

Pill Swallowing Ability and Training in Children 6 to 11 Years of Age

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Summary: Despite the widespread view that children have difficulty swallowing pills, data are limited. In an observational cohort study, pill swallowing ability (small oral tablet) was assessed in children age 6 to 11 years. A total of 113 of 124 subjects (91%) swallowed a tablet using an ordinary cup or a patented pill cup. All 57 subjects who initially said they could swallow a pill were capable. Forty-seven learned with an ordinary cup and nine with the pill cup. Eleven did not learn. The majority of children (91%) age 6 to 11 years were able to successfully swallow a small oral tablet. *Clin Pediatr.* 2006;45:725-733

Introduction

There is very limited information on when healthy children can be expected to learn to swallow a pill. This has led parents, with children of different ages, to coax, cajole, and even bribe their children to take their pills. Indeed, parents often resort to creative methods of disguising tablets, including mashing them in soft foods such as apple sauce, bananas, and yogurt, or diluting them in flavored liquids. Such approaches can be antago-

nistic and may ultimately be counterproductive. For example, a child may feel he or she is being "tricked" into doing something they would prefer to avoid. Moreover, some pills are available only in a tablet form that can neither be cut nor crushed, or can only be divided at the expense of losing the full dose.

The ability to swallow a pill is valuable for several reasons. It not only allows access to medications that are available in tablet formulation, but means that those liquid formulations that are unpalat-

able can be avoided, and it further allows ease of portability. Not surprisingly, various suggestions on the best approach to teach children pill swallowing exist. One of the more common behavior modification systems is to practice with increasingly larger pieces of candy. However, despite the abundance of anecdotes from seasoned parents and pediatricians, no prospective studies are available that have assessed the capability of pill swallowing in children. Therefore, research on this normal developmental task is warranted.

The objective of the observational cohort study reported here was to examine the ability of children, age 6 to 11 years, to swallow a small oral tablet. In addition, learning capability and ease of swallowing using an ordinary plastic cup and a special patented pill cup were investigated.

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Methods

Subjects

This prospective observational cohort study (survey study), conducted at a clinical research center in San Diego, CA, enrolled ethnically and socioeconomically diverse pediatric subjects, at least 6 but less than 12 years of age, who were healthy or had dermatologic and/or respiratory diseases. A medical history was obtained from the child's parent/legal guardian. Children and their parent/legal guardian presented at the research center for 1 visit, at any time of the day.

Children were excluded for the following reasons: if they were participating in a clinical research trial with an investigational product or device, if they had a history of significant intellectual impairment, or a history of swallowing difficulty, choking, or an anatomical malformation in the head and neck area.

The study was conducted after approval by an institutional review board in accordance with globally accepted standards of good clinical practice (International Conference on Harmonisation [ICH], GCP guidelines) and in agreement with the Declaration of Helsinki. Appropriately written assent and informed consent was obtained from all patients and from their respective parents/legal guardian. Children were provided with financial compensation for participation in the study.

Study Design

Children were asked if they thought they could swallow a tablet (yes/no). If the subject was not willing to try or refused to participate they did not proceed with the study. Those who said "yes" were asked to demonstrate this capability by swallowing a placebo

tablet using an ordinary 4-oz plastic cup containing water (up to two attempts). The placebo tablet was a 7-mm-diameter cylinder, with flat upper and lower surfaces and wax coated (matched to fexofenadine HCl 30 mg in volume and dimensions). For those subjects who said that they could not swallow a tablet but were willing to try, scripted swallowing technique instructions were given and then the child attempted to swallow a tablet using the ordinary cup (up to two attempts). If the subject was able to successfully swallow a pill, ease of swallowing assessment was completed and study participation ended.

For those subjects who were not able to swallow a tablet, scripted instructions were given and children attempted (up to two attempts) to swallow a tablet using water in a special patented pill cup (Promotions Unlimited, Inc, Baltimore, MD). If the child was unable to swallow the tablet with the aid of a pill cup, study participation ended. For those subjects who were able to successfully swallow a tablet using the special pill cup, ease of swallowing was assessed and children were asked to reattempt pill swallowing using an ordinary 4-oz plastic cup (up to two attempts). The ability of the child to swallow the tablet was recorded, ease of swallowing was assessed for those subjects who were successful, and study participation ended. Instructions to children were scripted to ensure equivalent conduct during the course of the study.

Instructions and Training for Swallowing a Tablet

To ensure consistency throughout the study, one clinical research coordinator, herself the mother of elementary school children, conducted all study visits.

