

Randomized Controlled Trial of a Pictogram-Based Intervention to Reduce Liquid Medication Dosing Errors and Improve Adherence Among Caregivers of Young Children

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Objective: To evaluate the efficacy of a pictogram-based health literacy intervention to decrease liquid medication administration errors by caregivers of young children.

Design: Randomized controlled trial.

Setting: Urban public hospital pediatric emergency department.

Participants: Parents and caregivers (N=245) of children aged 30 days to 8 years who were prescribed liquid medications (daily dose or "as needed").

Intervention: Medication counseling using plain language, pictogram-based medication instruction sheets. Control subjects received standard medication counseling.

Outcome Measures: Medication knowledge and practice, dosing accuracy, and adherence.

Results: Of 245 randomized caregivers, 227 underwent follow-up assessments (intervention group, 113; control group, 114). Of these, 99 were prescribed a daily dose medication, and 158 were prescribed medication taken as needed. Intervention caregivers had fewer errors in ob-

served dosing accuracy (>20% deviation from prescribed dose) compared with caregivers who received routine counseling (daily dose: 5.4% vs 47.8%; absolute risk reduction [ARR], 42.4% [95% confidence interval, 24.0%-57.0%]; number needed to treat [NNT], 2 [2-4]; as needed: 15.6% vs 40.0%; ARR, 24.4% (8.7%-38.8%); NNT, 4 [3-12]). Of intervention caregivers, 9.3% were nonadherent (ie, did not give within 20% of the total prescribed doses) compared with 38.0% of controls (ARR, 28.7% [11.4%-43.7%]; NNT, 3 [2-9]). Improvements were also seen for knowledge of appropriate preparation for both medication types, as well as knowledge of frequency for those prescribed daily dose medications.

Conclusion: A plain language, pictogram-based intervention used as part of medication counseling resulted in decreased medication dosing errors and improved adherence among multiethnic, low socioeconomic status caregivers whose children were treated at an urban pediatric emergency department.

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EVIDENCE SUGGESTS THAT PARENTS and caregivers make frequent errors when administering medications to children. These errors, which include inaccurate dosing as well as nonadherence to medication regimens, place children at risk for morbidity and mortality.¹⁻⁵ Misdosing is prevalent, with 50% or more of pediatric caregivers either measuring an incorrect dose or reporting having given a dose of liquid medication outside the recommended range.⁶⁻¹¹ Of further concern are reports of a poor overall adherence rate of 50% for pediatric medications,^{3,12,13} which has implications for treatment failure and drug resistance.^{2,12,14-16}

Medication-specific issues, as well as factors related to health care provider and caregiver characteristics, contribute to medication administration errors in children. Medication-specific issues in children are frequently related to reliance on liquid formulations,^{6,8,17-19} including availability of medications in different concentrations,^{11,20} palatability,^{8,12} and wide variation in the accuracy of dosing instruments.^{8,9,18,19,21} Health care provider communication issues contribute to confusion about medication administration, particularly when instructions are complex^{12,14,22,23} and when directions for liquid medications are given using different units of measure, including milliliters, teaspoons, or tablespoons.¹⁹ Caregiver-

specific issues include language barriers, literacy level, cultural perceptions, and cost.^{3,12,23,24} These caregiver-related issues disproportionately affect low socioeconomic status (SES) caregivers.

Few studies have examined strategies for decreasing medication administration errors among pediatric patients.⁶ Pictograms represent a promising approach in which simple diagrams are used to improve understanding of concepts.²⁵⁻²⁸ Pictorial-enhanced written materials have been shown to improve comprehension of and adherence to medical directions,^{25,29-35} particularly for patients with low literacy.³⁴⁻³⁷ However, existing studies of pictogram-enhanced medication instructions have assessed adult rather than pediatric medication regimens.^{29,30} Two additional strategies for which there is empirical support are “teachback,” in which patients or caregivers are asked to repeat back instructions or physically demonstrate steps involved in a task,^{38,39} and provision of oral dosing syringes.^{8,18}

We developed a pictogram-based intervention to decrease dosing errors and improve adherence. This was created as part of New York University/Bellevue Hospital Center’s Health Education and Literacy for Parents (HELP) project, which helps low literacy, limited-English-proficient parents of young children understand health information. The intervention, HELPix, or HELP pictograms, uses plain language, pictogram-based medication- and patient-specific instruction sheets to help facilitate counseling regarding medication dose and adherence, as well as correct usage of a standardized dosing instrument (<http://HELPix.med.nyu.edu>). In this study, we sought to assess whether this intervention would reduce medication dosing errors and improve adherence in a pediatric emergency department (ED) serving at-risk families.

