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Family and physician influence on asthma research-participation decisions for adolescents: The effects of adolescent gender and research risk

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Abstract

Objective: To examine parent and adolescent perceptions of decision-making authority and sources of influence on adolescent research participation decisions, and determine whether perceptions of influence differ based on adolescent gender and level of research risk.

Study design: Adolescents ($n=36$) with asthma and their parents reviewed 9 pediatric research protocols, decided whether they would choose to participate, rated the extent they would be responsible for the actual decision, and indicated the ability of family and physician to influence their decisions. Multivariate analyses of variance were used to evaluate differences in perceptions of decision-making authority and sources of influence on the decisions.

Results: Adolescents were less willing to cede decision making authority to parents than parents anticipated. Parents and adolescents acknowledged a greater openness to influence from physicians than from family for above minimal risk studies. Parents were more willing to consider to opinions from male adolescents.

Conclusions: Adolescents desire responsibility for research participation decisions, though parents may not share these views. Physician's views on research participation are important to families, especially for above minimal risk studies. Parents may grant more decision-making autonomy to adolescent males than to females.

Keywords

asthma-drug-therapy; biomedical-research-ethics; informed-consent; adolescent-assent; research-participation-decision-making; adolescent; child; parents; female; humans; male; research-support

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There is considerable ethical and legal ambiguity surrounding the role of adolescents in the adolescent research participation decision-making process. Depending on the nature of the study, adolescents' may have independent responsibility for providing informed consent, they may be asked to provide their assent, or they may be completely excluded from the decision process (1). The extent to which adolescents' opinions concerning research participation are actually solicited and honored depend on factors such as family decision-making styles and preferences, beliefs about the importance of adolescent autonomy, perceived risks and benefits of the research study, and perceptions of adolescent judgment, maturity and cognitive ability (2,3). Some have commented on the reluctance of the medical community and parents to recognize mature children and adolescents as having decision-making capacity. They note that a lack of clarity concerning the rules, and confusion about the basis for assent or dissent of a child with developing decision-making ability, may limit participation in research decisions (4,5).

Parents tend to exert greater control over children and young adolescents, especially girls (6-8). Moreover, young adolescents tend to perceive less autonomy and are likely to exercise less resistance to social influence in decision-making situations than older adolescents and young adults (8-10). Consequently, family members and physicians who refer adolescent patients to biomedical research are likely to affect perceptions of the adolescent's freedom to participate, and have considerable influence over the decision-making process.

The degree to which parents and adolescents influence one another and the extent to which they consider the opinions of physicians in the research participation decision-making process have received little empirical attention. Preliminary evidence suggests that both parents and adolescents claim decision-making responsibility for research participation decisions (3). Parents in this study were willing to consider their adolescents' opinions, but expected adolescents would acquiesce to their decision. However, adolescents appeared less amenable to parental influence, and indicated they would not have to follow their parents' wishes. Findings from focus group research on parent-adolescent need for parental consent for research participation found that older adolescents saw significantly less need for parental consent than did their parents for research on sensitive topics such as sexuality, drug and alcohol use (11).

There are diverse views on the participation of physicians in patient research decisions. Concerns have been raised that power and authority differentials between physicians and patients may pose threats to patient autonomy (12), and a range of possible conflicts of interest for both clinician-investigator and non-investigator physicians have been identified. (13,14). The potential for physicians to provide helpful guidance and support for research participation decisions has also been acknowledged (15). While no data directly addresses physician influence, trust in physicians has been identified as an important factor in some research participation decisions (3,16).

The purpose of the present study was to examine parent and adolescent perceptions of responsibility for adolescent research participation decisions, and examine the role of adolescents, parents and physicians as sources of decision-making influence. We hypothesized that parents would overestimate their adolescents' willingness to acquiesce to parental decisions, that both parents and adolescents would view physicians as an important source of decision-making influence, and that adolescent boys would have more influence over parents than would adolescent girls.

Method

Thirty-six adolescent-parent dyads (predominantly mothers) participated in this study. All adolescents had a prior diagnosis of asthma. Adolescents ranged in age from 11 to 17 (Mean

= 13, SD = 1.7) and parent age ranged from 30 to 60 years (Mean = 43, SD = 7.0) years. Ethnicity of the patient sample was representative of the southwestern United States, where data were collected: 36% Hispanic, 42% Non-Hispanic White, and 22% of mixed ethnicity. See Table 1 for additional demographic information.

