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BACKGROUND ON STERILE PREPARATION COMPOUNDING SAFETY

General information

Errors during pharmacy preparation of parenteral products and admixtures have frequently been reported to the ISMP National Medication Error Reporting Program (ISMP-MERP) and have also been a topic of discussion in the ISMP Medication Safety Alert.

In addition, a five-hospital observational study on the accuracy of preparing small- and large-volume injectables, chemotherapy solutions, and parenteral nutrition showed a mean error rate of 9%, meaning almost 1 in 10 products was prepared incorrectly prior to dispensing. Error rates for complex solutions such as parenteral nutrition were especially high—37% for manual preparation and 22% for preparations that were partly automated. A 2009 State of Pharmacy Compounding Survey showed that 30% of hospitals have experienced a patient event involving a compounding error in the past 5 years.

Clearly national efforts are needed to identify and eliminate or reduce errors and their causative factors. Therefore, the Institute for Safe Medication Practices (ISMP) held a national invitational Sterile Preparation Compounding Safety Summit on October 25-26, 2011 at the ACE Conference Center in Lafayette Hill, PA. Errors identified through the ISMP National Medication Errors Reporting Program and other reporting programs (e.g., U.S. Food and Drug Administration's MedWatch and MEDMARX), were reviewed. A literature review was also conducted to identify additional published admixture-related errors. Reports highlighted fatal medication errors associated with IV compounding in pharmacies, often involving infants or children.

At the summit, participants were asked a variety of questions regarding best practices when applied to preparation of 1) simple CSPs (those with one or two ingredients, such as patient controlled analgesia infusions, single electrolyte infusions, bolus doses, or maintenance IV infusions with no more than two ingredients), 2) complex CSPs (those with greater than two ingredients, such as parenteral nutrition (PN), cardioplegia solutions, or dialysis solutions), 3) pediatric and neonatal preparations, and 4) chemotherapy.

STAKEHOLDER COLLABORATION

Over 60 invitees agreed to attend the summit (see Appendix A). Those who participated came from a variety of backgrounds, including medication safety officers, experts in IV safety technology, pharmacy technicians, pharmacists, nurses, healthcare consumers and representatives of the medical product vendor community. The meeting was cosponsored by the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) and the American Society of Health-System Pharmacists (ASHP) and attended by a representative from the U.S. Food and Drug Administration (FDA) as well as a representative of the United States Pharmacopeia (USP) Committee that is overseeing future revisions of USP Chapter <797>.

Attendees were surveyed prior to the summit to gather information about their facilities, preparations compounded, standard practices, quality controls, automated processes, and software used related to compounded sterile products (CSPs). Participants were asked to review and comment on a compendium of ISMP recommended best practices that were sent to all attendees prior to the summit. Those practices with less than 90% agreement by attendees were...
included for discussion during the summit. Based on the pre-summit survey, one-third of responding participants represented hospitals with 100-299 beds and half were from hospitals with over 500 beds.

The summit comprehensively reviewed current methods used to prepare compounded sterile products (CSPs), identified manual and automated safeguards to provide assurance that the proper preparation is dispensed, addressed barriers that might inhibit safe practices, and sought to identify and standardize critical quality control practices needed for preparing and verifying the quality and safety of the final CSP. The summit resulted in a set of guidelines and safe practices, that were agreed upon by consensus to ensure the safe preparation of compounded sterile preparations (CSPs).

GOALS FOR THE SUMMIT

The goals for the summit included:

1) Review of currently employed quality control measures used to ensure the correct preparation of CSPs.
2) Identify quality control practices that should be standardized for incorporation into the manual process to ensure the correct preparation of CSPs.
3) Describe current and emerging technologies that assist the preparation of CSPs and how these technologies are utilized.
4) Identify the minimum safeguards that must be in place to prepare and dispense CSPs.
5) Recommend best practice guidelines to ensure the safe preparation of CSPs by pharmacies.