METHODS

PARTICIPANTS, RECRUITMENT, AND RANDOMIZATION

This study was a randomized controlled trial to test the efficacy of the HELPix intervention. Institutional review board approval was obtained from New York University School of Medicine and Bellevue Hospital Center. Parents and caregivers provided written, informed consent before participating in the study.

Subjects were enrolled from the pediatric ED at Bellevue Hospital Center, an urban public hospital, between July 12 and December 7, 2006. The Bellevue pediatric ED serves primarily at-risk families with low education and low SES and registers approximately 20 000 visits per year. During daytime and evening hours when study enrollment took place, research assistants consecutively assessed parents and caregivers to determine eligibility.

Inclusion criteria were having a child aged 30 days through 8 years who was prescribed a liquid medication (daily dose [short course (≤ 14 days)] or as-needed medication). Exclusion criteria were caregiver accompanying the child to the visit not being primarily responsible for administering medication or not fluent in English or Spanish; child requiring immediate medical attention; child typically taking medications in tablet form; or child having a psychiatric or child-protection-related visit.

Enrolled caregivers were randomized to receive the pictogram-based intervention or standard care (control group). Ran-

domization was performed using sealed envelopes in blocks of 50, 25 each for the intervention and control groups. Trained research assistants delivered the intervention to caregivers at the time of ED discharge.

INTERVENTION

Plain language, pictogram-based medication instruction sheets, in English and Spanish, were the core of HELPix (eFigure 1 and eFigure 2; <http://www.archpediatrics.com>). The instruction sheets used pictograms to convey information about medication name, indication, dose, dose frequency, length of treatment, preparation, and storage. The sheets also included a medication log for parents to keep track of medication administration. The 2-page medication information sheets were generated using software developed for this project and were based on data from standard pharmaceutical references.^{40,41} We developed separate templates for daily dose and as-needed medications, reflecting differences in the way these medications are administered.⁴²⁻⁴⁴

Research assistants trained and supervised by one of us (H.S.Y.) used the instruction sheets to facilitate medication counseling, including teaching about dosage and adherence. During counseling, research staff referenced the sheets as they demonstrated dosing with a standardized instrument; parents then demonstrated to research staff how they planned to administer medication, a process referred to as “teachback.” For medications with which a standardized dosing instrument was not included at dispensing, an oral dosing syringe was provided for the caregiver to use at home. After counseling, the caregiver was given the instruction sheet to take home and instructed to use it to facilitate and guide medication administration. The intervention, which included counseling and teachback, took 1½ to 3 minutes to complete for each caregiver, depending on the complexity of the regimen.

STANDARD MEDICATION COUNSELING

Families in the control group received standard care, including routine counseling regarding prescribed medications and postvisit counseling by the pediatric nursing staff. Dosing instruments were given at the discretion of the physician or nurse, but this was not part of routine practice. Medications were typically dispensed at a pharmacy outside the institution; medication counseling was provided by the pharmacist as mandated by state law.⁴⁵

ASSESSMENTS

Assessments were performed at baseline before the intervention as well as at follow-up. Interviews were conducted by research assistants in English or Spanish based on caregiver preference. A modest incentive was provided for families to encourage participation (\$5 for intake, \$20 for follow-up).

Baseline

We assessed sociodemographic characteristics, the child’s medical history, and caregiver health literacy level.

Sociodemographic data, including the child’s age and sex as well as caregiver age, marital status, country of origin, ethnicity, language, educational level, occupation, and relationship to the child, were obtained via a structured questionnaire. Family Hollingshead Four-Factor SES was based on education and occupation.⁴⁶

The child’s medical history was assessed, including history of chronic medical problems and whether the child took medication regularly.

