Keeping Pediatric Patients Safe

modified November 2025

Med errors are three times as likely to occur in infants and children than in adults. Up to one in four pediatric med orders results in an error, and just over 5% of pediatric inpatients may experience a med error.[1-3,5] About one-third of med errors in kids have the potential to cause serious harm.[9] Many aspects of pediatric med use (e.g., weight-based dosing, lack of commercially available dosage forms, complex calculations) pose safety challenges.[1-4] General safety strategies (e.g., tall man lettering) should always be used. In addition, regulatory and safety groups recommend maintaining current pediatric drug info resources, ensuring appropriate 24-hour coverage of pediatric pharmacy services, and including a pharmacist with pediatric training in oversight of technology (e.g., smart pumps, clinical content of electronic health records [EHRs]) and med use committees.[1,4] The following chart provides strategies to prevent med errors in pediatric patients in both inpatient and outpatient settings.

	Prevent ordering errors
	• Ensure that a medication and vaccine history is conducted for pediatric patients by a pediatric pharmacist, whenever possible.[1,9] o Use immunization information systems (US: www.cdc.gov/vaccines/programs/iis/contacts-locate-records.html; Canada: see your local provincial/territorial registry, where available) for vaccine histories.
	• Check that heights and weights are correct, and documented in metric units (e.g., kg) only.[1,6] o Patients should be weighed often (e.g., with new outpatient prescriptions, at inpatient admission [or within four hours of admission]).[4,6] o Ensure that weights are kept current (e.g., infants may require daily weights) during prolonged admissions and with chronic meds.
	• Use only metric units when ordering and giving directions for pediatric medications (e.g., mL instead of teaspoons).[1,8]
	• Ensure that pediatric doses are ordered as dose per weight (e.g., mg/kg) rather than just the total dose.[4,8,9]
	• Standardize and limit the number of concentrations of meds for pediatric patients, especially high-alert meds.[4] o Avoid ordering nonstandard concentrations. (You can access a list of national standardized concentrations online.)
	• Avoid verbal orders whenever possible.[1]
	• For handwritten orders, avoid the use of naked decimals (e.g., .1) or trailing zeros (e.g., 1.0) to prevent ten-fold dosing errors.[5,9]
	• Inquire about adding weight-specific and age-specific dosing alerts to your EHR, if they aren't already being used.[1,4,5]

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	Prevent dosing errors
	• Ensure that parents or caregivers understand all administration instructions, including which measuring device to use and how to measure the dose of liquid medications.[11]
	• Be aware of general age definitions used in pediatrics, which is commonly described as patients from birth to 18 years:[8] o a preterm neonate is born at <37 weeks gestation. o a neonate is <1 month old. o an infant is 1 month to 1 year old. o a child is 1 to 11 years old. o an adolescent is 12 to 18 years old.
	• Clarify if your EHR's reference ranges for vital signs and labs default to adult values for all patients. If so, ask if these can be adjusted to normal ranges for pediatric patients, when appropriate.[8] o As a rule of thumb, pediatric respiratory and pulse rates are higher than adults, blood pressure is lower than adults, and body temperatures are the same.[8]
	• Use an appropriate drug reference for premature babies and neonates. Examples include *NeoFax* and *Pediatric & Neonatal Dosage Handbook*. Don't rely on adult drug information references for these patients.
	• Use weight-based dosing for pediatric patients. But most pediatric doses should be capped at adult doses, even if a pediatric patient's weight-based dose is higher than an adult dose.[8,9] o Reassess chronic med doses frequently, as a patient's height and weight increase.[8]
	• Stay alert for mix-ups between units when calculating doses, such as mg/kg/DAY and mg/kg/DOSE.[8,9]
	• Stay alert for confusion with combination meds. For example: o piperacillin/tazobactam mg/kg doses for pediatric patients are based only on the piperacillin component. o amoxicillin/clavulanic acid products come with the components in different ratios that impact dosing frequency.
	• Ensure dose volumes are appropriate. For example, for IM injections, use a max of 0.5 mL in neonates and a max of 1 to 2 mL in children.[10] o If needed, divide doses between multiple syringes to avoid exceeding the max volume for a single injection.[10]
	• Use (and ensure your EHR is using) a pediatric equation (e.g., Schwartz, Bedside Schwartz) to assess kidney function. o Avoid using adult equations, which can overestimate in pediatric patients.[9] o Small changes in serum creatinine can be more significant in pediatric patients than in adults.[8]