Sixty-seven percent of adolescents and 61% of parents reported no prior clinical research experience. Asthma-symptom frequency was reported as twice a week or less in 53% of participants, with daily asthma symptoms in 25% of participants. In the four weeks before participation in this study, 44% of participants reported no awakenings due to nocturnal asthma symptoms (i.e. cough, wheeze), whereas 6% reported awakenings every night. Parents reported their adolescent typically missed a median of four days of school in the past year due to asthma symptoms, with a maximum of 70 missed days due to asthma. Adolescent participants had relatively few visits to the emergency department (83% had no visits) and few hospitalizations (95% had none) in the past year.

Stimulus Materials

Forty consent forms describing previously conducted publicly and privately funded studies from the 1990's and 2000, were obtained from pediatric asthma researchers in the United States and England. Consent forms were obtained in two ways. Prominent researchers known to the authors were contacted directly to request copies of their consent forms. Other researchers were identified via a Medline literature review of recently published pediatric-asthma studies. Requests for consent forms were made to all those for whom contact information was available. Specific attempts were made to obtain consent forms for studies that involved varied designs and procedural elements. An expert panel, consisting of 8 physicians, clinical pharmacists, and psychologists with expertise in ethics, pediatric asthma research, or both, evaluated the consent forms and selected a representative sample of nine studies.

Of the nine studies selected for evaluation, the expert panel unanimously rated four of the protocols as above minimal risk to participants and five as representing minimal risk to participants. The minimal risk protocols included procedures such as asthma education and symptom monitoring. Three of the above minimal risk studies involved medication trials. Details of each protocol are described elsewhere (17).

Key information about each of the selected protocols was extracted from the consent form and rewritten into a one-page standardized research vignette format. Each included an informative study title, a brief statement of the reason for the study, and details of the length and time required for participation. To facilitate presentation of multiple vignettes, procedures were summarized in bullet format. Risks of the procedures were described in an earlier part of the study and were available to participants during presentation of the vignettes. The medication trials included a description of medications and their known risks/side effects. A description of study incentives was included at the end of each vignette.

Procedures

Consent and assent procedures for this study were reviewed and approved by the Health Sciences Center Human Research Review Committee. All participants were recruited from a children's hospital pediatric pulmonary outpatient clinic that serves as the state-wide referral center for children with asthma. For those agreeing to participate, a separate appointment was made to conduct the research at an office located outside the medical clinic. Two families who had indicated earlier interest later declined to participate in the study.

At the beginning of the interview, parents and adolescents met together with a research assistant to review and sign informed consent and assent documents. Parents completed a 15-item

demographic form to determine socioeconomic status and other demographic characteristics. An asthma history questionnaire that contained 33 items developed from the Guidelines for the Diagnosis and Management of Asthma (18) to assess asthma symptomatology was also administered. Additional items developed for the current study, included questions pertaining to the names of current asthma medications and parent rating of the effectiveness of the current medication regimen. Parents were asked whether they or their adolescent had participated in other asthma-research studies, and if so, how many studies. Finally, seven questions were asked about the frequency of various asthma procedures that had been completed in the preceding 12 months (e.g., spirometry, allergy/skin testing, and venipuncture).

Parents and adolescents were then moved to separate rooms where independent data collection proceeded. Participants were first asked to evaluate separately the risks and benefits associated with ten common asthma research procedures, such as spirometry, allergy skin testing, and methacholine challenge. The findings for these evaluations are presented elsewhere (19). The nine vignettes describing the research protocols were then presented to participants. Alternate presentation orders were established for each parent-adolescent dyad using a standard Latin square design procedure.

For each of the nine vignettes, adolescents and parents were asked an identical series of 12 questions. All but one of the questions were evaluated on a 7-point Likert scale. The questions were designed to determine willingness to participate in each of the protocols, perceptions of the other family member's (parent or adolescent) willingness to participate, perceptions of responsibility for the participation decision, influence of family member and physician views on their decisions, and their overall evaluation of the risks, benefits, discomfort, hassle and appropriateness of compensation offered for participation in the protocol. Previously published findings from this set of questions include data comparing family members' willingness to participate in each of the protocols (17), and perceptions of fair compensation for participation (20). This paper reports on a subset of findings that compares parent and adolescent perceptions of family member authority and influence vs. physician influence on the research participation decision.

