

The Role of Closed System Transfer Devices in Mitigating the Risks Posed to Healthcare Workers in the Handling of Hazardous Drugs

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AN OVERVIEW OF THE RISKS POSED TO HEALTHCARE WORKERS

Cancer is the world's leading cause of death, claiming the lives of an estimated 7.9 million people in 2007 alone.¹ Experts expect these numbers to double before 2030.¹ The unsafe handling of hazardous drugs used to treat many forms of cancer has been recognized since the 1970s as a significant health hazard to workers. Studies have shown that workers can be at risk of exposure to these drugs throughout their lifecycle—from manufacture to distribution to use in the clinical or home care environment and all the way through to waste disposal. Healthcare workers who handle these drugs may be exposed by inhaling aerosols or dust generated during pharmacy preparation and nursing administration, or by direct contact with the skin during accidental needlesticks, spills, or spill cleanup.

The toxicity of hazardous drugs and the dangers of prolonged exposure to them have been proven to cause hair loss, skin rashes, infertility, miscarriage, birth defects, and even leukemia or other cancers in healthcare workers.^{2,3,4,5} A recent study even documented an increased incidence of learning disabilities in the children of nurses who had handled hazardous drugs during the course of their employment.⁶ Given the increase in the number of patients, the increasing number of new agents being developed to treat cancer, and the increasing complexity of chemotherapy combination therapies,

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it is estimated that eight million healthcare workers a year in the United States (US) alone are exposed to hazardous drugs, including the antineoplastic regimens used to treat cancer.⁷

The Occupational Safety and Health Administration (OSHA) and professional organizations began promoting the adoption of safe handling guidelines starting in the mid-1980s. Several organizations and government agencies in the US have published safe handling guidelines for hazardous drugs, including the American Society of Health-System Pharmacists (ASHP), the Oncology Nurses Society (ONS),⁸ the National Institutes of Health (NIH),⁹ the National Study Commission on Cytotoxic Exposure,¹⁰ and the American Medical Association's Council on Scientific Affairs.¹¹

In 1990, ASHP became the first organization to formally define "hazardous drugs" as those which place exposed animals or humans at increased risk for cancer, developmental or reproductive toxicity, or harm to organs.¹² Both OSHA and the National Institute for Occupational Safety and Health (NIOSH) have subsequently adopted this definition.^{3,13}

Best Practices to Mitigate Risk of Exposure to Hazardous Drugs

GUIDELINES

The basic occupational health approach to minimize exposure to any workplace hazard is a hierarchy of control methods, including elimination or substitution of hazard, engineering controls, administrative controls, and personal protective equipment (PPE). The current guidelines for the safe handling of hazardous drugs set forth by NIOSH, ASHP, and ONS are based on these occupational health principles.

PREPARATION

Procedures for drug preparation can vary from one institution to the next. In some locations, Class II or Class III biological safety cabinets (BSCs) are used for hazardous drug preparation, while others use isolators to achieve asepsis and containment.³ In either case, drug preparation should take place in a clutter-free and properly cleaned controlled environment with access limited to authorized personnel following all PPE recommendations.

ADMINISTRATION

Unfortunately, many healthcare facilities that have implemented safety equipment and procedures to protect pharmacy personnel during preparation have not taken similar steps to keep nursing staff safe during the administration phase. When administering hazardous drugs with conventional IV therapy products, spiking IV containers with IV tubing, and unspiking to remove tubing has been shown to result in leakage.¹⁴ One study demonstrated leakage from conventional non-closed needlefree connectors on IV equipment.¹⁵ Although these leaks result in contamination spots on healthcare workers' gloves, clothing, and hands after glove removal,¹⁶ the spray is not visible to the eye, and few workers are aware of the exposure.