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	Prevent compounding errors
	• Stock commercially available products for pediatric patients when they're available, to avoid the need for compounding.[1,4]
	• Stick to standardized concentrations for liquid meds (orals and injectables), whether they're commercially available or compounded.[1] o Example: The recommended concentration for compounded atenolol oral liquid is 2 mg/mL.[7]
	• When compounded meds are necessary, ensure that the pharmacy compounds them. Avoid having parents, caregivers, nurses, or others compound pediatric meds.[1]
	• Separate compounding of pediatric and adult doses.[4] o Example: Avoid prepping adult and neonatal parenteral nutrition in the same IV hood at the same time.
	Prevent dispensing and administration errors
	• Store adult and pediatric meds separately, whenever possible.[4] o Avoid stocking adult concentrations of meds on pediatric patient care units such as in automated dispensing cabinets.[4,9] o Example: Stock pediatric strengths of injectable vitamin K (1 mg/0.5 mL) instead of adult strengths of vitamin K (10 mg/mL) in automated dispensing cabinets in neonatal patient care areas.
	• Dispense patient-specific doses for pediatric patients whenever possible, and minimize necessary manipulation (e.g., splitting tablets) prior to administration.[1,2,4,5,9] o If manipulation is necessary after a med is dispensed, provide clear instructions.[5]
	• Ensure inpatient unit-dose packages have readable bar codes for scanning prior to administration.[1,2,4]
	• Dispense oral liquids in oral syringes to reduce the risk of accidental injection.[4,6]
	• Ensure your hospital has a policy on in-house use of insulin pumps.[1]
	• Ensure smart pumps are programmed with appropriate dose limits and hard stops for pediatric patients, and that libraries are maintained and reviewed at least once a year.[1,3,5,9] o Advocate for syringe pumps or modules in your hospital for accurate administration of very small volumes such as <0.1 mL/h.[9]
	• Avoid workarounds with bar-code scanning during med prep and administration.[1] Help identify and prevent issues such as difficulty scanning bar codes on labels on smaller med packaging, etc.[1]
	• Make sure oral syringes are available on patient care units in case an oral liquid dose would need to be drawn up by a nurse or other clinician.[4,6]
	• Recommend labeling IV lines with the name of the med being infused to prevent mix-ups, especially if tubing has to be detached.[5]

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	Use extra precautions in high-risk situations
	• Be aware that some medications and excipients may potentially be inappropriate in pediatric patients. o See the Pediatric Pharmacy Association's KIDS (**K**ey Potentially **I**nappropriate **D**rug**s**) list at https://www.jppt.org/doi/pdf/10.5863/1551-6776-25.3.175, for examples.
	• Keep in mind that children younger than five years old are most likely to experience med errors.[5]
	• Stay alert for age-appropriate dosing in areas where both pediatric and adult patients might be treated (e.g., outpatient pharmacies, perioperative areas, emergency department).[4,5] o Ensure high-risk meds (e.g., insulin, opioids) are not able to be auto verified for pediatric patients.
	• Keep in mind that intensive care units (e.g., neonatal ICU, pediatric ICU) are high-risk areas for medication errors.[5]
	• Be aware of meds that are most likely to be implicated in pediatric medication errors. o Example: Pediatric med errors seem most likely with antibiotics, IV fluids, opioids, and vaccines.[5] High-alert meds that seem most likely to be implicated in pediatric med errors include insulin, opioids, and parenteral nutrition.[5]
	Prevent errors in inpatient emergency situations
	• Keep meds for pediatric cardiac or respiratory arrests separate from adult meds.
	• Preprint weight-based dosing sheets for emergency meds for pediatric patients and have them available at bedside.[4]
	• Ensure teams such as CPR, emergency preparedness, rapid response, and trauma include a pediatric pharmacy representative.[1]
	• Ensure that a pharmacist with pediatric training participates in pediatric codes, and has appropriate training (e.g., pediatric advanced life support.[1]
	Safely manage pain in pediatric patients
	• Assess pain using scales and tools specifically designed for the patient's age.[12] o Consider patient behavior, physiologic measures, facial expressions, parental assessment, and patient self-report.[12]
	• Encourage parents/caregivers to try non-med pain relief strategies: distractions (e.g., videos, movies, games); repositioning, rocking, or stroking the child; or singing to them or providing soft music.[13] • See our checklist, *Vaccine Administration Strategies*, for more non-med ways to minimize injection pain.
	• Choose acetaminophen or ibuprofen for most types of pain in pediatrics.[14] • Avoid potentially harmful analgesics (e.g., topical benzocaine [for teething], codeine, and tramadol).[15] • Use strong opioids appropriately, and only when non-opioids are not enough.[16]

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	• See our chart, *Potentially Harmful Drugs in Children* for details and alternatives.

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What's New in Sterile Compounding?

