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Piped Pathogens

The Infectious Controversy That has the Bath Industry Whirling

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Taking Cover:
Single-use *vs.* Reusable Gowns and Drapes

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Executive Summary

Single-use drapes and gowns are used daily as protective barriers in a majority of U S hospitals. In today's healthcare environment, safety, barrier qualities, cost, and infection prevention are key words of supreme importance in patient care. Single-use products meet these challenges and more.

With the emerging knowledge of the harmful effects of bloodborne pathogens and the resulting federal OSHA rule, healthcare practices require that apparel and draping materials be constructed and used in a way that prevents cross-contamination of infectious agents.

The following factors should be carefully considered in decisions to use single-use *vs.* reusable gowns and drapes:

- Dual protection for both healthcare professionals and patients. Impermeability to moisture (to prevent "strike-through") is a significant criterion in choosing appropriate gowns and drapes. Also, adherence to federal regulations and professional guidelines is critical.
- Placing high importance on protection. Garment and draping materials that allow penetration of infectious body fluids and microorganisms can lead to "strike-through," contamination, and disease.
- Wisely selecting gowns and drapes. Assurance of asepsis, barrier effectiveness, comfort, economics, and environmental issues must be given priority in the selection process. Gowns and drapes are to be effective barriers when wet. For reusable materials, the ability to maintain barrier qualities throughout multiple washings is critical but also has been questioned.
- Correctly assessing reusable materials. The ability of reusable gowns to resist strike-through varies with the number of uses, washings, and sterilization cycles. There are no universally adopted methods for counting numbers of uses of a reusable gown or drape. Laundry workers risk exposure to bloodborne pathogens from contaminated gowns and drapes.
- Analyzing environmental issues. Single-use items are often falsely implicated for certain costs of waste disposal. Improper waste segregation, rather than use of single-use gowns and drapes, is usually the cause of increased amounts of RMW (regulated medical waste). There are advantages and disadvantages to both reusable and single-use systems.
- Reviewing costs. Accurate assessments of costs are difficult at best. A comprehensive evaluation of costs requires a review of all related costs, some of which may initially be unapparent. Credible conclusions of costs have not been published.
- Single-use items provide excellent barrier properties, consistent and reliable quality, and remarkable positive benefits to hospital staff and patients.

Introduction

Eighty percent of hospitals in the US use single-use gowns and drapes.[22, 25] Why? Clinical users are satisfied with the performance of single-use gowns and drapes in terms of barrier properties, safety, consistency, and comfort. Safety issues, especially those related to adequate protection of professional staffs and patients, are of paramount importance. Issues relating to cost and environmental impact have been studied and the results are inconclusive at this point. Each healthcare facility needs to establish their own cost and environmental evaluation programs.

Misleading statements are often used to convince healthcare professionals that reusables are superior to single-use items. This article contains factual information, derived from experts, professional organizations, literature, and respected publications that set the record straight. The importance and necessity of barrier protection, criteria for selection of gowns and drapes, and the reasons for selection of single-use over reusable items are all discussed and referenced in this article.

Necessity of Barrier Protection

The necessity of barrier protection and the adherence to federal regulations and professional guidelines make single-use gowns and drapes ideal choices. Barrier properties are of great importance with the shift from user comfort and cost to user and patient protection.[13] Dual protection (HCWs and patients) is of paramount importance.[11] Issues of safety and infection control are now being quantified by risk managers; these issues must be in the total equation when choosing between reusable and single-use gowns and drapes.[6]

Gowns and drapes act as barriers to prevent transmission of microorganisms from nonsterile to sterile areas. Impermeability to moisture (preventing "strike-through") is a critical factor in choosing materials for gowns and drapes.[11] Protection of HCWs from coagulase-negative *Staphylococcus aureus*, methicillin-resistant *Staphylococcus aureus* (MRSA) and other resistant organisms, and bloodborne pathogens is necessary for safe practices; choices are made on safety issues as well as cost.[11]

