

# Parents' Medication Administration Errors

## Role of Dosing Instruments and Health Literacy

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**Objectives:** To assess parents' liquid medication administration errors by dosing instrument type and to examine the degree to which parents' health literacy influences dosing accuracy.

**Design:** Experimental study.

**Setting:** Interviews conducted in a public hospital pediatric clinic in New York, New York, between October 28, 2008, and December 24, 2008.

**Participants:** Three hundred two parents of children presenting for care were enrolled.

**Main Outcome Measures:** Parents were observed for dosing accuracy (5-mL dose) using a set of standardized instruments (2 dosing cups [one with printed calibration markings, the other with etched markings], dropper, dosing spoon, and 2 oral syringes [one with and the other without a bottle adapter]).

**Results:** The percentages of parents dosing accurately (within 20% of the recommended dose) were 30.5% using the cup with printed markings and 50.2% using the cup

with etched markings, while more than 85% dosed accurately with the remaining instruments. Large dosing errors (>40% deviation) were made by 25.8% of parents using the cup with printed markings and 23.3% of parents using the cup with etched markings. In adjusted analyses, cups were associated with increased odds of making a dosing error (>20% deviation) compared with the oral syringe (cup with printed markings: adjusted odds ratio [AOR]=26.7; 95% confidence interval [CI], 16.8-42.4; cup with etched markings: AOR=11.0; 95% CI, 7.2-16.8). Compared with the oral syringe, cups were also associated with increased odds of making large dosing errors (cup with printed markings: AOR=7.3; 95% CI, 4.1-13.2; cup with etched markings: AOR=6.3; 95% CI, 3.5-11.2). Limited health literacy was associated with making a dosing error (AOR=1.7; 95% CI, 1.1-2.8).

**Conclusions:** Dosing errors by parents were highly prevalent with cups compared with droppers, spoons, or syringes. Strategies to reduce errors should address both accurate use of dosing instruments and health literacy.

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**R**ECENT FINDINGS INDICATE that most preventable adverse drug events in pediatric outpatients are attributable to errors in medication administration.<sup>1</sup> Errors occur frequently; 50% of parents or more make errors when dosing liquid medications.<sup>2-4</sup> Yet, there has been limited study of amenable factors such as parents' choice of and ability to correctly use dosing instruments.<sup>3,5-7</sup> Although it is well established that kitchen spoons are associated with errors,<sup>6-8</sup> little is known about which of the available standardized measuring devices parents are able to use with greatest accuracy. Presently, parents are exposed to a wide range of instrument types and styles, which also vary in their increments and units of measurement (ie, milliliter, teaspoon, tablespoon). This vari-

ability likely contributes to parents' confusion with dosing,<sup>2,6,7,9</sup> especially for those individuals with limited literacy.

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Advantages and disadvantages related to design, volume measured, and liquid attributes (ie, viscosity, surface tension) exist for each instrument.<sup>10</sup> Oral syringes are the instrument of choice of health care professionals when maximal accuracy is desired.<sup>6,10</sup> While studies have assessed parents' dosing using their choice of instrument,<sup>2,3</sup> to our knowledge little is known regarding parents' dosing abilities with the range of available instrument types.

In this study, we compared parents' dosing accuracy using a range of instruments. In addition, we sought to determine the extent to which health literacy

**Table 1. Sociodemographic Characteristics of the Study Population**

Characteristic	Value
Children in household	
Presence of child in household aged $\leq 8$ y, No. (%)	261 (86.4)
Children in household, mean (SD), No.	2.1 (1.2)
Presence of child with chronic medical problem, No. (%)	97 (32.1)
Caregiver	
Age, mean (SD), y	31.1 (8.6)
Relationship to child, No. (%)	
Mother	287 (95.0)
Father	8 (2.6)
Legal guardian	7 (2.3)
Marital status of single, No. (%)	91 (30.1)
Hollingshead SES level 4 or 5, No. (%) <sup>a</sup>	245 (81.1)
Non-US-born, No. (%) <sup>b</sup>	230 (76.4)
Race/ethnicity, No. (%)	
Hispanic	243 (80.1)
Non-Hispanic	
White non-Hispanic	9 (3.0)
Black non-Hispanic	30 (9.9)
Asian non-Hispanic	15 (5.0)
Native American, native Hawaiian, or Pacific Islander	1 (0.3)
Other	4 (1.3)
Spanish-speaking, No. (%) <sup>c</sup>	170 (56.4)
High school graduate or equivalent, No. (%)	154 (51.0)
Health literacy, No. (%) <sup>d</sup>	
High likelihood of limited literacy	121 (40.5)
Possible limited literacy	112 (37.5)
Adequate literacy	66 (22.1)

