ARTICLE

Evaluation of a Method to Reduce Over-the-Counter Medication Dosing Error

Karen S. Frush, MD; Xuemei Luo, PhD; Paul Hutchinson, BS; Jennifer N. Higgins, BS

Objectives: To introduce a simple method of dosing over-the-counter medication in a home setting using a color-coding concept and to compare dosing deviation from recommended dosage using the color-coded method with dosing deviation using conventional package labeling.

Design: Randomized controlled clinical trial.

Setting: Pediatric emergency center at a tertiary care medical center.

Participants: A sample of 101 caregivers of children with nonemergent complaints separated into 2 groups. One group used a conventional dosing method and the other group used a color-coded method to determine and measure a dose of acetaminophen for their child.

Main Outcome Measures: For both dose determination and dose measuring, percentage of deviation from recommended acetaminophen dosage was calculated and compared between the 2 groups.

Results: There was no significant difference in sociodemographic characteristics between the 2 groups. However, for dose determination, the average deviation (25.8% vs 1.7%) and median deviation (1% vs 0%) from recommended dosage were both higher for the group using conventional methods compared with the group using the color-coded method. The Wilcoxon rank sum test indicated that the median deviation was significantly different between the 2 groups ($P<.001$). Similar results were obtained for dose measuring. The average deviation (29% vs 0.5%) and the median deviation (17.2% vs 0%) from recommended dosage were higher for the group using conventional methods compared with the group using the color-coded method. The median deviation was also significantly different between the 2 groups ($P<.001$).

Conclusion: This study suggests a marked improvement in caregivers' ability to correctly determine and measure an over-the-counter medication for their child using a color-coded method compared with conventional methods.

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From the Division of Emergency Medicine (Dr Frush) and Center for Clinical Effectiveness (Dr Luo), Department of Surgery, Duke University Medical Center, Durham, NC, and Georgetown School of Medicine (Mr Hutchinson) and The Advisory Board Company (Ms Higgins), Washington, DC.

THE INSTITUTE OF MEDICINE reported in November 1999 that between 44 000 and 989 000 Americans die each year as a result of medical errors.[1] A large percentage of medical errors were directly related to adverse drug events,[2,3] and most of the adverse drug events were attributable to incorrect medication dosing.[4-6] Many studies have been published describing efforts to reduce medication dosing error in the hospital setting. Initiatives such as computerized physician order entry and decision support systems have led to substantial error reduction.[7,8] The participation of a pharmacist as a member of a clinical care team has also resulted in decreased medication dosing errors.[9] Review of the literature, however, reveals little information about strategies to reduce medication dosing error in the home setting, even though lay public medication dosing errors are known to occur. Several authors have examined the dosing of acetaminophen, an over-the-counter (OTC) medication that has been widely used in the home setting. Acetaminophen dosing by parents has been shown to be inaccurate up to 73% of the time, causing ineffective fever control and increased emergency department (ED) visits in two thirds of cases.[10] Even when parents were given access to appropriate dosing information along with their child's weight, a correct dose was given only 40% of the time.[11]

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The causes of dosing error in the home setting are complex and multifactorial, including a lack of adequate dosing instructions and use of inconsistent measuring devices.[12] One recent study,[13] however, demonstrated an improvement

in parental dosing when caregivers received a syringe with a line marked at the correct dose, in addition to written instructions and a demonstration. One hundred percent of parents who were educated in this way were able to give a correct dose of liquid medicine. Unfortunately, the hectic setting of an ED or outpatient clinic often precludes such time-consuming education for each patient and family.