Results

Data were analyzed using two separate full-factorial multivariate analyses of variance (MANOVA). The first set of analyses compared parent and adolescent perceptions of responsibility for the research participation decision. The second set of analyses compared parent and adolescent perceptions of the influence of family members versus physicians on research participation decisions. Preliminary analyses examining adolescent age and gender effects, indicated that age was not significantly related to the dependent measures. However, adolescent gender was retained in subsequent analyses of the findings.

Perceptions of decision-making responsibility

To compare parent and adolescent perceptions of responsibility for adolescent research participation decisions, we computed mean scores across the vignettes based on parent responses to the 7-point Likert scale question "Would your child agree to whatever you thought was best?" and adolescent responses to the question "Would you have to do what your parent (s) decided?" Separate minimal risk means were computed from parent and adolescent responses to the five minimal risk vignettes. Similarly, separate above minimal risk means were computed from parent and adolescent responses to the four above minimal risk vignettes.

We then conducted a gender \times family member \times protocol risk level mixed effects MANOVA on these mean scores. Adolescent gender was the between participants variable. Risk (minimal or above minimal) and family member (parent or adolescent) were treated as within-participant

repeated measure factors. Results revealed a significant family member effect, $F(1, 31) = 5.85$, $p = .022$, $\eta^2 = .16$. Across all research vignettes, parents reported adolescents were significantly more likely to yield to the parent wishes than adolescents indicated they would yield to the parent's decision [Parent mean (s. e.) = 5.52 (0.23), Adolescent mean (s. e.) = 4.57 (0.36)]. There were no other significant main effects or interaction effects in this analysis.

Perceptions of influence on the research decision

Perceptions of influence on the research participation decision were evaluated from parent and adolescent responses to two questions. Parents responded to the questions “Could your child's opinion change your mind (about research participation)?” and “Could the opinion of your child's doctor change your mind?” Adolescents responded to the questions “Could your parent's opinion change your mind?” and “Could your doctor's opinion change your mind?” All questions were in the form of a 7-point Likert scale. A gender \times protocol risk \times family member \times influence source mixed effects MANOVA was conducted with adolescent gender as the between participants variable, and protocol risk (minimal or above minimal), family member (parent or adolescent) and influence source (family or physician) as the repeated measures. Results revealed significant main effects for family member, protocol risk, and influence source. The significant family member effect, $F(1, 27) = 10.46$, $p = .003$, $\eta^2 = 0.28$, revealed that parents, overall, reported greater willingness to change their mind about research participation based on outside opinion than did adolescents [Parent mean (s. e.) = 4.83 (0.20); Adolescent mean (s. e.) = 3.84 (0.23)]. The significant protocol risk effect, $F(1, 27) = 4.59$, $p = .041$, $\eta^2 = 0.15$, indicated that both parents and adolescents were more open to outside influence on above minimal risk studies than on minimal risk studies [Above minimal risk mean (s. e.) = 4.53 (0.17); Minimal risk mean (s. e.) = 4.15 (0.17)]. The significant influence source effect, $F(1, 27) = 5.43$, $p = .028$, $\eta^2 = .17$, indicated that, overall, both parents and adolescents could be more influenced by a physician than by a family member [Physician mean (s. e.) = 4.56 (0.17); Family member mean (s. e.) = 4.12 (0.18)]. There were no significant main effects for adolescent gender.

However, these main effects were qualified by three significant interaction effects. Figure 1 depicts a significant protocol risk by adolescent gender effect, $F(1, 27) = 5.40$, $p = .028$, $\eta^2 = 0.17$. This finding indicated that both parents and adolescents were more likely to accept outside influence for above minimal risk studies when the adolescent was female. When the adolescent was male, or the study was minimal risk, both parents and adolescents were less likely to accept outside opinions.

There was also a significant risk by influence source interaction effect, $F(1, 27) = 8.74$, $p = .006$, $\eta^2 = 0.25$, Figure 2. This finding indicated that, for both parents and adolescents, physician opinion was more influential than family member views in above minimal risk studies, but not in the minimal risk studies.