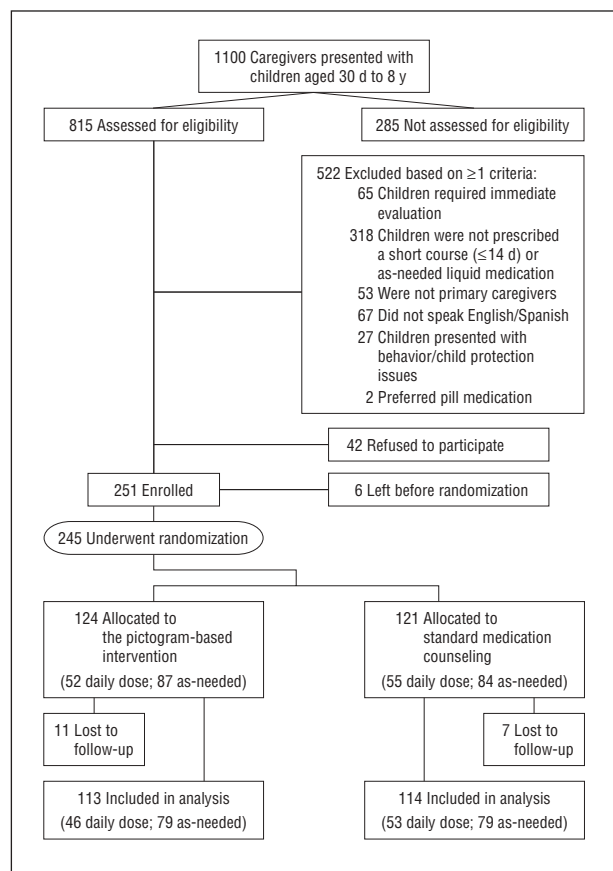


Figure 1. Study enrollment.

Caregiver health literacy level was assessed with the Test of Functional Health Literacy in Adults (TOFHLA).⁴⁷ Functional health literacy was categorized as inadequate, marginal, or adequate, as designated in the TOFHLA manual.⁴⁸ The test has been shown to correlate with the Wide Range Achievement Test as well as the Rapid Estimate of Adult Literacy in Medicine⁴⁷ and has been used in multiple studies to assess health literacy.^{16,49,50} The TOFHLA is validated in English and Spanish.⁵¹ In 8 cases, time constraints led us to administer a short version of the TOFHLA,⁵² which yielded the same set of categories.

Follow-up

Follow-up assessments took place either by telephone and/or in person, planned at 3 to 5 days after the ED visit for as-needed medications and within 1 day of the projected end date for daily dose medications. These included assessments of knowledge and behavior, dosing accuracy, and adherence (for daily dose medications only). Blinding was not maintained during follow-up assessments because caregivers who received the pictogram-based instruction sheets were aware of their randomization status and revealed their status during assessments. In addition, the same research assistants were frequently involved in both intake and follow-up assessments.

Knowledge and Related Medication Practices. Caregivers were asked about the name and indication of each prescribed medication, as well as dose frequency, preparation, storage, and dosing instrument use.

Caregivers were considered to have accurate knowledge of dose frequency if they reported a number of prescribed doses

per day that exactly matched the number of doses prescribed by the physician. Those who gave a response that was more or less than the number of doses prescribed were considered to be incorrect.

Related medication practices assessed included appropriate method of preparation and mode of storage. Responses were dichotomized as correct or incorrect on the basis of medication-specific information obtained from standard pharmaceutical references.^{40,41} Caregivers were also asked to report which dosing instrument they used at home.

Dosing Accuracy. Dosing accuracy was assessed by caregiver interview and through direct observation. For both self-reported and observed dosing accuracy, the primary criterion used was whether the amount was within 20% of the prescribed dose. We chose this criterion on the basis of other studies of medication dosing accuracy.^{9,53} We also analyzed the data using a criterion of 40% to determine the effect of dosing errors of larger magnitude.

To assess dosing accuracy via direct observation, caregivers underwent a structured observation at follow-up. Caregivers were asked to bring in any materials they used at home, including the medication bottle, dosing instrument, and instructions, and were asked to measure the dose as they would at home using a standardized medication bottle and their own dosing instrument. Those who did not bring in their dosing instrument were asked to select from the dosing instruments provided by research staff, which included a kitchen teaspoon, kitchen tablespoon, dosing spoon, measuring spoon, dosing cup, 5-mL dropper, acetaminophen infant dropper, ibuprofen-specific dropper, and 1-, 3-, 5-, 10-, and 12-mL syringes. Interrater reliability, measured by having 2 raters (including H.S.Y.) assess dosing accuracy using the 20% criterion for a subsample of 75 parents, was high ($\kappa > 0.9$).

Adherence. We estimated the total number of doses given by the caregiver from the time and date of first and last dose, reported frequency of doses, and number of doses reported missing. We then calculated the percentage of prescribed doses given (total number of doses given divided by total number of doses prescribed). We considered caregivers to be nonadherent if they deviated from the number of doses prescribed by more than 20%.⁵⁴⁻⁵⁷ We also compared the randomization groups for nonadherence using a criterion of 40%, as was done for dosing accuracy.

We also assessed nonadherence according to whether caregivers completed their medication course,⁵⁸ using the reported start time and date to calculate the appropriate final date of the treatment course. We compared nonadherence between the 2 groups based on 2 different criteria: not giving the last dose on the expected last date and not giving the last dose within 1 day of the expected last date.

