

## Pediatric IV Continuous Infusion: Guiding Principles

### Introduction

The Food and Drug Administration (FDA), through its Safe Use Initiative, awarded ASHP a multi-year contract to develop and implement national standardized concentrations for intravenous (IV) and oral liquid medications. *Standardize 4 Safety* is the first national, interprofessional effort to standardize medication concentrations in order to reduce errors and improve transitions of care. ASHP is partnering with national patient safety organizations such as the Pediatric Pharmacy Association (PPAG), the Institute for Safe Medication Practices (ISMP), the Association for the Advancement of Medical Instrumentation (AAMI), and regional and local healthcare organizations to further this work. Working with partner organizations, hospitals, and pharmacist, nurse, and physician experts from across the care continuum, *Standardize 4 Safety* is creating, testing, publicizing, and supporting the adoption of these national standardized medication concentrations.

These national standards will cover:

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

### Purpose

The purpose of this document is to provide guidance and principles used for the development of the pediatric ( $\leq 50$  kg) continuous infusion standard concentration grid.

### Disclaimers

- This project is supported by a contract with the FDA, Safe Use Initiative, FDA-BAA-15-00121, Section 8.5.
- This document is a working draft. Additional sections and lists will be added as the project moves forward.
- 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 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.
- 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.

## Guidance

This grid's purpose is to provide guidelines for infusion concentrations and dosing units. It is not meant to contain any drug information such as peripheral or central line administration, protection from light, use of in-line filters, etc. Consult product labeling and other drug information resources for this information.

- The grid was developed using the [adult \(≥50 kg\) continuous infusion guidelines](#) as a starting point. Pediatric concentrations were determined for many of the same medications.
  - Pediatric patients greater than 50 kg should use the adult concentrations.
- Commercially manufactured products should be used when they are available.
- The list was compared to the ISMP neonatal infusions that were published in 2011.
- Only adopt the concentrations that are applicable to your institution and patient population
  - There are some medications that may need four concentrations and if your institution has specialized populations that need a significantly dilute, or significantly concentrated infusion these are included in the concentration considerations.
- A concentration vs. unit mismatch occurs when the **labeled** unit of product does not match the **dosing** units. Whenever possible, hospitals should try to align the electronic health record (EHR), the product/pharmacy label, and the infusion pump.
  - Example: A propofol product labeled as 10 **mg**/mL may be administered as a bolus in mg/kg, but administered as a continuous infusion in **mcg**/kg/min.
- For some drugs with multiple indications (e.g. insulin, ketamine, lidocaine, octreotide, vasopressin) the panel recommends distinguishing the indications to prevent dosing confusion.
- There is a column for preferred dosing units but the panel fully recognizes this may represent significant change management for hospitals. Policies and procedures should be aligned with EHRs, information technology, and clinical practice.
- The panel does not recommend lorazepam continuous infusions because of its long half-life and the presence of propylene glycol which can be toxic when used in high doses. Pentobarbital also contains propylene glycol, but some clinical conditions require pentobarbital.
- Some drugs may present challenges within information technology systems, particularly with decimal points in the EHR and infusion pump depending on vendor-specific technology. Vasopressin is a good example due to conversion between units and milliunits.
- Epinephrine and norepinephrine remain different concentrations based on ISMP recommendations and the example set by dopamine and dobutamine; although the dosing is the same, there are technically used for different clinical indications.