Recently, a color-coded method was shown to reduce pediatric dosing error by health care practitioners in simulated pediatric stabilization events. A crossover trial[14] examined various aspects of provider performance with and without the use of the Broselow Emergency Tape, a length-based tool that subdivides pediatric patients into colored zones for equipment selection and into estimated body weight zones for medication dosing. Dosing error was measured as the percentage of deviation from reference ranges. Data analysis demonstrated a significant decrease in medication dosing error when participants used the color-coding method compared with when it was not used.[14] In another study,[15] the same color-coded zones were applied to computed tomography in the pediatric radiology setting. Researchers compared conventional pediatric computed tomography methods with the color-coded method and found the color-coded method was associated with a significantly lower error rate in individual parameters affecting radiation dose. These studies suggest that the concept of color-coded dosing zones has the potential to standardize medication dosage and enhance error detection and reduction.

In this study, we introduce a simple method that uses color-coded information and a corresponding color-coded measuring device to help caregivers determine and measure a dose of acetaminophen. We compare caregivers' dosing determination and measuring when using this color-coded method with conventional methods. We hypothesize that the color-coded method decreases the deviation from the recommended dosage for both dosing determination and measuring.

METHODS

STUDY PARTICIPANTS

This study was undertaken in the pediatric ED of a tertiary care medical center with approximately 65 000 total ED visits and 15 000 pediatric ED visits per year. Parents and caregivers of children aged 3 months to 12 years who were evaluated in the ED with nonemergent complaints were included, whereas those with emergent complaints were excluded from the study to prevent delay in care. All eligible caregivers were approached during study periods, which occurred in daytime and evening hours. There was no additional selection process. A total of 102 caregivers were enrolled between December 15, 2002, and March 1, 2003. All caregivers who were asked agreed to participate, and no one withdrew from the study. One caregiver had missing data and was excluded from the study.

DETERMINATION OF SAMPLE SIZE

Sample size for this study was determined based on a pilot study. During the pilot study, a total of 50 participants were recruited. They were randomly assigned to either a group using the color-coded method or a group using conventional methods by alternating assignment. For both dose determination and measuring, significant difference in dosing deviation was observed between the 2 groups. Based on these results, a total of 100 study participants being equally divided into 2 groups should provide sufficient power to detect a significant difference between the 2 groups.

STUDY DESIGN

This was a randomized controlled clinical trial. Caregivers were randomly assigned to the color-coded or conventional group by alternating assignment. The conventional group was instructed to use a conventional dosing method to determine (state) and measure a dose of acetaminophen for their child, whereas the color-coded group was instructed to use a color-coded method.

DATA COLLECTION

After receiving approval from the institutional review board (3977-02-7ROER), informed consent was obtained, and a questionnaire was verbally administered to each caregiver by research assistants or an interpreter if necessary. The questionnaire contained questions about the caregiver's relation to the child, age, race, and education.

After the questionnaire was completed, the researchers asked caregivers to determine (state) and measure (demonstrate) a dose of acetaminophen for their child. They were told they would not administer any medication to the child during this study scenario. For the conventional group, 2 formulations of acetaminophen were available (infant's, 80 mg/0.8 mL, and children's, 160 mg/5 mL); the box and all package inserts were also available. These formulations represent commercially available OTC medications for children. Measuring devices made available to caregivers included the devices enclosed in the OTC package and other devices believed to be available in a home setting: a plastic spoon, tableware spoon, a set of measuring spoons, a calibrated "medication spoon," and a 5-mL syringe. Caregivers were asked to state a dose for their child and then measure it, using a measuring device of their choice. The child's weight (obtained at triage) was verbally reviewed with the caregiver before determining the dose. No further discussion occurred unless initiated by the caregiver. No information regarding recommended dose was given. The intended dose stated by the caregiver was recorded and later converted to the corresponding number of milliliters and milligrams. For example, if a parent said, "1 teaspoon," this was recorded and later converted to the corresponding number of milliliters (5 mL) and milligrams (160 mg). The actual dose measured by the caregiver was observed and recorded in milliliters. No medication was administered to any child.