(last modified July 2024)

USP develops compounding standards to help ensure quality preparations while reducing variability and risks (e.g., contamination, incorrect dosing). This chart reviews updates to USP <797>, based on the 2023 revision, including compounding categories, assignment of beyond-use-dates (BUDs), and requirements for training and competency. The 2023 revision requires additional facility and engineering controls, such as high-efficiency particulate air (HEPA)-filtered ceiling air to reduce the risk of contamination with sterile compounding, compared to the 2008 version.[1] For a list of compounding CEs that cover USP <795>, <797>, and <800>, go to our CE & Training portal and select "Compounding and Hazardous Drugs" from the list of topics in the Available activities section.

Question	Answer/Pertinent Information
What are the differences between USP <795>, <797>, and <800>?	• USP <795>: pharmaceutical compounding of **NONsterile preparations**. • USP <797>: pharmaceutical compounding of **sterile preparations**. • USP <800>: handling of **hazardous drugs** in the healthcare setting. • If compounding a preparation that includes a hazardous drug, both applicable chapters should be followed. For example: o Follow USP <795> and <800> when compounding a **NONsterile prep containing a hazardous drug**. o Follow USP <797> and <800> when compounding a **sterile prep containing a hazardous drug**.
How is sterile compounding defined?	• Sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile preparation.[1]
How are compounded sterile preparations (CSPs) classified?	• Low-, medium-, and high-risk categories have been replaced with Category 1, 2, and 3.[1] o **Category 1** applies to CSPs prepared in a segregated compounding area.[1] o **Category 2** applies to CSPs prepared in a clean room suite.[1] o **Category 3** applies to CSPs prepared in a clean room suite, which can be assigned longer BUDs than Category 2 CSPs, but have more stringent requirements for garbing, environment sampling, etc.[1] **(This document will not cover requirements for Category 3 CSPs since many hospitals will not compound these.)** • There is an allowance for **immediate-use CSPs** (i.e., prepared outside of a sterile environment). Recall that immediate use applies to CSPs mixed from no more than three different sterile products and intended for direct and immediate administration to a patient.[1] Multiple containers of the same med count as one product. For example, prepping a norepinephrine drip using a normal saline bag and four ampules of norepinephrine is only two different sterile products.[2] While the emergency situation requirement for immediate use has been removed, there are specific conditions that must be met to use the immediate-use allowance.[1, a]

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Question	Answer/Pertinent Information
What are responsibilities of the "designated person?"	• A person or persons must be designated by a hospital as responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs.[1] • They must oversee compliance, including training and competency, and their documentation.[1,2] • Keep in mind that these roles might not fall to any single person. Depending on pharmacy size, there could be many designated persons who oversee various compliance elements.
What are training and competency requirements for sterile compounding?	• Training and competency requirements for sterile compounding are now more defined in the chapter. o **Initial training**, including demonstration of core skills (e.g., aseptic technique, calculations, cleaning and disinfection, garbing and hand hygiene, use of equipment), fingertip and thumb testing, and media-fill testing, continue to be required.[1,2] o **For Category 1 and 2 CSPs, demo of garbing, hand hygiene, and aseptic technique plus media-fill test followed by fingertip and thumb testing** is required **every six months** for **all compounding personnel**, and core skill testing is required annually.[1] o A surface sample of the direct compounding area (DCA) is a new additional viable testing requirement (post media-fill testing) for initial demonstration and ongoing frequencies of the determined compounding category. o For immediate-use preps, your standard operating procedure (SOP) must define training of personnel who prepare these.[2]
What are the space requirements for sterile compounding?	• Sterile compounding must take place in a clean room suite or a segregated compounding area.[1] o A **clean room suite** includes an anteroom and a buffer room housing a laminar airflow workstation (e.g., hood) or a restricted-access barrier system (e.g., glove box).[1] ▪ Clean room suites must achieve and maintain specified air quality.[1] o A **segregated compounding area** (SCA) is a location outside of a clean room suite, with a laminar airflow workstation or a restricted-access barrier system that meets certain specifications. Specific design for an SCA should be considered; for example, the area should not be near unsealed windows, doors that connect to the outdoors, or high-traffic areas. ▪ A segregated compounding area must have a visible perimeter.[1]
What are the maximum beyond-use dates for CSPs?	• Maximum BUDs: o **Category 1 CSPs**: 12 hours (room temperature) or 24 hours (refrigerated).[1] o **Category 2 CSPs** made from **sterile components**: 4 days (room temperature), 10 days (refrigerated), or 45 days (frozen).[1] o **Category 2 CSPs** made with one or more **nonsterile components**: 1 day (room temperature), 4 days (refrigerated), or 45 days (frozen).[1] ▪ Note that **BUDs for Category 2 CSPs may be longer** if they pass sterility testing or are terminally sterilized**.**[1] • For an **immediate-use CSP**, **administration must be started within 4 hours** from the start of prep.[1] This is in contrast to the 2008 version, where administration of immediate-use CSPs had to be started within 1 hour.

