Preparation and Handling

Compounded Sterile Preparation Verification (1903)
Source: Council on Pharmacy Practice
To advocate that health systems adopt automation and information technology to facilitate in-process and final verification of compounded sterile preparations (CSPs) to ensure CSP quality; further,

To advocate that, until such time as automation or technology can be implemented, independent in-process and final verification of CSPs be performed; further,

To oppose the use of the syringe pull-back method or other proxy methods of CSP verification.

This policy supersedes ASHP policy 1617.

Use of Closed-System Transfer Devices to Reduce Drug Waste (1813)
Source: Council on Pharmacy Practice
To recognize that a growing body of evidence supports the ability of specific closed-system transfer devices (CSTDs) to maintain sterility beyond the in-use time currently recommended by United States Pharmacopeia Chapter 797, when those CSTDs are used with aseptic technique and following current sterile compounding standards; further,

To foster additional research on and develop standards and best practices for use of CSTDs for drug vial optimization; further,

To educate healthcare professionals, especially pharmacists and pharmacy technicians, about standards and best practices for use of CSTDs in drug vial optimization.

Pharmaceutical Waste (0903)
Source: Council on Pharmacy Practice
To collaborate with regulatory bodies and appropriate organizations to develop standards for the disposal of pharmaceutical hazardous waste as defined in the Resource Conservation and Recovery Act (RCRA), for the purpose of simplifying the disposal of these substances by health systems; further,

To encourage pharmaceutical manufacturers and the Environmental Protection Agency (EPA) to provide guidance and assistance to hospitals and health systems in proper pharmaceutical waste disposal and destruction efforts; further,

To advocate that EPA update the list of hazardous substances under RCRA and establish a process for maintaining a current list; further,

To urge federal, state, and local governments to harmonize regulations regarding disposal of hazardous pharmaceutical waste; further,

To advocate that the Food and Drug Administration standardize labeling of drug products with information relating to appropriate disposal; further,

To promote awareness within hospitals and health systems of pharmaceutical waste regulations; further,

To encourage research on the environmental and public health impacts of drug products and metabolites excreted in human waste; further,

To encourage pharmaceutical manufacturers to streamline packaging of drug products to reduce waste materials.

This policy was reviewed in 2019 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Safe Disposal of Patients' Home Medications (0614)
Source: Council on Professional Affairs
To minimize the patient safety consequences and public health impact of inappropriate disposal of patients' home medications by working collaboratively with other interested organizations to (1) develop models for patient-oriented medication disposal programs that will minimize accidental poisoning, drug diversion, and potential environmental impact, (2) advocate that the pharmaceutical industry and regulatory bodies support the development and implementation of such models, and (3) educate health professionals, regulatory bodies, and the public regarding safe disposal of unused home medications.

This policy was reviewed in 2015 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Safe and Effective Extemporaneous Compounding (0616)
Source: Council on Professional Affairs
To affirm that extemporaneous compounding of medications, when done to meet immediate or anticipatory patient needs, is part of the practice of pharmacy and is not manufacturing; further,

To support the principle that medications should not be extemporaneously compounded when they are commercially and readily available in the form necessary to meet patient needs; further,

To encourage pharmacists who compound medications to use only drug substances that have been manufactured in Food and Drug Administration-approved facilities and that meet official United States Pharmacopeia (USP) compendial requirements where those exist; further,

To support the principle that pharmacists be adequately trained and have sufficient facilities and equipment that meet technical and professional standards to ensure the quality of compounded medications; further,

To encourage USP to develop drug monographs for commonly compounded preparations; further,

To educate prescribers and other health care professionals about the potential risks associated with the use of extemporaneously compounded preparations.

This policy was reviewed in 2015 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

ASHP Policy Positions 2009–2019 (with Rationales)
Drug Distribution and Control: Preparation and Handling

1903

COMPOUNDED STERILE PREPARATION VERIFICATION

Source: Council on Pharmacy Practice

To advocate that health systems adopt automation and information technology to facilitate in-process and final verification of compounded sterile preparations (CSPs) to ensure CSP quality; further,

To advocate that, until such time as automation or technology can be implemented, independent in-process and final verification of CSPs be performed; further,

To oppose the use of the syringe pull-back method or other proxy methods of CSP verification.

This policy supersedes ASHP policy 1617.

Rationale

Adoption of automation and information technology for preparing and dispensing compounded sterile preparations (CSPs) is increasing but not evenly distributed among healthcare organizations. A 2017 ASHP survey showed that 64% of hospitals did not use any technology for sterile product preparation activities. Only 26.9% of health systems surveyed employed barcode verification in their IV medication preparation and verification process. The survey found that 12.8% of all health systems surveyed used drug workflow software to manage IV drug preparation, verification, and dispensing. There are many reasons for these disparate rates of adoption. Each institution has a different break-even point of investment versus return, and challenges of implementation can be daunting. Some organizations have implemented automated compounding technology only to withdraw it later. These technologies may slow the preparation and verification process; however, the enhanced safety outweighs losses in operational efficiency.

