STANDARDIZE 4 SAFETY INITIATIVE

Standardize 4 Safety is the first national, interprofessional effort to standardize medication concentrations to reduce errors, especially during transitions of care.

These national standards will cover:

- Concentrations and dosing units for intravenous continuous medications for adult patients.
- Concentrations for compounded oral liquid medications.
- Concentrations and dosing units for intravenous continuous medications for pediatric patients.
- Doses for oral liquid medications.
- Concentrations for intravenous intermittent medications.
- Concentrations for PCA and epidural medications.

The Standardize 4 Safety initiative began in 2008 when a multi-stakeholder IV summit was held to address preventing patient harm and death from intravenous (IV) medication errors. Among the recommendations made by the participants was to establish national standards for IV medications in hospitals including standardized concentrations and dosing. In addition, it was recommended that the national standards be created in collaboration with the Food and Drug Administration (FDA), the pharmaceutical industry, and other stakeholders. Since the summit, establishing standardized concentrations has garnered strong support from ASHP members, the Joint Commission, the Institute for Safe Medical Practices (ISMP), and others. 1 2 3 4 5

In 2015 the FDA, through its Safe Use Initiative, awarded ASHP a grant to develop and implement national standardized concentrations for IV and oral liquid medications. The aims of the grant were to: (1) identify a nationwide expert interprofessional panel consisting of physicians, nurses, and pharmacists; (2) create standards for adult continuous IV infusions, compounded oral liquid medications, pediatric continuous IV infusions, doses for liquid medications, intravenous intermittent infusions, and PCA and epidural medications; (3) disseminate the standards and assess their adoption.

WHY STANDARDIZE

To Err is Human was published in 1999 and highlighted the harm to patients from healthcare error. In that report, medication errors were stated to be responsible for one of 131 outpatient and one of 854 inpatient deaths. Healthcare continues to struggle to eliminate harm to patients. A systemic review and meta-analysis in 2019 estimated one in 20 patients are exposed to preventable medical harm with the highest incidence of events due to medications. Compounded medications, especially those given intravenously, are known to be high risk for error due to added complexity and multiple steps required for determining dosing when ordering, concentrations for preparation, and rates of infusion for administering. Using standardization as a quality improvement tool decreases variation, improves safety, and is the foundation for using clinical pathways and evidence-based guidelines. Standardization allows providers to manage excessive and unintended variation as they customize care for patients.

HOW THE STANDARDIZED CONCENTRATIONS WERE DEVELOPED

A comprehensive environmental scan was conducted to identify the appropriate medications to be addressed in the respective standard concentrations. A multi-disciplinary expert panel was convened for each standard concentration category. Members were selected based on their expertise in the subject matter. Each expert panel was charged to establish standard principles to guide their decisions in creating the respective standard concentration recommendations. Once a draft of standards was established it was released for public comment and review by ASHP staff and ISMP. The expert panel subsequently met to address all comments and generate the National Medication Concentration Standards.

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DISCLAIMERS

- Suggested concentrations may differ from the package insert (PI) information for a drug. This is due to clinical needs that may have transpired postmarket. When this is the case, studies are available to support the use of a concentration different than what the parent company originally pursued through the new drug application (NDA) process.

- Please use the utmost caution when using a concentration different than the PI, especially if rate information is used from the PI.

- Dosing units were derived from PI information, commonly used drug-reference guides, and clinical practice guidelines.

- Of special note, the expert panel is recommending that weight-based dosing be used for vasopressors (i.e., per kg, per minute), which may differ from institution specific guidelines. We strongly encourage that drug libraries and electronic health records (EHRs), including the electronic medication administration record, make distinct differences for weight-based vs. non-weight-based dosing so nurses can easily distinguish what pump programming is needed.

- These concentrations are guidelines only and are not mandatory. It is our hope that organizations will voluntarily adopt these concentrations and join a national movement to use standardization across the care continuum as an error-prevention strategy for patient safety.