Abbreviation: SES, socioeconomic status.

<sup>a</sup>Lower level represents higher SES and greater family resources.

<sup>b</sup>Missing data for 1 subject.

<sup>c</sup>Language of Newest Vital Sign test administration; missing data for 3 subjects who did not complete the Newest Vital Sign test.

<sup>d</sup>Measured using the Newest Vital Sign test; missing data for 3 subjects who did not complete the Newest Vital Sign test.

affects the frequency and magnitude of dosing errors. A better understanding of these issues could inform clinical practice as well as medication packaging standards.

## METHODS

### DESIGN

This was an experimental study in which families were observed and assessed for dosing errors as they used a set of commonly available dosing instruments. Methods were approved by the institutional review boards at the New York University School of Medicine and Bellevue Hospital Center, New York.

### PARTICIPANTS AND SETTING

English- and/or Spanish-speaking caregivers (parents or legal guardians) presenting with a child to the pediatric clinic at Bellevue Hospital Center, an urban public hospital, between October 28, 2008, and December 24, 2008, were enrolled.

### MEASURES

Data included both observational and interview measures (conducted in the caregiver's language of preference). The primary

outcome variable was dosing accuracy, while primary predictor variables were instrument type and health literacy.

## DOSING ACCURACY

Parents were verbally asked to measure a dose of 1 tsp, or 5 mL, of acetaminophen suspension. Instrument order was randomized for each subject.

Dosing instruments included the following: 2 dosing cups (one with black printed calibration markings [included with Children's Tylenol Suspension Liquid; McNeil Consumer Healthcare, Fort Washington, Pennsylvania; 15 mL]; the other with clear etched markings [Duane Reade Inc, New York; 30 mL]), 1 dropper (Ezy Dose; Apothecary Products, Burnsville, Minnesota; 5 mL), 1 dosing spoon (Ezy Dose; 10 mL), and 1 oral syringe (Becton, Dickinson, and Co, Franklin Lakes, New Jersey; 5 mL). A second 5-mL syringe was tested with a bottle adapter (Medi-Dose, Inc/EPS, Inc, Ivyland, Pennsylvania).

Magnitude of error was calculated by comparing the weight of the measured dose (weight of the instrument containing the parents' measured dose minus the preassessment instrument weight) to a reference weight determined for a 5-mL dose (average weight of 5 mL measured by 5 pediatricians using a syringe). An electronic digital prescription class II scale (Torbal DRX-4; Fulcrum Inc, Clifton, New Jersey) was used.

Dosing accuracy was analyzed as both a continuous and categorical variable. The primary criterion used for categorical analyses was whether the measured dose fell within 20% of the recommended dose.<sup>3,11,12</sup> We also used a criterion of 40% to assess dosing errors of larger magnitude.<sup>12</sup> Parents were categorized as making no error (within 20% of the recommended dose [4-6 mL]), a small error (>20%-40% deviation), or a large error (>40% deviation). Our definition of error was conservative; the US Pharmacopeia's standard acceptable volumetric error is 10% for calibrated devices.<sup>13</sup>

## HEALTH LITERACY

Caregivers' health literacy was assessed with the Newest Vital Sign test.<sup>14</sup> A score of 0 or 1 reflected a high likelihood of limited literacy; 2 or 3, possible limited literacy; and 4 to 6, adequate literacy.

