



ASHP STANDARDIZE 4 SAFETY
IMPLEMENTATION
TOOLKIT



Developed by the Section of Inpatient Care Practitioners Advisory Group on Medication Safety

INTRODUCTION

Standardization is a well-recognized element of improving healthcare quality and preventing medication errors. According to the Institute for Safe Medication Practices (ISMP), “Standardizing drug administration times, drug concentrations, and limiting the dose concentration of drugs available in-patient care areas will reduce the risk of medication errors or minimize their consequences should an error occur.”¹

Standardize 4 Safety is a joint initiative of the Food and Drug Administration and ASHP to establish national standardized concentrations for oral and parenteral compounded medications — standards intended for universal adoption and use. Information about the background and development of the Standardize 4 Safety initiative can be found on the ASHP [Standardize 4 Safety](#) resource page.

STANDARDIZE 4 SAFETY STANDARDIZED LISTS

- Compounded oral liquids
- Adult continuous infusions
- Pediatric continuous infusions
- Epidural/patient-controlled analgesia
- Intermittent infusions (IV push and IV piggyback) *pending*

PURPOSE

The purpose of this toolkit is to promote adoption of Standardize 4 Safety and provide step-by-step guidance, using quality and implementation science principles, to achieve universal Standardize 4 Safety use in practice regardless of healthcare setting. National acceptance of standardized drug concentrations, both within and outside of hospitals and health systems, reduces the risk of error, especially during transitions of care.

PRE-IMPLEMENTATION PLANNING

ENGAGE STAKEHOLDERS

- Obtain buy-in to approve and allocate resources to implement Standardize 4 Safety.
 - » Goal of increasing patient safety
 - Standardize 4 Safety is based on medication safety principles and designed to prevent medication errors, particularly at transitions of care.
 - Evaluate medication error reports to demonstrate actual or potential events that may have occurred due to different concentrations.
 - » Goal of meeting regulatory requirements
 - The Joint Commission has several medication management standards and elements of performance that pertain to standardizing and limiting concentrations
 - » MM.02.01.01 (EP6): The hospital standardizes and limits the number of drug concentrations available to meet patient care needs.
 - » MM.02.01.01 (EP9): Medications designated as available for dispensing or administration are reviewed at least annually based on emerging safety and efficacy information.
 - » Endorsed as best practice by multiple organizations
 - American Academy of Pediatrics. Pediatrics 2019;143: e20183649.

- National Association of Neonatal Nurses. Medication safety in the NICU position statement #3073. https://nann.org/uploads/About/PositionPDFS/FINAL%202021_Medication%20Safety%20in%20the%20NICU.pdf
 - American Society of Anesthesiologists. Statement on drug concentration and standardization. October 23, 2019. <https://www.asahq.org/standards-and-practice-parameters/statement-on-drug-concentration-standardization>
 - Institute for Safe Medication Practices. *ISMP Medication Safety Alert!* Acute Care. 2022;27(12):1-4. <https://www.ismp.org/acute-care/medication-safety-alert-june-16-2022>
 - Society of Critical Care Medicine. Standard medication concentrations: an opportunity to reduce medication errors. *Critical Connections* 2019.
 - Joint Commission: MM.02.01.01 EP 6: The hospital standardizes and limits the number of drug concentrations available to meet patient care needs.
- Identify project owners from an oversight committee(s) or identify key stakeholder

Examples of Oversight Committees	Examples of Stakeholders
Medication Safety Committee	Physicians: hospitalist, critical care, anesthesia, emergency room, adult and pediatric providers
Patient Safety Committee	Nurses: critical care, emergency room, procedure room, adult and pediatric
Pump Governance Committee	Pharmacists: critical care, emergency room, OR, IV room, purchasing
Sterile Compounding Committee	Pharmacy technicians: IV room, purchasing
Pharmacy and Therapeutics Committee	Medication Safety Officers
Anesthesia and/or Perioperative Services	Quality Officers
Critical Care Committee	Information technology

GAP ANALYSIS USING ASHP STANDARDIZED CONCENTRATION INTERACTIVE CHECKLIST

Perform a gap analysis to identify which concentrations are currently in use at your site and how they compare to the Standardize 4 Safety concentrations. Identify drugs and concentrations to align with Standardize 4 Safety. The [ASHP Standardized Concentration Interactive Checklist](#), a web-based tool to enable this process, allows benchmarking with other institutions, which can help support adoption. The checklist can be downloaded for offline use.