Additionally, nursing personnel risk skin contact with hazardous drugs whenever leakage occurs at the tubing and when they perform routine tasks such as clearing air from the syringe or infusion line, making syringe or stopcock connections, clipping used needles, or crushing used syringes.¹⁷ The greater risk is in the inhalation of aerosolized drug that can occur when a vial is opened or broken, needles are withdrawn from drug vials, drugs are administered from pre-filled syringes, and during transfer of drugs with syringe and needle. In addition, the danger of an accidental needlestick when working with hazardous drugs can also present a significant health risk.

Detailed guidelines for the administration of hazardous drugs have been developed by the ONS that stress the criticality of PPE for the task being performed, the use of needlefree systems whenever possible, and the use of intravenous tubing primed by the pharmacy or primed at the point of care with a solution other than the drug.¹⁸

Sample List of Drugs that Should Be Handled as Hazardous

Drug Name	American Hospital Formulary Service Classification
Capecitabine	Antineoplastic agents
Carboplatin	Antineoplastic agents
Cisplatin	Antineoplastic agents
Cyclophosphamide	Antineoplastic agents
Cyclosporine	Immunosuppressive agents
Docetaxel	Antineoplastic agents
Doxorubicin	Antineoplastic agents
Epirubicin	Antineoplastic agents
Etoposide	Antineoplastic agents
Fluorouracil	Antineoplastic agents
Gemcitabine	Antineoplastic agents
Ifosfamide	Antineoplastic agents
Imatinib mesylate	Antineoplastic agents
Irinotecan HCl	Antineoplastic agents
Methotrexate	Antineoplastic agents
Oxaliplatin	Antineoplastic agents
Paclitaxel	Antineoplastic agents
Topotecan	Antineoplastic agents
Vinblastine sulfate	Antineoplastic agents
Vincristine sulfate	Antineoplastic agents
Vinorelbine tartrate	Antineoplastic agents

This is only a small sample of the drugs that NIOSH has identified as hazardous, and it does not represent a comprehensive list. For a more complete listing of drugs that NIOSH recommends be handled as hazardous, please see the publication: NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2010 available at <http://www.cdc.gov/niosh/docs/2010-167/pdfs/2010-167.pdf>

TRANSPORTATION

Inside an institution, hazardous drugs should be packaged and transported in such a way as to prevent damage and subsequent contamination of the environment, the drug itself, and all personnel involved in the routine handling and transportation of these drugs. In many facilities, hazardous drugs are transported in zippered plastic bags placed in containers that protect them. Protective containers should be made of molded foam or a sponge-like material so that the drugs are securely positioned. The containers should also be labeled to identify the contents as hazardous and to specify appropriate light and temperature conditions under which the drugs should be maintained.¹⁹ All personnel responsible for transporting the drugs should be aware of emergency procedures in the case of a spill.

BIOHAZARDOUS WASTE DISPOSAL

All waste from the preparation and administration of hazardous drugs should be segregated and disposed of according to hospital policy and applicable state and federal regulations.^{3,19,20} All personnel collecting and transporting waste materials should wear recommended PPE. All materials that come in contact with the drugs or patient waste such as vials, intravenous sets, syringes, gloves, gowns, bedpans, and bed linens should be handled as hazardous. Danger from exposure to these drugs is not just limited to clinical staff, as several studies have found drug in the urine of individuals who were not directly involved with preparation or administration. In fact, housekeepers who clean the infusion area and remove waste have been found to have drug in their urine, documenting uptake from a contaminated area.²¹

Adherence to recommended work practices and the use of engineering controls and PPE have been shown to substantially reduce worker exposure to hazardous drugs. However, compliance throughout the entire safe-handling continuum remains an issue.

Engineering Controls

PERSONAL PROTECTIVE EQUIPMENT

Since workers' hands are usually in the most prolonged and proximate contact with potentially harmful materials, the permeability of gloves is of considerable importance. However, contact allergies are a common problem limiting the use of latex gloves among healthcare workers,²² and polyvinylchloride (PVC) gloves are stiffer and more difficult to work with. Testing of medical-grade gloves indicates that not all gloves should be assumed to provide full protection when working with hazardous materials.^{23,24} As a result, recommendations related to safe use of gloves include doubling PVC gloves when not interfering with technique,²⁵ routinely changing gloves every 30 minutes,²⁶ immediately disposing of gloves after overt contamination, and hand washing before and after each glove change.