STATISTICAL ANALYSES

The baseline characteristics of the intervention and control families were compared using *t* tests and χ^2 tests or Fisher exact tests, as appropriate. Similar analyses were performed to compare families who did and did not undergo follow-up assessments.

Statistical analyses to assess differences in medication knowledge and related medication practices, as well as dosing accuracy, were performed for the daily dose and as-needed medication groups separately because of differences in administration,⁴²⁻⁴⁴ which then led to the creation of separate medication instruction sheet templates. For the limited number of patients who received more than 1 daily dose or as-needed medi-

Table 1. Baseline Characteristics by Randomization Group^a

Characteristic	Pictogram-Based Intervention (n=124)	Standard Medication Counseling (n=121)
Children		
Age, mean (SD), y	3.7 (2.2)	3.4 (2.3)
Female	47.9	35.5
Has a chronic medical problem	21.8	20.7
Uses medication(s) regularly	17.2	18.2
Caregivers		
Age, mean (SD), y	31.1 (8.2)	29.6 (6.9)
Relationship to child		
Mother	87.4	93.4
Father	10.5	5.8
Other	2.4	0.8
Marital status		
Single	21.8	34.7
Has a partner	30.6	26.4
Married	39.5	30.6
Separated/divorced/widowed	8.1	8.3
Education, mean (SD), y	11.5 (3.6)	11.3 (3.2)
High school graduate or equivalent	59.7	61.2
Born outside the United States	64.5	66.1
Latino ethnicity	77.4	79.3
Race		
Black	13.7	8.3
Asian	8.9	5.0
White	2.4	4.1
Native American/American Indian/Alaska native	0.0	1.7
Native Hawaiian/Pacific Islander	0.0	0.8
Other	75.0	80.2
Hollingshead SES level 4 or 5 ^b	75.8	77.7
Spanish speaking ^c	46.3	43.0
TOFHLA Score ^d		
Adequate	69.9	68.9
Marginal	17.9	17.6
Inadequate	12.2	13.4

Abbreviations: SES, socioeconomic status; TOFHLA, Test of Functional Health Literacy in Adults.

^aData are given as the percentage of participants, unless otherwise indicated.

^bLower number represents higher SES and greater family resources.

^cLanguage of TOFHLA administration.

^dData were missing for 3 subjects who did not complete the TOFHLA; Short TOFHLA was administered to 8 subjects because of time constraints.

cation (7 patients), only the first medication documented in the visit record was included in the analysis. For patients who received a medication prescription involving tapered dosing over time, the most recent dose was used for the analysis.

Outcomes were compared using Fisher exact tests for categorical variables and independent samples *t* tests for continuous variables. Absolute risk reduction, relative risk reduction, and number needed to treat, along with 95% confidence intervals, were calculated for each outcome of interest.

Because child's sex was close to being statistically significant between randomized groups ($P=.053$), we performed multivariate analyses adjusting for sex for each outcome of interest. Adjusting for sex did not change outcomes; therefore, we present unadjusted analyses only.

Data were analyzed using SPSS statistical software, version 14.0 (SPSS Inc, Chicago, Illinois). A 2-tailed P value $<.05$ was considered to be statistically significant. Sample size estimates were based on the outcome of dosing accuracy. A conservative estimate of the baseline rate of caregiver liquid medication dos-

Table 2. Prescribed Medication Characteristics by Randomization Group^a

Characteristic	Pictogram-Based Intervention	Standard Medication Counseling
Daily dose medication, No.		
Amoxicillin	21 (40.4)	23 (41.8)
Other antibiotic	17 (32.7)	18 (32.7)
Corticosteroid	11 (21.2)	13 (23.6)
Antihistamine	3 (5.8)	1 (1.8)
As-needed medication, No.		
Antipyretic/analgesic	77 (88.5)	73 (86.9)
Cold/cough	1 (1.1)	2 (2.4)
Antihistamine	9 (10.3)	9 (10.7)

^aData are given as the number (percentage) of subjects unless otherwise indicated.

ing error is 40% to 50%.⁶⁻¹¹ We calculated a sample size of approximately 245 parents enrolled in the study (with a 25% anticipated loss to follow-up) to achieve 80% power (2-sided $\alpha=.05$) to detect a reduction in dosing error rate of 20% to 30% in the group receiving the pictogram-based intervention compared with the group receiving standard counseling.

RESULTS

From July 12 through December 7, 2006, 3309 children who met inclusion criteria visited the ED; 1290 pediatric visits involving 1100 caregivers occurred during the daytime and early evening hours when research assistants were present (**Figure 1**). Of 1100 caregivers, 815 (74.1%) were assessed for additional inclusion criteria. Although research assistants endeavored to assess consecutive families, 285 caregivers (25.9%) were not assessed because their children were immediately called to be seen by the physician or because of competing demands as research assistants enrolled other families. Based on 1 or more of the study criteria, 522 caregivers (67.7%) were determined to be ineligible. There was no statistically significant difference between families who were and were not enrolled with respect to child's age and sex.