Please note: USP Chapter <797> provides a set of standards for assuring that compounded products are sterile at the time of dispensing. The ISMP summit was focused on another critical aspect of IV solution compounding: IV admixture error prevention. Summit attendees agreed to fully support the quality standards outlined in USP Chapter <797> and no discussion was specifically held to suggest any additions or revisions.

The remainder of this report will discuss agreed upon consensus statements for CSPs. Most of the consensus statements fit with a particular core process, but some span several core processes. Consensus statements are provided for the following core processes in the following order:

- Policies and Procedures for Compounding Sterile Preparations
- Order Entry and Verification
- Drug Storage
- Assembling Products and Supplies for Preparation
- Compounding
- Drug Conservation
- Preparation of Source/Bulk Containers
- Technology/Automation Used for Compounding CSPs
- IV Workflow Software
- Automated IV Compounding Devices
- Quality Control/Final Verification of Manually Prepared Product
- Product Labeling
- Record Keeping
- Staff Management
DISCLOSURE

All participants were volunteers and received no compensation other than travel and meeting expense reimbursement. ISMP acknowledges the expertise of these volunteer practitioners and appreciates their assistance in developing these guidelines. The summit and production of this guidance document was funded by the generous support of Ameridose, Baxa, Baxter, B. Braun, and Hospira.

ABOUT ISMP

The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit charitable organization that works closely with healthcare practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention. ISMP represents more than 35 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. ISMP is a federally certified patient safety organization (PSO). For more information on ISMP, or its medication safety alert newsletters and other tools for healthcare professionals and consumers, visit www.ismp.org. For access to our consumer website, please visit www.consumermedsafety.org.
The consensus statements are prioritized as follows:

- Level 1 (recommendation) - used to indicate a best practice that is strongly encouraged but which may not be applicable to all institutions or in all circumstances.
- Level 2 (standard) - used to indicate what should be considered a minimum standard of practice set forth in this document.
- Level 3 (mandate) - used to indicate a requirement established by law, regulation, accrediting bodies, or other binding authorities. It is realized that legal and regulatory requirements vary from state to state. Thus, only requirements that are required in the vast majority of states are included in this level.

Note: words that are in all capital letters have a definition in the glossary section at the end of the document.

Policies and Procedures for Compounding Sterile Preparations

- Organizational practices comply with USP <797> standards. (Level 2)
- Organizations have well-defined policies and procedures that guide the compounding of sterile preparations. (Level 3)
- Organizations identify standardized workflow processes that include quality control, PROCESS CHANGE CONTROL and documentation practices. It is recognized that workflow may vary depending on the type and quantity of CSPs prepared and the sophistication of technology employed in each organization. (Level 3)
- Organizations develop a drug conservation policy that addresses the handling and disposition of drugs (while maintaining their integrity and sterility) that may be in short supply due to market conditions, as these shortages can affect workflow conditions. (Level 1)
- Organizations develop detailed policies for BATCH production of CSPs. (Level 2).
  - Batch processing policies for simple, complex, pediatric, and chemotherapeutic CSPs include detailed preparation instructions and references when available. (Level 2)
  - Batch processing formulas are provided for all batch sizes (e.g., production of a 50 mL batch vs. a 250 mL batch), document theoretical yield versus actual yield, and account for all waste. (Level 2)

Order Entry and Verification

- All orders entered into a computerized prescriber order entry (CPOE) system are verified by a pharmacist. All orders entered into a pharmacy information system or transcribed onto pharmacy patient profiles by a non-pharmacist are verified by a pharmacist in accordance with state rules and regulations. (Level 3)
• For orders requiring pharmacy transcription for specific types of CSPs and/or selected individual products as identified by the organization (e.g., chemotherapy, Parenteral Nutrition (PN), other selected high-alert medications), the information entered into the pharmacy system or transcribed onto pharmacy patient profiles is verified by a second QUALIFIED INDIVIDUAL, even when the order was initially entered by a pharmacist (Level 2).
  