When preparing hazardous drugs, an impermeable, closed-front, long-sleeved gown with closed cuffs should be worn. Ideally, the gowns should be of a distinctive color to dissuade personnel from wearing them outside the laboratory.²⁷ Like gloves, gown materials have been shown to demonstrate variable degrees of permeability. The most impermeable to airflow are, understandably, less comfortable to wear for any length of time.²⁸

Eye protection, such as a face shield, is recommended when splashing is possible. Surgical masks are ineffective when worn to protect against aerosol inhalation.²⁹ Masks should be worn only to protect the biological quality of the product during preparation. A respirator is essential for cleaning up spills.

And while the availability and utilization of PPE by pharmacy personnel during the preparation phase is believed to be high, the same level of compliance is not found in nursing. A 2008 ONS chemotherapy survey of 4,000 oncology nurses found that while more than 93% of respondents said they used gloves during administration and disposal, fewer than 50% on average used gowns during the same phases.³⁰

BIOLOGICAL SAFETY CABINETS

When hazardous drugs are prepared without the use of a well-functioning ventilation hood, the prepared drug can be detected in the air of the preparation room,³¹ resulting in the systematic absorption of aerosolized cytotoxics through inhalation. Risks associated with inhalation of these drugs include light-headedness, nausea, headache, hair loss, nasal and mucosal ulceration, and even liver damage.^{32,33}

OSHA guidelines state that hazardous drug preparation must be performed in a BSC in a designated area, usually a pharmacy. A BSC has vertical airflow that moves away from the worker, as opposed to laminar-airflow (LAF) benches that use horizontal airflow to move air away from the product toward the worker to protect the sterility of the drug. Following the routine manipulation of drug products in a horizontal flow hood, the drug can contaminate the airflow over the product.³⁴ This air may be ejected from inside the hood into the breathing zone of the preparer; for this reason, its use in hazardous drug preparation is discouraged.^{35,36} In contrast, vertical airflow protects the worker by sending air from within the BSC through a high efficiency particulate air (HEPA) filter.

However, reliance on BSCs and PPE to provide total protection from exposure to hazardous drugs may provide a false sense of security. The effectiveness of BSCs during use of certain drugs such as cyclophosphamide has been called into question because molecules of vaporized drug are much smaller than the pore size (0.3 µm) of the HEPA filters. Thus, the gaseous particles may not be retained by the filters in the BSCs and could pass into the air of the work area.

Reliance on BSCs and PPE to provide total protection from exposure to hazardous drugs may provide a false sense of security. Other factors that may contribute to contamination include unreported or inadequately cleaned spills as well as transport and placement of contaminated objects.

Additionally, studies have demonstrated that there are contaminants in the air and on work surfaces in preparation areas, despite the proper use of BSCs.^{37,38,39,40,41,42} The contamination of the external surface of hazardous drug vials is another source of exposure to pharmacy workers.^{43,44,45,46,47} Other factors that may contribute to surface contamination include unreported or

inadequately cleaned spills, transport and placement of contaminated objects, patient body fluids, and spreading by hand or foot contact. BSCs, countertops, floors in and adjacent to preparation areas, tabletops, chairs, and floors in treatment areas may be contaminated with hazardous drugs.

One study examining contamination in six sites in the US and Canada found that measurable amounts of hazardous drugs (cyclophosphamide, ifosfamide, and fluorouracil) were detected in 75% of pharmacy samples and 65% of administration samples.⁴⁸ High pharmacy preparation volume was correlated with higher levels of contamination, indicative of the degradation of protocols that can occur when workloads increase. While drug exposure does not always result in absorption, the accidental dose can be measured in the urine of healthcare workers.¹⁶ One review reported that cyclophosphamide was present in the urine of healthcare workers in 11 of 12 studies, despite the use of precautions.⁴⁹

LACK OF COMPLIANCE

Adherence to recommended work practices and the use of engineering controls and PPE have been shown to substantially reduce worker exposure to hazardous drugs. However, it is known that compliance throughout the entire safe handling continuum—from preparation to transportation to administration to disposal—is an issue, implying that various guidelines are not followed aggressively enough.^{50,51,52,53,54,55,56} Several persistent factors in the healthcare setting such as increased workload, understaffing, improper training, budgetary constraints, and others can adversely affect how safely these drugs are handled.