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Question	Answer/Pertinent Information
	• With regard to **proprietary bag and vial systems**, docking and activation for immediate administration to an individual patient is not considered compounding. **Docking and storing for future activation is considered compounding, and the BUD must be no longer than what's specified by the manufacturer**.[1] • If a component of a CSP has an expiration date shorter than a CSP's maximum BUD, or stability that's less than the CSP's maximum BUD, the shorter BUD or expiration date will need to be assigned as the CSP's BUD.[1]
What's the maximum beyond-use date for a single-dose vial?	• A **single-dose vial** that's punctured in at least an ISO Class 5 environment **may be used for up to 12 hours** as long as storage requirements, such as refrigeration, are met.[1] This is in contrast to the 2008 version, where this BUD was only up to six hours.

What are requirements for air and surface sampling?	• For Category 1 and 2 CSPs
	  ○ The frequency of **surface sampling** has been changed from "periodically" to **every 30 days**.[1,2]
	  ○ The frequency of **air sampling** remains **every 6 months**.[1]

Where must a sink for hand hygiene be located?	• The sink may be located **inside the anteroom or outside the anteroom**. However, **if hazardous drugs are compounded** in a clean room suite, the sink must be located **inside the anteroom**.[2]
What are requirements with regard to cosmetics, jewelry, etc?	• **Cosmetics must be removed**, as well as **hand, wrist, and other exposed jewelry**, and **earbuds or headphones**.[1] ○ Jewelry that cannot be removed, such as dermal piercing, must be covered.[1,2] • **Eyeglasses** must be cleaned.[1] • **No food**, including gum or mints, should enter sterile compounding areas.[1] • The designated person may permit accommodations to personnel preparation as long as the quality of the CSP and environment will not be affected. Accommodations must be documented.
What are requirements for garbing?	• The same garb is required regardless of whether a Category 1 or Category 2 CSP is being compounded.[1] • Individual **hospitals must specify order of garbing**, since it will depend on the type of garb required and where the sink for hand hygiene is placed (i.e., inside or outside the anteroom).[1] ○ However, it's required that donning and doffing garb NOT take place at the same time and in the same place, to reduce the risk of contamination.[1]

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Question	Answer/Pertinent Information
What should be considered with regard to cleaning compounding areas?	• The addition of a **sporicidal agent to cleaning and disinfecting regimens** is now required at least monthly for clean room surfaces.[1] o One option is to use an Environmental Protection Agency (EPA)-registered one-step disinfectant cleaner, with sporicidal activity.[1,2] Note that isopropyl alcohol is **not** a one-step disinfectant cleaner.[2] • Cleaning, disinfecting, and sporicidal agents used within the compounding hood must be sterile.
What documentation is needed for CSPs?	• A m**aster formulation record** is required for CSPs:[1] o prepared for more than one patient. o prepared from nonsterile ingredients. o This "recipe" must include information such as the name, strength, and dosage form; the identities and amounts of all ingredients; complete instructions for preparation; the BUD; and the type and size of container that must be used. • A c**ompounding record** must be created for each Category 1, 2, or 3 CSP, and for rare cases when immediate-use CSPs are needed for more than one patient, to document the compounding process.[1] o A compounding record must include specific information such as name, strength, and dosage form; date and time of prep; individuals involved in prep and verification; and lot numbers and expiration dates of ingredients.[1] o Check your pharmacy policy to find out what will be used as a compounding record in your facility. For example, an order or label may be used, or these may be stored electronically.[1] • Keep the master formulation record, the compounding record, and results of any required release testing readily retrievable for at least two years after preparation of a CSP, or longer if required by state laws or regulations.[1]
When will the 2023 revision of USP <797> be enforced?	• The revision became official on November 1, 2023.[2] • Ensuring compliance with USP <797> is the responsibility of regulators (e.g., FDA, state board of pharmacy). Regulatory bodies may have a different official enforcement date. USP is not responsible for enforcing USP <797>.[2]

Abbreviations: BUD = beyond-use date; CSP = compounded sterile preparation; USP = United States Pharmacopeia.

a. Per USP <797>, the following conditions must be met to utilize the immediate-use provision:
   i. Written SOPs detailing processes, procedures and aseptic technique must be available.
   ii. Personnel must be trained and demonstrate competency in aseptic technique and facility SOPs.
   iii. Preparation is performed with evidence-based information (package insert, stability studies).
   iv. Preparation made with no more than 3 different sterile products.
   v. Single-dose containers used must be discarded after use and used for one patient only.
   vi. Administration must begin within 4 hours of start of preparation.
   vii. CSP must be labeled, unless administered by the person that who prepared it or witnessed by preparer

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