pouch using a Quick Solutions® paint roller. A single application of the cream was applied to each side of the small pouches and two applications to each side were made to the medium pouch, and three applications were applied to each side of the large pouch.

To approximate the amount of cream that was applied, we used the average of ten different trials for each size to create Table 7.

Table 7 - Amount of cream per pouch

	Average grams of cream per side (pumps)	Standard Deviation
Small pouch (1 side)	0.5735 (1)	0.3067
Medium pouch (1 side)	0.8128 (2)	0.4788
Large pouch (1 side)	2.0625 (3)	0.7606

n = 10

Healthcare professionals were asked to select and don the appropriate size of non-latex glove, at which point researchers coated their gloved hands (with the exception of the bottom of the thumbs and index fingers) using two pumps of Glitterbug® potion (Figure 8). Art Paint brushes made by Loew-Cornell (Englewood, NJ) were used to apply the cream to the gloves,

using one application per side of the glove. The purpose of not coating these digits is to ameliorate any problem that might result due to the change in friction, which could influence results.

Figure 8 - Glitterbug® Potion

The chevron area of the pouch and the material above it was not coated with cream. As with the gloves, this was done so that the cream, which served to simulate microbes, did not act as a lubricant between the digits and the pouch. The areas which were coated are shown in Figure 9.

Figure 9 - Coating (in blue) of gloves and pouch
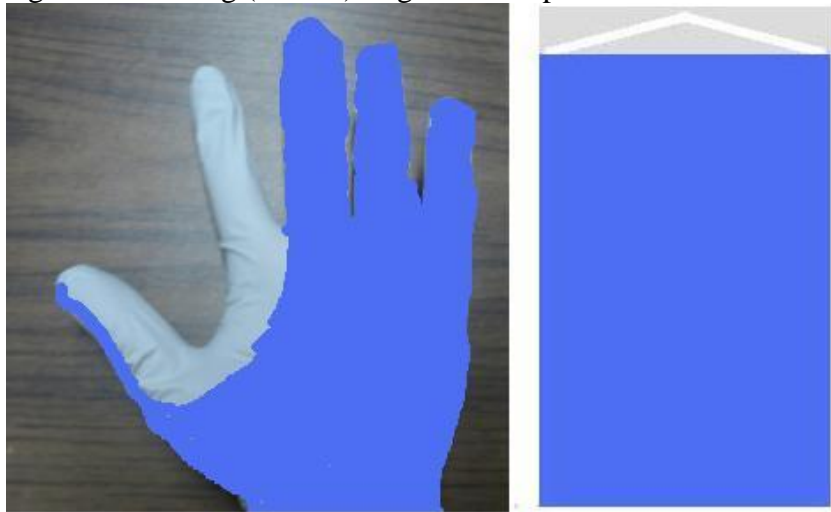
The Glitterbug cream served as a model for contamination, as the outside of the package

and the hands of a non-sterile circulator are assumed to be non-sterile. As the device makes

contact with non-sterile areas of the hands and/or package, the cream transfers from the package

or hands onto the porous tongue depressor, providing evidence of potential contamination of the

device. We utilized "clean" and "cream-contacting" researchers. Clean researchers did not

handle the cream or cream-contaminated objects. Their primary role was to prepare new drapes

(Kimberly-Clark, Roswell, GA) for each trial, record the process with the camcorder, and to

mark the data sheets, and slide the drape carefully to the scanning area. Clean personnel were

also tasked with scanning samples for positive cream transfer. By contrast, "cream-contacting"

personnel coated and removed pouches and gloves.

As mentioned previously, each participant opened and presented the contents of each size

of pouch twice, for a total of six openings per participant. A new pair of gloves, with newly

applied cream, was used for each package opening. Devices and drapes were then carefully

removed from the field by clean research personnel and inspected for contamination by a

designated sample collector. Contamination was recorded in binary fashion (yes/no), by

inspecting the devices under the UVA detector (black light lamp) and coding a "yes" for any that had visible transfer of the Glitterbug® cream (Figure 11).

Figure 10 - Glowbar UVA detector

An example of the interaction between the cream and the detector can be seen in Figure 11.

Figure 11 - Interaction of Detector and cream

Drapes were folded and separated into individual bags for transport. Bags were clearly marked with the subject number to link the drape with the participant's data. All collected footage was viewed post-hoc to quantify the hand repositioning for the participants.

Hand repositioning was quantified by a single member of the research team. The guidelines for what was deemed a "reposition" follow: If the subject moved the entire hand in either direction to re-grasp the opening of the pouch, if the subject did not move the hand but used an additional digit to manipulate the opening (i.e., used their ring or pinky finger to pull back another area of the opening of the pouch), or if the subject slid their hand or finger any distance across the opening of the pouch. Counting of hand positions commenced when the participant had the opening of the pouch gripped and poised to open. In cases where the participant did not have each flap in their hands, but began to snap open the seals on each of the corners, hand repositioning was counted as soon as the first seal was broken. Hand-to-pouch aspect ratio was calculated as the hand breadth (cm) divided by the pouch width (cm).

Chapter 6: Results

Ninety-nine subjects (81 females and 16 males) were recruited at the 42nd Association of

Surgical Technologists conference (San Francisco, CA), the 58th Annual Association of Peri-

Operative Registered Nurses conference (Philadelphia, PA), and the Pontiac Regional Medical

Center (Pontiac, MI). Two subjects were removed from the data set because they reported "0"

years of experience in the healthcare industry. Because the study focused on working

professionals, we chose to screen individuals with no prior experience. Therefore, the analyzed

data set is comprised of 97 subjects. Each time a participant opened a pack into the sterile field,

this counted as one "trial;" subjects trialed each of the three pouches twice for a total of six trials

per subject, or 582 trials across all subjects. Subjects were aged 26 to 64 with a mean age of

47.98 years and a standard deviation of 9.98 years. See Appendix A for tabulated demographical

information.

__Demographical Analysis__

Fifty-five (55) nurses were compared to forty-two (42) subjects who self-reported as

surgical technologists(40/42), doctors(1/42), or "other" (1/42). Within the "other healthcare

provider group," surgical technologists were predominant (40 out of 42); for the purpose of

analysis, their data was combined with that of the physician (1 subject) and the other healthcare

provider (1 subject). Subjects were categorized based on years of experience in both the

healthcare field, in general and, more specifically, their years of experience presenting to a sterile

field. The mean and standard deviation of experience (in years) in both of these categories is

reported in Table 8.

Table 8 - Average Experience of Nurses and Other Professions in Healthcare and Aseptic
Presentation

Profession	Mean Years of Healthcare Experience	Standard Deviation	Mean Years of Experience with Presenting to a Sterile Field	Standard Deviation	Sample Size (n)
Nurse	26.97	9.09	22.75	9.88	55
Other	14.00	12.93	12.88	12.51	42

See appendix A for means, standard deviations, and ranges across all subjects for age, experience

presenting to the sterile field, and hand size.

Nurse and Other Professions Experience Distribution

The distribution of nurses and other professions experience in healthcare and aseptic

presentation were analyzed using R software version 2.13.1. Box plots were generated using R

to display the demographics gathered from the two professions in terms of experience in

healthcare (Figure 12), aseptic presentation (Figure 13), and age (Figure 14).

