Influence of Viscosity and Consumer Use on Accuracy of Oral Medication Dosing Devices

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Abstract

Background: In response to numerous reports of overdoses with over-the-counter (OTC) liquid medications, the Food and Drug Administration has recommended that all OTC liquid drug products contain a measuring device but provided no recommendation on the type of device to be included. **Objective:** To evaluate the accuracy of liquid medication dosing devices (cup, dropper, syringe) in dispensing medications of varying viscosity in the laboratory and clinical settings. **Methods:** This experimental study evaluated dosing device accuracy. A pharmaceuticals laboratory was used to evaluate accuracy under ideal conditions and subjects ≥ 18 years of age were recruited from community pharmacies to evaluate accuracy when used by consumers. **Results:** In the laboratory setting, the syringe was the most accurate for the more viscous formulations (cherry and grape suspension; 1% error, 1.2% error, respectively), and the dropper was the most accurate for the less viscous formulation (solution; 0.8% error). A volunteer sample of 320 participants was enrolled from the clinical setting. In the clinical setting, the syringe was most accurate, followed by the cup and then the dropper for all formulations (mean error, 2%, 14%, 33%, respectively). The cup was the most likely to overdose (mean, 5.7 mL), while the dropper was most likely to underdose (mean, 3.3 mL). **Conclusions:** The results of this study suggest that medication viscosity, consumer use, and dosing device contribute to dosing accuracy. The syringe appears to be the most accurate dosing device, accounting for differences in medication viscosity and the impact of consumer use.

Keywords

OTC drugs, administration, drug delivery, dosage forms, dosing

Introduction

Most adverse drug events in the outpatient setting involving pediatric patients have been attributed to preventable errors in medication administration.¹ As young children cannot reliably self-administer medications, it can be assumed that these errors occur as a result of improper dosing by the parent or caregiver. Schillie et al reported that between 2004 and 2005 an estimated 71 224 emergency department visits for medication overdoses were made by children less than or equal to 18 years of age in the United States.² Numerous reports of overdoses with over-the-counter (OTC) liquid drug products have been attributed to inconsistent and misleading labeling of product and/or dosing device. Some products are packaged with delivery devices with the intent of increasing dosing accuracy; however, many of these devices contain markings that are inconsistent with labeled dosage directions.³ Yin et al evaluated the top 200 selling pediatric liquid OTC medications and found that dosing devices were only packaged with 74% of products.⁴ Although previous studies have found that more than 50% of parents make errors in dosing with cups,^{5,6} they were provided for 83.1% of these products.⁴

As a result, the US Food and Drug Administration (FDA) released voluntary guidelines for industry groups involved with liquid OTC medication manufacturing, marketing, or distribution recommending that “all OTC liquid drug products contain a measuring device” but provided no recommendation on the type of device to be included. They also recommended that studies be conducted to confirm accurate use by consumers.³ In addition to consumer influence on dosing accuracy, the chemical properties of a liquid medication can also affect dosing accuracy and must be considered when evaluating dosing devices. The US Pharmacopeia (USP) states that mass and density of liquid medications most accurately determines a deliverable volume,⁷ leading to additional variables that can determine the accuracy of a dosing device. The ability of the medication to enter and

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exit the device depends on its viscosity, which can also affect the accuracy and precision in which it can be delivered with a consistent volume.

Therefore, the purpose of this study was to evaluate the accuracy of the most commonly supplied liquid medication dosing devices. The first aim was to determine which measuring device is the most accurate in delivering a standard dose of 3 medication formulations varying in viscosity and density under ideal conditions in the laboratory setting. The second aim was to determine which measuring device is the most accurate in delivering an intended dose when used by adults in the clinical setting.

Methods

This experimental study received institutional review board approval from Duquesne University.

Three dosing devices commonly included with OTC liquid medications were evaluated in the laboratory (ideal) and clinical (practical) settings: a dosing cup with clear etched markings (Healthcare Logistics, Inc, Urbancrest, OH; 30 mL), an oral syringe with printed markings (Apex; Sioux Falls, SD; 10 mL), and a dropper with printed markings (Apex; Sioux Falls, SD; 3 mL). Three formulations of liquid acetaminophen (APAP), all varying in density and viscosity, were evaluated in the both settings: Children's Suspension Liquid Pain Reliever-grape (Sunmark; NDC 04934-8266-34), Children's Mapap Suspension Liquid-cherry (Major; NDC 00904-5116-20), and Acetaminophen Solution-cherry (Pharmaceutical Associates, Inc; NDC 00121-0657-05).