Exposure to blood has for years been recognized as a risk for infection, so barriers are needed.[11] The OSHA Bloodborne Pathogen Standard requires personal protective equipment (PPE) or clothing, such as gowns, in situations where blood or OPIM (other potentially infectious materials) may pass through and reach the HCW's clothes, skin, eyes, or mouth. The type of gown required is dependent on the task and the degree of exposure anticipated.[23, 20] The OSHA standard contains strict definitions of the employer's responsibilities for protection of hospital employees. There are severe penalties for violations. Clearly, an informed and prudent choice between reusable and single-use gowns and drapes requires more than a simplistic cost-comparison; more facilities are choosing single-use products to meet mandatory standards.[6]

An Association of periOperative Registered Nurses (AORN) statement says that barrier materials should prevent the penetration of microorganisms, particulates, and fluids. The protective barrier ability is of primary concern when evaluating materials, (*e.g.*, can withstand tears, punctures, fiber strains, and abrasions that could allow passage of fluids and microbes from nonsterile to sterile areas and expose HCWs to bloodborne pathogens). Liquid-resistant aprons, gowns, and shoe covers are worn when exposure to blood or OPIM is anticipated.[2, 1]

AORN further states that surgical gowns and drapes should be appropriate barriers, maintain adequate integrity and durability, resist tears, punctures, fiber strains, and abrasions, and should be used and processed according to manufacturers' written instructions.[2] AORN notes that reusable fabrics (woven materials) should maintain a protective barrier through multiple launderings and sterilizations.[2]

The Centers for Disease Control and Prevention (CDC) states that gowns and drapes are used to create a barrier between the surgical field and potential sources of bacteria. Both should be impermeable to liquids and viruses. Gowns and drapes should be effective barriers when wet (*i.e.*, consist of materials that resist liquid penetration).[18]

The Importance of Protection

Years of proven clinical performance, protection of the patient from infection and protection of the staff from bloodborne diseases, is the reason that a large majority of the surgical market chooses single-use surgical drapes and gowns. OSHA and the CDC instruct HCWs to assume that all patients are seropositive for bloodborne diseases and always to employ Standard Precautions. Protective gowns are to be worn whenever there is any potential for blood contact.[11]

At least seven cases of job-related HIV seroconversion were tentatively attributed to mucous membrane or skin splashes with contaminated blood. Blood strike-through, absorbed by a scrub-suit, directly contaminated surgeon's skin. Even small amounts of contaminated "strike-through" blood can have a sufficient inoculum to possibly

infect HCWs.[26] When protective garments are penetrated by infectious body liquids, microorganisms from the patient can infect the medical staff.[21]

Even though the risk is low, reports of HCW seroconversion to positive after contamination by infected blood have been noted.[11, 26, 7, 8] HBV, HCV, and HIV can be acquired via contact of contaminated body fluids with non-intact skin or mucous membranes. OSHA's standard was promulgated to minimize HCWs' risk of acquiring bloodborne pathogen diseases.[25] Potentially fatal diseases such as HBV and HIV can be transmitted to medical personnel through body fluids from the patient.[21] Skin is an efficient barrier although its barrier qualities may be compromised when exposed to patients' body fluids for prolonged periods of time. Skin's barrier qualities are compromised by abrasions or areas of inflammation.[26]

Selection of Gowns and Drapes

The choice of a single-use gown or drape becomes easier when considering criteria, (*e.g.*, barrier performance, safety, reliability, comfort, economics, strength, drapeability,) put forth by experts. Factors such as aseptic assurance, comfort, economics, and environmental issues are important considerations.[21]

Gowns and drapes must enhance sterile technique/procedures, have impeccable barrier qualities, be low-linting, and be of consistent and uniform quality.[5] They also must be effective barriers when wet (resist liquid penetration).[18]