Of 251 caregivers enrolled in the study, 6 left before randomization (0.2%). Of 245 caregivers randomized, 124 (50.6%) were allocated to receive the pictogram-based medication instruction sheets, whereas 121 (49.4%) were allocated to the control group. This included 107 families (43.7%) prescribed daily dose medications (intervention, 52; control, 55) and 171 families (69.8%) prescribed as-needed medications (intervention, 87; control, 84). (Some families received both as-needed and daily dose medications.) Randomized families were compared for baseline variables (**Table 1**). No statistically significant differences were seen, although a nonsignificant trend was seen for sex ($P=.053$). In addition, no statistically significant differences were seen in the type of medication prescribed to children in the intervention and control groups (**Table 2**).

Of 245 randomized families, 227 (92.7%) underwent follow-up assessments by telephone, in person, or both, and rates were similar for intervention and control families (91.1% vs 94.2%, respectively; $P=.50$). Follow-up as-

Table 3. Medication Knowledge and Related Practices: Error Rates^a

	Pictogram-Based Intervention	Standard Medication Counseling	RR (95% CI)	RRR (95% CI), %	ARR (95% CI), %	NNT (95% CI)	P Value ^b
Daily dose medication, No.	46	53					
Name	3 (6.5)	7 (13.2)	0.5 (0.1 to 1.8)	50.6 (−46.6 to 144.5)	6.7 (−6.2 to 19.1)	... ^c	.33
Indication	2 (4.3)	5 (9.4)	0.5 (0.1 to 2.3)	53.9 (−68.0 to 173.4)	5.1 (−6.4 to 16.4)	... ^c	.45
Frequency	0	8 (15.1)	0.0 ^d	100.0 (29.9 to 179.2)	15.1 (4.5 to 27.1)	7 (4 to 22)	.007
Preparation	5 (10.9)	15 (28.3)	0.4 (0.2 to 1.0)	61.6 (5.2 to 113.3)	17.4 (1.5 to 32.1)	6 (3 to 68)	.04
Storage	5 (10.9)	10 (18.9)	0.6 (0.2 to 1.6)	42.4 (−35.6 to 116.2)	8.0 (−6.7 to 21.9)	... ^c	.40
As-needed medication, No.	79	79					
Name	7 (8.9)	6 (7.6)	1.2 (0.4 to 3.3)	−16.7 (−138.6 to 104.2)	−1.3 (−10.5 to 7.9)	... ^c	>.99
Indication	7 (8.9)	2 (2.5)	3.5 (0.8 to 16.3)	−250.0 (−586 to 53.8)	−6.3 (−14.9 to 1.4)	... ^c	.17
Frequency ^e	21 (26.6)	20 (25.6)	1.0 (0.6 to 1.8)	−3.7 (−56.6 to 49.5)	−0.9 (−14.5 to 12.7)	... ^c	>.99
Preparation	17 (21.5)	34 (43.0)	0.5 (0.3 to 0.8)	50.0 (16.1 to 81.1)	21.5 (6.9 to 34.9)	5 (3 to 14)	.006
Storage	22 (27.8)	23 (29.1)	1.0 (0.6 to 1.6)	4.4 (−43.5 to 51.9)	1.3 (−12.7 to 15.1)	... ^c	>.99

Abbreviations: ARR, absolute risk reduction; CI, confidence interval; NNT, number needed to treat; RR, relative risk; RRR, relative risk reduction.

^aData are given as the number (percentage) of subjects who made a medication knowledge error or an error in medication practice unless otherwise indicated.

^bP < .05 indicates statistical significance.

^cNNT was not calculated for nonsignificant results.

^dA 95% CI was not calculated because the RR is equal to 0.

^eInformation was missing for 1 caregiver who received standard medication counseling.

assessments were conducted by telephone only for 46 families (20.3%), in person only for 62 (27.3%), and by telephone and in person for 119 (52.4%). Because assessment of observed dosing accuracy required in-person follow-up, only 181 of 245 randomized families (73.9%) were assessed for that measure. Mean (SD) follow-up time for observed dosing accuracy was 12.1 (9.8) days. There were no differences in caregiver characteristics for those who did and did not return for the observed dosing assessment.

All intervention caregivers received a standardized dosing instrument, from the ED research assistant (92.7%) and/or the pharmacy (33.3%), as a standard component of medication packaging. In the control group, 55.3% of caregivers received dosing instruments, from the ED staff (23.0%) and/or the pharmacy (38.4%).