Laboratory Measurements

The mass of each APAP formulation was measured under ideal conditions in the laboratory setting to serve as a reference weight when calculating accuracy of each dosing device under ideal (laboratory) and practical (clinical) conditions. The suspension formulations were shaken thoroughly prior to all measurements. The mass of 5 mL of each APAP formulation was measured using the ScoutPro SP402 electronic balance (Ohaus Corporation, Parsippany, NJ). An empty 10-mL graduated cylinder along with the accompanying lid was measured on the electronic balance. Each APAP formulation was then poured into the graduated cylinder until the convex meniscus was level with the 5-mL mark. After securing the lid to eliminate evaporation of the liquid, the mass of 5 mL of each APAP formulation, the graduated cylinder, and the accompanying lid was measured. The density of 5 mL of each APAP formulation was calculated by subtracting the mass of the empty graduated cylinder and lid from the mass of the graduated cylinder plus 5 mL of each respective formulation.

The mass of 5 mL of each APAP formulation dispensed from each dosing device under ideal conditions was determined by weighing the amount dispensed into a

tared weigh boat on the electronic balance. This was done 3 times for each device and formulation, and the average density was recorded. The average density dispensed from each device was compared with the previously determined reference weight of each formulation to evaluate the magnitude of error and accuracy of each device under ideal conditions. All measurements were conducted at room temperature (average 18°C).

The viscosity of each APAP formulation was measured using a standard solution and the Brookfield Dial Viscometer (Brookfield Engineering Laboratories, Inc, Middleboro, MA). These measurements were performed at 25°C because this is the temperature at which the viscosity of the standard solution was known.

Clinical Measurements

The accuracy of each dosing device was then evaluated in the clinical setting. Subjects were recruited from 3 regional chain community pharmacies. Three separate pharmacy locations were chosen to encourage a demographically diverse sample. One pharmacy was located in inner-city Pittsburgh, PA, while the other 2 pharmacies were located in suburbs north (Wexford) and south (McMurray) of the city.

Participants were enrolled from October 2012 through April 2013. A sign displaying the words "Are you dosing your child's medication correctly?" was displayed at a table set up outside of the pharmacy at each respective location to encourage engagement with study personnel. Subjects <18 years of age were not eligible to participate in the study, but were provided with educational material on medication administration. Subjects ≥18 years of age were informed about the study, its voluntary nature, and written informed consent was obtained for those who agreed to participate. Subjects enrolled in the study received education on medication administration after study completion. Each subject could only participate in the study one time. To encourage study participation, persons who enrolled in the study were entered into a raffle to win a gift card from the grocery store chain where the study was conducted.

Sociodemographic information was collected via participant self-report. Race was collected to further define the sample population and determine effect on dosing accuracy, and options were predefined by the investigators.

Participant dosing accuracy with the cup, dropper, and syringe was evaluated with each of the 3 APAP formulations. Participants were instructed to measure and dispense a standard volume of each formulation, using each dosing device, resulting in 9 total medication measurements. This standard volume was 5 mL, and was written on a sheet of paper placed in front of the participant. Investigators did not verbalize the volume of medication that was to be dispensed in an effort to account for the impact of health and numeracy literacy on dosing accuracy. The manufacturer-supplied dosing directions were either on the formulation bottle or placed next to

Table 1. Laboratory Measurements: Mean Density, Precision, and Viscosity of 5 mL of Each APAP Formulation/Mean Volume of Each APAP Formulation Dispensed From Each Dosing Device.

