Standardizing Pediatric Oral Liquid Compounded Medications

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**Presentation Objectives**

At the end of this presentation, the audience should be able to:

1. Explain the importance of adopting the statewide initiative to standardize pediatric oral liquid compounded medications
2. Describe the standardizations implemented at Munson Medical Center and within the Traverse City region as a result of the survey responses and the significance on improving pediatric safety
Background

Pediatric Safety: The Problem

- **Vulnerable Patient Population** 1-3
  - Dosing errors are the most common medical errors in children, and are likely to be detrimental
  - 2008 Sentinel Event Alert – The Joint Commission
    - Recommended that patients discharged on compounded oral liquids receive equivalent doses outpatient
  - Institute for Safe Medication Practices (ISMP)
    - Pediatric inpatients are at 3x the risk of experiencing a potential adverse event than hospitalized adults

- **Dosing Errors** 1,3,4
  - In order to help reduce preventable errors, the use of consistent and accurate volumes of measure is critical
  - USP MEDMARX Database
    - Of the pediatric medications errors reported between 2006-2007, 37.5% were due to improper dose or quantity, with the majority of errors resulting from performance or knowledge insufficiencies
  - The importance of standardized dosing metrics is imperative
    - Approximately 40% of parents make measurement errors, with 16.7% using nonmetric measuring devices
    - Utilizing teaspoon/teaspoon as measuring devices may be associated with twice the odds of a dosing error

- **Education Deficits** 5,6
  - Healthcare providers - lack of consistent practices
    - Education/discharge counseling, prescribing, medication labeling, and delivery of standard measuring devices
  - Parent/guardian - knowledge gaps
    - In 2010, the American Association of Poison Control Centers recorded:
      - 10,496 reports of therapeutic medication errors attributed to incorrect units of measure, with the majority of these errors reported in children <12 years of age

Literature Review

Rood et al. 7 - “Variability in compounding of oral liquids for pediatric patients: A patient safety concern”

- **Journal:** Published in Journal of the American Pharmacists Association in the July/August 2014 issue
- **Study Objective:** To determine the extent of variation in oral liquid compounding practices in Michigan pharmacies
- **Results:**
  - Demographics (n=244*)
    | Pharmacy Setting | Respondents: n (%) | Compounding Pharmacies: n (% of setting) |
    |------------------|---------------------|----------------------------------------|
    | Outpatient       | 187 (76.7)          | 135 (72.2)                             |
    | Inpatient        | 53 (21.7)           | 27 (50.9)                              |
    | Other            | 4 (1.6)             | 1 (25)                                 |
    | Total            | 244 (100)           | 163 (66.8)                             |
  - *240 actual pharmacies responded, 4 of which represented >1 type of pharmacy practice
  - Compounded Oral Liquid Medications
    - 470 concentrations were reported for the 147 medications surveyed with significant variation in the number of concentrations compounded for each medication, ranging from 1 to 9
    - 34% of reported concentrations were not supported by published references
  - **Conclusion**
    - The survey results identified a lack of consistency in regards to pediatric oral liquid compounded concentrations across Michigan, resulting in a potential increased risk of pediatric harm due to these inconsistencies
    - As a result, the University of Michigan set forth to implement standardized concentrations for these medications that would be used across Michigan, in order to have an expected decrease in dosing errors
Study Design: “Improving Pediatric Safety Through Standardizations”

Pharmacy Practice Question
• Is there a need to educate pediatric healthcare providers regarding standard pediatric oral liquid concentrations, standard metric prescribing in mg or mg/mL, and the importance of educating pediatric parents/guardians on proper oral liquid administration?

Overview
• The focus of this study was to identify and remediate knowledge gaps that may exist regarding the use of pediatric oral liquid compounded concentrations, standard metric dosing (mg/mL or mg), and to identify the education needs of pediatric parents/guardians on the safe use and administration of oral liquid medications.

Objectives
• Primary objective: To determine the need to improve pediatric safety by evaluating current education, prescribing and dispensing practices with regards to pediatric oral liquid compounded medications.