Figure 12 - Box and whisker plots of self-reported experience as a healthcare provider by profession

Reported Experience in Healthcare Distribution

Note: Solid black bars indicate medians, not means.
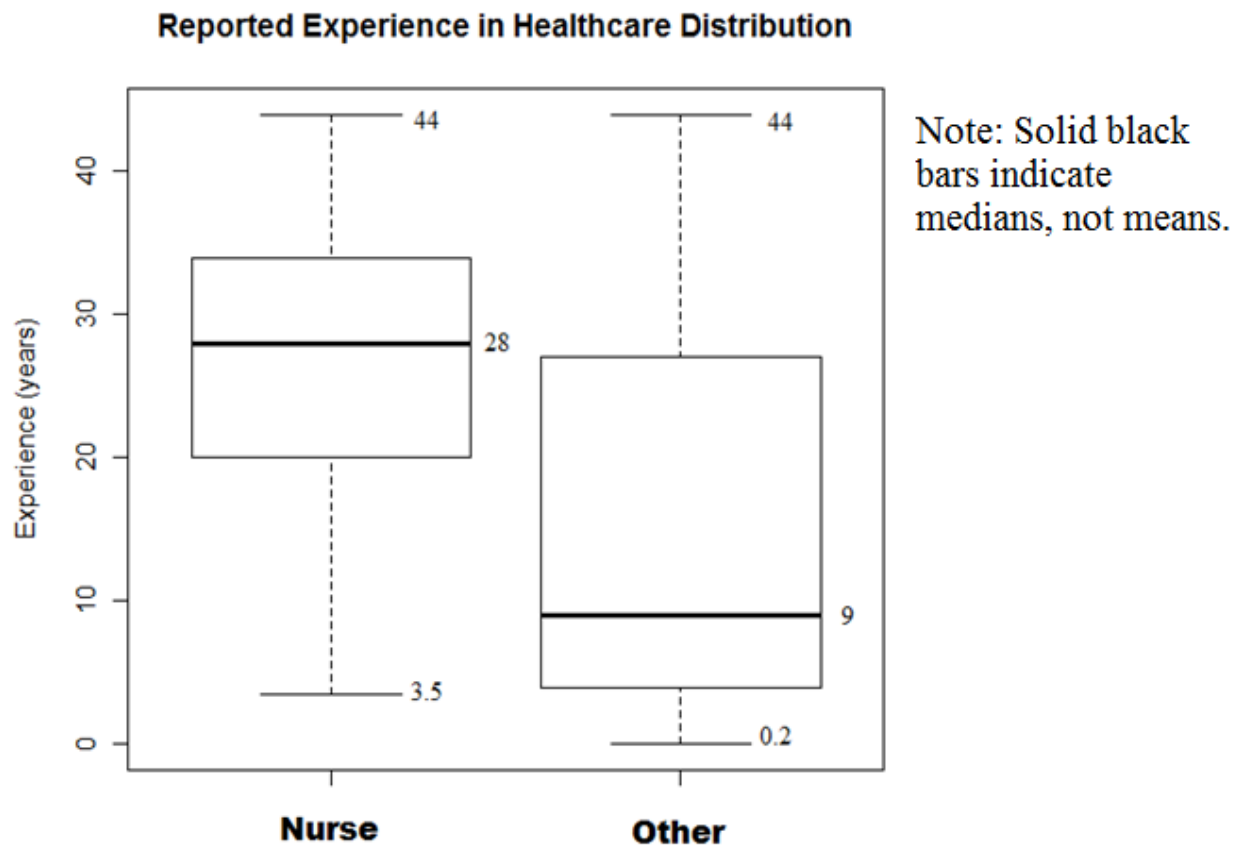
Figure 13 - Box and whisker plots of the distribution of self-reported experience with aseptic presentation by profession

Reported Experience in Aseptic Presentation Distribution

Note: Solid black bars indicate medians, not means.
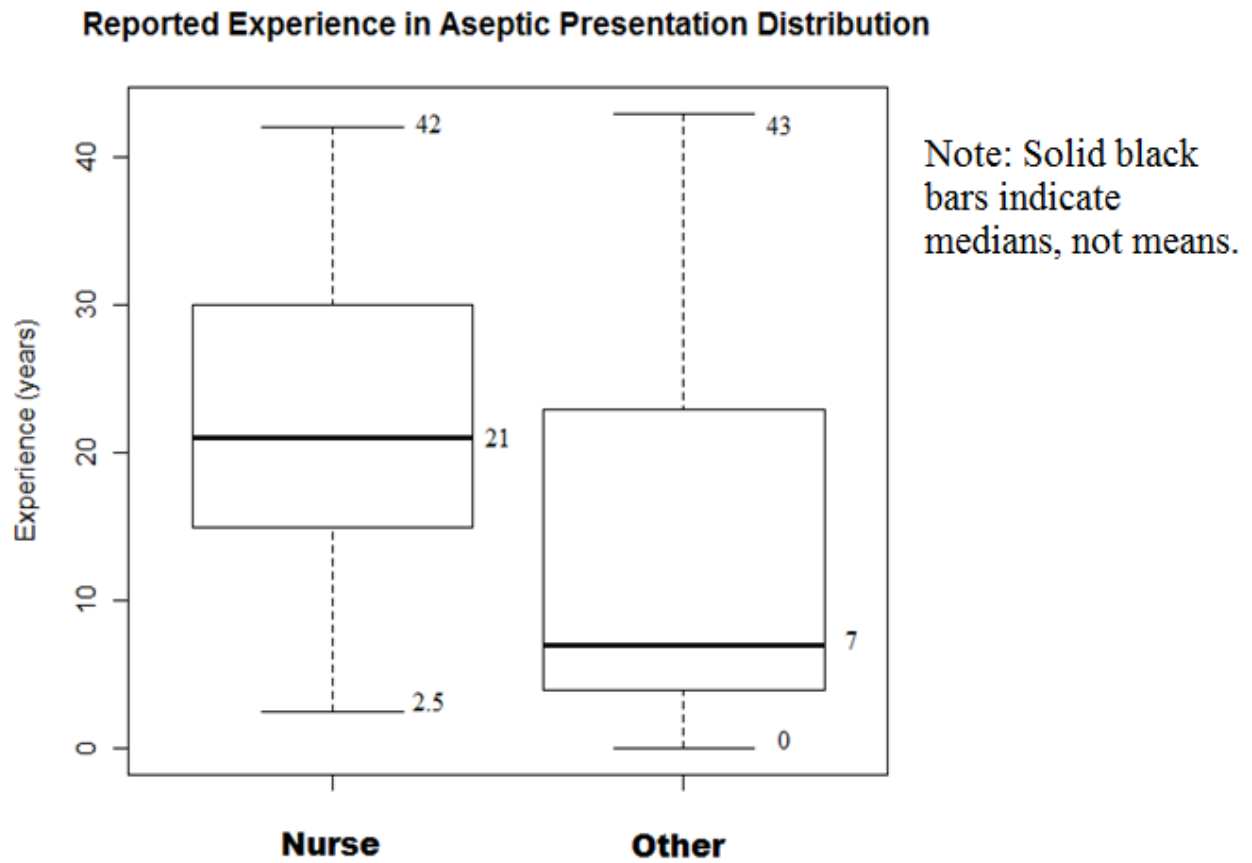
Age of Subjects