Barrier effectiveness is the ability to prevent penetration of liquids and microorganisms, acting as a repellent. For reusable products, the ability to maintain complete barrier effectiveness despite multiple washings is necessary.[25] Quality maintenance means consistent barrier effectiveness and reliability among all new products and, if used, among all reused products.[25] Safety and performance characteristics include providing appropriate protection against penetration of liquids and microorganisms; abrasion resistance, strength, softness, drapeability, breathability, stain resistance, meeting of flammability requirements; have low propensity for linting, no toxicity, and guaranteed sterility.[4] Fabric characteristics of construction, repellency, and pore size contribute to gown performance; higher fabric repellency ratings and smaller pore size generally correspond with barrier properties.[17]

For reusable manufacturers, there must be provision of appropriate data to substantiate claims of number of times product reprocessed and reused, correlated with the maintenance of acceptable safety and performance characteristics.[4] Users should delineate their understanding of the ideal gown or drape and base their purchase decisions on a balance between health and safety concerns and economic, environmental, and comfort issues.[19, 25]

Issues Unique to Reusables

Do you really expect your surgical gown to look, feel, and perform the same after 75 washings? Of course not. Repeated launderings of reusable hospital textiles do take a toll. There is a strong case supporting the use of single-use products because of regularity and consistency in barrier protection for both hospital staff and patients in what can be life and death situations.

The cumulative effect of laundering on barrier efficacy has been studied. In several studies, reusable (used) gowns provided less protection than new gowns.[16, 26, 17] The ability of reusable (cloth) gowns to resist strike-through varies with the material's age; if beyond their useful life, these gowns may give a false sense of security to the wearer.[26] In one study, each of three woven (reusable) fabrics allowed some transmission of specified bacteria.[17]

One manufacturer of reusable surgical gowns provides a written "warning" to its customers: ".... .expressly disclaims any warranty concerning the performance of surgical barrier fabric.....and makes no guarantee of results. No surgical gown can offer complete protection even when new, and its effectiveness may decline with use... Each purchaser and end user of gowns... is responsible for evaluating the ability...to meet particular protection requirements and specifications."[27]

Some reusable manufacturers predict 75 uses for a gown. A hospital's loss and damage (tears, holes) and resistance to blood and viral penetration for 75 launderings/sterilizations may drastically reduce the garment's life span and increase the cost per procedure. Cost estimates of reusable gowns must include standard allowance for loss and damage which often runs about 2%.[25] In a research report, laundering reduced the ability of the fabrics to prevent the penetration of bacteria through the fabrics.[16]

Reusable gowns eventually lose barrier properties. This results from abrasion and damage during wear and the breakdown of the fabric during laundering and sterilization. If such products are used, quality assurance programs must be used to determine when the product needs repair or needs to be removed from service.[26, 20]

Processing eventually diminishes protective barrier ability of woven materials. Tightly woven reusable fabrics will lose this barrier ability after repeated processing. Launderings and steam sterilization cause fibers to swell, and drying and ironing cause fibers to shrink, increasing the propensity to loosen the fibers, thereby altering fabric structure.[2] As the number of launderings of reusables increase, repellency ratings decrease.[16]

Improvements in reusable fabrics—layered fabrics with a highly-resistant membrane between two layers—provide good barrier protection on first use but maintenance is dependent on controlling all variables during the reprocessing. Studies document diminished barrier capabilities of laundered reusable fabrics.[16, 25]

Hidden costs of reusables include the carrying of inventory, loss replacement, and space for storage and processing.[22]

Laundry workers should be advised of the risk of exposure to bloodborne pathogens from contaminated gowns and drapes. There is a need for an effective exposure control plan that includes correct use of personal protective equipment. Infection control procedures and work practices are also needed to minimize the risk of contaminating clean laundry products.[4]