Nursing Compliance Rates for Use of Personal Protection Equipment

	Administration		Disposal	
	2003	2008	2003	2008
GLOVES	94%	94%	94%	93%
GOWNS	31%	51%	26%	45%

Despite guidelines and warnings of the dangers of exposure to hazardous drugs, use of PPE among nurses continues to present a compliance issue during administration and disposal.^{37,57}

CLOSED SYSTEM TRANSFER DEVICES

The use of a closed system transfer device (CSTD) in conjunction with other safety precautions such as gloves, gowns, masks, and vented preparation hoods presents a proven way to increase safety levels when preparing, transporting, administering, and disposing of hazardous drugs. CSTD is a generic term used to describe a device that does not allow any substance—including vapors, liquids, or powders—to escape outside the vial or bag during the entire safe handling process. NIOSH and The United States Pharmacopeia’s (USP) General Chapter 797 recommend using a CSTD to minimize occupational exposures to hazardous drugs.^{12,58} The NIOSH definition of a closed system is one that mechanically prevents the transfer of environmental contaminants into the system and the escape of drug or vapor out of the system.

Several studies have demonstrated the effectiveness of CSTDs in reducing surface contamination, airborne emission, and exposure to healthcare workers.^{59,60} One study compared surface contamination across 22 US hospital pharmacies following preparation with standard drug preparation techniques versus a CSTD. The study concluded that a significant reduction in levels of contamination was observed for all drugs sampled—cyclophosphamide, ifosfamide, and 5-fluorouracil—by 95%, 90%, and 65% respectively.⁶¹

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A separate evaluation of the effectiveness of a CSTD in a high-volume chemotherapy preparation environment concluded that the CSTD, in conjunction with the use of

BSCs in an IV admixture area, appeared to contain surface contamination resulting from the preparation of cyclophosphamide and ifosfamide.⁶² Another study examined healthcare workers exposure and found that the CSTD appeared to reduce exposure of personnel to cyclophosphamide and ifosfamide.⁶³ Furthermore, a study compared a CSTD with the traditional technique with regard to airborne emission and surface spillage of drugs. Mean airborne emission was reduced from 15 ng m(-3) with the traditional pump technique to 6 ng m(-3) with the CSTD, and the study observed that new techniques are desirable to consider for the staff work environment.⁶⁴

In 2007, USP introduced a section on CSTDs indicating the use of a CSTD within a BSC or Compounding Aseptic Containment Isolator (CACI) is acceptable without a negative pressure buffer area in facilities that prepare a low volume of hazardous drugs. Evidence documents a decrease in drug contaminants inside a Class II BSC when a CSTD is used.^{14,56,62} According to guidance provided by NIOSH, CSTD should be a consideration as well as glovebags and needlefree systems when transferring hazardous drugs from primary packaging (such as vials) to dosing equipment (such as infusion bags, bottles, or pumps).³ NIOSH recommends all CSTDs be used only in combination with a ventilated cabinet with proper PPE and work practices.

At present, the Food and Drug Administration (FDA) has approved four CSTDs, as defined by NIOSH, and one closed system device. The four companies with commercially available, FDA-cleared CSTDs are B.Braun Medical Inc., BD (Becton, Dickinson and Company), EquaShield Medical, and ICU Medical, Inc. CareFusion offers a closed system device, but not a CSTD as defined by NIOSH. More CSTDs are anticipated to enter the market in the near future.