Information technology and automation, including robotics, can be used to improve the safety of CSP compounding. Although IV workflow technologies continue to be developed and improved, the majority of pharmacy departments continue to compound manually without the assistance of barcode or other technologies. Health systems have been slow to adopt IV workflow technology, with only 27% of respondents to the 2017 survey indicating their departments use barcode scanning to verify the ingredients in CSPs. If automated procedures are not employed, there are only two methods of in-process or final verification: real-time, direct, and independent visualization, or retroactive, proxy verification (e.g., the syringe pull-back method). The dangers of the syringe pull-back method have been well demonstrated, and the 2016 Institute for Safe Medication Practices (ISMP) Guidelines for Safe Preparation of Compounded Sterile Preparations discourage its use.

1813

Use of Closed-System Transfer Devices to Reduce Drug Waste

Source: Council on Pharmacy Practice

To recognize that a growing body of evidence supports the ability of specific closed-system transfer devices (CSTDs) to maintain sterility beyond the in-use time currently recommended by United States Pharmacopeia Chapter 797, when those CSTDs are used with aseptic technique and following current sterile compounding standards; further,

To foster additional research on and develop standards and best practices for use of CSTDs for drug vial optimization; further,

To educate healthcare professionals, especially pharmacists and pharmacy technicians, about standards and best practices for use of CSTDs in drug vial optimization.

Rationale

A 2016 study estimated that the U.S. may spend close to $2 billion on oncology drug products that are discarded because they come in vials in which the volume of drug product exceeds what is needed for most doses. Considerable savings are gained when the leftover contents of those vials are used. One practice that has shown promise in optimizing use of leftover drug product is the use of closed-system transfer devices (CSTDs) to facilitate the transfer of drug product from one reservoir to another. CSTDs prevent the release of hazardous drugs during compounding and administration and have primarily been used throughout the medication-use process to minimize healthcare workers' exposure to hazardous drugs. Some CSTDs use a mechanical barrier that can also prevent the ingress of environmental contaminants, which has prompted study of their ability to safely prolong the sterility of drug product in vials. A growing number of studies have been generating data that indicate specific CSTDs have the possibility of maintaining sterility and extending in-use time when used under sterile conditions defined by United States Pharmacopeia Chapter 797. Although some CSTDs have an FDA-approved indication for use to prevent microbial ingress with studied dwell times of up to 168 hours when maintained in an ISO Class 5 environment using proper aseptic technique, they do not have an explicit indication for extending the in-use time of drug products. Until the data from the studies can be validated and applied, standard-setting entities and regulators will not permit this practice. ASHP therefore advocates that the existing evidence that supports the ability of properly used CSTDs to maintain sterility and extend in-use times be recognized, and encourages research and development of guidance by standard-setting entities and regulators regarding safe use of CSTDs for drug vial optimization.

0903

PHARMACEUTICAL WASTE

Source: Council on Pharmacy Practice

To collaborate with regulatory bodies and appropriate organizations to develop standards for the disposal of pharmaceutical hazardous waste as defined in the Resource Conservation and Recovery Act (RCRA), for the purpose of simplifying the disposal of these substances by health systems; further,

To encourage pharmaceutical manufacturers and the Environmental Protection Agency (EPA) to provide guidance and assistance to hospitals and health systems in proper pharmaceutical waste disposal and destruction efforts; further,

To advocate that EPA update the list of hazardous substances under RCRA and establish a process for maintaining a current list; further,

To urge federal, state, and local governments to harmonize regulations regarding disposal of hazardous pharmaceutical waste; further,

To advocate that the Food and Drug Administration standardize labeling of drug products with information relating to appropriate disposal; further,

To promote awareness within hospitals and health systems of pharmaceutical waste regulations; further,

To encourage research on the environmental and public health impacts of drug products and metabolites excreted in human waste; further,

To encourage pharmaceutical manufacturers to streamline packaging of drug products to reduce waste materials.

This policy supersedes ASHP policy 0231.

Rationale

ASHP seeks to define pharmacists' responsibility to the public for safe disposal of hazardous pharmaceutical waste as well as to assist with their responsibility to comply with applicable regulations. ASHP believes that barriers to safe disposal of hazardous pharmaceutical waste include obsolete waste lists, variability in requirements, inadequate labeling, and a lack of research.

Obsolete lists. The waste stream for hazardous pharmaceuticals is in part determined by the RCRA waste list (i.e., P or U list) to which the drug is assigned. However, these lists do not include all medications, especially newer products. If a drug is not listed, individual organizations either follow the method of disposal listed for similar drugs or drug classes or use no special disposal method at all. Minimally hazardous drugs are included on these lists, creating needlessly burdensome disposal requirements.

Variability in requirements. Regulations vary from state to state and even from county to county. Large hospital systems are forced to create site-specific policies, which complicates communication and education about the appropriate management of waste.

Labeling. Ensuring that products for disposal are directed into the proper waste stream is left up to health care organizations. Many apply auxiliary labeling on-site to communicate this information. It would be more logical and efficient for the manufacturer to include this information in product labeling. Labeling immediate containers with disposal directions would

ensure that this information reached the end-user of the product. One example of how this might be done is the method used by the National Fire Protection Agency, which identifies hazards with specific symbols.

Research. Little research or guidance is available on the environmental effect of hazardous metabolites excreted in human waste. More research is needed in this area.