Formulation	Mean Density of 5 mL (g/mL) $\pm$ SD	Viscosity (cP) at Speed 10 ^a	Measured Dose, mL, Mean $\pm$ SD (% error)		
			Dropper	Syringe	Cup
Grape suspension	1.19 $\pm$ 0.02	1240	4.47 $\pm$ 0.06 (10.6%)	5.06 $\pm$ 0.11 (1.2%)	4.03 $\pm$ 0.47 (19.4%)
Cherry suspension	1.27 $\pm$ 0.02	1090	4.27 $\pm$ 0.47 (14.6%)	5.05 $\pm$ 0.08 (1%)	4.51 $\pm$ 0.53 (9.8%)
Solution	1.27 $\pm$ 0.02	51.4	4.96 $\pm$ 0.03 (0.8%)	5.20 $\pm$ 0.04 (4%)	4.88 $\pm$ 0.04 (2.4%)

Abbreviations: APAP, acetaminophen; SD, standard deviation.

^aCorrected based on the measured viscosity of a 49.4 cP standard sample.

it, so that participants could reference any additional information needed for appropriate administration (ie, whether or not to shake the medication). Investigators did not provide any instruction on how to measure the standard volume or use the given dosing devices until the participant completed all 9 measurements. The order in which the formulations and devices were given to each participant was randomized in an effort to decrease any learning curve effects. After each measurement, the participants were instructed to dispense the medication into a tared weigh boat on the ScoutPro SP402 electronic balance. The weight in grams of each APAP formulation dispensed from each device was recorded and a new weigh boat was used for each measurement. Once all 9 measurements were complete, study personnel counseled participants on accurate medication administration.

The average density dispensed from each device was compared to the previously determined reference weight of each formulation to evaluate the magnitude of error and accuracy of each device in the clinical setting. The USP states that “under ideal conditions of use, the volume error incurred in measuring liquids for individual dose administration by means of such calibrated devices should be not greater than 10% of the indicated amount.”⁸ Thus, dosing errors were defined as mass dispensed >10% deviation from the reference weight, and the probability of making dosing errors was evaluated for each device and formulation.

Statistical Analysis

Most statistical analysis, including simple descriptive statistics and simple tests of hypotheses, were performed using SPSS version 14.0 statistical software (SPSS Inc, Chicago, IL). Dosing accuracy was analyzed as a continuous variable. Precision of the delivered volume was evaluated based on the standard deviation of the replicate measurements. A hypothesis test of association between 2 categorical variables was evaluated using a 2-way contingency test. We assessed the effect of medication viscosity, dosing device, and patient characteristics on dosing accuracy using bivariate (χ^2) and adjusted (logistic regression) analyses. In all cases, the α level for statistical significance was established at .05.

Results

Laboratory Measurements

Table 1 contains the mean density, precision, and viscosity of each APAP formulation. These values were used as a reference weight to calculate the volume of liquid dispensed from each device in both the laboratory and clinical settings. Table 1 also lists the mean volume of each formulation dispensed by instrument along with calculated magnitude of error. The syringe was the most accurate for the more viscous formulations (cherry and grape suspension), and the dropper was the most accurate for the less viscous formulation (solution).

Clinical Measurements

A total of 320 participants were enrolled in the clinical phase of the study. Sociodemographic information collected from participants at each location is displayed in Table 2.

When measured in the clinical setting, the syringe was most accurate, followed by the cup and then the dropper. The syringe also had the lowest probability of making a 10% or larger dosing error. The cup was the most likely to overdose, while the dropper was most likely to underdose. The mean volume of each formulation dispensed from each instrument along with magnitude of error is listed in Table 3. The probability of dosing error with each device and formulation is listed in Table 4. Statistically significant relationships between volume of medication dispensed and participant information are reported below.

Syringe

Participants reporting prior experience with dosing pediatric OTC medications were significantly more likely to dispense lower doses than those reporting no prior experience ($P = .04$).

Dropper

Older participants (greater than 45 years of age) were significantly more likely to dispense smaller volumes with the

Table 2. Participant Demographics.