  ➢ This review includes a comparison of the order to the pharmacy generated label. Such a transcription review should be performed for chemotherapy, complex CSPs, pediatric/neonatal CSPs and other CSPs as defined by the organization. (Level 2)

• For PN, the sequence of ingredients on any pre-printed order sets or order entry screens is consistent with that of the automated IV compounding screens, the patient-specific label and the medication administration record. (Level 1)

**Drug Storage in Sterile Compounding Areas**

• Drug inventory is minimized to avoid intermingling of products. (Level 1)

• Sufficient space for drug storage is provided to segregate each drug concentration. (Level 1)

• Concentrated electrolytes are isolated from other inventory. (Level 2)

• Labeling of bins or bin dividers includes generic drug name, and concentration. (Level 1)

• FDA and/or ISMP tall man lettering is employed for look-alike drug names and is incorporated into CPOE, pharmacy information systems and product labels. (Level 1)

• CSPs that have been compounded, and are waiting to be checked are placed in a clearly identified and designated storage location until the checking process has been completed. (Level 2)

• Environmental recommendations, as provided in the USP <1066>, for lighting, noise, workspace and distractions are followed. (Level 1)

**Assembling Products and Supplies for Preparation**

• Drugs, diluents, base solutions and other supplies are gathered and placed in a separate container, (e.g., a basket or bin) for each preparation or each batch to be prepared. When possible, the person gathering products should be different than the person preparing the CSPs. (Level 1)

**Compounding**

• When available, commercially-prepared, premixed IV products that meet the patient’s needs are used over manually compounded sterile products. (Level 1)
Additives are not manually incorporated into commercially-prepared, pre-mixed preparations other than those designed for the addition of additives, e.g., multi-chambered bags for parenteral nutrition. (Level 1)

Standard base solutions (e.g., dextrose 5%) are used when available to prevent the error prone process of preparing unique/unusual base solutions (e.g., dextrose 3.5%). (Level 2)

Outsourcing the production of CSPs is considered as an alternative to in-house compounding when (Level 1):

- the volume of certain CSPs is very low, thus making it difficult to maintain staff competency for preparing the product.
- the volume for certain CSPs is high and staff resources are limited or unavailable to prepare this quantity.
- the organization does not possess the technological resources to prepare certain products according to USP <797>.
- commercially-prepared, premixed product is not available, including product shortages.

Organizations use a tool, such as the ASHP Foundation’s document, “Outsourcing Sterile Products Preparation: Contractor Assessment Tool” (http://www.ashpfoundation.org/sterileproductstool), as one resource to analyze the capabilities and quality of external compounding providers prior to selecting a vendor. (Level 1)

STANDARD OPERATING PROCEDURES (SOPs) for compounding all CSPs are established and sufficiently detailed to prevent process variation in practice among practitioners. (Level 2)

Formulas (ingredients and the process to prepare) are established and standardized by the organization and are used to guide the compounding of complex CSPs, (e.g., dialysis solutions, cardioplegia solutions, dilutions, aliquots). (Level 2)

- SOPs and formulas are supported by current literature and periodically revised as new information becomes available. (Level 1)
- Pharmacy staff members compounding CSPs follow the sequence of steps and processes specified in the formulas and SOPs. (Level 2)

A preparation label, master formulation record, or worksheet is available for compounding chemotherapy, complex, and pediatric/neonatal CSPs. This document should express drug name, base solution, patient-specific dose, preparation calculations, final volume of the preparation and identify the appropriate drug dosage form to be used (e.g., concentration and size of the container). (Level 1)

Only one staff member is permitted to work in the DIRECT COMPOUNDING AREA when compounding chemotherapy and complex CSPs. (Level 2)
Two staff members are permitted to work in the compounding area simultaneously, if necessary, provided that the hood is 6 feet in length and a physical divide can be maintained between staff members, and the products being compounded are non-chemotherapy CSPs. (Level 2)

Only one CSP is prepared at a time (Level 1). An exception is:

- One practitioner can prepare multiple CSPs safely in the hood at one time only if preparing the same doses of the same drug with the same route of administration for one or multiple patients. It is not safe to prepare multiple CSPs at the same time in the hood for different doses or routes of administration, or multiple products for the same patient.