Finally, as shown in Figure 3, there was also a significant 3-way interaction of the adolescent gender, family member, and influence source variables, $F(1, 27) = 7.54$, $p = .011$, $\eta^2 = 0.22$. This interaction indicated that when the influence source was the physician, parents would be more influenced to change their minds than would adolescents, regardless of adolescent gender. However, when the influence source was the family, parents were significantly more willing to be influenced by their adolescent when the adolescent was male than when the adolescent was female.

Discussion

This study compared the views of parent-adolescent dyads concerning their beliefs about who maintains authority within the family to make research participation decisions for the

adolescent. Opinions concerning family and physician influence over participation decisions were also evaluated. Adolescent responses differed from those of their parents in several important ways.

Adolescents were relatively unwilling to cede decision-making authority to parents, while parents believed their adolescents would comply with parental wishes. Consistent with preliminary findings from our earlier research (3), these results provide additional evidence of an overall adolescent preference for autonomy in asthma research participation decisions.

Findings concerning the willingness of adolescents and parents to consider outside opinions when making these decisions were more nuanced. In general, parents reported more willingness than adolescents to be influenced by others in these asthma research participation decisions. Both parents and adolescents acknowledged a greater openness to input from others when considering above minimal risk rather than minimal risk studies, and both groups also acknowledged that physician's views would be more persuasive than family members' views. However, there were important clarifications for these findings. Physician influence would be strongest when considering participation in above minimal risk asthma studies. Moreover, physicians would have the greatest influence on both parents and adolescents when the adolescent was female. With regard to family influence and parent decision-making, our results suggest that adolescent boys may be granted more autonomy in research decisions than adolescent girls.

There are several implications of these findings for the conduct of research with adolescents. First, even the relatively young adolescents in this sample expressed the desire for decision-making responsibility, regardless of level of research risk. There is growing consensus that children ought to have more input into research participation decision-making, principally for non-beneficial research (21,22). However, our data suggest this view is not necessarily shared by parents, especially when the adolescent in question is female. Gender-based differences in adolescent autonomy have been noted elsewhere in literature (8). In the case of research participation decisions, the present gender finding points to the likelihood of differences in family decision-making processes that may appreciably limit the involvement of adolescent females. If substantiated, researchers may face unanticipated ethical quandaries in attempting to ensure the voluntary assent for participation of female adolescents in biomedical research.

Overall, the importance of determining authority for adolescent research participation decisions may actually be most significant for above minimal risk studies. We have demonstrated elsewhere (17) that adolescents appear more willing to enroll in above minimal risk asthma research than parents are willing to permit their enrollment. Were adolescents to obtain greater autonomy in research participation decision-making, enrollment in these studies might proceed more quickly. However, the ability of adolescents to appropriately weight research risks and benefits in the context of an actual clinical trial has not yet been empirically established, although it has been demonstrated in analog vignette studies (23).

The present findings also point to the importance of physician recommendations for parent and adolescent decision-making, particularly with higher risk research, where families may feel less able to appropriately judge the risks and benefits of a study. Commentators have identified a number of complex considerations related to the ethical involvement of physicians in research participation decisions, including limitations in professional integrity, conflicts of interest, and disparities of social power that may operate to inappropriately influence participant decision-making (12-14,24). Nonetheless, our findings highlight that physician guidance is important to families contemplating research participation, and the 'physician as advisor' may be especially important to adolescents as they begin to exercise greater independence from parents on both medical and research participation decisions. This finding emphasizes the need for

further study on the process of informed consent, especially to establish methods of physician dialogue with adolescents that enhance adolescent knowledge and appreciation of research participation while preserving and respecting their developing autonomy.

As data accumulates on the desire, ability, and process by which adolescents may exercise autonomy in research participation decision-making, policy makers and the legal system are the likely arbiters of parental versus adolescent rights in these decisions. Clarifying the perspectives of family members helps to explain the potential legal and ethical issues at stake. One limitation of these data is that they represent participants' beliefs about their own behaviors in a research setting, they do not measure actual behaviors. Further research examining actual research decision-making processes in families is needed to more fully explain family and physician influences on parent and adolescent research participation decisions.