When evaluating CSTDs, clinicians and healthcare facilities need to take into consideration several factors to determine which system is right for them. As mentioned above, studies have clearly shown that using a CSTD can significantly increase the safety of those tasked with handling hazardous drugs. And while these systems provide an enhanced level of protection for all those involved in the safe handling continuum—from preparation, to transportation, to administration, to disposal—the technology is still evolving, and no commercially available CSTD can, at this point in time, claim a 100% elimination of any and all exposure to hazardous drugs, despite their ability to substantially mitigate risk.

For example, BD's PhaSeal® system and the ICU Medical ChemoClave™ system have both been shown to provide an equivalent level of protection when operated properly.^{65,66} However, several risk factors in using the PhaSeal system have been identified, including the possibility of accidental needlesticks due to improper assembly and handling of the system, and accidental misconnects and spills at the system's multiple non-bonded connection and disconnection points.

Additionally, the complexity of the PhaSeal system has led to a lack of compliance in several hospitals, where nursing has refused to use the system during the administration phase, leaving this important clinical population at risk of exposure.⁶⁷

An editorial in the *Journal of Oncology Pharmacy Practice* concluded that, “If, in fact, the different closed systems currently available are equally effective, then the choice comes down to cost and ease of use.”

Likewise, in the preparation phase—which usually takes place in a controlled

environment under the hood of a BSC—the Spiros® closed male luer, a component of the ChemoClave system, has been shown to occasionally retain fluid residual of less than .00007 mL on the tip upon disconnection from the Genie® closed vial access device. This residual is easily removed under the hood using current hospital protocols for swabbing oncology connections upon disconnect with no further risk of exposure.

So, given that there is no 100% CSTD and that the two leading systems perform equivalently from a protection standpoint, healthcare providers must look at other attributes of the system—such as ease of use, safety, and cost—that provide value and differentiate the systems.

THE ICU MEDICAL CHEMOCLAVE SYSTEM

OVERVIEW

The ICU Medical ChemoClave CSTD meets all USP <797>, International Society of Oncology Pharmacy Practitioners (ISOPP), and NIOSH definitions of a CSTD. It is a mechanically and microbiologically closed, needlefree system compatible with virtually all hazardous drugs.

The ChemoClave system consists of a series of vial access devices, including the Genie needlefree closed vial access device, designed with an internal balloon that automatically equalizes drug vial pressure when extracting hazardous medications from vials, and the Spiros closed male luer with optional locking spin collar (Spinning Spiros). When the Spinning Spiros is attached to any male luer, it remains permanently attached to the device. Whether attached to a syringe or the end of an IV set, the Spiros remains closed whenever it is disconnected in order to protect the integrity of the IV fluid container. The Spiros can also access the Genie's bonded Clave® needlefree connector to maintain a closed system.

The integrated design ensures that clinicians cannot inadvertently or purposefully override the safety mechanisms. Thus, pharmacy can be assured that nurses are being kept safe through the effective utilization of the CSTD during administration.

Closed System Transfer Devices Throughout the Safe Handling Continuum



Safe Preparation



Safe Transportation



Safe Administration



Safe Disposal

An editorial in *Oncology Pharmacy Practice* urged hospitals to make sure that the CSTD they choose “is capable of containing the hazardous drug throughout all handling steps from reconstitution to administration.”⁶⁸

CLINICAL AND OPERATIONAL ADVANTAGES

In addition to meeting NIOSH and ASHP guidelines, ChemoClave is an intuitive, easy-to-use, needlefree system that is preferred by nurses, helping ensure compliance from beginning to end. A study comparing the PhaSeal and ChemoClave systems found that work practices and procedures regarding product operation appeared to be an important factor in hazardous drug containment and needle safety when using PhaSeal, but not when using ChemoClave, which requires fewer user steps and is needlefree.⁶⁵ In a previous report comparing the same two CSTDs in a head-to-head fashion, the authors concluded that there was no difference between the two systems in their efficacy at controlling surface contamination.⁶⁶