Characteristic	Store Location		
	Pittsburgh, n (% per location)	Wexford (North), n (% per location)	McMurray (South), n (% per location)
Number of Participants	178	73	69
Gender			
Male	70 (39.3%)	22 (30.1%)	18 (26.1%)
Female	108 (60.7%)	51 (69.9%)	51 (73.9%)
Age range (average age)	18-78 (37.6)	24-89 (50.9)	19-79 (48.6)
Race			
Caucasian	102 (57.3%)	70 (95.9%)	64 (92.7%)
African American	64 (36.0%)	1 (1.4%)	1 (1.4%)
Hispanic	2 (1.1%)	0 (0%)	0 (0%)
Asian	2 (1.1%)	1 (1.4%)	0 (0%)
Other/not specified	8 (4.5%)	1 (1.4%)	4 (5.8%)
Household income			
<\$20 000	75 (42.1%)	1 (1.4%)	5 (7.2%)
\$20 000-59 999	64 (36.0%)	27 (37.0%)	14 (20.3%)
\$60 000-99 999	19 (10.7%)	16 (21.9%)	10 (14.5%)
≥\$100 000	13 (7.3%)	16 (21.9%)	36 (52.2%)
Not specified	7 (3.9%)	13 (17.8%)	4 (5.8%)
Household size			
One	49 (27.5%)	7 (9.6%)	5 (7.2%)
Two	50 (28.1%)	27 (37.0%)	26 (37.7%)
Three	35 (19.7%)	15 (20.5%)	7 (10.1%)
Four	29 (16.3%)	15 (20.5%)	23 (33.3%)
Five	15 (8.4%)	8 (11.0%)	8 (11.6%)
Not specified	0 (0%)	1 (1.4%)	0 (0%)
Current children cared for			
Zero	82 (46.1%)	37 (50.7%)	34 (49.3%)
One	44 (24.7%)	13 (17.8%)	11 (15.9%)
Two	26 (14.6%)	10 (13.7%)	18 (26.1%)
Three	10 (5.6%)	6 (8.2%)	3 (4.3%)
Four	8 (4.5%)	2 (2.7%)	3 (4.3%)
Five	8 (4.5%)	2 (2.7%)	0 (0%)
Not specified	0 (0%)	3 (4.1%)	0 (0%)
Children cared for in past			
Zero	49 (27.5%)	6 (8.2%)	13 (18.4%)
One	27 (15.2%)	7 (9.6%)	10 (14.5%)
Two	34 (19.1%)	21 (28.8%)	22 (31.9%)
Three	14 (7.9%)	13 (17.8%)	10 (14.5%)
Four	17 (9.5%)	7 (9.6%)	4 (5.8%)
Five	37 (20.8%)	18 (24.7%)	9 (13.0%)
Not specified	0 (0%)	1 (1.4%)	1 (1.4%)
Relationship to child(ren)			
Parent	85 (47.7%)	57 (78.1%)	52 (75.4%)
Guardian	9 (5.1%)	1 (1.4%)	0 (0%)
Caregiver	12 (6.7%)	3 (4.1%)	2 (2.9%)
Grandparent	27 (15.2%)	5 (6.8%)	2 (2.9%)
Sibling	1 (0.6%)	0 (0%)	2 (2.9%)
Aunt/uncle	6 (3.4%)	1 (1.4%)	2 (2.9%)
Not specified	38 (21.3%)	6 (8.2%)	9 (13.0%)

(continued)

Table 2. (continued)

Characteristic	Store Location		
	Pittsburgh, n (% per location)	Wexford (North), n (% per location)	McMurray (South), n (% per location)
Highest level of education			
No high school diploma	25 (14.0%)	1 (1.4%)	0 (0%)
High school diploma/GED	29 (16.3%)	12 (16.4)	10 (14.5%)
Some college credit/no degree	53 (29.8%)	15 (20.5%)	10 (14.5%)
Associate degree	19 (10.7%)	6 (8.2%)	4 (5.8%)
Bachelor's degree	34 (19.1%)	23 (31.5%)	26 (37.7%)
Master's degree	11 (6.2%)	11 (15.1%)	11 (15.9%)
Professional/doctorate degree	7 (3.9%)	4 (5.5%)	8 (11.6%)
Not specified	0 (0%)	1 (1.4%)	0 (0%)
Frequency of pediatric liquid medication administration			
Never	57 (32.0%)	25 (34.2%)	17 (24.6%)
Not in past year	36 (20.2%)	21 (28.8%)	23 (33.3%)
Once every 6 months	31 (17.4%)	9 (12.3%)	12 (17.4%)
Once every 4 months	9 (5.1%)	3 (4.1%)	4 (5.8%)
Once every 2 months	13 (7.3%)	3 (4.1%)	5 (7.2%)
Once every month	11 (6.2%)	4 (5.5%)	3 (4.3%)
Once every 2 weeks	4 (2.2%)	2 (2.7%)	0 (0%)
Once every week	3 (1.7%)	2 (2.7%)	0 (0%)
Multiple times weekly	8 (4.5%)	3 (4.1%)	3 (4.3%)
Not specified	6 (3.4%)	1 (1.4%)	2 (2.9%)
Employed in health care			
Yes	114 (64.0%)	48 (65.7%)	45 (65.2%)
No	64 (36%)	24 (32.9%)	24 (34.8%)
Not specified	0 (0%)	1 (1.4%)	0 (0%)