Single-use products are sterilized once; reusables are sterilized multiple times. Additional contamination between washings can increase the sterilization failure rate if not properly taken into account at the time of sterilization.[22] Single-use products are sterilized in a manufacturing setting; reusables are sterilized in hospitals or laundry services. Certain manufacturers are regulated more stringently than laundry services, therefore, manufacturing settings may maintain more stringent control than hospital and laundry services.[22]

Occupational risks associated with handling, laundering, and disposal of surgical gowns and drapes are usually due to contact with sharps inadvertently mixed in with soiled gowns and drapes. Because single-use items require less intensive handling after use than reusables, the occupational risk for bloodborne infections is likely to be lower for single-use gowns and drapes than for reusables.[22]

A recommended practice, *ST65:2000, Processing of reusable surgical textiles for use in healthcare facilities*, is intended to provide guidance in the handling and processing of reusable surgical textiles. The guidelines describe numerous intricate processes and monitoring that should be undertaken in laundry facilities. Statements from the recommended practice are:

- "Barrier quality may be temporarily altered due to processing errors and/or degradation of the product fabric, therefore, it is important to incorporate into the quality system a procedure by which barrier performance of reusable surgical textiles can be evaluated."
- "Each product should include a tracking mechanism and manufacturer should provide recommendations for the number of times a product can be used."
- "The performance of reusable surgical textile products will change with repeated processing and use, therefore, it is important to identify the point at which each product no longer continues to perform adequately. Since variations in use and processing conditions among healthcare facilities can change the effective life of products, manufacturers' recommendations concerning the life expectancy of their products can only be used as a guideline."
- "ST65 formalizes what the industry has viewed as accepted practice—not that every laundry has followed that; staff in hospitals and laundries may not be able to comply with all of the prescribed tenets because they may not have the resources to implement everything up front."
- "Compliance with ST65 is strictly voluntary."[3]

At present, there is no universally adopted method for counting number of uses of a reusable

gown or drape. Reusable gown users have the dilemma of not knowing if a used and relaundered gown retains the liquid resistance claimed for it and they may not know the number of recyclings that each gown has undergone.[15] In one study, the authors report informal queries of hospital central supply and commercial hospital laundry personnel and found that many were not aware of the grid marking system or were using it incorrectly. As long as the gowns looked serviceable, they said, they would probably be used. Without proper education, this may allow widespread use of gowns with reduced protective value.[26]

For reusable products, one must consider not only the characteristics of the purchased items, but also the characteristics of the laundered products. Maintaining manufacturers' specifications is easier for single-use items.[25] Therefore, potential problems with reusables can be:

- Perception of less barrier protection
- Actual loss of barrier properties as a result of wear, abrasions, and breakdown of fabric during laundering and sterilization
- Uneven consistency of product with multiple reprocessings
- Lack of confidence in laundering and sterilization of reusables
- Warnings from manufacturers regarding lack of guarantees of performance or results
- Limited mandatory quality standards for laundries
- Inventory, storage, loss, labor, liability issues

Why Single-use?

The reasons for choosing single-use gowns and drapes are concise and logical. Evidence from journal articles and professional association guidelines further help define the need for single-use items.

Demand for single-use medical supplies in the US will increase 6% annually to $48 billion in 2002, according to an independent study. Convenience, labor savings, and performance benefits will push the demand. Reflected also are the contributions of disposables to healthcare cost efficiencies.[9] The overall conclusion of another independent study was that single-use gowns and drapes seem to offer better protection than standard linen reusables to patients, operating room personnel, and other hospital workers.[22]

A survey of operating room nurses listed key reasons for using single-use gowns: protection, sterility, repellency, staff preference, and convenience.[22] "Preference" was defined in another survey to include convenience, quality, reliability, availability, product design features, and staff evaluations.[22] The wide variety of garments and levels of barrier protection available in single-use equipment allows a hospital to match the garment to the procedure in a way that is both practical and cost-effective.[6]