Figure 14 - Box and whisker diagrams of ages by profession

Reported Age Distribution by Profession

Note: Solid black bars indicate medians, not means.
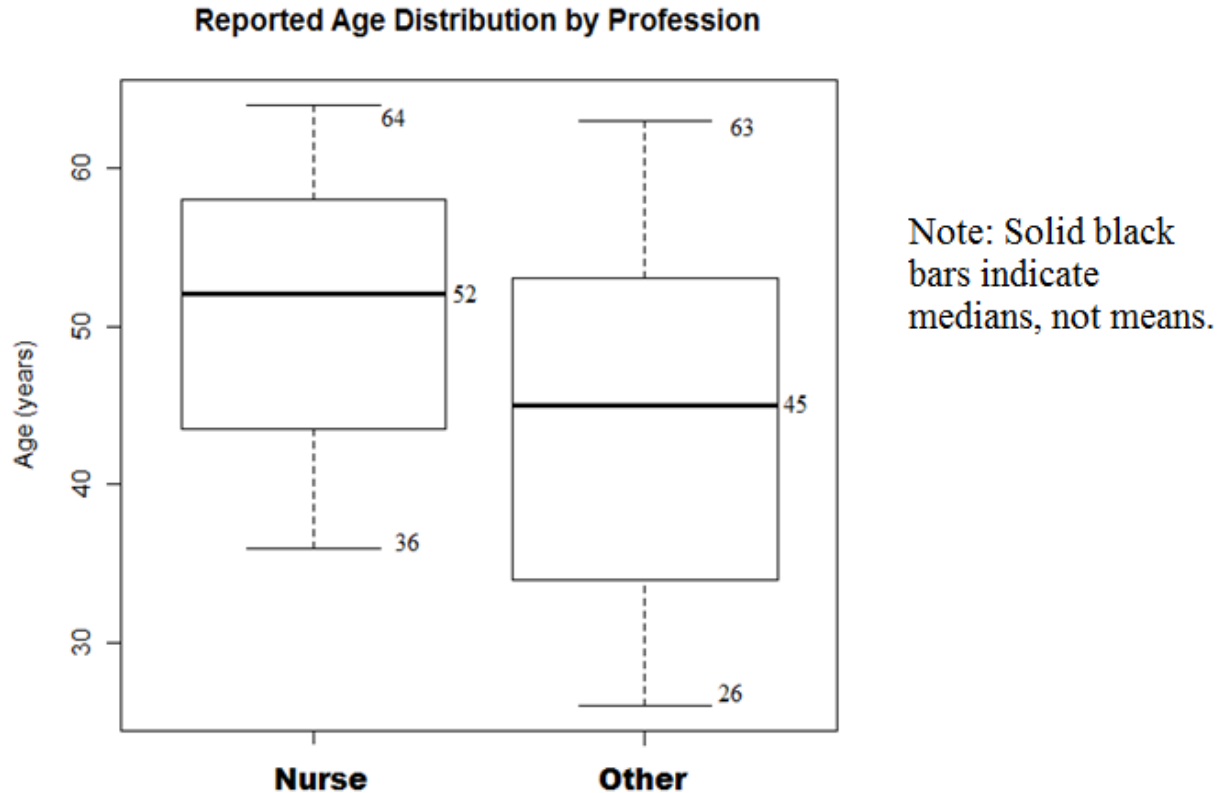
The average age of participants (overall) was 48.0 years (SD 10.0). They averaged 21.4 years of experience (SD 12.6), and 18.5 years of experience presenting to the sterile field (SD 12.1). Not surprisingly, Pearson correlation coefficients suggested that age was positively correlated with both years of work experience ($r = 0.78$) and experience with years of aseptic presentation ($r = 0.66$).

Cream Transfer by Trial

Each of the 97 subjects opened two each of three sizes of pouch, for a total of 582 openings (6 pouches x 97 subjects). Immediately following presentation to the sterile field, all

tongue depressors were examined under black light for any sign of contamination. A trial was considered contaminated in a binary fashion (i.e if ANY of the tongue depressors within the pouch were contaminated). A total of 65 opening trials (11.2%) tested positive for contamination (see Table 9).

Of the 65 contaminated trials, 49.23% (32/65) were attributed to large pouches. Just over 29% of the contaminations were found in the medium pouches (19/65). The small pouch contributed 21.54% of the pouches contaminated (14/65). The percentage of the large, medium, and small pouch trials with positive cream transfer in comparison to the total number of trials (582) was 5.5% (32/582), 3.3% (19/582), and 2.4% (14/582), respectively. See Table 9 for the findings.

Table 9 - Distribution of Contamination by Size

Trials with Cream Transfer by Size	Percent of Cream Transfer-positive Trials (Denominator = 65)	Percent of Trials for that size of pouch (denominator = 194)	Percent of all Trials (582= total number of trials)
Large	32 (49.23%)	32 (16.5%)	32 (5.5%)
Medium	19 (29.23%)	19 (9.8%)	19 (3.3%)
Small	14 (21.54%)	14 (7.2%)	14 (2.4%)
Totals	65 (100%)	N/A	65 (11.2%)

The 65 contaminated trials were further characterized by profession.

Figure 15 - Distribution of Cream Transfer Trials by Size and Profession

Distribution of Contaminated by Profession
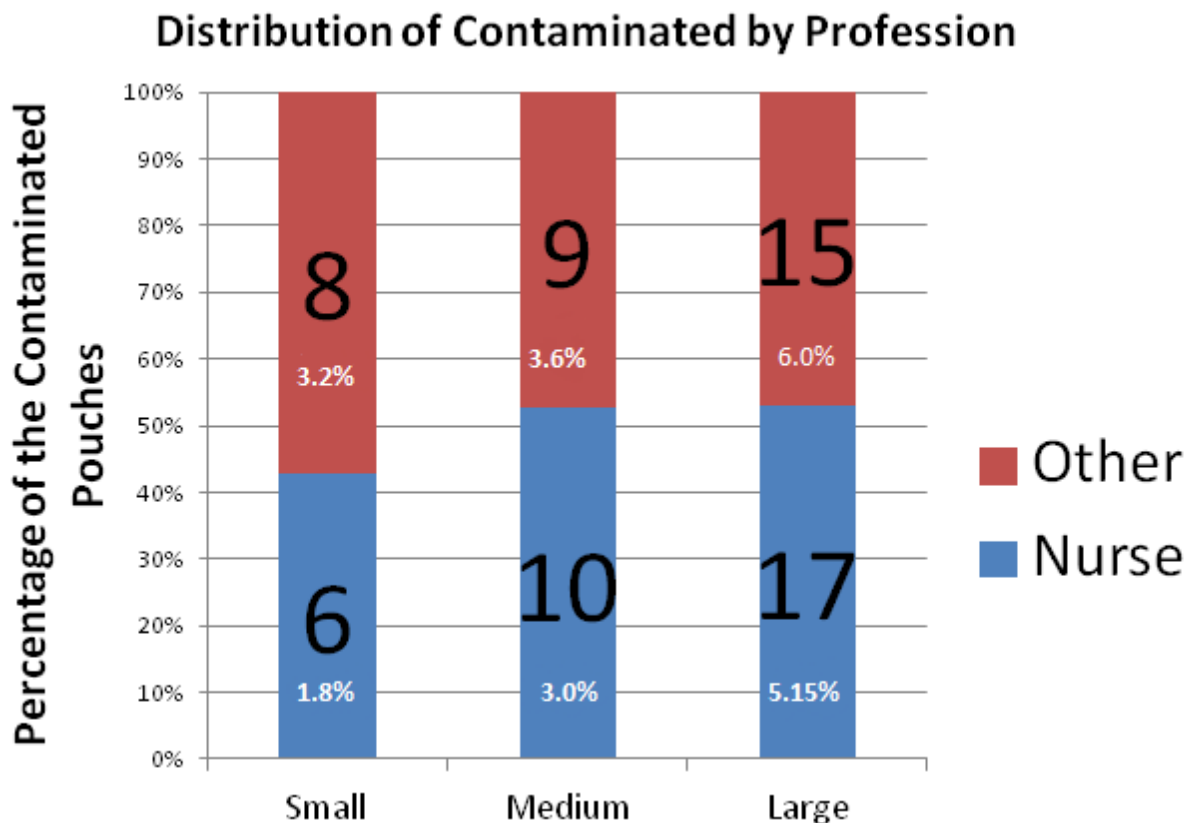
Of the 582 trials, a total of 330 were collected from nurses (55 nurses x 6 packages/nurse), and 252 trials were collected from "other healthcare professions" (42 other x 6 packages/other). Twelve trials of the 252 trials were the contribution of subjects that self-reported their professions as "Doctor" and "Other." Of the 65 contaminated trials, 61 were at the hands of either nurses or surgical technologists. The four (4) other contaminated trials came from 1 doctor and 1 "other" profession, contaminating two (2) each. Within Figure 15, the percentages presented on the bars are the percentage of cream transfer trials out of all trials within that profession by pouch width. For example, within the 252 trials conducted by those in "other healthcare" professions, eight of the small pouches were contaminated (3.2% or 8/252 that they trialed). Compare this with 15/252 for the large size, or 6.0% of the total that this

profession trialed. Of the 32 total contaminated trials for "large" pouches, 15 were contaminated by "other healthcare" professions and 17 were contaminated by Nurses.