Helpful information to gather in planning

- Standard concentration lists/policies
- Hospital formulary
- Purchasing information
- Prescribing records (e.g., computerized prescriber order entry (CPOE), paper order sheets)
- Compounding records, (e.g., master formula, compounding data)
- Smart pump library

IMPLEMENTATION

- Prioritize medications requiring updates. (This may include adding new concentrations or removing concentrations.)
- Develop a process for implementation and a desired time frame.
 - » The best strategy may include phased implementation (e.g., begin with oral solutions, then adult continuous infusions, then pediatric continuous infusions).
 - » For practice sites with more than one location, other considerations are:
 - Is the same EHR shared across sites?
 - Is the pump library shared across sites?
 - Are the same type of infusion pumps used at each site?
 - » For settings servicing patients from adults to pediatrics and/or neonatal units, determine how best to manage medications where dosing units, concentrations may differ.
- Utilize the chart below to evaluate the affected medication use processes.
- Create one formal list of approved concentrations (aka, “source of truth”), then evaluate other med use systems (e.g., CPOE, pump library, reference materials, EHR).
- Develop and implement a formal written procedure or policy or reference which is vetted/approved through appropriate institutional oversight committees and stakeholders.

Step	Assessment	Action
Planning	Who are the practitioners to consult regarding the use of specific medicines and concentrations that will change? What formulary changes are required?	<ul style="list-style-type: none"> ▪ Identify policies/practices that are impacted. ▪ Request changes to formulary. ▪ Align smart pump libraries and EHR/CPOE.
Procurement	What products and concentrations are currently purchased for the medications slated for change?	<ul style="list-style-type: none"> ▪ Consult with purchasing/buyers.
Prescribing	How are these medications ordered?	<ul style="list-style-type: none"> ▪ Update CPOE entries and order sets.
Compounding	How are these medications compounded?	<ul style="list-style-type: none"> ▪ Update master formula and compounding records.
Administering	How are these medications administered?	<ul style="list-style-type: none"> ▪ Review and approve with pump governance group. ▪ Implement pump library changes.
Education	Who are the practitioners affected?	<ul style="list-style-type: none"> ▪ Notify prescribers, nurses, and pharmacy staff of changes. ▪ Inform on reasons for change and educate on changes. ▪ Update policies, procedures, formulary.
Post-Implementation Compliance/Quality Assurance	Are alternate concentrations in use?	<ul style="list-style-type: none"> ▪ Measure and address compliance, identify and resolve any unanticipated issues.

SUSTAINING THE PROCESS

Develop a plan to monitor and sustain over time, using the following strategies:

- Assess adoption on a routine basis and report results to a designated oversight committee(s) (e.g., annual report to medication safety).
- Evaluate whether new commercial products have come to market which can/should replace compounded items.
- Evaluate whether any additional requested concentrations are needed for Standardize 4 Safety alignment.
- Evaluate compliance with Standardize 4 Safety, investigate noncompliance, and resolve as needed with patient care and safety as priorities.

MEDICATION SAFETY PEARLS

- Incorporate TALLman letters when applicable to differentiate look-alike/sound-alike drug names.
- Avoid 10-fold differences in doses or concentrations, when possible, as these are known contributors to errors.
- Whenever possible, incorporate system-based risk reduction strategies that are less susceptible to human fallibility.
- Minimize options for potential error, e.g., do not simply add the Standardize 4 Safety concentrations, but eliminate the non-Standardize 4 Safety concentrations whenever possible. Assess benefit versus risk of maintaining non-Standardize 4 Safety concentrations.
- Identify when a commercial product is available and appropriate for use. If the commercial product concentration varies from Standardize 4 Safety, assess benefit versus risk. Commercial products are preferred to use because they eliminate the chance of a preparation or compounding error, have a more reliable barcode that ties to the manufactured product, may have enhanced labeling, and typically have later expiration dates than compounded items. If new commercial items become available and desired, communicate them to ASHP Standardize 4 Safety.
- Monitor and assess smart pump library compliance.

ADDITIONAL CONSIDERATIONS

- Join the [Standardize 4 Safety community](#) on ASHP to receive updates and provide feedback to ASHP regarding any needs, concerns, or gaps.
- When outsourcing to 503B pharmacies, request products that align with Standardize 4 Safety concentrations.
- Develop a plan to safely add and remove any medications that may be impacted by drug shortages. Primary considerations should be safety and efficacy; secondary considerations can be cost and waste. ASHP offers resources on managing [drug shortages](#).
- Confirm whether concentration and bag sizes can be standardized across all practice sites.

REFERENCES

1. Key Elements of Medication Use (<https://www.ismp.org/key-elements-medication-use>)
2. The Joint Commission Sentinel Event Alert Issue 39 <https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea-39-ped-med-errors-rev-final-4-14-21.pdf>
3. The Joint Commission Hospital Accreditation Standards. <https://www.jointcommission.org/what-we-offer/accreditation/health-care-settings/hospital/learn/our-standards/>