MEDICATION KNOWLEDGE AND RELATED PRACTICES

As shown in **Table 3**, intervention caregivers who were prescribed daily dose medications were less likely to make errors in knowledge of dose frequency compared with control caregivers (0% vs 15.1%; $P = .007$). However, there was no difference in knowledge of dose frequency for as-needed medications. Intervention caregivers were also less likely than control caregivers to report incorrect medication preparation, related to shaking the medication before administration, for both daily dose (10.9% vs 28.3%; $P = .04$) and as-needed (21.5% vs 43.0%; $P = .006$) medications. No differences were seen in knowledge of medication name, indication, or storage. With respect to dosing instrument, caregivers in the intervention group were significantly more likely to report the use of a standardized dosing instrument compared with caregivers in the control group for both daily dose and as-needed medications (daily dose: 93.5% vs 71.7%, $P = .008$; as needed: 93.7% vs 74.7%; $P = .002$).

DOSING ACCURACY

Figure 2A and **B** show frequencies in observed dosing accuracy by randomization group for daily dose and as-needed medications, respectively.

As seen in **Table 4**, caregiver accuracy was higher among intervention families prescribed daily dose and as-needed medications, regardless of whether the cutoff point for a dosing error was set at 20% or 40% deviation from the prescribed dose. In the structured observation, for example, 5.4% of intervention caregivers whose children had been prescribed daily dose medications gave inaccurate doses at the 20% cutoff point, compared with 47.8% of control caregivers.

Because intervention families were more likely to use a standardized dosing instrument, we performed secondary analyses of observed dosing accuracy in which we included only those caregivers who used a standardized dosing instrument. Using the 20% cutoff point, we found that errors in observed accuracy remained significantly different in the intervention and control groups for both daily dose and as-needed medications (daily dose: 5.0% vs 35.3%; $P = .003$; as-needed: 16.4% vs 36.2%; $P = .02$).

ADHERENCE

Nonadherence was lower in the intervention group for both categories of adherence (percentage of total prescribed doses given and date of last dose given) as well as for each specific criterion (eg, 20% vs 40% of total doses) (**Table 5**). For example, 9.3% of intervention caregivers were found to be nonadherent (child not given within 20% of total prescribed doses) compared with 38.0% of control caregivers.

COMMENT

Although vigilance in the calculation of weight-based medication doses is considered to be a routine part of pe-

