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

The clinical trial described by Frush et al. 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. 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 one of the fundamental principles of randomization requires an inability to predict the next assignment. In this study, the enroller can determine the subject’s assignment simply by knowing the 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-
blinded study personnel who are collecting data may pro-
vide different interpretations of outcome variables.3,4

WERE THE GROUPS TREATED EQUALLY?
To accurately assess the effectiveness of an inter-
vention, 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 interven-
tion. First, participants in the color-coded group were
presented with both the children's formulation of acet-
aminophen and the infant's formulation, but only the chil-
dren'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 chil-
dren'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 com-
parisons 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 pack-
age offers 5 choices of doses based on both the child's
age and the child's weight, whereas the color-coded sy-
ringe was labeled with 8 colors presumably correspond-
ing 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 de-
termination 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 de-
viation 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 sub-
tantial, 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 medi-
cation. Thirty percent of conventional determinations and
38% of conventional measurements were overdoses com-
pared 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 conven-
tional group determined a dose that was greater than 2 times
the recommended dose of acetaminophen, and 4% of care-
givers in the conventional group actually measured a dose
this high. In contrast, for both determination and measur-
ing, 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 color-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 dra-
matic differences in the 2 arms of the study, with 20% and
34% (determination and measurement) of the conven-
tional group underdosing and only 2% (for both de-
termination and measurement) of the color-coded group
underdosing. This suggests that color-coding could po-
tentially 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 val-
ues. 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 prob-
lems. 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 con-
ventional 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 emer-
gency department setting, it is not clear whether the inter-
vention would have the same impact in a home setting (the
intervention was tested in an emergency department set-
ting but was intended for home use). Importantly, the chil-
dren in this study were weighed and the parents were in-
formed 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 sub-
stantially 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-
ring with instructions for measuring acetaminophen
doses made it less likely for parents to underdose and over-
dose their child with the medicine. Because acetamino-
phen is the most widely used nonprescription medica-
tion for children, changing the dosing mechanism for
this product likely would have a large impact. Random-
ized 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 an-
other article, “Health Consequences Associated With Fre-
cent Wheezing in Adolescents Without Asthma Dia-
gnosis,” 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 Medi-
cine has decided that these 2 articles represent dupli-
cate publication and they have been labeled as such in
MEDLINE.