Children who answered that they were able to swallow a tablet were allowed to do so without instruction. All other children were instructed to use an ordinary 4-oz plastic cup.

Ordinary cup

The plastic cup was three fourths filled with water and handed to the subject with the placebo tablet. Children were instructed to place the tablet on their tongue toward the back of their mouth and drink down the water using the following script: "I will hand you a pill and a cup filled with water. I want you to place the pill on your tongue towards the back of your mouth and drink down the water, tipping your head slightly back, swallowing the pill. We can try it one more time if you need another chance. It's OK if you can't swallow the pill, and it's OK if you can. Either way we just want you to try."

Pill cup

The pill cup is a novel device; when tilted into the child's mouth, water washes through the trap into the back of the throat, carrying the pill with it, so reducing pill swallowing to a one-step procedure, which may facilitate the learning of tablet swallowing.

The pill cup was opened to full size and filled with water to just below the pill-trap level. The placebo tablet was placed in the well near the top of the cup by study staff. Children were instructed to drink the water, allowing the tablet to fall into their mouth, and be swallowed along with the water using the following script: "I will hand you a cup filled with water that has a pill in a well at the top of it. I want you to drink down the water, tip your head slightly back, letting the pill fall into your mouth. Swallow the wa-

ter and the pill. We can try it one more time if you need another chance. It's OK if you can't swallow the pill, and it's OK if you can. Either way we just want you to try."

Assessment of Ease of Pill Swallowing

Ease of pill swallowing was assessed on a 6-point visual scale (Figure 1): 0=not difficult; 1=a little difficult; 2=little more difficult; 3=even more difficult; 4=whole lot difficult; 5=most difficult. The child and caregiver completed the ease of swallowing assessment separately.

Outcome Assessments

Outcome assessments included the number of subjects who predicted that they could swallow a pill and the number of children who were able to master this skill using an ordinary plastic cup or using the pill cup. Results were presented as the mean across all age groups and the mean in children grouped according to age, in years. The characteristics of the children who were able to swallow a pill versus those who could not were also assessed, and ease of swallowing was

assessed for all cases of successful pill swallowing.

Safety Assessments

Adverse events (AEs) that occurred during the study were recorded by the investigator. Any subjective or objective AEs such as bad taste or choking were recorded. Physical examinations, including vital signs measurements, were performed at Visit 1.

Statistical Analysis

A total of 124 children completed the study. Assuming that the majority of subjects (~75%) were able to swallow the oral tablet, with or without the pill cup, a sample size of 124 children provides an estimation of the proportion of pediatric subjects who could swallow a small oral tablet with a margin of error of 5% (one-sided) for 90% precision.

Descriptive statistics were used to summarize the characteristics of the children enrolled into the study. Descriptive statistics, χ^2 , and t tests were used to evaluate the characteristics of subjects who were able to swallow a pill versus those who could not.

Results

Subject Demographics

A total of 124 children were enrolled into the study, with an approximately equal distribution of children across age groups (Table 1). The mean age of subjects was 8.2 (\pm 1.7) years. Of the enrolled subjects, 13.7% were receiving treatment for allergic rhinitis, 4.0% were receiving treatment for asthma, and 13.7% of subjects were receiving treatment for both allergic rhinitis and asthma. None of the screened subjects stated that they were not willing to try or refused to participate in the study.

Outcomes Assessment

Overall, 113 (91%) of subjects were able to swallow a tablet using either an ordinary cup or with the assistance of a pill cup (Figure 2a).

Fifty-seven subjects (46%) initially said that they could swallow a pill, all of whom demonstrated proficiency in pill swallowing with an ordinary plastic cup without requiring assistance (Figure 2). Ease of swallowing assessment revealed that most subjects (89.5%) performed this task

