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Does a Color-Coded Method for Measuring Acetaminophen Doses Reduce the Likelihood of Dosing Error?

THE CLINICAL TRIAL DESCRIBED BY FRUSH ET AL[1] was conducted to assess whether a new color-coding method for measuring acetaminophen doses reduces medication-dosing errors. The study enrolled parents of children aged 3 months to 12 years who were seen for nonemergent care visits in the pediatric emergency department of a tertiary care center. One hundred one parents were assigned to either a color-coded dosing group or a conventional dosing group. Parents assigned to the color-coded group (n=51) used a color-coded scheme to determine the correct dose of acetaminophen, based on standard recommendations. They were given a color chart with written instructions to determine the appropriate dosing color for their child based on the child's weight, as well as a syringe marked with matching color lines. Parents of children in the conventional dosing group (n=50) were able to choose from several options of standard home-dosing methods (spoons, droppers, etc). Both groups of parents were asked first to state what amount of medication they would give their child and then to demonstrate the amount they would administer. No medication was actually given to the children. The deviation between the stated and demonstrated doses and a recommended dosing range (based on weight of the child) were determined. The investigators found that the parents who used the new color-coded method had significantly less deviation from the recommended dosing range as compared with those who used the conventional method. The authors concluded that a color-coded method of measuring over-the-counter medications could markedly improve caregivers' ability to correctly determine and measure medication doses.

We have evaluated this study according to the guidelines put forth in the *Users' Guide to the Medical Literature*.[2] We review the validity of results, the size and precision of the treatment effect, and the generalizability and applicability of outcomes.

RANDOMIZATION OF SUBJECTS

In regard to subject randomization, the following questions were posed. (1) Were patients randomized? (2) Were patients analyzed in the original groups to which they were allocated? and (3) Were patients in the conventional group similar to those in the color-coded group at baseline with respect to prognostic variables?

Caregivers were randomly assigned to the color-coded or conventional groups by alternating assignment. Although this was not explicitly stated, we assume that with alternating assignment, the subject's group allocation was determined simply by alternating assignments between treatment group (color-coded group) and control group (conventional group) for subsequent subjects. This method of alternating assignment raises concern for potential bias because 1 of the fundamental principles of randomization requires an inability to predict the next assignment.[3,4] In this study, the enroller can determine the subject's assignment simply by knowing the

See also page 620

assignment of the prior subject; thus, the decision to enter a participant into the trial could be influenced by his or her anticipated treatment assignment. We assume that all subjects were analyzed within their originally assigned group. The participants in the 2 groups were similar at baseline for some measures, but there was a trend for the participants in the color-coded group to have higher educational levels than those in the conventional group ($P=.07$). To be sure that the lower-dosing deviation in the color-coded group was not because of the higher educational level in this group, the authors appropriately performed a stratified analysis by educational level, and their findings were unchanged. However, the authors did not include a comparison of the distribution of the children's ages in the 2 groups at baseline. This is an important variable to consider because the range of appropriate medication dose is wider for older children.

BLINDED ASSIGNMENT

In regard to blinded assignment of participants, the following questions were posed. (1) Were patients blinded to the study hypothesis and group allocation? (2) Were outcome assessors blinded to group allocation?

No statement was made about participant knowledge of the study hypothesis. This study did not have the potential for participant blinding of group allocation. It is possible that parents using the new color-coded method would be more meticulous in their measuring than those using the conventional method. In addition, the researcher collecting the data was not blinded. This could lead to observer bias when assessing outcomes because un-

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blinded study personnel who are collecting data may provide different interpretations of outcome variables.[3,4]

WERE THE GROUPS TREATED EQUALLY?

To accurately assess the effectiveness of an intervention, participants in the treatment and control groups should be treated equally in all respects except for the intervention being tested. In this study, there were some differences between the conventional group and the color-coded group in addition to the color-coding intervention. First, participants in the color-coded group were presented with both the children's formulation of acetaminophen and the infant's formulation, but only the children's formulation was color coded, and only the color-coded syringe corresponding to the children's formulation was offered. Although this was not explicitly stated, we assume that, because only the color-coded syringe was offered, the parents of young infants in this group were directed to use the children's formulation. In contrast, in the conventional group, both the infant's and children's formulations of acetaminophen were offered, and the decision to use either formulation was based solely on the parent's choice. Since the dosing of the children's and infant's formulations differs substantially, the comparisons between the groups may be biased.

