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Individualized Dosing of Children's Liquid Medications in the Community Pharmacy Setting: A Survey of Parents and Guardians

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Keywords: Liquid medications, children's medications, medication errors, dosing device, individualized dosing

Abstract

Objectives: 1) To determine parents' and/or guardians' interest in having pharmacists provide children's liquid medications in a pre-measured, individualized dosing device 2) To assess parents' and/or guardians' perception of dosing liquid medications for a child.

Design: Observational survey

Setting: Regional chain pharmacy in North Carolina

Participants: ≥ 18 years old, parent/guardian of a child <13 who had prescription filled for liquid medication within the pharmacy chain, responsible for administering child's liquid medication

Intervention: 14 item questionnaire

Main Outcome Measure: Interest in pharmacists providing children's liquid medications in pre-measured, individualized dosing devices

Results: 250 questionnaires were mailed; 42 were marked "return to sender" (16.8%), 22 were returned completed (10.6%), and 20 of the 22 met inclusion criteria (9.6%). 95% of study participants reported being interested in having pharmacists provide children's liquid medications in the proposed dosing device, and 40% were willing to pay for such a service. 90% of respondents reported it is "not at all difficult" to understand the amount of dose a child is to receive, while 55% reported it is "not at all difficult" to measure doses. 25% of respondents reported sometimes using a kitchen spoon to measure a child's medication.

Conclusion: Community pharmacists should explore providing children's liquid medications in an individualized dosing device, as study results determined parents are interested in and willing to pay for the theoretical device. Further large-scale studies would be beneficial in determining interest in and willingness to pay for the dosing device in various pharmacy settings nationwide.

Introduction

Errors involving liquid medications for children have been reported with high frequency.¹ These errors include inaccurate dosing, misunderstood directions for use, and nonadherence to medication regimens, which place children at increased risk for morbidity and mortality.² Studies illustrate as many as 50-70% of caregivers have been found to measure doses incorrectly or state dosing outside recommended ranges.³⁻⁵ Liquid medications are prescribed frequently for pediatric patients, who are sensitive to the potential effects of a medication error. In addition, oral medications in the community and ambulatory care settings are unlikely to be

dispensed in unit doses, increasing the potential for such errors.

In June 2009, the Institute for Safe Medication Practices called for the elimination of teaspoonful and other non-metric measurements to prevent medication errors. This recommendation was established in response to several errors related to confusion measuring medication in teaspoonfuls vs. milliliters. Such errors have resulted in serious injury, hospitalization, and the need for treatment.⁶ The U.S. Food and Drug Administration (FDA) has also taken steps to address the problem of medication errors involving liquid medications. In May 2011, the FDA issued guidance to improve dosage

delivery devices for oral over-the-counter (OTC) drug products. The guidance was created following numerous reports of accidental overdoses attributed to dosing devices that were misleading or incompatible with labeled directions for use.⁷ The Consumer Healthcare Products Association has also published guidelines to standardize and improve the format for volume measures within dosing directions and on dosing devices of liquid drug products for children.⁸

Caregivers may struggle with appropriate dosing, have difficulty remembering whether or not they have given a child a dose of his or her medication, and/or have difficulty remembering when the next dose is due. To reduce such errors, pharmacists in the community setting could provide children's liquid medications in a pre-measured, individualized dosing device similar to a weekly pillbox. The proposed device, which is not commercially available, could resemble a test tube holder (Figure 1) and contain slots for each dose of pre-measured medication. Space to write in the day and time of each dose would be beneficial in assisting with adherence. If community pharmacies offered to dose liquid medications using the proposed product, patients would not only be more likely to receive the prescribed dose (e.g. a "kitchen spoon" would not be used to measure a teaspoon) but parents would also be able to visualize whether or not they have given a dose at the appropriate time.

Objectives

1. To determine parents' and/or guardians' interest in having pharmacists provide children's liquid medications in a pre-measured, individualized dosing device.
2. To assess parents' and/or guardians' perception of dosing liquid medications for a child.

Methods

This was an observational survey study of parents and/or guardians of children who had a prescription filled for a liquid medication at Kerr Drug, a regional chain community pharmacy with approximately 80 locations throughout North Carolina. Following University of North Carolina at Chapel Hill institutional review board (IRB) approval, the corporate office for Kerr Drug generated a report of children less than 13 years of age who had a prescription filled at any location for a liquid medication between October 1, 2010 and September 30, 2011. The Kerr Drug corporate office then provided a report of the names and addresses of those meeting the criteria to the principal investigator, who randomly selected 250 individuals using randomization features in Microsoft Excel (Microsoft Corporation, Redmond, WA). The quantity of 250 individuals was selected based on project budget. The parents and/or guardians of the 250 randomly selected children were then chosen for study inclusion. Participants of the study were

required to be a minimum of 18 years old and responsible for the oversight of administering a child's liquid medication.