Effect of Pouch Size on the Probability of Pouch Content Contamination

Data were analyzed with the primary objective of determining whether or not pouch size significantly affected the probability of contamination on pouch contents. As such, binary data (trial contaminated; yes/no) was analyzed using a General Linear Mixed Model, fitting the response variable with a logit link function in SAS. The linear predictor in this model was pouch size (a fixed effect). Explanatory variables (gender, education, profession) and the covariates (age, years of working experience, years of experience with aseptic presentation, hand breadth, number of repositions) were excluded from the model due to non-significant P values (P>0.10). Also, the variables were excluded based on maximum likelihood Bayesian Information Criteria for evidence of improved model fit. The model included "subject" as a blocking factor. The random effect of subject-by-pouch size was not included, due to the variance component of subject-by-pouch-size converging to zero during the estimation process. This random effect was excluded from the model. Kenward-Rogers was used to estimate the denominator degrees of freedom for the fixed effect of pouch size. Estimations were done manually with the goal of preventing inflation of degrees of freedom.

Data analysis suggested evidence of an effect of pouch size on the probability of pouch content contamination (P=0.01), with the probability of contamination increasing with increasing pouch size.

No over-dispersion was apparent after evaluation with a maximum likelihood-based Pearson Chi-Square/DF fit. The final model (the one analyzed) was fitted using residual Pseudo-

Likelihood. PROC GLIMMIX was used in SAS with Newton-Raphson with ridging as the optimization technique.

Post-hoc, pair-wise comparisons utilized Tukey-Kramer adjustments to prevent inflation of Type I error from multiple comparisons. When contamination rates of the small pouch were compared with the moderate sized pouch, no significant difference was evident (P = 0.6196) See Figure 16, letter A). The same was true when the large pouch was compared with the moderate sized pouch (P = 0.1123) (See Figure 16, letter B). However, when contamination rates in trials involving the small pouch were compared with trials from the large pouch, a significant difference was evident (P = 0.0130), with more contaminations occurring in trials involving the large pouch (14 contaminated in small versus 32 in large, see Figure 16).

Figure 16 - Least Square Mean Contamination by Pouch Size, α = 0.05
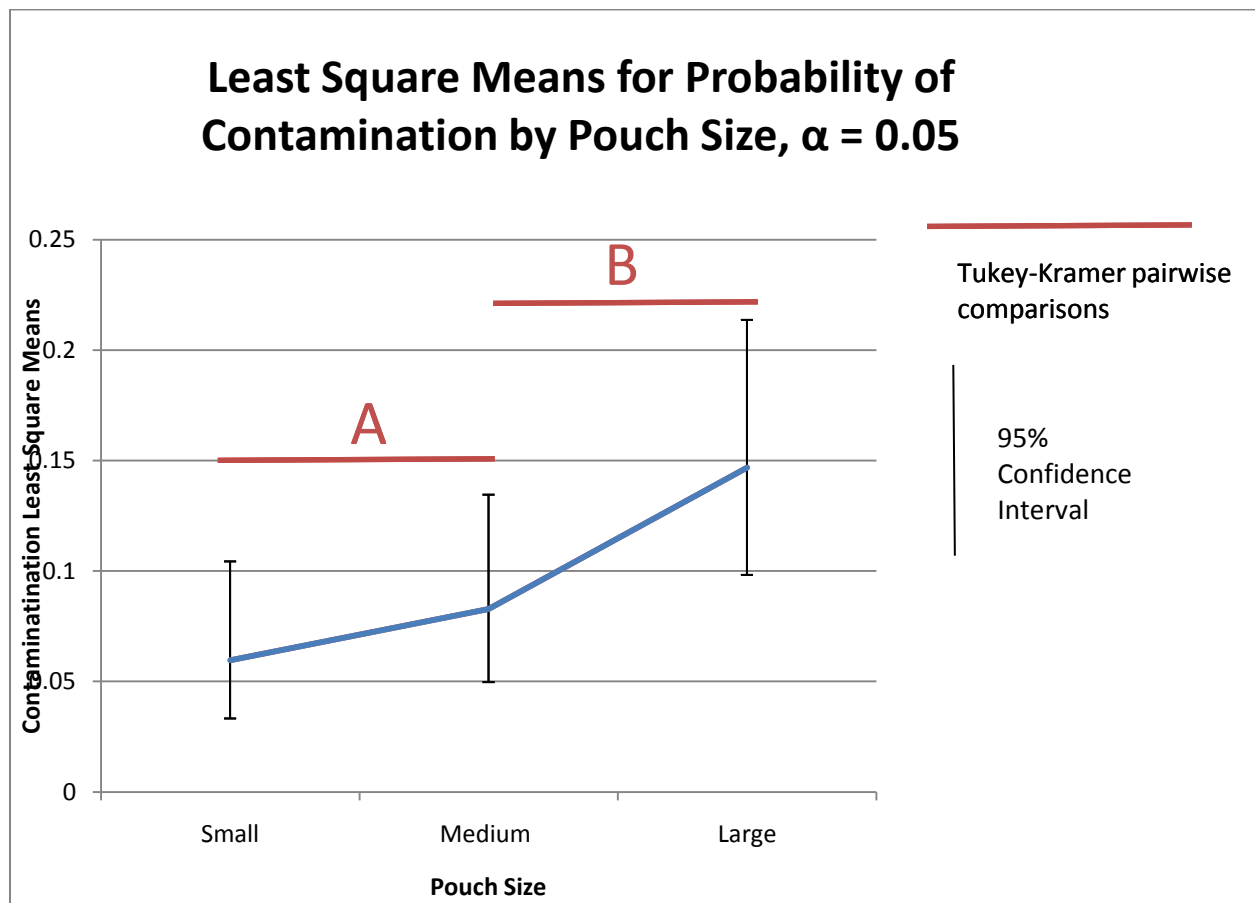
Hand Repositioning

Hand repositions were counted based on the guidelines presented in the methodology. The breadth of the hand (in cm) was divided by the width of the pouch (in cm) to determine an "aspect ratio" relationship between the two. The hypothesis was that a small aspect ratio (a small hand/large pouch) would result in a greater need to reposition the hand. Hand repositioning was plotted against aspect ratios (hand breath in centimeters/ pouch width in centimeters) for all 582 trials (See Figure 17).

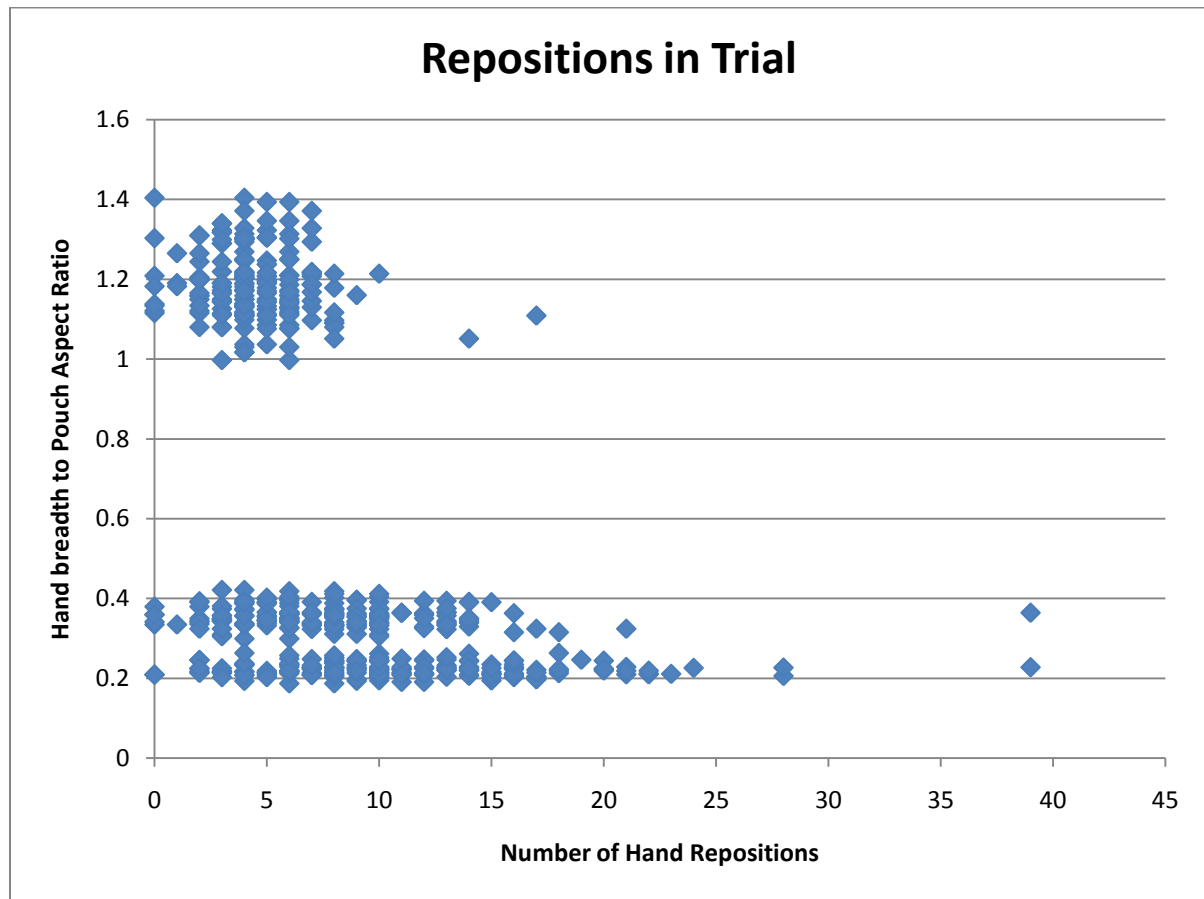Figure 17 - Hand-to-Pouch Aspect Ratio versus Hand Repositions