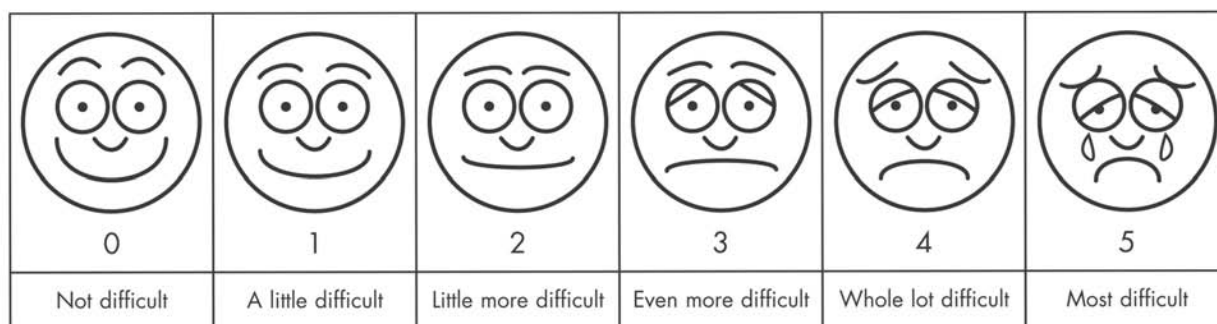


Figure 1. Ease of swallowing assessment.

Table 1**STUDY POPULATION DESCRIPTIVE STATISTICS (N=124)**

Characteristic	Mean (SD)	Range
Age (years)	8.2 (\pm 1.7)	6–11
	N (%)	
6 years	26 (21.0)	
7 years	24 (19.3)	
8 years	20 (16.1)	
9 years	22 (17.7)	
10 years	17 (13.7)	
11 years	15 (12.1)	
Sex		
Male	67 (54.0)	
Female	57 (46.0)	
Race		
African-American	15 (12.1)	
White	61 (49.1)	
Asian	11 (8.9)	
Hispanic	22 (17.7)	
Other	15 (12.1)	
Drug reasons		
Asthma	5 (4.0)	
Allergic rhinitis	17 (13.7)	
Both allergic rhinitis and asthma	17 (13.7)	
Other	4 (3.2)	
Pulse (beats per minute)	79.9 (\pm 9.6)	62–112
Temperature ($^{\circ}$ F)	98.1 (\pm 0.6)	96.9–99.7
Weight (lb)	67.7 (\pm 19.5)	37.5–152.5
Height (in.)	51.8 (\pm 4.3)	43.7–61.0

SD=standard deviation.

without difficulty and 10.5% of subjects exhibited a little difficulty (Table 2). Comparison of the characteristics of these patients with those who answered that they could not swallow a pill

showed significant differences in the mean age, ethnicity, and medication status between groups ($p=0.0009$, $p=0.0317$, and $p=0.0290$, respectively) (Table 2). Analysis of children according to

their age in years showed that, for children age 7 to 9 years, there was an even distribution between children who indicated that they were able to swallow a pill and those that answered that they could not. For 10- and 11-year-olds, a greater number of children indicated that they were able to swallow a pill, whereas for 6-year-olds, the reverse was observed. African-American children were more likely to say they could swallow a pill than not, in contrast to Asian children, for whom the reverse was true. Subjects who were white or Hispanic were equally likely to say they could or could not swallow a pill. Those patients who received medication for allergic rhinitis and/or asthma appeared more likely to believe that they were not able to swallow a pill at study entry.

Of the 67 children who answered that they could not swallow a pill at the start of the study, 56 patients (84%) successfully learned to swallow a pill with either an ordinary plastic cup or a pill cup (Figure 2a). Forty-seven subjects (70%) successfully learned how to swallow a pill with scripted instructions for tablet swallowing using an ordinary cup (Figure 2b). Ease of swallowing assessments, performed both by the caregiver and child, showed that more than half of the children exhibited proficiency of swallowing without difficulty (53.2%) and 34% of subjects showed little difficulty. Of the remaining subjects, 8.5% showed a "little more difficulty," 2.1% showed "even more difficulty," and 2.1% showed a "whole lot of difficulty." No differences were observed in patient characteristics between patients who were able to swallow a pill and those not able to swallow a pill with the ordinary plastic cup and scripted instructions (Table 2).