A 14-item de-identified survey (Appendix A), cover letter, and self-addressed, stamped envelope for survey return were mailed to study participants. The cover letter explained the purpose of the survey, and informed consent was obtained from voluntary participation in the study. The survey inquired about items related to dosing of liquid medications such as understanding dose amounts, measuring doses, and the use of unapproved devices to administer medications. The survey also assessed adherence by asking if a written log was used or if the participant had difficulty remembering timing relative to dosing. Additionally, the survey identified the participants' interest in having pharmacists provide children's liquid medications as pre-measured, individualized doses organized in a device similar to a weekly pillbox to assess the primary objective of the study. An image of the proposed dosing device was not provided to the study participants. Survey responses were recorded categorically based on question, with the exception of two open ended items- age and amount willing to pay. To strengthen survey validity and improve readability, the principal investigator collaborated with the Assistant Director for Survey Research and Development at the Odum Institute, an institute for research in social science located within the University of North Carolina at Chapel Hill. The survey was pre-tested with three parents.

As an incentive, study participants who returned a completed survey were included in a drawing for a gift card. In order to contact the winner of the gift card, the back of each survey was marked with a randomized number corresponding to a database containing participant names and addresses that only the principal investigator was able to access. The pre-marked number was also used to identify participants who did not respond to the survey. Five weeks after the initial survey mailing, a second reminder survey was sent to those who did not respond initially. Data was analyzed using descriptive statistics, contingency table analysis, correlation analysis, logistic regression (categorical responses), and regular regression (continuous responses). All tests were performed using SAS statistical software (SAS Institute Inc., Cary, NC).

Results

Of the 250 surveys mailed, 42 were returned to the principal investigator marked as "returned to sender" (16.8%), 22 were returned completed (10.6%) and 20 of the 22 met inclusion criteria (9.6%). Respondents' ages ranged from 24 to 48 years, with an average age of 36.2 years. The highest level of education completed was some college training for 8 participants (40%), an undergraduate/Bachelor's degree for 7 (35%), and high school for 2 participants (10%). One

participant (5%) listed 8th grade as his/her highest level of education completed, one (5%) listed a postgraduate degree (Master's, Professional, Doctorate) and one (5%) did not specify.

A total of 19 study participants (95%) reported being interested in having pharmacists provide children's liquid medications in a pre-measured, individualized dosing device, with 13/20 (65%) responding "very interested" and 6/20 (30%) responding "somewhat interested" (Figure 2). Eight participants (40%) were willing to pay for such a service with self-reported fees ranging from \$1-\$20 (Figure 3). The mean amount from those who expressed willingness to pay was \$5.19. Eighteen individuals (90%) reported it is "not at all difficult" to understand the amount of dose a child is to receive. One (5%) reported measuring the amount of dose a child is to receive to be "very difficult", with 8 (40%) reporting the same task to be "somewhat difficult". Six individuals (30%) reported it is "somewhat difficult" to remember when a child's last dose was given, and 5 (25%) reported it is "somewhat difficult" to remember when a child's next dose is due. When asked how often participants keep a written log of the times a child's medication is administered, 9 (45%) reported *never*, 9 (45%) reported *sometimes*, and 2 (10%) reported *always*. Five respondents (25%) reported *sometimes* using a kitchen spoon to measure a child's medication. See Table 1 for additional results.

To determine association between variables, logistic regression was performed for categorical responses and regression was used for continuous responses. A contingency table analysis and correlation analysis were also performed. From these analyses, the following results were obtained based on statistical significance:

1. A moderate relationship exists in that parents/guardians who have greater difficulty in remembering when the last dose of medication was given tend to be more interested in the individualized dosing device ($r=0.4706$, $p=0.0446$, $\alpha=0.05$).
2. A moderate relationship exists in that parents/guardians who have greater difficulty in remembering when the next dose of medication is due tend to be more interested in the individualized dosing device ($r=0.4195$, $p=0.0964$, $\alpha=0.1$).
3. A moderate relationship exists in that parents/guardians who feel it is more difficult to understand the amount of medication a child is to receive also have greater difficulty measuring doses ($r=0.5634$ and $p=0.0097$).

4. A strong relationship exists in that parents/guardians who feel it is more difficult to remember when the last dose was given also have greater difficulty remembering when the next dose is due ($r=0.9290$, $p<0.0001$).
5. A moderate relationship exists in that parents/guardians with a lower education level use a kitchen spoon more often to measure a child's medication ($r=-.5493$, $p=0.0490$, $\alpha=0.05$).
6. People of greater age and those who never keep a written log of the times they give the child his/her medication are more likely to pay for the device (OR 0.801).