Methods
• Observational, cross-sectional study comprised of an online survey that was submitted for IRB approval and was exempt.
• Inclusion Criteria: Inpatient/outpatient pharmacists within Munson Medical Center; Community pharmacists in the Traverse City region; Pediatric inpatient providers (MD, DO, NP, PA-C); Pediatric outpatient/community providers (MD, DO, NP, PA-C).

Survey
• A pediatric provider and pharmacist survey were developed and IRB approved for distribution.

Interventions
• Educational interventions were implemented to standardize practices due to the survey results demonstrating a need.
  o The need was defined as anything <100% of all respondents answering anything other than “always” in areas in which we wish to implement these standardizations:
    ▪ Pediatric oral liquid concentration standardization implementation
    ▪ Metric prescribing standardization implementation
    ▪ Educational implementation

Survey Results

Study Participants
• Pediatric Providers (n=19) - Inpatient: n=11; Outpatient: n=8
• Pharmacists (n=36) - Inpatient: n=29; Outpatient: n=7

Results
• The study results did show a need to implement the standardizations, with none of the pediatric providers or pharmacists surveyed always utilizing the proposed recommended standards.
  o None of the pediatric providers and only four pharmacists responded to the survey as always utilizing the proposed statewide standard concentrations for pediatric oral liquid compounded medications.
  o The majority of pediatric providers NEVER prescribe oral liquid compounded medications with the statewide standards.
  o Only 53% of pediatric providers are prescribing oral liquid medications with the dose specific in mg or mg/mL.
  o Less than one-third of pediatric providers and pharmacists always educate parents/guardians on proper storage, volume to administer, and how to safely and accurately measure the oral liquid medication.
• All of the pediatric providers and pharmacists felt that it was important to educate parents on proper administration and were willing to adopt the statewide initiative, with the belief that it will improve pediatric safety and reduce preventable dosing errors.
Standardizations

Standardized Compounded Oral Liquid Concentrations\textsuperscript{7,8}

- Concentrations for several pediatric oral liquid compounded medications that are commercially unavailable are not currently standardized, resulting in significant variability which may lead to detrimental medication dosing errors.
- Consistency of care between the inpatient and outpatient settings is remarkably important for the pediatric population due to their particular vulnerability and potential harm from medication errors.
- Standards available at: \url{http://mipedscompounds.org}

Metric Dosing Standards (mg/mL or mg only)\textsuperscript{3}

- Use of consistent and accurate volumes of measure is critical.
- Pediatric provider education on the avoidance of volume only prescribing is pivotal in order to improve patient safety.

Safe and Proper Administration of Pediatric Oral Liquids\textsuperscript{4}

- Parent education against the use of household devices, in order to reduce preventable dosing errors and improve the safe use/administration of pediatric oral liquid medications.

Implementation

Standardized Oral Liquid Concentrations\textsuperscript{4}

- Implementation within Munson Medical Center
  - Obtained Pharmacy and Therapeutics (P&T) approval for following 21 medications:

<table>
<thead>
<tr>
<th>P&amp;T Approved Oral Liquid Compounded Medication Concentrations</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Adderall 1 mg/mL</td>
</tr>
<tr>
<td>✓ Amlodipine 1 mg/mL</td>
</tr>
<tr>
<td>✓ Atenolol 2 mg/mL</td>
</tr>
<tr>
<td>✓ Baclofen 5 mg/mL</td>
</tr>
<tr>
<td>✓ Captopril 1 mg/mL</td>
</tr>
<tr>
<td>✓ Clonazepam 0.1 mg/mL</td>
</tr>
<tr>
<td>✓ Diltiazem 12 mg/mL</td>
</tr>
<tr>
<td>✓ Ganciclovir 25 mg/mL</td>
</tr>
<tr>
<td>✓ Hydralazine 4 mg/mL</td>
</tr>
<tr>
<td>✓ Hydrochlorothiazide 10 mg/mL</td>
</tr>
<tr>
<td>✓ Hydrocortisone 2 mg/mL</td>
</tr>
<tr>
<td>✓ Labetalol 10 mg/mL</td>
</tr>
<tr>
<td>✓ Lisinopril 2 mg/mL</td>
</tr>
<tr>
<td>✓ Methotrexate 0.5 mg/mL</td>
</tr>
<tr>
<td>✓ Metoprolol 10 mg/mL</td>
</tr>
<tr>
<td>✓ Metronidazole 50 mg/mL</td>
</tr>
<tr>
<td>✓ Methotrexate 0.5 mg/mL</td>
</tr>
<tr>
<td>✓ Metoprolol 10 mg/mL</td>
</tr>
<tr>
<td>✓ Methotrexate 0.5 mg/mL</td>
</tr>
<tr>
<td>✓ Metoprolol 10 mg/mL</td>
</tr>
</tbody>
</table>