Pill Swallowing in Children

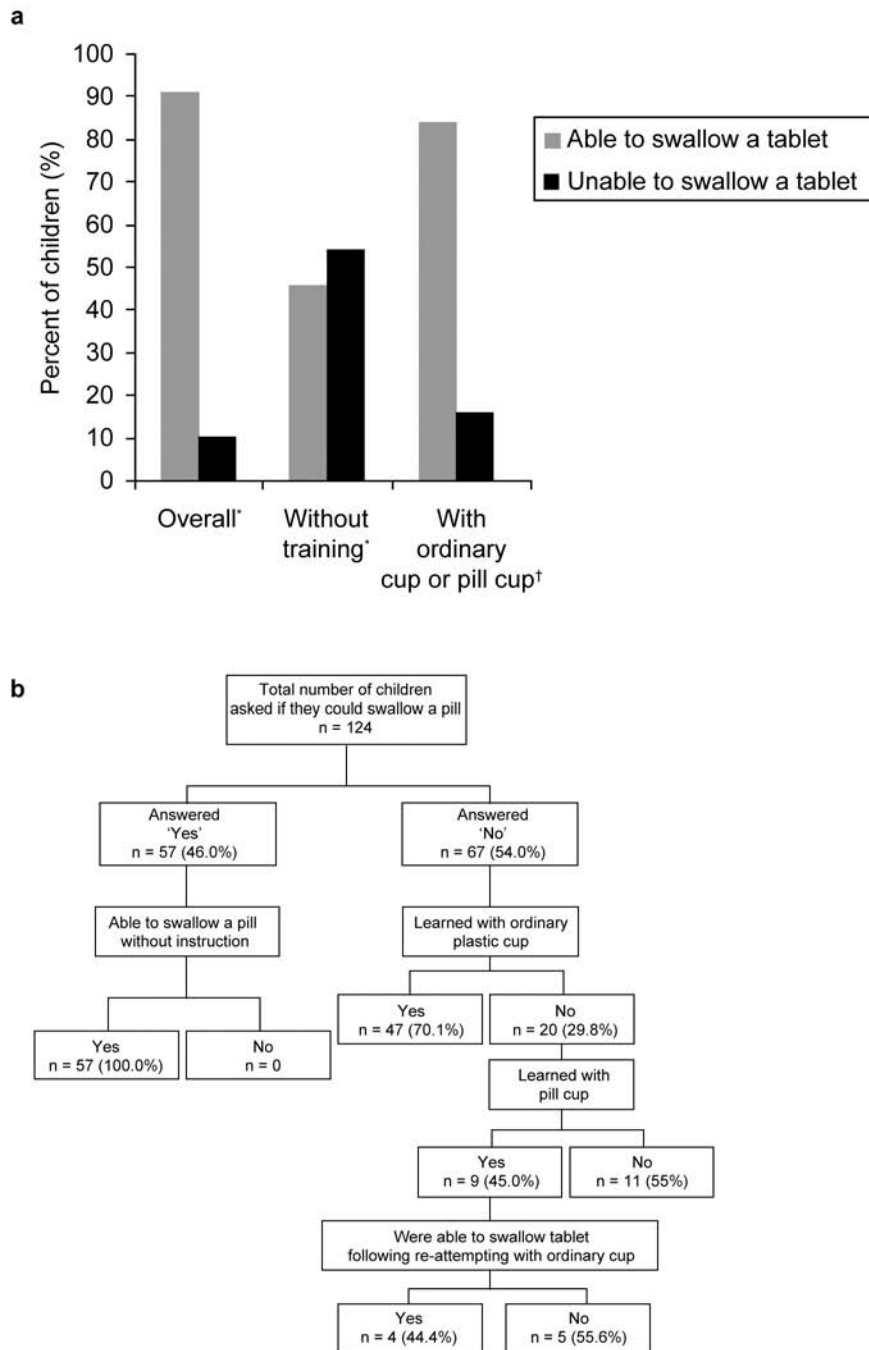


Figure 2. Ability of children to swallow a tablet using an ordinary cup or a special pill cup: **(a)** Percentage of children able to swallow a tablet in the study overall, without training and with training. **(b)** Flow diagram indicating the numbers of children able/not able to swallow a tablet at each study stage. *Percentage derived from the whole population (n=124); †percentage derived from the children who stated they were unable to swallow a pill at the start of the study (n=67).