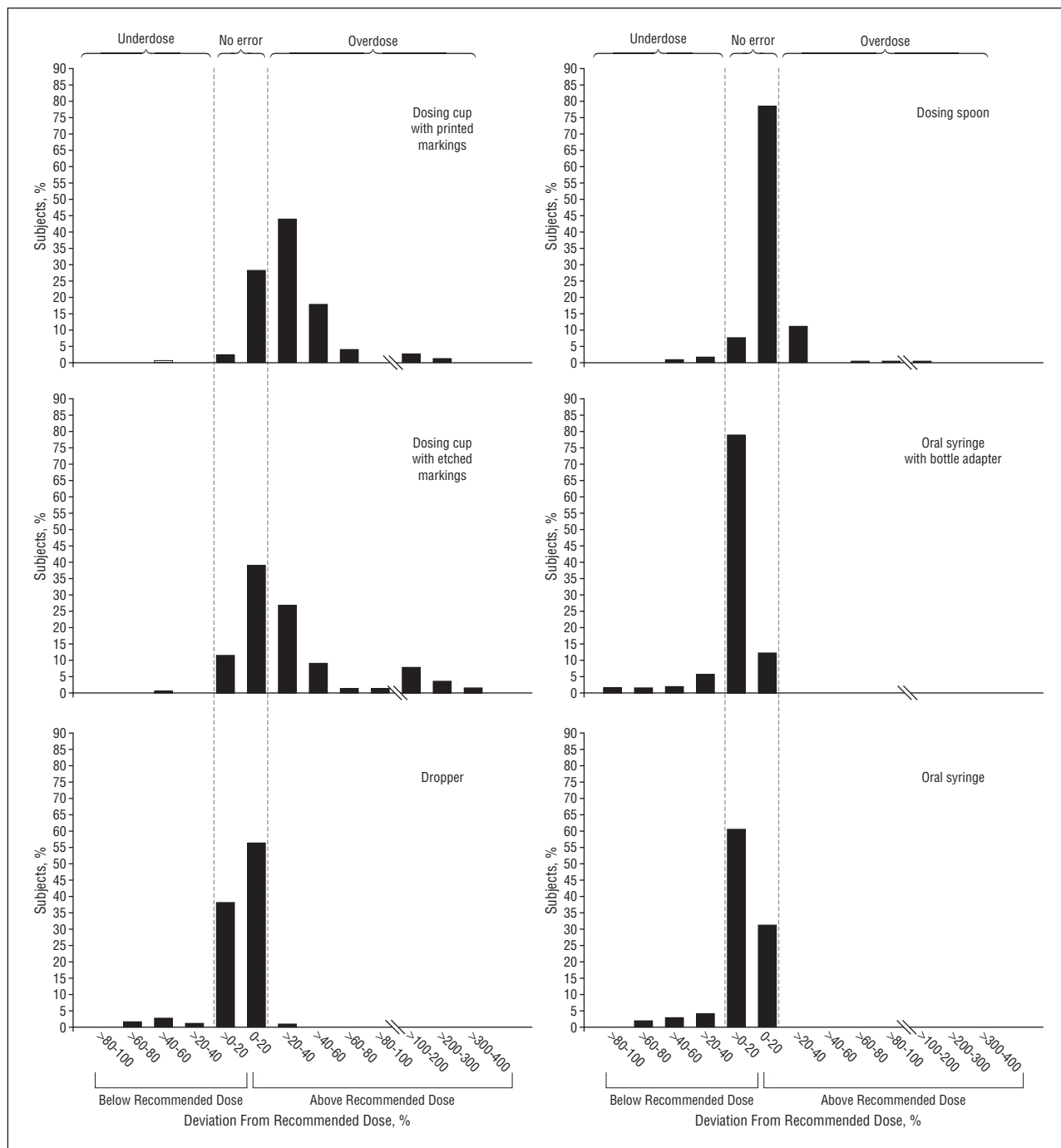
## SOCIODEMOGRAPHIC DATA AND CHILD HEALTH STATUS

Sociodemographic data included the caregivers' relationship to the child, marital status, country of origin, race/ethnicity, language, education, and socioeconomic status (assessed with Hollingshead's 4-Factor Index of Social Status<sup>15</sup>). Number of children in the household and ages of the parent and children were also obtained. Caregivers were categorized as having or not having a child in the household aged 8 years or younger (child aged  $\leq 8$  years likely to use liquid medications).<sup>12</sup> Child health status was assessed using the Children With Special Health Care Needs Screener.<sup>16-18</sup>