- The information contained in this table is subject to the professional judgment and interpretation of the practitioner. ASHP has made reasonable efforts to ensure the accuracy and appropriateness of the information presented. However, any reader of this information is advised that ASHP is not responsible for the continued currency of the information, for any errors or omissions, and/or for any consequences arising from the use of the information in the self-assessment tool. Any user of the table is cautioned that ASHP makes no representation, guarantee, or warranty, express or implied, as to the accuracy and appropriateness of the information contained in it, and will bear no responsibility or liability for the results or consequences of its use.

CONSIDERATIONS IN USING THE COMPOUNDED ORAL LIQUID STANDARDS

Medications with more than one recommended concentration are listed from lowest to highest concentration, with the numbering corresponding to the respective stability reference(s).
<table>
<thead>
<tr>
<th>Drug</th>
<th>Concentration Standards</th>
<th>References</th>
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<tbody>
<tr>
<td></td>
<td>2. 20 mg/mL for doses of 75 mg or greater</td>
<td></td>
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<tr>
<td>Drug</td>
<td>Concentration Standards</td>
<td>References</td>
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## Compounded Oral Liquid Standards

<table>
<thead>
<tr>
<th>Drug</th>
<th>Concentration Standards</th>
<th>References</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>formulations of lansoprazole and omeprazole stored in amber- colored</td>
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<tr>
<td></td>
<td></td>
<td>prepared lansoprazole suspension at two temperatures. *J Pediatr</td>
</tr>
<tr>
<td></td>
<td></td>
<td>extemporaneous delayed release liquid formulations of lansoprazole. *Am</td>
</tr>
<tr>
<td>Metoprolol</td>
<td>10 mg/mL</td>
<td>1. Allen LV, Erickson MA III. Stability of labetolol hydrochloride,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>metoprolol tartrate, verapamil hydrochloride and spironolactone with</td>
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<tr>
<td></td>
<td></td>
<td>hydrochlorothiazide in extemporaneously compounded oral liquids. *Am J</td>
</tr>
<tr>
<td>Morphine</td>
<td>400 mcg/mL</td>
<td>1. Sauberan JB, Rossi S, Kim, JH. Stability of dilute oral morphine solution</td>
</tr>
<tr>
<td></td>
<td></td>
<td>for neonatal abstinence syndrome. <em>Journal of Addiction Medicine.</em></td>
</tr>
<tr>
<td>NIFEdipine</td>
<td>4 mg/mL</td>
<td>1. Nahata MC, Pai VB. Pediatric Drug Formulations. 6th ed. Harvey Whitney</td>
</tr>
<tr>
<td>Pyrazinamide</td>
<td>100 mg/mL</td>
<td>1. Nahata MC, Morosco RS, Peritore SP. Stability of pyrazinamide in two</td>
</tr>
<tr>
<td>RifAMPin</td>
<td>25 mg/mL</td>
<td>1. Allen LV Jr, Erickson MA III. Stability of bethanechol chloride,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>pyrazinamide, quinidine sulfate, rifampin, and tetracycline hydrochloride</td>
</tr>
<tr>
<td>Drug</td>
<td>Concentration Standards</td>
<td>References</td>
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| Sodium chloride | 4 mEq/mL               | 1a. Using the injectable as straight drug: United States Pharmacopeia, USP 36-NF 31, General Chapter <795>, Pharmaceutical Compounding – Nonsterile Preparations.  

Updated: November 2021
NOTES

1. This drug needs to have a pH very close to 8 to assure particle consistency.
2. ISMP has recommended concentrations be displayed as mcg/mL and not mg/mL given the most common doses used. This may need to be addressed for ordering the drug and what is placed on pharmacy labels on products dispensed.
3. Label should state the 10 mg/mL concentration reflects base chloroquine and not the chloroquine salt.
4. This concentration is copyright protected by USP and can be used for internal purposes only.
5. The formulation for this concentration is based on the capsule dosage form and not the tablet dosage form.