Table 2

CHARACTERISTICS OF STUDY POPULATION BY ABILITY TO SWALLOW A TABLET

N (%)	Able to swallow pill without help?			If indicate that they cannot swallow pill without help can subject swallow pill with regular cup with help?			If unable to swallow pill with regular cup and help can subject swallow pill with pill cup and help?			If able to swallow with pill cup and help can subject now swallow with regular cup?		
	No	Yes	p Value	No	Yes	p Value	No	Yes	p Value	No	Yes	p Value
Age (years) Mean (± SD)	67 (54.0)	57 (46.0)	0.0009	20 (29.8)	47 (70.1)	0.6156	11 (55.0)	9 (45.0)	0.5592	5 (55.6)	4 (44.4)	0.5303
Age, N (%)	7.7 (±1.6)	8.7 (±1.3)	0.0009	7.9 (±1.4)	7.6 (±1.7)	0.6156	7.2 (±1.4)	8.1 (±1.4)	0.5592	8.2 (±1.3)	7.5 (±1.9)	0.5303
6 years	21 (80.8)	5 (19.2)	0.0272	5 (23.8)	16 (76.2)		3 (60.0)	2 (40.0)		0	2 (100.0)	
7 years	13 (54.2)	11 (45.8)		2 (15.4)	11 (84.6)		2 (100.0)	0 (0)		NA	NA	
8 years	11 (55.0)	9 (45.0)		6 (54.5)	5 (45.5)		2 (33.3)	4 (66.7)		3 (75.0)	1 (25.0)	
9 years	11 (50.0)	11 (50.0)		4 (36.4)	7 (63.6)		3 (75.0)	1 (25.0)		1 (100.0)	0	
10 years	6 (35.3)	11 (64.7)		3 (50.0)	3 (50.0)		1 (33.3)	2 (66.7)		1 (50.0)	1 (50.0)	
11 years	5 (33.3)	10 (66.7)		0 (0.0)	5 (100.0)		0 (0.0)	0 (0.0)		NA	NA	
Sex, N (%)	31 (46.3)	26 (45.6)	0.9419	12 (60.0)	19 (40.4)	0.1414	6 (54.5)	6 (66.7)		4 (80.0)	3 (75.0)	
Female	36 (53.7)	31 (54.4)		8 (40.0)	28 (59.6)		5 (45.5)	3 (33.3)		1 (20.0)	1 (25.0)	
Male	34 (50.7)	27 (47.4)	0.0317	9 (45.0)	25 (53.2)		5 (45.4)	4 (44.4)		2 (40.0)	1 (25.0)	
Race, N (%)	3 (4.5)	12 (21.0)		1 (5.0)	2 (4.2)		1 (9.10)	0		0	0	
White	9 (13.4)	2 (3.5)		3 (15.0)	6 (12.8)		0	3 (33.3)		2 (40.0)	2 (50.0)	
African-American	11 (16.4)	11 (19.3)		5 (25.0)	6 (12.8)		3 (27.3)	2 (22.2)		1 (20.0)	1 (25.2)	
Asian	10 (14.9)	5 (8.8)		2 (10.0)	8 (17.0)		2 (18.2)	0		0	0	
Hispanic												
Other												

(continued)

Table 2 (continued)

CHARACTERISTICS OF STUDY POPULATION BY ABILITY TO SWALLOW A TABLET

N (%)	Able to swallow pill without help?		p Value	If indicate that they cannot swallow pill without help can subject swallow pill with regular cup with help?		p Value	If unable to swallow pill with regular cup and help can subject swallow pill with pill cup and help?		p Value	If able to swallow with pill cup and help can subject now swallow with regular cup?		p Value
	No	Yes		No	Yes		No	Yes		No	Yes	
Medication, N (%)	67 (54.0)	57 (46.0)	0.0290	20 (29.8)	47 (70.1)	0.7234	11 (55.0)	9 (45.0)	5 (55.6)	4 (44.4)		
No	38 (56.7)	43 (75.4)	0.0290	12 (60.0)	26 (55.3)	0.7234	6 (54.5)	6 (66.7)	2 (40.0)	3 (75.0)		
Yes	29 (43.3)	14 (24.6)		8 (40.0)	21 (44.7)		5 (45.5)	3 (33.3)	3 (60.0)	1 (25.0)		
Degree of difficulty												
Not difficult	NA	51 (89.5)		NA	25 (53.2)		NA	3 (33.3)	NA	1 (25.0)		
Little difficult	NA	6 (10.5)		NA	16 (34.0)		NA	5 (55.6)	NA	3 (75.0)		
Little more difficult	NA	0		NA	4 (8.5)		NA	0	NA	0		
Even more difficult	NA	0		NA	1 (2.1)		NA	1 (11.1)	NA	0		
Whole lot difficult	NA	0		NA	1 (2.1)		NA	0	NA	0		
Most difficult	NA	0		NA	0		NA	0	NA	0		

SD=standard deviation; NA=not applicable.

The 20 children who were unable to swallow a pill with the ordinary cup were given instructions using a pill cup. Of these, 9 children (45%) successfully learned how to swallow a tablet and 11 subjects (55%) did not learn to swallow a tablet with either cup (Figure 2b). Of the subjects that successfully swallowed the pill, most patients found this “not difficult” (33.3%) or showed “little difficulty” (55.6%), with only 1 subject showing “even more difficulty.” No differences were observed in patient characteristics between groups (Table 2).