In facilities that care for adult, pediatric and neonatal patients, the computerized label runs for pediatric and neonatal CSPs are generated or printed separately from adult CSPs. (Level 2)

In facilities that care for adult, pediatric and neonatal patients, the preparation of CSPs for each population is separated by time or location. Separation strategies can include the use of different color bins for assembling products to be prepared. (Level 2)

Preparation of chemotherapy and complex CSPs is only performed based on the availability of qualified staff resources. (Level 2)

- Prescribers comply with predetermined cut-off times that have been established by the organization to permit safe preparation of CSPs. (Level 1)

Pharmacies create standard processes to address the volume of base solution when compounding CSPs. (Level 2). Such standard work practices address:

- If and when there is a need to remove base solution in amounts equivalent to drug additive(s). (Level 2)

- If and when there is a need to eliminate the manufacturer overfill from the base solution and the method used to accomplish removal (e.g., direct removal of overfill volume or pumping the amount of base solution from a commercial container into an empty bag). (Level 2)

**Drug Conservation**

- Partially used multi-dose vials, bulk containers or single dose containers are not left in the hood or direct compounding area for future use. (Level 1)
  - However, single dose containers of drugs in short supply that are covered by an organization-specific, drug conservation policy may be left in the hood for use up to 6 hours after initial needle puncture in accordance with USP 797 guidelines. (Level 2)

- Heparin and insulin vials are never in the hood at the same time. (Level 2)
• The organization-specific drug conservation policy includes safe practices that address: (Level 1)
  ✓ Maintaining the integrity and sterility of these medications.
  ✓ Methods used to segregate the drug from the direct compounding area.
  ✓ A pharmacist must perform a regular assessment of drug products stored in the hood for compliance with this policy.

Preparation of Source/Bulk Containers

• A detailed standard process is in place for preparing and checking pharmacy-compounded SOURCE/BULK CONTAINERS used to prepare multiple doses or batches. (Level 2)

  ➢ A pharmacist conducts an INDEPENDENT DOUBLE CHECK (IDC) of all diluents and drugs before the preparation of all source/bulk containers. (Level 2)

  ➢ Source/bulk containers prepared for use during compounding is labeled with the following information (Level 2):
    ✓ drug name
    ✓ concentration
    ✓ diluent
    ✓ date of preparation
    ✓ name of preparer
    ✓ name of person performing the IDC
    ✓ beyond use date

  ➢ See record keeping section for documentation requirements

Technology/Automation Used for Compounding CSPs

• Organizations develop a strategic plan for implementation of automation and technology for the sterile products service. (Level 1)

• Technology and automation such as bar code verification or IV robotics are utilized as much as possible for preparing and verifying CSPs. (Level 1)

• Routine preventive maintenance are performed, and calibration and certification are current and documented, for equipment used during the compounding of CSPs. (Level 3)

• All current service releases for software in use are installed and tested. (Level 1)

IV Workflow Software

• IV WORKFLOW SOFTWARE (e.g., DoseEdge, Script Pro Telepharmacy, and I.V. Soft or similar technology) is used to augment manual processes whenever possible. (Level 1)
• IV workflow software is well-maintained, and appropriately programmed with adequate infrastructure to support the system. (Level 2)

• Organizations have SOPs that ensure that the final check of the preparation has been completed by a pharmacist possessing training and experience with this technology, prior to dispensing. (Level 2)

Automated IV Compounding Devices

• Privileges to make changes in the database of AUTOMATED IV COMPOUNDING DEVICES are restricted to staff members who are well-trained in both the theory and the mechanics of this process. (Level 2)

• The use of a checklist/sign-off sheet is required when adding new products, new concentrations, new generics, and changes in vial size or when making other modifications to the database (e.g., changes in privileges, changes in data requirements). Two staff members possessing training and experience with this technology, one of whom is a pharmacist, are required to sign off or validate changes. (This process would not apply to inputting a new lot number for a product already in the database.) (Level 2)

• Organizations implement specific SOFT LIMITS and HARD (catastrophic) LIMITS for ingredients that are consistent with the needs of their patient population. (Level 2)