## STATISTICAL ANALYSIS

Data were analyzed using SPSS version 14.0 statistical software (SPSS Inc, Chicago, Illinois) and SAS version 9.1 statistical software (SAS Institute, Inc, Cary, North Carolina). For all analyses, 2-tailed  $P < .05$  was considered statistically significant.

We assessed associations between the 2 primary predictor variables (instrument and health literacy) and the primary outcome variable (dosing accuracy) to examine the degree to which these variables predicted dosing accuracy in bivariate ( $\chi^2$ ) and



**Figure.** Observed dosing accuracy by dosing instrument type. No error indicates within 20% of the recommended dose; underdose, below the recommended dose by more than 20% deviation; and overdose, greater than the recommended dose by more than 20% deviation.

adjusted (multiple logistic regression, generalized estimating equations [repeated measures]) analyses. Adjusted analyses were performed with a priori inclusion of potential confounders.

## RESULTS

Three hundred two subjects (287 mothers, 8 fathers, 7 legal guardians) were enrolled. Approximately 70% of approached subjects agreed to participate (refusals were primarily owing to concern about missing appointments). Descriptive data are shown in **Table 1**.

The **Figure** shows dosing accuracy for each type of instrument. **Table 2** shows dosing accuracy for each type of instrument, categorized by level of error. Overall, parents' dosing accuracy with both the cup with printed markings and the cup with etched markings was poor, with more than 99% of errors involving overdosing.

Health literacy was statistically significantly related to dosing errors with the cups as well as the dosing spoon, while a nonsignificant trend was seen for the dropper and the oral syringe with a bottle adapter (**Table 3**).

**Table 2. Dosing Errors by Instrument<sup>a</sup>**

Instrument	Measured Dose, mL		Dosing Error Category, No. (%) <sup>b,c</sup>		
	Mean (SD)	Range	No Error	Small Error	Large Error
Dosing cup with printed calibration markings	6.7 (1.7)	2.5-17.0	92 (30.5)	132 (43.7)	78 (25.8)
Dosing cup with etched calibration markings <sup>d</sup>	7.0 (3.2)	2.1-23.0	151 (50.2)	80 (26.6)	70 (23.3)
Dropper	4.9 (0.7)	1.2-6.2	285 (94.4)	5 (1.7)	12 (4.0)
Dosing spoon <sup>d</sup>	5.5 (0.7)	2.9-11.2	259 (86.0)	37 (12.3)	5 (1.7)
Oral syringe with bottle adapter <sup>e</sup>	4.6 (0.7)	0.7-5.8	272 (90.7)	16 (5.3)	12 (4.0)
Oral syringe	4.7 (0.7)	1.0-5.9	276 (91.4)	12 (4.0)	14 (4.6)

<sup>a</sup>The parent/caregiver was asked to measure a dose of 5 mL.

<sup>b</sup>No error indicates within 20% of the recommended dose; small error, greater than 20% to 40% deviation from the recommended dose; and large error, greater than 40% deviation from the recommended dose.

<sup>c</sup>Pearson  $\chi^2_0 = 579.44, P < .001$  for the comparison of dosing error categories between dosing instruments.

<sup>d</sup>Missing data for 1 measurement.

<sup>e</sup>Missing data for 2 measurements.

