Assessing the Understanding of Pediatric-Oriented Medication Education Materials Versus Standard Available Education Materials

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OBJECTIVES The objective of this study was to determine if education material targeting children would improve understanding of medication indication, administration, and common side effects in pediatric subjects.

METHODS This cross-sectional pilot study included students 7 to 11 years old from a suburban elementary school. Study participants were read either the US Food and Drug Administration–approved adult medication leaflet or a pediatric medication leaflet created at a first-grade reading level for levetiracetam (Keppra, UCB, Inc, Atlanta, GA). Students were asked a set of standardized survey questions to evaluate comprehension of side effects, medication indication, dosing frequency, administration, and overall impression of the leaflet.

RESULTS Fifty-eight children were included. Fifty percent of the children were male, 79% were Caucasian, and the average age was 9 years. There was no statistical difference for demographics in the adult leaflet versus the pediatric leaflet group. Children correctly stated the indication for the medication in 30% of participants (9/30) in the adult leaflet group and 79% of participants (22/28) in the pediatric leaflet group, $p = 0.002$. The administration frequency question was answered correctly in 93% of the pediatric leaflet group (26/28) as compared to 73% in the adult leaflet group (22/30), $p = 0.05$. For questions about side effects and how to administer the medication, there was no difference between the groups. The responses regarding readability and understanding of the leaflets were significantly different in the pediatric leaflet group compared to the adult leaflet group, $p = 0.001$ and $p \leq 0.001$, respectively.

CONCLUSIONS Leaflets designed for pediatric patients resulted in an improvement in the understanding of the indication for levetiracetam.

ABBREVIATIONS FDA, United States Food and Drug Administration

KEYWORDS education; health literacy; pediatrics

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Introduction

It is widely recognized that patient understanding is essential for the optimal management of health and medications.¹ Health literacy is defined by the Institute of Medicine and National Library of Medicine in the United States as the degree to which a patient has the ability to attain and comprehend elementary health information needed to make appropriate health decisions.²

A systematic literature review demonstrated that children with low literacy generally had worse health behaviors.¹ Parents with lower literacy levels had less health knowledge, which led to negative health-related behaviors. Furthermore, children of these parents often had worse health outcomes. In particular, lower literacy has been associated with problems adhering to medical instructions, as well as issues with understanding one's medical conditions and the associated

self-management skills. Results also demonstrated that enhancing written education material, coupled with short counseling sessions, improved health-related behaviors, including adherence.¹

There is a gap in current knowledge pertaining to the appropriate reading level of educational materials provided to patients, especially in the pediatric population. Current medication guides are of little value to adult patients, as they are too complex to understand especially for individuals with limited health literacy.^{3,4} In one study, only 52.7% of adult participants reported correct responses to questions assessing comprehension of medication guides.³ Similarly, another study in adults found that less than 20% of participants were able to correctly identify adverse effects associated with a medication.⁴ Furthermore, there is a lack of literature assessing understanding of available adult-oriented and pediatric-oriented patient education materials

Figure. Levetiracetam (Keppra, UCB, Inc., Atlanta, GA) pediatric leaflet.

among the pediatric population.

The majority of education materials are written for adults; however, there is a portion of the pediatric population who require chronic medications. When appropriate, children may require education on the proper use and potential side effects of their medications. Given literature showing that adult understanding of adult-oriented patient education materials is not optimal, it is reasonable to hypothesize that pediatric understanding of adult-oriented materials will be even lower.

This study aims to determine if education material targeting children will improve understanding of medication indication, dosing frequency, administration, and common side effects in pediatric subjects.

Materials and Methods

This cross-sectional study was approved by the institutional review board at the University of Maryland, Baltimore. Children 7 to 11 years of age from a suburban elementary school were recruited for the study. This age range was chosen to target school-aged children above first grade. Children were excluded if they were non-English speaking, currently taking any seizure medication, returned incomplete data on demographics, or were diagnosed with a developmental disability.

The pediatric leaflet was created by one of the researchers in approximately 2 hours by using Internet resources including the levetiracetam (Keppra, UCB, Inc, Atlanta, GA) product information and the Fry graph of readability (Figure).^{5,6} It was determined to be at a first-grade reading level using the Fry graph of readability. Levetiracetam was chosen as the medication for this study since it is a chronic medication and has a US Food and Drug Administration (FDA)-required medication guide.