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cost and ease of use.” In addition, the editorial urged hospitals to make sure that the CSTD they choose “is capable of containing the hazardous drug throughout all handling steps from reconstitution to administration.”⁶⁸ To that end, a recent study comparing all commercially available CSTDs found that ChemoClave provided significant cost savings to hospitals while scoring highest in terms of ease of use, practicality, and perceived safety by a cross-functional evaluation team of pharmacists, nurses, and value analysis professionals.⁶⁹

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Benefits of the ChemoClave System

NEEDLEFREE

As the world’s only 100% needlefree system, ChemoClave completely and totally eliminates the risk of hazardous needlestick injuries. Estimates indicate that 600,000 to 800,000 such injuries occur annually.⁷⁰ Most reported needlestick injuries involve nursing staff who are exposed to bloodborne pathogens, including HBV, HCV, and HIV, which can be potentially life threatening. The emotional impact of a needlestick injury can be severe and long lasting, even when a serious infection is not transmitted. Consequently, NIOSH and other organizations are encouraging efforts to eliminate needle-bearing devices where safe and effective alternatives are available.³

In contrast, needle-bearing systems pose not only needlestick risk but also increased exposure to the hazardous drugs they hold. In comparing the PhaSeal and ChemoClave CSTDs, researchers found that work practices and procedures regarding product operation contributed to surface contamination during the PhaSeal trial.⁶⁵ On two occurrences, the Injector Luer Lock protective needle caps on the PhaSeal system were not retracted when withdrawn from the drug vials, exposing the needle. Small droplets that normally would otherwise be contained could have possibly reached the BSC

workbench. In a separate study, researchers found similar contamination when using a spike connection at the point of care.¹⁵ ICU Medical's Clave needlefree connectors showed on average a forty-fold lower contamination than the spike connection evaluated, which showed by far the highest levels of contamination.

The Spiros and Clave components of ChemoClave both qualify as closed and needlefree transfer systems, each having a passive, fail-safe, self-sealing technology that automatically returns the device to the closed position when there is a disconnection, whether accidental or intentional. The closed, integrated tubing sets have permanently bonded connections that eliminate "add-on" components, the "un-spiking" of secondary bags, and the potential for unsafe disconnect points. Additionally, hub colonization and subsequent intraluminal contamination due to frequent opening and manipulation of intravenous systems have been shown to be the cause of many catheter-related bloodstream infections

(CRBSI). Use of the Clave needlefree connector has been shown to result in lesser incidence of hub, catheter tip, as well as skin colonization; fewer CRBSIs; and the elimination of accidental needlesticks when compared with conventional open systems.⁷¹

The ChemoClave system is efficient from both an economic and educational standpoint as it works within current pharmacy-nursing protocols and does not require radical new practices and procedures of its end users.

EASY-TO-USE

As with any medical device, a CSTD is only effective if used properly. If proper operation is cumbersome, it is likely that the facility will develop compliance issues as staff bypasses the device in favor of a less burdensome process. In the case of CSTDs, this is more likely to happen in the administration phase, where nursing staff have had less exposure to the importance of safe handling processes, and workload concerns lead to a desire to streamline processes wherever possible.

In one such case, The Cancer Therapy & Research Center at The University of Texas Health Science Center at San Antonio found that when pharmacy would send a chemo compound to the unit with a difficult-to-use CSTD applied, the nurses would commonly remove the adapters, throw them away, and attach the bag's line directly to the patient's IV line.⁶⁷ Nursing informed pharmacy that they found the system frustrating to use and the facility elected to implement the ChemoClave system after a thorough and formal review of the available systems on the market.

Benefits of Using the ChemoClave Closed System Transfer Device

- > **Needlefree** design enhances safety by completely eliminating the possibility of hazardous needlesticks. Completely closed system assures compliance with safe handling policies.
- > **Easy-to-use** system requires no cumbersome assembly of components and features automatic self-sealing technology.
- > **Less biohazardous waste** than any other closed system transfer device.
- > **Lower cost** to implement than any other closed system transfer device.