**Table 3. Dosing Error Rates for Each Instrument by Health Literacy Level**

Instrument	Health Literacy Level <sup>a</sup>	Dosing Error Category, No. (%) <sup>b</sup>			P Value <sup>c</sup>
		No Error	Small Error	Large Error	
Dosing cup with printed calibration markings	High likelihood of limited literacy	38 (31.4)	41 (33.9)	42 (34.7)	.01
	Possible limited literacy	31 (27.7)	56 (50.0)	25 (22.3)	
	Adequate literacy	22 (33.3)	35 (53.0)	9 (13.6)	
Dosing cup with etched calibration markings	High likelihood of limited literacy	54 (44.6)	37 (30.6)	30 (24.8)	.02
	Possible limited literacy	52 (46.4)	30 (26.8)	30 (26.8)	
	Adequate literacy	45 (68.2)	13 (19.7)	8 (12.1)	
Dropper	High likelihood of limited literacy	109 (90.1)	4 (3.3)	8 (6.6)	.07
	Possible limited literacy	107 (95.5)	1 (0.9)	4 (3.6)	
	Adequate literacy	66 (100.0)	0	0	
Dosing spoon	High likelihood of limited literacy	97 (80.2)	19 (15.7)	5 (4.1)	.01
	Possible limited literacy	97 (86.6)	15 (13.4)	0	
	Adequate literacy	63 (95.5)	3 (4.5)	0	
Oral syringe with bottle adapter	High likelihood of limited literacy	108 (89.3)	5 (4.1)	8 (6.6)	.11
	Possible limited literacy	99 (88.4)	9 (8.0)	4 (3.6)	
	Adequate literacy	64 (97.0)	2 (3.0)	0	
Oral syringe	High likelihood of limited literacy	107 (88.4)	7 (5.8)	7 (5.8)	.38
	Possible limited literacy	102 (91.1)	4 (3.6)	6 (5.4)	
	Adequate literacy	64 (97.0)	1 (1.5)	1 (1.5)	

<sup>a</sup>Measured using the Newest Vital Sign test; missing data for 3 subjects who did not complete the Newest Vital Sign test.

<sup>b</sup>No error indicates within 20% of the recommended dose; small error, greater than 20% to 40% deviation from the recommended dose; and large error, greater than 40% deviation from the recommended dose.

<sup>c</sup>From  $\chi^2$  analysis comparing error rates by health literacy level for each dosing instrument.

In adjusted analyses (**Table 4**), cup use was associated with increased odds of error compared with the syringe. Low health literacy was independently associated with dosing errors.

**COMMENT**

To our knowledge, this study is the first to compare rates of parents' dosing error across a range of standardized instruments and to examine the contributing role of limited health literacy. Our finding that both instrument type and health literacy have independent effects on the rate of error suggests 2 important target areas for intervention. Dosing cups were specifically associated with large overdosing errors, with parents who had low health literacy most at risk.

Errors involving cups are thought to arise from confusion about teaspoon vs tablespoon instructions (simi-

larity in "tsp" and "tbsp" markings), assumptions that the cup is the unit of measure, and assumptions that the full cup is the dose.<sup>6,9</sup> Inconsistencies of instrument markings with written instructions serve as additional contributors to error; differences in legibility may also play a role.<sup>9,22,23</sup> Part way through the study, we recognized that lack of eye-level dose verification, particularly with cups, may also be associated with errors. Although a uniform labeling system for cups has been recommended<sup>9</sup> and cup-related errors are tracked by the US Food and Drug Administration,<sup>9,22,23</sup> there has been limited study of how to improve dosing with cups and there remains significant variability in cup labeling and design.

A disproportionate burden of outpatient medication errors is shouldered by families with low health literacy. Our findings demonstrate that health literacy is

**Table 4. Multiple Logistic Regression Models Using Generalized Estimating Equations to Determine the Effect of Dosing Instrument and Health Literacy on Dosing Errors**

Model	Any Dosing Error <sup>a</sup>		Large Dosing Error <sup>b</sup>	
	AOR (95% CI) <sup>c</sup>	P Value	AOR (95% CI) <sup>c</sup>	P Value
<b>Instrument</b>				
Dosing cup with printed calibration markings	26.7 (16.8-42.4)	<.001	7.3 (4.1-13.2)	<.001
Dosing cup with etched calibration markings	11.0 (7.2-16.8)	<.001	6.3 (3.5-11.2)	<.001
Dropper	0.6 (0.4-1.04)	.07	0.8 (0.5-1.5)	.59
Dosing spoon	1.7 (1.1-2.7)	.02	0.3 (0.1-0.9)	.02
Oral syringe with bottle adapter	1.1 (0.7-1.6)	.69	0.8 (0.5-1.5)	.56
Oral syringe	1 [Reference]	NA	1 [Reference]	NA
<b>Health literacy level<sup>d</sup></b>				
High likelihood of limited literacy	1.7 (1.1-2.8)	.02	2.3 (1.2-4.6)	.01
Possible limited literacy	1.6 (1.02-2.6)	.04	1.9 (0.95-3.7)	.07
Adequate literacy	1 [Reference]	NA	1 [Reference]	NA