Participants were recruited at an elementary school by using a letter sent home to parents asking for consent to have their children participate at the school without parental supervision. The consent form was

filled out by the child's parent/caregiver and returned to the classroom teacher within approximately 1 week. Once these consents were completed, the researchers conducted the study during a visit to the school during school hours. Children were asked if they agreed to participate at this time. Participants were given stickers at the completion of the survey for their participation.

Using a random number generator, participants were randomized to the pediatric medication leaflet group that was written at a first-grade reading level or the adult leaflet group (FDA-approved levetiracetam [Keppra] medication guide) assessed at a 10th-grade reading level. The medication guide totaled 5 pages; however, researchers only read the sections titled "What is KEPPRA?" (first paragraph only), "How should I take KEPPRA?" and "What are the possible side effects of KEPPRA?"⁵ Researchers read each participant the assigned leaflet and asked each participant a set of standardized, open-ended survey questions to evaluate comprehension of medication indication, dosing administration, side effects, and overall impression of the leaflet. Researchers then recorded participants' answers. Each participant was allowed to view the leaflet during questioning. Each survey took about 10 minutes to complete; exact length of time was not recorded. Before collecting data, there was a training session among the researchers to ensure consistency while administering the surveys. The researchers discussed how the survey would be introduced to the participants, how to administer the survey, how to respond to participants' questions, and how to collect data so that this would be done in a similar manner. For the open-ended questions, any correct response was accepted. Survey questions related to indication, administration frequency, side effects, and how to administer were graded as correct or incorrect by at least 2 researchers. If more than 1 side effect was given by the subject, researchers were to evaluate the first answer. The questionnaire is available from the corresponding author (JMB).

Table 1. Demographics

	Adult Leaflet (n = 30)	Pediatric Leaflet (n = 28)	p value
Male, n (%)	17 (56.7)	12 (42.9)	0.3
Race, n (%)			
White	24 (80)	22 (78.6)	0.89
Other	3 (10)	2 (7.1)	
Hispanic	1 (3.3)	1 (3.6)	
Black	2 (6.7)	3 (10.7)	
Age, yr, mean $\pm$ SD	9.1 $\pm$ 1.2	9.3 $\pm$ 1.3	0.63
Health care provider in household; Yes, n (%)	4 (13.3)	7 (25)	0.21
Chronic medications; Yes, n (%)	3 (10)	3 (10.7)	0.63

Demographic data, including sex, race, age in years, health care provider presence in the household, and the use of chronic medications by the child, were collected for each participant from the parent on the written informed consent form. Data were analyzed with Fisher exact test and Mann-Whitney *U* test using VassarStats (www.vassarstats.net). Statistical significance was defined as $p < 0.05$.

Results

Of the 70 children screened, 58 were included (28 in the pediatric leaflet group and 30 in the FDA-approved adult leaflet group). There were 12 children excluded (1 with developmental disability, 8 children denied assent, and 3 with incomplete demographics).

Overall, participants were 50% male, 79% Caucasian, and an average of 9 years of age. Demographics by assigned group are in Table 1. There were no statistical differences between the pediatric leaflet and adult leaflet groups.

Significantly more children in the pediatric leaflet group were able to correctly answer questions regarding the medication indication (79% in pediatric leaflet group vs. 30% in adult leaflet group, $p = 0.002$) with a trend toward significance for frequency of administration (93% in pediatric leaflet group vs. 73% in adult leaflet group, $p = 0.05$). There was no difference for the following questions: name 1 side effect (86% in pediatric leaflet group vs. 87% in adult leaflet group, $p = 0.61$) and describe how to take the medication (93% in pediatric leaflet group vs. 90% in adult leaflet group, $p = 0.53$). There was a significant difference in the participants' perception on the ease (96% in pediatric leaflet group vs. 53% in adult leaflet group, $p = 0.001$) and understanding (93% in pediatric leaflet group vs. 37% in adult leaflet group, $p < 0.001$) of the pediatric leaflets compared to the adult leaflets (Table 2).

