

Standardization of Concentrations for Extemporaneously Compounded Oral Liquid Medications

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Many children require medications in oral liquid dosage forms when their dose does not conform to a manufactured tablet or capsule size. Liquid medications are also needed for children who are unable to swallow solid dosage forms. This statement from the PPAG is in support of standardizing the concentrations of extemporaneous formulations of liquid medications for the benefits of safety, accuracy, and overall communication between providers.

KEYWORDS compounded medications; extemporaneous compounding; liquid medications; oral liquid dosage forms' standardization; standard concentrations

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Background

Children are prescribed medications in oral liquid form for a variety of reasons, including the inability to swallow tablets or capsules, and the necessity to administer a dose that cannot be measured with existing solid dosage forms. Many medications are not commercially available as an oral liquid and therefore require extemporaneous compounding.

Development of national standardized concentrations for extemporaneously compounded oral liquids has been initiated; however, it only addresses a limited number of medications and has not been universally adopted by all pharmacies nationwide. As a result, the potential exists for different pharmacy settings to prepare oral compounds of the same medication at varying concentrations. This may lead to errors during a transition of care, for example, from inpatient to outpatient settings or between different pharmacies. A patient, or their caregiver, measuring a medication based on the volume in this situation would inadvertently deliver an incorrect dose.

Medication errors in pediatric patients have an increased potential to cause harm since this population has a decreased physiologic capacity to tolerate the effects of a dosing error.¹ Standardization of an oral medication concentration has been successfully implemented with acetaminophen liquid formulations, which was undertaken to reduce the risk of pediatric dosing errors. While this reflects a change to a commercially available product, the same goal should exist for compounded oral formulations. When determining standard concentrations, consideration must also be given to the components of an extemporaneous compound, including palatability, the safety of excipients, and the stability based on published references.²

Reasoning and Rationale

Extemporaneous compounding of oral liquids, not available commercially, is often necessary to provide medication for patients unable to swallow solid dosage forms and/or to accurately measure low doses. The need for standard concentrations for these compounded oral medications is imperative for patient safety, particularly since caregivers often report doses in units of volume, such as milliliters. Standard concentrations could lessen the risk of different concentrations being compounded when patients transition from inpatient to outpatient settings or vice versa and decrease the risk of administration of inappropriate doses. Standardization would also help ensure a specific volume of medication translates to the same dose whether a patient was in the hospital, clinic, or out in the community. Providers and caregivers need to be educated about the benefits of standardization to heighten their awareness of potential issues. This heightened awareness can also allow them to advocate for this crucial initiative.

Many pharmacies have developed their own “standards,” or recipe books, over the years and are comfortable with the formulas and processes. These formulations, as long as they are evidence-based, are not inappropriate but still do not adequately reduce the risk of an error if not uniformly accepted within a given region. However, acceptance of national standards will provide an extra layer of safety for patients. The more widespread a collection of standard concentrations become, the more continuity there will be between institutions and community pharmacies as patients transition between inpatient and outpatient care.

Recommendations

Standardization is a known factor for enhancing pa-

tient safety.² The standardization of oral compounded liquids has the potential to decrease the number of miscalculations in compounding, dispensing, and administration. In agreement, PPAG encourages national standardization of extemporaneously compounded oral medications and recommends that all pharmacies evaluate and implement standards to meet the needs of their patient population. One example of a national standard is The American Society of Health Systems Pharmacists Standardize 4 Safety initiative, which is funded by a FDA grant and includes input from experts and pediatric specialists from the PPAG along with other healthcare organizations. All institutions that provide extemporaneously compounded medications should adopt this national compounding formulary to enhance safety through standardization. These concentrations should also be included in electronic prescription standard databases to facilitate their use in e-prescribing. Information about the Standardize 4 Safety initiative as well as the recommended concentrations can be found at <https://www.ashp.org/Pharmacy-Practice/Standardize-4-Safety-Initiative>. Ultimately, working with other countries that have similar standardization processes could also improve the safety of oral medication preparation and dispensing worldwide.

While standardizing extemporaneous liquid medication concentrations will enhance safety for patients, it will require efforts of continual evaluation and process improvement. Once the standard concentrations are determined, accepted, and used for a period of time, there should be an evaluation to see if there are any outstanding exceptions to the standards that may require reconsideration. As more pharmacists and clinics accept and use national standard concentrations, practice may demonstrate that some concentrations do not meet the needs of the patients as expected. Open communication about the standard concentrations should continue after the initial implementation to ensure that recipes are being used as intended. If clinicians routinely have a need to go outside the standard concentrations and/or formulations, an investigation into the cause(s) and an evaluation of what would better meet the needs of the population should be undertaken.

Extemporaneous compounds may be needed that are outside of the accepted standards, such as medications not yet included in the Standardize 4 Safety list, along with patient specific situations where the standard concentration cannot work. These situations need to be handled with special care to ensure the patient receives the appropriate dose. The pharmacist and institution should ensure these recipes are evidence based and that all patient caregivers (nurses, family, pharmacists, and prescribers) are aware of the differences when filling and administering the medication to safeguard against medication errors. Developing communication tools, such as flyers, handouts, aux-

iliary stickers, or computerized clinical decision support, for example, are just a few ways to ensure that all caregivers understand the importance of checking the concentration of the medication prior to administration. Pharmacists should be familiar with and have access to resources that provide approved standards and alternative options when patients' needs dictate a different concentration.

In order to maintain a standard set of extemporaneous compounds, generate tools for education, and follow up with continuous evaluation and updating, funds will need to be allocated for this initiative. As more drugs are approved and studied for pediatric patients, there will be a consistent need to develop dosage forms, such as extemporaneous compounds, for accurate dosing and administration. Funding and field experts will need to be supported for this work.

PPAG recommends that pediatric pharmacists work together with other national organizations to come to a consensus on standards for oral extemporaneous compounds that will meet the needs of the majority of the pediatric population. Priority goals, second to the formulations, include education and tools to ensure all caregivers have the best information for the care of the patient.

Summary

- Standard concentrations of extemporaneously compounded oral liquid medications will potentially decrease dosing errors; patients/caregivers will know what volume to expect for the dose administered if the concentration and/or dose stays the same.
- Fewer transcription errors from facility to facility (i.e., in transitions of care) should be expected with standards; doses and their respective volumes should stay the same no matter where a patient is being treated.
- All pharmacies (e.g., inpatient and outpatient) and prescription databases should review their extemporaneous compounds and determine how standardization can be implemented using national recommendations.
- Communication tools should be developed to help patients, families, providers, and pharmacy practitioners understand the importance of standardizing for safety.
- Funding needs to be provided to evaluate the extemporaneous formulations currently used, as well as future compounding needs for newer medications.
- Continuous assessment and review of standards need to be owned and followed by national organizations to ensure the best decisions are made as more and more pharmacies dispense medications using approved standards.

ARTICLE INFORMATION

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