• Weight-based warning limits for doses should be developed by vendors. As an alternative, hospitals may develop and use their own weight-based warning limits. (Level 1)

• Only pharmacists are allowed to override alerts. (Level 2)

• Bar code verification is used to verify product identity during set up and replacement of ingredients. (Level 2)

• A double check process for the initial daily set up is performed with two staff members using a printed check list. (Level 2)
  ➢ Verbal affirmation with two staff members takes place to validate placement of all additives and base solutions including name, concentration, and container size. (Level 1)

• Tubing set(s) is traced from the source container to the port where it is attached during the initial daily set up and with each change in the source container. (Level 2)

• If multiple containers of a single additive are used during the preparation of a single CSP, all empty containers are presented to the pharmacist as part of the final check process prior to dispensing the final CSP. (Level 2)

• Staff members are trained in the use of automated IV compounding technology, and there is documentation of initial training, as well as ongoing competency assessment. (Level 3)
• The label generated by the IV compounding device ideally is the only label attached to the completed CSP. Ensure this label reflects the sequence of ingredients and units of measure as presented on the prescriber’s original order. (Level 1)

• CUSTOMIZED ORDER ENTRY TEMPLATES created by organizations have a documented standard review process by qualified staff which includes review and testing of the clinical decision support that is expected to alert the pharmacist to significant warnings. (Level 1)

• The use of a checklist/sign-off sheet is required and two staff members, (including at least one pharmacist) sign off or validate the template. (Level 2)

• When an automated IV compounder is used, it delivers all ingredients. (Level 1)

• Manual compounding is only used (Level 1):
  ▶ If the volume of an ingredient to be mixed is less than the compounder can accurately deliver.
  ▶ If there is an interaction between an ingredient and a component of the compounder (e.g., insulin and tubing).
  ▶ If there is a chemical interaction between ingredients that cannot be mitigated by sequencing the addition of ingredients.

**Quality Control/Final Verification of Manually Prepared Product**

• All personnel are able to “stop the line” and question any concerns about any order or any sterile preparation to be compounded. (Level 2)

• A visual check by a qualified individual is performed to verify the accuracy of all diluents and drugs (including volumes and concentrations). (Level 2)

• Organizations that do not use IV workflow software identify in their compounding policies those CSPs that require preproduction visual confirmation of the amount of each ingredient (prior to addition to the final container). (Level 2)
  ▪ At a minimum, this list should include the following:
    ▶ chemotherapy
    ▶ PN admixtures
    ▶ pediatric and neonatal preparations
    ▶ pharmacy prepared source/bulk containers
    ▶ preparations requiring the use of multidose vials of high-alert medications (e.g., insulin, concentrated electrolytes, heparin)
    ▶ CSPs administered via high-risk routes of administration (e.g., intrathecal, epidural, and intraocular)

• Proxy methods of verification such as the SYRINGE PULL-BACK METHOD of verification are never used in the preparation of chemotherapeutic, complex, pediatric/neonatal or
high-alert CSPs and shall not be used without the presence of the actual, original source containers (medication and diluent). (Level 2)

- Handwriting the amount of an additive on the final product label is not used as the sole method of verification of any CSP. (Level 2)

- Errors that occur during the compounding of CSPs and are identified by either the pharmacist or technician prior to dispensing are documented and reported through the organization’s reporting system for analysis. (Level 1)

- Serious incidents are reported to the ISMP Medication Error Reporting Program (ISMP forwards reports to FDA MedWatch) for learning purposes and dissemination of prevention measures. (Level 1)

- Proactive risk assessments, such as failure modes and effects analysis (FMEA) are used prior to the implementation of process changes. (Level 1)

- Internal as well as external information about medication errors, from sources such as ISMP, are reviewed and used to modify practices and procedures as needed. (Level 1)

### Product Labeling

- ISMP label guidelines are utilized when formatting computer generated labels for CSPs. These are available at http://www.ismp.org/Tools/guidelines/labelFormats/Piggyback.asp. (Level 1)