Second, because the research personnel were not blinded, the instructions and/or encouragement given to the subjects may have been different between the 2 groups. Third, the conventional children's acetaminophen package offers 5 choices of doses based on both the child's age and the child's weight, whereas the color-coded syringe was labeled with 8 colors presumably corresponding only to the child's weight.

MAGNITUDE OF TREATMENT EFFECT AND CLINICALLY IMPORTANT OUTCOMES

The study found a significantly higher dosing deviation (for both determination and measuring) for the conventional group as compared with the color-coded group. The mean deviation from recommended dosing range for dose determination was higher for the group using conventional methods as compared with the group using the color-coded method (25.8% vs 1.7%). Similarly, the mean deviation from recommended dosage for dose measuring was 29% for the conventional group compared with 0.5% for the color-coded group. Although these differences seem substantial, the clinical significance of this amount of error is not clear. The meaningful parameters are the number of subjects who measure an overdose of medication greater than 2 times the recommended dose of medication and the number of subjects who measure an underdose of medication. Thirty percent of conventional determinations and 38% of conventional measurements were overdoses compared with 6% of color-coded determinations and none of the color-coded measurements. These errors in dosing seen in the conventional group could lead to toxic side effects, particularly if multiple incorrect doses of medication were administered. In addition, 6% of subjects in the conventional group determined a dose that was greater than 2 times the recommended dose of acetaminophen, and 4% of caregivers in the conventional group actually measured a dose this high. In contrast, for both determination and measuring, no caregiver would have given more than 2 times the recommended dose with the color-coded method. This is clinically meaningful because it shows that there are fewer serious errors and thus less risk of toxic overdoses when the colored-coded method was used.

Underdosing, while not dangerous in itself, carries with it the risk of greater parental anxiety related to high fever, more emergency department visits for fever, and greater patient discomfort from fever. There were dramatic differences in the 2 arms of the study, with 20% and 34% (determination and measurement) of the conventional group underdosing and only 2% (for both determination and measurement) of the color-coded group underdosing. This suggests that color-coding could potentially prevent unnecessary office or emergency visits for fever.

PRECISION OF THE TREATMENT EFFECT

The 95% confidence intervals for the conventional group are wide for both determination and measurement values. This implies that there is significant variation and less precision in the subjects' responses compared with the more narrow confidence intervals for subjects in the color-coded group. Thus, the color-coded method may enhance consistency in dosing measurements.

GENERALIZABILITY

The study population included patients seen in a tertiary-care center emergency department for nonemergent problems. Therefore, their behavior may not be generalizable to all parents. A previous study showed that mothers with less than a high school education were more likely to use the emergency department as their usual source for sick care.[5] These parents may have greater difficulty with conventional method instructions for medication dosing, and a simple color-coded method of dose determination may be more helpful for these individuals as compared with other parents. Further, because the study took place in an emergency department setting, it is not clear whether the intervention would have the same impact in a home setting (the intervention was tested in an emergency department setting but was intended for home use). Importantly, the children in this study were weighed and the parents were informed of their child's weight to guide their medication dosing decisions. However, many parents at home would not have accurate knowledge of their child's current weight. Lastly, dosing of over-the-counter medications varies substantially by the child's age. While we know the age range of the children included, we do not know the mean age of the children or the distribution of children in different age categories. If the majority of children were in the older or younger age categories, the intervention effects may not be generalizable for children of other ages.

CONCLUSION

Despite the limitations in the design of this study, the results are promising. Using a simple color-coded sy-

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ringe with instructions for measuring acetaminophen doses made it less likely for parents to underdose and overdose their child with the medicine. Because acetaminophen is the most widely used nonprescription medication for children,[6] changing the dosing mechanism for this product likely would have a large impact. Randomized trials are needed in other settings to determine if the findings from this analysis hold true.

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Announcement

Notice of Duplicate Publication

In June 2003, we published an article titled "Health Consequences for Children With Undiagnosed Asthma-like Symptoms" (Yeatts K, Shy C, Sotir M, Music S, Herget C. *Arch Pediatr Adolesc Med.* 2003;157:540-544). We subsequently learned of another article, "Health Consequences Associated With Frequent Wheezing in Adolescents Without Asthma Diagnosis," published by 2 of the same authors in another journal (Yeatts K, Johnston Davis K, Peden D, Shy C. *Eur Respir J.* 2003;22:781-786). The National Library of Medicine has decided that these 2 articles represent duplicate publication and they have been labeled as such in MEDLINE.

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