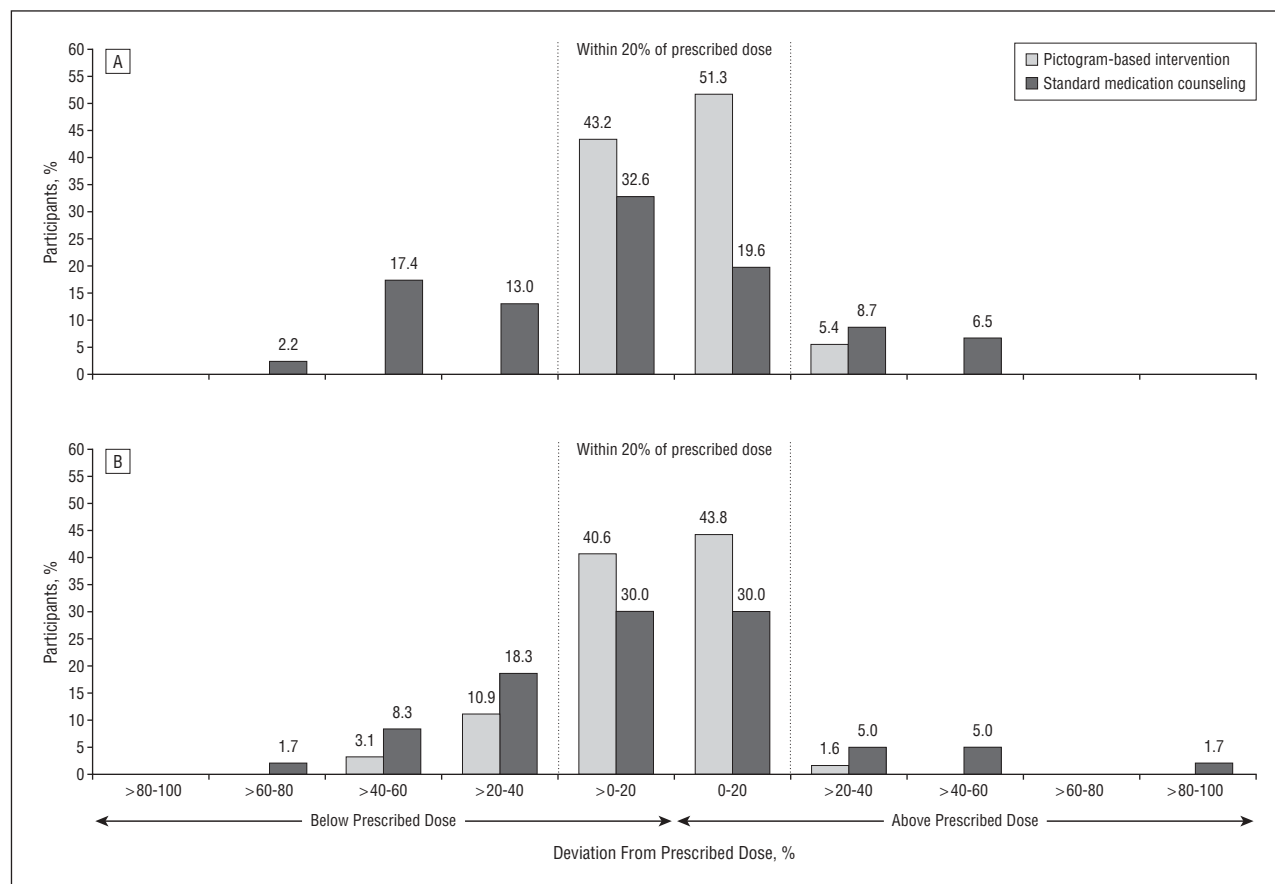


Figure 2. Observed dosing accuracy among caregivers whose children were prescribed daily dose (A) and as-needed (B) medications. Among those who were prescribed as-needed medications (B), 3 individuals who received standard medication counseling were excluded owing to a mismatch in the concentration of acetaminophen prescribed vs that given (infant drops vs children's concentration).

Table 4. Medication Dosing Accuracy: Error Rates^a

	Pictogram-Based Intervention	Standard Medication Counseling	RR (95% CI)	RRR (95% CI), %	ARR (95% CI), %	NNT (95% CI)	P Value ^b
Daily Dose Medication							
Reported dose, No.	46	53
>20% Above/below	0	13 (24.5)	0 ^c	100 (49.8-153.2)	24.5 (12.2-37.6)	4 (3-8)	<.001
>40% Above/below	0	11 (20.8)	0 ^c	100 (43.8-161.2)	20.8 (9.1-33.5)	5 (3-11)	.001
Observed dose, ^d No.	37	46
>20% Above/below	2 (5.4)	22 (47.8)	0.1 (0.03-0.4)	88.7 (50.2-119.2)	42.4 (24.0-57.0)	2 (2-4)	<.001
>40% Above/below	0	12 (26.1)	0 ^c	100 (46.0-154.3)	26.1 (12.0-40.3)	4 (2-8)	<.001
As-Needed Medication^e							
Reported dose, No.	79	76
>20% Above/below	5 (6.3)	24 (31.6)	0.2 (0.1-0.5)	80.0 (41.7-117.0)	25.3 (13.2-36.9)	4 (3-8)	<.001
>40% Above/below	3 (3.8)	15 (19.7)	0.2 (0.1-0.6)	80.8 (29.9-134.5)	15.9 (5.9-26.5)	6 (4-17)	.002
Observed dose, ^f No.	64	60
>20% Above/below	10 (15.6)	24 (40.0)	0.4 (0.2-0.7)	60.9 (21.6-96.9)	24.4 (8.7-38.8)	4 (3-12)	.003
>40% Above/below	2 (3.1)	10 (16.7)	0.2 (0.04-0.8)	81.3 (17.9-151.8)	13.5 (3.0-25.1)	7 (4-33)	.003

Abbreviations: ARR, absolute risk reduction; CI, confidence interval; NNT, number needed to treat; RR, relative risk; RRR, relative risk reduction; ellipses, not applicable.

^aData are given as the number (percentage) of subjects who made an error in dosing accuracy unless otherwise indicated.

^bP < .05 indicates statistical significance.

^cA 95% CI was not calculated because the RR is equal to 0.

^dObserved dosing accuracy was not assessed for 16 subjects.

^eThree control subjects were excluded owing to mismatch in concentration of acetaminophen prescribed vs given (infant drops vs children's concentration).