Figure 18 - Pouch Repositions in Small (top) and Medium (bottom) Pouches
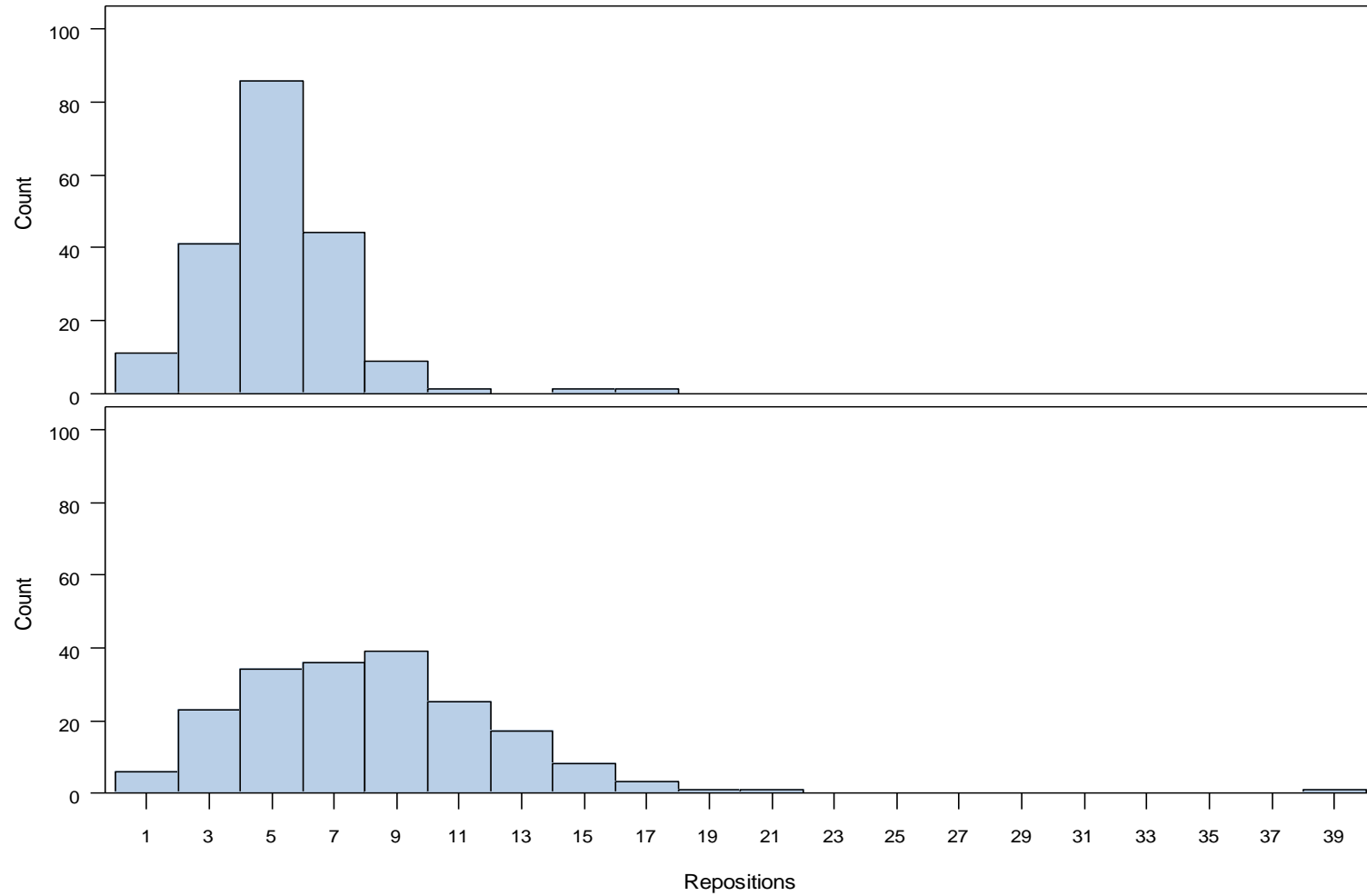
Figure 19 - Large Pouch Repositions
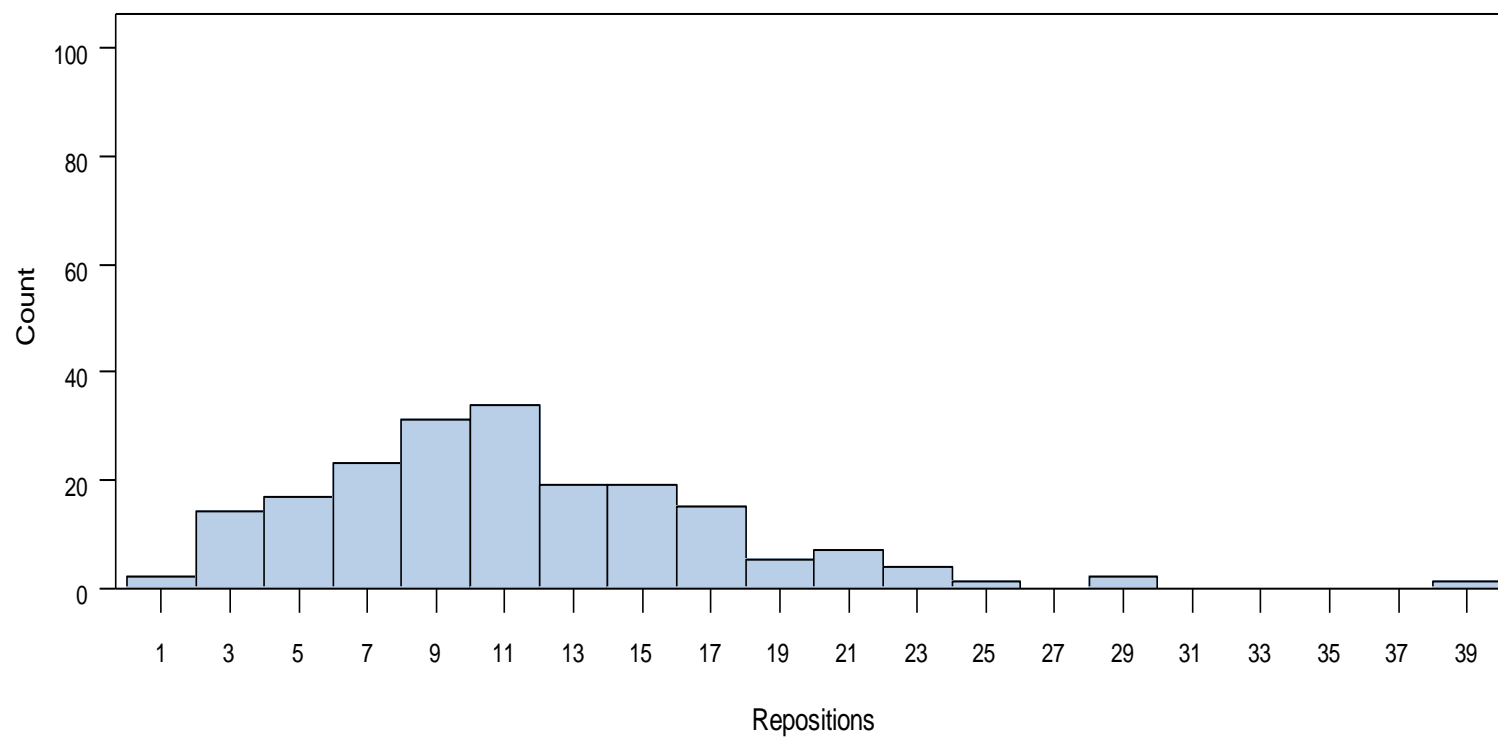
The effect of Pouch Size on the Number of Hand Repositionings During Pouch Opening