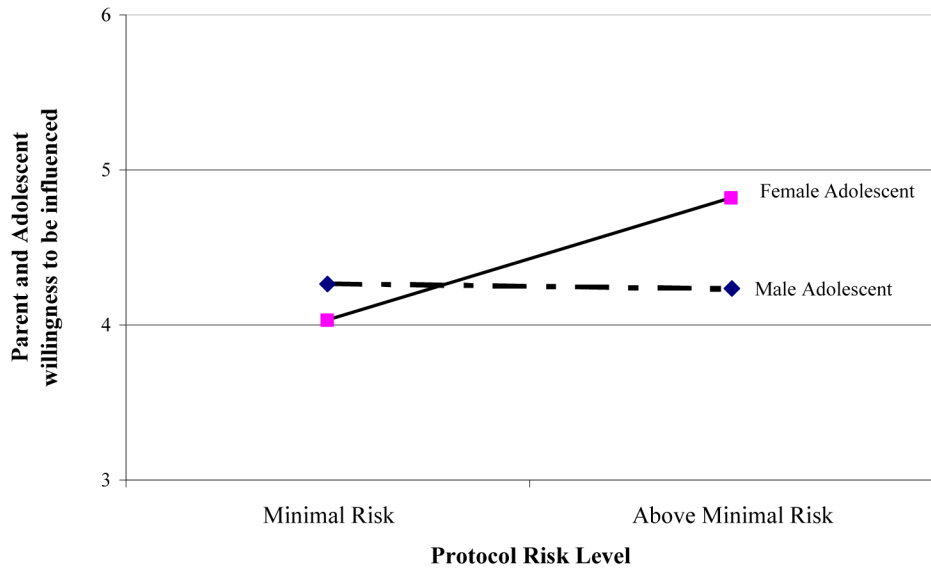
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Note: Full likert scale range is from 1-7; 1= not at all; 7= a lot

Figure 1. Parent and adolescent willingness to be influenced in research decisions based on level of protocol risk and gender of adolescent.