Abbreviations: AOR, adjusted odds ratio; CI, confidence interval; NA, not applicable.

<sup>a</sup>Defined as greater than 20% deviation from the recommended dose.

<sup>b</sup>Defined as greater than 40% deviation from the recommended dose.

<sup>c</sup>Confounders considered a priori to be related to the outcome variable (parents' age, relationship to the child, marital status, language, ethnicity, US birth, socioeconomic status, presence of a child in the household aged ≤8 years, and presence of a child in the household with a chronic medical problem) are included. Education was excluded from the model as education is considered to be in the causal pathway between health literacy and the outcome.<sup>19-21</sup>

<sup>d</sup>Measured using the Newest Vital Sign test; missing data for 3 subjects who did not complete the Newest Vital Sign test.

particularly important for dosing accuracy with cups. This suggests that provision of instruments designed to place fewer literacy demands on families is one strategy to decrease dosing errors.

There is growing recognition that health literacy is a dual function, involving not only an individual's literacy skills when a task is approached but also how navigable and clearly the task is presented.<sup>24</sup> Dosing devices are not "health literate" owing to their high degree of variability and complexity. Teaching caregivers how to accurately dose is daunting in light of this variability and complexity. Redesign of dosing devices as well as instructions for their use, with a focus on standardization and consistency, has the potential to decrease medication errors and improve safety and efficacy.

There are limitations to our results. Our assessment of dosing was performed as part of a hypothetical scenario and may not reflect caregivers' true ability to dose at home. Caregivers were also asked to dose with multiple instruments. Order of dosing, however, was randomized and had no effect on dosing accuracy in regression analyses. In addition, our results may not be generalizable. This study was performed in an urban pediatric clinic that serves a primarily immigrant Latino population with low socioeconomic status. Also, since the study involved a convenience sample, our findings are subject to selection bias as parents who were less confident in their dosing ability may have been less likely to participate. Our findings are thus likely to be conservative. Finally, we recognize that our assessment of health literacy relied on subject comprehension of written health information and does not measure other skills that contribute to health literacy, such as verbal comprehension.

In summary, we found that parents are at high risk for dosing error with cups and that health literacy plays an important role in dosing accuracy. These findings have significant public health and policy implications. The recent national focus on outpatient pediatric medication

errors, in part stimulated by morbidity related to pediatric overdoses involving cough and cold medications,<sup>25-27</sup> has increased pressure on the federal government and manufacturers to act. Given that a large proportion of parents use cups<sup>6,10</sup> and many medications are packaged with a cup, further study is indicated to address how to improve parents' ability to measure accurately with cups and to determine whether packaging standards should be changed.

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**Author Contributions:** Drs Yin, Mendelsohn, and Dreyer had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Yin, Mendelsohn, van Schaick, and Dreyer. *Acquisition of data:* Bazan and Kline. *Analysis and interpretation of data:* Yin, Mendelsohn, Wolf, Parker, Fierman, and Dreyer. *Drafting of the manuscript:* Yin, Mendelsohn, Bazan, and Kline. *Critical revision of the manuscript for important intellectual content:* Yin, Mendelsohn, Wolf, Parker, Fierman, van Schaick, and Dreyer. *Statistical analysis:* Yin, Mendelsohn, Fierman, and Dreyer. *Obtained funding:* Yin and Dreyer. *Administrative, technical, and material support:* van Schaick, Bazan, and Kline. *Study supervision:* Yin, Mendelsohn, and Dreyer.

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