   A generalized linear mixed model was fitted to "number of repositionings" (count response), assuming a Poisson distribution. The model was fitted using a log link function. The linear predictor in this model was pouch size (a fixed effect). Explanatory variables (gender, education, profession) and the covariates (age, years of working experience, years of experience with aseptic presentation, hand breadth, number of repositions) were excluded from the model due to non-significant P values (P>0.10). Also, the variables were excluded based on maximum likelihood Bayesian Information Criteria for evidence of improved model fit. The model included the random effect of subject for blocking, and the subject-by-pouch-size combination to recognize the appropriate experimental unit for pouch size. No over-dispersion was apparent after evaluation with a maximum likelihood-based Pearson Chi-Square/DF fit. The final model (the one analyzed) was fitted using residual Pseudo-Likelihood. Degrees of freedom were estimated using Kenward-Roger's. PROC GLIMMIX was used in SAS with Newton-Raphson with ridging as the optimization technique. Pair-wise comparisons (i.e. comparing small pouches to medium pouches) were done with Tukey-Kramer adjustments to prevent inflation of Type I error from multiple comparisons.

   There was evidence to indicate that pouch size increases repositioning (P<0.0001), whereby larger pouches induced more movement. The repositions increased by nearly 3 from the small to the medium, and from the medium to the large (See Table 10 and Figure 20).

Table 10 - Least Square Mean Repositions by Pouch size with 95% confidence intervals (alpha=0.05)

Pouch Size	Lower CI	Mean repositions	Upper CI
Small	3.8586	**4.3005**	4.7930
Medium	6.4059	**7.0810**	7.8273
Large	9.0300	**9.9428**	10.9479

Figure 20 - Least-Square Means for Repositionings by Pouch Size
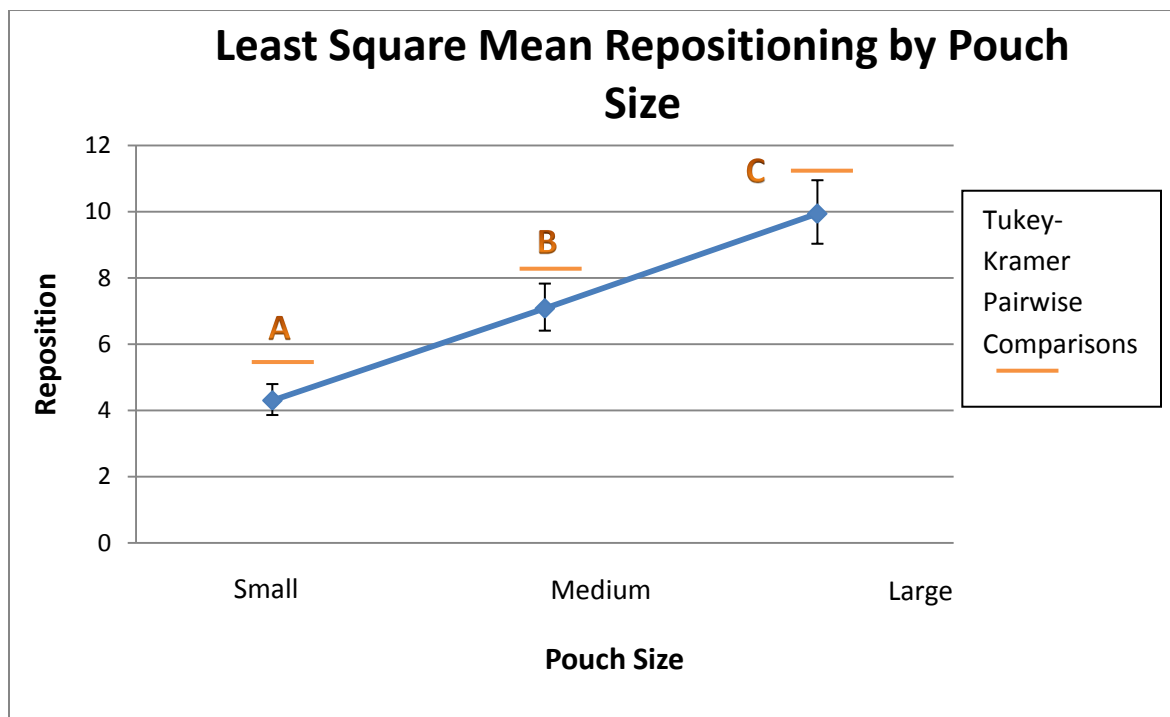
Figure 21 - Plot of repositions per pouch size
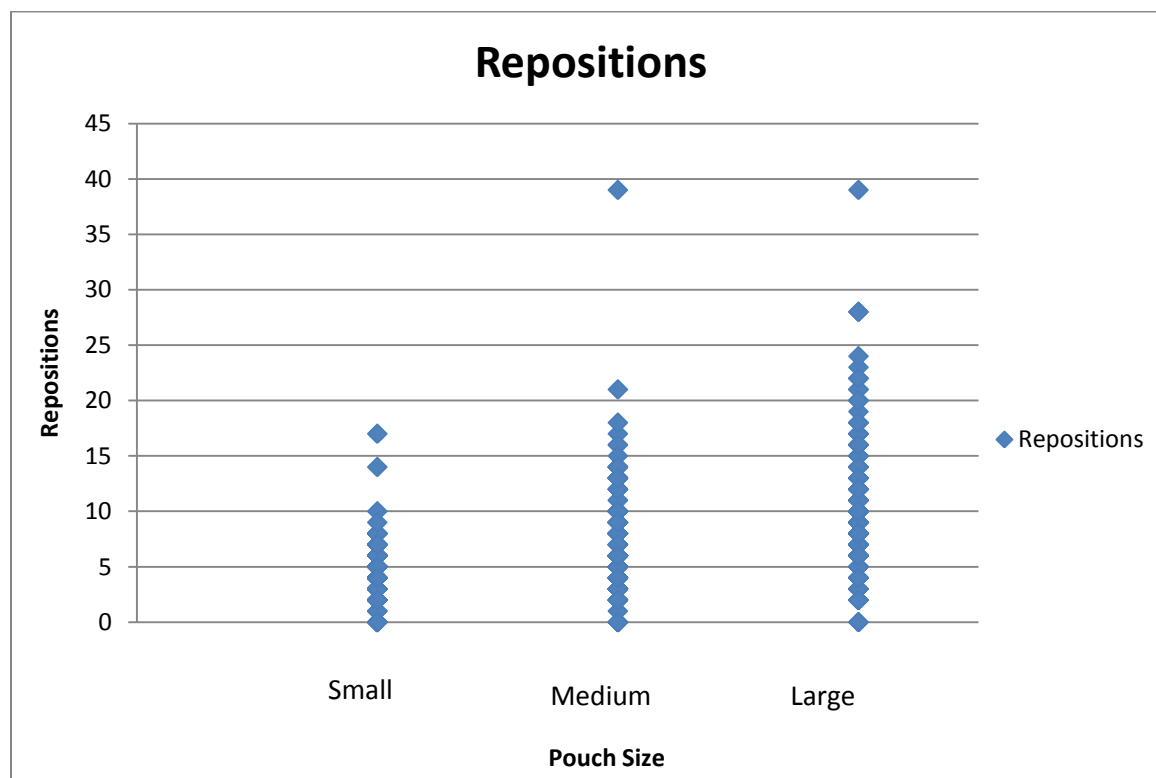
Figure 22 - Plot of Repositions per pouch size, overlaid with Tukey-Kramer comparisons and Least Square Means plot
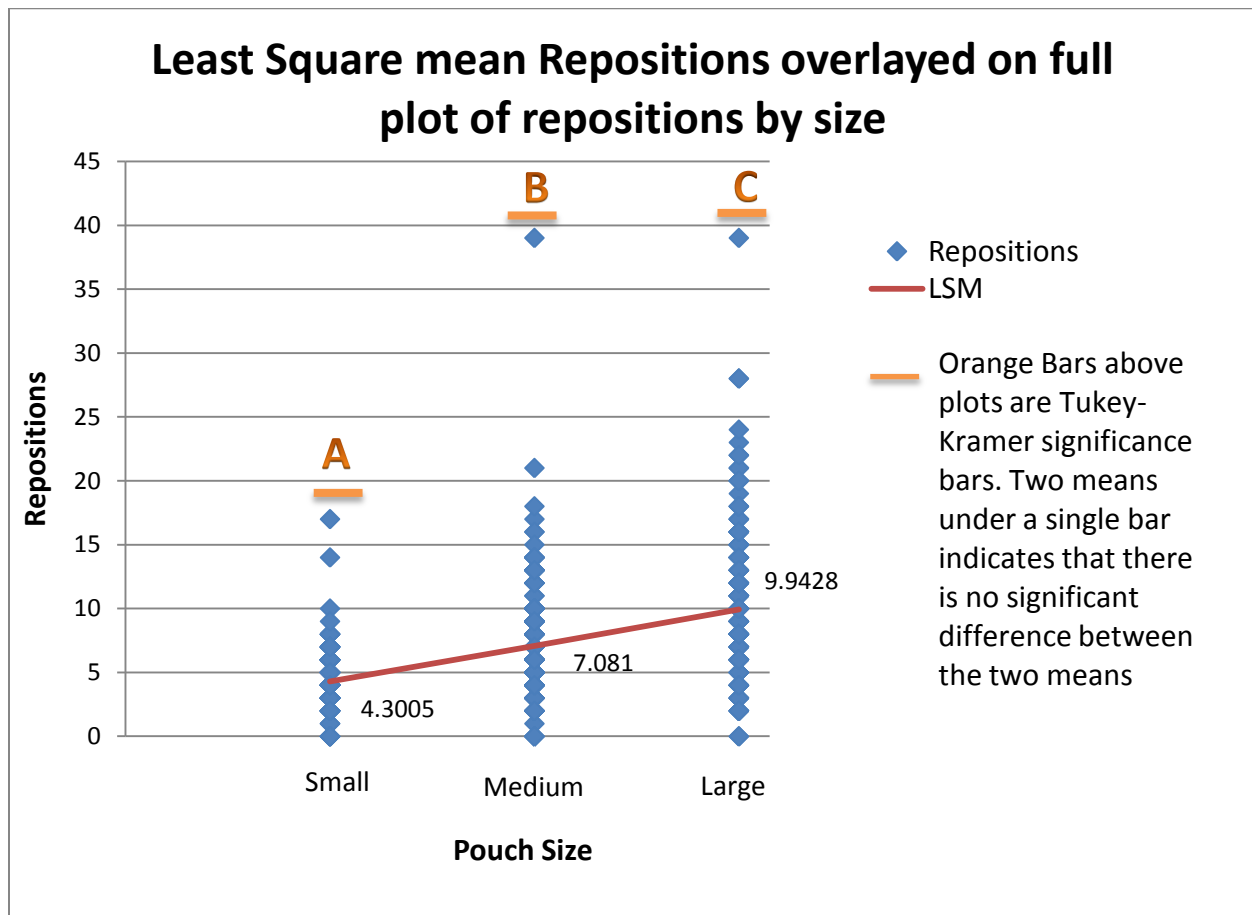
The results of the Tukey-Kramer pair wise comparison revealed that all sizes were significantly different from one another. Comparisons of hand repositioning were conducted using an LSM technique ($p < 0.0001$ in all 3 comparisons).