^fObserved dosing accuracy was not assessed for 31 subjects.

diatric medicine, there has been limited focus on prevention of medication administration errors made by parents and caregivers of young children. In a randomized

controlled trial, we found that a pictogram-based intervention significantly improved caregiver accuracy and adherence in administering liquid medications. Other ef-

Table 5. Medication Nonadherence Rates^a

Category of Adherence	Pictogram-Based Intervention	Standard Medication Counseling	RR (95% CI)	RRR (95% CI), %	ARR (95% CI), %	NNT (95% CI)	P Value ^b
No. of subjects	43	50					
% Deviation above or below total doses prescribed							
>20	4 (9.3)	19 (38.0)	0.2 (0.1-0.7)	75.5 (30.1-114.9)	28.7 (11.4-43.7)	3 (2-9)	.002
>40	0	10 (20.0)	0 ^c	100.0 (40.0-165.2)	20.0 (8.0-33.0)	5 (3-12)	.002
Last dose of medication administered							
Incorrect last day	12 (27.9)	29 (58.0)	0.5 (0.3-0.8)	51.9 (17.1-80.9)	30.1 (9.9-46.9)	3 (2-10)	.006
>1 d Before or after correct last day	2 (4.7)	15 (30.0)	0.2 (0.04-0.6)	84.5 (33.4-131.7)	25.4 (10.0-39.5)	4 (3-10)	.002

Abbreviations: ARR, absolute risk reduction; CI, confidence interval; NNT, number needed to treat; RR, relative risk; RRR, relative risk reduction.

^aData are presented as the number (percentage) of subjects making an error in adherence unless otherwise indicated. Data are missing for 6 subjects (3 from the intervention group and 3 from the control group): 2 were unable to report the end date, 3 were told to stop administering the medication by their physician, and 1 could not be reached for final telephone follow-up.

^bP < .05 indicates statistical significance.

^cA 95% CI was not calculated because the RR is equal to 0.

fects were also seen, including enhanced knowledge of dosing frequency for daily dose medications and improved medication preparation practices. The low resource requirements for this intervention, along with a large reduction in risk and a small number needed to treat, support its potential utility in clinical practice.

Two aspects related to research methods specifically support the validity of our results. First, we used different types of assessments, including parent report and observation, each of which yielded consistent findings. Second, we used multiple cutoff points as criteria for dosing accuracy and nonadherence, which also yielded consistent results. We note that there are no standard criteria for acceptable accuracy of dosing or nonadherence, with examples in the literature of 0.2 mL up to 20% deviation from the recommended or prescribed doses^{8,9} and 0% to 30% deviation from the prescribed number of doses for nonadherence.^{3,14,16,54,57,59,60}

Our findings are consistent with existing data regarding the use of pictorial illustrations and medication instructions.^{25,29,30,33} Pictorial illustrations have been found to reinforce and draw attention to written information^{26-30,61-63} and are particularly helpful for patients with low literacy.³⁴⁻³⁷ Few studies have assessed pictorial illustrations and medication administration for pediatric medications, although 1 study found improved maternal knowledge of oral rehydration therapy when pictorial-enhanced materials were used.⁶⁴

There are limitations to our study. We were unable to maintain blinding, in part owing to staff limitations but also because families frequently revealed their randomization group during the follow-up assessments, either verbally or when asked to show research assistants what written materials they had used to help them administer the medication. However, surveys used for assessments were highly structured and not likely to be subjective, and interrater reliability was high for observed dosing accuracy. In addition, although the overall rate of follow-up was high (more than 90%), the rate of in-person follow-up was lower. Nonetheless, results of observed dosing accuracy were similar to those of self-reported dosing accuracy. We were also unable to determine the rela-

tive effect of each of the components of the intervention: the pictogram-based sheets, teachback, and provision of the standardized dosing instrument. Although secondary analyses of caregivers in both groups who used standardized dosing instruments suggest that the pictogram-based sheets had an effect greater than that of the dosing instrument alone, additional randomized studies would be needed to fully address this issue. Finally, our results may not be generalizable because this study was performed in an urban pediatric ED that serves a primarily low SES, immigrant, Hispanic population, and only English- and Spanish-speaking caregivers were enrolled. The patients in this sample were at increased risk of medication error, and we do not know whether risk reductions would have been as large in a lower-risk group.

We do not yet know whether this intervention would be more or less effective with different subpopulations of parents, based on risk factors related to medication errors. Future analyses will be performed to compare the efficacy of the intervention by education, health literacy, and SES. In addition, we plan to further assess the intervention with medications used long term as well as with other medication formulations, such as tablets and creams.

In summary, we found that use of a plain language, pictogram-based intervention, which included teachback and provision of standardized dosing instruments, resulted in decreased medication dosing errors and improved medication adherence among caregivers whose children were prescribed liquid medications. This pictogram-based intervention represents a promising innovation with the potential to improve pediatric health and promote patient safety.

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