Discussion

Evidence suggests that low literacy is associated

with a variety of adverse health behaviors among both parents and children, including the misunderstanding of medication-related instructions.^{1,7} Compounding this issue is the fact that, even though most adults read at an eighth-grade level and 20% of the population reads at or below a fifth-grade level, much of the available health care education material is written at a 10th-grade reading level.⁸ Confusion with medication labeling has been associated with medication-related errors.⁹ Parents may make such errors when administering medications to themselves or their children. In addition, adult-oriented education materials may not highlight the most pertinent information needed for pediatric patients. Whether through inaccurate dosing or non-adherence to medication regimens, these errors have been shown to place the child at risk for morbidity and mortality.^{7,9–15} To avoid such errors and improve medication adherence, experts recommend clinicians communicate directly with children about medication in addition to caregivers.¹⁶ Data suggest that education materials for children and their families should be simple, short, clear and should include pictures.^{15,17,18} Methods geared toward simplifying educational materials for adult caregivers have included color coding and pictograms.^{15,19,20}

The aim of this study was to determine if education material developed for children would help improve understanding of how to take the medication and the associated common side effects. To our knowledge, this is the first study conducted evaluating pediatric knowledge of medications after exposure to pediatric-oriented written education materials. The children provided with the pediatric-oriented leaflet had a better understanding of medication indication and there was a trend toward significance for frequency of administration. There was no difference in the knowledge about side effects or how to take the medication between the 2 groups, despite those groups having a high percentage of correct answers for these 2 questions. The lack of statistical difference could be due to the open-ended questions used in the survey. Children

Table 2. Survey Results

Levetiracetam* Survey Question	Adult Leaflet Correct Answers (n = 30)	Pediatric Leaflet Correct Answers (n = 28)	p value
Indication, n (%)	9 (30)	22 (79)	0.002
Administration frequency, n (%)	22 (73)	26 (93)	0.05
Name 1 side effect, n (%)	26 (87)	24 (86)	0.61
How to take, n (%)	27 (90)	26 (93)	0.53
Easy to read, n (%)	16 (53)	27 (96)	0.001
Easy to understand, n (%)	11 (37)	26 (93)	< 0.001

* Keppra, UCB, Inc, Atlanta, Georgia.

were asked to name only 1 side effect from 13 possible correct answers. For the question regarding how to take the medication, any correct response was accepted including how to measure a dose, the necessity to swallow the medication whole, and the necessity to take the medication with food. Overwhelmingly, study participants thought the pediatric leaflet was easy to read and understand.

Children may be involved in self-care if maturational and cognitive abilities allow.²¹ Children aged 6 years and older are able to differentiate medications by brand names and indication for use, and children as young as 5 years are cognizant of medication side effects.¹⁶ Understanding the indication, administration, dosing frequency, and potential side effects of medications is likely to decrease fears or misinterpretations about taking medications. Improving the ability to communicate directly with children about medications may also empower the child to ask questions and become more involved in the administration of the medication at home. An increase in involvement in personal health care at a young age may result in improved adherence during adolescent years. However, it is still expected that caregivers discuss education materials with the child. Parents and caregivers may find medication leaflets written at a first-grade reading level easier to understand as well. By enhancing health literacy of the child, in conjunction with that of the caregiver, adherence and health outcomes are likely to improve. In cases where children require chronic medication, it may be especially important to support increased self-management when appropriate.²²

This study was limited by a single study site and the requirements for participants to immediately recall information read to them. Furthermore, the study excluded non-English-speaking subjects, subjects who were currently taking any antiepileptic medication, or those with developmental disabilities. Therefore, the results may lack external validity. Another study limitation was that the leaflets were read to the participants, and subjects' baseline literacy was not assessed. Since multiple researchers conducted the surveys, the delivery of information may have differed

from researcher to researcher. The leaflets were read to the participants with the purpose of minimizing the potential confounding effects of varying reading levels. In reality, the children would ideally read the leaflets. Furthermore, additional questions using a Likert-type scale may have validated the dichotomous questions related to readability and understanding. This research also only assessed 1 medication. Last, the information included in the pediatric-oriented leaflet was limited by the goal readability level.

Conclusions

Medication leaflets developed for children are easier for the pediatric population to understand. When medication leaflets are designed for children, there is better recall of the indication for use than with the adult-based leaflets; however, there is no difference in stating side effects or how to administer. Future research should aim for a larger sample size, multiple study sites, and other common medications used in the pediatric population.

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