Conclusion from Results

The data from the contamination trials suggests that probability of contamination increases with increasing pouch size. However, pairwise comparisons suggest that this difference was only significant in the comparison of the largest and smallest pouch ($P = 0.0130$).

With regard to handling, the data suggested that hand repositioning increased with

increasing pouch size. While the design of the study does not effectively allow us to statistically

analyze contamination as a function of repositioning by pouch size, the association indicates that

this phenomenon would benefit from further study. More specifically, what are the significant

factors? Is it the sheer amount of material that must be managed by the user? Is the amount of

manipulation that they require to accomplish the goal? Is it a combination of both?

Chapter 7: Recommendations for Future Work

It is recommended that future research examine aseptic technique with more realistic

products; presenting single items into the sterile field, fitted more to the pouch inside dimensions

versus several disconnected items, would be more realistic. An example of an expensive item

which also needs to maintain sterility is an artificial hip. Studying devices like implants would

not only be interesting from the standpoint of infections, but also due to the costs to healthcare

should this device get contaminated and returned to the manufacturer/thrown out. In addition,

the experiences and demographics of the subjects (and indeed the scope of the study) focused

more on the controlled contexts present in Operating Room environments. However, testing in

more realistic environments where people are unaware that the study focus is asepsis would

likely result in even higher levels of contamination than reported here. Environmental factors

that could be studied might include multitasking within the OR, and more chaotic environments,

such as the emergency department and care received by paramedics in emergency situations

(ambulance, road-side care, etc).

Biomechanical behavior observed in this study was somewhat subjective, as it is

observationally based. As such, the use of a kinematic system, which can fully characterize the

movement digits of hospital personnel, as well as the relationship between movement and the package design (as well as the sterile field), is strongly recommended.

One of the measurements considered for inclusion in this report was drape contamination. However, many positive results (without positive results on the tongue depressors themselves) were considered too questionable to report. Researchers felt that it was possible that false positives occurred because the simulant (cream) was flung onto the sterile field as the pouch was opened, though we did not have any evidence to support this. That said, aseptic presentation recommendations in both nursing and surgical technology literature indicate that the pouch should not be over the sterile field to begin with, as this would cause all contents of the drape to become contaminated. Also, research done by Smith investigated scattering upon opening pouches to the sterile field, indicating that there had been some contamination of the field from the act of opening the pack. Had the contaminated drapes been recorded, the contamination rate would have been much higher than rates reported herein (11.6%). Review of video did not allow us to characterize the breach of the sterile plane with absolute certainty and so the drape results were not reported. Future studies should utilize an objective method to monitor the position of the pouch and subject's hands near the sterile field, and score the trial as "contaminated" if the boundary is crossed.

Studies of package handling and use in medical settings are ripe in opportunity. Much of the nursing literature is largely anecdotal at its roots, and is based more on traditional practice than scientific justification. Possibilities present themselves when one considers that hospitals are not uniform in their practice; the localized nature of nursing guidelines to specific hospitals (or perhaps groups of hospitals) generates interesting questions: what would contamination rates look like, based on strict or lax adherence to the guidelines put forth by organizations such as

AST and AORN? Is contamination likely, even in strict adherence to these guidelines? Is the

sealed inner pouch still sterile once the pack is opened, or is it possible to be contaminated

simply by opening the package as the findings by Smith seem to indicate [29]?