Table 3. Mean Volume of Each Formulation Dispensed by Instrument in the Clinical Setting.

Formulation	Measured Dose, mL, Mean $\pm$ Standard Deviation (% Error)		
	Dropper	Syringe	Cup
Grape suspension	3.08 $\pm$ 1.90 (38.4%)	4.96 $\pm$ 1.99 (0.8%)	5.34 $\pm$ 3.92 (6.8%)
Cherry suspension	3.25 $\pm$ 1.91 (35%)	4.76 $\pm$ 1.42 (4.8%)	5.74 $\pm$ 4.86 (14.8%)
Solution	3.70 $\pm$ 2.05 (26%)	4.96 $\pm$ 1.65 (0.8%)	5.95 $\pm$ 3.36 (19%)

dropper than younger participants ($P < .05$). Participants reporting larger household size were more likely to dispense larger volumes with the dropper than those reporting smaller household size ($P = .01$). Participants reporting higher levels of education dispensed larger volumes with the dropper than those reporting less education ($P = .02$).

Cup

Older participants were significantly more likely to dispense larger volumes with the cup ($P < .001$), with subjects

over 45 years of age being much more likely to dispense doses greatly exceeding 5 mL. Female participants were also significantly more likely to dispense smaller volumes with the cup than male participants ($P = .03$).

Discussion

Laboratory Evaluation

The evaluation of dosing devices in the laboratory setting was determined under ideal conditions, in which the technique and handling of the APAP formulations and delivery

Table 4. Probability of Making Dosing Errors^a in the Clinical Setting.

	Cup			Syringe			Dropper		
	Cherry Suspension	Grape Suspension	Solution	Cherry Suspension	Grape Suspension	Solution	Cherry Suspension	Grape Suspension	Solution
# errors >10% deviation	198	240	153	152	123	121	299	303	179
Total # measured	320	320	320	320	320	320	320	320	320
Lower 95% CL	57%	70%	42%	42%	33%	32%	91%	92%	50%
Probability 10% error	62%	75%	48%	48%	38%	38%	93%	95%	56%
Upper 95% CL	67%	80%	53%	53%	44%	43%	96%	97%	61%
# >10% overdose	73	53	97	71	56	64	6	5	9
Probability >10% over	23%	17%	30%	22%	18%	20%	2%	2%	3%
# >10% underdose	125	187	56	81	67	57	293	298	170
Probability >10% under	39%	58%	18%	25%	21%	18%	92%	93%	53%

Abbreviation: CL, confidence level.

^aDosing error is defined as >10% deviation from the reference weight.

devices promoted the most accurate and precise measurement of medication delivery.

In the laboratory setting, product viscosity played an integral role in the accuracy of medication delivery from the studied dosing devices. While the syringe was the most accurate for the more viscous formulations, the dropper was the most accurate for the less viscous formulation, such that no single device provided superior results for all formulations. These results are consistent with those of Peacock et al, who also found the syringe to be more accurate than the dropper for viscous medications under ideal conditions.⁹ It can therefore be concluded that the accuracy and precision of dosage delivery depends not only on the type of device used but also on the chemical properties of the product dispensed. Despite most pediatric OTC medications being suspensions, and the cup being the most commonly included dosing device,⁴ laboratory results revealed that the cup was the least accurate for the most viscous suspension, with magnitude of error approaching 20%. This is significant given that the USP states that “under ideal conditions of use, the volume error incurred in measuring liquids for individual dose administration by means of such calibrated devices should be not greater than 10% of the indicated amount.”⁸ The dropper and cup had a magnitude of error that was approaching or greater than 10% for both suspensions. All 3 dosing devices had a relatively small magnitude of error with the less viscous solution. These results suggest that under ideal conditions and accounting for differences in medication viscosity, the syringe delivers the most accurate dose. The magnitude of error with the syringe was well below 10% for all 3 formulations.