- Labels are applied immediately after manual preparation of CSPs. (When certain technology is employed it may be necessary to apply the final product label prior to compounding the preparation.) (Level 2)

- Labels generated by an automated IV compounding device match the format and units of measure of the prescriber’s order, include the beyond use date, and are ideally the only label attached to the completed CSP. (Level 1)

- Preparation labels (or “prep tickets”) are never be used as the final product label. (Level 1)

- For chemotherapy and other CSPs identified by the organization, the final volume (e.g., bag volume + manufacturer’s overfill + additive volume) to be infused is present on the label. (Level 2)

- Information on the final label matches the format and units of measure of the prescriber’s order and the medication administration record. The product label does not contain unnecessary information (e.g., vial size used to prepare the CSP). (Level 1)

### Record Keeping

- When preparing CSPs intended for storage for anticipated needs, batch records includes (Level 1):
  - Date of production
- Individual components, including lot numbers and expiration dates
- Expected and actual yield of the batch
- Example of label
- Calculations
- Beyond use date
- Person preparing batch
- Person checking batch
- Label count

Staff Management

- Pharmacy technicians involved in preparation of CSPs are Certified Pharmacy Technicians having passed the appropriate tests administered by the Pharmacy Technician Certification Board. (Level 1)

- All staff members involved in preparing CSPs or supervising the preparation of CSPs participate in a comprehensive orientation and training program as well as an ongoing competency assessment program. (Level 2)

- Pharmacists and pharmacy technicians who prepare CSPs have annual competency evaluation for all aspects of sterile compounding which might include (Level 1):
  - performing calculations and preparing dilutions
  - compounding base solutions
  - using aliquots as a method of measuring ingredients below the sensitivity of a scale (by proportional dilution with inactive ingredients)
  - aseptic technique including media-fill testing
  - preparing medications for complex routes of administration (e.g., intrathecal)
  - proper use of technology (if available)

- A national certification program for sterile-compounding specialists should be developed. (Level 1)

- The American Association of Colleges of Pharmacy should instruct their Academic Affairs Committee to add hands-on experience with sterile compounding into pharmacy training to achieve minimum competencies, which are developed by an interdisciplinary stakeholder group. (Level 1)
Glossary and Abbreviations

- **Automated IV compounding devices** - equipment used by pharmacists for the extemporaneous preparation of parenteral nutrition admixtures and other types of intravenous admixtures.

- **Batch** - Preparing a number of non-patient specific doses with the intention to use based on future patient need.

- **CSP** - compounded sterile preparation

- **Customized order entry templates** - templates created in Automated IV Compounders that are not part of the manufacturer’s original library and are created by the individual institution.

- **Direct compounding area** – the area within the hood where the critical site (vial septum and needle) are exposed to first-air.

- **Hard limits** – alerts that indicate that something is outside a determined safe range. Hard limits will not allow the operator to proceed with the selection.

- **Independent double check** - a procedure in which two individuals, preferably two licensed practitioners, separately check each component of the work process. An example would be one person calculates a medication dose for a specific patient and a second individual independently performs the same calculation (not just verifying the calculation) and then matching their results.

- **IV workflow software** – software that manages pharmacy workflow required for selecting, compounding, inspecting, tracking and reporting for IV doses.

- **PN** – parenteral nutrition

- **Process change control** - a formal process used to ensure that changes to a product or system are introduced in a controlled and coordinated manner.

- **Qualified individual/staff** – staff members adequately trained and approved to perform a particular function.

- **Soft limits** – alerts that are displayed but can be overridden by the operator who may then proceed with the selection.

- **SOP** – standard operating procedure

- **Source/bulk container** – a sterile container (bottle, vial, or bag) manufactured by a commercial vendor or prepared by pharmacy, which is then used as a source from which to withdraw multiple doses.
• Syringe pull-back method – presentation of the syringe(s) pulled back to display amount of medication or diluent that was added to the infusion container AND the actual drug or diluent source container(s) from which the drug or diluent was withdrawn prior to the addition to the infusion container.

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