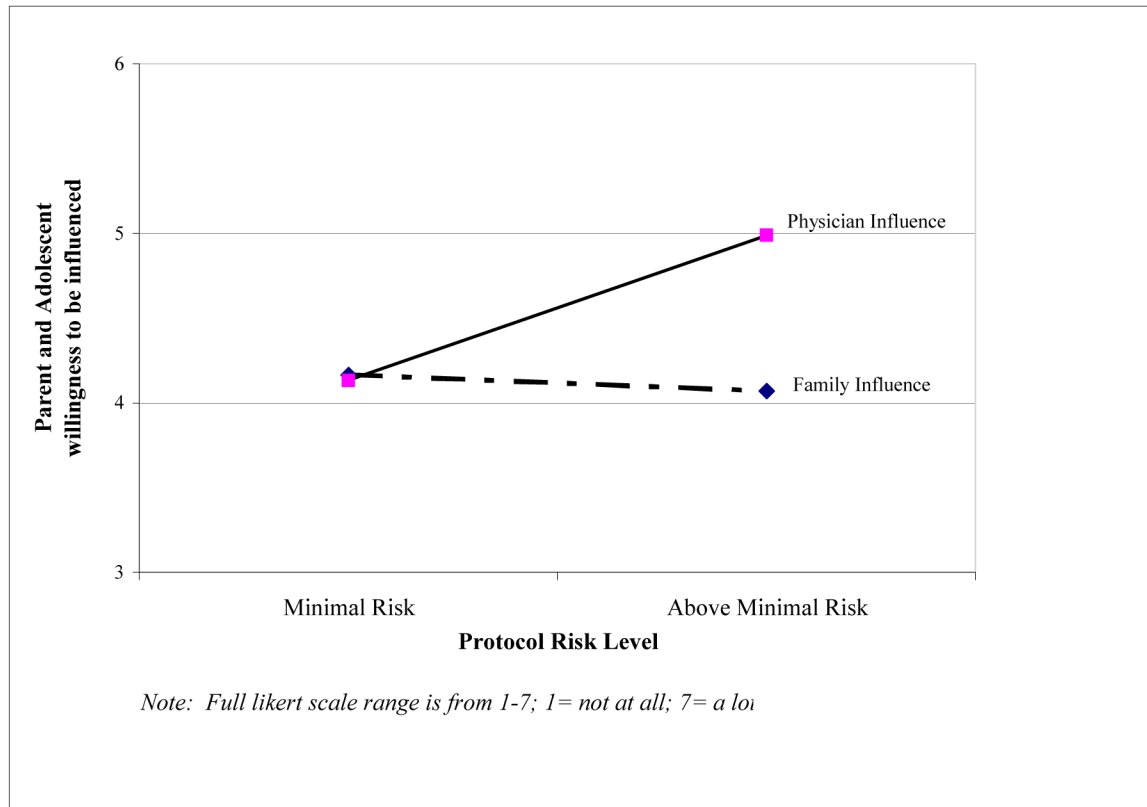
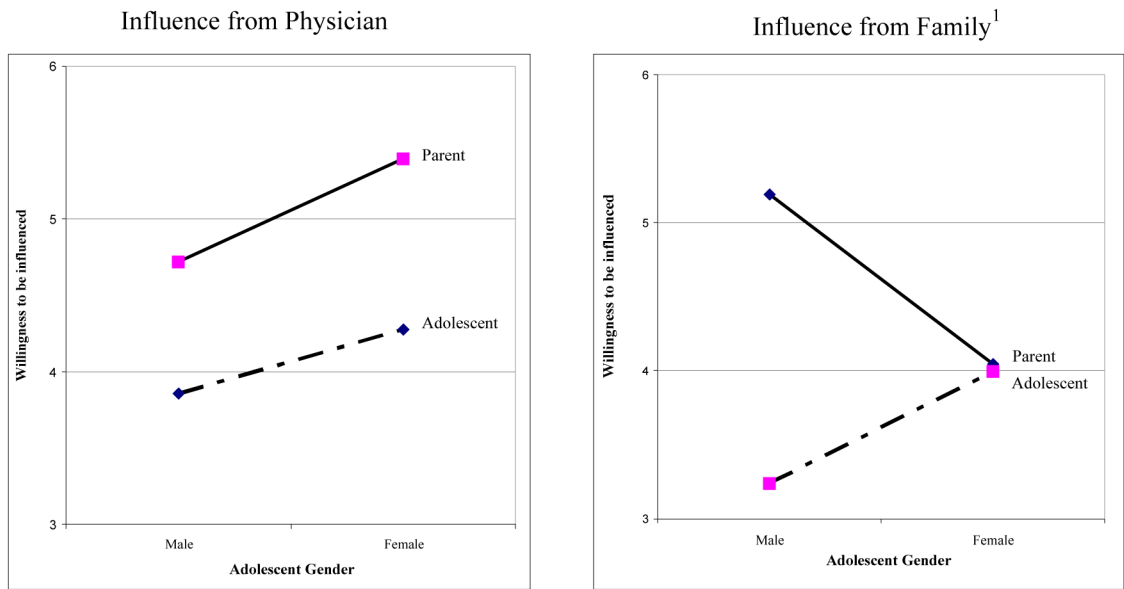


Figure 2. Parent and adolescent willingness to be influenced in research decisions based on level of protocol risk and source of influence.



¹ On Influence from family, parents rate influence from adolescents and adolescents rate influence from parents.

Note: Full likert scale range is from 1-7; 1= not at all; 7= a lot

Figure 3. Differences in parent and adolescent willingness to be influenced by others based on influence source and adolescent gender.

Table 1
Demographic characteristics of adolescent and parent participants (N=36 dyads).

	<u>n</u>	<u>%</u>
Relationship with adolescent		
Parent	34	94.4
Other	2	5.6
Adolescent ethnicity		
Non-Hispanic, White	15	41.7
Hispanic	13	36.1
Other (Mixed)	8	22.2
Adolescent gender		
Male	22	61.1
Female	14	38.9
Highest parental educational level		
High School Diploma	8	22.2
Associates/Vocational Degree	9	24.0
Bachelors Degree	8	22.2
Post-graduate degree	8	12.3
Missing	3	8.3
Yearly household income		
< \$20,000	9	25.0
\$20,001-\$40,000	8	22.2
\$40,001-\$60,000	3	8.3
> \$60,001	16	44.4