The ICU Medical ChemoClave provides clinicians with a simple, safe, and secure needlefree CSTD to help enhance healthcare worker safety and comply with OSHA, NIOSH, ASHP, ISOPP, ONS, APHON, and USP <797>.

Several commercially available CSTDs, such as PhaSeal and EquaShield, require the assembly and disassembly of multiple complex parts to be effective. Work practices and procedures regarding product operation have been documented to be an important factor in hazardous drug containment and needle safety when using some of these devices, but not when using ChemoClave, which requires fewer user steps and is needlefree.⁶⁶ In a study following the trial and subsequent independent evaluation of all commercially available CSTDs, the ChemoClave system was chosen over all others because of the high scores the system received on ease of use, practicality, and perceived safety.

The ChemoClave system is efficient from both an economic and educational standpoint, as it works within current pharmacy-nursing protocols and does not require end users to learn radical new practices and procedures. For nurses, ChemoClave’s design concept is intuitive and allows them to infuse medication using the same techniques used in general IV therapy practice, therefore minimizing the educational burden and disruption to workflow.

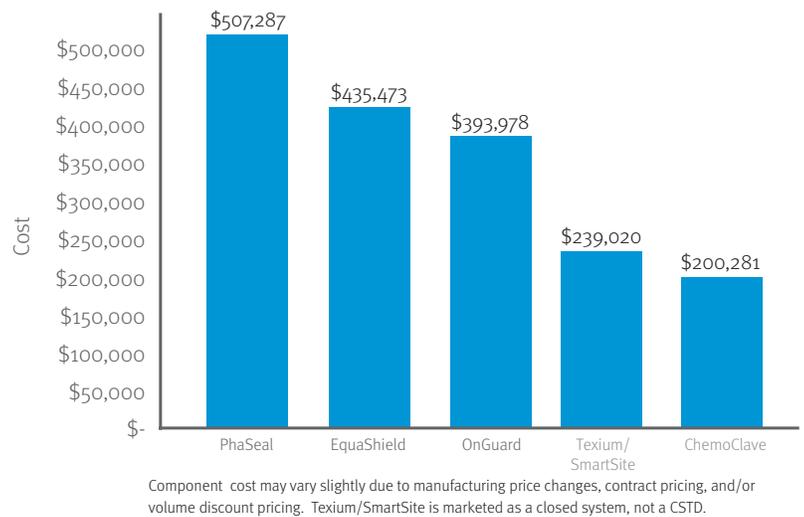
END-TO-END SOLUTION

The safe handling of hazardous drugs impacts worker safety in drug receipt and storage, drug preparation, administration, transportation, waste handling, and laundry. The ChemoClave system is used by hospital pharmacists to mix, prepare, and subsequently transport hazardous drugs, and by nurses to administer the drugs to patients at the point of care and dispose of the device after use. Hence, the ChemoClave system addresses key clinical audiences in the safe handling of hazardous drugs. ChemoClave is the only needlefree system and provides a complete end-to-end solution capable of addressing the four key points in the medication use cycle: preparation, transport, administration, and disposal.