Choosing single-use garments in custom kits and packs, complete with all disposable supplies needed for each procedure, limits the number of supplies and contains the costs of purchasing (standardization).[6] Single-use nonwovens have absorbency where liquid control is required, repellency which creates a microbial barrier, and impermeable laminates which provide increased barrier protection.[5] Why single-use? Considerations include:

- Conviction that disposable gowns provide improved protection
- Guarantee of consistent barrier quality and performance
- Quality and dependability
- Staff choice
- More convenient due to ready availability
- Peace of mind about barrier protection
- Ease of disposal
- Minimal impact on amount of regulated medical waste (RMW)
- Opportunity to educate re: appropriate segregation of RMW from non-RMW [24, 10]

Waste Disposal and the Environment

In spite of the relatively insignificant amount of waste that is generated in hospitals, this waste is usually associated with strong emotions and community concerns. Proper segregation and treatment of hospital waste can lead to very substantial cost savings and should be a part of every hospital educational program. Single-use items often are given "credit" for waste costs that are not properly theirs. Presently, there are many choices in treatment and disposal of hospital wastes. Governmental regulations and professional association guidelines help to prioritize and assist staff in dealing with waste.

Hospital waste accounts for 2% of national municipal wastes. Gowns and drapes contribute approximately 2% of all hospital waste. Thus, disposable gowns and drapes constitute about 0.04% of all municipal wastes.[22, 25] Disposal costs for single-use items averaged, in an A.D. Little study, only 4-5% of total disposal costs.[22, 25]

On solid waste generation, single-use items are sometimes bulky, highly visible, and often overdesignated as "infectious" or "red-bag" waste, with much higher costs of disposal.[22] One study's estimates were that more than 80% of hospitals identify RMW beyond accepted (CDC) guidelines.[6] Often, disposables are implicated in the increase in amount of RMW when, in fact, a more probable cause is improper segregation of waste, especially gowns and drapes that are blood-contaminated (which may or may not constitute RMW). Federal, state, and local regulations must be followed. Neither the CDC or the EPA provide detailed guidance on whether blood-contaminated gowns and drapes should be considered RMW.[25]

Educational programs for properly segregating RMW (infectious) from non-RMW have substantially helped to reduce costs of disposal in many institutions. One 17-hospital consortium undertook an extensive educational program with a goal of reducing waste disposal costs by 20%. By 3 months, the cost reduction was already 33.5%. The group estimated savings of $3.7 million annually.[14]

Regarding landfill capacity and disposal of hospital waste: The number of landfills has decreased during the past 10 years but availability has increased with larger regional landfills replacing smaller sites. There is now more landfill capacity available than at any time during the past 10 years.[12,10] According to an independent study, neither single-use nor reusable products studied are clearly superior from an environmental standpoint. Single-use products consume more raw materials and energy, and generate more solid waste than the reusable products. Reusable products consume significantly more water and produce more water pollution with detergents and chemicals. They also generate more volatile organic compounds as air emissions, generally associated with smog levels in the atmosphere.[22]

There are advantages and disadvantages to both reusable and single-use systems. When making decisions, it is most important to balance the considerations of barrier properties and effectiveness, safety for patients and personnel, infection prevention issues, and the environment.[12]

Cost

It is difficult, at best, to calculate costs of reusable *vs.* single-use items since there are many visible as well as hidden factors that need to be considered. Finding the actual bottom line of costs requires a review of all related costs, some of which may be initially unapparent.[6] One cannot focus only on cost-per-use because there are other factors that influence the total cost equation.[6] There are no conclusions from clinical studies about cost-effectiveness of various types of surgical gowns.[15]

Summary

Against any standard, the choice is clear: Single-use items offer substantial benefits. The reasons are sound: Single-use gowns and drapes provide optimum barrier protection, consistent quality, and dependability each time they are used. The result is peace of mind; there is always satisfaction in using single-use items with their proven positive properties.

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