Discussion

Although $\geq 55\%$ of parents/guardians reported no difficulty administering liquid medications across all categories (understanding dose, measuring medication and adherence), almost all (95%) reported interest in pharmacists providing children's liquid medications in a pre-measured dosing device. The categories in which parents/guardians found to be most difficult were measuring the amount of dose a child is to receive and remembering when a child's last dose was given. The proposed dosing device would eliminate the hassle involved with each of these categories; parents would no longer have to measure doses (this would be done in the pharmacy, likely by a technician, and then verified by a pharmacist), and a parent could simply look at the device to determine if/when a child's last dose was given. There could be an area on the device where parents write in the time the medication was administered next to the empty medication slot so that the exact time could be known. An alarming finding was that one-quarter of parents/guardians sometimes use a kitchen spoon to measure a child's medication. This proves a need for education and improved dosing devices/strategies exists.

While the primary study objectives could be assessed with descriptive statistics, associations between variables were examined to add to the data analysis. Those who have greater difficulty remembering doses of medications may be more interested in the proposed dosing device because they see the value the device could offer in terms of assistance with dosing relative to timing. Intuitively, it makes sense that those who find it more difficult to understand the amount of medication a child is to receive have greater difficulty measuring doses because they likely do not know the exact quantity to measure or how to use the measuring device. For pharmacists, this emphasizes the importance of ensuring patients understand how much medication a child is to receive per dose and can properly demonstrate measuring the dose. Because those with a lower education level are more likely to use a kitchen

spoon to measure a child's medication, when educating patients pharmacists can make sure to stress the importance of using provided measuring devices to those patients they know have completed less schooling than others. If the proposed individualized dosing device was to be marketed and utilized for sale in community pharmacies, staff may wish to target sale of the device to people of greater age considering the data analysis showed these individuals would be more likely to pay for the device.

Limitations

A limitation of the study was the small response rate, which could partially be attributed to numerous surveys returned to the principal investigator due to incorrect or outdated addresses. For those surveys that were returned, very few included incomplete responses. One individual did not answer questions 11-14 (see Appendix A), one did not specify his/her age, and one responded "whatever it takes" for question 12 as opposed to providing a numerical value. In addition, the study did not control for verbal education that may have been conveyed to participants at the time of picking up the medication. Consequently, the level of pharmacy service experienced across the respondents and its potential influence on the response or behavior of the study participants is unknown.

Statistical power was not calculated because the sample size was dictated by budget. Other limitations to consider are that dosing perception may not accurately identify or predict dosing-related problems, nonresponse bias may exist, and survey responses were limited to patients of one pharmacy chain in North Carolina. Additional research with a larger, more diverse sample would be beneficial to more adequately assess the study objectives.

Conclusion

The results of this study suggest that community pharmacists should explore providing children's liquid medications in an individualized dosing device. Further large scale studies would be beneficial in determining patient and caregiver interest in and willingness to pay for a dosing device in various pharmacy settings. This study provides a foundation to conduct larger scale studies that compare the provision of liquid medication in the presented dosing fashion to the norm in order to assess

medication use and safety. In order to accomplish this, it would be helpful if pharmacies tracked errors related to liquid dosing. If the device was to be manufactured and utilized, data could be collected on whether or not the device increases adherence and/or reduces liquid medication errors.

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Appendix A: Parent/Guardian Survey

Please indicate your response to the questions below and return the survey using the included self-addressed, stamped envelope.

	Yes ▼	No ▼
1. Are you 18 years of age or older?	<input type="checkbox"/>	<input type="checkbox"/>
2. Are you the parent or guardian of a child 12 years of age or younger?	<input type="checkbox"/>	<input type="checkbox"/>
3. Have you administered a liquid prescription medication to a child (whether or not it was your own child) within the last year?	<input type="checkbox"/>	<input type="checkbox"/>

If **NO** was chosen for *any* of the above questions, the survey ends here. If **YES** was chosen for questions 1-3, please answer the remaining questions. For the rest of the questions, please think about what things are typically like when you administer LIQUID medications ONLY.