Clinical Evaluation

The introduction of an additional variable, human influence, on accuracy of medication dosing resulted in even

greater rates of error than those observed under ideal conditions. The mean volume of medication dispensed by participants was highly variable for each dosing device. Participants dispensed the most accurate volume of medication from the syringe, followed by the cup and then the dropper. The rate of error was less than 5% with all 3 formulations when participants used the syringe. The syringe had the lowest probability of making a 10% or larger dosing error (either over or under the intended dose). These findings are consistent with Madlon-Kay and Mosch, who examined patient’s ability to interpret instructions and administer medications and similarly found the oral syringe to be the most accurate.¹⁰

Although participants in our study dispensed more accurate doses from the cup when compared to the dropper, they were more likely to provide doses exceeding the intended 5 mL with the cup. Yin et al evaluated 6 dosing devices among parents in a pediatric clinic and found that “large” dosing errors (greater than 40%) were made by 25.8% of participants using the dosing cup with printed markings and 23.3% using the dosing cup with etched markings. Not only did both cups have the largest rate of error among dosing devices, but participants also measured doses greatly exceeding the intended 5 mL.⁵ In our study, as viscosity decreased, the mean volume dispensed from the cup increased. The less viscous suspension (cherry) and the solution had error rates exceeding 10% when participants used the cup. As resistance to flow decreases, it makes sense that participants would be more likely to pour more medication into the dosing cups, resulting in mean doses exceeding 5 mL.

The dropper was the least accurate dosing device in the clinical setting. The dropper was highly likely to produce an underdose and very unlikely to produce an overdose. The magnitude of error in dosing all 3 formulations greatly exceeded 10%. Brown and colleagues reported that precision

and accuracy of doses dispensed from medication droppers is influenced by viscosity and the angle in which the dropper is held, with volume dispensed decreasing when the dropper is held at an angle approaching 45° compared to vertical.¹¹ Therefore, the angle in which participants held the dropper could have contributed to the increased magnitude of error seen in the clinical setting compared to the laboratory setting. Additionally, study investigators noted that many participants did not realize that 2 separate medication draws were required to dispense 5 mL from the 3 mL dropper.

Study investigators noted that only 6 participants (1.9%) read the directions for at least one formulation, and only 19 participants (5.9%) shook either of the suspensions prior to administration. This too could have contributed to the differences in accuracy and precision of each dosing device in the laboratory versus clinical setting.

Several interesting relationships were discovered between volume of medication dispensed, dosing device, and participant information. Experience, age, household size, education, and sex were found to have an effect on the amount of medication dispensed from the various devices. Future studies are needed to further explore these relationships.

There were several limitations to this study. Although investigators made every attempt to recruit participants from diverse racial/ethnic, socioeconomic, and educational backgrounds by using 3 separate pharmacy locations, these findings are subject to selection bias. The mean age of participants was 46 years, and the majority were Caucasian, female, and had completed at least some college credits. Additionally, participants may not have exercised the same caution in this hypothetical study as they would have if actually dosing medication for a child. Last, there are various types of each delivery device available, differing in volume, markings, opacity, and so on. Although standard devices were used throughout this study, the results may not be applicable to all available dosing devices on the market.

Conclusion

The results of this study suggest that medication viscosity, consumer use, and dosing device contribute to dosing accuracy. The syringe appears to be the most accurate dosing device, accounting for differences in medication viscosity and the influence of consumer use. These results support those of previous studies and suggest that mandating the inclusion of the syringe with all pediatric OTC medication products could potentially improve dosing accuracy.

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Declaration of Conflicting Interests

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