For the color-coded group, caregivers were given a color chart, with written, self-explanatory materials, to identify their child's color and a syringe marked with color lines. The color chart is available on request. The syringe was marked in a manner where the color corresponded to the appropriate dose of acetaminophen for that color zone. Further instructions indicated that the color-coded syringe could only be used with the formulation of medicine showing the color-coded dosing method on its label. The children's formulation (160 mg/5 mL) was indicated as the color-coded formulation, whereas the infant's formulation (80 mg/0.8 mL) was not color coded. The syringe was a standard 20-mL oral syringe with 8 marks added in the following sequence: pink, red, purple, yellow, white, blue, orange, and green. Caregivers were asked to state a dose for their child and then measure it, using the color-coded syringe. The

Table 1. Individual Characteristics of Caregivers in the Conventional and Color-Coded Groups

Characteristics	Conventional (n = 50)	Color Coded (n = 51)	*P* Value*
Caregiver's age, mean (SD), y	31.2 (7.5)	30.8 (10.1)	.83
Caregiver's relation to child, No. (%)			
Mother	42 (84)	37 (73)	.36
Father	5 (10)	11 (22)	
Grandmother	2 (4)	1 (2)	
Grandfather	0	0	
Other	1 (2)	2 (4)	
Caregiver's race, No. (%)			
Asian	0	3 (6)	.16
Black	26 (52)	22 (43)	
Hispanic/Latino	9 (18)	4 (8)	
White	14 (28)	21 (41)	
Other	1 (2)	1 (2)	
Caregiver's education, No. (%)			
High school or less	37 (74)	29 (57)	.07
College or greater	13 (26)	22 (43)	

*The 2-sample test was used for the comparison of continuous data. The χ^2 test was used for the comparison of categorical data.

Table 2. Deviation From Recommended Dose Range for Dose Determination in the Conventional and Color-Coded Groups

Dose Determination	Conventional (n = 50)	Color Coded (n = 50)*
Magnitude of dose determining error, % (95% CI)		
Mean dosing deviation	25.8 (4 to 48)	1.7 (–1.4 to 4.8)
Median dosing deviation	1 (0 to 14.7)	0
Direction of dose determining error, % (95% CI)		
Subjects underdosed	20 (9 to 32)	2 (–2 to 6)
Subjects correctly dosed	50 (36 to 64)	92 (85 to 100)
Subjects overdosed	30 (17 to 43)	6 (0 to 13)
Cases with serious dose determining error, %		
Subjects with >2 times the recommended dose	6	0
Maximum dosing deviation	520	77

Abbreviation: CI, confidence interval.
*The number for this group is 50, not 51, due to missing information for 1 study subject.

intended dose stated by the caregiver was recorded and later converted to the corresponding number of milliliters and milligrams. For example, if a parent stated, "red," this was recorded and later converted to the corresponding number of milliliters (3.5 mL) and milligrams (112 mg). The actual dose measured by the caregiver was observed by a researcher and recorded in milliliters. No medication was administered to any child.

DATA ANALYSIS

We chose a recommended dosing range of 10 to 15 mg/kg based on current literature and pharmaceutical manufacturers' recommendations.[16] Dosing deviation from recommended dosage range was calculated as the absolute value of percentage deviation from the recommended dosage range.[14] Based on our calculation, if a participant determined the dose incorrectly but correctly measured this dose, dosing deviation for the measuring was regarded as 0. For both dose determinations and dose measuring, the average, median, and maximum deviations were calculated for each group. Since the dosing deviation scores were not in normal distribution, the Wilcoxon rank sum test was used to compare whether the median deviation was significantly different between the group using the color-coded method and the group using conventional methods. In addition to these statistics, we described 4 dosing categories and calculated the percentage of participants who (1) dosed correctly, (2) underdosed, (3) overdosed, and (4) overdosed using more than 2 times the recommended dose.

RESULTS

INDIVIDUAL CHARACTERISTICS BETWEEN THE 2 GROUPS

No significant difference in individual characteristics of caregivers was observed between the group using the color-coded method and the group using conventional methods (**Table 1**). For both groups, the average caregivers' age was approximately 31 years. Most caregivers described themselves as the "child's mother." A large proportion of caregivers were either African American or white. Less than half of them received college or postgraduate education (Table 1).