	Not at all difficult ▼	Somewhat difficult ▼	Very difficult ▼
4. How difficult is it to understand the amount of dose the child is to receive?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. How difficult is it to measure the amount of dose the child is to receive?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. How difficult is it to remember when the child's last dose of medication was given?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. How difficult is it to remember when the child's next dose is due?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Never ▼	Sometimes ▼	Always ▼
8. How often do you use a kitchen spoon to measure the child's medication(s)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. How often do you keep a written log of the times you give the child his/her medication(s)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Not at all interested ▼	Somewhat interested ▼	Very interested ▼
10. How interested would you be in a pharmacist providing the child's liquid medication(s) as pre-measured, individualized doses organized in a tool similar to a weekly pill box?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Yes ▼	No ▼	
11. Would you be willing to pay extra to have a pharmacist provide the child's liquid medication(s) as pre-measured, individualized doses organized in a tool similar to a weekly pill box?	<input type="checkbox"/>	<input type="checkbox"/>	
12. How much extra would you be willing to pay to have a pharmacist provide the child's liquid medication(s) as pre-measured, individualized doses organized in a tool similar to a weekly pill box?	\$ _____		
13. Please indicate your age.	_____ years old		
14. What is the highest level of education you have completed?	<input type="checkbox"/> No schooling <input type="checkbox"/> 8 th grade <input type="checkbox"/> High school <input type="checkbox"/> Some college <input type="checkbox"/> Undergraduate degree (Bachelor's) <input type="checkbox"/> Postgraduate degree (Master's, Professional, Doctorate)		

Figure 1: Individualized Dosing Device Example Layout

<http://www.pocdsscientific.com.au/>

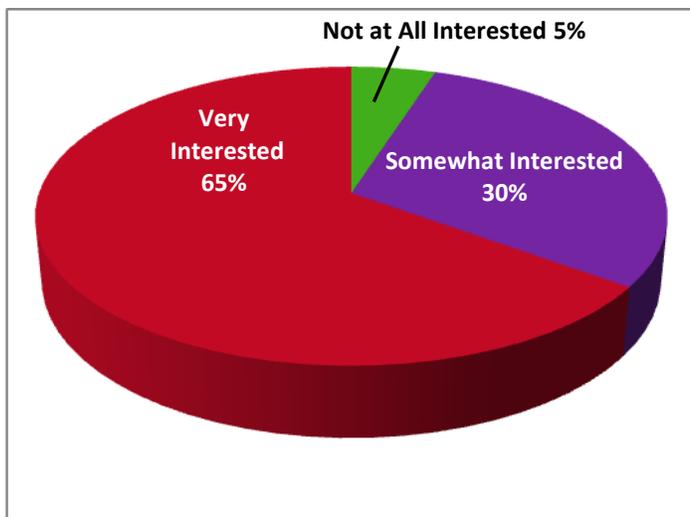
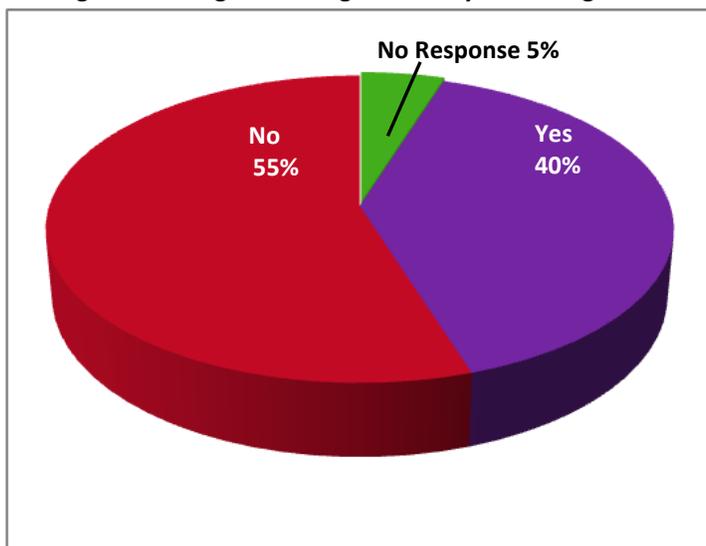
Figure 2: Caregiver Interest in Dosing Device**Figure 3: Caregiver Willingness to Pay for Dosing Device**

Table 1: Parent/Guardian Perception of Dosing Liquid Medication for a Child

Question	Not at all Difficult	Somewhat Difficult	Very Difficult
How difficult is it to <i>understand</i> the amount of dose the child is to receive?	90%	10%	0%
How difficult is it to <i>measure</i> the amount of dose the child is to receive?	55%	40%	5%
How difficult is it to remember when the child's <i>last dose</i> was given?	65%	30%	5%
How difficult is it to remember when the child's <i>next dose</i> is due?	70%	25%	5%
Question	Never	Sometimes	Always
How often do you use a <i>kitchen spoon</i> to measure the child's medication?	75%	25%	0%
How often do you keep a <i>written log</i> of the times you give the child his/her medication(s)?	45%	45%	10%