APPENDICES

APPENDIX A – SUPPLEMENTARY TABLES

Table 11 - Nurse Experience in Healthcare Distribution (years)

Minimum Experience	First Quartile	Median	Mean	Third Quartile	Maximum Experience
3.50	20.00	28.00	26.97	34.00	44.0

Nurse Experience Presenting to a Sterile Field Distribution

Table 12 - Nurse Experience Presenting to a Sterile Field Distribution (Years)

Minimum Experience	First Quartile	Median	Mean	Third Quartile	Maximum Experience
2.50	15.00	21.00	22.75	30.00	42.00

Other Profession Reported Experience in Healthcare

Table 13 – Other Profession Reported Healthcare Experience Distribution (Years)

Minimum Experience	First Quartile	Median	Mean	Third Quartile	Maximum Experience
0.02	4.00	9.00	14	26.00	44.00

Table 14 – Other Profession Experience in Aseptic Presentation Distribution

Minimum Experience	First Quartile	Median	Mean	Third Quartile	Maximum Experience
0.00	4.00	7.00	12.88	22.50	43.00

Table 15 - Nurse Age Distribution

Minimum Age	First Quartile	Median Age	Mean Age	Third Quartile	Maximum Age
36.00	43.50	52.00	51.09	58.00	64.00

Table 16 - Surgical Technologist Age Distribution

Minimum Age	First Quartile	Median Age	Mean Age	Third Quartile	Maximum Age
26.00	34.00	45.00	43.90	52.75	63.00

Table 17 - Mean Overall Statistics for Age, Experience Presenting to Sterile Field, and Hand Size

	Mean	Standard Deviation	Minimum	Maximum
Age (years)	47.98	9.99	26.00	64.00
Experience Presenting to Sterile Field (years)	18.48	12.03	0.00	43.00
Hand Size (cm)	9.04	0.65	7.60	10.70

APPENDIX B – APPROVED FORMS

Demographic Information

1. Gender

    ❑ Male   ❑ Female   ❑ Trans gendered

2. Profession

    ❑ Nurse
        RN   LPN

    ❑ Doctor
                    General Practitioner   Specialist

    Area of Specialization_____

    ❑ Surgical Technician

    ❑ Other _____

3. Years   of   Experience   in   nursing   or   a   healthcare   related   field
    _____
    _____
    _____
    _____

4. Years   of   Experience   aseptically   presenting
    _____
    _____
    _____

5. Age   _____

6. Highest level of Education Completed

    ❑High school/GED   ❑Associates   ❑Bachelors   ❑Graduate

    ❑Other_____

7.   Work setting (home health, nursing home, acute care facility, etc. If acute care
     facility, also indicate unit)_____

Data Collection Sheet

Dominant Hand Size (palm down):

(image file imported here)

1st Pouch _____ (Size)

Hand repositions_____

Total number of Tongue Depressors in pouch_____

# of Tongue Depressor Contaminated _____

Drape Contaminated _____

# of Depressors outside of sterile field_____

2nd Pouch _____ **(Size)**

Hand repositions_____

Total number of Tongue Depressors in pouch_____

# of Tongue Depressor Contaminated _____

Drape Contaminated _____

# of Depressors outside of sterile field_____

3rd Pouch _____ **(Size)**

Hand repositions_____

Total number of Tongue Depressors in pouch_____

# of Tongue Depressor Contaminated _____

Drape Contaminated _____

# of Depressors outside of sterile field_____

4th Pouch _____ **(Size)**

Hand repositions_____

Total number of Tongue Depressors in pouch_____

# of Tongue Depressor Contaminated _____

Drape Contaminated _____

# of Depressors outside of sterile field_____

5th Pouch _____ **(Size)**

Hand repositions_____

Total number of Tongue Depressors in pouch_____

# of Tongue Depressor Contaminated _____

Drape Contaminated _____

# of Depressors outside of sterile field_____

6th Pouch _____ **(Size)**

Hand repositions_____

Total number of Tongue Depressors in pouch_____

# of Tongue Depressor Contaminated _____

Drape Contaminated _____

# of Depressors outside of sterile field_____

Research Participant Information and Consent Form

Research study: An investigation of the effect of pouch size on hand repositioning and contamination of a medical device

1. **Explanation of the Research and What you will do**
   - You are being asked to participate in a research study, which investigates the link between package design and the ability to aseptic present package contents to the sterile field. Your participation in this study is voluntary, and you may choose to discontinue participation at any time without penalty (i.e. you will still receive a $10 Starbuck's gift card).
   - In order to participate, you need to :
       i. Be at least 18 years of age
      ii. Have no history of skin conditions (i.e. eczema).
     iii. Be currently, or formerly, a healthcare professional.
      iv. Be willing to be video taped.
   - You will initially be asked a series of questions regarding your professional background, years of experience within that field, and years of experience presenting to sterile fields.
   - We will then take a picture of your hand using a digital camera and a measuring grid.
   - You will be asked to put on a lab coat.
   - You will be asked to put on a pair of latex-free gloves. A member of our research team will coat your gloves with Glitterbug® cream.Glitterbug is a cream that is commonly used to teach proper hand washing technique. It is invisible in regular light, but glows under a black light. We are using it to simulate contamination. You will be asked to present the tongue depressor within the package to a simulated field. You will then remove your gloves, and this process will repeat 5 additional times (for 6 total presentations).
   - This study should take no more than 15 minutes of your time
2. **Choose whether or not to participate and stopping participation at any time**

- You are voluntarily participating in this study. As such, you may choose to opt out of portions of this study, or discontinue participation at any time.

3. **Compensation**
   - You will be paid with a $10 Starbucksgift cardas a result of your participation in the study. In the event you choose to withdraw from the study, or not participate in any portion, you will still receive this card.

4. **Confidentiality**
   - All information will be tied to a subject number; you will not be identified by name and your confidentiality will be maintained to the maximum extent of the law. Information collected during this study will be stored in a password protected computer in a locked laboratory in the School of Packaging at Michigan State University for a MINIMUM of 3 years. The room will be accessible only to authorized researchers and members of the Institutional Review Board at MSU.

5. **Risks and Benefits**
   - There are minimal risks associated with participating in this study. You will be videotaped and it is possible that you will be embarrassed as a result of this. If you do not wish for your videotaped image to be shown in public forums (classrooms and conferences); please indicate this below by initialing the appropriate box on this consent. Although the glitterbug cream is being applied to the gloves, it is possible that it could irritate your skin or soil your clothing. To minimize these risks, the research team will ask you to wear a lab coat and will only apply the cream to gloved hands.
   - Although there is not direct benefit to you for participating in this research, it is our hope that the data gathered can be used to understand the interface between healthcare professionals and packaging in order to create designs that will facilitate presentation of contents to the sterile field.

- If you are injured as a result of your participation in this research project, researchers from Michigan State University will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of what are paid by your insurance, including deductibles, will be your responsibility. The University's policy is not to provide financial compensation for lost wages, disability, pain or discomfort unless required by law to do so. This does not mean that you are giving up any legal rights you may have.

6. **Contact information**
   - If you have any concerns or questions about this research study, such as scientific issues, how to do any part of it, or if you believe you have been harmed because of the research, please contact the researcher Laura Bix 517-355-4556; 153 Packaging Building East Lansing MI 48824 bixlaura@msu.edu.

   - If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 202 Olds Hall, MSU, East Lansing, MI 48824.

By completing this form, you consent to participate in the study and meet the pre-requisite requirements for participation.
I voluntarily agree to participate in the study of pouch contamination and design.

_____

Date: _____

May we use your footage for academic purposes (conferences, presentations to students and faculty, etc.)? Important: this is not a question regarding the filming that is done solely for data gathering purposes.

❏ Yes   ❏ No

I have received my $10 Starbucks gift card.

_____

Date: _____

You will be provided with a copy of your signed consent form.

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