DOSING DEVIATION BETWEEN THE 2 GROUPS

Table 2 gives the comparison of deviation from recommended dosage range for dose determination. The average deviation was higher for the group using conventional methods compared with the group using the color-coded method (25.8% vs 1.7%). Median dosing deviation was also higher for the conventional group compared with the color-coded group (1% vs 0%), as was maximum dosing deviation (520% vs 77%). The conventional group also had a higher percentage of participants overdosed (30% vs 6%), a higher percentage of participants underdosed (20% vs 2%), and a higher percentage of participants with more than 2 times the recommended dose (6% vs 0) than the color-coded group. Finally, the Wilcoxon rank sum test indicated that the median dosing deviation was significantly higher for the conventional group compared with the color-coded group ($P<.001$).

Similar results were observed for dose measuring (**Table 3**). The group using conventional methods had a higher average dosing deviation (29% vs 0.5%) and higher median dosing deviation (17.2% vs 0%) from the recommended dosage range than the group using the color-coded method. The maximum dosing deviation was also higher for the conventional group compared with the color-coded group (520% vs 23.4%), as was the percentage of participants overdosed (38% vs 0%), percentage of participants underdosed (34% vs 2%), and percentage of participants with more than 2 times the recommended dose (4% vs 0%). The Wilcoxon rank sum test demonstrated that the median dosing deviation was significantly higher for the conventional group compared with the color-coded group ($P<.001$).

COMMENT

The results of our study suggest that a color-coded, zone-dosing concept, which has been shown to reduce medication dosing error in the hospital setting,[14,15] may be helpful in reducing dosing error of OTC medications in the home setting. Color-coded dosing information can easily be given to families of children at the time of discharge, and the information could simplify and standardize dosing by parents and caregivers. The color-coded method is easy to use and, as indicated by caregivers' comments, many felt more confident they could give an appropriate dose to their child when using color-coded materials.

Our results are consistent with previous studies that demonstrate inaccurate dosing of OTC medications by caregivers using conventional dosing methods. Few of these studies, however, suggest strategies to improve dosing accuracy. Our results indicate that a color-coded method could improve accuracy in determining and measuring OTC medication by caregivers. In our study, for both dose determination and measuring, the average, median, and maximum deviations and the percentage of participants underdosed, overdosed, or overdosed with more than 2 times the recommended dose were greater for the group using the conventional dosing methods compared with the group using the color-coded method. For dose determination, the median deviation between the 2 groups, although statistically significant ($P<.001$), seemed to be small (1% vs 0%) and may not be clinically significant. However, the difference in average deviation (25.8% vs 1.8%), maximum deviation (520% vs 77%), percentage of participants overdosed (30% vs 6%), and percentage of participants underdosed (20% vs 2%) between the 2 groups were not small, even from a clinical perspective.

In closely examining the cases with serious dosing error, we found that the maximum dosing deviation for both dose determination and dose measuring in the conventional group was 520%, and 4% to 6% of participants determined or measured more than 2 times the recommended dose of the medication. In contrast, the maximum dosing deviation was only 77% for dose determination and 23% for dose measuring in the color-coded group. No participant in this group determined or measured more than 2 times the recommended dose of the medication. A more detailed analysis of the maximum dosing deviation observed in the conventional group indicated an overdose of the medication (data not shown). Administration of a dose 5 times higher than the recommended dosage may lead to serious toxic or even lethal effects. Although these are rare cases, they may indicate potential problems in medication dosing associated with the conventional dosing methods.