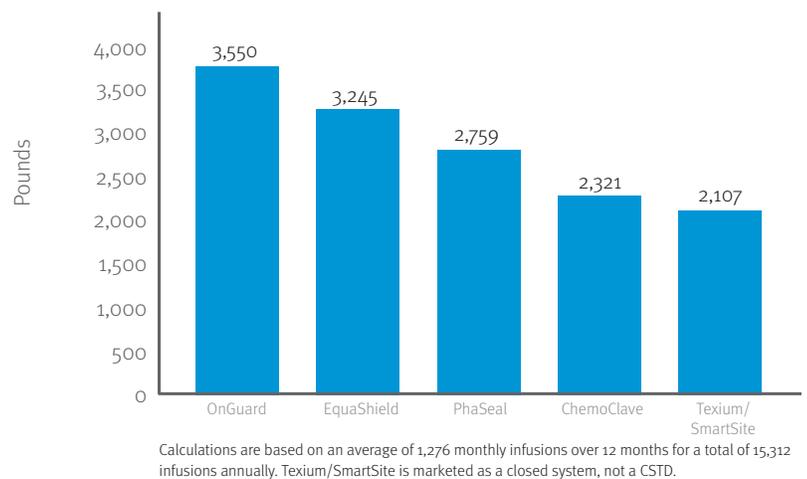
PREPARATION

The ChemoClave system provides mechanically and microbiologically closed, needlefree, vial access to minimize exposure and protect the sterility of compounded drugs. With no pieces to assemble and integrated bonded connections, pharmacy preparation is facilitated, all aerosols and vapors are contained, and staff can operate free from the risk of accidental needlestick injuries and bag punctures.

Total Annual Costs Associated with Implementing Competing CSTDs



Total Annual Biohazardous Waste Generated by Competing CSTDs



TRANSPORTATION

Because all of the ChemoClave system connections are bonded, nurses are not exposed to unsafe disconnect points, which can lead to both contamination and expensive drug loss during transport.

ADMINISTRATION

The ChemoClave system is compatible with multiple needlefree connectors and is employed using a simple and easy-to-use concept familiar to nurses. There is no new technique to learn to properly administer pharmaceuticals using the ChemoClave system. Permanent and bonded sets also help enhance nurse and patient safety by preventing spills and drips during tubing change out and accidental disconnection.

DISPOSAL

The ChemoClave system protects against environmental contamination by eliminating leaks and drug vapor escape in treatment areas and during the disposal process.

The ChemoClave system from ICU Medical offers the most comprehensive solution to address the unique concerns of pharmacy, nursing, and environmental services staff as it provides a safe, simple, and secure way to ensure safety throughout the medication use cycle.

REDUCED WASTE

In considering the impact of biohazardous waste generated by CSTDs, the weight and mass of all components and packaging of the devices need to be taken into account. Because of the simplicity of the system itself, ChemoClave generates the second least amount of biohazardous waste than any of the other three commercially available CSTDs. A prospective study of the waste implications of available

CSTDs showed that the ChemoClave system allows a high-volume cancer center to reduce biohazardous waste by nearly 2,300 pounds each year. Calculations were based on the amount of waste generated by each of the systems if used at a single high-volume oncology facility/hospital preparing 1,276 monthly infusions over twelve months for a total of 15,312 infusions annually.⁷²

COST EFFECTIVE

The ChemoClave system also costs less to implement than any other commercially available CSTD. The same study that compared the waste implications of available CSTDs also looked at the costs associated with implementing these systems throughout the clinical delivery continuum, including the preparation, transportation, administration, and disposal of hazardous drugs. Again, five CSTD systems were evaluated, and the study assumed that a high-volume oncology center prepares 1,276 monthly infusions over twelve months for a total of 15,312 infusions annually. The total cost of the systems was based on the cost of all of the components required to mix and administer the pharmaceuticals, as well as by adding in a \$.40/pound average hazardous waste removal cost based on the Baxa Corporation Star Center® course on the Safe Handling and Preparation of Hazardous Drugs.

Using these assumptions, real cost savings are estimated to be as much as \$307,000 a year with the ChemoClave system for a single high-volume cancer facility as compared to other CSTD systems.⁷² Another study that analyzed costs of available CSTDs estimated that using the ChemoClave system could save a facility between \$57.50 and \$112.50 for every 100 chemotherapy bags administered.²¹

CONCLUSION

CSTDs are a widely recognized advance in the safe handling of hazardous drugs used for chemotherapy treatment of cancer patients. When used with other proven safeguards and practices, CSTDs significantly reduce the potential for exposure to hazardous drugs. The ChemoClave system from ICU Medical, in particular, offers the most comprehensive solution to address the unique concerns of pharmacy, nursing, and environmental services staff as it provides a safe, simple, and secure way to ensure safety throughout the medication use cycle. ChemoClave is the only commercially available system in the world that combines the benefits of being needlefree, easy-to-use, generating less waste, and costing less to implement.

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