- Implementation within the Traverse City region
  - Pediatric providers and pharmacies have been provided with the tools needed to ensure unified pediatric care between transitions of care and were educated on the statewide oral liquid compounded concentrations.
  - Distributed copies of the parent/guardian educational handout that will be used within Munson Medical Center to ensure consistency within our region.

Education

Inpatient/Outpatient Pediatric Provider and Pharmacist Education (Refer to Appendix A)

- Educational handouts were distributed within Munson Medical Center and the Traverse City region.
- Follow up emails were sent with the attached educational handouts.

Pediatric Parent/Guardian Education (Refer to Appendix B)

- Educational handouts are available to be utilized during the discharge process of pediatric patients at Munson Medical Center.
- This handout was also disseminated to the pediatric provider offices and pharmacies throughout the Traverse City region for distribution to their pediatric parents/guardians of patients on oral liquid medications.
Conclusion

Pharmacy Practice Questions

- Is there a need to educate pediatric healthcare providers regarding standard pediatric oral liquid concentrations, standard metric prescribing in mg or mg/mL, and the importance of educating pediatric parents/guardians on proper oral liquid administration?
  - Yes, the study results showed a need to implement the standardizations, with none of the pediatric providers or pharmacists surveyed always utilizing the proposed recommended standards. As a result, standardizations were implemented to improve pediatric safety.

University of Michigan Website — www.mipedscompounds.org

Overview

- Home – description of the statewide initiative to standardize compounding of oral liquids for pediatrics
- Standards – compounding sheets available for each individual medication
- Toolbox Kit – letter template to send to parent/caregivers regarding concentration changes
- Contact us – email subscription for quarterly updates regarding changes in pediatric oral compounded liquid standards

References


Statewide Standardized Pediatric Oral Liquid Compounded Concentrations

- The University of Michigan implemented a *statewide initiative* to standardize the compounding of oral pediatric liquids, which was funded by The US Food and Drug Administration Safe Use Initiative.
- Currently, concentrations for several of our pediatric oral compounded medications that are commercially unavailable, are not standardized, which exposes our patients to significant variation and as a result, an increased potential of dosing errors.
- In order to reduce these preventable dosing errors during transitions of care, it is kindly encouraged that all pediatric healthcare providers implement these standardized concentrations.
  - The statewide standardized concentrations are available at: [http://mipedscompounds.org](http://mipedscompounds.org)

Prescribing in Standard Metrics (mg/ml or mg) to Reduce Potential Oral Liquid Medicine Dosing Errors

- Pediatric oral liquid medication dosages should **ONLY** be prescribed in mg/ml or mg.
- It is important to avoid the use of tablespoon/teaspoon in the directions when prescribing due to the potential for significant variation in doses given if these non-standardized measuring devices are used.
- This standardized metric dosing should be done in order to prevent potential dosing errors associated with variations in concentrations.
- Dosing errors are commonly made due to the prescribing of oral liquid medications in milliliters when the medication is available in multiple strengths.
- By omitting the use of non-standardized prescribing of pediatric oral liquid medications, it is anticipated to help reduce dosing errors and improve pediatric safety.

Education to Pediatric Parents on The Safe Use & Administration of Oral Liquid Compounded Medications

- Educating parents/guardians of pediatric patients on proper administration and measurement of oral liquid compounded medications is imperative in order to reduce the risk of overdosing/underdosing.
- Please make sure that *all* parents/guardians are educated about how to safely administer new oral liquid medications before they are sent home with the prescriptions.
- Pediatric dosing measurement devices should be provided with *all* oral liquid medications to ensure that an accurate dose is being given, in the physician office, at the time of discharge or when the medication is dispensed.
- An education guide is available to distribute to parents/guardians as a reference regarding how to accurately measure pediatric oral liquid medications.