Four of the nine children who successfully learned to swallow a tablet with the pill cup were then able to successfully swallow a tablet when reattempting with the plastic cup (Figure 2b). Assessment of ease of swallowing showed that children performed this task with either no or little difficulty (25% and 75%, respectively). Successful learning of pill swallowing using either the plastic cup or the pill cup occurred in similar proportions across age groups.

Safety Assessment

No AEs were associated with this trial; this included events such as bad taste, choking, or vomiting.

Discussion

The assumption that children with diseases or conditions similar to adults respond similarly to pharmacotherapy has encouraged the use of the same medications in both populations without full safety and efficacy assessments in children.¹ This has often occurred with a lack of reference to psychological and physical dif-

ferences that exist between these groups. In particular, there appear to be no publications that assess the capability of healthy children to swallow oral tablets. The findings reported here show, for the first time, that the vast majority (91%) of children age 6 to 11 years enrolled into this study were able to successfully swallow a small oral tablet irrespective of whether they initially answered “yes” to the question, “can you swallow a pill?” In all cases of successful pill swallowing, this was achieved with only 6% of children expressing more than “a little difficulty.” In addition, it should be noted that many of the parents were surprised by the findings. Frequently, they were thrilled with their child’s ability to learn to swallow a tablet. Some parents were so shocked that they thought the result must be incorrect, and others appeared adamant that their child did not know how to swallow a pill, even when this was proved otherwise.

The findings showed that of a group of 124 children, almost half answered “yes” when asked if they could swallow a pill, and all these demonstrated proficiency in pill swallowing, without requiring instruction, and with almost no difficulty. Overall, the average age of children who could swallow a pill without instruction was higher than those who answered that they could not swallow a pill. These differences may reflect differences in familiarity with pill swallowing in the older age group and/or a greater understanding of the importance of accepting medication to improve health. However, children who were already receiving medication for allergic rhinitis and/or asthma were less likely to answer that they could swallow a pill at study entry, suggesting that age, rather than

acceptance of medication, enhances the belief that pill swallowing is possible. Interestingly, the ethnicity of the subjects may have affected their likelihood to initially state whether they could swallow a pill as a significant difference in ethnicity between the “yes” and “no” groups was observed. One possible explanation for these findings is that children from different cultural environments may have different attitudes toward medication.

Of the children who answered that they could not swallow a pill, 84% successfully learned to swallow a tablet using either a regular cup or using a special pill cup; age did not affect this learning ability, since successful learning of pill swallowing occurred in similar proportions across age groups. Children were initially given instructions for pill swallowing using an ordinary plastic cup filled with water and 70% were successful at this stage. Of the remaining children, a further 45% mastered pill swallowing using a special patented pill cup.

A large number of children require medication, so the results from this study are pertinent to health-care professionals and parents alike. For example, allergic rhinitis is a common chronic condition in childhood,² with reports estimating prevalence to be as high as 40% in some countries.^{3,4} The ability to swallow a pill is important for several reasons; it allows access to the medications that are only available in tablet formulation, it improves portability of medications, and it avoids the problem of liquid formulations that are relatively unpalatable and/or sweetened. Moreover, measures that enhance the ability of children to take prescribed medicines are important, to maintain optimal effectiveness

for those medications that require long-term adherence.

The high success rate of pill swallowing and the absence of AEs using the approaches in this study may represent new guidelines for teaching children this capability. It should be noted that none of the children in the current study stated that they were unwilling to try to swallow a pill or refused to participate in the study; the willingness experienced in these children may not be representative of the general population. Furthermore, the study was not designed to assess the efficacy of a patented pill cup to teach children to swallow pills, but rather to evaluate whether, given the opportunity to learn pill swallowing, the pill cup would aid in this process. Numerous psychological factors, such as the child wanting to please the clinic staff, the belief that swallowing the pill was a game or challenge, or the financial reward may have influ-

enced the desire for the child to swallow pills. Further studies are now required to examine swallowing capability using different pill sizes and/or shapes in diverse pediatric populations.

In conclusion, the very high success rate of pill swallowing determined in this study should give confidence to health-care professionals, parents, and children in the ability of children age 6 years and older to perform this task if asked to do so and/or when given instructions on pill swallowing. Successful pill swallowing allows greater access to medications that are available only in tablet formulation and avoidance of those liquid formulations that are less desirable.

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