We did not detect a significant difference in caregivers' individual characteristics between the color-coded and conventional groups. However, the educational level of the color-coded group seemed to be higher. To be sure that the lower dosing deviation observed in the color-coded group was not due to the higher educational level, we stratified the participants by the educational level and further compared within each stratum the dosing deviation between the 2 groups. For dose measuring, both educational groups demonstrated a significantly lower dosing deviation in the color-coded group compared with the conventional group (data not shown). Similar results were observed for dosing determination, except that the difference in dosing deviation between the color-coded and conventional groups was only marginally significant for participants with higher levels of education (data not shown). Our results suggest that higher education was not likely contributing to the lower dosing error in the color-coded group.

Table 3. Deviation From Recommended Dose Range for Dose Measuring in the Conventional and Color-Coded Groups

Dose Measuring	Conventional (n = 50)	Color Coded (n = 51)
Magnitude of dose measuring error, % (95% CI)		
Mean dosing deviation	29 (7.8 to 50.3)	0.5 (–0.5 to 1.4)
Median dosing deviation	17.2 (10.4 to 23.1)	0
Direction of dose measuring error, % (95% CI)		
Subjects underdosed	34 (20 to 48)	2 (–2 to 6)
Subjects correctly dosed	28 (15 to 41)	98 (94 to 102)
Subjects overdosed	38 (24 to 52)	0
Cases with serious dose measuring error, %		
Subjects with >2 times the recommended dose	4	0
Maximum dosing deviation	520	23.4

Abbreviation: CI, confidence interval.

Although the concept of color coding in the home setting seems logical, there have been no such applications by drug manufacturers, and no previous studies, to our knowledge, to evaluate this method. We postulate that this may be due to 3 major constraints of the color-coded method. First, the method cannot be used by color-blind individuals. Second, the color syringe would have to be directly correlated to a specific formulation of medicine (ie, children's acetaminophen, 160 g/5 mL). Use of the syringe with a different formulation (ie, infant acetaminophen, 80 mg/0.8 mL) would cause a dosing error. Use of a color-coded syringe, then, would require changes in the current manufacturing methods for OTC medicines, such as standardization of formulations. This concept would have to be further explored with manufacturers, and perhaps a cost-effectiveness analysis may be helpful. Third, the color zones of the Broselow Emergency Tape were used to determine dosing in this study, since no other color-coded dosing zones are known to the authors. One must consider whether the 8 color zones suggested by the tape are appropriate for home dosing or if this is an excessive number. If the goal is to standardize and simplify home dosing, perhaps a less complex zoning system, one that has fewer dosing zones, should be considered.

This study has several limitations. First, the study was conducted in a single medical center. The study results, therefore, may not be generalized to other medical centers or community hospitals. Second, we re-

What This Study Adds

Since the Institute of Medicine report was released in November 2000, medical practitioners and researchers have been working to develop new strategies and systems to reduce medication dosing errors. Several systems have been shown to be effective in reducing dosing error in the hospital setting, but few studies have described effective strategies to reduce dosing error in the home setting. This study describes an application of a color-coded concept to the home setting and suggests that this method may be effective in reducing medical error across the continuum of care.

cruited a relatively small number of study participants. The decision to not include more participants was based on our pilot data. The pilot study suggested that a sample size of 100 should give us enough power to detect significant results. Indeed, with this number of study participants, we found significant difference in dosing deviation for both dose determination and dose measuring between the 2 groups. The number of participants being recruited seems to be sufficient for this study. Finally, the researcher who collected data from study participants was not blinded to the participant group assignment. Blinding was not possible, since the researcher had to know the group assignment to instruct participants on dose determination and measuring.

This study demonstrates marked improvement in dosing accuracy by caregivers using color-coded instructions compared with contemporary (conventional) OTC dosing methods. These results are consistent with other recent studies that indicate a reduction in medical error through use of a color-coded method in pediatric health care. Further studies need to be performed to confirm our findings and to evaluate other methods to reduce medication dosing error by caregivers in the home setting.

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Correspondence: Karen S. Frush, MD, Duke University Medical Center, Box 3055, Durham, NC 27710 (k.frush@duke.edu).

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