The potential harm that is associated with medication errors in the pediatric population warrants the need to implement standardized oral compounded concentrations statewide in order to reduce preventable errors, in addition to adopting a standard metric prescribing protocol for pediatric providers.
Parent/Guardian Education Guide
For the Safe Use & Administration of
Pediatric Oral Liquid Medications

Medication Information
- Medication Name: _______________________________
- Dose: _______________________________
- Administration Instructions: _______________________________
- Storage: _______________________________

Why is being informed on how to properly measure & administer pediatric oral liquid medications important?
- It is for the safety of our most vulnerable population, pediatric patients
- Accurate measuring of pediatric oral liquid medications is very important to make sure that your child is receiving the correct dose of their medication
- Children usually require small volumes of these oral liquid medications, and it is important to be aware that errors in measuring their doses could be potentially harmful

Things to AVOID to help reduce the risk of oral liquid medication dosing errors
- It is very important to NOT use household measuring devices, such as tablespoons/teaspoons, to measure these pediatric oral liquid medications
  - Why? Household measuring devices are NOT standardized which can result in significant variation in the dose given if these devices are used -- this leads to the potential to give your child too much of their medication, or too little

Steps to ensure safe and accurate pediatric oral liquid medication administration
- Always make sure to double check the prescription to see how many milliliters to administer and how often
- When picking up the oral liquid prescription for the child, make sure to verify that the pharmacist/doctor provided you with an accurate pediatric measuring device to use at home
- It is very important to only use standard measuring devices that are provided by your physician or pharmacy to make sure the correct dose is being given to your child, some examples of these may include:
  - Pediatric oral syringe, measuring spoon, or oral dropper

If you have any questions regarding the safe and proper administration of pediatric oral liquid medications, please call your local pharmacist or healthcare provider!
## Appendix C: Compounding Pharmacies in Northern Michigan

<table>
<thead>
<tr>
<th>Pharmacy</th>
<th>City</th>
<th>Phone</th>
<th>Address</th>
<th>Adopted UofM Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thompson Pharmacy</td>
<td>Traverse City</td>
<td>(231) 947-4212</td>
<td>324 S. Union St</td>
<td>Yes</td>
</tr>
<tr>
<td>Hometown Pharmacy</td>
<td>Traverse City</td>
<td>(231) 947-6921</td>
<td>4000 Eastern Sky Drive</td>
<td>Yes</td>
</tr>
<tr>
<td>Sixth Street Drug</td>
<td>Traverse City</td>
<td>(231) 946-4570</td>
<td>1030 Sixth St</td>
<td>Yes</td>
</tr>
<tr>
<td>MCHC Pharmacy</td>
<td>Traverse City</td>
<td>(231) 935-8730</td>
<td>550 Munson Ave</td>
<td>Yes</td>
</tr>
<tr>
<td>Cadillac Family Pharmacy</td>
<td>Cadillac</td>
<td>(231) 775-8200</td>
<td>108 N Mitchell</td>
<td>Yes</td>
</tr>
<tr>
<td>River Pharmacy Compounding</td>
<td>Elk Rapids</td>
<td>(231) 264-8430</td>
<td>115 Ames St</td>
<td>Yes</td>
</tr>
<tr>
<td>Kingsley Pharmacy</td>
<td>Kingsley</td>
<td>(231) 263-7701</td>
<td>114 S Brownson Ave</td>
<td>Yes</td>
</tr>
<tr>
<td>Modern Pharmacy</td>
<td>Cheboygan</td>
<td>(231) 627-9949</td>
<td>127 N Main St.</td>
<td>Yes</td>
</tr>
<tr>
<td>McLaren Northern Michigan</td>
<td>Petoskey</td>
<td>(231) 487-2147</td>
<td>560 W Mitchell St.</td>
<td>Yes</td>
</tr>
<tr>
<td>Prescription Pharmacy Services</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
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